PROVISIONAL SUMMARY RECORD OF THE FIFTEENTH MEETING

WHO Headquarters, Geneva
Tuesday, 21 January 1997, at 14:30

Chairman: Dr E. NAKAMURA
later: Mr S. NGEDUP

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Note

This summary record is provisional only. The summaries of statements have not yet been approved by the speakers, and the text should not be quoted. Corrections for inclusion in the final version should be handed in to the Conference Officer or sent to the Records Service (Room 4113, WHO headquarters), in writing, before the end of the session. Alternatively, they may be forwarded to Chief, Office of Publications, World Health Organization, 1211 Geneva 27, Switzerland, before 3 March 1997.

The final text will appear subsequently in Executive Board, Ninety-ninth session: Summary records (document EB99/1997/REC/2).
FIFTEENTH MEETING

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The meeting was held in private from 14:30 to 15:20, when it resumed in public session.

1. AWARDS: Item 20 of the Agenda

**Léon Bernard Foundation Prize** (report of the Léon Bernard Foundation Committee): Item 20.1 of the Agenda

**Decision:** The Executive Board, having considered the report of the Léon Bernard Foundation Committee, awarded the Léon Bernard Foundation Prize for 1997 to Academician E. Chazov (Russian Federation) for his outstanding service in the field of social medicine.

**Dr A.T. Shousha Foundation Prize and Fellowship** (report of the Dr A.T. Shousha Foundation Committee): Item 20.2 of the Agenda

**Decision:** The Executive Board, having considered the report of the Dr A.T. Shousha Foundation Committee, awarded the Dr A.T. Shousha Foundation Prize for 1997 to Professor M.K. Gabr (Egypt) for his outstanding contribution to the improvement of the health situation in the geographical area in which Dr Shousha served the World Health Organization.

The Board awarded the Dr A.T. Shousha Foundation Fellowship to Dr N.A.E. El-Ashry (Egypt).

**Ihsan Dogramaci Family Health Foundation Prize and Fellowship** (report of the Ihsan Dogramaci Family Health Foundation Committee): Item 20.3 of the Agenda

**Decision:** The Executive Board, having considered the report of the Ihsan Dogramaci Family Health Foundation Committee, awarded the Ihsan Dogramaci Family Health Foundation Prize for 1997 to Mrs S. Nazarbayeva (Kazakhstan) for her service in the field of family health.

**Sasakawa Health Prize** (report of the Sasakawa Health Prize Committee): Item 20.4 of the Agenda

**Decision:** The Executive Board, having considered the report of the Sasakawa Health Prize Committee, awarded the Sasakawa Health Prize for 1997 to the Mongar Health Services Development Project (Bhutan) for outstanding innovative work in health development. The Board noted that the Mongar Health Services Development Project would receive US$ 40 000.

**Francesco Pocchiari Fellowship** (report of the Francesco Pocchiari Fellowship Committee): Item 20.5 of the Agenda

**Decision:** The Executive Board, having considered the report of the Francesco Pocchiari Fellowship Committee, awarded the Francesco Pocchiari Fellowship for 1997 to Dr M. Kassaye (Ethiopia) in order to enable him to acquire relevant research experience from another country.
United Arab Emirates Health Foundation Prize (report of the United Arab Emirates Health Foundation Committee): Item 20.6 of the Agenda

**Decision:** The Executive Board, having considered the report of the United Arab Emirates Health Foundation Committee, awarded the United Arab Emirates Health Foundation Prize for 1997 to Dr A.R.A. Al-Awadi (Kuwait) and to Dr R. Salvatella Agrelo (Uruguay) for their outstanding contribution to health development. The Board noted that Dr Al-Awadi and Dr Salvatella Agrelo would each receive US$ 20 000.

The CHAIRMAN announced that the Executive Board, at its private meeting, had approved a new paragraph 3 to Article 6 and a change in Article 8 of the Statutes of the United Arab Emirates Health Foundation, which related to the reimbursement of the travel expenses incurred by the representative of the Founder in attending the sessions of the Foundation Committee out of income derived from the Foundation’s capital. He invited the Legal Counsel to read out the changes.

