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REPORT

drawn up on behalf of the Committee on the Environment,  
Public Health and Consumer Protectionon the export of pharmaceutical products from the  
European Community to the countries of the Third  
World

Rapporteur: Mrs Mary BANOTTI

PE 96.643/fin.  
Or.En.

At its sitting of 9 October 1984, the European Parliament referred the motion for a resolution tabled by Ms Quin and Mr Adam on the export of drugs from the EEC to the countries of the Third World (Doc. 2-565/84) to the Committee on the Environment, Public Health and Consumer Protection and the Committee on Development and Cooperation for their opinion, pursuant to Rule 47 of the Rules of Procedure.

At its meeting of 20 November 1984, the Committee on the Environment, Public Health and Consumer Protection decided to draw up a report and appointed Mrs Banotti rapporteur.

At its meetings of 17 March and 23 April 1986, the committee considered the draft report. At the last meeting it adopted the report unanimously.

The following took part in the vote: Mrs WEBER (Chairman), Mrs SCHLEICHER (Vice-Chairman), Mrs BANOTTI (rapporteur), Mr ALBER, Mr AVGERINOS (deputizing for Mr SCHMID), Mr BARRAL, Mr BOMBARD, Mr DURAN CORSANEG (deputizing for Mr GAIBISSO), Mr GOMES (deputizing for Mr TOGNOLI), Mrs GREDAL (deputizing for Mr VITTINGHOF), Mrs HAMMERICH (deputizing for Mr ROELANTS DU VIVIER), Mr HUGHES, Mr Van der LEK, Mrs LLORCA LA PLANA, Mrs MAIJ-WEGGEN (deputizing for Mrs LENTZ-CORNETTE), Mr MARTIN (deputizing for Mr NORDMANN), Mr MERTENS, Mr MUNTINGH, Mr PEREIRA V, Mr RENAUX I MANEN, Mr SHERLOCK, Mr SIMPSON (deputizing for Mr COTTRELL), Mrs SQUARCIALUPI, Mr STAES (deputizing for Mrs BLOCH von BLOTTNITZ) and Ms TONGUE.

The opinion of the Committee on Development and Cooperation is attached.

This report was tabled on 29 April 1986.

The deadline for tabling amendments to this report will be laid down in the draft agenda for the sitting in which it is included.

PE 96.643/fin.

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution together with explanatory statement:

A.

MOTION FOR A RESOLUTION

on the export of pharmaceutical products to the Third World

The European Parliament

- having regard to the Motion for a Resolution tabled by Ms QUIN and Mr ADAM on the export of drugs from the EEC to the countries of the Third World (Doc. No. 2-565/84),
  - having regard to its Resolution on the export of pesticides to the Third World (Doc. 458/83)<sup>1</sup>,
  - having regard to the Council of Europe's Parliamentary Assembly Report by Mr LIND on the sale of European Pharmaceutical products in the countries of the Third World,
  - having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the Opinion of the Committee on Development and Cooperation (Doc. A 2-36/86),
- A. Aware of the widespread public concern in Europe about the problem of ill-health in the Third World,
- B. Aware that more than half of the world population suffers from a chronic lack of proper medical care,
- C. Noting that industrial countries which account for 15% of world population consume more than 50% of pharmaceutical products,
- D. Noting also that almost 90% of world pharmaceutical production is based in industrialised countries so that Third World countries depend almost entirely on imported pharmaceutical products and because of this it is important that international standards should exist in relation to the quality and usage of these products,
- E. Aware of the World Health Organisation certification scheme on the quality of pharmaceutical products moving in international commerce,

<sup>1</sup> OJ No C 307 of 17.11.83, p. 109

- F. Aware of the World Health Organisation's policy and Action Programme on Essential Drugs,
- G. Aware, too, of the important part which both the Lomé Convention and the other agreements linking the European Community to the developing regions or countries can also play in respect of this problem,
- H. Notes, with approval, the outstanding work being done by development and health voluntary workers (both lay and religious) from the Member States throughout the Third World,
- I. Having regard to the economic importance of the pharmaceutical industry to the European Community and that the European Pharmaceutical Industry subscribes to an International Code of Pharmaceutical Marketing Practices which was adopted by the International Federation of Pharmaceutical Manufacturers Associations in 1981,
- J. Aware that within the Community, legislation already exists to ensure that pharmaceutical products are manufactured to high quality standards and require authorisation before being placed on the market,
- K. Conscious of the overwhelming shortage of high quality, safe, effective and inexpensive essential drugs throughout much of the Third World,
1. Believes that national drugs policies should be based on the concept of essential drugs, (i.e. a basic list of those drugs which are needed for health care of the majority of the population and should be available at all times in adequate amounts and in the proper dosage forms);
2. Calls on the Community, as well as its Member States individually, through participation in the World Health Organisation, to assist Third World countries in
- establishment of a national drug regulatory authority in every country,
  - the provision of complete and unbiased information in the form of W.H.O. guidelines on minimum requirements for national drug regulation so that all countries would be in a position to set up such mechanisms beginning with drug registration;

