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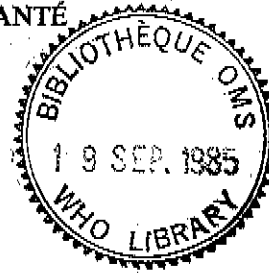
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Agenda item 2



THE WHO CERTIFICATION SCHEME ON THE QUALITY OF
PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE

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THE WHO CERTIFICATION SCHEME ON THE QUALITY
OF PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE

OBJECTIVES OF THE SCHEME

1. 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 marketed under their aegis. Where there is no independent quality control laboratory, sub-standard, degraded or even spurious products will remain undetected, and where there is no effective system of drug registration the sale of unlicensed and mislabelled products will remain unchallenged.

2. These deficiencies can be corrected in locally manufactured products only by upgrading 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 purposes, it is available in the domestic market.

3. Such assurances are important because in some countries drugs intended for export are not necessarily subjected to the same control procedures as those produced for domestic use. In general, more comprehensive assurances can be offered for products that are both registered and sold in the country of origin, than for unregistered products or supplies manufactured to the specification of the importing agent. Moreover, a valid assurance is obtainable only when the product is exported from the manufacturer directly to the importing agent.

4. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (Annex 1), which was adopted in its present form in 1975 by the Twenty-eighth World Health Assembly, extends and unifies various schemes previously operated by some drug-exporting countries which issued so-called "free-sale" certificates on request to foreign importers in respect of registered products that had been subjected to control. 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 WHO

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

5. Whereas the Scheme imposes specific obligations and responsibilities on governmental authorities in exporting countries in connection with inspection of manufacturing premises, sampling of finished products, and enforcement of internationally recognized standards of manufacturing practice, countries that do not export drugs are invited to notify their participation in the Scheme exclusively as importers without such commitment.

OTHER UN INITIATIVES BEARING UPON THE EXPORT OF PHARMACEUTICAL PRODUCTS

6. Coincidentally with the promulgation of the WHO Certification Scheme the United Nations General Assembly became engaged in a protracted and, as yet, ongoing debate on products harmful to health and the environment with special reference to exported pharmaceutical products. One of the consequential resolutions, GA37/137 (Annex 2), addresses two practices that the Certification Scheme is intended to prevent, namely:

- "the continued production and export of products that have been banned and/or permanently withdrawn on grounds of human health and safety from domestic markets."
- "the export of pharmaceutical products ultimately intended also for consumption and/or sale in the home market of the exporting country, but which have not yet been approved for use there."

7. The resolution calls upon countries to ensure:

- that products banned from domestic consumption and/or sale on grounds of safety are sold abroad only upon the request of the importing country or when the consumption of such products is officially permitted in the importing country
- that full information, including clear labelling in a language acceptable to the importing country, is provided for products that are either severely restricted or not approved for domestic consumption and/or sale.

8. In addition the Secretary-General is requested to strengthen the national capabilities of developing countries to identify such products by ensuring the provision of the necessary information and assistance by the United Nations system and, in particular, by preparing and regularly updating a consolidated list of products that have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by governments.

9. The first of these consolidated lists⁽¹⁾ was prepared in English by the UN Secretariat in December 1983. It will now be issued in six of the working languages of the UN system and regularly updated in a biennial cycle. Formal responsibility for the listing and annotation of pharmaceutical substances is now accorded to WHO which will rely for notifications primarily on its network of designated national information officers. The list will thus derive from and complement the monthly compendia of regulatory decisions currently issued by WHO to all national drug regulatory authorities (see working paper WHO/CONRAD/WP/1.2).

IMPLEMENTATION OF THE CERTIFICATION SCHEME

Participation in the Scheme

10. In 1980, five years after the promulgation of the Scheme, less than one-third of the Member States of WHO had formally notified the Organization of their intention to participate. The World Health Assembly in that year approved a Secretariat proposal to review its operation.⁽²⁾ Since then a questionnaire has

(1) Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments. UN, New York, 30 December 1983.

