COMMITTEE ON PROGRAMME AND BUDGET

PROVISIONAL MINUTES OF THE TENTH MEETING

Palais des Nations, Geneva
Saturday, 14 May 1966, at 9 a.m.

CHAIRMAN: Professor P. MACÚCH (Czechoslovakia)

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Note: Corrections to these provisional minutes should be submitted in writing to the Chief, Records Service, Room A.843, within 48 hours of their distribution.
1. REVIEW AND APPROVAL OF THE PROGRAMME AND BUDGET ESTIMATES FOR 1967: Item 2.2 of the Agenda (Resolution EB37.R19; Official Records Nos. 146 and 149; Documents A19/P&B/10 and A19/P&B/17) (continued)

   Detailed Review of the Operating Programme: Item 2.2.3 of the Agenda (continued)

INTERNATIONAL MONITORING OF ADVERSE REACTIONS TO DRUGS: Item 2.7 of the Agenda (Resolutions WHA18.42 and EB37.R14; Official Records Nos. 148, Annex 11, and 149, Chapter III, paragraphs 57-67)

The CHAIRMAN explained that he was taking the Chair at the request of the Chairman, Dr Nabulsi, who was prevented from attending the meeting. He wished to take the opportunity of expressing his appreciation of the honour paid to his country, his delegation and himself by his election as Vice-Chairman.

He invited the Committee to continue its discussion on Programme activities, as contained in Official Records No. 146.

4.4 Health Statistics

There were no comments.

4.5 Biology and Pharmacology

The CHAIRMAN drew the Committee's attention to item 2.7 of its agenda relating to international monitoring of adverse reactions to drugs, which should be considered in conjunction with the present section.

Dr EVANG, representative of the Executive Board, recalled that the Executive Board had studied the subject of international monitoring of adverse reactions to drugs on the basis of resolution WHA18.42 and of the report submitted by the Director-General (Official Records No. 148, Annex 11).
Several members of the Board had emphasized the importance of the problem as well as the complexity of the present situation, where there existed a serious risk of drug-induced illnesses. Indeed, drugs could now be considered as an addition to man's chemical environment. Stress had been laid on the fact that great quantities of drugs were being consumed by normally healthy as well as by sick people. It had been felt, therefore, that it was essential for WHO to find a way at least to start to tackle that immense problem.

He drew attention to resolution EB37.R14, on which the Executive Board had reached speedy agreement.

Dr Kaul, Assistant Director-General, said that the Health Assembly had, since its Fifteenth Session, been continually engaged in the development of a programme for the promotion of the therapeutic safety of drugs. It had been decided that a major part of such a programme should consist of the systematic registration and evaluation of those drug effects which, though inseparably linked to the therapeutic effect, were not intended by the physician and were adverse to the recipient of the drug. The earliest possible knowledge about such effects would enable an appraisal of the therapeutic hazards, i.e. risk versus benefit, to be made early enough to prevent major drug catastrophes. The limitations in that respect of animal experimentation, and hence the need for observations in man, had been pointed out by various scientific groups convened by the Director-General over the past three years, and the Director-General's report to the Executive Board summarized those basic considerations.
In response to resolution WHA18.42, the Director-General had invited in 1965 a group of consultants to examine problems concerning the establishment of an international programme for monitoring adverse reactions to drugs. Those consultants had been unanimously of the opinion that WHO should undertake such a responsibility, but that the precise nature of the programme could not be defined without a preliminary period of research on a pilot basis. The need for monitoring was undoubtedly urgent, especially in respect of unexpected severe reactions. However, the dangers of misleading interpretation of records by those not fully cognizant of conditions in the country of observation and collection, as well as the novelty of the scientific methods to be employed, required operational and methodological research before the establishment of monitoring as a standard safeguard of health.

A pilot study should involve sharing of information and co-operation between national centres in countries in which a start had been made, through a WHO centre staffed and equipped for data-processing and for clinical and statistical appraisal of the records. The study would indicate whether or not a larger operational programme was feasible for giving early warning of drug hazards, for drawing attention to suspected reactions that deserved more intensive study, and for providing national health authorities with systematic statements of evidence relevant to action on drug safety that they contemplated taking. The methodological research required in the initial pilot phase should be one of the tasks of the proposed Division of Research in Epidemiology and Communications Science. The activities of that division would be closely linked to the Pharmacology and Toxicology unit, which would organize and operate the international drug-monitoring research project. The Scientific Group on International Drug Monitoring, which had met in November 1965,
had outlined the method of operation, including the types of record appropriate for transmission from national centres to the WHO centre, the responsibilities of National centres, and the role the WHO centre should play. The recommendations of that group were reproduced in the supplementary report by the Director-General (Official Records No. 148, pages 71-72). The Scientific Group made it clear that, both in the initial phase and subsequently, WHO should co-ordinate national activities but should not issue recommendations or make decisions on what were essentially national responsibilities.

The proposed pilot research project demanded considerable computer facilities of a kind that could not be created in WHO without some delay. At the Eighteenth World Health Assembly the United States Government had offered use of data-processing facilities in the United States. The consultants had recommended that the offer of the United States should be accepted for the international pilot research project. That would involve no commitment on the part of WHO to any details of practice in the United States in respect of data collection, analysis or interpretation, but only the utilization of excellent data-processing facilities. The WHO international team would have to be a distinct entity to which the United States National Centre could transmit data exactly as would other national centres. The Director-General was, therefore, recommending the acceptance of the offer of the United States in furtherance of the objective of international drug monitoring.

The Executive Board had discussed the matter at length at its thirty-seventh session, and the conclusions of the Board could be found in Official Records No. 149, pages 30-31, as well as in resolution EB37.R14 adopted by it.
Dr GODDARD (United States of America) said that the Director-General was to be commended on the diligence and efficiency with which he had implemented resolution WHA18.42.

He wished to reaffirm the offer made by his Government to provide facilities for processing information on adverse drug reactions. His delegation shared the view expressed by the Assistant Director-General on the desirability of that activity being viewed as a pilot project. There was much to be learnt as to the optimum manner for collection and dissemination of such information and also on how such information could best be evaluated.

He also wished to express appreciation to the Executive Board for its timely review of the subject. His delegation strongly supported the development by WHO of an international monitoring system for adverse reactions to drugs.

Dr SCHINDL (Austria) said that the present international monitoring of adverse reactions to drugs had raised several questions, the solution of which would be desirable for his country. The pharmacological institute of an Austrian university had drawn attention to the fact that the information on drugs supplied by WHO did not go into sufficient detail on decisions taken by Member States with regard to a particular drug, and it had been suggested that such information should henceforward contain adequate reference to the relevant documentation. An example he had in mind related to the use of the drug meclyzin, on which there appeared to be divergent opinions. While he was fully aware of the need to avoid loss of time in all serious cases, it seemed none the less preferable to have a thorough examination of reports and the relevant documentation by WHO experts, when such reports emanated from a single source, before Member States were informed.
Dr JOHNSON (Australia) said that the implementation of a pilot research project along the lines indicated by the Director-General was wholeheartedly supported by his delegation. It was essential that the reports on adverse reactions to drugs from Member States be collated and examined so that those adverse reactions could be adequately assessed and the resulting information disseminated to Member States for their information and action.

Degree of safety and degree of risk had to be kept in proper perspective and balance, as most drugs in use, even aspirin, seemed to produce in at least a minority of patients some effect other than purely therapeutic and varying from trivial to severe.

Australia had developed an efficient system for the reporting of adverse reactions to drugs by the medical profession and hospitals throughout the country to a central registry in the Therapeutic Substances Branch of the Commonwealth Department of Health. Reports received were evaluated in co-operation with the Australian Drug Evaluation Committee, which advised on all aspects of drug safety and, in particular, on adverse reactions. Recording systems were being developed for participation in a proposed pilot project under the auspices of WHO. Reports of official action to restrict or ban the use of various drugs had been communicated to WHO in accordance with resolution WHA17.39.

