



COMMITTEE A

TWENTY-THIRD WORLD HEALTH ASSEMBLY

COMMITTEE A

INDEXED

PROVISIONAL SUMMARY RECORD OF THE TENTH MEETING

Palais des Nations, Geneva
Saturday, 16 May 1970, at 10 a.m.

CHAIRMAN: Dr M. ALDEA (Romania)



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Note: Corrections to this provisional summary record should be submitted in writing to the Chief, Records Service, Room A.843, within 48 hours of its distribution.

1. TRAINING OF NATIONAL HEALTH PERSONNEL: Item 2.8 of the Agenda (Resolutions WHA21.20 and .EB45.R29)

The CHAIRMAN drew attention to the relevant resolutions of the World Health Assembly and Executive Board.

DR LAYTON, representative of the Executive Board, reported that the Director-General had informed the forty-fifth session of the Executive Board that, in pursuance of resolution WHA21.20, the regional committees had given consideration to the subject at their 1969 sessions and had adopted resolutions thereon to which reference was made in resolution EB45.R29. It had been noted that since the regional committees had met late in the year - after the Twenty-second World Health Assembly had itself met in Boston later than usual - it had not been possible to present the general evaluation of the experience accumulated by the Organization to the Board at its forty-fifth session or to the Twenty-third World Health Assembly.

The Board had agreed with the Director-General's proposal to suggest to the Health Assembly that, since there had not been time to prepare a report to the present session and since a similar subject had been selected for the technical discussions, consideration of the matter should be deferred to the forty-seventh session of the Board, and that the report requested in operative paragraph 2(e) of resolution WHA21.20 should be presented to the Twenty-fourth World Health Assembly. He drew attention to the relevant provision of resolution EB45.R29.

Dr KAREFA-SMART, Assistant Director-General, added that the Director-General had reported to the forty-fifth session of the Executive Board on the following action taken by regional committees:

The Regional Committee for Africa at its nineteenth session had discussed reports on the evaluation of the problems of training medical and health personnel in the African Region and on the review of the fellowships programme, 1959-1968. It had also considered a report by Dr L. P. Aujoulat on "What happens to African and Malagasy graduates trained in France". Emphasis had been laid on the need to find long-term solutions for the gradual attainment of self-sufficiency in the training of health personnel by the Region. At the same time it had been recognized that targets must be realistic and based on a better knowledge of the existing situation and the way it was likely to develop taking into account the overall amount of manpower available, socio-economic development, and public health priorities. The plea had often been repeated for more concerted action, especially in the planning and setting-up of regional and sub-regional university centres, the utilization of existing facilities, and the exchange and employment of teaching and servicing staff among the African countries. The resolution on education and training (resolution AFR/RC19/R6) adopted by the Regional Committee congratulated the Regional Director and his staff on the excellent report submitted to the Committee; requested the Regional Director to continue his activities on the lines of the recommendations contained in the report; and invited the governments to do all in their power to (a) undertake analysis of the available data with a view to better defining the educational objectives, and (b) promote integrated teaching in the training centres for health service personnel of the countries of the African Region. Finally, it requested the Regional Director to transmit to the Director-General, in accordance with operative paragraphs 2(c) and (d) of resolution WHA21.20 for inclusion in his report to the forty-fifth session of the Executive Board the recommendations and conclusions expressed at the session. A second resolution (resolution AFR/RC19/R7) had been adopted on the exodus of qualified medical and health staff.

During the discussion on long-term planning in the 1969 session of Sub-Committee A of the Regional Committee for the Eastern Mediterranean, it had been stated that, on the basis of the priorities established by WHO for the Second United Nations Development Decade, the programme for the Region for the period 1971-1980 would include emphasis on education and training of undergraduate medical personnel, nurses, dental health staff, sanitary engineering and veterinary personnel, and post-graduate education and specialization in various clinical, preventive and other professional fields.

