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REPORT OF THE ECONOMIC AND SOCIAL COUNCIL

Exchange of information on banned hazardous chemicals and unsafe pharmaceutical products

Report of the Secretary-General

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* A/36/50.

I. INTRODUCTION

1. Concern has been expressed in various forums that many countries, in particular many developing countries, may not be able to put into effect adequate arrangements for the evaluation of the hazards to health and safety resulting from the growing use of various imported chemicals and pharmaceutical products and for the effective control of those found to present such hazards. Such products are being exported in increasing quantities from producing or intermediary countries to countries without adequate control measures, with possible adverse consequences for the health of the population or the environment in the importing country. This concern has found expression in the resolutions and work programmes of many international organizations and particularly in General Assembly resolutions 34/173 of 17 December 1979 and 35/186 of 15 December 1980, in response to which the present report is submitted, through the Economic and Social Council, to the Assembly.

2. At its thirty-fourth session, the General Assembly, in resolution 34/173, urged Member States to exchange information on hazardous chemicals and unsafe pharmaceutical products that had been banned in their territories and to discourage, in consultation with importing countries, the exportation of such products to other countries. The Assembly also requested the Secretary-General, in co-operation with the United Nations agencies and bodies concerned, especially the World Health Organization (WHO), to assist Governments in exchanging information and to submit a report to the Assembly at its thirty-fifth session, through the Economic and Social Council, about the experience of Member States and the United Nations agencies and bodies concerned.

3. In resolution 35/186, the General Assembly invited Member States to provide information on the measures they had taken to exchange information on hazardous chemicals and unsafe pharmaceutical products banned in their countries and requested the Secretary-General to submit to the Assembly at its thirty-sixth session the report called for in Assembly resolution 34/173, since it had not been possible to prepare it in time for the thirty-fifth session. In the same resolution, the Assembly requested the Commission on Transnational Corporations to study, at its seventh session, ways and means within the information system on transnational corporations of improving the exchange of information on such chemicals and products, with a view to formulating appropriate recommendations.

4. It may be mentioned in this connexion that the Governing Council of the United Nations Environment Programme (UNEP) had adopted relevant decisions at its fifth and sixth sessions, 1/ extracts from which appear in annex IV below.

5. As a preliminary step, it is necessary to determine the scope of control of the chemicals and drugs that can be practically envisaged in an exercise such as this without becoming involved in related problems covered elsewhere. Thus, for the

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1/ Official Records of the General Assembly, Thirty-second Session, Supplement No. 25 (A/32/25), annex I, decision 85 (V); and ibid., Thirty-third Session, Supplement No. 25 (A/33/25), decisions 6/3 B and 6/4.

purposes of the present report, the term "banned hazardous chemical" is interpreted to mean a chemical that has been significantly restricted for use in a particular country on the basis of a determination in such a country that the restricted uses of it are or may be hazardous. This interpretation recognizes that significant uses of such a chemical may not have been banned or deemed to be hazardous and that determination of hazard may vary from one country to another either because of differing views on what constitutes a hazard or because of differing national needs. Thus, such chemicals, although banned for certain uses may not be completely banned and may still be produced. In particular, they may be produced for export even when internal use is severely restricted. There is no ideal solution to this question; the balance between risks and benefits must be made in each country in accordance with priorities of the authorities concerned. An example would be the production of D.D.T., particularly for malaria control, a use which may not be significant in the producing country.

6. It is also assumed that no reference is made to chemical wastes, as they are usually intractable mixtures of unwanted chemicals of no value. Chemical wastes are the subject of a questionnaire sent by the Executive Director of UNEP to all countries in compliance with a request by the Governing Council in its decision 8/8 of 29 April 1980; 2/ the Economic Commission for Europe is also working on various aspects of this question.

7. Likewise, radioactive chemicals and wastes, since they present specific health hazards because of their radioactivity and not because of their chemical nature, are not dealt with in the present report. Problems of this kind are being fully considered by agencies specializing in the evaluation of radioactive hazards, such as the United Nations Scientific Committee on the Effects of Atomic Radiation and the International Atomic Energy Agency.

8. Precautions for the transport of hazardous chemicals constitute a separate problem, which is currently taken into account by the United Nations recommendations on the transport of dangerous goods, 3/ which are continuously being brought up to date. These include classification and labelling requirements for the purposes of safe transport and storage and could serve as a preliminary warning of potential hazards in relation to the risks involved. For very hazardous substances, such as sensitive explosives, special bilateral arrangements are expected to be made. These recommendations are used as a common basis, whatever the means of transport. Thus, the transport of hazardous chemicals by sea has been considered by the Inter-Governmental Maritime Consultative Organization (IMCO) (IMCO Marine Pollution Convention, 1973) and by the Joint Group of Experts on the Scientific Aspects of Marine Pollution (GESAMP) for the evaluation of possible pollution hazards from harmful substances carried by ships.

