



THIRTY-FIRST WORLD HEALTH ASSEMBLY



COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE ELEVENTH MEETING

Palais des Nations, Geneva
Friday, 19 May 1978, at 14h30

CHAIRMAN: Dr N. N. MASHALABA (Botswana)

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Note: Corrections to this provisional summary record should reach the Chief, Office of Publications, World Health Organization, 1211 Geneva 27, Switzerland, before 7 July 1978.

ELEVENTH MEETING

Friday, 19 May 1978, at 14h30

Chairman: Dr N. N. Mashalaba (Botswana)

1. PROGRAMME BUDGET FOR 1978 AND 1979 (FINANCIAL YEAR 1979): Item 2.2 of the Agenda

Dr MWAKALUKWA (United Republic of Tanzania), Chairman of the drafting group, introducing the group's amendments to the draft resolution presented at the beginning of the tenth meeting, said that a consensus had been reached on the deletion of the references to resolution WHA28.75 in the first and second paragraphs of the preamble and in operative paragraph 2; and on the addition at the end of the first paragraph of the preamble of a reference to resolution WHA30.30. The phrase beginning at "ranging from" and ending "health programmes" should be deleted from the third paragraph of the preamble, which would thus end with the words "many forms". And the fourth paragraph of the preamble (second half) should read:

". . . to enable the Executive Board and the World Health Assembly to assess the progress of technical cooperation with individual countries in order to detect shortcomings and introduce improvements, as well as to assist WHO and all countries to benefit from the valuable experience thus accumulated".

Dr KLIVAROVÁ (Czechoslovakia) said that, since everyone had agreed to the amendments put forward at the tenth meeting, including the references to resolution WHA28.75, she would prefer that the reference should remain.

The CHAIRMAN asked if the Chairman of the drafting group would agree to retention of the reference to resolution WHA28.75.

Dr MWAKALUKWA (United Republic of Tanzania) replied that the Chinese delegation had not wanted any reference to resolution WHA28.75 in the draft resolution.

Dr YANG Tsun-hsing (China) thought that the Committee should abide by the decision of the drafting group to delete the reference to resolution WHA28.75. The first paragraph of the preamble was unacceptable to the Chinese delegation, which had already made its stand clear in the United Nations General Assembly, the Health Assembly and many other international organizations. In its view, resolution WHA29.48 was the important resolution, and reference to resolution WHA28.75 was unnecessary.

Dr KLIVAROVÁ (Czechoslovakia) said that resolution WHA28.75 had been acceptable to all the delegates at the Twenty-eighth World Health Assembly when it had been adopted. It would seem unconstitutional to reject an amendment merely because it was unacceptable to one delegation.

The CHAIRMAN asked if the delegate of China would be prepared merely to have his reservation recorded.

Dr YANG Tsun-hsing (China) said that, since the question had been brought up again, he felt obliged to repeat his delegation's stand, which was that to speak of reducing military budgets by 10% (as was done in the third paragraph of the preamble to resolution WHA28.75) was idle talk that merely deceived people, because it did not signify genuine disarmament. It was therefore unacceptable to the delegation of a country such as China, which believed in real disarmament.

Mrs BRÜGGEMANN (Secretary) said that, during the discussion in the drafting group, attention had been drawn to the fact that the second paragraph of the preamble referred to the historical events leading up to the revised concept of programme budget policy and strategy. Those events were considered as having been mainly due to resolutions WHA28.76 and WHA29.48.

In view of the fact that the draft resolution under discussion dealt with the policy and strategy of the Organization and its monitoring, the drafting group had felt that, from the point of view of the historical development, the reference to resolution WHA28.75 was less relevant. That, at least, had been the Secretariat's impression.

Professor JAKOVLJEVIĆ (Yugoslavia) said that although very important from the point of view of technical cooperation with developing countries, resolution WHA28.75 was not as relevant as resolutions WHA28.76 and WHA29.48 from the point of view of programme budget policy and strategy. As he understood it, that had been the only reason for deleting the reference to resolution WHA28.75 from the draft resolution. He recalled that resolutions WHA28.76 and WHA29.48 had been prepared by the Group of 77.

The CHAIRMAN asked if the Committee was prepared to accept deletion of the reference to resolution WHA28.75 from the draft resolution.

The SECRETARY read out the draft resolution as amended.

Dr KLIVAROVÁ (Czechoslovakia) said that to delete the reference to resolution WHA28.75 showed a lack of understanding of the whole concept of technical cooperation, which had been based precisely on that resolution, which indicated how the necessary resources could be found for such cooperation. It might be advisable to read out the text of resolution WHA28.75 since the vast majority of the delegates were perhaps unaware of the aspects that were unacceptable to the Chinese delegation.

Dr YANG Tsun-hsing (China) reiterated that all the members of the drafting group had agreed to deletion of the reference to that resolution: it was not only his delegation that had objected to it. However, he did not wish the position of the Chinese delegation to lead to further lengthy discussions and controversy.

The CHAIRMAN asked if the delegate of Czechoslovakia would accept that explanation.

Dr KLIVAROVÁ (Czechoslovakia) said she could not agree with the drafting group's decision. Since no one in the full Committee had objected to the reference to resolution WHA28.75, the group must have been swayed by the Chinese delegation's objection. She again proposed that the resolution should be read out.

Professor JAKOVLJEVIĆ (Yugoslavia) said that it was not only the delegate of China who had objected to the reference to resolution WHA28.75: the whole drafting group, i.e. the delegates of Cuba, China, Mozambique, the Soviet Union, the United Republic of Tanzania and Yugoslavia, had unanimously agreed that it should be deleted. He therefore proposed that the discussion cease and that, if necessary, the matter be put to the vote.