The Regional Committee for Europe at its nineteenth session had adopted resolution EUR/RC19/R8, recommending that Member States (a) give high priority to education and training programmes for health personnel, and (b) promote health manpower studies with particular reference to their educational aspects; and requesting the Regional Director (a) to emphasize teacher training in all fields of health; (b) to promote further the application of modern educational concepts to the education and training of health personnel, taking into account the specific needs of the countries of the Region; and (c) to study how the countries of the Region might co-operate in the establishment and function of training facilities for health personnel in developing countries.

The Regional Committee for South-East Asia at its twenty-second session had discussed a report on the training of national health personnel prepared by the Regional Director and referring to the collection of data on which to base an analysis of the problems of training professional and auxiliary health personnel. The Committee had been informed of the measures being undertaken by governments in the Region to train the various categories of health personnel and to increase their numbers. Resolution SEA/RC22/R11 had been adopted, it urged the governments of the Region: (i) to give the highest priority to the planning of the production of adequate numbers of suitably trained health staff; (ii) to review critically their training programmes, ensuring that the curricula were adapted to the needs of the country; (iii) to ensure that adequate, full-time faculties were available to undertake teaching duties, particularly in the field practice areas; and (iv) to carry out operational studies of existing health services. It also requested the Regional Director to assist, when requested, by (i) providing consultants to help in evaluation studies, in developing teaching techniques, and in reviewing curricula content; (ii) promoting the development of more teaching institutions in the countries of the Region; and (iii) providing fellowships and organizing training, particularly for faculty members.

The subject had also been discussed by the Regional Committee for the Western Pacific at its twentieth session. The Committee had endorsed the suggestions made in the report for simple guidelines for the collection of basic information and for the type of information which might be collected; and it had recognized the importance of the subject. It had considered, however, that there was insufficient time to collect accurate data for a study in detail before the forty-fifth session of the Executive Board, and had adopted resolution WPR/RC20/R9 recommending that countries should be invited to collect the necessary data which should then be analysed and made the subject of a seminar or, alternatively, referred for consideration to an expert committee. The Regional Director had been requested to transmit to the Director-General the report, summary records and resolution for the information of the Executive Board.

Dr CASTILLO (Venezuela), Rapporteur, read out the following draft resolution (A23/A/Conf.Doc. No. 16):

The Twenty-third World Health Assembly,

Having considered resolution EB45.R29 of the forty-fifth session of the Executive Board, pursuant to resolution WHA21.20 adopted by the Twenty-first World Health Assembly,

1. THANKS the regional committees which have carried out the analysis of the problem of training professional and auxiliary health personnel in their own regions and urges the remaining regional committees to undertake this study at their next session;

2. REQUESTS the Director-General to prepare a report based on these regional analyses for the consideration of the Executive Board;
3. REQUESTS the Executive Board to carry out a general evaluation of the experience accumulated by the World Health Organization, taking into account the conclusions reached by the regional committees on the training of professional and auxiliary health personnel; and
4. REQUESTS the Director-General to present to the World Health Assembly, in the light of the discussions of the Executive Board, a report on any concrete measures that the World Health Organization might appropriately take to assist further the training of national health personnel of all levels.

Dr SULIANTI SAROSO (Indonesia) proposed the addition of the words "including the methodology employed in such training" to the end of operative paragraph 4 of the draft resolution. She was anxious to see that aspect included in the report requested from the Director-General, as it had been covered by the work of the regional committees.

Dr DURAISWAMI (India) said that his delegation supported the draft resolution, with the amendment proposed by the delegate of Indonesia.

Before the advent of independence in India in 1947, training had been concentrated on doctors, nurses and hospital technicians. Afterwards large numbers of all categories of paramedical personnel had been trained. In 1947 there had been twenty-five medical colleges with an admission capacity of about 2000; at present there were ninety-five medical colleges with a capacity of 12 000, 253 schools training about 5000 nurses annually, eight colleges for degree courses in nursing with a capacity of eighty, and 336 schools training about 4000 auxiliary nurse/midwives. Several thousands of various other types of paramedical personnel were also being trained.