3. Welcomes the World Health Organisation commitment to guidelines on ethical norms on drug advertising and calls on all governments to implement and enforce such 'norms';
4. Supports the W.H.O. Certification Scheme on the quality of pharmaceutical products moving in international commerce and believes that the scheme should both be strengthened to include criteria of drug effectiveness and to cover the active ingredients of pharmaceutical compounds and should be more availed of by Third World countries and recommends that the Commission should urge Member States to participate fully in the extended scheme;
5. Points out that the existing sources of information within the W.H.O. and the United Nations, such as:
  - . the W.H.O. Bulletin on pharmaceutical products,
  - . the International Conference of Registration Authorities,
  - . the U.N. Secretariat's list of proscribed, withdrawn or severely restricted products, drawn up under the aegis of the W.H.O.,should also be more widely used by the countries of the Third World;
6. 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;
7. Requests that a rule be included in the above-mentioned directive providing that the scientific committee on drugs be given authority to determine what is to be understood by special restrictions. In the light of how the special restrictions are defined, this committee shall draw up a list of drugs subject thereto. This list shall be regularly updated and published;

8. Requests the Commission that this directive should also ensure the supply of complete product information of a standard equivalent to that available in Europe to be provided for users and prescribers in the principal language of the importing country;
9. Asks the Commission to investigate whether a system can be devised whereby, by means of a statutory ruling, sales of products which
  - (a) are found to have been placed on the market in violation of the directive,
  - (b) are found to represent an immediate risk to public health, owing to incomplete or incorrect information,
  - (c) have to be regarded, on the basis of new information, as dangerous to public health,are stopped and such products are withdrawn from the market as soon as possible, not only in the Member States but in all countries in which they are marketed;
10. Commends the W.H.O. Action Programme on Essential Drugs and Vaccines and calls on the Community and the individual Member States to provide additional resource support for that programme and to implement its recommendations in health related aid programmes;
11. Calls on both the Community and the governments of Third World countries to take stringent measures to prevent the counterfeiting of pharmaceutical products ;
12. Calls for increased funds for, and a more co-ordinated approach towards, research, by Member State Governments, medical and academic institutions and the pharmaceutical industry, to find cures for tropical diseases;
13. Instructs its President to forward this resolution to the Commission, the Council, the Council of Europe, the World Health Organization, the ACP countries and the countries linked to the EEC by other agreements.

B.

EXPLANATORY STATEMENT

1. There is a widespread public concern in Europe about the problems of the Third World, most recently highlighted by the European response to famine.

Europeans are increasingly distressed and baffled by the fact that millions of people die annually in the Third World from often relatively 'simple diseases' which in Europe are minor and easily curable ailments. Diarrhoea alone is the largest single killer of children under the age of five with almost 8 million deaths a year.

There is, at present, an inequitable distribution of health resources in the world, particularly in relation to supplies of drugs. The most urgent need regarding drugs at this stage is to make it possible for the vast majority of the world's people who live in the developing countries to have access at a cost they can afford to those 30 or 40 drugs that are vital to them as part of their primary health care, and to ensure that these drugs are used rationally.

In the industrialised countries there are thousands of drugs on the market, many of them identical or highly similar but sold under different names, and many of them incorporating a variety of active ingredients. In the Third World, while the situation in some urban areas may resemble that in the industrialised world, the vast majority of people who live in rural areas have little or no systematic access to drugs.

Also in developing countries, doctors are few and far between. Most people rely for health care mainly on other categories of health workers such as nurses and pharmacists, but more usually on non-professional health workers with limited training or traditional practitioners. There are few, if any, pharmacies outside the towns, whether private or government owned, and other arrangements have to be made to ensure the availability of drugs, in places such as hospital outpatient departments, drug corners in health centres, village drug co-operatives and small village shops. The inadequacy of the health infrastructure and the weakness of distribution, transport and communication systems make it extremely difficult for drugs to reach those people who need them even if drugs are centrally available.