Mr TOPPING (Legal Counsel) first read out the new paragraph 3 of Article 6 of the Statutes:

3. The travel expenses of the representative of the Founder in attending the sessions of the Foundation Committee shall be considered to be an expense of the Foundation and reimbursed, in accordance with the travel rules of the Administrator, out of the income derived from the Foundation’s capital.

The second amendment, to Article 8 of the Statutes, was the deletion of the word "upwards" from paragraph 1 concerning the fixing of the sum of money to be awarded as a prize. He read out the last sentence of that paragraph, as amended:

This sum may be adjusted from time to time by the Committee, based on the changes in the capital of the Foundation, variation in interest rates and other relevant factors.

2. **REPORTS OF ADVISORY BODIES AND RELATED ISSUES:** Item 16 of the Agenda (Document EB99/40) (continued)

Report on the thirty-fourth session of the global Advisory Committee on Health Research (ACHR): Item 16.1 of the Agenda (Document EB99/26) (continued)

Future research agenda: Item 16.6 of the Agenda (Document EB99/INF.DOC./4) (continued)

Professor GIRARD said that Professor Fliedner’s report had clearly stated the problems underlying the major strategic issue of WHO’s role in research. Although the Organization was obviously not a research institute, it had a key role to play in steering research towards health requirements and urging researchers to serve the community by focusing on health rather than on medical, scientific and technological research.

The figures on the subjects and originating countries of scientific articles mentioned by Professor Fliedner showed clearly that the idea of health for all was not being supported by research for all. WHO must take steps to speed up transfer activities.

With regard to the idea of a forum mentioned by Professor Fliedner, he felt that the global Advisory Committee on Health Research (ACHR) should play a general policy role, providing the framework within which a forum would discuss programme implementation and institutional implications. As he saw it, the two functions were distinct but complementary.

Health research was a relatively recent idea and it was essential that WHO should serve as its custodian, playing its role in research to the full but remaining within the appropriate boundaries.
Dr BERNARD (alternate to Dr Boufford) thanked ACHR for its work, particularly its emphasis on the importance of research as a tool for policy-setting and decision-making in relation to the renewal of the health-for-all strategy. He also welcomed the emphasis placed on the economic environment and government infrastructure needs. On the other hand, behavioural processes leading to health outcomes were not being given adequate attention.

He urged ACHR and others to accelerate investigation of burden-of-disease measures that could be used in health policy decision-making. In particular, he encouraged the relevant ACHR subcommittee to continue its work on the matter.

The debate on measurable indicators should take place at the most collegial and informed levels and should not lose sight of the potential risks and real benefits of bringing evidence-based thinking to bear on the topic. Disability-adjusted life years (DALYs) were one possible indicator of how resources should be used. Simpler forms of analysis could sometimes be misleading. If mortality rates were used, for example, adequate weight might not be given to conditions that caused great suffering or significant costs but were slow to kill.

In addition to investigating the burden of disease, research agendas should focus on areas of prospective scientific progress; that also applied to selecting health areas for coverage by public programmes, health insurance or other mechanisms.

He endorsed the ACHR recommendation concerning a WHO global initiative on health in border areas with the caveat that its implementation needed very careful consideration in view of the limited resources available. WHO attention to border areas or refugee camps was appropriate because of the risk of border countries denying responsibility for the populations concerned. WHO could play a valuable role in preparing health strategies for border countries, including guidelines for monitoring health and stimulating support for health services.

He asked for clarification of the meaning of the word "stakeholders" in paragraph 5 of document EB99/26.

Dr LEPPØ said that scientific research was an essential component of the health-for-all strategy for the twenty-first century. Ideally, health policy development should be based on reliable scientific evidence and every effort should be made to turn research findings into practical tools for a renewed health-for-all policy. Although health research was one of WHO's constitutional functions, most of the Organization's estimated total research budget of about US$ 160 million for the next biennium came from extrabudgetary resources and was used for special programmes such as human reproduction or tropical disease research or for agencies such as IARC or the Kobe Centre for Health Development. The regular budget contribution accounted for only about 10% of total expenditure and was distributed among smaller projects. The strategic role of the research agenda in the development and implementation of the health-for-all strategy raised the question whether the Organization's research policy and programme were fully compatible with its mission and principles. He wondered whether appropriate mechanisms were being used for the development of the research programme and for the coordination and monitoring of research within the Organization. Several previous and current research programmes had had a major impact on health in both developing and developed countries. On the other hand, several areas had been neglected despite their importance for global health - for example, research on health policy and health systems, research on social behaviour, and cultural and economic research in support of health.