2/ Ibid., Thirty-fifth Session, Supplement No. 25 (A/35/25), annex I.

3/ For the latest edition, see Transport of Dangerous Goods; Recommendations Prepared by the Committee of Experts on the Transport of Dangerous Goods, revised ed. (United Nations publication, Sales No. E.77.VIII.1).

9. Thus, for "banned hazardous chemicals", the present report focuses on the relevant information received from countries and international organizations on hazardous chemicals that have had practical, limited bans imposed on their domestic production and use (while still available for export), and the information systems available for the purpose of informing importing countries, before shipments arrive on their territory, about the producing or exporting countries' restrictions, so that the importing countries may be in a position to take any action that they deem appropriate.

10. The term "unsafe pharmaceutical products" has been interpreted, for the purposes of the present report, as products which may be unsafe for a variety of reasons, such as deterioration of the pharmaceutical when it has been subject to conditions such as heat or time, which diminish its safety; or because claims for therapeutic effectiveness without dangerous side-effects have not been justified to the satisfaction of producer or other user countries; or because toxic by-products are present etc.

11. All these factors can be controlled by the use of the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, adopted by the World Health Assembly in its resolution WHA 28.65, in that exporting countries have to reveal all this information to the importing country, on request, as described in paragraph 19 below. Furthermore, WHO has made evaluations of pharmaceuticals, resulting in a list of essential drugs which, if applied in a country, provide a range of substances treating the large majority of common diseases and which could be used to limit the variety of drugs that would be imported.

II. PROBLEMS AND EXPERIENCE OF MEMBER STATES AND INTERNATIONAL ORGANIZATIONS

12. A note verbale was sent to Governments on 6 June 1980, in pursuance of General Assembly resolution 34/173, seeking information from them on their experience in the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products. A reminder was sent on 17 November 1980 and as at 10 February 1981 replies had been received from 28 countries. A similar note was sent to the international organizations in the United Nations system and replies have been received from those concerned most involved in this matter.

13. In most cases, the replies of Governments refer to multilateral international arrangements rather than to bilateral exchanges of information, which generally seem to occur on an ad hoc basis. In one case, however, there is a legislative mandate for the presentation of information to the importing country if the product is covered under various acts of that country dealing with toxic substances.

14. Some countries provided lists of banned chemicals or pharmaceuticals including substances under control or banned under the provisions of the Single Convention on Narcotic Drugs, 1961, 4/ or of the 1971 Convention on Psychotropic Substances. 5/ These international conventions are discussed further in paragraph 19 below.

4/ United Nations, Treaty Series, vol. 520, No. 7515, p. 204.

5/ United Nations publication, Sales No. E.78.XI.3, p. 7.

A. Banned hazardous chemicals

15. In connexion with banned hazardous chemicals, some countries mentioned that they would be willing to provide information upon request concerning such substances exported from their territories and one indicated that it had legislation requiring that, on export, information on such substances be furnished to importing countries. A number of countries mentioned in their replies the International Register of Potentially Toxic Chemicals (IRPTC), a programme activity centre of UNEP situated at Geneva, which has as a first priority the collection and dissemination of information on such substances. 6/ They suggested that, as IRPTC became fully operative, it would serve with its national networks as a focus for accumulating legal and other types of information on "banned" hazardous chemicals. Indeed, it commenced this work in 1977 with a regular bulletin containing information on chemicals that caused concern or had been banned in certain countries. In 1980, IRPTC produced a report entitled "Legal data profiles for selected chemicals of concern", covering 200 chemicals. The portions of the IRPTC programme relevant to fulfilling the intent of General Assembly resolution 34/173 are summarized in annex I below. A number of countries mentioned the International Programme on Chemical Safety situated at WHO headquarters at Geneva and jointly sponsored by the International Labour Organisation (ILO), UNEP and WHO. The Food and Agriculture Organization of the United Nations (FAO) is considering the possibility of joining the programme in the near future. When it is fully operative, this new programme should, inter alia, provide internationally agreed evaluations of the health and environmental effects of new and existing chemicals, and of specific effects, such as carcinogenicity and mutagenicity, and should develop guidelines on exposure limits. Already, joint FAO/WHO programmes have dealt with such specific topics as determining (jointly with FAO) acceptable daily intakes on a substance-by-substance basis of such chemical substances in foods as food additives and pesticide residues. WHO is also engaged in the development of environmental criteria documents (prepared jointly with ILO and UNEP) on various chemicals in the environment, including many industrial chemicals; and data sheets (prepared with FAO) on the hazards to health from the use of individual pesticides. The WHO guidelines to the use of the WHO Recommended Classification of Pesticides by Hazard (VBC/78.1/Rev.2) are a useful guide to the hazards presented by practically all the pesticides in current use. The World Health Organization is also working with the ILO on the formulations of internationally recommended occupational exposure limits for hazardous industrial chemicals.

