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FORTY-FIRST WORLD HEALTH ASSEMBLY

COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE SEVENTH MEETING

Palais des Nations, Geneva
Wednesday, 11 May 1988, at 9h00

CHAIRMAN: Professor A. R. Y. ABDUL RAZAK (Kuwait)

CONTENTS

SEVENTH MEETING

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1. FIRST REPORT OF COMMITTEE A (Document A41/30)

The CHAIRMAN invited the Rapporteur to read out the Committee's draft first report.

Mr MYA THAN (Burma), Rapporteur, read out the report.

The report was adopted.

2. RATIONAL USE OF DRUGS (REVIEW OF IMPLEMENTATION OF WHO'S REVISED DRUG STRATEGY) (REPORT BY THE DIRECTOR-GENERAL): Item 23 of the Agenda (Resolution WHA39.27; Document EB81/1988/REC/1, resolutions EB81.R9 and EB81.R10 and Annexes 6 and 7; Documents A/41/17 and Corr.1, A41/A/Conf.Paper No. 5 and A41/INF.DOC./8) (continued)

Mr PERDOMO (Colombia) commended the Director-General and his staff for the Organization's work on drugs, which were extremely important in medical practice and health programmes. Not only governments but also the pharmaceutical industry had a responsibility for ensuring product quality and accessibility and supervising marketing processes. Measures designed to achieve those ends would always fall short of the ideal because that was to provide the best, in the best conditions, but at affordable prices. The developing countries needed maximum support from WHO in order to help them adopt essential drugs policies and basic drugs lists, and introduce quality and price control systems and ethical marketing procedures. The need for such measures was born out by the fact that in Colombia, drugs accounted for 64% of the population's health expenditure. His country therefore supported all the work being done by WHO and governments in those fields and would participate in the first Latin American conference on pharmaceutical policies and essential drugs to be held in Mexico in October 1988. He appealed to the pharmaceutical industry to collaborate in the campaign for the rational use of drugs by helping to discourage their indiscriminate use and guaranteeing the highest quality of product.

His delegation would support the draft resolutions before the Committee.

Dr CABRAL (Mozambique) commended the quality of the report on the implementation of WHO's revised drug strategy and on the proposed ethical criteria for medicinal drug promotion (documents A41/17 and Corr.1 and EB81/1988/REC/1, Annex 7, respectively). His delegation welcomed the comments brought to the attention of the Executive Board and the Assembly by the Board's Ad Hoc Committee on Drug Policies (document EB81/1988/REC/1, Annex 6) and it regretted that the "Report on the world drug situation" (document DAP/87.5) had not been circulated to the Assembly as recommended by the Ad Hoc Committee.

The success achieved by the WHO Action Programme on Essential Drugs in the 10 years of its existence showed the extent to which Member States and the Director-General had his staff had realized the importance of drug policies to the attainment of health for all. WHO had used extrabudgetary resources wisely to help countries to implement their programmes and mobilize technical expertise from outside the Secretariat. He hoped the Director-General would adopt the same approach in implementing the less advanced components of the Action Programme.

Mozambique was deeply grateful to those countries which had supported its pioneering drug policy technologically and financially. However, although that policy had included training for health personnel, those who handed out drugs in the national health service pharmacies were not always capable of giving patients proper instructions for taking drugs. Another unsolved problem was to strengthen the information system for national drug distribution management. Microcomputer programmes were being introduced in drug warehouses and efforts were being made to upgrade drug warehouse conditions. Legislation was under way to set up a national licensing body for the registration of drugs for sale on the national market.

He agreed with previous speakers on the need for forceful action to ensure acceptance of the ethical criteria for medicinal drug promotion. His delegation would support the draft resolutions contained in resolutions EB81.R9 and EB81.R10 and the draft resolution on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (document A41/17, Annex 2), on the assumption that the latter would be adopted on the basis of the corrected version of the proposed amendments to the Scheme (document A41/17 Corr.1). His delegation also approved the draft resolution on traditional medicine and medicinal plants (document A41/A/Conf.Paper No. 5).

Professor AMBROISE-THOMAS (France) expressed his approval of the documents before the Committee. His country fully supported WHO's revised drug strategy and applied its principles both internally and in its relationships with Third World countries. A large volume of legislation and recommended manufacturing practice laid down detailed optimum standards for the production, conservation and shipment of drugs destined for abroad. Their implementation was closely monitored by a national inspectorate, particularly where the product concerned was going to a country which did not yet have its own control system. The French drug certification scheme was based on the principle of the responsibility of each State for its own good manufacturing and certification practices. Because of the importance of that principle, he thought that WHO should confine itself to making suggestions or recommendations on such practices, rather than develop guidelines on the subject as recommended by the Executive Board Ad Hoc Committee in paragraph 14 of its report on the rational use of drugs.

The revised drug strategy called for information and training activities which would enable States not yet possessing independent drug manufacturing and inspection systems to acquire them and achieve a certain self-reliance in those matters. His country, in collaboration with WHO, had embarked on a series of training and information programmes to help friendly French-speaking countries in those fields and it hoped to place a real-time computerized drug information system at their disposal very shortly. It responded willingly to requests for assistance in training and also in helping friendly countries to frame national legislation. It also participated in launching small manufacturing units. All his Government's activities in the fields he had mentioned were fully in line with WHO's recommendations.

Professor BORGOÑO (Chile) expressed his satisfaction at the progress achieved by the Action Programme. WHO Drug Information should at some stage be translated into Spanish, but in any event it should be circulated more widely in order to reach those who might really benefit from it, particularly in the developing countries. The "Report on the world drug situation" would also be of great value. He wished to stress the importance of drug certification schemes, not only for quality control but also in connection with developing countries' export to each other. In the Region of the Americas, it was the rule to insist on certification which met the requirements of the WHO Scheme. That was a great step forward and would help the development of quality control for drugs manufactured from imported raw materials in developing countries.

The subject of ethical criteria for medicinal drug promotion was a delicate one in view of the large number of interests involved. The criteria should be heeded not only by producers but also by purchasers and consumers. The work being done by WHO in regard

to ethical criteria was highly commendable and the criteria should be given wide publicity. The Action Programme should take account of what was being done by the various Latin American countries among themselves, with the support of Spain, in regard to the production or possibility of production, of raw materials for drugs.

His delegation would support the resolutions recommended by the Executive Board and the draft resolution on traditional medicine and medicinal plants.