Dr MUREMYANGANGO (Rwanda) formally moved that the debate be closed and that the Committee immediately vote on the draft resolution as amended.

The SECRETARY said that in that case, the Committee should first vote on the proposal made by the drafting group to delete the reference to resolution WHA28.75, since that was the proposal farthest removed from the original resolution.

Dr KLIVAROVÁ (Czechoslovakia) formally proposed that the reference to resolution WHA28.75 should be included in the first paragraph of the preamble to the draft resolution, and asked that her amendment be voted on first.

Professor SENAULT (France) said he had understood the delegate of Rwanda to have moved the closure of the debate and asked whether, in accordance with the Rules of Procedure, the Committee should not proceed to a vote.

The SECRETARY said that the Committee had two proposals before it: (1) the inclusion of a reference to resolution WHA28.75 in the draft resolution; and (2) the drafting group's amendments to that draft resolution. According to the Secretariat's interpretation, the second proposal, which included the deletion of the reference to resolution WHA28.75 should be voted on first.

Professor SENAULT (France) said that the Committee should first vote on the point of order moved by the delegate of Rwanda.

The SECRETARY concurred. Under Rule 63 of the Rules of Procedure, once a delegate had moved the closure of the debate, the Committee should first vote on that motion. Two delegates were entitled to speak against the closure of the debate but, since no delegates opposed the present motion, there was no need for a vote. The Committee might therefore proceed to vote on the deletion of the reference to resolution WHA28.75 from the draft resolution, since that was the proposal farthest removed from the original.

Decision:

- (1) It was agreed, by 54 votes to one, with 23 abstentions, to delete the reference to resolution WHA28.75 in the first and second paragraphs of the preamble to the draft resolution.
- (2) The draft resolution, including all the other amendments of the drafting group, was approved.

2. REVIEW OF SPECIFIC TECHNICAL MATTERS: Item 2.6 of the Agenda (continued)

Drug policies and management: Item 2.6.1 of the Agenda (Resolutions WHA28.66 and EB61.R17; Official Records No. 245, pp. 10-11, paragraphs 56-68; Document A31/12) (continued)

The Committee, in addition to the draft resolution on an action programme on essential drugs presented at the tenth meeting, had before it a draft resolution on medicinal plants sponsored by the delegation of Italy, Malaysia, Rwanda, Togo and Viet Nam, and reading:

The Thirty-first World Health Assembly;

Having considered the ever-increasing importance of medicinal plants in health care, particularly in developing countries;

Noting with satisfaction that WHO has already organized meetings on medicinal plants in the regions;

REQUESTS the Director-General:

- (1) to compile a list of medicinal plants used in the different countries and to establish international nomenclature for the ones most widely used;
- (2) to establish international specifications for the most widely used crude drugs and simple preparations thereof;
- (3) to collaborate with countries desirous of improving the use of medicinal plants and/or their derivatives;
- (4) to coordinate regional efforts in the screening, scientific evaluation and better use of medicinal plants;
- (5) to disseminate information on methods of scientific evaluation of vegetable drugs;
- (6) to designate regional research centres for the study of medicinal plants;
- (7) to ensure collaboration with other United Nations specialized agencies;
- (8) to report on the subject to a subsequent Health Assembly.

The CHAIRMAN said that the representative of the Council for International Organizations of Medical Sciences had asked to make a statement.

Dr GELLHORN (Council for International Organizations of Medical Sciences) said that the adoption and implementation of the guidelines set out in the perceptive and far-reaching resolution proposed to the Health Assembly . . . would have a significant impact on the delivery of medical care to the peoples of the world at present denied the benefits of advances in medicine; and would make it possible for physicians and other health professionals to make better use of the knowledge gained in the course of their training. CIOMS, which comprised 68 international organizations of the medical sciences and 23 national members, had long been concerned with the issues that were being discussed by the Thirty-first World Health Assembly. In 1968, it had organized a round-table conference in collaboration with WHO, entitled "Evaluation of drugs: Whose responsibility?". Even a decade ago, progress in the drug field had required that governments consider the scientific and socioeconomic problems of modern drugs: the 1968

conference had been particularly concerned with the roles to be played by basic medical research, the pharmaceutical industry, government regulatory agencies and medical practitioners in the evaluation of the safety of drugs and their therapeutic value. It had concluded that there was a pressing need to establish a central repository of such information, which could be internationally disseminated as needed. Despite the complexity of such an information centre, WHO had undertaken to fulfil that international obligation.

In December 1977, CIOMS had organized another conference in collaboration with WHO entitled "Trends and prospects in drug research and development", which had dealt with many of the issues set out in the resolution before the Committee and been attended by representatives of the pharmaceutical industry, national drug regulatory agencies, academic medicine and the international organizations, as well as health officials from both developed and developing countries. The discussions that had taken place on the reasons for the disparity in drug research on the problems of importance to different parts of the world were particularly pertinent to the deliberations of the present Health Assembly. Over two billion dollars was annually invested in drug research, but only a very small proportion of those funds were spent on research into drugs for the treatment of major diseases endemic in most tropical countries. The conference had also discussed possible ways of ensuring a more equitable research effort directed to world health needs, and immediate measures to make existing useful drugs available at a reasonable cost to the people of developing countries. Also in collaboration with WHO, a follow-up meeting of experts to implement the conclusions of the conference was now being organized.