In both developing and developed countries a comprehensive national drug policy forming an integral part of a national health policy is the exception rather than the rule.

Sometimes, the most appropriate therapy does not include drugs. But, when it does, the rational use of drugs demands that the appropriate drug be prescribed, that it be dispensed correctly, and that it be taken in the right dose at the right intervals and for the correct length of time. The appropriate drug must be effective, and be of acceptable quality and safety.

2. Poverty, of course, is the root cause of ill-health in developing countries where the majority of the population suffers from a chronic lack of medical care. The types of health care problems in these countries are quite different from those in industrialised countries. In the Third World, infectious diseases remain a major cause of death and almost one billion people (a quarter of the world's population) are affected or threatened by tropical disease. Currently, treatment facilities and medication are simply not available in time to a majority of people. The reasons for this range from a lack of funds and medical personnel, inadequate transport facilities and, it must be added, inefficiency and corruption. It is also, unfortunately apparent that health care is not accorded the high priority it deserves by certain developing countries, ranking lower on the national budget scale than military spending.
3. The availability of pharmaceutical products is a central element in the establishment and maintenance of equitable health care systems.

Industrial countries which account for only 15% of world population consume more than 50% of pharmaceutical products. 90% of world pharmaceutical production is based in industrialized countries.

The pharmaceutical industry is of major importance to the economy of the European Communities, employing almost half-a-million people, many of whom are highly qualified. Pharmaceuticals make an important contribution to the balance of trade in the EC three Member States (UK, FRG and France) are among the top five pharmaceutical exporting countries in the world. Ireland is in tenth position.

Within the European Community, legislation exists to ensure that pharmaceutical products are manufactured to high quality standards and are properly tested before being placed on the market. EEC Directive 319 of 1975 requires that 'all medicinal products to be manufactured in the Community require authorisation, and official inspections take place to ensure compliance with proper manufacturing standards. In addition, an authorisation to place products on the market is required for those medicinal products which are to be sold in the Community'.

4. Since Third World countries import almost all of their drugs it is important that international standards should exist in relation to the quality and usage of pharmaceutical products. Countries lacking a comprehensive and fully independent system of drug control are limited in their capability to assure the quality, safety and efficacy of pharmaceutical products which they import; and where there is no effective system of drug registration the sale of unlicensed and mislabelled products will remain unchallenged.

These deficiencies can be corrected in locally manufactured products only by improving or indeed establishing national control mechanisms. When a product is imported, however, the regulatory authority in the country of origin should be in a position to provide an assurance on the conditions under which it is manufactured together with information on whether, and for what purpose, it is available in the domestic market.

The World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was adopted in 1975 and it provides a simple administrative mechanism whereby importing countries can:

- (i) ascertain whether a given product has been registered for marketing in the exporting country and, when appropriate, request an explanation of the reason registration has not been accorded;
- (ii) obtain assurance that the manufacturing plant in which the product is produced is subject to periodic inspection and conforms to requirements for good practices in the manufacture and quality control of drugs as recommended by W.H.O.

- (iii) obtain details of the inspection and control procedures exercised by the authority in the exporting country and request inquiries to be instituted by the exporting authority should a certified product be found to be of unacceptable quality.

About 100 countries out of 158 participate in the scheme. The scheme stresses the role of the importing country providing a right for it to obtain information.

Increased use of the scheme should be encouraged. Also possible ways to increase the strength and scope of the scheme include its extension to cover 'active ingredients' as well as finished pharmaceutical products and the creation of an international inspectorate of independent arbitration procedures to supervise its implementation.

5. The marketing of drugs by the pharmaceutical industry has been the subject of much criticism because of its alleged aggressivity and bias and there is wide agreement on the need for recognised norms.

It is not easy for prescribers to select drugs properly and use them wisely when they face a bewildering amount and variety of information and consumers believe that there is 'a pill for every ill'. To inform and influence prescribers and the public, manufacturers and distributors resort to various forms of promotion such as advertising, offering samples, using sales representatives, sponsoring symposia, and even providing financial and other incentives. Some of this conforms to acceptable ethical standards; some does not.

