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COMMITTEE A

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PROVISIONAL SUMMARY RECORD OF THE FIFTH MEETING

Palais des Nations, Geneva
Thursday, 23 May 1996, at 9:00

Chairman: Professor B. SANGSTER (Netherlands)

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Note

This summary record is **provisional** only. The summaries of statements have not yet been approved by the speakers, and the text should not be quoted.

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The final text will appear subsequently in **Forty-ninth World Health Assembly: Summary records of committees** (document WHA49/1996/REC/3).

FIFTH MEETING

Thursday, 23 May 1996, at 9:00

Chairman: Professor B. SANGSTER (Netherlands)

IMPLEMENTATION OF RESOLUTIONS (PROGRESS REPORT BY THE DIRECTOR-GENERAL): Item 17 of the Agenda (Document A49/4) (continued)

Revised drug strategy (resolutions WHA47.13 and EB97.R14)

The CHAIRMAN drew attention to the draft resolution, on the revised drug strategy, recommended by the Executive Board in resolution EB97.R14.

Further, the following draft resolution on the quality of biological products moving in international commerce had been proposed by the delegations of Argentina, Australia, Bahrain, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, Egypt, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Morocco, Namibia, Nicaragua, Peru, Togo, United States of America, Uruguay and Venezuela:

> The Forty-ninth World Health Assembly,
>
> Noting the increasing movement across international boundaries of vaccines and other biological and biotechnological products aimed at prevention and/or treatment of diseases, together with the rapid development and introduction into public health programmes of medicines produced by modern biotechnology;
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> Recalling previous resolutions of the Health Assembly mentioning the vital need to ensure the quality, safety and efficacy of both established and new biological products;
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> Bearing in mind the responsibility of governments to ensure that biological products, whether imported or manufactured locally, are of good quality;
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> Recognizing the specialized technical expertise needed for evaluating and controlling biological products;
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> Recalling the role of WHO in coordinating technical assistance to countries from various sources, including assistance given on a bilateral and multilateral basis, and aware that, according to its Constitution and the decisions of previous Health Assemblies, WHO's coordinating role is one of its most important functions,
>
> 1. URGES all Member States:
>
> (1) to use only vaccines and other biological products of recognized and certified quality, safety and efficacy and to adopt WHO requirements as part of their national regulations or to ensure by national regulations that products are at least as safe and as potent as those prepared in accordance with the requirements of WHO;
>
> (2) to strengthen their national regulatory authorities and national control laboratories;
>
> 2. REQUESTS the Director-General:
>
> (1) to strengthen the mechanisms for providing clear norms and active leadership to guarantee the quality, safety and efficacy of biological products;
>
> (2) to ensure that the importance and global effectiveness of WHO's biological standardization programmes is given the greatest attention and that decisions taken by the WHO Expert Committee on Biological Standardization are widely disseminated in good time;
>
> (3) to keep Member States informed of the development of new biological products and of their potential value and application;

(4) to extend the assistance offered to Member States within the limits of existing resources to develop and to strengthen their national regulatory authorities and control laboratories so as to increase their competence in this area.

In his own opinion, the importance and complexity of the drug regulatory issues raised in the second draft resolution were such that the Committee should hear expert opinion in order to be able to discuss the content satisfactorily.

Dr ANTELO PÉREZ (representative of the Executive Board), introducing the draft resolution recommended by the Executive Board in resolution EB97.R14, explained that the Board had reviewed the revised drug strategy, including the role of the pharmacist in the light of resolutions WHA47.12 and WHA47.13. Members had praised the success of the Action Programme on Essential Drugs and had welcomed the news that 60 countries were implementing a national drug policy while 120 countries had a national list of essential drugs. The Board had agreed on the need for WHO to continue its work on ethical criteria for drug promotion.

The importance of national pharmaceutical policies could not be overestimated, and a greater effort must be made to ensure the rational utilization of drugs. The use of generic names was vital for rational use and also reduced drug costs.

The Board considered that pharmacists had an important role to play in assuring drug quality and in performing certain regulatory functions, as well as in supplying information on the appropriate handling of drugs. The Board had expressed concern regarding the importation of low-quality drugs and the lack of adequate quality control in industrially produced drugs, emphasizing WHO's responsibility in the promotion of appropriate manufacturing practices. Other topics discussed had been the privatization of the purchase and sale of drugs, the trend towards drug deregulation, the growing importance of drugs in the financing of health care, the provision of assistance to countries establishing national pharmaceutical enterprises, the advisability of making extensive use of WHO's recommendations on pharmaceutical legislation, and the considerable value which recommendations for the fixing of drug prices would have for a number of countries. The Board had adopted resolution EB97.R14, which contained a draft resolution recommended for adoption by the Forty-ninth World Health Assembly.

The CHAIRMAN drew attention to the informal document containing amendments to the draft resolution contained in resolution EB97.R14 which had been circulated to members.