The Government was about to implement a new scheme under which a mobile training-cum-service hospital with fifty beds would be attached to each of the existing ninety-five medical colleges so that in-service training of medical and nursing students, interns and paramedical workers in rural areas could be carried out for a specific period, under the close supervision of their respective teaching staffs. Details of the scheme were published in a pamphlet entitled "Multipurpose role of mobile hospitals in rural India", which had been circulated to delegations.

Dr SOUPEKIAN (Iran) said that in 1969 an inter-regional training course on health and manpower planning had been conducted in Teheran under the auspices of WHO, in association with the Ministry of Health of Iran, the School of Public Health of the University of Teheran, and the Institute of National Planning in Cairo. It had been assumed that the participants would be public health officials working full-time in health planning units at central or provincial level, sanitary engineers in administrative posts, and nursing administrators in the countries of the Eastern Mediterranean and African Regions who had had little or no formal training in planning. But in fact the participants had included assistant directors of public health schools, health educators, and even a surgeon. In general the course had been successful, but naturally, with such a composition, it had not been easy to design a suitable curriculum. He requested that in future careful attention should be paid to the selection of applicants for similar training courses in order to ensure a more harmonious composition of the group; they should include health officials from various disciplines but with comparable backgrounds and experience.

Dr BLAGOJEVIĆ (Yugoslavia) asked whether pharmacists were covered by the evaluation. In many countries pharmacists occupied posts in public health laboratories.

Dr BÉDAYA NGARO (Central African Republic) supported the amendment proposed by the delegate of Indonesia.

Dr AL-AWADI (Kuwait) proposed the addition of the following words to operative paragraph 4 of the draft resolution:

"and to standardize as far as possible the training programmes for the different health personnel".

Professor BRZEZINSKI (Poland) said that the report on the technical discussions at the Twenty-third World Health Assembly provided a good illustration of the progress made in the training of national health personnel. Developments in Poland since he had reported on that subject to the Twenty-second World Health Assembly concerned in the first place co-ordination between health agencies and educational institutions. All levels of medical training were the responsibility of the Ministry of Health and Social Welfare. A new approach had recently been adopted to co-operation, each medical school being assigned a defined territory in such a way that the whole country was covered. These schools used the institutions of the health services located in the same area and assumed certain responsibilities for post-graduate teaching and professional supervision. The staff of the schools were encouraged to carry out research work, especially epidemiology, so as to assess the health status and needs of the population.

His country appreciated the activities of the Regional Office for Europe in the co-ordination of medical education, thanks to which it had been able to organize a conference on objective methods of evaluation in medical education. Representatives of the Polish medical schools had been joined by four experts from other countries and a group of medical students; the discussions had been fruitful, although there had been more differences of opinion among the students than among the teachers. Such regional conferences were very useful.

Poland was setting up two small laboratories for research in medical education and training to study the teaching methods used in medical schools and the organization of education; to examine the progress of students through medical training; and to improve the knowledge and educational skill of medical teachers. The group working at the laboratory in the Warsaw Medical School was itself involved in the teaching; it included an educationist, a psychologist and a sociologist who were trying to improve the knowledge and educational skills of medical students. The intention was, in line with what Dr Evang had said during the technical discussions, to make each medical student a health educator.

Dr ALAN (Turkey) commenting on the amendment proposed by the delegate of Kuwait, said that it would be difficult for the Director-General to ensure standardization of training in all countries; each had different requirements, varying according to local conditions. It would perhaps be preferable to ask the Director-General simply to provide information on the minimum standards that should be observed in training health personnel. He referred to the difficulties met with by the Committee on Public Health of the Council of Europe when it tried to draw up criteria for the standardization of nurses' training.