Dr RAKCEEV (Union of Soviet Socialist Republics) noted with satisfaction that the broad lines of the Action Programme were clearly described in the reports before the Committee. The WHO programme on rational drug use deserved every support. However, some problems remained for the future, one of the most important being the need for improved training of personnel involved in drug manufacture, control and distribution. An important requirement was that reliable and timely information on the effectiveness of essential drugs and their manufacture, the cost of drug consumption, and procedures for drug supply and distribution should be available. More attention should be given to WHO's role in the exchange of information, especially on cases of serious adverse side-effects, especially of essential drugs. To collect and distribute information on that subject would necessitate expenditure, but the money would be well spent and could lead to savings in Member States by obviating the need for national authorities to duplicate it.

His delegation believed that the Executive Board Ad Hoc Committee on Drug Policies should pay greater attention to questions of general requirements for the testing and licensing of new pharmaceutical products, and their harmonization. The continuation of the useful work done by the Regional Office for Europe in that connection would promote the use by medical practitioners of the most promising and acceptable, and the safest drugs.

The scientific and ethical criteria for pharmaceutical advertising formulated 20 years previously needed to be updated. The new criteria endorsed by the Executive Board were more realistic, for example with regard to advertising. A surveillance mechanism should be established to monitor their practical application.

Mr KUROKAWA (Japan) joined previous speakers in welcoming the Director-General's report on rational use of drugs. A significant change brought about by the Nairobi Conference of Experts on the subject was a generally heightened concern that the supply and usage of medicinal drugs was a key factor in ensuring health for all. It was gratifying to see, in the documents before the Committee, the results of strenuous efforts made by all concerned since that Conference to ensure the supply of safe and effective drugs at an affordable cost.

His delegation fully supported all the draft resolutions before the Committee and hoped that they would be approved by consensus.

Dr VONIATIS (Cyprus) welcomed the Director-General's report and that of the Executive Board Ad Hoc Committee. His country had been actively involved in the WHO Action Programme, which, with Swedish and WHO support, had enabled it to introduce a fully computerized drug supply system comprising registration, central inventory control and international tendering. The system was new and his Government was assisting WHO in testing the software and demonstrating it to other countries. It was also helping WHO by performing quality control tests for countries in the Region which did not have their own laboratories. His delegation would support the draft resolutions on rational use of drugs and the WHO Certification Scheme.

Dr GONGOL (Nepal) thanked the Director-General for his valuable report on rational drug use. His Government had recently developed a list of essential drugs for manufacture and supply within the country, but it continued to rely on extensive drug imports. Lack of quality control in manufacturing countries had caused Nepal

considerable prejudice and his country could benefit greatly from WHO assistance in monitoring drug quality at the regional level. In order to ensure the increased availability of drugs in peripheral health institutions, his Government had successfully launched a pilot scheme to ensure that drugs reached people at a price they could afford. Rational drug use had to be inculcated in health personnel from the beginning and so had to be appropriately stressed in the curricula of training institutions and through continuing education.

His delegation was gratified at the interest shown in herbal medicines, in keeping with the aim of "Saving Lives by Saving Plants". Traditional herbal medicines had long been used in his part of the world and should go a long way towards providing the people of developing countries with cheaper and easily available drugs and achieving the objective of health for all by the year 2000. His delegation fully supported WHO's revised drug strategy to promote the rational and ethical use of drugs, as well as the draft resolutions recommended by the Board in resolutions EB81.R9 and EB81.R10.

Professor HIZA (United Republic of Tanzania) said that his country had consistently implemented WHO's strategy for the rational use of drugs and had established its own essential drugs policy and programme. It had also strengthened its drug regulatory authority in such a way as to give it a major role in controlling the rational use of drugs.

Two major problems confronted his country in that respect. Firstly, inequalities in drug supplies in neighbouring countries had led to pilfering of its drug supplies. He therefore appealed to his country's neighbours to revise and strengthen their drug policies so as to eliminate those inequalities. Secondly, numerous voluntary-agency hospitals and dispensaries continued to receive many donations of expired drugs shipped without regard to the recipient's ability to use them properly. The drug regulatory authority had taken stern measures to intercept unsuitable donations and would inspect all drug donations to voluntary agencies at the port of entry. He appealed to all Members of WHO to ensure that their drug shipments conformed to the Organization's recommendations.

His Government had drawn up an essential drugs list and given training and advice to all drug personnel, medical officers and consultants and professors concerned. It had also drawn up revised medical school curricula. It was gratifying to see that most multinational pharmaceutical firms were conforming more and more to the ethical criteria for medicinal drug promotion. His delegation would support the draft resolutions contained in resolutions EB81.R9 and EB81.R10, and fully endorsed the WHO Action Programme.

Dr BALASUBRAMANIAM (International Organization of Consumers Unions) speaking at the invitation of the Chairman, said that IOCU, an organization with 164 members in some 60 developing and industrialized countries, had, since its inception, been concerned about the impact of the irrational use of drugs on the health and safety of consumers. Since 1981, it had been working to encourage the rational use of drugs with Health Action International (HAI).

Both IOCU and HAI had consistently supported the efforts of WHO, its Member States and other institutions and bodies, to achieve a more rational use of drugs. They therefore wholeheartedly supported WHO's revised drug strategy and applauded the work of the Action Programme on Essential Drugs and Vaccines. The amendments to the WHO Certification Scheme, the ethical criteria for medicinal drug promotion and the guidelines for the development of national drug policies were all welcome additions to the tools needed by governments, health workers and people themselves to implement strong national measures on drugs.

It must be pointed out, however, that the work on pharmaceuticals was taking place in a world plagued by social and health inequity. The report on the world drug situation made it quite clear that up to half the people in the world had no access to essential drugs and that in all countries, whether developing or industrialized, the gap between health "haves" and the health "have-nots" was widening.

It should be remembered that some 50 developing countries had populations of less than one million and in about 100 countries the population was less than 3 million. In those countries, the basic infrastructure for ensuring the rational use of drugs was often rudimentary or even absent. The ability of such countries to implement the revised strategy was limited and had therefore to be strengthened through increased support for national and regional initiatives, if the inequity was to end.

Another example of inequity was that far more resources were devoted to the irrational use of drugs than to their rational use. While the more than US$ 500 million mobilized to promote the rational use of drugs was to be warmly welcomed, it should be noted that that sum represented only about 5% of the amount spent in a single year by the world's pharmaceutical industry on promotion. There was no longer any doubt that much of that promotion contributed to irrationality and inequity in the use of drugs. A case in point was the promotion of antidiarrhoeal medicines containing antibiotics, which were expensive, ineffective and potentially harmful, particularly when, for a few cents, life-saving oral rehydration salts could prevent the unnecessary deaths of millions of children. Yet a recent survey carried out by IOCU and HAI had found that nearly two out of every three antidiarrhoeal products on the world market contained an antibiotic. He had been glad to hear from the delegate of Malaysia that irrational combinations were to be removed from the market in that country and urged other Member States of WHO to follow that example.

