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EC Regulation of the Export of Dangerous Pharmaceuticals to Third World Countries: Some Prospects

ABSTRACT. "Double standards" in the regulatory status of pharmaceuticals enable the pharmaceutical industry to dump to third world countries medicines whose use is restricted or banned domestically. Numerous initiatives have been taken at the international level to tackle the problem, namely by the World Health Organisation. The European Community remained for a long time silent and promoted a laissez-faire policy, thereby giving carte blanche for the uncontrolled export of pharmaceuticals. However, a change of the European Community's attitude towards the export issue seems to be in the offing. The paper analyses the possibilities of the European Community to participate in the already existing WHO regulatory mechanisms and to design Community actions with the aim of curbing the trade with dangerous pharmaceuticals.

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

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formulated in such an irrational manner as to rule out any meaningful therapeutic applications (Barber & Barnacel, 1984; Broch, 1984; Medawar, 1984).

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. It is thus 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 (Medawar, 1979; Melrose, 1982). 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 (WHO Expert Committee, 1983). 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.

INTERNATIONAL REGULATION OF PHARMACEUTICAL EXPORTS: AN OVERVIEW

In order to locate the possibilities for the European Community of formulating an export policy, it is indispensable to look at the regulatory initiatives already taken at the international level.

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 (Cone, 1983; Kay,

1976; Stenzel, 1981). It was really only the Thalidomide disaster which prompted WHO to perceive pharmaceutical supplies as a political and 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. The '70s brought a more strongly interventionist style of policy, as also in the industrial countries with the United States taking the lead. A direct expression of this policy is the Essential Drugs Programme (Stenzel, 1981, p. 217) and regulation by means of a Code of Conduct (Cone, 1983, pp. 331–361) particularly aimed at combatting 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 was adopted, calling on the General Secretariat to draw up a Consolidated List of banned or severely restricted products.[1]

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. In 1983 the Council of Europe passed Recommendation 969 (1983) on the Sale of European Pharmaceutical Products in the Countries of the Third World.[2] 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 75/313.[3] Moreover, the Council of Europe, alongside WHO, represents the most important international body which deals with the regulation of pharmaceuticals.

In the EC it appears that the way is also being paved towards a change in the export policy pursued until now. The European Parliament has taken up the gauntlet, flung down by the Council of Europe. The Banotti Report and the Resolution based upon it[4] 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.

PROSPECTS AND INSTRUMENTS FOR EC REGULATION OF THE EXPORT OF DANGEROUS PHARMACEUTICALS

Competence of the EC to Issue Export Restrictions

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."[5] 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 (Bourgoignie, 1986; Pallemaerts, 1985; Pescatore, 1969). Now it could be argued that in so doing the EC is in violation of Regulation 2603/69 on the establishment of common export rules.[6]

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 (Krämer, 1986; Reich, 1987).

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.

Exchange of Information

EC procedures. 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,[7] does not cover pharmaceuticals.

1. According to Art. 33 of Directive 75/319 "(each Member State) shall take 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."[8]

2. According to Art. 9 and 13 of Directive 65/65, as amended by Directive 83/570,[9] 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.[10] 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 (Bourgoignie, 1986), 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 infor-

mation. 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.

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.

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" (Stenzel, 1981), 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[11] 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 (Wehrli, 1986). In the case in point, this would simply consist 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 (ICDRA, 1984), 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.

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 pharma-

ceutical 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"[12] 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. The scheme is freely accessible to anyone.

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:

> 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.[13]

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. 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 (Lindsay, 1985). 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.

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.

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,[14] 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:

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.

Envisaged regulation of chemicals and pesticides as a model? 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, FAO, and UNEP (EC Commission, 1986, p. 1).

The consensus reached is best reflected in the OECD recommendation dating from 1984 (OECD, 1984) directed at the member States. At the same time it found its way into the FAO Code of Conduct on Pesticides (FAO, 1985) and into the UNEP Provisional Notification Scheme (UNEP, 1984). 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. 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.*

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 (EC Commission, 1986, Art. 4(1)). 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 (CADE, 1986). 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 — 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! Astonishingly enough, the European Parliament has recently taken over most of CADE's proposals for improvement — introduction of Prior Informed Consent and enlargement of the list.[15]

The future of export notification. 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 (UNEP, 1986). 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[16] 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."

It might well be that a comparable solution will be found in the Council of Ministers, viz., the adoption of the OECD system, combined with a mandate to the Commission to participate in the international negotiations. 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.

