LEGAL ASPECTS OF TRADE IN MEDICINES

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This thesis considers from a comparative legal basis the existing controls upon the supply of medicines throughout the world. It assesses the desirability and effectiveness of those controls and makes recommendations as to how these could be improved.

Part I describes and analyses the legislative controls over medicines as contained in the United Kingdom Medicines Act 1968. In particular there is discussion of licensing systems, the role of the prescribing doctor and aspects of consumer safety.

Part II considers the effect upon the United Kingdom of entry in to the European Economic Community in relation to trade in medicines. Free movement of goods, competition policy and harmonisation of the legislation of Member States are the main themes discussed.

Part III deals with trade in medicines in relation to the Third World. The external relations policy of the EEC is discussed and its interaction with GATT. Also considered are the roles played by the various agencies of the United Nations in relation to the supply of medicines and the activities of transnational pharmaceutical companies in this field.

Part IV is concerned with some specific problems posed by trade in medicines, including consumer safety, product liability, price control and post-marketing surveillance.

Part V deals with the development of the supply of medicines as a human right and the part played by non-government organisations in securing that aim upon a global basis.

Part VI contains conclusions and recomendations, in which the role of the World Health Organisation is discussed in relation to a new pharmaceutical code of conduct.

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List of abbreviations

AC	Appeal Cases
ACP	African, Caribbean and Pacific States
All E.R.	All England Reports
BIRA Journal	The Journal of the British Institute of Regulatory Affairs
BYIL	British Yearbook of International Law
CMLR	Common Market Law Reports
CML Rev.	Common Market Law Review
ECOSOC	Economic and Social Council of the United Nations
ECR	European Court Reports
EEC	European Economic Community
EL Rev.	European Law Review
GATT	General Agreement on Tariffs and Trade
HAI	Health Action International
ICLQ	International and Comparative Law Quarterly
IFPMA	International Federation of Pharmaceutical Manufacturers Association
JAMA	Journal of the American Medical Association

LQR	Law Quarterly Review
MLR	Modern Law Review
MNE	Multi-national Enterprise
NHS	National Health Service
PPRS	Pharmaceutical Price Regulation Scheme
QB	Queen's Bench
UN	United Nations
UNAPEC	United Nations Action Programme for Economic Co-operation among developing countries
UNCTAD	United Nations conference on Trade and Development
UNIDO	United Nations Industrial Development Organisation
WHA	World Health Assembly
WHO	World Health Organisation
WLR	Weekly Law Reports

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INTRODUCTION

There has existed some form of regulation over the supply of medicines for human use since the earliest times. Indeed, evidence of such regulation exists for almost a long a period as evidence exists of medicine taking itself. In speaking of medicines in this context is meant those substances used by man for the purpose of preventing or treating illness, alleviating symptoms or improving health. This definition clearly includes sophisticated medicines maufactured for rare diseases as well as simple herbal remedies and extends to products which may be used on a world-wide basis, thereby emphasising the unique nature of medicines.[1] Illicit trade in medicines is not within the scope of this thesis.

In the United Kingdom three main periods of control may be identified. First, the period from about 1316 to 1500, when the Guilds imposed some jurisdiction over the quality of products used in medicines. Secondly, the period from 1501 to 1858, during which the concept of the pharmacopoeia was developed. Thirdly, from 1858 (which marked the passing of the Medical Act of that year) until the present day, during which the method of control has been largely by legislation.

It is being increasingly recognised that these legal controls have wide ranging implications, at both a national and international basis, for many aspects of the world's welfare. Some of these implications have been considered and the discussion has been developed later in Part I in relation to the United Kingdom, in Part II in relation to the EEC and in Part III in relation to the Third World.

First, there are some obvious ecnomic considerations. One of the main reasons for introducing controls has been to contain costs. In those countries where the medicines bill under a National Health Service programme as part of the welfare state is a clearly defined portion of national expenditure, there is an obvious interest in curbing costs. It is also well recognised that the pharmaceutical industry is research orientated, innovation being the life blood of the industry. Such innovation needs to be converted into commercial profits, which must be paid for, either directly by the consumer or indirectly by the tax payer. In the Third World[2] it will be seen in Part III that most of the medicines provided are made available by multi-national enterprises. This has an important bearing upon the policy of the World Health Organization and its illustrative list of essential drugs. There may, therefore, be a potential conflict between the pharmaceutical industry, which is continually seeking to introduce new products, and the policy of the Third World countries, which requires rationalisation and concentration of their resources on products suited to meet their most common ailments.

A further legal aspect of control over medicines concerns the nature of the restrictions imposed and some consideration of the procedure for registration of a product and by whom decisions are taken. The United Kingdom Medicines Act 1968 provides a sophisticated system for decision making to be shared between the Government licensing authority on the one hand and independent committees drawn from medical experts on the other. There are also some international aspects to this, as membership of the EEC has introduced the possibility of applying for a single licence upon a Community basis. Further scope for the future may be upon the lines of a new international body for the worldwide licensing of medicines.

It is intended to show that any consideration of supply of medicines must also take account of the restrictions placed on doctors and others responsible for the distribution and administration of medicines. These restrictions must be enforced and changed in the light of scientific advance. Patients need to have access to medicines on prescription or otherwise and to obtain reliable information about these products. There is a role for a regulatory authority in both legislation and enforcing these restrictions, again both at national and international level.

It has been argued later, there are trends on an international level which are operating in different directions upon national authorities. The EEC is clearly seeking to harmonise the approaches of its Member States to various aspects of regulation over medicines. This is in keeping with its emphasis upon the free movement of goods provisions of the Treaty of Rome. But the regulation of medicines is surely of concern to the world at large rather than to merely one section of it. Inter-governmental co-operation of the establishment and monitoring of controls over the safety and quality of medicines should logically act as an incentive to increased international trade. Other provisions, such as the monitoring of adverse reactions and information about medicines on the market, are also of universal interest. But the problems of the Third World may require a different approach. There the problem is not one of harmonisation but of small markets for medicinal products and industrial resources which are both scarce and under developed. For them the transfer of technology to provide self-sufficiency and industrial growth may be more important than free trade. Attempts have been made in Part VI to suggest how these conflicting approaches may best be resolved.

With regard to trade in medicines, various trends may be identified. Prior to the Second World War there was little control over either the export or import of medicines from or to the United Kingdom. Part II of the Medicines Act 1968[3] contains various provisions about the export of medicines from the United Kingdom. First, Section 48 of that Act provides that the licensing restrictions of that Act were not to take immediate effect in relation to exports unless and until Ministers had made an Order for the purposes of that section. Such Order was not to be made unless it appeared to Ministers "to be necessary or expedient to do so for the purpose of giving effect to an agreement to which the United Kingdom or Her Majesty's Government in the United Kingdom is a party or will be a party on the day appointed by the Order".[4] Secondly, Section 49 contained further provisions in respect of the exportation of products consisting wholly or partly of substances the purity or potency of which cannot be adequately tested by chemical means. Neither of these provisions has yet been implemented.

Recent Government policy in relation to the export of medicines generally may be seen from a question raised by Lord Brockway in the House of Lords on 21st February 1979.[5] This question asked whether, in view of exposures made by Social Audit, the Government would conduct an enquiry into the promotion of drugs and food sales in Third World countries. On behalf of the Government Lord Wells-Pestell replied that it was for Third World countries themselves to decide whether particular products should be made available in their jurisdiction. It was the Government's policy to control the activities of multi-national enterprises by participating in the work for codes of conduct for such organisations through participation in the United Nations.

A third provision contained in the Medicines Act 1968 relating to the export of medicines is Section 50, which is in operation. This enables exporters to obtain from the licensing authority of the United Kingdom a certificate giving certain information about the product in question. As may be seen from the reply of Lord Wells-Pestell mentioned above, present controls over the exportation of medicines from the United Kingdom take the form of negotiated codes of conduct rather than legislative provisions. But, as regards trade between Member States of the European Economic Community, certain provisions of the Treaty of Rome are relevant. Some of the Community case law relevant to trade in medicines is considered in Part II.

It will be seen that the Medicines Act 1968 is concerned with safety and that many of its provisions are orientated towards consumer protection. In spite of this there is nothing contained in that Act, or indeed elsewhere in United Kingdom legislation, which is specifically related to providing compensation for those patients who may be injured by the use of a medicine. This is at present left to the general law of negligence and product liability. It will be considered whether this is satisfactory from the consumer's point of view, particularly having regard to the principle of freedom to prescribe which is generally enjoyed by the medical profession. This freedom has come under attack in recent years from both consumer interests and from within the medical profession itself. It is also of concern to Government as the paymaster for the medicines bill. This interchange between the medical profession, Government and the pharmaceutical industry has also been explored.

Some particular safety issues have been dealt with in Part IV and the subject of Product Liability has also been discussed there as this is likely to provide a more

satisfactory basis upon which consumers suffering damage as a result of taking medicines will be provided with remedies in the Courts.

It will be seen that Western Europe is important for the pharmaceutical industry, both in terms of its share of world consumption of medicines, and its dominant position with regard to their manufacture. Thus, in 1980 one-third of the world consumption of medicines took place in Western Europe, while 32.5% of the world's production was manufactured there.[6] In the United Kingdom alone, exports of medicines to the developing countries were estimated at about £250m; this being about one-ninth of total United Kingdom production.[7]

Part V discusses the influence of some national and international agencies in the field of trade in medicines (with particular reference to human rights), while Part VI contains general conclusions.

It is submitted as axiomatic that trade in medicines is different from trade in other products because of the potential hazards (often hidden) for human health which it involves. As has been stated by the Council of Europe in this context:-

> "The sale of pharmaceutical products cannot be considered as an ordinary trade since it involves human health and well-being".[8]

It is for this reason in particular that the legal aspects of trade in medicines is considered to be of some international importance.

NOTES

1. Although the term "medicines" is mainly referred to hereafter, in some places reference is also made to the words drugs, pharmaceuticals and pharmaceutical products.

2. There is no other satisfactory way of describing the group of countries with a very high proportion of poor people than by reference to the term "the Third World". "Bitter Pills: Medicines and the Third World Poor", Oxfam (1982) Dianna Melrose estimates that the Third World includes about one hundred countries containing some 3,000 million people.

3. c.67.

4. See Section 48(2) of the Medicines Act 1968.

5. Hansard, House of Lords, "Social Audit Report: Drugs and Food Sales"; 21st February 1979, columns 1809-1811.

6. United Nations, "Transitional Corporations in the Pharmaceutical Industry of Developing Countries", ST (CTH) 49, New York, 1984.

7. Taylor, D. "Medicines, Health and the Poor World", Office of Health Economics, London, 1982, p 29.

8. Parliamentary Assembly of the Council of Europe, Report on the Sale of European Pharmaceutical Products in the Countries of the Third World, (Rapporteur: M Lind), Document 5113, 21st September 1983, p 3.

PART I

CHAPTER I

EARLY LEGISLATION AND GENERAL BACKGROUND TO THE PRESCRIBING OF MEDICINE AND THE PHARMACEUTICAL INDUSTRY

1.1 INTRODUCTION

The first legislation governing the control of medicine was concerned with the quality of the product. These controls were aimed at establishing both the identity of the active substance and its freedom from any contamination. Riley[1] has described how the ordinances of the Guild of Pepperers of Soper Lane laid down the first written code of quality control in 1316. During the following centuries there was a period of inter-professional conflict. Henry VIII founded the College of Physicians in 1518 and this was followed by an Act of Parliament (32 HEN VIII c.40 for Physicians and their Privileges). This statute gave power to the College of Physicians to appoint four inspectors of "apothecary wares, drugs and stuffs". From the early 17th Century those inspectors were joined in their statutory duties by representatives from the Society of Apothecaries. It was from the apothecaries that two separate professions emerged - those who eventually established themselves as general medical practitioners and those who, together with the chemists and druggists, later founded the Pharmaceutical Society. This combination thus formed the profession of what is now known as pharmacists.

1.2 DEVELOPMENT OF THE PHARMACOPOEIA

Apart from legislation, another important method of ensuring quality control of medicines was the development of the pharmacopoeia, which is an authoritative list of ingredients for medicinal products and standards for quality. In 1498 the Florentine Guild issued the New

Compound Dispensatory. Penn[2] regards this as the first official pharmacopoeia in Europe in the sense that its standards were related to a specific political unit. Other European cities followed Florence, the Pharmacopoeia Londinensis being published in 1618 for the whole of England. Subsequent editions followed and this eventually led to the passing of the Medical Act 1858, which established the General Medical Council. This Council had, as one of its statutory duties, the compilation of an official pharmacopoeia for the United Kingdom. This was achieved by the publication of the British Pharmacopoeia in 1864. This method of control is now governed by Section 65 of the Medicines Act 1968[3], which makes it an offence to sell or supply a medicinal product which does not comply with the standard specified in certain monographs where it can be shown that this standard formed the basis of transaction. These publications include the European Pharmacopoeia.

With regard to the status of the British Pharmacopoeia, this has originally no precise legal standing. But it became to be the presumptive legal standard for any medicines or preparations it contained.[4] With the advance of scientific knowledge during the 19th Century, each successive edition showed advances over the last. The edition published in 1914 included for the first time such important medicines as adrenalin, aspirin, the first barbiturate (barbitone) and the first synthetic urinary antiseptic (hexamine).

With the outbreak of the World Wars there was understandably delay in the publication of the British Pharmacopoeia. An edition published in 1932, after the passing of the Therapeutic Substances Act 1925, included biological assays for such new discoveries as antitoxins, sera and insulin.[6] With the next edition in 1948, assays were introduced for both tablets and injections and

important new changes were made for sterilisation procedures. Two later editions, those published in 1963 and 1966, introduced further advances. These were ultra-violet and infra-red methods for the examination of steroids in the former and new monographs and methods of expressing with greater accuracy any variation in preparations for the latter.[7]

Closely related to the British Pharmacopoeia was the introduction of the British Pharmaceutical Codex. This has a much wider scope than the Pharmacopoeia and also became the presumptive standard for preparations described in it. An edition of the Codex published in 1934 introduced qualitative standards for dressings, while that published in 1949 introduced standards for blood products.[8] Both Pharmacopoeia and Codex were and are kept continuously under review and the committees advising both the publications contain common members.

1.3 MODERN LEGISLATIVE CONTROLS OVER MEDICINES IN THE UNITED KINGDOM

Control over the sale and supply of medicines in the United Kingdom has, until comparatively recently, been on a haphazard and irrational basis. Until the passing of the Medicines Act 1968[9] those few controls which existed were related to the sale and distribution of poisons. It is significant that the words "drug", "medicine" and "poison" were not defined in the early legislation. Thus, Section 22 of the Offences Against the Person Act 1861 referred to the unlawful applying or administrating of "... chloroform, laudanum or other stupefying or overpowering drugs, matter or thing ..." and to the unlawful administering of "... any poison or other destructive or noxious thing". At the time when the 1861 Act was passed, the only substance subject to any legal restruction on sale was arsenic.[10] Then the Pharmacy

Act 1852 provided for the registration of pharmaceutical chemists and prohibited those who were not duly registered from assuming that title.

It was, however, the Pharmacy Act 1868[11] which introduced the first really effective control over substances used as medicines. This Act extended the registration requirements of those who compounded the prescriptions of medical practitioners and called themselves "chemists and druggists". It also set out a list of 15 substances, which were specified as poisons and placed restrictions upon their sale. This list of poisons was steadily increased over the years, many of the substances being used as medicines.

A separate but inter-related body of legislation, beginning with the Food and Drugs Act 1875, provided for standards of drugs and legislated against adulteration, although it avoided the use of that term. It did, however, require the appointment of both analysts and inspectors. It was made a criminal offence to sell a drug to the "prejudice" of a purchaser on the grounds that it was "not of the nature, substance and quality of the article demanded, or that it was not compounded in accordance with the demand of the purchaser". From the point of view of effective control over standards, therefore, the 1875 Act had a very limited scope.

This unsatisfactory approach to the control of medicines did not pass entirely without criticism. A select committee of the House of Commons reported in 1914 upon the unregulated sale of the patented drugs in the following terms:

> "For all practical purposes British law is powerless to prevent any person from procuring any drug, or making any mixture whether potent or

> without any therapeutical activity whatsoever (so long as it does not contain a scheduled poison), advertising it in any decent terms as a cure for any disease or ailment, recommending by bogus testimonials and the invented opinions and facsimile signatures of fictitious physicians, and selling it under any name he chooses, on payment of a small stamp duty, for any price he can persuade a credulous public to pay".[12]

In their report the Committee recommended that a special commission should be appointed to authorise the marketing of patented drugs, and that drug manufacturers should be registered and that checks should be made by a Government chemist upon the composition of, and medicinal claims made for, these products. But none of these recommendations was acted upon, and the piecemeal approach of passing legislation upon different aspects of control of medicines continued.

By the Dangerous Drugs Act 1920, which implemented the Hague Convention of 1912, the manufacture, trading in and possession of opium and certain narcotics without express authority was prohibited. These drugs were, by virtue of widespread international agreement, felt to be worthy of control because of their addictive properties.

Also in 1920 a committee was set up by the Minister of Health to advise upon the controls of therapeutic substances which could not be tested adequately by chemical means. The report of this committee included the outlines of a draft Bill to implement their recommendations.[13] This led to the passing of the Therapeutic Substances Act 1925, which included most of the recommendations of the Committee. It provided for the licensing by the Health Ministers of the premises, quality control, and employment of approved trained staff in

relation to the therapeutic substances brought subject to the Act's control. These included vaccines, sera, toxins, antigens and posteria pituitary injections. Subsequent regulations made under that Act brought blood products and cortico-steroids under control. Similar controls were imposed in relation to penicillin by the Penicillin Act 1947 and the Penicillin (Merchant Ships) Act 1951. Later, the Therapeutic Substances Act 1956 consolidated these restrictions by merging the manufacturing, quality and distribution controls for both therapeutic substances and penicillin into one Act.

Some miscellaneous pieces of legislation may also be briefly mentioned. Both the Venereal Diseases Act 1917 and the Cancer Act 1939 were concerned to prevent the advertisement to the public and promotion of medicine for the conditions mentioned respectively in the titles of those Acts, and to prevent the sufferers of those conditions from inadequate and unsuitable treatment and fraudulent claims. Under the Radioactive Substances Act 1948 powers were contained to control the sale and supply of radioactive substances intended to be taken internally by, injected into or supplied to human beings, and to control the use of certain irradiating apparatus for therapeutic purposes.

1.4 THE PHARMACEUTICAL INDUSTRY IN THE UNITED KINGDOM

In considering the legislative controls over the sale and supply of medicines it is also necessary to examine the structure of the pharmaceutical industry in the United Kingdom and its relationship with the National Health Service and the ultimate consumer. This close knit inter-relationship was described in the following way by the Sainsbury Report:

"The National Health Service, which pays almost the entire bill for prescription medicines, is not an ordinary buyer. The medicines are developed, manufactured and supplied by the pharmaceutical industry; they are prescribed by the doctors; they are consumed by patients; and, through the National Health Service, the tax payer eventually pays for them. But neither the doctor who prescribes or the patient who consumes is immediately concerned with prices. It is the indirectness of their relationship with the industry which imposes on the Health Departments both a difficulty in controlling costs and a special duty to exercise a surveillance over prices in order to ensure, as far as possible, that they are fair both to the industry and to the tax payer".[14]

A feature of the pharmaceutical industry is that it is comprised of companies having diverse national backgrounds. In the United Kingdom there are eighty-five major manufacturers, of which thirty-six are American, thity-three are European owned, leaving only sixteen companies British owned.[15] During the last thirty years, five countries have dominated the industry in terms of both sources of innovations and of volume of word trade. These countries are the USA, Switzerland, the United Kingdom, West Germany and France. A sixth country - Japan, should be mentioned. Although exports of pharmaceutical products from Japan are currently small, the large amounts which that country is spending on research and development suggest that it will not be long before Japan becomes one of the major exporters.[16]

Among the companies in the pharmecutical industry which are United Kingdom owned, there is a wide range if different types of company. Some are small specialist companies which deal in particular sectors of the market, while some are huge conglomorates such as ICI, for whom

pharmaceuticals represent only one component of the company classified as belonging to the chemical sector. Of those companies whose major interests are concerned with pharamecutical investment, there are only nine companies listed in the Financial Times All Share Index under the classification "Health and Household". Two of these may be said to dominate the sector - Glaxo Holdings plc and Beecham Group plc. Two further companies in the sector, Fisons plc and Amersham International plc, may also be said to be research based.[17] One company in this sector is unusual in that it is privately owned, the shares being held (until 1986) by a charitable trust,[18] while another[19] is largely a wholesale operation with pharmaceutical distribution listed as its principal activity.[20]

From this brief survey it may be seen that the United Kingdom pharmaceutical industry forms an important part of the world pharmaceutical industry. But many of the companies, although based in the United Kingdom, are foreign-owned and form part of multi-national enterprises. The subsidiaries of international companies are often based in the United Kingdom with perhaps a dominant position in both the international as well as the United Kingdom market. This international aspect of the pharmaceutical industry has important effects upon pricing policies of Government. There is a potential conflict between a desire to control the prices of medicines, particularly where the National Health Service is a monopoly purchaser of medicines prescribed by doctors, and the need to attract multi-national enterprises to set up business in the United Kingdom so as to increase employment and profits there. There are also implications here for the free movement of goods provisions of the Treaty of Rome, which has been discussed in Part II.

Although the pharmaceutical companies operating in the United Kingdom have varied backgrounds and interests, they have in common a heavy reliance upon exports. This was originally founded upon the supply of the medicines to the Commonwealth but is now becoming increasingly orientated towards other countries and, in particular, the USA.[21]

1.5 REGULATIONS THROUGH CONTROL OF PRICES

Although by Section 20(2) of the Medicines Act 1968 the cost at which a medicine is to be sold must not be taken into account in considering an application for a licence under that Act, there are other provisions which are concerned with price control. These take the form of the Pharmaceutical Price Regulation Scheme (PPRS), a voluntary agreement between the Department of Health and Social Security and the Association of the British Pharmaceutical Industry, designed to secure that -

> "Safe and effective medicines should be available on reasonable terms to the National Health Service, but also that a strong, efficient and profitable pharmaceutical industry should exist in the United Kingdom".[22]

The PPRS operates by controlling the costs and profits of companies which sell prescription medicines to the National Health Service but does not control the price of individual medicines. An annual return on capital employed on National Health Service business is allowed under the scheme for the pharmaceutical industry as a whole. Individual profit targets for companies are expressed as a return on capital employed in producing medicines for the National Health Service and vary according to the contribution each company makes to the United Kingdom economy in terms of investment, value added manufacture, research and exports.

In a report[23] the Public Accounts Committee of the House of Commons investigated the PPRS and found that the scheme had not, in the Committee's view, ensured the reasonableness of drug prices generally. As a result of discussions with the pharmaceutical industry, a reduction of £25m in the drugs bill was agreed in August 1983.[24] This reduction was achieved through price reductions of 2 1/2% on average and a freeze on prices until 31 March 1984. Further details of changes in the PPRS were announced in Parliament on 8 December 1983 as follows:

> (1) A reduction in the industry target profit rate of an average of 4% (from 25% to 21%) from 1 April 1984.
>
> (2) A change in the method, and a reduction in the size, of the area of discretion the Department allows in certain circumstances when companies exceed their target profit rates from a flat 10 percentage points addition to a maximum of one-third of the company's target profit.
>
> (3) Stiffer penalties on companies which exceed their sales promotion allowance permitted by the Department.

These savings were estimated to amount to £65m in 1984-85 and over £100m per annum in later years.

One of the points brought out by the witnesses of the Department of Health and Social Security before the Public Accounts Committee was the substantial long-term investment undertaken by the pharmaceutical industry in its continuing search for new products. With the period of patent promotion for medicines being twenty years, it could take between eight and ten years to develop a new drug, leaving only twelve or ten years within which its

monopoly could be exploited. After that period, other manufacturers could introduce similar products and capture a share of the market. It was argued that if a product failed at a late stage of its development, it was difficult if not impossible to recover the investment of research and development.

Evidence from the Association of the British Pharmaceutical Industry was also submitted to the Public Accounts Committee.[26] This emphasised that, in the pharmaceutical industry, the normal commercial risks were greater than in most other industries. In addition to these commercial risks, there was also what were described as the medical and scientific risks attached to the introduction of a new product, related to the difficulty of forecasting the actual safety and efficacy of a product in man based solely upon laboratory studies. All of these risks resulted in the need for the industry to earn a substantial premium profit over forms of investment for innovation to continue in a competitive international environment. One example quoted in the evidence submitted by the Association of British Pharmaceutical Industry was the product proxyeromil. This had been developed by Fisons as a potentially important product which had eventually fallen down on safety grounds at a very late stage during final clinical studies. As a result of this failure the company concerned had suffered a 27% fall in its share price overnight due to fears about future profitability.

In its conclusions the Public Accounts Committee welcomed the overall profit target for the industry and other proposed changes to achieve the savings indicated. But it believed that the savings expected to be achieved by these measures confirmed the earlier findings of the Committee to the effect that the PPRS had not ensured the reasonableness of drug prices generally.

1.6 GENERIC PRESCRIBING

When a doctor writes a prescription for a medicine he may either indicate the brand name of the product he wishes the patient to have or the approved name describing the active ingredient, which may perhaps be produced by several different manufacturers. In 1960 the Hinchcliffe Committee on the cost of prescribing[27] recommended that official names should be used on prescriptions in preference to proprietary names. Despite this recommendation only 20% of prescriptions were written by approved names in 1980.[28] There are undoubted cost savings to be achieved by the adoption of a policy of widespread generic prescribing because generic medicines are generally cheaper than branded equivalents. As against this potential savings in cost, however, are some important reservations which need to be considered.

In its report[29] the Greenfield Committee recommended that generic prescribing should be encouraged in general practice by providing a box on form EP10[30] which the doctor would initial if the branded version of the medicine prescribed was required. If that box were not so initialled, a generic version of the medicine (if it existed and was available) could be dispensed by the pharmacist.

By putting forwrd this recommendation the Greenfield Committee recognised that the final decision about which medicine a patient should receive must rest with the doctor concerned but it was felt that this proposal could be implemented without interfering with the traditional principle of clinical freedom.[31] Support for the view that generic prescibing could achieve substantial savings to the National Health Service was confirmed by a report subsequently published by the Royal College of General Practitioners.[32] In this is was suggested that much of

the financial saving could come from six products alone - Mogadon, Valium, Indocid, Aldomet, Lesix and Inderal. Calculations made in the report concluded that a doctor with a patient list of average size could reduce his prescribing costs by more than £1,000 a year by prescribing these medicines by their generic names.[33]

The report published by the Royal College of General Practitioners assumed that the policies of the advisory committees such as the Committee on Safety of Medicines made generic prescribing safe. This point was also considered by the Greenfield Committee, which was conscious of the fact that advertisements of manufacturers often drew attention to the advantages in the quality and efficacy of a branded product as opposed to its generic equivalent. The Greenfield Committee concluded that the implementation the Medicines Act 1968 had imposed high enough standards to enable prescribers to ignore any differences there might be between generic and branded products.

A further objection to generic prescribing considered by the Greenfield Committee concerned the presentation of the product. It was felt that prescribing by an approved name might result in difficulties arising out of differences in size, shape and colour of the medicines supplied. While recognising these difficulties, the Committee concluded that the problems could be overcome by careful examination undertaken by both prescribing doctor and dispensing pharmacist.

The most potent objection to generic prescribing, however, came from the pharmaceutical industry itself and was related to patent protection. It has been seen that the length of effective patent protection may be limited to twn years or even less.[34] If a new medicine has resulted in a large financial outlay to the manufacturer,

the effective patent life may expire before these research costs have been recouped. After a patent expires for a medicine, it is only the brand name which remains to protect the profits of the manufacturer. If generic prescribing were widely practised, an innovating manufacturer might lose all of his profits after the expiration of his patent rights. This might result in manufacturers becoming reluctant to undertake research, with the consequent loss of employment and exports for the United Kingdom. The Greenfield Committee, while recognising this argument[35] did not consider it in detail as it was not within its terms of reference.

It is difficult to quantify this problem in financial terms. But it must be accepted that the arguments of the industry have some force. It should be pointed out, however, that a system of generic substitution, as recommended by the Greenfield Report, is already in use at National Health Service hospitals, where the medicine bill is subject to cash limits. In these circumstances it is difficult to accept that the pharmaceutical industry could not adapt to a generic prescribing regulation, if such a provision were to be introduced. In this connection it may be noted that a Bill entitled "Generic Prescribing (National Health Service)" was introduced into the House of Commons on 22 July 1983 by Mr Laurie Pavitt. Under its terms, a pharmacist would have been able to substitute a generic product for a medicine prescribed by a doctor under the National Health Service, unless that prescription was marked "no substitute". But such a Bill was not supported by the Government and lapsed.

NOTES

1. Riley, H T "Memorials of London Life in the XIII, XIV and XV Centuries", London, Longman Green 1968.

2. Penn R G "The State control of Medicines: The first three thousand years", British Journal of Clinical Pharmacology, Basingstoke, 1979, October, Vol 8, pp 293-305.

3. This is further discussed in Section 3.8.

4. Whittet, T D "Drug Control in Britain - from World War I to the Medicines Bill of 1968", in Safeguarding the Public, Blake, John B (Ed), The John Hopkins Press, Baltimore and London, 1970.

5. Whittet, op cit.

6. Whittet, op cit.

7. Whittet, op cit.

8. Whittet, op cit.

9. The Medicines Act 1968 remains in force substantially as when passed. An amending Act, the Medicines Act 1971, made some minor changes, mainly relating to fees.

10. See the Arsenic Act 1851 (14 Vict c.13).

11. The Pharmacy Act 1868 (31 & 32 Vict c.121).

12. Report from the Select Committee of Patented Medicines 1914.

13. Report of the Departmental Committee appointed to consider and advise upon the legislative and administrative measures to be taken for the effective control of the quality and authenticity of such therapeutic substances offered for sale to the public as cannot be tested adequately by direct chemical means. London: HMSO 1921.

14. Report of the Committee of Inquiry into the Relationship of the Pharmaceutical Industry with the National Health Service 1965-67. London: HMSO, Cmnd 3410.

15. "Pharmaceutical Innovation: Recent Trends, Future Prospects", Office of Health Economics, 1983.

16. A special report on the pharmaceutical industry, The Times, 1st November 1984.

17. The Times, 11th June 1984.

18. The Wellcome Foundation Limited.

19. Macarthys Pharmaceutical plc.

20. "Growth and Prospects: Financial Study of the British Pharmaceutical Industry, 1984", Faxtel International Inc. (1985)

21. "Pharmaceuticals: An Industry Sector Overview", Key Note Report (5th Edition), London, 1984, p 9.

22. A detailed account of the PPRS may be found on the report on dispensing of drugs in the National Health Service (10th Report, Session 1982/83) of the Committee of Public Accounts.

23. Ibid.

24. See Memorandum prepared for the Public Accounts Committee by the Department of Health and Social Security published in the 29th Report from the Committee of Public Accounts, Session 1983/84.

25. Ibid.

26. This evidence was in the form of a memorandum, which is set out in an appendix to the Report.

27. Final Report of the Committee on Cost of Prescribing, London HMSO 1959, paragraph 210.

28. Report to the Secretary of State for Social Services of the Informal Working Group on Effective Prescribing (the Greenfield Report), February, 1982, paragraph 17.

29. Ibid. The Group's terms of reference were to identify ways of encouraging effective prescribing.

30. This is the form upon which most prescriptions are written in the National Health Service by general medical practitioners.

31. See paragraphs 16-24 of the Greenfield Report.

32. Harris, C T et al "Prescribing - A Suitable Case for Treatment", Royal College of General Practitioners, London (1984).

33. See pages 10-11 of the Report of the Royal College of General Practitioners.

34. Under the Patent Act 1977 the length of patent life for innovations in Great Britain was extended from sixteen to twenty years. But the grant of a patent under the Patents Act 1977 does not exclude the need for a licence

to be granted for the product under the Medicines Act 1968. Nor, indeed, does it guarantee that such a licence will ever be granted.

35. See paragraph 23 of the Greenfield Report.

CHAPTER II

The Medicines Act 1968

2.1 INTRODUCTION

In 1960 the Ministry of Health, aware of the unsatisfactory nature of the legislation upon medicines, set up an informal committee to examine the position. Then, in 1962, a more formal committee[1] was appointed with the following terms of reference:

> "To advise the Minister of Health and the Secretary of State for Scotland on what measures are needed:
>
> (1) To secure adequate pharmacological and safety testing and clinical trials of new drugs before their release for general use;
>
> (2) To secure early detection of adverse affects arising after their release for general use; and
>
> (3) To keep doctors informed of the experience of such drugs in clinical practice".

This Committee recommended a voluntary system of toxicity testing and clinical trials for drugs released on to the market.[2] This was to be administered by a Committee on the Safety of Drugs, appointed by the Health Ministers. It is interesting to see that in a strongly worded note of dissent[3] two members of the Committee drew attention to what they described as "the present chaos of authorities". In their view there was no alternative but for the Government to introduce comprehensive legislation

dealing with drugs and medicines under the responsibility of the Health Ministers, advised by a central body of experts. There was little doubt that this report focused the attention to the public upon the medicines problem. A spokesman for the Opposition in a debate in the House of Commons put it in this way:

> The House and public suddenly woke up to the fact that any drug manufacturer could market any product, however inadequately tested, however dangerous without having to satisfy any independent body as to its efficacy or its safety".[4]

Following the advice of the Committee, and pending the introduction of legislation, the Committee of the Safety of Drugs was appointed by the Health Ministers under the Chairmanship of Sir Derrick Dunlop and began to work in January 1984. Sir Derrick has described the work and constitution of his Committee in the following way:

> "It consisted of eleven fairly part-time, originally unpaid scientists, physicians and pharmacists whose careers depended in no way on their membership of the Committee, on which they served largely as an altruistic public chore. They were assisted by a small staff of civil servants who did most of the preparatory work but the members of the Committee took full responsibility for the ultimate decisions".[5]

It its annual report for 1966[6] the Committee of the Safety of Drugs emphasised that it was an expert group and not a respresentative body. It operated through three sub-committees dealing with toxicity, clinical trials and adverse reactions respectively. Drug manufacturers voluntarily submitted details of drugs to the Committee

before they were either used in clinical trials or placed upon the market. A register of adverse reactions was also established by the Committee so as to monitor the effects of drugs once they were on the market. The 1966 report of the Committee stated that in that year, as in the past, no new drug had been used in a clinical trial or placed upon the market without the Committee's agreement.[7] One further point of some general importance was also mentioned in the Committee's report for that year. This was the fact that the Committee's terms of reference did not require it to consider the efficacy of a drug, except insofar as its safety was concerned. As a result of this, the Committee was conscious that it has approved a number of products for use which were relatively worthless, although not unsafe. It therefore felt constrained to point out that, in clearing a drug for use, it did not thereby imply that the product would be efficacious for its intended use. When the Medicines Act 1968 was eventually passed, the efficacy of a product (as well as its safety and quality) were expressly set out as separate and independent factors which were to be satisfied before a drug could be placed on the market.[8]

In its report for 1967[9] two factors emerged which began to cast doubt upon the desirability of having a voluntary method of control without proper sanctions. First, two varieties of a drug were placed upon the market without the agreement of the Committee. The Health Ministers were at once informed of this and, when doctors and others were warned not to dispense these drugs, they were immediately removed from the market by the manufacturer concerned. Secondly, and of some more immediate impact from the viewpoint of the consumer, was the position regarding misleading trade names. The Committee drew attention to the fact that mixtures of drugs were sometimes made available under trade names which were similar to those of only one ingredient of the product. While deploring this

practice, the Committee pointed out that it had no power to prevent it. Its action was limited to eliciting the support of the Association of the British Pharmaceutical Industry and the Proprietary Association of Great Britain with a view to stopping the practice.

The Committee's report for 1968[10] shows that one company had marketed a number of products in the United Kingdom without first obtaining the consent of the Committee. Again, Health Ministers had been alerted to this, and had advised against the use of the products. Also during that year the Committee had received some reports of adverse reactions after the use of a product for arthritis. When the manufacturer of the product was told of this information, the product had been voluntarily taken off the market. Upon a more general point, the Committee advised that containers for drugs should be labelled with the name of medicine prescribed unless otherwise specified by the doctor. The Committee stated its disappointment that the procedure for implementing this proposal had not been introduced. This once again emphasised the lack of legislative powers to implement its advice.

2.2 THE WHITE PAPER

In September of 1967 a White Paper was published outlining the Government's proposals for legislation relating to medicine.[11] One of the reasons given for the proposals to legislate was the fact that Directives governing medicines were then being prepared by the members of the European Economic Community.[12] Having regard to the possibility of the United Kingdom joining the Community, the proposals for legislation were designed to be compatible with the contents of those Directives. In addition, the proposals for legislation drew heavily upon the experience gained by the Committee of the Safety of Drugs, and recommended the establishment of an expert

advisory committee recognised by statute to succeed it. Central to the proposals was a statutory system for controlling the safety, quality and efficacy of medicines by licensing, including toxicity testing of new drugs before being authorised for use in clinical trials. Proposals were also put forward relating to official standards for substances used in the manufacture of medicines, controls over retail sale and supply, and for labelling and advertising.

Further impetus to the movement towards statutory control over medicines was provided by the Sainsbury Report.[13] A Committee had been appointed by the Minister of Health and the Secretary of State for Scotland in May of 1965 with the following terms of reference:

> "To examine the relationship of the pharmaceutical industry in Great Britain with the National Health Service, having regard to the structure of the industry, to the commercial policies of the firms comprising it, to pricing and sales promotion practices, to the effects of patents and to the relevance and value of research and to make recommendations".

In some far-reaching recommendations, not all of which were implemented, Lord Sainsbury proposed the setting up by statute of an independent body to be known as the Medicines Commission to advise the Government upon all questions relating to medicines.[14] One of the specific terms of reference proposed for this Commission was that no prescription medicine should be licensed without its approval. In relation to this it was recommended that the role of the Commission should be merely advisory, with the final decision as to whether or not a medicine should be licensed being left to Ministers.[15] As will be seen later, this suggestion was incorporated into the Medicines Act 1968, but in a slightly modified form.

One important recommendation made by Sainsbury, relating to the control of advertisements for medicines, should also be mentioned. This was the introduction of a "control document" to be agreed between the proposed Commission and the manufacturer of the product, against which all advertisements for it could be checked.[16] Part of the system of control was that a copy of the agreed document should be sent to all practising doctors and pharmacists before the product could be advertised. It was also intended that all advertisements for the product in question should be consistent with the control document and that it should be a requirement that the firm's representative should place a copy of the control document before any doctor or pharmacist with whom he discussed his firm's product. These proposals were largely included in the Medicines Act 1968.[17]

But it was not until the thalidomide tragedy that the Government was galvanised into introducing comprehensive legislation. A Bill was introduced into the House of Commons on 2 February 1968 and received Royal Assent as the Medicines Act in October of that year, although many of its provisions did not come into operation until appointed days.

2.3 THE ACT

The purpose of this Act may be said to be to provide a comprehensive framework for regulating the manufacture, sale and supply, and advertising of medicines. It has enabled a new foundation to be laid for regulating all aspects of legal control over medicines in the United Kingdom in place of the piecemeal legislation which had been introduced over the previous century.[18]

By Section 2 of the Act a body is established known as the Medicines Commission, which is appointed by Ministers to

advise them on matters relating to the execution of the Act and on any matter which relates to medicines.[19]

One of the specific functions of the Commission is to make recommendations to Ministers about the number of Advisory Committees to be appointed and about their membership and functions. Following the advice of the Commission, Ministers have established a Committee on the Safety of Medicines, which has the following terms of reference:

> "(1) giving advice with respect to the safety, quality and efficacy of medicinal products, and
>
> (2) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given".[20]

Thus statutory effect has now been given to the former voluntary Committee of the Safety of Drugs.

Under the Act the main method of control is a system of licensing, which operates at a number of levels. In relation to human medicines[21] this system provides for product licences and clinical trial certificates. In general it is unlawful for any person, in the course of the business carried on by him, to manufacture, sell, supply or import any medicinal product without holding the appropriate licence or certificate. There are, however, various exemptions from these restrictions. This choice of licensing as the main method of control has EEC implications, which are discussed in Part II.

In dealing with an application for a product licence the licensing authority[22] must, in particular, take into consideration the safety, quality and efficacy of the product.[23] Considerations of safety are taken as

including the extent to which the product is capable of causing danger to the health of the community if used without proper safeguards and the possible harm to the person who administers it.[24] This is an important safeguard for the consumer, whether he is in the United Kingdom or elsewhere. But as will be seen, it does not mean that a patient who is injured by taking a medicine will necessarily have an effective cause of action for damages. The licensing authority must not refuse to grant a licence on any grounds relating to the safety, quality or efficacy of medicinal products without consulting the appropriate committee.[25] This will normally be the Committee on Safety of Medicines. If the appropriate committee have reason to think they may be unable to advise the grant of a licence, the applicant must be given the opportunity of appearing before the committee or of making written representations to it.[26] If, after this procedure, the Committee maintain their refusal, or are only prepared to advise the grant of a licence subject to conditions, the licensing authority must serve notice upon the applicant stating the advice of the committee and the reasons stated for giving that advice.[27] An applicant may then give notice that he wishes to be heard by the Medicines Commission or that he wishes to submit written representations to them.[28] After this, the Medicines Commission report their findings and advice to the licensing authority, which must take their report into account in determing the application.[29] When the licensing authority has taken a final decision, neither the validity of the licence, not of any decision of the licensing authority, may be questioned in any legal proceedings.[30] But a person to whom any decision relates may question its validity upon limited grounds within three months. Such a person may apply to the High Court upon the grounds that the decision is not within the powers of the Act or that the requirements of the Act or of regulations made under it have not been complied with.[31]

From this description of the adjudication system provided for the licensing of medicines it may be seen that the legal position is that the power of taking executive decisons rests with the Ministers forming the licensing authority, acting on the expert advice made available to them by the appropriate committee or the Medicines Commission. In practice, however, the licensing authority invariably follow the recommendations made to it. The advice of the Committee on Safety of Medicines was not, however, followed in connection with the recommendation not to revoke the injectable contraceptive depot-provera in 1982.[32]

This interaction between licensing authority taking decisions but acting on the advice of an expert committee presents difficulties for a potential litigant, which are discussed in Section 3.8.

It has been clearly settled by the Courts that an applicant for a licence is in general entitled to a fair hearing and must also be given the opportunity of knowing the basis of any allegation made against him so that he may deal with it. This was established in A-G -v- Ryan,[33] which concerned the question of whether a Minister in the Bahamas had given a fair hearing to an application for registraton of a citizen. In the course of his opinion Lord Diplock stated:

> "... the Ministry was a person having legal authority to determine a question affecting the rights of individuals. This being so it is a necessary implication that he is required to observe the principles of natural justice when exercising that authority and if he fails to do so, his purported decision is a nullity".

It is suggested that these principles apply to applications for licences made under the 1968 Act and, in particular, to hearings before the Medicines Commission and the statutory Committees established by that Act. Similarly, where it is proposed that a licence already granted under the Act should be revoked, suspended or varied, it would seem then the licence holder should again rely on the principles of natural justice so as to defend his position. In relation to the revocation of a licence it further appears that there is a heavier onus upon the licensing authority in justifying its decision that when considering the initial refusal of a licence. This position has been described by Professor S A de Smith in the following terms:

> "There ought to be a strong presumption that prior notice and opportunity to be heard should be given before a licence can be revoked. It should be especially strong where revocation causes deprivation of livelihood or serious pecuniary loss, or is dependent on a finding of misconduct. The presumption should be rebuttable in similar circumstances to those in which summary interference with vested property rights may be permissible. That the considerations applicable to the revocation of licences may be different from those applicable to refusal of licences has indeed been recognised by some British statutes and judicial dicta and a number of judicial decisions in other Commonwealth jurisdictions".[34]

This right of legitimate expectation may also apply to renewals of licences under the Act. Licences expire after a period of five years unless previously revoked but may be renewed for further periods of five years, with or without modification.[35]

Section 24(3)(c) of the 1968 Act provides that the licensing authority may refuse to renew a licence if, having regard to the provisions of the Act, they consider it necessary or expedient to do so. It has been held in Canada that a new condition ought not to be attached to a renewed licence without the holder of the licence having first been offered that opportunity of making representations against the proposed new conditions.[36] Similar considerations would, it is submitted, apply to licences coming up for renewal under the 1968 Act.

Further restrictions upon dealing in medicinal products were introduced by the Act where those products are to be used for the purpose of a clinical trial certificate.[37] Similar adjudication provisions apply in relation to applications for clinical trial certificates apply to the applications for product licences under the Act. Efficacy, however, is of course excluded from consideration in relation to products the subject of an application for a clinical trial certificate. Clinical trial certificates expire at the end of two years[38] but are renewable.[39]

2.4 CONSULTATION BY GOVERNMENT

There is a wide range of policy issues affecting medicines upon which there is consultation by various Government Departments in the United Kingdom with the pharmaceutical industry. Some of these issues arise out of the licensing provisions of the Medicines Act 1968. Indeed before Ministers make any regulations or an order under powers contained in that Act (except an order made in case of urgency with immediate effect) they must consult with organisations as appear to them to be representative

of interests likely to be substantually affected by the instrument in question.[40] In relation to human medicines, such consultation is undertaken by the Department of Health, while the Ministry of Agriculture, Fisheries and Food consults in relation to animal medicines.[41] Other issues may arise in this context which involve other Departments. Some of these are both national and Community laws on patents, trade marks, product liability and animal experiments, which affect the Department of Trade and Industry, the Foreign and Commonwealth Office and the Home Office respectively.

Organisations with whom Government consult reflect their respective interests, particularly the differentiation of the pharmaceutical industry between manufacturers of prescription and non-prescription medicines. With regard to prescription medicines, there were one hundred and fifty-five companies listed in the Annual Report of the Association of the British Pharmaceutical Industry for 1981/82 which produces nearly 99% of medicines supplied to the National Health Service.[42] In contrast to this is the Proprietary Association of Great Britain. This organisation represents both manufacturers of non-prescription medicines and companies which provide services to those manufacturers, such as advertising agencies with prioprietary medicine accounts.[43] These two organisations have, in general, interests which are complementary rather than competitive and they often collaborate when consulted by Government bodies on matters of common interest to their members.[44]

Three other organisations which represent interests in the pharmaceutical industry may be briefly mentioned.[45] First, the Association of Manufacturers

of Medicinal Products, which is concerned with manufacturers of comparatively little used medicines such as tonics. Secondly, the Proprietary Articles Trade Association, which is an alliance of mainly retail pharmacies to ensure there is a system of resale price maintenance in existence for their products. Thirdly, the British Herbal Medicines Association which was established in 1964 to promote co-operation between those interested in the supply of herbal remedies.

In addition to these are those that represent the interests of relevant professional bodies. As regards doctors, these include the British Medical Association and the Royal College of General Practitioners. The interests of pharmacists are represented by the Pharmaceutical Society of Great Britain.

Outside the recognised consultative bodies mentioned above may also be noted various organisations concerned with consumer interests. Among these are Health Action International and Oxfam. Their work in relation to the Third World is discussed in Part V.

2.5 CRITICISM OF THE REQUIREMENTS IMPOSED BY THE MEDICINES ACT 1968

A recent study by Hartley and Maynard[46] has been critical about the effects of the detailed requirements of the Medicines Act 1968 upon the pharmaceutical industry. In particular this study suggested that the statutory restrictions imposed were having an adverse effect upon the industry's competitive position and economic performance. The study in fact argued that a major reappraisal of the regulatory arrangements for medicines in the

United Kingdom should be undertaken. It was suggested that as a direct result of the passing of the Medicines Act 1968 an additional delay of about one year occurred up to the clinical trial certificate stage and that the licensing authority took some seven and a half months to handle an application for such a certificate. It was pointed out that the former Committee of the Safety of Drugs[47] had seldom taken more than four months to grant approval for a clinical trial.

Two changes to the regulatory requirements were introduced as a result of this criticism. First, an exemption scheme for clinical trials was introduced in 1981[48] which enabled clinical trials to take place at an earlier stage in suitable cases without the necessity of a formal application for a clinical trial certificate. The data requirements under the exemption scheme are identical to those for an application for a clinical trial certificate but, for an exemption, only a summary of the raw data is required.[49]

The second easement introduced was greater flexibility in the data required for a clinical trial.[50] Thus, teratology studies are no longer requested if women of child-bearing potential are excluded from the trial. Further, tests for long-term carcinogenicity are only required if there are serious grounds upon which to suspect risks.

A detailed explanation of the clinical trial exemption scheme[51] outlined its objectives in the following terms:

"(It brings) benefits to patients from newly marketed drugs hvaing been adequately tested in the therapeutic environment of the United Kingdom ... that it enables industry to speed up the "brain to bottle time"; it encourages the development of departments of clinical pharmacology both from the stimulus of new work and the financial support afforded by the industry; it provides an incentive for the research and development element of industry to develop in the United Kingdom, and it eases the task of the licensing authority and the Committee of Safety of Medicines in assessing drugs at marketing stage if trials to a high standard have been conducted in the United Kingdom".

A subsequent study[52] has attempted to provide what it describes as an interim report upon the safety of operating the scheme. This did not, however, attempt to assess whether any of the major adverse events which occurred during the clinical trials taking place under the exemption provisions were attributable to drug culpability or other causes. It was found that the total number of applications for an exemption under the scheme was two hundred and ten from 1 April 1981 until 31 March 1982, of which two hundred and seven were granted. Four clinical trials were suspended on the grounds of safety where exemption had been granted. Twenty-three of the exemption applications originated in the USA, nine from Switzerland, seven from West Germany and five from Japan.

In their conclusion the authors of the study[53] found that the number of new clinical entities submitted for evaluation in a clinical trial has increased two-fold in the first year of the operation of the scheme. This figure was reached by comparing the number of applications for an exemption with the average number of applications

for a clinical trial exemption in the previous three years. It was also concluded that the operation of the exemption scheme had resulted in no increased risk to those patients who had participated in the clinical trials which were granted exemption under the scheme. This conclusion suggests that a limited amount of deregulation may not necessarily be detrimental to patient safety. In addition the exemption scheme had considerable reduced delays due to the licensing authority in enabling new products to be approved for the purpose of evaluation in clinical trials.

A later study[54] has shown that the increase in the number of new chemical entities submitted for evaluation through the clinical trial exemption scheme in the United Kingdom has been sustained throughout the first three years of its operation. This study has also found that there has been a high degree of consistency between the licensing authority's initial decision in issuing an exemption and the subsequent advice of the Committee on Safety of Medicines in granting a product licence for the product. The study estimated that some increase had been shown in both the number of extra jobs created and the research budgets of certain companies as a direct result of the introduction of the exemption scheme.

NOTES

1. The Joint Sub-Committee on Safety of Drugs of the Standing Medical Advisory Committee. Their final report was dated March 1963. London; HMSO 1963.

2. Paragraphs 8-10 of the Report.

3. Set out at pages 12-14 of the Report.

4. Hansard, Vol 677, 8 March 1963.

5. Dunlop, D "The Growth of Drug Regulation in the United Kingdom", Journal of the Royal Society of Medicine, London 1980, June, Vol 73, no 6, pp 405-407.

6. Introduction to the Report of the Committee of the Safety of Drugs 1966. London; HMSO 1967.

7. Ibid.

8. Section 19(1).

9. Report of the Committee of the Safety of Drugs 1968. London; HMSO 1969.

10. Report of the Committee of the Safety of Drugs 1968. London; HMSO 1969.

11. Forthcoming legislation on the safety, quality and description of drugs and medicines 1966-67. London; HMSO, Cmnd 3395.

12. See paragraph 9 of the White Paper.

13. Report of the Committee of Enquiry into Relationship of the Pharmaceutical Industry with the National Health Service 1965-67. London; HMSO, Cmnd 3410.

14. Paragraphs 30 and 363 of the Report.

15. Paragraph 337 of the Report.

16. Paragraph 344 of the Report.

17. See Section 96 of the Act, where the "control document" is given the name "data sheet", the latter term being defined in Section 96(6).

18. See Dunlop, D "Medicines, Governments and Doctors", Drugs, Sydney 1972, Vol 3, pp 305-313.

19. The term "medicinal product" is used in the Act and this is given a fairly wide definition in Section 130.

20. Section 4(3) of the Medicines Act 1968 and the Medicines Committee on Safety of Medicines Order 1970 [SI 1970 No 1257].

21. The Medicines Act 1968 is concerned with medicinal products as defined, whether for human or animal use.

22. The licensing authority for the purposes of the Act means one or more of the body of Ministers specified in Section 1(1) of the Act see Section 6.

23. Section 19(1).

24. Section 132(2).

25. Section 20(3).

26. Section 21(1).

27. Section 21(3).

28. Section 21(4).

29. Ibid.

30. Section 107(1).

31. Section 107(2) and (3). It has been suggested that, notwithstanding the precise wording of the sub-sections, it may be possible to obtain judicial review on the

grounds of palpable unreasonableness, see Hodges, C J S "Appeals to the Medicines Commission and Beyond", BIRA Journal, Vol 3, No 2, p.33.

32. Controversy has long surrounded depot-provera, particularly in connection with the risk that it may cause heavy or prolonged bleeding in some women. The Minister of Health prohibited its use despite advice from the Committee on Safety of Medicines that use in certain circumstances was permissible. Following an appeal by the manufacturer Upjohn Limited, the persons appointed by the licensing authority advised that the product should still be available as a contraceptive but not for long-term use. The report of the persons appointed was published by the Department of Health and Social Security and this is discussed in Part IV.

33. [1980] AC 718.

34. de Smith, D A "Judicial Review of Administrative Action", London, Stevens and Sons Limited (4th edition) p 224.

35. Section 24.

36. Re: CTV Television Network Limited, [1980] 116 DLR (3d) 741.

37. See Sections 31, 36, 38 and 39 of the Act.

38. Section 38(1).

39. Section 38(2).

40. See Section 129(6) of the Medicines Act 1968.

41. See Section 1(1)(b) of the 1968 Act.

42. Sargent, Jane A "The Organisation of Business Interests in the UK Pharmaceutical Industry", London School of Economics, [1983] p 15.

43. Ibid, p 18.

44. Ibid, p 18.

45. Ibid, p 32.

46. Hartley, J and Maynard, A "The Costs and Benefits of Regulating New Product Development in the UK Pharmaceutical Industry", Office of Health Economics, London, March 1982.

47. For the work of the Committee on the Safety of Drugs, see Section 1 of this Chapter.

48. The Medicines (Exemption from Licences) (Clinical Trials) Order 1981 [SI 1981 No 164].

49. See Medicines Act 1968, Guidance Notes on Applications for Clinical Trials Certificates and Clinical Trial Exemptions, [1984], HMSO.

50. These new requirements were drawn up by a Working Party set up by the Committee on Safety of Medicines under the Chairmanship of Professor D G Grahame-Smith. See "Data Requirements for Clinical Trial Certificates" [MLX130], Medicines Division of the Department of Health and Social Security, [1981].

51. Griffin, J P and Long, J R "New Procedures Affecting the Conduct of Clinical Trials in the United Kingdom", British Medical Journal, (1981), 283, pp 477-479.

52. Speirs, C J and Griffin, J P "A Survey of the First Year of Operation of the New Procedure Affecting the Conduct of Clinical Trials in the United Kingdom", British Journal of Clinical Pharmacology, [1983], 15, pp 649-655.

53. Ibid.

54. See Speirs, J et al "The UK Clinical Trial Exemption Scheme Its Effects on Investment and Research", Pharmacy International, Amsterdam, 1984, Vol 5, No 4, pp 254-256.

CHAPTER III

Consumer Safety

3.1 INTRODUCTION

One thing, which may be said to run like a golden thread through the Medicines Act 1968, is the question of safety. Having regard to the reason for the introduction of that legislation in the first place - namely, the thalidomide tragedy of the early 1960s, it is not perhaps surprising that this is so. From the viewpoint of the consumer it is reasonable for him to assume that any medicine placed upon the market has undergone controls to ensure that it is reasonably safe for the purpose for which it is provided. But is must be accepted that there can be no such concept as absolute safety in relation to medicine. Potential benefits to patients must be weighed against potential risks, particularly in the case of new and powerful products. It is the role of the licensing authority under the Medicines Act 1968 to weigh those risks and benefits having regard to developments in science and the advice (which may of course change in time) of the expert committees which are made available to them. It is now proposed to consider such aspects of consumer safety in relation to medicines.

3.2 ADVERTISING

Part VI of the Medicines Act 1968 contains wide powers giverning sales promotion of medicinal products, and these include both the issue of advertisements and the making of representations. An "advertisement" includes every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter (whether circular or addressed to a

particular person) or other document, or by words inscribed on any article, or by the exhibition of a photograph of a cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way.[1] Both the sale or supply of a medicinal product in a labelled container and the supply of a leaflet are excluded from the definition of advertising. This is because they are both governed by other provisions of the Act.[2]

Before an advertisement is sent or delivered to a doctor or dentist, or a representation is made to him about medicinal products of any description, it is a requirement that a data sheet should have been sent or delivered to him within the last fifteen months.[3] Such a data sheet is prepared by the holder of the appropriate product licence and must conform to the prescribed form and contents and contain no other information.[4] The 1968 Act contains a power for the licensing authority to be provided with copies of any advertisement issued within the previous year.[5] Further controls on advertising to doctors and dentists are contained in the Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978.[6]

Enforcement of Part VI of the Act is achieved by two methods. First, there are criminal penalties imposed, although these powers are rarely exercised. Secondly, there are various codes of practice which have been drawn up and are observed by the appropriate bodies. One of the most important of these is the code of practice for the pharmaceutical industry prepared by the Association of the British Pharnaceutical Industry after consultation with the British Medical Association and the Department of Health and Social Security.[7] This code recognises that it is important in the public interest to provide the medical profession with accurate, fair and objective

information about medicinal products so that rational prescribing decisions can be made. The code provides[8] that any claims made must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly. It is also provided[9] that the word "new" should not be used to describe any product or presentation which has been generally promoted, for more than twelve months in the United Kingdom.

This code of practice also contains guidance for medical representatives, who are required to be adequately trained and possess sufficient medical and technical knowledge to present information on the company's products in an accurate and responsible manner.[10] Upon the subject of hospitality offered for the purpose of sales promotion, this should be secondary to the main purpose of the meeting and not out of proportion to the occasion.[11]

Although it may seem from these comprehensive controls imposed in relation to the advertising of medicines that the restrictions are stringent, there are in fact a number of indications that suggest that they do not unduly hinder the promotional activities of the manufacturers. There are in the United Kingdom a very large number of medicines available on prescription. Those total about six thousand five hundred products, which should be compared with the one thousand nine hundred products available in Norway and the two thousand five hundred prescribable in Sweden.[12] Even this figure for Norway may seem high in considering that the Norwegian authorities have licensed some seven hundred and thirty active ingredients, which is about three times as many as have been identified as essential drugs by the World Health Authority for use in the Third World.[13] Some indication of the promotional activities of medicine manufacturers in the United Kingdom may be obtained from

the fact that they spent about £150m on this in 1982. This is the equivalent of £4,000 ro £5,000 on each general medical practitioner in the United Kingdom.[14]

Having regard to this large level of promotion it is not surprising to learn that doctors are increasingly coming to depend upon literature provided by medicine manufacturers as the source of their information about medicines. According to the Office of Health Economics[15] the medicine manufacturers were virtually the sole source of information and education of doctors about drugs in the 1950s. In 1967 the Sainsbury Committee[16] produced the following table showing that industry was still the main source of such information:

Sources of Information which most Influence General Practitioners' Prescribing Habits

Source	%
Drug Firm Representatives	29
Recommendations from Consultants	27
Articles in Journals	12
Drug Firm Literature	10
Professional Contacts with other Doctors	8
Advertisement in Journals	1
Drug Firm Meetings	1
Other Source	10
Don't know	2

Surveys carried out since the Sainsbury Committee Report have shown that doctors still rely heavily on the industry's literature and representatives to provide information to them.[17]

3.3 CLINICAL FREEDOM

In considering this heavy reliance by doctors upon the information made available to them by the industry it is important to bear in mind that doctors in the United Kingdom enjoy almost complete clinical freedom in the choice of the medicine they prescribe for their patients. Although some limited controls are now imposed upon what doctors prescribe under the National Health Service[18] the wide freedom for doctors to prescribe whatever they regard as necessary, and a wide range of products from which to choose, give them almost complete discretion as to the products they select for their patients. Doctors are also free to ignore, if they so choose, the cost to the National Health Service of the treatment they prescribe.

There has been, however, mounting criticism of this clinical freedom and even suggestions made that it should be removed. J R Hampton, Professor of Cardiology at Nottingham University Hospital has concluded:

> "Clinical freedom died accidentally, crushed beneath the rising cost of new forms of investigation and treatment, and the financial limits inevitable in an economy that cannot expand indefinitely. Clinical freedom should, however, have been strangled long ago, for at best it was a cloak of ignorance and at worst an excuse for quackery. Clinical freedom was a myth that prevented true advance. We must welcome its demise, and seize the opportunities now laid down before us".[19]

A more direct attack upon this long held freedom has been mounted by the Government. In the Queen's Speech for 1984 the Secretary of State for Social Services,

Mr Norman Fowler, announced[20] that in future only generic medicines would be prescribable under the National Health Service for certain conditions. These were identified as the less serious conditions such as coughs and colds and tranquillisers and sedatives.

Under these proposals it would be possible for a patient to have a particular branded product in one of two ways. If it was not a prescription-only medicine, it could be purchased from a chemist. Alternatively, if it was a prescription-only medicine, it would be possible for the doctor to write a private prescription for the patient. It was estimated that the savings for the National Health Service by introducing such a scheme would amount to about £100m per annum. In explaining these proposals it was stated[21] that the drugs bill for the National Health Service was almost £1,400m per year, compared to about £250m ten years before. Further, more medicines than ever were being prescribed, with general medical practitioners issuing one hundred million more prescriptions each year as compared to twenty-five years previously.

In its consultation with the medical profession and the industry upon these rather radical changes the Government met with fierce opposition. The Association of the British Pharmaceutical Industry, in particular, issued a series of advertisements[22] which argued that the plan was both unnecessary and uncaring. Their arguments are that the effect of the scheme would be to reduce the prescribing freedom of doctors under the National Health Service, impair the treatment of some patients and harm the British pharmaceutical industry. Some less fundamental criticisms have been mounted by the Royal College of Physicians. The position of this influential body was made clear in a letter to The Times.[23] The President stated that his College was critical of the

presentation and many of the details of the Government's list, but supported the general principle of limited prescribing, subject to several important safeguards:

1. That the quality of the drugs on the list must be assured;

2. That drugs should be available to meet the full range of desired therapeutic activity;

3. That an appeal mechanism should exist through which a non-listed product should be considered for inclusion; and

4. That there should be a regular review of the list.

With effect from 1 April 1985 general medical practitioners may no longer prescribe at National Health Service expense certain products listed in Schedule 3A to the National Health Service (General Medical and Pharmaceutical Services) Amendment Regulations 1985.[25] Such doctors may, however, issue a non-National Health Service prescription to National Health Service patients for products so listed to be issued in the course of National Health Service treatment, if their patients so wish.[26]

Thus some legal restraint has been imposed upon the hitherto unchallenged right of clinical freedom enjoyed by general medical practitioners under the National Health Service although in a very limited form.

But the Government scheme hardly provides anything that could seriously be regarded as a national essential drug policy. The Greenfield Committee on effective prescribing did consider the point but produced little evidence to

support the introduction of a limited drug list. Its report stated:

> "There are in the region of six thousand five hundred preparations available for prescribing at NHS expense and the BNF lists some four thousand five hundred of these. In comparison, the average prescriber is said to use a range of two hundred to three hundred drugs. A number of schemes for the introduction of a national limited list of drugs has been proposed at various times by different people. We have considered these, but it is our view that a limitation on prescribing at NHS expense would be interpreted by some doctors as an attempt to curtail their clinical freedom. Since we have not seen convincing evidence suggesting that financial benefits would outweigh the administrative problems in drawing up and maintaining the list, we have concluded that such a move would not be justified and we do not recommend any measures to introduce nationwide a limited list".[27]

This recommendation has been criticised by Medawar[28] on two main grounds. First, the Committee seems to have ignored the experience from other countries such as Norway and New Zealand, where limited drug lists have been successfully introduced. Nor did it make any reference to the initiatives of the World Health Organization in drawing up a list of essential drugs for countries in the Third World.[29] Even more surprising was the omission of the Committee to consider the successful and widespread use of drug formularies in National Health Service hospitals. Secondly, the Committee (composed of eleven doctors out of a membership of twelve) failed to produce a recommendation which reflected the interests of either the

tax payer, as the national paymaster for the drugs bill, or the consumer. For these reasons the recommendation of the Greenfield Committee on the introduction of a limited drug list cannot be said to carry much authority. It is significant that the Government has thought to ignore it in implementing its limited list, even though this is on a very small scale.

