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PROVISIONAL SUMMARY RECORD OF THE TWELFTH MEETING

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CHAIRMAN: Dr S. BUTERA

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Smallpox Eradication Programme (Document EB61/WP/1)

The CHAIRMAN invited the Board to continue its discussion of the Director-General's report on the smallpox eradication programme.

Dr GALEGO PIMENTEL, noting that the programme was in its final stage, said that if all went well it would be possible in two years' time to declare that smallpox had been eradicated throughout the world. That was a triumph for humanity on which the Director-General and the Organization were to be congratulated. Smallpox eradication meant more than the elimination of a terrible scourge. It was the first transmissible disease to be eradicated and the experience thus gained could serve as a guide and as a focus of hope to encourage the Organization in its role. It also demonstrated that, through the combined efforts of WHO and Member States, it was possible to bring about such a feat. She supported the draft resolution submitted in the Director-General's report.

Professor SPIES said that the success achieved in the smallpox eradication programme was proof of the benefits to be derived from peaceful cooperation. Though there was every cause for satisfaction, he would urge the need for caution on the part of Member States, and would suggest that a recommendation to that effect be incorporated in the draft resolution. It was important to provide for unseen eventualities, and to ensure that preventive measures were not abandoned too soon.

He was a little surprised to note that the recommendations of the Consultation on Worldwide Certification of Smallpox Eradication in Annex 2 to the Director-General's report stressed the managerial and administrative aspects of the programme as opposed to the medical and biological. Not enough was known, for example, about the poxviruses nor about the question of transmission between man and animals. He also considered that the recommendations should place more emphasis on further study of the whole matter by the Global Commission.

He would underline, in particular, the recommendation in paragraph 7 of Annex 2 of the report regarding variola virus stocks. All countries should be reducing the number of laboratories that still retained such stocks and effective control should be introduced. Possibly the Organization's action should be strengthened by a more stringent recommendation that could perhaps be adopted by the United Nations. Once smallpox had been declared eradicated, further thought should be given to whether additional measures were needed. He would also underline the recommendation in paragraph 8 regarding animal orthopoxvirus studies. Further studies should be carried out on animal poxviruses other than monkeypox. With regard to the recommendation in paragraph 9 relating to vaccination policy, he agreed that it was for each country to decide when to stop vaccinating. The Board could only make recommendations but he trusted that, in so doing, it would take account of the points he had raised. The holding of vaccine stocks, referred to in paragraph 10, was likewise a matter for decision by governments. He considered, however, that certain stocks of vaccines should be retained to meet unforeseen eventualities.

Subject to those remarks, he endorsed the recommendations and supported the draft resolution.

Dr TAJELDIN (alternate to Dr Al-Baker) said that four of the cases of monkeypox in children that had occurred in Africa had proved fatal. He asked the Secretariat for more details about the disease, particularly in regard to its relation to smallpox, its transmission to man, its similarity to the smallpox virus, and the effectiveness of immunization.

Dr OLIVER (alternate to Dr Casselman), agreeing on the need for caution, said that it would be unwise to equate the lack of reports of clinical cases of any disease with the nonoccurrence of the causative agent. So long as the variola virus existed, it would pose a hazard. He joined other speakers in commending the Secretariat on the progress made. The results were very encouraging and his country would continue to support the programme.

Dr SEBINA praised the Director-General and his staff for a magnificent achievement, which afforded a striking example of the fruits of international cooperation. Quite phenomenal amounts had been donated, both nationally and internationally. It was to be hoped that the Organization and Member States would continue their efforts. He only regretted that such savings as the Director-General had been able to effect had been offset by currency fluctuations: he would rather they had been used to pay a bonus to the staff who had contributed to that achievement. He agreed that no premature decision on vaccination should be taken, and that surveillance should be continued for as long as necessary.

Dr DLAMINI, supporting the draft resolution, expressed admiration for the way in which funds and equipment had been mobilized in the campaign against smallpox, and congratulated the Organization on its direction of that campaign.