(2) Proposed Programme Budget 1982-1983, p. 143, WHO, Geneva, 1980.

been issued to governments, consultants have visited 13 representative countries in four regions, recommendations for extension of the Scheme have been formulated by the Third International Conference of Drug Regulatory Authorities,⁽¹⁾ an informal consultation has been convened to discuss these recommendations and guidelines on the implementation of the Scheme are being drafted. These activities have themselves stimulated interest in the Scheme to the extent that, to date, 110 Member States have advised WHO that they are actively participating.

11. The questionnaire, which was issued to all governments in 1983, elicited 87 replies.⁽²⁾ These showed that more countries utilized the Scheme than had formally acceded to it. Others, nominally participating, had apparently never used it. A total of 116 countries were reported to have requested certificates from the 47 exporting countries that provided relevant information.

12. Although the original intention of the Scheme was to assist the flow of information to developing countries it was most extensively used between countries within the European region. Countries within Europe, the Americas and the Eastern Mediterranean region had generated between them about 65% of the requests for certificates.

13. In contrast, countries within the African region used the Scheme least. It is relevant that six of the 22 countries from this region that responded to the questionnaire had yet to introduce a national drug registration system. In others, there was an apparent dissociation between the agencies responsible, respectively, for drug procurement and drug control.

14. Overall, however, more certificates were issued year by year. The aggregate of requests received by the 47 exporting countries contained within the sample increased from 15 000 in 1978 to 27 000 in 1982. This trend may be expected to continue because several countries are committed to introduce statutory provisions for certification of imported drugs. Seventeen countries from four regions indicated that they had already introduced such requirements or were in the process of promulgating them. Among these are five developed countries from the European region.

Circumstances in which certificates are provided

15. Only 27 of 51 exporting countries that responded to the questionnaire explicitly confirmed that they issued certificates in full conformity with the WHO Scheme. Six others acknowledged that their procedures differed from those proposed but in only one instance were details offered. In this case the attestation related only to the registration status of the product and not to inspection of manufacturing premises. It remains uncertain in what particulars certificates issued by the remaining countries differed from the WHO format.

16. A majority of exporting countries (36 of 51) did not require drugs intended exclusively for export to be submitted to a registration procedure. However, at least some of these authorities assessed and registered such products at the

(1) Proceedings of the Third International Conference of Drug Regulatory Authorities, 11-15 July 1984, Stockholm, Sweden. Swedish National Board of Health and Welfare, WHO, Geneva (in press).

(2) Slight perturbations in the size of the samples cited arise because some governments did not respond to all items in the questionnaire.

request of the manufacturer, in which case full certificates were issued. Among the 13 countries that did make specific provision in this regard, the regulations were varied:

- In one instance registration was limited to preparations that differ only in strength from products registered domestically.
- In another, registration was conditional upon receipt of a specific order from an importing country; lack of any reason to believe that the product would have been refused registration for domestic sale on grounds of quality, efficacy or safety; and adequate assurance that the product satisfied required pharmacopoeial specifications and any other criteria imposed by the importing country.

17. Although the Scheme refers to the issuance of batch certificates providing the results of a full, independent analysis of a sample of a specific consignment and offering an attestation that the consignment conforms to the declared specification, most exporting countries find this commitment impracticable and place the responsibility for these analyses on the manufacturer. However, a few countries newly entering into an export trade in pharmaceutical products have accepted to implement this provision, at least in selected circumstances, to provide additional independent assurance on the performance of manufacturers attempting to establish a reputation internationally.