The offer of data-processing facilities by the United States for processing reports submitted by Member States of WHO would be a valuable contribution towards the success of the project. The information when disseminated by WHO would be of great benefit to the medical profession in every country and would undoubtedly improve prescribing standards and, by so doing, would protect the general public against the occurrence of
adverse reactions to drugs. The project was all the more to be commended as, over the past two decades, the world seemed to be emerging from the era of dangerous surgery only to find itself in an era of dangerous pharmacology.

The project would be successful only if the medical profession gave its wholehearted co-operation throughout the world, and that should be stimulated by WHO.

Dr HAQUE (Pakistan) wholeheartedly supported the pilot project proposed.

He emphasized the difficulties facing the developing countries in connexion with new drugs. In Pakistan no new drugs were put into use unless they had been thoroughly tested. Cases had arisen, however, where some imported drugs had not had complete tests, since the disease to which they related did not exist in the manufacturing country; in such instances toxicological, pharmacological and clinical testing was carried out in Pakistan. He wondered whether WHO could seek to improve that situation.

Dr ENGEL (Sweden) recalled that his delegation had first introduced the subject of adverse drug reactions in the World Health Assembly. It had consequently followed the progress of activity in that sphere with the greatest interest and wished to express its satisfaction with the preparatory work accomplished by the Director-General as well as with the conclusions arrived at by the Executive Board.
His delegation would support the resolution submitted by the Executive Board. While there was no need to mention the point specifically in that resolution, his delegation thought it necessary to draw particular attention to the need for dependence-producing drugs to be included in such reporting, following the recommendations made by the Expert Committee on Dependence-Producing Drugs in July 1965.

Dr DANNER (Federal Republic of Germany) said that the Medical Association of the Federal Republic of Germany had some five years previously established a centre for collecting information based on experience with drugs, particularly regarding adverse reactions. All practitioners were required to communicate their observations in that respect and a considerable amount of information had been collected. His delegation supported the collection of such information on a world-wide scale by WHO and greatly appreciated the action taken so far.

His delegation supported resolution EB37.R14 and was prepared to participate in such a pilot research project.

Dr DOUBEK (Czechoslovakia) supported the realistic view of the Executive Board that it was premature to speak of a world-wide monitoring system for drugs. The problem at issue was one of extreme complexity and, while he supported the proposal for a pilot project, which in two or three years could provide a great deal of information, particularly on the use of computer facilities, he doubted whether action on a world scale would be possible after such a period, i.e., whether the results obtained could be of use to all physicians. A striking instance of the type of complicating factor which he had in mind was the extent and type of variation of adverse reactions to certain drugs as between different areas of the world, and in that connexion he cited differing reactions to antituberculosis drugs.
Another important problem was how to collect rapidly sufficient instances of adverse side-effects to enable specific recommendations for preventive action to be formulated. The chances of quick detection of complications depended to a large extent on the system of health services. As an example he mentioned that, three years previously, Czechoslovakia had informed WHO of the serious side-effects of some long-acting sulfonamides which its health administration had discovered very rapidly and, as a result, some countries had already taken precautionary measures.

He wished to stress the fact that he was not opposed to the project; indeed, his country wished to participate in it.

Mrs RIDEOUT (Canada) said that the rapid proliferation of new drugs, together with the rise in demand for them, had led to a concomitant increase in adverse reactions. There was almost total lack of knowledge at present regarding the reactions and the risks involved, particularly taking into account the use of combinations of drugs and possible chronic effects.

She referred to the measures taken by the Drug Directorate in her country for compiling information obtained from reports on adverse reactions to drugs. Following a meeting of scientific experts to appraise that work it had been decided to continue the activity, with suggested changes in methodology. Her delegation would be happy to provide information on the work being carried out. She assured WHO of co-operation from the Canadian authorities wherever possible in that task.
Dr VASILJEV (Union of Soviet Socialist Republics) said that the question of monitoring adverse reactions to drugs was an extremely complex scientific problem. His delegation viewed favourably the resolutions which had been adopted on the subject by the Health Assembly and the Executive Board. In view of the ever-increasing number of drugs on the market, there was a need for more careful study of all possible side-effects, so that physicians could be informed of any risks involved.

Another aspect of the problem concerned the quality of drugs exported, particularly to developing countries. It not infrequently happened that pharmaceutical firms, for purely commercial reasons, exported to such countries drugs of a quality inferior to those destined for use in the producing country. In the USSR, drugs for export were required to conform to the same standards as those produced for home consumption. Adverse reactions to drugs did not constitute as severe a problem in his country as they did in some others. Nevertheless a centre was being set up for controlling the safety of all medicinal preparations manufactured in the country.

His delegation viewed with interest the work of the well organized national centres for the study of side-effects in the United States of America and in Canada. It was, however, convinced that it would be premature to set up an international centre. The people of different countries did not by any means all use identical pharmaceutical preparations; a study of the catalogues put out by pharmaceutical firms showed variations of pharmaceutical forms even for the same pharmacological substance. There were variations in purity, additives, etc. And the position
was even more complicated in respect of combined drugs containing more than one active substance, the quantity of which was constantly growing. Some pharmaceutical firms kept the composition of their drugs secret. There was also the problem that certain drugs deteriorated under some climatic conditions. In some cases adverse reactions were caused not by the basic drug but by additives. All those factors seemed to point to the need for action at the national level. The most suitable course would appear to be for WHO to undertake in the first place a study of the experience of national centres and to leave open the question of whether or not to set up an international centre for at least two to three years.

Dr KENNEDY (New Zealand) said that in his country an active monitoring system for adverse drug reactions had been functioning for over a year, and New Zealand was therefore in a position to testify to the undoubted value of drug monitoring as a public health measure.

Under the Food and Drug Act a system of notification of new and changed drugs operated, and about 450 such drugs were thus brought to the notice of the Department of Health each year. Approximately one-third of those related to truly novel drugs in that there had been little or no experience of them in clinical practice. While those drugs had been the subject of thorough study by animal-toxicity tests and by clinical and investigational trials for efficacy and human toxicity, administratively they were regarded as being "on probation" for an indefinite period after marketing in the country.
The system of monitoring for adverse reactions was regarded as an important epidemiological tool for keeping those drugs under surveillance. Information from sources outside New Zealand was welcomed and of great value. His country supported the concept of an international monitoring system, and would gladly cooperate with other Member States with national drug monitoring systems in a pilot monitoring system from which a full world monitoring system could evolve.

The Adverse Drug Reaction Committee in New Zealand had during its first year of operation considered reports on single drug reaction associations. However, it believed that the question of adverse drug reactions was complex, and the interrelationship when more than one potent pharmacological preparation was used in therapy was of great importance. In situations where potent chemicals were part of the general environment, and where those chemicals had pharmacological effects, the possible potentiation of chemical with drug toxicity should also of course be considered.

Dr RAO (India) said that his delegation welcomed the recommendation contained in resolution EB37.R14, as also the United States offer of data-processing facilities and the action proposed by the Director-General. The Indian delegation wished to suggest that the proposed pilot project should be undertaken by means of individual projects carried out in each region.
The Organization should encourage countries to establish national monitoring systems and should give advice upon their development. In a vast country such as India, there was also a need for sub-units to deal with such problems as differing reactions to drugs, to which the delegate of Czechoslovakia had referred. Thioacetazone, for example, had given rise to varying reactions in the northern and southern parts of the country owing to the different dietary habits, way of life, and degree of resistance of the respective populations. The matter was of paramount importance to India, particularly in view of the nutritional deficiencies now affecting the country. Although facilities for study existed in certain cities, they would need to be increased; and the advice of WHO with regard to the establishment both of a national monitoring system and of sub-units would be much appreciated.