3.4 QUALITY OF PRESCRIBING

Some concern has also been expressed about the quality of prescribing practised by the medical profession. Against a background of almost total clinical freedom, and a large measure of dependence by doctors upon the information provided by the medicine manufacturers for their knowledge, it is necessary to consider whether their knowledge and education is satisfactory so as to ensure that medicines are prescribed effectively. The evidence suggests that doctors may not be so prescribing and that they may lack the necessary expertise to do so. Medawar has described the problem in the following way:

> "The emphasis in the training of doctors is still very much on diagnosis - on learning how the body works and how its responds to disease. Medical students do learn how to manage different diseases, and how to use different drugs when doing so. But they are still taught very little about the principles about drug use and drug effects and are not taught much about assessing the efficacy and safety of drugs in clinical trials".[30]

This concern was also reflected in some passages of the Greenfield Report. In recommending that medical students should be given basic training in both pharmacology and therapeutics the Committee said:

> "We believe that the pre-clinical years should provide an introduction to the general aspects of drug action, absorption, execretion, and metabolism ... the aim should be to view the link between physiology, pharmacology and therapeutics".[31]

Greenfield also made recommendations about the postgraduate training of doctors and the importance of prescribing in general practice. The report said:

> "We consider that prescribing should have a prior priority in vocational training. There are strong reasons to put forward to support this argument: the increasing incidence of iatrogenic disease (disease caused by doctors or medicine), particularly in elderly patients; the frequency of prescription given in a high proportion of GP consultations resulting in high and sometimes unnecessary cost to the NHS; the need for trainees to understand that there are alternatives to a prescription which should be considered; and the attraction as a subject for review by the individual doctor".[32]

These passages suggest that both the knowledge and education of doctors are lacking, with the result that prescribing is not really so effective as it should be. Having regard to the economic and therapeutic consequences which invariably flow from this, it logically leads to a conclusion that some legal constraint upon the freedom to prescribe would be a perfectly justified approach for Government to take.

3.5 COMMERCIAL INFLUENCE ON PRESCRIBING

The Greenfield Committee also considered the question of whether the industry exercised some commercial influence on the prescribing pattern of doctors. In its report the Committee said:

> "With constant developments in drugs and therapeutics, doctors can soon become out of touch. It is clearly important that they should be in a position to assess the data presented to them by the drug companies".[33]

A related subject, and one of much public concern, is the ethical position of some of the relationships between the medical profession and the pharmaceutical industry.

This particular concern has recently been described in this way by Rawlins:

> "The charge against us that in many of our dealings with the industry we have become corrupt; that in return for needlessly and sometimes recklessly prescribing their expensive products we accept or even demand rewards on a breath-taking scale. Most doctors believe that they are quite untouched by the seductive ways of the industries marketing men, that there are uninfluenced by the promotional propaganda they receive; that they can enjoy a company's generosity in the form of gifts and hospitality without prescribing its products. The degree to which the profession, mainly concerned of honourable and decent people, can practice such self-deceit is quite extraordinary. No drug company gives away its shareholders' money in an act of disinterested generosity. The harsh truth

> is that not one of us is impervious to the promotional activities and that the industry uses its various sales techniques because they are effective".[34]

Quite clearly there is a real danger that doctors may lose the public's confidence if it is seen that their relationship with the suppliers of the medicines they prescribe is not one of total independence. If it is suggested that the choice of drug may depend, not upon an objective and scientific basis, but upon mercenary considerations, the whole foundation upon which the concept of clinical freedom is erected may crumble away. That this is real rather than a mere theoretical problem may be seen from the fact the Royal College of Physicians has published a report giving guidelines for the profession to follow in their dealings with the industry.[35] Announcing the proposed publication of these guidelines Sir Raymond Hoffenburg said:

> "We are not afraid of offending some member of the medical profession or the pharmaceutical industry, and indeed we probably will because there is no question that some of the behaviour is completely unsatisfactory".[36]

In the report the close working relationship between doctors and the pharmaceutical industry was stressed. In considering this relationship it was stated:

> "The over-riding principle is that any benefit in cash or kind, any gift, any hospitality or any subsidy received from a pharmaceutical company must leave the doctor's independence of judgment manifestly impaired. When it comes to the margin between what is acceptable, judgment may

sometimes be difficult: a useful criterion of acceptability may be 'would you be willing to have these arrangements generally known?'".[37]

3.6 GOVERNMENT CONTROLS AND INFLUENCE

It would not give a balanced picture of the influence of the pharmaceutical industry over the medical profession if no reference were made to the policy of the Department of Health in the context of the use of medicines. This has been officially described in the following terms:

> "To help doctors to be reliably informed about drugs and therapeutics and the effect of that in prescribing habits".[38]

This policy is carried out in a number of ways. First, it pays for doctors to be sent publications which encourage effective prescribing, including the British National Formulary, Prescribers' Journal, Drug and Therapeutics Bulletin and comparative charges prepared by the Department setting out the various costs of prescribing similar products. Secondly, it arranges meetings between its own Regional Medical Officers and prescribers to discuss prescribing matters. Such meetings might be arranged if the prescriber's costs were unusually high or the prescriptions were unusual in some way such as if the combinations of drugs on one prescription for a particular patient was considered dangerous.[39] In England the Prescription Pricing Authority collects all prescriptions written by general medical practitioners and analyses a sample so that the prescribing costs of practices may be compared with the norm. This information enables the Regional Medical Officers to discuss the prescribing habits of doctors upon an informed basis, but the emphasis is upon education and encouragement to prescribe more

effectively than upon legal sanctions. Thirdly, the Government has some little used legal controls contained in the National Health Service (Service Committees and Tribunal) Regulations 1974.[40]

Under Regulation 20 of those Regulations, if a Medical Service Committee decide that a substance prescribed by a general medical practitioner is not a drug or medicine forming part of the pharmaceutical services provided by the National Health Service, it must recover the cost from the doctor by deduction from his remuneration. This cost is to be apportioned where any substance not a drug is an ingredient in a preparation of which other ingredients are drugs. Either the Committee or the Secretary of State, if dissatisfied with the decision, may refer the question to independent referees (not exceeding three), one of whom must be a doctor appointed by the Secretary of State.

One decision given by such referees has been considered by the High Court.[41] In that case a proprietary preparation containing about fifty per cent drinking chocolate, was prescribed by three general medical practitioners for patients suffering from depression. In the view of the referees the drinking chocolate moiety could not be described as a drug, with the result that the doctors were surcharged for the proportion of the preparation. The doctors then appealed to the High Court for the decision of the Secretary of State to be quashed and the Divisional Court allowed their appeal. It was held that the referees had concerned themselves not so much with the question whether the drinking chocolate moiety as a masking agent made the preparation a drug, but whether the masking agent itself was a drug. It was not the only flavouring agent which could have been used and patients could add their own. In the opinion of the Lord Chief Justice the preparation should have been viewed as one and indivisible. As a whole, it was a drug "even though in other cases, the reasons which might seem good

to them, either the medical practitioner or the Committee might seem to have a substance considered which was combined with other ingredients".

A further form of control is contained in Regulation 16 of the National Health Service (Service Committees and Tribunal) Regulations 1974. Under this provision, where the Secretary of State considers that the character or quantity of drugs prescribed by a general medical practitioner for his patients is excessive, he may refer the matter to the Local Medical Committee for their consideration. If the complaint is upheld there is provision for withholding money from the doctor concerned, subject to a right of appeal.

3.7 ADVERSE REACTIONS

Part of the terms of references of the Committee on Safety of Medicines is "promoting the collection and investigation of information relating to adverse reactions".[42] But the adverse reaction reporting system began in May 1964 when Sir Derrick Dunlop, Chairman of the Committee of Safety of Drugs, wrote to all doctors and dentists in the United Kingdom asking for reports of "any untoward condition in a patient which might be the result of drug treatment". The Register of Adverse Reactions set up by the Committee of Safety of Drugs was continued by the Committee on Safety of Medicines.[43] Doctors were originally asked to report on the yellow card, which has given its name to this system of reporting. Each doctor is given a supply of yellow cards which they are requested to fill in whenever they come across a doubtful drug reaction. Speirs has estimated that of one hundred and twenty-two thousand doctors who were eligible to report an adverse reaction during the period from 1972 until 1980, only sixteen per cent in fact did so. From this it was

concluded that the yellow card system was considerably under-used, and that this was itself a cause for concern. It has been suggested that for a variety of reasons, such as inertia, complacency and the fear of litigation, only some ten per cent of adverse reactions are in fact reported.[44]

One obvious difficulty arising out of the yellow card system is where a patient is taking more than one medicine. In these circumstances it may be difficult to say which particular medicine has caused the adverse reaction in the patient. It is to overcome this difficulty that the concept of prescription event monitoring has been introduced, which is often looking for specifically suspected adverse effects, by the Drug Surveillance Research Unit at Southampton University. This unit is able to rely upon the availability of British National Health Service prescriptions.[45]

In addition to reports received through the yellow card system the licensing authority regards the information contained in medical journals as an important source of evidence for adverse reactions. A medical member of the Medicines Division of the Department of Health and Social Security has evaluated this source and commented favourably upon it.[46] A third potential source of information relating to adverse reactions is the manufacturer of the medicine itself. They have a legal obligation[47] to record any adverse reaction of which they are informed. Failure to comply with that provision is a ground upon which a product licence granted under the Medicines Act 1968 may be suspended, varied or revoked.[48]

Serious doubts about the effectiveness of the yellow card system of reporting have, however, been raised. Two editorials in important medical journals published in 1982 questioned the utility of the system's failure to detect

the adverse reactions associated with either practolol or benoxabrofen.[49] Venning has also concluded that the system has made a negligible contribution to detecting adverse reactions[50] and Crombie has identified an important reason for the failure of doctors to report adverse reactions - namely, the number of adverse reactions seen by an individual doctor.[51] His study has shown that a general medical practitioner is unlikely to see more than one example of an adverse reaction. In contrast to this, a hospital doctor has a greater chance of seeing more than one adverse reaction. This is because hospital doctors specialise in particular branches of medicine and are likely to see larger numbers of patients taking the medicine causing the adverse reaction and are able to detect the relationship between medicine and reaction. It is because of this that Crombie has suggested[52] that the yellow card system would have more effect if concentrated upon hospital doctors.

Because of criticism surrounding the delay in taking action on Opren the Committee on Safety of Medicines established a working party on the subject of adverse reactions under the chairmanship of Professor D J Grahame Smith. In Part I of its report[53] the working party recognised that it was unusual for more than about one thousand patients to have received a new drug prior to its being placed on the market. From this it was noted that, if the prescription rate for the new drug was low, it might be many years before a rare adverse drug reaction was identified. The working party also recognised that the yellow card system had been criticised upon a number of grounds - including failure to detect unsuspected reactions quickly enough, under-reporting by doctors and failure to communicate information to the medical profession. While recognising these problems, the working party concluded that the yellow card system was, in terms of numbers of reports per doctor or patient

population, among the best centralised national systems for reporting adverse reactions in the world. It was felt that the yellow card system should be retained in its present form but that some further publicity should be given to the system so that doctors would report more freely and that guidance should be circulated to the pharmaceutical industry clarifying the extent of its legal obligation to report adverse reactions.

3.8 CONSUMER SAFETY

Various provisions are contained in the Medicines Act 1968 relating to consumer safety and protection. Of these, one of the most important is Section 62. This enables an order to be made by statutory instrument prohibiting either totally or subject to exceptions the sale, supply or importation of medicinal products. Before making such an order the appropriate Ministers must be satisfied that it is necessary to do so in the interests of safety and they must, unless they consider it essential to make the order with immediate effect to avoid serious danger to health, first consult with the appropriate committee or the Medicines Commission. Where an order under Section 62 is made without prior consultation it may only have effect for a period of three months, though this does not prevent further orders being made for periods of three months without prior consultation. These powers were exercised in 1976/77 in relation to a baby tonic known as Bal Jivan Chanco. Here two temporary three-month orders were made without consultation, followed by a permanent order made after consultation with both representatives and the Committee on Safety of Medicines.[54] Section 67(3) of the Medicines Act 1968 makes it a criminal offence to sell, supply or import any medicinal product in contravention of an order made under Section 62 of that Act.

A further consumer protection provision is contained in Section 65 of the Act. This makes it an offence to sell or supply a medicinal product which does not comply with the standard specified in certain monographs where it is shown that this standard formed the basis of a transaction. The publications to which these requirements extend are the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex and any compendium published under Part VII of the Act.[55] A case decided before the passing of the Medicines Act 1968 illustrates how this provision would operate.[56] A purchaser went into a chemist shop and asked to be supplied with "mercury ointment". This ointment was one of the medicines contained in the British Pharmacopoeia. An ointment was supplied to the purchaser which contained a lesser proportion of mercury than that prescribed in the monograph. It was held that the chemist had committed an offence by having sold a drug not being of the quality demanded of the purchaser.

These provisions, however, are enforced by means of penalties in the criminal Courts. This may result in a fine being imposed upon the manufacturer or supplier by provide no right to compensation for a patient suffering from the adverse effects of taking a medicine. At present the general position in the United Kingdom is that a manufacturer will only be liable in damages if he is proved to have been negligent. In many cases, there may be no fault which can reasonably be attributed to the manufacturer, particularly where the adverse reaction experienced was unexpected. At present no person has obtained judgment for personal injury against a drug manufacturer in the English Courts,[57] although some actions are still pending. A number of factors contribute towards this position. Firstly, there are the difficulties of identifying the fact that the injury caused has resulted from the medicine in question, which must be determined by medical evidence. Secondly,

there are strict financial limitations imposed upon potential plaintiffs under the Legal Aid Scheme. Few people are wealthy enough to be prepared to sue a large international corporation in such a speculative cause of action. There is no provision in the United Kingdom for a contingency fee basis, which applies in some States of the USA, whereby the lawyer only receives a fee if and when he has recovered damges for his client. Thirdly, there may be a bewildering choice of potential defendants, which may include the doctor who prescribed the medicine, the Health Authority concerned, the licensing authority who granted the licence for the medicine, and the Advisory Committee upon whose advice the licensing authority relied, as well as the manufacturer of the product. As MacKintosh has observed:

> "The juxtaposition of other defendants not only complicates the litigation and, to the detriment of the plaintiff, slows it down but also makes it more difficult for early out of court settlements."[58]

As regards the position of the licensing authority in the United Kingdom as a potential defendant to an action for negligence, the position seems to be that although there may be as a general principle a possible cause of action, there seems little likelihood of it being successful in practice. The principle has been expressed by Lord Denning in the following terms:

> "This principle has received powerful support from the House of Lords. If a statute imposes a duty on a public authority - or entrusts it with a power - to do this or that in the public interest, but expresses it in general terms so that it leaves it open to the public authority to do it in one of several ways or by one of several

> means, then it is for the public authority to determine the particular way or the particular means by which the performance of the statute can best be fulfilled. If it honestly so determined - by a decision which is not entirely unreasonable - its action is then ultra vires and the courts will not unterfere with it: see especially by Lord Diplock in Dorset Yacht Company Limited -v- The Home Office ... but if the public authority flies in the face of the statute, by doing something which the statute expressly prohibits, or by failing to do something which the statute expressly enjoins, or ... otherwise so conducts itself - by omission or commission - as to frustrate or hinder the policy and objects of the Act, then it is doing what it ought not to do - it is going outside its jurisdiction - it is acting ultra vires. Any person who is particularly damnified thereby can bring an action in the Courts for damages or an injunction, whichever be the more appropriate."[59]

While this principle has never had occasion to be tested in the Courts in relation to the liability of the licensing authority under the Medicines Act 1968, it does seem unlikely that such an action would be successful. This is particularly so where the licensing authority has acted in accordance with the advice given to it by a committee established under the Act or the Medicines Commission.

This is in contrast to the position in the United States, which is generally accepted as the most favourable forum for plaintiffs seeking damages for personal injuries. There the influence of powerful consumer organisations has ensured that pharmaceutical companies have been

successfully sued in product liability actions. In recent years, however, a number of action groups have been established in the United Kingdom such as the Association for Parents of Vaccine Damage to Children[60] and the Opren Action Group. There are a number of actions pending the British Courts claiming damages against the Eli Lilly Company and its British subsidiaries in respect of damage allegedly suffered as a result of taking the anti-arthritis drug Opren.[61]

It cannot be argued with any conviction that the common law remedy of negligence has provided a satisfactory remedy to potential litigants in this area. Indeed the position may be accurately expressed in terms that the manufacturer of medicines is insulated from direct legal action in relation to his activities. Such a position cannot be viewed with equanimity where no redress may be obtained for personal injuries suffered by the adverse reactions of a medicine. As Cranston has remarked in the context of thalidomide:

> "The thalidomide tragedy illustrates the deficiencies of negligence as a system of compensating consumers injured by defective products".[62]

An EEC Council Directive (85/374/EEC), introducing strict liability for damage caused by defective products, came into effect on 25 July 1985. It must be implemented within three years from that date and its implications for medicines has been discussed in Section 10.5.

3.9 CONCLUSION

It is generally accepted that the United Kingdom has one of the most stringent controls in the world for medicines.[63] While absolute safety for the consumer can

never be guaranteed, the Committee on Safety of Medicines has an enviable international reputation for the quality of its advice in this field. In this review of the regulation of the Medicines Act 1968 Teff has concluded that:

> "As we have seen, one cannot quantify with precision the benefits of regulation in the terms of safer, better quality and more effective drugs. But set aside industry profits estimated to have exceeded calculations to minimise the risk of disasters such as thalidomide in the future and to help maintain standards in the industry generally, especially given the reality of imperfect prescribing. All things considered the Medicines Act now embodies a prescription for health - not a regulatory over-dose".[64]

It is difficult to argue against Teff's conclusion upon this but there are a number of additional factors which may be criticised as being less than satisfactory from the point of view of the consumer. Control over the safety of medicines has not been matched by a corresponding control over prices. In spite of various changes in the voluntary price regulations schemes, the reasonableness of drug prices has still not been achieved, as found by the Public Accounts Committee. An introduction of some form of compulsory generic prescribing would undoubtedly do much to reduce the national drug bill, without any additional risk to consumer safety.

Safety of medicines is, however, a much wider concept than the regulation of which medicines should be granted a licence. Unless doctors are sufficiently educated, and kept up-to-date with current developments in medicines by independent evaluations of new products, they will not be in a position to choose the appropriate medicines for

their patients. This will not be achieved by an over-reliance upon information provided by the pharmaceutical industry itself. The proposed introduction of ethical guidelines is an indication that the influence of commercial pressures upon prescribing is felt necessary by the medical profession itself. Such a form of control, being a form of self-regulation by the profession, may also be more effective than Government controls, which are likely to be regarded as interference with clinical freedom.

There are two further areas in which additional provisions for safeguarding the interests of consumers are clearly required. First, the system of reporting of adverse reactions. Recent experience has shown that the yellow card system of reporting is not adequate to detect all cases of serious adverse reactions. What may be required is a more closely controlled system of post-marketing surveillance for new products, particularly those which may reasonably be regarded as potentially hazardous. Secondly, it is clear that the existing law in the United Kingdom is inadequate in that it fails to provide for compensation for patients suffering from the effects of taking medicines. Those actions for negligence which have been pursued up to the present time have proved extremely costly and have not resulted in awards of damages. That such a system of compensation is possible may be seen from the corresponding position in the USA, which is regarded as the most favourable forum for those seeking damages against manufacturers in respect of personal injuries.[65] As Lord Denning has cogently remarked:

> "As a moth is drawn to the light, so a litigant is drawn to the United States. If he can only get his case into their Courts, he stands to win a fortune".[66]

It remains to be seen whether the implementation of the EEC Directive on Product Liability will remedy this deficiency.

NOTES

1. See Section 92(1) of the Medicines Act 1968.

2. See Section 86(1).

3. See Section 96(3).

4. See Section 96(6) of the Medicines (Data Sheet) Regulations 1975.

5. See Section 97 of the Act.

6. Statutory Instrument 1978 No 1020.

7. The Sixth Edition of this Code came into effect in January of 1984 and contained the constitution and procedure for the Code of Practice Committee.

8. Paragraph 5.1 of the Code of Practice.

9. Paragraph 5.4 of the Code of Practice.

10. Paragraph 7.1 of the Code of Practice.

11. Paragraph 20 of the Code of Practice.

12. Medawar, Charles "The Wrong Kind of Medicine?", Consumers Association, London, 1984.

13. Ibid.

14. Ibid.

15. "Sources and Information for Prescribing Doctors in Britain", Office of Health Economics, 1977.

16. Report of the Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service 1965-67. London; HMSO, Cmnd 3410.

17. See Medawar, op cit.

18. Section 6 of this Chapter.

19. British Medical Journal (29 October 1983): 287-238.

20. Hansard, 27 November 1984, Vol 68, Column 761.

21. Hansard, 18 March 1985, Vol 75, Column 692.

22. See, for example, page 9 of The Times for 15 Janaury 1985.

23. This was written by the President of the Royal College and dated 11 January 1985.

24. Report to the Secretary of State for Social Services of the Informal Working Group on Effective Prescribing (the Greenfield Report), February 1982.

25. Statutory Instrument 1985 No 290, as amended by Statutory Instrument 1985 No 540.

26. See the statement made by the Secretary of State for Social Services (Mr Norman Fowler) in a debate to annul the regulations - Hansard, 18 March 1985, Vol 75, Column 696.

27. See paragraph 29 of the Greenfield Report.

28. Medawar, Charles "The Wrong Kind of Medicine?", Consumers Association, 1984.

29. This subject is dealt with in Part III.

30. Medawar, Charles, op cit, at pages 72/73.

31. See paragraph 32 of the Greenfield Report.

32. See paragraph 33 of the Greenfield Report.

33. See paragraph 34 of the Greenfield Report.

34. The Lancet, 4 August 1984, 276-8. Professor Rawlins is a Clinical Pharmacologist with the University of Newcastle-upon-Tyne and a member of the Committee on Safety of Medicines.

35. "The Relationship between Physicians and the Pharmaceutical Industry: a Report of the Royal College of Physicians", Journal of the Royal College of Physicians of London, Vol 20, No 41, 4 October 1986.

36. The Times, 12 October 1986.

37. See the conclusion and recommendation of the Report.

38. Hansard, H C Deb, 19 June 1980, Column 635.

39. Darby, F J and Greenberg, G "Data Collection in England" in "Studies in Drug Utilisation", (World Health Organization, Copenhagen, 1979), p 83-91.

40. Statutory Instrument 1974 No 455.

41. R -v- Referees of the National Health Service ex parte Drs H H Ronn and C Tennant, unreported. The appeal was heard by the Divisional Court of the Queen's Bench Division.

42. See Section 4(3)(b) of the Medicines Act 1968.

43. See Speirs, C J et al "Demography of the United Kingdom Adverse Reactions Register of Spontaneous Reports", Health Trends (1984) Vol.II pp 49-52.

44. Teff, Harvey "Regulation under the Medicines Act 1968: a Continuing Prescription for Health", Modern Law Review (1984) pp 303-323.

45. Teeling-Smith, G "Adverse Reactions and the Community", Office of Health Economics, 1982.

46. Venning, G R "Validity of Anecdotal Reports of Suspected Adverse Drug Reactions: the Problem of False Alarms", British Medical Journal (1982) Vol 284, pp 249-252.

47. See the Medicines (Standard Provisions for Licenses and Certificates) Regulations 1971 - Statutory Instrument 1971 No 972, as amended.

48. Section 28(3)(b) of, and Schedule 2 to, the 1968 Act.

49. British Medical Journal, "Benoxaprofen", Vol 285, pp 459-460 and The Lancet, "Lesson from the Benoxaprofen Affair", ii, pp 529-530.

50. Venning, G R (1983), "Identification of Adverse Reactions to New Drugs", British Medical Journal, Vol 286, pp 199-202, 289-292, 365-368, 458-460 and 544-547.

51. Crombie, I "Inherent Limitations of the Yellow Card System for the Detection of Unsuspected Adverse Drug Reactions", Human Toxicol, 3, pp 261-269.

52. Crombie, I op cit.

53. Part I of the Report of the Working Party on Adverse Reactions of the Committee on Safety of Medicines, June 1983.

54. The relevant Statutory Instruments are:

    The Medicines (Bal Jivan Chanco Prohibition) Order 1976 (SI 1976 No 1861);

    The Medicines (Bal Jivan Chanco Prohibition) Order 1977 (SI 1977 No 172); and

    The Medicines (Bal Jivan Chanco Prohibition) (No 2) Order 1977 (SI 1977 No 670).

55. See Section 103(1) of the Medicines Act 1968.

56. Dickens -v- Rounderson [1901] 1 QB 537.

57. Teff, Harvey "Regulation under the Medicines Act 1968: A Continuing Prescription of Health", MLR (1984) p.321.

58. McIntosh, D A "The Effect of Consumerism on Claims against the Pharmaceutical Industry", BIRA Journal, Vol 3, No 2, 38-41.

59. Meade -v- Haringey London Borough Council [1979] 1 WLR 637 at page 647.

60. In the very limited area of vaccine damage, the Vaccine Damage Payments Act 1979 (c.27) provides for a flat-rate payment of £20,000 to children who are disabled as a result of vaccine damage.

61. See The Times, 1 February 1985.

62. Ross, Cranston "Consumers and the Law", Weidenfeld and Nicolson, London, (Second Edition) p 152.

63. See The Times, 1 November 1984, Special Report on Pharmaceuticals".

64. Teff, Harvey op cit, p 323.

65. McIntosh, D A op cit, p 38.

66. Smith, Kline and French -v- Bloch [1983] 1 WLR 730 at page 733.

PART II - THE EFFECT UPON THE UNITED KINGDOM OF ENTRY INTO THE EUROPEAN ECONOMIC COMMUNITY

INTRODUCTION

On the 1st January 1973 the Treaty of Accession entered into force and Denmark, Ireland and the United Kingdom became Members of the three Communities. As the name of the European Economic Community implies, this Community is largely concerned with economic affairs and seeks to promote the free exchange of goods, services, persons and capital between the Member States. Article 9(1) of the Treaty[1] provides that the Community "shall be based upon a customs union which shall cover all trade in goods and which shall involve the prohibition between Member States of customs duties on imports and exports and of all charges having equivalent effect, and the adoption of a customs tariff in their relations with third countries". In the case of the United Kingdom, Article 37 of the Act of Accession provided for the abolition of all charges between the new Member States themselves, by the 1st January 1987 at the latest.

During periods of economic crisis it is clearly tempting for Member States, who can no longer resort to tariff restrictions on trade or quotas, to protect their markets in other ways. It is for this reason that Articles 30 to 34 of the Treaty establishing the European Economic Community prohibit quantitative restrictions and all measures having equivalent effect, for both imports and exports, in relation to intra-Community trade. A considerable body of case law has now been established by the European Court dealing with these Articles which shows that the prohibition interacts with a wide range of national regulatory powers including, in relation to medicines in particular, industrial property rights. Also related to this prohibition is the harmonisation programme of the Community to eliminate technical barriers to trade under Article 100 of the European Economic Community Treaty. In this connection the elimination of administrative barriers to trade in the pharmaceutical

sector has been particularly slow and difficult and has in fact not even yet become fully achieved. As the European Economic Community produces 30% of the world's medicines, and this represents 50% of the world export of medicines[2] the sector has a considerable importance.

Article 3(f) of the Treaty establishing the European Economic Community states that one of the purposes of the Community is the institution of a system ensuring that competition is not distorted. This emphasis upon competition policy has been described by the Commission in the following terms:

> "Competition is the best stimulant of economic activity since it guarantees the widest possible freedom of action to all. An active competition policy pursued in accordance with the Treaties establishing the Communities makes it easier for the supply and demand structures continually to adjust to technological development. Through the interplay of decentralised decision-making machinery, competition enables enterprises continuously to improve their efficiency, which is the sine qua non for a steady improvement in living standards and employment prospects within the countries of the Community. From this point of view, competition policy is an essential means for satisfying to a great extent the individual and collective needs of our society".[3]

There are essentially two separate aspects of the competition policy of the Community. First, where undertakings which are economically independent of each other enter into agreements, or adopt practices, which may affect trade between Member States and which distort competition. Secondly, where an undertaking or group of undertakings abuse its or their monopoly or dominant

position. Medicines have posed problems falling under each of these heads, which are dealt with in Articles 85 and 86 respectively of the Treaty.

NOTES

1. This Article has been held to be directly applicable. Cases 2 & 3/69 Sociaal Fonds Voor de Diamantarbeiders -v- Brachfeld and Chougal Diamond Company [1969] ECR 211, [1969] CMLR 335.

2. Poggiolini, D (ed), Technical Guidelines for Pharmaceuticals in the European Economic Community", New York, Raven Press Books Limited, page v.

3. First Report on Competition Policy [1971] page 11.

CHAPTER IV - FREE MOVEMENT OF GOODS

4.1 ARTICLES 30 TO 36 OF THE EUROPEAN ECONOMIC COMMUNITY TREATY

Articles 30 to 36 of the European Economic Community Treaty prohibit quantitative restrictions and all measures having equivalent effect, for both imports and exports, in relation to intra-Community trade, The term "quantitative restriction" has been explained in the following way:

> "The prohibition of quantitative restrictions covers measures which amount to a total or partial restraint of, according to the circumstances, imports, exports or goods in transit".[1]

A quantitative restriction may, therefore, be equated with a quota, although it is more extensive and includes a total ban.

A consideration of the case law on this subject suggests that these prohibitions may be brought into play by a variety of actions, which may be in the form of legislation, judicial decisions, or even administrative decisions.[2] Article 2(2) of Directive 70/50/EEC[3] provides that measures having an equivalent effect to quantitative restrictions include measures which "..... make imports or the disposal at any marketing stage, of imported products subject to a condition - other than a formality - which is required in respect of imported products only or a condition differing from that required for domestic products and more difficult to satisfy". Article 3 of that Directive provides that certain measures (concerned mainly with requirements as to shapes, sizes, weights, identification, etc), which apply equally to domestic products and to imports, but bear more

heavily on the latter, constitute measures having equivalent effect where their restrictive effect is out of proportion to their purpose.[4]

A proposition that has been clearly established is that the concept of what constitutes a measure of equivalent effect is a wide one. This is clearly illustrated by the decision of the European Court in Procureur du Roi -v- Dassonville.[5] Scotch whisky, which had been purchased from distributors in France, was imported into Belgium. Under Belgian legislation there was a requirement that such goods should be accompanied by a certificate of origin. The goods in question were not so accompanied and the necessary certificate could have been obtained only with great difficulty. It its judgment the Court held that the requirement contained in the Belgian legislation constituted a measure having equivalent effect because it favoured direct imports from the country of origin, as opposed to imports from a Member State where the goods were in free circulation. According to the Dassonville judgment: "All trading rules enacted by Member States, which are capable of hindering directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions".[6]

This formula established in the Dassonville decision has been repeated, although sometimes with some minor changes of wording, in many subsequent decisions.[7] But the Court did recognise an important exception to the basic formula. It stated that:

> "In the absence of a Community system guaranteeing for consumers the authenticity of a product's designation of origin, if a Member State takes measures to prevent unfair practices in this connection, it is however subject to the

condition that these measures should be reasonable and that the means of proof required should not act as a hindrance to trade between Member States and should in consequence be accessible to all Community nationals".[8]

From this it can be seen that the correct interpretation of Articles 30 to 34 demands a broad approach. Not only is actual hindrance to trade caught by the prohibitions - they extend to any potential hindrance. Further, as is illustrated by Case 12/74[9] any national rule which is in operation must be compatible with any existing Community rules. This raises the question, however, as to the scope left to Member States once it is accepted that any national trading rules must not conflict with Community law. That this scope may be narrow is illustrated by the Van Haaster case,[10] where the European Court of Justice was concerned, not with a trading rule stricto sensu, but with a national regulation govering the production quotas of hyacinth bulbs. It was held that this measure was capable of hindering Community trade and so in contravention of Article 30 of the EEC Treaty.

4.2 DEROGATION UNDER ARTICLE 36

Article 36 of the EEC Treaty provides some derogation from Articles 30 to 34. It states:

"The provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archeological value; or the protection of industrial or commercial property. Such

prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States".

The extent of the exemption provided by Article 36 has been narrowly defined by the Court of Justice and it is also clearly stated that this relates solely to Articles 30 to 34 of the Treaty and not to any of the Treaty's other provisions. Both of these principles are illustrated by the case of Salgoil,[11] who wished to import some Fuller's Earth into Italy. The Italian Ministry for Foreign Trade refused to grant an import licence, whereupon Salgoil brought an action for compensation arising out of damage caused by such refusal. One question raised before the Court of Justice was to what extent, if at all, Article 36 could be relied upon to deny that Article 31 was directly applicable in its effects. In its judgment, given on a reference under Article 177 of the Treaty, the Court clearly stated that Article 36 was concerned with an exceptional case which was clearly defined by the words of the Treaty. That being so, the Article could not be given a wider interpretation. This judgment followed the Opinion of Mr Advocate-General Gand, who stated:

"It will be enough to say that Articles 36, 224 and 226 all have a limited scope and cover a special situation. These are provisions authorising exemptions, which should be interpreted strictly, and which cannot be invoked to deny the existence of rights created by other provisions of the Treaty".

A further example of the Court's strict approach to Article 36 is afforded by Case 12/74/[12] The German Government claimed, as one of its defences, that the

German law was justified under Article 36 of the Treaty because it protected industrial and commercial property. The Court held that, although the Treaty did not prohibit Member States from legislating in the field of designation of origin, Article 36 prohibited them from promulgating measures which has an arbitrary and unjustified nature. This was precisely the case where the legislation granted the protection of a product's designation of origin to designations having only a generic nature. An additional argument raised by the German Government in the case was that the national law was justified on the grounds of public policy. To this argument the Court replied that new measures in the field of public policy were only exempted from the prohibition of Articles 30 to 34 to the extent that they were necessary for the protection of the producer and consumer against commercial fraud. This the German Government could not show.

4.3 THE CASSIS DE DIJON DECISION

A leading case upon the interaction between the "reasonable measures" exemption established in the Dassonville judgment and the derogation provided by Article 36 of the Treaty is Case 120/78.[13] The Plaintiff Company wished to import a French liqueur known as "Casis de Dijon" into Germany. The liqueur contained 15-20% by volume of alcohol. Rewe was informed by the German authorities that it could not sell the product there as German law provided that only spirits which contained a wine-spirit content of at least 32% could lawfully be marketed. A preliminary ruling from the Court of Justice was then sought upon the compatibility of this marketing prohibition and Articles 30 and 37 of the EEC Treaty. The Court held that Article 37 was inapplicable and concerned itself exclusively with Article 30.

In the case the Plaintiff argued that the requirement for a minimum alcohol content constituted a measure having equivalent effect to a quantitative restriction. Such a measure could not be justified for the protection of human health within the meaning of Article 36; indeed it contravened the second sentence of Article 36 because it contributed to the artificial partitioning of markets between Member States. The approach of the Court was to apply the Dassonville formula. As there was no community system for the production or marketing of alcohol, it was for Member States to regulate those matters. Any obstacles resulting from the distortions between the national laws of Member States were only acceptable insofar as they were necessary in order to satisfy requirements such as the protection of public health and the defence of the consumer.

In its judgment the Court concluded that the prohibition on a minimum alcohol content infringed Article 30 of the Treaty and that it did not serve a purpose which was in the general interest such as to take precedence over the fundamental rule of free movement of goods. Finally, the Court added:

> "There is therefore no valid reason why, provided they have been lawfully produced and marketed in one of the Member States, alcoholic beverages should not be introduced into any other Member State; the sale of such products may not be subject to a legal prohibition on the marketing of beverages with an alcohol content lower than the limit set by the national rules".[14]

This judgment suggests that the Court takes the view that products which are lawfully produced and marketed in one Member State may only properly be prevented from being exported or imported into other Member States on the

grounds of some valid reason which protects specified mandatory requirements. An importing Member State, under the principles established by this case, may only oppose such importation on the ground of some essential requirement such as if the product is likely to affect the health and safety of its consumers.

Although the judgment makes no specific reference to Article 36 of the Treaty, a communication was issued by the Commission concerned with the consequences of that judgment in which reference was made to that provision. This communication took the form of a letter sent to Member States and notified to the European Parliament and the Council.[15] While the communication can have no binding effect, it does give some indication as to how the Commission approaches what it has described at a press conference as "a new strategy" in this important area. Having regard to the important role of the Commission under Article 169 of the EEC Treaty in bringing actions against Member States who have failed to fulfil a Community obligation, the Commission's views on the Cassis de Dijon judgment are of particular importance.

In the communication the Commission stated that Articles 30 to 36 of the EEC Treaty, as interpreted by the Court, require in principle that any product lawfully produced and marketed in one Member State must be admitted to the market of any other Member State. Where a product "suitably and satisfactorily" fulfils the legitimate objective of a Member State's own rules upon such matters as public safety, or the protection of the consumer, an importing Member State cannot justify the prohibition of the sale of the product in question in its territory by claiming that the way it fulfils the objective is different from that imposed on domestic products.

No view is expressed in the communication as to whether "the reasonable measures" clause expressed in the Dassonville formula and the derogation contained in Article 36 are one and the same or whether they are separate considerations. It is likely, however, that these are properly to be regarded as separate considerations. Article 36 contains specific derogations which have been given a narrow interpretation by the Court. In contrast to this the "rule of reason" has introduced within its scope such concepts as the protection of the consumer, which is not referred to in Article 36 itself. Nor is it yet clear whether this communication will influence the Court's interpretation of future cases bsed upon Articles 30 to 36 as the text of the communication has not been expressly considered by the Court. The communication does, however, make clear that the Commission fully supports the extension of the Dassonville formula to include the "additional passage" based upon the Court's Cassis de Dijon judgment.

In relation to medicines, three matters of large importance relating to the provisions discussed above arise. These are the protection of the consumer under the "reasonable measures" provisions of the Court's interpretation of Article 30 of the EEC Treaty; and the express derogations for industrial property and public health mentioned in Article 36. Each of these is now to be considered in turn.

4.4 SAFETY AND CONSUMER PROTECTION

Barents has observed that the Commission initially took a rather casuistic approach to the problems posed by the concept of measures having equivalent effect.[16] His view is that the Court was more concerned to find an equitable solution to the particular facts before it rather than to establish or maintain a legal theory upon

which to base its judgments. But the Cassis de Dijon decision has now established a more sympathetic approach to determine the applicability of the reasonable measures clause. In the first place the Court considers whether there has been any Community measure governing the facts under consideration. If there is, the Court will consider the compatibility of the national law with that Community measure. Secondly, the Court will consider the effect of the national law on trade between Member States. Thirdly, the Court considers whether there is scope for the application of "reasonable measures" clause or whether the purpose of such a provision would be achieved by alternative means.[17]

This approach may be illustrated by the judgment of the Court in Case 788/79,[18] when an Italian decree prohibited the sale in Italy of all vinegar other than wine vinegar. The Defendants were charged before an Italian Court with having sold imported cider vinegar. Upon a reference to the European Court of Justice under Article 177 it was accepted that cider vinegar did not constitute any risk to health. Further, it had been labelled so as to prevent any possible risk of confusion on the part of the consumer. In these circumstances the Court held that the Italian decree contravened Article 30 and could not be justified under Article 36. In the case it was clear that the prohibition under consideration constituted an obstacle to trade under Article 30. There was no factor which justified the restriction on the ground of the protection of public health or the defence of the consumer. From this it followed that the restriction was incompatible with the provisions of Article 30 and could not be justified.

Some refinement of the Court's position in relation to Article 30 may, however, be discerned by its decision in the Irish Souvenirs case.[19] Here two statutory

instruments prohibited respectively the sale from Ireland, and importation into Ireland, of certain items of jewellery unless marked with the country of origin if manufactured outside Ireland. The Irish Government contended that these measures were justified in the interests of consumer protection and of commercial fairness between producers. This argument was rejected by the European Court, which found that the orders constituted measures having equivalent effect to quantitative restrictions. In reaching this view the Court expressly stated that as neither the protection of consumers nor the fairness of commercial transactions was included among the excpetions set out in Article 36 of the Treaty, the Irish Government could not rely upon either of these grounds. The Court stated:

> "..... it is only where national rules, which apply without discrimination to both domestic and imported products, may be justified as being necessary in order to satisfy imperative requirements relating in particular to ..... the fairness of commercial transactions and the defence of the consumer that they may constitute an exception to the requirements arising under Article 30".[20]

This passage suggests that a measure which contravenes Article 30 that is both distinctly applicable and discriminatory cannot escape as a "reasonable measure" for the protection of the consumer. Such a measure may only be justified if it falls within the derogations provided by Article 36.

But these examples of the application of the Court's rule of reason apply only to national trading rules which apply in the absence of the introduction of Community rules. Such introduction may take the form of either a common

organisation of the market or the issue of Directives under Article 100 of the EEC Treaty so as to remove administrative obstacles to trade by way of harmonisation.[21] After a measure of harmonisation has been introduced, Member States may rely upon the derogations provided by Article 36, provided that they act within the limits set by that harmonisation. Much of the case law upon Article 36 has been upon the subject of industrial property.

4.5 THE PROTECTION OF INDUSTRIAL PROPERTY

It has already been seen that the Court has adopted a strict interpretation towards Article 36 of the EEC Treaty. An examination of the case law shows that the Court considers a number of factors in determining whether any derogation may be permitted. An exception to the free movement provisions of the Treaty must be "justified". Any such justification will only be accepted if the measure in question is essential to protect the interest under consideration. If these objectives could be achieved by the introduction of less restrictive measures than those actually adopted, then the Court will hold that the measure is not justified. Finally, even if some derogation from the free movement provisions is justified, the two additional conditions laid down by Article 36 must still be complied with - namely, there must be no arbitrary discrimination or disguised restriction of trade between Member States.

In relation to industrial property there exist separate systems for the legal protection of such rights as patents and trade marks in Member States. These rights have assumed particular importance in relation to medicines. Unless and until the law of industrial property is unified, there will be a potential source of conflict between the national systems for protection of those

rights and the provisions of free movement of goods contained in the EEC Treaty. But it is not only in relation to free movement of goods that potential conflicts arise in relation to industrial property. Difficulties also arise out of the competition rules of the Treaty contained in Articles 85 and 86. Article 85 prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States, and which have as their object or effect, the prevention, restriction or distortion of competition within the Common Market. Article 86 prohibits any abuse by one or more undertakings within the Common Market, or a substantial part of it, insofar as it may affect trade between Member States.

These difficulties have been succinctly summarised by the European Court in the following way:

> "The national rules relating to the protection of industrial property have not yet been unified within the Community. In the absence of such unification, the national character of the protection of industrial property and the variations of creating obstacles both to the free movement of the patented products and to competition within the Common Market".[22]

Two related cases which illustrate the Court's approach to these difficulties are Centrafarm -v- Sterling Drug[23] and Centrafarm -v- Winthrop.[24] An American company, Sterling, was the patent holder in relation to a medicine in both the United Kingdom and the Netherlands, while Winthrop was the holder of the trade mark for that product in those two countries. A reference was made to the Court under Article 177 of the Treaty in relation to

infringement proceedings affecting both the Dutch patent and trade mark. The Court held that the specific subject matter of a patent was:

> "..... the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well as the right to oppose infringements".[25]

Applying this definition the Court refused to allow a derogation from the principle of free movement of goods where the product had been lawfully put on the market by the patentee in the Member State from which it had been imported. Sterling's rights had been exercised and exhausted by placing the product on the market in the United Kingdom. It is the right to manufacture, sell at a profit and oppose infringements which the Court regards as the essential interest protected by a patent.

In relation to trade marks the Court said that the specific subject matter of this industrial property was:

> "..... the guarantee that the owner of the trade mark has the exclusive right to use that trade mark, for the purpose of putting products protected by the trade mark into circulation for the first time, and is therefore intended to protect him against competitors waiting to take advantage of the status and reputation of the trade mark by selling products illegally bearing that trademark".[26]

The Court held that the holder of the trade mark for the product in one Member State could not prevent the importation of the product from another Member State if they had been marketed there either by him or with his consent. Again, therefore, no derogation under Article 36 could be permitted to the provisions of free movement of goods.

Oliver[27] has summarised the general principles which have emerged from the case law of the Court in this field under the following basic rules:

Rule (1)

While the Treaty does not affect the existence of industrial property rights, the exercise of those rights may contravene the Treaty if there is a breach of Article 30 et seq in relation to the provisions on free movement of goods, or Articles 85 or 86 in relation to competition. This rule is based upon Article 222 of the Treaty, which states that:

> "This Treaty shall in so way prejudice the rules in Member States governing the system of property owndership".

Rule (2)

The exclusive right guaranteed by national legislation is exhausted in relation to industrial property rights when a product has been lawfully placed on the market of a Member State by the owner of the right or by some other person with the consent of the owner of the right. This is the exhaustion of rights principle and was first established in Case 78/70[28] in relation to rights and again to copyright. As has been seen above

in relation to Centrafarm -v- Sterling Drug and Centrafarm -v- Winthrop, this principle has been applied to both patents and trade mark rights.

Rule (3)

A trade mark may not be relied upon with a view to prohibiting the marketing in a Member State of goods lawfully produced in another Member State under an identical trade mark having the same origin. This is the common origin principle established in Case 192/73[29] in relation to fairly unusual circumstances involving the war-time confiscation of enemy property.

Rule (4)

Where the same person holds a particular industrial property right in all Member States, another person holding that right with respect to a third country may not manufacture or market his goods within the EEC in reliance of that right, even where there is common origin. This rule was established in Cases 51, 86 and 96/75.[30] These three cases concerned proceedings for trade mark infringement in Courts in the United Kingdom, Denmark and Germany respectively, to restrain the importation and sale of records manufactured by CBS in the United Kingdom and bearing the trade mark "Columbia". EMI was the proprietor of the trade mark in all the three Member States of the EEC, while the Defendants to the actions were subsidiaries of CBS, the proprietor of the trade mark in the United States.

Upon a reference under Article 177 the European Court was asked to consider whether the use of its trade mark rights by EMI was compatible with the EEC rules on free movement of goods and competition.

Until 1917 the Columbia trade mark had been in the owndership of the same company in both Europe and the United States. Then in 1931 EMI acquired the European trade marks and CBS acquired the United States trade mark in 1938. Thus, the trade marks had had a common origin, although they had been in separate ownership since 1931. CBS, in reliance of the rule of common origin, established in the HAG decision, argued that the exclusion of its products from the market amounted to an unjustifiable restriction upon the free movement of goods. But the Court held that the EEC Treaty was concerned with trade between Member States, as opposed to trade from third countries. It was held that:

> "..... the exercise of a trade mark right in order to prevent the marketing of products coming from a third country under an identical mark, even if this constitutes a measure having an effect equivalent to a quantitative restriction, does not affect the free movement of goods between Member States and thus does not come under the prohibitions set out in Article 30 et seq of the Treaty".[31]

Rule (5)

Subject to Rules (2) and (3) above the holder of an industrial property right may rely on that right to prohibit the importation or sale of goods from other Member States. But such rights must not be exercised so as to constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. (See Case 119/75, where a German company sought to prevent the marketing in Germany of a British manufactured product bearing a

similar name.[32] Nor must the exercise of such rights conflict with the rules on competition laid down in Articles 85 and 86 of the Treaty.

There are, however, some legislative proposals which will eventually have the effect of reducing the application of these rules. In relation to patents, the Convention for the European Patent for the Common Market was signed on 15th December 1984.[33] Once this Convention has been put into effect, it will introduce a specific doctrine of exhaustion affecting both Community and national patents within the Common Market. Thus, once patented goods have been placed on the market in any part of the EEC by the patentee, or with his express consent, the rights cobferred by the Community or other national patents within the EEc will no longer extend to them, unless Community law provides some express exception for them.

Similar provisions for exhaustion of trade mark rights are likely to be introduced by the proposed Trade Mark Regulation and Directives which are presently under active consideration.[34]

A further aspect of the free movement of medicines within the Community is provided by three decisions of the European Court in relation to repackaging. In the first of these[35] the tranquilliser valium was marketed in the United Kingdom by the British subsidiary of Hoffman la Roche. Some of this product was imported into Holland, where it was repackaged. Centrafarm then re-exported the valium for sale in Germany, having placed the trade mark owned by Hoffmann la Roche and a notice giving its own name and address, as the seller of the product, on the new package. The Court held that the function of a trade mark was to act as a guarantee of the identity of origin of the product in question to the consumer. In the view of the Court this guarantee meant:

> "..... the Consumer, or ultimate user can be certain that a trade marked product which is sold to him and has not been subject at a previous stage of marketing to interference by a third person, without the authorisation of the proprietor of the trade mark, such as to affect the original condition of the product".[36]

In its judgment the Court also dealt with the point as to whether the rights of a trade mark owner operated as a disguised restriction of trade within the meaning of Article 36. In this connection it was held that the owner of a trade mark could only be prevented from exercising his rights if three conditions were fulfilled. First, the repackaging must not affect the original condition of the product. Secondly, prior notice of the marketing of the repackaged product must have been given to the owner of the trade mark. Thirdly, the new packaging must show by whom the operation had been performed.

In a second case[37] the product concerned was another tranquilliser, sold by American Home Products Corporation under different trade marks. In the United Kingdom, the trade mark used was Serenid, while in the Benelux countries the product was sold under the name of Seresta. Supplies of the product, which American Home Products Corporation had put into circulation in the United Kingdom under the trade name Serenid, were imported into the Netherlands by Centrafarm and sold there after the original trade mark had been removed and the name Seresta substituted. The Court held that, in principle, the proprietor of a trade mark in one Member State was justified in opposing the sale by a third party of a product bearing that mark, even if the product had been previously sold in another Member State under a different trade mark held by the same proprietor. With regard to the proviso in Article 36, the Court stated that this

would apply if the trade marks were exploited so as to constitute a disguised restrictions on trade between Member States. It was for the national Court to decide whether the rights of the trade mark owner were being properly exercised.

In a third case dealing with repackaging[38] Eurim-Pharm imported into Germany quantities of an antibiotic called vibramycin, which had been produced and marketed in Britain by the British subsidiary of Pfizer. The trade marks "vibramycin" and "Pfizer" for Germany were owned by Pfizer. Eurim-Pharm removed the blister packs of the product from the original packaging and put them inside the new packets. These new packets contained a window through which could be seen the words "vibrmycin" and "Pfizer". The outer packaging also stated that the products had been produced by "Pfizer" Limited of Great Britain and that they had been repacked and imported by Eurim-Pharm and Pfizer has been informed of this.

In an action for infringement of the trade mark the German Court asked the European Court of Justice whether a trade mark could be relied upon to prevent such imports in these circumstances. In its judgment the European Court said the trade mark could not be relied on to achieve this. Its reasoning was given the following terms:

> "Article 36 of the Treaty must be interpreted to the effect that the proprietor of a trade mark may not rely on that right in order to prevent an importer from marketing a pharmaceutical product manufactured in another Member State by the subsidiary of the proprietor and bearing the latter's trade mark with his consent where the importer, in repackaging the product, confined himself to replacing the external wrapping without touching the internal packaging and made

> the trade mark affixed by the manufacturer to the internal packaging visible through the new external wrapping, at the same time clearly indicating on the external wrapping that the product was manufactured by the subsidiary of the proprietor and repackaged by the importer".[39]

These three cases show how the Court has attempted to balance two potentially conflicting interests. On the one hand there are the interests of the owners of the trade mark rights. On the other hand, there are the principles of the free movement of goods, these being subject to the exceptions for the protection of human life and health and the protection of industrial and commercial property, under the express terms of Article 36 of the Treaty. If the repackaging will interfere with the identity of origin of the product or its original condition, then the trade mark owner will normally be allowed to exercise his rights under the provisions of Article 36 of the Treaty. Thus, the specific subject matter of the trade mark right has been extended to include not only the right to place the product on the market, but also to prevent any use which undermines the guarantee of origin which the mark provides. Any prohibitions or restrictions permitted by Article 36 may not, however, be allowed to constitute either a means of arbitrary discrimination or a disguised restriction of trade between Member States. The second sentence of Article 36 will be infringed if the use of the trade mark will contribute to an artificial partitioning of the markets between Member States.[40]

4.6 THE PROTECTION OF HUMAN LIFE AND HEALTH

A further derogation provided by Article 36 of the Treaty is for the protection of life and health and humans, animals or plants. Only cases which concern human life and health are considered. It will be seen that the

European Court of Justice has developed its approach in the case law which has come before it in a reasonably consistent way.

In de Peijper[41] the Court was asked to consider whether restrictive provisions of Dutch legislation, which favoured imports by dealers securing the co-operation of the manufacturer of the product, were justified as being necessary for the protection of the life and health of humans. A provision of the Dutch legislation required that an importer had in his possession certain records and information relating to medicines before they could be put on the market in the Netherlands. Those records and information would only be supplied with the co-operation and consent of the original manufacturer of the product.

Dr Peijper argued that this Dutch provision contravened Article 30 of the Treaty because it constituted a measure having an effect equivalent to a quantative restriction. He further argued that, even if the measure was justified within the meaning of the exception contained in Article 36 on the grounds of the protection of health and life of humans, it constituted an arbitrary discrimination or disguised restriction on trade between Member States. As such, it could not fall within the restrictions provided by Article 36. Three Member States (the United Kingdom, Denmark and the Netherlands) put forward arguments that the Dutch measure was necessary in order to comply with the Pharmaceutical Directives.[42] Neither Advocate-General Mayras nor the Court accepted this argument. It was held that directives adopted pursuant to the approximation of laws provisions of Article 100 of the Treaty could not possibly have the effect of extending the very considerable powers reserved to Member States in the field of public health by Article 36. This was so, even

if the interests protected by Article 36 were related to human health and life, which the Court acknowledged were ranked first in the interests protected by Article 36.

Upon the main question referred, it was held that the Dutch measure did in fact constitute an infringement of Article 30. Further, this measure could not be justified under Article 36 unless it was clearly proved "..... that any other rules or practice would obviously be beyond the means which can reasonably be expected of an administration operating in a normal manner". By adopting this approach the Court was applying the principle of proportionality which has been defined as follows:

> "Citizens may only have imposed on them, for the purposes of the public interest, obligations which are strictly necessary for those purposes to be attained".[43]

Thus, the Dutch legislation could not properly impose on traders greater burdens than those necessary to achieve the results which the legislation had within its objectives. National measures could not fall within the exception if the health or life of humans could be protected by alternative means which were less restrictive from the point of view of intra-Community trade.

In the reference, the Court went on to give guidance to the competent authorities of Member States and suggested ways in which the burdens imposed upon parallel imports could be eased without in any way putting public health at risk. In the course of its judgment the Court stated:

> "National authorities possess legislative and administrative methods capable of compelling the manufacturer or his duly appointed representative to supply particulars making it possible to

> ascertain that the medicinal preparation which is in fact the subject of parallel importation is identical with the medicine preparation in respect of which they are already informed. Moreover, simple co-operation between the authorities of the Member States would enable them to obtain on a reciprocal basis the documents necessary for checking certain largely standardised and widely distributed products".[44]

Thus, Member States were placed under a duty to ensure that the registration formalities for parallel importers were kept to a minimum by ensuring that their respective competent authorities co-operated with each other, particularly where commonly used products were concerned.

The decision in the de Peijper case was largely in the Kortmann case[45] with which it has close connections. Following the earlier proceedings, the Dutch authorities introduced measures providing that a parallel importer of a medicinal product previously registered at the request of the manufacturer could comply with a simplified registration procedure. This simplified registration procedure required the payment of fees, including an annual charge to cover the cost of checks on the product. Kortmann was charged with marketing imported medicinal products in the Netherlands without having complied with the simplified registration procedure. In his Defence he argued that this registration system contravened Article 30 of the Treaty. Although the European Court was mainly concerned with the legality of the new system in relation to the charges imposed, it did also deal with Article 36 in relation to the protection of human health. It was held that checks of parallel imports for safety purposes, to ensure that they were identical to products

already registered, could be permitted under the Treaty. This remained the position notwithstanding the fact that the provision gave rise to the payment of fees.

These decisions in de Peijper and Kortmann were concerned with the extent to which Article 36 of the Treaty could be invoked to permit derogation under the human health exception in relation to registration procedures. Two later decisions are concerned with a related problem, very relevant to the sale of pharmaceutical products, as to whether certain ingredients should be permitted to be included in products where scientific evidence as to the safety of such additives may be divided or simply non-existent.

Eyssen[46] was concerned with a prohibition on the use of a preservative known as Nisin in processed cheese sold in the Netherlands. Nisin is an antibiotic found in certain types of bacteria and it occurs naturally in varying quantities in most varieties of cheese. A World Health Organization Committee had made a recommendation as to what amount of Nisin in cheese was safe but no Community measure had been passed dealing with the subject. Dutch law permitted the sale of cheese for export which contained Nisin but such domestic sales were prohibited. Eyssen produced cheese for sale both on the domestic market and for export to other Member States. It was held by (the First Chamber of) the European Court that the prohibition of Nisin for the domestic market was permissible under Article 36 on the ground of protection of human health. In reaching this decision on a preliminary ruling under Article 177, the Court accepted that there was some scientific controversy about what was an acceptable daily intake of the additive and that research by the Food and Agriculture Organization and the World Health Organization, two very relevant specialised Agencies of the United Nations, was being undertaken to establish the critical threshold for the intake of the additive.

A similar problem was raised in Sandoz[47] where the Court was asked whether it was justified for a Member State to prohibit the sale of food containing added vitamins without a specific authorisation from that Member State. It was accepted by the Court that vitamins were not in themselves harmful substances but that excessive consumption of them over a prolonged period might have harmful effects. Once again, scientific research was not sufficiently advanced to determine with any degree of certainty a critical intake for the vitamins in question.

In its judgment (the Fifth Chamber of) the European Court held that the prohibition was justified, always providing that the marketing of the products was authorised where the addition of vitamins met a technical or nutritional need. This followed the decision in Eyssen. In relation to the second question raised, the Court was asked to decide whether it was justified under Article 36 for a Member State to impose on an importer of a product the burden of proving that the product was harmless for the purpose of obtaining authorisation to sell it. This raised the question of "positive lists" whereby, in the scientific field, additives are presumed to be harmful until the contrary is proved. Upon this the Court said that it was for the national authorities to assess whether the product was harmful or not. In order to make this assessment the national authorities could request information from the importer, provided this was relevant and not already in the possession of the authorities concerned. This decision enables Member States to apply the system of "positive lists" by acting on the assumption that a product is harmful unless the contrary is proved. But Member States must take such steps as they deem appropriate to put themselves into a position to decide whether the evidence is such that the presumption should be rebutted in relation to the particular facts before them.

These decisions in Eyssen and Sandoz[48] may also be seen as extensions of the earlier decision in the Frans-Nederlands case.[49] In this earlier case a company was prosecuted under Dutch law for selling a plant protection product which had not been expressly approved under that legislation. It was accepted by the European Court that products such as these, which eliminated any trace of mouldiness from the air used for the production or storage of foodstuffs, could be harmful for public health. The company claimed that the Dutch law amounted to a measure having equivalent effect to a quantitive restriction, contrary to Article 30 of the Treaty. The product had been imported from France, where it had been approved for sale under the French Public Health law. In its replies to the Court, the Commission stated that the French legislation was comparable to, and sought to protect the same public health interest as, the Dutch legislation.

Upon a reference under Article 177 the Court accepted that national rules, intended to protect public health, came within the exception provided by Article 36 as there was no directly relevant Community legislation. But the Dutch authorities were not entitled unnecessarily to demand scientific tests to be repeated which had already been carried out in the State of origin which had been available to the importing authorities. It was for the Dutch authorities to determine whether the procedures governing the approval requirements were justified for the purpose of Article 36. If it was decided that the approval system which the imported products had to satisfy simply duplicated the public health procedures already complied with in France, the measure would constitute a disguised restriction on trade between Member States. In her Opinion Advocate-General Rozes accepted that technical difficulties might be raised for Member States if reliance could not be placed upon the exemption clause of

Article 36 by national authorities. She suggested, however, that these diffiuclties could be overcome by calling upon expert opinions in cases of difficulty. Thus, while safety checks in the interests of public health may be permitted as justifiable under Article 36, the European Court will not allow this measure to justify the duplication of checks already carried out. To do so would be to permit a disguised restriction on trade between Member States.

A similar approach to that in Sandoz was adopted in the van Bennekom case.[50] This concerned a prosecution for possession of vitamin preparations with a view to sale. Under Dutch law any medicinal product in a pharmaceutical form must be registered by the public authorities before it may be marketed. In his Defence, van Bennkom argued that the preparations in question were not medicinal products but foodstuffs for the purpose of both the Dutch law and Directive 65/65/ECC. In answer to the first three questions referred under Article 177 of the Treaty, (the Fifth Chamber of) the Court found:

i. That substances, such as the vitamin preparations at issue, which were not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may nonetheless constitute substances "presented for treating or preventing disease" within the meaning of the Directive.

ii. that the product which fell under neither part of the Community definition of "medicinal product" could not be considered as a medicinal product within the meaning of the Directive.

iii. that the classification of a vitamin as a medicinal product within the second part of the definition in the Directive must be carried out case by case, having regard to the pharmacological properties of each of them, to the extent to which they had been established in the present state of scientific knowledge.

The Court stressed[51] that Directive 65/65/ECC constituted only the first stage in the harmonisation of national laws dealing with the production and distribution of pharmaceutical products. As a result of such harminisation, recourse to Article 36 of the EEC Treaty must gradually become unnecessary.[52] But as Directive 65/65/EEC was only a first step on the harmonisation process, reliance on Article 36 was no at present excluded. In the circumstances, the Court found that the application of the procedures of the Directive could in principle be justified in relation to products such as vitamins. This was so even if the various Member States adopted different solutions to the problems. It was, however, for the national authorities to show that the marketing of the product would cause a serious risk to public health and that the principle of proportionality made the restrictions compatible with the requirements of health protection.

These cases upon the derogation for human life and health have important implications for trade in medicines between Member States. Where some Community measure exists, some limited freedom of action may remain for Member States to take under Article 36, if that action can be justified and the Community provision merely introduces a minimum measure of control.[53] With regard to the co-operation between the authorities of Member States in relation to medicines (referred to in the de Peijper decision) it is the functions of the Committee for Proprietary Medicinal

Products and the Pharmaceutical Committee whose work is important in several ways. They play an essential role in ensuring that the licencing systems of Member States do not offend against the free movement of goods provisions of the Treaty of Rome. It is also these Committees whose views are sought and relied upon by the Commission when proposals for new legislation are being made. They also enable expert opinions to be given on matters arising relating to human life and health, which are not expressly covered by Community measures, such as arose in relation to food in the Eyssen and Sandoz decisions.

Gormley[54] has identified an important point in relation to the effect on the Pharmaceutical Directives upon various classes of medicine. This arises out of the definition of the term "proprietary medicinal product" in the Pharmaceutical Directives. Those medicines which fall outside that definition are not governed by the procedures of those Directives. That being so, the exception provided by Article 36 of the Treaty could still (in a proper case) be relied upon by Member States in relation to them. This will continue to be the position unless and until full harmonisation of all medicinal products is achieved throughout the Common Market.

4.7 PRICE CONTROLS ON MEDICINES

It has been seen that the United Kingdom has introduced a number of measures in an attempt to reduce the national medicines bill.[55] In all Member States (including Greece, Portugal and Spain) there was some form of price control over prices of pharmaceuticals before 1978 except in Germany and the Netherlands.[56] Thus, the Luxemberg Government was given power to regulate the prices and margins on pharmaceuticals coming from outside Belgium and controls on quantities were also introduced there. As from 1982 doctors in the Netherlands were restricted to

supplying one month's supply of pharmaceuticals under the National Insurance Scheme.[57] Having regard to the contraversial nature of these controls, it is not surprising that some of the issues arising from them have been the subject of cases brought before the European Court. Two of these decisions are concerned with the changed position adopted in the Netherlands. Certain measures were introduced by the Dutch Government in 1982 to control maximum prices and to exclude certain expensive medicines from reimbursement under the State Social Security Fund.

In Roussel[58] a reference was made to the European Court relating to an action brought by a number of pharmaceutical companies claiming that the price controls introduced by the Dutch Government contravened Article 30 of the Treaty. Under the new Dutch legislation maximum profit margins for medicinal products were calculated on the basis of the factory gate price of each product in the Member States of production, although additional factors such as transport costs and VAT were also taken into account. In relation to products produced in the Netherlands, however, the maximum price remained unchanged, with the effect that the pricing scheme was unfavourable for imported products. The reason for this change was that some 80% of the medicines consumed in Holland were imported, the cost of which was borne by the Sickness Insurance Scheme.

