Exports of "Dangerous" Pharmaceuticals to the Third World

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This paper has arisen out of my activities as a consultant to the International Organisation of Consumers Unions. In this respect the paper also forms an integral part of the issue which encompasses products in general of exports of "banned and severely restricted products". It would not have been possible for me to prepare this contribution without the assistance of a large number of people who are committed to combating the uncontrolled export of "dangerous" pharmaceuticals to the Third World.

C O N T E N T S

I. Introduction

The export of pharmaceuticals to the countries of the Third World is the subject of emotionally-charged arguments in our prosperous industrial society to a greater extent than almost any other issue. The industrial countries and the pharmaceutical industry established there have sought and are still seeking to create the impression that the export of pharmaceuticals per se deserves to be promoted and supported because it helps to alleviate the yawning deficits in the health care sector of the developing countries. On the other side, there is mounting criticism of a health philosophy founded on the view that the more pharmaceuticals are exported to the Third World countries, the sooner the health problems will be resolved. It is not more pharmaceuticals that are required, but "essential drugs", which take into account the medicinal needs of the developing countries. The European and American pharmaceutical industries are vehemently resisting export restrictions and advocate free world trade in pharmaceuticals as the best guarantee of optimal health care in the developing countries. But despite all the protests of the pharmaceutical industry, the reality of the situation affirms the need for regulation. It is not essential, or not solely essential, drugs which are exported, but principally a whole host of products whose use poses a hazard to the consumers in the developing countries, which are simply ineffective or unsuitable, unnecessarily overpriced or else formulated in such an irrational manner as to rule out any meaningful therapeutic applications (1). Every one of these problem areas would justify an in-depth discussion. However, this paper is confining itself to the category of "dangerous" pharmaceuticals. In informed circles it is clear what is meant here: the export of pharmaceuticals whose use in the industrial countries is restricted or whose marketing or manufacture is banned, but which nevertheless are exported to the Third World. This

practice goes under the heading "double standards" internationally. The task of this paper is thus defined. It is not the supply of pharmaceuticals to the Third World or the international trade in pharmaceuticals, but solely the export of "dangerous" pharmaceuticals which forms the subject of our study. Strictly speaking this constitutes one small facet of a vast problem (2). And yet the everyday practice of "double standards" is a reflection of the overall problem of the supply of pharmaceuticals in the Third World. The search for appropriate control instruments is conditioned by the very much broader context of pharmaceutical supplies of "essential products" to the developing countries (3). To this extent the development of a plan for regulating exports of dangerous pharmaceuticals must be seen as a first attempt to deal with the whole problem of pharmaceutical supplies in the countries of the Third World.

II. The Problem of Double Standards

At international level "double standards" is synonymous with the export of "banned and severely restricted products". On closer examination the definition of the term "double standards" or "banned and severely restricted products" becomes less clear-cut. For when is a pharmaceutical deemed to be banned and when, in the final analysis, is the use of a pharmaceutical "severely restricted" ? What we must do first of all is illustrate the different cases in which "double standards" exist. In so doing, we have taken a large number of studies by the International Organisation of Consumers Unions (IOCU) and by Health Action International (HAI) (4) as a basis. Health Action International, founded in 1981, today embraces a world-wide network of initiatives with the objective of putting a stop to exports of "dangerous" pharmaceuticals. Significantly, neither the pharmaceutical industry nor the World Health Organisation nor any other international organisation has conducted studies

into the true extent of the problem. The pharmaceutical industry plays down the importance of double standards, whilst not denying its existence, treating it as an aberration which has been repeatedly practised by black sheep in the industry (5). The international organisations evidently shy away from examining closely such a political hot potato and emotionally-charged subject.

1. Categories

In order to understand the dimensions of the problem of dangerous pharmaceuticals exports, it is necessary to briefly remind ourselves about the health care situation in the countries of the Third World. A key factor is the distinction between public health care and private health care (6). The comparatively well-developed public health care system suffers from the drawback that it can only reach a fraction of the population. Hospitals are located, as a rule, in the major towns, and the rural population must either travel great distances into the towns or else try to obtain their drugs without adequate medical advice. This situation is further exacerbated by the fact that advice by pharmacists is also largely lacking. For these reasons pharmaceuticals in the Third World countries are sold "over the counter" on a large scale, regardless of the type of product or whether it needs to be administered under medical supervision. To add to this fragile infrastructure, already a problem by itself, "dangerous" pharmaceutical supplies are now brought in.

For perhaps the biggest and most critical problem of drugs supplies in the Third World is the circumstances of use (7). Already in the "normal case" of pharmaceutical exports which comply with the regulations of the exporting countries in every respect, even the most well-intentioned pharmaceutical company cannot guarantee that its product will be stored, prescribed,

dosed and used in the way required to achieve the optimum therapeutic effect. But while the normal case is already problematic, and one of the issues in the debate on the conditions needed for a properly-functioning health care system in the Third World countries, the export of banned or severely restricted pharmaceuticals very quickly enters the twilight zone of ruthless entrepreneurial profit-seeking.

a) Bans and Recalls

All the industrial countries have differentiated legal machinery for prohibiting the further manufacture of dangerous pharmaceuticals or for ordering their recall. For the member states of the EC the legal regulations are laid down in Directives 65/65; 73/319; 75/320 and 83/570 (8). Alongside the national marketing restrictions there are the schemes of voluntary recall by the manufacturers. Since a European pharmaceutical authority does not exist and even world-wide decisions on the banning or recall of a particular pharmaceutical are not co-ordinated amongst the countries, differences in regulation are bound to emerge when one country decides to order a ban or a recall. This produces a domino effect both amongst the industrial countries and in their relations with the developing countries. Once one country has issued a marketing restriction and this decision becomes general knowledge, shortly afterwards other countries follow suit with similar or identical decisions. A prerequisite for the domino effect is that the industrial countries - for it is they who are principally concerned - exchange information about the decisions of the national pharmaceutical authorities. It seems that the pharmaceutical industry is sorely tempted to exploit this difference in regulation. For in such a situation potential markets may be opened up both in those industrial countries which have not yet got around to introducing regulation, and in

the export of pharmaceuticals to the Third World - the particular subject of this paper.

Whereas the decisions by the national pharmaceutical supervisory authorities are either intentionally published or at least gradually filter out to the public, the voluntary recalls by manufacturers and the voluntary recalls "induced" by the state remain largely concealed from the public eye. An obligation to give notification of recalls or to publish notified recalls does not exist either in the European Community or in the United States. However, since the national supervisory authorities tend to persuade the manufacturers to apply voluntary restrictions themselves before taking official action, this creates the opportunity for pharmaceuticals withdrawn voluntarily in one country to be dumped, in particular, in Third World countries. Such products include: Clioquinol, Phenylbutazone, Benoxaprofen, Indoprofen, etc. (9). The best-known is certainly Clioquinol, because it has been blamed for causing the SMON disease (10).

Also falling under this category are those products which have been approved in the exporting country, but which may no longer be sold there. In the Federal Republic of Germany the practice seems to have grown up of not withdrawing or even extending the approval if the manufacturer guarantees that products recognised as dangerous are exported (11).

b) Severe Restrictions

This category forms the second plank of the internationally conducted debate on possible export controls for dangerous pharmaceuticals. Their undefined nature simply invites conflicting situations. For it is neither clear which marketing restrictions should come under this category nor is it an easy matter to find cast-iron criteria for distinguishing between

"severe" and "non-severe" restrictions on use. For the industrial countries themselves the method of ordering marketing restrictions enables them to respond in a flexible manner to hazards arising after the pharmaceutical has been placed on the market. The lowest stage of intervention consists in imposing restrictions on the indications so that the pharmaceutical may only be recommended for particular clinical syndromes, or else is excluded for use by particular groups of patients (children, pregnant women). At the next stage is the possibility of moving non-prescription drugs into the category of prescription drugs. Marketing restrictions of this kind may be effective in the context of a well-developed system of health care in the industrial countries, but in the countries of the Third World such complex marketing restrictions are definitely not attuned to the realities of life over there. For if the alternative is "this" drug or "no" drug at all, if medical attention is not guaranteed and if even a well-developed system of sale through pharmacies does not exist, there remain only the hospitals which may be able to supervise the use of such restricted drugs. It is not without good reason that the International Organisation of Consumers Unions and Health Action International have repeatedly pointed out that prescription drugs can only be put to meaningful use to a limited degree (12). They would only meet the needs of the developing countries if at the same time medical supervision were to be ensured and if it could also be guaranteed that the patients were prevented from obtaining prescription drugs over the counter. In this respect prescription drugs, which cum grano salis come under the category of severe restrictions, are per se a problem group, at any rate in the field of private health care (13).

It is not very helpful to denounce the export of prescription drugs without at the same time working towards the creation of a sound infrastructure in the developing countries. Consumer organisations should promote this objective and constantly

underline the problems involved in the use of prescription drugs in health care. From the point of view of double standards, however, marketing restrictions are much easier to deal with in the prescription/non-prescription category.

Restricted indications and partial exclusion of higher risk groups should tend to come under the "severely restricted" category. Double standards can occur when the drugs manufacturer does not indicate the restrictions on use for the exported drugs. Since in the industrial countries they are obliged to give the restrictions on use in the accompanying leaflet - for the EC countries this is laid down in Art. 13 65/65 (14) - a simple comparison of the leaflets for pharmaceuticals on the domestic and export market gives sufficient proof of the existence of double standards. In this respect, the "severely restricted" category is linked to the labelling of pharmaceuticals. For unlike the case of exports of banned, withdrawn or unapproved pharmaceuticals, it is not the availability on the markets of the developing countries which is the stumbling block, but rather the availability of the drugs under different - and as a rule overpriced - conditions. It therefore makes sense to deal with the problem of double standards in the severely restricted category in the context of pharmaceutical labelling and advertising.

c) Non-Registration and Non-Approval of Pharmaceuticals

In the wake of the Thalidomide disaster, the World Health Organisation recommended that pharmaceuticals should be subject to approval inspections (15). The adoption of EC Directive 65/65 refers back to the recommendation by the World Health Organisation. Leaving aside the in some cases very long delays in translating this directive into national legislation, pharmaceuticals marketed in the EC member states are now subject to approval inspections. By contrast, pharmaceuticals intended

only for export are not subject to the internal national approval inspections. These products do not even have to be notified under current EC law, so the extent to which unapproved pharmaceuticals - because rejected or not even registered - are freely circulating in the developing countries is totally unknown. Of the different categories of double standards this is the most sensitive group. Third World countries have accused the pharmaceutical industry of using their citizens as guinea-pigs for testing new drugs (16). The marketing of Depo-Provera is thought to have provoked the biggest reaction in this area (17). Depo-Provera is an injected form of contraceptive which is intended to provide protection for several months. However, at the same time it carries considerable health risks for the woman, for which reason its approval was refused in the United states. The debate is still raging the world over on whether, and under what conditions, Depo-Provera should be administered in the countries of the Third World. The battle-lines of the proponents and opponents cut right across the industrial countries and the developing countries. For whereas, for example, the womens organisations, in industrial countries too, are staunchly opposed to the export of Depo-Provera, on the other side doctors in the developing countries favour the wide use of this contraceptive (18). The reason for their support is that the drug requires no permanent medical supervision and dispensing of drugs, which in itself, they consider, outweighs the higher health risks.

Although until now only a few cases (19) have come to light, there are many indications that the number of unknown cases is higher. For the ever-more stringent controls on pharmaceuticals has made it increasingly difficult for the pharmaceutical industry to obtain approval for a new drug. At the same time, however, the pharmaceutical industry needs newly-approved products because the large number of expired patents erodes their liquidity levels (20). The opportunities which have been

opened up in particular to the pharmaceutical industry by biotechnology are therefore very much in line with their interest in developing new products. So there is a very real danger for the developing countries that the pharmaceutical industry will divert its attention there and test completely new procedures and substances which will only be submitted for approval by the domestic pharmaceutical authorities at a very much later date.

d) Advertising and Marketing

The EC Commission has made several attempts to introduce regulations on the advertising and marketing of pharmaceuticals. Although these endeavours have not met with any success, a number of the member states do have national special rules (21). Accordingly, there exists an extensive body of customary practice, partly by the authorities and partly by the courts, from which it can be inferred what limits are set to advertising and marketing measures. Double standards in this sector do not relate to the differences in regulation between the industrial countries and the developing countries. Rather it is the pharmaceutical marketing as a whole which is the object of criticism, the legal distinction between advertising and sales methods being in this respect of secondary importance.

The criticism is levelled at the attempts by the pharmaceutical industry to awaken a consciousness of the superiority of Western pharmaceutical in the developing countries (22). In this way the traditionally evolved methods of natural healing are supplanted (23) and the consumers in the developing countries are driven "into the arms of the pharmaceutical industry". This "taste transfer" (24) has, where it succeeds, grave consequences

for consumers in the developing countries. For medicines are prohibitively expensive and their high cost means that the consumers in those countries often face the choice of buying expensive medicines instead of the needed foodstuffs. Against this background it is clear why the International Organisation of Consumers Unions as well as Health Action International have condemned the pharmaceutical industry for its attempts to sell pharmaceuticals as food to the consumers of the Third World (25). In the firing line of the criticism are vitamins and anabolic steroids (26). Breast-milk substitutes are also included in this problem area (27). It is a fact that vitamin preparations and anabolic steroids form an integral part of the prescribing practice of doctors and it is not least for that reason that they are consumed in far larger quantities than in the industrial countries (28). Since the money would frequently be better spent on qualitatively high-value foodstuffs and that these are actually very widely available, the question arises as to whether the export of such unsuitable pharmaceuticals deserves to be promoted and is necessary (29).

Added to this, and here we return again to an essentially more concrete level of double standards, there is the fact that in many instances the pharmaceutical industry can be proved to be making claims in its advertising to properties for its products or suggesting a range of indications which would not stand up to the legal provisions applying in the industrial countries by any manner of means. Such double standards in advertising relate not only to the pharmaceuticals which are supplied as food substitutes. Rather it has been established that in actual advertising practice the pharmaceutical industry adopts a very free-and-easy attitude to information which is necessary and laid down in the home country. Restrictions on use are left out, contra-indications are not given and references to known side effects are "forgotten". A sorry role is played above all by the pharmaceutical industry's advertising of drugs for

diarrhoea. We need only mention Lomotil and Chloramphenicol; other examples are easy to find (30).