The European Community pharmaceutical industry is represented internationally by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and subscribes to its Code of Pharmaceutical Marketing Practices. This code, which is voluntary, is the industry's policing system and was adopted in 1981. It seeks to ensure that all products are issued according to adequate procedures and strict quality assurance, that qualities claimed for products are based on valid scientific evidence, and factual and honest information is provided about them to medical officials and the public. In 1982, the IFPMA set up procedures to handle complaints alleging violations of the code. In 1983, IFPMA took the decision to make public the results of the consideration of all complaints made under the code.

The procedures for dealing with complaints are as follows:

In the case of complaints made directly to IFPMA, these are forwarded for consideration to the Association (s) concerned. Their findings are then passed on the IFPMA whose responsibility it is to respond to the complainant. In addition, an ex-officio committee of the IFPMA council, consisting of the President, the two Vice Presidents and the Executive Vice President, oversees all matters involving the Code. Where complains are addressed to member Associations, they are replied to by the Member Association (s) after consultation with the company or companies involved. International companies, through membership by the parent company of an IFPMA Member Association, are regarded as being bound by the Code in all countries in which they operate whether or not there is an IFPMA Member Association in that country.

Member Associations have been advised to set up their own procedures for monitoring the code and many of them have done so IFPMA has had instances of unofficial complaints that have been forwarded to the Federation by interested parties, including officials of WHO, and the Federation's Secretariat is itself active in looking for possible breaches of the Code. The outcome of cases considered under the Code is made public by means of regular Status Reports. According to the IFPMA, to date in all cases where claims of breaches of the Code by companies in membership of IFPMA member Associations have been upheld, the company concerned has agreed to remedy the lapse.

The IFPMA Code has been criticised because it carries no penalty provisions: Material penalties can only be imposed with the backing of the law and this law would have to be national law.

Neither the IFPMA nor WHO can impose direct penalties on companies violating the Code unless national legislation existed to enable this to be done. The only sanction that the IFPMA can impose is adverse publicity which is a matter of concern for the reputation of international companies. Also the IFPMA Member Associations can, if they wish and some do, have a provision in their statutes allowing them to expel any company refusing to abide by the IFPMA Code.

Another criticism is that not all the world's pharmaceutical industry is covered through IFPMA membership.

The IFPMA has member associations in just fifty countries but the Code applies throughout the world to all companies belonging to those fifty members. It is estimated that about 80% of the pharmaceuticals sold outside the Warsaw Pact countries and China fall within its scope.

The Code has been criticised as weak and ineffective. In partial reply to such criticism multinational companies have stated that even if policy decisions are taken centrally, the decisions may not be carried out by all subsidiaries, and that it is impossible for the corporate headquarters of a multinational company to know all the time what is happening in every market. In many developed countries there are regulatory constraints on promotional methods, but in many Third World countries Governments are not yet in a position to assume that responsibility. This places even greater emphasis on the necessity for industry to apply in these countries the same norms that they apply in developed countries.

At international level, the twenty-first World Health Assembly in 1968 adopted a series of ethical and scientific criteria to be truthful and reliable and statements should be supported by adequate scientific evidence. It is stipulated that promotional material should maintain a fair balance between effectiveness on the one hand and adverse reactions and contra-indications on the other. It should provide a full designation of the nature and content of active ingredient(s) per dose using generic or non-proprietary names. It is further stipulated that advertisements to the public should not be permitted for prescription drugs for the treatment of conditions which can be treated only by a doctor or in a form that could provoke fear or distress or that claims infallibility or suggests that the drug is recommended by members of the medical profession.

The Rapporteur welcomes WHO plans to strengthen and improve such guidelines but stresses that it is up to national Governments to adopt, implement and enforce them.

6. In 1977, the World Health Organisation launched its Policy on Essential Drugs and Vaccines: The Policy is based on the concept that essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms. The choice of such drugs depends on many factors,

such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic and environmental factors: Only those drugs should be selected for which, sound and adequate data on efficacy and safety are available from adequate clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.

The stability of the drugs under the anticipated conditions of storage must be established. Where two or more drugs appear to be approximately similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety quality, price and availability. In the great majority of cases, essential drugs should be formulated as single compounds.

An essential drugs list may be modified or augmented according to the specific needs of a country, and does not imply that no other drugs are necessary.

The 158 Member Countries of the W.H.O. contribute financially to the Essential Drugs Programme and many European pharmaceutical companies provide technical assistance, training and drugs at preferential prices.