IOCU wished also to stress the importance of the provision of positive, independent information on drugs to health workers, prescribers, patients and consumers of drugs. As had been pointed out by the Riga meeting which reviewed progress towards health for all and reaffirmed the Declaration of Alma-Ata, the provision of information, technical support and decision-making possibilities were essential means for enabling people to share in opportunities and responsibilities for action in the interest of their own health. HAI had recently adopted a four-year plan of action for the production and dissemination of objective information on drugs, including the encouragement of independent drug bulletins at national level, and work with the media and health professionals to improve the transmission of positive health messages to the general public. He urged Member States and WHO similarly to intensify their efforts to disseminate objective drug information.

Another startling health inequity was that most efforts to improve the rational use of drugs had been focused on the public sector. Yet, in most countries of the world, and particularly in developing countries, the public sector accounted for only something between 10% and 30% of drug use. That irrationality must be tackled.

WHO and its Member States had a strategy and possessed the technology, but must now engage in the more difficult task of implementation at the national level. Cooperation with or control of the drug industry would be essential. IOCU and HAI intended, therefore, to focus attention on the implementation and monitoring of codes of practice or legislation based on the ethical criteria for drug promotion, on providing support for the training of essential drug promoters, on encouraging the development of local, national and regional drug formularies, on providing objective information and ensuring its dissemination and, thus, on empowering people to join in those efforts.

During the Health Assembly, the Director-General had spoken of challenges to the world health community: the challenge of the eradication of poliomyelitis, and the challenge of subjecting health policies and practices to a kind of "social audit", whereby efforts were judged by how much they contributed to social equity. Both IOCU and HAI were prepared to help in the realization of those challenges and wished to offer a few challenges of their own to the world health community. They would challenge that: by the Forty-third World Health Assembly (1990), there should no longer be any antidiarrhoeal preparations containing unnecessary antibiotics on the market; and the amount spent on promoting the rational use of drugs should have at least doubled; by the Forty-fifth World Health Assembly (1992), the majority of Member States should have implemented regulations to control unethical drug promotion; by the Forty-seventh (1994)

all Member States should have national drug policies in place as an integral part of primary health care and national health policies; and by the Forty-ninth (1996), the majority of Member States should have established continuing medical education programmes for health workers which were free from undue commercial influence. By taking up those, and a host of other challenges embodied in the revised drug strategy, WHO might be able in another ten years to join in an even more impressive celebration of progress towards social and health equity and enable the children of the future to talk of a healthy future without a question mark hanging over it. IOCU and HAI were committed to taking up the challenges on the road to better health and the more rational use of drugs, and to playing their part in the continuing social audit of the world health community both at the present, in the year 2000 and beyond.

Dr NASHER (Democratic Yemen) welcomed WHO's achievements in more fields than had been thought possible 40 years previously, achievements which were especially to be attributed to the flexible and progressive nature of the Organization and, during the past fifteen years to the dynamic and dedicated leadership of the retiring Director-General. Among those achievements was the development of the essential drugs policy and that of the rational use of drugs, basic elements of primary health care. Everyone appreciated that those policies did not mean the provision of fewer and cheaper drugs, but ensuring better and more economic procurement and storage, efficient and wide distribution, in addition to ensuring their efficacy, safety, acceptability and rational use. Such a policy was particularly needed by the developing countries as many of the speakers who had preceded him had stated. That did not, of course, mean that developed countries also did not need such a drug policy, but they have the resources to implement the policy, whereas developing countries did not.

His delegation was pleased to note from the Director-General's report that more than 100 countries had developed an essential drugs list, and some were operating essential drugs programmes. Democratic Yemen was one of the latter, and, although the programme had started only four years previously with the support of WHO, it was one of the most successful. A recent evaluation had noted the following features: nearly three-quarters of recommendations made in consultants' reports had been implemented; 35 fellowships had been awarded to top- and second-level managers of the Department of Pharmaceuticals and Medical Supplies at the Ministry of Public Health, 40% of regional health units were covered by the project and the proportion of essential, as opposed to non-essential drugs stocked there had increased; the method of prescribing had improved, fewer antibiotics being prescribed, and the number of drugs per prescription had been cut by half, from an average of three to one-and-a-half; the programme was run entirely by national staff with WHO technical support.

His delegation hoped that WHO, despite financial difficulties, would be able to continue to support countries in the development of their essential drugs programmes. Finally, his delegation fully endorsed the resolutions submitted by the Executive Board.

Dr SALCEDO (Venezuela) expressed his country's support for WHO's revised drug strategy.

Venezuela had its own programme for essential drugs in which the universities, the pharmaceutical industry, the national executive, professional associations and the community were taking part. The Ministry of Health and Social Assistance produced some 27 essential drugs in its own laboratories. They were distributed free of cost to health centres throughout the country. The possibility was being considered of extending the programme with the support of various international and national organizations.

Mrs KADANDARA (Zimbabwe) expressed her approval of the excellent work done on the rational use of drugs. Her delegation strongly supported the draft resolutions before the Committee, in particular, the one concerned with traditional medicine and medicinal plants. The important role in health care played by medicines derived from plants, especially at the primary health care level, should be stressed. Her delegation therefore endorsed the Chiang Mai Declaration (document A41/INF.DOC./8) and commended the Director-General for organizing that important international consultation.

Her country was grateful for the help given by WHO in developing its rational use of drugs policy and the quality and efficacy of drugs used. It looked forward to continued support.

Dr PRADO (Cuba) expressed his delegation's appreciation of the documentation provided. The implementation of the revised drug strategy merited careful examination.

The Action Programme on Essential Drugs had enabled his country to make good quality and low cost drugs available, as part of its strategy for health for all and primary health care, and had promoted their rational use. It had also enabled Cuba to develop its own production of some drugs.

It was encouraging to note that governments had responded positively to the spirit of the Nairobi Conference of Experts on the Rational Use of Drugs by adopting policies for drug supply and quality control, better personnel training and more rational use; his own country had made progress in those areas, avoiding, for instance, the duplication of brands containing the same active principle and increasing the range of useful drugs available, within the limitations of a developing country, of course.

It was essential for those countries to be helped to increase their drug manufacturing capacity, especially for essential drugs, but they should beware of having the manufacture of non-essential drugs urged upon them. It was pleasing to learn that many countries had been able to increase the availability of drugs, but tragic that many people did not have access to them because of their high cost. Such countries needed information on firms offering "starting materials" and "half finished products" at reasonable prices and it was to be hoped that WHO would provide help of that kind. Tropical countries needed help with special problems, in particular, with transportation and refrigeration to prevent the deterioration of drugs. Thus, an integral approach was called for, which would take into account the particular requirements of such countries and their resources.