The pharmaceutical industry does not confine itself to influencing the consciousness of Third World consumers indirectly by means of advertising urging them to buy drugs. One of the most important marketing measures is to exert influence over the prescribing practice of doctors by the extensive use of pharmaceutical representatives (31). Whereas a representative in the Federal Republic of Germany serves 18 doctors, in the developing countries the figure stands at 1:4 (32). Particularly criticised here is the practice of handing out free samples of drugs.

e) Labelling of Pharmaceuticals

For the member states of the European Community it is not least as a result of various directives that it has become a matter of course for regulatory measures concerning the use of pharmaceuticals to be passed on to the consumer in the accompanying leaflets (33). So the consumers in the European Community today receive the principal necessary information about the dosage of drugs, medical indications, possible side effects and, where available, conceivable contra-indications. Every measure taken by the pharmaceutical authorities which affects the conditions of use requires that the consumer information is modified. For the consumers of the Third World the situation is fundamentally different. Double standards in information on drugs, whether as part of advertising or in the accompanying leaflets, are certainly not a universal sales strategy of the pharmaceutical industry. However, in practice, the IOCU and HAI have uncovered a whole host of "violations" by the pharmaceutical industry and new ones are constantly coming to light (34). It is not surprising that in their criticism of the double standards the IOCU and HAI are focusing on the

particular area of advertising and labelling of pharmaceuticals. For it is in these areas that double standards are easy to prove. Meanwhile, it is difficult to lend credence to the pharmaceutical industry's attempts to minimise the problem. Even when the motives of the pharmaceutical industry are simply opportunism rather than profit-seeking (35), nonetheless the question should be asked as to why it is not possible for concerns operating internationally to establish uniform marketing conditions for their products.

2. Double Standards Strategies

Just as double standards can be split up into different categories, it should also be possible to work out strategies which are linked to the individual product groups of double standards. This task appears to be of such importance because it offers a basis for developing appropriate instruments to deal with the double standards problem.

a) Dumping of Stocks

This method is open to the pharmaceutical industry when the marketing of a pharmaceutical is restricted or totally banned or else a pharmaceutical is recalled by the pharmaceutical supervisory authorities because of hazards which have become apparent subsequent to their placing on the market. For in these cases the industry runs the risk of being left with large stocks on its hands and possibly sustaining financial losses. Exports to the Third World, and not only there, offer a "suitable" way out. The fact that this is not simply a figment of the consumers organisations' imagination is acknowledged by the industry itself (36). For at international level the industry has often only declared its willingness to withdraw such products after the sale of products in the developing countries which have been banned in the industrial countries has

fully exhausted its earning potential. So long as different criteria for assessing health risks exist, this practice will continue. The difficulties of the European Community in creating a common market for pharmaceuticals illustrate just what a long way there is still to go before uniform criteria have been achieved world-wide.

b) "Differentiation of Information"

In theory, the different evaluation criteria for the approval, banning and recall of pharmaceuticals are reflected in the advertising information and pharmaceutical labelling. In this respect there are differences in information, although this is not the primary target of criticism. Under the heading of double standards, it is the pharmaceutical industry's practice of not passing on information which is fully available in the home countries to the consumer in the Third World which is condemned. It looks as if the pharmaceutical industry is, in particular, exploiting the lack of regulatory powers in the Third World countries. The extent to which this happens "intentionally" or simply as the consequence of an "inadvertent error" remains to be seen. In practice, this constitutes an unfair marketing measure which could be dealt with by regulation at international level. The Breast Milk Substitutes Code (37) may act as a red rag to the pharmaceutical industry, but for the consumer organisations throughout the world this Code is a successful example of international product regulation.

c) Defence of Double Standards

The pharmaceutical industry has never attempted to defend the differences in the information given in accompanying leaflets or in advertising. Such double standards were generally presented as exceptions made in error or due to the independent actions of subsidiaries in the Third World and, after exerting appropriate

pressure, remedial steps were taken. It is a different matter, on the other hand, for the export of pharmaceuticals whose marketing has been banned or which have been recalled in the industrial countries. This category also includes pharmaceuticals which have not even been subjected to an approval procedure in the industrial countries. All attempts at justification by the pharmaceutical industry have one thing in common: a reference to the different socio-economic and socio-cultural conditions in the industrial countries by comparison with the developing countries (38). In other words, the impression is given that those pharmaceuticals whose marketing has been restricted in the industrial countries could be very useful to the developing countries. The pharmaceutical industry knows how to tailor this line of argument to the specific product being criticised so as to avoid trite over-simplification. That is not expressed in this way, the pharmaceutical industry is careful not to justify dumping indiscriminately. Arguments are product related, i.e. linked to specific cases making them, in the final analysis, individualistic in nature. That is why it is so difficult for the opposing side to respond to the justification strategy of the pharmaceutical industry because it can in individual instances be appropriate to approve the export of "dangerous" pharmaceuticals. It could be a task for doctors and pharmacologists to list those product groups for which export could be considered under suitably defined conditions.

d) "Guinea-Pigs"

The suspicion is there, the accusation is a grave one and since, until now, proof has been thin on the ground, those people who made the accusation are urged to come forward with the evidence to back up their suspicions (39). So long as this has not been achieved there should be no talk of a "strategy". This should apply even though the indications exist to suggest that the

accusation is not totally unjustified.

3. Dimensions of the Double Standards Problem

In order to avoid arousing false susceptibilities in this sensitive area it must once again be stated quite clearly that no definitely-established information exists on the extent to which pharmaceuticals are dumped in the Third World (40). The International Organisation of Consumers Unions as well as Health Action International can do no more than repeatedly point out new scandals. In this way it has been possible to pinpoint advertising and drugs marking as one of the key areas of double standards. The evidence in all the other categories can only be furnished by means of individual examples. The share of products dumped in this way as a proportion of total pharmaceutical exports is not quantifiable. This may change if appropriate inspection instruments are found and implemented at international level to provide an overall picture of the pharmaceuticals actually exported together with their regulatory status. On the other hand, the lack of knowledge should not provide a pretext for immediately concluding that this is a problem worth disregarding. What is needed, rather, is to recognise the causes behind the practice of double standards and to seek to remedy the situation.

III. International Regulation of Pharmaceuticals Exports

Strictly speaking there is no international regulation of pharmaceutical exports, or to be more precise, a regulation of this kind is, at the most, in the process of emerging. For even the World Health Organisation (WHO) as the most important international actor is pursuing no special export policy and has never done so. In the 40 years since the founding of WHO a

whole range of initiatives has been launched with export regulation as their objective, but all the time the goalposts were moving farther apart (41). It was really only the Thalidomide disaster which prompted WHO to perceive pharmaceutical supplies as a politico-social problem. The next advance took place in the '70s when the supply of pharmaceuticals in the Third World had become a problem which could no longer be ignored. As a consequence the World Health Organisation was compelled to gear its health policy more closely to the needs of the Third World.

The '60s saw above all the attempts to place Third World nations in a position to take their own decisions as consumers who have, as it were, "reached maturity", by means of an organised information exchange (42). The '70s brought a more strongly interventionist style of policy, as also in the industrial countries. A direct expression of this policy is the Essential Drugs Programme (43) and regulation by means of a Code of Conduct (44) particularly aimed at combating unfair marketing practices by the pharmaceutical industry. At present, in a fundamentally different international political situation, in which the World Health Organisation has to live with the permanent threat by the USA to withdraw its funds, it is a matter of consolidating the policy of the '70s, although all too often this is thinly-veiled regression. The World Health Organisation has lost the momentum of the '70s, and the United States has watered down the interventionist elements so that it is scarcely appropriate to talk about a Marketing Code any longer. The Third World countries have registered the attempts of the industrial states to put a stop to a further politicisation of WHO's health policy and have moved the debate on exports of dangerous drugs to the forum of the UN General Assembly. Against the fierce resistance only of the United States, the famous Resolution 37/137 (45) was adopted, calling on the General Secretariat to draw up a Consolidated List of

banned and severely restricted products.

Europe had until then played no part in the international debate on the export of drugs. A laissez-faire policy prevailed into the '80s, giving a carte blanche for the export of drugs to the member states of the European Community as well as to the EC itself. The first move towards a change was made by the Council of Europe with its precisely-formulated support, more particularly, of the Essential Drugs Programme in 1983 (46). In the EC it appears that the way is also being paved towards a change in the export policy pursued until now. This will be at the instigation of the European Parliament (47). The magic phrase of the day, devised and disseminated by the International Organisation of Consumers Unions as well as by Health Action International is: "Prior Informed Consent". A sideways glance at the situation for exports of hazardous waste (48) and chemicals (49) shows the willingness of the EC to see export notification as a generalised instrument of export regulation. In this manner the boundaries are marked out within which the regulation of drugs exports takes place: information exchange, export notification and export controls. It is on these three categories that international attempts to master the problem of "dangerous" pharmaceuticals exports have centred.

1. Exchange of Information

This covers all steps taken with a view to providing the Third World countries with information about pharmaceuticals, which they may request if needed. It is therefore assumed that the countries of the Third World possess the staff and technical resources to make the request, process detailed information and translate this into their own product regulations. In actual fact, many countries of the Third World have no drugs supervisory authority at all, and even where this exists it has

few staff who are also responsible for carrying out many other tasks. Finally, the necessary legislation on pharmaceuticals is also lacking (50). In this respect a discussion of the information exchange scheme can only be objectively justified if it is assumed that the resources necessary for processing the information are actually available.

a) WHO Drug Bulletin and WHO Drug Circular

With the memory of the Thalidomide disaster still fresh in its mind, the General Assembly of the World Health Organisation passed Resolution 16.36 (51). This resolution was to represent a milestone in the development of an information exchange scheme (52). It called upon the member states of WHO to notify this body of the following decisions taken by their drugs supervisory authorities: bans and restrictions on use of pharmaceuticals on the market, refused applications for the approval of new pharmaceuticals, and approvals of pharmaceuticals where these impose restrictive conditions of use. However, only those decisions are covered by the compulsory notification which are taken on grounds of serious adverse reactions. At the same time, the member states were also asked to state the reasons which had prompted them to impose marketing restrictions. In various resolutions: 23.48 (53), 28.66 (54) and 37.33 (55), the General Assembly affirmed the need for an effective information exchange scheme.

With a view to giving effect to Resolution 16.36, the World Health Organisation brought out the Drug Information Circular, by means of which decisions notified by the member states can be passed on to the Governments. The information contained in the circular is not available to the public and is confined to Government circles or the competent drugs supervisory authorities. Not least in order to ensure that information is made publicly available, the World Health Organisation

supplemented the Drug Circular with the Drug Bulletin, which reports at irregular intervals on notified decisions. In contrast to the circular, the bulletin does not publish the decisions of the national Governments in full, but instead in a revised form together with comments. The Drug Bulletin is highly-regarded in the medical profession, although its irregular publication is criticised.

In 1984 the General Secretariat of the UN presented a report to the General Assembly on the different information exchange schemes of the UN and its agencies (56). The report is equally critical of the Drug Information Bulletin and the Drug Information Circular. Both schemes are, it is true, acknowledged to provide to some degree a reasonable and complete information service for interested circles, particularly for states which do not have a well-developed system of drugs inspection. At the same time, they are criticised for the fact that the World Health Organisation is only notified of a small number of the drugs which are actually withdrawn. The cause of this deficiency, according to the report, can be attributed to the limited scope of the information exchange scheme. For voluntary recalls by the drugs manufacturers are not included in the Drug Circular and Drug Bulletin any more than are those drugs which, without ever even having been approved, are produced solely for export (57).

b) WHO Certification Scheme (58)

The primary objective of the certification scheme is to establish a mechanism which enables the developing countries to be certain that exported drugs are of perfect manufactured quality. With the certification scheme the World Health Organisation is taking steps to allay the repeated accusations by the developing countries that they are being supplied with inferior quality drugs. The information exchanged through the

certification scheme between the exporting and importing countries also includes information on the regulatory status of the product in the exporting country.

Already in 1969 the General Assembly of the World Health Organisation directed the Secretariat to elaborate a certification scheme on the quality of pharmaceuticals in international commerce. One year later the General Assembly emphatically reaffirmed its concern in Resolution 22.50 (59). It was another 5 years before the certification scheme was to be adopted in Resolution 28.65 (60) in the form which is still in effect today. Behind the scenes a dispute immediately broke out between the exporting and importing countries on the detailed organisation of the certification scheme. In the first place WHO put forward a dual certification scheme for discussion (61). Under this scheme the competent drugs authority of the exporting country would, at the request of an importing country, certify that (A) a specific pharmaceutical manufacturer is authorised to manufacture and sell the drug in the exporting country, as well as to confirm that the pharmaceutical manufacturer's company is subject to regular quality inspections; and (B) in response to a further request, to inform the importing country of the name of the manufacturer of the individual batch, his authorisation to manufacture the drug and at the same time to confirm that all relevant details about the manufacture and tests on the batches have been submitted for examination by the drugs supervisory authorities. The exporting countries rejected such an organisation of the certification scheme (62). Their objections to variant (A) were that the legislation, in any case at that time (63), in most of the exporting countries did not provide for any quality inspections for exports of certain pharmaceuticals. Variant (B) did not meet with approval either. This variant would also have required an amendment of the laws in the exporting countries. For an inspection of batches of pharmaceuticals was and is not compulsory under the national laws.

The certification scheme introduced in 1975 complies fully with the demands of the exporting countries (of the pharmaceutical industry). Since then the drugs supervisory authorities are only obliged to provide certification which clearly indicates that the sale of the product in the exporting country is approved (or if not, the reasons for the ban) and that the undertaking in which the product is manufactured is subject to regular inspections in accordance with the "Good Manufacturing Practices" developed by the World Health Organisation. These were adopted by the General Assembly of the World Health Organisation as far back as 1970. They define a common basis for assessing the requirements imposed on the manufacture of drugs. If this information is not enough for the importing country it can then require additional particulars from the drugs supervisory authorities: which indications, contra-indications and side-effects are known in the exporting country, as well as an inspection analysis of the specific batch for export, obtained either from the drugs supervisory authority or from the pharmaceutical manufacturer himself.

In 1980, 5 years after the introduction of the certification scheme, the General Assembly called on the Director-General of the World Health Organisation to prepare a report on experiences with the scheme (65). The Secretariat thereupon conducted a survey of all the 163 member states of the World Health Organisation and also sent a number of consultants to various countries with a view to gathering information on the spot about the use of the scheme. The results of the survey were first presented at the Third International Conference of Drug Regulatory Authorities (ICDRA) (66). Subsequently the certification scheme has enjoyed growing popularity, particularly amongst the developing countries who use it with different objectives. For those developing countries who are completely dependent on pharmaceutical imports and do not have

any kind of infrastructure for drugs inspection this scheme is the only source of information. For other countries who are not solely dependent on imports and already possess their own rudimentary system of inspection, the information serves as a first step towards forming their own opinions. India and Egypt, which themselves manufacture pharmaceuticals on a large scale, use the certification scheme for their own exports. The major industrial countries, on the other hand, particularly in Europe, are, it is true, willing in principle to issue certification at the request of the importing country, but amongst themselves they rely on bilateral or multilateral arrangements.