Dr HASAN (Pakistan) proposed the addition, at the end of operative paragraph 3 of the draft resolution, of the words "and an assessment of the utilization of the personnel so trained".

Professor PACCAGNELLA (Italy) supported the draft resolution. He had reservations about the proposal of the delegate of Kuwait, for the reasons put forward by the delegate of Turkey. Health training at all levels must be adapted to local needs, and he would not wish to see the concept of standardization introduced unless the analysis of health training being carried out by the regional offices revealed its necessity. He expressed appreciation of the work of the Regional Office for Europe.

The importance attached to training for the health professions in Italy was illustrated by the growing interest of medical faculties in WHO's reports and recommendations, when curricula had to be reformed or adapted to the needs of the country. This provided a good example of co-operation between WHO and national health organizations which did not come under the ministry of health.

Dr BÉDAYA NGARO (Central African Republic) asked whether the delegate of Kuwait would, in view of the remarks of the delegate of Turkey and others, accept the idea of "adaptation" or "adjustment" in place of standardization. His amendment to the draft resolution might then read:

and to encourage as far as possible the adaptation of training programmes for the various categories of health personnel:

Dr JESUDASAN (Ceylon) agreed with the delegate of Turkey that there was a need for certain standards of training. Such standards would depend however on different factors in different countries, and also on the basic educational requirements set by each country. It would therefore be advisable to have a minimum level of training for health personnel rather than to fix a uniform standard.

Dr OTERO HART (Peru) said that his experience of postgraduate courses had convinced him that the teaching of public health in schools of medicine, at least in the South American countries, was insufficient. He emphasized the need to introduce or improve such teaching.

Dr FAKHRO (Bahrain) proposed the division of operative paragraph 4 into two parts, subparagraph (a) to contain the original text, and a new subparagraph (b) to be added with the following text:

- (b) to urge Members in each region to formulate a minimum standard of curriculum for training programmes of health personnel, taking into consideration the needs of the region.

Dr AHMETELI (Union of Soviet Socialist Republics) said that the amendment proposed by the delegate of Kuwait deserved support. It had been motivated by the fact that Kuwait employed doctors from many countries, so that the national health authorities had the difficult task of ascertaining what kind of training the doctors coming to work there had received. The proposed amendment was related, moreover, to the question of the equivalence of medical degrees, which had been studied in great detail in WHO; and also to the fact that in a number of African countries new medical institutes were being established for which, in the absence of standards, it would be a complex task to select training programmes.

His delegation therefore supported the amendment proposed by the delegate of Kuwait and would ask the Director-General to prepare the documentation necessary for a full discussion on the subject at the Twenty-fourth World Health Assembly.

Dr ESCALONA (Cuba) thought that the Committee was getting too far away from the spirit of the original draft resolution, with which his delegation found no fault. It was not necessary in the present discussion to go into details about the report the Director-General was to be asked to make.

Dr IBRAHIM (Iraq) supported the amendments proposed by the delegates of Indonesia and Turkey.

Dr BROTHERSTON (United Kingdom of Great Britain and Northern Ireland) agreed with the delegate of Cuba: the details of the study on training of health personnel should be left to the Executive Board. It would be unwise in the resolution to make any recommendations about

standardization, as suggested by the delegate of Kuwait. He agreed, however, with the delegates of Turkey, Italy and Ceylon. Among the reasons for not stressing standardization was the fact that the technical discussions at the present Assembly had laid great stress on adaptability to local needs, and that some delegates in the discussions had expressed anxiety lest standardization lead to an increase in the "brain-drain".

Moreover, many educators of health personnel were trying to break away from stereotyped patterns of training. Developments in the health sciences and services were taking place so rapidly that adaptability was essential.

Dr MARTÍNEZ (Mexico) endorsed the remarks of the delegate of Cuba. The Mexican delegation would support the draft resolution unamended.