Dr MILLER (Barbados), speaking as one of the original sponsors of resolution EB97.R14 in the Executive Board, said that after consultations with delegates to the current Health Assembly and with other members of the Executive Board it had been felt that resolution EB97.R14 could be strengthened by making some of the statements in the operative section more explicit and by adding some operative paragraphs. There were several proposed amendments. First, a new paragraph 1(4) should be added, reading: "to establish and strengthen as appropriate programmes for the monitoring of the safety and efficacy of marketed drugs", the remaining subparagraphs being renumbered consequentially. Second, paragraph 2(4) should be replaced by the words "to disseminate the interagency Guidelines for Drug Donations produced by WHO in May 1996 and to encourage, in collaboration with all interested parties, its use and review after one year". Third, paragraph 2(5) should be replaced by a new text reading: "to strengthen market intelligence, review in collaboration with interested parties information on prices and sources of information on prices of essential drugs and raw materials of good quality, and provide this to Member States". Fourth, a new paragraph 2(7) should be added reading: "to continue the development and dissemination of information on pharmaceutical products, thereby assuring the safe, effective and rational use of drugs". The present paragraph 2(7) would be renumbered 2(8).

Dr LUETKENS (Germany) said that in his country drugs intended for export were generally subject to the prohibition of the marketing of unsafe drugs and were protected against fraud, although exceptionally drugs that did not meet the necessary requirements might be exported if the competent authority in the

country of destination had issued an import authorization indicating that it was well informed of the grounds on which marketing had been refused in Germany. In addition, Germany participated in WHO's Certification Scheme and was therefore willing to provide the importing country with information on the status of the marketing authorization and the proper manufacture of the exported drugs and to confirm that information by a certificate. Considerable use was made of that possibility.

The pharmaceutical industry had a self-regulation code for marketing, especially in developing countries. Under it there was an obligation to provide exact, proper and objective information on pharmaceutical products and to describe them in such a way that the information given complied not only with the legal requirements but also with ethical principles. Any criticism of the marketing strategies of individual companies abroad should be submitted to the management of the pharmaceutical enterprise concerned, which, by virtue of its membership in the self-regulation system, had undertaken to ensure that the code was complied with.

His delegation supported the draft resolution recommended in resolution EB97.R14.

Professor PICO (Argentina) said that it was very important that WHO should continue to promote the rational use of drugs. The progress made by the Action Programme on Essential Drugs was most welcome. Argentina, in fact, had received valuable support from WHO for the development of its national food, medicine and health technology administration, which was already having a positive effect on the country's health, especially through the control of drugs and biologicals. WHO had not only helped with the design and start up but was also providing permanent technical assistance and making periodic assessments for the administration, which had been placed at the disposal of Mercosur.

The drug programme had been one of WHO's most successful programmes over the past few years. In order to adapt it to the new world situation, its activities should be strengthened in the light of current health economics. The essential drug concept had constituted an important support for health sector reform, which should be continued with new strategies. For that reason Argentina was among the 26 Member States sponsoring the draft resolution on the quality of biological products moving in international commerce to which the Chairman had drawn attention. Being absolutely convinced of the vital need to guarantee quality, safety and efficacy in drugs and biologicals, Argentina also supported the draft resolution recommended by the Executive Board in resolution EB97.R14, as well as the amendments to it.

The CHAIRMAN said that any support expressed for the draft resolution recommended by the Board would be taken to include support for the amendments proposed by Barbados.

Dr NIGHTINGALE (United States of America) said that the brief report on the implementation of the revised drug strategy demonstrated that substantial progress had been made in the work of WHO's various pharmaceutical components, both the normative components and those concerned with technical cooperation. The United States Food and Drug Administration especially valued the emphasis given to safety, quality and efficacy and the high quality and practical utility of the information-sharing documents and of the helpful articles that appeared in drug bulletins and circulars.

His delegation strongly endorsed the amended form of the draft resolution recommended by the Executive Board in resolution EB97.R14, which presented a very appropriate series of recommendations to be implemented by Member States and by the Director-General.

Dr GARCÍA (Spain) said that his delegation fully supported the draft resolution recommended by the Executive Board but wished to make a few minor amendments to it. First, paragraph 1(3) should be amended to read "to enhance drug regulatory mechanisms and mechanisms for the inspection, surveillance and control of drug quality and safety", which would cover the full range of requirements that a drug ought to meet. Second, a new subparagraph should be added somewhere in paragraph 2 in which the Director-General would be requested "to encourage the regulation of appropriate conditions for the storage and distribution of drugs". Finally, another new subparagraph requesting the Director-General to encourage research and development in respect of drugs for rare and tropical diseases should also be added in paragraph 2.

Dr EL SHAFEI (Egypt) supported the draft resolution contained in resolution EB97.R14, as amended. Egypt had 24 indigenous pharmaceutical companies, whose production met 94% of local requirements, with strict quality controls. WHO had an important role to play in supervising measures to control the activities of pharmaceutical companies. The Organization should provide assistance in the research and development of drugs for rare diseases, as well as helping to ensure that the stocks of drugs required to deal with sudden epidemics could be made speedily available. It was very important that health authorities in developing countries should be provided with adequate information about the drugs they intended to use. His country supported the use of nonproprietary drug names and the preparation of pricing protocols.

Dr VIOLAKI-PARASKEVA (Greece) said that, as part of its revised drug strategy, WHO should provide operational support for national drug policies based on essential drug programmes. The promotion of education and training for health workers and the public was particularly important. She supported the draft resolution recommended by the Executive Board, with the following further amendments. The first was the addition of a new preambular paragraph reading: "Recognizing with satisfaction the increasing awareness of all parties concerned of their responsibilities in the implementation of the revised drug strategy". The second was the amendment of paragraph 1(2) to read: " to increase efforts to promote the rational use of drugs through intensification of training and education of health workers and the public".