The principal users of the scheme, the developing countries, have considerable difficulty in putting into practice the scheme outlined in model form. This may be due to the highly formal style of language. In any case, the survey has brought to light the need to formulate directives for the use of the certification schemes. These essentially technical difficulties should be comparatively easy to resolve.

Far more serious are the structural deficits which have been revealed. Among these is the non-inclusion of raw materials. And yet the developing countries, who are in the process of building up their own pharmaceutical industries, need information about the basic substances from which the finished pharmaceutical product is manufactured. The competent inspection authorities in the developing countries complain that the certification scheme provides no information at all about the safety and efficacy of drugs.

A third criticism concerns the inadequate information about the regulatory status of the drug in the exporting country. This criticism is hardly surprising. It was after all foreseeable that pharmaceuticals produced solely for export, and which do not have to be either registered or approved in the exporting

country, could not be incorporated at all. A structural shortcoming of the certification scheme is, furthermore, the absence of a mechanism enabling the importing countries to be informed about any changes in the regulatory status in the exporting country. Since the developing countries as a rule require certification for the export of the first batch, it can occur that the information in the certification scheme about the regulatory status in the exporting country is totally out-of-date. The exporting countries discharge their responsibilities by notifying the World Health Organisation of any changes, which are then passed on in the Drug Circular. A direct exchange of information with the inspection authorities in the developing countries - who had previously applied for information through the certification scheme - does not take place.

The ICDRA drew up proposals to eliminate the deficiencies outlined (67). These proposals were discussed one year later at the Conference of Experts on the Rational Use of Drugs" (68). There was agreement on the inclusion of information on raw materials in the certification scheme, and on the development of a mechanism to enable the developing country to obtain information about the safety and efficacy of the drug. However, it was a different matter for the complex issue of information on the regulatory status of the drug in the exporting country. The problem was, it is true, discussed more or less in depth, but the proposals for a solution remained vague and, above all, are not linked up to the information mechanisms already in existence (the Drug Circular and the Consolidated List). It will therefore come as no surprise to learn that in 1986 the General Assembly of the World Health Organisation, in connection with its "revised strategy on drugs" (69), called for the scheme to be extended to raw materials and product information about safety and efficacy, while ignoring the problems of the regulatory status of drugs in the exporting country.

Nevertheless, the new resolution by the General Assembly is important because the inclusion of information about the safety and efficacy of drugs opens up possibilities for an upgrading of the certification scheme. The Secretariat of the World Health Organisation is currently conducting a survey among the member countries on just what form a possible change in the certification scheme could take. Perhaps the most crucial question is whether in the opinion of the member state the information on the safety and efficacy of a drug should contain a summary of the decisive criteria in the approval of the drug. The questionnaire refers, for example, to the "Summary Basis of Approval" document of the US Food and Drug Administration. But it could also equally have referred to the evaluation reports in EC Directive 83/570 (70). The prospects for a European pharmaceutical export policy, in the light of the latest developments in the World Health Organisation will still require our attention. For the time being, any grounds for a possible rising euphoria should be nipped in the bud by pointing out that the deficiencies diagnosed in 1984 were known about as early as 1981 and now in 1987 are to be the subject of a feasibility study.

c) EFTA - Pharmaceutical Inspection Convention (71)

The discussion of the Pharmaceutical Inspection Convention has a place here for two reasons: for one thing - whether rightly or wrongly remains to be seen - it is regarded as the forerunner of the WHO Certification Scheme (72); for another it comes into direct competition with the WHO Certification Scheme because since 1981 non-EFTA members may also participate in the information exchange provided for.

The preparatory work of EFTA on the Pharmaceutical Inspection Convention was set in motion by the adoption of Directive 65/65 (73). With this directive the EC embarked upon the difficult

task of harmonising the legal provisions on drugs in the member states. EFTA then found itself faced with the question as to whether it should follow in the footsteps of the EC and also seek to remove the technical barriers to trade caused by the divergent drugs legislation by harmonising the legal systems. The alternative was to leave the existing differences in legislation as they were and instead promote an unimpeded exchange of goods based on mutual recognition of drugs supervision. EFTA has seen its sceptical attitude confirmed in view of all the attempts to achieve a common market in Europe by harmonising laws and regulations. For it is a well-known fact that the EC's harmonisation plans have come up against some major obstacles.

The thinking which underlies EFTA's Pharmaceutical Inspection Convention is that drugs can in any case circulate freely if it is ensured that the manufacture of drugs in all countries is subject to identical requirements. This has been the objective of many guidelines on "Basic Standards of Good Manufacturing Practice for Pharmaceutical Products", which, however, is significantly higher in standard than the World Health Organisation's "Good Manufacturing Practices" referred to above. Of critical importance now is how the importing country can be provided with a guarantee that the batch awaiting export has been manufactured in accordance with the commonly established manufacturing requirements. The convention seeks to overcome this hurdle by means of an exchange between the member states of so-called "Inspection Reports" (74) drawn up in a standard format. These inspection reports always concern a specific pharmaceutical manufacturer who has been subjected to an inspection as part of the activities of the drugs supervisory authorities. The report has to give particulars of the purpose of the inspection, the sample taken, previous inspections, the persons dealt with, a general description of the company (size, integration with other companies, situation), staff employed including an outline of the company's organisational structure, as well as details about

what was actually inspected: the manufacture of tablets, packaging, laboratories or warehouses. If the inspection is confined to the manufacturing process, it should also be mentioned that the manufacturer's system of quality control is also taken into consideration.

EFTA has made considerable efforts to standardise these inspection reports. And yet the Pharmaceutical Inspection Convention can only operate if a climate of mutual trust can be created amongst the member countries. Regular meetings of the competent persons, training seminars, etc. should be organised to this end. A description of the convention would be incomplete without a reference to the undertaking entered into on all sides to notify each other by the quickest possible means if the inspection brings to light indications that a product represents a considerable and grave hazard to the public (75). The information to be exchanged covers that which has not yet led to regulatory action by the competent drugs supervisory authorities. In this respect the exchange of information falls below the threshold of the merely formal notification of marketing restriction measures which have already been adopted.

For the developing countries the Pharmaceutical Inspection Convention has assumed such importance because in 1981 EFTA passed a resolution which opened up the system to also include countries which are non-EFTA members (76). At their request, the competent inspection authorities in the developing countries can obtain basic information concerning the drugs inspection. It was made clear from the outset that the inspection reports of the drugs supervisory authorities would not be placed at the disposal of the developing countries. They only receive particulars about how long the pharmaceutical manufacturer concerned has already been making the product, the range of his production, the size of the company, a statement that the production is inspected by expert staff whose qualifications

satisfy the requirements laid down in national law and, finally, a statement that the company is regularly inspected and complies with EFTA's "Basic Standards of Good Manufacturing Practice". To date it is not known to what extent the developing countries have made use of the opening up of the convention. But it seems to be over-hasty to write off the Pharmaceutical Inspection Convention solely because it places "second-best" information at the disposal of the developing countries. For although the information does not cover the regulatory status of the drug in the exporting country, the statement made does still constitute a guarantee that the drug has been manufactured in accordance with quality standards which are higher than those of the World Health Organisation. In this respect it may be entirely in the interests of a developing country to combine the advantages of both systems: the WHO Certification Scheme and the Pharmaceutical Inspection Convention.

d) UN Consolidated List (77)

For the countries of the Third World, the Consolidated List is the most important source of information world-wide on banned and severely restricted products (chemicals, pesticides, pharmaceuticals and also consumer products). The creation of this list was hotly contested and its continued existence cannot be regarded as beyond doubt.

When the developing countries found that they were not making much headway with their efforts within WHO, FAO and UNEP to implement stricter export controls or even an export ban for "dangerous" products, they shifted the focus of their activities to the political forum of the General Assembly. The objective of the developing countries was not primarily to draw up a "blacklist", but rather to prevent or severely restrict the export of dangerous products on principle.

The developing countries set the ball rolling with the adoption of Resolution 35/186 by which the UN Commission on Transnational Corporations (CTC) was instructed to prepare a report on how to deal with the problèm of exports of hazardous products. As early as 1981 (78) the UN CTC put forward a recommendation for a list of banned and restricted products to be drawn up in which both the trade names of the products and the manufacturers concerned would be specified. It was just such a politicisation of the issue which the industrial countries had feared and which had turned them against the assignment of this mandate to the UN CTC. For the latter has a reputation for being a political department in which mutually sympathetic UN officials, Third World countries and Non-Governmental Organisations (IOCU, HAI) come together to co-ordinate their policy (79). The industrial countries wanted to have the subject dealt with by the technical organisations (WHO, FAO, UNEP) where, in their view, the necessary expertise is on hand and which would not seek to find a hasty political solution to a scientific and technical problem.

So further developments within the UN hinge upon the argument over whether the problem of exports of "dangerous" products should be resolved on a scientific and technical or on a political level. With the adoption of Resolution 37/137 the developing countries achieved the first breakthrough. With the backing of the EC countries, but against the vote of the USA, the resolution was passed which opened the way for work to start on the Consolidated List. To the very end the USA sought to prevent the adoption of the resolution. The USA advanced budgetary considerations as a reason, claiming that the drawing up of the Consolidated List would incur additional costs - the figures ranging between 100 and one million US Dollars. What really lay behind this were fundamental objections to the policy associated with a blacklist in which the main manufacturers and their trade marks would be named. The countries of the EC

probably only voted in favour of the resolution because it contains an escape route allowing products to be marketed even when they are banned or severely restricted in the home country. For the directive permits the export of such discriminated products even in these cases, as long as their consumption in the importing country is "officially permitted". Since legally speaking everything which is not banned is permitted, the exporting countries are free to export dangerous products provided the importing country has not introduced any regulations. The West European exporting countries can therefore still claim in such cases that they are acting in conformity with Resolution 37/137.

But the struggle between the disputing parties only really started in earnest when it came to preparing the actual list. The industrial countries showed their opposition with different stances and differing degrees of intensity. The West European countries adopted stalling tactics by casting doubt on the need for a separate source of information. The existing instruments, such as the WHO Certification Scheme and the Drug Circular and Drug Bulletin would, in their view, suffice to meet the information needs of the developing countries. It took new resolutions by the General Assembly and new reports by the General Secretary to overturn this objection (80). Once it became clear that the UN General Secretariat was firmly rsolved to draw up the list, countries such as the Federal Republic of Germany and the United Kingdom confined themselves to simply giving notification for the category of banned products. As for the rest, they said that they required a more precise definition of the term "severely restricted" before they could give any further information for this category. It was at this point that the United States stepped in with its reasons for refusing to even participate in preparing the list. In its official refusal to the UN Secretariat the USA indulged in considerable verbal acrobatics regarding the terms involved and even went as

far as to state that banned and severely restricted products did not exist as a category in the United States, with the result that its own participation was superfluous (81). All that we can say here is that these are political categories which are certainly in need of interpretation and supplementing. However, the legal parrying tactics employed by the USA only poorly conceal the obstruction policy which is emerging. The only crucial question is whether the industrial countries possess the political will to co-operate on the Consolidated List. By doing so they will be able to iron out the problems standing in the way of a standardisation of the concepts used. The OECD's recommendation on the export of chemicals (82) demonstrates that the same countries used identical terminology within this organisation, without finding this any hindrance to formuling a common export policy.

In spite of all this opposition, in December 1983 the UN Secretariat published the first edition of the Consolidated List. It was reissued in a slightly revised form in 1984. The long-announced second edition of 1986 was made available a couple of weeks ago. The 1984 list contains 195 drugs, half of which drawn from the WHO Drug Bulletin and the remainder supplied by 60 member countries (83). The missing input from the USA, as the most important international actor, was not - or only marginally - noticeable because the USA and the Food and Drug Administration (FDA) respectively notify WHO of their decisions so that they do make their way into the Consolidated List via this roundabout route. The non-governmental organisations, finally, who have access to the files of the FDA under the Freedom of Information Act, made a further contribution to softening the impact of the State Department's refusal. Nevertheless, the 1984 list is above all a tribute to the commitment of the UN Secretariat, as well as of the UN CTC, which endeavoured to track down the trade names and manufacturers. However, the latter did not succeed in this aim

for the 195 drugs. The member states, even Canada and Sweden, declined to give the necessary particulars. The World Health Organisation showed only a limited readiness to co-operate. Basically it seems that the prevailing view there is that the necessary drugs information is in any case accessible from other WHO sources; which would however then have to be supplemented by additional information to place the marketing restriction in its relevant context.

At any rate, WHO was not prepared to place the Drug Circulars at the disposal of the UN Secretariat. In all probability these circulars contained information about more than just 100 products. If in addition one takes into account the industrial countries' policy, then the reaction to the published first list will not surprise anyone. The developing countries together with the non-governmental organisations backed the UN Secretariat (84) setting the following priorities: a single list in the UN system for hazardous products, an inventory of regulatory measures, and an inventory of trade names and manufacturers; but they refrained from making criticisms so as not to jeopardise further work. The industrial states, meanwhile, adopted a very different stance, and WHO also took a perhaps rather more cautious line: the latter concentrated its criticisms on the list's undoubted deficiencies and shortcomings (85). For instance, the list contains 8 drugs which are simultaneously incorporated in the List of Essential Drugs, which apparently did not debar them from inclusion in the Consolidated List. Part of the information is also obsolete, with generic drugs being mentioned which are scarcely to be found on the market any more. The Americans would prefer to transform the Consolidated List into a simple index with references to data available elsewhere in the UN system (86). This would nullify the policy objective of the Consolidated List. But the other West European exporting countries as well as the technical and scientific agencies of the UN - principally WHO and UNEP - also

expressed reservations about the incomplete information scheme which, it must be added, they have also themselves to answer for.

WHO, UNEP, and the UN (not the UN CTC) had already held a meeting in 1985 at which they concluded an interagency agreement (87) which reads like a request list of the industrial states:- shifting of responsibility away from the UN Secretariat to the scientific and technical organisations; - joint editorship by WHO, UNEP and UN; - deletion of trade names and manufacturers from the list; - removal of drugs which have been withdrawn from the market only because of their lack of usefulness; and - clear provisions defining the categories "banned and severely restricted". Except for the deletion of trade and manufacturers' names, all these proposals for amendment have found their way into the Secretary-General's report on the first experiences with the Consolidated List (88).