It was therefore gratifying to note that WHO's revised drug strategy envisaged providing commercial information on sources of starting materials and half finished and finished products, as well as prices, and availability. Efforts to provide representative commercial information should be intensified in view of the importance of that information for planning and the extension of health care coverage, and its relevance to quality control. In that connection, priority should be given to fostering clinical pharmacology and cooperation between developed and developing countries.

Training in clinical pharmacology and, especially, in drug control and quality assurance was needed and WHO could help in that respect. The WHO Certification Scheme represented an advance, but might not be applicable to developing countries which manufactured their own products of adequate quality. The development of plant for the production of drugs in Cuba with the help of the government of India was a good example of the opportunities for international multilateral technical cooperation particularly between developing countries.

The Cuban delegation supported both draft resolutions recommended by the Executive Board and wished to become a co-sponsor of the draft resolution on traditional medicine and medicinal plants.

Dr MOJI (Lesotho) said that Lesotho had adopted a list of essential drugs and, to ensure that their use was rational, had established a national drug formulary, in which drugs were categorized according to their level of use within the health care delivery system. Despite having made progress in the procurement and distribution of drugs, two major problems still remained, namely, irrational and costly prescribing practices and inappropriate estimates or ordering habits by pharmacy staff.

In collaboration with WHO, a research study had recently been undertaken with regard to estimating essential drugs requirements by hospitals and health centres. In addition, the national drug stockpile committee was due to embark on an analysis of the effectiveness of the present pharmaceutical distribution chain, its structure and manpower status, as well as the necessary stock levels. It was also to draw up guidelines for formulating a policy for drugs entering Lesotho, and to review the Bamako Initiative and advise on its implications

Lesotho had a small manufacturing plant producing generic drugs. The importation of drugs to supplement those continued to be a problem area, since imported drugs were often found to be of substandard quality. The WHO Certification Scheme was therefore very welcome. Lesotho received periodical information from WHO on general manufacturing practices to ensure that it continued to follow the established guidance.

In an endeavour to avoid producing poor quality drugs itself and to ensure the protection of other countries which bought drugs from Lesotho, his country had initiated cooperation with such countries, inviting them to visit the Lesotho plant and satisfy themselves of the quality and efficacy of the drugs. He urged other Member States to follow that example.

Lesotho was a co-sponsor of the draft resolution on traditional medicine and medicinal plants since, as an exporter of raw materials, it was particularly interested in that subject. It felt there was a need for a research into the potency of locally available plants for use in drug preparation at home. Collaboration in that respect with traditional healers was obviously essential. Traditional medicine had existed for centuries in Lesotho and continued to be used by many. The continued destruction of natural vegetation as a result of overgrazing and other factors was a matter of concern. It was therefore imperative to embark on systemic study to identify plants of value so as to protect them and use them for the benefit of man within his ecosystem.

Dr MIRCHEVA (Bulgaria) expressed her delegation's gratitude to the Director-General and his staff and the Executive Board for their interesting reports.

Bulgaria used the principles outlined in the document in its drug production. Drug quality and safety were dealt with by the State institute for the control of pharmaceutical products which used the most modern methods for that purpose. In the assessment of new drugs, whether produced in Bulgaria or imported, full information was needed on the pharmacology, clinical trials and analytical methods, both for raw materials and finished products. Special attention was given to the quality control of both well-established and new drugs before certification. If defects were found, the necessary steps were taken.

The State institute had a centre which dealt with the side-effects of drugs after they had been introduced and widely used. Since 1975, that centre had collaborated with WHO on the subject and more than 2000 incidents of side-effects had so far been recorded in Bulgaria. Such studies made it possible to verify therapeutic effectiveness, discover new therapeutic possibilities, drug interactions and side-effects. WHO methods for studying side-effects were used, supplemented by voluntary reports. Each year a bulletin was issued, while steps were now being taken to inform health workers quickly of undesirable side-effects recorded in Bulgaria, by WHO or by other national centres with recommendations as to the prohibition or reduced use of the drugs concerned. The State Pharmacy and the Ministry of Health provided consumers with up-to-date, precise, objective and comprehensive information.

Dr OKWARE (Uganda) commended WHO for the work undertaken so far on the rational use of drugs. Further emphasis should be given to the dissemination of information on drugs, in particular to a better flow of independent information from WHO to Member States. Unfortunately, much of the information available at country level was provided by manufacturers and tended to emphasize the good points, giving little information on adverse reactions and contraindications. WHO had both the neutrality and competence to supply the vital information on essential drugs and on the latest drugs on the market that countries needed.

Although the ethical criteria were good, their implementation at the national level would need more technical and legal support. He suggested that neutral drug promoters should be established at the national level to keep a check on any excesses in promotion by local representatives of drug manufacturers.

His delegation hoped to see a continuing medical education programme that was not funded exclusively by industry. At seminars and conferences, it was difficult to discuss critically and objectively when funding was provided by those criticized. Integrity and neutrality were essential, and WHO should insist on full participation in them.

His delegation wished to be included among the sponsors of the proposed draft resolution on traditional medicine and medicinal plants.

Dr KLIVAROVA (Czechoslovakia) said that her delegation commended the Director-General's report and endorsed WHO's revised drug strategy.

Timely information on drugs, indications for their use, and adverse reactions was of particular help in speeding up the registration and use of new drugs in Czechoslovakia. Her country's health services paid particular attention to the rational use of drugs, considering it an important part of medical care. In the course of registration of drugs, great care was taken to assess the results of clinical trials and only those drugs shown to be both safe and effective were registered. Information on drugs was the responsibility of a group of specialists within the Ministry of Health which was entirely independent of the drug industry.

Czechoslovakia had long given consideration to the rational use of drugs, and 30 years earlier had established a pharmacotherapy committee which systematically ensured that the appropriate drug treatment was used at all levels, monitored the prescribing of drugs, and also the costs involved. The committee was also responsible for informing physicians and pharmacists on new drugs and the adverse effects of drugs.

New information on drugs and appropriate chemotherapy were included in specialized journals, and, in addition, all physicians and pharmacists regularly received from relevant government departments objective information on therapeutic properties and uses of certain drugs. The national pharmacopoeia had been established to ensure a high level of quality control. Tests were carried out on both raw materials and during manufacture so as to ensure that manufacturing practices were correct. Czechoslovakia had not yet introduced the certification of such practices, but would do so in the near future. For both nationally produced and imported drugs, regular quality control as well as control of storage conditions was undertaken at two institutes, located in Bratislava and Prague.

Czechoslovakia also actively cooperated with the countries belonging to the Council for Mutual Economic Assistance (CMEA), with a view to establishing a CMEA pharmacopoeia. It had a good system for obtaining information on adverse drug reactions, each doctor having forms for that purpose which, when completed, were sent to the relevant centre. A centre had also been set up in Prague to deal with information received from the member countries of CMEA.