16. The ILO International Occupational Safety and Health Hazard Alert System, just now emerging from the second experimental phase, has established a network of 94 countries to channel the rapid exchange of information in this field. The ILO International Occupational Safety and Health Information Centre distributes abstracts and a thesaurus from a fully computerized data base with the collaboration of 36 national centres. ILO has also adopted a number of conventions and recommendations, supplemented by guidelines dealing specifically with occupational

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6/ See Official Records of the General Assembly, Thirty-first Session, Supplement No. 25 (A/31/25), annex I, decision 52 (IV); and ibid., Thirty-third Session, Supplement No. 25 (A/33/25), annex I, decision 6/3 B.

safety and health matters. These are international legal instruments with formal obligations for the Governments of subscribing member States, which do not, however, specifically involve restrictions on exports. ILO is also involved in establishing occupational safety and health institutes, through its technical co-operation programmes in developing countries, to serve as centres for documenting and transmitting knowledge and expertise in this field.

17. Many development aid programmes, such as those of the World Bank, have provisions for ensuring that any enterprise or programme financed by these organizations would comply with requirements regarding occupational safety in the use of hazardous chemicals and environmental considerations.

18. A majority of the countries replying that are also members of the Organisation for Economic Co-operation and Development (OECD) mentioned the work of the Chemicals Group of the Environment Committee of that organization, which has a notification system for chemicals that present a hazard. This group is in the process of considering the feasibility of a system of export notification on hazardous chemicals, which may work to the advantage of non-member importing countries, and developing a system of harmonized requirements for the testing of new chemicals. The new concept of compulsory export notification required from the exporter for hazardous chemicals has only been applied in one country. At the present time, one of the constraints on the utility of such a system is the limited facilities of many recipient importing countries for digesting the voluminous, highly technical information and taking action on it in good time.

B. Unsafe pharmaceutical products

19. Narcotic drugs and psychotropic substances are good examples of "unsafe" pharmaceutical products, which are nevertheless used and needed in medical practice. These substances are very closely controlled under the international treaties which provide a model for complete control as Governments authorize both export and import. This, however, is because the demand for these drugs is often so intense that criminal activities are involved and because of the very serious health and social consequences associated with the abuse of these drugs. The complex system of control is administratively very demanding, requiring as it does an exchange of import certificates and export authorizations for hundreds of shipments, with a corresponding control of all aspects of the use and transfer of ownership of these products within the country, ultimately to the final consumer. Such a system would probably not be appropriate or needed for the products considered here, since the same driving force of intense illegal demand on the part of individuals does not exist in their case.

20. As regards other "unsafe" pharmaceuticals and banned chemicals or pharmaceuticals covered by the conventions mentioned in paragraph 14 above, the replies of those countries discussing the international aspects of this problem all referred to WHO programmes. For the control of these pharmaceuticals a mechanism already exists - the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, summarized in annex II below, by which importing countries can demand a certification from the exporting country (or, ultimately, the manufacturing country). This

certification involves a guarantee that the product is authorized for sale or distribution within the exporting State or, if not, the reasons therefore would be stated on the certificate. Other qualities of the drug, for example, purity, also have to be certified. Thus, if the drug were deemed "unsafe" in the producing country, this would become evident in the certification. WHO regional schemes for drug testing are also under consideration. They would permit the chemical testing of certain qualities of a drug on a referee basis.

21. WHO drug information circulars and the quarterly WHO Drug Information Bulletin distribute information gathered from highly evolved national regulatory authorities and give details of government decisions on the prohibition or limitation of the availability of a drug already in use, on refusal of approval of a new drug, and on new uses. Since, however, decisions on drug availability on a market are not always made by governmental regulatory action or reported to WHO, coverage is inevitably incomplete. A proposal is before WHO for a standing advisory committee on drug regulation and information to improve the situation and to make WHO activities in this field more responsive to the diverse needs of States (see annex II, sect. E below). Further information on the role of WHO in the transfer of information on drugs pertinent to the questions dealt with by this report is also summarized in annex II below.

22. A number of related issues concerning pharmaceutical products were raised in some of the responses, for example the question of the facilities available in developing countries for evaluation, use and application of the relevant information, including that supplied through the WHO programmes. In such countries, the expertise and resources that can be devoted to drug evaluation and control may not be adequate to handle the problems. The question was also raised of drug procurement for developing countries, possibly involving centralized regional purchasing, regional manufacture of drugs in developing countries for trade among themselves and associated factors, such as the use of a list of essential drugs of the kind developed by WHO. In addition to the issuance by WHO to Governments of official governmental information on "unsafe" pharmaceuticals, commercial information on medical specialities is provided directly to physicians. This differs between various regions of the world, depending on the extent of governmental control over claims that may be made for pharmaceuticals. It is to be feared that unsubstantiated claims may be made in such material to physicians in developing countries, which may tend to create an undesirable demand for a drug.