No other disease would ever pose such a threat to the world as smallpox and the major effort harnessed to eradicate it could therefore never be repeated. One fact was clear, however, namely, that control and eradication of disease could be brought about by vaccination and that, given the will, vaccines could be made readily available to any developing country at virtually no cost. It was a tragic fact that there was an exceedingly high rate of mortality among children from diseases that could be prevented by immunization. That applied particularly to measles vaccine which was still unavailable to the developing world. He therefore appealed to the Director-General and, through him, to the international community to make a concerted effort to save the lives of those children so that they could grow up to become better members of the same community.

He agreed as to the danger of premature complacency, and asked the Secretariat whether there was any scientific basis for requiring a two-year period to elapse following the last reported case of smallpox before the disease could be declared eradicated.

Dr FARAH observed that the word "eradication" had been correctly used in the context of smallpox. Members would recall the objections raised to its use in connexion with tuberculosis and malaria, on the ground that its literal meaning was the extinction of a disease.

He agreed on the need for caution but trusted that within a few years the Organization would be able to furnish striking proof of the effective eradication of a disease. He supported the draft resolution but would like to know more about the relationship between the four laboratories that were going to retain virus stocks and the three that were going to retain 300 million doses of vaccine. Also, with regard to paragraph 10 of the recommendations of the Consultation contained in Annex 2 of the report, had some strategy been formulated so that, in the unlikely event of a recurrence of smallpox, countries could on request be rapidly supplied with vaccines? He had himself witnessed the panic following the outbreak of an epidemic and had seen people actually attack health centres and dispensaries.

Dr DE CARVALHO SAMPAIO congratulated the Director-General on an outstanding achievement, which demonstrated how much could be done with cooperation and trust.

He supported the draft resolution and the recommendations of the Consultation. The recommendation in paragraph 8 relating to animal orthopoxvirus studies merited special attention since, in other diseases, it had not at first been discovered that animals, as well as man, were the host. He trusted that in a few years' time it would be possible to implement a similar programme on some other disease, possibly measles.

Dr FERNANDES (alternate to Dr Fresta), endorsing the Director-General's report, said he understood from contacts he had had at the Regional Office for Africa that monkeypox might occur in the Congo. He regarded the Organization's work as extremely important for it had benefited the whole world and not just a part of it.

Dr ABDUL HADI endorsed previous speakers' remarks and congratulated all those who had contributed to an outstanding international achievement. The eradication of smallpox, once little more than a dream for many countries, was now on the verge of being attained. That confirmed the effectiveness of technical cooperation and of the new policy which would lead the Organization on to even greater achievements in the future.

He agreed on the need to guard against complacency and considered that the experience gained should serve as an example. He also agreed that the many other communicable diseases from which millions were suffering could be eradicated or controlled if the necessary resources were mobilized, measles and poliomyelitis being two examples. He suggested that, once smallpox eradication had been declared, another disease should be selected to be the subject of an intensive international campaign with a view to its eradication.

Mr PRASAD observed that, a decade earlier, few could have predicted the dramatic reversal in the fortunes of the smallpox and malaria programmes. The achievements of the former were little short of a miracle and WHO's action would be applauded throughout the world. He did, however, share the concern of those who were anxious to ensure that the disease did not rear its head again, as had been the case with malaria when an element of complacency had set in. It might be worthwhile to maintain the incentive scheme whereby a reward was offered to anybody reporting a case of smallpox. That scheme had proved very effective during the campaign and, even if no cases of smallpox were reported, some other dread disease - monkeypox, for instance - might be brought to light.

He agreed that the success of the smallpox campaign should provide the encouragement needed to deal with some other major disease. His own preference would be for malaria, although the final choice was, of course, for the experts to decide. At the same time, he would urge that any such campaign should not be carried out at the expense of the basic health services and primary health care, otherwise the campaign itself would come to grief or that any successes achieved would not endure.

Professor JAKOVLJEVIĆ, supporting the draft resolution, said that the smallpox eradication campaign provided an example from which all countries could benefit. So long as one small focus remained, however, no country would be safe in ceasing to take precautionary measures. In that connexion, he would remind the Board of the situation that had prevailed in Europe at the beginning of the decade. Smallpox eradication was a major achievement in not only health but also economic terms, for the money thus saved could now be devoted to other health problems. He agreed that malaria should be the next disease to be the subject of an international campaign.