Mr CHAUHAN (India) said that the Federal Government of India developed the legislation governing drug regulation, while the state governments were responsible for its enforcement. India had produced pharmaceuticals to the value of 700 million rupees in 1992-1993, and production was likely to reach a value of 1600 million rupees by the year 2000. A number of measures were planned to improve drug regulation, including the establishment of six new regional drug testing laboratories and a national drug authority, which would be responsible for new drugs, updating the essential drugs list, monitoring adverse drug reactions, controlling clinical trials and similar activities. A National Institute of Biologicals was being set up to supervise quality-testing of vaccines, blood and blood products, and laboratory reagents.

The Indian Ministry of Health and Family Welfare had recently compiled a national essential drugs list of approximately 300 drugs. Standards designed to improve the quality of drugs used in traditional medicine systems were also planned. He supported the draft resolution recommended by the Board, as amended.

Mr AMEDON (Togo) supported the draft resolution, with one further amendment: The original paragraph 1(5) should read: "to eliminate inappropriate donations of drugs and adopt national regulations governing other types of donation".

Dr LOSSEV (Russian Federation) supported the draft resolution with the amendments proposed by Barbados and Spain, although they would slightly widen the scope of the activities of the Action Programme on Essential Drugs.

Dr BELLAMY (United Kingdom of Great Britain and Northern Ireland) noted with satisfaction that the interagency Guidelines for Drug Donations acknowledged the fact that the wishes of potential recipients of drug donations must be taken into account. The amendment to paragraph 2(4) called upon the Director-General to collaborate with all interested parties in a review of the guidelines in 1997.

The United Kingdom was concerned that information on the prices of drugs and raw materials approved by WHO should confine itself to drugs and materials which were of good quality and up to date. A list currently available on the World Wide Web and supported by the Action Programme on Essential Drugs included drugs and materials which appeared to be based on a pharmacopoeia that was nearly 10 years old. It would be helpful to know when that list would be updated. He supported the draft resolution, as amended by Barbados and with the following amendment to new operative paragraph 2(5): "... prices of essential drugs and raw materials of good quality, which meet current requirements of internationally recognized pharmacopoeias or equivalent regulatory standards, and provide this information to Member States".

Dr RABESON (Madagascar) said that his country had developed a national pharmaceuticals policy with the assistance of WHO, France, Switzerland and Germany. The World Bank and the European Union had helped to set up a central purchasing authority for drugs and medical supplies. Prescribing guidelines had been drawn up, and some physicians had received special training in pharmacology. He supported the draft resolution recommended by the Executive Board.

Mr NGEDUP (Bhutan) also expressed support for the draft resolution, as amended.

Mr CHIBAMBO (Malawi) said that his country had adopted a national drug policy in 1991, providing a systematic approach to the choice of medicines in the public sector. A national quality control laboratory assessed the quality of drugs before they were approved for use, using the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and other protocols. An independent drug regulatory authority, the Pharmacy, Medicines and Poisons Board, was now fully operational. A task force of police and customs officers had been set up to curb the import of illegal drugs, and many drug dealers had been arrested. The Government was considering the best ways of addressing the shortage of personnel in the pharmaceutical industry. Other problems facing the Government were the difficulty of obtaining narcotic drugs, even in emergency situations, and the provision of instructions for the use of donated drugs only in a foreign language. Such problems were addressed by the draft resolution which Malawi endorsed.

Ms STEGEMAN (Netherlands) said that the Director-General's progress report (document A49/4, section III) provided no information on the important area of drug donations. The Netherlands supported an information campaign by a number of nongovernmental organizations intended to inform both the Netherlands public and the pharmaceutical industry about the adverse effects of drug donations. She supported the interagency Guidelines for Drug Donations, and hoped that the Organization would be involved in their implementation. It was important to ensure that possible loopholes in the guidelines were not exploited, such as the donation of drugs which did not appear on the WHO essential drugs list or the waiving of authorization in advance for drug donations in emergency situations.

She supported the draft resolution, as amended, on the understanding that "market intelligence" in new paragraph 2(5) covered pricing mechanisms. She suggested the inclusion of a new subparagraph after the present paragraph 1(2), to read: "to promote efforts to adopt legislation concerning national essential drugs policies".

Dr DINARVAND (Islamic Republic of Iran) said that although his country produced 97% of its medicines, it had to import most of the pharmaceutical raw materials needed for their formulation; that was very expensive, so it considered it important to retain the original text of paragraph 2(5) of the draft resolution, which had requested the Director-General "to determine ways to monitor and report on prices and pricing mechanisms for essential drugs and raw materials". His Government subsidized the sale of medicines, which were made available at very low cost; as a result it was having problems with overconsumption, which had financial implications, and there were also side-effects related to the unnecessary use of drugs. His country was experimenting with setting up prescription control committees in all provinces, which provided information to prescribers reminding them of the content of prescriptions. The measure had been found to be very effective in reducing drug consumption and encouraging the rational use of drugs. His country had adopted a national drug policy based on essential drugs and the generic concept 17 years ago, and it had ensured equitable access by all people to essential drugs. The Islamic Republic of Iran was very much concerned about the impact of the World Trade Organization on pharmaceutical industries in developing countries, and proposed that the resolution be amended to include an additional subparagraph to paragraph 2, which would read as follows: "to report to the Fiftieth World Health Assembly on the impact of the World Trade Organization on national drug policies based on essential drugs and generic concepts".