III. PRELIMINARY EVALUATION OF THE EFFECTIVENESS OF INTERNATIONAL FACILITIES AND THE MAIN ISSUES DESERVING FURTHER CONSIDERATION

23. In the case of banned hazardous chemicals, the IRPTC system of network contacts provides importing countries with the bulletin referred to in paragraph 15 above and an opportunity to obtain answers on request as to the status of many potentially hazardous chemicals now being used. The "Legal data profile for selected chemicals", in expanded form to cover more chemicals, countries and data fields, should also serve to answer, in advance and in documented form, some of the questions that might arise. The effectiveness of this system depends, however,

upon the use that can be made of the information in the importing countries to stop any unwanted shipment. At this stage, therefore, this solution may not be a completely adequate response to the problem. A more stringent solution, for which agreement would probably be more difficult, would require the halting of shipments at origin, at the request of the prospective importing country. Ultimately, such exports might even be restricted by the exporting country, as envisaged in decisions 6/4 and 85 (V) of the UNEP Governing Council. Such a restriction might, however, constitute in some cases a hindrance to the freedom of choice of chemical or pharmaceutical goods by the importing country. It might also lead to unfair competition and restriction of trade to the disadvantage of an exporting country prepared to exercise restraints on its exports on the basis of hazard, as compared with exporting countries not prepared to do so.

24. Among the reasons for which the General Assembly raised the issues treated in the present report were the potential hazards posed to consumers by the use of pesticides and to consumers of foods contaminated with unacceptable residues of pesticides. This matter may be considered in the context of the comprehensive report on consumer protection, which is also before the Economic and Social Council. The role of FAO in furnishing advisory services on good agricultural practices in the use of pesticides is important in this connexion. This advice has been supplied up to now on an ad hoc basis by FAO, on demand. Some aspects of this problem, particularly with respect to foods, are covered by the Joint FAO/WHO Meeting on Pesticide Residues, the Committee on Pesticide Residues of the joint FAO/WHO Codex Alimentarius Commission, in particular the work on good agricultural practices for food crops, and the establishment of maximum and practical limits of pesticide residues in food. Non-food crops, however, are not covered by these bodies. The hazards to the applicators and farmers are summarized in the data sheets on individual pesticides and the guidelines to the use of the WHO Recommended Classification of Pesticides by Hazard, which are prepared by the Division of the Vector Biology and Control in WHO, as mentioned in paragraph 15 above. Their general availability and applicability at the working level depends, however, on the extent to which the Governments concerned pass the information down in a useful form.

25. As for pharmaceutical products, the Certification Scheme of WHO requires, as indicated in paragraph 20 above, that the importing country be supplied with the information concerning the practices in the exporting country. This requirement can be extended further to obtain the information from the country manufacturing the drug. More comprehensive information on the restrictions on the pharmaceutical in question is only available from a study of the existing WHO documents (drug information circulars) and the WHO Drug Information Bulletin over the years. Already, queries have been addressed to WHO on the broader question of the constraints on the use of certain drugs which have been generally agreed upon, not only in the exporting country, but also in any other country.

26. Key questions that arise in connexion with both information systems and notification requirements are: (a) whether the information is appropriate and adequately oriented to the needs of the user and is as simple to understand as possible, bearing in mind that only those in the importing country can know all the complex factors that have to be considered; and (b) whether the importing

country has the regulatory machinery to keep out undesired imports. If there is a wish to proceed beyond existing information systems activated in response to demands from importing countries, the next step would seem to be the establishment, particularly in developing countries, of control systems capable of using the information. Existing scientific inspection and regulatory staff already used for similar purposes in developing countries could be given brief awareness training in recognizing such issues and taking appropriate action on them within their legal frameworks, provided the problems are extensive and serious enough to justify the use of United Nations training fellowships. Assistance would also have to be given in setting up the appropriate legal measures in existing or new legislation to handle such problem substances. In principle, it would also be possible for producing countries, within the limits of their constitutional and legislative systems, to impose restrictions on their exports of controlled hazardous chemicals and pharmaceutical products of doubtful therapeutic value. In order to avoid any implication of imposing unilateral restrictions, which would deprive importing countries of the freedom of choosing the chemicals or pharmaceuticals they wish to have, or of allowing the unnecessary circulation of dangerous substances, decisions on such restrictions should be taken in consultation with the importing countries concerned.