Dr ELOM NTOUZO'O (Cameroon) said that the subject of training had already been discussed by regional committees, in technical discussions at the Twenty-third World Health Assembly, and in Committee B the previous day. The draft resolution had been prepared in order to eliminate unnecessary work but it seemed to be having the opposite effect. It might be advisable to set up a working group to integrate the various amendments proposed.

He agreed that the training of health personnel should depend on local conditions and needs, and that standardization was therefore not desirable.

Dr MIKEM (Togo) agreed with the comments of the delegate of Cuba.

Dr KAREFA-SMART, Assistant Director-General, emphasized that the draft resolution was intended to permit the Health Assembly to ask the Executive Board to carry out an evaluation of the experience in training that WHO had acquired, taking into account the conclusions of the regional committees; and to request the Director-General to present a report on that subject to the Twenty-fourth World Health Assembly. At the present stage little more could be done than take note of the situation. All the comments made by members of the Committee had been noted, and delegates might wish to reconsider the draft resolution and the proposed amendments in that light.

In reply to the delegate of Yugoslavia he said that pharmacists were included in the evaluation of the training of professional and auxiliary health personnel.

Dr TEOUME-LESSANE (Ethiopia) moved the closure of the debate.

Dr SACKS, Secretary, read out Rule 61 of the Rules of Procedure, on closure of debate.

The CHAIRMAN asked if there were any speakers against the motion.

Dr AL-AWADI (Kuwait) spoke against the motion.

The CHAIRMAN asked for a show of hands in the vote on the motion for closure of the debate.

Decision: The motion for closure of the debate was carried by a large majority, with two votes against the motion and no abstentions.

Dr AL-AWADI (Kuwait), speaking on a point of order, withdrew his amendment in favour of that of Bahrein.

Dr SULIANTI SAROSO (Indonesia), speaking on a point of order, supported the amendment of the delegate of Bahrein but asked that her own amendment should stand.

Dr SACKS, Secretary, said that the amendment proposed by the delegate of Pakistan to operative paragraph 3 would modify that paragraph by the insertion, at the end, of the words "and an assessment of the utilization of the personnel so trained." The Bahrein amendment to operative paragraph 4, which incorporated the Indonesian amendment, would modify that paragraph to read as follows:

REQUESTS the Director-General

(a) to present to the World Health Assembly, in the light of the discussions of the Executive Board, a report on any concrete measures that the World Health Organization might appropriately take to assist further the training of national health personnel of all levels, including the methodology employed in such training;

(b) to urge Members in each region to formulate a minimum standard of curriculum for training programmes of health personnel taking into consideration the needs of the region.

The CHAIRMAN put to the vote the various amendments and the draft resolution as finally amended.

Decision:

(1) The Bahrein amendment, incorporating the Indonesian amendment, was adopted by 36 votes to 26, with 16 abstentions;

(2) The Pakistan amendment was rejected by 29 votes to 16, with 38 abstentions;

(3) The draft resolution as a whole, as amended, was adopted by 76 votes to none, with 7 abstentions.

2. COMMUNITY WATER SUPPLY PROGRAMME: Item 2.6 of the Agenda (Resolution WHA21.36; Documents A23/P&B/5, A23/A/Conf.Doc. No.6 and Corr.1, A23/A/Conf.Doc. Nos.10, 11, 12 and 17) (continued)

The CHAIRMAN drew attention to the revised draft resolution on community water supply in document A23/A/Conf.Doc. No.17, presented by the delegations of Colombia, Ethiopia, India, Iran, New Zealand, Niger, Nigeria, Panama, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, Uruguay and Venezuela.