Circumstances in which certificates are requested

18. Twelve countries among 72 that used the Scheme primarily for importation required a certificate on each occasion an order was placed for a consignment of a product. A more common requirement, operative in more than half of these countries, was to request certification (either routinely or on a selective basis) on the first occasion that a product is imported. Among these, seven countries required recertification as a condition of renewal of product registration. The period of validity of product licences within these countries ranged from three to 15 years. Ten countries cited special situations in which certificates were required on a non-routine basis, and 21 had occasionally requested additional information as provided for within the Scheme. Several authorities in exporting countries commented that they occasionally received requests for information on manufacturers that they considered to be extraneous to the implementation of the Scheme.

19. Only eight of the 72 importing countries routinely requested product certificates directly from the regulatory authority in the country of manufacture. The remainder obtained them either through the importing agent or the manufacturer. However, returns from exporting countries suggested that a higher proportion of requests was submitted directly to the competent regulatory authority.

20. Batch certificates were requested on a routine or selective basis by more than half (41 of 71) of the importing countries within the sample. A higher proportion (46 of 71) commissioned independent laboratory analyses of products on or prior to importation and, of these, 10 authorities arranged for this work to be undertaken abroad. Thirty-seven drug exporting countries were prepared to arrange for these analyses to be performed in independent quality control laboratories at the request of the importing countries on a charge for service basis.

THE PERFORMANCE OF THE SCHEME

21. The results of the questionnaire, the country visits, and discussions within the Third International Conference of Drug Regulatory Authorities (ICDRA 3) and

within informal consultations, have resulted in a consensus on broad issues of principle. It has been generally accepted that a system of independent certification of pharmaceutical products moving in international commerce is of value to all countries, and not only those lacking comprehensive administrative and laboratory facilities for drug control. It is evident, however, that the Scheme is not functioning effectively in all countries. Moreover, reports of the alleged infiltration of counterfeit drugs, commonly labelled as antibiotics, into some developing countries, underscores the need for substantial improvement in current standards of control. The reasons are manifold.

22. Some countries still lack the prerequisite administrative infrastructure for drug control. Some have no national registration system for pharmaceutical products. Others do not coordinate drug procurement with drug control. Sustained promotion of the Scheme is evidently necessary - even where it may previously have been operated to useful effect - particularly in countries with small national regulatory authorities and a high turnover of staff.

23. The formal language of the Scheme requires interpretation in simplified guidelines that are now in preparation and that will discuss not only the provisions of the Scheme but also the administrative structure required for its implementation, the circumstances in which certificates are of greatest value, the arrangements now in operation internationally for independent analyses of samples, the value of a national quality control laboratory, and the relationship between the Scheme and other systems of exchange of information operated under the aegis of WHO.

24. Some exporting countries that have formally notified WHO of their intention to participate have, on occasion, issued certificates that make no allusion to the WHO Scheme. Certificates have sometimes been difficult to interpret and, on occasion, they have proven to be unreliable in so far, for example, as they have provided no explicit assurance regarding inspection of manufacturing premises.

25. Ambiguities and misunderstandings have arisen because drug registration or licensing differs conceptually and operationally in different countries. Moreover, communications between competent national authorities have sometimes failed, either because the names and addresses of competent authorities are published in the official working languages of WHO rather than in the relevant national language, or because exporting countries with a federal structure do not identify the competent authority of each constituent state.

26. Competent authorities in importing countries are either reluctant to challenge an apparent misrepresentation or uncertain how to resolve a consequential dispute. The Scheme envisages resolution of disputes by direct negotiation, but countries have felt obliged, on occasion, to refer to WHO as an adviser or mediator.

27. Regulatory authorities in exporting countries are evidently best placed to provide information on products that are both registered and sold in the country of origin. When a product is not registered under their aegis they may be able to offer little more than an attestation that the manufacturer is regularly inspected and is permitted to manufacture products of the nature specified in the certificate. However, two categories of unregistered products are of particular importance and merit further consideration:

- generic products commissioned to be manufactured in response to a tender issued by, or on behalf of, a foreign agency
- products for which no market and/or no indication exists in the country of origin.