Before the European Court it was argued by Advocate-General Rozes that, while the measure contravened Article 30, it was justified on the ground of public health under Article 36 and also under Article 103 on the ground that it was an anti-inflationary measure. With regard to the application of Article 30 to price controls, the point had already been settled by the European Court in the Tasca and Sadam cases,[59] which related to Italian

legislation fixing maximum retail prices for sugar. In all of these cases preliminary rulings were sought from the Court on the question whether the fixing of such prices was consistent with the principles established by Article 30. In its judgment the Court replied:

> "Although a maximum price applicable without distinction to domestic and imported products does not in itself constitute a measure having an effect equivalent to a quantitive restriction, it may have such an effect, however, where it is fixed at a level such that the sale of imported products becomes, if not impossible, more difficult than that of domestic products. The maximum price in any event insofar as it applies to imported products, constitutes therefore, a measure having an effect equivalent to a quantitative restriction especially when it is fixed at such a low level that, having regard to the general situation of imported products compared to that of domestic products, dealers wishing to import the product in question into the Member State concerned can do so only at a loss".[60]

Having regard to these earlier decisions the Court in Roussel found no difficulty in holding that the Dutch legislation contravened Article 30. This was because the price controls applied to imported products in a different way to national products, so as to put those imported products at a disadvantage. This discrimination clearly contravened Article 30. With regard to Article 36, earlier decisions[61] had firmly rejected the suggestion that Article 36 could be invoked for economic reasons. To allow an exception under Article 103 of the Treaty would be to permit a unilateral derogation from a specific provision of the Treaty. This was not permitted in the

Sadam case[62] and it was similarly rejected in Roussel. This principle had already been settled in the earlier cases 6 and 11/69,[63] where the Court stated:

> "The exercise of reserved powers cannot therefore permit the unilateral adoption of measures prohibited by the Treaty".[64]

As Oliver has commented in relation to the Roussel decision,[65] if a price control system operates so as to discriminate against imported products, it is relatively easy to show that Article 30 has been contravened. The case also serves to reaffirm that Article 36 cannot be used for economic reasons and reliance cannot be placed upon other exceptions contained in the Treaty (such as Article 103) so as to contravene other specific provisions of the Treaty.

A second decision concerned with the Dutch medicinal insurance legislation is the Duphar case.[66] This concerned a measure containing a list of medicines which were not permitted to be supplied to persons under the Sickness Insurance Scheme, which could only be supplied if certain conditions were fulfilled. The purpose of the legislation was to reduce the cost of the scheme. It was found in the case that about 80% of the medicines consumed in the Netherlands were imported, most of them from other Member States of the EEC. Listed in the legislation were the products which did not qualify for reimbursement, including some which were excluded by reason of price.

In a reference under Article 177 the Dutch Court first asked whether the effect of the legislation was to contravene Articles 30 and 34. Advocate-General Mancini argued, in his Opinion, that Article 36 could apply even if the immediate aim of the legislation was to restore the finances of the Sickness Insurance Scheme and only

indirectly to protect public health. But he added that the choice of products for which reimbursement was not available must be based on objective criteria which were easily recognisable and capable of verification at the request of the traders concerned.

A second question raised was whether certain Articles of the Pharmaceutical Directives[67] prevented Member States from adopting measures such as those contained in the Dutch legislation. As the Dutch legislation did not concern the question of licensing or access to the market, it was clear that no contravention on the Pharmaceutical Directives could be established and the Court ruled accordingly.

Upon the first question however, the Court did not follow the Advocate-General but held (in a way consistent with its earlier decisions) that Article 36 related to measures of a non-economic nature which excluded such things as the reduction of the operating costs of a Sickness Insurance Scheme. While accepting that the Dutch legislation might have an effect on imports because of the dominance of the Health Service as a customer for medicines, this did not contravene Article 30 so long as the criteria for exclusion on the lists were non-discriminatory and transparent. In particular, it was essential that the list should be capable of amendment whenever it was established that a particular product complied with this specified criteria.

In its judgment, the Court drew attention to the special nature of the trade in pharmaceutical products, which it identified as the fact that Social Security institutions were substituted for consumers as regards responsibility for the payment of the products concerned. It is true that the cost of medicines can have a considerable impact on public expenditure because of the introduction of

National Health Service or Sickness Insurance Schemes.[68] But it is difficult to see why this alone should enable the measure to escape the restriction of Article 30, even though the products were not treated differently because of their country of origin. Evidence was adduced by Duphar to show that their sales had been drastically reduced after the introduction of the Dutch measures. This, as the Advocate-General pointed out, was some evidence to show that the measures constituted a real obstacle to Community trade within the meaning of the Dassonville formula. The effect of the decision, therefore, seems to be to establish an exception to the Dassonville formula which cannot be justified upon the basis of the Court's earlier decisions. Taken with the decision in Roussel, however, it may be seen that scope for Member States to introduce measures to curb their medicines bills may be severely limited.

As Oliver has commented:

> "In Duphar the Court decided the main point before it in terms which are hardly capable of being applied to other cases. The ruling is based on the idea that, in choosing two competing products, the State was in effect exercising the function of a consumer".[69]

4.8 CONCLUSION

The Court has adopted a broad definition of what constitutes a measure having equivalent effect to a quantitative restriction. This was clearly established in the Dassonville formula and has been followed consistently. In contrast, a strict approach has been taken to any derogation under Article 36, whether upon the basis of the protection of life and health of humans or the protection of industrial and commercial property.

Mortelmans[70] has suggested that there has been an evolution in the development of the judgments of the Court under Articles 30 to 36 because of the changing economic conditions. First, there has been an emphasis upon the protection for industrial and commercial property in relation to holders of patents and trade marks. This trend relates to the period prior to 1975 and before the present economic crisis began. It is exemplified by such cases as Centrafarm -v- Sterling Drug and Centrafarm -v- Winthrop.[71] Secondly, during the period from 1975 to 1980 there was a concentration upon the public health aspects of the provisions of Article 36. The cases of de Peijper and Kortmann[72] are relevant in this connection. It was in the de Peijper case, in particular, that the doctrine of proportionality was applied to prevent national restrictions being introduced which, although beneficial, imposed a burden exceeding a limit which could reasonably be required.

Thirdly, there is the period of economic crisis from 1982 onwards in which the focus of the Court's attention has been on exceptions of an economic nature. In this connection, the cases of Roussel and Duphar[73] are relevant in connection with pharmaceuticals and the decision in Campus Oil[74] in connection with the relationship between Article 36 and Articles 223 to 235.

Many of the cases on free movement of goods decided by the European Court of Justice have arisen out of references by national Courts under Article 177 of the Treaty. Under this part of the Court's jurisdiction it is required to rule on the interpretation of the Treaty and the interpretation and validity of secondary legislation. It has no power to apply the law to the particular facts before it. In some of the cases (in particular those discussed in Section 5 above) the Court had to consider scientific evidence and expert opinions in giving guidance

to national Courts. Where this has happened such guidance has been in very general terms and has not offered much assistance to national Courts. This suggests that the European Court of Justice is not well constituted to give guidance in these cases because of the very technical nature of the questions referred to it, particularly where expert opinion is itself divided, as is often the case where medicines are concerned.

Throughout the whole of these periods the Court has performed the difficult task of attempting to balance the competing aims of the free movement of goods provisions of the Treaty with the legitimate exceptions granted under Article 36. A further complication in this consideration is the question of harmonisation, which is concerned with the inter-relationship between national and Community legislation. This is considered in Chapter VI.

NOTES

1. Case 2/73, Geddo -v- Ente Nazionale Risi [1973] ECR 865 at page 879.

2. See Evans, A C "Economic Policy and the Free Movement of Goods in EEC Law", International and Comparative Law Quarterly, Vol 32, [1983] 577 at page 578 and the cases there cited.

3. O J 1970 L13/29.

4. For a discussion upon the different possible interpretations of this Directive and the main proponents of those views see Oliver, Peter "Free Movement of Goods in the EEC", [1982] European Law Centre Limited, at paragraph 6.28 et seq.

5. Case 8/74 [1974] ECR 837, [1974] 2 CMLR 423.

6. See paragraph 5 of the judgment.

7. See for example, Case 12/74 Commission -v- Germany, [1975] ECR 181; [1975] 1 CMLR 340, where a German statute reserved certain well-known names of wines for national production only. As a result the products of other Member States were obliged to bear less familiar names. The Court of Justice held that the German legislation constituted a measure having equivalent effect to a quantitative restriction because it constituted an obstacle to intra-Community trade.

8. See paragraph 6 of the judgment.

9. See note 7 above.

10. Officier van Justitie Van Haaster, Case 190/73, [1974] ECR 1123; [1974] 2 CMLR 521.

11. Case 13/68, Salgoil -v- Italy [1968] ECR 453; [1969] CMLR 181.

12. See note 7 above.

13. Rewe-Zentral AG Bundesmonopolverwaaltung fur Branntwein [1979] ECR 649; [1979] CMLR 494.

14. At paragraph 14 of the judgment.

15. O J, C 156, 3.10.1980.

16. Barents, R "New developments in measures having equivalent effect", 18 CML Rev [1981] 271 at page 272.

17. See Barents, op.cit, at page 295.

18. Gilli and Andres [1980] ECR 2071; [1981] 1 CMLR 146 and see also the judgment in Case 27/80, Fietje [1980] ECR 3839; [1981] 3 CMLR 722.

19. Case 113/80, Commission -v- Ireland (jewellery) [1981] ECR 1625; [1982] 1 CMLR 706.

20. At paragraph 10 of the judgment, affirming its earlier decisions upon this point.

21. Harmonisation in relation to medicines is discussed in Chapter VI.

22. Case 214/67, Parke Davis -v- Centrafarm [1968] ECR 55 at page 71.

23. Case 15/74, [1974] ECR 1147; [1974] 2 CMLR 480.

24. Case 16/74, [1974] ECR 1183; [1974] 2 CMLR 480.

25. [1974] ECR 1147 at page 1162.

26. [1974] ECR 1183 at page 1194.

27. Oliver, Peter "Free Movement of Goods in the EEC", [1982] European Law Centre Limited, paragraph 8.61 et seq and also Wyatt, Derrick and Dashwood, Allan. "The Substantive Law of the EEC", [1980], London, Sweet and Maxwell at pages 360-362.

28. Deutsche Grammophon -v- Metro-Grossmarkte, [1971] ECR 487; [1971] CMLR 631.

29. Van Zuylen -v- Hag [1974] ECR 731; [1974] 2 CMLR 127. This decision has been much criticised - see in particular, Ladas, Dr Stephen P, "The Court of Justice of the European Community and "Hag"", [1974]

5 Industrial Review of Industrial Property and Copyright 302; and Mann, Dr F A , "Industrial Property and the EEC Treaty", [1975] 24 International and Comparative Law Quarterly 31; and Lewis, Kynnic, "Cafe Hag: a critical comment", [1975/76] 1 EL Rev 71. See also Johannes and Wright, 1 EL Rev, [1975/76] 2 30 where the deicision is defended. It has been suggested by Cornish [1975] 38 MLR 329 that if it is possible to sue for unfair competition or passing off upon proof of deception, having regard to the established trade reputation of the Plaintiff, the rule in Cafe Hag may be distinguishable.

30. EMI Records -v- CMS United Kingdom Limited [1976] ECR 811; [1976] 2 CMLR 235; EMI Records -v- CMS Grammofon A/S, [1976] ECR 871; [1976] 2 CMLR 62 and EMI Records -v- CBS Schalplatten GmbH, [1976] ECR 913; [1976] 2 CMLR 235.

31. At paragraph 10 of the judgment in EMI Records -v- CBS United Kingdom Limited.

32. Terrapin -v- Terranova [1976] ECR 1039; [1976] 2 CMLR 482.

33. O J 1976, L17/1.

34. See working documents 1-611/83 CORR - drawn up the Legal Affairs Committee for the European Parliament dated 31st August 1983 (Rapporteur: Mr A Turner).

35. Case 102/77 Hoffmann-La Roche -v- Centrafarm [1978] ECR 1139; [1978] 3 CMLR 217.

36. At paragraph 7 of the judgment.

37. Case 3/78 Centrafarm -v- American Home Products Corporation [1978] ECR 1823; [1979] 1 CMLR 326.

38. Case 1/81 Pfizer -v- Eurim-Pharm [1982] 1 CMLR 406.

39. See the Court's ruling at page 422.

40. See Guy, Diana and Guy, Leigh "The EEC and Intellectual Property", London, Sweet and Maxwell [1981], at page 138.

41. Case 104/75 Officier van Justitie -v- de Peijper [1986] ECR 613; [1976] 2 CMLR 271.

42. These Directives are discussed in Chapter VI.

43. A/G De Lamothe in Case 11/70 Internationale Handelsgesellschaft -v- Einfuhr [1970] ECR 1125; [1972] CMLR 255.

44. At paragraphs 26 and 27 of the judgment.

45. Case 32/80 Officier van Justitie -v- Kortmann [1981] ECR 251; [1982] CMLR 46.

46. Case 53/80 Officier van Justitie -v- Eyssen [1981] ECR 429; [1982] 2 CMLR 20.

47. Case 174/82 Criminal Proceedings against Sandoz [1983] ECR 2445; [1984] 3 CMLR 43.

48. These decisions are discussed by Oliver, Peter "A Review of the Case Law of the Court of Justice on Articles 30 to 36 EEC in 1983", in 21 CML Rev 221 at page 236 et seq.

49. Case 272/80, Frans-Nederlandse Maatschappij voor Biologische Produkten [1981] ECR 3277.

50. Case 227/82, [1983] ECR 3883.

51. At paragraph 11 of its judgment.

52. At paragraph 14 of its judgment.

53. The problems which arise out of the inter-relationship between Articles 36 and 100 of the Treaty are discussed in Chapter VI.

54. Gormley, Laurence W "Prohibiting Restrictions on Trade within the EEC", North Holland [1984] page 157.

55. See Chapter III.

56. See Abel-Smith, Brian "Cost Containment in Health Care: the Experience of Twelve European Countries 1977/83", Commission of the European Communities [1984] page 11.

57. Op.cit, page 12.

58. Case 181/82 [1983] ECR 3849; [1985] 1 CMLR 834.

59. Case 65/75 Criminal Proceedings against Riccardo Tasca [1976] ECR 291; [1977] 2 CMLR 183 and Cases 88-90/75, Sadam -v- Comitato Interministeriale dei Prezzi [1976] ECR 323; [1977] 2 CMLR 183.

60. At paragraph 3 of the judgment in the Tasca decision.

61. Case 7/61, Commission -v- Italy [1961] ECR 317 ; [1962] CMLR 39 and Case 93/81, Commission -v- Italy, [1982] ECR 2187.

62. Case 65/75 Criminal Proceedings against Riccardo Tasca [1976] ECR 291; [1977] 2 CMLR 183 and Cases 88-90/75, Sadam -v- Comitato Interministeriale dei Prezzi [1976] ECR 323; [1977] 2 CMLR 183.

63. Commission -v- French Republic [1969] ECR 523; [1970] CMLR 43.

64. At paragraph 17 of the judgment.

65. Oliver, Peter "A Review of the Case Law of the Court of Justice on Articles 30 to 36 EEC in 1983", 21 CMLRev 221 [1984] at page 234.

66. Case 238/82, Duphar B V and others -v- The States of the Netherlands [1985] 1 CMLR 256.

67. Articles 5, 11 and 21 of Council Directive 65/65 of 26th January 1965 and Articles 28, 31 and 32 of Council Directive 75/319 of 20th May 1975.

68. See Deleau, G (Rapporteur) "Report drawn up on behalf of the Committee on Economic and Monetary Affairs", for the European Parliament, dated 15th December 1982 at page 20.

69. Oliver, Peter "A Review of the Case Law of the Court of Justice on Articles 30 to 36 EEC in 1984", 22 CMLRev [1985] 301.

70. Mortelmans, K "Annotation on Case 72/83", Campus Oil Limited and others -v- The Minister for Industry and Energy and others [1984] 3 CMLR 544 in 21 CMLRev [1984] 687 at page 698.

71. Case 15/74, [1974] ECR 1147; [1974] 2 CMLR 480. Case 16/74, [1974] ECR 1183; [1974] 2 CMLR 480.

72. Case 104/75 Officier van Justitie -v- de Peijper [1986] ECR 613; [1976] 2 CMLR 271. Case 32/80 Officier van Justitie -v- Kortmann [1981] ECR 251; [1982] CMLR 46.

73. Case 181/82 [1983] ECR 3849; [1985] 1 CMLR 834. Case 238/82, Duphar B V and others -v- The States of the Netherlands [1985] 1 CMLR 256.

74. Case 72/83, Campus Oil Limited and others -v- Minister for Industry and Energy and others [1984] 3 CMLR 544.

CHAPTER V - COMPETITION

A - RESTRICTIVE PRACTICES UNDER ARTICLE 85 OF THE EEC TREATY

5.1 INTRODUCTION

Article 85 of the Treaty prohibits all agreements between undertakings, decisions by associations of undertakings, and concerted practices which may affect trade between Member States if their object or effect is to prevent, restrict or distort competition within the Common Market. Such a provision is included in the Treaty because the effect of removing barriers to trade was inevitably to increase competition between firms in different Member States. This Article, in particular, prohibits self-protective arrangements, such as market sharing or price fixing agreements which would frustrate the objects of establishing the Common Market.

This strict prohibition is, however, somewhat relaxed by the so-called "rule of reason" contained in Article 85(3). This provision allows, in relation to an arrangements which falls within Article 85(1), for an exemption to be granted by the Commission provided that it is satisfied that certain conditions are fulfilled. These conditions fall into two categories. First, the two positive conditions are that the arrangement contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit. Secondly, the arrangement must not impose on the undertakings concerned restrictions that are not indispensable to the attainment of the objectives or afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question. All of these conditions must be

fulfilled before an exemption under Article 85(3) may be granted ie the positive conditions must be present and the negative conditions must be absent. Some particular examples will now be discussed in which there has been an interaction between the competition provisions of Article 85 of the EEC Treaty and the pharmaceutical industry.

5.2 PATENT LICENSING

In the early years of the Community a very tolerant approach was taken towards agreements which were concerned with industrial property rights. By virtue of Article 4(2)(2)(b) of Regulation 17/1962[1] this type of agreement between two parties was not notifiable unless it imposed obligations on the party granting the licence. Then the Commission in its Patent Notice[2] stated that the grantor's obligation to regard the licence as exclusive to the licencee was not caught by the prohibition contained in Article 85(1) of the Treaty. But the Commission reserved its position on patent pools, cross-licences and similar forms of mutual horizontal restraint. In subsequent decisions[3] the Commission modified its position, with the result that a clause granting exclusive rights is not "inherent" in the exploitation of an industrial property right by granting licences. As a result of these decisions it was concluded that there was a need for a regulation governing the application of Article 85(3) of the EEC Treaty to some categories of patent licensing agreements. By its Regulation 19 of 1965,[4] the Council of Ministers gave the Commission power to deal with exemptions on a group basis by specifying in Regulations different categories which would qualify en bloc. The Block Exemption for Patent Licences is made under this power.[5]

Case 24/67[6] was concerned with the inter-relationship between the patent law of Member States and the competition provisions of the Treaty of Rome. Parke Davis was the holder of the Dutch patent for chloramphenicol. Three companies unconnected with Parke Davis then marketed or resold the product in the Netherlands without consent. Parke Davis later brought an action against those three companies in the appropriate Dutch Court for breach of patent, damages and an order requiring them to refrain from any further infringement. In particular, Parke Davis alleged that the product had been manufactured by one of the processes for which it held a patent in the Netherlands. Having regard to this it was argued that, not only was it entitled to intervene in the action, but was under an obligation to do so because of the licence it had granted to a Dutch company for the exploitation of those patents.

In the proceedings all three of the Defendant Companies challenged both the facts and the interpretation of the Dutch patent law. It was accepted that no patent could be granted for pharmaceuticals or the processes for their preparation under Italian law. When the case came before the Gerachtshof at the Hague, Centrafarm (one of the three Defendant Companies) argued that Parke Davis was in breach of Articles 85 and 86 of the EEC Treaty by using its Dutch patent to prevent the importation of the product into Holland, after this has been manufactured and freely sold in Italy outside patent rights. Two questions were referred to the European Court:

i. whether Articles 85 and 86 prevented the holder of a national patent from stopping imports from a company where they could be lawfully produced without a patent; and

ii. whether it was of significance that the price of the patented product produced in Holland was higher than the price of the product which has been imported from Italy.

In its replies to these two questions the Court concluded that the existence of the patent rights in Holland was not in itself affected by the prohibitions contained in Articles 85 and 86 unless accompanied by the exercise of those rights in a way which contravened those provisions. In relation to Article 85, the exercise of such rights would have to be accompanied by an agreement, decision or concerted practice. In relation to Article 86, the exercise would have to be accompanied by evidence on the abuse of a dominant position in the market. In either case, it would be necessary to show that trade between Member States was liable to be affected. On the second question the Court simply replied:

> "Although the sale price of the protected product may be regarded as a factor to be taken into account in determining the possible existence of an abuse, a higher price for the patented product as compared with the unpatented product does not necessarily constitute an abuse".[7]

As neither Article 85 nor 86 had application, and as the proceedings had been referred under Article 177, it was for the national Courts to decide the issue. But it seems clear that Parke Davis were entitled to enforce their patent rights so as to exclude the Italian product. As Mr Advocate-General Roemer concluded in his Opinion:

> "Neither Article 85 nor 86 of the EEC Treaty prevents the holder of a patent granted in a Member State from seeking from the Courts, on the grounds of his patent rights, an injunction

prohibiting the importation of products of the kind protected from another Member State in which the products and the manufacturing process are not patentable".[8]

5.3 JOINT RESEARCH

Another area in which the activities of the pharmaceutical industry have become involved with Article 85 of the EEC Treaty is in the field of research and development. The Commission had emphasised on several occasions[9] that it views favourably joint research and development projects beteen undertakings with complementary skills and resources where this may lead to technical or economic progress.

But this encouragement does not extend to the joint implementation of such research work. A decision of the Commission which illustrates the approach of the Commission is that relating to an agreement between Beecham and Parke Davis.[10]

Beecham is a medium-sized British manufacturer of pharmaceutical products in Europe, whose worldwide turnover for 1976/77 was £720,000,000. Parke Davis is a subsidiary of Warner Lambert, USA, with a worldwide turnover in a variety of fields of 2.5 billion dollars in 1977. During 1973 the companies entered into an agreement with the aim of creating a new pharmaceutical product intended for the long-term prophylactic treatment of heart disease caused by problems of blood circulation. Neither company had a product on the market which had those therapeutic effects, although each company had undertaken preliminary research which had been abandoned because of the high risk factors involved. The companies then agreed to divide the necessary research in such a way that each company had its own range of compounds for evaluation in

separately conducted laboratory tests, based on joint planning and with an exchange of results so as to avoid duplication of cost and effort. Each party to the agreement was of the view that the research and development required for the desired product would be long and expensive. It was estimated that the period of time involved would be in the region of ten to twelve years, of which at least five to seven years would be devoted to development. The total cost over the ten to twelve year period was likely to exceed 20 billion dollars.

By 1978 the companies had completed the research stage and were beginning a development programme, involving extensive pharmacological and clinical testing. This stage would be superseded by a production stage during which both companies would exchange information relating to the experience gained from the initial manufacturer of the new product. In considering the agreement the Commission noted that the co-operation between the companies did not serve for information only, nor was it limited to research but extended to the whole period of research and development and to the first years of industrial application of the results of the joint programme. Having regard to this the Commission were clear that the agreement fell outside the group exemption provided by Article 1(1)(b) of Council Regulation 2821/71[11] by which the Commission was entitled to grant an exemption to agreements which had as their objectives:

> "The research and development of products or processes up to the stage of industrial application, and exploitation of results, including provisions regarding industrial property rights and confidential technical knowledge".

In its decision, the Commission granted an exemption five years after the agreement had been notified and after the two companies had successfully completed the research stage. The exemption remained in force until 31st December 1988. Little discussion is contained in the Commission's decision about either technical and economic progress or consumer benefit. Provided that the companies were successful in creating a new product with the desired properties, a new remedy would be made available which differed from any existing product. Such a resulting benefit was directed at, and would be readily made available to the patient/consumer. Upon the question of the indispensibility of the restrictions imposed by the agreement, various points were discussed. In particular, a full exchange of research information during the project and development programmes were considered indispensable to the attainment of the advantages of the collaboration of the research. Another consideration was the requirement that the parties to the joint venture should be free to compete after the exemption had expired. As the timing of the date for first marketing of the product could not be specified, the Commission limited the period of the exemption so as to give itself the opportunity of reassessing the effects of the commercial aspects of the agreement and to ensure that the companies could compete freely and without restrictions as regards the product after the expiration of the exemption. A further consideration was the fact that the agreement entitled each company to use the results of the common research as patent owner or licencee of the other company and to grant licences or sub-licences freely to third parties and without the consent of the other party to the agreement.

The Commission was also satisfied that the agreement was likely to affect trade between Member States. This was because the research and development was taking place in an area of intense activity ie the pharmaceutical market,

by two companies, each of importance and considerable size. There was also the fact that the new product would have a unique therapeutic application. Always provided that the companies were successful in finding a product with the desired properties, it was likely that the agreement might affect trade between Member States.

There are, however, a number of restrictions which the Commission will not accept in joint research agreements. This is because they offend against general principles of the Community's competition policy, such as territorial restraint upon the party's freedom of action within part or whole of the Common Market. Anything which tends to divide a market within the Community such as splitting one Member State from its co-members will be closely scrutinised. So too, in relation to research agreements, the parties may wish to reach some agreement of how the market should be divided and exploited once the research results have been obtained. Such agreements may include provisions for such subjects as royalty payments, profit sharing and the licensing policy of the parties in relation to the developed product once this is ready to be marketed. In relation to Beecham/Parke Davis agreement, the exemption was given subject to the parties accepting a number of amendments to the agreement as notified. After the Commission had raised these objections, the parties agreed to remove clauses relating to royalty payments, to the exclusion of France from the licensing provisions and to a profit sharing clause relating to France and Japan. The parties to the agreement also limited the obligatory exchange of information of improvements to ten years from the date of first marketing the product by either party. Each party also undertook to grant royalty-free licences to the other party with power to sub-licence.

5.4 SPECIALISATION AGREEMENTS

A further area in which Article 85 of the EEC Treaty may impinge upon the activities of the pharmaceutical industry is in relation to specialisation agreements. An agreement under which two competing, or potentially competing, undertakings agree with each other to specialise in the manufacture of goods which the other will not produce will prima facie breach Article 85(1) of the EEC Treaty. This is subject to the assumption that the agreement will be capable of affecting trade between Member States of the EEC. Many of these agreements may, however, be of a kind which improve the production or distribution of goods or will lead to technical or economic progress within the meaning of Article 85(3) of the Treaty. Further, it may well be that consumers within the EEC may be capable of deriving benefit from such specialisation agreements, perhaps through lower prices. It has long been the policy of the Commission to encourage co-operation between undertakings in the EEC. In its Notice of Co-operation Agreements,[12] the Commission expressly declared that it supported co-operation which would lead to rationalisation and increase productivity. Having regard to this declared policy, it is the practice of the Commission to grant exemptions under Article 85(3) of the Treaty for those agreements which are properly notified to it and which satisfy those conditions. It is, of course, only those agreements which do not contain restrictions not indispensible to the attainment of the specialisation objectives, and not resulting in the possibility of the elimination of competition, which may be granted such exemption. Some restrictions have also been introduced by virtue of Regulation 2779/71,[13] Article 3 of which excludes agreements which have as their object products representing more than 15% of the market for all such products in a substantial part of the EEC and where the aggregate annual revenue of the participating parties

exceeds 300 million units of account. An example of the Commission's willingness to exempt a specialisation agreement involving undertakings exceeding the market share and size limits prescribed by this Regulation is the Commission's decision in the agreement between Bayer and Gist-Brocades.[14]

Bayer is one of the largest manufacturers of pharmaceuticals in Europe, having product, processing and distribution establishments throughout the Common Market. The greater proportion of its exports were to non-Community countries. Gist-Brocades is primarily an undertaking which used fermentation techniques, using products such as enzymes, yeast and alcohol. Its main business is to sell intermediate products. Both undertakings manufactured penicillin and penicillin derivatives when, in 1969, they concluded a specialisation agreement and supply contracts regarding their mutual manufacture of penicillin. Bayer agreed not to expand its raw penicillin plant but to purchase its increased requirements from Gist-Brocades, who in turn agreed to exchange its raw penicillin capacity, partially with the financial help of Bayer. Gist-Brocades also agreed not to expand its production facilities for 6-APA (an intermediate product) and to obtain any additional requirements from Bayer.

These agreements also contained a number of detailed obligations for each undertaking upon the purchase and supply of its products, including quality control and pricing. Each company retained the right to inspect the other's books and records through experts so as to verify the price calculations, which were related to such factors as manufacturing costs.

Through a licensing agreement concluded at the same time, Gist-Brocades granted Bayer a non-exclusive, non-transferable licence for its chemical process and provided Bayer with the necessary know-how for the manufacture of 6-APA in Germany. As long as Bayer continued to supply Gist-Brocades with 6-APA the licence was to be free of charge. If the supply agreement terminated, an appropriate royalty was to be charged. Each undertaking agreed to release the other from the obligation not to contest the validity of existing or future industrial property rights.

In 1971, these supply contracts and licensing agreements were supplemented by a further agreement, called the basic agreement. This was concerned with the financing of new production plants or extensions to existing plants, or raw penicillin in the case of Gist-Brocades and for 6-APA in the case of Bayer. There was also provision made for the transfer of these plants to two joint subsidiaries and the creation of a joint co-ordinating committee and the exchange of information and research results. Each company was to take a 50% share in the two subsidiaries and to appoint an equal number of directors.

When the Commission began its investigations, the results of the various agreements entered into by the companies were becoming apparent. Gist-Brocades had expanded its raw penicillin and Bayer its 6-AMA capacity. Gist-Brocades was one of the world's largest raw penicillin manufacturers, having about 16% of the world production. Bayer was one of the world's leading manufacturers of 6-AMA, accounting for about 15% of world production. Further, the Commission found that the highest concentration of world production for both raw penicillin and 6-AMA was located in the Common Market, with approximately 60% of world output for each product. In these circumstances the Commission had no difficulty in

finding that the agreements were in breach of Article 85(1). In giving up part of its business in favour of the other, each undertaking has in effect (although there was no express clause in the agreements so stating) agreed not to compete. There was also no doubt that the agreement for reciprocal long-term supply between the two companies was capable of affecting trade between Member States. This finding was based upon the fact that the two undertakings were from different Member States (namely, Germany and Holland respectively) and that the products in question were traded within the EEC.

In May 1975, after the Commission had opened its investigation, the companies gave formal notification to the Commission of their agreements and asked for an exemption under Article 85(3) of the Treaty. After certain changes in the relationship between the companies had been made, and certain amendments to the agreements had been agreed, the Commission granted an exemption for the period of eight years. But substantial obligations were placed upon the undertakings as to the supply of detailed information to the Commission.

There were two provisions in the agreement which the Commission was not prepared to accept. First, the Commission insisted upon the termination of the agreement relating to the formation of the equally owned subsidiaries of the companies upon the grounds that such an extensive restriction on investment and production could not be regarded as indispensible to the specialisation agreement. Upon reaching this decision the Commission argued that:

> "The formation of these joint subsidiaries would have had the effect of bringing the production of raw penicillin and 6-APA and investment under joint control. Since each firm was to be equally

> represented, both in the management of the subsidiary and on the co-ordinating committee, either would have been able to veto any management decision with which it did not agree. The result would inevitable have been that output would have been determined by joint agreement; neither firm would have been able without the other's approval, to increase the quantities available to the resale to other firms or for processing, and hence to increase to the detriment of the other, quantities supplied to the market by it:.[15]

These subsidiaries had been set up before the Commission had intervened but the Commission offered no solution to the problem of what was to happen, leaving the parties to the agreement to reach their own solutions. It was agreed tha Bayer should divest itself entirely of its holdings, while Gist-Brocades was to take over one of the subsidiaries completely.[16]

Secondly, the Commission took exception to the "no challenge" clause in the licensing agreement for the following reason:

> "The no-challenge clause in the licensing agreement has also been reviewed as an unnecessary restriction. If Gist-Brocades and Bayer, two of the world's largest 6-APA manufacturers, had continued to agree not to contest the validity of each other patents, the result might have been that third parties would have been prevented from exploiting freely for the benefit of the consumer processes which did not in fact merit the protection of a patent".[17]

Here, the Commission's concern was that agreements entered into by undertakings should not result in the elimination of competition in respect of a substantial part of the products in question. To safeguard against this possibility, the Commission will seek to ensure that specialisation agreements do not exceed their role by extending into agreements that the undertakings will not compete in the market place. To provide a possibility of challenging a patent is a way of ensuring that firms may compete, always providing that they wish to do so. This is particularly important where, as in the Bayer-Gist-Brocades case, the marker under consideration is the world market.

5.5 CONCLUSION

In relation to all three of the types of agreement considered above - namely, patent licensing, joint research and specialisation agreements, the Commission has been prepared to grant exemption under Article 85(3) of the Treaty. In the case of Bayer-Gist-Brocades agreement, the Commission took it for granted that Article 85(1) applied, even though there was no express contractual obligation on the parties to the agreement to obtain their respective products from each other. Here it was assumed that the parties would in fact purchase supplies from each other because the terms of supply in so doing were extremely favourable.

There is, however, some difficulty in defining precisely what form such an agreement may take or what it may contain. This vagueness has been described by Ritter and Overbury in their discussion of what constitutes a joint venture in the following terms:

"The concept of a joint venture is certainly as wide and imprecise as other frequently used terms such as co-operation and concentration. The term joint venture has been applied to almost every kind of economic activity undertaken jointly by two or more companies. It is chiefly used in respect of a legally independent entity under the joint control of the participants, so-called corporate joint venture, but the term is also used to describe other enterprises to which no legal status is afforded but where the participants control their joint affairs by means of a Committee or Management Team or other body to which has been delegated the power to make decisions".[18]

In relation to the Bayer-Gist-Brocades agreements, the Commission was particularly concerned to see whether the agreements enabled the parties to gain a competitive position over others. It is in relation to research and development projects, in particular, that joint control and investment may logically lead to competitive restrictions that cannot properly be regarded as indispensible to achieve the objects of the agreement. Where such extension leads to this result, the Commission is not slow to take steps to insist upon amendment of the offending agreement, leaving the parties themselves with the problem of the consequences which may flow from this rearrangement of the terms.

Article 85 of the Treaty is applied to the kinds of agreement described above, as in relation to any other such agreement, in the usual way. Exemptions under Article 85(3) are granted in a fairly flexible way, upon a limited basis, having regard to the economic consequences of the agreements concerned. If necessary, the Commission may grant a limited exemption but provide a clause in its

decision to enable information to be provided on a continuing basis by the undertakings concerned so that the terms of the exemption may be kept continuously under review. Where, however, a notifiable agreement is deliberately withheld from notification prior to the deadline set for that purpose, there is no possibility of an exemption under Article 85(3) being granted.[19]

B - ABUSE OF A DOMINANT POSITION

5.6 INTRODUCTION

Article 86 of the Treaty provides that:

> "Any abuse by one or more undertakings of a dominant position within the Common Market or in a substantial part of it shall be prohibited as incompatible with the Common Market insofar as it may affect trade between Member States".

Four examples of such possible abuse are then listed, including directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions. While the fact of an undertaking having a dominant position is not per se a breach of the Treaty, that position is only compatible with the objectives of the Treaty if trade between Member States is not affected and some evidence is shown that that position has not been abused.

No definition is contained in the Treaty as to what constitutes a dominant position but in Case 6/72[20] the Court said:

> "Undertakings are in a dominant position when they have the power to behave independently, which puts them into a position to act without

> taking into account their competitors, purchasers or suppliers. That is the position when, because of their share of the market, or of their share of the market combined with the availability of technical knowledge, raw materials or capital, they have the power to determine prices or to control production or distribution for a significant part of the products in question. This power does not necessarily have to derive from an absolute domination permitting the undertakings which hold it to eliminate all will on the part of their economic partners, but it is enough that they be strong enough as a whole to ensure to those undertakings an overall independence of behaviour, even if there are differences in intensity in their influence on the different partial markets".[21]

In relation to the market in pharmaceutical products, there are some salient features which should be emphasised.[22] One of these is that a limited number of producers and their products account for a very large part of the market. This concentration of the market upon relatively few producers has been particularly marked in France, where the number of laboratories has dropped from 2,000 to only 350 in the space of thirty years.[23] A further feature is that the industry is research-orientated, with innovation being jealously protected by both patent and trade mark rights. A third feature is that the prices for pharmaceutical products are highly inelastic. In most countries the choice of product is made by a medical practitioner who has, either completely or within certain limits, freedom of clinical judgment. Generally, the choice of product is based upon medical rather than upon economic grounds. All of these features have resulted in multi-national enterprises playing a large part in the pharmaceutical industry, with

the risk of abuse of dominant position of the market. Given this background to the pharmaceutical industry, it is not surprising that several of the leading cases decided by the European Court upon Article 86 have concerned pharmaceutical undertakings and those manufacturing related products.

5.7 SIRENA -v- EDA

In Case 40/70[24] an American company called Mark Allen registered a trade mark "Prep" in 1933 in respect of a shaving cream. By an agreement concluded in 1937 Mark Allen transferred the mark to Sirena in Italy. Sirena later renewed the registration of the mark in Italy on its own behalf and also registered two new marks comprising the words "Prep Good Morning". On a unspecified date Mark Allen allowed a German company to use its mark in Western Germany. The German company then began to sell its products on the Italian market at a much lower price than Sirena's. Sirena then brought an action in the appropriate Italian Court against the importing company and the retailers alleging them of imitating the three registered marks.

One of the questions referred to the Court under Article 177 was whether Article 86 of the Treaty allowed the owner of a validly registered trade mark to prevent a third party from marketing products bearing that mark which had been imported into that territory. In his submission Advocate-General de-Lamothe argued that Article 86 contained three elements:

i. the existence of a dominant position;

ii. the improper exploitation of that position; and

iii. the possibility that trade between Member States might be affected by it.

Upon this question the Court held that the owner of a trade mark did not enjoy a dominant position within the meaning of Article 86 merely because he could prohibit third parties from marketing products bearing that same mark. To constitute a breach of Article 86 it was also necessary to show that the trade mark owner had the power to prevent effective competition in a considerable part of the market in question. While the higher price imposed by the trade mark owner did not per se constitute sufficient proof of a dominant position, it might become so if, because of its size, it did not seem to be objectively justified.

5.8 COMMERCIAL SOLVENTS

A second decision upon Article 86 is the judgment into joined Cases 6 and 7/73.[25] This concerned a world monpoly held by Commercial Solvents Corporation of New York in the production of products derived from the nitration of paraffin.

One of these products is the raw material which was itself indirectly a substance used for the treatment of tuberculosis. Until 1970 Commercial Solvents supplied the substance to customers in the EEC through subsidiaries and distributors. In particular it supplied the Italian market through an Italian company of which Commercial Solvents owned 51% of the voting shares. This share ownership gave Commercial Solvents the power of appointing directors of the Italian company and of determining its policy. Another Italian company "Zoja" had been the main customer for suppliers of the substance in question since 1966. When Zoja asked for further supplies of the substance in November of 1980 it was informed that

Commercial Solvents no longer had supplies for sale. Zoja then complained to the Commission that Commercial Solvents and its subsidiaries had infringed the competition rules of the Treaty by ceasing to provide any further supplies.

The Commission held that:

i. Commercial Solvents was able to exercise, and did in fact exercise, such a degree of control over the Italian company in which it held 51% of the shares that it should be treated as forming, in their relations with Zoja and for the purposes of Article 86, a single undertaking;

ii. this single undertaking held a dominant position, namely a world monopoly of the supply of the raw materials necessary for the manufacture of Ethanbutol;

iii. the undertakings had abused its dominant position in ceasing to supply raw materials to one of the principal producers of Ethanbutol in the EEC, conduct that must lead to the elimination of that producer and so to a reduction in competition;

iv. such abuse affected trade in Ethanbutol between Member States as Zoja exported the substance to both France and Germany.

In its decision the Commission ordered Commercial Solvents to supply Zoja with specified quantities of the substance at a price no higher than the maximum price charged. The Commission also required Commercial Solvents to submit to it within two months proposals for the subsequent supply of the substance of Zoja. It also imposed the fine of 200,000 units of account upon Commercial Solvents and its subsidiary jointly and severally, to be paid within three months. From this decision both companies appealed.

Several interesting points emerge from the judgment of the Court, in which it upheld the decision of the Commission but halved the level of the penalty imposed. In relation to the relevant market Advocate-General Warner argued that there was a large measure of disagreement between the parties as to how this should be defined. Commercial Solvents argued that the relevant market should be that of anti-tuberculosis drugs, while the Commission had taken the view that the relevant market was that of the raw materials for the production of Ethanbutol. The argument of the appellants was that there were other drugs available to treat tuberculosis - the Commission having found that these other drugs were used in combination with Ethanbutol rather than as replacements for it. The Court held:

> "Contrary to the arguments of the appellants it is in fact possible to distinguish the market in raw material necessary for the manufacturer of a product from the market on which the product in sold. An abuse of a dominant position on the market in raw materials may thus have effects restricting competition in the market on which the derivatives of the raw material are sold and these effects must be taken into account in considering the effects of an infringement, even if the market for the derivative does not constitute a self-contained market. The arguments of the applicants in this respect and in consequence their request that an expert's report on the subject be ordered are irrelevant and it must be rejected".[26]

In this passage the Court seems to accept that the raw material for the product may constitute a relevant market quite separate from the market in which the end product is sold. But the Court then goes on to suggest that it may

be valid, in determining whether or not there has been an abuse of a dominant position, to take account of any restriction of competition which has taken place on the market for the derivative. Valentine Korah[27] has criticised this part of the Court's decision because it failed to analyse the market and did not discuss the public interest. In relation to the market for medicines it is, of course, necessary to consider whom the ultimate consumer may be. Although the material Ethanbutol was purchased by other drug companies, the ultimate consumer of the final end product is the patient. The decision contains no reasoning upon why the conduct of Commercial Solvents should be found to be undesirable or anti-competitive from the point of view of the ultimate consumer. As Valentine Korah has pointed out[28] it had been previously assumed that Article 86 was intended to protect consumers. Upon this point it is to be observed that the term "consumer" is mentioned in both Article 86(3) and 86(6) of the Treaty. It has, however, been suggested[29] that this term should be interpreted as being wider than the usual English sense of member of the consuming public because the French text of the Treaty uses the word "utilisateur".

A further point emerging from the Commercial Solvents decision is the treatment of the American parent company and its Italian subsidiary as a single enterprise for the purposes of the competition provisions of the Treaty. Upon this Advocate-General Warner relied heavily upon the judgment of Lord Denning MR in a decision of the English Court of Appeal to justify the lifting of the corporate veil[30]. In pleading for the European Court of Justice to take a commonsense and realistic view, Mr Warner put forward the following arguments for consideration:

1. that there is a presumption that a subsidiary will act in accordance with the wishes of its parent because according to common experience subsidiaries generally do so act;

2. that, unless that presumption is rebutted, it is proper for the parent and the subsidiary to be treated as a single undertaking for the purposes of Articles 85 and 86 of the EEC Treaty; and

3. that the presumption can only be rebutted if it is shown affirmatively, by those seeking to rebut it, that the subsidiary in fact conducted its business autonomously.

I confess, that to my mind, this must be a very difficult onus to discharge. I can conceive of its being discharged in such a case as that of (say) an insurance company, or of a company which a trustee of a pension fund, acquiring by way of investment a controlling interest in a trading company, or in a case where what is at first sight the subsidiary of one company is shown to be in reality a joint venture between that and another company in unequal shares. But I would think it almost impossible to discharge in the ordinary case of a parent and subsidiary carrying on related business".[31]

Upon the facts Commercial Solvents held 51% of the voting shares in the Italian subsidiary, five out of the ten members of the subsidiary were high-ranking executives of Commercial Solvents and three out of six members of the subsidiary's Executive Committee were nominees of Commercial Solvents. But the Court found in its judgment that the two companies had always acted independently, so

that Commercial Solvents could not be deemed responsible for the acts of its subsidiary or vice versa. Nevertheless, the Court held that Commercial Solvents and its subsidiary had formed one single undertaking or economic unit for the purposes of Article 86, although the language used was not so general or sweeping a nature as that of Mr Warner.[32]

Upon the criteria of what constitutes a dominant position for the purpses of Article 86, the Commission had found that Commercial Solvents had a world-wide monopoly of the production and sale of the substances used in the manufacture of Ethanbutol. This was accepted by the Court, which decided that the references to possible alternative sources of the substances were not sufficient to justify setting aside the Commission's decision as these were only of an experimental nature or practised on a small scale. Clearly, on these findings, the criteria of dominance was not in doubt. Other cases had suggested that no fixed percentage of the market will necessarily amount to dominance - much will depend upon the structure of the market. Thus, in United Brands[33] the Court said:

> "A trader can only be in a dominant position in the market for a product if he has succeeded in winning a large part of this market. Without going into a discussion about percentages, which when fixed are bound to be to some extent approximations, it can be considered to be an established fact that UBC's share of the relevant market is always more than 40% and nearly 45%".[34]

Further, in Hoffmann-la-Roche[35] the shares held by Roche for the market of the seven vitamins in question varied as follows (although these figures were not accepted by the company):

Vitamin A	-	47%
Vitamin B^3	-	18.9-51%
Vitamin C	-	63-66.2%
Vitamin H	-	93-100%
Vitamin B^2	-	74.8-87%
Vitamin B^6	-	83.9-90%
Vitamin E	-	50-64%

(These being the lowest and highest figures for value or quantity.) The Court held that Roche had a dominant position, because of market share alone or in combination with other factors, for all of these markets except that for Vitamin C.

While the existence of a dominant position in the market is clearly an important element in considering a possible breach of Article 86, such a dominance is not per se an abuse of that position. No definition of what constitutes an abuse is contained in the Treaty, apart from the four examples contained in Article 86. It will be seen that this list of examples is not exhaustive but that the Court seeks to distinguish between a company's conduct which properly makes use of its dominant position and conduct which is prohibited. For example, in United Brands the Court accepted that a company in a dominant position was perfectly entitled to respond to competition and protect its commercial interests in the relevant market. This behaviour must, however, be based upon the principle of proportionality. The Court was not prepared to sanction United Brands to refuse supplies to a long-established customer after it had embarked on a major advertising campaign for products of one of United Brand's competitors, which it was selling simultaneously with United Brand's bananas.

That refusal to supply a customer could amount to a breach of Article 86 was first established in the Commercial Solvents decision.[37] There the Court said:

> "However, an undertaking being in a dominant position as regards the production of raw material and therefore able to control the supply to manufacturers of derivatives, cannot, just because it decides to start manufacturing these derivatives (in competition with its former customers) act in such a way as to eliminate their competition which in the case in question would amount to eliminating one of the principal manufacturers of Ethanbutol in the Common Market. Such control is contrary to the objectives expressed in Article 3(f) of the Treaty and set out in greater detail in Articles 85 and 86, it follows that an undertaking which has a dominant position in the marker in raw materials and which, with the object of reserving such raw materials for manufacturing its own derivatives and therefore risks eliminating all competition on the part of the customer, is abusing its dominant position within the meaning of Article 86".[38]

These decisions clearly show that refusal to supply an existing customer may constitute an abuse of a dominant position in the market. This is particularly so where, as in Commercial Solvents, the refusal to supply would have the effect of removing a major producer from the relevant market.

A final element in the Commercial Solvents case concerns the effect of the abuse upon trade between Member States. However, once it has been shown that the abuse will have repercussions on the pattern of competition in the Common

Market, this will be sufficient to satisfy the conditions. This remains true even where the abuse relates to export sales from the EEC to third countries. In Commercial Solvents the appellants argued that it was principally the world market which was affected because Zoja sold 90% of its production outside the Common Market. To this the Court replied:

> "The Community authorities must therefore consider all the consequence of the conduct complained of for the competitive structure in the Common Market without distinguishing between production intended for sale within the market and that intended for export. When an undertaking in a dominant position within the Common Market abuses its position in such a way that a competitor in the Common Market is likely to be eliminated, it does not matter whether the conduct relates to the latter's export or its trade within the Common Market, once it has been established that this elimination will have repercussions on the competitive structure within the Common Market. Moreover, the contrary argument would in practice mean that the control of Zoja's production and outlets would be in the hands of CSC and Instituto. Finally its cost prices would have been so affected that the Ethanbutol produced by it would possibly become unmarketable. Moreover, it emerged at the hearing that Zoja is at present able to export and does indeed export the products in question to at least two Member States. These exports are endangered by the difficulties caused to this company and by reason of this trade between Member States may be affected".[39]

These passages seem to indicate that any conduct by an undertaking which holds a dominant position in the relevant market may be a breach of Article 86 if this is likely to affect competition within the Common Market. This may be so even if exports between Member States are not affected. On the facts, however, trade between Member States was likely to be affected because Zoja had exported to France since 1971 and was beginning to export to Germany. This approach by the Court seems to be consistent to that which it adopts when considering Article 85 of the Treaty. In relation to the latter Wyatt and Dashwood have said:

> "Recent cases have tended to show that the effect on trade may be purely hypothetical and thus to confirm that the "restrictive" approach was not likely to be followed. in Kabel Metal/Luchaire for instance, it appears that the grant of an exclusive patent licence to a French company by a German one affected trade because the grantor and other licensees would be prevented from manufacturing in France. Of course it was not at all certain that the grantor or such others would actually have ever done so, and the only effect on trade was perhaps to alter the precise manufacturing location within France from which the goods could be exported".[40]

Thus, a consistent stance is being adopted by the Court upon the point in relation to both Articles 85 and 86, with the effect that the phrase "..... may affect trade between Member States" does not impose a very large burden upon the Commission in seeking to establish an infringement under those Articles.

5.9 HOFFMANN-LA-ROCHE -v- COMMISSION

In Hoffmann-la-Roche[41] it has already been seen that the Court were asked to consider the market for vitamin products. Roche operated on a world-wide basis and had subsidiaries in nearly all of the Member States. Roche had approximately five thousand customers in the Common Market, who were engaged in the manufacture of pharmaceuticals, foodstuffs and animal feeding stuffs. In a period from 1963/1973 agreements for the supply of requirements were entered into between Roche and a number of its customers. These agreements had the effect of binding the chief purchaser of vitamins to Roche, either by way of express undertakings to purchase in respect of the whole or the major part of their requirements or by means of fidelity rebates or preferential prices. In its decision the Commission took the view that Roche had a dominant position in a number of vitamin markets and that the agreements entered into by the customers of Roche were capable of hampering their freedom of choice and equality of treatment of purchasers.

In its judgment the Court held that an obligation by customers to buy all or a considerable part of their requirements from an undertaking which held a dominant position in the market was an abuse. The Court said:

> "The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering

> the maintenance of the degree of competition still existing in the market or the growth of that competition".[42]

Then the Court considered the question of fidelity rebates and the so-called "English clause". It was held that it was also an abuse if fidelity rebates were given under the terms of a contract, even without any obligation on the part of the customer, or unilaterally, without contract. Such practices had the effect of removing the freedom of choice of customers and of preventing other suppliers having access to the market. With regard to the "English clause", this operated so that if a customer got an offer of supply at a price below that being asked by Roche, the latter could have the option of meeting that reduced price of allowing a customer to buy at the lower price without losing the fidelity rebate. The operation of such a clause enabled Roche to know when competitors were offered lower prices, even when its customers had an interest in not disclosing them which, the Court held, made the abuse more serious. Upon this to was held that even if fidelity rebates were given without the customer being obliged to buy exclusively from Roche, they were such a powerful encouragement towards exclusive purchasing that they were in breach of Article 86. Further, where the rebate was given over the whole range of vitamins sold by Roche, this in itself was contrary to Article 86(b).

A further point raised by the judgment was the Court's consideration of what constituted the relevant market. The Commission had decided that each group of vitamins constituted a separate market. It was an established fact that Vitamins C and E, quite apart from their use in the pharmaceutical and food industries, were also used as anti-oxidents, fermentation agents and additives. Roche argued that these two groups of vitamins were part of a much larger market comprising these other products and

that the Commission had exaggerated Roche's share of the market by failing to take this into account. The Court held[44] that if a product could be used for different purposes in accordance with economic needs, there were good grounds for accepting that the product might belong to separate markets. What the concept of the relevant market implied was that there could be effective competition between the products which formed part of it, and this presupposed that there was a sufficient degree of interchangeability between these products. There had been no such interchangeability during the period under consideration.

This decision in Roche supports a conclusion that the Court's definition of what constitutes the relevant market for the purpose of Article 86 will be defined in a narrow way so as to facilitate the proof of establishment of a dominent position. This approach is consistent with its treatment of the relevant market under Article 85. This , in Bayer-Gist-Brocades[45] the Commission decided that the various manufacturing stages for the production of penicillin products each constituted a separate market. Consequently, raw penicillin, an intermediate product and the finished product each belonged to a different market for the purpose of Article 85.

5.10 CONCLUSION

Relatively few cases have been decided by the European Court upon Article 86 of the Treaty. It must be accepted that no clear dividing line may be drawn between behaviour of an undertaking having a dominant position in the market which is acceptable and behaviour which is contrary to that provision.

With regard to the relevant market, this is considered in relation to the products concerned from both a geographical and economic view, and has resulted in the Court adopting a narrow view of what constitutes the relevant market. Where products have a sufficient degree of substitutability, however, they will be included in the market definition. In relation to pharmaceuticals, different stages in a manufacturing process from raw materials to finished products may require a consideration of different markets, each separately considered from the point of view of abuse of a dominant position.

Upon the issue of dominance, the most important consideration is the question of whether the undertaking under scrutiny has the power to act independently of its competitors. Abuse is regarded as an objective concept and may arise irrespective of the intention of the undertaking. Those abuses which are specifically listed in Article 86 itself are not an exhaustive list.[46] Although the provision requires that the abuse in question affects trade between Member States, Commercial Solvents shows that this requirement is satisfied where the abuse has repercussions on the pattern of competition in the EEC, without any proof that the abuse has in fact appreciably affected trade between Member States.

NOTES

1. J O 1962, 204; O J 1959-62 57.

2. This Notice was dated 24th December 1962 and is known as the Christmas message.

3. See, in particular, Burroughs-Delplanque Agreement [1972] CMLR D67 and Davidson Rubber's Agreement [1972] CMLR D52.

4. Regulation 19.65, J O 1965, 533; O J 1975-1966, 35.

5. The draft Regulation is set out at [1979] 1 CMLR 478. The final version of this, Regulation 2349/84 of 23rd July 1984 was finally published in the Official Journal of 16th August 1984, No L219, 15-24.

6. Parke-Davis -v- Probel and Centrafarm [1968] ECR 55; [1968] CMLR 47.

7. At [1968] ECR 72 in its grounds of judgment.

8. At [1968] ECR 80/81.

9. See its Notice governing Agreements, Decisions and Concerted Practices in the field of Co-operation between Enterprises, O J No C75, 29th July 1965, page 3, corrected by O J No C84, 28th August 1984, page 14.

10. Commission Decision 79/298/EEC of 17th January 1979.

11. Regulation 2821/71, J O 1971, L285/46; O J 1971, 1032.

12. O J No C75, dated 29th July 1968.

13. Regulation 2779/712, J O 1971, L285/46; O J 1971, 1032.

14. [1976] 1 CMLR D98.

15. See paragraph [63] of the Commission's Decision.

16. See paragraph [29] of the Commission's Decision.

17. See paragraph [65] of the Commission's Decision.

18. Ritter, L and Overbury, C "An attempt at a practical approach to Joint Ventures under the EEC Rules on Competition", 14 CML Rev 601.

19. An example of this is provided by a decision of the Commission dated 25th June 1969 [69/202/EEC] in relation to the International Quinine Cartel. Substantial fines were imposed upon various French, German and Dutch companies who were the principal manufacturers of quinine products in their respective national markets. The undertakings concerned which entered into the agreements in question held a dominant position in the market and the products themselves were of particular importance because, in some cases, there were no substitute products available.

20. Europemballage and Continental Can -v- Commission, [1973] ECR 215; [1973] CMLR 199.

21. J O 1972 L7/25 at L7/35. Translated from [1972] CMLR D11 at D35.

22. Deleau G (Rapporteur), Report drawn up on behalf of the Committee on Economic and Monetary Affairs, for the European Parliament, dated 15th December 1982, at page 16 et seq.

23. Deleau op.cit, at page 17.

24. Sirena -v- Eda [1971] ECR 69; [1971] CMLR 260.

25. Instituto Chemisterapico Italiano SpA and Commercial Solvents Corporation -v- Commission [1974] ECR 223; [1974] 1 CMLR 309.

26. At paragraph 22 of its judgment.

27. See her discussion of this case in 11 CML Rev 248.

28. Ibid, page 271.

29. By Dashwood and Wyatt, "The Substantive Law of the EEC", London, Sweet and Maxwell, [1980] at page 274.

30. Littlewoods Mail Order Stores -v- C I R, [1969] 1 WLR 1254.

31. [1974] ECR 264.

32. See paragraph 37 of the judgment.

33. Case 27/76, United Brands Company -v- Commission, [1978] ECR 207; [1978] 1 CMLR 429.

34. See paragraphs 107 and 108 of the judgment.

35. Case 85/76, Hoffman-la-Roche -v- Commission, [1979] 3 CMLR 211.

36. Case 27/76, United Brands Company -v- Commission, [1978] ECR 207; [1978] 1 CMLR 429.

37. Instituto Chemisterapico Italiano SpA and Commercial Solvents Corporation -v- Commission [1974] ECR 223; [1974] 1 CMLR 309.

38. At paragraphs 33 to 35 of its judgment.

39. [1974] ECR at pp 252 to 253.

40. Op.cit. at note 29 above at pages 260/261.

41. Case 85/76 [1976] 3 CMLR 211.

42. At paragraph 91 of its judgment.

43. At paragraph 111 of its judgment.

44. At paragraph 28 of its judgment.

45. See Commission Decision of 15th December 1975, O J No L30 page 13.

46. The point is strikingly illustrated by Case 6/72 Europenballage and Continental Can Company -v- Commission, [1973] ECR 215; [1973] CMLR 199. There it was argued that the Commission was attempting to introduce a control over mergers of companies that the Treaty of Rome did not permit. Unlike Article 66 of the European Coal and Steel Community Treaty, Article 86 does not expressly contain any provision related to the control of mergers or acquisitions in the Common Market. The Court rejected this argument on the Grounds that Article 3(f) of the Treaty provided for the establishment of a system which ensured that competition in the Common Market was not distorted. This necessarily required that competition was not eliminated. This functional approach by the Court was expressed in the following terms:

> "To resolve this problem it is necessary to resort to the spirit, structure and wording of Article 86 and to the system and finality of the Treaty as a whole. Article 86 forms part of the chapter of common rules on competition, derived from Article 3(f) ..... The general principle set out in Article 3 constitute aims which are indispensible to the achievement of tasks of the Community. Article 86 is to be interpreted in the light of Article 3".

CHAPTER VI - HARMONISATION

6.1 INTRODUCTION

Three main categories of law-making may be identified in the Treaty of Rome.[1] First, there is a category aimed at ensuring that all persons in any Member State may enjoy the freedoms provided by the Treaty upon an equal basis. This includes, for example, freedom of movement for workers in accordance with Article 48 with no restriction upon the basis of nationality.[2] Also included within this category is the right of free movement of goods, discussed in Chapter IV. Secondly, there are provisions which give effect to common Treaty rules, such as the policies for agriculture, transport and the common commercial policy towards third states. Included in this category is the competition policy of the Treaty, certain aspects of which are discussed in Chapter V. Thirdly, there is a category of law-making aimed at the approximation of the national laws of Member States. Article 3(h) of the European Economic Community is the basis for this and states that the activities of the Community shall include:

> "..... the approximation of the laws of Member States to the extent required for the proper functioning of the Common Market".

It is necessary to consider other specific Articles of the Treaty to see where approximation is authorised and the procedure through which it is to be achieved. Thus, Article 99 provides for the harmonisation of indirect taxes of Member States in the interests of the Common Market. Article 100 contains a more general clause, which provides for the issue of "directives for the approximation of such provisions laid down by law, regulation, administrative action in Member States as

directly affect the establishment or functioning of the Common Market". Article 100 requires unanimity in the Council of Ministers, based on a proposal from the Commission, before such Directives may issue. The terms "approximation" and "harmonisation" are used interchangeably in the Treaty - here, the latter term will be used. A series of Directives have been issued governing the control of pharmaceuticals, which have invoked Article 100 of the Treaty as the legal authority for their issue and which are discussed below.

There have been several cases decided by the Court of Justice which deal with the inter-relationship between Articles 36 and 100 of the Treaty. In particular, three cases decided in 1979 deal with this subject. In Ratti[3] the Court was concerned with the implementation of two Council Directives dealing with the classification, packaging and labelling of dangerous preparations such as solvents, varnishes and similar products. Italian national law imposed requirements more strict than those imposed by those Directives. It was held that a Member State could not introduce into its law conditions which were more restrictive than those laid down in the relevant Directive, once the date for implementation of that harmonisation measure had passed. With regard to Article 36, the Court said:

> "When, pursuant to Article 100 of the Treaty, Community directives provide for the harmonisation of measures necessary to ensure the protection of the health of humans and animals and establish Community procedures to supervise compliance therewith, recourse to Article 36 ceases to be justified and the appropriate controls must henceforth be carried out and the protective measures taken in accordance with the scheme laid down by the harmonising directive".[4]

In Commission -v- Germany[5] the German law prohibited the importation of meat products unless certain conditions were fulfilled. One of those conditions was that the product had been manufactured in an establishment which had been approved by the appropriate Federal Ministry. While the German Government accepted that this measure had an effect equivalent to a quantitative restriction, it was argued that it was justified under Article 36 of the Treaty on grounds relating to the protection of human health. But a Community Directive had been issued dealing with intra-Community trade in fresh meat so as to allow free movement of fresh meat from animals slaughtered under a procedure approved and supervised by Community provisions. In these circumstances the Court held that the German measure imposing the prohibition contravened Article 30 and could not be justified under Article 36.

A similar decision was reached in Denkavit,[6] where the Court was concerned with certain German restrictions on the importation of animal feeding stuffs in connection with Community provisions. In dealing with Articles 30 and 100 the Court stated:

> "The Court of Justice has held in Carlo Tedeschi -v- Denkavit Commercials [1977] ECR 1556 that Article 36 is not designed to reserve certain matters to the exclusive jurisdiction of Member States but only permit national laws to derogate from the principle of free movement of goods to the extent to which such derogation is, and continues to be, justified for the attainment of the objectives referred to in that Article. Consequently when, in application of Article 100 of the Treaty, Community directives provide for the harmonisation of the measures necessary to guarantee the protection of animal and human health and when they establish procedures to

check that they are observed, recourse to Article 36 is no longer justified and the appropriate checks must be carried out and the protective measures adopted within the framework outlined by the harmonisation directive".[7]

These three cases show that the implementation of harmonisation measures under Article 100 of the Treaty has important effects upon the powers of Member States under Article 36. Where controls and restrictions are imposed by Community measures in these circumstances, it is those Community measures which will take precedence over conflicting national measures. This preserves the supremity of Community law and is unexceptional. If those harmonisation measures introduce their own procedures and controls, then these must be invoked, rather than others in reliance upon Article 36. Article 189 provides that Directives shall be binding upon each Member State to which it is addressed as to the result to be achieved. The position of the Court is based upon the word "justified" in Article 36; unilateral measures by Member States are neither justified nor necessary once relevant harmonisation measures have been adopted. The purpose of a Directive would clearly be frustrated if a Member State were allowed to exercise reserve powers so as to legislate in a way contrary to the objectives of the directive. Such action would lead to new restrictions on trade being imposed in an area where the Community had legislated to ensure freedom for trade.

In relation to Article 189(3) of the Treaty it is left to Member States themselves to decide the forms and methods to be used to implement a Community Directive. This discretion must, however, be exercised so as to ensure that the provisions of national law have the same legal force as those governing the same subject matter in other Member States. This is clear from Case 145/82[8], where

the Court held that the failure by Italy to adopt legislation to implement EEC Directives 65/65, 73/318 and 75/319 on the marketing of proprietary medicinal products was a failure to fulfil its Community obligations. It appears from the facts of the case that a Bill to implement the Directives in question had been prepared and had also been approved by the Senate. It had not, however, received final Parliamentary approval because of the premature dissolution of the Chambers.