27. In conclusion, some further modification of existing information (IRPTC for potentially hazardous chemicals and the WHO system for pharmaceuticals) may be envisaged with a view to providing more oriented and responsive systems of information exchange. Progress in the development of these systems should be reviewed after two or three years, on the basis of information derived from specific questionnaires, to see if they are being used to the fullest extent and to assess the true magnitude of the residual problems. Consideration might then be given to determining whether more elaborate international control systems would be needed. Efforts should be made to co-ordinate activities in the United Nations system with those of other organizations such as OECD (see para. 18 above) working to develop information exchanges with respect to exports of these substances. Such work is to take into account the interests of importing countries around the world. Meanwhile, greater aid should be given, as is now being done on a limited scale, to help developing countries establish adequate import control systems for drugs of dubious therapeutic value and hazardous chemicals and for the training of scientific staff to handle the problems. Such systems should be appropriate to the needs of developing countries and should operate with reasonable effectiveness and without too great a cost. During this interim period, however, the main reliance would continue to be placed on the present international information systems, which could be improved in the ways suggested above.

ANNEX I

Summary of relevant information on the International Register of Potentially Toxic Compounds

A. Background

1. Recognizing the need for an international register, the United Nations Conference on the Human Environment, held at Stockholm in 1972, inter alia, recommended that:

> "the Secretary-General, drawing on the resources of the entire United Nations system and with the active support of Governments and appropriate scientific and other international bodies:
>
> "...
>
> "(a) Develop plans for an International Registry of Data on Chemicals in the Environment based on a collection of available scientific data on the environmental behaviour of the most important man-made chemicals and containing production figures of the potentially most harmful chemicals, together with their pathways from factory via utilization to ultimate disposal or recirculation." a/

2. The Governing Council of UNEP, in its decision 29 (III) of 2 May 1975, b/ authorized the Executive Director of UNEP to establish a programme activity centre for the International Register of Potentially Toxic Chemicals (IRPTC), to serve as an essential tool in optimizing the use of chemicals for human well-being and at the same time to provide a global early warning system of undesirable environmental side effects.

3. At its fourth session, in its decision 63 (IV) of 13 April 1976, c/ the Governing Council decided that IRPTC should be a component of Earthwatch, the global environmental assessment programme of UNEP. Earthwatch consists of four components, namely: evaluation and review; research; monitoring; and information exchange. The Register, along with the International Referral System (INFOTERRA) for sources of environmental information, forms the information exchange component of Earthwatch. The Register has close links with all the agencies and bodies mentioned in the present report, as well as with information networks regionally and nationally and with non-governmental organizations dealing with environmental problems and with groupings dealing with chemicals that are the cause of concern.

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a/ Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972 (United Nations publication, Sales No. E.73.II.A.14), chap. II, recommendation 74, subpara. (e).

b/ See Official Records of the General Assembly, Thirtieth Session, Supplement No. 25 (A/10025), annex I.

c/ Ibid., Thirty-first Session, Supplement No. 25 (A/31/25), annex I.

4. The Register's objectives are the following:

(a) To facilitate access to existing data on the effects of chemicals on man and his environment, and thereby contribute to a more efficient use of national and international resources available for the evaluation of effects of chemicals and their control;

(b) On the basis of information in the Register, to identify important gaps in the existing knowledge of the effects of chemicals and to call attention to the need for research to fill those gaps;

(c) To identify or help to identify potential hazards from chemicals and to improve the awareness of such hazards;

(d) To provide information on national, regional and global policies, regulatory measures and standards and recommendations for the control of potentially toxic chemicals.

5. The strategy to meet these objectives involves the following activities:

(a) Rendering the IRPTC Programme Activity Centre capable of handling data and answering questions;

(b) Involving correspondents designated at the national, regional and sectoral levels in the operations of IRPTC;

(c) Building a network of participating data systems, which may make their files available to the IRPTC Programme Activity Centre for incorporation in its central data files, or may respond directly to users' queries;

(d) Developing and continuously updating computerized central data files;

(e) Publishing selected information on chemicals.

6. In its decision 6/3 B of 24 May 1978, d/ the Governing Council requested the Executive Director of UNEP to ensure that IRPTC would facilitate access to available information, to intensify his efforts to increase the number of national correspondents, to hold workshops to familiarize developing countries with the use of the Register, and to give priority to providing countries with information on legal and administrative limitations, bans and regulations on potentially toxic chemicals. Member States were also requested to assist the Executive Director positively by appointing national correspondents and to improve their national mechanisms in terms of personnel, facilities and organization so as to enhance the capability of IRPTC to fulfil its task efficiently and effectively.

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d/ Ibid., Thirty-third Session, Supplement No. 25 (A/33/25), annex I.