Dr GJEBIN (Israel) said that the efficiency of the proposed pilot project might be augmented if the number of national centres were increased and if more countries complied with the terms of operative paragraph (2) of resolution WHA18.42. The most important question was how to obtain the best information from the greatest number of countries. To do so, the first step would be to ensure reliable information by establishing a uniform pattern of methodology. A panel of experts could perhaps be appointed to prepare a preliminary scheme for data collection, in accordance with WHO recommendations in that connexion, and to assist countries in the initial phase of organizing national centres. Thus, a standard process, which could be adapted to local conditions, would be instituted and a uniform and
practicable international drug monitoring service achieved in countries representing a cross-section of the nations of the world. A pilot project based on the systems used in the more advanced nations might well prove impracticable when applied to other countries.

The establishment of a world centre under the aegis of the Organization could not, in his opinion, be envisaged for a number of years. For that reason, the generous offer of the United States Government to provide data-processing facilities was greatly to be appreciated. It was evident that the final interpretation of the data submitted, as well as the results thereof, should, in accordance with WHO practice, rest with a group of international scientists drawn from a panel of experts.

Sir George GODBER (United Kingdom of Great Britain and Northern Ireland) said that, as Dr Evang had already stated, the problem was increasing in importance: that was the inevitable consequence of the advance in pharmaceutical research. The general public was exposed to the risk of industry foisting dangerous substances upon an uninformed population. The only way to avoid adverse reactions completely was to disallow potent drugs. The aim now was to achieve a uniform pattern for the information on adverse reactions and a more effective means of collecting and analysing it. In that connexion, the automatic data-processing facilities, generously offered by the United States delegation, would be extremely useful.

An important element was the validation of information in the country from which it was obtained. The computer provided ready access to detailed information, but it could not make judgements. The major problem therefore was the assessment of results, which should be reported consistently.
Another difficult problem was to ascertain the quantities of the individual drugs used, especially those in wide use such as the progesterones. In the United Kingdom, a simple system had been established whereby doctors reported on cards, with postage pre-paid, to a central committee which undertook the analysis. The difficulty was to ensure that all adverse reactions were reported - which of course was not the case. However, any publicity in the medical journals resulted in an immediate increase in the number of reports. Some reminder to doctors, issued sufficiently frequently, was necessary to attract their attention.

It was also important to appraise the information gathered, which in the case of many drugs was extremely difficult. As the delegate of Czechoslovakia had rightly stated, there could be no speedy answer to the problem. Some progress had been made in that connexion, but further improvement could be achieved by international co-operation along the lines suggested in resolution EB37.R14. The Organization had done valuable work in endeavouring to obtain reasonable standardization between the different countries and a large part of the studies suggested by the delegate of the USSR had in fact already been undertaken by WHO.

In a system for monitoring the adverse reactions to drugs it was essential, first, to remain alert with regard to reporting and, secondly, to make reliable analyses of the information received. Resolution EB37.R14 should be welcomed and supported as a valuable contribution to that end.
Dr. ZELKAI (Hungary) said that his country had participated in the collection of information regarding the side-effects of drugs, which had been undertaken in accordance with resolution WHA16.36 of the Sixteenth World Health Assembly. The special administrative work in that connexion had been entrusted to the National Pharmaceutical Institute which, during the past two years, had taken certain measures, particularly with regard to the modified use of certain drugs. In Hungary, before release of a drug, the manufacturer had to submit all brochures and instructions relevant to its use to the National Pharmaceutical Institute.

On a number of occasions, the Institute had given wide circulation, in its monthly journal on pharmaceutical preparations, to communications received from WHO on such subjects as the use and dangers of antibiotics belonging to the tetracycline group, prescriptions during pregnancy, and the toxic effects of the chronic use of phenacitin. A report had also been prepared in Hungary on the side-effects of sulfamethoxypyridazine; the information contained therein had been circulated to Member States.

For the past ten years, doctors in Hungary had been required to report to the health authorities any unusual experience or side-effects resulting from the use of drugs; and it was hoped, in the near future, to improve upon that service. Questionnaires would be circulated to doctors and to pharmacies, and would be drawn up so as to enable the health authorities and the panel of experts to reach their conclusions as rapidly as possible.
In the opinion of the Hungarian delegation, international co-operation in the matter should be intensified. It was the duty of WHO to collate, elaborate and disseminate to the national health authorities information on the best methods to be used in the introduction and testing of new drugs. Reference was indeed made to the subject in the Director-General's annual report for 1965 (Official Records No. 147, page 69) but, in the interests of public health, international co-operation should be promoted more speedily.

Dr FERRET (Switzerland) said that his delegation supported the proposal to initiate a pilot research study on the monitoring of adverse reactions to drugs and agreed that the information collected should be closely checked before dissemination. In so doing, the data accumulated by the manufacturer of the drug concerned, even if it represented only one side of the problem, should not be ignored. Furthermore, the Swiss delegation agreed with the Swedish delegation that dependence upon a given drug should be considered an adverse reaction. That suggestion had also been made by the Expert Committee on Dependence-producing Drugs.

Dr CIGUÍN (Argentina) emphasized the importance of the project in view of the development of chemotherapy and of certain tragic occurrences in that connexion. The United States offer of data-processing facilities was particularly welcome, since co-ordination and comparison at the international level was absolutely essential. In considering the question, it was important to stress the contribution which national centres could make, as well as the need for the medical corps to supplement the work carried out in laboratories by providing certain information. The whole question was closely linked to education. Adequate legislation, co-ordinated where possible at the national level, and administrative control were also of paramount importance.
In Argentina, control over drugs was exercised by the Ministry of Social Welfare and Public Health, by means of technical appraisal, inspection and laboratory examination. Furthermore, legislation existed with regard to the technical and quality aspects of drugs, supplemented by emergency measures relating to the cost of drugs.

In conclusion, he suggested that it should be compulsory to indicate, in the descriptive leaflets circulated with drugs, their exact contents and possible adverse reactions which might occur. His delegation would support the proposed pilot project, the importance of which had been underlined by a number of previous speakers.

Dr ALDEA (Romania) said that, in his country, a national institute existed for research into, and control of, drugs. There were also a number of branch laboratories which carried out drug control. The pharmaceutical industry in Romania belonged to the State and a product had to be authorized by the national institute before it could be manufactured. In line with the remarks made by the delegates of Hungary and Argentina regarding the need for publicity, the institute referred constantly to the adverse reactions of certain drugs in the various medical publications which it issued. Also, packaging was numbered, to provide information in the event of accident.

He agreed that an important aspect of the work was collaboration between the national research centres, in which the Hungarian authorities were ready to assist. In that connexion, the most important factor was information, as rightly pointed out
by the United Kingdom delegate. The information that would reach WHO would be of two types: first, the results of laboratory research and, secondly, information gained after field testing of the drug. With regard to the first type of information, if uniform results were to be obtained, some standardization of laboratory animals would have to be assured. As far as the second was concerned, the Organization should either work out standards or a draft questionnaire for the noting of observations.

Since many conflicting interests were involved, the information obtained should be regarded as confidential until a final decision had been reached. Otherwise, the Organization might be placed in an invidious position with regard to the commercial interests. Some consideration should also be given to the way in which information might be obtained in the case of bilateral contracts between two countries for the sale and purchase of drugs.

Dr AMMUNDESEN (Denmark) expressed her delegation's satisfaction at WHO's initiative in the field of adverse reaction to drugs.

A national monitoring system, as recommended in resolution WHA18.42, was essential for a country like Denmark. In fact, a national committee, composed of highly qualified scientists, was being established in her country and it was hoped that it would be possible to co-operate with other countries. That, in her opinion, would
be the only way of ensuring that the information obtained was uniform and consequently the computer used to best advantage. It was to be hoped that the recommendation before the Committee would convince the financial authorities, both in her country and in others, of the need for such action.