In its Defence the Italian Government argued that it was not in breach of its Community obligations because the Directives had been implemented by administrative means - namely, by the issue of circulars. The Court held that administrative practices were not a sufficient implementation. This was because the circulars could, by their very nature, be altered at the whim of the authorities and their issue lacked the appropriate publicity. In any event, the circulars in fact issued were defective because they did not govern either the suspension or revocation of marketing authorisations for the products concerned, the labelling of the products or the rules to be applied for products imported from third countries. Having regard to these factors, the circulars could not be regarded as proper implementation of the Directives.

Criticism has been directed at the choice of directives for implementation of the Community harmonisation programme. Slot[9] has drawn attention to three main points of criticism. First there is the problem of the delay which may occur in the implementation of the Directives into national law. As the discussion of Case 145/82[10] above shows, national Governments may not always be able, for a variety of reasons, to implement a Directive by the due date. Where such delays occur, it is of course possible for other Member States or the

Commission to take proceedings under Articles 169 or 170 of the Treaty so as to encourage other Member States to honour their Community obligations. But these are in themselves lengthy proceedings and they do not provide an immediate remedy. Secondly, the text of any national laws may not always accurately reflect the text of the Directives which they seek to implement. This may again give rise to litigation, with consequence delay and expense while the position is adjudicated upon by the Courts. Thirdly, there is the question of whether the directives to be implemented give rise to direct effect so as to enable an individual to enforce his legal rights under its terms, regardless of whether or not the directives have been incorporated into national law.

Since the decision of the Court in Case 41/74[11], the direct applicability of Directives has been clearly established, subject to certain conditions. In that case the Court held that:

> "If, however, by virtue of the provisions of Article 189 Regulations are directly applicable and, consequently, may, by their very nature have direct effects, it does not follow from this that other categories of acts mentioned in that Article can never have similar effects. It would be incompatible with the binding effect attributed to a directive by Article 189 to exclude, in principle, the possibilities that the obligation which it imposes may be invoked by those concerned. In particular, where the Community authorities have by directives, imposed in Member States the obligation to pursue a particular course of conduct, the useful effect of such an act would be weakened if individuals were prevented from taking it into consideration as an element of Community law. Article 177,

> which empowers national Courts to refer to the Court questions concerning the validity and interpretation of all acts of the Community institutions, without distinction, implies furthermore that these acts may be invoked by the individuals in the national Courts. It is necessary to examine, in every case, whether the nature, general scheme, and wording of the provision in question are capable of having direct effects on the relations between Member States and individuals".[12]

Although the Van Duyn case was concerned with a directive based upon Article 48, there is no reason to suppose that the same principle would not be applied in relation to a directive based upon Article 100.

As Slot has argued[13] a Regulation would have been a more satisfactory instrument for the Community to have chosen to implement harmonisation of laws under Article 100. A Regulation would apply directly in all Member States, the provision being incorporated automatically into national legislation without delay. Unless and until Article 100 of the Treaty is amended, however, the Directives must remain the act by which harmonisation measures are achieved in Community law.

In the Marshall case[14] the European Court of Justice decided that the fixing of a lower age of compulsory retirement for women as opposed to men amounted to discrimination on the grounds of sex contrary to Directive 76/207.[15] This case also settled the controversy about the "horizontal", as opposed to the "vertical", direct effect of Directives. It was held that a Directive may not impose obligations on an individual and may not be relied upon as such against an individual. In this the Court followed Case 148/78.[16] In the Marshall decision

the Court preserved the obligation of a Member State to implement a Directive addressed to it and the discretion to choose the form and means of doing so, even after the time limit for implementation had passed. Thus, the Court ensured the greatest possible effectiveness for Directives and preserved their essential characteristics as compared to Regulations. The Court's solution was to impose a limited form of direct effect which applied against the Member State in breach of its Community obligations.

A further development in the use of Directives stems from the Commission's White Paper "Completing the Internal Market".[17] This has introduced a programme of reforms aimed at completing the internal market by 1992. This publication has led to the signing of the Single European Act[18] by Member States in February 1986. Article 13 of the Single European Act introduces a new Article, numbered 8A, into the EEC Treaty. This requires the Community to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31st December 1992. It also contains the following definition of what constitutes the internal market:

> "The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty".

By way of derogation from Article 100 of the EEC Treaty that Article is supplemented by Article 100A,[19] whereby the Council may act by a qualified majority (instead of unanimously) on proposals from the Commission and in co-operation with the European Parliament to adopt measures having as their object the establishment and functioning of the internal market.

Article 100A also enables Member States "to apply national provisions on grounds of major needs referred to in Article 36" if they deem it necessary. The major needs referred to in Article 36 include the protection of human health and life or the protection of industrial and commercial property. In a Declaration made on Article 100A it was stated that:

> "In its proposals pursuant to Article 100A(1) the Commission shall give precedence to the use of the instrument of a directive if harmonization involves the amendment of legislative provisions in one or more Member State".[20]

6.2 IMPLEMENTATION OF THE PHARMACEUTICAL DIRECTIVES

At the time when the United Kingdom Medicines Act 1968 was being drafted, the possibility of membership of the Common Market was a distinct probability. Having regard to this, comparatively little of the Act required to be adjusted upon entry. This adjustment involved the accommodation of three directives dealing with medicinal products. These were:

(1) Directive 65/65/EEC (hereinafter called "the first Directive");[21]

(2) Directive 75/318/EEC (hereinafter called "the norms and protocols Directive");[22] and

(3) Directive 75/319/EEC (hereinafter called "the second Directive").[23]

These three Council Directives recorded in their respective preambles that disparities existed in the various national provisions for controlling medicinal products. While recognising that rules regarding the

safeguard of public health were of importance, the Pharmaceutical Directives stated that this objective had to be achieved by means which would not hinder the development of the pharmaceutical industry or trade in pharmaceutical products within the Community. All three Directives were issued by the Council under Article 100 of the Treaty of Rome, which provides in part that:

> "The Council shall, acting unanimously on a proposal from the Commission, issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the Common Market".

One point of definition in relation to the scope of the Pharmaceutical Directives should be made. This is that the Directives apply only to proprietary medicinal products, that term being defined as "any ready prepared medicinal product placed on the market under a special name and in a special pack".[24] Some express exclusions from this definition are specified, which include vaccines, products based upon human blood and homoeopathic products.[25] In relation to their consideration of whether or not ro grant or refuse a licence under the Medicines Act 1968, the licensing authority of the United Kingdom is now expressly required to have regard to Community obligations. In a similar way, they are also given power either to refuse the renewal of a licence, or to suspend, revoke or vary a licence already granted upon the ground of contravention of Community obligations.[26]

The first Directive sets out the scope of the terms "medicinal product", which corresponds very largely to that contained in the Medicines Act 1968. Article 4 of the first Directive introduces the requirement of Member

States to ensure that an authorisation is held by any person who wishes to place a proprietary medicinal product on the market. Such an authorisation (a product licence in the terms of the Medicines Act 1968 must be refused if it is shown that three matters, which largely correspond to the concepts of safety, quality and efficacy, are not satisfactory. Article 7 introduces a time factor into any consideration of an application for a licence for a proprietary medicinal product. Such applications must be dealt with within a period of one hundred and twenty days of the date of submitting an application though, in exceptional cases, this time limit may be extended for a further ninety days. There is, however, no sanction provided against a licensing authority which exceeds these time limits. The obligation to apply the full licensing provisions required by the first Directive to proprietary medicinal products already on the market has now been extended to fifteen years from the date of notification of the second directive.[27] As Directives concern only a limited number of persons, they must be notified directly to those to whom they are addressed. Further provisions contained in the first Directive related to labelling requirements and the requirement that the manufacturer of the proprietary medicinal product is authorised to produce the product in question.

The norms and protocols Directive sets out detailed data requirements for applications to place proprietary medicinal products on the market. These requirements expand upon those set out in Article 4 of the first Directive. Part 1 of the Annex to the Directive contains the physio-chemical, biological or micro-biological tests, Part 2 toxicological and pharmacological tests, and Part 3 the particulars and requirements necessary to accompany applications for clinical trial authorisations. These provisions have been implemented by administrative means, as opposed to legislation, in the United Kingdom.

The second Directive contains requirements for good manufacturing practice. This is achieved by the issue of manufacturers' authorisations having due regard to the conditions of the plant, premises and staff; the compulsory presence of a qualified person with prescribed qualifications and experience permanently and continuously available at the disposal of the holder of the manufacturer's licence; and on inspections carried out on the manufacturer's premises by officials representing the competent authority of Member States. Also contained in the second Directive are the procedures to be followed by a Member State before grating an authorisation to place a product on the market. Any application for such an authorisation must be accompanied by detailed reports signed by experts holding the necessary technical or professional qualifications.[28] It is a further requirement that the particulars which accompany an application should be examined by the competent authorities in Member States. In cases where the competent authorities (ie the licensing authority as regards the United Kingdom) require further information, or procedure for either oral hearings or written representations are invoked, the time limits specified in Article 7 of the first directive do not run.[29]

Subsequent amendments have been made to the Pharmaceutical Directives. Directive 83/570/EEC[30] amends each of the Pharmaceutical Directives. Article 1 amends the first Directive in relation to the labelling of the product pack, which must in future include the international non-proprietary names recommended by the World Health Organization, where such names exist or, where no such names exist, the usual common names. Further changes made to the first Directive relate to a requirement for a summary of the characteristics of the product and for the expiry date of the product to be given in plain language. Article 2 of Directive 83/570/EEC amends some of the

detailed data requirements of the norms and protocols directive - notably, by the introduction of both mutagenic and bioavailability testing. Article 3 of directive 83/570/EEC makes changes to the procedures of the Committee for Proprietary Medicinal Products which is discussed below.

Three miscellaneous provisions, relating to pharmaceuticals, should also be briefly mentioned. First, by a Council Decision of 20th May 1975 a Committee called the "Pharmaceutical Committee" was set up and attached to the Commission.[31] This is an advisory and policy-making Committee, which the Commission is obliged to consult before preparing proposals for directives in the field of proprietary medicinal products. Its functions are stated to be without prejudice to the tasks of the Committee for Proprietary Medicinal Products referred to in Article 8 of the second directive.[32] The Pharmaceutical Committee consists of one senior expert in public health matters from the administration of each Member State and each representative has a deputy.[33]

Secondly, Council Directive 78/25/EEC[34] is concerned with the permitted colours for use in medicinal products. This directive was also made under the provisions of Article 100 of the Treaty of Rome. While acknowledging that the primary purpose of any law concerning medicines must be to safeguard public health, the preamble to the directice stated "..... this objective must be obtained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community". Subject to transitional provisions, this directive provides that the only colouring matters to be used for medicinal products are those permitted for foodstuffs by directive 1962 of 23rd October 1962[35] (as amended). Thirdly, Council

Recommendation 83/571/EEC[36] set out detailed safety testing guidelines which Member States are recommended to adopt. Council Recommendation 87/176/EEC[37] makes further recommendations adopting new notes of guidance (supplementing those annexed to Council Recommendation 83/571/EEC) aimed at facilitating the taking into consideration of marketing authorisations already granted by other Member States.

These supplemental notes deal with such subjects as single dose toxicity, the testing of products for mutagenic potential, the evaluation of cardiac glycosides, the clinical investigation of oral contraceptives and the presentation of technical information on anti-microbial drugs.

By Council Directive 87/21/EEC[38] an easement is introduced so that the results of pharmaceutical and toxicology tests or clinical trials do not have to be supplied when applying for a licence for a product which is similar to a product to which the liecnce has already been granted. Council Directive 87/19/EEC[39] provides for a Committee on the Adaptation to Technical Progress on the Removal of Technical Barriers to Trade for proprietary medicinal products to be set up. By establishing this Committee, which consists of representatives of Member States with a representative of the Commission as chairman, draft proposals for changes in technical progress within the remit of the Committee may be considered and voted upon as provided in Article 148(2) of the Treaty of Rome. This may provide a more rapid and more flexible procedure for testing medicinal products. Council Directive 87/22/EEC[40] introduces special provisions for the marketing of high-technology medicinal products whereby the opinion of the Committee for Proprietary Medicinal Products may be obtained as soon as an application for a marketing authorisation is received

by a Member State. Such products are listed in an annex to the Directive and include those based upon radio-isotopes or containing an entirely new substance.

6.3 THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

The Pharmaceutical Directives discussed above are solely concerned with the harmonisation of laws within Member States relating to medicines and do not relate to anything which may be described as a European licensing system. Chapter III of the second Directive introduced a procedure to enable an applicant for a licence to make multiple applications for a marketing authorisation in one of them. The second Directive has now been extensively amended by Council Directive 83/570/EEC.

In relation to this alternative licensing procedure, the Committee established by Article 8 of the second Directive plays a key role. This Committee is known as the Committee for Proprietary Medicinal Products and consists of representatives of Member States and of the Commission. Its responsibility is to examine questions referred to it by Member States relating to refusals to grant authorisations to market medicinal products and the suspension or revocation of authorisations which have already been granted. Article 8 expressly states that the establishment of this Committee is to facilitate the adoption of a common position by Member States regarding marketing authorisations. To enable it to do so the Committee is empowered to draw up its own rules of procedure.[41]

One of these specific functions of the Committee is to consider multiple applications for authorisations by one manufacturer throughout several Member States. This procedure was clearly designed to give added impetus to the free movement of medicinal products throughout the

Community. Where a manufacturer of medicines proposes to place a new medicinal product on the market throughout the Community, separate applications for authorisation in each Member State would normally be required. It is to prevent this duplication of effort that the licensing procedures of the Committee have been designed, although applicants may still apply to the individual Member States if they so wish.

Under the original procedure of the Committee, a manufacturer applied to the competent authority of any one Member State in the usual way, but indicating his wish to market it in other specified Member States. Once the application had been considered and the market authorisation granted, the Member States concerned forwarded the authorisation it had granted, together with copies of the original application, to the Member States nominated by the applicant and to the Committee.[42] Then the competent authorities of Member States had one hundred and twenty days within which to forward any objection to the Committee.[43] If no objection was received by the Committee, it so notified the Member States, who had thirty days in which to decide whether to grant or refuse a licence. If an objection to the grant of an authorisation was received, the Committee had sixty days within which to consider the matter and give a reasoned opinion. This opinion, which was not binding, was communicated to the Member States. Member States were given a further thirty days to reach a final decision upon the application in the light of the Committee's opinion.[44] As soon as a competent authority of a Member State had agreed to grant an authorisation, the formalities of licensing were arranged between the applicant and that authority.

At the end of the first ten years of the existence of the Committee, only thirty-six applications were received through the use of this procedure, of which thirteen were from the United Kingdom, four from Belgium, six from Denmark, seven from France and six from Germany.[45] From this it is clear that the use of the alternative procedure has not been widely adopted by the pharmaceutical industry. There has, apparently, been much delay in granting authorisations for which the applicants themselves seem partly to blame, as they have delayed their replies to fairly straightforward queries about their applications.[46] But a more radical criticism of the procedure is difficult to avoid. First, although one application for an authorisation will suffice for marketing throughout the Community, decisions upon the application still continue to be made on a national basis by the same competent authorities. Thus, there can be no guarantee that the co-ordinating role of the Committee will prevent Member States from continuing to adopt their existing standards and opinions in reaching a decision upon the application. Secondly, the system provides no final appellate machinery upon a Community basis for dealing with cases where one or more Member States have refused to grant an authorisation. This system does not, therefore, seem to provide an effective or quicker alternative to individual decisions based upon separate applications to the competent authorities of Member States.

Some important amendments have now been introduced for both the remit of, and the procedure to be followed by, the Committee. These changes were made by Council Directive 83/570/EEC.[47] First, an application under the procedure may now be made to only two Member States. Secondly, the application is now sent direct to the competent authorities concerned rather than to the Committee. Thirdly, the applicant must certify that all the applications submitted under the procedure are

identical and he must notify the date upon which the applications were forwarded to the Member States should be notified to the Committee. Fourthly, any reasoned objections of Member States must be forwarded to both the Committee and to the applicant within a one hundred and twenty day period.

Where objections are raised by Member States under the revised procedure, the applicant forwards a copy of the application to the Committee, which must deliver a reasoned opinion within sixty days. There is now provision for the applicant to make either written representations or to have an oral hearing, at his request, before the Committee gives its opinion. This opinion is then communicated to Member States and the applicant. Member States are given sixty days within which to inform the Committee of their decision. It is clear that Member States will not, in the foreseeable future, accept mutual recognition of national decisions upon the licensing of medicines.[48] Until such mutual recognition is accepted the Committee acts as a discussion group for Member States and attempts to co-ordinate national approaches. As progress is made towards the completion of the internal market within the EEC, the object must logically be mutual recognition of licensing decisions by Member States. It is suggested that this policy of harmonisation should not be undertaken in isolation. Relationships with other countries such as Japan, the USA and those of the Third World should also be developed if more universal solutions to the problems posed by medicines is to be achieved on a world-wide basis.[49]

6.4 COMMENT

Article 100 of the Treaty of Rome provides for the approximation of provisions laid down in Member States as directly affect the establishment or functioning of the Common Market. In relation to the pharmaceutical industry the elimination of administrative barriers has been particularly slow and difficult. The Commission started work on this area as long ago as 1960[50] but Member States have still not met their full obligations under the directives which have been issued.[51] National legislation and requirements could, in a technical area such as this, impose unsurmountable barriers to international trade in the absence of a harmonisation programme. Some considerable progress has been made, however, towards the aim of abolishing barriers to the free movement of medicinal products without putting public health at risk. As a result, all medicinal products produced in Member States are manufactured and tested in accordance with the same regulations and under the supervision of persons having equivalent qualifications. Further, procedures have developed for submitting an application for a marketing authorisation in Member States on the basis of an authorisation granted in one Member State according to criteria set out in the Pharmaceutical Directives. Committees have also been established to enable discussion and the interchange of views between representatives of Member States and members of the Commission.

As has been pointed out by a Report of the Committee on Economic and Monetary Affairs, however, the European pharmaceutical industry is beginning to be exposed to international competition, particularly from Japan.[52] This stresses the fact that medicines are used and traded upon an international basis and there may be a danger of the Community becoming too parochial in its concentration

upon its harmonisation programme. Even within Member States themselves it is likely to be a long time before such considerations as therapeutic indications and side effects are agreed upon a unanimous basis and the proposed membership of additional States will add to such difficulties. Scott has drawn attention to this isolation in relation to the procedures of the Committee for Proprietary Medicinal Products in the following terms:

> "Unfortunately a certain amount of isolationism has crept unwittingly into the relationship between the guidelines which are being produced by the EEC and those produced from other major areas such as the United States, Japan, Eastern Europe, WHO and Scandinavia, and it is one of our hopes that in the next few years there will be a certain amount of compatibility introduced to the area of present confusion".[53]

The harmonisation programme established by the Pharmaceutical Directives does, therefore, suffer from the potential difficulties of both slowness in its implementation and isolationism in the context of international trade. Possible further developments would seem to lie in the direction of either mutual recognition of authorisations between Member States themselves or a Community authorisation to be granted by a competent authority of the Community itself. Such approaches would, however, be likely to be opposed by the industry itself and would be outside the scope of Article 100 of the Treaty of Rome as presently in force, even with the amendments introduced by the single European Act.

6.5 PARALLEL IMPORTATION OF MEDICINES

A much debated issue in the pharmaceutical industry is the problem posed by entrepreneurs in exploiting the large differences in the price of medicines throughout the world. By taking advantage of such pricing differentials, and exploiting the free movement of goods provisions of the Treaty of Rome, considerable profits have been made. This practice is known as parallel importing and has raised several legal problems as to whether the activities concerned are permitted under national or EEC law. In relation to the United Kingdom, the practice of parallel importing has been estimated to cost the tax payer about £50,000,000 per annum.[54] The reason for this is that the pharmacists who buy cheap imported medicines from other countries in the EEC do not pass on the savings in costs to the National Health Service but charge the full recommended price. This practice has not, however, been confined to imports into the United Kingdom. During the late 1970s pharmaceutical prices were lower in the United Kingdom than in either Holland or West Germany, with the result that drugs were exported by entreprebeurs into those countries. Also, some products were even exported from the United Kingdom, parallel-imported into the United Kingdom and then re-exported once again.[55]

As has been seen from Part I above if a product has been imported into the United Kingdom and no product licence has been issued in respect of it, then prima facis it was contrary to the provisions of the Medicines Act 1968[56] for such product to be offered for sale in the United Kingdom. In July of 1982 a wholesaler named Malcolm Town was fined £6,300 plus £500 costs under these provisions.[57] The Defence to the proceedings was based upon the argument that there had been no question of the importation of illicit drugs for illegal use. On the contrary, it was argued that the Defendant was a parallel

importer whose activities were in the public interest, since some companies charge the National Health Service up to ten times the prices they charged for the same products abroad. An appeal by Malcolm Town to the Norwich Crown Court was dismissed and the Defendant was ordered to pay costs of up to £250, although the size of some of the fines was reduced.[58]

Following these proceedings, attention was drawn to the exemption from the effects of Sections 7 and 8 of the Medicines Act 1968 provided by the Medicines (Exemptions from Licences) (Importation) Order 1978.[59] Although the wording of the Order clearly related to the importation of medicinal products for particular named patients, Town argued that provided the importer held a licence and fulfilled certain specified conditions, including notification to the licensing authority, his activities would be legal.[60]

It was also in the 1980s that the EEC Commission carefully considered its position in relation to parallel importation. Following the decision of the European Court in the de Peijper case[61] the Commission had proposed to issue a directive upon parallel imports of proprietary medicinal products. This proposal was later withdrawn in view of objections raised by the Economic and Social Committee and a negative vote taken by the European Parliament on 16 October 1981. Then the Commission issued a communication on the subject,[62] having no binding force, but reminding Member States that intervention by the Commission would be necessary if it became aware that Community law was being breached as a result of national restrictions placed on parallel importers by Member States. In the communication the Commission pointed out that Member States were not entitled to oppose the marketing of any medicinal product which had been parallel-imported on the ground that the importer was not

able to produce documents which only the manufacturer had at its disposal. In its role as guardian of the Treaty of Rome the Commission also emphasised that any rules or practices introduced by Member States to govern parallel importing of medicinal products must remain within the limits compatible with Articles 30 to 36 of the Treaty. Any such measures must, in particular:

i. be strictly necessary from the health standpoint;

ii. obstruct intra-Community trade as little as possible;

iii. require Member States to adopt an active and vigilent attitude towards pharmaceutical companies.

On 9 December 1983 the Department of Health and Social Security announced proposed amendments to the existing regulations in order to control more fully the practice of parallel importing of medicines.[63] These proposals included a requirement for a special form of product licence, which would be necessary for parallel imported from any other Member State. On 16 May 1984 the Medicines (Exemption from Licences) (Importation) Order 1984[64] came into operation, which implemented the proposals contained in the consultation letter. This Order revoked and replaced the Medicines (Exemption from Licences) (Importation) Order 1978. Among the conditions which must now be satisfied before an import exemption may be granted are:

i. that written notice is given to the United Kingdom licensing authority prior to each importation;

ii. that such notice states the name of the product, the name and address of the manufacturer, assembler or supplier and the quantity to be imported;

iii. that the quantity of the product to be imported is restricted to sufficient for a course of treatment, not exceeding three months, for twenty-five patients.

Now that a legal framework has been established in the United Kingdom for the practice of parallel importation, it remains to be considered the effect which the new legislation will have on the pharmaceutical industry.[65] It has been suggested that this will be to concentrate the practice in the hands of just a few companies and that the smaller suppliers will find it difficult to compete because of the financial outley and the additional cost of the paper work involved in keeping records of transactions.[66] A clear indication of this concentration may be seen from the formation of the Association of Pharmaceutical Importers, which has set up a trading company to hold common product licences for parallel imports for its member companies. This in turn may suggest that there will be a concentration in respect of the products parallel imported. This is because it will only be profitable to obtain licences for those products which have a high price differential between the United Kingdom and other Member States.[67]

There are, however, arguments which suggest that the legitimation of parallel importation by the new legislation is likely to attract a large number of new companies in the trade, with whom wholesalers and pharmacists in the United Kingdom will be anxious to trade. This augurs well for the medicines bill for the National Health Service, provided that pharmacists are reimbursed on the basis of prices they have actually paid. But the dangers of such a cheap medicines policy

for the United Kingdom are that this might threaten the United Kingdom base of the pharmaceutical industry because reduced profits for manufacturers might reduce the amount spent on research and in development for new products. The pharmaceutical industry in the United Kingdom has always been export orientated and this is one of the fastest growing sectors of the economy. If parallel importation leads to decreased profits for the United Kingdom pharmaceutical industry, the exportation of medicines might decrease, with unfortunate consequences for the balance of trade. It also illustrates the point that, although the scope for legislation by Member States after harmonisation is necessarily reduced, Member States may still introduce measures upon a narrow basis provided they act within the limits set by that harmonisation. Full harmonisation of all aspects of trade in pharmaceutical products has still not been achieved in the Community. The addition of new Member States will obviously delay further achievement of that goal.

6.6 CONCLUSION

It is the essential and fundamental aim of the Treaty of Rome to unite the national markets of Member States into one single market. Article 3(a) of the Treaty requires:

> "..... the elimination, as between Member States, of customs duties and of quantitative restrictions on the import and exports of goods, and of all other measures having equivalent effect".

Free movement of goods is, therefore, one of the basic requirements laid down by the Treaty, both as a general philosophy and in the detailed provisions of such Articles as 9 and 30 to 36.

But the Court has had to reconcile this general aim with other, sometimes conflicting, provisions of the Treaty. Two of these are Articles 36 and 222. In the former are laid down some derogations from the free movement of goods provisions for the protection of certain rights, such as the protection of life and health of humans and the protection of industrial and commercial property. In the latter there is a more general declaration that the terms of the Treaty should in no way prejudice the rules in Member States governing the system of property ownership. Thus a balance had had to be struck by the Court in its decisions whereby the principles of free movement of goods are applied in a way which does not ignore the national protection of property rights such as patents and trade marks.

This conflict has been particularly apparent in the field of pharmaceuticals, where patents and trade marks are widely relied upon to protect valuable commercial interests. Membership of the EEC has imposed the duty upon national courts (in the first instance) to decide whether the exercise of a national provision protecting a patent or trade mark should be construed as a disguised restriction on trade or as an arbitrary discrimination. If so, then the national provision cannot be replied upon so as to oppose the principles of free movement contained in the Treaty.

In the case of parallel importers, special national provisions may be permitted (as recent United Kingdom legislation has shown)[68] so as to define their rights. This is permitted where, as in the pharmaceutical field, some progress has been made in harmonising free movement between Member States but the directives which have been issued under Article 100 of the Treaty have not yet succeeded in removing all administrative barriers to trade.

A further point for consideration is whether the case law of the European Court upon Articles 30 to 36 of the EEC Treaty maintains a fair balance between the principle of free movement of medicines and the protection of the consumer. Article 36 expressly allows Member States to derogate from the free movement provisions of the Treaty upon the grounds (inter alia) of the protection of health and life of humans. Consumers may, therefore, properly call upon their national Courts to offer protection to their interests under this provision. It is submitted that the case law places an undue emphasis upon the free-movement principle at the expense of the consumer. Even if manufacturers of medicines comply with the Pharmaceutical Directives it does not automatically follow that the public health interests of a Member State are best served by allowing medicines to flow freely across its frontiers. In his discussion of this problem in the wider context of both drugs and alcohol Dr Chatterjee has concluded:

> "The principle of free movement of goods has an economic basis. Under the EEC system, this principle, as it stands now, has not been fully considered from a public health and societal point of view. There exists a dilemma: by ensuring full operation of the principle of free movement of goods, which is a fundamental principle of a common market, individuals are made subject to the ill-effects of its application. Again, should health and other societal conditions and effects prevail over Treaty provisions".[69]

This problem is not confined to the Common Market. In the USA it has been stated that the law concerning exports has permitted "adulterated, contaminated, unsafe, ineffective, or misbranded products [to be] dumped on the market in

Latin America, Africa and Asia ..... when the shelf-life of a batch of a product has expired, and it is no longer safe and effective".[70] This is despite the strict regulation of medicines made available within the USA by the Federal Drugs Authority. The case of Commission -v- Germany[71] is an illustration of the Court's approach to the interests of the consumer. The German authorities reserved the placing of medical preparations on the market to pharmaceutical undertakings having their headquarters in the Federal Republic of Germany. Their reason for this approach was:

i. So that defective products could be withdrawn from the market as quickly as possible. Experience has shown that this was not always possible when menufacturers were established in certain Member States, even leaving aside the problem of language.

ii. Without the presence in Germany of a person representing the manufacturer of a product, patients harmed by a medicine had a much greater difficulty in bringing an action for damages against the manufacturer.

iii. To ensure the effect of penal and administrative sanctions.

In its judgment the Court considered the effect of the Pharmaceutical Directives and the fact that the licensing system provided by those measures necessarily implied some contact between the competent authorities and the person responsible for the placing of the product on the market. There was also the possibility of suspending or revoking a marketing authorisation in the case of difficulty. Having regard to this, the Court was satisfied that the German measure infringed Article 30 of the Treaty and could not be justified under Article 36. While accepting that the

arguments put forward by the German authorities could not be disputed[72] the Court decided that the provisions under consideration could only be justified to attain the protection of public health if that objective could not be attained by means which were less restrictive of trade within the Community. Thus, the interests of the consumer were considered of less importance than those of the principle of free trade.

In considering the concept of harmonisation within the meaning of the Treaty, the object of this is to bring about an adjustment to the national laws of Member States so as to remove obstacles "to the extent required for the proper functioning of the Common Market".[73] Several factors have militated against rapid progress in achieving a programme for harmonisation under the Treaty. Article 100 does not contain any timetable for the harmonisation of national legislation - either generally or in relation to any specialised field. Further, by originally requiring that the Council should only act under Article 100 unanimously on proposals from the Commission, no harmonisation measure could proceed unless all Member States were agreed. Some more detailed criticism has also been made about the choice of the directive as the vehicle for achieving harmonisation. All of these factors have contributed towards the slow and unsatisfactory progress which has been made in making free movement of pharmaceuticals a reality within the Common Market. It remains to be seen whether the amendments introduced by the Single European Act will accelerate progress.

Closely related to the free movement provisions are the competition provisions of the Treaty. In the field of industrial property, in particular, it is often necessary to consider both together.[74] It is in connection with these competition provisions and, in particular

Article 86, that international considerations on a scale wider than the Common Market are raised. This wider concept has been recognised by the European Parliament which has passed a resolution[75] to the effect that the competition rules applying on the World market should be harmonised and that there should be international co-operation in the fight against restrictive practices and abuses of dominant positions which are not caught by Community or national laws.

With regard to the prices which medicines are made available to consumers in the EEC, this is determined by the national markets in the Member States concerned. Those prices are, however, usually influenced by the policies laid down by social security reimbursement schemes and, in the United Kingdom, by the voluntary price regulation scheme.[76] This concern with high prices is reflected in the Annual Reports of the Commission on competition policy. At paragraph 2 of the Report for 1974, for example, the Commission set itself the task of examining cases of high price disparities, with the aim of enforcing the competition provisions of the Treaty in appropriate cases. Following the judgment of the European Court in such cases as Sirena -v- Eda[77] the Commission has accepted that:

> "..... while high price disparities do not necessarily permit a finding of abuse in the case of a dominant position, they can, in the absence of objectively justifiable reasons, be a decisive pointer to an abuse".

Further, in Written Question No 196/77 raised by Mr Cointat to the Commission on the 22nd December 1977,[78] it was asked to explain the considerable variations in the prices charged for the same medicine in

different Member States. In the answer to this question, given on the 16th March 1978, the folowing passage was included:-

> "The price charged for a medicine in the different Member States can vary for a number of reasons, such as price controls in force in some Member States but not in others, price reductions imposed by certain public authorities, obstacles to the free movement of medicines, the VAT rate applied to medicines, exchange rates, fluctuations and company pricing policies. In other words, the variations in price often reflect differences in the economic, monetary, financial and social policies of the Member States".

Having regard to these explanations it is clear that no uniform policy exists in the Common Market for the pricing of medicines at the present time. It is also apparent that no such policy is likely to emerge in the foreseeable future. While such price disparity continues to exist in Member States, the possibilities of exploitation by entrepreneurs such as parallel importers will continue. From the viewpoint of the consumer, this must be an unsatisfactory situation.

Another aspect of consumer protection is the provision for compensation for patients when damage has been suffered. At the present time this is again left to the individual rights which may be available in the national Courts of Member States themselves. An EEC Directive on liability for defective products, the purpose of which is the approximation of the laws, regulations and administrative provisions of Member States on this subject seeks to establish throughout the Community that producers shall be strictly liable for defects in their products,

subject only to certain clearly degined defences and limitations. Further discussion on this draft directive and its effects on limitations in the fields of pharmaceuticals is left for detailed comment and discussion in Part IV below.

NOTES

1. Stein, Eric "Harmonisation of European Company Laws: National Reform and Transitional Co-ordination", Bobbs-Merrill Company Inc [1971] page 7.

2. Article 7 contains a general prohibition against discrimination on the grounds of nationality.

3. Case 148/79, Pubblico Ministero -v- Tullio Ratti, [1979] ECR 1629; [1980] 1 CMLR 96.

4. [1979] ECR 1644.

5. Case 163/78, [1979] ECR 2555.

6. Case 251/78, [1979] ECR 3369.

7. At paragraph 14 of its judgment.

8. Re: the Marketing of Medicines: EC Commission -v- Italy, [1984] 1 CMLR 148.

9. Slot, Peter, J "Technical and adminstrative obstacles to trade in the EEC", A W Sijthoff, Leyden [1975] page 89 et seq.

10. Re: the Marketing of Medicines: EC Commission -v- Italy, [1984] 1 CMLR 148.

11. Van Duyn -v- Home Office, [1974] ECR 1337; [1975] 1 CMLR 1.

12. See paragraph [12] of the judgment.

13. Op.cit, at note 9 above.

14. Case 152/84, Marshall -v- Southampton and South West Hampshire Area Health Authority (Teaching), [1986] 1 CMLR 688.

15. Directive 76/207 on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and working conditions, O J 1976 L39/40.

16. Case 148/79, Pubblico Ministero -v- Tullio Ratti, [1979] ECR 1629; [1980] 1 CMLR 96.

17. White Paper from the Commission to the European Council: "Completing the Internal Market", June 1985.

18. Single European Act and Final Act, European Communities No 12 [1986], HMSO, Cmnd 9758. See also the European Communities (Amendment) Act 1986 (c.58).

19. Article 100A was introduced by Article 18 of the Single European Act.

20. Single European Act and Final Act page 25.

21. O J No 22, 9.2.1965, page 369/65.

22. O J No L147, 9.6.1975, page 1.

23. O J No L147, 9.6.1975, page 13.

24. See Article 1(1) of the first Directive.

25. This definition was incorporated into the licensing provisions of the Medicines Act by the Medicines (Medicines Act 1968 Amendment) Regulations 1977.

26. See the amendment made to Section 20(1)(b) and the additions contained in Section 24(1)(j) of the Medicines Act 1968. These modifications were also effected by the Medicines (Medicines Act 1968 Amendment) Regulations 1977.

27. Article 24 of the first Directive, as substituted by the effect of Article 39 of the second Directive.

28. Articles 1 and 2 of the second Directive.

29. Article 4 of the second Directive.

30. O J No L332, 28.11.1983, page 1.

31. This was established by Council Decision 75/320/EEC; O J No L147, 9.6.1975, page 23.

32. Article 2 ibid.

33. Article 3 ibid.

34. O J No L11, 14.1.1978, page 18.

35. O J No 115, 11.11.1962, page 2645/62.

36. O J No L 332, 28.11.1983, page 11.

37. O J No L 73, 16.3.87, page 1.

38. O J No L 15, 17.1.87, page 38.

39. O J No L 15, 17.1.87, page 31.

40. O J No L 15, 17.1.87, page 41.

41. See Article 8(3) of the second directive.

42. Article 9 of the second directive as substituted by Article 1 of directive 78/420/EEC (O J No L123, 11.5.1978, page 26).

43. Article 10 of the second directive.

44. Article 12 of the second directive.

45. See Williams, A "CPMP Procedure from the Industry's Viewpoint", BIRA Journal, Vol 3, No 3, page 57.

46. Scott, A "Working of the CPMP Procedure and Progress towards Mutual Recognition", BIRA Journal, Vol 3, No 3, page 52.

47. O J No L332, 28.11.1983, page 1.

48. Hankin, R "The Role of the Committee for Proprietary Medicinal Products in the late 1980s", BIRA Journal, Vol 5, No 4, 6 at page 9 and Jones, G "U.K. Applications submitted to the CPMP", Drug Information Journal, Vol 20, 373, at page 376.

49. Schneiders, B "The CPMP as seen from a Member State", BIRA Journal, Vol 5, No 4, 10 at page 11.

50. See point 160 of the Third General Report EEC and point 56 of the Sixth General Report EEC.

51. See point 12 of the Seventh General Report EEC.

52. Report drawn up on behalf of the Committee on Economic and Monetary Affairs on the production and use of pharmaceutical products in the Community, Rapporteur: Mr G Delau, European Parliament Working Documents, 1982/83.

53. Scott, A "The Working of the CPMP Procedure and Progress towards Mutual Recognition", BIRA Journal, Vol 3, No 3, page 51.

54. Byan, J "Drugs Ring with a Difference", The Times 12th August 1983.

55. Sackett, J (editor) "Parallel imports - a new dimension to the UK Pharmaceutical Market", PJB Publications Limited, 1984.

56. See Section 7(3) of the 1968 Act.

57. Sackett, J op.cit, page 16, which contains a full report of the proceedings and an analysis of its implications.

58. Sackett op.cit.

59. Statutory Instrument 1978 No 1461.

60. See Sackett, J op.cit, page 17.

61. Case 104/75, discussed more fully in Chapter IV.

62. O J No L115, 6.5.1982, page 5.

63. See consultation letter MLX 150 issued by the Department.

64. Statutory Instrument 1984 No 673.

65. In R v Secretary of State for Social Services, ex parte Wellcome Foundation Limited (The Times, 3rd June 1987), the Court of Appeal had to determine whether trade mark rights, and the possibility of their infringement, were relevant considerations in deciding whether to grant product licences for parallel imports. It was held that such rights were irrelevant to this consideration. The Master of the Rolls said that the wording of the Medicines Act 1968 indicated that the Secretary of State was not required to take account of policy considerations extending beyond safety, efficacy and quality. On appeal to the House of Lords it was confirmed that trademark infringement was not a factor which the licensing authority should take into account when determining applications for licences.

66. See Sackett, J op.cit, page 50.

67. See Sackett, J op.cit, page 51.

68. See Section 5 of this Chapter.

69. Chatterjee, Dr S K "The application of the principle of the free movement of goods in the European Community Market to the trade in drugs and alcohol", in Contemporary Drug Problems, Winter 1982, pages 631-656, at p.649.

70. Drug Regulation Reform Act of 1978: Hearing HR11611 before the sub-committee on Health and the Environment of the Committee on Interstate and Foreign Commerce, 95th Congress, Second Session, 1323 (1978). (Statement by Milton Silverman, Senior Faculty, Health Policy Programme, University of California).

71. Case 247/81 [1984] ECR 1111.

72. See paragraph 7 of the judgment.

73. See Article 3(h) of the Treaty of Rome.

74. See, for example, pargaraph 5 of the judgment of the European Court of Justice in Sirena -v- Eda [1971] CMLR 260, where the Court dealt with this inter-relationship in the following terms:-

> "In this sphere of provisions relating to the free movement of products, prohibitions and restrictions on imports justified on the grounds of protection of industrial and commercial property are allowed by Article 36, subject to the express condition that they "shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States". Article 36, although it appears in the Chapter of the Treaty dealing with quantitative restrictions on trade between Member States, is based on a principle equally applicable to the question of competition, in the sense that even if the rights recognised by a Member State on the subject of industrial and commercial property are not affected, so far as their existence is concerned, by Articles 85 and 86 of the Treaty, the exercise may still fall under the prohibition imposed by those provisions".

75. O J C14, 27.5.1973, page 8.

76. For which, see the discussion in Part I above.

77. See Section B2 of Chapter V.

78. O J No C98/8 [1978].

PART III - THIRD WORLD CONSIDERATIONS

INTRODUCTION

One of the most significant developments in international trade since the end of the Second World War has resulted from the transition from colonisation to independence in much of the Third World. Lall[1] has identified the ending of British rule in the Indian Peninsula in 1947 as marking the beginning of this change. It was the United Nations Organisation, set up in 1945 with its subscription to the principle of self-government, that encouraged nations to seek this new status. By declaring that:

> "All people have the right to self-determination; by virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development,"[2]

the period of European domination was drawn swiftly to a close. As a result, the number of sovereign countries admitted as members to the United Nations rose from fifty-one, the original signatories to the United Nations Charter in 1945, to ninety-eight in 1960.

These developing countries have largely looked to the United Nations and its specialised agencies for help in developing their policies on pharmaceuticals.[3] In response to this the United Nations has established a number of technical programmes on a variety of aspects in relation to this subject.[4] These programmes involve the resgulation of international trade in medicines, which has attracted the attention of a large number of international bodies. These include the World Health Organization (WHO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Industrial Development Organisation (UNIDO), the United Nations

General Assembly,[5] the United Nations Economic and Social Council,[6] and a coalition of non-government organisations.[7] It is submitted that, even where these policies of the United Nations and its specialised agencies have no legal force, the principles underlying them should be treated as morally binding upon Member States of the developing world.[8] It is, there- fore, necessary to consider whether these policies are being implemented by Member States of the developed world in a way which is beneficial to the Third World.

These political developments were mirrored by, and closely interconnected with, economic developments. After the signing of the Articles of Agreement of the International Monetary Fund and the World Bank at Bretton Woods in 1944, it was proposed that the Havana Charter should establish an International Trade Organisation. But this was not concluded. Instead, a smaller group of countries (including the USA) entered into an agreement which became effective on 1 January 1948 known as the General Agreement on Tariffs and Trade.[9] This is a multi-lateral inter-governmental agreement whereby the contracting parties agree to grant reciprocal rights and duties to other Member States with respect to the exchange of goods between them. Its aim is to liberalise international trade and it was established before the European Economic Community was created.

A third development of the post-war years was the creation of the European Economic Community, certain aspects of whose internal policies has been considered in Part II. The EEC has, however, an external relations policy as the Treaty provides for a uniform approach by its members to specified subjects as regards third countries. Articles 110 to 116 of the EEC Treaty provide, for example, for a common commercial policy to be developed. Further, Articles 229 to 231 require the EEC Commission to

maintain appropriate relations with international organisations in general, and for the Community to establish "all appropriate forms of co-operation" with the Council of Europe and close co-operation with the OEEC (now known as the OECD).[10] The EEC is now the largest trading bloc in the world and three of its members (Germany, Italy and the United Kingdom) have a substantial export market in medicines. Its external trade policy has raised doubts about whether this is in conformmity with GATT.

It is against this background that the pharmaceutical industry must be considered upon a global basis. In the 1930s, this industry was a commodity business, with the manufacturers selling the ingredients needed by the pharmacist to make up a doctor's prescription.[11] By the end of the 1950s the industry had been transformed into a specialised research and advertising- orientated business. Vertically integrated companies developed and began to dominate the industry. These companies were engaged in research for new and improved products, and production and marketing of these products upon an international basis. When government regulations banned the advertising of certain products to the public at large, those firms began to promote their products to the medical profession.[12]

Gereffi[13] has described how the discovery of sulfanilamide, the first of the new sulfa drugs, by the German company I G Fargen in the 1930s attracted other large chemical companies into the pharmaceutical industry. The discovery of penicillin, and the other antibiotics in the 1940s and 1950s drew other chemical firms, with experience in fermentation, into the manufacture of medicines because this micro-biological technique was found the most efficient for large-scale production. Further research and the production of

medicines was stimulated by the Second World War. Since then factors such as advances in medical science, the technological innovation of the pharmaceutical industry and new techniques of commerce and advertising have all contributed to the growth in the number of medicines on the market. These now include antibiotics, anti-depressants, antidiabetics, antihistomines, oral contraceptives, tranquillisers. vitamins and vaccines against measles, mumps, and poliomylitis.[14]

Most Third World countries are in the tropical zones where epidemics are frequent and where the general levels of health, sanitation, nutrition and hygiene are low. It follows that developing countries have a basic need for medicines to cope with their wide-ranging and persistent health problems.[15] The manufacture and sale of medicines is dominated by MNEs based in developed countries, many of whose products are sold to the Third World. This dependance of Third World countries upon the developed countries, and upon MNEs in particular, has been a particular point of focus and concern. This dependence has also led many countries of the Third World to seek guidance to ensure that their pharmaceutical needs are being properly met.

NOTES

1. K B Lall, "The Third World and New Economic Role of EEC and India", XXIII, Studiat Diplomatica, (Number 14), (1980).

2. UN General Assembly Resolution 1514(XV), entitled Granting of Independence to Colonial Countries and Peoples, adopted on 14th December 1960.

3. Ellen N Cone, "International Regulation of Pharmaceuticals", Virginia Journal of International Law, (1983) p. 331, at 332.

4. Cone ibid., at p.346.

5. The UN General Assembly passed a resolution in November 1981 asking the contracting parties to assist in co-ordinating the international regulation of, and exchange of information on, the pharmaceutical industry. G A Res A/36/166 (30th November 1981).

6. The role of the Economic and Social Council of the United Nations is considered below in Section 7.1.

7. A group of non-governmental organisations has formed a coalition called "Health Action International" with a view to protecting the interests of the consumer. This organisation is considered in Section 11.3.

8. It is suggested that the authoritative recommendations of a specialised agency of the United Nations carries much weight, both morally and politically, which will not in practice be ignored by Member States. While Resolutions of the General Assembly of the United Nations are generally not considered to be legally binding, legal controversy as to their status persists. Johnson has suggested that the term "moral effect", when used in connection with such Resolutions, has no valid meaning. He accepts that such Resolutions may have a political effect, and many even result in a legally binding obligation, if there is a clear intention to be so bound. (Johnson, D H N "The Effect of Resolutions of the General Assembly of the United Nations", 1955-6 (BYIL) 97 at p 121). Sloan accepts that most of such Resolutions have no legal force, but asserts that they nevertheless exert

great moral force, which has much influence as an expression of world opinion. (Sloan, F Blaine "The Binding Force of a 'Recommendation' of the General Assembly of the United Nations", 1948 (BYIL) 1 at p.31. See also Higgins, Rosalyn "The Development of International Law through the Political Organs of the United Nations", Oxford, Oxford University Press (1963) p.5.

9. Hereinafter referred to as GATT.

10. Organisation for Economic Co-operation and Development.

11. Clymer, H A "The Economic and Regulatory Climate: US and Overseas Trends", edited by Robert B Helms, Washington DC, American Enterprise Institute for Public Policy Research, [1975] pages 137-154.

12. Temin, Peter "The Origin of Compulsory Drug Prescriptions", Journal of Law and Economics, 22 Number 1, pages 91-105.

13. Gereffi, Gary "The Pharmaceutical Industry and Dependency in the Third World", [1983], New Jersey, Princeton University Press, page 169.

14. See Cone, op.cit. at Note 3, page 331.

15. Melrose, Dianna "Bitter Pills : Medicines and the Third World Poor", Oxford, Oxfam, (1982), Chapter 1.

CHAPTER VII - POLICIES AND INFLUENCE OF VARIOUS INTERNATIONAL BODIES

7.1 THE ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS

In its resolution dated 12th February 1946 the General Assembly of the United Nations stated that it was willing to take the necessary measures to ensure the continued exercise of functions of a technical and non-political character conferred by certain international instruments of the League of Nations.[1] This question was referred to the Economic and Social Council of the United Nations, which was also empowered to make or initiate studies and reports concerning international economic, social, cultural, educational, health and related matters and to make recommendations to the General Assembly, members of the United Nations and the specialised agencies concerned.[2] The Charter of the United Nations provides that it will establish a relationship with specialised agencies "established by inter-governmental agreement and having wide international responsibilities ... in economic, social, cultural, educational, health, and related fields".[3] There are presently agreements with most of such specialised agencies, including WHO.

The Economic and Social Council has very wide powers including institutional law-making powers. Most of its recommendations are based upon consensus and its meetings provide an international forum for debate on a wide range of issues.[4] It is the primary organ of overall review and harmonisation and is authorised to make "suitable arrange- ments for consultation with non-governmental organisations which are concerned with matters within its competence".[5] In relation to medicines, it wields less effective power than the specialised agencies, which have more specific functions. It was the growing dissatis- faction among the developing countries with regard to the

inadequacy and ineffectiveness of the Council's functions that led to the creation of both UNCTAD and UNIDO.[6] Each of the latter is an autonomous body with direct responsibilities to the World Health Assembly. Under Article 62 of the United Nations Charter the Economic and Social Council may:

> (i) take or initiate studies and reports with respect to, inter alia, international economic, social, educational, health and related matters, and may make recommendations with respect to any such matters to the General Assembly, the members of the United Nations, and the specialised agencies concerned;
>
> (ii) prepare draft conventions for submission to the General Assembly with respect to matters falling within its competence; and
>
> (iii) call international conferences in accordance with rules prescribed by the United Nations.

Other functions of the Economic and Social Council involve the co-ordination of the various specialised agencies and to bring them into relationship with the United Nations. This relationship is to be established only by inter-governmental agreements concluded under Articles 57 and 63 of the United Nations Charter.[7] It also has the primary responsibility for making effective the arrangements for co-ordination envisaged in the Charter.[8]

7.2 THE WORLD HEALTH ORGANIZATION

WHO is a specialised agency of the United Nations. It was created in 1946 to carry out activities relating to health issues.[9] WHO is composed of three bodies: the World Health Assembly,[10] the Executive Board[11] and the Secretariat[12] headed by the Director-General.[13] The

World Health Assembly is the general policy-making body of WHO, while the Executive Board reviews reports by the Director-General and expert committees and recommends action to the World Health Assembly. It is also the function of the Executive Board to give effect to the decisions and policies of the World Health Assembly and to advise the latter on matters referred to it.[14]

With regard to pharmaceuticals, the constitution of WHO authorises it to "develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products".[15] WHO also has powers to "propose conventions, agreements and regulations, and make recommendations with respect to international health matters".[16] Such general powers clearly include such matters as medicines within WHO's general jurisdiction.

Allied to these varied functions are powers which may be described as quasi-legislative.[17] First, the World Health Assembly may, by a two-thirds majority vote, adopt conventions or agreements "with respect to any matters within the competence of the Organisation".[18] Although an instrument adopted in this way only comes into force when each Member State accepts them in accordance with its own national law, Article 20 of the WHO Constitution requires each State "to take action relative to the acceptance of such convention or agreement" within eighteen months after its adoption by the Health Assembly. Further, each State is required to provide a statement of reasons for non-acceptance, as well as an annual report to the Director-General in the case of acceptance.[19]

Secondly, Article 21 enables the World Health Assembly to adopt regulations in specific areas, including "standards with respect to the safety, purity and potency of

biological, pharmaceutical and similar products moving in inter- national commerce".[20] Article 22 modifies the effect of Article 21 by allowing Member States to contract-out if they so wish. The position is that a regulation made under Article 21 automatically comes into operation upon notice of its adoption by the World Health Assembly unless the Director-General is notified of a rejection. These powers enable the World Health Assembly to adopt a regulation by a majority vote which may come into force in all Member States without the requirement of any ratification or formal approval by Member States. In 1948 WHO adopted the Nomenclature Regulations, which standardised drug terminology, under the provisions of Article 21. Then in 1951 WHO used Articles 21 and 22 to adopt the International Sanitary Regulations. These codified in one instrument the earlier sanitary conventions and were renamed as the International Health Regulations in 1969. These Regulations were designed to co-ordinate national efforts to prevent cholera, plague, typhus, smallpox and yellow fever without placing an undue burden on international traffic.[21]

Thirdly, Article 23 enables the World Health Assembly "to make recommendations to members with respect to any matters within the competence of the Organisation".[22] While such recommendations are not legally binding upon Member States, they clearly carry some moral weight, constituting as they do the collective judgment of the membership of WHO.

WHO has adopted two main programmes for medicines which involve national action and international co-operation, namely, the Certification Scheme and the Action Programme for Essential Drugs. The Certification Scheme provides that the competent authority of the exporting Member State

issues an appropriate certificate for any pharmaceutical product which it exports. Such a certificate provides two assurances:

(1) that the exporting country has authorised the product for domestic sale or distribution, and

(2) that the plant where the product was manufactured is subject to regular inspection and conforms with the standards set by WHO in its Good Practices in the Manufacture and Quality Control of Drugs Act.[23]

If the importing country considers the certificate provided to be inadequate, it may apply to the appropriate country to supply further information.[24] By their participation in the Certification Scheme, exporting Member States guarantee that appropriate tests and adequate facilities have been used, that the manufacturers of the product conform to WHO's good manufacturing practice standards, that appropriate investigations of manufacturers are carried out and that the inspectors who carry out those investigations have satisfactory qualifications and experience[25] according to the national standards set for the purpose.

The number of countries participating in the Certification Scheme has risen from seventy-eight in 1981 to one hundred and two in 1983.[26] It also represents a rather unusual legal approach in that it is open to participation by Member States on a voluntary basis, being neither a Treaty or an Convention which requires ratification.[27] The Scheme enables Member States to import medicines with the safeguard that they conform to international standards of quality. This provides some assurance to Third World countries about the quality of medicines they import, particularly for those which have no, or no adequate, system of control of their own. But the Scheme does not

provide any assurance of quality for products once they have left the exporting State. For this reason importing countries will still need to develop and maintain quality control procedures of their own to deal with the effects of transport, distribution and storage once the products have been imported.

In February of 1981 WHO formally established its Action Programme on Essential Drugs,[28] the purpose of which is to enable Governments to establish national drug policies as part of a wider national health plan. This concept of making available essential drugs for all has been developed by WHO over a number of years. In their Reports the WHO Expert Committee have advanced the view that a relatively small number of about two hundred generic medicines in a limited number of formulations would cover over ninety per cent of all the pharmaceutical requirements of developing contries, including preventative and treatment needs.[29] This list of essential drugs is reviewed periodically and in December 1982 eleven items were addeed to the list and six were removed. This revised list is set out at Appendix II. Several countries have adopted the concept of the WHO list of essential drugs as part of their national health policy. WHO, with the support from the Danish International Development Agency, has given assistance in this connection in both Kenya and Tanzania with three year projects begun in 1983.[30] Bangladesh is also developing a national drug policy consistent with the WHO Action Programme on Essential Drugs with support from both the Danish International Development Agency and the Swedish International Development Authority.[31]

WHO's objective in embarking upon this Action Programme is to ensure that there is a regular supply of safe and effective drugs and vaccines of acceptable quality at the lowest possible cost.[32] WHO's role in this programme is

to co-ordinate this essential part of the national health policy upon an international basis. To this end WHO has brought together Governments, international organisations,[33] representatives from the pharmaceutical industry[34] and academic and technical experts to develop its policy. It is not only the identification of pharmaceutical requirements of the Third World with which WHO is concerned, but also the procurement of those products at reasonable prices and their distribution, storage, and quality control. Local drug production is only encouraged where it proves to be "technically and economically feasible and desirable".[35] Information and training to users and suppliers of the products is also considered to be part of the programme, as are also the training of health care personnel and the exchange of information.[36]

This Action Programme on Essential Drugs is part of a global strategy of Health for All by the year 2000 adopted by the Health Assembly of WHO in 1981.[37] In conjunction with this a plan of action was drawn up requiring Member States to review their health policies in the light of this global stategy.[38] WHO is also involved in the dissemination of information about drugs, particularly where adverse drug reactions are concerned.[39]

In 1973 the World Health Assembly reiterated its demand that all drugs made available to consumers should comply with adequate standards of safety, quality and efficacy and stated that WHO has a major role to play in the collection and dissemination of relevant information.[40] Some of the activities in which WHO takes part are:

(1) The issue of a monthly communication addressed to Member States about decisions of national regulatory bodies restricting the availability or application of drugs already on the market.

(2) Participation in a system, involving twenty-seven national collaborating centres, for the monitoring of adverse reactions to drugs and the exchange of information and data.

(3) Publication of the bulletin Drug Information dealing with general policy issues and reviews of literature on products which have been withdrawn or restricted in use by Member States.[41]

In addition to the above two international drug control treaties, the Single Convention on Narcotic Drugs 1961, as amended by the Protocol of 1972, and the Convention on Psychotropic Substances 1971, have assigned to WHO the responsibility for evaluating psychotropic drugs in relation to risk/benefit factors. These include their therapeutic usefulness, their dependence- producing propensities and the public health and social problems generated by them.[42] As part of its Action Programme on Essential Drugs and Vaccines WHO is also involved in such areas as local formulation plants, the establishment of quality control laboratories and providing equipment and technical expertise.[43] WHO plays a co-ordinating role in these activities, sometimes supported by regional development banks, the World Bank, UNDP and UNICEF.[44] The ASEAN countries have also started technical co-operation in six areas of pharmaceuticals, with financial support from UNDP and WHO.[45]

7.3 UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

It may be observed that the Charter of the United Nations does not require its members to follow any specific economic policy, although membership of GATT imposes its own obligations, as discussed in Part III above. The decolonisation which has taken place since the end of the

Second World War and the mounting criticism of the Third World about its position in relation to world trade have led to special consideration being given to the problems of under-developed countries by the United Nations. A resolution entitled "International trade as a primary instrument for economic development"[46] drew attention to this problem. This resolution called for the:

> "... holding of an international conference on international trade problems relating especially to primary commodity markets".

In 1982, the Economic and Social Council decided to convene a United Nations Conference on trade and development. This Conference was finally held in Gevena from 23rd March to 16th June 1984 and was attended by one hundred and twenty countries.[47] At the end of this Conference seventy-seven developing countries issued a joint declaration in which the establishment of UNCTAD was stated to be the beginning to a new era in the history of trade and development. UNCTAD was then established as an institution under the General Assembly in accordance with Article 22 of the United Nations Charter. The principal functions of UNCTAD, as listed by General Assembly Resolution 1995 (XIX) which established it, are as follows:

> "(a) To promote international trade, especially with the view to accelerating economic development, particularly trade between countries at different stages of development, between developing countries and between countries with different systems of economic and social organisation, taking into account the functions performed by existing international organisations;

(b) To formulate principles and policies on international trade and related problems of economic development;

(c) To make proposals for putting these policies into effect;

(d) ... to review and facilitate the co-ordination of activities of other institutions within the United Nations system in the field of international trade and related problems of international development;

(e) To initiate action, where appropriate, in co-operation with the competent organs of the United Nations for the negotiations and adoption of multi-lateral legal instruments in the field of trade with due regard to the adequacy of existing organs of negotiations and without duplication of their activities;

(f) To be available as a centre for harmonising the trade and related development policies of Governments and regional economic groupings in pursuance of Article 11 of the Charter;

(g) To deal with any other matters within the scope of its competence".[48]

These wide terms of reference show that UNCTAD has many functions. Not only does it provide a forum for debate in the field of international trade, but it is also charged with formulating principles and putting these into effect by the adoption of multi-lateral legal instruments. As Petersmann has observed,[49] the establishment of UNCTAD by a resolution of the United Nations General Assembly distinguishes it from organisations created by

international agreements such as the International Monetary Fund or the World Bank. As an organ of the United Nations, it is assured of universal membership, with competence in relation to almost the whole world economy. Within UNCTAD itself there are three levels at which decisions may be taken. First, the Conference of UNCTAD is its supreme organ, having jurisdiction in all matters within its terms of reference. It is the conference which decides upon the activities of the organisation and the constitution of its committees. Conference meets at periodic intervals. A Trade and Development Board has also been set up, meeting every year, which exercises the functions of the Conference when the latter is not in session. It is the Board which prepares the work of the Conference and establishes contacts with other organisations. The permanent secretariat of UNCTAD is part of the Secretariat of the United Nations. While the Board decides on all matters by a simple majority of representatives present and voting, decisions in the Conference on substantive matters require two-thirds majority. As a subsidiary organ of the United Nations, UNCTAD cannot perform any function which would be outside the scope of the General Assembly itself. From this it follows that the resolutions of UNCTAD do not create legally binding obligations. Some of the activities of UNCTAD have had an important influence on other international economic organisations. Thus, in 1964, GATT adopted a protocol concerning the addition of the new Part IV to the General Agreement with the title "Trade and Development". This has, in the view of Petersmann[50], marked a reorientation of the trade policies of GATT towards the promotion of overseas trade in the developing countries. Indeed, the main objectives of UNCTAD may be said to be to increase the share of the less developed countries in world trade.

There are three specific areas in which the policies of UNCTAD are relevant to the pharmaceutical industry. First, UNCTAD has been active in the making of recommendations for facilitating the transfer of technology from the developed to the developing countries. The term technology may take a variety of forms, including patent licences and specialised services for such activities as production, marketing, financing and storage.[51] MNEs own a large part of such technology and, in particular, patents and trade mark rights.

It is obviously in the interests of such corporations to be able to exploit their monopoly rights for as long as possible, preferably through wholly-owned direct investment. International organisations are attempting to find solutions to this problem with a view to enabling developing countries to strengthen their position and to allow them to have access to this technology. In a resolution adopted at its conference held in May 1976 UNCTAD decided to establish an inter-governmental group of experts to draft a code of conduct on the transfer of technology.[52] A number of studies have been made by UNCTAD, upon both a general and national basis, upon this subject.[53] In addition to this, developing countries have asked both WHO and UNCTAD to draw up an international code of conduct on pharmaceuticals.[54] This is intended to cover such areas as marketing, distribution and trade and technology. Two other areas in which the activities of UNCTAD are specifically relevant to pharmaceuticals - namely, transfer pricing and a code of conduct for transnational corporations, are dealt with in Sections 8.2 and 9.5 respectively.

7.4 UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANISATION

Since its first involvement with the pharmaceutical industry UNIDO has developed its policy as part of its consultation programme. This programme has the overall aim of increasing pharmaceutical production in the developing world. Lall[55] has described the earlier involvement of UNIDO with pharmaceuticals in the following terms:

> "Its emphasis was almost exclusively on production and how to increase it. The international structure of the industry, the proliferation of drugs, the role of patents, all were noted but taken as given: production was to develop within this structure, according to established rules".

This limited approach did not satisfy the Third World countries, who were anxious to see the introduction of a new international economic order in relation to trade in medicines. This dissatisfaction led to a Declaration and Plan of Action on Industrial Development and Co-operation adopted at the UNIDO second general conference held in Lima, Peru in March 1975. This Declaration was based on a document drafted by the group of seventy-seven[56] and set the target that by the year 2000, twenty-five per cent of the world's pharmaceuticals should be produced in the Third World.[57] This contrasts with pharmaceutical production of 11.4 per cent of the whole world's total produced by Third World countries in 1977.[58]

In accepting the need for a more comprehensive programme on the supply of medicines, UNIDO joined with WHO, UNCTAD and UNAPEC (United Nations Action Programme for Economic Co-operation among developing countries) in endorsing the "Colombo" resolution in 1976 by the Fifth Conference of Heads of State of Non-alligned Countries. This resolution

of co-operation among developing countries in the production, procurement and distribution of pharmaceuticals contained seven main recommendations:

i. The listing of priority medicines;

ii. The obtaining of information about medicines from official (ie Government) sources only;

iii. The encouragement of the use of generic names for medicines, with the ultimate elimination of all brand names;

iv. The development of an indigenous industry for pharmaceuticals;

v. The withdrawal of patent protection;

vi. The establishment of national medicine buying agencies; and

vii. The establishment of co-operative pharmaceutical production and technology centres.[59]

This listing of priorities of essential drugs was given equal prominance by separate recommendations made by UNIDO, WHO and UNCTAD. It resulted in the production by WHO of its "model" list of essential drugs. Of the other recommendations made by the Colombo resolution, those numbered iii, iv and V are likely to antagonise the pharmaceutical manufacturers in the developed world, and in particular, the MNEs seeking to trade in the Third World. Some of the potential conflicts arising out of the interaction between the adoption of policies implementing the Colombo resolution and the activities of MNEs are discussed in Chapter VIII.