CIOMS, which was a nongovernmental organization, had the means to communicate with medical research and professional health personnel throughout the world through its international and national membership, and was prepared to continue its collaboration with WHO in all aspects of drug development and in ensuring the accessibility of drugs to those who needed them - and indeed, in any other health issue that required collaboration between governments and the professional health community.

Dr GAUDICH (Federal Republic of Germany) stated that considerable progress had been made since the Health Assembly had taken up the matter of drug policies three years ago. The delegation of the Federal Republic of Germany welcomed the activities of WHO and related organizations in respect of prophylactic and therapeutic substances, activities that were based on resolution WHA28.66 - one of the Health Assembly's most important decisions.

Drug policies covered far more than the list of essential drugs: research, drug monitoring, and education and training should not be disregarded. Nevertheless, the satisfaction of the basic needs in drugs of large segments of the world's population, which totally lacked or had only inadequate supplies of the 10 or 15 vital drugs (such as analgesics, antimalarials and antibacterial and tuberculostatic drugs) included in the long list of essential drugs, was of even greater importance.

As it had done the year before, the delegation of the Federal Republic of Germany wished to stress that the only way to solve the problem was to launch a worldwide campaign to provide essential drugs at cost price to the underserved population in the least developed countries. Over the past year, governments, technical cooperation agencies and the pharmaceutical industry had had discussions on whether and how such a campaign could be rapidly carried out, since immediate action and cooperation between all the parties concerned was essential. Those discussions had shown that a number of pharmaceutical firms in European countries were prepared to cooperate in such a campaign and to provide the 10-15 basic drugs of high quality most needed in primary health care. It was now incumbent on the governments and agencies concerned to ensure that those precious and delicate goods reached the people who required them in good condition. That called for an effective distribution system, comprising not only transport facilities such as trucks, freight trains and cargo boats, but also trained manpower, such as storekeepers, quality control staff and dispensers, capable of both making the best use of the transportation, storage and quality control facilities available.

Those should be the two main activities of WHO's action programme, in order to ensure achievement of the common objective of attainment by all the citizens of the world of a level of health that would permit them to lead socially and economically productive lives.

The sponsors of the draft resolution on an action programme on essential drugs were to be congratulated on having framed it in such a way as clearly to show the crucial points on which WHO should concentrate its activities. However, operative paragraph 2(3) urging Member States to "enact appropriate legislation covering . . . prescription by generic names . . . [and]

price control", if it were meant exclusively, would make it difficult for the delegation of the Federal Republic of Germany to accept the resolution, since it might conflict with the Federal Constitution. It therefore supported the amendments proposed by the delegates of the United States, Canada and the United Kingdom and hoped that a compromise would be found to which everyone could agree, for the German Federal Republic would very much regret being unable to support the resolution as it stood, particularly as it was anxious to cooperate in the action programme.

Dr MEZEVITINOV (Union of Soviet Socialist Republics) said that the recent Technical Discussions and various WHO meetings of experts had demonstrated the urgency and importance of the action programme on essential drugs. The Organization's programme deserved full support, and he congratulated the Director-General on the concise report now before the Committee.

There was clearly a need for a list of essential drugs that would enable physicians to provide the necessary medical care, particularly as a number of developing countries did not yet have adequate facilities for ensuring proper evaluation of drug safety and efficacy. It was vitally important that each country should have the drugs necessary for the prophylaxis and treatment of the diseases that called for priority attention, and lists of essential drugs based on therapeutic classification would be useful. The lists would need to be constantly revised by countries as some diseases vanished and others appeared. In preparing such lists steps should be taken to ensure that there was not too great a variety in the drugs included. In the Soviet Union, for example, new drugs were not only examined for their effectiveness and safety, but also to compare their efficacy with that of already existing drugs, so as to avoid duplication and keep the number of drugs within reasonable bounds. It was important that, along with recommendations regarding essential drugs, information should be available concerning drugs whose use had been forbidden in some countries, owing to adverse side effects.

Advertising of drugs - which encouraged self-medication and unnecessary use of drugs - was prohibited in the Soviet Union. Scientific symposia were held regularly to acquaint practising physicians with new drugs, and detailed instructions regarding their administration were distributed.

The Soviet delegation supported the draft resolution on an action programme on essential drugs and was prepared to assist developing countries - through WHO and also on a bilateral and multilateral basis - in training specialists, so as to enable those countries to set up their own national pharmaceutical industries.

Professor KAYAALP (Turkey) expressed satisfaction with WHO's efforts over the past three years to identify the main obstacles preventing large segments of the world's population from having access to the most-needed drugs. Since the problems of pharmaceutical supply, particularly in the developing countries, were already known the action programme proposed by the Executive Board in resolution EB61.R17 should be implemented without delay. He praised the report of the WHO Expert Committee on the Selection of Essential Drugs (Technical Report Series No. 615), which contained a list of the drugs most needed for basic health care delivery systems. In the expectation that WHO would take more concrete action to achieve its goals in that field, he supported the draft resolution on the action programme on essential drugs, as amended by the delegate of the United Kingdom. Pharmaceutical supply systems and the selection of essential drugs for primary health care would, he hoped, be considered at the Alma-Ata conference in September 1978.

Dr SPAANDER (Netherlands) commended WHO on the progress it had made in work under discussion, which would have an enormous impact, not only for the Organization, but also at the national level.