The Danish delegation was grateful to the United States of America for its offer of data-processing facilities and would support resolution E637.R14.

Dr PERERA (Ceylon) said that, in his country, a committee had been appointed by the Ministry of Health to advise on the rational and economic use of drugs by the medical officers employed in government service. That committee had recently established a sub-committee to examine the adverse reactions to drugs which studied and analysed reports in that connexion and brought the results to the notice of the Ministry of Health and the Department of Health Services. At the beginning of 1966, the committee had published for the first time a journal, which was distributed quarterly (in some 3000 copies) to all government medical officers free of charge. It would also contain information regarding adverse reactions to drugs.

Dr KAUL, Assistant Director-General, recalling that in resolution WHA18.42 the Director-General had been asked to study the possibility of collecting, analysing and disseminating information on adverse drug reactions, said that developments at the national level were of fundamental importance, since they would enable information to be disseminated internationally.
The Secretariat considered that at the present stage WHO needed further experience, which was the reason behind the proposal for a pilot study. Reference had rightly been made during the discussion to the complexity of the question of adverse reactions to drugs. While the immediate purpose of the pilot research project was to develop suitable monitoring methods, general dissemination of information was not intended at that stage. For the time being the Organization could only disseminate notifications received from governments under resolution WHA16.36. With regard to dependence-producing drugs, to which reference had been made during the discussion, when such effects were revealed in the course of monitoring activities, they would of course be made known, and the recommendations made by the experts in that connexion would be followed.

Certain questions had been raised regarding the quality control of drugs. Since, however, that subject was to be considered under a separate item on the agenda, he would refrain at the present juncture from commenting upon it.

As far as detailed studies on the possibility of international drug monitoring were concerned, the Organization had in fact been engaged in that work for some time, and many of the studies referred to by the delegate of the USSR had been carried out sufficiently extensively to provide guidance. For instance, a scientific group convened in 1965 to study methods of operation had examined the type of records appropriate for transmission from national centres to WHO and the responsibility of the national centres and WHO respectively. The guidance thus obtained would serve the Organization in undertaking its pilot study.
Another complex aspect of the problem, which had been mentioned by the delegate of Pakistan and which the Director-General was studying, related to testing of drugs for safety and efficacy. The recent convening of an expert group in that connexion, which had formulated the principles for pre-clinical testing of safety, marked the beginning of a useful and important programme. In its effort to assist with the development of national monitoring centres, the Organization would examine the suggestions made during the discussion.

Dr EVANG, representative of the Executive Board, pointed out that the item under consideration was the international monitoring of adverse reactions to drugs. During the discussion, however, some reference had been made to the quality control of pharmaceutical preparations, but that was a separate item and the Committee would have the opportunity to consider it further at a later stage if it so desired.

At the invitation of the CHAIRMAN, Professor FERREIRA (Brazil), Rapporteur, read out the following draft resolution (A19/P&B/Conf.Doc. No. 21):

The Nineteenth World Health Assembly,

Having examined the reports of the Director-General on the international monitoring of adverse reactions to drugs;

Recalling resolutions WHA15.41, WHA16.36, WHA17.39 and WHA18.42 of the Fifteenth, Sixteenth, Seventeenth and Eighteenth World Health Assemblies on the importance of systematic collection, evaluation and dissemination of information on adverse drug reactions;
Considering resolution **EB37.R14** on the international monitoring of adverse reactions to drugs;

Convinced of the urgent need to collect and disseminate at the international level information on adverse drug reactions; and

Taking into account that the utilization of the data-processing facilities available in the United States of America would facilitate the international monitoring envisaged,

1. REQUESTS the Director-General to initiate a pilot research project along the lines indicated in his report, with the aim of establishing an international system of monitoring adverse reactions to drugs; and

2. ACCEPTS the generous offer of the United States of America of data-processing facilities for this purpose.

Dr VASILJEV (Union of Soviet Socialist Republics) said that, as the delegates of Ceylon, Israel and Denmark had stated, the establishment of national centres was of paramount importance. The draft resolution, however, made no reference in that connexion and he therefore wished to propose the addition at the end of operative paragraph (1) of the words "based on the work of national centres".

Dr WILLIAMS (United States of America) asked that the amendment proposed by the delegate of the Union of Soviet Socialist Republics should be circulated in writing.

Dr GONZALEZ (Venezuela) was of the opinion that operative paragraph (1) as drafted was quite clear; it was implicit therein that the Director-General was required to stimulate the development of national centres. He therefore asked the delegate of the Union of Soviet Socialist Republics to reconsider his proposal so that the resolution as drafted could be maintained.
Dr VASILJEV (Union of Soviet Socialist Republics) said that it might be useful if a small working group were appointed to examine the draft resolution in detail.

Sir George GODBER (United Kingdom of Great Britain and Northern Ireland) suggested that the difficulty regarding the USSR amendment might be overcome if the words "based on the work of national centres" were replaced by the words "using information derived from national centres".

Dr ALAN (Turkey) supported the draft resolution as it stood. He also agreed with the comment of the delegate of Venezuela. In paragraph 2 of the Director-General’s supplementary report to the Executive Board (Official Records No. 148, Annex 11, page 71), it was stated that national monitoring organizations which would be prepared to comply with the principles, measures and technical requirements specified in the report should be invited to participate. It was obvious, therefore, that if the Director-General were requested to undertake a pilot research project, he would invite national organizations to co-operate. The draft resolution seemed to him to cover all aspects of the problem.

Dr JALLOUL (Lebanon) also supported the draft resolution. The USSR amendment gave the impression that every country had a monitoring centre, which was not necessarily the case. He suggested that a phrase should be added to the effect that countries which had no centres should be invited to establish them.

Dr GONZALEZ (Venezuela), on a point of order, said that the Committee had before it a draft resolution and a proposed amendment, and the subject had been thoroughly discussed. He moved that the debate should be closed and the draft resolution and its amendment put to the vote.
At the request of the CHAIRMAN, Dr BERNARD, Assistant Director-General, Secretary, indicated that, under Rule 61 of the Rules of Procedure of the Health Assembly, two delegates could speak against the motion of closure before it was put to the vote.

Dr DOUBEK (Czechoslovakia) supported the USSR amendment.

The CHAIRMAN, in the absence of opposition to the motion, consulted the Committee and declared the debate closed. He invited the Committee to vote on the USSR amendment, as modified by the United Kingdom. As presented in A19/P&amp;/Conf. Doc. No. 22 it now read:

1. In the last paragraph of the preamble, after the words "Taking into account that" insert the words "the co-operation with national centres for monitoring of adverse reactions to drugs and", the remainder of the paragraph being unchanged.

2. In operative paragraph (1), last line, after the words "reactions to drugs" add: "using information derived from national centres".

Decision: The amendment was adopted by 44 votes to 4 with 22 abstentions.

The CHAIRMAN put to the vote the draft resolution as amended.

Decision: The draft resolution as amended was adopted by 71 votes to none, with 3 abstentions.

4.7 Communicable diseases

Dr WILLIAMS (United States of America), referring to section 4.7.1 (Tuberculosis), thought that a budgetary provision of little more than $100 000 a year was inadequate, and did not reflect the importance of tuberculosis as a world health problem, with its serious human and economic repercussions. The Director-General had stated at an earlier meeting that it was very difficult to combat the disease because the available
drugs and vaccines were not effective enough. That was true, but the drugs and vaccines were nevertheless of some value and were certainly effective in reducing deaths from tuberculosis. He hoped that the Director-General would give more attention to tuberculosis in future budgets.

Dr KAUL, Assistant Director-General, said that the comments of the United States delegate would be noted. He pointed out, however, that in addition to headquarters activities, there were field programmes in tuberculosis involving considerable budgetary provision, as would be seen on page xx of the proposed programme and budget estimates. He agreed, however, with the delegate of the United States that work on the tuberculosis programme should be intensified.