Mr JOHNSON (United States of America) introduced the revised draft resolution, which read as follows:

The Twenty-third World Health Assembly,

Having considered the progress report of the Director-General on the community water supply programme;

Noting the progress achieved to date by Member States in various regions, particularly in the American Region;

Welcoming the increasing assistance to Member States from such sources as the United Nations Development Programme, the United Nations Children's Fund, bilateral aid programmes and international and regional financing agencies towards achieving the health objectives of the community water supply programme, particularly the support given in connexion with the rural water supply programmes;

Believing that, on a world-wide basis, the progress in implementing the community water supply programme in relation to the needs is too slow to meet these needs within the foreseeable future;

Recognizing that water supply developments, particularly in urban areas, can be placed largely on a self-sustaining financial basis;

Noting that WHO has generated considerable additional external financing for community water supplies;

Understanding that external financing continues to be available to increase the rate of implementation of water supply projects, provided sound projects can be developed;

Re-emphasizing the long-range nature of the community water supply programme and its vital role in the improvement and maintenance of health;

Reaffirming the recommendations included in resolutions WHA19.50 and WHA21.36; and

Recognizing further that the achievement of WHO targets for the Second Development Decade, as stated in the Director-General's report to the Twenty-third World Health Assembly, may require for a period a doubling of annual rates at which new acceptable projects, rural and urban, are achieved,

1. NOTES the report of the Director-General, and endorses the general principles and programme therein;

2. RECOMMENDS to Member States:

(i) that they intensify their efforts to identify community water supply problems as an essential first stage in national water supply development;

(ii) that they give high priority in their development plans to programmes for the provision of community water supply and sewerage;

(iii) that they continue to strengthen co-ordination between ministries of health and such other ministries or governmental bodies as may be responsible for the planning and implementation of community water supply programmes and sewerage;

(iv) that they take full advantage of the assistance obtainable from multilateral and bilateral agencies for the implementation of water supply programmes;

3. REQUESTS the Director-General:

(i) to pursue co-operative activities with Member States, research institutions, and with multilateral and bilateral agencies for the stimulation and promotion of community water supply research and development programmes;

(ii) to intensify assistance to Member governments in the development of community water supply so as to make use of the maximum amount of assistance from external financing resources to establish acceptable projects within the WHO targets proposed for the United Nations Second Development Decade;

(iii) to report on the financial consequences of the programme for WHO to the Twenty-fourth World Health Assembly.

Mrs JOHANNING (Norway) said that her delegation considered the revised draft resolution a great improvement on the original draft, and was prepared to support it. However, she thought that operative paragraph 3 (ii) should be clarified.

Mr JOHNSON (United States of America) suggested that, in order to meet the concern of the delegation of Norway, operative paragraph 3 (ii) should be amended to read:

(ii) to intensify assistance to Member governments in the development of community water supply so that those governments may make use of the maximum amount of assistance from external financing . . .

Dr AHMETELI (Union of Soviet Socialist Republics) said that his delegation had been a member of the group which had prepared the revised text now before the Committee and considered it a great improvement on the original text. The USSR delegate on the group had, however, expressed the fear that the Organization might become too deeply involved in the question of community water supply and had stated that his delegation would abstain when the revised draft resolution was put to the vote as a whole.

The CHAIRMAN put the revised draft resolution in document A23/A/Conf.Doc. No.17 to the vote.

Decision: The revised draft resolution, as amended by the delegate of the United States of America, was adopted by 78 votes to none with 4 abstentions.

3. QUALITY CONTROL OF DRUGS: Item 2.10 of the Agenda (Official Records No. 176, Resolution WHA22.50 and Annex 12; Document A23/P&B/8)

Dr BERNARD, Assistant Director-General, introducing the report by the Director-General in document A23/P&B/8, referred to resolution WHA22.50, and said that the Director-General had sent a circular letter in September 1969 to all Member States, asking them for comments on any improvements they considered necessary in the texts of the requirements for Good Practices in the Manufacture and Quality Control of Drugs (Official Records No. 176, Annex 12, part 1) and the certification scheme on the quality of pharmaceutical products moving in international commerce (Official Records No. 176, Annex 12, part 2).

The document before the Committee was a progress report and referred to comments already received from nineteen States. The Director-General fully understood that more time was necessary for countries to reply to his circular.