Mr OPOLSKI (Poland) welcomed the Director-General's progress report on the implementation of the revised drug strategy in document A49/4 but said there was still an imbalance between commercially

produced drug information and the information made available to prescribers and consumers; in some countries that could have an unfavourable impact on the fulfilment of existing drug policies. While supporting the draft resolution EB97.R14, recommended by the Executive Board and the various amendments proposed at the current meeting, Poland was particularly interested in developing a clear strategy for the review and assessment of the effectiveness of WHO's Ethical Criteria for Medicinal Drug Promotion, and was ready to collaborate closely with WHO on that issue.

Mr FREIJ (Sweden), speaking on behalf of the Nordic countries, said that WHO's normative and advocacy functions in the development of national drug policies had to be maintained and strengthened; that was a crucial matter at a time of changing health care systems and greater decentralization and privatization. The Organization could make an important contribution by supporting Member States with guidelines, based on sound evidence, on the various elements of national drug policies including safety, quality, rational use and ethical promotion. That required analysis and evaluation of the various mechanisms that existed, and the comparative drug policy analysis project in nine countries was an important step in that direction. As was stated in the draft resolution recommended by the Board, enforceable drug legislation was urgently needed in many countries, since there continued to be an imbalance between commercially produced drug information and independently validated information on drugs for prescribers, dispensers and consumers. Systems had to be put in place to monitor the safety and quality of drugs and to implement the WHO ethical criteria and norms. The Nordic countries looked forward to the report on the multiple-country participatory evaluation of WHO's Ethical Criteria for Medicinal Drug Promotion to be presented to the Executive Board in January 1997. They were, however, concerned that WHO's drug programmes in some sense stood at a crossroads: there were requests for assistance to be given to more countries in implementing essential drug programmes according to well-established and successful guidelines, but on the other hand the world was changing and new situations had to be addressed. WHO had to be able to develop technical excellence in its normative functions within strategic areas.

He underlined the importance of paragraphs 2(4) and 2(5) of the draft resolution, since access to reliable price information on quality-assured raw materials was important for the local pharmaceutical industries of many countries. Broad-scale implementation of the strategy of rational use of drugs required partners, not least among them the World Bank. Maintaining standards of excellence was a prerequisite for productive partnerships, so WHO had to continue to invest in research and development. Resources being limited, it was necessary to select the agenda for action carefully; the Nordic countries fully agreed that the design and implementation of drug policies on normative functions should be a primary focus of the Organization in the years to come. Available financial and programme resources within the two divisions concerned should be used in a coordinated way to achieve optimum cost-effectiveness.

Dr WIUM (Norway) said that two expressions used in the draft resolution needed clarification. Firstly, the "interested parties" mentioned in the new paragraph 2(4) should be understood to mean those specified at the time of the adoption of WHO's revised drug strategy by the Thirty-ninth World Health Assembly in 1986 - namely, governments; the pharmaceutical industry; prescribers; universities and other teaching institutions and professional nongovernmental organizations; the public, patients' and consumer groups; the mass media; and WHO (document WHA39/1986/REC/1, Annex 5). Secondly, the original wording of paragraph 2(5) had used the word "monitoring", but Norway had been informed by the Secretariat that the phrase "market intelligence" which replaced it was a broader notion that included the monitoring of both prices and pricing mechanisms. If the Secretariat could confirm his understanding of the two expressions he had mentioned, Norway was ready to adopt the draft resolution with the amendments proposed.

Mr MEGHJI (United Republic of Tanzania) said his country already had a national drug policy and a national plan for the pharmaceutical sector, and regarded the draft resolution as a timely guideline. The key to empowering the community to make rational use of drugs was to strengthen information, education and communication. The private pharmaceutical sector and private pharmacies would have to be closely monitored and fully involved. His country valued and encouraged international collaboration on issues regarding the use, export and import of drugs, and on dealing with the distribution of counterfeit drugs; it

was through such efforts that countries would become sensitive to the drugs they exported and imported and would put in place an efficient monitoring mechanism. The United Republic of Tanzania supported the resolution recommended by the Board and wished to emphasize the need to avoid the importing of non-essential and expired or near-expiry drugs by developing countries.

Dr CICOGNA (Italy) also supporting the draft resolution, wished to emphasize how important it was that WHO should improve its ability to provide support and technical assistance to Member States in strengthening their drug regulatory structures. He was concerned to notice that five posts had been abolished since 1995 in the Action Programme on Essential Drugs (DAP) and the Division of Drug Management and Policies (DMP). That seemed to be a disproportionate response to the budgetary crisis in a field where there was a clear need for WHO technical advice and expertise.

Mr KAMWI (Namibia) expressed support for the activities carried out by the Division of Drug Management and Policies (DMP) and said he was pleased to note that in light of increasing resistance to anti-infective agents a programme was being developed to control the spread of resistance by linking the rational use of essential anti-infective agents to surveillance. In the subregion in which Namibia was situated it was alleged that some US$ 70-80 million worth of counterfeit drugs was being circulated, and he welcomed the fact that the increase in substandard and counterfeit medicines had necessitated a comprehensive strategy to detect and deter the manufacture and distribution of such products. He also welcomed the fact that in the light of advances in modern communications technology, it had been envisaged that it would be necessary to apply appropriate and affordable technology for drug safety and regulatory communication. Namibia would like to see a mechanism put in place to determine how the prices of pharmaceutical products were set.

Mr SAKAMOTO (Japan) expressed his country's support for the draft resolution recommended by the Executive Board and the amendments proposed by Barbados.