28. A product manufactured on commission in response to an international tender is made to the express specification and requirement of the importing agency. The same item may be available in the manufacturer's normal product range, but this is not necessarily so. Moreover, the packaging and labelling requested by the importer may differ from those specified in the product licence. In this case it is for the authority in the exporting country to detail in the certificate those respects in which the product, as ordered, differs from its licensed counterpart. By the same token, it is for the competent authority in the importing country to determine, on the basis of this information, whether to commission an independent analysis of the product, and to review any discrepancies in packaging and labelling requirements, and associated product literature. It is also important for the authority in the importing country to realize that the Certification Scheme provides an assurance on a product or a consignment only up to the moment that it leaves the safe keeping of the manufacturer. Once a third party becomes involved as a broker or procurement agency, the transaction has to be undertaken on the basis of trust rather than attestation, in that the reputation of the immediate supplier becomes the decisive consideration for the importing country.

29. The apportionment of responsibility between the competent authorities in the exporting and importing countries raises more complex considerations in the case of a catalogued product offered for export by a manufacturer, and for which no market exists in the country of origin. Legislative approaches to the export of such products differ among the major drug exporting countries. These range from debarring from export products not registered for use on the domestic market, through various provisions for the export of unlicensed products (subject to various safeguards particularly in relation to attestation of quality and provision of information), to registration of products specifically and exclusively for export markets. In exercising the last of these options a national regulatory authority is faced with a conflict of interest in so far as the certifying authority is acting at the behest of the exporting company rather than the importing authority, in which case the resulting certificate might reasonably be perceived as promotional rather than regulatory in concept.

30. There are, none the less, situations - exemplified by the regulatory status of piperazine and injectable contraceptives - in which a preparation withdrawn or unregistered in the country of origin on grounds of safety may be regarded by other countries as having important utility.^(1,2) Less developed countries thus need to have recourse to authoritative, independent, internationally representative advice. This falls within the constitutional mandate of WHO. In creating its major research-based programmes concerned with tropical and diarrhoeal diseases and human reproduction, the World Health Assembly has cast the Organization in the role of an impartial technical adviser on certain categories of drugs and vaccines, and particularly those of strategic importance in developing countries. The practical significance of WHO's international status in this regard has been indelibly established in the elimination of smallpox. Unless its counsel is heeded on the registration and use of drugs crucial to the control of the major transmissible diseases, as now in the case of the new antimalarial compound mefloquine, the prodigious effort involved in bringing such substances into medicinal use could be rapidly and irretrievably dissipated.

(1) Piperazine and nitrosation. WHO drug information, 83.1, pp. 5-7.

(2) Injectable contraceptives. WHO drug information, 84.2, pp. 7-11 and 84.3, pp. 7-12.

POSSIBILITIES FOR FURTHER DEVELOPMENT OF THE SCHEME

31. The WHO Certification Scheme is dependent upon acceptance by exporting countries of the obligations they incur as participants. It can operate effectively only if trust is developed between the authorities of the importing and exporting countries. It is inevitable that, occasionally, the quality of an imported product will be called into question. An explicit obligation is placed on the responsible authority of the exporting country to institute appropriate inquiries on request.

32. An essential distinction between the WHO Scheme and, for instance, the Pharmaceutical Inspection Convention⁽¹⁾ operated under the auspices of the European Free Trade Association, is that the capacity of a country to meet the stated requirements for exportation is determined autonomously by its own administration, rather than by an international body. The Scheme thus devolves directly from the existing legal and administrative powers and responsibilities of national drug regulatory authorities. There is no provision, either within the Scheme itself or within the mandate of WHO, to create an international inspectorate force or independent arbitration procedures to supervise its implementation. Nor does the Scheme create or anticipate any mechanism for external inspection of manufacturing facilities by officials from importing countries. Any such arrangements, should they materialize, must evolve from bilateral or multilateral agreements and undertakings outside the ambit of the WHO Scheme.