As regards the draft resolution on the action programme on essential drugs, he endorsed the suggestions made by the United Kingdom delegate, and had the same attitude as his colleagues from Canada, the United States of America, and the Federal Republic of Germany towards the implementation of the programme. The action proposed by the Board in resolution EB61.R17 included continued identification of drugs and vaccines, drug legislation and regulatory control, and the establishment of a regional quality control laboratory. Without internationally accepted, uniform procedures for quality control and biological standardization, such proposals would be impossible to implement, especially if the aim was decentralization in the shape of regional and national laboratories. Biological standardization was one of the oldest activities

in the international field, since it had been dealt with by the Office International d'Hygiène Publique, and by the League of Nations, before the WHO Expert Committee on Biological Standardization took it over in 1948. The twenty-ninth report of that Committee was in preparation, and the documents for the decisions to be taken at the thirtieth meeting had already been distributed for comment to the 83 experts from 26 Member States, who were on the expert advisory panel. He was disturbed to note from Official Records No. 236 that no budgetary provision had apparently been made for future meetings of the Expert Committee, and asked if it was intended to discontinue those meetings. His delegation considered the regular activities of WHO in biological standardization to be essential. The continuation of the regular yearly meetings of the Expert Committee were of basic significance for the action proposed in EB61.R17, particularly that indicated in operative paragraph (7), which requested the Director-General "to assist in the development of a system of quality control of the products provided under such a programme of technical cooperation".

Dr FÄLLER (Hungary) said that his Government regarded the development of national drug policies and practices as a very important task of WHO. Every country aspired to establish a national drug policy, institute an adequate drug procurement and distribution system, and ensure the quality control of drugs. The first step in that direction was for each country to set up a national institute to select and control drugs and to provide drug registration, free from commercial interests. Such institutes should carry out their work exclusively in the interests of the population, take decisions independently, and be subordinated only to the highest health authorities.

The experience gained in many Member States had shown that an action programme on essential drugs should include all means for achieving an up-to-date national health policy with an efficient drug supply system. The draft resolution on an action programme on essential drugs served that purpose well; he therefore supported it, together with the amendments proposed by the delegations of the Soviet Union and United Kingdom, and pledged his country's assistance in its implementation.

Professor RENGER (German Democratic Republic) believed the list of selected essential drugs to be a useful first step. Additional lists were needed for subregional groups of countries having a similar spectrum of diseases. The cooperation of those countries should be promoted and should include quality control and the local production of drugs. His own country had a central institute of drug control and an expert committee for drugs. The latter - an organ of the Ministry of Health - received recommendations from specialized medical associations and was responsible for deciding what new drugs were needed and what less effective drugs could be eliminated. As a result, the tendency towards a rapid increase in the number of drugs used was inhibited and the national register included only the really essential drugs. He commended WHO on document A31/12 and fully supported resolution EB61.R17.

Dr VALLE (Bolivia) thought that the draft resolution might have paid more attention to the high cost of drugs for developing countries, especially landlocked countries such as his own.

Dr KLIVAROVÁ (Czechoslovakia) emphasized that an adequate supply of drugs was a prerequisite for efficient prophylaxis and therapy. Her delegation supported the recommendations in EB61.R17, particularly with respect to assistance to developing countries in the selection of essential drugs. The establishment of a list of such drugs was the first step to reducing the great number of drugs available, whose commercial significance exceeded their real significance for health. She had been interested in the statement of the delegate of Mozambique regarding the wider use of international nonproprietary names of drugs. Conditions in that respect were favourable in Czechoslovakia because the pharmaceutical industry was responsible to the Ministry of Health, which selected the drugs to be produced and ensured quality control (the strictness of the Czechoslovak pharmacopoeia was well known). She agreed with the recommendations on drugs made at meetings in Manila and Colombo in March 1978, particularly those regarding cooperation with countries in ensuring adequate drug supplies. The recommendation of the Colombo meeting to set up a stock of drugs for use in emergencies or to alleviate currency difficulties was fully justified. It could be objected, of course, that setting up such a stock might result in financial speculation that would negate the right of many populations to health.

Her delegation supported the conclusions of document A31/12. Results would depend on the approach adopted by the individual countries. Czechoslovakia was ready to cooperate, both by supplying drugs and by organizing a course in clinical pharmacology. She supported both draft resolutions - on the action programme on essential drugs and on medicinal plants - as they stood. An excessive number of amendments might, in her view, obscure the positive recommendations made in those resolutions.

Dr NGUYEN VAN DAN (Viet Nam) supported the draft resolution on the action programme on essential drugs, particularly operative paragraph 3(4), which called for the establishing of local production corresponding to the health needs of interested countries, and paragraph 3(9) regarding the fostering of technical cooperation among developing countries.

He had also co-sponsored the draft resolution on medicinal plants. In its health policy, Viet Nam gave priority to prophylaxis, while promoting curative medicine and it aimed to achieve a systematic alliance between modern and traditional medicine, both preventive and curative. Doctors and pharmacists were trying to make the fullest use of the country's own resources in all branches of medicine and pharmacology, especially that concerning medicinal plants, which were a simple but effective remedy accessible to all. With the help of WHO, his country hoped to collaborate with other countries in enriching the pharmacopoeia at a time when the creation of synthetic drugs was causing popular remedies of vegetable origin to be overlooked.

Dr GOTHOSKAR (India) emphasized that no health care programme could succeed without an adequate supply of drugs, which countries had either to import or manufacture - or both. While local production of drugs might not be feasible for all countries, as many countries as possible should try to produce at least some of their requirements locally, depending on the demand, the expertise available, and the infrastructure of the country. There was considerable scope for collaboration among developing countries and between developed and developing countries in the field of drug manufacture, either on a bilateral basis or through a United Nations agency. It was gratifying that such collaboration had been mentioned in the draft resolution on the action programme on essential drugs.