Mr CHATTY (Syrian Arab Republic) also supported the draft resolution but said it was still very hard for the smaller developing countries which were putting a great deal of effort into establishing a sound national drug industry to find sufficient objective information on how and where to obtain good and effective raw materials and what price to pay for them. He wondered if more could be done to help them; the same applied to blood and blood products.

Professor KASONGO-NUMBI (Zaire) supported the draft resolution and expressed appreciation for the statement made by the delegate of Germany regarding the control of drug exports. In order to strengthen the control of drug exports and imports Zaire proposed the addition of a new subparagraph within paragraph 1 to the effect that Member States should be urged to permit the export only of pharmaceutical products expressly authorized by the competent officials of the importing country.

Mr OUAZAA (Algeria) said that access to drugs was becoming a matter of concern to his country in a way that it had not been before. The question was whether the availability of drugs should be allowed to be determined by the socioeconomic situation of a country. Unfortunately the drug market continued to be dominated by commercial pharmaceutical information; information that was objective and genuine was far from the concerns of manufacturers or distributers. It was deplorable that such information was not provided by the manufacturers themselves; very often it was official departments which sought out and offered quality information. Donations of drugs from various nongovernmental and other sources remained a concern for the public authorities, which should ensure that they met the current regulations and safety conditions. There was also a need to think about how drugs were used: by definition they were toxic and needed to be handled with care. Most developing countries had national drug policies, but they were often poorly presented and had to conform to the political, economic and sociocultural environments in which they functioned. Governments seemed to be more sensitive to proposals and recommendations from WHO, and while national drug policies were backed up by university research studies, there was a need to promote international and interregional cooperation.

Algeria belonged to a regional grouping in the Maghreb, and while that grouping took the form of South-South cooperation, it was worth noting that as far as the effort to combat counterfeit drugs was concerned, the flow of drugs was exclusively in a North-South direction. The developing countries were encountering difficulties with information for prescribers, and it was important to begin the process of acquiring a result-oriented approach to treatment at the student level. National drug policies required a political will and the regulatory mechanisms and quality control they instituted governed not only individuals but the whole drug structure.

Turning to the role of the pharmacist, he said that resolution WHA47.12, which called on pharmacists to develop their profession at all levels in accordance with the reports of the WHO meetings held in New Delhi in 1988 and Tokyo in 1993 offered hope and promise for a group of workers whose role as distributors of pharmaceuticals was an eminently social one.

Dr SIDHOM (Tunisia) said that the drug budget represented an ever-increasing proportion of the total budget of health institutions and structures, and physicians occasioned what was often sizeable expenditure by their manner of prescribing. He said he would like the next report of the Director-General to include a paragraph on the role of the doctor as prescriber. He supported the draft resolution, with the amendments proposed by Barbados, and in order to emphasize the need for regional or subregional coordination of national strategies he proposed that a new subparagraph be added after paragraph 2(1) to read as follows: "to encourage Member States, as far as possible, to establish a system for the coordination and harmonization of their national strategies".

Mr MUÑOZ (Chile) expressed support for regulatory policies designed to improve access to drugs and for the strategy and programmes aimed at ensuring quality control of drug consumption and technology utilization. National formularies should be constantly updated and the pharmaceutical industry should be required to supply essential drugs at reasonable prices. Chile therefore supported the draft resolution and the proposed amendments. In the light of that resolution and the statement by the delegate of Tunisia regarding medical prescriptions, it was to be hoped that WHO would continue to work towards equitable access to and rational use of drugs.

Dr AVILA DÍAZ (Cuba) said that 87% of his country's demand for drugs was met by local manufacturers, which were subject to state regulatory quality control. The activities of the national epidemiological and pharmacological surveillance centre were being decentralized to municipal level.

The aim of promoting general access to safe, low-cost and high-quality drugs was obviously linked to the question of pricing of drugs and raw materials, and his delegation supported the draft resolution and the proposed amendments, though it would have welcomed the opportunity to see a revised text incorporating all the proposed new material.

Dr MTSHALI (South Africa) said that her country had recently adopted a national drug policy and essential drugs list with WHO's assistance. Her delegation fully supported the draft resolution with all the proposed amendments.

She urged the Director-General to provide technical, financial and other forms of assistance to help countries, especially developing countries, to become self-reliant in drug and vaccine production so that they were not in thrall to multinational pharmaceutical companies and were able to respond to changing market and economic conditions.

Dr YU Zonghe (China) said that his delegation fully supported the draft resolution.

Dr OWONA-ESSOMBA (Cameroon) said that his delegation broadly supported the draft resolution but proposed that paragraph 1(6) should be expanded to include the same provisions as paragraph 2(4). It would then read: "to eliminate inappropriate drug donations by implementing the interagency Guidelines on Drug Donations produced by WHO in May 1996 and to promote their use in collaboration with the other interested parties".

Dr MAHJOUR (Morocco) said that quality control was a key aspect of action to ensure general access to essential drugs. His delegation therefore supported the draft resolution, in particular paragraphs 1(3), 1(4), 1(5), 2(3) and 2(6).

Mr YANG (Republic of Korea) said that shortages in the supply of essential drugs had impeded disease control in a number of countries. He urged WHO to review the supply of and demand for essential drugs and to report the results to the next World Health Assembly.