More information was also badly needed on the so-called grey zone that was not covered either by disease-oriented vertical research or by systems-oriented health research. WHO should serve as a forum for interdisciplinary research on the interface between those areas.

At a time when the Organization was undergoing a profound reassessment of its key functions, WHO's mechanisms for research strategy and policy-making and the structures for research coordination should be seriously reviewed and certain questions should be asked regarding research objectives and policy. Were the current mechanisms for the formulation of research strategy appropriate? Did the research strategy contribute properly to the renewal of the health-for-all policy? Did the global and regional advisory committees on health research receive adequate resources? Could the interaction between the Executive Board and ACHR be further improved? Were the existing mechanisms and guidelines for acceptance of extrabudgetary
resources appropriate and were the rules duly observed? Were research projects adequately monitored and evaluated? And, lastly, were there strategically important areas of research that were currently receiving less attention than they deserved?

He was particularly interested in hearing whether Professor Fliedner felt that research policy and administration would benefit from an analysis similar to those carried out in other key areas of the Organization.

Professor PICO (alternate to Dr Mazza), expressed his full agreement with the comments of Professor Girard and Dr Leppo. He was convinced that, with the guidance over the years of WHO’s governing bodies, gradual progress was being made in developing research in the service of health at national, regional and international levels. Such research should be promoted by mobilizing the scientific community and making the results widely available for application. Scientific and technical progress must continue but care should be taken to ensure that advances were incorporated into health policies, in accordance with the capacity of each country to absorb them.

During discussion of the topic the previous year, he had indicated the need for further progress in health services research in order to discover how best to organize, provide and manage services in the specific situation of each country, as well as to measure user acceptance, for it was essential to take into consideration the end-users of national health policies. Further research should therefore be promoted in order to identify problems at local level, making it possible to act more rationally and as effectively as possible by the development of policies through strategic planning and the use of appropriate technology. He believed it was essential to stress the new, modern concept of health research which provided a significant input for developing health policies and strategies, especially in the context of a renewed health-for-all strategy. He therefore considered that the Board should support the work proposed by ACHR.

Dr SANOU-IRA said the topic was of particular interest to her as an attempt was being made to develop research in the African Region. There were, however, difficulties both in setting research priorities and in knowing how to determine them. Document EB99/INF.DOC./4 recommended that countries with very limited resources should give high priority in research and services to nutrition, immunization and sanitation, but she considered that in many African countries there were greater priorities such as health systems research. She asked how to set regional priorities and what had dictated the choice of the three topics mentioned in the document.

Dr BLEWETT, thanking Professor Fliedner for his presentation, said he would be particularly interested to see the analyses of health deficits as his own country was among the first twenty to be the subject of those country profiles.

His unease at the matters on which Dr Leppo had raised questions was strengthened by document EB99/INF.DOC./4, which outlined a future research agenda of ACHR. He felt it amounted to little more than a massive, academic check-list and was concerned to know whether priorities, timing, and resources were being used to best effect at a time of severe financial and human resource limitations. He also had the impression that the documents did not take into account the ferment which had been taking place in health research in recent years, particularly in research on the interrelationships of health and development. He would like to see an effort made on the health research agenda to set priorities in the light of developing countries’ needs and on the basis of the important research already carried out elsewhere.

Dr ITO (alternate to Dr Nakamura) said that it was only two years since the Board had endorsed the establishment of the WHO Centre for Health Development in Kobe, Japan. He expressed his sincere gratitude on behalf of the people of Japan for the sympathy expressed by the Board members at that time when Kobe had been struck by a serious earthquake. It was less than a year since the Director of the Centre had been appointed, but already his work was greatly appreciated by people locally and throughout Japan. Considering that the Centre had begun from scratch, the research carried out there was quite remarkable and an international symposium on the implications of earthquakes and other natural disasters would be held there later in the current month. The information before the Board showed that the Centre’s development was well
in keeping with the global strategy of WHO, as ACHR testified, and he believed that the institution was developing along the right lines. In conclusion, he thanked the Director of the Centre for his leadership and the Director-General of WHO for his support of the Centre’s work.