Dr AZURIN (Philippines), referring to section 4.7.9 (International Quarantine), drew attention to a problem of particular concern to the Western Pacific Region. In 1961 cholera had appeared and had spread rapidly despite all measures adopted to combat it. Notification had been carried out effectively by WHO, and every country had imposed restrictive measures under the International Sanitary Regulations, in some cases even exceeding the international requirements. Nevertheless, it had not been possible to halt the disease. Some of the measures adopted had certainly transgressed the International Sanitary Regulations and the trade of the Philippines had suffered from some of the restrictions imposed by
other countries, particularly on food and timber imports and on travel. Since restrictive measures had not stopped the disease, other solutions had been necessary and it had been decided that research was the only valid solution to the problem. In 1964 his Government had signed a tripartite research agreement with Japan and WHO, in order to determine the efficiency of the cholera vaccine; the role of the carrier in disease transmission; and the viability of the vibrio in food-stuffs.

Experience in his country was that the vaccines now in use gave only short immunity and were not very effective: the six-monthly immunity hitherto accepted was not a fact - there was need for research to find a new and more effective vaccine if cholera was to be controlled. Other facts were that a cholera carrier had been discovered who had been excreting vibrio for the past three years; and that many of the restrictions of the International Sanitary Regulations concerning the vibrio in food were not justified. He urged that the International Sanitary Regulations should be reviewed with the object of lifting some of the restrictions that interfered induly with trade or passenger traffic.

He wished to thank WHO for the important part it had played in the research project in his country and to express his appreciation of the consultants and scientists who had worked there. He also wished to thank the Japanese Government for its co-operation and its help in personnel and resources. He hoped that WHO would publish the report on his country's project as soon as possible.
Dr ALDEA (Romania), referring to section 4.7.10 (Global Epidemiological Surveillance), spoke of the problem of endemic nephropathy, which he had raised at the Eighteenth World Health Assembly. The clinical manifestations of the disease - of which certain symptoms had first appeared in 1958 - were chronic renal insufficiency, progressive azotaemia, anaemia, absence of arterial hypertension, and renal atrophy leading eventually to death within two to four years. Its particular characteristics were its abnormally high incidence within a limited area and within certain families. Statistical analysis showed that in the period 1951 to 1966, it had affected between eight and nine per cent. of the populations in the affected area (the average for the rest of the country was 0.1 per cent.).

The disease, which affected south-eastern Romania, had also been identified in Bulgaria and Yugoslavia. Joint investigations by the three countries had been concerned with three possibilities in the etiology of the disease: infectious, toxic and allergic. So far, none of those possibilities had been confirmed, but research was continuing. International symposia had been held on the problem in 1960 and 1963 in Sofia, and in 1964 in Dubrovnik, under the auspices of WHO. The etiology of the disease was of vital importance, and WHO could give valuable assistance in obtaining data on possible morbidity from the disease in other parts of the world.

4.8 Public Health Services

There were no comments.
4.9 Health Protection and Promotion

Dr BERNARD, Assistant Director-General, Secretary, said that a number of draft resolutions had been submitted which he would introduce under the relevant sections of the budget volume. In connexion with section 4.9.1 (Social and Occupational Health) the following draft resolution had been submitted by the delegations of Finland, Iceland, Norway and Sweden on the prevention of traffic accidents (A19/P&EB/Conf. Doc. No. 13):

The Nineteenth World Health Assembly,

Believing that an important task of health administrations is the protection of people against health hazards of every kind;

Having in mind the heavy losses resulting from the ever-increasing number of traffic accidents;

Believing that further research is required, on an international basis, to elucidate the role, already demonstrated by scientific work, of human and medical factors in traffic accidents; and

Noting with satisfaction the steps already taken by WHO to inform Member States of the importance of this problem,

REQUESTS the Director-General to consider the possibilities of WHO playing a more active role in prevention of traffic accidents, with special emphasis on the human and medical aspects of the problem and on the co-ordination of international research in this field.

The delegation of France had proposed (A19/P&EB/Conf. Doc. No. 15) that a second paragraph be added to the operative part of the draft resolution, reading:

2. FURTHER REQUESTS the Director-General to inform the Executive Board and the Assembly of the amount of additional annual expenditure that would be entailed in giving effect to the possibilities referred to in the previous paragraph.

Professor PESONEN (Finland) recalled that in many countries people were protected against infectious diseases by such means as vaccination campaigns and environmental sanitation. However, while the number of deaths from infectious disease had decreased
considerably, especially in the younger age-groups, another kind of hazard was increasing rapidly and causing more deaths in the same age-groups than all the infectious diseases together. According to available statistics, more than 100,000 people were killed in road traffic accidents every year and the number was still increasing. Males between the ages of fifteen and twenty-five continued to be a high-risk group, for which road accidents were the commonest cause of death in highly motorized countries, sometimes causing more than 30 per cent. of total mortality in that age-group.

At the same time, statistics showed that, for every person killed in a road traffic accident, between ten and fifteen were seriously injured and between thirty and forty received minor injuries. Road traffic accidents were thus imposing a heavy strain on hospital surgical services; accident and permanent disability cases were occupying a large number of hospital beds and requiring treatment by large numbers of highly qualified medical personnel. There seemed little hope of improvement in the situation: on the contrary, the most recent figures obtainable from WHO's *Epidemiological and Vital Statistics Report* for 1965 showed that the situation was deteriorating year by year. A comparison of the figures for traffic deaths for the period 1950-52 and a comparable period ten years later showed that in Austria, Belgium, Canada, Denmark, England and Wales, the Federal Republic of Germany, Finland, France, Italy, Japan, Scotland, Sweden, Switzerland, and Venezuela there had been a considerable rise. There were, however, a few exceptions to the disastrous trend, one of them being the United States of America. That, and other facts in the report, showed that the right kind of preventive action could be successful; but deaths and serious
Injuries from traffic accidents continued to increase, and the health authorities in almost all the Member countries of WHO were facing increasing difficulties.

The causes of traffic accidents involved a variety of factors, of which the medical and human aspects were particularly important to the health authorities. There was a widespread belief that the medical condition of the driver was responsible for only a small proportion of road traffic accidents, compared with psychological and behavioural variations; but there had been no reliable research to confirm that opinion. He himself considered that the psychological and behavioural aspects had a greater effect on traffic accidents than was generally assumed. The matter needed careful and detailed study.

Regrettably little was known of the effect of human factors, although investigations to date suggested that they were among the important causative factors of road traffic accidents. According to some investigations, over 90 per cent. of traffic accidents were caused by human factors, but much more research was needed before the problem could be solved.

It was vital that methods should be devised for preventing traffic accidents and halting the growing catastrophe. Preventive methods had already helped in many dangerous situations. The sponsors of the draft resolution considered that the problem was a matter for the public health authorities and not merely for communication
and transport authorities. They wished to stress the importance of the problem in relation to people's health; and to ask the Director-General to consider the possibility of WHO playing a more active part in solving the problem, for example by co-ordination of research and by educational activity.

Dr AUJOUJAT (France) said that his delegation fully shared the concern of the co-sponsors of the draft resolution about the seriousness of the problem of traffic accidents, and was convinced that it would be useful for WHO to study the human and medical aspects of the problem and to co-ordinate international research in that field. He felt, however, that it would be useful to obtain information about the amount of additional expenditure that would be involved in giving effect to the possibilities of WHO playing a more active role in the prevention of traffic accidents and, for that reason, had proposed an additional paragraph to the resolution that he hoped would be acceptable to the co-sponsors.

Professor PESONEN (Finland), Dr ENGEL (Sweden), Dr TJØNN (Norway), and Dr SIGURDSSON (Iceland) accepted that amendment.