In a first step towards its consultation programme for the pharmaceutical industry, UNIDO arranged two meetings of experts, both held in Vienna, in July of 1977 and in March of 1978 respectively.[60] At the second of those meetings a report was discussed which had been prepared by the UNIDO Secretariat outlining the steps involved in establishing a pharmaceutical industry in developing countries, which it classified into the following categories:-

> Group I - countries with no pharmaceutical manufacturing facilities and dependant upon imports of finished products.
>
> Group II - countries which had started to repack formulated medicines and to process bulk medicines into dosage forms.
>
> Group IV - countries which produced a broad range of bulk medicines from intermediates and which manufactured some intermediates, using locally-produced chemicals, and
>
> Group V - countries which manufactured most of the intermediates required by the pharmaceutical industry and undertook local research on the development of products and manufacturing processes.[61]

This report also gave examples of countries belonging to each of these groups, which are set out in the following table:

Classification of Countries by Stage of Development of their Pharmaceutical Industries

Area	Group I	Group II	Group III	Group IV	Group V
Africa	Burundi Chad Lesotho Rwanda Sierra-Leone Somalia Swaziland Togo	Madagascar Sundan Tanzania Uganda Zambia	Algeria Ghana Morocco	Egypt Tunisia	None
Latin America	Honduras Trinidad	Haiti El Salvador Guatemala	Colombia Ecuador	Argentina	Brazil Mexico
Asia, Middle East	Jordan Yemen (S)	Afghanistan Burma Malaysia Nepal Sri Lanka Vietnam	Iran Iraq	Pakistan Turkey	India

In January of 1979 an international expert group meeting was held in Cairo with a view to establishing priority issues to be discussed between the developed and the developing countries.[62] These issues were further developed at a global preparatory meeting convened in Cancum, Mexico, in April 1980, where the following three action areas were identified:

i. The pricing and availability of intermediate and bulk drugs;

ii. Guidelines for licensing arrangements for the transfer of technology for the manufacture of essential drugs and formulations; and

iii. The availability, terms and conditions for the transfer of technology for the manufacture of twenty-six essential drugs.[63]

All three of these areas were discussed at the UNIDO first consultation on the pharmaceutical industry held in Lisbon on 1st to 5th December 1980.[64] This meeting was attended by representatives from both the developing and developed world, and from the pharmaceutical industry itself. At the meeting the industry placed on record its "willingness to expand further under mutually fair and acceptable terms its contribution to industrial growth in the Third World and its support for the general UNIDO objectives of raising the developing countries' share of world industrial output".[65]

On the issue of transfer of technology a consensus was reached at the meeting on the following conclusions:

i. The twenty-six essential drugs identified by UNIDO constituted an illustrative list for undertaking basic manufacture in developing countries.

ii. The developing countries, as a group, constituted large markets for these drugs in certain cases where the patents had lapsed.

iii. There was a willingness on the part of the developed countries, centrally planned economies and pharmaceutical companies to enable the transfer of technology to developing countries.

iv. Transfers of technology had to take place on mutually acceptable and equitable terms.

v. Manufacture should be based on maximum feasible backward integration to raw materials.[66]

Following this first consultation a meeting was held in Mohammedinia, Morocco, in December 1981 to discuss how the recommendations could best be implemented. Later meetings were held by a committee of experts in Paris in October 1982 and an ad hoc panel of experts in Vienna in December of 1982 and April of 1983. A further meeting was convened in Tunis in September of 1983 to discuss co-operation among developing countries.[67]

At the second consultation of the pharmaceutical industry held in Budapest on 21st to 25th November 1983, two new issues emerged for discussion. The first of these was a development of drugs based on medicinal plants, this having been identified as an important point as many plants of use in medicine were found growing in developing countries.[68] The second was the manufacture of vaccines in developing countries. A paper prepared by UNIDO had identified the paradox that, while infectious diseases were most prevalent in developing countries, vaccines to treat those diseases were mainly produced in the developed countries.[69]

As in the case of all United Nations activities, progress in reaching agreement on these controversial issues is painfully slow. This is because a consensus must be reached by all participating countries before recommendations may be implemented. But Both UNIDO and UNCTAD have suggested that developing countries may be able to improve their pharmaceutical needs by providing their own units of production.[70] These recommendations have been put into practice in some instances. An example is a project funded by UNIDO under which Sarabhai Enterprises, the largest private drug company in India, has set up a plant in Cuba to manufacture fifteen different drugs from raw materials.

7.5 THE EXTERNAL RELATIONS POLICY OF THE EUROPEAN ECONOMIC COMMUNITY

(i) Express powers

There can be little doubt that the Member States who founded the EEC Treaty expected that the EEC Common Market would make a significant contribution to world trade. Article 2 of the Treaty of Rome states that the Community shall have as its task the harmonious development of economic activities. Article 3 of that Treaty establishes the Common Market, involving both the formation of an internal market and relations with Third Countries. Further, in both the preface to the Treaty and in Article 3(k), reference is made to the need to help the prosperity and economic development of the overseas countries.

Internally, the Common Market required the elimination, as between Member States, of customs duties, quantitative restrictions and other measures having equivalent effect. These provisions are contained in Articles 12 to 28 and Articles 30 to 37 of the Treaty respectively. These objectives were achieved, as between the original Member States, over a transitional period lasting twelve years; ie by July 1968. The three Member States comprising the United Kingdom, Ireland and Denmark achieved this goal by 1st January 1978. Upon an external basis, the Common Market involves the introduction of a common customs tariff by Articles 18 to 29 of the Treaty. These Articles have the effect of making the Common Market a Customs Union, thereby distinguishing it from a free-trade area.

There are four main areas in the Treaty of Rome which give express powers to the Community in relation to external relations. The first of these is Articles 100 to 116, which deal with commercial and trade relations.

Article 113(1) provides for a common commercial policy, based on uniform principles to be devised and implemented by the Community institutions. This Article also specifically provides for "the conclusion of tariff and trade agreements" and "export policy and measures to protect trade such as those to be taken in the case of dumping or subsidies". A transfer of competence from Member States to the Community in relation to foreign trade policy took effect on 31st December 1969 and, since 1st January 1973, Member States have not been free to negotiate bi-lateral trade agreements.[71] Article 113 is also closely inter-related to GATT, of which all Member States of the Community are parties. This inter-relationship is discussed in Section 7.6.

With regard to procedure, Article 113(2) requires the Commission to submit proposals to the Council for the implementation of the common commercial policy. Article 113(3) then provides:

> "Where agreements with third countries need to be negotiated, the Commission shall make recommendations to the Council, which shall authorise the Commission to open the necessary negotiations.
>
> The Commission shall conduct these negotiations in consultation with a special committee appointed by the Council to assist the Commission in this task and within the framework of such directives as the Council may issue to it".

In exercising these powers, the Council is to act by a qualified majority.[72]

A second area in which the Treaty of Rome gives express treaty-making powers is in Part Four, dealing with Association of the Overseas Countries and Territories. When the Treaty of Rome was being negotiated four of the

countries involved namely, Belgium, France, Italy and the Netherlands maintained special relationships with overseas countries and territories. These special relationships included preferential trade agreements. France favoured a continuation of the status quo and the association scheme set out in Part Four of the Treaty was to last initially for five years. Article 131 of the Treaty declares that:

> "The purpose of association shall be to promote the economic and social development of the countries and territories[73] and to establish close economic relations between them, and the Community as a whole".

For the countries which had gained their independence, association was to take the form of a Convention. The first of these, the Yaounde Convention between the six Member States of the Community and eighteen independent African States was concluded on 20th July 1963 and renewed for five years on 29th July 1969. On 24th September 1969 the Arusha Convention brought English-speaking African States into the framework of these provisions for the first time. This culminated in negotiations between the enlarged nine Member Community and forty-six African, Caribbean and Pacific States (known as the ACP States) leading to the first Lome Convention signed on 28th February 1975. This has been succeeded by the Second and Third Lome Conventions, the latter running from 1985 to 1990.

These Conventions were originally conceived as treaties between equals but association does not concern membership of the EEC as only European States may become members of the Community.[74] For some of the European associates, however, association is regarded as a transitional phase, leading eventually to full Community membership.[75]

The Third ACP-EEC Convention of Lome (Lome III) was signed there on 8th December 1984. Its signatories were the sixty-five ACP States and the then ten Member States of the European Community and the Convention is to last for five years. Of the sixty-five ACP States which signed the Convention, fifty-four are African, thirteen are Caribbean and eight are Pacific. Their combined population amounts to some 368,000,000.[76]

An introductory Part to the Convention sets out the objectives and guidelines for co-operation between the signatory states. Article 10(1) of the Convention states:

> "Co-operation shall be aimed at supporting development in the ACP States, a process centred on man himself, and rooted in each people's culture. It shall back up the policies and measures adopted by those States to enhance their human resources, increase their own creative capabilities and promote their cultural identities. Co-operation shall also encourage participation by the population in the design and execution of development operations".

In a speech[77] given to the ACP-EEC Consultative Assembly meeting in Berlin in September 1983, M Pisani made it clear that this provision embraced the concept of fundamental human rights. A joint declaration related to Article 4 of the Convention makes a commitment by the signatory States to the eradication of apartheid, which is recognised as a violation of human rights.

Provisions are included in the Convention covering (inter alia) trade, industrial, financial and technical co-operation and protection of investment. Simmonds[78] has concluded that Lome III represents a remarkable and encouraging achievement which, in some respects, should

provide realistic and practical models for co-operation between North and South. It undoubtedly represents the cornerstone of the foreign policy of the EEC towards the Third World.

Article 238 of the Treaty of Rome provides for another category of association. By virtue of this:

> "The Community may conclude with a third State a union of States or an international organisation agreement establishing an association involving reciprocal rights, and obligations, common action and special procedures".

Both European and non-European States have undertaken this form of association.

Lipstein[79] has identified the following five main categories of agreement entered into between the Community and third countries:

i. Association agreements with former colonies and other developing countries, embodying the principles contained in Articles 131 to 135 of the Treaty by opening up the EEC customs territory to certain products in return for concessions;

ii. Agreements with States in the Mediterranean basin;[80]

iii. Agreements unequally balanced in favour of the associated countries but envisaging a gradual transition into full membership of the EEC;[81]

iv. Fully equal agreements with EFTA countries[82] and Iceland; and

v. Treaties with other countries and other international organisations opening up certain tariff positions.

A third area of the Treaty of Rome dealing with external relations is contained in Articles 228 to 231. These are not express treaty-making powers as such but simply require the Commission to maintain appropriate relations with international organisations in general and for the Community to establish "all appropriate forms of co-operation" (the details to be determined by common accord) with the Council of Europe and what is now the OECD. General provision for the procedure to be adopted for all international agreements to be made under the EEC Treaty are contained in Article 228(1), which states:

> "Where this Treaty provides for the conclusion of agreements between the Community and one or more States or an international organisation, such agreements shall be negotiated by the Commission, subject to the powers vested in the Commission in this field, such agreements shall be concluded by the Council, after consulting the Assembly where required by the Treaty".

A last area in which the Treaty of Rome gives express treaty-making powers to the Community is in Article 237. This provides for any European State to apply for membership of the Community. This Article states that the conditions of admission and any necessary adjustments to that Treaty are to be the subject of an agreement between the Member States and the state applying for membership.

(ii) Implied powers

While the text of the Treaty of Rome considered above suggests that the treaty-making powers of the Community are confined to the provisions discussed, the European Court has firmly rejected this view.[83] Member States originally took the view, understandable in the context of foreign policy, that

the Community could only exercise those powers which were specifically granted to it under the terms of the Treaty. Following from this, it was considered that when association agreements were entered into by the Community as such they could only deal with tariffs and trade within the provisions of Article 113(1). Where it was desired to include provisions falling outside of this, such as development aid, a procedural device was developed known as the "mixed agreement". This is an agreement concluded by both Member States and the Community. It is entered into where it is considered that there is no power for the Community to act under its own powers in relation to the agreement as a whole but is not, as such, recognised by the terms of the Treaty itself.[84]

In a series of cases[85] the European Court of Justice has gradually developed treaty-making powers with the result that the EEC now appears to possess implied powers equivalent to those expressly granted by the Euratom Treaty, Article 101 of which gives the Community power to conclude international agreements "within the limits of its powers and jurisdiction". In reaching this position the Court has had regard to the whole scheme of the Treaty and not just its substantive provisions. It has also endorsed the doctrine of "parallelism" whereby the external competence of the Community is regarded as matching its internal competence.

(iii) Medicines

In relation to medicines the EEC's external policy has not yet developed, though there are signs that this will happen in the near future.

On 9th October 1984 the European Parliament referred a motion for a resolution on the export of drugs from the EEC to the countries of the Third World, to the Committee on the Environment, Public Health and Consumer Protection.[86] As a result of this reference a report[87] has been drawn up by the relevant committee. This report noted that while industrial countries accounted for fifteen per cent of the world population, they accounted for the consumption of more than fifty per cent of the pharmaceutical products manufactured, and that almost ninety per cent of world production in pharmaceuticals was based in the industrial countries.[88] The report also recognised that as Third World countries imported almost all of their medicines, it was important that international standards should exist for the quality and usage of medicines.[89] In recognition of this the report recommended the adoption of a Directive by Member States to harmonise their laws relating to the export of medicines which are banned, withdrawn or subject to special restrictions or not registered within the EEC. This provision is to be subject to the proviso that the authorities in the importing state may specifically request such a product, once they have been informed of the existing controls within the EEC.[90]

While the approach proposed by the report is to be welcomed, it cannot be said that the adoption of such a Directive would represent a major advance in the control of international trade in medicines. There are two main reasons for this. First, such legislation could only have effect within the Community, which would exclude such major world manufacturers as Japan and the U.S.A. Secondly, the proposals relate only to a comparatively few products where a known reservation is agreed about their use. Such restrictions fall far short of the International Health Order discussed in Part VI.

It is submitted that a much more fundamental solution to the problem, enforced by legal sanctions upon an international basis, is required. It is likely that the Third World will continue to look to the United Nations rather than to the EEC for moral leadership in relation to pharmaceutical policy at an international level.

There is, however, scope for the EEC to become more directly involved in the wider issues concerning international trade in medicines if it so chooses as a matter of policy. In its internal policy the Community is becoming increasingly concerned with such matters as consumer protection, human rights and the control of MNEs, all of which have interactions with trade in medicines. Such concerns could, in the long-term, be focused upon the international aspects of trade in medicines having regard to the wide range of powers, both express and implied, available to the Community if it seeks to expand its interests in this area.

7.6 GATT AND ITS INTER-RELATIONSHIP WITH THE EEC

Although GATT has no specific policy relating to trade in medicines, any decision on the part of the EEC to regulate this market would have to come to terms with the free trade approach of GATT. In an early decision of the European Court of Justice in Re Italian customs duties on radio valves[91] this interaction between the EEC Treaty's effect on obligations under ealier agreements entered into within the framework of GATT was considered. It was held that, as between Member States, the EEC Treaty took precedence over GATT provisions. Non-Member States of the Community could not object to the manner in which the Member States reduced customs duties, even if such Non-Member and Member States

were all parties to GATT. This was so notwithstanding the terms of Article 234(1) of the EEC Treaty, which provides:

> "The rights and obligations arising from agreements concluded between one or more Member States on the one hand, and one or more third party states on the other hand, before this Treaty came into force, shall not be affected by its provisions."

Article 229 of the EEC Treaty provides for the maintenance of appropriate relations by the Community with (inter alia) the GATT. This is a multi-lateral Treaty intended to provide a framework for the progressive elimination of tariff barriers. In the preamble to the Agreement references are made to its main objectives. These are identified as "the substantial reduction of tariffs and other barriers to trade" and the "elimination of discriminatory treatment in international commerce".

In several parts of the Agreement, however, statements of principle are followed by exceptions. This balance of aims with important exceptions reflects the historical background to the Agreement. Petersmann[92] has described this in the following way:

> "The Charter represented a compromise between the emphasis of the United States on freedom of trade, on the one hand, and the priority given to the goals of full employment and economic re-construction by Western Europe and the developing countries on the other".

At the present time GATT has not been ratified by the contracting parties, its binding character deriving from the Protocol of Provisional Application of GATT.[93] By April of 1979 the GATT had eighty-four Member States, with a further twenty-eight States applying the Agreement on a de-facto basis, so that almost ninety per cent of world trade was governed by the Agreement.[94] No timetable is set out in the Agreement for tariff reductions but several "negotiating rounds" have resulted in significant reductions in the level of world tariffs.[95]

Article I of the Agreement set out the "most favoured nation" principle. Under this any privilege or favour granted by any contracting parties to the products of any other countries in respect of customs duty or charges must be accorded immediately and unconditionally to similar products originating in the territory of any other contracting parties. Article II of the Agreement imposes upon each contracting party an obligation to accord the commerce of other parties treatment no less favourable than that provided by the Schedules annexed to the Agreement. These Schedules occupy several volumes and incorporate the outcome of original bi-lateral negotiations between contracting parties and renegotiations under the GATT itself.[96]

Articles VI and XIX of the Agreement set out some important exceptions. The former deals with anti-dumping and countervailing duties. Anti-dumping duties may, however, only be imposed if material injury to a domestic industry is threatened. Article XIX provides an escape clause whereby concessions may be withdrawn if, due to "unforeseen developments", the importation of a product is causing or threatening "serious injury to domestic producers". This clause is limited in both extent and time as may be necessary to prevent or remedy such injury.

Article XI of the Agreement contains a general prohibition upon quantitative restrictions other than duties. This prohibition extends quotas to both, which limit the importation of products and to licensing schemes which may involve an element of discretion as to whether a particular import is to be allowed or refused. But this provision is subject to the wide-ranging exceptions for balance of payments difficulties (Article XII), agricultural products (Article XI) and the particular problems arising from trade with the developing countries (Article XVIII). There are also exceptions to the general principles of the Agreement for both the formation of customs unions or free trade areas by contracting parties to the Agreement.[97]

GATT contains no provision either for disputes between contracting parties to be settled by judicial process or for an authoritative interpretation of its terms to be given which would be binding upon contracting parties. Article XXII of the Agreement, however, provides some procedure for settlement of disputes. It states:

> "i. Each contracting party shall accord sympathetic consideration to, and shall afford adequate opportunity for consideration for consultation regarding, such representations as may be made by another contracting party with respect to any matter affecting the operation of this Agreement.
>
> ii. The contracting parties may, at the request of a contracting party, consult with any contracting party or parties in respect of any matter for which it has not been possible to find a satisfactory solution through consultation under paragraph i".

In practice, matters of dispute are referred to the GATT Council or the General Assembly of GATT.[98] There is no institution in relation to GATT which corresponds to the European Court of Justice of the Community. For GATT the approved method of settling disputes is, therefore, consultation and conciliation rather than Court proceedings. There have, however, been a number of cases in which the European Court of Justice has been asked to consider provisions of GATT in relation to Community provisions. In this case law the European Court of Justice has held that Articles II, III, VI, VIII and XI of GATT were not of direct effect.[99]

An examination of the case law of the European Court of Justice on GATT shows that there are many interactions between GATT provisions and Community law. This arises from the fact that Member States of the EEC are also contracting parties to GATT and that Article 229 of the EEC Treaty provides for the maintenance of approach relations between the Community and GATT. As Petersmann has observed:

> "In negotiating the Community Treaties, the Member States had to adjust these Treaties to the requirements of the General Agreement (Article XXIV) and to submit the Treaties to the scrutiny of several working parties. In addition to their Member States the three European Communities became legally bound by GATT law entailing joint international legal responsibility of the Communities and their Member States for the fulfilment of GATT obligations. The trade policy instruments of the EEC have to conform to GATT law and are closely regulated by GATT provisions on, inter alia, non-discrimination, tariff matters, customs

procedures and customs evaluation, import licences, quantative restrictions, government procurement, exchange control, technical and other non-tariff barriers to trade, subsidies, anti-dumping and countervailing duties, safeguard measures, free trade areas and customs unions. Most of the Tokyo Round Agreements required specific measures of implementation which were taken by means of EEC regulations, decisions, directives, communications, recommendations and certain complementary national implementing measures. Community regulations, for example, on customs tariffs and anti-dumping, have respectively been construed by the Court by reference to GATT provisions. In the absence of an express provision securing the freedom of transit, Community law has been construed to comprise unwritten legal principles corresponding to the freedom of GATT law (Article V GATT)".[100]

A decision of importance concerning the effectiveness of GATT was that concerning the International Fruit Company Cases,[101] in which the main point at issue concerned the obligations arising out of the GATT provisions in respect of contracting members. The specific question raised was whether an act of the Community could be declared invalid because of its incompatibility with a GATT provision. First, the Court considered whether it had jurisdiction to give a preliminary ruling under Article 177 of the Treaty where the compatibility of national measures with international agreements (which are binding upon the Community) was in issue. Upon this the Court accepted that its jurisdiction should not be limited by the grounds on which the validity of the measure in question was contested.[102] It seems that the Court felt that this conclusion was not confined to the interpretation of an international agreement such

as GATT but extended to any rule of international law.[103] Upon this aspect of the judgment there can be little criticism. GATT is concerned with matters which fall almost entirely within the competence of the Community and the European Court of Justice held that GATT was binding on the EEC. Strictly however the Community as such is not a member of GATT as only Member States are entitled to membership. In this case, the Court took the view that the Community had assumed the powers provisionally exercised by Member States in the area covered by GATT and accepted that GATT was binding on the Community.[104]

The Court then turned to the question as to whether Article XI of GATT was capable of conferring on citizens of the Community rights which they could invoke before the Courts. In order to reach a view upon this the Court considered the purpose, general scheme and terms of GATT. In its consideration of these matters the Court found that GATT was based upon the principle of negotiations undertaken on the basis of "reciprocal and mutually advantageous arrangements". It was characterised by the flexibility of its provisions. Attention was also drawn to the method of settling disputes contained in Article XXIII of GATT, providing for "sympathetic consideration" to be given to written representations and the provisions for consultation and negotiations. Article XIX was also considered, which provides for a contracting party to suspend a concession unilaterally on a temporary basis without prior consultation. Having regard to these features, the Court concluded that Article XI of GATT did not have the effect of confering on Community citizens rights which could be invoked before the Courts. From this it followed that the Commission regulations under consideration could not be affected by the GATT provisions within the context of the proceedings in the national Court.

It is surprising, and unsatisfactory, that the Court has repeatedly refused to give direct effect to GATT provisions in actions brought by private parties as opposed to contracting members. In has done this on the grounds that those parties cannot enforce those rights in national Courts. In contrast to this, the Court has accepted that GATT is legally binding on Member States of the Community. Three reasons have been put forward by the Court as to why citizens of the Community may not rely on GATT provisions before Courts in contesting the validity of trade restrictions. These are: the GATT principles of "reciprocal and mutually advantageous arrangements", the great flexibility of the GATT provisions and the context and system of GATT. Petersmann[105] has subjected each of these reasons to a detailed scrutiny and has concluded that none of them is satisfactory. He has argued that an observance of GATT provisions would help to strengthen GATT itself and that this would be in the interests of the Community. Mastellone[106] has also been critical of the Court's approach and has concluded that:

> "... the refusal by the Court of Justice to interpret GATT provisions, while insufficient to encourage national Courts to take a more serious attitude towards GATT, may well jeopardise a uniform interpretation and application of the General Agreement within the Community".

It is true that the Court has not in terms specifically stated that GATT provisions cannot have direct effect. But the terms of its judgments have been so strictly confined that it is almost impossible to conceive a situation in which a GATT provision could be given direct effect, except as in the NTN Toyo Bearing case[107], where the GATT provision had itself been expressly incorporated into Community law.

Having regard to its general objectives of a progressive elimination of tariff barriers, it is hardly surprising that GATT has no specific policy relating to medicines. Its anti-dumping provisions do not give rise to legal problems in relation to international trade in medicines because it is very largely the case that manufacturers of medicines are seeking to export their products to Third World countries, which generally do not have the facilities for producing those products themselves. There also seems little scope for GATT to become directly involved in the wider issues concerning trade in medicines such as consumer protection, or in the control of MNEs, which is discussed in Chapter VIII. Finally, as mentioned above, any decision by the EEC to participate in international proposals to regulate trade in medicines would have to reconcile such policy with the binding effect of GATT within the Community.

NOTES

1. UN Doc E/CN.7/471, p.3. See Chatterjee, S K Legal Aspects of International Drug Control", Martinus Nijhoff, The Hague, [1981] page 228.

2. Chatterjee, ibid., at p.228.

3. UN Charter, Article 57, paragraph 1.

4. Chatterjee, op.cit. at p.232.

5. UN Charter, Article 71.

6. Chatterjee, op.cit., at p.300.

7. Jenks, C W "Co-ordination in International Organisation : An Introductory Survey", 28 (1951) BIYB 29-89, at p.78 et seq.

8. Ibid., p.81.

9. Under Article 57, Article 1 of the UN Charter.

10. The World Health Assembly consists of a maximum of three delegates per Member State and meets once a year. See Articles 11 and 13 of the Constitution of the World Health Organisation.

11. The Executive Board meets twice a year, its members being designated by Member States of WHO and named by the World Health Assembly. The Board Members must be technically qualified in the field of health. See Aryicles 24 and 26 of the Constitution of the World Health Organisation.

12. By Article 30 of its Constitution the Secretariat is the administrative and technical organ of WHO.

13. The Director-General, as the chief officer, appoints staff and is responsible to the World Health Assembly through the Executive Board. See Article 31 of the Constitution.

14. See Article 28 of the Constitution.

15. See Article 2(u) of the Constitution.

16. See Article 2(k) of the Constitution.

17. Although the language of the powers is in legislative terms, there is no supra-national organ in WHO which is able to enact and enforce its provisions. WHO's rule-making powers proceed on the basis of consent by Member States, which may be regarded as "international regulation". See Cone, Ellen N "International Regulation of Pharmaceuticals", Virginia Journal of International Law, Vol 23 [1983] 331 at page 342.

18. Article 19 of the Constitution.

19. Articles 61 to 65 of the Constitution.

20. The complete Article states:

> "The Health Assembly shall have authority to adopt regulations concerning:
>
> (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;
>
> (b) nomenclatures with respect to diseases, causes of death and public health practices;

(c) standards with respect to diagnostic procedures for international use;

(d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;

(e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce".

21. WHA Technical Report Series No 41 [July 1951].

22. Article 23 of the Constitution.

23. See Section 3 of the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, WHO, Official Records, No 226, Annex 12 [1975].

24. Idem, Part 2, Section 1.

25. Idem, Part 3, Section 2.

26. See "The Work of WHO 1982/83", Biennial Report of the Director-General to the World Health Assembly and to the United Nations, WHO, Geneva [1984], page 1.

27. Wassermann, WHO Pharmaceutical Certification Scheme", 10 Journal of World Trade Law [1976] 185 at page 187.

28. See 35th World Health Assembly, Action Programme on Essential Drugs : Report by the Executive Board ad hoc Committee on Drug Policies on behalf of the Executive Board, WHO Document A35/7 [1982]. Appendix I sets out the WHO Revised Model List of Essential Drugs.

29. See "The Selection of Essential Drugs", Second Report of the WHO Expert Committee, WHO Technical Report Series 641, Geneva [1979] pages 9 to 29 and "The Selection of Essential Drugs", WHO Technical Report Series 615, Geneva, [1977].

30. See the Report at Note 26 at page 147.

31. See the Report at Note 26 at page 147.

32. See Cone, Ellen N "International Regulation of Pharmaceuticals : The Role of the World Health Organisation", Virginia Journal of International Law, Vol 23 [1983] 331 at page 351.

33. In 1981 the UNICEF/WHO Joint Committee on Health Policy adopted a joint programme to support the Action Plan on Essential Drugs. See WHO Document EB68/1981/REC/1, Annex 2, paragraph 62.

34. In January of 1982 the International Federation of Pharmaceutical Manufacturers Associations declared to the WHO Executive Board that the companies it represents would start supplying essential drugs for a few pilot countries.

35. See paragraph 27 of Section 6 of the Report mentioned in Note 28 above.

36. Op.cit.at, paragraph 28.

37. Resolution WHA 34.36.

38. See "The Work of WHO 1983//1983", Biennial Report of the Director-General to the World Health Assembly and to the United Nations, WHO, Geneva [1984], page 1.

39. In 1963 the Sixteenth World Health Assembly passed a resolution (WHA 16.36) stressing that international co-operation was essential for the achievement of the best possible protection against the hazards which may arise out of the use of drugs.

40. Resolution WHA 26-31.

41. See Jayasuria, D C "Regulation of Pharmaceuticals in Developing Countries : Legal Issues and Approaches", WHO, Geneva, [1985] page 58.

42. Idem.

43. Seventh General Programme of Work covering the period 1984-89, Essential Drugs and Vaccines, WHO, Geneva, 20th December 1983 (Document EDV/MT10/83.1).

44. Ibid.

45. Ibid.

46. General Assembly Resolution 1707 (XVI) of 19th December 1961, UN Yearbook 1961, 191.

47. ECOSOC Resolution 917 (XXXIV) of 3rd August 1962, UNCTAD Basic Documents on Its Establishment and Activities (Geneva, 1966) 1-3.

48. See Proceedings of UNCTAD I (New York, 1964) I, 66-68.

49. Petersmann, Ernst-Ulrich "International Governmental Trade Organisations", in International Encyclopaedia of Comparative Law, Volume XVII, Chapter 25, page 28.

50. Op.cit., page 19.

51. Wartensleben A V "Major Issues Concerning Pharmaceutical Policies in the Third World", in World Development, Volume 11, No 3, page 173.

52. Resolution 89 (IV) of 13th May 1976.

53. A - General

i. "Major Issues in the Transfer of Technology to Developing Countries : a case study of the pharmaceutical industry", (TD/B/C/6/4).

ii. "Technology Policies and Planning and the Pharmaceutical Sector in the Developing Countries", (TD?B/C/6/56).

iii. "Guidelines on Technology Issues in the Pharmaceutical Sector in Developing Countries", (UNCTAD/TT/49).

B - Reports of Workshops

iv. "Report and Recommendation of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector in the Caribbean Market", (UNCTAD/TT/41/REV1).

v. "Report and Recommendations of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector", (Abidjan, Ivory Coast), (UNCTAD/TT/48).

C - Country Case Studies

vi. "Case Studies in the Transfer of Technology : the pharmaceutical industry in India", (TD/B/C6/20).

vii. "Case Studies in the Transfer of Technology : pharmaceutical policies in Sri Lanka", (TD/B/C6/21).

viii. "Technology Policies in the Pharmaceutical Sector in Venezuala", (UNCTAD/TT/25).

ix. "Technology Policies in the Pharmaceutical Sector in Cuba", (UNCTAD/TT/33).

x. "Technology Policies in the Pharmaceutical Sector in Nepal", (UNCTAD/TT/34).

xi. "Technology Policies in the Pharmaceutical Sector in the United Republic of Tanzania", (UNCTAD/TT/35).

xii. "Technology Policies in the Pharmaceutical Sector in the Philippines", (UNCTAD/TT/36).

xiii. "Technology Policies in the Pharmaceutical Sector in Costa Rica", (UNCTAD/TT/37).

54. Report and Recommendations of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector", Abidjan (UNCTAD/TT/48).

55. Lall, Sanjay "Growth of the Pharmaceutical Industry in Developing Countries : Problems and Prospects", UNIDO, ID/204, 1978.

56. The formal name for the organisation of the developing countries.

57. Lima, Declaration, UNIDO, ID/CONF3/31, 1975.

58. "Global Study of the Pharmaceutical Industry", UNIDO, ID/WG/331/6, 1980.

59. Tucker, David "The World Health Market", Euro-Monitor Publications Limited [1980] pages 145-146.

60. "UNIDO Consultation Programme on the Pharmaceutical Industry", PJB Publications Limited [1983] page 4 et seq.

61. See "UNIDO Consultation Programme on the Pharmaceutical Industry", page 5.

62. See "UNIDO Consultation Programme on the Pharmaceutical Industry", page 8.

63. Op cit, page 8.

64. Op cit, pages 14 to 27.

65. UNIDO "First Consultation Meeting on the Pharmaceutical Industry", Lisbon, Portugal, 1-5 December 1980, Report ID/259. (ID/WG331/10/REV 1).

66. UNIDO Consultation Programme on the Pharmaceutical Industry", page 27.

67. Op.cit. pages 28 to 33.

68. Op.cit. page 42

69. Op.cit. page 43. Two papers produced by UNIDO were: "The Manufacture of Vaccines in Developing Countries", Issue paper (ID/WG393/12) and Background Paper (ID/WG393/13).

70. Peretz, S Michael "Pharmaceuticals in the Third World : the Problem from a Supplier's Point of View", in World Development, Volume XI, No 3, 259 at page 269.

71. See Carol Anne Cosgrove and Kenneth J Twitchett, "The External Relations of the European Community", Open University Press [1974], Unit 4, page 137.

72. See Article 148(2) of the European Economic Community Treaty as to the meaning of this phrase.

73. These were listed in Annex IV to the Treaty but this list has been amended several times. Most of the territories which have ceased to be associated under Part Four of the Treaty are now parties to the Lome Convention.

74. See Article 237 of the European Economic Community Treaty.

75. As in the case of Greece.

76. Simmonds, Kenneth "The Third Lome Convention", 22 CML REV [1985] 389 at page 394.

77. Quoted in Simmonds, op.cit. page 410.

78. Simmonds, op.cit. page 417.

79. Lipstein, K "The Legal Structure of Association Agreements with the EEC", 47 BYIL page 201.

80. See, for example, the Agreement with Morocco, contained in Regulation 1462/69, O J 1969, L197/1.

81. An example is the Agreement dated 12 September 1968 establishing an Association between the EEC and Turkey. J O 1964, 3687, Encyclopaedia of European Community Law, Vol B,B12-030 et seq. This Agreement was less comprehensive than that with Greece and was intended to allow for the gradual modernisation of the Turkish economy prior to consideration of full membership of the Community.

82. An example is the Agreement with Austria, contained in Regulation 2836/72 O J 1972, L300/1.

83. For a discussion of two rival theories about the powers of the Community to conclude treaties, see Costonis, J J "The Treaty-Making Power of the European Economic Community", [1968] 5 C M L, REV 421 at page 429 et seq, and Leopold, Patricia M "External Relations Powers of EEC in Theory and in Practice", [1977] 26 ICLQ, 54 at pages 62/63.

84. Cf. Article 102 of the Euratom Treaty.

85. These cases are:

(1) Commission -v- Council (ERTA Case), Case 22/70, [1971] ECR 263; [1971] CMLR 335.

(2) Local Cost Standard Case, Opinion 1/75, [1975] ECR 1355.

(3) The North-East Atlantic Fisheries Convention Case, Cases 3, 4, 6/76, [1976] ECR 1279; [1976] 2 CMLR 440.

(4) Opinion on the Laying-Up Fund for Inland Waterway Vessels, Opinion 1/76, [1977] ECR 741.

(5) The Natural Rubber Agreement Case, Opinion 1/78, [1979] ECR 2871; [1979] 3 CMLR 639.

See Hartley, T C "The Foundations of European Community Law", Clarendon Press, Oxford, [1981] pages 150 to 165, where these cases are discussed.

86. Document 2-565/84.

87. Working Document A 2-36/86, Report drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection on the export of pharmaceutical products from the European Community to the countries of the Third World, Rapporteur, Mrs Mary Banott.

88. Page 5 of the Report.

89. Page 11 of the Report.

90. Page 7 of the Report.

91. Commission v Italy [1962] ECR1

92. Petersmann, Ernst-Ulrich "International Governmental Trade Organisations - GATT and UNCTAD", in International Encylopaedia of Comparative Law, Vol XVII, Chapter 25, page 4.

93. Petersmann, op.cit. page 8.

94. Petersmann, op.cit. page 9.

95. One of these, "the Tokyo Round", was concluded in April of 1979.

96. Steiner, Henry J and Vagts Detler, F "Transnational Legal Problems", The Foundation Press Inc, [1976] page 1151.

97. See Article XXIV of the Agreement, which requires that free trade areas and customs unions be examined to determine their effect on other States. If their commerce has suffered, compensation may be payable.

98. See Petersmann, op.cit. page 25.

99. These cases are:

(1) Joined cases 21 to 24/72, International Fruit Company v Produktschap, [1972] ECR 1219; [1975] 2 CMLR1;

(2) Case 9/73, Carl Schluter v Haptzollant Lorrach, [1973] ECR 1135;

(3) Case 39/75, Nederlandse Spoorwegan v Inspector der invoerrechten, [1975] ECR 1439;

(4) Case 113/79, NTN Toyo Bearing Case, [1979] ECR 1185; [1979] 2 CMLR 257;

(5) Case 266/81, The SIOT Case, [1984] 2 CMLR 231;

(6) Joined cases 267 to 269/81, Societa Petrolifere Italiana Cases, [1984] 1 CMLR 354; and

(7) Joined cases 290 and 291/81, Singer Company Cases, [1983] ECR 847.

100. Pescatore, Pierre "International Law and Community Law - a Comparative Analysis", [1970] 7 CML REV 167 at page 171.

101. Joined Cases 21 to 24/72, International Fruit Company v Produktschap, [1972] ECR 1219; [1975] 2 CMLR 1.

102. Paragraphs 4 and 5 of the judgment.

103. See paragraph 6 of the judgement and the comment by Petersmann, Ernst-Ulrich "Application of GATT by the Court of Justice of the European Communities", in [1983] CML REV 397 at page 407.

104. At paragraph 18 of the judgment.

105. Petersmann, Ernst-Ulrich Application of GATT by the Court of Justice of the European Communities", [1983] CML REV 397 at page 416.

106. Mastellone, Carlo in Case Note at [1983] CML REV 559 to 580.

107. Case 113/77, [1979] ECR 1185; [1979] 2 CMLR 257.

CHAPTER VIII - MULTI-NATIONAL PHARMACEUTICAL ENTERPRISES

8.1 INTRODUCTION

It is in the developed countries of North America, Europe, Australasia and Japan that the main production and demand for pharmaceuticals are centred. These countries are estimated to have a combined share of about two-thirds of both output and demand.[1] But of the estimated ten thousand companies in the world which may be described as manufacturers of pharmaceuticals, only about one hundred are significant in terms of participation in the international market. Of those one hundred companies, they supply about ninety per cent of the total world shipments of pharmaceuticals for human use.[2] As Lall wrote in 1975:

> "The leading drug companies possess an exceedingly high degree of market power".[3]

More recently, it has been estimated that the thirty-five largest MNEs are responsible for almost fifty per cent of the total world production of pharmaceuticals. This figure includes seventeen US companies, which account for twenty five per cent of total sales, and fifteen West German, Swiss, British and Japanese, which account jointly for a further twenty-five per cent.[4] At the present time, most Third World countries have either no manufacturing facilities at all for pharmaceuticals or manufacturing facilities which consist of repackaging and simply formulations of some bulk drugs.[5] Some countries which are able to produce most of their own domestic requirements are Egypt, Argentina, Brazil, Mexico, India and Cuba.[6]

While these figures tend to suggest that the pharmaceutical industry may be dominated by MNEs, some reservations to this proposition must be entered. First, the world recession has made survival more difficult for small firms generally and the pharmaceutical industry has been no exception to this general trend. Secondly, the degree of concentration in the pharmaceutical industry is not as high as in other manufacturing industries, such as the car industry. As Tucker[7] has pointed out, no pharmaceutical company has so large a share of the world market as General Motors or any of the top six car manufacturers. It is thought that no one MNE accounts for more than five per cent of total output and that the four largest MNEs account for as little as sixteen per cent of total industry sales.[8] This low degree of concentration arises because the pharmaceutical industry is divided into about twelve sub-markets, such as antibiotics and tranquillisers. Each of these sub-markets may, however, have a higher level of concentration than the average for the industry. This is because each sub-market tends to be dominated by a small group of MNEs. Most MNEs obtain the bulk of their income from say two or four of such sub-markets.[9]

The relationship between MNEs and their host countries may often be a difficult one because their objectives may be different. Some of the legal aspects arising out of their inter-relationships are now considered.

8.2 TRANSFER PRICING AND PROFITS

Transfer pricing is one of the practices of MNEs which is of particular concern in the countries where they operate. This may be defined as the determination by a MNE of the price at which goods or services will be supplied between that MNE and its foreign subsidiary. Lall has described the practice in the following terms:

> "The essential difference is simply that in transactions on the open market or between unrelated firms, the buyers and sellers are trying to maximise their profits at each other's expense, while in an intra-firm transaction, the price is merely an accounting device and the two parties are trying to maximise joint profits".[10]

This practice is of considerable importance as it has been found that more than one-quarter in value of all international trade in goods is of an inter-group nature.[11] Lall has also concluded that the pharmaceutical industry has the highest differentials between transfer prices and arms' length prices.[12] This conclusion was reached after examining evidence from many countries, including Latin America, Iran, Sri Lanka and the United Kingdom. This practice of transfer pricing is operated by MNEs for various purposes, such as moving capital to where it can be used most effectively, avoiding Government controls and minimising taxes.[13]

While detailed information about transfer pricing is difficult to obtain, some references in the United Kingdom literature are well documented. Thus, the Sainsbury Report [14] commented on the possible use of transfer prices by foreign companies and the consequences for this in relation to declared profits. More recently, the Monopolies Commission Report on the supply of Chlordiazapoxide and Diazepam[15] drew attention to the practices of Hoffman-la-Roche, which had consistently declared low profits in England. It was found that while Roche had been charging its British subsidiary £370 and £922 per kilo respectively for the active ingredients used to formulate librium and valium in Britain, these active ingredients were available from Italian manufacturers at £9 and £20 per kilo respectively. Upon the basis of these figures it was estimated that although Roche had been

declaring profits generally below five per cent on capital employed, its real profits were over seventy per cent between the years 1966 and 1972.[16]

Examples of transfer pricing in the Third World are numerous. In the late 1960s it was estimated by the Columbian Government that the weighted average of over-pricing for a wide range of pharmaceutical imports was between eight-seven per cent and one hundred and fifty five per cent.[17] Another study in Argentina found that the prices of certain medicines was one hundred and forty three per cent to three thousand, eight hundred per cent higher than the minimum import prices for those same products in the same country. Some of these products were particularly overpriced, such as antibiotics (six hundred and fifty per cent), vitamins (seven hundred and thirty per cent) and sera (three thousand, eight hundred per cent).[18] In relation to India, Deolalikar has made a detailed study in which he produced evidence to show that foreign companies frequently misrepresented the cost of imports of raw materials for medicines, and also the cost of building plant for manufacturing the product.[19]

This problem of transfer pricing is clearly a difficult one for the Governments involved both to identify and then to tackle but it is clearly one which is commanding attention upon an international level. As the United Nations Working Group of the Department of Economic and Social Affairs have stated:

> "In the long run, a fair amount of research and fact-finding is necessary for the evolution of sound practices and policies. We note with satisfaction the transfer pricing has been engaging the attention of the United Nations group of experts on tax treaties, the

International Fiscal Association, the Organisation for Economic Co-operation and Development and the Commission of the European Communities. We trust that, as a result of their efforts, it will be possible for the International Community to agree upon a code which home and host countries alike will find practical and advantageous to enforce".[20]

With a view to finding a solution to the problems posed by transfer pricing, the Group have made the following three recommendations:

i. That home and host countries should enforce "arms' length" pricing wherever appropriate; and should elaborate rules on pricing practices for tax purposes.

ii. That home and host countries should introduce provisions into bilateral tax treaties for the exchange of available information, and should consider the feasibility of an International Agreement on the rules concerning transfer pricing for purposes of taxation.

iii. Host countries should review their exchange controls in order to reduce differences of treatment as regards remittances abroad for remunerations which are broadly equivalent, such as dividends and interest.[21]

This report recognises that the basic solution to make transfer prices public knowledge, either generally or upon request, so as to make the practice self-restraining. This would also make possible the application of the principle of non-discrimination was expressed in such provisions as the Robinson-Packman Act in the USA,[22]

whereby a seller is prohibited from charging different prices to different buyers unless the difference can be justified by differences in the quantity or regularity of supply. This, so the Group argue, would go far towards eliminating undesirable practices by MNEs.[23]

8.3 PATENTS AND THE TRANSFER OF TECHNOLOGY

Pharmaceuticals is a field where both patents and trade marks have been exploited by manufacturers more than in almost any other sector of industry.[24] While the early sulpha drugs such as suffanilimide, penicillin, cortesone and hydrocortesone were not patented, the improved versions of these products (such as streptomycin, which was introduced concurrently in 1946) were patented.[25] New products have been introduced to the market as a result of substantial expenditure and investment in research and development. It is of course the rationale for patents that they provide an incentive for innovation. Patents are obtained in order to protect investment and recoup expenditure over the period allowed by law for exploitation of the monopoly position. Some discussion of the role played by patents in relation to MNEs is therefore necessary.

It has been seen[26] that both Articles 30 to 36 and Articles 85 and 86 of the Treaty of Rome raise problems which concern intellectual property rights such as patents and trade marks. Difficulties have arisen when it has been sought to use these rights in a way which is outside their scope as defined by the European Court of Justice. If the rights sought to be exercised by the property owner stray outside their proper scope, the question then to be answered is whether that exercise constitutes such an unlawful restraint as to amount to a breach of the Treaty's provisions.

Upon a global basis MNEs have clearly taken advantage of the patent system to reinforce their market power in the pharmaceutical field. It has been found that eleven US based MNEs involved in pharmaceuticals were among the most active domestic companies on the patent file. Four of these (Upjohn, Merck and Company, American Home Products and Warner Lambert) registered more than one thousand patents each in the period from 1969 to 1977.[27] From these four same MNEs, three are among the ten leading pharmaceutical firms in the world on the basis of number of products under development.[28] But in considering the world patent system it must be borne in mind that it does not reclude the development of "me-too" drugs. These are products which are molecularly distinct but therapeutically identical.[29] A former Medical Director of the MNE Squibb gave evidence before a sub-committee of the Senate that while he was with that company an estimated twenty-five per cent of research funds were devoted to "worthwhile" projects, while the remaining seventy-five per cent were spent on the development of "me-too" drugs and unimportant combination products.[30] In his survey of nearly forty developing countries, Chudnovsky found that none of them was prepared to confer patents on pharmaceutical products.[31] This study also noted that no developing country had revised its policy in the direction of granting patent protection to pharmaceutical products in the second half of the 1970s. In contrast to this, it was found that developed countries had extended the patentability of products to include pharmaceuticals. Such patentability had, for example, been introduced in France in 1958, the Federal Republic of Germany in 1968, Japan in 1976 and Italy in 1978.[32]

One of the main reasons why developing countries do not give patent protection to pharmaceuticals is to enable their own manufacturers to produce medicines through the importation of raw materials.[33] In addition to this,

some developing countries have encouraged the manufacture and importation of "generic" drugs - namely, those without patent protection. The prices of such drugs are often significantly lower than those of patented products. Such a policy affords considerable financial savings to developing countries.[34] Chudnovsky has also observed that the lack of patent protection in some developing countries has not resulted in any significant reduction in the leading positions held by MNEs in those countries. Market shares held by MNEs in developing countries have usually been higher than fifty per cent and in some cases (eg in Brazil, Columbia and Mexico) have reached eighty to ninety per cent.[35] International trade is increasingly important to MNEs as the patents for their products expire. It has been estimated that, of the two hundred leading brand-name medicines in the USA, one hundred and four of their patents had expired in 1980.[36]

While the patent system remains firmly entrenched as part of the industrial property system of the developed world, it is difficult to envisage MNEs voluntarily giving up those valuable rights. From the point of view of the Third World, it is important for it to have access to new technology to enable pharmaceutical production to develop. Both UNCTAD and WHO are taking initiatives towards the framing of an International Code of Conduct on Pharmaceuticals. This is expected to cover such issues as marketing, distribution, trade and the transfer of technology.[37]

8.4 TRADE MARKS AND GENERIC PRESCRIBING

The legal protection provided by trade marks to pharmaceuticals has come under an attack from many countries in a similar way to that against patents.[38] Unlike patents, however, the protection given by a trade mark is not limited to a period of years but lasts for

ever. It has been estimated that more than forty per cent of the trade marks used throughout the world are related to pharmaceuticals and related products.[39] Some countries in the Third World have encouraged the manufacture and importation of generic medicines without patent protection, thereby achieving considerable savings in costs.[40] This is particularly important in developing countries, where expenditure on medicines alone may constitute forty to sixty per cent of individual medical care costs, compared to about fifteen to twenty per cent in the industrialised countries.[41] From this it follows that any reduction in the costs of medicines may have an important bearing upon the quality of health care available to Third World countries.

There can be little doubt that the brand name system results in a bewildering list of different names for what is basically the same medicine with the same active ingredient. Brooke[42] has estimated that for the seven hundred separate names available for medicines in the USA, there are an estimated twenty thousand brand names. This position is not unique. It has been shown that the number of brand names for medicines registered in 1974 was as follows:

Argentina	17,000
Belgium	9,000
Brazil	14,000
Canada	17,000
Columbia	15,000
Federal Republic of Germany	24,000
France	8,500
India	15,000
Iran	4,200

Italy	21,000
Japan	17,400
United Kingdom	9,000[43]

In considering the use of trade marks by MNEs it is important to bear in mind the role played by the prescribing doctor. As it is he who will usually choose the product to be consumed by the patient, and the cost will often be borne by the State, the crucial link between demand for the product and payment of the price for it is broken. As the result of this characteristic of the supply of medicines, it is easy to understand the large expenditure incurred by MNEs in seeking to influence the choice of brand of medicines made by doctors. The pharmaceutical industry in the USA, the Federal Republic of Germany, Italy, South Africa, Belgium and Canada annually spends more than twenty per cent of its total sales on product promotion.[44] This expenditure takes the form of advertising, visits by representatives of the MNEs to prescribing doctors and by the provision of free samples of the product to be promoted.[45]

In 1975 the Hathi Committee reported on the Indian Drug Industry.[46] It found this in relation to the control of market power by MNEs:

> "Attractively got up medical literature and international brand names of drugs appearing in advertisements in foreign medical journals with which top consultants in the medical profession were acquainted, played their part in popularising the drugs of the foreign companies. Large sums of money were spent by foreign companies in systematically training their "Medical detailers" and the general tone of detailing resorted to was that their products contained "something plus"

over products with identical composition marketed by Indian Units and that the edge in their quality was the outcome of their superior expertise and international standing".[47]

There is nothing to suggest that the position of India is alone in this respect. Silverman has subjected the promotion of medicines by MNEs in Latin America to a detailed examination.[48] This study examined the promotion of forty different prescription drug products marketed in both the USA and Latin America by twenty-three MNEs from the USA, Switzerland, the Federal Republic of Germany and France. Silverman found that there were marked differences in the way in which the same product, marketed by the same MNE, was described to prescribing doctors in the USA and Latin America respectively. The general trend was that the listed indications (the diseases for which the product is recommended) were usually few in number for the USA, with contra-indications, warnings and potential adverse reactions being shown in detail. In contrast to this, the listed indications were often more numerous when the product was sold in Latin America, while the other information was either omitted completely or mentioned only briefly.

Silverman also found that similar differences to those could be found in non-Third World countries, which suggests that the position in Latin America is not the only place in which different standards may be adopted by MNEs. In the case of Chloramphenicol, differences were found in the marketing of the product in France, Italy, Spain, Australia and New Zealand respectively.[49] A further survey conducted by Dunne et al[50] has also drawn attention to the wide differences in the marketing of Chloramphenicol throughout the world. Dunne's startling point is that the product has limited indications and that its side effects and contra-indications are well

established. Despite this, the survey found that the information provided by the manufacturers varied widely, with unwarranted indications being shown and either no, or inadequate warnings, being given. This survey covered leaflets for fifty-five packs of the product covering twenty-one countries. In its recommendations this survey concluded that a more uniform and consistent approach in the way the product was promoted was desirable. This was seen as primarily the responsibility of manufacturers, with encouragement from national drug control authorities and other interested parties. It was also suggested that WHO could help by making information more easily available to its member countries.[51]

Yudkin[52] has drawn attention to a similar problem in a slightly different context. He has pointed to the difference between the major health problems which arise in developing countries as opposed to those arising in Britain. In the former, health problems still arise from poverty and lack of adequate sanitation, factors which have ceased to have a significant impact on major health problems in Britain. In spite of this difference Yudkin found that the prescribing pattern in the large hospitals in a developing country was similar to that found in the developed countries. In each case there was an emphasis upon psychotropic drugs and expensive proprietary preparations. Yudkin's conclusion was that this similarity in prescribing patterns was due to the promotional activities of pharmaceutical companies, which he has suggested should be curbed. His concluding words are:

> "... the drug companies must not be permitted to become hazards to health in the under-developed world by failing to provide information or by drawing care resources away from more effective projects".

As Chudnovsky[53] has pointed out, a quality identification function in respect of manufactureres' brand names has become largely redundant in those countries where national licensing systems have set up satisfactory facilities for testing the standards of the medicines they manufacture or import. Once such facilities exist, it may be possible to introduce a policy of encouraging the use of generic, as opposed to branded, products by the medical profession. Nearly all states in the USA have now introduced laws which require prescribing doctors to indicate specifically if the product they prescribe is medically necessary or if a substitute may be dispensed and a policy of introducing generic prescribing in Cuba, Costa Rica and Sri Lanka has achieved significant results.[54]

8.5 CONCLUSION

It has been seen that MNEs in the pharmaceutical industry make extensive use of both patents and trade marks to protect their property rights. In the case of patents, MNEs obviously wish to have the longest period of protection within which to expoit their monopoly. This policy may conflict with that of developing countries who wish to import raw materials or finished products from the cheapest source available. In order to protect their position, it may be in the interests of developing countries to have a weak, or perhaps even no, patent protection. From this it is clear that the patent system plays an important role in the transfer of technology to developing nations. Lall has argued[55] that it is necessary to consider the political-economic structure of the country seeking to develop the technology in question. If this follows a Socialist pattern, the international patent system has nothing to offer in seeking to attract foreign technology or in promoting domestic innovation. If, on the other hand, the

developing country adopts a capitalist regime it may be better to remain within the international patent system and use this as a bargaining position to obtain the best terms of transfer.

In the case of trade marks, these enable MNEs in the pharmaceutical field to maintain their hold on their market share for a period much longer than that for which the patent period extends. This influence may be weakened by the implementation of a policy of encouraging generic prescribing by doctors, such as being done in many states of the USA. Such a policy may be successful in reducing the medicines bill. Chudnovsky[56] has, however, identified a trend which suggests that MNEs, conscious of the success of generic prescribing, are themselves beginning to concentrate on the generic part of the pharmaceutical market, thereby undermining the desired savings in costs which led to the adoption of the original policy.

The main sources of market power held by MNEs stem from their resources for both research and development and extensive marketing promotion for the product thereby invented. This power is developed by the exploitation of property rights in patents and trade marks so as to obtain, and hold for as long a period as possible, their market share. Given the international nature of the market in pharmaceuticals, it seems clear that only an international body such as WHO, UNIDO or UNCTAD has a sufficiently wide jurisdiction and influence to be able to negotiate on an equal footing for terms upon which technology in the pharmaceutical industry may be transferred from the developed to the developing countries of the world. Practices such as transfer pricing also require action upon an international level to be successfully combatted.

NOTES

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16. See paragraph 164 of the Report.

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21. Op.Cit. at Note 11 above at pages 89 to 90.

22. Public Law Number 692 in United Statutes at Large, Volume 49, Part I, page 1526.

23. Op.cit. at Note 11 above at page 90.

24. Chudnovsky, Daniel "Patents and Trade Marks in Pharmaceuticals", World Development, Volume XI, Number 3, page 187.

25. Gereffi, Gary "The Pharmaceutical Industry and Dependency in the Third World", Princeton University Press, 1983, page 107.

26. See Part II.

27. Scrip, Number 403, 4th July 1979, page 6.

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31. Chudnovsky, Daniel "Patents and Trade Marks in Pharmaceuticals", World Development, Volume XI, Number 3, page 187.

32. Chudnovsky, op.cit., page 188.

33. Chudnovsky, op.cit., page 188.

34. Norris, Ruth "Pills, Pesticides and Profits : the International Trade in Toxic Substances", North River Press Inc. [1982], page 10.

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CHAPTER IX - SOME LEGAL PROBLEMS CONCERNING THE SUPPLY OF MEDICINES TO THIRD WORLD COUNTRIES

9.1 INTRODUCTION

MNEs in the pharmaceutical field have, in recent years, come under criticism from many quarters about alleged marketing abuses in the Third World. It is proposed to examine some of these criticisms which contain a legal element to form a view as to whether they are justified. As a general background to this it is necessary to bear in mind the differing circumstances prevailing in the developed and developing countries respectively. In the latter, organised health care may be limited to urban areas, where there are doctors, pharmacists and hospitals. Rural areas may well lack these services either entirely or to an adequate level.[1] Clean drinking water and proper sanitation may be lacking and poverty and malnutrition widespread. Given these conditions it may well be understood that the requirments of the Third World differ considerably as to the medicines marketed in the Developing countries of, say, Europe and North America. An important aspect of any supply system for medicines is the control over safety and quality of both imported and locally produced products. A recent Report[2] has revealed that more than one-half of the developing countries of the Commonwealth do not have control laboratories for medicines. Further, it was considered doubtful whether some of them had any other control facilities such as legislation governing the registration and inspection of medicines.[3]

9.2 APPROPRIATE PRODUCTS

In considering whether the supply of pharmaceutical products is appropriate to the needs of the Third World, two aspects of this question need to be discussed.

First, whether the products are effective in reducing mortality and morbidity rates. Secondly, whether the products supplied are relevant to the disease pattern encountered in the Third World.[4] Medicines are not synonymous with good health, but merely one factor which may promote it - others being nutrition, education, hygiene and poverty. This first aspect is concerned with the efficacy of the product and must be largely determined by the prescribing doctor. It is his experience which will ultimately determine whether the product in question compares with rival products on the market. In the developed countries, where large numbers of products are available for similar conditions, that comparison is much easier to make than in the developing countries, where the doctor may be faced with a much smaller, or perhaps no effective, choice at all.

The second aspect of the question of whether products are appropriate is more complex. With regard to the diseases encountered in the Third World, Goodwin[5] has listed the following six as identified by WHO has been particularly important for drug therapy for large groups of people:

Disease	Number of People Infested
Malaria	200,000,000
Schistosomiasis	200,000,000
Filariasis	300,000,000
Trypanosomiasis	8,000,000
Leishmaniasis	2,000,000
Leprosy	11,000,000

In connection with these six diseases, Goodwin observed that none of the sixty-one new drugs registered for use for the year 1975 had anything to do with these or any

other tropical disease and that this was not unusual. Yudkin[6] has identified the fact that it is the promotional activities of pharmaceutical companies that is a major factor in determining a developing country's expenditure on drugs. Evidence for this proposition was obtained by an analysis of the prescribing pattern in the large hospitals in the country studied. This pattern had an emphasis on psychotropic drugs and expensive proprietary forms, which was similar to that found in an industrialised country. But Yudkin found a more serious ground for complaint. Many medicines found in his study were being promoted in the developed country for indications for which they were not authorised in their country of origin, and for which their use could be dangerous. In addition to this, some of these products were being supplied without adequate warnings for possible side-effects or contra-indications. In his conclusion, Yudkin (inter alia) called for a more responsible approach by the pharmaceutical industry to the problems of the Third World whereby:

> "... the drug companies must not be permitted to become hazards to health in the underdeveloped world by failing to provide information or by drawing scarce resources away from more effective projects".

Evans et al[7] have looked at this problem from a broader base. They have observed from experience drawn in such underdeveloped countries as China, where there is access to primary health care, that there is a rapid increase in the consumption of medicines where this occurs. Almost universal access exists in China through the "barefoot doctor service", with nearly all patients receiving some form of medication.[8] From this Evans et al. have

concluded that the search for health technology at an appropriate financial and organisational level must be a high priority for the developing world and, in particular:

> "Greater attention should be given to research and development on the "tropical" diseases, which are a major component of the disease burden of developing countries but have been largely neglected by the world's scientific community. Pharmaceuticals are of special importance since the timely supply of essential drugs is critical to the quality of health care and the credibility of community health workers. The dangers of excessive use or inappropriate choice of drugs necessitate the introduction of policies on procurement, prescription, pricing and quality control to avoid health hazards and excessive costs".[9]

In relation to the provision of vaccines to developing countries, Simon[10] has drawn attention to some figures presented to the Senate Sub-committee on Health and Scientific Research in 1977. It was reported that some 15.6 million children under the age of five had died throughout the world in 1976. Of these children, 15.1 million had lived in one of the developing countries, where 2.6 million had died of diseases against which cheap, effective and safe immunising agents exist: 1.2 million had died from measles; six-hundred thousand from tetanus; five hundred thousand from poliomyelitus; and three hundred thousand from whooping cough. Further evidence presented to that sub-committee showed that six hundred and fifty million people in the world were infected with ascaris; four hundred and fifty million with ancylosteomiasis; two hundred and fifty million with filariasis; eighty million with schistosomiasis; two hundred million with malaria; four hundred million

people had trachoma; twenty million people were estimated to be infected with tuberculosis and ten million with leprosy. In spite of these figures, however, there were no vaccines available against any of these diseases. The Senators concluded that the humanitarian interests of the USA demanded an involvement in seeking a solution to these problems. Simon's conclusion was that the evidence showed that the USA played a fairly small role in the search for pharmaceuticals which could be used against the diseases of primary concern to the Third World. Upon a similar theme is the suggestion that the pharmaceutical industry should fund a new Institute of Tropical Disease Research.[11] Such an approach would, it is suggested, do much to demonstrate the goodwill of the pharmaceutical industry towards the Third World.

There is further evidence that the Third World is being supplied with many medicines of an inappropriate kind. In India, Deolalikar[12] established that the most prevalent diseases found in the sub-continent were primarily parasitic - namely, filariasis, malaria and dysentry, with leprosy and tuberculosis also being fairly common. In spite of this, vitamins, cough and cold preparations, tonics and health restorers accounted for almost twenty-five per cent of the total sales of pharmaceuticals. The position is the same in both Sri Lanka and Tanzania. In the former Agarural[13] found that over fifty per cent of the production of the seven private companies that had control of the pharmaceutical industry in 1972 consisted of vitamin preparations, cough remedies and soluble aspirin. Five of those companies were subsidiaries of MNEs, while the remaining two were manufacturing under licence from MNEs. In Tanzania, Yudkin[14] noted that the five patented medicines used most frequently for the treatment of tropical diseases amounted to only 2.6 per cent of the national medicines budget, whereas the sales of the two tranquillisers,

valium and serenace represented more than three per cent of the medicines budget. Melrose has found similar facts in relation to Bangladesh prior to the new drug policy announced there in 1982.[15] She has reported that almost one-third of the market consisted of products not essential to the pressing needs of the poor. In contrast to this, the subsidiaries of MNEs which had the ability to produce essential drugs, were in fact producing large quantities of vitamin mixtures, tonics and cough and cold preparations. A document prepared by WHO has summarised the position in this way:

> "In recent years many medicinal products have been marketed with little concern for the differing health needs and priorities of different countries. Promotion activities of the drug manufacturers have created a demand greater than the actual needs".[16]

In defence of the pharmaceutical industry, the International Federation of Pharmaceutical Manufacturers' Association has drawn attention to the research carried out, and products introduced, by its members on diseases of the Third World.[17] Among several MNEs which are listed, two should be mentioned. First, Parke-Davis, a subsidiary of the Warner-Lambert company, began working in parasitology more than forty-five years ago, concentrating on malaria. During the 1960s, it invested some sixteen thousand dollars in anti-parasitic research, which accounted for between six per cent and thirteen per cent of its annual research budget. As a result of its research, the company had developed and marketed seven different drugs for malaria, two for leprosy and one for leishmeniasis.