Dr MOREL (alternate to Dr Tsuzuki) said that the institutions selected for review by ACHR in the current year were the Centre for Health Development in Kobe and IARC. He proposed that in 1998 ACHR should carry out a review on the Council on Health Research for Development (COHRED), which worked on the sort of problems referred to by Dr Sanou-Ira, namely priority-setting, mostly in African countries. In addition, he supported Dr Leppo’s proposal that the research mechanism in WHO be reviewed since there were currently so many initiatives in health research.

Dr SHIN said that research was the backbone of progress in every area of society and entailed very long-term investment. ACHR had been one of the core activities of WHO for some years and had achieved a great deal with scant resources. However, the time had come to reconsider priorities and envisage the adoption of different methods in order to streamline and give a clearer focus to research conducted in the framework of WHO. He was disappointed that the report on the thirty-fourth session of ACHR (document EB99/26) seemed not to deal with the same important issues as those raised at the previous meeting by Professor Fliedner. He therefore joined Dr Leppo and Dr Blewett in thinking that priorities and goals should be better determined in order to make the most effective use of the resources available.

Dr ALLEYNE (Regional Director for the Americas) said he was sure that, had more time been available, Professor Fliedner would have elaborated on the areas in which more focused research was needed. In the Americas the focus of the health research promoted by the regional ACHR was restricted to the priorities established by the governing bodies. Resources were limited, however; and unless mechanisms could be found for funding research, research workers were reluctant to present proposals, even in areas given priority. In the area of health systems and health services research, which had received a great deal of attention recently, a continent-wide competition for research grants had been initiated in the Americas and, aided by a subcommittee of the regional ACHR, some 90 proposals submitted for possible funding had been reviewed; unfortunately, the paucity of resources had meant that only a few exceptional proposals had been accepted. Nevertheless, he could assure the Board that in certain currently important sectors some activity was being promoted by WHO.

Dr LÓPEZ BENÍTEZ said that Professor Fliedner’s presentation contained many valuable ideas for the guidance of all Board members in their respective countries. Professor Fliedner’s reference to the need to bring medicine, science and public health closer together was particularly appropriate to developing countries. They needed both specific and broader basic research projects, of the type that had often been conducted by the developed countries but with application to their own circumstances. Such work needed support; sometimes it was not necessary to obtain a great deal of financial support, but technical support to guide the research was essential. In his own country, a surprisingly large number of research activities had been carried out over the past three years in the fields of health administration, health services, public health and science. The financial resources had been relatively slender, but technical support had been of prime importance. Established research centres, of course, worked at a much higher level of complexity and should continue to develop, in line with medical progress. He was not referring to those; his statement was concerned with pragmatic local or national research.

Dr SANGSINGKEO observed that, according to the World Bank’s report on investing in health, in the poorer and middle-income developing countries the budget for research and development in health amounted to some 2 billion US dollars, as compared with about 50 billion US dollars in the rich countries. He supported the recommendations made there that developing countries should increase their budgets for research and development in health up to 1% of the national health budget. He also supported the notion of establishing an international forum on research and development, at least half of whose members should be drawn from poor and middle-income countries.
Professor FLIEDNER (Chairman, global Advisory Committee on Health Research), speaking at the invitation of the CHAIRMAN, expressed his gratitude for the Board’s comments, which reflected support for the continuation of ACHR’s work. It should be borne in mind that ACHR was not a research body of WHO; its task was to advise on WHO research and also to bring all scientific evidence generated throughout the world to bear in support of global health development. ACHR acted as a catalyst to increase the rate of reaction of the scientific research community in response to national and international needs for new knowledge necessary to promote health throughout the world. Regarding the respective importance of priorities and research opportunities, if the opportunities that could be seized at a given time with the available resources fitted the priorities, there was no problem; if not, the priorities had to be turned into opportunities. It was now the time, therefore, to mobilize the scientific community to address global health issues. The scientific community in the developed world had a responsibility to transmit its vast resources in knowledge and experience to the rest of the world, so that the 80% of countries that did not have their own research resources and manpower could participate in the technological advances made in the countries that did. That called for new type of research networks that were problem-oriented and used the most advanced communication technologies, such as teleteaching, teleconsultation, and telecommunication, to assist in delivering health care. That frequently required a change of attitudes, new ways of allocating resources, and the mobilization of interested parties capable of providing the seed money.