Dr LADNYI (Assistant Director-General) said that several important questions had been raised, not only with regard to what should be done to consolidate the results achieved in the smallpox eradication programme, but also concerning the need to choose another disease as a target for eradication. On behalf of the Director-General and all those who had worked in this field, he thanked the Board for their remarks.

It was planned to carry out epidemiological surveillance for a period of two years, in the form both of searches and intensified surveillance, especially in the countries of East Africa, where there had been outbreaks of smallpox only three months previously. Experts had come to the conclusion that a two-year period was sufficient. Experience had shown that that was fully adequate for the detection of cases; smallpox was a disease that could not be hidden for long from health workers, since its symptoms were apparent and it could be suspected even without any special medical knowledge. He shared the view that things should not be hurried. It was therefore planned to work over a two-year period with the cooperation not only of those now working in the field but also the Global International Commission. In accordance with the Health Assembly's decision, during that period a summary would be made, in the form of a treatise of the experience acquired and work done; work had already begun on the preparation of that publication.

Many speakers had raised the question of monkeypox in humans. It was in 1958 that for the first time an orthopoxvirus was isolated from a monkey and named "monkeypox". The first recorded instance of the "monkeypox" virus being isolated from a person was in 1970. Since then, there had been 29 cases, all in Africa - mainly in Zaire, one case each in Sierra Leone and the Ivory Coast, four in Liberia, and two in Nigeria. The virus was different from the smallpox virus, and the viruses could be differentiated without difficulty by a specialist working in a laboratory. It was officially recorded that four of those 29 cases had been fatal. At least one of the fatal cases, however, had not actually been due to the monkeypox: the child had in fact recovered, and then fell ill with measles - the real cause of death. The mortality rate for monkeypox was considerably lower than for smallpox. Experts were

coming to the conclusion that the risk of man-to-man infection with monkeypox was practically nil. There had been two cases in which it had been suspected, taking into account the incubation period and the fact that the cases were in the same family. However, there were no reliable data indicating man-to-man infection; in fact, available data tended to argue against that hypothesis. Nevertheless, further special research on the subject was being planned. In other words, the possibility of local outbreaks was not being prematurely written off. There were poxviruses of cows, camels, elephants and many other animals that could infect man (for example, cowpox) - but they did not give rise to such epidemiological complications as smallpox.

It was proposed to set up a stock of vaccines in Geneva so that it would be possible in emergencies to supply them rapidly, in the quantities required; in the space of one day a single vaccinator could vaccinate some 10 000 people, using the jet injector.

Regarding the discontinuation of vaccination, he repeated that the experts' point of view was that, until the Global Commission had certified global eradication of smallpox, countries should themselves decide whether or not to continue primary vaccination. Some countries had decided already in 1971 to discontinue compulsory primary vaccination. On the other hand, countries neighbouring Somalia and Ethiopia would no doubt wish to continue it for a while.

Considerable work had been done regarding the danger posed by laboratory stocks of variola virus, and WHO had carried out an investigation on the subject. A large proportion of the 74 laboratories registered as stocking variola virus had already destroyed their stocks, and it was planned to reduce the number to four by 1980. The special precautions to be taken during the removal of the virus from the laboratory had been studied by a group of experts that met in Geneva in August 1977. Dr Klivarová had asked whether it was necessary to reduce so quickly the number of laboratories stocking variola virus. Since the virus was not needed for the production of vaccine, he could see no reason for delaying that process.

Dr Dlamini and other speakers had raised the question of selecting other diseases for eradication - in particular, measles. The first steps in that direction had in fact already been taken - in the form of Expanded Programme on Immunization. However, he thought it would be premature to speak at present of the eradication of the six diseases included in that programme. With measles, for example, the difficulty was that as yet there was no thermostable vaccine available - in other words, the "cold chain" problem. Work was being done on those problems within the framework of the Expanded Programme on Immunization.