7. Without going into technical details, it may be said that IRPTC operations involve the collection and storage of information, filing of documents, inventorying of existing information systems on chemicals, dissemination of information through bulletins and other means, and the preparation and publication of data profiles for chemicals.

8. These data profiles for chemicals provide the information necessary to evaluate the potential hazards posed by chemicals to the health of man and to his environment, or indicate the absence of such information in publicly available literature. They are prepared by IRPTC mainly for the use of those responsible for protecting human health and the environment from the noxious effects of chemicals. The data profiles contain information on, inter alia, production and use, pathways into the environment, concentrations in and transformation of the environment, chemi-biokinetics, toxicity to mammals and man, effects on non-mammalian organisms and plants, treatment of poisoning, and national and international recommendations and regulations for the control of chemicals in the air, water, drinking water, wastes, soil, food and beverages, and consumer goods.

9. The legal data profiles for chemicals furnished in response to the request of the UNEP Governing Council in its decision 6/3 B d/ that priority should be given to providing countries with information on legal and administrative limitations, bans and regulations placed on potentially toxic chemicals in the producing countries are of particular interest. Legal data profiles containing data on recommendations/legal mechanisms, one of the 17 data fields covered by the Register, are therefore being developed as a priority, although they form part of the Data Profile series. National (eight selected countries) and international recommendations and regulations for the control of about 200 chemicals in the air, water, wastes, soil, food, beverages and consumer goods have already been collected and published (IRPTC, Data Profile Series No. 2 - Legal Data Profiles for Selected Chemicals, 1980). The chemicals were selected from the IRPTC working list of priority chemicals, based on existing national and international lists.

10. The IRPTC Data Register, providing the information for strengthening the data profiles, is designed as a system which allows for data collection and exchange through network arrangements with world-wide partners. The Register will eventually contain data for many chemicals in the various attribute fields. At present, IRPTC is striving to complete data profiles for a limited number of chemicals of international significance through systematic searches for relevant data for all attribute fields. For that purpose, in 1979, IRPTC prepared a working list of priority chemicals, based on existing national and international lists. Priority attention was given to lists received from developing countries containing the names of chemicals causing concern to health and environmental protection authorities in these countries. The list, which now consists of 350 chemicals (over 160 agro-chemicals) is open-ended and more chemicals will gradually be added according to the information needs of the countries concerned.

B. Query-response service

11. Since its establishment in March 1976, IRPTC has responded to queries on chemicals using several computerized bibliographic files, handbooks and other reference works, criteria documents, reviews and regulations. Where necessary, it has sought the assistance of WHO, the International Occupational Safety and Health Information Centre of ILO and national correspondents (see paras. 12-14 below). Queries have been received from United Nations bodies, Governments, industry and individuals; they have ranged from questions on general toxicity information to questions on a sophisticated mathematical equation relating intake of chemicals to retention.

12. The Governing Council fo UNEP has decided that IRPTC should facilitate access to available information by national institutions and intergovernmental and non-governmental organizations. It is therefore advantageous if all queries are sent to IRPTC through, or with the knowledge of, the national correspondent; this would help the national correspondent to build his own register and thus, in some cases, to answer the queries himself and, where necessary, clarify the queries so that an effective response can be made by IRPTC organizations in one country.

13. In this connexion, Governments have been invited to monimate national correspondents to act as national co-ordinating centres for interaction with IRPTC and to provide them with the necessary resources. The functions of the national correspondent are the following:

(a) To provide information on relevant expertise, criteria documents, reviews and monographs, data banks and information systems, legislation and regulations on chemicals, accidents involving chemicals and chemicals causing concern in his country;

(b) To assist in the development of the query-response service;

(c) To distribute IRPTC publications (Bulletin, etc.) and information about IRPTC and its services in his country.

14. So far, 89 countries have appointed national correspondents. IRPTC staff members visit the national correspondents and discuss with them their tasks and the best means of effectively co-operating with IRPTC in the development of IRPTC and of their own national registers. The Governing Council, in its decision 6/3 B, d/ urged the Executive Director to provide, within available resources, assistance to developing countries by organizing workshops to familiarize them with the use of IRPTC. Workshops have been held at Bangkok, in August 1979, for national correspondents in the Asia and Pacific region and at Nairobi, in November 1980, for the national correspondents of the Africa and West Asia regions. The consensus was that these workshops gave the national correspondents a clear understanding of the development and operation of IRPTC and of their own tasks. It also helped them to establish contacts with one another and gain from the experience of other national correspondents in the region where the environmental problems were similar. A third workshop is planned for later in 1981 for national correspondents in the Latin American region.