Her delegation supported the draft resolution on ethical criteria, and also that on the rational use of drugs, recommended by the Executive Board.

Mr GHACHEM (Tunisia) commended the Director-General and the Executive Board on their efforts to promote the rational use of drugs, and all those working to implement WHO's revised drug strategy.

Tunisia had rethought its drug policy in order to promote effective pharmacotherapy and standardized prescribing, and with a view to reducing abusive levels of drug consumption. Established lists were re-examined bearing in mind developments in the pharmaceutical industry in Tunisia and worldwide. Particular emphasis was being placed on the use of international nonproprietary names, quality control, and purchase of medicaments in accordance with appropriate standards. In addition, particular stress was

being placed on training, and therapeutic methods taught in medical faculties had been modified so that future physicians would avoid developing the habit of prescribing drugs which were often useless, sometimes harmful, and always costly.

The documents provided did not sufficiently emphasize the importance of the role of managers in promoting the rational use of pharmaceutical products. In Tunisia the assignment of pharmaceutical specialists in hospitals and the establishment of a specially trained drug inspectorate within the framework of overall management had led to improved drug management both in university hospitals and in basic health centres. The computerization of drug stock control at certain hospitals had also improved management practices. However, further attention was still needed in the area of drug management.

Dr GODANA (Kenya) commended the documentation provided on the rational use of drugs. His delegation requested clarification regarding the wording of the proposed amendments to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce contained in Annex 1 of document A41/17 Corr.1. In Part III, paragraph 2(d), the wording of the English version "the inspectors of the services of its competent authority have appropriate qualifications and experience." did not correspond exactly to that of the French version "les inspecteurs au service de l'autorité compétente possèdent les qualifications et l'expérience appropriées." He proposed that the English version should be amended to read "the inspectors in the service of its competent authority have appropriate qualifications and experience".

Dr N'JIE (Gambia) said that the extensive list of speakers on the issue of the rational use of drugs indicated the importance of the topic to Member States and the quality of the Director-General's report. The nature of the debate attested to the progress achieved thus far. In many countries, essential drugs were a way of restoring the credibility of the pharmaceutical sector in their communities and it was therefore not surprising that the level of interest continued to be significant.

Although there were reasons for satisfaction, as had been pointed out to the Executive Board at its eighty-first session (document EB81/1988/REC/1, page 78, paragraph 24), unless coverage and rational use of available and future essential drugs were dramatically improved within the next few years, it was unlikely that the goal of providing essential drugs by the year 2000 would be achieved. In the past, his delegation had reported on the varying degrees of success of the Gambia's collaborative efforts with industry, WHO and bilateral agencies, and it was because of that positive experience that he felt it necessary to highlight some of the potential obstacles to achieving national objectives.

The reports of the Director-General and the Executive Board had highlighted a significant shortfall in the level of national commitment to the programmes and objectives collectively agreed to by Member States. Ten years after Alma-Ata, 1.5 thousand million people still had no regular access to the most basic of essential supplies. Other information including the UNIDO assessment of the global drug situation, indicated that the dollar value of drugs consumed globally had doubled in that time. Of the drugs consumed in 1976, 75% were consumed by 27% of the world's population. Since, in 1985, 79% were consumed by 21% of the world's population, mostly living in the developed world, there had been no improvement. He was stressing those aspects because the philosophy behind the primary health care principle of collaboration at different levels had promised such great possibilities. In the past, his delegation had reported on: a successful project with industry to refine drug management, which was still operating satisfactorily; and the Gambia's collaboration with WHO's Action Programme on Essential Drugs, not only in manpower development but in refining the management and implementation of national policy, national legislation and the national regulatory system. The latter programme had recently been extended to include computerization of the drug registration system, stock control and the accounting system. The Gambia had also had fruitful bilateral cooperation with countries such as the Netherlands, which had generously financed the establishment of a national revolving fund for the drug supply system.

The original strategy envisaged at Alma-Ata and at Nairobi in 1985 at the Conference of Experts on the Rational Use of Drugs, involving partnership at the international, national and multilateral levels, appeared to offer significant possibilities and yet, as he had said earlier, 1.5 thousand million people still had no access to drugs. Reports indicated that the problems at all levels were neither simple nor uniform. As far as national commitment was concerned, it appeared that in countries striving to "keep their house in order" there was a willingness to pursue the concepts envisaged at Alma-Ata. Thus, in the Gambia, despite economic difficulties, the Government had made it a priority to guarantee continued support to the drugs programme and sufficient foreign exchange to permit the purchase of supplies; the drug allocation had increased six-fold in the previous year. However, procurement procedures were still causing problems and there was an absence of information on market intelligence at the country level. He therefore welcomed the proposals that WHO should provide such information that the scope of the WHO Certification Scheme should be extended. In trying to stretch scarce resources for drug purchases, there was a danger of sacrificing quality control.

He wondered whether it would be possible to develop an appropriate mechanism, in a spirit of collaboration between industry, WHO, UNICEF, and other organizations, to utilize the reputation and expertise of the larger pharmaceutical manufacturers to ensure that reliable supplies of drugs were made available at reasonable prices. An "honest broker" was required, particularly for countries purchasing only small quantities of drugs. The goodwill demonstrated in the past few years led him to believe that such a mechanism should be possible.

The Health Assembly should ensure that the progress made since Alma-Ata was pursued relentlessly, since the rational use of drugs was one of the areas of primary health care in which the objective set could be achieved, provided that determination was sustained.

Dr EL AWAD (Sudan) commended the Director-General on his report, on an issue of great importance for the developing countries. Increased support should be given to the developing countries to ensure the rational use of drugs.

The Sudan had already endorsed a national policy and developed an essential drugs list and programme. The technical support and cooperation received from WHO over the past two years in respect of donor coordination in the drugs field, the establishment of a computerized system for drug registration, and implementation of the Nile Province essential drugs project had been greatly appreciated. WHO had prepared the technical documents that had formed the basis for considerable financial support from donors.

His delegation supported the proposed amendments to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and the draft resolution.

Dr JAKAB (Hungary) said that the efforts of the Director-General to implement WHO's revised drug strategy, aimed at ensuring the rational use of drugs, were greatly appreciated by her Government, and document EB81/1988/REC/1, Annex 6, Appendix gave an excellent overview of the strategy's implementation. However, the information concerning WHO collaborating centres (contained in paragraph 19) was not quite complete, since no mention was made of the activities of the WHO Collaborating Centre for Drug Information and Quality Assurance in Budapest. The editing of the Drug Regulation Index by the Centre constituted a worthwhile contribution to the implementation of WHO's revised strategy, although she felt that the Index had not been properly publicized and distributed. She proposed that copies should be distributed to Committee A.