Secondly, Ciba Geigy had developed a product (Ambilhar) used for the treatment of schistosomiasis throughout the Middle East, Africa and Latin America and two further products (Rimactin and Lanprene) for the treatment of leprosy. Among other companies involved in research in tropical diseases, Pfizer was noted for its introduction of Oxamniquine in 1970 for the treatment of schistosomioasis. Further, Wellcome Research Laboratories (a division of Burroughs Wellcome Company) was reported as spending between fifteen per cent and twenty per cent of its total research budget on tropical diseases. That there is a range of modern medicines developed by the research orientated pharmaceutical industry for the treatment of tropical diseases may be seen from the following table taken from Taylor's Paper written for the Office of Health Economics:[18]

Approved names	Indications
Amoxycillin	Typhoid Fever
5-Fluorocytosine	Anti-Fungal agent (especially for Chromomycosis)
Sulfametopyrazine and pyrimethamine	Anti-malarial
Freeze-dried preparation of the living attenuated 17D vaccine voris strain	Yellow Fever
Trimethoprime and Sulphamethoxazole	Typhoid and Paratyphoid fever. Bacillary dysentry, cholera, acute brucellosis, mycetoma, systemic fungal infections
Metrifonate	Schistosomiasis
Praziquantel	Schistosomiasis, Helminthiasis

Approved names	Indications
Sulfadoxine and Pyrimethamine	Suppressive and curative treatment of malaria
Stibophen	Schistosomiasis
Secnidazole	Amoebecide, Trichomonacide
Metronidazole	Amoebiasis
Bitoscanate	Hookworms (Ankylostome duodenale and Necator americanus)
Levamisole	Roundworm infestations
Nifurtimox	Chagas disease
Clofazimin	Leprosy (all forms)
Pyrimethamine and Dapsone	Prophylaxis of malaria, especially where resistance to antifolates exists
Benznidazole	Chagas disease
Rifampcin	Tuberculosis, Leprosy
Ornidazole	Giardiasis (lamlliacide) and for all forms of amoebiasis

There is evidence to suggest that the international pharmaceutical industry has experienced a declining rate of innovation of the more important products in recent years. Grabowski has put forward the following hypothesis for this decline:

i. Stricter control of the industry by the USA Food and Drug Administration.

ii. A depletion of research opportunities brought about by the rapid rate in new drug development in the 1950s.

iii. The effect of the thalidomide tragedy of the early 1960s, which made both doctors and pharmaceutical companies more anxious in their decisions about the marketing and prescribing of new products.

iv. Advances in pharmaceutological science, which have led to increased safety testing and therefore higher costs in the development of new products.[19]

Grabowski's analysis[20] found that productivity, as defined by the number of new chemical entities discovered and introduced in the USA per dollar of expenditure on research and development, declined about six-fold between 1960 and 1961 and 1966 and 1970. In contrast to this, the corresponding decrease in the United Kingdom was about three-fold.[21] Douglas has also drawn attention to the steep decline in the productivity of drug research in the USA following the amendments made in 1962 to the Food, Drug and Cosmetic Act 1938.[22] These amendments, the so-called Kefauver-Harris amendments, had the effect of tightening up the safety of requirements for testing new prescription drugs. They also provided that products had to be proved effective, as well as safe, before being placed on the market.[23] While these studies are of general application, not being confined to products designed for Third World diseases, it is suggested that this overall decline in the introduction of new products would affect the numbers of the Third World as much as (if not more) than products designed for the home market.

More recently there have been further changes in the USA which are likely to have a significant impact upon the pharmaceutical industry. One of these changes is the rewriting and modification of the regulations to be complied with in connection with applications for the use of a drug for clinical testing and of placing a new

product on the market. Mattison[24] has expressed the view that the proposed new regulations appear to be designed to affect development and approval in several ways by:

i. eliminating or simplifying some regulatory requirements.

ii. clarifying existing policy and practice and stating these for the first time in the regulations.

iii. improving co-operation between the regulatory authority and industry.

iv. setting specific time limits on both industry and the regulatory authority for completion of action.

This revision of the regulations has taken place within the context of the Reagan Administration's commitment to reduce all Federal regulation and Mattison has noted[25] that a more open relationship now exists between the Food and Drug Administration and the pharmaceutical industry than that which prevailed during much of the 1970s.

The second recent change identified by Mattison[26] is the increased demand for safety, following several tragedies which have occurred in the 1980s involving products under the aegis of the Food and Drug Administration. There has also been an increase in both the numbers of Court cases brought against pharmaceutical companies in the USA in recent years and also higher levels of compensation and legal costs. As an example of high settlement costs is the payment by Eli Lily of six million dollars to settle the first of several cases brought by a family of a benoxaprofen victim.[27]

An additional change noted by Mattison is two legislative Acts - namely, the Drug Price Competition and Patent Term Restoration Act of 1984 and the Orphan Drug Act of 1982. The first of these lengthens the patent life remaining after a new product has been granted approval for marketing to compensate for time lost in meeting requirements for research data and review by the regulatory authority.[28] Under the Act, a five year period of exclusivity is guaranteed for products approved after enactment (ie after 24th September 1984), regardless of patent status. In addition to this, some of the patent life that expires during research and review may be restored after approval. Taking these two provisions into account, a product is guaranteed exclusivity for a period up to fourteen years (any patent life remaining at the time that approval is granted plus time granted under the enactment). Whilst it is yet too early to make an assessment as to how this Act will affect the pharmaceutical industry, it is suggested that it will be beneficial to those companies which rely on research and development and produce products which may benefit from strengthened patent and protection. It has been described as "unquestionably the most important piece of legislation affecting the [United States] drug industry on twenty years",[29] and will undoubtedly give an incentive to innovation,, which may indirectly benefit the Third World.

The second recent enactment, the Orphan Drug Act, is of more direct relevance to the Third World. Under its provisions companies are given special incentives to develop these drugs, including a fifty per cent tax credit and a period of exclusive marketing for non-patentable drugs.[30] The term "orphan" is defined in the Act as one intended to treat a disease or condition with a prevalence in the USA of less than two hundred thousand patients. By

September of 1985, thirty-seven drugs had been granted orphan status under the Act, of which five had received marketing approval.[31]

It is, however, not only legislation passed in developing countries which may have a significant impact upon the supply of appropriate medicines to the Third World but also legislation passed in the Third World itself. In this connection the position in Bangladesh presents a useful case study. Earlier legislation was based upon the Drugs Act of 1940 which was described in the following terms by the Drug (Control) Committee which reported its recommendations on 11th May 1982:

> "Much of the unethical practices in manufacture and trade is possible because of the weakness of existing legislation ... There is no provision in the Drugs Act for the control of prices of pharmaceutical raw materials or finished products".[32]

On 12th June 1982 the Bangladesh Government promulgated the Expert Committee's recommendation as the Drugs (Control) Ordinance 1982. The Expert Committee had evaluated the four thousand, one hundred and forty allopathic medicines on the market according to scientific criteria and recommended that about one thousand seven hundred of them should be banned according to three schedules. Drugs in Schedule I were deemed positively harmful: both production and importation of these products was to stop immediately and they were to be withdrawn from the market within the period of three months. Drugs in Schedule II required some reformulation, for which a six-month period was allowed for disposal of existing stocks and submission of proposals for reformulation. Schedule III consisted of products falling into one of two groups - first, combinations of little or no proven

therapeutic value; secondly, useful products which were either being manufactures under licence by a MNE with no factory in Bangladesh or were being imported whilst also being manufactured locally, or were simple preparations. This last category were to become the manufacturing responsibility of local companies. Schedule III drugs were to be banned after a period of three months. On 7th September 1982 the Drugs (Control) (Amendments) Ordinance (1982) was passed, which made some amendments to the Drugs (Control) Ordinance 1982.[33]

Opposition to the policy of the Bangladesh Government has been severe but it did receive support from the Director-General of WHO, who congratulated Bangladesh on "Its courage in starting to put its drugs house in order along the lines recently endorsed by the World Health Assembly".[34] Rolt has expressed the view that the new policy of the Bangladesh Government had a significant impact upon the production and costs of essential drugs and that even more dramatic improvement may be expected in the future.[35] Jayasuriya has suggested that the new Bangladesh drug policy is not an unqualified success.[36] His conclusion is that new efforts still need to be made to create an environment in which all concerned - government, drug manufacturers, health care providers, pharmacists and others can work together to identify the policy strengths and correct its weaknesses.

While legislation may have the effect of reducing the exploitation of MNEs of underdeveloped countries, it does not necessarily follow that this will be successful. Yudkin[37] has commented that reforms in drug legislation in Sri Lanka failed because there were not accompanied by a change of attitudes towards health and health care. But Mozambique has been able to achieve some major changes in health care provision since liberation, with the number of drugs on the national list having been reduced from

one thousand one hundred before independence to less than three hundred.[38] In Tanzania the Ministry of Health, by administrative means, restricted the list of medicines which were purchased and sold by the Central Medicinal Stores, which provides about ninety per cent of the medicines through goverment hospitals and health units.[39] In his analysis of the prescribing pattern in the largest hospitals in Tanzania, Yudkin found that this followed what he had found in developed countries. His view was that it was often "inappropriately extravagant" for patients to be treated in those hospitals, who frequently had conditions that could be managed at the primary or secondary level. In addition to this, a large number of the medicines used were expensive proprietary medicines.[40] Yudkin's conclusion is that future developments in the supply, distribution and use of medicines were essential to the implementation of appropriate health care strategies in Tanzania, committed as it is to a policy of rural development and Socialism. Part of this policy will be to distribute some health care expenditure away from hospital services towards prevention and primary care.[41]

9.3 APPROPRIATE PRICES

In the last decade, almost seventy-five per cent of world production of pharmaceuticals has taken place in only six developed countries. Despite the fact that there are no significant economies of scale in the manufacture of medicines, over fifty per cent of the world production in pharmaceutical products was concentrated in thirty MNEs.[42] While there is this concentration of production in the control of MNEs the prices at which medicines are made available on the market vary considerably from country to country.[43] One result of this price variation is that the cost of medicines to the Third World is often unnecessarily high. It has been found that

prices for chloroquine and talbutamide may vary by a factor of seven times, prices for tetracycline vary by more than ten times and prices for penicillin may vary by fourteen times.[44]

Part of this large variation in price level may be accounted for by the practice of transfer pricing, which has been discussed above. Other factors which may be relevant are the size of markets, government regulation, research costs and the absence or presence of a National Health Service.[45] In a free market economy, one would expect that the price of medicines would be at the level which the market would bear, particularly when sold by MNEs.

A number of policies have been advanced which might have the effect of reducing the price of pharmaceutical products to the Third World. UNCTAD has, in particular, detailed five possible policies which might achieve this result:

i. A rational choice of medicines.

ii. A public distribution system.

iii. The use of bulk import orders.

iv. The use of generic names.

v. The domestic production of medicines.[46]

The first of these may be linked to the WHO list of two hundred basic and essential drugs, discussed in section 7.2. In support of this approach Dr Mahler is reported to have expressed the view that more than ninety per cent of the medicinal needs of developing countries could be met with more than two per cent of the drugs sold on the market.[47]

Patel[48] has suggested a way in which MNEs might assist in the implementation of the WHO policy. This could be achieved by pricing the sale of these medicines to the Third World at average, rather than marginal, costs. In this way, revenue from the products (as opposed to profits) would be maximised.

The second form of policy initiative proposed is the use of a public distribution system. This would have the effect of improving the quality of the medicines made available and reduce promotion and distribution costs of the manufacturers.[49] Related to this is the third proposal, whereby public purchases in bulk would replace numerous small private orders, thereby saving costs.[50] Overall savings in costs, by adopting these policies, has been estimated as reducing the costs of many medicines by a factor of over ten times.[51] Patel has suggested that the overall savings by the adoption of these policies might be sufficient to establish a national pharmaceutical industry in many Third World countries but the adoption of such policies would require the active support of such international agencies as WHO or UNCTAD.[52]

9.4 APPROPRIATE MARKETING

An area of particular legal concern in the field of supply of pharmaceuticals to the Third World is labelling. In this context the term "labelling" refers, not only to the information which appears on the package of the product but also additional information which may be directed to the prescribing doctor or pharmacist in the form of a data sheet, leaflet, advertisement or package insert. As may be seen from the IFPMA Code of Pharmaceutical Marketing Practices, set out in Appendix II, manufacturers have agreed "to base claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions for use".[53]

Nevertheless, it may well be that labelling differences may occur, for a variety of reasons, in the way in which the same product is labelled in different countries. In the developed world, the pharmaceutical industry is divided into two distinct sectors: the proprietary and ethical sectors respectively. For proprietary products, these are considered safe for self-medication, provided that labelling instructions are followed by the patient. In respect of ethical products, however, these may only be supplied on the basis of a doctor's prescription.[54] In most Third World countries the situation may be different. There, although a doctor's prescription may be legally required, many patients are able to obtain an ethical medicine from a pharmacist or even from an unqualified person without such a formality.[55]

From this it follows that the labelling of a medicine may be particularly important in the country of origin if the product is to be ultimately used in the Third World. Labelling of a medicine may serve a dual function. First, it may provide a prescribing doctor with scientific information about the product and how it should be used. Secondly, it has the function of seeking to gain and ultimately of retaining, a secure position in the market for that product. A large amount of money is spent by the pharmaceutical industry so as to make products distinguishable from one another. It has been estimated that the pharmaceutical industry in the USA, the Federal Republic of Germany, Italy, South America, Belgium and Canada spends more than twenty per cent of its total annual sales on product promotion.[56] A further difficulty for product labelling is that the regulatory authorities may, in different countries, disagree about the potential hazards of a product. The company may therefore have a number of choices open to it in deciding which warnings a medicine should carry if marketed in the Third World.[57]

9.5 CONCLUSIONS

It is submitted that the evidence examined above suggests that the supply of medicines to the Third World should not be left to market forces of supply and demand alone. International organisations such as WHO and UNCTAD have drawn attention to the desirability of establishing and implementing a policy of a basic medicines list drawn up with due regard to the particular health requirements of the country concerned. Such a list must contain only those products which are safe, efficacious and of good quality, based upon present scientific criteria. Supply of such medicines must also be reinforced by scientifically based and objective information about those products, made available to prescribing doctors and pharmacists. Diffusion of this information may also have to be carried out by public undertakings to ensure that the policies are properly understood and followed. Once such policy has been decided upon, consideration must be given as to how the listed medicines may be made available at the most reasonable price by appropriate imports and domestic production. It is by the implementation of such policies that the power of MNEs may be contained and controlled. There is clearly much to be gained by the Third World, and much to be lost by MNEs, in the adoption of such proposals. Clearly, some reconsideration of the appropriate roles of patents and trade marks would have to be undertaken if these proposals were implemented. There is also an important part to be played by international health organisations in enabling these policies to be pursued.

MNEs have a dominant position in the world market for medicines: the top fifty companies, all based in industrialised countries control the supply and promotion of one-half of all the medicines sold.[58] It has long been recognised that the Third World cannot effectively

control the activities of MNEs and that MNEs and their host countries may well have conflicting objectives. With a view to dealing with these problems, the United Nations Programme of Action on the Establishment of a New International Economic Order has recognised the need for an international Code of Conduct for MNEs:

> i. to regulate their activities in host countries, to eliminate restrictive business practices and to conform to the national development plans and objectives of developing countries.
>
> ii. to bring about assistance, transfer of technology and management skills to developing countries on equitable and favourable terms.
>
> iii. to regulate the repatriation of the profits accruing from their operations, taking into account the legitimate interests of all parties concerned; and
>
> iv. to promote the recruitment of their profits in developing countries.[59]

Such a Code of Practice would undoubtedly improve the position of Third World countries with regard to the distribution of essential medicines. Nor is there any conflict in the adoption of such a policy with the trading influence of either GATT or the EEC, neither of which has yet developed a trading policy with regard to medicines. This would not, however, result in there being no continuing need for legislation governing various aspects of the supply of pharmaceuticals upon a national basis. Jayasuiya[60] has set out the principal reasons why such legislation is needed and why this has been introduced in almost every country of the world. Such laws govern such considerations as the safety, quality and efficacy of products; the condition that certain medicines may only be

supplied by a qualified doctor on prescription; and controls on the manufacture and distribution of medicines. A further aspect of legislation of this kind has been given prominance in recent years. This concerns the need for full and accurate disclosure of basic information about medicines in labelling and advertising. Differing practices in various countries have been made a special study by various writers.[61]

While it is a common feature of legislation in all countries that there is some degree of control and regulation over the pharmaceutical industry the measures adopted often have contradictory aims. Thus, a Ministry of Health may be primarily concerned with the safety of medicines, while the cost of those products may be the responsibility of the Ministry of Finance. Again, a Ministry for Industry may be anxious to develop a national pharmaceutical industry, while the concern of a Ministry of Trade may be to reduce a balance of payments deficit. These conflicting aims may well be found in both the developed and the developing countries. There has also been a certain degree of harmonisation in the EEC by the adoption of the Pharmaceutical Directives, resulting in the removal of trade barriers in this areas over the last twenty years. It has been seen that medicines manufactured and controlled in one Member State may in principle be imported into another Member State without further controls being imposed. Once the process of applying Community requirements to products which were already on the market before the adoption of the Pharmaceutical Directives has been completed, some real and effective progress towards the establishment of a real common market in medicines will have been made in Member States of the EEC. But WHO has the potential legislative power to impose legal provisions on a wide-ranging basis upon all of the Member States of the United Nations. These powers are not in practice exercised without the

consent of Member States, these powers not being (unlike those of the EEC) upon a supranational level. In addition to these powers, however, WHO has a world-wide influence on international trade in medicines through its Certification Scheme, its Action Plan on Essential Drugs and the information which it collects and disseminates.

With regard to the pattern of world trade in pharmaceuticals, several trends can be identified.[62] Trade in finished pharmaceuticals is very largely from the countries of Western Europe to the Third World. Despite their large output and consumption, both the USA and Japan both import and export relatively small amounts of such products. In relation to intermediate products, the USA provides twenty-three per cent of all exports and has a trade surplus with all of its partners on this account, with some of this being between the USA patent companies and their overseas affiliates. Japan, Canada, Australia and South Africa are all substantial net importers. One-third of world trade for intermediates is within Europe, which has a negative balance with the USA but a large surplus with the Third World. With regard to the United Kingdom pharmaceutical industry, between 1974 and 1984 exports to Commonwealth countries more than doubled at 1984 prices, those to Japan trebled, those to EEC countries increased five-fold, while those to the United States increased by more than seven-fold.[63] These figures suggest that the United Kingdom is increasing its trade in medicines with countries of the developed world rather than the Third World.

The Third World imports both finished and intermediate products on a large scale. Europe dominates in the supply of finished products to the Third World, particularly France, Germany, the United Kingdom and Switzerland. There are large developing markets in Africa and the OPEC countries of the Middle East. There is a suggestion that

former colonial ties are still maintained with commercial links. France exports nearly forty per cent of her total trade in pharmaceuticals to French-speaking African States. The United Kingdom dominates the trade in pharmaceuticals within English-speaking Africa and similar patterns emerge in relation to trade between Belgium and Zaire, Portugal with Angola and Mozambique and Spain in South Africa. During the past twenty years, world trade in medicines has increased from about twelve per cent to sixteen per cent of output, while the proportion of intra-OECD trade in medicines has risen from fifty-one per cent to sixty-eight per cent. There has bee a steady increase in trade between the European countries. In the USA its share of world trade in pharmaceuticals has fallen from twenty-nine per cent in 1960 to fifteen per cent in 1970, where it has remained constant. This reflects the advance in the manufacture of medicines by other countries and the adoption of a multi-national strategy by the major American countries. There is little doubt that the competitive strength of Japan in pharmaceuticals is rising, with Japanese companies now accounting for more than twenty per cent of new chemical entities introduced each year, although it still lacks international orientation compared to larger established organisations.[64]

It is submitted that these complex trade patterns should be subjected to the jurisdiction of one international organisation with responsibilities over the whole range of pharmaceutical policy. This would be more likely to achieve a uniform approach in this field than if it were left to the piecemeal controls which presently exist. It is suggested that the concept of some international regulation of the pharmaceutical industry would be generally desirable. Of the existing international organisations which could assume this role, WHO seems at present to be the most appropriate candidate, although the

EEC could conceivably do so if it chose to apply the doctrine of parallelism to an external trade policy in pharmaceuticals.[65]

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60. Jayasuriya, D C "Regulation of Pharmaceuticals in Developing Countries : Legal Issues and Approaches", WHO, Geneva [1985], pages 7 and 8.

61. Medewar, C and Freeze, B "Drug Diplomacy", Social Audit, London [1981]; Yudkin, John S "Provision of Medicines in a Developing Country", The Lancet 1: 810-812 [1978]; Jayasuriya, D C "Regulating the Drug Trade in the Third World", World Health Forum, 2: 423-426 [1981]; Fazel, A "The right pharmaceuticals at the right prices : consumer prospectives", World Development, 11: 265-270 [1983].

62. "The Pharmaceutical Industry : trade related issues", Organisation for Economic Co-operation and Development, Paris [1985]; and Burtsall, M J "The Community's Pharmaceutical Industry", Commission of the European Communities, Luxemburg [1985], page 125.

63. "A New Focus on Pharmaceuticals", (Pharmaceutical EDC), HMSO (1986), page 4.

64. Burtsall, op,cit., page 125 et seq.

65. It has been formally recognised that the WHO and the EEC have common interests in a number of fields relating to health on a global level. Representatives from each body attend as observers at each others' meetings on these subjects. See the exchange of letters between the EEC and WHO laying down the procedure for co-operation between the two organisations dated respectively the 28th April 1982 and 2nd June 1982. [O J 1982, L300/20 and 21 respectively.]

PART IV

CHAPTER X

CERTAIN LEGAL PROBLEMS PRESENTED BY THE MANUFACTURE AND SUPPLY OF MEDICINES IN RELATION TO INTERNATIONAL TRADE

10.1 INTRODUCTION

In this Part some underlying and recurring themes are considered which arise in relation to international trade in medicines by reference to some case studies. Some discussion is also included of some current trends in this field which are likely to result in future legislation or non-legal controls. These themes concern the safety and quality of pharmaceutical products and the prices at which they are placed upon the market. In relation to safety there also falls for consideration the question of whether satisfactory national legislation is available to provide a framework for redress to those who are injured by unsafe products.

The thalidomide tragedy is the most serious of modern episodes in relation to safety of medicines. But, as will be seen, other products have been placed upon the market after that which have subsequently been found to be unsafe. As a result of this damage has been suffered which, under the existing United Kingdom law, has singularly failed to provide a satisfactory remedy for injured persons in this area. Related to the question of redress is the problem of providing systems which will be likely to provide swift warning of adverse reactions and thus alert both manufacturers of products and licensing agencies of safety problems. This is particularly important where medicines are moving across national boundaries, which the GATT and EEC treaties encourage. It is in this context that the concept of post-marketing surveillance is examined.

Also related to the issue of safety is the gradual emergence of some consensus, at least in Europe and the USA,about the concept of product liability as a mechanism to enable consumers to have a legal remedy where damage is suffered as a result of a defective product. Product liability poses some particularly difficult problems for medicines but no exception has been made for them in the proposed legislation for the United Kingdom.

With regard to quality (although there are also obvious safety connections) there has been come measure of harmonisation upon a non-statutory basis. This has been achieved by the Pharmaceutical Inspection Convention, originally developed by the European Free Trade Association, which has enabled exchange of information about manufacture of medicines and some consensus upon what constitutes Good Manufacturing Practice.

A further theme is the question of prices for pharmaceutical products. Here, a study is made of the Tranquillisers Report of the Monopolies Commission. There are some general conclusions arising from this which have important implications for international trade in medicines in relation to the problem of transfer-pricing.

10.2 THALIDOMIDE

Between 1958 and 1961 the Distillers' Company (Biochemicals) Limited put a medicine on the market in Great Britain called Disteval which contained Thalidomide.[1] This medicine was prescribed as a sedative to, among others, pregnant women. It was then discovered that Thalidomide, when taken by pregnant women, might cause deformities in the child. In England there were more than four hundred such cases. It has been estimated that ten thousand deformed children were born in those

countries where the product had been taken by pregnant women.[2] In its report upon this tragedy the Ministry of Health said:

> "The information obtained suggests that there are between two hundred and two hundred and fifty living children with limb deformities resulting from Thalidomide and a further fifty with deformities other than those of the limbs. The extreme upper and lower limits for the total of children with limb deformities are given on differing assumptions as four hundred and thirty and one hundred and fifty. The total foetus loss including abortion and still birth cannot be computed".[3]

Thalidomide was first launched in Germany in 1957 under the trade name Contergan, after which it was distributed in numerous countries throughout the world both alone and in combination with other substances.[4] In 1960 Richardson-Merell Incorporated made an application to the USA Food and Drug Administration for permission to sell Thalidomide as Kevadon. That application was refused[5] and was subsequently withdrawn, although pre-marketing trials by one thousand two hundred and seventy doctors resulted in the product being taken by over twenty thousand patients.[6]

None of the actions begun as a result of the Thalidomide affair was ever fully litigated, although various aspects of the case involving infant settlements were ventilated in the Courts.[7] This may seem surprising having regard to the fact that in 1958 Chemie Grunenthal circulated over forty thousand doctors in Germany stating that Contergan "Does not damage either mother or child".[8] Further, in October 1961 (and only a few weeks before the product was withdrawn from the market in the United Kingdom), the

British manufacturers and licencees issued an advertisement which stated that:

> "Distaval can be given with complete safety to pregnant women and nursing mothers without adverse effect on mother or child".[9]

It has been seen[10] that at the time when Thalidomide was put on the market in the United Kingdom there was no legislation to control the safety of medicines. As professor Sir Eric Scowen, a past Chairman of the Committee on Safety of Medicines remarked:

> "Lulled into security by the quiet years, both public and Government were unprepared for the therapetuc explosion of the last thirty years. This complacency was rudely shattered by the Thalidomide tragedy".[11]

There are three main points to be made arising out of the Thalidomide tragedy. First, it led to the enactment of the Medicines Act 1968 in the United Kingdom, with the responsibility for the giving of advice upon the safety of medicines being passed to an independent committee of experts.[12] This Committee of Safety on Medicines has also taken over the functions of monitoring adverse reactions to the use of medicines once they have been placed upon the market. In the United States the Kefauver-Harris amendments[13] to the Federal Food, Drug and Cosmetic Act 1938[14] were passed.

Under those amendments the powers of the Federal Drugs Authority have been much strengthened. In particular, products may now be summarily withdrawn from the market if they present "an imminent hazard to the public health". In relation to the Third World it must be remembered that the poor state of knowledge about medicines and their

correct use in Europe in the 1960s may be compared with the present state of such knowledge in the Third World today.[15]

If medicines continue to be traded across national boundaries the controls for safety which exist in the countries which manufacture those products must be extended to the countries which import them. If this is not done, then the danger of exporting a tragedy of Thalidomide proportions may become a real possibility.

Secondly, it has now become standard practice for data to be required to be supplied to show a product's effect upon the foetus of pregnant laboratory animals before such product is licensed for sale.[16] It must be emphasised that although legislation has an important role to play in controlling the safety of medicines, it is not the only relevant factor. With the advance of science, medical knowledge rapidly becomes out of date. There is a continuing need for safety aspects of products placed on the market to be monitored so as to ensure that risks are minimised. As Teff and Munro have concluded in relation to the Thalidomide tragedy:

> "As often happens with changes in the law, the very enormity of the disaster and manifest inadequacy of the legal structure to cope may yet be the spur to constructive reform".[17]

Tausigg, an American paediatrician who investigated the Thalidomide tragedy in Europe has made the cogent comment that the failure of Kevadon to reach the American market was "because a lucky combination of circumstances ... not because of the existence of any legal requirement that the drug might have failed to meet".[18]

Thirdly, it is apparent that the increased safety measures which were introduced as a result of Thalidomide have undoubtedly led to increased prices for medicinal products. In the Monopolies Commission report on the proposed merger between Beecham and Glaxo, and Boots and Glaxo, it is stated:

> "... the cost of research and development appears likely to increase in real terms. As official requirements for the safety of drugs are made more stringent, more time and effort are involved before a new drug becomes marketable, and risk and costs increase. A larger enterprise, such as that which would result from the proposed merger, would in principle be able to engage in research projects which might have been too costly or too risky for either company alone. Resources might be saved in some cases where each of the two companies would, in the absence of the merger, be doing similar work or using similar facilities. Further, insofar as the enlarged enterprise had advantages in international marketing this could provide more funds for research and development. By increasing this possible award of innovation it could also stimulate the devotion of resources to this purpose".[19]

10.3 SAFETY PROBLEMS AFTER THALIDOMIDE

There have been a number of products withdrawn from the market upon the grounds of safety since the Thalidomide tragedy, either voluntarily by the manufacturers or compulsorily by licensing authorities. Haas et al. have prepared a Report[20] comparing the relative rates of discontinued new chemical entities in the United States and the United Kingdom respectively during the period from

1960 to 1982. During this time some six hundred and fourteen new chemical entities were introduced on to the markets of those countries.[21]

By the end of this period ninty-three of the products introduced to the United Kingdom market, and forty of the products introduced to the USA market, had been withdrawn. Ten of the United Kingdom withdrawals, and eight of the USA withdrawals, were associated with severe safety issues.[22] Practolol was withdrawn from general use in the United Kingdom in 1974 for safety reasons. But as it was still available in hospitals in the United Kingdom at the end of 1982 for emergency control of certain arrhythmias, it is not included in the list of products withdrawn from the market for the purpose of the studies.[23] These figures show that effective legislation and control over licensing systems have been able to identify safety issues arising in connection with products recently placed upon the market. But such controls have not been able to ensure that products with potential safety problems never reach the market. Some specific safety issues which have arisen since the Thalidomide tragedy are now considered.

Two of the more recent examples of medicines placed upon the market, and then subsequently withdrawn because of serious safety issues, have concerned products which have been long recognised as having a substantial potential for producing toxic effects. First, the non-steroidal, anti-inflammatory agent Opren was marketed in the United Kingdom in 1980[24] by the American company Eli Lilly. Advertisements for the product described it as a brand new anti-arthritic agent with only mild side-effects which could modify the arthritic disease process.[25]

Then, just twelve months after the launch of the product on the United Kingdom market, an assessment of the product by the Drug and Therapeutic Bulletin included an assertion that "Opren appears no better than other drugs in this category, nor effective when the others have failed".[26] In May of 1982, the Committee on Safety of Medicines recommended that the dosage of the product in elderly patients should, as a precaution, be halved.[27] Important evidence considered by the Committee included a Paper by Taggert and Alderdice[28] which reported that five patients over eighty years of age who had been taking the product had developed jaundice and had died.[29]

Opren was given an extensive coverage in the Annual Report of the Chief Medical Officer for 1982.[30] In this Report it is stated that the product licence for Opren was suspended on the grounds of safety after the Committee on Safety of Medicines had received over 3,500 reports of adverse reactions associated with the drug, including sixty-one deaths, predominantly among elderly users. Following from this suspension by the Committee, the manufacturer withdrew the product on a world-wide basis and surrendered the licences which had originally been granted by the licensing authority in the United Kingdom.[31]

In its comments upon the Opren episode, the Lancet observed:

> "The Opren case has shown us, yet again, that new drugs can have new and serious unwanted effects, it has confirmed the importance of reporting "events" rather than merely "adverse effects"; it has shown that doctors will prescribe a drug with novel pharmacological properties in the absence of evidence from clinical trials that these

properties confer any benefit upon the recipients; it has demonstrated that intensive marketing methods are effective even when directed at a highly sophisticated consumer; and it implies that the CSM has formed an unflattering, but perhaps realistic, opinion of the prescribing abilities of doctors".[32]

Parliamentary questions raised and discussed in connection with Opren established that it had been marketed for about twenty-two months, during which time some 1,500,000 prescriptions were issued for it in the United Kingdom.[33]

Phillipson[34] has drawn attention to the vulnerable position of the increasing population of the elderly in the United Kingdom having regard to their dependence upon medicines. Some three-quarters of those over the age of seventy-five years are taking one medicine and one-third take between four and six medicinal products at the same time.[35] As a result of the review of Opren and other anti- inflammatory agents, the Committee on Safety of Medicines have indicated that data on the effects of a new drug on the elderly would have to be provided in specified circumstances before such products were put on the market in future.[36] More than seven hundred writs were issued against Eli Lilly as a result of the marketing of Opren and both the Committee on Safety of Medicines and the Department of Health and Social Security were joined as defendants to the actions.[37] On 9th December 1987 Hirst J commented in open Court upon the proposed terms of settlement of the Opren actions and on the desirability of a settlement being reached by the parties.[38] It was stated that after prolonged and intense negotiations Eli Lilly had made an offer of a global sum in full and final settlement of the claim without any admission as to causation of injury or as to liability.[39] Certain special features of the case were mentioned, one being

that it had involved the discovery and inspection of millions of documents, and assessment and scrutiny by several categories of scientific, medical, pharmaceutical and legal experts.[40]

A second recent episode concerned the product Osnosin, a sustained release version of the non-steroidal, anti-inflammatory agent Indomethacin. This product was first placed on the market in the United Kingdom in December 1982 and soon became subject to the attention of the Committee on Safety of Medicines. In its comments upon the product the Committee drew attention to the supposed method of action "by an Osmotic pump action as the tablet passes along the gut".[41] In this same publication the Committee noted two reports of intestinal perforation, distal to the duodenum and observed that "this is an unusual site for damage with non-steroidal, anti-inflammatory drugs".[42]

It was also noted that about two hundred "yellow card" reports about adverse reactions associated with the product had been received, although only a little over four hundred thousand prescription had been written for it. This was regarded as a high level of reporting even for a newly marketed product.[43] This product was eventually withdrawn from the world market in September 1983 and the United Kingdom product licence was surrendered in January 1984.[44] A total of forty deaths have been estimated as having been attributable to the product. In Parliamentary replies the Health Minister gave the following figures for deaths registered by the Committee on Safety of Medicines in respect of Osmosin and three other products, all of which had been recently withdrawn from the market:[45]

Product	Number of Deaths
Zomax	7
Zelmid	7
Osmosin	40
Flosint	8

Another product which became associated with adverse side-effects, this time of a completely unexpected nature, was Practolol. This product was first marketed in 1970 as a Beta-blocking agent and was subsequently found to cause permanent serious eye and skin disorders.[46] It was not until 1975 that the full extent of the problems associated with the drug became apparent, by which time it had received some three hundred thousand patient-years of use in the United Kingdom and about one million such years of use on a world-wide basis. A total of nine hundred and fifteen cases of the syndrome were reported to the manufacturer.[47]

Practolol was withdrawn from general use in 1975. Although the manufacturers claimed that actions brought against them would be unsuccessful in view of the rigorous testing carried out before marketing and the unforeseeability of the long-term side-effects, a number of claims were settled out of court.[48] After the withdrawal of Practolol from the market, the episode was reviewed by an anonymous article in the British Medical Journal, which concluded that:

> "At the end of the day, then, no magic solution had been found that could guarantee that future drugs would be free of serious, unexpected adverse effects. Closer attention to the recording of events (rather than side-effects) in

> clinical trials would help, and there seemed an overwhelming case for some system of recording and storing details of the patients given such new drug as it comes onto the market".[49]

A further product which has been associated with adverse reactions is depo-provera. This is the proprietary name of an injectable drug which was originally licensed in the United Kingdom for short-term contraception for women who had received Rubella vaccination, or whose husbands had recently had a vasectomy, and for the treatment of certain cancers.[50] Among the advantages of the product for contraception is the fact that it is almost completely effective in preventing pregnancy, provided that the injection is repeated every three months. Disadvantages of the product include the fact that side-effects are common, including disruption of the menstrual cycle and irregular and prolonged bleeding.[51] In May of 1980, the manufacturer applied to the licensing authority in the United Kingdom for a licence to market the product as a long-term contraceptive agent. When this application was considered by the Committee on Safety of Medicines, the Committee advised that the application should be granted, subject to certain warnings and subject to the condition that it was recommended for use only in women for whom other contraceptives were contra-indicated or had caused unacceptable side-effects or were otherwise unsatisfactory.[52] This advice followed that given in Sweden and West Germany but the advice of the Committee on Safety of Medicines was not accepted by the licensing authority on the ground that the product was open to abuse.[53]

Upjohn Limited (the manufacturers) appealed against that decision and the licensing authority appointed persons under the provisions of Section 21(5) of the Medicines Act 1968 to hear representations before a final decision upon the application was taken.[54]

The issue of abuse in relation to the product revolves around the question of consent.[55] In giving its reasons for its provisional view that a licence for long-term use of the product should be refused, the licensing authority stated that it was:

> "... particularly desirable that the risk-benefit ratio should clearly be favourable before the application is granted in a case such as this where the Committee (the Committee on Safety of Medicines) have advised that its administration be restricted to a group of women many of whom will have difficulty in giving informed consent to their treatment".[56]

In view of the common side-effects associated with the product the persons appointed concluded that its use was only acceptable if informed consent was obtained from the patient.[57] Problems of absence of consent arise because of lack of information and understanding of patients due to their level of education. There are also suggestions of discrimination against women on the grounds of colour, class and nationality.[58] In connection with the use of this product, these considerations are also of much importance in relation to the Third World,[59] where it is often the third most frequently used method of contraception after the pill and the coil; it may even be the first or second most frequently used method and no method of contraception may be easily available.[60]

Following consideration of the Report of the Persons Appointed, the licensing authority granted a licence for the long-term use of the product with restrictions. Such a decision has important consequences for the use of the

product in the Third World. While it may continue to be made available there, there may be little or no control over the way in which this takes place and, in particular, whether the restrictions imposed by the United Kingdom licensing authority will be enforced outside its jurisdiction. Such a position is not unique but the depo-provero episode is an important example of a decision taken in the developed countries having repercussions elsewhere for products moving across national boundaries.

It is interesting to note that the product was also the subject of a Report from a United States Public Board of Inquiry to evaluate its safety based on scientific data.[61] In October 1984 this Board found the data insufficient to determine the issue of long-term use and recommended to the Commissioner of the Food and Drug Administration that Depo-Provera should not be approved for contraceptive use.[62] Thus, the US Board of Inquiry and the UK Persons Appointed reached different conslusions on the safety of the product, although each had essentially the same data available to it.[63] This comparison provides further evidence for the view expressed by Wardell,[64] that the United Kingdom has a less restrictive policy on drug safety than the USA.[65]

10.4 POST-MARKETING SURVEILLANCE

From the case studies discussed above, and particularly since the Thalidomide disaster, it has been generally accepted that some form of monitoring of medicines should be carried out after they have been released on to the market. This is particularly so in relation to new potent medicines, where adverse drug reactions may be suspected for products containing a new chemical entity. With the advance of computer technology, the collection and the storage of medical data upon a nationwide basis is now possible, in theory, for countries such as the United Kingdom. These advances may lead to a more scientific approach to surveillance of medicines in the near future.[66]

Some discussion of the adverse reactions reporting system originally established by the Committee on Safety of Medicines (the "yellow card" system) has already taken place,[67] where the limitations of this system have been mentioned. Some further points about this and some developments in this field from outside the United Kingdom will now be considered.

In relation to medicines which have recently been based on the market in the United Kingdom, these are indicated by an inverted black triangle in the British National Formulary, the Data Sheet Compendium published by the Association of the British pharmaceutical industry and the monthly index of medical specialties (MIMS).[68] Doctors are specifically asked to report any adverse or any unexpected event, however minor, for these products which could conceivably be attributed to the drug. These reports should be made despite uncertainty in the doctor's mind about a causal relationship, irrespective of whether the reaction is well-recognised, and even if other drugs have been given concurrently.[69]

In connection with established drugs, doctors should report any suspected adverse drug reaction which is potentially dangerous, incapacitating or lethal. Such reports should be made even if the toxic effect is well-recognised. Thus, the attention of doctors is particularly directed to adverse reactions which may be associated with new products, although the reporting of such events relies upon the limitations found by Crombie[70] in the yellow card system which identifies wider recognition as a potentially significant problem. Even with the limitations of the yellow card system, a number of decisions by the Committee on Safety of Medicines to withdraw a number of drugs from the market have been made primarily on the evidence of spontaneous adverse drug reaction reports.[71] Buckley has recently

called attention to the present unsatisfactory procedures available in the United Kingdom to monitor the effect of medicines recently licensed.[72] These are the monitoring by the Committee on Safety of Medicines of reports of possible adverse reactions prepared by general practitioners, the system of prescription effect monitoring organised by the Drug Safety Research Unit in Southampton whereby information is requested from general practitioners who have prescribed selected new drugs, and the studies organised by the pharmaceutical manufacturers about their own products.[73]

One additional limitation to the yellow card system is the fact that adverse drug reactions reported to the Committee on Safety of Medicines are not analysed unless signed by a doctor or dentist. It has been suggested[74] that a clinical pharmacist, working in close collaboration with hospital doctors, could improve the reporting of adverse drug reactions. This conclusion was reached following a study carried out during a twenty-one month period during which a pharmacist was seconded to four consultants in the acute medical and renal units of a two hundred and seventy-four bed hospital. In the period of the study some forty-four adverse drug reactions were recorded, which compared with only two reports from the same units in the twelve month period prior to the study. Bussey concluded that a pharmacist with a medication orientated approach, with access to the relevant information, was the ideal professional person to follow up and advise on the reporting of adverse drug reactions.[75]

Spencer[76] has also suggested that the role of the hospital pharmacist in this area has been neglected. He has drawn attention to studies in the USA[77] where participation by pharmacists has made a contribution to both surveillance and evaluation of adverse drug reactions. Further involvement by hospital pharmacists in post-marketing surveillance in the United Kingdom seems likely. Some further impetus to this possibility was

provided by the Report of the Grahame-Smith Working Party on Adverse Drug Reactions, which recommended that the role of the hospital pharmacist in "assisting doctors in reporting adverse drug reactions" should be considered.[78]

This concern about the recording and assessment of adverse drug reaction is not confined to the United Kingdom but is of international interest. While medicines continue to be traded across national boundaries it is not surprising that this should be so. In France, for example, hospital adverse drug reaction monitoring centres have existed since the mid-1970s. This activity led the French Government to decree, on 25th May 1984, that all prescribing physicians, midwives and dentists should report all unexpected or toxic drug reactions to their regional monitoring centre.[79] These centres have a three-fold purpose - to collect data on adverse drug reactions, to inform the medical community about this, and to do connected research.[80] This system has led to the withdrawal of several products from the market by the French Ministry of Health. One notable example concerns indalpine, an anti-depressant drug, which was first marketed in June 1983. As a result of adverse drug reaction reports received the product was first restricted to use in the elderly, to those suffering from severe depression and resistance to other drugs and finally removed completely from the market in June of 1985.[81] Venulet[82] writing about the position in Switzerland, has drawn attention to the important fact that, while health authorities are concerned only with adverse drug reactions in their own areas, a manufacturer's interest is often upon an international level. This is particularly so for the MNE producers. But Venulet has argued that it is of general interest that an international co-ordinated databank of information about products should be made available so as to prevent a drug safety problem from arising.[83]

Venulet has described what he regards as probably a unique project of such co-operation which was undertaken by Professor Hoigne in Berne and which consisted of a comprehensive hospital monitoring system. The project involved the three companies Ciba-Geigy, Hoffman-la-Roche and Sandoz, which fully shared data relating to all patients.[84] Venulet has suggested that drug manufacturers, regulatory authorities, doctors and consumers should work together and discuss problems of general concern about drug safety, so as to avoid public confusion.[85]

Such an approach must have some risks for manufacturers, who may be sued by patients who obtain evidence as a result of such co-operation and exchange of information and may not be a viable proposition under the existing law. There may, however, be a role for an international body such as the WHO collaborative centre for international drug monitoring if information upon an international basis could readily be made available and freedom of access allowed on a widespread basis.

In the USA the collection and evaluation of adverse drug reactions is a responsibility of the Office of Epidaemiology and Bio-statistics of the Food and Drug Administration, which has a computer-based adverse drug reaction reporting system. Post-marketing drug surveillance in the USA had traditionally relied upon the voluntary reporting of suspected reactions by doctors to the Food and Drug Administration or manufacturing companies, hospital-based research programmes or large-scale cohort studies conducted by pharmaceutical companies.[86] These methods of collecting data on adverse drug reactions were, however, felt to be inadequate and the Food and Drug Administration has founded and developed an alternative system called the Computerised On-Line Medicaid Pharmaceutical Analysis and Surveillance System (hereinafter called "COMPASS").[87] This is a large-scale conputerised database based upon

data collected for the cost control of Medicaid. It enables research upon cohorts of patients exposed to specific diseases who are being treated with specific medicines. A comparison with such patients and matched or unmatched control groups is possible, with some five million patients forming the system population.[88] In spite of its size, the COMPASS system has some disadvantages, notably the fact that important variables such as diet, exposure to cigarette smoking and occupation of the patients are not recorded. Further, there may be gaps in the data because it is based upon eligibilty for the Medicaid Health Programme, which is itself based upon income.[89] Nevertheless, Strom et al. have concluded that COMPASS provides a useful new resource for post-marketing surveillance.[90] It certainly demonstrates the fact that new technology can, and it is felt, should be utilised to provide a comprehensive and relatively cheap way of collecting data for adverse drug reactions. Data collected on an international basis in this way would enable valuable information to be accumulated in a much shorter time than with reliance upon national systems because of the much larger populations at risk.

A particularly difficult problem for licensing authorities in this field is the proper evaluation of spontaneous reports of suspected drug associated fatalities. Edlavitch et al.[91] have proposed that the United States National Death Index should be used to calculate the mortality rates for selected products as part of the post-marketing surveillance system. This Index is a central computerised index of death record information which enables investigators to determine if persons in their studies have died anywhere in the United States.[92] This study argues that the cost of supplying this information would be small compared to the cost of either putting a new product on the market or alternative post-marketing strategies to determine mortality.[93]

An introduction of such a system would certainly embrace a sufficiently large population to make it effective. As Parke has recently argued, in the context of adverse effects of drugs:

> "Safety, of course, will always be relative, absolute safety is highly improbable and likely to be associated with little or no pharmacological effect and therapeutic benefit. Certainly, a drug should be as safe as modern medical science can make it".[94]

Parke has accepted[95] that ways in which adverse side-effects of drugs may be minimised include extending pre-marketing human studies to comprise clinical and pharmokinetic investigations in a wider patient population to include the elderly and to phase the marketing of new drugs with appropriate monitoring of safety and efficacy. Improvements in methods of post-marketing surveillance should play an important part in advancing the safety of medicines. This would have the greatest impact if introduced upon an international basis with the support of modern computerised databanks. It is suggested that there is no real conflict of interest or ethics here, it surely being of common concern to both the manufacturer of the product and the prescribing doctor that the safety of the patient is paramount.

10.5 PRODUCT LIABILITY

The long-awaited EEC Council Directive introducing strict liability of producers and others for damage caused by defective products came into effect on 25th July 1985.[96] In the United Kingdom it was implemented by the Consumer Credit Act 1987, which received Royal Assent on 15th May 1987.

In the Pearson Report[97] it was recognised that the United Kingdom law in relation to defective products was unsatisfactory, being based upon the traditional dichotomy between contract and tort. Contractual remedies arise from a breach of Section 14 of the Sale of Goods Act 1979 (as amended), whereby a contract of sale in the course of a business normally implies that the goods are of "merchantable quality", that is to say that they are reasonably fit for the purpose for which goods of that kind are usually bought. The plaintiff will have to prove that the product was not reasonably fit for its purpose and that this has caused him harm.[98] Because of the doctrine of privity of contract, the buyer of a product has in general no special claim against the manufacturer. If the article the subject of the contract proves to be defective, the purchaser may sue the seller for damages in respect of any injuries sustained resulting from the use of the product in the way it was intended to be used. But such action may only be maintained against the seller and may only be brought by the purchaser. Subject to these limitations, the effect of the law of contract is to impose strict liability and is not dependent upon proof of any negligence on the part of the seller.[99]

In contrast to this, the law of tort is dependent upon proof of negligence, although it may be brought against whoever is responsible for the defect and by anyone who has suffered injury by it. A plaintiff must prove that the product was defective, that the defective product caused the injury in question, and that the defendant has failed in his duty of care because the injury was a foreseeable consequence of the defect. It has been long established that a duty of care is owed by a manufacturer of a product to a consumer by the historic case of Donoghue -v- Stevenson where Lord Atkin stated in the course of his opinion:

> "A manufacturer of products which he sells in such a form has to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care".[100]

It has been argued that the main shortcoming of the law of tort is that it is fault-based and that in many cases it is extremely difficult or even impossible for a consumer to prove to the satisfaction of the Court that a producer has been negligent.[101] This remains so notwithstanding that the consumer may rely upon the maxim res ipsa loquitur to support his case.[102]

Apart from the provisions of the Vaccine Payments Act 1979, there are no special rules governing the legal liability for injuries suffered as a result of consuming defective medical products in the United Kingdom.[103] There is, however, a distinction to be drawn between a patient receiving medicines under the National Health Service and a private patient. It is well settled that the supply of a medicine by a pharmacist by dispensing a National Health Service prescription is not a sale of goods by the pharmacist to the patient. This remains the position even though a prescription charge is made. In a case concerned with Section 46 of the Patents Act 1949[104] Lord Reid considered the legal position where a drug was supplied to a hospital out-patient on a National Health Service prescription which might be dispensed either in the hospital dispensary or by an outside pharmacist. In the course of his opinion he stated:

> "But in my opinion, there is no sale in this case. Sale is a consensual contract requiring agreement express or implied. In the present case, there appears to me to be no need for any agreement. The patient has a statutory right to demand the drug on payment of [the prescription charge]. The hospital has a statutory obligation to supply it on each payment. And if the prescription is presented to a chemist, he appears to be bound by his contract with the appropriate authority to supply the drug on receipt of such payment. There is no need for any agreement between the patient and either the hospital or the chemist, and there is certainly no room for bargaining. Moreover, the [prescription charge] is not in any sense the price, the drug may cost much more and the chemist has a right under his contract with the authority to receive the balance from them. It appears to me that any resemblance between this transaction and a true sale is only superficial".[105]

In contrast to the position under the National Health Service, a private patient will usually be supplied his medicine under a contract for sale, where the conditions or merchantable quality and fitness for purpose will be relevant. In either of these situations there may also be the question of negligence, either by the prescribing doctor, or the manufacturer of the product, to be considered.[106]

It is against this background that the Council Directive on Product Liability must be considered. There has been much support for a change in the law, which the Law Commission, the Scottish Law Commission[107] and the Pearson Commission all agreed was unsatisfactory. They recommended the introduction in the United Kingdom of a system of strict (no fault) liability for death and personal injury resulting from defective products. In

considering the implementation of the Directive the Government stated that they were much influenced by the following reasoning put forward by the Pearson Committee for their recommendation:

> "(i) All consumers should have the same protection as that enjoyed by the direct purchaser.
>
> (ii) The producer reaps benefits if the product is a success; he should also accept losses if the product fails and injures people (the doctrine of implied warranty).
>
> (iii) Strict liability would encourage higher safety standards.
>
> (iv) The producer is in the best position to arrange insurance cover, and can pass the extra cost to the consumer by the price mechanism.
>
> (v) The strong European trend towards strict liability should not be ignored".[108]

Member States were required to enact legislation to implement the terms of the Product Liability Directive within three years of its notification, ie by 30th July 1988.[109]

Under the Directive a product is defective if it does not provide "the safety which a person is entitled to expect, taking all circumstances into account", which include the presentation of the product, the use to which it can reasonably be expected that the product will be put and the time when it is put into circulation.[110]

It is recognised that this provision raises complex issues for medicines. As the Government have stated:

> "Establishing the existence of a medicine administered to a patient is complicated by the fact that not only is the human body a highly complex biological organism but at the time of treatment it is already subject to an adverse pathological condition. In order to avoid an adverse reaction, a medicine will have to be able to cope successfully with already faulty organs, disease, and almost infinite variations in individual susceptibility to the effect of medicines from person to person. The more active the medicine, and the greater its beneficial potential, the more extensive its effects are likely to be, and therefore the greater the chances of an adverse effect. A medicine used to treat a life-threatening condition is likely to be much more powerful than a medicine used in the treatment of a less serious condition, and the safety that one is reasonably entitled to expect of such a medicine may therefore be correspondingly lower.
>
> Attention would also have to be paid to related environmental factors (emergency or routine, method of administration, situation and supervision etc) and to possible interactions and co-relations between the various factors, for example, between a patient's diet and the medicine, or published warnings and the patient's ability or opportunity to understand them. These are all circumstances which should be taken into account in determining the level of safety the person is reasonably entitled to expect, and hence, in determining whether a particular medicinal product is defective".[111]

From this it is clear that the safety of a medicine, and the question of whether it is defective, must be considered having due regard to both its intended purpose and normal use. It may be possible for a product to show that damage suffered by a patient was not attributable to any defect in the product itself but to the patient's use of the product, particularly if that use was obviously unintended by the manufacturer. In relation to this, it will be important to consider whether adequate instructions and warnings were provided with the product. It is, however, expressly provided that a product is not defective solely because a better product is put into circulation.[112]

Further, the liability of a producer may either be reduced or disallowed where damage is caused both by a defect in the product and by the fault of the injured person, or any person for whom the injured person is responsible.[113] But where the damage is due both to the defective product and the act or omission of a third party, as opposed to that of the injured person himself, then the producer is not relieved of his liability.[114]

The principle established by Article 8 seems to be that an injured person is granted a right to compensation, with the producer being able (in a suitable case) to take whatever steps that are open to him to obtain a contribution for any third party whom he considered is partially responsible for the damage. This principle is regarded by the Government as compatible with the existing United Kingdom law of contributory negligence.[115]

Under Articles 1 and 9 of the Directive a producer will be liable in respect of damage caused by death or personal injuries. The term "product" is defined as "all moveables, with the exception of primary agricultural products and game, even though incorporated into another moveable or into an immoveable".[116]

Although the aim of the Directive is clearly to make producers of a product liable when that product causes damage,[117] certain defences are provided where the producer will not be held liable, two of which are of particularly relevance for producers of medicines - namely, that the defect was due to compliance of the product with mandatory regulations issued by public authorities and the so-called "state of the art" defence.[118] Each of these is considered in turn.

With regard to the first of these, this seems to raise a possible defence for producers of medicines whose products have been licensed by the licensing authority upon the advice of the United Kingdom Medicines Commission or the Committee on Safety of Medicines, under the Medicines Act 1968. This point was considered by the Law Commission and the Scottish Law Commission in their Report on Liability for Defective Products.[119] Their conclusions were that compliance with standards laid down by statutory bodies or licensing authorities could be evidence, but not conclusive evidence, that a product was not defective when put into circulation. In the words of the Scottish Law Commission:

> "... compliance with standards laid down by a body such as the Medicines Commission should not by itself be taken to indicate that a medicine is not defective, and should not be regarded in itself as a reason why producers of pharmaceuticals should not be strictly liable".[120]

This was also examined by the Pearson Committee, which recommended that the producer of medicines should not be allowed a defence of official certification because this would be inconsistent with their approach to strict liability.[121] In its evidence to the Pearson Committee

the Association of the British Pharmaceutical Industry stated that that industry did not regard the approval of a new product by the Committee on Safety of Medicines as diminishing their own responsibility for it.[122]

Diamond has drawn attention to a major criticism of such a defence in that it does not take account of the fact that specifications and standards quickly become out-dated.[123] It is surely reasonable for the consumer to have protection in circumstances where new dangers are exposed as a result of new scientific knowledge not known at the time when the standards were laid down. It remains to be seem whether the pharmaceutical industry will continue to accept that official certification by bodies such as the Committee on Safety of Medicines as not diminishing their own responsibility for new products, once the Directive has been implemented in the United Kingdom. While it may be unlikely that licensing bodies will be joined as parties in product liability actions in the future, it will certainly be relevant to consider policies adopted and warnings issued by such authorities as an important part of the evidence in such actions in determining whether or not a product was defective when put into circulation. It has been stated by the Government that mere compliance with a regulation will not necessarily discharge a producer from liability and that he would also have to show that the defect was the inevitable result of compliance, ie that it was impossible for the product to have been produced in accordance with the regulation without causing the product to be defective.[124]

Article 7(e) of the Directive permits Member States to include a defence whereby a producer shall not be liable if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the

defect to be discovered. This "state of the art" defence is included in the Directive subject to derogation by Member States.[125] This defence is highly controversial and has caused considerable disagreement among Member States.[126] As a result of such controversy, the Directive includes provision for a review after an initial ten year period by the Council of Ministers, on the basis of a Report to be submitted by the Commission, of the effect of the inclusion of the defence, in order to decide whether it should be repealed.[127] Producers have argued that the inclusion of this defence would be a disincentive to innovation, especially in high risk industries,[128] which must surely include the pharmaceutical industry. For its part the United Kingdom has included a state of the art defence in the legislation implementing the Directive and has stated that this will be interpreted as meaning that the producer will not be liable if he proves that, given the state of scientific and technical knowledge at the time when the product was put into circulation, no producer of a product of that kind could have been expected to have discovered the existence of the defect. The burden of proof will be on the producer to show that the defect could have been expected to be discovered.[129]

It is understood that a state of the art defence is likely to be included in the implementing legislation of at least the following countries (in addition to the United Kingdom): West Germany (with the exception of the pharmaceutical industry), Denmark, the Republic of Ireland, Italy and the Netherlands.[130] Thus, at least during the initial ten year period prior to review by the Council of Ministers of the effects of the defence it is possible that some Member States will interpret the defence more strictly than others and that the defence will not be available at all in other Member States. From this it follows that potential litigants may have a choice of the most favourable country in which to commence

proceedings, where medicines are, for example, produced in one Member State and sold in another under the importer's trade or brand name.

In this connection the EEC Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters is relevant.[131] This contains provisions enabling the Courts of each contracting State to entertain proceedings in civil cases (including product liability) and requiring other contracting States to give effect to their judgments. In relation to product liability the Directive will not completely eliminate differences between Member States because of the derogations provided for in the Directive and the procedural rules of Member States, which will of course remain subject to national law.[132] Thus, there will still be cases where a prudent plaintiff will need to make a choice as to which country would be the best to bring his action. This choice will depend upon several factors, such as the availability of witnesses, procedural rules and the availability of the "state of the art" defence. In relation to the choice of defendant to an action founded in product liability, it is necessary to consider the definition of "producer" for the purpose of the Directive.[133] This terms includes the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and "any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer". Thus, intermediate suppliers and retailers may be held liable as producers if they place an own-brand label on the product.[134] Further, any person who imports a product into the EEC for sale or any form of distribution in the course of his business is deemed to be a producer and responsible as such.[135] This appears to be so whether or not the product is supplied under the importer's own trade mark or other distinguishing feature.

Any supplier of a product may also be liable under the contingent liability provision of the Directive.[136] Under this provision where the producer of a defective product cannot be identified, each supplier of the product is treated as the producer of the product unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with it. The Government have recognised that the position of the medical and allied professions requires particular consideration in this context. In the Explanatory Note of the Department of Trade and Industry it is stated:

> "Many doctors and health care personnel are the last link in the chain of supply from manufacturer to patient, and as such might be liable under the provision of this Article when the producer of a defective medicinal product could not be identified. However, for NHS staff, the supplier would be the health authority, not the member of staff concerned. It is expected that the authority's records would need to provide particulars of the sources of its drugs if it is to be sure of avoiding liability under the Directive. Some health care personnel such as General Medical and Dental Practitioners are not employees of health authorities but are self-employed and under contract to the authorities. Their position is similar to that of retail pharmacists, who would be expected to maintain adequate records or, in the absence of such records, to be subject to liability when the producer cannot be identified. It should be stressed that the exercise of clinical judgment in favour of one medicical product rather than another will not of itself create a liability under the Directive on the practitioner concerned for damage caused by the product; nor will the exercise of such judgment of itself affect the patient's right of action against the producer".[137]

Thus, when an identical product is produced from more than one source and is not labelled, any person in the chain of supply (including the retailer) would be liable unless he could show who supplied the product to him. Where, as a result of this provision of the Directive, two or more persons are liable for the same damage, they will be jointly and severally liable.[138]

Existing rights of contribution and recourse are not to be affected under national law. Thus, a manufacturer or supplier in the United Kingdom may be able to claim under the Civil Liability (Contribution) Act 1978 from another producer or supplier in respect of any compensation ordered to be paid.

The Directive provides for a limitation period of three years commencing on the date the plaintiff became aware, or should reasonably have become aware, of the damage, the defect in the product and the identity of the producer.[139]

In the view of the United Kingdom Government any national laws governing the suspension or interruption of this limitation period will not be affected by the provisions of the Directive.[140] This limitation period of three years is, however, subject to a product's ten year "liability life" under the terms of Article 11 of the Directive. Under this all rights conferred on an injured person are to be extinguished on the expiry of ten years from the date on which the product was put into circulation. A person injured by a latent defect which does not appear in a product for at least ten years may not claim compensation by virtue of the Directive but may be able to proceed with a cause of action in tort. The combined effect of Articles 10 and 11 of the Directive seems to be that an injured person must bring an action before the expiry of the limitation period of three years under Article 10, or the product's "liability life" of ten years under Article 11, whichever is the earlier.

There is no financial limit under the terms of the Directive. But any Member State may provide that a producer's total liability for damages for personal injury (not damage to property) caused by identical items with the same defect shall be limited to an amount not less than seventy million ECU.[141] As regards the United Kingdom, the Department of Trade and Industry has stated that the Government believes that there could be disadvantages in setting such a financial limit, particularly as it could in some cases lead to injustice where there are multiple claims and to lengthy delays in the payment of compensation award where there is a possibility of further claims in respect of the same product.[142]

It is understood that only West Germany, Denmark and possibly the Republic of Ireland are in favour of imposing a financial limit.[143]

It should be mentioned that, quite apart from the involvement of the European Community in product liability, the Council of Europe appointed a Committee of Experts in 1970 to propose means of harmonising the product liability laws of Member States. This resulted in the Strasbourg Convention on Product Liability, which was opened for signature in January 1977. It was signed by Austria, Belgium, France and Luxembourg. This Convention does not permit the introduction of a development risks defence and, as there are a number of inconsistencies between the Convention and the EEC Directive on Prodict Liability, the United Kingdom has stated that it does not propose to sign the Convention.[144]

Implementation of the Directive on Product Liability should result in a significant improvement in the ability of consumers to obtain compensation for defective medicines and other similar products. It will enable

actions to be brought against manufacturers and other suppliers without the legal requirement of having to prove negligence. An increased awareness among consumers of medicinal products is likely to lead to an increase in the number of claims brought in this field. One practical result of the implementation of the Directive is that producers will have to insure their risks, with this cost being passed on to consumers as the price to be paid for higher safety standards.

But the degree of harmonisation achieved by the Directive is not complete. The United Kingdom Government has stated that it would have preferred a more fully harmonised Community regime.[145] Further, the Commission has reserved the right to review some important aspects of the working of the Directive after ten years, which may eventually lead to a greater degree of harmonisation than provided for in the original Directive. In this connection the main points of concern are the question of whether there should be limits on a producer's total liability for damage[146] and the state of the art defence.[147] Finally, it should be noted that the rights of an injured person under the laws of contract and tort of Member States remain unaffected by the provisions of the Directive.[148]

The Directive also expressly states that the rights of an injured person under a "special liability system existing at the moment when this Directive is notified" are also unaffected by it.[149] This refers to the Pharmaceuticals Act passed by the West German Bundestag in 1976. This provides for the liability of a producer of a pharmaceutical product, irrespective of fault, for the injurious effects of that product. A financial limit of DM200 million is provided for the total damage suffered and DM500,000 in any individual case. This law came into force on 1 January 1978.[150]

Even with the implementation of the Directive on product liability the problem of proving "causation" will remain. This is particularly difficult where the patient injured has been taking more than one medicine during the relevant period. Diamond[151] has drawn attention to the fact that statistical evidence may be inadmissable upon the grounds that it is hearsay,[152] although the opinions of an expert based upon statistics prepared by others is admissable if the expert refers to that material in his evidence so that the cogency and probative value of his conclusion can be tested by reference to that material.[153] It has also been clearly established that expert witnesses may refer to articles by others, so as to admit into evidence those other references.[154]

Even with the limitations and difficulties facing potential plaintiffs under the product liability provisions outlined above, it is submitted that this seems to represent an advance for the protection of consumers of pharmaceuticals over negligence as the basis of liability. By the acceptance of the provisions of the Directive the EEC has enabled some harmonisation upon this subject to proceed and provided that further harmonisation may follow later. Upon a wider prospective the EEC has, by the acceptance of the Product Liability Directive, come to terms with the problem which is of significance in all industrial nations of the world which carry on trade in medicines. In fourteen States of the United States legislation has been passed dealing with product liability in some form, and in some States (Arizona, Indiana, Nebraska and New Hampshire) conformity with the state of the art is a defence.[155] It is desirable that this common approach to the problems posed by product liability should be reached so as to remove this potential barrier to international trade.

Two reservations about the effectiveness of the Directive in providing a satisfactory remedy for consumers should be entered. First, the inclusion of the state of the art defence may nullify the aim of imposing strict liability upon producers, As Lord Scarman stated in the course of the debate upon the Directive in the House of Lords:

> "[If] you introduce the "state of the art" defence, you are really introducing negligence or fault by the back door".[156]

Whittaker has expressed this view in the following terms:

> "It has been argued that the Directive on Product Liability's claim to innovation is somewhat weak. The concept of defect, the requirement of proof of causation and the number and extent of defences available (even where loaded against producers by the burden of proof) all tend to bring the plaintiff back to a situation practically little different from the present position in the tort of negligence".[157]

Secondly, it must be remembered that the present difficulties experienced by potential plaintiffs in bringing negligence actions stem from the impossibility of obtaining satisfactory evidence to support their claims against manufacturers of medicines. The Thalidomide tragedy is an illustration of the position which may arise where persons suffer death or personal injury not caused by negligence and are unable to obtain compensation from the Courts. Unless the substantive provisions of the legislation which implements the Directive are supplemented by corresponding changes in procedures, the apparent improvement in the plaintiffs' position in this area may be more apparent than real.