Dr FEKADU (Eritrea) said that his delegation fully supported the draft resolution and the statements by the delegates of Togo and Malawi regarding drug donations. While developing countries welcomed such donations, they strongly recommended that all donated drugs should appear on the relevant national list of essential drugs and should meet the needs of the recipient country. Unnecessary donated drugs were a burden in terms of customs clearance, transportation, storage and eventual disposal.

Mr CÓRDOBA (Colombia) expressed support for the draft resolution. He agreed with the delegate of the Netherlands and other speakers that it should include a reference to drug pricing mechanisms. Furthermore, the Organization should carry out a more thorough economic analysis of the use and supply of drugs and study the implications for the pharmaceutical sector of the agreements of the World Trade Organization.

Mrs DRABYSHEVSKAYA (Belarus) said that her country had drawn on the standards and principles established by WHO in formulating its national drug policy. A bill concerning drugs was currently before the Supreme Soviet and a strategy for ensuring general access to drugs was being finalized. Since 1992 the Ministry of Health had been operating a register of drugs to keep counterfeit and substandard products out of the market. Cooperation agreements had been signed with the competent authorities in France, Ukraine and the United States of America, and agreements with other countries were being prepared. The list of essential drugs was continually updated and formed the basis for drug supply contracts.

The issue of drug donations was of vital importance and WHO should publish its guidelines on the subject as soon as possible. Provision should be made for a mechanism that would induce donors to comply with WHO recommendations instead of using recipient countries as a dumping-ground for substandard drugs.

WHO seminars should take into account the different levels of development of national drug policies in newly independent States. In developed countries, practical on-the-job pharmaceutical training was more effective than seminars. It would be useful to prepare recommendations on the privatization of pharmaceutical institutions. Lastly, she suggested that seminars should be held on the organization of pharmacy activities and stocks, centralized and decentralized drug purchases and other practical matters.

She expressed support for the draft resolution.

Dr ABU BAKAR BIN SULEIMAN (Malaysia) said that his delegation fully supported the Organization's work on the rational use of drugs and the Action Programme on Essential Drugs. Malaysia was developing a national list of essential drugs and working on consumer drug education.

His delegation supported the draft resolution with the amendments proposed by Barbados. It wished to see greater emphasis being placed on the cost of drugs.

Dr HLA MYINT (Myanmar) said that a new drugs act had been promulgated in Myanmar two years previously. A list of essential drugs and a national formulary for drugs had also been introduced. His delegation fully supported the draft resolution.

Dr LARIVIÈRE (Canada) wondered how the Committee proposed to reconcile the multiple amendments proposed to the draft resolution. New paragraphs and new issues had been introduced in line with the rapidly evolving dimensions of the issue being discussed. He suggested that, for convenience to save time, the Committee should perhaps restrict its amendments to those proposed by Barbados.

WHO must clearly develop its involvement in standard-setting activities, in the monitoring of aspects of drug marketing and in other related areas, all of which called for proper documentation and careful study, particularly by the Executive Board.

Dr KUNENE (Swaziland) supported the draft resolution and looked forward to publication of the Guidelines on Drug Donations, as the poor economic performance of his country meant that it continued to rely on donations, particularly from western countries. Although there was concern that some of the donated drugs were not appropriate, Swaziland had no option but to accept whatever was offered. Drug pricing was also a serious issue; in particular the cost of drugs for treating patients with HIV/AIDS was prohibitively high. He requested WHO's assistance in ensuring that such drugs became affordable, so that no patient was denied access to treatment.

Mr DE PIERREDON (Order of Malta), speaking at the invitation of the CHAIRMAN, commented that the Order of Malta had long been involved in assisting people who were suffering because of inadequate access to medicinal drugs. A system had been established for the collection, transport and distribution of drugs donated by various groups and individuals. For several decades, the Order had obtained drugs by buying them, or as donations from pharmaceutical companies or, more recently, by recovering unused drugs from pharmacists and individuals. Unused drugs were sorted without charge by pharmacists, who rejected opened boxes and vials and those, if they were for shipment overseas, for which there was less than a year before the stated expiry date. As the recipients agreed to the shipment and its contents before dispatch, there was no risk that the donation would be returned. In France, there were about 100 collection centres and four shipping centres, and almost 1000 tonnes were shipped annually to 80 countries. Other centres existed, for example in Italy, Switzerland and the United States of America.

The Order was thus fully aware of the numerous difficulties that arose at each stage of a humanitarian action and understood why WHO had considered it necessary to establish rules for activities that were based on a spirit of generosity but could have unwanted effects if inadequately planned. The Order of Malta supported the planned Guidelines for Drug Donations and the draft resolution, as its own actions complied closely with the main recommendations outlined in those documents. He emphasized, however, that unforeseen circumstances often led to exceptional situations; action should not be precluded for that reason. The Order of Malta welcomed the channelling of generosity from people who had a surplus of drugs to those who lacked the basic means of relieving their suffering.

Dr BALASUBRAMANIAM (International Organization of Consumers Unions - Consumers International), speaking at the invitation of the CHAIRMAN, said that Consumers International, a federation of 215 consumer organizations in 90 countries, worked closely with Health Action International, a global network of health, development and consumer groups active in more than 70 countries. The draft resolution recommended by the Executive Board would strengthen implementation of the revised drug strategy and national drug policies; it was particularly important for the least developed countries. When drugs were marketed in a way that led to their irrational use, it was the consumer who suffered. For instance, the marketing of antihistamines as appetite stimulants for children in countries where malnutrition was rife and commonly led to loss of appetite aggravated the situation by diverting scarce resources from the purchase of food. Wide dissemination of WHO's Ethical Criteria for Medicinal Drug Promotion and their incorporation into national legislation could prevent such situations from occurring, but the preliminary results of a study under way in six Asian countries indicated that the criteria were not being applied adequately. WHO should mount a concerted plan of action to combat unethical drug promotion and its negative effects on health.