After the establishment of the 1977 W.H.O. model list of Essential Drugs, many developing, but not industrialised, countries made attempts to establish national lists suited to their own needs. Today, the number of countries with lists of essential drugs or national formularies containing chiefly essential drugs exceeds 80.

The establishment of a national list, however, does not necessarily lead to implementation of the concept of essential drugs. In some developing countries the new list of essential drugs became just another list added to the many existing lists! The importation, distribution, and use of expensive non-essential drugs continued as before in the growing private sector. In some countries (such as Kenya, Mozambique, Tanzania, etc.), the list was applied vigorously to the primary health care system.

The Action Programme was formally established in 1981 as an operational programme to support countries in the establishment of essential drug policies. Its aim is to help assure the regular availability of essential drugs of good

quality and at the lowest possible prices. In 1981, W.H.O. joined forces with the UNICEF to support the provision of essential drugs for primary health care in developing countries. UNICEF has widespread operational activities in most developing countries and concentrates mainly on procurement and distribution.

7. The cost of drugs for developing countries gives rise to deep concern. In addition to lacking financial resources in general, these countries have severely limited amounts of convertible currency for drug procurement. Recent experience with international tenders for generic drugs in developing countries has been very encouraging; thanks to purchasing larger quantities required for a longer period of time, and thus benefitting from the economies of scale. But greater efforts are required to help Third World countries to overcome their convertible currency problems as they relate to drug imports.

W.H.O. in close cooperation with the UNICEF Packing and Assembly Centre (UNIPAC), collaborates with countries to improve procurement procedures. Tender documents, price lists and names of reputable suppliers are available on request. UNIPAC has managed, through international competitive bidding, to achieve considerable reductions in the prices of about 140 essential drugs. Countries can obtain essential drugs at these low prices through a re-imbusement scheme, which, however, requires prepayment in 'hard' currency. A financing agreement is being developed whereby countries with essential drugs programmes will be provided with credit for drug procurement. In some instances, local currency may be accepted in part payment.

8. Once drugs are either manufactured or imported, they have to be properly stored and distributed. Problems of storage and distribution include pilfering, waste, inappropriate buildings, insufficiency of shelf space to store drugs and equipment, lack of staff trained in modern storage and distribution management, shortage of fuel and poor roads.

Experience in a few countries has, however, showed that it is possible to improve both storage and distribution. Essential drugs are, in fact, reaching the most distant units in several countries on a regular basis and with a minimum of wastage. The ration kit system used in Kenya and Tanzania, appears to be a feasible approach. Drug quantities tailored to the needs to a health unit and designed for a specific number of patients are pre-packed in sealed boxes. New kits are supplied on the basis of attendance rates rather than on monthly or quarterly schedules that ignore the number of patients treated.

kit packaging adds to the cost of procurement because of the packaging material and labour needed. But this additional cost would seem to be more than offset by the reduction in waste and theft of drugs.

W.H.O., together with UNICEF, collaborate with several countries in improving storage and distribution systems and training store managers in better techniques. Manuals and teaching material on storage and logistics have been developed and the first few workshops have taken place.

Research to determine the stability of drugs stored under tropical conditions is under way.

9. The complexity of the international drug market and the urgency with which messages sometimes need to be relayed requires efficient international channels of communication between national drug regulatory authorities. International systems of exchange of information relieve regulatory authorities in developing countries of the need to undertake fully independent assessments of the drugs registered under their aegis. However, no mechanism for international exchange of regulatory information can operate effectively where there is no indigenous system of drug registration.

To introduce rationality into the naming of drug substances W.H.O. assigns internationally recognised generic names (International Nonproprietary Names - INNs). It has established an International Drug Monitoring Scheme on the adverse effects of drugs. It provides specifications in the international Pharmacopoeia for assuring the quality of drug substances. It plans and co-sponsors the biennial International Conference of Drug Regulatory Authorities through a network of national information officers it disseminates details of restrictive national regulatory decisions taken in respect of marketed drugs, when necessary by telex. It provides evaluated information on national regulatory decisions through the W.H.O. Drug Information Bulletin, and work is in hand to produce a W.H.O. model formulary based on the model list of essential drugs. It has also developed a simplified system of drug quality control that could be applied by countries with even the most limited resources.