Judging by the replies so far received, there was agreement both with the letter and spirit of the resolution adopted at the Twenty-second World Health Assembly. Some countries had pointed out that they were already applying certain measures; others were studying the possibility of instituting a certification scheme taking into consideration the decisions of the World Health Assembly.

He emphasized that the more replies received from Member States the better, since that would lead to a better understanding of the question. The Director-General hoped that by the Twenty-fourth World Health Assembly he would be able to give a representative picture of the way in which the Good Practices in the Manufacture and Quality Control of Drugs and the proposed certification scheme had been received and were being applied.

Dr BRZEZINSKI (Poland) said that his delegation appreciated the Director-General's report on the quality control of drugs. It showed a further improvement in the requirements for good manufacturing practice.

He pointed out that the quality control of drugs systems in Poland were comparable with those recommended by WHO. In several instances more detailed procedure had been elaborated or introduced. The drug registration system in Poland had been fully operative for many years and no drug was permitted to enter the internal pharmaceutical market without the approval of a special advisory body called the "Drug Council" in the Ministry of Health and Social Welfare.

At previous World Health Assemblies the Polish delegation had given details of its procedure as regards the quality control of drugs and it would be very happy to provide interested delegates with information.

He expressed the hope that the recommendations and requirements outlined in the twenty-second Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (Technical Report Series, No. 418) would be introduced in all countries.

Dr SAUTER (Switzerland) said that his country was among those which had not yet submitted comments to WHO on the requirements for Good Practices in the Manufacture and Quality Control of Drugs and the certification system.

The study made by Switzerland had only recently been concluded and had led to a series of observations; the reaction had generally been favourable. It would seem, however, that some clarification might facilitate the application of the Good Practices, especially as regards definitions. In drawing up rules, the differences existing between countries and regions as regards the practice of drug control must be borne in mind.

Dr WELTON (Australia) said that as far as Australia was concerned there were two aspects of the question before the Committee, first, licensing and, secondly, certification.

The Commonwealth and states in Australia had adopted and applied the requirements for Good Practices in the Manufacture and Control of Drugs. The licensing of manufacturers was the concern of the states, and appropriate legislation was required. That legislation already existed in Victoria and would soon be introduced in New South Wales. Those two states represented 95 per cent. of all pharmaceutical manufacturers in the Commonwealth. It was expected that the inspection of all manufacturers would be completed early in 1972.

He felt that the code of Good Practices should be enlarged to cover radiation sterilization. The question of radiation sterilization of medical products had been discussed at an international symposium in 1967 and it had been indicated that WHO was taking an interest in the matter. Although such sterilization of goods might be carried out by the primary manufacturer, the very specialized nature of the equipment used for the sterilization frequently led to it being carried out in independent radiation sterilization facilities. Under the latter circumstances, the success of that method of sterilization depended upon the collaboration of the two parties; it depended on the primary manufacturer submitting goods for sterilization which bore only a slight microbial contamination, and on the operator of the radiation facility administering an agreed sterilizing dose of radiation. That matter was important and it concerned both the code of Good Practices and the availability of adequate radiation facilities. It therefore related to two organizations: first, WHO, through its unit concerned with the quality control of pharmaceutical substances; and, secondly, the International Atomic Energy Agency. Australia would recommend that discussions take place between those two bodies so that suitable amendments could be made to the code of Good Practices with regard to radiation sterilization procedures and testing.

He pointed out that biological products were not covered by the present code. He thought that certain parts of the excellent report of the Expert Group on Requirements for Biological Substances (Technical Report Series No. 323 (1966)) should be included in the code of Good Practices, so that the latter document would include all aspects of production of medicinal preparations.