33. The prime responsibility of the competent authority in the exporting country is to attest that a given product has been produced in accordance with internationally accepted standards of manufacturing practice. As yet, although a declaration is also required as to whether or not the product is registered in the exporting country, no details are specifically requested of any attendant conditions or restrictions. At the time the Scheme was conceived in the early 1970s few national regulatory authorities had developed a system of approving product information including labelling, prescribing information and promotional material.

34. Now, most highly evolved authorities include within the licence of newly registered products details of the indications, dosage, contraindications, warnings, precautions and known adverse reactions to which all product-related information, including advertising material and promotional activities, should conform. The Third International Conference of Drug Regulatory Authorities (ICDRA 3) consequently recommended that the Scheme be extended, by formal amendment, if necessary, to include provision of product information approved in the country of origin. Since most countries have yet to review all longer established pharmaceutical products currently marketed under their aegis, an effective system of attestation of information would need to confirm that the information had been approved by the certifying authority and to indicate the date of approval.

35. ICDRA 3 also stressed the importance of complementing the certification procedure with:

- more systematic exchange of information on the results of formal reviews of marketed drugs undertaken by national regulatory authorities

(1) Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products. Geneva, European Free Trade Association, 1970.

- periodic status reports on the categories of drugs that have been reviewed by each national authority and on those that are pending for assessment.

Effective international exchange of this information will directly assist regulatory authorities in their responsibility of revising labelling requirements and removing from national markets products that do not conform with prevailing standards of efficacy and safety. It could also relieve many national authorities of a substantial technical and administrative burden by reducing the need for independent and duplicative reviews.

36. The Certification Scheme, as it now stands, is concerned exclusively with finished pharmaceutical products. As a consequence of the growth of local manufacturing capability in many developing countries the feasibility of extending the Scheme to embrace active ingredients has been raised within several countries. Whereas a start has been made in some countries to license ingredients as well as finished products, this remains the exception rather than the rule. Indeed, in some major exporting countries the relevant enabling legislation makes no provision for licensing anything other than the finished pharmaceutical products. At present, therefore, local manufacturers need to place reliance in the reputation of their suppliers, in the published pharmacopoeial specifications, and in their own responsibility of ascertaining through full analyses the compliance of all active ingredients with stated specifications. None the less, independent certification of these materials, in so far as it proves to be feasible, could offer an important contribution to quality assurance and the possibility of extending the Scheme in this context will remain under review.



2. CERTIFICATION SCHEME ON THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE

Part I — Certification of Pharmaceutical Products

1. For the purpose of this Certification Scheme "pharmaceutical product" means any medicine in its finished dosage form, intended for human use, that is subject to control by legislation in the exporting Member State and in the importing Member State.

2. A pharmaceutical product exported or imported under this Certification Scheme would be certified by the competent authority of the exporting Member State on a Certificate of Pharmaceutical Products, issued at the request of the interested party, to be sent to the competent authority of the importing Member State, which would decide to grant or to refuse the authorization for sale or distribution of the certified product, or to make the authorization conditional on the submission of supplementary data.

3. The issue of the Certificate of Pharmaceutical Products would be subject to the conditions required by the competent authority of the exporting Member State in order to certify that:

(a) the product is authorized for sale or distribution within the exporting Member State (if not, the reasons therefore would be stated on the certificate); and

(b) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals to show that the manufacturer conforms to requirements for good practices in manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported.

A suggested layout of a Certificate of Pharmaceutical Products with explanatory notes is attached.

4. If certificates of individual batches of products covered by a Certificate of Pharmaceutical Products are required, such certificates could be issued either by the manufacturer or by the competent authority of the exporting Member State, according to the nature of the product and the requirements of the exporting Member State or of the importing Member State. The batch certificate would indicate the name and dosage form of the product, the batch number, the expiry date and storage conditions, a reference to the Certificate of Pharmaceutical Products, and a statement that the batch conforms either to the requirements of the competent authority for sale or distribution within the exporting Member State (with reference to the authorization) or, as the case may be, to published specifications, or to established specifications to be provided by the manufacturer. The

certificate could also include data on packaging, labelling, nature of the container, the date of manufacture, results of analysis, and other data.