The collaborating centre in Budapest, in cooperation with several European drug regulatory agencies and the WHO Regional Office for Europe, had undertaken a study on the possible relation between quality defects and adverse drug reactions, the results of which would be presented in a report. The study had shown that, in some countries, a percentage of drugs, mainly arriving by unofficial channels, were counterfeited and substandard and she wondered how the rational use of such drugs was possible.

Drug abuse was a world problem. WHO's response, the drug dependence programme, aimed to cooperate with countries in the prevention of drug abuse and the treatment of drug-dependent persons. There were also programmes to develop the rational prescribing and use of narcotic drugs and psychotropic substances. Collaboration among those different aspects should be more explicit.

Her delegation supported the draft recommended in resolution EB81.R9 but wished to propose certain amendments, which she would submit to the Secretariat, in the light of a resolution adopted by the United Nations Commission on Narcotic Drugs requesting governments to prevent the introduction of falsely labelled or falsified medicaments containing narcotic drugs or psychotropic substances. While it was true that many such pharmaceutical preparations that were fraudulently introduced to countries contained drugs under international control, the problem was more general, and the marketing of, for example, an alleged antibiotic preparation that contained no active ingredient was something that had to be prevented. The prevention of such activities should constitute a priority issue for WHO and, consequently, it should be highlighted in the draft resolution under consideration.

Dr BANKOWSKI (Council for International Organizations of Medical Sciences) speaking at the invitation of the Chairman, welcomed the opportunity to inform the Health Assembly of those activities of CIOMS that were closely related to the rational use of drugs, namely, the safety of drug use, and particularly the monitoring of adverse drug reactions observed after products had been licensed for marketing ("post-marketing" adverse drug reactions).

Over the past decade, CIOMS had collaborated closely with the WHO pharmaceuticals unit in a variety of matters of concern to regulatory authorities, manufacturers, prescribers and drug users. Activities had been accelerated two years earlier when, at the request of national drug regulatory authorities and manufacturers, CIOMS had initiated a pilot project aimed at coordinating and improving international reporting on post-marketing adverse drug reactions. Six countries and six pharmaceutical manufacturers were collaborating to establish a mechanism consonant with new national requirements calling for accelerated exchange of information on newly-discovered adverse drug reactions. The aim of the project was to provide a standardized means whereby manufacturers could report such adverse reactions rapidly, efficiently and effectively to regulatory authorities. The system was not intended to replace domestic reporting procedures and requirements, but was exclusively concerned with the transfer of information from one country to another through the manufacturers. It therefore complemented and did not duplicate the WHO international drug monitoring programme which received domestic reports from regulators.

The Federal Republic of Germany, the United Kingdom and the United States of America had moved to modify requirements to make them compatible with the proposed reporting scheme. France and Italy had agreed to accept the CIOMS form for reporting of foreign adverse reactions and Sweden had indicated its willingness to accept summaries based on that form. Most of the manufacturers involved were at varying stages of project implementation. Over the two-year period, the CIOMS working group had held five meetings and had made considerable progress. A preliminary report had been published and sent for comment by WHO to national regulatory authorities and by the International Federation of Pharmaceutical Manufacturers Associations to manufacturers. During 1989 data would be made available to assess the volume and utility of the reporting method. The final report to be completed by the middle of 1989, would be transmitted to WHO for consideration of the system as a globally acceptable option for accelerated interchange of information.

Those participating in the pilot project considered the system to be a significant improvement for the reporting of adverse drug reactions. In his opinion, the most important feature was that it had proved possible to bring together manufacturers and regulatory authorities to elaborate, without difficulty, a reporting system that should improve the safety of drugs on the market, in the spirit of previous meetings and

resolutions of the Health Assembly. Such efforts should be pursued to ensure further collaboration between manufacturers and regulatory authorities. The rapid collection and transmission of reports of post-marketing adverse drug reactions were crucial to interpretation and follow-up for ensuring drug safety and proper use. It was not only a statutory obligation but also a moral responsibility to make all possible efforts to ensure that the users of medicaments were protected from unnecessary risks.

Dr ARNOLD (International Federation of Pharmaceutical Manufacturers Associations), speaking at the invitation of the Chairman, welcomed the opportunity of addressing the Committee. The manufacturers of prescription medicines throughout the world, who comprised the membership of the Associations in membership of the International Federation of Pharmaceutical Manufacturers Associations were committed to the rational use of drugs. There were still some thousands of millions of the world's population who had no regular access to modern high-quality medicines, and many diseases for which either no effective treatment existed or for which the available therapies, while useful, were less than ideal. The rational use of drugs would not be achieved unless effective drugs were available to all the world's population.

In working towards rational drug use in the more economically deprived countries, the pharmaceutical industry believed that certain actions, some of which had been identified in the revised drug strategy, deserved priority attention. The industry fully supported the proposed strengthening of the WHO Certification Scheme, as it could only improve the quality of products available in the importing countries. Similarly, the work to elaborate guidelines for the establishment of drug regulatory systems in developing countries could only be beneficial.

The industry had always believed that priority should be given to improving the infrastructure in developing countries for the procurement, distribution and storage of medicines in the public sector. Several member associations had given and were giving practical help and support to that objective, for example, work in the Gambia and Sierra Leone with help from the United States of America, and in the Maldives with assistance from the United Kingdom. Opportunities for further initiatives were being sought and other projects were under discussion.

The industry was continuing to support the improvement of quality control resources in certain countries - the training of government personnel in industrial laboratories under the WHO-International Federation of Pharmaceutical Manufacturers Associations scheme, which had been proceeding well for some years, was continuing, and applications from over 80 candidates had been processed. Substantial material assistance from international industry sources had been provided for the establishment of a quality control laboratory in Zimbabwe. Time did not permit further examples from the exhaustive list of the contributions of many member associations and their member companies.

Rational drug use required that the right information was available for those needing it, and the Federation therefore supported the development of improved public-sector mechanisms for the distribution of accurate and reliable pharmaceutical information for health-care workers. As the generator of the majority of the information on the use of its products, the industry had a key role to play in the provision of information, and a responsibility that it should be accurate and reliable and should not mislead. The Federation Code, drawn up in 1981, was important in that respect. The Federation had taken steps to publicize the existence of the Code and had operated the complaint mechanism in a highly transparent manner; to date some seven status reports had been published and widely distributed. Nearly 500 cases had now been resolved and there was no doubt that the majority of companies associated with the Federation operating in all countries of the world were making every effort to comply with the Code. A recent International Federation of Pharmaceutical Manufacturers Associations meeting, attended by some 120 industry personnel, had indicated the ways in which companies had improved their internal review mechanisms for ensuring compliance. He reminded the Committee that the Code complaint procedure was available for all to use, and that the Code applied to companies responsible for some 80% of the pharmaceutical business worldwide. Furthermore, it required the use of no government resources in its operation.