10. W.H.O.'s Member States have therefore at their disposal an array of measures for improving their drug situation. If they apply them properly, they could have better access to objective information on drugs, improve their manufacturing practices and quality control measures, ensure that the drugs they import conform to the standards of the exporting country, introduce sound drug policies to ensure that all their people have regular access to the essential drugs they need, and reduce the cost of importing drugs. In short, they could take significant steps towards a rational use of drugs.

This of course requires a change in political will and a huge increase in the provision of resources (both human and financial) from the developed to the developing world.

The aim is Health for All by the year 2000. It is not an impossible dream.

#### ACKNOWLEDGEMENTS

The Rapporteur, in drawing up this Report, consulted a wide range of interested individuals, companies, organisations and institutions. She expresses her thanks to them all and especially the following:

1. The World Health Organisation, GENEVA
2. The international Federation of Pharmaceutical Manufacturers Associations (IFPMA), GENEVA
3. Health Action International, the HAGUE
4. The Bureau of European Consumers Organisations (BEUC), BRUSSELS
5. The European Federation of Pharmaceutical Industries Association, BRUSSELS
6. COMHLAMH (Association of Irish Returned Development Workers), DUBLIN
7. WAR ON WANT, LONDON
8. 'THE OBSERVER' Newspaper, LONDON
9. TROCAIRE, DUBLIN
10. The Association of the British Pharmaceutical Industry, LONDON
11. OXFAM, LONDON
12. BBC Radio 4, LONDON
13. The Government of the Republic of Kenya
14. The Irish Embassy, NAIROBI
15. Medecins Sans Frontières, PARIS

MOTION FOR A RESOLUTION, Rule 47  
tabled by Ms QUIN and Mr ADAM  
on the export of drugs from the EEC to the  
countries of the Third World (doc. 2-565/84)

THE EUROPEAN PARLIAMENT,

- A - recognising the importance of the EEC in the world trade in drugs,
  - B - concerned at reports that Third World countries, as a result of drug companies' marketing methods, often purchase inessential yet expensive drugs instead of essential (and often cheaper) ones,
  - C - noting with approval the example of the Bangladeshi government which, in 1982, announced a new drug policy giving priority to drugs essential for public health needs,
  - D - considering that the European Community, by virtue of its aid and trade programme, needs to do all it can to help promote improved standards of health care and the treatment of diseases in the Third World,
  - E - concerned that manufacturers do not always seem to apply the same standards in drug sales to the Third World as those which they conform to in developed countries,
1. Calls on its competent Committee to examine the situation on the world drug market as it affects developing countries and to put forward proposals to enable the Community to make an effective contribution to rational drug use in the Third World;
  2. Instructs its President to forward this resolution to the Commission and Council.

OPINION  
(Rule 101 of the Rules of Procedure)  
of the Committee on Development and Cooperation  
Draftsman: Mr Anthony Simpson

On 18 December 1984, the Committee on Development and Cooperation appointed Mr Simpson draftsman of the opinion.

The Committee considered the draft opinion at its meetings of 24 April 1985 and 22 May 1985. It adopted the draft opinion on 22 May 1985 by 17 votes to 1 with no abstentions.

The following took part in the vote: Mr Bersani, vice-chairman, acting chairman; Mr de Courcy Ling, vice-chairman; Mr Simpson, draftsman; Mr Baget Bozzo, Mrs Barbarella (deputising for Mr Pajetta); Mrs Cinciari Rodano, Mrs De Backer-Van Ocken, Mr Jackson, Mr Lemmer, Mr Luster, Mr d'Ormesson, Mr Prout (deputising for Mrs Daly); Mrs Rabbethge, Mrs Schmit, Mrs Simons, Mr Trivelli, Mr Ulburghs (deputising for Mr Pannella); Mr Verbeek.

A.

The Committee on Development and Cooperation

- having regard to the motion for a resolution tabled by Mrs Quin and Mr Adam on the export of drugs from the EEC to the countries of the third world (Doc. 2-565/84),