ANNEX II

The role of the World Health Organization in the transfer of information on drugs

A. Summary

1. The World Health Assembly has remained constantly alert to the need for efficient channels of communication between member States on all issues bearing on the safety and efficacy of drugs moving in international commerce, including the standards by which these criteria are determined. The basic fields of activity were identified in a resolution adopted by the World Health Assembly in 1962 (WHA15.41), in which the Director-General was requested to study means of:

(a) Establishing minimum requirements and recommending standard methods for the clinical and pharmacological evaluation of pharmaceutical preparations;

(b) Securing regular exchange of information on the safety and efficacy of pharmaceutical preparations;

(c) Securing prompt transmission to national health authorities of new information on serious side-effects of pharmaceutical preparations.

2. The World Health Organization has responded to this call and to a series of further resolutions adopted by its governing bodies by issuing reports of scientific groups on the general principles of toxicological testing of drugs and, specifically, on the assessment of bio-availability, mutagenicity and carcinogenicity; by developing an international scheme for monitoring adverse drug reactions; by devising a Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce; and by transmitting verbatim to all member States, through its drug information circulars, decisions taken by national authorities to withdraw or restrict the availability of specific drugs on grounds of safety.

B. The international drug monitoring programme

3. For over a decade, WHO has fostered internaticnal collaboration in monitoring suspected adverse drug reactions. The primary objective was to identify at the earliest possible moment the liability of a drug to produce undesirable effects which were not detected during its clinical trials, and it was assumed that a population of international dimensions would facilitate and accelerate the detection of serious but relatively rare reactions.

4. The number of actively participating countries has increased from 10 to 22; more than 140,000 reports are in the cumulative data base; these are being added to at a rate of approximately 2,000 per month. Although the vast majority of these reports were received from countries with highly evolved drug regulatory

authorities, developing countries also demonstrated an active interest in the scheme. The operational activities take place at the WHO Collaborating Centre for International Drug Monitoring, at Uppsala, Sweden. However, WHO retains full responsibility for co-ordination of the programme, participation of national and other centres and dissemination of information, including publications.

C. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

5. The World Health Organization has long expressed concern that drugs intended for export are not always subjected to the same quality control procedures as those produced for the home market. In this case, developing countries lacking adequate laboratory facilities for drug analysis are placed at a particular disadvantage. To redress this unsatisfactory situation, WHO has sought to extend and unify schemes already operated by the health authorities of some exporting countries, who issue a certificate on request to foreign importers in respect of drugs that have been subjected to statutory control.

6. The Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was adopted in 1975 in resolution WHA28.65, and 54 countries have now agreed to participate through designated national authorities. The health authority of the exporting country is required to certify on request whether a specific product offered for export is available on the home market, and whether the manufacturer has been found, on inspection, to comply with defined standards of practice in the manufacture and quality control of drugs. In the case of a product not authorized for sale or distribution in the exporting country, the reasons are explicitly stated and, when relevant, grounds for refusal of registration are disclosed. e/

D. Drug information circulars and the Drug Information Bulletin

7. In 1963, the World Health Assembly, in its resolution WHA16.36, requested member States to communicate immediately to WHO any decision to prohibit or limit the availability of a drug already in use; any decision to refuse the approval of a new drug; and any approval for general use of a new drug when accompanied by restrictive decisions.

8. Many resolutions to reinforce this request have been adopted subsequently, and the scope of WHO responsibility in this context was broadened in 1975 with the adoption of resolution WHA28.66 in which the Director-General was requested, inter alia, to disseminate to member States evaluated information on drugs.

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e/ For more details on this scheme, see annex III below.

9. The WHO drug information circulars and the quarterly WHO Drug Information Bulletin are now established as vehicles for the transfer of information on the safety and efficacy of drugs. The former service offers countries a mechanism to provide all member States with a rapid verbatim notice concerning any restrictive regulatory action taken in connexion with an internationally available product, while the Bulletin provides an edited commentary on such decisions, in which any differences in national viewpoints can be contrasted and discussed.

10. In principle, these documents provide a reasonably comprehensive information service for interested administrative bodies and individuals, and particularly those in member States that lack highly evolved drug regulatory systems. In practice, however, the drug information circular system falls short of fulfilling its potential, since only a relatively small proportion of product withdrawals are reported to WHO. The system also suffers from inherent bias, for, whereas these decisions frequently devolve from controversial issues, only those countries persuaded of the need to take restrictive regulatory action provide a notification. The Drug Information Bulletin has the virtue of being able to place these decisions in a broader perspective but it cannot necessarily cover the omissions created within the drug circular system.

11. The roots of the deficiency of information provided by the drug information circulars are two:

(a) Drugs are most frequently removed from national markets by voluntary agreements with manufacturers rather than by enforcement of statutory controls;

(b) Drugs intended solely for export may not be subjected to regulations that apply to products destined for domestic markets. (Although this can be found out by the use of the clause in the Drug Certification Scheme, it requires a specific request from the importing country.)