In his address to the Committee on the same subject at the Thirty-ninth World Health Assembly, he had expressed doubts about some of the priorities assigned to achieve the rational use of drugs, in particular the need for, and relevance of, the exercise on ethical criteria. Although those doubts remained, the Code defined comprehensively principles of ethical marketing behaviour which were fully compatible with the objectives of the ethical criteria defined by the Executive Board which were under consideration.

He had been heartened by the constructive tone of the debate and believed that, when the draft resolutions contained in resolutions EB81.R9 and EB81.R10 and the draft resolution on the WHO Certification Scheme had been adopted, the industry represented by the Federation would be encouraged to make further significant efforts to collaborate with WHO and other parties to improve drug utilization and availability in the developing countries.

Mr DAVY (World Federation of Proprietary Medicine Manufacturers) said that the objective of the World Federation and its members was to advance the practice of responsible self-medication throughout the world, in collaboration with WHO and national governments. Responsible self-medication was the proper use of medicines legally available to the general public without a prescription. Those medicines were intended for the relief of minor illnesses and injuries which people could recognize and manage without the supervision of a health professional. Consumer behaviour research had shown that people wanted to take that responsibility, knew what illnesses they could treat themselves, used medicines with caution and knew when to seek professional help. A great deal had taken place since the 1985 Conference of Experts on the Rational Use of Drugs in Nairobi: there had been a need on everyone's part to learn from each other and to try to define the most appropriate role within WHO to further future productive cooperation.

With regard to ethical criteria for medicinal drug promotion, the information system was of crucial importance for self-medication. That system was the combined information on the package, label and any leaflet and, to a lesser degree, any promotion and advertising of an over-the-counter product, that would provide all the information a person needed to choose and take the medicine safely. Labelling was the foundation of responsible self-medication, and labelling information, available in the right place and at the right time in words that people could understand, helped to ensure the safe and proper use of medicines, and was indeed the most direct and effective way of conveying the necessary information to the consumer.

The second important element of the revised drug strategy was the WHO Certification Scheme. In connection with the issue of exported medicines, the World Federation firmly believed that the importing country should receive the necessary information from the exporting country's regulatory authority and the manufacturer, with a sample of the full labelling of the product. The decision on what information the label should contain when put on the importing country's market should, however, be taken by that country's regulatory authority.

The third important issue was the draft resolution on traditional medicines and medicinal plants. He could assure delegates that the self-medication industry was very much involved in research into traditional medicines and that the members of the World Federation of Proprietary Medicine Manufacturers were willing to collaborate in programmes relating to those medicines and plants.

Although the World Federation was not in agreement with all the details of the ethical criteria, it was willing to accept the objectives reflected therein. The Nairobi conference had stressed the responsibility of national governments for developing policies appropriate to the needs of their populations, and the Director-General had emphasized that it was impossible for WHO to set itself up as any kind of supranational regulatory authority. The World Federation believed that the resolutions before the Committee would give it and its member associations an opportunity to collaborate with national governments in advancing the future contribution of self-medication.

Mr INFANTE (Spain), after expressing appreciation of the reports before the Committee and support for the WHO revised drug strategy, said that Spain's efforts to ensure the safety and quality of pharmaceutical products manufactured in the country were conducted in a European context. It had always chosen the most stringent of the standards laid down by such organizations as the European Economic Community, WHO and the Council of Europe. The national programme launched in 1983 was entering its fourth phase and had already led to a substantial reduction of the number of pharmaceutical products manufactured in the country, and to a high level of safety. Over 80% of the drugs consumed were produced nationally, and the use of irregularly prescribed or overprescribed drugs had been reduced by common agreement between the pharmaceutical industry, distributors and prescribing doctors.

Spain had recently adhered by special agreement to the European Pharmacopoeia of the Council of Europe, from which standards would shortly be extracted to appear in the future Royal Spanish Pharmacopoeia. A special edition of the European Pharmacopoeia, prepared for Spanish-speaking countries, would be presented shortly in Salamanca and would be distributed free of charge to public administrations and health institutions in those countries. Moreover, a meeting of representatives of the Latin American group of countries, held recently in Madrid with the collaboration of PAHO, had yielded tangible results in the joint processing of raw materials by private firms in Argentina, Brazil, Mexico and Spain, to be confirmed at a further meeting in Buenos Aires during the current year between representatives of the administrations and the manufacturers of those countries; the main subjects of discussion would be guarantee of adequate profit for the industry and the need to maintain fair sale prices for essential drugs.

Spain was cooperating in a specific programme for the provision of humanitarian aid in the form of essential drugs in the event of disaster. It also provided technical support for the preparation of national pharmacopoeias and lists of essential drugs and helped to train specialists in that field. In doing so, it adhered closely to the WHO programme, particularly with regard to the specifications of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and the ethical criteria for medicinal drug promotion.

Dr BRAMER (German Democratic Republic) said that his delegation fully supported the report by the Director-General. In the German Democratic Republic, as in all developed countries, practically every measure of medical treatment involved medicament. Apart from the provision of effective and safe drugs, the question of their rational application was gaining in importance, for even a high-quality medicine failed in its purpose if how it was to be used by the patient was not indicated, or if it was not used appropriately. That was why his delegation supported all WHO's efforts to increase the efficacy and safety of drug application.

A new Drug Act that had come into force in the German Democratic Republic in 1987 covered a sphere of action that, in the past, had been mainly concerned with trade in medicines - starting with control and registration through manufacture to distribution - but had now been extended to the users - health facilities, physicians, dentists, veterinarians and other medical and veterinary personnel and the public at large. The relevant WHO documents had contributed to the formulation of those regulations.

The need to improve drug information should be stressed, and his delegation supported the view that information for physicians and for patients should fulfil the respective needs in a target-oriented way. In the German Democratic Republic conditions were very favourable for pharmacists and other pharmaceutical personnel to play an important role in providing information on drugs, since the pharmacies were not interested in increasing the turnover of drugs for commercial reasons.

Professor KHAN (Pakistan) expressed appreciation of the emphasis placed, in the report of the Director-General and of the Executive Board, on the problems facing developing countries, and particularly on the need for national drug regulatory mechanisms. The Certification Scheme on the Quality of Pharmaceutical Products moving in

International Commerce was also useful, especially for countries without a sound drug control system. Exporting countries should be advised to see to it that information on both quality and expiry date was made available, not only on the certificate but also on the package itself.