Dr ARITA (Smallpox Eradication) said that the Assistant Director-General had covered most of the important points raised, but he would provide some supplementary information. Reference had been made to international health legislation with regard to smallpox eradication. A consultation held in October 1977 had endorsed resolution WHA29.54, urging all governments to restrict their requests for International Certificates of Smallpox Vaccination to travellers who within the preceding 14 days had visited a smallpox-infected country. There were currently no known smallpox-infected areas in the world, and 12 weeks had elapsed since the onset of the last known case. If all countries implemented the recommendation of the Twenty-ninth World Health Assembly, no vaccination certification should be required for travellers. As global certification proceeds the revision of the International Health Regulations would become increasingly appropriate.

On the question of the number of laboratories retaining variola virus, there were at present 6 WHO Collaborating Centres which retained the virus, following recommendations made by the WHO Committee on International Surveillance of Communicable Diseases in its nineteenth report and resolution WHA30.52. The indications were that 4 laboratories which have maximum safety precautions would be sufficient to maintain research and diagnostic activities in the disease for the future.

With regard to monkeypox, the first case had been detected in Zaire in 1970. Since 1971, when the last smallpox case was recorded in Zaire, intensive surveillance has been carried out which resulted in no cases of smallpox being discovered but 12 more cases of monkeypox. That finding supported the epidemiological observation that, as the disease was very difficult to transmit from person to person, it would not establish itself in endemic form in such areas. Several meetings had been held on monkeypox and other poxvirus diseases, and the conclusion had been that monkeypox would not thwart the smallpox eradication programme. He appreciated the need for caution that had been stressed by several speakers.

The programme was going well, but it was vital that no mistake should be made in its last stages.

A further question that had been raised was whether any ecological changes were likely to affect the achievements of the smallpox eradication programme. Substantial epidemiological experience has been gained during the last 10 years. There had been no smallpox outbreaks in which the source of infection had not been traced to a smallpox patient. In many countries including those in Central America, Australia, New Zealand, and the Philippines, smallpox had disappeared for a great number of years - some for over 20 years.

The recommendations of the consultation contained in Annex 2 of the report describe the administrative procedures for certification, however these procedures are being supported by continuous intensive field activities including surveys and house visits to confirm there are no hidden foci. Such activities were undertaken by the countries prior to the visits of the International Commission.

A question had been raised concerning the two-year period for surveillance after the last known case of smallpox. This period was based on experience during the eradication programme, for example in Indonesia hidden continuing foci were detected 8 months after what was thought to be the last known case. Similarly 3-6 months elapsed in Botswana, Brazil and Nigeria before the last cases were finally traced. It was considered that multiplying the longest period of continuing undetected foci, namely 8 months by 3 to give 24 months of intensive surveillance would provide a sufficient safety margin to ensure nil incidence.

On the subject of the 4 laboratories retaining the variola virus, he pointed out that vaccine reserve stocks were not kept at those laboratories but at cold storage depots located at convenient geographical points for the speedy dispatch of the vaccine wherever it was needed. One depot was in Geneva, and another was being established in New Delhi.

Dr VIOLAKI-PARASKEVA agreed that each country would know its own epidemiological situation and would have its own policy on smallpox control, but it would nevertheless be helpful to have guidance from WHO on the conditions under which it could recommend that primary vaccination should be abolished.

Dr ABDUL HADI did not agree with the Assistant Director-General that the time was ripe to select another disease for eradication through an international campaign. As he understood it, there was in fact no disease for which a vaccine was available which would confer protection in the same degree as the smallpox vaccine.

Dr LADNYI (Assistant Director-General) said that eradication should be understood in different ways where different diseases were concerned. Smallpox could be considered as eradicated: there was no reason to believe that a further outbreak could occur, since there was no natural reservoir of the virus and man did not remain a carrier for long. The situation was different with regard to typhus, for example, which had disappeared from most countries because of improvements in social and economic conditions rather than because of medical advances, but which might reappear if conditions were to change. The same was true of a number of other diseases. However, six diseases were being brought under control through the Expanded Programme on Immunization, and he felt that it would be possible in the near future to select a disease for which complete eradication could be undertaken.