Dr LAYTON (Canada) wondered if the amendment was really necessary: Rule 13 of the Rules of Procedure of the World Health Assembly, and Rule 18 of the Rules of Procedure of the Executive Board, both stipulated that the Director-General should report on the technical, administrative and financial implications of all agenda items submitted to them.
Professor VANNUGLI (Italy) associated himself with what the Finnish delegate had said when introducing the draft resolution. The prevention of traffic accidents was of paramount importance. It had become widely accepted over the past few years that, in a large majority of cases, it was the man who caused the accident. Public health administrations were studying the problem, as were WHO, the Council of Europe and many non-governmental organizations. In Italy a special division had been established in the Ministry of Health to deal with all problems connected with the prevention of traffic accidents. It was appropriate that WHO should be asked to evaluate what was being done, to make a kind of inventory of ways and means of preventing traffic accidents. In that way, information would become available which could be used as a basis for action.

As far as prevention was concerned, problems could be divided under two main headings, namely (1) prevention of accidents as phenomena and (2) prevention of the results of accidents. Under the first of those headings would come such problems as safety inside vehicles themselves, and under the second, teaching people what and what not to do when involved in an accident, first aid, and the provision of a network of first-aid posts and centres. Studies were needed; governments required advice as to what they should do, for example, about providing first-aid posts or centres.

The Italian delegation supported the draft resolution and, since the co-sponsors had accepted the French amendment, it was prepared to do likewise.
Dr NAYAR (India) agreed wholeheartedly with the purpose of the draft resolution, which she said she would support. She considered the French amendment unnecessary, but felt that no harm would be done if it were accepted.

Dr HAQUE (Pakistan) recalled that the Director-General at the previous meeting had reminded the Committee that the duties that were his responsibility should not be laid down in resolutions.

The DIRECTOR-GENERAL said that Rule 13 of the Rules of Procedure of the World Health Assembly, which was very important, provided that no proposals should be considered by the Health Assembly, except in case of urgency, unless the Director-General reported on the financial implications. If the French amendment were adopted, it would allow the Director-General to report to the Executive Board, and the necessity of his having to report in a hurry to the present Health Assembly would thus be avoided. The amendment was acceptable to him.

Dr HAQUE (Pakistan) expressed himself satisfied with that explanation.

The CHAIRMAN said that, as the amendment had been accepted by the sponsors of the resolution, he would seek the Committee's decision on the resolution as amended.

Decision: The draft resolution proposed by the delegations of Finland, Iceland, Norway and Sweden, as amended by the delegation of France, was approved.
The CHAIRMAN drew the Committee's attention to a draft resolution relating to rehabilitation (A19/P&В/Conf. Doc. No. 12) submitted by the delegations of Finland, Iceland and Norway, which read as follows:

The Nineteenth World Health Assembly,

Referring to the definition of health in the Constitution as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity";

Noting that medical progress in the treatment of illness and injury, while permitting a higher ratio of survival, results in an increasing number of chronic cases and permanently disabled persons;

Stressing the role of rehabilitation in reducing the physical, mental and social consequences of disease or injury; and

Noting with satisfaction the measures already taken by the Organization in this field,

1. REQUESTS the Director-General to continue collecting information on the need for rehabilitation services, quality and quantity of existing rehabilitation facilities and on the administrative organization of rehabilitation services in the different Member countries;

2. INVITES attention to the need for developing rehabilitation services not only for injuries and diseases affecting locomotive organs but also disabling diseases, particularly mental and cardiovascular diseases, and to the opportunities for promotion of these services by the Organization;

3. REQUESTS the Director-General when planning the programme of the Organization to take into consideration the need for intensified training of medical and paramedical personnel to assist the expansion of rehabilitation services; and

4. INVITES the attention of the Member States to the importance of developing their rehabilitation services as an integrant part of the national health service.

The French delegation had submitted an amendment (A19/P&В/Conf. Doc. No. 16) proposing that the order of the last two operative paragraphs be inverted and than an operative paragraph (5) should be added, to read as follows:
5. REQUESTS the Director-General to inform the Executive Board and the Assembly, prior to any extension of the activities of the Organization in this field, what would be the implications of such an extension for the budget of the Organization; and the Austrian delegation had submitted an amendment (A19/P&B/Conf. Doc. No. 19) proposing that the words "on obstacles opposed to an effective medical rehabilitation" should be inserted after the word "facilities" in the third line of operative paragraph (1).

Dr SCHINDL (Austria) said that the public health services and the social insurance and social welfare services had set themselves a special task, namely the effective rehabilitation of all disabled persons. In Austria, the efforts of the responsible public health officers were, at present, focused on the problem of obtaining the co-operation of the most important person in the process of rehabilitation, namely the disabled person himself. The disabled person must be made conscious of his own responsibilities with regard to his health and rehabilitation and also of the need to participate actively in his own rehabilitation. Some features of social legislation (for example, the level of the pension given to disabled persons after an accident or the pension for a person retiring early) might not always act as a stimulus to those persons to take an active part in the rehabilitation process. Moreover, under the legislation of some countries, efforts to rehabilitate a person ended when it became obvious that it would be impossible to reintegrate him as a worker.
He felt that efforts should be made to continue to give medical and humanitarian help to those persons, to enable them to live a life which was worthwhile and at as high as possible a level. For those reasons, his délégation had proposed that the words "on obstacles opposed to an effective medical rehabilitation" should be inserted after the word "facilities" in the third line of operative paragraph (1) of the draft resolution. He hoped that that amendment would be acceptable to the Committee.

Professor PESONEN (Finland) observed that, in the matter of rehabilitation, very great emphasis had been laid on the prevention of diseases and injuries which were likely to lead to permanent disability and remarkable results had been achieved. Increasing attention had also been paid to developing methods and means for physical, vocational and social rehabilitation; but, in spite of all that, the problem of rehabilitation in the whole scheme of health deserved more attention from public health administrators. The number of old people was increasing in almost all countries of the world and, at the same time, the number of chronically ill was continuously increasing. In the report on the technical discussions at the present World Health Assembly, mention had been made of the importance of chronic diseases, and it had been said: "In the field of morbidity the emphasis in developing countries would be on communicable disease, and in developed countries more on chronic disease and disabilities, particularly among old people".
It was hardly necessary to refer to the situation in hospitals, where a very great number of beds was now occupied by patients suffering from some kind of chronic illness. There was also a great number of seriously injured patients, and the number was still increasing very rapidly. Little wonder, then, that health administrators in some countries were afraid of having almost all their hospital beds occupied by victims of traffic accidents. Furthermore, there were many kinds of badly handicapped people such as the blind and the deaf, living outside hospitals. He did not intend to give a complete list of all possible diseases that caused disability, but he could not forbear from mentioning one often neglected group, namely the great number of psychiatric patients who had been badly handicapped by too long a stay in hospitals, who received very little rehabilitation treatment. If that situation continued, almost all mental hospitals would be crowded with chronic mental patients, who were completely unable to leave hospital. Many kinds of rehabilitation methods existed which could be used to prevent the complete disablement of those patients; those methods had been used so effectively in some countries that the need for hospital beds had decreased considerably. New methods could also no doubt be found and introduced that would enable psychiatric patients to benefit from the great advances in medical science.

Rehabilitation should start early on during the acute state of a disease, and its treatment and should continue throughout the whole period a patient was kept in hospital. It should, moreover, continue until he was able to resume his earlier occupation in the community or be in a position, after training, to take a new post.
The rehabilitation process was a complex one, involving several disciplines and different techniques. Team-work was essential in order to achieve the best results for the handicapped person and, what was also most important, to prevent a sick person from becoming handicapped.

Advances in medical science had, in many countries, led to the prevention of many diseases; but, at the same time, it had created new problems of rehabilitation because severely disabled patients, who would formerly have died, now survived.