In reply to Dr Bernard’s query about "stakeholders", he said he disliked the word, which was not used in ACHR. Unfortunately, it was widely used elsewhere although it suggested the idea of investing risk capital in order to obtain more health. Health was too serious and too important to be compared with a market in which money was injected on one side and healthy people emerged on the other.

Regarding results from other activities in the research field, ACHR had reported to the ninety-fifth session of the Board on its peer group’s review of the report of the Ad Hoc Committee on Health Research relating to Future Intervention Options and had undertaken to incorporate all approaches, new results and thinking generated in various circles into the research agenda that it would propose to the Health Assembly, to accompany the renewed health-for-all strategy. He renewed that undertaking. ACHR could also draw upon an extensive series of papers concerning research priorities and research development. Research in health systems and policies should be looked at from the viewpoint of the opportunities and deficits in the various fields affected by the work of the health systems.

It was impossible for ACHR to review each year all the programmes and their respective research components. WHO programmes had their own advisory bodies, and it was not the responsibility of ACHR to judge the quality of the programmes’ work and research but rather to consider the research outcome that was relevant to further dynamic development of a global health research agenda. ACHR would of course continue steadily to review programmes every two or three years.

He appealed to members of the Board to identify opportunities for research that could only be carried out at global level, involving a new type of interdisciplinary, transnational research that could advance the manpower development and knowledge necessary to promote global health in the next century.

The CHAIRMAN said that he took it that the Executive Board wished to take note of the Director-General’s report on the thirty-fourth session of the global Advisory Committee on Health Research.

It was so agreed.

Mr Ngedup took the chair.

**Regulations for expert advisory panels and committees: reporting to the Executive Board:** Item 16.2 of the Agenda (Document EB99/27)

Mr TOPPING (Legal Counsel) introduced document EB99/27 containing the report by the Director-General, in pursuance of the Board’s discussions at its previous session concerning the role of the Board in
reviewing expert committee reports. The report set out four alternatives (paragraphs 12 to 15) for the Board to consider, in the context of the current Regulations.

He recalled that the First World Health Assembly had adopted a set of regulations applicable to expert committees, which had been revised at the Second and which had provided that such reports were to be submitted to the Health Assembly and to the Board. The former, or the latter acting on its behalf, was to decide whether a report should be published and could preface such a report by a statement approving it in whole or in part, or setting forth its own views on the subject. The further revision of the Regulations adopted at the Fourth Assembly stipulated that the reports should be submitted only to the Board, which retained those same powers.

The role of the Board in reviewing expert committee reports had been the subject of three subsequent reconsiderations. Following controversial and time-consuming discussions during the 1950s, the Board agreed in 1960 to give the Director-General authority to decide whether reports should be published, and to submit a covering document to the Board setting forth the action to be taken with respect to such reports. However, no clear understanding had been reached as to whether the Board was to comment on the Director-General’s report or on the expert committee reports. A review in 1979 led to the drafting of new Regulations in the early 1980s. After heated debate in the Board, it was decided that the reports should be published without the Board’s comments, so as to avoid infringing the independence of the committee reports, particularly as regards technical substance; any comments from the Board would be published separately. The revised Regulations, which were the Regulations currently in force, made it clearer that the Director-General’s report should set forth his observations on the public health implications of the reports and his recommendations on follow-up action. The Board in turn was to consider those two aspects. Following a complaint by one Board member at the eighty-first session of the Executive Board, that the reports had already been published, it was proposed that all reports should be submitted first in draft form to the then Programme Committee and subsequently to the Executive Board for general approval. After further study it was agreed at the eighty-third session that the Board should limit its considerations to the public health implications of the reports in terms of the future work of the Organization, with selection by the Director-General of certain reports which he considered to be of critical importance for public health or WHO’s future priorities, for closer examination by the Programme Committee.