This report formed the basis for the compilation of the second fundamentally revised edition of the Consolidated List dating from 1986, which has been published in 1987. The list contains more than 600 products, of which 253 drugs. It was compiled from information from 77 member countries, also including the United States. The new allocation of responsibilities within the UN organisation led to a tug-of-war behind the scenes between the UN Secretariat and WHO over which drugs were to be included in the list, and which not. WHO continued to pursue a restrictive policy, considering it unwarranted that every known decision by a drugs authority should automatically be put on the list. Whenever the UN Secretariat discovered that drugs had been filtered out in this manner - possibly from other sources - it sought to use its editing rights to get them "smuggled back" into the list.

According to the unanimous opinion of all the participants, the 1986 List is substantially improved. The following are probably contributory factors: - the henceforward more clear-cut criteria for the categories "banned and severely restricted" (banned = total ban on sale; severely restricted = restriction with regard to particular clinical syndromes or to particular groups of people, children, the elderly); - the reference to the source of the regulatory measure; - the statement of the reasons for the marketing restriction (abridged version of the WHO Drug Bulletin); - and the documentary evidence of risk-free administration. As before, the 1986 list contains the trade names and manufacturers but not for drugs. The recommendation in the Secretary-General's report that the trade names and manufacturers names be published in a separate list proved to be a boomerang. For the discriminatory effect which it was intended to avoid was in fact shown up more conspicuously than if they had been set out in a single compendium. For this reason, not least owing to the intensive lobbying of the non-governmental organisations, the trade names and manufacturers' names were also incorporated in the list. The UN CTC has taken responsibility for the compilation.

For more than half a year the interested circles have been waiting for the publication of the 1986 list. A critical factor here could have been the financial crisis in the UN (89). The continuation of the work is also under threat from another quarter. The office responsible for the list, the Program Planning and Co-ordinating Office, may possibly be split up as part of the reorganisation within the UN. As a consequence the office might lose the necessary personnel for compiling the list.

2. Export Controls

Strictly speaking, it is not possible to talk about export controls as part of an international regulation of the trade in drugs. For WHO is not a supranational body with the authority to take regulatory action (90). Nevertheless, in the '70s WHO sought to give itself a supranational outlook. This goes back to the new orientation in the World Health Organisation's policy prompted by the growing difficulties surrounding supplies of pharmaceuticals in the Third World countries. WHO's policy on drugs was no longer to be founded on purely technical and scientific considerations, but rather on a broader socio-economic embedment of the drugs supply question within the overall context of the "New International Economic Order". Attempts by the World Health Organisation - backed up in particular by the developing countries, the majority of whom had become members of WHO - to take stronger action (not to say introduce regulation) with regard to the trade in pharmaceuticals, brought an actor onto the scene who was to cause WHO a great deal of trouble: the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The pharmaceutical industry mobilised its interests through the IFPMA and opposed every effort by the World Health Organisation to go beyond simply exchanging information and to actively bring about the "right" kind of pharmaceuticals procurement in the developing countries. The power of the pharmaceutical industry was, it is true, not sufficient to prevent the new formulation of policy in the World Health Organisation. But, not least owing to the active support of the Reagan administration it did succeed in taking the edge off the "interventionist" elements of WHO policy in the '70s.

a) "Essential Drugs" for the Developing Countries

WHO's Essential Drugs Programme strikes at the nerve centre of

the pharmaceutical industry. For it is founded on the view that the supply of drugs in the developing countries is adequately covered by the provision of between about 200 and 250 drugs. A radical reduction in the drugs to between 200 and 250 products, primarily generic drugs, would wipe out the problem of exports of banned or severely restricted products. For provided that the developing countries kept to this recommendation they would only import the products on the list or, where possible, manufacture them themselves.

This change of course in WHO policy was ushered in by Resolution 28.66 (91) in which the General Assembly underlined the necessity of developing a pharmaceuticals policy which catered for the health needs of the Third World countries. The new approach led in 1977 to the drafting of a prototype list of essential drugs, which was published as a technical report together with recommendations for the necessary accompanying information (92). Things did not rest there. Such a list may have a signalling effect, but this in no way guarantees that the developing countries will adopt the prototype list as part of their own policy. That is why the General Assembly then adopted an Action Programme (Resolution 31.32) (93), in which the member states (in particular the developing countries) were urged to set up the necessary infrastructure (supply, storage, distribution) with a view to: - making the essential drugs available at reasonable prices; - drawing up national prototype lists; - as well as creating the necessary regulatory basis for supervising the pharmaceuticals market. The General Secretariat was called upon, with the help of UNIDO and UNCTAD, to see to it that the developing countries do actually receive the drugs or else are able to manufacture them themselves.

The initial reaction of the pharmaceutical industry was decidedly negative, even outright hostile. In their view the use of the List of Essential Drugs, whether in the form

recommended by WHO or in a variant form tailored to the needs of a developing country, would not improve the supply of drugs in the developing countries, but rather undermine the successes already achieved. Sri Lanka (94) and Bangladesh (95) were to find that the pharmaceutical industry did not stop short at just verbal opposition. For when they set about not only drawing up a list of essential drugs modelled on the WHO prototype, but also radically cutting down the number of drugs available in their countries, the pharmaceutical industry gave them an ultimatum: either the national lists were extended or all supplies of the essential drugs on the list would be stopped.

Towards the World Health Organisation the pharmaceutical industry adopted a more conciliatory approach. But only after the World Health Organisation had decisively limited the function of the List of Essential Drugs in an official position document. According to this the list was assigned a purely model character in two senses: firstly in that those countries interested in WHO's policy would have to decide for themselves whether to take it over as it was or in a modified form; and secondly because of the self-evident need to reassess and supplement the WHO list in the light of new medical knowledge. In order to demonstrate their readiness to co-operate, the pharmaceutical industry made a proposal, which in publicity terms was well prepared, at the General Assembly of the World Health Organisation in 1982, to supply the "poor countries" with essential drugs on "favourable conditions" (96). For three years the World Health Organisation and the pharmaceutical industry negotiated fruitlessly. At any rate partly to blame for the failure of the discussions were probably the motives behind the offer - which were never expressed in public. In reality there was supposed to be a bargain: the supply of (some) essential drugs in return for recognition of patent rights and trade mark protection (97). However, relations between the World Health Organisation and at least some of the international

pharmaceutical enterprises do seem to have eased recently. For there is a growing number of reports of successful co-operation in implementing the Essential Drugs Programme (98), which cannot however be accepted without corroboration.

The further fate of the programme is unclear. Its long-term effect will not least hinge upon whether the World Health Organisation publishes the Data Sheets, promised back in 1977, and which were supposed to have been prepared for each of the drugs on the list. These data sheets are designed along the lines of the drugs information leaflets which accompany the finished product. They are supposed to provide the prescriber (not necessarily a doctor in the developing countries) with all the information needed to decide whether the diagnosed illness can be treated with the drug. The World Health Organisation has been accused of having prepared the data sheets 6 years ago and then shelving them rather than release them for publication. The World Health Organisation, for its part, stresses the difficulty of drawing up standardised information. Health Action International has stepped into this vacuum with "Problem Drugs". This Action Pack contains up-to-date information on 44 particularly important but at the same time problematic drugs (99).

As was the case previously, and despite perhaps the most ambitious programme which the World Health Organisation has elaborated since its foundation, the export of banned and restricted drugs to the developing countries remains a malignant problem. Only Sri Lanka, Bangladesh and Tanzania have succeeded in taking the first steps towards tackling the problem of exports of "dangerous products" by using the List of Essential Drugs as a guide for their supplies of drugs.

b) Code of Marketing Practices for the Pharmaceutical Industry

The very same resolution, namely 31.32, in which the Action Programme on Essential Drugs was adopted, called upon the General Secretariat of WHO to draw up a Code of Marketing Practices. In view of its objectives, such a code could above all contribute towards removing the double standards in advertising and labelling of drugs.

While the criticisms levelled at the Essential Drugs Programme may already have been fierce enough, they pale beside the comments of the pharmaceutical industry on WHO's idea of a Code of Marketing Practices. According to the industry, the Code has been highly stylised as part of a New International Economic Order, as an instrument of the social redistribution of wealth world wide, and as an expression of the contempt for private ownership and the incentives which emanate from the profit motive in drugs development. Finally, WHO is accused of acting as an international authority and thereby overstepping its constitutional limits.

After WHO had clearly shied away from even attempting to grasp the nettle, i.e. to start work on a code, the General Assembly issued an express reminder to WHO in 1982 of the mandate assigned to it (100). But it was already too late to implement the mandate given in 1978. For the political balance had changed, mainly as a consequence of the election of Reagan in the United States. The USA made it perfectly clear that it would not consider supporting WHO and that it favoured the idea of a voluntary code for the pharmaceutical industry. Instead of regulation, then, negotiation (101) ! For its part, the pharmaceutical industry adopted some skilful tactics and took advantage of WHO's inactive phase between 1978 and 1982 to prepare the International Code of Pharmaceutical Manufacturing Practices. When the WHO Code then came up for renewed

discussion in 1982 by the interested developing countries, non-governmental organisations and the Netherlands, as the only industrial state, the IFPMA was able to refer to its Voluntary Code and be sure of the agreement not only of the United States. It is not least thanks to Health Action International, which had itself submitted a comprehensive Draft Code of Pharmaceuticals (102) to stimulate the drawing up of a WHO Code, that IFPMA found itself compelled to set up a supervisory authority to monitor the regulations of the Voluntary Code. However, the political pressure was not enough on its own to spur WHO into action. It was the shockwaves emanating from the adoption of the WHO Code on Breast Milk Substitutes (103) which finally prompted WHO to act. Evidently WHO did not want to have to undergo another such ordeal, or at least not for the second time within such a short period.

At present the prospects for the drafting of a Who Code of Marketing Practices are bleak. The only instrument by which double standards can be measured is IFPMA's Voluntary Code. IOCU and Health Action International criticise the fine words which conceal the lack of substance, and condemn the absence of an independent supervisory authority (104). The pharmaceutical industry has had its plans validated and emphasises the positive impact on the marketing practices of the industry. Be that as it may, until now no one has taken on the perhaps impossible task of examining the Voluntary Code for its practical significance. One thing only is certain, the double standards continue to exist and there has been no obvious change in the situation for exports of banned and severely restricted drugs.

c) US Exports of Unapproved Pharmaceuticals (105)

Until November of last year the United States of America was the only country in the world in which the export of unapproved drugs was prohibited without exception. Massive pressure by the

US pharmaceutical industry, supported by Senator Kennedy, has led to a change in the 50-year old rule. On 14 November 1986 President Reagan signed the Omnibus Health Care Bill (106). Under this Bill henceforward the export of drugs, animal pharmaceuticals and biotechnology products to 21 industrial countries (the EC countries, Australia, Japan, etc.) is permitted even if permission has only been applied for to the Food and Drug Administration, but not actually given. Such drugs have to be separately labelled "for export only". The export ban on deliveries to the developing countries does still stand, however. The latter will therefore, theoretically at any rate, be protected from being exploited as a testing ground for new drugs. Even though the US regulation only covers one aspect of the double standards problem, it does still deserve to be highlighted.

3. Export Notification

The World Health Organisation, it must be emphatically repeated, has until now not sought to develop special instruments for regulating the export of dangerous drugs. Its policy, at any rate as it has been formulated by the General Assembly, was directed during the '70s at securing the supply of drugs to the developing countries as a whole. Seen against such a broad perspective, the export problem appears as a question of detail - not to be under-estimated it is true - but still one which has been pushed to the periphery of public attention by the situation of inadequate or poor nutrition and dreadful conditions of hygiene in those countries (107). This perspective may change in the future. Not least because the World Health Organisation has had to sustain considerable setbacks with its major programmes. The Code of Marketing Practices can be viewed as an attempt to resolve all the problems of the international trade in drugs at one fell swoop. Export notification, meanwhile, represents a special regulation

instrument which offers a means to a solution at a much more modest but also more detailed level. By comparison with a Who Code of Marketing Practices, the export notification instrument appears to almost tend to push up exports. For export notification is not an instrument for regulating market practices. It is not intended to exert control over the export of banned or severely restricted drugs, but only to define the conditions in which export can nevertheless take place. The basic thinking behind it is simple and already sufficiently well-known from the consumer protection debate. Under this system, the developing country is supposed to receive the necessary information to be able to build up its own picture of the risks posed by the drug in question. The scheme therefore relies on the ability of the "mature" importing states to take the decision. But since they do not have the necessary information to hand it is forwarded to them in the form of notification by the exporting country. In the export notification model the exchange of information about banned and dangerous drugs is linked to the actual export. If export does not take place, the exchange of information is also dropped.

Export notification was developed as an export policy instrument in the United State in the late '70s, not for drugs but for the export of chemicals and pesticides (108). Through the OECD the United States have internationalised export notification as an instrument of policy action. In fact, at the beginning of the '80s the OECD acted as a clearing-house for the divergent regulation interests of all the industrial countries concerned. The consensus reached is reflected in the OECD recommendation dating from 1984 (109) which is directed at the member States. At the same time it found its way into the FAO Code of Conduct on Pesticides (110) and into the UNEP Provisional Notification Scheme (111). The critical passages in each of these regulation documents are not only identical in content but even in wording, apart from a few minimal differences. The developing countries

as well as the non-governmental organisations have sought in vain to get the concept of Prior Informed Consent internationally accepted. In this case the export of banned and severely restricted chemicals and pesticides is only possible if the importing countries are informed about the export prior to shipment and on the basis of such information have given their express permission. The notification model advanced by the OECD is far-removed from such a system since it allows notification "at the time of the export". The exporting countries are, it is true, urged to give notification of the export prior to shipment where possible, but under this model it would be enough for the exporting states to simply inform the developing countries on a single occasion that the export of dangerous pesticides or chemicals of this type has already taken place. Such a thoroughly "lenient" interpretation of the OECD model reduces the export notification to almost nothing more than an exchange of information.

The developing countries and the non-governmental organisations are seeking, now as before, to establish the concept of prior informed consent in the course of the work to revise the FAO Code of Conduct (suspended in the autumn of 1987, but possibly postponed until 1989) and to revise the UNEP Notification Scheme which was adopted in June 1987 (111a). The latest developments in the European Community itself show that the non-governmental organisations are moving towards also promoting the concept of prior informed consent as a means of regulating the export of dangerous drugs.