Although drug donation guidelines had been prepared by WHO, many inappropriate donations continued to occur. One of the poorest countries in Africa had received a shipment of 100 000 tablets of loperamide, an antidiarrhoeal agent that did not prevent dehydration, the major cause of death from acute diarrhoea; furthermore, the tablets had arrived only one month before their expiry date. In emergencies, particular attention was needed to ensure that drug donations corresponded to the real local health needs, were essential drugs and were accompanied by full information in locally understood languages. Health Action International could distribute and encourage use of the guidelines and contribute to their review after one year.

WHO's review of its Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce had shown that it failed to function as intended and stressed the need for reformulation and effective regulation. Member States and industry had an important role to play in assuring the quality of exported drugs and the information accompanying them.

Drug prices were always of concern. A comparative survey of the retail prices of 11 essential drugs carried out by Health Action International at the end of 1995 had shown wide variations in the prices of both generic and brand-name drugs; 10 commonly used essential drugs in 16 dosages were much more expensive in some developing countries of Asia than in several industrialized countries. It should be noted that in developing countries 70-90% of the total expenditure for pharmaceutical products was met by the consumers, although a significant percentage of the population of those countries lived below the absolute poverty line. Expansion of WHO's efforts to strengthen market intelligence and review prices and pricing mechanisms for essential drugs and raw materials, together with provision of that information to Member States, could help national governments to develop and implement sensible pricing policies and could help to avoid situations in which poor consumers paid unnecessarily high prices. Those conclusions reflected the recommendations of the international conference on national drug policies that had been cosponsored by the Australian Government and WHO in October 1995.

There were four key issues: assuring better control of drug promotion by monitoring, implementing and reviewing ethical criteria; ensuring that drug donations met the needs of recipients by wide dissemination of WHO's guidelines; assuring the quality of exported and imported drugs within an appropriate regulatory control system by implementing the Certification Scheme; and promoting the use of generic drugs, establishing pricing policies and disseminating international drug prices.

He assured WHO of continued collaboration to improve access to essential drugs and to independent information leading to more rational use of drugs.

Dr ARNOLD (International Federation of Pharmaceutical Manufacturers Associations), speaking at the invitation of the CHAIRMAN, raised two areas of concern with regard to the draft resolution under consideration, although the proposed amendments had somewhat assuaged those concerns. The pharmaceutical industry made substantial donations each year of drugs that were essential for saving lives, preventing disease and relieving acute and chronic suffering. While the proposed guidelines would discourage donations that did not meet those objectives, they might result in a situation in which most really useful donations could be made only by invoking the provisions for special circumstances or exceptions. He therefore supported the proposal that the guidelines be reviewed after the first year of use in the light of the experience of Member States and of the members of his Federation.

The dissemination of information on the pricing of essential drugs and raw materials raised further questions. A transparent, competitive market resulted in the best prices, and there was no reason why valid information should not be provided to potential buyers. It was important, however, that, given the international credibility of information issued by WHO, prices or sources of essential drugs and raw material should be published with due care. WHO must assure that the material met current international specifications and was provided by a manufacturer who observed the standards of good manufacturing practice. In many cases, material was offered by brokers, and its origin and quality were uncertain.

Mr GALLOPIN (International Pharmaceutical Federation), speaking at the invitation of the CHAIRMAN, said that he represented almost 500 000 pharmacists, all of whom played a part in fighting disease. His Federation had been active in implementing resolution WHA47.12, and most national associations had discussed the possibility of joint action programmes with their governments. It was recognized that pharmacists played a key role in drug management, which was achieved by a partnership of health professionals. The Foundation for Education and Research of his Federation had sponsored international conferences in Bangladesh, Chile and El Salvador in order to provide further education for pharmacists; conferences were planned to be held in West Africa, Kazakstan and the Syrian Arab Republic. In 1993, his Federation and WHO had cosponsored a meeting that had resulted in recommendations on pharmaceutical care, primarily by the use of prescribed medicines. The Federation considered, however, that protocols should also be developed for the supply of non-prescription medicines to the public, as people took

increasingly more responsibility for their own health. He invited WHO to organize a meeting on that subject, which was of particular importance for developing countries.

Dr ANTEZANA (Assistant Director-General) said that the discussion demonstrated the importance to Member States of pharmaceutical and biological agents, blood products and other devices used in health care. *The world health report 1996* showed that one of the factors hampering control of newly emerging diseases was a lack of adequate treatment. The elements of equity, universal access, and the quality, safety and efficacy of drugs had been highlighted. All the comments, and particularly the technological and economic concerns of developing countries, would be taken into consideration.

With respect to the question by the United Kingdom delegate about updating the price-indicative list of drugs and raw materials, he said that the list was based on a joint publication of the International Trade Centre and WHO and was revised frequently, the most recent re-evaluation having been undertaken 18 months previously; another was planned before the end of 1996. The information provided by WHO was evidence-based; technical cooperation was a major tool for providing guidelines and standards based on evidence derived at the country level.

The changing, important role of pharmacists in respect of technological developments had been noted.