10.6 THE TRANQUILLISERS REPORT[158]

It is, however, not only in relation to issues of safety that Governments may find themselves in difficulties over the supply of medicines, such difficulties may also arise where it is felt that medicines are being placed upon the market by a monopoly supplier at excessive prices. This position arose in the United Kingdom in relation to Librium and Valium. From 1967 to 1969 the National Health Service felt that the manufacturers of those products, the Swiss firm of Hoffmann-la-Roche, were making too much profit. In fact the manufacturers made three substantial voluntary payments during this period but then declined to repay further. Roche had a virtually complete monopoly in the supply of the products and had patented the products in the United Kingdom.[159]

In addition to the legal protection afforded by these patents, Roche were able to prescribe and fix the price of the products in question because of their exemption from re-sale price maintenance.[160] This enables manufacturers to enforce the prices at which products are sold down the chain of supply from manufacturer to customer. In September 1971 the Department of Trade and Industry referred to the Monopolies Commission for investigation and report the level of profits made by Roche and to find out whether or not this operated against the public interest. The Monopolies Commission was first established as the Monopolies Commission in 1948.[161] It consists of twenty-five experts drawn from business, individual and academic circles to report, inter alia, on the ways in which the public interest may be affected by a monopoly situation.[162]

The terms of an investigation by the Monopolies and Mergers Commission are governed by its terms of reference, but there are two restrictions placed upon the institution of such an investigation. First, one quarter of domestic

or exported goods of any description, or of services of certain descriptions supplied within the United Kingdom, must come from a single business or group of companies, or from a complex of businesses acting together to restrict competition.[163] It is the primary task of the Commission to determine whether a "monopoly situation" exists within the terms of this definition in relation to any reference. Secondly, in the course of its assessment no account is to be taken of restrictive trading agreements within the definition of that term in the Restrictive Trade Practices Act 1976.[164] These are matters for the Restrictive Practices Court rather than the Commission.[165] The Commission does not exercise judicial powers, and is not obliged to follow the procedures of a Court, but must observe the rules of natural justice.[166]

In their Report the Commission found that:

> "... the excessive prices charged up to the present have already produced excessive profits on a very large scale ... no further price which it is practicable to recommend for the reference drugs could take full account of the excessive profits which have been made on them at the expense of the NHS in the past and will continue to be made until the prices are reduced ...".[167]

In its Report the Commission concluded with the important recommendation[168] that the prices charged by Roche should be reduced:

> (i) as regards Librium to not more than 40% of the selling price in 1970, and
>
> (ii) as regards Valium, to not more than 25% of the selling price in 1970.

The Secretary of State for Trade and Industry then made Orders under the powers conferred by Section 3 of the Monopolies and Mergers Act 1965 regulating the prices at which the products could be sold.[169] These Orders were attacked by Roche on the grounds that the Commission had failed to observe the rules of natural justice. But the House of Lords, upholding the decision of the Court of Appeal,[170] refused to set the Orders aside as they had been approved by both Houses of Parliament.[171]

The Tranquillisers Report raised some fundamental questions upon both a national and international level about the control by Government over the activities of MNEs. Upon a national level, one of the issues involved was the protection afforded by the patent system. Roche was in the position of being able to exploit its monopoly position, from which it derived substantial profits. But even though the Commission recognised the protection afforded by the grant of a patent,[172] the public interest demanded that the price at which the products should be sold would be one that was fair.[173]

As the Commmission found:

> "In the light of these facts, the question of what rate of profit should be allowed in determining a fair price becomes, as we have said in paragraph 230, barely relevant to our problem, since the group has already obtained from the sale of these drugs in this country profits far in excess of what is justifiable".[174]

Viewed from an international standpoint, the Tranquillisers Report may be seen as the exposure of a blatent case of transfer-pricing practised by an MNE. The Report found that Roche had charged its British subsidiary £370 and £922 per kilo for the active ingredient used to

formulate Librium and Valium respectively in Britain. It was found that these same active ingredients were available from Italian manufacturers at £9 and £20 per kilo respectively. From these figures it was estimated that although Roche had been declaring profit generally below 5% on capital employed, its real profits were in fact over 70% for the period from 1966 until 1972.[175]

As Melrose has commented in relation to the Tranquillisers Report:

> "When developed countries like Britain, with sophisticated market intelligence sources to hand, are hard put to monitor transfer-pricing, it is hardly surprising that developing countries end up paying high drug prices because raw materials are over-priced".[176]

10.7 INSPECTION OF MANUFACTURERS OF MEDICINES

It has been generally accepted that responsibility for medicines, and particularly new and potent products, should not be left to the sole responsibility of menufacturers.[177] As has been found in Parts II and III above, there are a number of Governmental and inter-Governmental regulatory bodies and agencies with duties to supervise and control the manufacture of pharmaceutical products. Part of this system of control is the enforcement of Good Manufacturing Practice (hereinafter referred to as "GMP") to ensure that products placed upon the market and moving in international trade are safe, effective and of satisfactory quality. It is also only logical that a country which controls the manufacture of its domestic products should also be concerned to ensure that products which are manufactured abroad but then imported into the home country should be produced in similar conditions to the home product.[178]

Principles of GMP are enforced in various ways. In the United Kingdom Medicines Act 1968[179] little is said about manufacture and control standards. But wide powers are contained[180] to enable regulations to be made governing standard provisions which must be contained in any licence for clinical trial certificates granted or issued under that Act. Regulations have been made under these powers[181], though even these regulations contain very little by way of detail and lay down very general requirements such as that the manufacturer should provide and maintain the necessary staff, premises, plant and equipment. Clearly more detailed requirements are necessary and these are provided in the "Orange Guide".[182] This so-called "Orange Guide" is not, however, solely for use within the United Kingdom medicines. It is used by inspectors appointed under the Medicines Act 1968 in their inspection of the five hundred manufacturers of medicines in the United Kingdom and the eight hundred manufacturing sites abroad which are suppliers of medicines to the United Kingdom.[183]

It is, however, as its name implies only a guide, from which it follows that it has no statutory force and is certainly not intended to be regarded as an authoritative interpretation of any statutory provision or directive of the EEC. The definition of what constitutes GMP is contained in the Orange Guide in the following terms:

> "That part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with both manufacturing and quality control procedures".

This non-statutory basis for the Orange Guide is entirely in keeping with the original co-operative spirit which existed between Government, the pharmaceutical industry and the relevant professions at the passing of the Medicines Act in 1968,[184] which spirit is still alive to a large extent.

In addition to the method of control imposed by the Medicines Act 1968, the United Kingdom is also a founder member of the Pharmaceutical Inspection Convention.[185] This Convention is an agreement originally made between the European Free Trade Association countries. Some of the long-standing members of the Convention are Austria, Denmark, Finland, Iceland, Norway, Portugal, Sweden, Switzerland and the United Kingdom. But membership of EFTA is not a prerequisite of membership of the Convnetion and Hungary, Rumania and West Germany have recently joined.[186]

It seems that the basis of the Convention is that all of its members have similar (but not, of course, identical) legal frameworks for the manufacture of medicines, similar approaches to inspection of manufacturing premises and similar standards for GMP.[187] Such inspections which are carried out by, say, the United Kingdom inspectors outside their jurisdiction do not have any legal powers. Any formal action which is taken as a result of such inspections must be through the licensing systems under the Medicines Act 1968. Some basic standards for GMP for pharmaceutical products have been adopted by the Pharmaceutical Inspection Convention.[188]

These basic standards are intended to incorporate the main principle of GMP and are supplemented by guidelines on specific topics. These standards are based upon resolution WHA 28.65 of the World Health Assembly which made recommendations for the standards of GMP for pharmaceutical products,[189] including recommendations for such standards as qualifications and training of personnel, construction and facilities for premises, documentation (including records for each batch and reference sample) and quality control.[190] In addition, every manufacturer is required to maintain written instructions for dealing with complaints about the quality

of the product and should operate a retrieval system allowing him to review all products which may have been affected by a repetitive error or a failure in the procedures of the manufacturer.[191]

The World Health Organisation is also very much concerned with quality control for pharmaceutical products. Its Expert Committee on Specifications for Pharmaceutical Preparations has produced several reports upon this subject. In its 29th Report[192] it laid down detailed recommendations for national laboratories for drug surveillance and control. This Report lays stress upon the fact that developing countries are particularly vulnerable to the supply of sub-standard drugs.[193] Having regard to this the Report gives guidance for the structure and management of a National Drug Quality Control Laboratory where no such facility has yet been established. This Report also deals with collaboration between non-Government organisations in the field of pharmaceutical standards.[194]

While recognising that the certification scheme on the quality of pharmaceutical products moving in international trade provided valuable assurance upon the quality of imported products, the Report takes the view that this does not alter the desirability of the responsible authorities in the importing countries being able to check on the quality of those products for themselves.[195]

Having regard to these developments in GMP it is submitted that harmonisation of inspection standards by reference to common standards of GMP upon a world-wide basis may be possible in the foreseeable future. In moving towards this goal the United Kingdom has, through its membership of the Pharmaceutical Inspection Convention, played an important role in the progress which has been made. Although the main thrust of this movement towards harmonisation is upon quality, and quality control in particular for the products in question, the implications for safety of those products is also self-evident.

10.8 CONCLUSION

In relation to international trade in medicines, safety, quality and pricing issues clearly arise both for the producing and the importing State. This particularly concerns MNEs and their role in the Third World and it is for consideration whether home Governments should be required to impose legal controls over their activities upon a trans-national basis. It may be argued that consumers in the Third World should have a free choice of product, always provided that there is no breach of the domestic legislation. But in practice, MNEs create their own markets in pharmaceuticals by various means. Further, it is not all countries which have the necessary expertise and resources to evaluate properly the products which the MNEs have to offer or the legal controls which are taken for granted in developed countries.[196]

As has been seen from the Thalidomide and other case product histories discussed above, such episodes may arise in developed countries in spite of the legislation and other controls which have been imposed. In relation to prices, the Tranquillisers Report has shown that even in the United Kingdom the activities of a sophisticated MNE may tax the ingenuity of a Government of the developed world. If such problems can arise there, they will certainly arise with even greater impact in the Third World. It is suggested that only at an international level could progress be made in controlling MNEs, perhaps by codes of conduct enforceable through the home State.[197]

Safety of medicines, however, embraces more than immediate control over the sale and supply of pharmaceutical products. Standards of scientific knowledge constantly change and need to be revaluated on a regular basis. The Pharmaceutical Inspection Convention has shown a way by which inspection of manufacturers' premises may provide

some measure of harmonisation for GMP which can be accepted across national boundaries without the necessity for legislation. It is suggested that such an approach could eventually be accepted upon a global basis without much difficulty, with desirable results for international trade. Other aspects of safety concern the keeping of records and production of evidence to prove that products, originally thought to be safe, may in practice be shown to be otherwise when larger numbers of patients are exposed to the product than is possible for a clinical trial. Here it is suggested that natural justice demands that the necessary evidence should be made available to enable products to be reassessed, and if necessary taken off the market if that evidence is shown to justify such a decision. It is here that an effective system of post-marketing surveillance is necessary to ensure that such evidence is forthcoming.

Finally, if patients are able to show that they have suffered damage as a direct result of a product shown to be unsafe, it is necessary to have substantive legislation and adequate procedural rules to enable those persons to obtain a legal remedy for their loss. As has been shown, it is hoped that product liability legislation will soon provide that for Member States of the EEC. If it proves effective there, there is no logical reason why its impact should not be extended to the whole world: it has already been introduced into some of the States of the USA.

NOTES

1. Thalidomide is a compound derived from Glutanic acid and was first synthesised by Kunz, Keller and Muckter in the laboratories of the German chemical company of Chemie Grunenthal. See Mann, R D "Modern Drug Use : an inquiry on historical principles", MTP Press Limited [1984] page 598.

2. Teff, Harvey and Munro, Colin R "Thalidomide : the legal aftermath", Saxon House [1976], page xi.

3. 2. Ministry of Health, Reports on Public Health and Medical Subjects, Number 112 "Deformities caused by Thalidomide", London, HMSO, [1964], page iii.

4. Mann, R D "Modern Drug Use : an inquiry on historical principles", MTP Press Limited, [1984], page 598.

5. Teff and Munro, op.cit, page 1.

6. Mintz, M "The Therapeutic Nightmare", Haughton [1975] Ch 12.

7. See, in particular, S -v- Distillers [1969] 3 All ER 1412; Re: Taylor's Application [1972], 2 QB 369, and Allan -v- Distillers [1974], 2 All ER 365.

8. Teff and Munro, op.cit. page 2.

9. Ibid.

10. See page 29 in section 2.1.

11. Financial Times, 10 August 1971.

12. See Chapter III.

13. Act of 10 October 1962, Public Law 87 - 781.

14. Act of 25 June 1938, Ch 675.

15. Muller, Mike "The Health of Nations : A North/South Investigation", Faber and Faber Limited, [1982], page 100.

16. Teff and Munro, op.cit. page 113.

17. Teff and Munro, op.cit. page 148.

18. Tausigg, Dr Helen. Article in Scientific American, August 1962, quoted in Teff and Munro, op.cit. pages 120/121.

19. A Report on the proposed mergers, presented to Parliament in pursuance of Section 9 of the Monopolies and Restrictive Practices (Inquiry and Control) Act 1968 (as applied by Section 6(5) of the Monopolies and Mergers Act 1965) HMSO, London) [1972], paragraph 248. Thus quotation is specifically concerned with the comments of the Monopolies Commission on research and development in relation to the then proposed merger between Beecham and Glaxo. But the comments of the Commission at paragraph 23 of their Report about the industrial and commercial background to the pharmaceutical industry in general in the 1970s also mention the same point.

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22. Op.cit. page 9.

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50. Report of the Panel of Persons Appointed by the licensing authority to hear the application by Upjohn Limited for a product licence to market the drug Depo-Provera as a long-term contraceptive, Department of Health and Social Security [1984], paragraph 1.4.

51. Berer, Marge "Who Needs Depo-Provera?", Community Rights Project, 1984, page 7.

52. Report of the Persons Appointed, paragraph 7.1.

53. Report of the Persons Appointed, paragraph 1.5.

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55. In Gillick -v- West Norfolk Area Health Authority [1986] 1 AC 119 the question of consent was considered in relation to the giving of contraceptive advice and treatment to a girl under the age of sixteen years, without the consent and knowledge of her parents. Three of the judges in the House of Lords (Lord Fraser of Tullybelton, Lord Scarman and Lord Bridge of Harwich) were of the opinion that in exceptional cases a doctor could give such advice and treatment if satisfied that:-

    (1) the girl will understand the advice,

    (2) he cannot persuade her to inform her parents or to allow him to inform her parents,

    (3) she is likely to begin or continue to have sexual intercourse with or without contraceptive treatment,

    (4) unless she receives contraceptive advice her physical or mental health is likely to suffer,

    (5) her best interests require him to give her contraceptive advice, treatment or both without parental consent.

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125. Article 15(1)(b) of the Directive.

126. See Explanatory Note by the Department of Trade and Industry, paragraph 21.

127. Article 15(3) of the Directive.

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131. The EEC Convention has been incorporated into English law by the Civil Jurisdiction and Judgments Act 1982, and by amendment to the Rules of the Supreme Court RSC (Amendment No 2) Order 1983 SI 1181. The Convention came into operation in the original six Member States of the EEC in 1975.

132. Explanatory Note of the Department of Trade and Industry, Annex III.

133. This term is defined in Article 3.

134. Explanatory Note of the Department of Trade and Industry, paragraph 45.

135. Article 3(2) of the Directive.

136. See Article 3(3) of the Directive.

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138. Article 5 of the Directive.

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143. Ibid, paragraph 25.

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146. Article 16 of the Directive.

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152. See the decision of the House of Lords in Myers -v- Director of Public Prosecutions [1965] AC 1001.

153. R -v- Abadon [1983] 1 All ER 364, where Myers -v- Director of Public Prosecutions was distinguished.

154. Seyfang -v- Searle and Company [1973] 1 QB 148, where Cooke J stated:

> "The four articles now form part of the corpus of medical expertise on this particular subject: I apprehend that in England a medical expert witness with the proper qualifications would be allowed to refer to the articles as part of that corpus of expertise, even though he was not the author of the articles himself".

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162. It is now governed by Sections 50 and 51 of the Fair Trading Act 1973.

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190. Ibid, paragraphs 1, 2 and 3.

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PART V

CHAPTER XI

TOWARDS A NEW INTERNATIONAL HEALTH ORDER

11.1 INTRODUCTION

It has been seen in Part III, that the large increase in the number of States joining the United Nations after the end of the Second World War altered the character of the international community. The Security Council of the United Nations became in effect responsible for international peace and security for practically the whole world.[1] This universality has provided a legal basis for a new world order.[2] This new world order identified the indisputable fact that inequalities in wealth between different parts of the world was both unacceptable in principle and a potential cause for instability. Mesarovic has described this problem in the following way:

> "Call for the establishment of a new world economic response to a real need: to reduce the inequality of wealth which presently exists among different parts of the world. While some countries live in conditions of unprecedented abundance, an increasing part of humanity lives constantly in poverty and on the brink of starvation. Such a state of affairs cannot be accepted as permanent - even less to allow to further deteriorate - not only for moral and ethical reasons, but also because it creates conditions of instability which in the increasingly interdependent world present a political as well as an economic danger to all".[3]

Many of the newly constituted nations realised that their economic problems were inter-related to the policies pursued by the developed world. The Declaration of Lima by the Group of 77[4] gave a warning that it was no longer possible for poverty and affluence to co-exist. It is

submitted that this new world order extends beyond the establishment of world peace and a new economic order. This is because the international community has accepted a collective responsibility to give its members equal opportunities for various social/economic rights, including good health.[5] In relation to this wider concept of a new world order Mahler has expressed the view that:

> ... an integrated socio-economic approach to development is required, with co-ordination of policies for agricultural development, food production, education and health".[6]

It is not, however, merely the terms of the United Nations Charter that may be relied upon to support an argument that health (which includes the supply of appropriate medicines) should be regarded as an essential element in this new world order. Further support may be found in the development of the concept of health as a fundamental human right. The objective of WHO is the attainment by all peoples of the highest possible level of health.[7] In relation to this objective the preamble to the Constitution of WHO states that:

> "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
>
> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition".

In recent years there have been major changes in the policies of both manufacturers of medicines and nation states. These changes have come about very largely because of the considerable influence of international bodies such as the United Nations, UNCTAD, WHO and UNIDO.[8] Influence has also been exerted by organisations representative of the pharmaceutical industry itself, such as IFMPA.[9] This body represents associations of the industry from some forty-eight countries. It has responded to criticism of the industry by the publication of a code of pharmaceutical marketing practice.[10]

Consumer movements are also becoming increasingly active on pharmaceutical issues at an international level. Quite apart from the issues of human rights and the establishment of the new international order, pressure groups such as HAI[11] and Oxfam[12] have brought their influence to bear upon how medicines should be made available and controlled throughout the world. All of these matters have had an influence upon world trade in medicines and the view has been expressed that international health could become one of the dynamic and basic foundations of the new world order.[13]

11.2 THE RIGHT TO MEDICINES AS A HUMAN RIGHT

Three aspects of the right to health are enshrined in the international instruments on human rights. These include the general declaration of the right to health as a basic human right, the laying down of standards appropriate to the needs of particular groups of people, and the implementation of those rights.[14] Thus, Article 25(1) of the Universal Declaration of Human Rights states that:

"Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelilhood in circumstances beyond his control".[15]

Further, Article 12 of the International Covenant on Economic, Social and Cultural Rights[16] recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In putting forward this general strategy for implementing the right the Article states that:

"... the full realisation of this right shall include ... (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) the creation of conditions which would assure to all medical services and medical attention in the event of sickness".

Both the European Social Charter and the African Charter contain similar rights relating to health. Article 11 of the former provides:

"With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organisations, to take appropriate measures designed inter alia:

(1) to remove as far as possible the causes of ill-health;

(2) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;

(3) to prevent as far as possible epidemic, endemic and other diseases".

Article 16 of the African Charter states:

"1. Every individual shall have the right to enjoy the best attainable state of physical and mental health.

2. States Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick".

From this, it is clear that the supply of appropriate medicines may properly be regarded as part of the basic human right to health. It is submitted that this right must also be recognised as forming an essential element in any consideration of the international trade in medicines. This is particularly so as the International Covenant on Economic, Social and Cultural Rights provides for a system of implementation whereby Member States have undertaken to submit reports on the measures they have adopted, and the progress made in achieving, the observance of this right.

In September of 1978 WHO and the United Nations Childrens' Fund held a conference on primary health care at Alma-Ata, the capital of the Soviet Republic of Kazakstan. This conference reaffirmed that "Health, which is a state of

complete physical, mental and social well-being and not merely the absence of disease or infirmity, is a fundamental human right".

This conference found that the gap between the level of primary health care provided in the affluent countries was widening from that provided in the Third World. Further, the disadvantaged groups of the Third World (constituting four-fifths of the world's population) had no access to any permanent form of health care.[17] It was recognised that the supply of medicines played an important part in the provision of primary health care as the conference concluded that:

> "Medicinal drugs are an important component of health technology. It is universally agreed that fewer drugs are necessary than the number at present on the market in most parts of the world. A model list of about two hundred essential drugs is now available, prepared after international consultation.[18] The number of drugs needed for primary health care may be lower than two hundred, but this list can be used as a basis from which to select those drugs required in specific local circumstances. Drugs for use in the community should be simply and clearly labelled, carry clear instructions and be safe for community health workers to use".[19]

In 1979 the World Health Assembly resolved that the main social target of Governments and WHO should be the attainment by all citizens of the world by the year 2,000 of a level of health that would permit them to lead a socially and economically productive life.[20] It was the Declaration of Alma-Ata that stated that primary health care was the key to attaining this target.

It must be accepted that the declaration of "Health for All by the Year 2000" is not one capable of realistic attainment.[21] Passmore has, however, suggested that some specific targets could well be achieved by the turn of the century. These include the possible irradication of diseases such as poliomylitis, diphtheria, tetanus, tuberculosis, measles and whooping cough and the provision of a sufficient supply of those drugs which are needed from the list of essential drugs provided by WHO.[22]

The protection of human rights is incorporated into the constitutional traditions of all the Member States of the European Communities and has been incorporated into Community law by the forceful and resolute determination of the European Court of Justice in the development of its case law.[23] Of particular importance in the context of the EEC is the clear declaration made at the signing of Lome III to the effect that human rights form part of that Convention.[24]

Some controversy does, however, surround the inter-relationship between those fundamental human rights under the respective constitutions of Member States and the rights under the European Convention on Human Rights.[25] What may be stated is that the concept of health as a human right, at least as far as the Third World is concerned, will have no real meaning without the intervention of global agencies such as WHO. Within this concept of health may be included the supply of necessary and efficacious medicines at prices which are reasonable to the needs of the Third World. In view of the growing importance of human rights it is suggested that the world suppliers of medicines must recognise that these rights must be accepted and respected as having an important role to play in world trade in medicines.

Recognition of the right to health as a fundamental right is, however, of little assistance if it remains a pious aspiration to be achieved at some indeterminate date in the future. Such a concept is only meaningful if the right is presently justiciable with procedural rules that may be enforced through a court of law. It is this procedural aspect of the right that seems so lacking at the present time. Muchlinski has identified the unsatisfactory position in international law whereby the individual has no capacity to initiate proceedings, which he describes in this way:

> "We are therefore left with this paradox. On the one hand international law is striving to involve the individual more and more with it, while on the other it denies him the right to seek legal remedies before a court of law".[26]

It is submitted that unless this procedural difficulty can be overcome, the right to health will have no real meaning in much of the Third World. As Eze has stated, in relation to the particular problems of Africa:

> "The law can only secure the basic interests that are articulated within the framework of a given political system. Seen in this light a jurist, and a Third World jurist at that, should be able to distinguish between real rights and supposed rights. For most, if not all African countries, the right to health is still very far from being guaranteed and protected".[27]

It is apparent that this conclusion is relevant, not only to African states, but also most of the Third World today.

11.3 NON-GOVERNMENT ORGANISATIONS

International intervention in the supply of and trade in pharmaceuticals has not been confined to action taken by organisations acting on behalf of Member States. Two main developments have been the issue, in March of 1981, of a "Code of Pharmaceutical Marketing Practices" by IFMPA[28] and the establishment by several non-Government organisations, including the International Organisation of Consumers' Unions, of an international coalition (HAI).[29] The charity Oxfam is also active in this field.

The Code of Practice of IFMPA, which has been accepted by all of its member associations in forty-eight countries, was published in the WHO International Digest of Health Legislation, Volume 32, Number 3, 1981. This Code commits the companies of all member associations to the following aims:

i. to ensure that all products it makes available for prescription purposes to the public are backed by the fullest technological service and have full regard to the needs of public health;

ii. to produce pharmaceutical products under adequate procedures and strict quality assurance;

iii. to base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions of use;

iv. to provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contra-indications, tolerance and toxicity;

v. to use complete candour in dealing with public health officials, health care professionals and the public.[30]

It is not difficult to criticise the text of the Code. As in all documents of this kind, it is written in very general terms and contains exemptions to cover national differences in medicinal factors and legal provisions. An example of this is Clause 6 of the general principles, which provides:

> "Particular care should be taken that essential information as to pharmaceutical products' safety, contra-indications and side effects or toxic hazards is appropriately and consistently communicated subject to the legal, regulatory and medicinal practices of each nation". (Emphasis supplied.)

A more general point is the nature of the sanction available to punish a breach, which is merely adverse publicity for the manufacturer concerned. In an attempt to meet this criticism that such a sanction is not really effective, the IFPMA's Council voted in October 1983 to publish quarterly, and to distribute to the press and interested public, each allegation of a Code violation and the final disposition of the complaint.[31] This approach has been supported by the Director General of WHO who has said "... maximum self-monitoring should be one of the principles of the pharmaceutical industry".[32]

In March 1982 the IFPMA issued a supplementary statement.[33] This statement laid down a procedure for dealing with alleged breaches of the Code. It also provided that the IFPMA would supply Government Health Departments of the Third World with free copies of current standard compendia such as the Physicians Desk Reference (USA) and the ABPI's Data Sheet Compendium (UK). Such a

provision will enable central Governments in the Third World countries to be provided with up-to-date information about products produced in the main developed countries and their indications, contra-indications and known side effects.

The IFPMA is well aware that its critics would have preferred a compulsory code to be imposed upon its members by an independent organisation rather than the system of self-regulation which has been introduced.[34] It remains to be seen whether this voluntary code will provide an effective mechanism to ensure that marketing practices for pharmaceuticals meet acceptable ethical standards upon an international basis.

HAI comprises a network of consumer, professional, development action and other groups. It was formed in May 1981 at an international seminar on pharmaceuticals attended by participants from twenty-seven countries. Its purpose is to create a coherent international campaign for the rational use of medicines.[35] Amongs its activities are consumer education and research and the co-ordination of activities of its world-wide membership.[36] More specifically HAI has taken part in discussions upon the IFPMA Code of Practice and at World Health Assembly meetings to reflect the consumer's position.

At the inaugural meeting of HAI it was agreed that one of its first tasks should be to consider the Code of Pharmaceutical Marketing Practice of the IFPMA.[37]

HAI duly considered this document and prepared a paper, a revised edition of which was produced for the World Health Assembly held in Geneva in May of 1982.[38]

In this paper HAI criticised the IFPMA Code, suggesting that it was not a serious attempt by the pharmaceutical industry to regulate its own affairs. Its conclusion was that:

> "It remains for the International Federation of Pharmaceutical Manufacturing Associations to demonstrate convincingly that its proposed code of pharmaceutical marketing practice is something better than a sham. As it is, the provisions of the proposed code - and the arrangements for interpretation, monitoring and enforcement - appear to be consistently and transparently inadequate. There is also clear evidence that the code was proposed <u>not</u> to curb industrial malpractice - but to prevent any serious attempt to do this by independent authorities".[39]

In October of 1982 HAI circulated its own draft proposal for a Code of Pharmaceuticals.[40] This document reaffirms that good health is a fundamental human right and the right of every sick person to have access to essential pharmaceuticals.[41] This Code is a wide-ranging document making suggestions for the registration of medicines, close control of clinical trials for new medicines, Governmental control over information supplied by manufacturers in respect of their products, provisions for transfer of technology in pharmaceuticals todeveloping countries and the setting aside of money by pharmaceutical manufacturers for research and development.

It is the stated aim of the Code to enable consumers, particularly those from the developing countries, to procure safe and effective pharmaceuticals essential to their real health needs, at costs they can afford.[42] Particular recognition is given in the Code to the expertise of other international agencies active in the

field of pharmaceuticals, notably UNCTAD and WHO. Each of these bodies is, under the terms of the Code, to provide (on request) technical support to countries preparing measures to implement the principles of the Code.[43] These two bodies are also, under the terms of the proposals, to submit a report to the World Health Assembly and UNCTAD reviewing all its aspects and to make proposals for its improvement and further development.[44]

Oxfam is a charitable organisation which has launched a campaign for rational health in many countries of the Third World. This practical work in the field has led Oxfam to believe that millions of the poorest people of Asia, Africa and Latin America have no access to the modern medicines for which there is real medical need at prices which those people are able to afford.[45] In spite of this state of affairs, Oxfam has found that in many countries of the Third World inappropriate imported medicines are available on the market, such as vitamin tonics and remedies for coughs and colds, for which there is little real medical need.[46] This has led Oxfam to conclude that the existing supply of medicines by the developed countries to the Third World often results in little good, and sometimes even results in positive harm, to the actual consumers.[47]

Oxfam continues to devote funds to improve the supply of essential medicines to the Third World.[48] It has also made some valuable suggestions as to how the benefits of modern medicines could more readily be made available to the under-developed countries.[49] These include the adoption of comprehensive legislation by Third World Governments for medicines, covering such areas as price control, fair conditions for the transfer of technology, restricted patent protection and controls on marketing practices. A further recommendation is for improved co-operation between the regulatory agencies for medicines

in both the developed and developing countries, so that a more uniform approach could be adopted to the evaluation of medicines and improved access to information about such products. With regard to manufacturers, Oxfam has recommended that they should adopt uniform standards of safety upon a world-wide basis and co-operate with developing countries which wish to be self-sufficient in essential medicines through local production.

11.4 COMMENT AND CONCLUSION

In recent years there has been an increasing tendency for health issues to be viewed upon an international level. Patel has described this trend towards internationalism in relation to medicines in the following terms:

> "The drug question from now on will never be the same - buried beneath the cliches of the sanctity of the free market and private enterprise, and hidden under the umbrella of patents and trade marks. The drug question is now in the main-stream of active world concern. The developing countries have played a crucial role in bringing this about".[50]

Three main strands in this international trend may be identified. First, there is the legislative approach adopted by the Charter of the United Nations. Here the aims and aspirations of Member States are set out and a formal commitment to a new international order is made. Such policies are however normative. When translated into more specific policy objectives, it is difficult to see how these are to be achieved. Secondly, there is the incorporation of the right to health into a fundamental human right. This is again partly legislative in that this right is incorporated into such documents as the Constitution of WHO and the Draft Proposal for an

International Code on Pharmaceuticals, prepared by HAI. Neither of these documents provide a mechanism whereby a person who feels his right to health is being violated may seek redress. If such a right is not justiciable, it ceases to be a true right. Thirdly, there is the Code of Practice approach adopted by the IFPMA Code of Pharmaceutical Marketing Practice and the Draft Proposal for an International Code on Pharmaceuticals prepared by HAI. Once again, the rights purported to be granted by these Codes are not enforceable by legal means. Without effective sanctions it is doubtful whether these Codes can be made to operate satisfactorily so as to protect the conflicting interests of both producers and consumers, particularly as their enforcement is in the hands of non-government organisations.

It is submitted that this piecemeal approach is not conducive to a firm control over the pharmaceutical industry, either upon a national or an international basis. Further, it is suggested that unless a more systematic control is introduced, the influence of this new international health order upon trade in medicines in general, and upon MNEs in particular, will be ineffective.

NOTES

1. Charter of the United Nations (San Francisco, 26th June 1945; TS 67 [1946]); Cmnd 7015, Article 24(1).

2. The term "order" is used in the sense of a natural or moral system in which things proceed according to definite laws.

3. Mesarovic, M D Scareity - Discussion Paper Report of the Symposium on a New International Economic Order, The Hague, May 22nd to 24th 1975, page 17.

4. This Declaration was held at a preparatory meeting of Third World countries for UNCTAD III at Santiago.

5. Article 55 of the United Nations Charter provides that:

> "With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations ... the UN shall promote:
>
> a. higher standards of living, full employment, and conditions of economic and social progress and development;
>
> b. solutions of economic, social, health and related problems; and international cultural and educational co-operation; and
>
> c. universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion".

By virtue of Article 56 of the Charter, all members pledge themselves to take action (in co-operation with the United Nations Organisation) for the achievement of the purposes set out in Article 55.

6. Mahler, H. Introduction of the Director-General on the Activities of the World Health Organisation: <u>The New International Economic Order</u>, WHO Off Rec No 229, Geneva [1976] page 1.

7. See Article 1 of the Constitution of WHO.

8. See Part III where the influence of these bodies on international trade in medicines is discussed.

9. Council of the International Federation of Pharmaceutical Manufacturers Assocation.

10. This is set out in Appendix II.

11. Health Action International, whose activities are discussed Section 11.3.

12. See Section 11.3.

13. Pannenborg, Charles O "A New International Health Order", Sijthoff & Noordhoff, The Netherlands, [1979] page 79.

14. Van Boven, Theo C "The Right to Health". Paper submitted by the United Nations Division of Human Rights to a Workshop held by the Hague Academy of International Law, 27th-29th July 1978 in "The Right to Health as a Human Right", Rene-Jean Dupoy (Ed.), [1979] Sijthoff & Noordhoff, The Netherlands, page 54.

15. The General Assembly of the United Nations adopted the Universal Declaration of Human Rights on 10th December 1948 (UN 2 [1949] Cmnd 7662). This Declaration does not by itself impose any legal obligations upon Member States of the United Nations, nor does it by itself provide legal rights for individuals.

16. New York, 16th December 1966; Misc 4 [1967]; Cmnd 3220.

17. International Conference on Primary Health Care, Alma-Ata, USSR, 6th-12th September 1978. Joint Report by the Director-General of WHO and the Executive Director of the United Nations Childrens' Fund, paragraphs 2 and 4.

18. WHO Technical Report Series, No 615, 1977 (The Selection of Essential Drugs : Report of a WHO Expert Committee). See Appendix I.

19. See paragraph 73 of the Joint Report.

20. WHO Executive Board Sessions Draft Resolution EB63/47, "Formulation Strategies for Health for All by the Year 2000", January 1979.

21. Passmore, R "Declaration of Alma-Ata and the Future of Primary Health Care", The Lancet, 10th November 1979, 1005 at page 1007.

22. Passmore, op.cit. page 1008.

23. Dauses, Manfred A "The Protection of Fundamental Rights in the Community Legal Order", [1985] 10 EL Rev 398.

24. Dauses, op.cit. page 410.

25. Statement made by M Pisani to the ACP-EEC Consultative Assembly Meeting held in Berlin in September 1983.

26. Muchlinski, P T "The Status of the Individual Under the European Convention on Human Rights and Contemporary International Law", (1985) 34 ICLQ, 376 at page 381.

27. Eze, Osita C "Right to Health as a Human Right in Africa", op.cit. at note 14 above at page 91.

28. This Code is set out in Appendix II.

29. Health Action International.

30. See the text of the Code under the heading "Obligations of Industry".

31. IFPMA, "Medicines and the Developing World", [1984] page 25.

32. Mahler, Dr Halfdan, Keynote address to Eleventh IFPMA Assembly, Washington DC, June 1982.

33. This supplementary statement is included in Appendix II.

34. See Peretz, Michael A "Pharmaceuticals in the Third World : The problem from the supplier's point of view", World Development, Volume II, No 3, 259 at page 263.

35. See Beardshaw, Virginia "Prescription for Change : Health Action International's Guide to Rational Health Projects", [1983].

36. Fazal, Anwar "The Right Pharmaceuticals at the Right Prices : Consumer Prospectives", in World Development, Volume II, No 2, 265 at page 266.

37. Fazal, op.cit. page 267.

38. "An International Code of Pharmaceutical Marketing Practice", a Discussion Document, Health Action International.

39. Op.cit., page 14.

40. This document forms Appendix IV.

41. See paragraph 1 of the Preamble to the Code.

42. See Article 1 of the Code.

43. See Article 13.2 of the Code.

44. See Article 14 of the Code.

45. Melrose, Dianna "Bitter Pills : Medicines and the Third World Poor", Oxfam, [1982] page 1.

46. Melrose, op.cit. page 3.

47. Ibid.

48. Melrose, op.cit. page 198.

49. Melrose, op.cit. Chapter II.

50. Patel, Surendra J in Editor's Introduction to World Development, Volume II, No 3, page 165.

PART VI - GENERAL CONCLUSIONS

CHAPTER XII

Medicines are a unique consumer product because a denial of them may result in a continuation of ill-health or even death. It is because of this unique feature that the right to appropriate medicines at a reasonable price has been developed into an important human right, recognised by most of the countries of the world. All member States of WHO are committed to the strategy of Health for All by the Year 2000. In relation to medicines, this strategy envisages that national policies will be formulated to control their importation, local production, and sale and supply. Some of the key issues for such a strategy, such as pricing policies, safety and consumer protection, and licensing controls have been discussed in Parts I to III. These issues have as their ultimate goal a system of effective legal control to facilitate the availability of safe and effective medicines of acceptable quality at reasonable prices throughout the world. Thus, the development of international trade in this field impinges upon an important human right - namely, the right to health. It has rightly been said that "The drug question is now in the main stream of active world concern".[1]

In the development of world trade in medicines some legal framework is essential for the formulation and implementation of policies for medicines upon a national basis.[2] Such legislation should ensure that medicines are only made available in accordance with acceptable levels of safety, quality and efficacy and procvide for the enforcement of such provisions. It should also sanction the conditions under which medicines are manufactured, imported or exprted and made available to the ultimate consumer. In Part I the Medicines Act 1968 of the United Kingdom was discussed as a model of how such legislation might be framed. In relation to the Third World, WHO has attempted to identify the essential elements of legislation governing medicines for any developing country, whatever its stage of development.[3]

Three possible approaches to making substantive legal changes have been identified by Jayasuriya:

> (1) The revision or updating of existing legislation by way of amending legislation;
>
> (2) The replacement of existing legislation by entirely new legislation; and,
>
> (3) The enactment of comprehensive legislation, where none existed previously, by the consolidation and revision of certain sections in different existing laws, supplemented by new or additional provisions.[4]

An example of the first approach is provided by India, where the Drugs Act of 1940 was enacted during the colonial period. After many minor amendments, substantial amendments were incorporated into the legislation which became the Drugs and Cosmetics (Amendments) Act,[5] which came into effect on 1 February 1983.[6]

Such is the complexity of international trade in medicines, and the power of MNEs in many Thirld World Countries, that legislation and policies adopted by individual nations cannot alone ensure that appropriate medicines are made available at reasonable prices upon a global basis. This remains the position even where some attempt is made to harmonise the laws reating to medicines in several states, as has been done in relation to membership of the EEC by the adoption of the Pharmaceutical Directives, as discussed in section 6.2. There a variety of factors have contributed to very slow progress being made in removing all administrative barriers to trade. Some of the general difficulties in achieving a complete internal market comprising the Member States of the EEC were identified by the House of Lords in its debate upon the EEC internal market. In this debate Lord Seebohm[7] compared the position between the EEC and the United States. The latter has a population of some 255,000,000, all having a common language, laws and currency and with complete mobility of persons and

services within a single internal market. These advantages are not yet enjoyed in the EEC, nor will they be in the foreseeable future.

The European Court has attempted to balance the sometimes conflicting issues of free movement of goods and the interests of the consumer. It is submitted that the interests of the consumer have been largely neglected by the European Court.[8] In particular the price disparity which exists in the levels at which pharmaceuticals are put upon the market in the Member States of the EEC cannot be a satisfactory position. Again, in relation to its competition policy, the European Court has not accepted that high price disparities necessarily amount to abuse of a dominant position in the market.[9]

Even within the powerful trading block of the EEC there is a real danger that parochialism may be allowed to weaken the progress made in the harmonisation of free movement in medicines. This may arise in relation to safety standards which may, unless care is taken, become out of step with advances in other parts of the world, particularly the USA and Japan. Further, the activities of MNEs may result in only a global approach being effective to control restrictive practices and abuses of a dominant position in the pharmaceutical market. It is true that the EEC is at last wakening to its responsibilities in this area in relation to the Third World. On 9 October 1984 the European Parliament referred a motion for a resolution on the export of drugs from the EEC to the countries of the Third World, to the Committee of Environment, Public Health and Consumer Protection.[10] As a result of this reference a report[11] has been drawn up by the relevant committee. This report noted that while industrial countries accounted for 15% of the world population, they accounted for the consumption of more than 50% of the pharmaceutical products manufactured, and that almost 90%

of world production in pharmaceuticals was based in the industrial countries.[12] The report also recognised that as Third World countries imported almost all of their medicines, it was important that international standards should exist for the quality and usage of medicines.[13] In recognition of this the report recommended the adoption of a Directive by Member States to harmonise their laws relating to the export of medicines which are banned, withdrawn or subject to special restrictions or not registered within the EEC. This provision is to be subject to the proviso that the authorities in the importing state may specifically request such a product, once they have been informed of the existing controls within the EEC.[14]

While the approach proposed by the report is to be welcomed, it cannot be said that the adoption of such a Directive would represent a major advance in the control of international trade in medicines. It is submitted that a much more comprehensive approach to the problem is required. It is also unfortunate that the European Court has continued to adopt an approach which in practice means that the GATT provisions cannot have direct effect within the EEC. If a less restrictive approach had been adopted, it would have been possible for the EEC to have a much greater influence upon the international trade in general, and international trade in medicines in particular, than it presently enjoys. From the series of Treaties forming the Yaounde and Lome Conventions, it is clear that the EEC desires to have a much wider sphere of influence than one confined to Member States themselves. Given the inter-relationship which exists between Community Law and GATT, and the overlap of membership between the two, it is a matter for regret that there seems likely to be little integration between them. Given the widespread esteem in which the European Court is held, this institution could

have provided a common bond and a means whereby human rights could be protected on a much wider basis. It has recently been said that:

> "Bodies such as the European Economic Community have indeed been endowed with greater powers but also with a greater measure of conservatism and inertia when it comes to planning ahead or fundamentally changing society's deficiencies. The EEC is very much an economic community, with a vast industrial influence and only a very secondary interest in health matters; bearing in mind its activities to date, it is highly debatable whether it is capable of sparking off fundamental changes.".[15]

It is difficult to disagree with such a view, one result of which is effectively to prevent the institutions of the EEC from assuming a leading role in this field.

But it is in relation to the activities of MNEs, and in particularly their use of patents, trademarks and transfer pricing, that leads to a conclusion that it is only upon a world-wide basis that effective control of international trade in medicines could be achieved. It is clear that many of the Third World countries are not yet in a position to control the activities of MNEs in the manufacture of medicines.[16] In this area, it seems clear that the international institutions such as WHO, UNCTAD and UNIDO have a leading part to play. This embraces the effective monitoring of MNEs, the development of the WHO list of essential drugs, and the fostering of new manufacturing industry in the Third World to enable them to become more self-sufficient for their own needs for pharmaceutical products. At the present time some 90% of the world's production of pharmaceuticals takes place in the developedcountries, which also account for 80% of

their consumption.[17] In this connection, it has already been observed that the post-colonial phase has been characterised by the rapid growth in the number and power of MNEs, the advance of centralised Governments and the development of international bodies with a global impact upon world issues, such as UNCTAD. Related to such movements, and of specific concern to the pharmaceutical field, is the concept of what has been termed "drug-colonialism". Governments of many Third World countries have accepted, often without considering the consequences, that Western medicine is superior to any other. This has resulted in the importation into the Third World of a dependence upon the products of MNEs, sometimes to the detriment of more reliable alternatives in health care.[18] This approach by some Third World Governments is encouraged by MNEs engaged in the pharmaceutical industry, which wish to maximise their profits in these new markets. Shiva has drawn attention to the paradox that, in spite of having a large pharmaceutical industry, countries like India still have a severe shortage of essential drugs for major diseases.[19]

In many Third World countries there has been a tendancy to dismiss traditional medicine as unscientific. Further, as Shiva has pointed out, most medicines in historic terms have been plant based: in India's indigenous medical system over 1,500 drugs are derived from plants; while in China, one billion people still depend on traditional medicines, many of which are derived from plants.[20] It is suggested that this traditional element in the provision of medicines should no longer be neglected, provided that safety considerations are not forgotten.

It falls for consideration whether some international control of medicines is desirable and, if so, which is the most appropriate body to perform such a task. One possible body to adopt this role is WHO. It is suggested that the adoption of the global strategy of Health for All

by the Year 2000 by the Member States of WHO at the Alma Ata Conference held in 1978 is evidence of the need for some international code to improve the use of medicines. This conference recommended that Member States should:

> "... formulate nationalpolicies and recommendations with respect to the import, local production, sale and distribution of drugs and biologicals to ensure that essential drugs are available at the various levels of primary health care at the lowest feasible cost; that specific measures be taken to prevent the over utilisation of medicines; that proved traditional remedies be incorporated; and that effective administrative and supply systems be established".[21]

It is clear that the achievement of Health for All by the Year 2000 is too large a goal to be achieved by individual states and could only realistically be undertaken by some international organisation.[22] It is suggested that such a policy should embrace all of the following elements:

(i) The adoption of limited lists of essential medicines upon an international basis at reasonable cost.

(ii) The control of new medicines coming onto the market which, although satisfactory from the point of view of safety, quality and efficacy, fail to demonstrate any therapeutic advance upon existing products.

(iii) The provision of independent and scientifically accurate information about all products available on a limited list of medicines.

(iv) The removal of unsatisfactory products from the market upon a compulsory basis.

(v) The provision of finance to generate research for the particular medicinal needs of widespread diseases of the Third World where there is at present no satisfactory cure available.

(vi) The provision of some effective control over the activities of MNEs with effective sanctions.[23]

(vii) The provision of an effective means of redress for consumers of products who suffer injury as a result of taking medicines.

(viii) An adequate means of redress for anyone who is deprived of essential medicines.

WHO is a focal point for those interests which are affected by the regulation of medicines such as consumers, the pharmaceutical industry and member states. That WHO has an explicit mandate to act in this area is clear from Article 21 of its Constitution, which states that the World Health Assembly:

> "... shall have power to adopt regulations covering, inter alia, standards with respect to the safety, purity and potency of biological pharmaceuticals and similar products moving in international commerce and the advertising and labelling of biological, pharmaceutical and similar products, moving in international commerce".

But this involvement may itself operate as a being able to act as a body controlling these conflicting interests in an impartial manner. As Medewar has observed, it would be

very difficult for WHO to maintain both a close working relationship with the industry and control it at the same time.[24] In view of this conflict it may, therefore, be impossible for WHO to take a leading role in what would amount to a new world therapeutic order.

Nevertheless, the establishment of a new code of pharmaceutical practice to include the elements above defined would seem to be both desirable and essential if real meaning is to be given to the strategy of Health for All by the Year 2000. WHO's Director-General has emphasised that "Health for All by the Year 2000 is no idle slogan"[25] and that the 160 countries co-operating through WHO are formally committed to this policy.[26] Yet the Brandt Report has found that:

> "Recent World Bank projections (which contain fairly optimistic assumptions about economic growth, but do not incorporate any major changes in national development efforts) suggest that there will still be 600 million absolute poor in the countries of the South by the year 2000".[27]

Having regard to these predictions, it is difficult to see how the ideal of Health for All can be achieved in the time-scale proposed.

A new code of pharmaceutical practice would also have to have a legal framework for the adjudication of disputes, with public hearings. Provisions would have have to be made for effective enforcement in respect of breaches of the code and awards of compensation in appropriate cases. Such an approach is similar to, but much more comprehensive than, that which the developing countries have asked both WHO and UNCTAD to formulate.[28] In the light of these considerations it is hoped that some real and meaningful action will be taken towards achieving the aim of Health for All by the Year 2000. By the same token

it is felt that the law of international trade in medicines could, if developed upon the lines outlined above, play a significant part in ensuring that the goal is reached.

One significant aspect of the approach of WHO is its international, as opposed to supranational, role. This point was recently emphasised by the Director-General of WHO[29] and means that although policies are debated and agreed by WHO, they are not imposed by WHO but by national Governments.[30] A related topic which has become the subject to a code is that concerned with formulae sold as substitutes for mothers' milk in feeding infants.[31] This achieved some limited success and has shown that such a code may be incorporated into national legislation.[32] This experience may perhaps be drawn upon to launch the more far-reaching and comprehensive Code of Practice which would be required for pharmaceuticals. It is suggested that there is one approach which might enable WHO to play a key role in formulating a global policy for a new Pharmaceutical Code as outlined above, while at the same time not requiring it to become an enforcement agency for member states. This would be for WHO to have a coordinating role in drawing up the proposed code, in consultation with other international institutions, but leaving the enforcement of its provisions to member states themselves. By this means the expertise of WHO could be brought to bear upon the control of international trade in medicines, while the investigation and enforcement of the Code would be undertaken by responsible agencies of member states. This pattern of control would be must upon the lines of Directives issued by the institutions of the EEC, where implementation of policy and enforcement are largely left to member states.[33] As has been discussed in Parts I to III, there are many aspects of control over medicines which are of international concern to enable this approach to be feasible. Such an approach would also enable the social, manpower and economic resources of each state to be taken into account in deciding which methods of enforcement were appropriate within the general framework of the Code.

NOTES

1. Patel, Surendra J, Editor's Introduction to World Development, Vol 11, Number 3, page 167.

2. Jayasuriya, D C "Regulation of Pharmaceuticals in Developing Countries: legal issues and approaches", World Health Organisation, Geneva (1985), page 5.

3. "Report of a consultation on basic elements of drug legislation and regulatory control for developing countries". Unpublished WHO Document DAP/81.3.

4. Jayasuriya, op.cit., page 13.

5. Act Number 68 of 1982.

6. Jayasuriya, op.cit., Annex I.

7. Hansard, 10 October 1986, Vol 480, Number 147, column 476.

8. It must be accepted that the adoption of the Product Liability Directive (which is set out in Appendix III), and its acceptance into the legislation of Member States by 30 July 1988, may provide some important protection for the consumer of medicines in the fullness of time. In relation to medicines the difficulty of proving negligence in the United Kingdom Courts will be replaced by the task of interpreting the new legislation implementing the Directive, as discussed in Part IV.

9. Sirena -v- Eda [1971] CMLR 260 at page 276.

10. Doc 2 - 565/84.

11. Working Document A 2-3686 dated 12 May 1986, Rapporteur: Mrs Mary Banotti.

12. Page 5 of the Banotti Report.

13. Page 11 of the Banotti Report.

14. Page 7 of the Banotti Report.

15. Dukes, M N G "Towards a Healthy Pharmaceutical Industry by the Year 2000", in Development Dialogue (1985), Vol 2, 108 at page 117.

16. Jayesina, K "Drugs - Registration and Marketing Practices in the Third World", in Development Dialogue (1985), Vol 2, 38 at page 45.

17. Sterky, Goran "Another Development in Pharmaceuticals", Developing Dialogue (1985), Vol 2, 5 at page 9.

18. Shiva, Mira "Towards a Healthy Use of Pharmaceuticals: an Indian Perspective", Development Dialogue (1085), Vol 2, 69 at page 73.

19. Shiva, op.cit., page 74.

20. Shiva, op.cit., page 69.

21. "Primary Health Care", Report of the International Conference on Primary Health Care jointly organised by WHO and UNICEF at Alma Ata, USSR, 6-12 September 1978, published by WHO, Geneva (1978).

22. Medewar, Charles "International Regulation of the Supply and Use of Pharmaceuticals", Development Dialogue (1985), Vol 2, 15 at page 16.

23. It may be questioned whether codes of conduct based upon international guidelines can be an effective method of enforcement against MNEs. Vagts has concluded tha they can play a useful role, provided that not too much is expected of them. Their limitations are exposed when there is a need for the resolution of a specific dispute where large sums of money are at stake. (See Vagts, Detler F "Multinational Corporations and International Guidelines", 18 CML Rev (1981), 463 at page 474.)

24. Medewar op.cit., page 29.

25. Mahler, H, Address to 11th Assembly of the IFPMA, June 1982.

26. "One Common Goal", WHO, Geneva, 1983.

27. Brandt, W (Chairman) et al "North-South: A Programme for Survival", (London, Pan, 1981), page 51.

28. "Report and recommendations of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector", Abidjan (UNCTAD/TT/48).

29. Mahler, H "The Rational Use of Drugs", Report of the Conference of Experts, Nairobi, 25-29 November 1985 (WHO, Geneva, 1987), at page 6.

30. Ibid., page 72.

31. On 21 May 1981 the 34th World Health Assembly approved an international code of marketing of breast-milk substitutes by a vote of 118 to 1. (WHO, International Code of Breast-Milk Substitutes, Resolution WHA 34.22, Geneva, 21st May 1981).

32. By July 1984, twelve countries had adopted the code in its entirety, either as law or as a voluntary measures, while another thirty-four countries were drafting legislation on the subject. (UNICEF, Ideas Forum, Issue No 19, 1984 (4).

33. In relation to this pattern of control proposed for WHO it must of course be accepted that nothing comparable to the European Court of Justice woul dexist to act either as a Court of Appeal or as an interpreter of the Code.

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R v Referees of the National Health Service, ex parte Drs H. H. Ronn and C. Tennant (unreported).

R v Secretary of State for Social Services, ex parte Wellcome Foundation Limited [1988] 2 All E.R. 684.

Re: Taylor's Application [1972] 2 QB 369.

S v Distillers [1974] 2 All E.R. 365.

Seyfang v Searle and Company [1973] 1 QB 148.

Smith, Kline and French v Bloch [1983] 1 WLR 730.

APPENDICES

I - WHO Revised Model List of Essential Drugs (1979).

II - IFPMA Code of Pharmaceutical Marketing Practices (1981).

III - Council Directive of 25th July 1985 (85/3741EEC).

IV - A Draft Proposal for an International Code on Pharmaceuticals - Health Action International (HAI) Discussion Document (1982).

WHO: Revised Model List of Essential Drugs (1979)*

EXPLANATORY NOTES†

I. Numbers in parentheses following the drug names indicate:

(1) listed as an example of this therapeutic category: choose cheapest effective drug product acceptable;
(2) specific expertise, diagnostic precision or special equipment required for proper use;
(3) greater potency;
(4) in renal insufficiency, contraindicated or dosage adjustments necessary;
(5) to improve compliance;
(6) special pharmacokinetic properties for purpose;
(7) adverse effects diminish benefit/risk ratio;
(8) limited indications or narrow spectrum of activity;
(9) for epidural anaesthesia;
(10) drugs subject to international control under the Single Convention on Narcotic Drugs (1961) and the Convention of Psychotropic Substances (1971).

II. Letters in parentheses following the drug names indicate the reasons for the inclusion of *complementary drugs*:

(A) when drugs in the main list cannot be made available;
(B) when drugs in the main list are known to be ineffective or inappropriate for a given individual;
(C) for use in rare disorders or in exceptional circumstances.

* See 'The selection of essential drugs'. Second report of the WHO Expert Committee. World Health Organization. Technical Report Series 641 (Geneva: 1979), pp. 9–29.

† The numbers preceding the drug groups and subgroups in the model list (e.g. 11; 17.6.2) have been allocated, in accordance with the English alphabetical order, for convenience in referring to the various categories; they have no formal significance.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
	1. Anaesthetics	
	1.1 *General anaesthetics and oxygen*	
Ether, anaesthetic (2)		Inhalation
Halothane (2)		Inhalation
Nitrous oxide (2)		Inhalation
Oxygen		Inhalation (medicinal gas)
Thiopental (2)		Powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule
	1.2 *Local anaesthetics*	
Bupivacaine (1, 2, 9)		Injection, 0.25%, 0.5% (hydrochloride) in vial
Lidocaine (1)		Injection, 1%, 2% (hydrochloride) in vial
		Injection, 1%, 2% + epinephrine 1 : 100 000 in vial
		Topical forms, 2–4% (hydrochloride)
	2. Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs and Drugs Used to Treat Gout	
Acetylsalicylic acid		Tablet, 100–500 mg
		Suppository, 50–150 mg
Allopurinol (4)		Tablet, 100 mg
Ibuprofen (1)		Tablet, 200 mg
Indometacin		Capsule or tablet, 25 mg
Paracetamol		Tablet, 100–500 mg
		Suppository, 100 mg
	Colchicine (B, C) (7)	Tablet, 0.5 mg
	Probenecid (B, C)	Tablet, 500 mg
	3. Analgesics, Narcotics and Narcotic Antagonists	
Morphine (10)		Injection, 10 mg (sulphate or hydrochloride) in 1-ml ampoule
Naloxone		Injection, 0.4 mg (hydrochloride) in 1-ml ampoule
	Pethidine (A) (1, 4, 10)	Injection, 50 mg (hydrochloride) in 1-ml ampoule
	4. Anti-allergics	
	Antihistamines	
Chlorphenamine (1)		Tablet, 4 mg (maleate)
	5. Antidotes	
	5.1 *General*	
Charcoal, activated		Powder
Ipecacuanha		Syrup, containing 0.14% ipecacuanha alkaloids calculated as emetine
	5.2 *Specific*	
Atropine		Injection, 1 mg (sulphate) in 1-ml ampoule
Desferoxamine		Injection, 500 mg (mesilate) in vial
Dimercaprol (2)		Injection in oil, 50 mg/ml in 2-ml ampoule
Sodium calcium edetate (2)		Injection, 200 mg/ml in 5-ml ampoule
Sodium nitrite		Injection, 30 mg/ml in 10-ml ampoule
Sodium thiosulfate		Injection, 250 mg/ml in 50-ml ampoule
	Methylthioninium chloride (C)†	Injection, 10 mg/ml in 10-ml ampoule
	Penicillamine (C) (2)	Capsule or tablet, 250 mg

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

† Synonym: methylene blue.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
	6. Anti-epileptics	
Diazepam		Injection, 5 mg/ml in 2-ml ampoule
Ethosuximide		Capsule or tablet, 250 mg
Phenobarbital (10)		Tablet, 50 mg, 100 mg
		Syrup, 15 mg/5 ml
Phenytoin		Capsule or tablet, 25 mg, 100 mg (sodium salt)
		Injection, 50 mg (sodium salt)/ml in 5 ml vial
	Carbamazepine (B, C)	Tablet, 200 mg
	Valproic acid (B, C) (2, 4, 7)	Tablet, 200 mg (sodium salt)
	7. Anti-infective Drugs	
	7.1 *Amoebicides*	
Metronidazole		Tablet, 200–500 mg
	Diloxanide (A)	Tablet, 500 mg (furoate)
	Emetine (A, B) (1, 7)	Injection, 60 mg (hydrochloride) in 1-ml ampoule
	Paromomycin (B)	Capsule, 250 mg (as sulphate)
		Syrup, 125 mg (as sulphate)/5 ml
	7.2 *Anthelmintic drugs*	
Mebendazole		Tablet, 100 mg
Niclosamide		Tablet, 500 mg
Piperazine		Tablet, 500 mg (citrate or adipate)
		Elixir or syrup (as citrate) equivalent to 500 mg hydrate/5 ml
Tiabendazole		Chewable tablet, 500 mg
	Bephenium hydroxy-naphthoate (B) (8)	Granules, 5 g (equivalent to 2.5 g bephenium)
	7.3 *Antibacterial drugs*	
Ampicillin (1, 4)		Capsule or tablet, 250 mg, 500 mg (anhydrous)
		Powder for oral suspension, 125 mg (anhydrous)/5 ml
		Powder for injection, 500 mg (as sodium salt) in vial
Benzathine benzylpenicillin (5)		Injection, 1.44 g benzylpenicillin (= 2.4 million IU)/5 ml in vial
Benzylpenicillin		Powder for injection, 0.6 g (= 1 million IU), 3.0 g (= 5 million IU) (as sodium or potassium salt) in vial
Chloramphenicol (7)		Capsule, 250 mg
		Powder for injection, 1 g (as sodium succinate) in vial
Cloxacillin (1)		Capsule, 500 mg (as sodium salt)
		Powder for injection, 500 mg (as sodium salt) in vial
Erythromycin		Capsule or tablet, 250 mg (as sterate or ethylsuccinate)
		Oral suspension, 125 mg (as stearate or ethylsuccinate)/5 ml
		Powder for injection, 500 mg (as lactobionate) in vial

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
Gentamicin (4)		Injection, 10 mg, 40 mg (as sulphate)/ml in 2-ml vial
Metronidazole		Tablet, 200–500 mg
Phenoxymethylpenicillin		Tablet, 250 mg (as potassium salt)
		Powder for oral suspension, 250 mg (as potassium salt)/5 ml
Salazosulphapyridine (2)		Tablet, 500 mg
Sulphadimidine (1, 4)		Tablet, 500 mg
		Oral suspension, 500 mg/5 ml
		Injection, 1 g (sodium salt) in 3-ml ampoule
Sulphamethoxazole + trimethoprim (4)		Tablet, 100 mg + 20 mg, 400 mg + 80 mg
Tetracycline (1, 4)		Capsule or tablet, 250 mg (hydrochloride)
	Amikacin (B, C) (1, 4)	Injection, 250 mg (sulphate)/ml in 2-ml ampoule
	Doxycycline (B) (5, 6)	Capsule or tablet, 100 mg (as hydrochloride) injection, 100 mg (as hydrochloride)
	Nitrofurantoin (A, B) (4, 7)	Tablet, 100 mg
	Procaine benzylpenicillin (A) (7)	Powder for injection, 1 g (= 1 million IU), 3g (= 3 million IU)
	7.4 *Antifilarial drugs*	
Diethylcarbamazine		Tablet, 50 mg (citrate)
Suramin sodium		Injection, 1 g in vial
	7.5 *Antileprosy drugs*	
Dapsone		Tablet, 100 mg
	Clofazimine (B)	Capsule, 100 mg
	Rifampicin (B)	Capsule or tablet, 150 mg, 300 mg
	7.6 *Antimalarials*	
Chloroquine (1)		Tablet, 150 mg (as phosphate or sulphate)
		Syrup, 50 mg (as phosphate or sulphate)/5 ml
Primaquine		Tablet, 7.5 mg, 15 mg (as phosphate)
Pyrimethamine		Tablet, 25 mg
Quinine		Tablet, 300 mg (as bisulphate or sulphate)
		Injection, 300 mg (as dihydrochloride)/ml in 2-ml ampoule or 250 mg (as formiate) in 1-ml ampoule
	Sulphadoxine – pyrimethamine (B)	Tablet, 500 mg + 25 mg
	7.7 *Antischistosomals*	
Metrifonate		Tablet, 100 mg
Niridazole (7, 8)		Tablet, 100 mg, 500 mg
Oxamniquine		Capsule, 250 mg
		Syrup, 250 mg/5 ml
	Antimony sodium tartrate (B)	Injection, 60 mg in 1-ml ampoule
	Sodium stibocaptate (B)	Injection, 500 mg
	7.8 *Antitrypanosomals*	
Melarsoprol (5)		Injection, 3.6 % solution
Nifurtimox		Tablet, 30 mg, 120 mg, 250 mg
Pentamidine (5)		Powder for injection, 200 mg (isetionate or mesilate)

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
Suramin sodium		Powder for injection, 1 g in vial
	7.9 *Antituberculosis drugs*	
Ethambutol		Tablet, 100–500 mg (hydrochloride)†
Isoniazid		Tablet, 100–300 mg
Rifampicin		Capsule or tablet, 150 mg, 300 mg
Streptomycin (4)		Injection, 1 g (as sulphate)
	7.10 *Leishmaniacides*	
Pentamidine (5)		Powder for injection, 200 mg (isetionate or mesilate)
Sodium stibogluconate		Injection, 33%, equivalent to 10% antimony, in 30-ml vial
	7.11 *Systemic antifungal drugs*	
Amphotericin B		Injection, 50 mg in vial
Griseofulvin (8)		Tablet or capsule, 125 mg, 250 mg
Nystatin		Tablet, 500 000 IU
	Flucytosine (B) (1, 4, 8)	Tablet or capsule, 250 mg
	8. Antimigraine Drugs	
Ergotamine (2, 7)		Tablet, 2 mg (as tartrate)
	9. Antineoplastic and Immunosuppressive Drugs	
Azathioprine (2)		Tablet, 50 mg
		Powder for injection, 100 mg (as sodium salt) in vial
Bleomycin (2)		Powder for injection, 15 mg (as sulphate) in vial
Busulfan (2)		Tablet, 2 mg
Calcium folinate (2)‡		Tablet, 15 mg
		Injection, 3 mg/ml in 10-ml ampoule
Chlorambucil (2)		Tablet, 2 mg
Cyclophosphamide (2)		Tablet, 25 mg
		Powder for injection, 500 mg in vial
Cytarabine (2)		Powder for injection, 100 mg in vial
Doxorubicin (1, 2)		Powder for injection, 10 mg, 50 mg (hydrochloride) in vial
Fluorouracil (2)		Injection, 50 mg/ml in 5-ml ampoule
Methotrexate (2)		Tablet, 2.5 mg (as sodium salt)
		Injection, 50 mg (as sodium salt) in vial
Procarbazine (2)		Capsule, 50 mg (as hydrochloride)
Vincristine (2)		Powder for injection, 1 mg, 5 mg (sulphate) in vial
	10. Antiparkinsonism Drugs	
Levodopa		Tablet or capsule, 250 mg
Trihexyphenidyl (1)		Tablet, 2 mg, 5 mg (hydrochloride)
	Levodopa + carbidopa (B), (1, 5, 6)	Tablet, 100 mg + 10 mg, 250 mg + 25 mg
	11. Blood, Drugs Affecting the 11.1 *Antianaemia drugs*	
Ferrous salt (1)		Tablet, equivalent to 60 mg iron (as sulphate or fumarate)

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

† Two strengths are required for individual dose adjustment.