Part II — Exchange of Information

1. Upon the request of the competent authority of the Member State into which a pharmaceutical product covered by this Certification Scheme is to be or has been imported, the competent authority of the exporting Member State should provide:

(a) information on the implementation of the Requirements for Good Practices in the Manufacture and Quality Control of Drugs as recommended by the World Health Organization;¹

(b) information on controls of the product as exercised by the competent authority of the exporting Member State;

(c) the names and functions of the persons designated to sign certificates of individual batches of the product to be exported.

Information on general and specific standards of quality control of the product to be exported, in so far as they are required to comply with legislative provisions of the importing Member State, could also be supplied with the consent of the manufacturer.

2. In the case of quality defects of products imported under this Certification Scheme that are considered to be of a serious nature by the importing country, not attributable to local conditions and circumstances, and appearing after the introduction of a particular batch into the importing Member State, the competent authority should notify the occurrence, together with the relevant facts, to the competent authority of the exporting Member State that had issued the Certificate for the product concerned, with a request to institute inquiries. Conversely, if the competent authority of the exporting Member State ascertains serious quality defects, that competent authority should notify the competent authority of the importing Member State.

Part III — Participating Member States

1. Each Member State agreeing to participate in the Certification Scheme shall communicate (a) the name and address of its principal authority to be considered as competent within the meaning of the

¹ It is realized that in some countries this may require the consent of the manufacturer.

Certification Scheme, and (b) any significant reservations relating to its participation, to the Director-General of the World Health Organization, who would notify all other Member States.

2. Exporting Member States participating in the Certification Scheme shall ensure that:

- (a) authorization for sale or distribution of pharmaceutical products is subject to appropriate testing measures, by the competent authority, designed to ensure their quality, and that adequate laboratory facilities are available for this purpose;
- (b) the pharmaceutical industry is obliged to conform to requirements for good practices in the manufacture and quality control of drugs as recommended by the World Health Organization;

(c) the competent authority is empowered to conduct appropriate investigations to ensure that manufacturers conform to the requirements referred to in (b), including, for example, the examination of records and the taking of samples;

(d) the inspectors of the services of its competent authority have appropriate qualifications and experience.

3. Exporting Member States participating in the Certification Scheme should, whenever possible, ensure that the international nonproprietary names, whenever available, are used in the description of the composition of the product on the Certificates and, as far as possible, appear on the labelling of pharmaceutical products to be exported under the Certification Scheme.

CERTIFICATE OF PHARMACEUTICAL PRODUCT(S)¹

Name and dosage form of product:

Name and amount of each active ingredient:²

Manufacturer, and/or when applicable, the person responsible for placing the product on the market:

Address(es):

It is certified that:

This product has been authorized to be placed on the market for use in this country.

Number of permit and date of issue (if applicable):

This product has not been authorized to be placed on the market for use in this country for the following reasons:

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It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals, and (b) the manufacturer conforms to requirements for good practices in the manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported. (See Explanatory Notes.)

(Signature of designated authority)

(Place and date)

Explanatory Notes

Certificate of Pharmaceutical Product(s)

This certificate is intended to define the status of the pharmaceutical product and its manufacturer in the exporting country. It is issued by the competent authority in the exporting country in accordance with the requirements of the competent authority of the importing country. It may be required by the importing country at the time of the first importation and subsequently if confirmation or updating is required.

The requirements for good practices in the manufacture and quality control of drugs mentioned in the certificate refer to the text adopted by the Twenty-eighth World Health Assembly in its resolution WHA28.65 (see Official Records No. 226, Annex 12, Part 1).