IV. Prospects for Export Regulation of Dangerous Pharmaceuticals by the EC

The international balance of forces has altered because since the early '80s the United States of America has cast off its

previous strong claims to the role of moral leadership of the industrial countries. This withdrawal has manifested itself in a narrower scope for action for WHO, but also for the UN General Secretariat. The question is now whether the EC is able and willing to step into this vacuum. The opportunity is there to come out of the USA's shadow and to take the lead in pursuing an export policy. The political ground in Europe is already prepared. In 1983 the Council of Europe passed Recommendation 969 (1983) on the Sale of European Pharmaceutical Products in the Countries of the Third World (112). This recommendation calls on the governments of the member countries to support WHO in drafting a Code of Marketing Practices, to step up their participation in the WHO Certification Scheme, to stand by the developing countries in their efforts to build up a rational and economically-acceptable drugs policy, to help WHO to implement the Essential Drug Action Programme, as well as to subject drugs intended for export to identical rules to those for domestic consumption. The work of the Council of Europe is institutionally linked to the harmonisation efforts of the EC to create a common market for pharmaceuticals. For the European Pharmacopoeia has provided the EC with a significant basis upon which to build and to which it also refers in Directive 75/318 (113). Moreover, the Council of Europe, alongside WHO, represents the most important international body which deals with the regulation of pharmaceuticals. The European Parliament has taken up the gauntlet. The Banotti Report and the resolution based upon it (114) is the first EC/European document concerning the export of pharmaceuticals. The resolution calls for greater co-operation between the EC and WHO, while no longer advocating the necessity of establishing a WHO Code of Marketing Practices. Instead it recommends that pharmaceutical exports be notified and suggests looking into the possibility of instituting an export ban in particular cases.

Objections that the EC could not pursue any export policy to regulate dangerous drugs were overturned by the Commission proposal for a "Council Regulation concerning export from and import into the Community of certain dangerous chemicals" (115). The Commission bases its project on Art. 113 of the EEC Treaty. Nowhere in the EEC Treaty is it stated what is to be understood by export policy within the meaning of Art. 113 of the Treaty. However, there seems to be a unanimous view that an export policy very probably may formulate restrictions, and does not have to be solely guided by economic and trade policy considerations (116). Now it could be argued that in so doing the EC is in violation of Regulation 2603/69 (117) on the establishment of common export rules.

In the introduction to this regulation it is stated that: "Exports from the Community to third countries (are free), i.e. are not subject to any quantitative restrictions". However, any regulation of exports interferes with the "free" export of goods. Two arguments show that the principles of export regulation cannot have a pre-emptive effect. In the first case Art. 11 of the regulation leaves it up to the individual member states to introduce export restrictions for public health reasons. In this respect the autonomy enshrined in Art. 36 of the EEC Treaty is guaranteed. Secondly, the member states can partially relinquish their autonomy and override the purely trade oriented export policy with regulations based on health policy considerations. The adoption of the Consumer and Environmental Protection Programme in the '70s was, after all, no more than just that (118).

More important still than the formal legal disputes over competence - which have never yet made an impression on the Commission and the Council - is the absence of a European pharmaceuticals authority. Unlike WHO the EC does, it is true, have regulatory powers, but it is not, any more than WHO itself,

a supranational supervisory authority. In concrete terms this means that the Commission has a scope for action in the area of pharmaceuticals control only to the extent that the Council confers the appropriate powers upon it through directives or regulations. In fact the Commission has only succeeded to a limited degree in wresting such powers from the member states. To start with there is the information about the activities of the national pharmaceuticals inspection authorities, quite apart from the Commission's own regulatory powers for the creation of a common market. For this reason the EC itself has very little information which could serve as a basis for an EC export policy. But the prerequisite of any EC internal market or export policy must be centrally-administered information in the hands of the Commission. Strictly speaking, therefore, the formulation of an export policy is closely associated with the completion of the internal market and, more concretely, an extension of the regulatory powers of the Commission. We want to confine ourselves to examining the input which the EC can make towards the international exchange of information in the present legal situation as well as the form to be taken by, where appropriate, Commission-administered export notification or export control for dangerous pharmaceuticals.

1. Exchange of Information

There are two avenues open to the EC for obtaining information about the regulatory decisions of the supervisory authorities in the member states. A third instrument, the rapid information system set up in 1984 (119), does not cover pharmaceuticals (120).

- According to Art. 33 of Directive 75/319 "(each Member State) shall take (121) all the appropriate measures to ensure that decisions authorizing marketing, refusing or revoking a marketing authorization, cancelling a decision

refusing or revoking a marketing authorization, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Committee (for Proprietary Medicinal Products) forthwith,"

- According to Art. 9 and 13 of Directive 65/65, as amended by Directive 83/570 (122), the Committee for Proprietary Medicinal Products shall receive the following documents, in the event that a pharmaceutical manufacturer has made use of the Multi-State Procedure: among the submitted documents the summary of the characteristics of the product according to the information given by the manufacturer, and the evaluation report drawn up by the national supervisory authority. The basis for the work of the Committee is formed by the manufacturer's product summary and the authority's evaluation report. The Multi-State Procedure should facilitate the EC-wide approval of a pharmaceutical product which has already undergone the full inspection procedure in one member state.

Each of these two avenues of information has its own particular drawbacks. The obligation of notification in Art. 33 is, it is true, unlimited, so that the Commission, through the Committee, should have a complete overall picture of all the regulatory measures of the member states. However, this obligation does have a weak point with far-reaching consequences: it does not include the very measures which are in practice of relevance in this area. These measures are the temporary decisions of the authorities and "voluntary recalls" by the manufacturers, which are very often induced by gentle pressure from the authorities. In practice, however, it seems that an exchange of information between the national authorities, and including the Commission, is actually starting to take place which goes beyond the formal limits of Art. 33. There is unanimous agreement about this. In

this way the Commission should have to some degree a complete overall picture of the content and extent of both the official and voluntary marketing restrictions. Only what is actually happening remains concealed from the public since the exchange of information is subject to secrecy.

The Multi-State Procedure first came into force in October 1985 so that any assessment would seem to be premature. However, the structural deficits cannot be disregarded. The whole procedure is optional, i.e. a pharmaceutical manufacturer may make use of the regulation if he anticipates that it would speed up his application for drug approval in another EC country. The evaluation reports and product summaries are exchanged between the authorities as soon as a pharmaceutical manufacturer has initiated the multi-state procedure. The Commission is only notified through the committee when the member state applied to decides not to give its authorisation or if a member state withdraws, suspends, etc. authorisation which it has approved previously, even though the product still continues to circulate unrestrictedly in another member state. This is awkward as far the Commission is concerned because both reports, one from the manufacturer's viewpoint and the other from that of the drugs approval authorities, sum up the results of the analytical, toxicological and pharmacological clinical examination. The information transferred is substantially more specific in nature than the mere "indication of grounds" laid down in Art. 33. So in the final analysis, the information situation at the Commission depends on how widely the drugs evaluations of the member states differ. Only in the case of the recently adopted new regulation on the approval of biotechnology drugs does the product summary and evaluation report have to be forwarded to the Committee for Proprietary Medicinal Products (123). Here, for the first time, the approval procedure has been centralised to some degree.

The deficiencies analysed demonstrate the urgent need to develop an effective rapid information system for pharmaceuticals (124), without which the Commission will be unable either to respond to any gaps in regulation within the EC itself, or to make any fundamental contribution to the international exchange of information. Among the measures needed here are the formal inclusion of voluntary marketing restrictions in the notification obligation in Art. 33, but in particular the unrestricted circulation of the product summaries and evaluation reports amongst the competent authorities of the member countries and the Commission. The secrecy problem is awaiting a solution. The Commission interprets Art. 214 of the EEC Treaty very broadly and in this way has considerably restricted the degree of external access to the information sources. There is an urgent need to strike a balance between the public interest and the interest of protecting secrecy. This requires a fundamental review of what has been the practice until now.

a) WHO Drug Circular, WHO Drug Bulletin, UN Consolidated List

If the EC member states adhere to the notification obligations entered into with WHO and the UN, the separate input of the EC alone would simply double the amount of information already available. In actual fact it is likely that the information flow will be better in the opposite direction, i.e. the Commission may possibly acquire more information, and in more detail, through the WHO Bulletin than it possesses itself. Matters may be otherwise for the products on the Consolidated List because some member states (FRG, United Kingdom) are pursuing a restrictive notification policy. What exactly the EC information situation is, it is not possible to tell. The EC is not formally empowered to store all detailed decisions as data and to compile a list. The reports of the Committee for Proprietary Medicinal Products are still the only source of

information. However they are brief and are often published after a considerable time lag.

b) WHO Certification Scheme and Evaluation Reports

In the short term, perhaps the most interesting possibilities for co-operation reside in the further development of the certification scheme. However this is subject to WHO and the EC finding a basis for working together in a climate of mutual trust. WHO regards the EC as a "Club of Pharmaceutical Manufacturers" (125), while the EC for its part has considerable reservations about the Essential Drugs Action Programme and the WHO "Code of Marketing Practices".

The object of the WHO Certification Scheme is to give a quality guarantee for exported products. The provisions of Chapters IV "Manufacture" and V "Supervision" of Directive 75/319 (126) are also applicable to products intended for export. In this respect the EC defines a universal quality standard above the standards of the WHO "Good Manufacturing Practices". It constitutes a violation of current EC law for the member countries to export drugs which do not satisfy the standards laid down there. Even though sanctions mechanisms do not exist, the supply of inferior quality products would nevertheless be a political matter which could damage the reputation of the pharmaceutical industry. However, such cases are seldom made public because the developing countries concerned - even assuming that they (can) register such an occurrence - tend to insist on a substitute or further supply. The pharmaceutical company concerned, meanwhile, is likely to only agree to this if it is assured of strict secrecy.

WHO is currently conducting a survey to see whether the member states are prepared to supplement certification by means of accompanying documents on safety and effectiveness (127). In the case in point, this would simply comprise of the evaluation

reports. In the event of a positive response the Commission could therefore bring the existence of these evaluation reports in the member states to the attention of the WHO. Since the developing countries generally send their requests under the certification scheme to WHO (128) it would be easy for the latter to include a reference to the existence of the evaluation reports in its reply to the developing countries or to ask the exporting countries to hand over the evaluation reports. A similar procedure could be used for the manufacturer's product summaries.

c) Product Summaries and Evaluation Reports as a Basis for Compiling a European Pharmaceutical Users Handbook

The Commission is largely resting its hopes for creating an internal market for pharmaceuticals on the prospects associated with the many potential uses of both the newly-acquired sources of information. These are, it is true, to be treated confidentially, even if notified to the Committee. But it is still a question of fundamental importance whether this policy is sustainable in the long run. The United States of America do not have manifold restrictions on access to data, without this having had any known adverse impact on the US pharmaceutical industry until now. Publicly accessible product summaries and evaluation reports could provide the basis on which to develop a European Users Handbook. This handbook would in effect be based on officially-checked information and not on information given by the pharmaceutical industry. What the Commission is considering is modelled on the French VIDAL scheme under which checked information is separately labelled.

For the developing countries such a document, particularly in the official EC languages, would be of great value. In this project a large number of existing international initiatives could be drawn together and channeled into the compilation of an

international handbook. WHO could contribute its Data Sheets on Essential Drugs and revive the ideas advanced at the time in Copenhagen to register "Scientific Evaluation Documents" (129) throughout the world. From the point of view of the non-governmental organisations the handbook would have to be measured against the standard of the Action Pack on Problem Drugs. Even by modest standards, this could produce the companion piece to the International Register of Potentially Toxic Chemicals (IRPTC). This contains basic information broken down into 17 categories concerning the 500 main chemicals (130). The scheme is freely accessible to anyone.

2. Export Notification

The crucial passage in the resolution of the European Parliament is quoted below because it seems eminently suitable as a basis for discussion (131) :

> "The European Parliament calls on the Community Institutions to develop and adopt a directive to approximate the Member States' laws, regulations and administrative provisions relating to the export of pharmaceutical products with the intention of prohibiting the export of products which are banned, withdrawn, or subject to special restriction within the Community market or which have not been registered for that market, unless authorities in the importing country specifically request the product having first been fully informed of the controls on its use in Europe, and that all notifications and responses by importing countries should be published by the Commission; ....

By taking over such a regulation the Commission would be treading new political ground. The pharmaceutical industry will for that reason put up even more vigorous opposition to

regulation than the chemical industry, which has been confronted with demands for export notification for years. In reality a sense of company identity often exists, although this does not appear to have caused any breach in the industry's ranks. However, the different nature of chemicals and pharmaceuticals does not provide any grounds for objections to export notification. For export notification has not been discussed internationally until now only because the World Health Organisation had advocated far tougher intervention measures to deal with the double standards problem. The main arguments against export notification as such continue to revolve around the suitability of the instrument, the definition of its scope and what form the procedure would take in practice. The opponents of export notification fear a bureaucratisation of the pharmaceutical trade which could quite easily hamper the exchange of goods and yet still not achieve its intended objective. The assessment criteria in the industrial countries still continue to be so different that it would not be possible to find a standard definition for the two key categories of banned and severely restricted products. Finally, it is argued, prior informed consent as the most highly-developed form of export notification would have the effect of hindering trade with the developing countries and would be tantamount to an export control.

Admittedly, export notification results in a bureaucratisation of pharmaceutical trade with the developing countries. This would apply all the more if, as the non-governmental organisations have been demanding for some time, every shipment had to be notified separately (132). Also not to be brushed aside are the difficulties involved in the processing of detailed information in the developing countries. In many cases these countries do not have sufficient personnel and technical resources. Preliminary studies of the efficacy of notifications are not exactly encouraging (133). Most of the notifications

sent by the American Environmental Protection Agency get no further than the US Embassy of the developing country concerned, and are never received at the intended destination, namely the competent authority in the importing country. Anyone who, on the one hand, stresses the "maturity", or better the own responsibility, of the developing countries, ought on the other hand to also provide them with the information which they need to make their decisions. Naturally the industrial countries only have limited powers to remedy the deficiencies in the official infrastructure in the developing countries. But from these undoubted shortcomings to then draw the conclusion that export notification is an unsuitable means for tackling the double standards problem, in the case in point, is simply to patronise the developing countries. For without information from the industrial countries the latter are unable to make an informed decision on their own responsibility. The mere exchange of information, decoupled from the export, does not suffice in itself because there is no guarantee that the competent authority in the importing country really has the necessary information to hand. The notification must compensate for the organisational and information deficiencies of the developing country. In the industrial countries the view that consumer information is sufficiently provided for when it can be obtained "on the market" has long been out of date. Likewise, a mechanism needs to be built into the notification scheme between industrial and developing countries which not only provides them with the opportunity to obtain the information, but ensures that they really are given it in practice.