In answer to the question raised by Dr Violaki-Paraskeva, he said that the official view was that those countries which were located near to possible foci (for example, the Ogaden), or where the International Commission had not yet confirmed smallpox eradication, should continue with primary vaccination. For other countries, including Europe and North America, there was every reason to stop vaccination; some had in fact already done so. Whether or not WHO should actually recommend the discontinuation of vaccination was a decision which was in the hands of the Board and the Health Assembly.

The DEPUTY DIRECTOR-GENERAL read out the following draft resolution:

The Executive Board,

Having examined the report of the Director-General on the smallpox eradication programme;

Noting resolution WHA30.52;

1. EXPRESSES appreciation for the intensive efforts being made by the World Health Organization and the countries concerned to interrupt smallpox transmission and verify this achievement;

2. ENDORSES the recommendations of the Consultation on Worldwide Certification of Smallpox Eradication as annexed to the report of the Director-General;

3. REQUESTS the Director-General to establish as soon as possible an International Commission for the Global Certification of Smallpox Eradication (Global Commission);

4. URGES all governments to continue full support and cooperation to this final phase of the programme, so that global eradication of smallpox can be certified by the end of 1979.

Decision: The resolution was adopted.

Dr PINTO said that the question of drug policies had been widely debated both in the Executive Board and the Health Assembly. He was surprised that only the Western Pacific and South-East Asia Regions had taken up the subject at regional level. Other regions would do well to hold meetings on it. He supported the technical cooperation aspects of the proposed action programme. Although, in many countries, health ministries were organizing the production of essential drugs, problems arose due to variations in the raw material price and to delays in receiving these raw materials. There had been particular problems in buying vaccines. There was a great financial advantage to countries in producing their own medicines.

Mr ANWAR associated himself with the remarks made by other members of the Board regarding the importance of providing essential drugs, especially to developing countries. The main objective was to ensure that essential medicines were available to the vast mass of the population at a reasonable cost, i.e., relative to the purchasing power in the countries. He suggested that collaboration with established pharmaceutical companies might be counter-productive; it might be better to concentrate on local production in developing countries. Although there were expertise constraints in developing countries, labour costs were cheap. Pharmaceutical companies were governed by factors which were outside the control of WHO and there was the additional problem of transport costs from developed to developing countries. For example, in a certain country, medicines were being produced more cheaply by dispensing with the sugar coating. Consideration had also been given to making the tablets in a different shape so that they could not easily be remarketed. As far as terminology was concerned, he found the terms, "traditional system" and "modern system", acceptable. In many countries the traditional system was well established, whereas the modern system had failed to reach a large section of the community. This was one reason for attempting to mobilize the traditional system for health care. A suggestion had been made to resort to the traditional system "in order to optimize the utilization of local resources". He asked for clarification on whether the intention was to integrate the traditional system with the modern system or whether to keep the two systems running in parallel.

Dr DE CAIRES said that the topic had been discussed at various meetings over several years. Four regional offices had organized visits to 25 countries at different stages of development during 1976 and 1977. Apart from involving pharmaceutical companies, several considerations should be added to the proposals. There should be a development of the infrastructure in order to ensure that the essential drugs would reach the populations in need. There should be a reversal of the present concentration of health care in the cities to provide services in rural areas. It was extremely important for WHO to assure the quality of the essential drugs provided under the action programmes. In the short term, it was obvious that the existing resources of the pharmaceutical industry would be needed. It was, therefore, logical that the Director-General should continue the dialogue he had already started with pharmaceutical companies and with governments. He fully supported the medium-term objectives outlined in the report and, especially, the detailed feasibility study of the action programme. Dr Hellberg had mentioned the role of WHO in the international drug monitoring programme. It was essential that WHO control the evaluation of drugs and disseminate information about possible dangers.