During all those extensive discussions, efforts had been made to obtain the optimum balance between maintaining the scientific integrity and independence of the expert committees and making full use of the public health expertise of the members of the Executive Board.

Dr SAVEL’EV (alternate to Professor Dmitrieva) was not opposed to maintaining the current practice, and adopting alternative 1, but felt that a simpler variant might be adopted. The Board’s practice in considering expert committee reports had been to confine itself to approving their conclusions and recommendations without any changes of substance and merely to make recommendations to the Director-General to take those conclusions and recommendations into account in the Organization’s work programme. Expert committee reports should be published as quickly as possible, in the interests of using the material promptly. In future, therefore, it might be possible to present the Board with information on the expert committee reports in the form of an information document that would be annexed to the report of the Programme Development Committee. That option, which had already been proposed at a previous session of the Board, would enable the Board’s resources to be used more rationally and the entire procedure to be simplified and accelerated. Consideration of his proposal could be deferred to a later date; meanwhile, he would not object to maintaining the status quo and therefore the adoption of alternative 1.

Professor BADRAN (alternate to Professor Sallam) said that the expert advisory panels and Committees were made up of distinguished scientists in their field who were best equipped to discuss, study and offer recommendations, but the reports bore the name of the World Health Organization and might contain recommendations which some countries would take as being the official recommendations of the Organization. He therefore favoured alternative 3.
Dr DOSSOU-TOGBE emphasized that there was a difference between the opinion of the experts and the opinion of WHO. The experts were independent, and were expressing an opinion on behalf of their committee and not on behalf of WHO. Their independence must be respected. An effort should be made to reduce the time between the delivery of the expert opinion and the publication of its results, so the current practice should be maintained. If the Board took any decisions or passed any resolutions regarding the opinions, they should be considered separately as measures instigated by the Board.

Dr BERNARD (alternate to Dr Boufford) agreed with Professor Badran that the expert committee reports were often seen as WHO policy statements, but was concerned that his proposed solution might have the disadvantage of delaying their publication to the point where they might not be quite as useful as they might have been. Dr Savel’ev’s proposal that the current system be maintained but the Director-General’s report expanded to include more content might enable the Board to engage in a genuine debate and possibly to produce a paper that could contribute to the expert committee reports rather than making comments that were quickly forgotten.

Mr TOPPING (Legal Counsel) said that the Board appeared to favour maintaining the current practice but making it even clearer that the reports were those of independent expert committees rather than necessarily reflecting the views of WHO, and basing the Board’s discussions on a more substantial report from the Director-General so that it could engage in a real debate on what the Organization should do with the scientific views expressed by the expert committees.

It was so decided.

Report on meetings of expert committees and study groups (including report on appointments to expert advisory panels and committees): Item 16.3 of the Agenda (Documents EB99/28 and EB99/28 Add.1)


The CHAIRMAN drew attention to document EB99/28 in which the Director-General reported on three meetings of expert committees whose reports had been prepared since the previous session of the Board. He invited members of the Board to comment on the reports, drawing attention to the draft resolution contained in paragraph 12 of the document. Mr Boyer (alternate to Dr Boufford) and Dr Nakamura had tabled amendments to that draft resolution. Also before the Board was a report by the Director-General on appointments to expert advisory panels and committees (document EB99/28 Add.1).

Professor REINER, commending the report, said that because the period of education was so critical, the time when lifestyles and habits were formed that could later influence or determine an individual’s health status, any action to enable schoolchildren to acquire information and knowledge about their physical and mental health and to adopt healthy lifestyles should be supported. The European Network of Health Promoting Schools was contributing to that objective, and was a good example of collaboration between WHO, UNESCO, UNICEF, the European Community and the Council of Europe. All WHO programmes dealing with school health should establish a similar kind of collaboration at global level.