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 (Childress, 1981; Scherr, 1985; Schulberg, 1979). For the EC, until now, only the BEUC and IOCU have called for such measures (BEUC & IOCU, 1985; Bourgoignie, 1986; Harland, 1985). 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 the way will be open to think about the mechanisms of an EC control. The European Parliament expressly calls upon the Commission to do just this (see Footnote 4, Resolution Proposal No. 9). Lastly, it remains to be made clear just how the EC can help to promote WHO's efforts to introduce controls.

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 (Melrose, 1982, p. 166) see export control as interference in the sovereignty of the developing countries (Chetley, 1985, 1986). 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 article has asked: Can the United States be a nanny to the Third World (International nanny, 1980)? 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 (Chetley, 1985, 1986).

The proponents — countries of the Group of 77 — as well as a number of non-governmental organisations, are pursuing a legitimation strategy on two levels (BEUC & IOCU, 1985). 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*, 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. The latter, when they do not support a pure laissez-faire export policy, advocate an "information model" (Simitis, 1976). 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 (Reich & Micklitz, 1980), would be regarded as justified in the industrial countries in cases where the citizens 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 (Seferovich, 1981). 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.

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" (Childress, 1981, p. 685). 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 lays 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 (Baldridge & Haig, 1982) the U.S. 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 (BEUC & IOCU, 1985). 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 time 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; 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 U.S. 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,[17] 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.

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. 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 (see Bourgoignie, 1986, for the same suggestion). 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 (Reich & Smith, 1983).[18]

CONCLUSION

Whether it will ever be possible to develop an export policy in the EC is inextricably linked to the completion of the internal market to be achieved by 1992. 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.

ADDENDUM

On February 8, 1988, the Commission of the European Communities published a draft directive (OJ No. C 36, 22ss) regulating for the first time the export of pharmaceuticals. The Commission rejects export notification but enhances participation in WHO's Certification Scheme, Drug Bulletin and Drug Circular: importing countries should be entitled to request a manufacturer's permit as well as a product summary; member states should be obliged to notify regulatory actions as well as voluntary suspensions and recalls directly to WHO.

NOTES

[1] United Nations, General Assembly A/RES/37/137, 3 March 1983.

[2] 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.

[3] Official Journal of the European Community (OJ) No. L 147/1 ss. of 9.6.75.

[4] OJ No. C 176/133 ss. 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 of the countries of the Third World, Rapporteur Mrs Mary Banotti, EP Doc. A-36/86 12.5.1986 OJ No. C 176/135, 6th Resolution Proposal.

[5] 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 ss. of 15.7.86.

[6] Council Regulation No. 1934/82 of 12 July 1982 amending Regulation (EEC) No. 2603/69, OJ No. L 211/1 ss. of 20.7.82.

[7] 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, OJ No. L 70/16 ss. of 13.3.84.

[8] OJ No. L 147/13 ss. of 9.6.75.

[9] OJ No. L 332/1 ss. of 28.11.83.

[10] 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), OJ No. L 15/38 ss. of 17.1.87.

[11] OJ No. L 147/13 ss. of 9.6.75.

[12] 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).

[13] OJ No. C 176/135, 6th Resolution Proposal.

[14] 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.

[15] OJ No. C 281/196 ss. of 19.10.87.

[16] United Nations Environmental Programme, Governing Council 14/L 37, 16. June 1987.

[17] OJ No. L 369/65 ss. of 4.2.75.

[18] 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, OJ No. C 287 of 9.11.81; OJ No. C 28 of 30.1.85, 3 ss.; OJ C 128 of 16.5.83, 15 ss.

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ZUSAMMENFASSUNG

Die Regulierung des Exports gefährlicher Arzneimittel in die Dritte Welt durch die EG. "Double Standards" im regulatorischen Status von Arzneimitteln ermöglichen es der pharmazeutischen Industrie, Produkte, deren Vertrieb in den Industrieländern verboten oder "streng" beschränkt ist, in die Länder der Dritten Welt abzusetzen. Die Weltgesundheitsorganisation (WHO) hat eine Reihe von Initiativen unternommen, um dem Problem Herr zu werden. Die Europäische Gemeinschaft hat sich zurückgehalten und bis in die 80er Jahre eine reine Laissez-Faire Politik betrieben. Exporte unterliegen auch nach den derzeitigen gemeinschaftlichen Regeln praktisch keinen Beschränkungen. Es mehren sich aber die Anzeichen dafür, daß diese Position nicht mehr haltbar ist. Dieses Papier unternimmt den Versuch, die Möglichkeiten der EG an einer verstärkten Teilnahme an den vorhandenen Mechanismen der WHO auszuloten. Hauptsächlich geht es aber um eine Klärung der Frage, ob die EG eine eigenständige Exportpolitik formulieren kann und welche Form sie haben könnte und müßte, um die Mißstände zu beseitigen.

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