The report of the WHO Expert Committee on the Selection of Essential Drugs (Technical Report Series No. 615) did not fully meet the needs of a developing country which, as the delegate of Mozambique had pointed out, chiefly needed a national formulary. However, the report did provide a basis for the list of essential drugs that would need to be drawn up for such a formulary.

Suitable quality control machinery was necessary to ensure the quality of drugs imported into or produced in a country. The WHO certification scheme guaranteed to some extent the quality of drugs imported, but as soon as Member States began to produce drugs locally they needed to establish their own quality control systems. However, the WHO certification scheme was a good interim measure and India had decided to participate in it.

The action programme on essential drugs was comprehensive. His delegation therefore supported the draft resolution, but agreed with the delegates of the United Kingdom, the United States of America and Canada that drafting changes might be necessary; if a drafting group was constituted, he wished to be a member. The draft resolution on medicinal plants was of particular interest to India, where such plants were used extensively, especially in the traditional system of medicine. There was a need for clinical evaluation of medicinal plants used in various parts of the world, but such evaluation was a long and arduous matter. Of the 2400 medicinal plants investigated for pharmacological activity at the Central Drug Research Institute, Lucknow, only about 10 to 15 had shown any promise. Medicinal plants were an area where there might be useful collaboration between developed and developing countries and among developing countries. The Lucknow Institute was already cooperating with certain other countries in that field, and was prepared to extend its collaboration within the South-East Asia Region and with other regions. He supported the draft resolution, though he thought that some of the operative paragraphs might be difficult to implement.

Dr FERNANDO (Sri Lanka) said that his delegation was pleased to be among the co-sponsors of the draft resolution on the action programme on essential drugs.

In developing countries such as his own, the supply of essential drugs depended on the budgetary provision made for them. In Sri Lanka, between 7% and 10% of the health budget was set aside for that purpose. A rationalization process for drugs had begun as far back as 1959, when the 1000 drugs used in the public sector had been reduced to 500 by a

formulary committee. Similarly, in the private sector, in 1962, 4000 drugs with 6000 dosage forms had been rationalized to 2100 and later, in 1972, to about 630. In addition, there was a special list of life-saving drugs. The National Formulary Committee met monthly to review the drug list and amend it as required. Unfortunately, because of financial constraints, the population's need for drugs had to be subordinated to the amount of money available, and imports of drugs fell short of requirements. Consequently, those engaged in importing drugs tended to import the maximum amount that could be afforded. The cost of drugs was thus extremely important, and there was little point in importing drugs of inferior quality. The key factors in choosing drugs were efficacy, cost, and safety.

All the drugs imported into Sri Lanka were completely formulated, and 19 others were formulated in the country. In some 60% of cases drugs were imported by tender, the remainder being subject to restricted or monopolistic quotations. Quality control was a greater problem with the former group. Despite the stringent criteria for passing imported drugs as satisfactory, some of those drugs were found by clinicians to be relatively ineffective. He therefore urged WHO to set up regional quality control laboratories to which drugs could be submitted for testing. Collective purchases would substantially reduce the cost, and WHO should play a more positive role in identifying suitable manufacturers, so that developing countries with a fixed budget could obtain more safe and effective drugs at reasonable cost. No programmes of primary health care or preventive and curative medicine could succeed unless developing countries could obtain adequate supplies of drugs with the budgets available to them.

Dr GALEGO PIMENTEL (Cuba) said that, no matter how intensive were the efforts made for health, little could be achieved without an adequate supply of essential drugs, efficiently distributed and reasonably priced. The local production of drugs was a legitimate right of all countries, depending on their resources. The pharmaceutical industry was complex, since it might begin as a processing industry and move on to more complex activities connected with the chemical industry. A basic principle had to be borne in mind: local production or procurement of drugs should depend on the health needs of the country. She agreed with previous speakers about the need for research into medicinal plants, which was very important because it could lead to self-sufficiency in raw materials as well as to exchanges with other countries.

She fully supported the draft resolution on the action programme, and shared entirely the opinions expressed by the delegate of Mozambique.

Dr MUREMYANGANGO (Rwanda) said that it would be impossible to develop drug policies and management that would ensure health for all unless Member States planned their health programmes and solved the problem of training. A list of essential drugs was indispensable for developing countries. The local manufacture, quality control, and utilization of drugs were steps towards achieving national self-reliance. Inflation and the specific conditions in Rwanda had lately aggravated the problem of drug supply in that country. Most drugs were flown in. A list of essential drugs had therefore been drawn up and would be implemented as from 1978. Traditional medicine was being reorganized, and a department of Rwanda's university laboratory had extracted from medicinal plants products that were already being used. His country would be glad to cooperate with anyone interested in that field.

Only by the application of a sound policy and management for pharmaceuticals would it be possible - at least for developing countries - to attain the goal of "Health for all by the year 2000". Efforts to achieve a dialogue between WHO, the pharmaceutical industry, and Member States required special attention. His delegation supported the arguments contained in document A31/12 and was a co-sponsor of both the draft resolutions before the meeting.

Mr LI Chao-chin (China) said that drugs were the basic material for preventing disease and could not be separated from the overall structure of medicine. When instituting a health policy, it was important to take into account the drugs essential for carrying out the programme in question and take adequate measures to make them available. A list of essential drugs, corresponding to the real needs of developing countries, was an absolute necessity. It could serve as a reference in choosing drugs to combat endemic diseases, besides making it possible for countries to develop their own pharmaceutical industries to meet their real needs. In connexion with bilateral or multilateral cooperation, it was of

prime importance that developing countries should make full use of their resources (including medicinal plants), develop their scientific research, and train health personnel. WHO should play a major role in that area.