With regard to certification, a scheme had been approved by a working party of the State Commonwealth Committee on the Uniform Control of Therapeutic Goods. Certification would be instituted gradually when requests for such certification were made. Such certification presupposed the inspection of a company before it exported drugs, and unless a priority system for exporting companies were developed, certification would be delayed. However, it might be possible to effect a full certification system within a year. The wording of the documentation before the Committee appeared to assume a registration system which a number of countries did not have in operation. The certificate that Australia had prepared covered all matters in the WHO proposed document except that of the registration number.

No discussions had yet been held on whether Australia at some time in the near future would require certification of imported products, as outlined by the WHO proposal. It would not be appropriate for Australia to require such a certificate until it was prepared to issue a certificate for export; and it would not be in a position to do that fully for another twelve to eighteen months. Another point was whether Australia should act unilaterally in such a decision or wait until the major exporting countries were ready to comply with such a scheme. Hence, for both licensing and certification, a period of at least eighteen months would be necessary before the scheme could be fully implemented in Australia.

Dr DURAISWAMI (India) said that in his country the manufacture of drugs was governed by the Drugs and Cosmetics Act, which contained provisions covering the conditions and site of manufacture, equipment, technical experience of personnel, maintenance of proper records, standards, and labelling. His delegation supported the certification scheme since it would ensure that drugs exported had been manufactured in conformity with the code of Good Practices. However, he suggested that more time be given to countries like India which were developing their export trade, in order that the new requirements did not hinder the building up of that trade.

Since India had gained independence in 1947 drug manufacture there had increased twenty-fold, but further progress was hampered by the lack of sophisticated equipment the purchase of which required foreign exchange. India hoped that such equipment would be acquired with the assistance of WHO, in line with the recommendations made during the seminar on the quality control of drugs, held in Bombay for the South-East Asian Region in January 1969.

Dr FELKAI (Hungary) said that his delegation was in general agreement with the requirements of the Good Practices in the Manufacture and Quality Control of Drugs, recommended by the Twenty-second World Health Assembly.

In connexion with section 2 (Definitions), his delegation wished to suggest that the batch number, besides enabling the batches to be identified should also show the date of their manufacture. His delegation therefore proposed that the last four figures of the batch number, separated from the preceding figures by a full stop, should indicate the month and year of manufacture. For example, a batch produced in September 1969 would have a batch number bearing .0969 at the end of the serial number.

Referring to section 3 (Personnel), he suggested that the last sentence of the first paragraph should be amended by the insertion of the words "to enable them to make independent decisions" before the words "based on the application of scientific principles".

As regards section 8.2 (Equipment and containers), his delegation suggested that the wording at the end of the first sentence should be "bearing the name and the identification code of the processed materials or the necessary batch identification data"; and that the last phrase of the last sentence should read "listing the name and the identification code of the manufacture produced or its batch identification."

Referring to section 8.6 (Batch manufacturing records), he said that the data proposed were important and in Hungary were kept in the recording system of the pharmaceutical industry. Such systems might differ greatly according to the methods used by factories and so forth, and therefore his delegation suggested that the title of section 8.6 should be amended to read "Recording". The text should also be modified and sub-section (6) omitted.

As regards section 9 (Labelling and packaging), his delegation considered that the text of labels affixed to cartons, boxes and so forth should be approved in advance by the responsible authorities. The wording of sub-section (2) should be amended to read "(2) a list of active ingredients, showing the amount in each single unit."

As regards sub-section (4), his delegation considered that the expiry date should be shown on the label in all cases when the shelf-life was under five years. Should the date of expiry not be indicated on the label, the drug should be considered as having a shelf-life of under five years.

Hungary would welcome fellowship-holders to study its drug control system, and was ready to receive candidates from the developing countries for long-term fellowships.

In view of the difficulties which many developing countries might experience in setting up an adequate control system for drugs, because of lack of equipment, funds and personnel, his delegation considered that regional laboratories should be developed. Hungary was ready to make available to WHO well-trained personnel for the establishment, promotion and maintenance of control laboratories, both at the regional and at the national level.