‡ Drug for 'rescue therapy' with methotrexate.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
Folic acid (2)		Tablet, 1 mg
		Injection, 1 mg in 1-ml ampoule
	Iron dextran (B) (1, 5)	Injection, equivalent to 50 mg iron/ml in 2-ml ampoule
Hydroxocobalamin (1, 2)		Injection, 1 mg in 1-ml ampoule
	11.2 *Anticoagulants and antagonists*	
Heparin (2)		Injection, 1000 IU/ml, 25 000 IU/ml in 5-ml ampoule
Phytomenadione		Injection, 10 mg/ml in 5-ml ampoule
Protamine sulphate (2)		Injection, 10 mg/ml in 5-ml ampoule
Warfarin (1, 2, 6)		Tablet, 5 mg (sodium salt)
	12. Blood Products and Blood Substitutes	
	12.1 *Plasma substitute*	
Dextran 70		Injectable solution, 6%
	12.2 *Plasma fractions for specific uses*	
Albumin, human normal (2, 8)		Injectable solution, 25%
	Antihaemophilic fraction† (C) (2, 8)	(Dried)
	Fibrinogen (C) (2, 8)	(Dried)
	Plasma protein (C) (2, 8)	Injectable solution, 5%
	Factor IX complex (coagulation factors II, VII, IX, X, concentrate (C) (2, 8)	(Dried)
	13. Cardiovascular Drugs	
	13.1 *Antianginal drugs*	
Glyceryl trinitrate		Tablet (sublingual) 0.5 mg
Isosorbide dinitrate (1)		Tablet (sublingual) 5 mg
Propranolol (1)		Tablet, 10 mg, 40 mg (hydrochloride)
		Injection, 1 mg (hydrochloride) in 1-ml ampoule
	13.2 *Antiarrhythmic drugs*	
Lidocaine		Injection, 20 mg (hydrochloride)/ml in 5-ml ampoule
Procainamide (1)		Tablet, 500 mg (hydrochloride)
		Injection, 100 mg (hydrochloride)/ml in 10-ml ampoule
Propranolol (1)		Tablet, 10 mg, 40 mg (hydrochloride)
		Injection, 1 mg (hydrochloride) in 1-ml ampoule
	Quinidine (A, B) (1)	Tablet, 200 mg (sulphate)
	13.3 *Antihypertensive drugs*	
Hydralazine (1)		Tablet, 50 mg (hydrochloride)
Hydrochlorothiazide (1)		Tablet, 50 mg
Propranolol (1)		Tablet, 40 mg (hydrochloride)
Sodium nitroprusside (1, 2, 3)		Injection, 10 mg/ml in 5-ml vial
	Methyldopa (A, B) (7)	Tablet, 250 mg
	Reserpine (A), (1, 7)	Tablet, 0.1 mg, 0.25 mg
		Injection, 1 mg in 1-ml ampoule

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

† Synonym: factor VIII.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
	13.4 *Cardiac glycosides*	
Digoxin (4)		Tablet, 0.0625 mg, 0.25 mg
		Oral solution, 0.05 mg/ml
		Injection, 0.25 mg/ml in 2-ml ampoule
	Digitoxin (B) (6)	Tablet, 0.05 mg, 0.1 mg
		Oral solution, 1 mg/ml
		Injection, 0.2 mg in 1-ml ampoule
	13.5 *Drugs used in shock or anaphylaxis*	
Dopamine (2)		Injection, 40 mg (hydrochloride)/ml in 5-ml vial
Epinephrine†		Injection, 1 mg (as bitartrate) in 1-ml ampoule†
	Isoprenaline (C)	Injection, 1 mg (hydrochloride)/ml in 2-ml ampoule
	14. Dermatological Drugs	
	14.1 *Antiinfective drugs*	
Neomycin + bacitracin (1)		Ointment, 5 mg neomycin + 500 IU bacitracin zinc/g
	14.2 *Antiinflammatory drugs*	
Betamethasone (1, 3)		Ointment or cream, 0.1% (as valerate)
Hydrocortisone (1)		Ointment or cream, 1% (acetate)
	14.3 *Astringents*	
Aluminium acetate		Solution 13% for dilution
	14.4 *Fungicides*	
Benzoic acid + salicylic acid		Ointment or cream, 6% + 3%
Miconazole (1)		Ointment or cream, 2% (nitrate)
Nystatin		Ointment or cream, 100 000 IU/g
	14.5 *Keratoplastic agents*	
Coal tar		Solution, topical 20%
Salicylic acid		Solution, topical 5%
	14.6 *Scabicides and pediculicides*	
Benzyl benzoate		Lotion, 25%
Gamma benzene hexachloride		Cream or lotion, 1%
	15. Diagnostic Agents	
Edrophonium (2, 8)		Injection, 10 mg (chloride) in 1-ml ampoule
Tuberculin, purified protein derivative (PPD)		Injection
	15.1 *Ophthalmic*	
Fluorescein		Eye drops, 1% (sodium salt)
	15.2 *Radiocontrast media*	
Adipiodone meglumine (1)		Injection, 25% in 20-ml vial
Barium sulphate (1)		Powder
Iopanoic acid (1)		Tablet, 500 mg
Meglumine amidotrizoate (1)		Injection, 60% in 20-ml ampoule
Sodium amidotrizoate (1)		Injection, 50% in 20-ml ampoule
	16. Diuretics	
Amiloride (1)		Tablet, 5 mg (hydrochloride)
Furosemide (1)		Tablet, 40 mg
		Injection, 10 mg/ml in 2-ml ampoule
Hydrochlorothiazide (1)		Tablet, 50 mg

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

† Epinephrine is the L-isomer. Appropriate dosage adjustment is required when the racemic form (racepinefrine) is used.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
Mannitol		Injectable solution, 10%, 20%
	Chlortalidone (B) (6)	Tablet, 50 mg
	17. Gastrointestinal Drugs	
	17.1 *Antacids (nonsystemic)*	
Aluminium hydroxide		Tablet, 500 mg
		Oral suspension, 320 mg/5 ml
Magnsium hydroxide		Oral suspension, equivalent to 550 mg mganesium oxide/10 ml
	Calcium carbonate 9 (A, B)	Tablet, 600 mg
	17.2 *Antiemetics*	
Promethazine (1)		Tablet, 10 mg, 25 mg (hydrochloride)
		Elixir or syrup, 5 mg (hydrochloride)/5 ml
		Injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
	17.3 *Antihaemorrhoidals*	
Local anaesthetic, astringent and antiinflammatory drug (1)		Ointment or suppository
	17.4 *Antispasmodics*	
Atropine (1)		Tablet, 1 mg (sulphate)
		Injection, 1 mg (sulphate) in 1-ml ampoule
	17.5 *Cathartics*	
Senna (1)		Tablet, 7.5 mg (sennosides)
	17.6 *Diarrhoea*	
	17.6.1 *Antidiarrhoeal*	
Codeine (1, 10)		Tablet, 30 mg (phosphate)
	17.6.2 *Replacement solution*	
Oral rehydration salts (for glucose-salt solution)		
For 1 l. of water:	(Sachet)	mmol/l
Sodium chloride (table salt)	3.5 g, Na^+	90
Sodium bicarbonate (baking soda)	2.5 g, HCO_3^-	30
Potassium chloride	1.5 g, K^+	20
Glucose (dextrose)	20.0 g, glucose	111
Ethinylestradiol + norethisterone (1)		Tablet, 0.05 mg + 1.0 mg
	Norethisterone (B)	Tablet, 0.35 mg
	18. Hormones	
	18.1 *Adrenal hormones and synthetic substitutes*	
Dexamethasone (1)		Tablet, 0.5 mg, 4 mg
		Injection, 4 mg (sodium phosphate) in 1-ml ampoule
Hydrocortisone		Powder for injection, 100 mg (as sodium succinate) in vial
Prednisolone (1)		Tablet, 5 mg
	Fludrocortisone (C)	Tablet, 0.1 mg (acetate)
	18.2 *Androgens*	
Testosterone (2)		Injection, 200 mg (enantate) in 1-ml ampoule
		Injection 25 mg (propionate) in 1-ml ampoule
	18.3 *Estrogens*	
Ethinylestradiol (1)		Tablet, 0.05 mg

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*	
	18.4 *Insulins*		
Compound insulin zinc suspension (1)		Injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial	
Insulin injection		Injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial	
	18.5 *Oral contraceptives*		
Ethinylestradiol + levonorgestrel (1)		Tablet, 0.03 mg + 0.15 mg, 0.05 mg + 0.25 mg	
	18.6 *Progestogens*		
Norethisterone (1)		Tablet, 5 mg	
	18.7 *Thyroid hormones and antagonists*		
Levothyroxine		Tablet, 0.05 mg, 0.1 mg (sodium salt)	
Potassium iodide		Tablet, 60 mg	
Propylthiouracil (1)		Tablet, 50 mg	
	18.8 *Ovulation inducer*		
	Clomifene (C) (2, 8)	Tablet, 50 mg (citrate)	
	19. Immunologicals		
	19.1 *Sera and immunoglobulins*		
Anti-D immunoglobulin (human)		Injection, 0.25 mg/ml	
Antirabies hyperimmune serum		Injection, 1000 IU in 5-ml ampoule	
Antivenom sera		Injection	
Diphtheria antitoxin		Injection, 10 000 IU, 20 000 IU in vial	
Immunoglobulin, human normal (2)		Injection	
Tetanus antitoxin		Injection, 50 000 IU in vial	
	19.2 *Vaccines*		
	19.2.1 *For universal immunization*		
BCG vaccine (dried)		Injection	All vaccines should comply with the WHO Requirements for Biological Substances†
Diphtheria–pertussis–tetanus vaccine		Injection	
Diphtheria–tetanus vaccine		Injection	
Measles vaccine		Injection	
Poliomyelitis vaccine (live attenuated)		Oral solution	
Smallpox vaccine		Multiple puncture	
Tetanus vaccine		Injection	
	19.2.2 *For specific groups of individuals*		
Influenza vaccine		Injection	
Meningococcal vaccine		Injection	
Rabies vaccine		Injection	
Typhoid vaccine		Injection	
Yellow fever vaccine		Injection	

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

† Dried BCG Vaccine (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Diphtheria Toxoid, Pertussis Vaccine, Tetanus Toxoid, and Combined Vaccines (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Measles Vaccine (Live) and Measles Vaccine (Inactivated) (WHO Technical Report Series, No. 329, 1966); Poliomyelitis Vaccine (Oral) (Revised 1971) (WHO Technical Report Series, No. 486, 1972); Smallpox Vaccine (WHO Technical Report Series, No. 323, 1966); Tetanus Toxoid (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Influenza Vaccine (Inactivated) (Revised 1978) (WHO Technical Report Series, No. 638, 1979); Meningococcal Polysaccharide Vaccine (WHO Technical Report Series, No. 594, 1976), Addendum 1977, incorporating Addendum 1976 (WHO Technical Report Series, No. 626, 1978); Rabies Vaccine for Human Use (WHO Technical Report Series, No. 530, 1973), Revision available 1980; Typhoid Vaccine (WHO Technical Report Series, No. 361, 1967); Yellow Fever Vaccine (Revised 1975) (WHO Technical Report Series, No. 594, 1976).

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
20. Muscle Relaxants (Peripherally Acting) and Cholinesterase Inhibitors		
Neostigmine (1)		Tablet, 15 mg (bromide)
		Injection, 0.5 mg (metilsulphate) in 1-ml ampoule
Suxamethonium (2)		Injection, 50 mg (chloride)/ml in 2-ml ampoule
Tubocurarine (1, 2)		Injection, 10 mg (chloride)/ml in 1.5-ml ampoule
	Pyridostigmine (B) (2, 8)	Tablet, 60 mg (bromide)
		Injection, 1 mg (bromide) in 1-ml ampoule
21. Ophthalmological Preparations		
21.1 Antiinfective		
Silver nitrate		Solution (eye drops) 1%
Sulphacetamide		Eye ointment, 10% (sodium salt)
		Solution (eye drops), 10% (sodium salt)
Tetracycline (1)		Eye ointment, 1% (hydrochloride)
21.2 Antiinflammatory		
Hydrocortisone (2, 7)		Eye ointment, 1% (acetate)
21.3 Local anaesthetics		
Tetracaine (1)		Solution (eye drops), 0.5% (hydrochloride)
21.4 Miotics		
Pilocarpine		Solution (eye drops), 2%, 4% (hydrochloride or nitrate)
21.5 Mydriatics		
Homatropine (1)		Solution (eye drops), 2% (hydrobromide)
	Epinephrine (A, B) (2)	Solution (eye drops), 2% (as hydrochloride)
21.6 Systemic		
Acetazolamide		Tablet, 250 mg
22. Oxytocics		
Ergometrine (1)		Tablet, 0.2 mg (maleate)
		Injection, 0.2 mg (maleate) in 1-ml ampoule
Oxytocin		Injection, 10 IU in 1-ml ampoule
23. Peritoneal Dialysis Solution		
Intraperitoneal dialysis solution (of appropriate composition)		Parenteral solution
24. Psychotherapeutic Drugs		
Amitriptyline (1)		Tablet, 25 mg (hydrochloride)
Chlorpromazine (1)		Tablet, 100 mg (hydrochloride)
		Syrup, 25 mg (hydrochloride)/5 ml
		Injection, 25 mg (hydrochloride/ml in 2-ml ampoule
Diazepam (1)		Tablet, 5 mg
Fluphenazine (1, 5)		Injection, 25 mg (decanoate or enantate) in 1-ml ampoule
Haloperidol (1)		Tablet, 2 mg
		Injection, 5 mg in 1-ml ampoule
Lithium carbonate (2, 4, 7)		Capsule or tablet, 300 mg
25. Respiratory Tract, Drugs Acting on the		
25.1 Antiasthmatic drugs		
Aminophylline (1)		Tablet, 200 mg
		Injection, 25 mg/ml in 10-ml ampoule
Epinephrine		Injection, 1 mg (as hydrochloride) in 1-ml ampoule

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths*
Salbutamol (1)		Tablet, 4 mg (sulphate)
		Oral inhalation (aerosol), 0.1 mg (sulphate) per dose
		Syrup, 2 mg (sulphate)/5 ml
	Beclometasone (B) (8)	Oral inhalation (aerosol), 0.05 mg (dipropionate) per dose
	Cromoglicic acid (B) (2, 8)	Oral inhalation (cartridge), 20 mg (sodium salt) per dose
	Ephedrine (A)	Tablet, 30 mg (as hydrochloride)
		Elixir, 15 mg (as hydrochloride)/5 ml
		Injection, 50 mg (sulphate) in 1-ml ampoule
	25.2 *Antitussives*	
Codeine (10)		Tablet, 10 mg (phosphate)
	26. Solutions Correcting Water, Electrolyte and Acid–Base Disturbances	
	26.1 *Oral*	
Oral rehydration salts (for glucose-salt solution)		For composition, see 17.6.2 *Replacement solution*
Potassium chloride		Oral solution
	26.2 *Parenteral*	
Compound solution of sodium lactate		Injectable solution
Glucose		Injectable solution, 5% isotonic, 50% hypertonic
Glucose with sodium chloride		Injectable solution, 4% glucose, 0.18% sodium chloride (Na^+ 30 mmol, Cl^- 30 mmol/l)
Potassium chloride		Injectable solution
Sodium bicarbonate		Injectable solution, 1.4% isotonic (Na^+ 167 mmol/l, HCO_3^- 167 mmol/l)
Sodium chloride		Injectable solution, 0.9% isotonic (Na^+ 154 mmol/l, Cl^- 154 mmol/l)
Water for injection		In 2-ml, 5-ml, 10-ml ampoules
	27. Surgical Disinfectants	
Chlorhexidine (1)		Solution, 5% (gluconate) for dilution
Iodine (1)		Solution, 2.5%
	28. Vitamins and Minerals	
Ascorbic acid		Tablet, 50 mg
Ergocalciferol (1)		Capsule or tablet, 1.25 mg (50 000 IU)
		Oral solution, 0.25 mg/ml (10 000 IU)
Nicotinamide (1)		Tablet, 50 mg
Pyridoxine		Tablet, 50 mg
Retinol		Capsule or tablet, 7.5 mg (25 000 IU), 60 mg (200 000 IU)†
		Oral solution, 15 mg/ml (50 000 IU)
Riboflavin		Tablet, 5 mg
Sodium fluoride		Tablet, 5 mg
Thiamine		Tablet, 50 mg (hydrochloride)
	Calcium gluconate (C) (2, 8)	Injection, 100 mg/ml in 10-ml ampoule

* When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word 'as'.

† For use in the treatment of xerophthalmia with a single dose, not to be repeated before four months have elapsed.

IFPMA Code of Pharmaceutical Marketing Practices (1981)

PREAMBLE

The Statute of the Federation article 3 states that one of the objects of the Federation is 'to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntarily agreed on' and 'to coordinate the efforts of its members towards the realization of the above objects'.

It is believed that in keeping with the pharmaceutical industry's international responsibilities, the members of the Federation will be prepared to accept certain obligations, in so far as their marketing practices are concerned, and to ensure respect for them.

IFPMA recommends a Code of Marketing Practices to its member associations, recognizing the difficulty of setting out a simple Code which will be applicable in all parts of the world. It seems clear that national and regional conditions and legal restrictions will continue to vary to such an extent as to make a simple world Code impractical. Nevertheless, the Federation believes that it has a duty to encourage its member associations to either introduce such Codes of Practices or where such Codes already exist, to continually re-examine and where necessary revise them so that a voluntary system based on such a Code keeps pace with modern medical knowledge and changing health services and conditions.

It is recognized that many individual member associations of IFPMA have laid down their own Codes of Marketing Practices and this recommended Code is not intended to replace similar Codes or instruments already in force by members of the Federation. The following voluntary Code is therefore put forward as a model for IFPMA's member associations.

A Code of Marketing Practices of this sort should be the responsibility of member associations who should also provide guidance to their members on matters of compliance and interpretation.

OBLIGATIONS OF INDUSTRY

The obligations of the industry may be identified as follows.

The pharmaceutical industry, conscious of its special position arising from its involvement in public health, and justifiably eager to fulfil its obligations in a free and fully responsible manner, undertakes:

- to ensure that all products it makes available for prescription purposes to the public are backed by the fullest technological service and have full regard to the needs of public health;
- to produce pharmaceutical products under adequate procedures and strict quality assurance;
- to base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions of use;
- to provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contra-indications, tolerance and toxicity;
- to use complete candour in dealings with public health officials, health care professionals and the public.

SUGGESTED CODE OF MARKETING PRACTICES

We hereby declare our intention to voluntarily conform to the following Code of Marketing Practices:

I. *General Principles*

1. The term 'pharmaceutical product' in this concept means any pharmaceutical or biological product intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, which is promoted and advertised to the medical profession rather than directly to the lay public.
2. Information on pharmaceutical products should be accurate, fair and objective, and presented in such a way as to conform not only to legal requirements but also to ethical standards and to standards of good taste.

3. Information should be based on an up to date evaluation of all the available scientific evidence, and should reflect this evidence clearly.
4. No public communication shall be made with the intent of promoting a pharmaceutical product as safe and effective for any use before the required approval of the pharmaceutical product for marketing for such use is obtained. However, this provision is not intended to abridge the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media, nor to restrict public disclosure to stockholders and others concerning any pharmaceutical product as may be required or desirable under law, rule or regulation.
5. Statements in promotional communications should be based upon substantial scientific evidence or other responsible medical opinion. Claims should not be stronger than such evidence warrants. Every effort should be made to avoid ambiguity.
6. Particular care should be taken that essential information as to pharmaceutical products' safety, contraindications and side effects or toxic hazards is appropriately and consistently communicated subject to the legal, regulatory and medical practices of each nation. The word 'safe' must not be used without qualification.
7. Promotional communications should have medical clearance, or where appropriate, clearance by the responsible pharmacist, before their release.

II. *Medical Representatives*

Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate and responsible manner.

III. *Symposia, Congresses and Other Means of Verbal Communication*

Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging such meetings, and entertainment and other hospitality shall not be inconsistent with such objectives.

IV. *Printed Promotional Material*

Scientific and technical information shall fully disclose the properties of the pharmaceutical product as approved in the country in question based on current scientific knowledge including:

- The active ingredients, using the approved names where such names exist.
- At least one approved indication for use together with the dosage and method of use.
- A succinct statement of the side-effects, precautions and contraindications.

Except for pharmaceutical products where use entails specific precautionary measures, reminders need not necessarily contain all the above information providing that a form of words is used which indicates clearly that further information is available on request.

Promotional material, such as mailings and medical journal advertisements, must not be designed to disguise their real nature and the frequency and volume of such mailings should not be offensive to the health care professionals.

V. *Samples*

Samples may be supplied to the medical and allied professions to familiarize them with the products, to enable them to gain experience with the product in their practice, or upon request.

SUPPLEMENTARY STATEMENT

This Code, it will be recalled, was approved by IFPMA Council in March 1981, and has since been accepted by all IFPMA's Member Associations. A printed version in English, French and Spanish was published in August 1981, and over 7000 copies of this publication have been distributed to the international pharmaceutical industry worldwide. Most recently the full text of the Code was printed in WHO's *International Digest of Health Legislation* (Vol. 32, No. 3, 1981).

IFPMA and its Member Associations have agreed the following statement which they believe will further demonstrate the industry's commitment to the observance and monitoring of the Code. It should be emphasized however

that this supplementary statement does not vary in any way the provisions of the original Code.

1. Major pharmaceutical multinational companies (MNCs) belonging to IFPMA Member Associations, have been asked to commit themselves to the observance of the Code wherever they market their products.
2. To meet the criticism that many Third World countries are not aware of the indications, contraindications, side-effects, etc., of individual drugs that have been accepted in the developed countries, IFPMA will offer to supply free of charge to Government Health Departments of Third World countries, copies of up-to-date standard compendia such as, *The Physician's Desk Reference* (USA), the *ABPI's Data Sheet Compendium* (UK), *the Rote Liste* (Federal Republic of Germany) and the *Dictionnaire Vidal* (France).
3. The following procedure has been agreed to deal with alleged breaches in the observance of the Code. IFPMA Member Associations have been recommended to set up their own separate procedures for monitoring such complaints; many of the Major Associations have already done this. A procedure has also been agreed to deal with complaints received by IFPMA itself and an ex officio committee of IFPMA's Council consisting of the President, the two Vice-Presidents and the Executive Vice-President will oversee all IFPMA matters involving the Code.

   The major sanction against any company that transgresses the Code will continue to be the sanction of adverse publicity. However, IFPMA wishes to stress that its main objective and that of its Member Associations will be to effect, as rapidly as possible, the correction of any proven breaches in the observance of the Code.
4. Comments have been made from time to time about the problem that industry faces in providing uniform information world-wide on labelling, packaging leaflets, data sheets and general advertising claims. The industry's position on the important matters of information on scientific claims, contraindications and side-effects is set out in the Code itself. This makes it clear that labelling, packaging leaflets, the information and data sheets and advertising claims should be consistent with the body of scientific and medical evidence pertaining to that product. This should be interpreted as meaning that such information given in Third World countries, should be consonant with what is being done in the companies' markets in the developed world. However, it should be borne in mind that countries which have their own regulatory procedures (and this includes many Third World countries) may well dictate a non-uniform approach to such matters, which industry has no option but to follow.

The voluntary adoption of this IFPMA Code is in line with one of the key objectives of the Federation as set out by its Founder Members in 1968 'to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntarily agreed on'.

Council Directive of 25 July 1985

on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

(85/374/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,[1]

Having regard to the opinion of the European Parliament,[2]

Having regard to the opinion of the Economic and Social Committee,[3]

Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;

Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;

Whereas liability without fault should apply only to movables which have been industrially produced; whereas, as a result, it is appropriate to exclude liability for agricultural products and game, except where they have undergone a processing of an industrial nature which could cause a defect in these products; whereas the liability provided for in this Directive should also apply to movables which are used in the construction of immovables or are installed in immovables;

[1] OJ No C 241, 14, 10. 1976, p.9 and OJ No C 271, 26.10.1979, p.3

[2] OJ No C127, 21.5.1979, p.61

[3] OJ No C 114, 7.5.1979, p.15.

Whereas protection of the consumer requires that all producers involved in the production process should be made liable, in so far as their finished product, component part or any raw material supplied by them was defective; whereas, for the same reason, liability should extend to importers of products into the Community and to persons who present themselves as producers by affixing their name, trade mark or other distinguishing feature or who supply a product the producer of which cannot be identified.

Whereas, in situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them;

Whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances;

Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances;

Whereas the protection of the consumer requires that the liability of the producer remains unaffected by acts or omissions of other persons having contributed to cause the damage; whereas, however, the contributory negligence of the injured person may be taken into account to reduce or disallow such liability;

Whereas the protection of the consumer requires compensation for death and personal injury as well as compensation for damage to property; whereas the latter should nevertheless be limited to goods for private use or consumption and be subject to a deduction of a lower threshold of a fixed amount in order to avoid litigation in an excessive number of cases; whereas this Directive should not prejudice compensation for pain and suffering and other non-material damages payable, where appropriate, under the law applicable to the case;

Whereas a uniform period of limitation for the bringing of action for compensation is in the interests both of the injured person and of the producer;

Whereas products age in the course of time, higher safety standards are developed and the state of science and technology progresses; whereas, therefore, it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product; whereas, therefore, liability should expire after a reasonable length of time, without prejudice to claims pending at law;

Whereas, to achieve effective protection of consumers, no contractual derogation should be permitted as regards the liability of the producer in relation to the injured person;

Whereas under the legal systems of the Member States an injured person may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible;

Whereas, to the extent that liability for nuclear injurt or danage is already covered in all Member States by adequate special rules, it has been possible to exclude damage of this type from the scope of this Directive;

Whereas, since the exclusion of primary agriculture products and game from the scope of this Directive may be felt, in certain Member States, in view of what is expected for the protection of consumers, to restrict unduly such protection, it should be possible for a Member State to extend liability to such products;

Whereas, for similar reasons, the possibility offered to a producer to free himself from liability if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered may be felt in certain Member States to restrict unduly the protection of the consumer; whereas it should therefore be possible for a Member State to maintain in its legislation or to provide by new legislation that this exonerating circumstance is not admitted; whereas, in the case of new legislation, making use of this derogation should, however, be subject to a Community stand-still procedure, in order to raise, if possible, the level of protection in a uniform manner throughout the Community;

Whereas, taking into account the legal traditions in most of the Member States, it is inappropriate to set any financial ceiling on the producer's liability without fault; whereas, in so far as there are, however, differing traditions, it seems possible to admit that a Member State may derogate from the principle of unlimited liability by providing a limit for the total liability of the producer for danage resulting from a death or personal injury and caused by identical items with the same defect, provided that this limit is established at a level sufficiently high to guarantee adequate protection of the consumer and the correct functioning of the common market;

Whereas the harmonisation resulting from this cannot be total at the present stage, but opens the way towards greater harmonisation; whereas it is therefore necessary that the Council receive at regular intervals, reports from the Commission on the application of this Directive, accompanied, as the case may be, by appropriate proposals;

Whereas it is particularly important in this respect that a re-examination be carried out of this parts of the Directive relating to the derogations open to the Member States, at the expiry of a period of sufficient length to gather practical experience on the effects of these derogations on the protection of consumers and on the functioning of the common market,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The producer shall be liable for damage caused by a defect in his product.

Article 2

For the purpose of this Directive 'product' means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable. 'Primary agrilcultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. 'Product' includes electricity.

Article 3

1. 'Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

2. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

3. Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.

Article 4

The injured person shall be required to prove the damage, the defect and the casual relationship between defect and damage.

Article 5

Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.

Article 6

1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

(a) the presentation of the product;

(b) the use to which it could reasonably be expected that the product would be put;

(c) the time when the product was put into circulation.

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.

Article 7

The producer shall not be liable as a result of this Directive if he proves:

(a) that he did not put the product into circulation; or

(b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or

(c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or

(d) that the defect is due to compliance of the producer with mandatory regulations issued by the public authorities; or

(e) that the state of scientific and technocal knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or

(f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instruction given by the manufacturer of the product.

Article 8

1. Without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omissions of a third party.

2. The liability of the producer may be reduced or dosallowed when, having regard to all the circumstances, the damage is caused by both a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible.

Article 9

For the purpose of Article 1, 'damage' means:

(a) damage caused by death or by person injuries;

(b) damage to, or destruction of, any item or property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property:

(i) is of a type ordinarily intended for private use or consumption, and

(ii) was used by the injured person mainly for his own private use or consumption.

This Article shall be without prejudice to national provisions relating to non-material damage.

Article 10

1. Member States shall provide in their legislation that a limited period of three years shall apply to proceedings for the recovery of damages as provided for in this Directive. The limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the danage, the defect and the identity of the producer.

2. The laws of Member States regulating suspension or interruption of the limitation period shall be affected by this Directive.

Article 11

Member States shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.

Article 12

The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability.

Article 13

This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-cintractual liability or a special liability system existing at the moment when this Directive is notified.

Article 14

This Directive shall not apply to injurt or danage arising from nuclear accidents and covered by international conventions ratified by the Member States.

Article 15

1. Each Member State may:

(a) by way of derogation from Article 2, provide in its legislation that within the meaning of Article 1 of this Directive 'product' also means primary agricultural products and game;

(b) by way of derogation from Article 7(e), maintain or, subject to the procedure set out in paragraph 2 of this Article, provide in this legislation that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

2. A Member State wishing to introduce the measured specified in paragraph 1(b) shall communicate the text of the proposed measure to the Commission. The Commission shall inform the other Member States thereof.

The Member State concerned shall hold the proposed measure in abeyance for nine months after the Commission is informed and provided that in the meantime the Commission has not submitted to the Council a proposal amending this Directive on the relevant matter. However, if within three months of receiving the said information, the Commission does not advise the Member State concerned that it intends submitting such a proposal to the Council, the Member States may take the proposed measure immediately.

If the Commission does submit to the Council such a proposal amending this Directive within the aforementioned nine months, the Member State concerned shall hold the proposed measure in abeyance for a further period of 18 months from the date on which the proposal is submitted.

3. Ten years after the date of notification of this Directive, the Commission shall submit to the Council a report on the effect that rulings by the courts as to the application of Article 7(e) and of paragraph 1(b) of this Article have on consumer protection and the functioning of the common market. In the light of this report the Council, acting on a proposal from the Commission and pursuant to the terms of Article 100 of the Treaty, shall decide whether to repeal Article 7(e).

Article 16

1. Any Member State may provide that a producer's total liability for damage resulting from a death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million ECU.

2. Ten years after the date of notification of this Directive, the Commission shall submit to the Council a report on the effect on consumer protection and the functioning of the common market of the implementation of the financial limit on liability by those Member State which have used the option provided for in paragraph 1. In the light of this report the Council, acting on a proposal from the Commission and pursuant to the terms of Article 100 of the Treaty, shall decide whether to repeal paragraph 1.

Article 17

This Directive shall not apply to products put into circulation before the date on which the provisions referred to in Article 19 enter into force.

Article 18

1. For the purposes of this Directive, the ECU shall be that defined by Regulation (EEC) No 3180.87,[1] as amended by Regulation (EEC) No 2626/84.[2] The equivalent in national currency shall initially be calculated at the rate obtaining on the date of adoption of this Directive.

2. Every five years the Council, acting on a proposal from the Commission, shall examine and, if need be, revise the amounts in this Directive, in the light of economic and monetary trends in the Community.

Article 19

1. Member States shall bring into force, not later than three years from the date of notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.[3]

2. The procedure set out in Article 15(2) shall apply from the date of notification of this Directive.

Article 20

Member States shall communicate to the Commission the texts of the main provisions of national law which they subsequently adopt in the field governed by this Directive.

Article 21

Every five years the Commission shall present a report to the Council on the application of this Directive and, if necessary, shall submit appropriate proposals to it.

[1] OJ No L 379, 30.12.1978, p.1.
[2] OJ No L 247, 16.9.1984, p.1.
[3] This Directive was notified to the Member States on 30 July 1985.

Article 22

This Directive is addresed to the Member States.

Done at Brussels, 25 July 1985.

For the Council

The President

J.POOS

A Draft Proposal for an International Code on Pharmaceuticals – Health Action International (HAI) Discussion Document (1982)

This document is a first draft. It is intended for further discussion and amendment in the light of comments from experts worldwide. The scope of the proposed code is such that its adoption will require the expertise of various UN agencies, most importantly WHO and UNCTAD.

CONTENTS

PREAMBLE

The participating countries:

1. ~~Re~~affirming that good health is a fundamental human right;
2. Recognizing that governments have a responsibility for ensuring the health of their people;
3. Recalling that a main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all the peoples of the world by the year 2000, of a level of health that will permit them to lead a socially and economically productive life;
4. Convinced that the promotion and protection of the health of the people is essential to sustained economic and social development;
5. Drawing attention to the fact that provision of an adequate supply at reasonable cost of essential drugs, among other things, is a prerequisite for the promotion and protection of the health of the people;
6. Aware that a majority of the world population, particularly those in the rural areas and urban slums of developing countries, does not have regular access to even a few essential drugs necessary for primary health care whilst the drug bills in these countries may account for up to 40–50% of the total health expenditure;
7. Affirming the right of every sick person to have access to essential pharmaceuticals;
8. Considering that a limited number of transnational corporations based in developed countries manufacture almost 90% of the world output of pharmaceuticals and control drug technology and world trade and that the existing system of marketing practices of these corporations is inappropriate to meeting the health needs of the people, particularly in developing countries;
9. Bearing in mind that in a number of instances the prices of pharmaceuticals do not relate to the actual cost of manufacture but are determined by what the market can bear;
10. Drawing attention to the fact that there are wide discrepancies in the prices of drugs on the world market which cannot be explained by market forces;
11. Recognizing that the pharmaceutical industry is characterized by an unusual degree of market power;
12. Recalling that the Non-Aligned and other developing countries have expressed an urgent desire to reform the existing system for the procurement and provision of pharmaceuticals;
13. Taking into consideration that a large num-

ber of developing countries have already established local manufacture of pharmaceuticals and are purchasing pharmaceutical technology on the world market and that some of them are forced to pay exorbitant amounts of foreign exchange for their technology imports;

14. Convinced that the development and strengthening of indigenous technological capacity in the pharmaceutical sector is critically dependent on ongoing research and development activities and that a research base in developing countries is necessary to insure against underdevelopment;
15. Believing that certain fundamental principles associated with trade and technology in the pharmaceutical sector transcend national and regional boundaries and are universally applicable;
16. Recognizing that the indispensable role of pharmaceuticals in the control of disease and the prevention of human suffering distinguishes them from other consumer goods which are subject to the laws of supply and demand;
17. Believing that, in the light of the foregoing considerations, an International Code of Pharmaceutical Marketing Practices, including norms on promotion, pricing, sales, distribution, trade, technology, research and development, in the pharmaceutical sector would, under mutually agreed and advantageous terms to all parties, enable all participating countries, particularly developing countries to provide to all their people, safe and effective essential drugs at prices they can afford;
18. Agree on the adoption of the following International Code of Pharmaceuticals Marketing Practices.

ARTICLE 1: AIM OF THE CODE

The aim of this code is to enable consumers, particularly those from the developing countries, to procure safe and effective pharmaceuticals essential to their real health needs, at costs they can afford.

ARTICLE 2: SCOPE OF THE CODE

2.1 This Code shall apply to all international activities connected with the procurement of pharmaceuticals and pharmaceutical technology.

2.2. The Code applies to the following activities associated with the pharmaceutical sector:
- drug registration
- registration of new drugs
- pre-registration clinical trials of new drugs
- provision of information
- labelling, package inserts and promotional material
- sales promotion of pharmaceutical products
- pricing, sales and distribution
- pharmaceutical technology
- research and development.

ARTICLE 3: DEFINITIONS

3.1 'Active substance': that portion of a drug product intended to produce a therapeutic effect.

3.2 'Adverse reaction': a reaction to a drug which is noxious or unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.

3.3 'Advertisement': any representation conveyed by any means whatever for the purpose of promoting directly, or indirectly, the distribution or sale of any drug.

3.4 'Auxiliary pharmaceutical substance': a substance added to the active substance to give the latter suitable consistency, so that a convenient dosage form can be formulated.

3.5 'Benefit/risk ratio': the ratio of benefit to risk in the use of a drug: a means of expressing a judgement concerning the role of the drug in the practice of medicine, based on efficacy and safety data along with consideration of misuse potential, severity and prognosis of the disease etc. The concept may be applied to a single drug or in comparing two or more drugs used for the same indication.

3.6 'Clinical trial': a procedure for comparing the relative advantages and disadvantages of one drug with another by administering them according to a planned protocol to a group of patients under controlled conditions.

3.7 'Contra-indications': conditions which make the administration of a drug positively harmful. These conditions include diseases, physiological states (e.g. preg-

nancy, lactation), specific groups (neonates, infants) etc.

3.8 'Drug' (synonymous with 'pharmaceutical product'): any substance or a mixture of substances that is manufactured, sold, offered for sale or represented for use in: (i) the treatment, mitigation, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof in humans, or (ii) the restoration, correction or modification of organic functions in humans.

3.9 'Drug registration': the term used for the procedure of release, compliance or approval for marketing after a drug has undergone the process of drug evaluation (by a competent health authority).

3.10 'Efficacy': the ability of a drug to produce the purported effect as determined by scientific methods.

3.11 'Ethical drug': a drug that can be purchased only after obtaining a valid prescription for it from a medical doctor or other authorized health personnel. This is also referred to as a 'prescription drug'.

3.12 'Interactions': a noxious or unintended reaction which occurs when two or more drugs are administered simultaneously at normal doses. This term also refers to similar reactions between a drug and food taken together.

3.13 'International non-proprietary name' (INN): this is the offical name assigned to a drug by the World Health Organization and is internationally recognized. It is also known as a generic name.

3.14 'Label': a display of written, printed or graphic matter upon the immediate container or the outside container or wrapper of a drug package.

3.15 'Marketing': product promotion, distribution, sales, advertising, product public relations and information services.

3.16 'New drugs': a drug which has not been previously registered or marketed for medical purposes, including any new salts and esters of an already registered active substance, new fixed combinations of substances previously marketed, or of any drug previously marketed if its indications, mode of administration, or formulation are changed.

3.17 'Over the counter drug': a drug that can be purchased without a prescription from a medical doctor or other authorized health personnel. This is also referred to as a proprietary drug.

3.18 'Package insert': a leaflet containing specified relevant information on a drug included in every package containing that particular drug.

3.19 'Pharmaceutical manufacturers': all persons involved in the production of a drug, including processing, compounding, formulating, filling, packing, repacking, altering, finishing and labelling with a view to its storage, sale and distribution.

3.20 'Pharmaceutical traders': all persons involved in the process of import, storage, sale and distribution of drugs whether as wholesalers or retailers.

3.21 'Purity': the degree to which other chemical or biological entities are present in any substance.

3.22 'Sample': single or small quantities of a product supplied without cost.

3.23 'Side-effects': expected but noxious or unpleasant effects produced by a drug at normal doses.

3.24 'Trade name' (also called brand name): this is a name given to a drug by the manufacturer which if registered and protected under national legislation, can be used exclusively by the manufacturer to distinguish his product from other products containing the identical active chemical substance or substances.

ARTICLE 4: DRUG REGISTRATION

4.1 All pharmaceutical products, both ethical drugs and over-the-counter (OTC) preparations offered for sale in a country, should be duly registered by a competent authority in that country.

4.2 Pharmaceutical manufacturers and traders will abstain from making available in a country pharmaceutical products which are not registered in that country.

4.3 Pharmaceutical manufacturers and traders must provide the national registration authorities with all the information available to them on a pharmaceutical product, including all information they have given to countries with an efficient drug registration system, even if all this information has not been requested by the registration authority.

4.4 Pharmaceutical manufacturers and traders must provide the registration authority with a list of all countries in which the specific product has not been accepted for registration.

4.5 Pharmaceutical manufacturers and traders should inform the registration authority if

a pharmaceutical product already registered in that country has been removed from the register of any other country together with the reasons for its removal.

4.6 Pharmaceutical manufacturers and traders, when applying for registration of a product, must undertake that subsequent to the product's registration they will provide the registration authority and consumers with all new information they receive on its effects, adverse reactions and interactions.

ARTICLE 5: REGISTRATION OF NEW DRUGS

5.1 Pharmaceutical manufacturers and traders shall apply for registration of a new drug only if the new drug:

(a) in comparison with existing drug/drugs used for the same conditions
- has an equal or superior benefit/risk ratio *or*
- has equal or better pharmaceutical properties *or*
- can be marketed at a lower price;

(b) is recommended for a condition for which no suitable drug treatment is available.

ARTICLE 6: PRE-REGISTRATION CLINICAL TRIALS OF NEW DRUGS

6.1 No new drug comprising of a single or more than one pharmaceutically active substance may be tested on human beings without formal and written permission from national, regional or international public health authorities.

6.2 Clinical trials of new drugs on human beings will only be permitted for products which have been accurately tested on experimental animals. Animal tests will be carried out in accordance with national or international legislation and must provide, in the case of each new drug, complete information on the main general and organ system directed pharmacological effects; whether such effects may be therapeutically useful or not; on the absorption, distribution, metabolism and excretion of the active substance/substances contained in a drug; on interactions with other drugs in use, environmental chemicals or food; on acute and short-term toxicity for all drugs and on long-term toxicity for such drugs as may be used for extended periods in human beings and on the environmental toxicity of drugs or drug metabolites liable to be excreted by users of the drugs.

6.3 Requirements for animal testing of new drugs before human trials should be unified and internationally standardized.

6.4 Laboratories both within the premises of pharmaceutical manufacturers or those consulted by manufacturers must be open to inspection by the public health authorities of all countries in which a new drug may be submitted for trial on human subjects.

6.5 Clinical trials of new drugs on human subjects may only be carried out by suitably qualified and experienced researchers who must be qualified physicians, and according to procedures which must be authorized by the public health authorities. The conduct and protocols for the conduct of clinical trials must be open to inspection by public health authorities at any time. Protocols and information on these trials must also be made available to the registration authorities of countries in which a drug, which has been primarily tested in another country, is proposed for marketing.

6.6 Whenever a new drug is tested on healthy human subjects or on patients, the clinical trial must be authorized and monitored by a local 'ethical committee' and must be carried out only with the full informed consent of the people and patients concerned. Governments may require written consent in countries in which the majority of the population is literate; and in countries where the majority of the population is not literate, orally, in the presence of a witness. Consent to volunteer to participate in the trial of a new drug can only be given by the subject, not by his/her legal representative. In the case of children and the insane, consent given by a legal representative to the use of a new drug will be accepted only in situations in which there is a serious and nearly certain danger to the life or to the health of the subject which cannot be averted by existing available pharmaceutical products.

6.7 If permission for the clinical trial of new drugs on human subjects has been refused by the competent authorities of one country, any attempts to obtain such permission in other countries may only be undertaken with the disclosure of full

information on the previous refusal of permission and submission of all the documents relating to this refusal of permission.

6.8 Drugs which have been banned from sale after being marketed for some time in one country may not be submitted for clinical trials or marketing in another country, unless the competent authorities of the second country are provided with complete information on the reasons for the drug's withdrawal from the market.

6.9 Physicians in charge of clinical trials of a new drug must rapidly be brought up to date with all new findings on the properties of the drug obtained during the time of a study on human subjects.

6.10 Unnecessary duplication of trials of new pharmaceutical products should be avoided. Procedures for pre-registration trials of new drugs should be internationally agreed.

ARTICLE 7: INFORMATION

7.1 Governments should be responsible for ensuring that objective and consistent information is provided on all pharmaceutical products marketed in the country. This responsibility should cover either the design, provision and dissemination of information or their control.

7.2 All information on pharmaceutical products must be accurate, balanced, objective and complete. It must be presented in such a way as to conform to legal requirements, to defined ethical standards and to standards of good taste. It should not mislead either directly or by implication. Information must be provided in a language readily understandable to the person who will use it.

7.3 All information provided must be based on up-to-date evaluations of all available scientific evidence and must reflect this evidence accurately and clearly. Sources of evidence must be identified.

7.4 Information submitted to registration authorities and other public health authorities should include both all information required by these authorities and all other information which the pharmaceutical manufacturer possesses which may be relevant to their deliberations.

7.5 The minimum information which must be made available by pharmaceutical manufacturers for all products to be marketed will include:

(i) *Package inserts* – a package insert must be added to every package to be sold to a consumer. For drugs sold to public health authorities for distribution, a sufficient number of package inserts for distribution to each potential user must be provided.

For over-the-counter (non-prescription) drugs the package insert must state the name of the drug, the names of all its pharmaceutically active ingredients which must be given as approved international non-proprietary names if such names exist, and the names of all auxiliary pharmaceutical substances.

Furthermore, the package insert must state the indication or indications (use or uses) of a drug and precise instructions for dosage and the spacing of doses in adults, as well as in children of the main age groups. If a drug is not to be used in a certain age group, this must be stated in the package insert.

Furthermore, the package insert must enumerate all major side-effects of the active drug(s) and possible known side-effects of the auxiliary pharmaceutical substances and must instruct the user on what to do if such side-effects occur. Furthermore, warnings of known interactions (instructions as to which drugs or food should not be combined with that particular pharmaceutical product) and precautions (e.g. drugs not to be used in pregnancy etc.) must be enumerated. Package inserts for drugs sold over-the-counter, as well as for prescription drugs or drugs to be distributed by health officials, must convey information that is readily intelligible to all prospective consumers and not in a language restricted to the prescriber or distributor. Such medical or scientific terms as are used must be explained in lay language.

For drugs sold without a prescription, the package insert must explain for how long a drug may be taken without consulting a health professional and the period of time after which a health professional must be consulted in the case of lack of effect of the pharmaceutical product or after the occurrence of side-effects.

(ii) *Scientific data sheet for the use of physicians and other health professionals*

This data sheet may be written in a

language intelligible to its prospective readers, i.e. physicians or health professionals. It must contain a full description of the pharmaceutical product, listing all active substances by their international non-proprietary name, if such a name exists, and their doses, and must enumerate all auxiliary pharmaceutical substances used. In the case of organic chemicals for which there is no accepted non-proprietary name, chemical names should be given and illustrated by structural formulas. The scientific data sheet should briefly summarize experimental pharmacological and toxicological data on the pharmaceutically active substances used. It must contain a full description of suggested and accepted therapeutic uses of the pharmaceutical product. Suggested uses may only be included if they are substantiated by reliable scientific evidence which must be quoted. Furthermore, there must be a short but complete description of contra-indications to use of the pharmaceutical product; precautions over its use; mechanisms of action (if known); known interactions with other pharmaceutical products, chemicals or food; and of dosage regimens in adults, as recommended for the different indications. Doses for children of different age groups must also be stated unless the pharmaceutical product is marked: 'Not for use in children under the age of . . . ' Doses in the elderly must be stated if they are different from doses in other adults.

The scientific data sheet must include the address/es of the manufacturers and their representatives or the address of other persons from whom additional information on a pharmaceutical product may be obtained. Furthermore the data sheet must state the address of the manufacturers' representative or of the competent national authority to be informed in the event of unforeseen side-effects or interactions.

7.6 All materials containing drug information must be cleared by the national registration authorities which must also be consulted before any changes can be made to subsequent editions of the materials.

7.7 Information must be presented in scientifically acceptable, precise terms. None of the following words – 'safe', 'effective', 'potent', or 'cure' should be used without qualification.

7.8 Longer information booklets on a specific pharmaceutical product must include the standard information contained in the scientific information sheet and as much additional information as the manufacturer can provide. The information reproduced should be reliable and its validity must be capable of scientific substantiation by independent experts. Longer information booklets should not be distributed to all potential prescribers or distributors, but only to those who specifically request them after learning of their existence from publicity or promotional material. The contents of information booklets must be modified if registration authorities require amendments.

ARTICLE 8: LABELLING, PACKAGE INSERTS AND PROMOTIONAL MATERIAL

8.1 Pharmaceutical products are either sold to the public for self-medication (over-the-counter drugs) or sold to the public on prescription from a physician or other health officials, or used by physicians or other health officials on human beings. The intended mode of sale will be clearly indicated on all containers and packaging materials for pharmaceutical products.

8.2 The international non-proprietary name of each pharmaceutically active substance for which such a name exists must be stated prominently on each package insert and on all promotional material. For pharmaceutically active substances for which no accepted non-proprietary name exists, a suggested non-proprietary name should be indicated.

8.3 In countries in which drugs may be sold and prescribed only under their international non-proprietary names, the packages must not bear any trade name for pharmaceutically active substances. However, the information from the manufacturers may refer to trade names used in other countries, specifying the country in which a given trade name is used.

On the packaging material, the names of manufacturers may be mentioned in brackets after the non-proprietary name and in lettering of the same size as that used for the non-proprietary name.

8.4 In countries where drugs may be sold or distributed under protected trade names,

non-proprietary names of the pharmaceutically active ingredients must be stated on all packages and promotional materials in a size of lettering not smaller than one half the size used for the protected trade name.

8.5 Each pharmaceutical product belongs to a class and/or a category or a sub-category of therapeutic or diagnostic products. The class and, if relevant, the category or sub-category must be stated on the packaging material.

8.6 Indications for the therapeutic or the diagnostic use of a pharmaceutical product will not be stated on the packaging material but will be enumerated in package inserts and information for health professionals. Only indications approved by the public health authorities, or generally recognized and endorsed by reputable and independent scientific publications will be included.

8.7 Contra-indications against the use of a pharmaceutical product will be mentioned on the packaging material if the use of a pharmaceutical product in certain categories of human beings may endanger their life or severely endanger their health. All other known contra-indications will be explicitly stated in the package inserts and in the information for health professionals.

8.8 The amounts of the active substance(s) and of auxiliary pharmaceutical substances contained in a pharmaceutical product will be stated in package inserts, as well as in information sheets. Only the active substance(s) and their doses must be stated on the packaging material. Active substance(s) will be designated by their international non-proprietary names if and when such names exist. Auxiliary pharmaceutical substances will be designated by names which can be readily identified by physicians, pharmacists or public health officials. The grade of purity of active substances and of auxiliary pharmaceutical substances found in a pharmaceutical product will be identified by reference to a standard list of internationally recognized pharmacopoeia.

ARTICLE 9: SALES PROMOTION OF PHARMACEUTICAL PRODUCTS

9.1 Pharmaceutical products that may legally be sold to the public without a prescription ('over-the-counter drugs') may be promoted to the public through advertisements in the press or displayed publicly or by the media, but not by direct mailings. All promotional texts must state the non-proprietary names of the pharmaceutically active substances contained in a pharmaceutical product, the approved uses, contra-indications and precautions. All statements used in the promotion must represent strict scientific truth. The texts must be designed in such a manner as to avoid promoting the use of a drug by persons who do not need to take the drug and may be quite as well off without using it. Promotion may suggest the use of one drug rather than of another but must then state scientifically backed reasons. All promotional material must be cleared by the drug registration authority.

9.2 Drugs that may legally be sold only on prescription by physicians or other professionally trained prescribers cannot be advertised publicly and must not be promoted through either advertisements or articles inserted in the lay press or by radio, television or interviews. Promotion must be limited to professional journals and to personally addressed mailings to prescribers; promotion is also permitted in radio or television programmes addressing exclusively a professionally trained audience. Promotion material for advertising to health professionals must include the information required for the scientific data sheet. In promotional material, this data may be summarized or abbreviated. In this case attention should be drawn to the scientific data sheet. All promotional material must be cleared by the drug registration authority.

9.3 Pharmaceutical products to be distributed by public health officials may be promoted to them under conditions similar to those outlined above for medical prescribers. All promotional material must be cleared by the drug registration authority.

9.4 All promotional material must be modified if registration authorities request an amendment. Any given promotional item may be banned by a ruling from the competent public health authorities.

9.5 Pharmaceutical products which may legally be sold only under prescription may be promoted by medical representatives in all countries where medical representatives are allowed to work. Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present complete, accurate and valid

information on their company's products. The manufacturer and his representatives are responsible for all statements made by their representatives and may be held liable. Governments may prescribe particular training courses for medical representatives and impose examinations or other evaluations of their knowledge and their skills. Oral statements made by medical representatives must contain the minimum information required for printed promotional material. The number of medical representatives working for one company in a given country must not exceed one representative per promoted pharmaceutical product per 500 registered physicians or other prescribers.

9.6 Pharmaceutical products to be sold under prescription may be promoted through the organization of scientific meetings, symposia and sessions within congresses. If more than 50% of the total cost of such meetings is financially supported by a pharmaceutical manufacturer, this fact must be clearly and visibly stated on all programmes, invitations or abstracts. The information displayed must always draw attention to the minimum information required for the scientific data sheets and must be scientifically accurate and presented objectively and in good taste. Entertainment and hospitality offered during promotional meetings must be limited and must be secondary to the main purpose of the meeting. The level of hospitality must not exceed the provision of goods or services which the participants could not afford to buy or might not normally pay for in everyday life.

9.7 Samples of pharmaceutical products may be provided free of charge to prescribers only at their request. All samples must be clearly labelled as samples in such a manner that they can under no conditions be sold.

9.8 Drug samples for clinical trials may be supplied by manufacturers free of charge to physicians only, and only in the framework of a correctly designed therapeutic trial. The conduct of such a trial must be approved by an 'ethical committee' responsible for the control of medical experiments on humans in a given institution or region, or else by public health authorities.

ARTICLE 10: PRICING, SALES AND DISTRIBUTION

10.1 With a view to regulating the equitable distribution of drugs throughout the country, the Government of that country may fix the maximum price at which a drug shall be sold.

10.2 In order to encourage indigenous technological development, the Government shall carefully examine and compare the cost of production of every locally manufactured drug with the landed cost of a similar but imported drug. If the cost of local production is higher than the landed cost of the imported drug, the Government may, in order to reduce or eliminate the wide discrepancies in the retail price of these two categories of the same drug, impose a suitable excise tax on the landed cost of the imported drug to bring it closer to or on par with the cost of local production.

10.3 Every importer of a drug shall within fourteen days of the import of a drug make an application to the Government in Form 1 (see below at end of Article 10). The Government may, after taking into consideration the information furnished in Form 1 and examining the cost of production of a similar locally manufactured drug, impose, if necessary, a suitable excise tax on that drug as mentioned in Article 10.2.

10.4 While fixing the cost of production of a locally manufactured drug as mentioned in Article 10.2, the Government may take into account the average cost of production of such a drug by an efficient manufacturer and also take into consideration material cost, labour charges, overhead costs, etc. For the purpose of this article, an efficient manufacturer means a manufacturer:

(i) whose production of a drug in relation to the total consumption of that drug in that country is comparatively large, *or*

(ii) who employs efficient technology in the production of such a drug.

10.5 The Government shall fix a maximum retail price for a drug by specifying the maximum mark-up on the cost of production or the landed cost (if applicable landed cost plus an excise duty as described in Article 10.3). The mark-up will include the manufacturers'/importers' margin, transport and distribution costs, promotional expenses and retailers' commission.

10.6 Every manufacturer, importer or distributor of a drug intended for sale shall

display an indelible print mark on the label of the container of the drug or the minimum pack thereof offered for retail sale, the maximum retail price of that drug with the words 'retail price not to exceed' preceding it.

10.7 No dealer shall sell any drug to any person at a price exceeding the maximum retail price indicated on the label of the container or pack thereof.

10.8 No dealer shall sell loose quantities of any drug drawn from a container of such a drug at a price which exceeds the *pro rata* price of the drug plus five *per cent* thereof.

10.9 In order to make a limited number of essential drugs easily accessible to the poorer sections of the population, the Government may fix a lower mark-up for these compared to the other drugs. For the purpose of this article, the limited number of essential drugs refer to those which are so defined and listed by a competent health authority (e.g. Formulary Committee).

10.10 The Government may oblige an importer or manufacturer to allocate a minimum percentage of his total annual turnover to import or locally manufacture (whichever is applicable) essential drugs described in Article 10.9.

10.11 The Government may oblige a retail distributor to carry always a sufficient inventory of essential drugs referred to in Article 10.9.

10.12 A retail dealer shall maintain a list of all drugs available with him and their prices; this list should be easily accessible to any person wishing to consult the same.

10.13 No importer, wholesaler or manufacturer shall withhold from sale or refuse to sell to a retail dealer any drug available to him without good and sufficient reasons.

10.14 No retail dealer shall withhold from sale or refuse to sell any drug available to him/her to a customer wanting to purchase such a drug for which he/she has a valid prescription or which is sold over the counter.

10.15 An officer authorized by the Government may, with a view to securing compliance with this Article or to satisfy himself/herself that the provisions of this Article have been complied with:

(a) enter and search any place;

(b) seize any drug, along with containers, packages or coverings in which the drug is found, in respect of which he/she suspects that any provision of Article 10 has been, is being, or is about to be, contravened.

10.16 When the Government (but not a private trader) imports drugs and the landed cost of an imported drug is lower than the cost of production of a similar drug locally manufactured, the Government may purchase the total output from the local manufacturer after fixing the cost of production as described in Article 10.4 and allowing him a reasonable return on his investment and then fix a common pooled wholesale price for both the imported and the locally produced drug.

Form 1

(To be submitted in duplicate by an importer, within fourteen days of the import, for each imported consignment)

1. Name of the company
2. Address of Registered/Head Office/Factory if any
3. Reference to permission given by the drug registration authority for import of the drug
4. Name of the drug
5. Specifications of the drug
6. Country from which the drug is imported
7. Quantity imported (kg/litres/tonnes, etc.)
8. C.i.f. value in foreign currency

	Total local currency	*Per unit* local currency
a. Total c.i.f. paid in local currency	...	...
b. Customs duty paid	...	...
c. Clearing charges with full details	...	...
d. Landed cost (a + b + c)	...	...

(*Note*: The figures given here should be certified by a practising Cost Accountant/Chartered Accountant)

ARTICLE 11: PHARMACEUTICAL TECHNOLOGY

The general provisions contained in the draft International Code of Conduct on the Transfer of Technology being negotiated in UNCTAD shall apply to all technology transfer transactions in the pharmaceutical sector.

Alternatively this Code could include the following provisions which are in the UNCTAD draft Code.

11.1 The pharmaceutical technology transferred to a developing country should be appropriate to the economic and social development objectives of that country.

11.2 Upon request of the technology acquiring party, the technology supplying party shall make arrangements, as far as possible, to unpackage the technology in terms of information concerning the various elements of the technology to be transferred, such as that required for technical, institutional and financial evaluation of the offer.

11.3 In a technology transfer agreement specific provisions should be made for the maximum use of locally available resources.

11.4 Technology transfer agreements should not contain restrictive practices which adversely affect the economic and technological development of the acquiring country. These restrictive practices include, among others:

- grant back provisions
- restrictions on research
- restrictions on use of personnel
- price fixing
- restrictions on adaptations
- tying agreements
- export restrictions
- payments and other obligations after expiration of industrial property rights
- restriction after expiration of agreement
- restrictions on the scope, volume and capacity of production and field of activity
- obligation to use trademarks
- requirement of the acquiring party to provide equity capital or to allow supplying party to participate in management
- unlimited or unduly long duration of transfer agreements
- limitations upon the use of the imported technology

11.5 When negotiating, concluding and performing a technology transfer agreement, the parties should observe fair and honest business practices which include, among others:

- fair and reasonable terms and conditions
- provision of all relevant information
- access by the acquiring party during the period of the agreement to any improvements to the technology transferred under the agreement
- the right to cease negotiations if, during the negotiations, either party determines that a satisfactory agreement cannot be reached
- the supplying party shall, to the extent feasible, provide the acquiring party, during the period of the agreement, with spare parts, accessories and raw materials produced by the supplying party for using the technology transferred particularly where alternative sources are unavailable
- the technology suppliers' guarantee that the technology meets the description contained in the transfer agreement
- the technology suppliers' guarantee that the technology, if used in accordance with the description in the transfer agreement, is suitable for the manufacture of goods as agreed upon by the parties and stipulated in the agreement
- the supplying party shall provide adequate training to the personnel of the acquiring party or to the personnel designated by it, in the knowledge and operation of the technology transferred, on the terms stipulated in the agreement
- the prices, charges or other considerations made for all elements involved in the transfer of technology transactions shall be distinctly specified for each item
- where the acquiring party has no other alternative than to purchase goods and/or services from the supplying party, or from any enterprise designated by it, the prices for such inputs shall be fair and not higher than current world prices for goods or services of the same quality offered on comparable commercial terms and conditions
- the supplying party shall be liable for the loss of, damage or injury to property or persons arising from the technology transferred or the goods produced by it, provided that the tech-

nology is used as specified in the agreement, or in the absence of such specification, in a technically correct manner.

11.6 Patent protection should not be given to pharmaceutical products or processes.

If, however, some form of protection has to be given, only process patents should be granted and adequate safeguards aimed at ensuring satisfactory working of the patented invention should be provided. These safeguards would be to:

(a) specify that importation does not constitute working of the patent;
(b) provide for an expeditious system of compulsory licensing;
(c) use forfeiture or revocation of the patent on specific grounds;
(d) shorten the duration of the patent and use it to ensure satisfactory working of the patented invention.

ARTICLE 12: RESEARCH AND DEVELOPMENT

12.1 Since the national pharmaceutical industry in most developing countries is still in its formative stages, Governments shall enter the area of research and development by setting up special research and development institutions and linking their activities to production and innovation.

12.2 Pharmaceutical manufacturers, if they are not engaged in research and development activities themselves, and pharmaceutical importers, shall set aside an agreed percentage of their total turnover for research and development. This money may be credited to the state sponsored research institutions.

12.3 Pharmaceutical manufacturers and traders may be allowed tax relief on their contributions to research and development.

12.4 The Governments shall, in view of the requisite manpower and facilities, the small volume of total research effort, and the low research capability in most developing countries, set up appropriate organizations to define the priorities and problems needing research and coordinate the entire research activities between the specialized institutions set up by the Government, universities, and institutes of technology.

ARTICLE 13: IMPLEMENTATION AND MONITORING

13.1 Countries which have accepted the Code should take appropriate steps at the national level to meet their commitment to the Code, including the adoption of national legislation, regulations or other suitable measures. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aims of the Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of pharmaceutical products.

13.2 WHO and UNCTAD shall, on request, provide technical support to countries preparing national legislation or regulation or taking other appropriate measures in implementation and furtherance of the principles and aims of this Code.

13.3 Monitoring the application of this Code lies with the governments of the countries acting individually and together with WHO and UNCTAD. Pharmaceutical manufacturers and traders, appropriate non-governmental organizations, professional groups and consumer organizations should collaborate with governments to this end.

13.4 Independently of any other measures taken for implementation of this Code, pharmaceutical manufacturers and traders should regard themselves as responsible for monitoring their marketing practices, according to the principles and aims of this Code and for taking steps to ensure that their conduct at every level conforms to them.

13.5 Non-governmental organizations, professional groups, consumer organizations and individuals concerned should also undertake to draw to the attention of pharmaceutical manufacturers and traders activities which are incompatible with the principles and aims of this Code so that they can take appropriate action. The appropriate government authority should also be informed.

13.6 Pharmaceutical manufacturers and traders should appraise each member of their marketing personnel of the principles and aims of this Code and of their responsibilities under it.

13.7 WHO and UNCTAD should provide fora for consultations, discussions and

exchange of views between countries on matters related to this Code, in particular to its application and greater harmonization and the experience gained in its operations.

ARTICLE 14: REVIEW PROCEDURE

WHO and UNCTAD shall submit a report in four years to the World Health Assembly and the United Nations Conference on Trade and Development, respectively, reviewing all the aspects of the Code with proposals for the improvement and further development of the Code.