Quality control of drugs should be increased. Each country should set up its own drug control centres so as to provide effective drugs. Increased cooperation in that field also was necessary. It was particularly important to provide developing countries with reliable and effective drugs of high quality at reasonable prices. It was essential to oppose the acquisition of excessive profits in that area. WHO could play a useful role in drawing up a list of essential drugs, and in so doing, it should stress the quality and price of drugs.

The delegation of China supported document A31/12, resolution EB61.R17, and the two draft resolutions before the Committee.

Mr WONDEPAGEGNEHU (Ethiopia) appreciated the understanding shown in the progress report of the major problems of the developing countries in the field of drug policies and management and commended the background document to the Technical Discussions for the commitment it showed to meeting the needs of the world's underserved population.

His delegation endorsed resolution EB61.R17 and supported both the draft resolutions before the Committee. He requested that his delegation be added to the list of sponsors.

Dr BLANC (International Pharmaceutical Federation), speaking at the invitation of the Chairman, said that the Federation was made up of the national pharmaceutical associations of over 60 countries representing about 300 000 pharmacists. Its statutes stipulated that close contact be maintained with WHO. Several of its members had served, or were serving, on WHO expert committees and other groups concerned with pharmaceutical products. The Federation held annual scientific congresses of 1500-2000 pharmacists, at which WHO was represented. A delegation from the various branches of the Federation had participated in the Technical Discussions.

In connexion with the draft resolutions before the Committee the Federation wished to make a number of points. Many drug policy and management problems were directly related to the practice of pharmaceuticals and pharmaceutical technology. In that connexion a distinction should be made in quality control between the active ingredient and the finished pharmaceutical product. The pharmacist was equipped by training to make a useful contribution to the solution of the problems of selection and cost of drugs including local production, quality control, keeping qualities, management, storage, and distribution. He could also take his place in the health team and play a useful part in the education of the public and of health personnel in the proper use of drugs. Accordingly, WHO and many countries could with advantage collaborate more closely with professionals in pharmaceuticals.

The Federation would be holding its General Assembly in Cannes in September 1978 and the delegation that had taken part in the Technical Discussions would take that opportunity to propose to the Federation's member associations that they work out practical means of helping to solve the often dramatic drug supply problems of several of the developing countries.

Professor ORHA (Romania) said that drug policies and management in their various aspects had far-reaching socioeconomic implications for the majority of Member States. He had in mind particularly the selection, control, use, distribution and cost of drugs, as seen against the spectacular development of the pharmaceutical industry and the proliferation of its products in recent decades. However, given broad collaboration and a sound understanding of the situation, it would be possible for the Health Assembly to adopt resolutions and programmes that would be a starting-point for international cooperation, based on the principles of a new economic order, that would lead to achievement of the purposes of resolutions WHA28.76 and WHA29.48.

Alluding to his Government's policy of making proven high-quality drugs available to the entire population, he said that the recommended list of essential drugs could be of great assistance to developing countries in the establishment of their drug policies and could also be of interest to industrialized countries. All the drugs in the list should meet uniform quality requirements established in the form of technical specifications. The packaging should be standardized and carry the international nonproprietary name and the statement that the drug was on the WHO list and had been manufactured to standards approved by WHO. WHO should also periodically make available information on the prices and price trends of finished and semi-finished products and raw materials, and WHO technical and informational publications about drugs should be expanded and supplemented.

The medicinal plants used in traditional systems of medicine and known for centuries for their therapeutic properties had so far not received the attention they deserved. His delegation therefore particularly welcomed the support that WHO was providing to the developing countries in establishing their own laboratories for the study of such plants. It would also be useful for the Organization to compile an inventory of that valuable phytotherapeutic heritage and set up an information system based on WHO methodology.

Dr FOG (Denmark) emphasized the importance of providing continuing information to and training health workers in the proper use of drugs and in drug utilization surveillance throughout their career. That point, which was dealt with in section 5.9.5 of the background document to the Technical Discussions (A31/Technical Discussions/1), was only indirectly reflected in the draft resolution that he was co-sponsoring, but it should be included in national drug policies in order to ensure that, through the discriminating use of drugs, pharmacotherapy remained as rational, effective and cheap as possible in the interests of all, especially the developing countries. It was not enough to provide current information about new drugs and about recent experiences with those already introduced, however well presented, objective and of high quality; health professionals of all levels should regularly attend well-planned short courses. Such courses were particularly important at the primary health care level, where most drug consumption began and came under supervision. His own country and, he thought, other Nordic countries had had encouraging experience of how prescribing habits could be changed in the interests of effectiveness and economy. Local drug committees attended by hospital health workers, primary health workers, pharmaceutical experts and health administrators met to select a suitable range of drugs for use in their area and played an important part in disseminating their knowledge systematically and regularly to their colleagues. Even the working of the committees had provided useful experience.

One of his reasons for emphasizing continuing education was the crucial problem of recruiting teachers and providing teaching materials, especially in small countries. Others might wish to follow the example of the Nordic countries which, by pooling their teaching resources, had always been able to recruit teachers for the short courses in rational pharmacotherapy for primary health physicians that were repeated twice or three times a year in order to cover the whole country. The Nordic countries were committed to sharing with developing countries their experience in that field, not only at the level of ideas but also, on request, in the form of manpower support.

WHO also had an important role to play as initiator and coordinator in cooperation between Member States and as an important source of knowledge and support.