12. An additional problem arises as a result of the inevitable and understandable reticence on the part of regulatory authorities to release information on a safety issue until a definitive position has been adopted on the implications of the available data and on the need for any restrictive action. Whereas this ensures that public concern is not aroused prematurely and perhaps unnecessarily on the basis of unrealized suspicions, it can frustrate or delay international discussion - and even international collaboration - as a problem develops. The need for confidentiality is thus counterbalanced by a need for each national authority to be fully and efficiently informed of any reservations about the safety of a product subject to its control, and by a need to establish international understanding on a given issue at the earliest opportunity. The WHO Drug Information Bulletin, however, has had a discernible impact on regulatory decisions taken in many third world countries.

E. Proposal for a standing advisory committee on drug regulation and information

13. Existing channels of communication need to be further improved, and interrelations between drug regulatory agencies and WHO require strengthening. The possibility is consequently now under consideration of establishing a standing advisory committee comprising representatives of drug regulatory authorities in both developed and developing countries that would advise WHO on matters concerning drug information and regulation. The committee would, in particular:

(a) Encourage the more complete and timely reporting to WHO by national health authorities of important drug-related regulatory decisions and developments;

(b) Assess the adequacy of existing means of disseminating drug information to member States and advise on their improvement;

(c) Aid WHO in identifying and evaluating emerging drug problems and report progress toward their solution to member States;

(d) Advise WHO on the means of strengthening the technical capability of member States to utilize available drug information.

ANNEX III

Description of the World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

The following material has been taken from section B, entitled "Certification scheme for products moving in international commerce", of the 1977 WHO publication Quality Control of Drugs. a/ It describes the Scheme, including its legal implications and the limits of its scope.

"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.

"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

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a/ Reprint from WHO Chronicle, vol. 31, No. 12.

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.

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

"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 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."

ANNEX IV

Extracts from relevant decisions of the Governing Council of the United Nations Environment Programme

Decision 85 (V) of 25 May 1977 a/

"The Governing Council,

"...

"2. Urges Governments to take steps to ensure that potentially harmful chemicals, in whatever form or commodity, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing country;

"3. Requests the Executive Director, in co-operation with the competent organizations of the United Nations system, especially the Codex Alimentarius Commission, to assist developing countries in developing and strengthening their capabilities for evaluating chemicals, foods, drugs and cosmetics being distributed within their countries."

Decision 6/3 B of 24 May 1978 b/

"The Governing Council,

"...

"1. Notes the importance of wide dissemination of information on potentially toxic chemicals;

"2. Calls upon the Executive Director to ensure that the International Register of Potentially Toxic Chemicals will, upon request and as appropriate, facilitate access to available information by national institutions and intergovernmental and non-governmental organizations of standing;

"3. Invites Member States to improve their national mechanisms, in terms of personnel, facilities and organization, so as to enhance the capability of the Register to fulfil its task efficiently and effectively;

"4. Urges the Executive Director to intensify his efforts to increase the number of national correspondents of the Register, and urges Governments to respond positively in this respect;

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a/ See Official Records of the General Assembly, Thirty-second Session, Supplement No. 25 (A/32/25), annex I.

b/ Ibid., Thirty-third Session, Supplement No. 25 (A/33/25), annex I.

"5. Further urges the Executive Director to provide, within available resources, assistance to developing countries by organizing workshops to familiarize them with the use of the Register;

"6. Requests the Executive Director to give priority to providing countries with information on legal and administrative limitations, bans and regulations placed on potentially toxic chemicals in the producing countries;

"7. Further requests the Executive Director to intensify the dissemination of information covered by the Register."

Decision 6/4 of 24 May 1978 b/

"The Governing Council,

"1. Appeals to the countries exporting potentially harmful chemicals, in whatever form or commodity, to prevent the export of items which are restricted, or not registered for use, in the countries of origin until the exporting countries have ascertained that the results of tests and evaluations on the effects of these chemicals on the health of people and the environment (as well as detailed instructions in mutually agreed languages for the safe use of these products) have been provided to the designated authorities in the recipient countries, so as to make it possible for these authorities to make fully informed decisions on the import and utilization of the products;

"2. Further appeals to the Governments of recipient countries to take appropriate measures to strengthen the capabilities of the authorities designated to make the decisions referred to in paragraph 1 above;

"3. Calls upon the Governments of both exporting and recipient countries to institute adequate monitoring, evaluative and protective measures in this regard;

"4. Requests the Executive Director to explore ways and means of assisting recipient countries in instituting the measures referred to in paragraph 3 above, and in finding solutions to problems involving potentially harmful chemicals including the provision of information on alternatives for their use."