In Pakistan WHO's cooperation had been valuable, not only in providing the necessary information, but also through the visit of a team from the Action Programme on Essential Drugs that had studied the availability of drugs and had helped to prepare a very useful report. The adequate and regular availability throughout the country of safe, effective and high quality drugs at reasonable prices was an integral part of his Government's national health policy. To achieve that objective at both the federal and the provincial level, a Drug Act had been passed - providing for the compulsory registration of drugs, and the control of their import, export, manufacture, pricing and publicizing to be the responsibility of the federal authorities, while their sale was a function of the provincial authorities. The Act was amended from time to time to ensure effective control.

A salient feature of the Act was that drug manufacture was permitted under licence, granted by the federal Government through a licensing board, and issued for a two-year period renewable under prescribed conditions, including that of official inspection. Another important part of the Act related to drug registration. Both imported and locally manufactured drugs had to be registered by the federal Government for a period of five years. If, as a result of the monitoring and surveillance carried out during that time, the drug was found to be toxic or to have serious side-effects, the registration was not extended.

The main objective of price control under the Act was to keep prices within the reach of the common man, while allowing a reasonable profit for industry and trade. The formula adopted for importing drugs, whatever their CIF price, was to allow a 40% mark-up, which became the maximum retail price. For locally manufactured drugs, a 75%-125% mark-up was allowed on the basic cost, including the cost of the raw materials and the packaging - the figure depending on the form of the drug.

The public advertising of drugs was restricted to over-the-counter products and was subject to approval by the federal Government acting on the advice of a committee on drug advertising. Most manufacturers and importers of drugs in Pakistan had their own supply arrangements. Information on drugs was provided to the medical and allied professions mainly by manufacturing companies, through their medical representatives and through the medical press. With the help of WHO, the Government was considering making a drug bulletin regularly available to the 40 000 doctors in Pakistan.

The Act gave high priority to the quality control of both imported and locally manufactured drugs, providing for the mandatory enforcement of good manufacturing procedures, among other measures. It had been made compulsory to indicate the expiry date on all drug packages, including the free samples supplied to the medical profession. A charge of 1% was levied on all drug sales which went to a research fund.

The transfer of pricing was a problem. Multinational pharmaceutical companies imported raw materials for their formulations at very high prices and raised the prices of their exports correspondingly under the pretext that the raw materials were of very high quality. It had been found, however, that there was no difference between the quality of their materials and those of competing producers. The Government was negotiating with a number of multinational companies on the source of their raw materials and was glad to note that most were cooperating, with the result that their prices were being reduced by as much as 50% of the retail price to the consumer.

Some 9000 formulations were currently registered in Pakistan - a large number, posing problems of control and making it difficult for a physician to select the right drug for treatment. In the face of opposition from the pharmaceutical companies, which maintained that other countries had as many as 50 000 registered formulations, the

Government was pursuing its efforts to reduce the number, the aim being to ensure that all the preparations on the WHO Model List of Essential Drugs, were available throughout the country at a reasonable price. A formulary containing some 500 drugs had been prepared for government institutions which had to dispense drugs only from that formulary.

Another serious problem that was being brought under control to some extent, but still remained a danger, was that of spurious drugs. These were either drugs manufactured clandestinely and marketed with the connivance of unscrupulous retailers; remedies marketed by unscrupulous traders as traditional medicines, sometimes containing harmful substances, that escaped control because genuine traditional medicines were not subject to the Drug Act; and harmful drugs manufactured in certain countries abroad and exported as innocuous remedies. Industrialized countries bore a responsibility for ensuring that such products were not exported to the developing countries.

Pakistan appreciated the cooperation of WHO in regularizing the availability of drugs and fully supported the Action Programme on Essential Drugs. His delegation also supported the draft resolution recommended in resolution EB81.R9 and the proposed revisions to the WHO Certification Scheme.

Dr NGALY BOSENGE (Zaire), commending the Director-General on his excellent report, said that the provision of essential drugs was a component of primary health care that could play a catalytic role in attaining the goal of health for all by the year 2000. Zaire, which was going through a difficult financial situation particularly marked by a currency shortage, was faced with enormous problems in the supply of drugs, since practically all pharmaceutical products were imported, by private individuals, agencies, cooperatives and nongovernmental organizations, especially religious ones. Health workers had to obtain drugs as best they could, very often using most of the income from patients' contributions.

After having drawn up a national list of essential drugs, Zaire was studying the modalities of installing some 40 pharmaceutical depots throughout the country in order to supply the district health services more easily and regularly, and at low cost, with products whose quality could be controlled. However, the programme for installing the depots was encountering difficulties owing to the low level of national production and the shortage of currency to pay for imports. Zaire therefore urged WHO to work in cooperation with UNICEF to ensure that the programme launched at Bamako during the last session of the Regional Committee for Africa soon entered into the implementation phase. His delegation fully supported the draft resolutions recommended in resolutions EB81.R9 and EB81.R10.

Mr HALLIDAY (United Nations Children's Fund), referring to UNICEF's activities in providing drugs to health systems in countries where it was supporting government health services, and specifically primary health care, said that of the total US$ 213 million's worth of UNICEF purchases in 1987, US$ 24.5 million had been spent on essential drugs, US$ 34 million on vaccines and US$ 25 million on related supplies. The drugs had, of course, been exclusively those on the WHO Model List of Essential Drugs and those identified by the ministries of health concerned as being appropriate for the needs of the countries' health system. It should be noted that for all those purchases UNICEF had benefited from the advice and assistance of WHO staff, in both policy matters and in technical questions of quality and assurance. That close collaboration would, of course, continue as UNICEF's purchases of drugs increased.

UNICEF attached enormous importance to the Bamako Initiative, launched by the African ministers of health at the 1987 session of the WHO Regional Committee for Africa, in the belief that, with careful planning and development, it could assure the delivery of essential drugs to the end of the logistics line - to the outlying districts and villages, which so often suffered from any shortage. UNICEF would be working closely with WHO, the World Bank and the ministries of health of the countries concerned in following the Initiative through.

Dr HARRIS (United Kingdom of Great Britain and Northern Ireland) said that the United Kingdom continued to support the programme on the rational use of drugs. In following-up the offer made by the United Kingdom delegation to the historic Nairobi Conference of Experts in the Rational Use of Drugs to help in setting up and strengthening drug regulatory authorities in developing countries, the Department of Health and Social Security had provided experts who had cooperated with a number of national and state health authorities in that endeavour. The United Kingdom would be pleased to continue to cooperate in such a way and, in addition, would provide training for national staff in all aspects of the programme, particularly drug regulatory control. The United Kingdom had increased its extrabudgetary contribution to the programme for the current year by 50%. His delegation supported all the draft resolutions before the Committee.

The meeting rose at 11h45.

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