Resolution WHA28.66 urged "governments and professional bodies to ensure that the health personnel and the public are adequately educated and kept informed as to the proper use of prophylactic and therapeutic substances". He assumed that that resolution was still in force and was not being overlooked. His delegation would not therefore propose amendments along those lines to an already long and complicated draft resolution. However, it supported the amendments proposed by the delegate of the United Kingdom.

Dr MWAKALUKWA (United Republic of Tanzania) agreed with previous speakers on the importance to all countries of the item under discussion.

Noting that the report of the WHO Expert Committee on the Selection of Essential Drugs (Technical Report Series No. 615) provided the scientific basis for making a selection of such drugs, he requested WHO to continue cooperating with Member States in establishing lists of drugs for use at the various echelons of health care; his own country had already established such lists as well as a national formulary. The Organization should also enlist the cooperation of the drug companies so that some control could be achieved over their promotional methods. He welcomed the emphasis placed in the draft resolution on the use of generic names; the policy of his country was to use them.

As far as drug production was concerned, with one small plant producing valuable drugs and one vaccine plant producing BCG and smallpox vaccine, his country was far from self-sufficient. It looked forward to increased technical cooperation with the Organization and with other Member States.

His delegation supported the programme on essential drugs and welcomed the opportunity of co-sponsoring the draft resolution on the subject.

Mr YEAP (Malaysia) expressed his appreciation of the progress made in the implementation of resolution WHA28.66, noting in particular the establishment by the Executive Board of an Ad Hoc Committee on Drug Policies. The Organization had now developed a programme that Member States could each take up at the stage appropriate to its development, in cooperation with WHO.

His country had found that central procurement and distribution of drugs, combined with local production for the public sector, was a useful system for optimizing expenditure on drugs. It was currently expanding production and distribution facilities and completing a study with a view to the use of electronic data-processing in its stock control system.

Plans for central procurement and distribution systems called for a multisectoral approach taking into account, for instance, the port and transport infrastructure. He therefore welcomed the establishment of the intersecretariat task force with UNCTAD and UNIDO. It should direct its attention to such problems as the industrial property protection system, the cost of transfer of technology and its effect on drug prices.

Much had been said about economy of scale in connexion with the local production of drugs. When the pros and cons were evenly balanced, the decision should, in the interests of self-reliance, be in favour of establishing local drug industries.

Where quality control was concerned, the WHO Certification Scheme went some way towards protecting the consumer in the developing countries, but it did not obviate the need for facilities in those countries because so much could happen to drugs - particularly vaccines - on the way to the consumer. However, developing countries should beware of oversophistication in quality control, which could play into the hands of those who, applying modern marketing methods in countries where growing affluence was producing a demand for a choice of more sophisticated consumer goods, were encouraging the erroneous belief that the more expensive a drug the more effective it would be.

His delegation had welcomed the opportunity of co-sponsoring the draft resolution on essential drugs because it reflected the views expressed in the Technical Discussions and in the General Chairman's report to the Health Assembly, and because it would sustain the impetus of WHO's efforts in the important programme under discussion.

Dr LEPPÖ (Finland) commended the reorientation of the WHO programme under review, which broke new ground in a sphere of vital importance to Member States.

His alternate in the Executive Board had stated his views (WHO Official Records, No. 246, p. 131) and the main points that he had had in mind at the current meeting had already been made by the delegate of Norway in his introduction and by other speakers, and were reflected in the draft resolution that his delegation was supporting as a co-sponsor. His delegation could accept the amendments proposed by the delegate of the United Kingdom if they were acceptable to the other co-sponsors, because they did not affect the substance of the resolution, but it could not subscribe to the other amendments. He expressed the hope that the draft resolution would be approved by consensus, without a vote or referral to a drafting group, because it was already a thoroughly discussed and well thought out compromise.

Dr CLAVERO GONZÁLEZ (Spain) said that his Government was well aware of drug problems - of the inadequate supply in some countries and overconsumption in others and of the shortcomings in their use - and it realized that the problems were particularly acute in countries with limited resources where access to even the most essential drugs was difficult. His delegation endorsed the view expressed in the report that essential drugs and vaccines were indispensable elements in health care and disease control; drugs accounted for too big a proportion of national health budgets, and the rationalization of drug supplies was of great importance in meeting the needs of Member States.

Pharmacotherapy, within the framework of integrated health care, was part of the State's response to the community's demand for health. The recently established Ministry of Health and Social Security in his country had embarked on the task of bringing up to date national drug policy and management in order to make the necessary drugs accessible to the entire population regardless of economic status and place of residence. The Government had recently approved standards in a number of specific fields. His delegation therefore supported the draft resolution on essential drugs and urged the Organization to pursue the implementation of the programme as a matter of urgency.

Expressing its continued interest in the fullest cooperation with the Organization and other Member States, he announced that, in agreement with the authorities of the

Organization, his Government would increase its contribution to cooperation with developing countries by supplying documentation on standards and regulations on such matters as drug registration and advertising; providing information on standards and systems of quality control and good manufacturing practice, training specialist personnel; providing means of promoting full technical cooperation and supplies of essential drugs on the most favourable terms; and ensuring quality control of pharmaceutical specialities to WHO standards.

Professor CHRUSCIEL (Poland) considered that, as the General Chairman of the Technical Discussions had suggested, the Organization should study the feasibility of drawing up a standard therapeutic classification of registered drugs to include guidelines for classification and a list of all the essential, life-saving and other registered drugs in the world, divided into therapeutic classes, groups and subgroups. The drugs should be listed singly, not as preparations, and the classification should be frequently revised to bring in newly registered drugs. Such a standard classification could serve as a basis for the selection of drugs essential to primary health care. WHO had already taken the first steps in that direction and the WHO International Centre for Monitoring of Adverse Reactions to Drugs was using such a classification; it did, however, need review and modernization.