Consequently, the attempts to repudiate prior informed consent as an instrument of export control are also hardly convincing. By providing the developing countries with a procedural safeguard, prior informed consent should enable them in practice to take decisions on their own responsibility.

The opponents of prior informed consent see in the necessary approval of the competent authorities in the importing country a restriction on the movement of goods because not only the importer but also an authority must decide on whether or not to give the go-ahead for the export. There are two arguments here: guaranteeing the sovereignty of the developing country requires the involvement of the competent authority in the export; and on the other hand, it is a matter of course for the industrial countries that the import of products which are potentially harmful to health is subject to state control (134).

The idea of prior informed consent is a very familiar concept in the health sector. For in our legal system the patient must give consent for treatment and in some cases a written statement is even required.

Not to be shrugged off, on the other hand, are the difficulties involved in a precise formulation of terms. In its first report on the assessment of the Consolidated List, the UN showed a way which appears to hold considerable promise. Since the disputes over the definition of, in particular, the "severely restricted" category are receiving more and more attention, this attempt at a definition is quoted in full below (135) :

Severely restricted: a product containing :

(b) A substance that may be incorporated in pharmaceutical dosage forms only within the specific limits determined by statute;

(c) A substance that is approved by competent national authority subject to restrictions that exclude its use in a substantial proportion of the potential target population of patients.

Of course, this definition of terminology does not remove all doubt. There is much which remains to be clarified. Without pragmatism, however, it will not be possible, even at EC level, to fix on a standard notification practice. The UN Secretariat has set itself the task of defining the term more precisely in the light of detailed information. So in the future it may be possible to define for certain groups of drugs and for certain indications, those restrictions on use which are deemed to be so serious that they should fall under the obligation of notification. Finally there is always the reference to the much called for own responsibility of the developing countries. The latter should be able to decide for themselves whether a restriction on sale imposed once constitutes sufficient grounds for refusing to approve the export or whether they wish to first wait for the opinion-forming process to run its course in a number of industrial countries.

In the event that a discussion takes place within the Commission on whether export notification for pharmaceuticals should be introduced, it is to be expected that the proposal for a regulation of the "export of certain dangerous chemicals" will be taken as a model. It is therefore worth taking a closer look at the proposal. By this initiative, the EC's aim is to honour the international commitments entered into by its member countries in the OECD and UNEP (136). In actual fact, the EC's regulation proposal goes beyond the consensus reached internationally (in the OECD) of the industrial countries. As from 1.1.1989 the principle of "informed choice" is to take effect, according to which hazardous chemicals may only be exported to those countries which have given their prior consent to the import (137). However, this would only apply if unanimity is achieved on this at international level. At the same time the Commission would be assigned the mandate, on behalf of the member states, to work with the OECD and UNEP towards modifying the export notification arrangements. In

practice, this relates to the inclusion of the USA in the informed choice solution. The developing countries will welcome any improvement to the notification scheme.

The criticisms of the non-governmental organisations are set out in a position paper by the Coalition Against Dangerous Exports (138). In this paper the organisations belonging to the coalition criticise the abandonment of the concept of prior informed consent. For according to the EC proposal, the export would still be possible if the Commission had not received any communication from the country of destination within 60 days from the date of despatch of notification. This provision could in the long run lead to an undermining of the actual concept of informed consent itself. For many developing countries, despite good intentions, are not likely to be in a position to take an "informed" decision in 60 days. The developing countries would be faced with the doubtful choice of whether to allow the deadline to pass without taking any action, or else to consent to the export before the deadline expires even though they have not actively taken a decision at all.

A second point of criticism concerns the scope of the measures to be notified. According to the regulation proposal, the Commission (139) - not the member states, it should be noted, but the Commission - notifies the country of destination of the export of all the measures set out in the annex to the regulation proposal. These concern 23 products which are subject to a ban or severe restriction on sale within the Community. The Coalition Against Dangerous Exports is demanding that the Commission be empowered to also notify the developing countries of those regulatory measures introduced by the member states to apply in their own territory. The reason for this demand is the justified assumption that restrictions on marketing at EC level only represent the smallest common denominator and in no way reflect the contradictions in the

different assessments of the risks associated with chemicals by the member states. This demand may be politically desirable, but for the time being it is thwarted by the Commission's lack of authority to pass on information about the regulatory measures of the member states. A European environment authority simply does not exist either !

The debate on export notification has made great strides internationally. Quite another question is whether the member states are prepared to agree to a legally binding regulation. The initial discussions on the proposal within the EC have dampened the hopes of the developing countries and the non-governmental organisations. The "bureaucratisation" of the flow of information has met with disapproval, nor does "prior informed choice" seem to have overturned the objections to notification. For these reasons it seems possible that the industrial countries will push for the establishment of the compromise negotiated in the OECD in 1984. The revision of the UNEP Provisional Notification Scheme in February 1987 has confirmed this assumption (140). All the industrial countries, except for the Netherlands, defend the OECD/FAO formula as a compromise line, beyond which it would currently be difficult to attain a regulation. The Governing Council of UNEP has recently opened a new round of negotiations on Prior Informed Consent. Together with the adoption of the notification scheme the Governing Council "requests the Executive Director to convene an ad hoc Working Group of experts with a view to : - (a) Developing procedures of prior informed consent and other approaches which could usefully supplement the procedures of the London Guidelines (the Notification Scheme); (b) Recommending measures for incorporating the principle of prior informed consent in the Guidelines; (c) Reporting on its findings to the next regular session of the Governing Council". In any case the export notification of drugs can only succeed if the problem of severely restricted drugs has been resolved. Efforts will have

to be directed towards precisely defining this category.

3. Export Controls

Since the European Community can lay down legally binding law for its member states, in theory it is free to make the export of drugs subject to the issue of a special licence or permit, or else to some other form of official requirement. A restrictive control policy which extends beyond the exchange of information and export notification, was first discussed in the United States under President Carter and even brought into effect for a short period (141). For the EC, until now, only the BEUC and IOCU have called for such measures (142). In view of the above comments on the pharmaceutical industry's attitude to any kind of intervention in exports, it is not hard to imagine how they would react to this. The nature and quality of the arguments put forward to justify export controls are therefore of crucial importance. Only when this hurdle has been surmounted will the way be open to think about the mechanisms of an EC control. The European Parliament expressly calls upon the Commission to do just this (143). Lastly, it remains to be made clear just how the EC can help to promote WHO's efforts to introduce controls.

a) Justification for Export Controls

The opponents and proponents have been swapping arguments for a long time. Each side has adopted its stance and the positions have hardened. Yet it is the exporting pharmaceutical industry which stands to gain the most from the status quo of the laissez-faire policy.

The debate on export controls has a profoundly moralist slant to it. The opponents who, as well as the pharmaceutical industry, until now have included all the industrial states with the exception of the Netherlands (144), see export control as

interference in the sovereignty of the developing countries (145). No country has the right to force upon another its own criteria of assessment for public health and safety. Or, in polemical terms, as the author of a newspaper has asked: Can the United States be a nanny to the Third World (146) ? Developing countries, thus goes the unanimous view, should be able to decide for themselves what risks they are to impose on their people. The sovereignty argument is backed up with references to possible differences of a cultural and socio-economic nature which necessitate a different way of looking at health risks. Put less diplomatically: the deplorable state of health care in the developing countries can justify double standards because the cost-benefit analysis is different (147).

The proponents - countries of the Group of 77 (148), as well as a number of non-governmental organisations, are pursuing a legitimation strategy on two levels (149). On the one hand, they are appealing to the moral responsibility of the exporting countries and in particular of the pharmaceutical industry. The exporting countries, with their high level of scientific and technological knowledge, could and should not expose consumers in the developing countries to risks which they no longer impose on their own citizens. The pharmaceutical industry is damaging itself if it exports inferior products since this would tarnish its image. On the other hand they point to the irrationality of the sovereignty argument. For this assumes first of all that the importing countries actually have all the personnel and technical resources required to be able to take sovereign decisions on their own responsibility. Furthermore, the industrial countries would have far fewer scruples about limiting the sovereignty of the developing countries if possible quid pro quo's were involved (such as supply conditions) in return for development aid. Socio-cultural differences, finally, could lead to a divergent evaluation in individual cases (150), but this does not justify the

unrestricted export of drugs which contravene the standards of the manufacturing country.

Since it cannot be a question of finding out "who is right", it is difficult to assess the pros and cons. It would be better rather to work on the basis of options. "Partisanship" is made difficult because the poorest of the poor, namely the developing countries and Africa in particular, participate in the international debate - if at all - through their representatives in Health Action International. The self-assured developing countries, who can perhaps be described collectively as the emergent newly-industrialising countries, are inclined to make a show of their sovereignty, even though they may not have the personnel and technical resources to take their own decisions. The opponents' argument is based on the ideal situation of equal partner countries. Behind this assumption can be glimpsed the provisions of Article 36 of the EEC Treaty which leaves questions of health protection up to the member states. On the other hand, the developing countries react with extreme sensitivity if they feel they are being patronised.

The discussion recalls the dispute over the scope and extent of consumer protection in numerous programmes in the industrial countries (151). The latter, when they do not support a pure laissez-faire export policy, advocate an "information model" (152). The developing countries should receive the necessary information to be able to make their own decision. Export controls, by contrast, would be the purest form of "paternalist consumer protection", designed to take the decisions away from the developing countries. Such "socially-compensating" (sozial-kompensatorische) consumer protection - i.e. consumer protection which compensates for particular social conditions - (153) would be regarded as justified in the industrial countries in cases where the destination countries lack the resources and capability to speak for themselves and to look after their own

interests. There is a tendency for this approach to be transposed to the relations between industrial and developing countries. A "socially-compensating" export control should place the responsibility with the industrial countries but at the same time protect the sovereignty of the developing countries.

Apart from on a moral level, the dispute is principally conducted over the possible impact on international competition. Export controls, according to the opponents, would weaken the position of those countries which have stringent rules, whereas exporting countries with a "more lenient" policy would protect their domestic industry. Conversely, the proponents emphasise the possible distortions in competition between the EC countries, but also in relations between the EC countries and the USA. An international export control policy would avoid such distortions in competition and define identical standards. It seems to me that the discussion on export controls at trade policy level is being conducted with exaggerated arguments on both sides. The United States is probably the only country which can lay any claim to having defined an export policy which is reflected in practice in the pharmaceuticals trade with the Third World. But whether, as Senator Kennedy asserts, the American pharmaceutical industry is actually sustaining harm because it cannot export unapproved drugs seems to me pure speculation. After all, there are no obstacles standing in the way of the export of banned, withdrawn or severely restricted drugs (154). At the present time there are probably scarcely any distortions in competition between the industrial countries. The differences in detail are insignificant. To a greater or lesser extent, all the industrial countries - with the possible exception of the United States in the matter of the export ban on unapproved drugs - are pursuing a laissez-faire policy. If one industrial country had actually taken, or were to take a

lead in this area, it would considerably facilitate the debate on the "moral" level.

b) Options for Export Control Regulation

President Carter's Executive Order of 1981, in addition to the export notification of "banned and severely restricted products", also made provision for a licensing procedure for "extremely hazardous products" (155). After identification by the Department of State and the Department of Commerce, these products were to be placed on a Commodity Control List. It was then the task of the Department of Commerce, after consultation with the State Department and the FDA, to decide whether an export licence could be issued. The licence was to be issued if the Government of the country of destination had raised no objections of any kind and the "export would not cause clear and significant harm to United States foreign policy interests". Since practical experiences could not be gathered, an evaluation must be based on the model. A striking feature is the cumbersome nature of the procedure, which involved the participation of three different bureaucracies. The final decision lay with the Department of Commerce which could only refuse the licence if the foreign policy interests were threatened with serious harm. If, added to this, it is considered that only "extremely hazardous products", and not for instance the whole range of "double standards" categories, would be subjected to the licensing procedure, it can be seen that the US regulation is substantially more restrictive than it might appear at first sight. Although one of Reagan's first actions in office was to revoke the Order (156), the American approach still stands as the best-conceived instrument - not least because of the wide-ranging debate which preceded its adoption.

The IOCU and BEUC have outlined a proposal in their position paper on the Banotti Report which goes into the different facets

of the opposition to introducing export controls (157). The key element of the proposal is the ban in principle on the export of banned, unapproved and withdrawn drugs, as well as on those drugs whose use is restricted in the home country. Exemptions should be possible to this ban, for which the pharmaceutical manufacturer could apply for a licence. With this exception-to-the-rule principle, the IOCU and BEUC want to put an end to the double standards problem, while at the same opening the way for export in cases where this is proved to meet the needs of the developing countries. In order to prevent the exception from becoming the rule, both organisations are calling for an objective and transparent licensing procedure. All the parties should be involved, also and in particular the developing countries who should be assigned an active role. In concrete terms, a pharmaceutical company which applies for a licence would have to accompany its application by information on the following: the effectiveness and safety of the drug; the grounds for any restriction on marketing; in the case of an unapproved drug: comparable documents to those for the normal approval; the packaging and marking in the form to be used for the export, as well as an outline of the projected advertising measures. The information collected, together with any comments by the competent export authorities, should then be forwarded to the importing country or to the relevant authorities in that country. Once the importing country has given advice of receipt, the parties can then enter into negotiations with each other. If agreement is reached the licence would be issued. The precise conditions for granting the licence would be set down in writing.

Placing domestic products on the same footing as exported products would not eliminate the problem of exports of unapproved drugs. In this respect the proposal of the IOCU and BEUC is not in itself consistent. What the proposal amounts to is the taking over of the American regulation. At the same time

the problem of double standards in advertising and labelling of drugs would no longer apply. For the manufacturers would also have to label the products intended for export in accordance with Art. 4 of Directive 65/65 (158), i.e. indicating any restrictions.