Dr VALLE said that the preparation of a list of essential drugs could lead to reducing expenditures. As Dr de Caires had pointed out, it was essential that the distribution of drugs be under strict control. Some drugs did not always arrive in good condition. Pharmaceutical companies had huge incomes and some of their profits ought to be devoted to drug research. There had been a suggestion that 5-10% of overall expenditure should be used for research purposes but this suggestion had not, apparently, been taken up. Instead, drug companies supplied huge quantities of samples and promotional literature. Some countries were fortunate in having local medicinal plants and the introduction of drugs in such countries, where hitherto not even an aspirin had been available, might damage rather than enhance the already precarious health status of the population. Since only a small proportion of the inhabitants received any kind of medical care and the great majority had no access to medicaments, drug costs could be cut by some 80% if production facilities were available locally. A factory could turn out in a quarter of an hour a week enough drugs to meet the needs of a small country. It was, therefore, sensible for small countries to work together. He supported the objectives set out in the report.

Dr ABDUL HADI said that the proposals for an action programme on essential drugs were timely. He supported the suggestion that the Director-General appeal to governments to cooperate in the programme. If WHO were to rely on pharmaceutical companies to provide

essential drugs under special conditions for use in less developed countries, care should be taken to see that packaging and labelling were acceptable. Drugs labelled "for export only" tended to produce suspicious reactions from consumers.

Dr KASONDE supported the proposals set out for the supply of essential drugs. Special consideration should be given to the difficulty experienced by some countries, not so much in being able to pay for supplies, but in being able to obtain the appropriate currency at the right time for payment. He asked whether WHO could set up some sort of fund to avoid this difficulty. Concerning the pharmaceutical industry, countries needed to buy particular drugs but were subjected to such a barrage of promotional literature that it was difficult to compare the products and costs of various suppliers. WHO could usefully provide information on this and on patent law for those countries wishing to produce their own drugs. He asked whether elementary surgical supplies could be subject to the same action programme as essential drugs.

Dr MWAKALUKWA fully supported the proposals contained in the document and, in particular, the suggested action programme on essential drugs. The report of the Expert Committee provided the scientific basis for the identification of indispensable drugs and vaccines. He asked whether WHO could collaborate with countries in establishing lists of drugs to be used at each level of health care. As Dr de Caires had pointed out, the distribution of drugs to ensure that they reached the population in need should be an essential part of the programme. He said that there should be some control of the promotional tactics employed by some pharmaceutical companies. Health workers should not be "forced" to use particular products, but it was difficult for governments to restrain the activities of affluent multinational companies. Perhaps WHO would have more success in obtaining the cooperation of the drug companies.

Dr KLIVAROVÁ (alternate to Professor Prokopec) shared the satisfaction expressed by previous speakers regarding WHO's programme in this important field. The subject of drug policies and management was one that greatly affected developing countries, and work in this sphere represented a considerable contribution to technical cooperation. She was therefore surprised that so far only two regions - South-East Asia and the Western Pacific - had dealt with the subject. She thought that it would be difficult for WHO to retain full responsibility for coordination of the programme of international drug monitoring when it was transferred to a WHO Collaborating Centre in Uppsala. How could it, in practice, ensure the "participation of national and other centres and dissemination of information, including publications" (as stated in paragraph 1.5 of the report before the Board)? A recent article in the Lancet had raised doubts as to whether the Organization could in fact fulfil its role vis-à-vis Member States and, in particular, the developing countries. She expressed satisfaction with the main points of the proposed action programme on essential drugs, and asked which particular pharmaceutical companies had been approached by WHO concerning the production and supply of drugs.

Dr A. HASSAN welcomed the proposals for the action programme which attempted to meet the needs of countries regarding essential drugs and vaccines. It was important that there should be a control system for such drugs. This would help countries provide the best possible health care. Both developed countries and pharmaceutical companies could play a vital role in making the programme a success. He said that WHO should make pharmaceutical companies conscious of their duties in the health field.

Dr S. HASAN supported the objectives of the proposed action programme on essential drugs. He agreed with Dr Cumming that pharmaceutical companies could be encouraged to provide drugs for the public sector as a first step to further cooperation. As Dr Abdul Hadi had pointed out, care should be taken to avoid adverse psychological reactions produced by inappropriate labelling of drugs. He supported the medium-term objectives which aimed to strengthen national capabilities in the pharmaceutical field and promote good manufacturing practices and quality control. He asked the Director-General to take steps to ensure that essential drugs would be provided at cheap rates to those countries which could not, or could not yet, produce their own drugs.

The meeting rose at 12h30

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