Batch certificates

If certificates of individual batches of products covered by a Certificate of Pharmaceutical Products are required, such

certificates could be issued either by the manufacturer or by the competent authority of the exporting Member State, according to the nature of the product and the requirements of the exporting Member State or of the importing Member State. The batch certificate would indicate the name and dosage form of the product, the batch number, the expiry date and storage conditions, a reference to the Certificate of Pharmaceutical Products and a statement that the batch conforms either to the requirements of the competent authority for sale or distribution within the exporting Member State (with reference to the authorization) or, where appropriate, to published specifications or to established specifications to be provided by the manufacturer. The certificate could also include data on packaging, labelling, nature of the container, the date of manufacture, results of analysis, and other data.

¹ This form may be adapted to cover several products of the same manufacturer.

² Use, whenever possible, international nonproprietary names (INN) or national nonproprietary names.

37/137. Protection against products harmful to health and the environment

The General Assembly,

Aware of the damage to health and the environment that the continued production and export of products that have been banned and/or permanently withdrawn on grounds of human health and safety from domestic markets is causing in the importing countries,

Aware that some products, although they present a certain usefulness in specific cases and/or under certain conditions, have been severely restricted in their consumption and/or sale owing to their toxic effects on health and the environment,

Aware of the harm to health being caused in importing countries by the export of pharmaceutical products ultimately intended also for consumption and/or sale in the home market of the exporting country, but which have not yet been approved there,

Considering that many developing countries lack the necessary information and expertise to keep up with developments in this field,

Considering the need for countries that have been exporting the above-mentioned products to make available the necessary information and assistance to enable the importing countries to protect themselves adequately,

Cognizant of the fact that almost all of these products are at present manufactured and exported from a limited number of countries,

Taking into account that the primary responsibility for consumer protection rests with each State,

Recalling its resolution 36/166 of 16 December 1981 and the report on transnational corporations in the pharmaceutical industry of developing countries,¹ and acting in pursuance of Economic and Social Council resolution 1981/62 of 23 July 1981,

Bearing in mind in this context the work of the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organisation, the United Nations Environment Programme, the General Agreement on Tariffs and Trade, the United Nations Centre on Transnational Corporations and other relevant intergovernmental organizations,

1. *Agrees* that products that have been banned from domestic consumption and/or sale because they have been judged to endanger health and the environment should be sold abroad by companies, corporations or individuals only when a request for such products is received from an importing country or when the consumption of such products is officially permitted in the importing country;

2. *Agrees* that all countries that have severely restricted or have not approved the domestic consumption and/or sale of specific products, in particular pharmaceuticals and pesticides, should make available full information on these products with a view to safeguarding the health and environment of the importing country, including clear labelling in a language acceptable to the importing country;

3. *Requests* the Secretary-General to continue to ensure the provision of the necessary information and assistance by the United Nations system in order to strengthen the national capacities of developing countries to protect themselves from the consumption and/or sale of banned, withdrawn, severely restricted or, in the case of pharmaceuticals, non-approved products;

4. *Requests* the Secretary-General, based upon the work already being done within the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organisation, the United Nations Environment Programme, the General Agreement on Tariffs and Trade, the United Nations Centre on Transnational Corporations and other relevant intergovernmental organizations, to the maximum extent possible within existing resources, to prepare and regularly update a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments, and to make this list available as early as possible and, in any case, not later than December 1983;

5. *Agrees* that the consolidated list referred to in paragraph 4 above should be easy to read and understand and should contain both generic/chemical and brand names in alphabetical order, as well as the names of all manufacturers and a short reference to the grounds and the decisions taken by Governments that have led to the banning, withdrawal or severe restriction of such products;

6. *Decides*, on the basis of the above-agreed criteria, to keep under review the format of the consolidated list with a view to its possible improvement;

7. *Requests* Governments and the relevant organs, organizations and bodies of the United Nations system to provide all the information and assistance necessary for the prompt and effective fulfilment of the task entrusted to the Secretary-General.

*109th plenary meeting
17 December 1982*

¹ E/C.10/85.