A unit on blood safety had been established at WHO, which would collaborate with other units to assure the safety of blood and blood products used in both prevention and therapy. Standards would be set in consultation with regional offices and with individual countries.

The Executive Board had recommended that a report on progress in establishing ethical criteria be presented in January 1997.

Dr THYLEFORS (Secretary) suggested that in view of the number of amendments proposed to the draft resolution recommended by the Executive Board in resolution EB97.R14, the Committee might wish to see a revised text that incorporated them all, while maintaining the intention of the original. To avoid possible omission and duplications, the task of revision might be entrusted to a drafting group composed of the delegations that had put forward amendments, together with any other delegations that might wish to participate

It was so agreed.

The CHAIRMAN informed the Committee that in informal discussions the sponsors of the draft resolution on the quality of biological products moving in international commerce (to which he had drawn attention at the start of the meeting) had said they were willing to withdraw their text if the Committee concurred with its aims and intentions and agreed that the importance of the issues warranted a closer analysis of the technical and legal implications than could be made at the present time.

The Committee might also wish to agree that an ad hoc working group should examine those implications in time for a report to be submitted to the Executive Board at its ninety-ninth session, with a view to recommending a resolution for adoption by the Fiftieth World Health Assembly.

Professor PICO (Argentina), Dr LARIVIÈRE (Canada), Dr NIGHTINGALE (United States of America), Dr HERNANDEZ (Venezuela), Dr NARRO (Mexico), and Dr GARCIA (Spain) expressed their agreement.

The Chairman's proposal was adopted (see summary record of the ninth meeting).

Reproductive health (Resolution WHA48.10)

Dr HERZOG (representative of the Executive Board) said that the Executive Board had reviewed the Director-General's report on the implementation of resolutions EB95.R10 and WHA48.10, which had requested the Director-General "to develop a coherent programmatic approach to research and action in reproductive health within WHO, to overcome present structural barriers to efficient planning and

implementation". It had also had the benefit of updated information from the Executive Director responsible for Family and Reproductive Health (FRH).

A Reproductive Health programme had been established comprising research and technical support divisions. In addition to promoting a comprehensive reproductive health approach in country programmes through primary health care, the Reproductive Health programme would concentrate mainly on three global priority issues: family planning, maternal and newborn health, and reproductive tract infections, including sexually transmitted diseases. The Reproductive Health programme was closely linked to the Adolescent Health programme and to the Women's Health Development programme. In recognition of the impact of reproductive ill health on future generations and of the need to ensure a continuum of care across the course of life, those programmes were all linked to a Child Health and Development programme within the overall framework of Family and Reproductive Health.

Reproductive health was a priority issue for WHO as well as for developing countries in terms both of providing resources and of providing an opportunity for WHO to assert its world leadership role.

The Executive Board had strongly endorsed the new approach and reformulation of programmes under the Family and Reproductive Health heading.

Dr ALVIK (Norway), speaking on behalf of the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden), welcomed the new and more unified approach to reproductive health reflected in resolution WHA48.10 and being implemented in WHO. Every effort should be made to ensure the adequate participation of representatives of developing countries in the advisory and technical committees for the new Reproductive Health Programme. Increasing interagency cooperation and a better focused role for WHO, as well as the Organization's contribution to the guidelines for the Resident Coordinator system, had been noted with satisfaction. WHO was in a position to bring about a balanced response to reproductive health needs through well-researched, tested and technically sound strategies and tools for improving access to and the quality of reproductive health services, with well-defined linkages to broader health policies.

Matters of women's health issues and of sex and gender should be dealt with in appropriate interaction with the Reproductive Health programme. More resources were needed in order to ensure the integration of gender aspects in all WHO's programmes and related normative work. Data on reproductive health throughout the world needed to be of better quality and widely disseminated to facilitate policy development and reality-based reporting on progress.

WHO should avail itself, without restriction, of all opportunities where advocacy would contribute towards reducing maternal mortality, morbidity, unwanted pregnancies and unsafe abortions; towards making it possible for adults and adolescents of both sexes to make informed choices in matters related to sexuality and reproduction; and towards providing quality services in line with people's needs. There should be regular reporting to the World Health Assembly on the programme area under discussion, and the Nordic countries requested that a comprehensive report on reproductive health be prepared for the Fiftieth World Health Assembly.

Dr AKIN (Turkey) said that reproductive health should be an integral part of primary health care as had been discussed thoroughly at the United Nations conferences on women in Cairo and Beijing. For many countries it was a priority health issue and the importance accorded to it by WHO and other bodies of the United Nations system was noted with appreciation by Member States. However, WHO's programme, to be successful, would have to be implemented at country level. That would mean providing technical guidance and the tools needed for assessment and research, which could be achieved if WHO collaborating centres were strengthened. Those centres could also play a useful role in ensuring that the care provided was of good quality and that it was monitored and evaluated. Technical cooperation among developing countries was another available tool for implementing and sustaining the Reproductive Health programme.

Dr KAISAI (Japan) welcomed the restructuring of the Family and Reproductive Health programme area and called for the collaboration of Member States in a sector where the health of women and children was most at stake. Japan had undertaken to increase substantially its contribution in that area.

Dr MUÑOZ (Chile) said that it was of the utmost importance that there should be an integrated approach to reproductive health care aimed specifically at adolescents and young people and linked to programmes on mother and child health, family health and control of sexually transmitted diseases.

The meeting rose at 12:35.

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