The ban in principle on exports is considerably more stringent by comparison with the American solution. Whereas under Carter's Order only "extremely hazardous products" were to be placed on the blacklist, the BEUC and IOCU want to impose an export ban on all the products in the different categories of double standards. Even if such a solution appears to be desirable in the long term, the export control stemming from this demand threatens to lead to over-bureaucratisation. The USA wanted to avoid this by only subjecting extremely hazardous products to export controls. The IOCU/BEUC are seeking to deal with the problem by means of a strictly regulated exemption procedure. But the exemption procedure may perhaps become the rule for the very reason that too many drugs tend to come under the ban in principle on exports. It is therefore worth considering whether a general export ban could not be put into the concrete form of a list of all those products for which export would run counter to the needs of the developing countries. Whether such a limitation of the general ban is advisable depends very much on whether the plan to compile such a list is successful. The preparation of such a list would have to include the participation of the Committee for Proprietary Medicinal Products, as well as representatives from WHO, the developing countries and HAI. In any case, and it is certainly thanks to IOCU/BEUC that this had been made clear, the licensing procedure must be regulated in a precise manner. However, a decisive factor in the issue of the licence should be whether the developing countries still want to be supplied the product after the various stages of the procedure have run their course. The foreign policy interests of the exporting country are not a

decisive factor. In this respect the sovereignty principle is upheld.

On purely practical grounds, the question arises as to who should administer such a system, the Commission or the member states. In the long term the issuing of a licence should be placed in EC hands, but such an extension of powers is once again bound up with the creation of a European Pharmaceutical Authority. But also conceivable would be a mechanism in which the decisions would be co-ordinated with the participation of the EC, but without the Commission being responsible for the decision itself.

c) Support of WHO Policy

In theory the EC could step up its efforts to promote the Action Programme on Essential Drugs. A major step forward would be to place the co-ordination of the member countries' various aid programmes in the hands of the EC (159). Co-ordination does not mean administration, but does create transparency and possibly closer harmonisation as a consequence in relations among the EC countries, but also between the EC and WHO.

The EC is theoretically called upon to support the drawing up of a WHO Code of Marketing Practices. For its members had at the time taken this decision jointly. If this falls through owing to opposition from the United States, there is still the possibility of seeing whether the EC could not draw up a Code of Marketing Practices in co-operation with the European pharmaceutical industry (160). Such a code should add to but not replace the option of export control. Either way would call for a fundamental reorientation for the EC. The extreme slowness in dealing with the WHO Breast Milk Substitute Code, as well as its incomplete implementation, in the EC bodies is emphatic proof of this (161).

V. Conclusions

Whether it will ever be possible to develop an export policy in the EC is inextricably linked to the completion of the internal market. Only when the EC achieves this aim can it obtain the necessary powers to conduct an export policy itself. But the interdependence of the policies should not lead to a ranking of priorities. Export policy is part of internal market policy and can even act as a lever to actually drive it forward. The EC is presented with a favourable opportunity to take the lead on the international front, and on behalf of the industrial countries, to honour the many international obligations to apply tougher controls on the export of banned and severely restricted pharmaceuticals.

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Footnotes

1) For classification Ch. Medawar, Drugs and World Health, An International Perspective, IOCU and the systematic reply by the pharmaceutical industry to the criticisms, M.S. Barber / P.A. Barnacel, Better Pills - the Right Kind of Medicine, Surrey, 1984, 57 ff.

2) This is admitted by the Non-Governmental Organisations as well, Ch. Medawar, Insult or Injury. An Enquiry into the Marketing and Advertising of British Food and Drug Products in the Third World 1979, 125 and D. Melrose, Bitter Pills, Medicines and the Third World Poor, Oxfam 1982, 178

3) The Use of Essential Drugs, Report of a WHO Expert Committee, Technical Report Series 685, World Health Organisation, Geneva 1983; more details on the history and background under III 2a

4) HAI was set up following the NGO Seminar on Pharmaceuticals in Geneva, 27-29 May 1981. The only summary description of HAI from the perspective of the pharmaceutical industry is to be found in M.S. Barber/P.A. Barnacel op.cit. Fn. 1, 1 ff.; HAI is responsible for the following publications, on which the paper is based: Ch. Medawar, op.cit. Fn. 1 and 2; D. Melrose, op.cit. Fn. 2 as the central summary exposition of the problem; reference should also be made to a series of important case studies: Clioquinol: Availability and Instructions for Use, IOCU 1975; Anabolic Steroids: Availability and Marketing 1983; HAI African Safari 1983/85 by Wilbert Bannenberg IOCU 1984; Cleared for Export. An examination of the European Community's pharmaceutical and chemical trade, by A. Chetley CADE 1985 - abbreviated version published in JCP, 9, 1986, 155 ff

5) Medicines, Health and the Poor World, a study by David Taylor for the British Office of Health Economics (OHE), London, April 1982

6) for fundamental issues see D. Melrose op.cit. Fn. 2, 16 ff, particularly 23 ff.; likewise OHE Medicines, Health and the Poor World, op.cit. Fn. 5, 426 ff.

7) Thus Ch. Medawar in Report on NGO Seminar on Pharmaceuticals, Geneva 27-29 May 1984, 24; A. Chetley and D. Gilbert, Problem Drugs, HAI 1986 in supplement Introduction, What is a Problem Drug; P.K.M. Lunde, A New Global Medicine Policy - From Knowledge to Life in Marketing of Medicine. Selected Lectures from a Conference on Marketing of Medicine organised by Consumer Council of Norway in March 1984, Consumer Council Norway 1985

8) All printed at the Commission of the European Communities, The Rules on Medicinal Products in the European Community, 1984

9) See HAI's Problem Drugs 1986 by A. Chetley and D. Gilbert, which sets out the information on the risks and different assessments for 9 categories of medicines; as already carried out in Forty-Four Problem Drugs, A Consumer Action and Resource Kit on Pharmaceuticals, IOCU 1981

10) Clioquinol: Availability and Instructions for Use, IOCU 1975; D. Melrose op.cit. 2, 100/101. Geneva Press Conference on SMON, Proceedings April 18, 1980 Geneva, published by the Organising Committee of General Press Conference on SMON

11) The BuKO Pharmaceuticals campaign is preparing documentation on this subject which is intended to provide evidence of this policy of the Federal Health Office with relevant examples.

12) L. Broch, Corporate Responsibility in the Pharmaceutical Industry in Marketing of Medicine, op.cit. Fn. 7, 38 ff.; the study can also be obtained separately from IOCU

13) Thus the Council of Europe Parliamentary Assembly, Report on the Sale of European Pharmaceutical Products in the Countries of the Third World, Rapporteur Mr Lind, Special Document IOCU, undated, 21

14) op.cit. 8, 12 ff.

15) see the Resolution of the WHO General Assembly 15.41, reproduced in the Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume I 1948-72, WHO Geneva 1973, 138

16) Proof in J. Braithwaite, Corporate Crime in the Pharmaceutical Industry, London 1984; special statement by J. Kiavio, Minister of Water Development Kenya: "...detests the use of developing countries as experimental or dumping grounds for chemical products" in D. Weir/M. Shapiro, Circle of Poison, 1981, 66

17) Exposition of the problem in D. Melrose, op.cit. Fn. 2, 129 ff. (130); The Association of the Bar of the City of New York, Committee on International Human Rights towards the Development of a Response to the Problem of Hazardous Exports, 21 ff.; recently K. McDonnell, Adverse Effects on Women and the Pharmaceutical Industry, IOCU 1986 with a comprehensive exposition of the arguments on the permissibility of Depo-Provera in India.

18) see D. Melrose op.cit. Fn. 2, 129 ff. (130)

19) thus D. Melrose op.cit. Fn. 2, 37

20) Pills, Pesticides & Profits, The International Trade in Toxic Substances, A.K. Ahmed; S.J. Scherr, R. Richter, New York 1982, 9; N. Reich's Analysis of the modified US patent law "Innovation and Imitation on the drugs market", GRUR Int.

1986, 765 ff., shows that the revision of the patent law has mainly benefited newly-approved generic drugs, but does not help to clear up the "regulatory backlog" (769)

21) see the relevant contribution by L. Krämer, EWG Verbraucherrecht, Baden-Baden 1985, Rdnr. 224 for the legal situation in the EC; for the situation in the Member States: N. Reich/H.-W. Micklitz, Consumer Protection in the EEC Countries - A Comparative Analysis, New York, etc. 1980

22) see on this subject in particular Ch. Medawar op.cit. Fn. 2, 37 ff.; similarly D. Melrose op.cit. Fn. 2, 117 ff.

23) D. Melrose op.cit. Fn. 2, 117 ff.; Council of Europe op.cit. 12, 21

24) Ch. Medawar op.cit. Fn. 2, 17 ff.

25) this is one of the prime objectives in the study by Ch. Medawar op.cit. Fn. 2, see also the works of M. Silverman inter alia together with M. Lydecker "The Promotion of Prescription Drugs and Other Puzzles", in Pharmaceuticals on Provision and Control of Medicines, edited by N. Blum, A. Herxheimer, C. Stenzel and J. Woodcock, London HAI 1983, 78 ff.

26) D. Melrose op.cit. Fn. 2, 102 ff.; Anabolic Steroids and Marketing IOCU 1983; A. Chetley, op.cit. Fn. 4, 6 ff. under the heading "non essential drugs"

27) comprehensive treatment, Assignment Children, A Journal concerned with Children and Youth in Development. Breast-Feeding and Health, 55/56 1981, UNICEF; as well as numerous publications by IOCU and IBFAN; inter alia Ch. Medawar op.cit. Fn. 2, 96 ff.

28) Proof in D. Melrose op.cit. Fn. 2, 86 ff. and in W. Bannenberg HAI African Safari IOCU 1983

29) on this subject, Ch. Medawar op.cit. Fn. 1, 4 ff. and A. Chetley op.cit. Fn. 4, 6 ff.; for the opposing position of the pharmaceutical industry: M.S. Barber/P.A. Barnacel op.cit. Fn. 1, 57 ff.

30) D. Melrose, op.cit. Fn. 2, 98 ff.

31) Ch. Medawar op.cit. Fn. 2, 121 ff.

32) Proof in Forty-Four Problem Drugs, A Consumer Action and Resource Kit on Pharmaceuticals, IOCU 1981, 68 ff.

33) see Art. 13 of Directive 65/65 op.cit. Fn. 13, assessment in L. Krämer op.cit. Fn. 21, item 192-193

34) Ch. Medawar op.cit. Fn. 2, 113 ff.; D. Melrose, 101 ff.; A. Chetley op.cit. Fn. 4, 7 ff.

35) Ch. Medawar op.cit. Fn. 2, 126 starts out from this basis

36) Proof in M.S. Barber/P.A. Barnacel op.cit. Fn. 1, 45 and 54, indirectly because the study was paid for by the pharmaceutical industry and there must therefore have been close contact between the party commissioning the study and the authors

37) International Code of Marketing of Breast-Milk Substitutes, WHO 1981

38) Proof from the comments of the pharmaceutical industry in A. Chetley op.cit. Fn. 4, 9 ff. under the heading "Risks and Benefits

39) the study by J. Braithewaite does not suffice, op.cit. Fn. 15

40) thus Ch. Medawar op.cit. Fn. 2, 13; D. Melrose op.cit. Fn. 2, 9; OHE op.cit. Fn. 5, 4

41) for basic issues see D. Kay, The International Regulation of Pharmaceuticals, 1976; C. Stenzel, The Role of International Organisations in Medicines Policy, in Pharmaceuticals and Health Policy, op.cit. Fn. 24, 211 ff., E. Cone, International Regulation of Pharmaceuticals, The Role of the World Health Organisation, Virginia Journal of International Law 23 (1983), 331 ff.

42) D. Kay op.cit. 41, 34 ff.

43) see for context C. Stenzel op.cit. Fn. 41, 217

44) see E. Cone, op.cit. Fn. 41, 354 ff.

45) United Nations, General Assembly A/RES/37/137, 3 March 1983

46) also reproduced by Council of Europe, op.cit. Fn. 13

47) Entschliessung zur Ausfuhr von Arzneimitteln aus der Europäischen Gemeinschaft in Länder der Dritten Welt, OJ No. C 176/133 ff of 12.6.86 based on the report on behalf of the Committee on Environmental Questions, Public Health and Consumer Protection on the export of drugs from the European Community to the countries of the Third World, Rapporteur Mrs Mary Banotti, EP Doc. A-36/86 12.5.1986

48) Council Directive of 12.6.1986 86/279, Official Journal No. L 181/13 ff. of 4.7.86

49) Proposal for a Council Regulation (EEC) relating to the export from and import into the Community of certain

dangerous chemicals, 86/C 177/05, OJ No. C 177/5 ff. of 15.7.86

50) This is the background to the mandate of the WHO to draft a kind of model law, D.C. Jayasuriya, Regulation of Pharmaceuticals in Developing Countries, Legal Issues and Approaches, WHO, Geneva 1985

51) Handbook of Resolutions I, op.cit. Fn. 15, 139

52) on this subject, C. Stenzel, op.cit. Fn. 41, 214/215

53) Handbook of Resolutions I, op.cit. Fn. 15, 142

54) Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II 1973-1988, 129

55) Handbook of Resolutions II, op.cit. Fn. 54, 133

56) United Nations General Assembly Economic and Social Council, Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products, Report of the Secretary-General A/39/290 E/1984/120 18 June 1984, 19 ff.

57) see OECD ENV/CHEM/CM/83.7 of 20.4.83, Chemicals Group and Management Committee, Information Exchange Related to Export of Hazardous Chemicals, Report on Current International Exchange Schemes, 29 ff.

58) a coherent exposition is to be found in D. Kay op.cit. Fn. 41, 45 ff.; see also C. Stenzel, op.cit. Fn. 41, 215/216

59) Handbook of Resolutions I, op.cit. Fn. 15, 133

60) Handbook of Resolutions II, op.cit. Fn. 54, 134

61) on this subject, D. Kay, op.cit. Fn. 41, 45 ff.

62) thus D. Kay, op.cit. Fn. 41, 46

63) for the legal situation after the promulgation of Directive 75/319 see under IV.1

64) for the detailed background see D. Kay, op.cit. 41, 41 ff.

65) see on this subject, A. Wehrli, Quality Control of Drugs, SWISS PHARMA 8 (1986) No. 11a, 29 ff, 30

66) see Proceedings of the Third International Conference of Drug Regulatory Authorities, sponsored jointly by the Swedish National Board of Health and Welfare and the WHO, Stockholm, 10-15 June 1984, Session Two WHO Certification Scheme, A. Wehrli, Review of National Responses to a WHO Questionnaire, 8 ff.

67) op.cit. Fn. 66, Assessment, Possible Upgrading, Role of WHO, 38 ff.

68) Conference of Experts on the Rational Use of Drugs, 25-29 November 1985, Nairobi, Kenya, The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, WHO/CONRAD/WP/2.6. 15 September 1985

69) on this subject, A. Wehrli, op.cit. Fn. 65, 32

70) reproduced in EC Commission, op.cit. Fn. 8, 41 ff.

71) Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products, Geneva - October 1970

72) thus A. Wehrli, op.cit. Fn. 65, 30

73) B. Jøldal, Origins and Purpose of the Pharmaceutical Inspection Convention, in Pharmaceutical Inspection Convention, 10th Anniversary Symposium, Geneva, 19th May 1981

74) R.-G. Kinnander, The Format of Inspection Reports exchanged under the Convention, in Pharmaceutical Inspection Convention, op.cit. Fn. 72, 49 ff.

75) Art. 5, op.cit. Fn 71

76) Recommendation by the Committee of Officials to the Competent Authorities of the Pharmaceutical Inspection Convention, PH 3/81 27th May 1981

77) the only comprehensive treatment is to be found in M. Pallemaerts, Diplomacy and Double Standards, The Regulation of International Trade in Pesticides, Master Thesis Harvard Law School, May 1985, unpublished manuscript, 26 ff.

78) United Nations, Economic and Social Council, Commission of Transnational Corporations, Role of the information system on transnational corporations regarding the exchange of information on banned hazardous chemicals and unsafe pharmaceuticals E/C. 10/90, 20 July 1981

79) M. Pallemaerts, op.cit. Fn 77, 44

80) Resolutions 38/149 and 39/229 as well as reports 38/290, 39/452 and 39/290, see on this subject M. Pallemaerts, op.cit. Fn 77, 45 ff

81) the reply of the United States Mission to the United Nations of 27.7.1983 to the official request of the UN runs as follows: "In the United States ... regulation relates to the use and manufacture of a product rather than to the nature of a product, per se."

82) OECD c(84) 37 Final 27.4.1984. Recommendation of the Council concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals (author's emphasis)

83) Peter Hansen, General Assembly Resolution 37/137, Banned, Withdrawn, Severely Restricted and Not Approved Drugs in ICDRA Conference, op.cit. Fn 66, 8 ff.

84) Consumer Interpol Focus Number 9, September 1984, A Life-Saving List by Martin Abraham; Institute for Consumers Policy Research/Consumers Union, Natural Resource Defense Council, International Organisation of Consumers Unions. A Discussion Paper on U.N. Resolution on "Protection against products harmful to health and environment" (37/137; 38/149; A/C.2/39/L.25) and the Consolidated List of Products Whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments, November 12, 1984

85) J. Dunne, Review of National Responses, in ICDRA Conference, op.cit. Fn 66, 8

86) see on this subject the Statement of Assistant Secretary Gregory J. Newell, Department of State, before the Subcommittee on Human Rights and International Organisations of the House Foreign Affairs Committee, January 31, 1985

87) Summary of arrangements agreed upon for the production of the consolidated list of products, 10.6.1985, and on this question the position of the CU, NRDC, IOCU and National Women's Health Network, November 29, 1985

88) United Nations General Assembly, Economic and Social Council A/41/329 E/1986/83, 23 May 1986, Products harmful to health and the environment, Report of the Secretary General

89) Up to January 1987 the USA as the largest contributor (25%) has only paid 100 million Dollars for 1986, instead of the 210 million Dollars which it owes according to the allocations ratio, see Frankfurter Allgemeine Zeitung of 10.1.87

90) see on this subject, E. Cone, op.cit. Fn 41, 352

91) Handbook on Resolutions II, op.cit. Fn 54, 129

92) C. Stenzel, op.cit. Fn 41, 217

93) Handbook on Resolutions II, op.cit. Fn 54, 129

94) D. Melrose, op.cit. Fn 2, 185 ff, Evaluation and Planning Centre for Health Care, Essential Drugs and Developing Countries, London 1985, 28 ff

95) D. Melrose, op.cit. Fn 2, 187 ff; the dispute has become considerably more acrimonious since the IFPMA "bought" a

consultant to WHO, D.C. Jayasuriya (see op.cit. Fn 50) to describe and analyse the consequences in Bangladesh, "The Public Health and Economic Dimensions of the New Drug Policy of Bangladesh", Pharmaceutical Manufacturers Association, 1985, and IOCU's reply to the report which it considered a "defamation", D.J. Tiranti, Essential Drugs, the Bangladesh Example - Four Years On, 1986

96) on this subject, D. Melrose, op.cit. Fn 2, 164 ff; Evaluation and Planning Centre for Health Care, op.cit. Fn 94, 23 ff - HAI has suggested that the pharmaceutical industry's offer was made with a view to exploiting the African market, HAI - WHO and the Pharmaceutical Industry Briefing Paper for the 35th World Health Assembly 1982, 5

97) on this subject, D. Melrose, op.cit. Fn 2, 166

98) D. Melrose, op.cit. Fn 2, 190 ff and Evaluation and Planning Centre for Health Care, op.cit. Fn 94, 28 ff

99) HAI 1986 by A. Chetley and D. Gilbert; the forerunner was the "Consumer Action and Resource Kit" on "Forty-Four Problem Drugs", op.cit. Fn 32

100) D. Melrose, op.cit. Fn 2, 166

101) for the USA's reaction at the General Assembly, D. Melrose, op.cit. Fn 2, 167; the philosophy also "won over" the EC and was reflected in, for instance, the 2nd Consumer Protection Programme, O.J. No. C 133 of 3.6.81

102) cf. the HAI document of the same name in which all the demands on the consumer side are outlined in great detail.

103) D. Melrose, op.cit. Fn 2, 166

104) L. Broch, op.cit. Fn 12

105) for basic issues of drugs exports under US law, S. Goland, Export of Pharmaceutical Products under the Federal Food, Drug and Cosmetic Act, Cornell International Law Journal 13 (1980), 125 ff and also the so-called Hatch-Kennedy Bill, 99th Congress 1st Session, p. 1848 of 13.11.1985; for the opposing position, Testimony of L. Greenfield, S. Wolfe, The Export of Unapproved Drugs, Before the United States House of Representatives Committee on Energy and Commerce, Sub-Committee on Health and the Environment, July 27, 1984

106) Th. E. Byers, Through my Washington Window, Industrie Santé No. 118 - January 1987, 41 ff

107) there is no disagreement among the disputing parties about the diagnosis, "only" about how to deal with the problem

108) comprehensive treatment in M. Pallemaerts, op.cit. Fn 77; but see also P. Alston, International Regulation of Toxic Chemicals, Ecology Law Quarterly 7 (1978), 397-456

109) op.cit. Fn 82

110) FAO - International Code of Conduct on the Distribution and Use of Pesticides 1985, Art. 9

111) United Nations Environment Programme Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals (in particular Pesticides) in International Trade UNEP/W6.96/5, 2 May 1984; adopted as the Provisional Notification Scheme for Banned and Severely Restricted Chemicals by the Governing Council by Decision 12/14 of 28.5.84

111a) UNEP / GC. 14/L.37 16 June 1987

112) op.cit. Fn 13

113) op.cit. Fn 8, 17 ff

114) op.cit. Fn 47

115) op.cit. Fn 49

116) see M. Pallemaerts, op.cit. Fn 77, 105 with reference to the Institut d'Etudes Européennes, Le Droit de la Communauté Economique Européenne 413 (1976); Pescatore, La Politique Commerciale in Les Nouvelles - Droit des Communautés Européennes 925 (1969); Th. Bourgoignie, Exports of Dangerous Medicinal Products from the Territory of the European Community to Third World Countries, Université Catholique, Centre de Droit de la Consommation - CDC doc 3/1986

117) Council Regulation No. 1934/82 of 12 July 1982 amending Regulation (EEC) No. 2603/69 establishing common export rules, O.J. No. L 211/1 ff of 20.7.82 in the recitals

118) N. Reich, Förderung und Schutz diffuser Interessen, Baden-Baden 1987, L. Krämer, op.cit. Fn 21

119) Council Decision of 2.3.1984 on the introduction of a Community System for the Rapid Exchange of Information about the Hazards in the Use of Consumer Goods, 84/133, O.J. No. L 70/16 ff of 13.3.84

120) Provisional Report on the Rapid Information System for the Hazards associated with the Use of Consumer Goods, Com (86) 552 Final 24.10.86

121) op.cit. Fn 8, 36

122) op.cit. Fn 8, 48

123) Council Directive of 22.12.1986 on the Approximation of the National Measures concerning the Placing on the Market of High Technology Medicinal Products, Particularly those derived from Biotechnology (87/22/EEC), O.J. No. L 15/38 ff of 17.1.87

124) see on this subject, Th. Bourgoignie, op.cit. Fn 116, 30/31

125) this is naturally never expressed in so many words, but see for example C. Stenzel's exposition on the EC's pharmaceutical policy, op.cit. 41, 230 ff - it is purely an internal market policy whereby safety and health are just by-products. (230)

126) op.cit. Fn 8, 33 ff

127) see on this subject, A. Wehrli, op.cit. Fn 65 in fine

128) for proof, ICDRA Conference, op.cit. Fn 66

129) see WHO Regional Office for Europe, Consultation on an International Scheme for Drug Evaluation: Summary Report, No. I CP/DPM 003 (S), Rev. 1, 5927 B (1981); on this subject, E. Cone, op.cit. Fn 41, 353

130) this subject is covered in the Report of the General Assembly, op.cit. Fn 56, 9 ff

131) op.cit. Fn 47, OJ No. C 176/135, 6th Resolution Proposal

132) American NGOs in particular have called for this in their negotiations with that country's industry to be achieved by changing the law, PAN Newsletter, Fall 1985; see also Business Week, March 10, 1986, A delicate compromise on pesticides. An explanation is needed as to why changes in the law are negotiated between NGOs and the industry. It is simply that the NGOs action is closely connected with the inactivity of the US law-making machinery

133) A. Lindsay, The Faith Halter Report, Chemistry and Industry, 7 October 1985

134) this statement cannot be gone into further here; but it is sufficient to make a comparison of the regulations for goods exports with those for goods imports

135) op.cit. Fn 88, 12

136) Proposal for a Council Regulation concerning Export from and Import into the Community of Certain Dangerous Chemicals, Com (86) 362 Final, 25.6.1986, 1

137) op.cit. Fn 136, Art. 4 (1)

138) CADE Position Paper on the Commission Proposal for a Regulation concerning Export from and Import into the Community of Certain Dangerous Chemicals, Com (86) 362 Final

139) this was disputed in the preliminary work between DG III (Internal Market) and DG XI (Environmental Protection). In the end the issue was decided with the 6th Amending Directive 79/83/O.J. No. L 259/10 of 15.10.79 giving the EC Commission a central position

140) UNEP/WG. 155/2 12.11.1986, Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals in International Trade - Second Revised Draft Guidelines for the Exchange of Information on Potentially Toxic Chemicals in International Trade - Comments of governments, organisations and bodies within the UN System and other intergovernmental and non-governmental organisations - Paper prepared by the UNEP secretariat.

141) what this refers to is the Executive Order which was signed by Carter only a few days before the end of his term of office after a lengthy domestic policy debate. The US move provoked a veritable flood of comment. Particularly recommended is the article by F. Schulberg "United States Export of Products Banned for Domestic Use", Harvard International Law Journal 20 (1979), 331 ff, which gives a complete overall picture. A summary of the discussion on the basis of the present situation is given in S.J. Scherr, Hazardous Exports: United States and International Policy Developments, May 1985, unpublished manuscript. A detailed exposition on the Executive Order itself is contained in S. Children, Executive Authority: Revocation of Executive Order Requiring Notification of Export of Hazardous Substances, in Harvard Law Journal 22 (1981), 683 ff

142) BEUC and IOCU Recommendations for Community Legislation "Exports of Dangerous Medicinal Products from the Countries of the European Community to the Third World" (this text is the document submitted to Mrs Banotti) 4.3.1985; the remarks are identical to those in the contribution by Th. Bourgoignie, op.cit. Fn 116, who was also one of the authors; see also D. Harland, 8, JCP 1985, 209 ff

143) op.cit. Fn 47, Resolution Proposal No. 9

144) D. Melrose, op.cit. Fn 2, 166; the Netherlands, as the first West European country, has subjected the export of chemicals to controls

145) A. Chetley, op.cit. 4, 9 ff

146) AEI Journal on Government and Society, November/December 1980, 8 ff - International Nanny - Regulating Hazardous Exports

147) A. Chetley, op.cit. 4, 9 ff

148) these play a role, above all, in the international discussion on the export notification of chemicals and pesticides

149) see on this subject the BEUC/IOCU Paper, op.cit. Fn 142, in which the arguments are again summarised

150) Ch. Medawar in NGO Seminar, op.cit. 7, 23 ff; ibid. A. Herxheimer 18 ff (Lomotil); the latter with W. Lionel in Pharmaceuticals and Health Policy, op.cit. Fn 25, "Coherent Policies on Drugs Formulation and Implementation", 240 ff

151) see on this subject, N. Reich - H.W. Micklitz, op.cit. Fn 21, 1 ff

152) for a concise treatment, K. Simitis, Verbraucherschutz - Schlagwort oder Rechtsprinzip, Baden-Baden 1976

153) see on this subject, N. Reich - H.W. Micklitz, Consumer Protection in the Federal Republic of Germany, New York, etc. 1980, 1 ff

154) see, for example, P.B. Seferovich, United States Export of Banned Products: Legal and Moral Implications, Denver Journal of International Law 10 (1981) 537 ff (552)

155) S. Children, op.cit. 141, 685

156) see on this subject, M. Baldrige/A.M. Haig, Report to the President on the Review of U.S. Hazardous Substances Export Policy and cover letter to USTR Brock from secretaries Haig and Baldrige, U.S. Export Weekly 1982, 335 ff

157) op.cit. Fn 142

158) op.cit. Fn 8, 9

159) in reaction to WHO's Action Programme on Essential Drugs, the USA have taken back the assignment of development programmes into their own hands, C. Stenzel, op.cit. Fn 41, 223

160) this is supported by Th. Bourgoignie, op.cit. Fn 116, 31

161) from the Proceedings in the European Parliament, Doc. 2 - 1530/84; Doc. 2 - 1608/84: Doc. B 2 - 528/35, Doc. ACP - EEC 20/85; PE 101.909 A 8.11.85; from Commission O.J. No. C 287 of 9.11.81, O.J. No. C 28 of 30.1.85, 3 ff; O.J. C 128 of 16.5.83, 15 ff; on the question of the permissibility of an advertising ban, N. Reich/J. Smith, Implementation of the International Code of Marketing of Breast Milk Substitutes by the EEC JCP, 1983, 355 ff