Dr NIGHTINGALE (alternate to Dr Boufford) said that both the report and the health-promoting schools programme were models of collaborative international public health, with WHO fulfilling a coordinating and leadership role. WHO was to be commended on its school health programme. Such technical programmes were working well in the field in promoting health. The process adopted by the Expert Committee had been exemplary.

Dr BERLIN (European Commission), speaking at the invitation of the CHAIRMAN, said that the European Commission had been pleased to collaborate in the health-promoting schools programme with WHO
and the Council of Europe. The Commission was increasing efforts in that area and, since the programme was open to countries which had signed association agreements with the European Union, hoped that it would be expanded and the existing collaboration maintained.


Dr SAVEL’EV (alternate to Professor Dmitrieva), welcoming the report, stressed the importance to Member States of the guidelines and procedures it contained. Since compliance would require harmonization at country level, national regulatory bodies would need time in which to become properly acquainted with the specifications. He thus proposed that the draft resolution contained in document EB99/28 be amended by the insertion after "The Executive Board," of the following:

Having considered the Thirty-fourth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations;

RECOMMENDS to the Fiftieth World Health Assembly the adoption of the following resolution:

The Fiftieth World Health Assembly,

Dr NIGHTINGALE (alternate to Dr Boufford) commended the report, noting the scope of the Expert Committee and the aims of issuing the specifications as outlined in paragraphs 1-3 of document EB99/28. He expressed support for the amendment to the draft resolution proposed by Dr Savel’ev. The guidelines for implementation of the WHO Certification Scheme could not be implemented in the form proposed by the Expert Committee in the United States of America owing to legal, regulatory and resource constraints, which were primarily the consequence of recently enacted legislation on exports of pharmaceuticals regulated by the national Food and Drug Administration. Reservations concerned the user fee, legislated time requirements for certificates and lack of information in a form facilitating the use of WHO-type certificates. Those matters would be brought to the Director-General’s attention through the formal means outlined in the Scheme. The Food and Drug Administration strongly supported the spirit and principle behind the various revisions and had itself participated in the Scheme for many years. However, it was important to allow for flexibility in the Scheme’s implementation. Mr Boyer therefore wished to propose that the draft resolution before the Board be amended by deleting the word "exclusively" from paragraph 2, which would become paragraph 2(1) and adding a new operative paragraph 2(2) to emphasize the importance of formally identifying and submitting any necessary national reservations and reading as follows:

to inform the Director-General of their intent to apply the Scheme and of any significant reservations they intend to observe relating to their participation as provided for in article 2.1 of the guidelines.

The proposed amendments did not diminish the importance of participating in the Strengthened Certification Scheme or change the basic meaning of the resolution.

Professor REINER commended the efforts to the Expert Committee. Harmonized regulations for the registration and marketing of pharmaceuticals at national and international levels and strengthening of the Certification Scheme were essential to ensure the supply of high-quality, effective drugs for all countries.

Dr LÓPEZ BENÍTEZ said that in Honduras, as in many developing countries that were not self-sufficient in the manufacture of pharmaceuticals, the high proportion of the budget spent in purchasing foreign currency to cover the cost of imports was a considerable burden. The least such countries could expect was that such imports would conform to minimum standards. Currently, some did not even correspond to their own labelling. While legal mechanisms were already available at the national level, he supported the adoption
of international standards for pharmaceutical manufacture and marketing, established by WHO, which he hoped all Member States would, in due course, respect.

The draft resolution in document EB99/28, as amended was adopted.


Dr NIGHTINGALE (alternate to Dr Boufford) commended the report. The Expert Committee’s work was crucial to the FAO/WHO Codex Alimentarius Commission and its recommendations formed a basis for discussions within the Codex Committee on Residues of Veterinary Drugs in Foods. Once reviewed, the recommendations became official Codex standards used by the World Trade Organization as internationally recognized scientific benchmarks for resolving disputes. The Committee’s work thus had important public health and trade implications.

Decision: The Executive Board considered and took note of the Director-General’s report on the meetings of the following expert committees and study groups:¹ WHO Expert Committee on Comprehensive School Health Education and Promotion (Promoting health through schools),² WHO Expert Committee on Specifications for Pharmaceutical Preparations, thirty-fourth report,³ and Joint FAO/WHO Expert Committee on Food Additives, forty-fifth report (Evaluation of certain veterinary drug residues in food).⁴ It thanked the experts who had taken part in the meetings, and requested the Director-General to follow up their recommendations, as appropriate, in the implementation of the Organization’s programmes, bearing in mind the discussion in the Board.