- A. Noting that developing countries are overwhelmingly dependent for drug requirements on imports from industrialised countries,
  - B. Having regard to resolution adopted on 17 May 1984 by the World Health Assembly in Geneva calling for a meeting of experts to be held in 1985 to discuss ways of ensuring the rational use of medicines and the role of marketing practices in this field, particularly in the developing countries,
  - C. Noting that the European Community is by far the largest exporter among the industrialised countries of pharmaceutical products to the Third World,
  - D. Noting that aggressive sales campaigns conducted by certain pharmaceutical companies may encourage developing countries to import expensive, non-essential drugs,
  - E. Noting that the World Health Organisation has prepared a list of some 220 essential medicines as part of its Action Programme on Essential Drugs,
  - F. Noting that in 1982 the government of Bangladesh formulated a new drug policy giving priority to drugs deemed essential for health needs,
1. Calls for full exchange of information with the authorities in developing countries concerning drugs banned or severely restricted in any of the Community Member States;
  2. Proposes that developing countries, particularly the least developed, should be encouraged to give priority to imports of those drugs deemed most essential, and for this purpose to draw up lists thereof;

3. Commends the W.H.O. Certification Scheme of Pharmaceutical Products moving in International Commerce as a useful method of guaranteeing the quality of drugs and urges importing developing countries to make more use of its provisions;
4. Insists on drugs manufactured for export being produced to the same standards as drugs intended for sale in the country of manufacture;
5. Calls on drug producers to label all medicines exported to developing countries clearly, in a way understandable to those concerned, and insists on indications and counter-indications being indicated as fully as on drugs intended for use in industrialised countries;
6. Notes that in 1981 the International Federation of Pharmaceuticals Manufacturers' Associations (IFPMA) drew up a voluntary code of marketing practice with regard to drug exports, but regrets that reports indicate that this code has not been fully effective due to inadequate monitoring;
7. Consequently requests the Committee on the Environment, Public Health and Consumer Protection and the Commission of the European Communities to take all necessary steps to ensure a more effective international code of conduct for drug exports to developing countries, in particular with regard to marketing practices, advertising and labelling; a firm timetable should be established for the entry into force of this code of conduct;
8. Notes that such a code of conduct could not be effective unless it were established on an international basis under the aegis of a body such as the World Health Organisation, and in consultation with the pharmaceutical companies concerned;
9. Calls on the Commission and Council of the European Communities and the ACP-EEC institutions to support the efforts of UNIDO to develop pharmaceutical industries in the third world, inter alia by favouring the formation of joint ventures, where appropriate, between Community and ACP companies operating in the pharmaceutical sector;

10. Notes with approval that one of the sub-programmes in the research programme "Science and Technology for Development" is concerned with medicine, health and nutrition in the tropical zones; asks that further programmes of this nature will be initiated in the future;
11. Believes that in developing countries priority should be given to primary public health care, especially vaccination and immunisation, disease prevention and eradication, and education in health and hygiene; feels that the pharmaceutical companies should be encouraged to make a particular effort to develop appropriate low-cost drugs of high standard, while noting that many already do so, and asks the Committee on the Environment to monitor the follow-up;
12. Believes that the use of traditional medicines can make an important contribution to health in developing countries, and that the production of such medicines should be encouraged.

## I. Introduction

The European Community is a major drug producer and exporter, being responsible for some 25% of world drug production and 50% of world trade in pharmaceuticals. In 1983, the last year for which statistics are available, the Community exported pharmaceutical products and medicines to a value of 5329 mECU, of which 49% (valued at 2613 mECU) were exported to developing countries.<sup>(1)</sup> It should be emphasised, however, that the European Community is not by any means the only major drug exporter. During the same year the US exported drugs valued at 643 mECU to developing countries, while exports from Switzerland and Japan to the third world amounted to 479 mECU and 142 mECU respectively.<sup>(2)</sup> In addition COMECON exports drugs to the developing world, as do other non-Community European countries.

The third world has a growing need of drugs, both in the form of human and veterinary medicines. An overwhelming proportion of these products, some 89%, are produced in industrialised countries. Most are manufactured by major drug companies, many of which are organised on a transnational basis. It is obvious that drug companies can only continue to operate if they make an overall profit on their operations, and that manufacturing costs, as well as research and development expenses, must be recovered from sales.

At the same time as a growing number of developing countries are experiencing food crises connected with drought and the spread of desertification, obliging them to devote an increasingly higher proportion of national income to food imports, the need for drugs increases as the health situation of the population deteriorates. Meanwhile less finance is available for drug purchases. Under these circumstances developing countries have to make difficult decisions regarding what drugs should be purchased.

Many observers of developing countries, and most particularly of the poorest LDCs, have commented on hospitals and health centres operating without medicines. This is generally due to lack of hard currency with which to import pharmaceutical products. At the same time certain drug companies have encouraged the authorities in developing countries to purchase a very wide range of pharmaceuticals at considerable cost.