His delegation considered that the existing programme of information on new drug registration should be expanded to include all registered drugs.

The Organization's programme of drug consumption studies should be expanded to cover the new pharmaceutical discipline of social pharmacology. He hoped that the studies in social pharmacology taking place in his country would be of assistance in working out new methodologies applicable by other countries in developing better drug policies. His country would also provide assistance with the organization of drug control laboratories at the request of WHO or of its Member States.

He would welcome information on the future of the drug consumption programme. The cumulative list of International Nonproprietary Names would be more useful if it contained indications of the therapeutic category to which each drug belonged and in the case of registered drugs, of the country of registration.

He endorsed the comment of the delegate of Denmark on the need for training in clinical pharmacology. His Government was willing to provide assistance to developing countries in the form of training opportunities in all areas of pharmacology, clinical pharmacology and drug control.

As a co-sponsor of the draft resolution he accepted the amendments proposed by the delegate of the United Kingdom, and he joined the Finnish delegate in expressing the hope that the draft resolution would be approved by consensus.

Dr SIWALE (Zambia) suggested that the Secretariat comment on the points made in the discussion and that the Committee then proceed immediately to approval of the draft resolution.

Professor SULIANTI SAROSO (Indonesia) said that such a procedure might be acceptable provided that there were no further amendments to the draft resolution. Her delegation wished to propose the substitution of the words "control of diseases prevalent in" for the words "disease control" in operative paragraph 3(1) and the addition of the word "management" before the word "programmes" in operative paragraph 3(2).

Professor SENAULT (France) said that he would oppose a motion for the closure of the discussion.

The DEPUTY DIRECTOR-GENERAL outlined various procedures from which the Committee might wish to choose.

Dr AUNG-THAN-BATU (Burma) suggested that it might in future be desirable to limit the number of speakers by applying Rule 60 of the Rules of Procedure.

The CHAIRMAN asked the speakers remaining on the list if they wished to be heard and if they had any amendments to propose.

The delegations of Angola, Kenya, and Madagascar expressed their wish to become co-sponsors of the draft resolution.

Dr GAUDICH (Federal Republic of Germany) proposed the replacement of the word "control" in operative paragraph 2(3) by the word "regulation".

Dr BAMBOSE (Nigeria) proposed the addition of the word "storage" after the word "procurement" in operative paragraph 2(1).

A brief discussion ensued, in which the delegations of Cape Verde, France, Ghana, Iran, Iraq, Mozambique, Norway, Panama and Switzerland took part, on whether the debate should be closed or continued; whether a fresh text was required for the draft resolution and, if so, whether a working group should be set up to consider it; and whether the amendments to the draft resolution should be voted on separately or the draft resolution be adopted, as amended, by consensus.

It was agreed to continue the discussion to seek approval by consensus.

Dr MORK (Norway) said that he and his co-sponsors accepted all the amendments except that of the French delegation.

Professor SENAULT (France) considered the original version of the draft resolution acceptable but for the mention of "generic names" in operative paragraphs 2(2) and 2(3). If the reference to generic names was maintained the recommendation would not be applied in his country, since it would then be incompatible with its legislation and in opposition to the principles of prescription and the free exercise of medicine in France. Accordingly, if the draft resolution was adopted his delegation would vote against it. If it had been decided that a working group should be set up, he would have wished to be a member of it.

Professor AUJALEU (France) said that, in order to enable the Committee to adopt the draft resolution without resorting to voting, it would be sufficient to have a statement in the summary record that his delegation was opposed to the words "by generic names" in operative paragraphs 2(2) and 2(3).

The CHAIRMAN asked whether the Committee was prepared to approve the draft resolution co-sponsored by the delegations of Angola, Bangladesh, Bolivia, Cuba, Denmark, Ethiopia, Finland, Ghana, Italy, Kenya, Madagascar, Mozambique, Nepal, Norway, Panama, Philippines, Poland, Romania, Rwanda, Somalia, Sri Lanka, Swaziland, Sweden, United Republic of Tanzania, Venezuela, Viet Nam and Yugoslavia, as amended by the delegations of the Federal Republic of Germany, Indonesia, Nigeria and the United Kingdom.

Decision: The draft resolution, as amended, was approved.

Dr FATTORUSSO (Director, Division of Prophylactic, Diagnostic and Therapeutic Substances), speaking on the comment by the delegate of the Netherlands, said that there would be no meeting in 1979 of the WHO Expert Committee on Biological Standardization. The Director-General, however, would examine the situation in the light of that comment.

With regard to the question by the delegate of Poland about the future of the drug consumption programme, he would reply to him directly after the meeting had risen.

Dr CH'EN Wen-chieh (Assistant Director-General) thanked the delegates on behalf of the Director-General for their support for the new WHO programme on drug policies and management. The programme was now becoming extremely important, not only for developing countries but also for developed countries, because it was impossible to extend health care without an adequate supply of essential drugs. The first step had been to identify the problems through visits to many developing and some developed countries. It was now clear that action could take place only in the countries themselves, with WHO acting as a catalyst, a coordinator and, most importantly, a means for fostering technical cooperation with and among countries.

Reference had been made to the importance of developing countries making the best possible use of locally available medicinal plants. Action to enable them to do so already formed part of the drug policies and management programme. A meeting would be convened by the end of 1978 to consider selecting the most widely used medicinal plants, and a network of WHO collaborating research and training centres for the use of medicinal plants in health care would be established.

The meeting rose at 18h10

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