In some countries rehabilitation schemes had reached an advanced stage, at least as regards certain kinds of disability. They had proved to be of social and economic importance by reducing the total period of invalidism, through savings made in the cost of institutional care, sickness benefits, disability pensions and, above all, in the timely restoration of the sick and injured to a useful life, including productive employment. Advances in medical science had made it possible to introduce new methods of rehabilitation, and new categories of patients could have their condition remarkably improved through rehabilitation. It was, therefore, of very great importance to develop ways and means of improving the possibilities for medical rehabilitation.

He hoped that the draft resolution submitted to the Committee would obtain unanimous approval. The amendments submitted by the delegations of Austria and France were acceptable to him.

Dr AUJOULAT (France) said that his delegation had suggested inverting the order of the last two operative paragraphs in the draft resolution because operative paragraph (4) seemed to be connected with operative paragraph (2). The additional paragraph it had suggested was similar to the one it had proposed should be added to the draft resolution on traffic accidents.
Dr. SIGURDSSON (Iceland) and Dr. TJÖNN (Norway) said that the Austrian and French amendments were acceptable to them.

The CHAIRMAN said that he assumed that the amendments proposed by the Austrian and French delegations would be acceptable to the Committee. He put to the vote the draft resolution submitted by the delegations of Finland, Iceland and Norway, as amended by the delegations of Austria and France.

**Decision:** The draft resolution submitted by the delegations of Finland, Iceland and Norway, as amended by the delegations of Austria and France, was unanimously approved.

The CHAIRMAN drew the Committee's attention to a draft resolution on research on cardiovascular diseases (A19/P&EB/Conf.Doc. No. 17), submitted by the delegation of Czechoslovakia at the previous meeting, which read as follows:

The Nineteenth World Health Assembly,

Cognizant of the importance of cardiovascular diseases and their control, in particular atherosclerosis;

Recalling resolution WHA8.43 of the Eighteenth World Health Assembly, which invited the Director-General to continue studying the role of the Organization in promoting medical research;

Aware of the great contribution that research centres can make to the development of such research; and

Having examined the programme of the Organization in the field of cardiovascular diseases,

1. REQUESTS the Director-General to study the modalities for further expansion of the programme of the Organization in cardiovascular diseases and, in particular, the establishment of a WHO international centre for research in the causation, control and prevention of atherosclerosis and ischaemic heart disease; and

2. INVITES the Director-General to report on this subject to the Twentieth World Health Assembly.
Dr DOUBEK (Czechoslovakia) said that he would not repeat what he had already said at the ninth meeting about the extent to which cardiovascular diseases were becoming a major health problem. His delegation felt that WHO's resources could be used to speed up research in cardiovascular diseases and that one way of doing so would be to establish an international centre for research in the causation, control and prevention of atherosclerosis and ischaemic heart disease.

Dr SPAANDER (Netherlands) said that, while he thought it was desirable that studies of the cardiovascular diseases should be continued, his delegation felt that it would be premature to establish a WHO international centre of the type being suggested in the draft resolution. The possibility of establishing such a centre required much more study, and expert advice would have to be obtained. He suggested that the last part of operative paragraph 1 should be deleted, which would mean that the paragraph would end after the words "cardiovascular diseases".

Dr NAYAR (India) supported that proposal, although she recognized the importance of ischaemic heart disease as a cause of death and ill health. When studying the modalities for expanding the programme for cardiovascular diseases, the Director-General might give some thought to the role played by hydrogenated oils and saturated and unsaturated fatty acids in heart disease. She was in favour of WHO encouraging further research in different regions, collecting information and disseminating it and helping to intensify and improve activities already being carried out rather than establishing a centre of its own.

Dr ALAN (Turkey) supported the views expressed by the two previous speakers, in spite of the fact that his delegation attached great importance to research in the medical field. He proposed that operative paragraph 2 be redrafted to read:
REQUESTS the Director-General to inform the Executive Board and the Assembly, prior to any extension of the activities of the Organization in this field, what would be the implications of such an extension for the budget of the Organization.

That would bring the draft resolution into line with the two previous draft resolutions adopted by the Committee.

Professor GOOSSENS (Belgium) supported the proposal to delete the second part of operative paragraph 1 and to redraft operative paragraph 2 in the way proposed by the delegate of Turkey.

Dr DOUBEK (Czechoslovakia) said that he was not very happy about the deletion of the second part of operative paragraph 1, but he was willing to accept the deletion and to accept the new wording proposed for operative paragraph 2.

The CHAIRMAN said that in the absence of any objection to the amendments that had been proposed, he would assume that they were approved.

It was so agreed.

Decision: The draft resolution submitted by the delegation of Czechoslovakia, as amended in the course of discussion, was approved.

The CHAIRMAN invited the Committee to consider the draft resolution on the effects of atomic radiation (A19/P&B/Conf.Doc. No.18) submitted by the delegations of Afghanistan, Argentina, Brazil, Ceylon, Ethiopia, Ghana, India, Indonesia, Iraq, Mauritius, Nigeria, Norway, Philippines, Singapore, Sudan, United Arab Republic and Yugoslavia. It read as follows:
The Nineteenth World Health Assembly,

Recognizing the mounting concern of world opinion at the harmful effects to present and future generations resulting from the increase in the levels of radiation to which man is exposed from nuclear and thermo-nuclear weapon tests, superimposed on other sources of radiation;

Noting that the United Nations General Assembly has been seized with the question of the urgent need for the suspension and discontinuance of all test explosions of nuclear weapons since 1954;

Noting further that a United Nations Scientific Committee on the Effects of Atomic Radiation was established in 1955 and has since submitted three reports on the effects of atomic radiation, and that it would be submitting another report of its estimates of risk from such explosions to the forthcoming twenty-first session of the General Assembly;

Conscious of the warning given in the second report of the Scientific Committee on the Effects of Atomic Radiation that "the effects of any increase in radiation exposure may not be fully manifested for several decades in the case of somatic diseases and for generations in the case of genetic damage;

Recalling in particular the United Nations General Assembly resolution 1762 (XVII), which condemned all nuclear weapon tests, and resolution 2032 (XX), which calls upon all countries to respect the spirit and provisions of the treaty banning nuclear weapon tests in the atmosphere, in outer space and under water; and

Deploring that, notwithstanding these resolutions, nuclear weapon tests have taken place,

1. COMMENDS the United Nations Scientific Committee on the Effects of Atomic Radiation for its valuable contribution to wider knowledge and understanding of the deleterious effects and levels of atomic radiation, and WHO and other international bodies for the valuable assistance rendered by them to the Scientific Committee;

2. REITERATES resolution WHA13.56, which emphasizes the need for national health authorities "to accept their major role and accelerate their activities in the public health aspects of radiation from all sources", and resolution WHA17.47, which reaffirmed "the responsibility of WHO at the international level for activities in the field of health involving ionizing radiation, including protection from radiation hazards and the medical uses of radiation and radioactive isotopes";

3. CALLS UPON all countries to co-operate in preventing an increase in the level of background radiation in the interests of the health of present and future generations of mankind;
4. REQUESTS the Director-General, in view of the special danger to the health of present and future generations, to continue a thorough study of the effects of radiation on man and report to the World Health Assembly at appropriate intervals so as to focus attention on necessary action on the part of Member States; and

5. URGES Member governments to make use of WHO's assistance in the development and strengthening of their programmes in the control of health hazards due to radiation.

Dr QUIRÓS (Peru) said that his delegation warmly supported the draft resolution. He would avail himself of the opportunity to record a protest, on behalf of the peoples of the world whose health was threatened thereby, against the carrying out of nuclear and thermo-nuclear tests. The Committee would be aware that the peoples living on the south-west coast of Latin America were particularly endangered.