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(1) Source Eurostat

(2) Source COMTRADE (UNO Geneva)



In 1982 the government of Bangladesh formulated a new drug policy which gave priority to a restricted list of essential drugs, while restricting imports of what were considered inessential, which were generally among the more expensive products.

The World Health organisation (WHO) has drawn up a list of some 220 essential medicines which - if used rationally and effectively as part of an overall national health strategy - would help to overcome the most serious health problems caused or aggravated by lack of medicines in developing countries. All these drugs are of proven therapeutic value, but should nevertheless only be prescribed when really necessary. Over 95% of these drugs can be produced as off-patent generic medicines instead of expensive branded drugs, and bulk purchasing can reduce costs still further. The Committee on Development and Cooperation sees the logic behind the establishment of lists of essential priority drugs by poor third world countries, while recognising that the circumstances vary from country to country according to the overall health situation and the availability of foreign exchange.

It is the Committee's belief that priority must be given to primary public health care including vaccination and immunisation, disease prevention and eradication and education in health and hygiene. The development of low-cost pharmaceutical products required therefor should be accorded a particular priority by drug manufacturers.

The Committee on Development and Cooperation feels strongly that drugs produced for export must be made to the same standards as drugs intended for sale in the country of manufacture. It is not acceptable to sell drugs in third world countries that would be banned in the industrialised world. Most of the major Community drug producers are members of the International Federation of Pharmaceuticals Manufacturers' Associations (IFPMA). In 1981 this organisation drew up a voluntary code of marketing practice according to which signatories undertake "to ensure that all products .... have full regard to the needs of public health". In addition, members are required to "provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contra-indications, tolerance and toxicity." In practice it would appear that this voluntary code is not monitored or enforced, and that abuses in drug marketing continue, even by companies that have agreed to the IFPMA code.

The Committee on Development and Cooperation sees the need for an effective and adequately-monitored code of conduct for companies exporting pharmaceutical products to ensure against

- i) excessively aggressive sales campaigns in favour of expensive non essential drugs
- ii) the exportation of sub-standard drugs and products that, for long-term health reasons, are not permitted in industrialised countries
- iii) inadequate or misleading indications or labels, as well as indications and/or labels that are not readily understood by drug users;

It must be pointed out however, that, though a major source of drugs for export to the third world, the European Community is by no means the only exporter (see first paragraph of this explanatory statement). It is thus not possible for the European Community acting in isolation to prevent abuses by drug exporters. Furthermore, as most of the major drug companies are transnational, if restrictions were to be imposed on a company's operations from the European Community, it would be easy for the same company to continue manufacturing restricted drugs for export in its factories situated outside the Community. It is thus necessary for a more effective code of conduct for pharmaceutical marketing to be drawn up

- (i) in close collaboration with the companies concerned
- (ii) on a broad international basis, under the aegis of a body such as the World Health Organisation.

Medicines which have been banned in Europe sometimes continue to be exported to developing countries. The Committee on Development and Cooperation believes that the authorities of developing countries should be fully informed when any drugs are banned or severely restricted in a Member State. Such information should be provided before these products are exported, along with the reasons for imposing restrictions.

Some of the problems could be solved if more drugs were produced in developing countries. At present only 11% of world pharmaceutical production is carried out in developing countries, and this is mostly concentrated in the more developed third world nations, particularly Brazil, India, Mexico, Egypt, Argentina, Colombia and Venezuela. Most of this industrial activity consists of

further processing or packaging of products imported in bulk. The U.N. Industrial Development Organisation (UNIDO) has prepared a programme to foster the development of the pharmaceutical industry in the Third World, but little has been achieved to date. It is essential that the pharmaceutical industry in the third world should concentrate on the production of drugs deemed essential. The Community institutions should encourage this initiative, perhaps by favouring joint ventures between Community and ACP industries through the good offices of the Centre for Industrial Development.

In conclusion the Committee on Development and Cooperation recognises the value of lists of priority drugs for the poorer developing countries, with corresponding restrictions on expensive non-essential medicines, and calls on the Committee on the Environment, Public Health and Consumer Protection to examine the situation of the world drug market as it affects developing countries, to investigate the means whereby a more effective and adequately monitored international code of conduct can be established, and to put forward proposals to enable the Community to make a positive contribution to rational drug use in the third world.