Dr BA (Senegal) said that in principle his delegation, too, endorsed the draft resolution. It was, however, incomplete in that no reference was made to the cessation of nuclear testing, which was the only way whereby the danger to human health could be eliminated. His country's policy, as enunciated by its President, was to promote the continuous struggle for peace and hence it stood for general and controlled disarmament; the vast sums expended on destruction could be put to better use for positive purposes.

Since the last paragraph of the preamble would be inadequate unless a reference was added to the need for destruction of all stock-piles of nuclear and atomic weapons; he would propose its deletion rather than suggest the incorporation of a point which the sponsors might not have had in mind.

Dr EL-KAMAL (Algeria) said that he too fully agreed with the draft resolution in principle but, as it stood, the text might be open to the charge of bias. His delegation would be prepared to vote in its favour if the amendment just proposed was
accepted. The partial test-ban treaty now in operation was not enough; and, in face of the new techniques evolved by certain countries, and the dozens of explosions that had already taken place, one might well query whether the explosion of the Chinese bomb would greatly add to the health hazards involved. Algeria was in favour of the banning of all nuclear tests and the destruction of all stock-piles of nuclear weapons.

Dr SOW (Mali) said that his delegation fully supported the views expressed by the two previous speakers. In its view, the last paragraph of the preamble brought no new element to the condemnation of the use of nuclear weapons. He would therefore urge the sponsors to agree to its deletion.

Dr AZURIN (Philippines) said that his delegation was glad to have the opportunity of co-sponsoring the draft resolution, which sought to diminish and perhaps eradicate a modern and terrible menace to human health, more deadly than any disease known to medical science. Indeed, the menace of radioactive fall-out tended to nullify all that man had achieved in public health and medicine.

Most of humanity had heaved a sigh of relief when the partial atomic test ban, to which his country among many others had adhered, had been concluded. That had been a significant step towards the goal of complete prohibition. Unfortunately, however, some countries still continued to conduct weapon tests in the atmosphere, thus threatening human welfare by defying the painful efforts of the United Nations to halt the proliferation of nuclear weapons and to bring about nuclear disarmament; by increasing the extensive atmospheric radioactive pollution to the peril of world health; and by retarding the efforts to convert atomic energy to medical, industrial and other peaceful uses.
The Health Assembly would be failing in its duty as the guardian of human health if it did not add its authoritative voice to the condemnation of all activities likely to increase the level of atomic radiation. Accordingly his delegation strongly urged that the draft resolution before the Committee be approved unanimously.

Mr DEDEI (Albania) added his delegation's support to the stand taken by Senegal and Algeria. The problem of disarmament must be viewed in its entirety. His delegation supported full disarmament, accompanied by the destruction of all existing stock-piles of nuclear weapons. All testing should be banned without exception if the world was to be at peace. His delegation supported the proposed amendment to delete the last paragraph of the preamble.

Dr GOMEZ-CRESPO (International Atomic Energy Agency) said that, under Article III, A.6, of its Statute, the International Atomic Energy Agency was required to draw up safety regulations for application to every operation with which it was concerned. The Agency had accordingly adopted safety regulations on every major aspect of the peaceful use of atomic energy, from the safety of uranium mining to the safe operation of nuclear reactors and the safe transport of nuclear fuel.

That work was being done, where appropriate, in collaboration with WHO, FAO, ILO and WMO, and the Agency was also contributing to the work of the United Nations Scientific Committee on the Effects of Atomic Radiation.

It was recognized that the public health authorities had far-reaching responsibility in the protection of the public against radiation hazards; the same was true for the Agency, and those responsibilities could be efficiently carried out only through close co-operation at both the national and the international level.
The need for such collaboration had been explicitly recognized by the World Health Assembly and by the Directors-General of the two organizations. Unless it recognized the need for that co-operation, the draft resolution under consideration would be deficient and perhaps also inconsistent with resolutions adopted by the General Conference of the Agency.

Dr NAYAR (India), speaking as a co-sponsor of the draft resolution, pointed out that the mention of previous resolutions adopted by the Health Assembly covered the point just made, since those resolutions clearly pointed to the importance and need for close co-operation and collaboration between the various agencies that had been mentioned.

Secondly, the object of the sponsors had been to concentrate attention purely on the health hazards inherent in rising levels of radiation. Considerations regarding disarmament, partial or complete, important as they might be, had no place in the context. Another forum existed for their discussion.

The last paragraph of the preamble had been taken from earlier Health Assembly resolutions and the sponsors had had no intention of trying to impute responsibility or blame to one country or another.

Mr GOMEZ-CRESPO (International Atomic Energy Agency), thanking the delegate of India for her explanations, said he still thought that the draft resolution would be more positive if, in the operative part, a reaffirmation were included of the importance of close co-operation between the Agency and WHO in the particular field concerned.
The CHAIRMAN put to the vote the amendment to delete the last preambular paragraph of the draft resolution, as proposed by the delegate of Senegal and supported by the delegates of Algeria, Mali and Albania.

The amendment was approved by 53 votes to 12, with 9 abstentions.

Decision: The draft resolution, as amended, was approved by 76 votes to 2, with 2 abstentions.

Dr AUJOULAT (France) said that his delegation had been unable to vote for the resolution just adopted, although in agreement with the operative provisions, because some of the preambular paragraphs were not quite acceptable, and furthermore because France had opposed resolution 1762 (XVII) of the United Nations General Assembly.

4.9 Health Protection and Promotion

The CHAIRMAN invited further comments on section 4.9 of Official Records No. 146.

Dr SPAANDER (Netherlands) said that a study of the report on a technical basis for legislation on irradiated foods, drawn up by the FAO/IAEA/WHO Joint Committee (Technical Report Series No. 316) showed that promising new techniques of food irradiation might have a distinct influence in the near future on the preservation of food. In the circumstances, the advice of WHO on the health aspects of food and food programmes and the use of new techniques such as food irradiation was of great importance. Clearly, much collaboration and co-ordination at the national and the international level was required in order to evolve well-balanced guidance on such new developments; as also was co-ordination within WHO and among the various organizations concerned, such as IAEA and FAO.
When considering the physiological, toxicological and microbiological aspects of food, the question arose whether WHO had some internal mechanism whereby work on pharmacology and toxicology, veterinary public health and environmental pollution was co-ordinated with work on nutrition and on radiation and isotopes in so far as the use of ionizing radiation in foodstuffs was concerned. Evaluation of the possible health hazards of a general consumption of irradiated food required the closest internal co-operation among the divisions and units concerned.

His delegation noted with great satisfaction the collaboration already established between WHO, FAO and IAEA in that area of work. Obviously such collaboration stemmed from resolution WHA17.47, which reaffirmed WHO's responsibility at the international level for activities in that field of health involving ionizing radiation, and requested the Director-General to continue to ensure the closest collaboration with the other agencies concerned on matters of mutual interest.

His delegation had noted that a joint FAO/IAEA division had been set up in Vienna to be responsible for work of concern to both organizations where atomic energy related to agriculture. Further, the active and productive joint FAO/WHO Committee on Nutrition had been in existence since 1948 to advice on technical problems concerned with nutrition, and it was within the context of that committee's work that the technical report to which he had referred had been prepared. His delegation had been very impressed by the recommendations made in that report and would like to stress the great significance it attached to close collaboration among the three organizations in question in matters of food preservation and handling and decontamination of animal feed. WHO should of course continue to play the directing role in those matters.
Dr EL-KAMAL (Algeria) said he would like to draw attention to the over-riding importance of work in nutrition at a time when millions of people throughout the world were dying of hunger. It was most disturbing to find that the budgetary provision for nutrition work in 1967 had risen but little, whereas other activities of less fundamental importance, such as those in dental health and in cardiovascular diseases, were given proportionately higher increases. Most countries represented in the Committee would, he was sure, prefer that greater emphasis should be placed on work in nutrition, particularly in present-day circumstances where the general expectation of life in the less-developed countries was no more than forty years.

The meeting rose at 1.40 p.m.