Report of the ad hoc working group on health systems development for the future: Item 16.4 of the Agenda (Document EB99/39)

Dr AL-SAIF said that during its discussions at the previous session of the work of the Forty-ninth World Health Assembly, the Board had emphasized that health systems development was critical for sustainable health development, but that it was not making sufficient progress in many countries. An ad hoc working group had thus been established in order to review the needs of countries and determine the effectiveness of WHO’s response. Its progress report was contained in document EB99/39; a final report would be submitted to the Board at its next session.

The report listed some of the issues preoccupying countries, including those meriting further consideration. The group had felt that WHO should strengthen its capacity in health systems development and design an expanded and intensified international initiative for research, training, development and action for health systems development. Moreover, it had recommended that The world health report 1999 be devoted to the theme of health systems development. Concern had been expressed that the subject was not given sufficient priority in the proposed programme budget for the coming biennium. The Board was invited to consider the draft decision contained in paragraph 13.

Professor LEOWSKI noted that in the course of the discussions a great deal had been said about policy directions for the future. In particular, what he would term essential public health functions had been identified as a crucial element. However, the Board had not received any response concerning the importance of that type of activity in WHO’s future work.

Dr DOSSOU-TOGBE said all Board members would be aware that health systems were a vital tool for all countries that had adopted health-for-all as their objective. The members of the ad hoc group were to be commended on the speed and quality of their work. In view of the importance of the subject, he urged the Board to adopt the draft decision.

The draft decision in document EB99/39 was adopted.

Report of the ad hoc working group on the quality of biological products moving in international commerce: Item 16.5 of the Agenda (Decision WHA49(11); Document EB99/29)

The CHAIRMAN drew attention to the following draft resolution on quality of biological products moving in international commerce, proposed by Dr Antelo Pérez, Dr Blewett, Dr Boufford, Dr Ferdinand, Dr Leppo, Dr López Benítez, Dr Mazza and Dr Tsuzuki:

The Executive Board,
Having considered the report of the ad hoc working group on the quality of biological products moving in international commerce,

RECOMMENDS to the Fiftieth World Health Assembly the adoption of the following resolution:

The Fiftieth World Health Assembly,
Noting the increasing movement across international boundaries of vaccines and other biological products for prevention and/or treatment of diseases, together with the rapid development and introduction into public health programmes of medicines produced by modern biotechnology;
Recalling previous resolutions of the World Health Assembly mentioning the vital need to ensure the quality, safety and efficacy of both established and new biological products;
Bearing in mind the responsibility of governments to ensure that biological products, whether imported or manufactured locally, are of good quality;
Recognizing the specialized technical expertise needed for evaluating and controlling biological products;
Recalling the role of WHO in coordinating technical assistance from various sources, including assistance given on a bilateral and multilateral basis, and aware that, according to its Constitution and the decisions of previous Health Assemblies, WHO's coordinating role is one of its most important functions;
Recognizing that WHO's standardization activities need strengthening to meet the challenges of rapid growth and expansion in the field of biologicals and of evaluation of their newly observed potential impact on international trade as a result of the entry into force of World Trade Organization agreements;
Recognizing the long-standing and valuable role of WHO's biologicals unit and the Expert Committee on Biological Standardization;
Recognizing the report and recommendations of the ad hoc working group on the quality of biological products moving in international commerce and as reflected in the Director-General’s report,¹

1. URGES all Member States:
   (1) to use only vaccines and other biological products of demonstrated quality, safety and efficacy;

¹ Document EB99/29.
(2) to adopt, as part of national regulations, WHO requirements or equivalent requirements of competent national control authorities to ensure that their products are safe, effective and of good quality;
(3) to strengthen their national regulatory authorities and national control laboratories;

2. REQUESTS the Director-General:
(1) to strengthen the mechanism for providing clear norms and active leadership to promote the quality, safety and efficacy of biological and biotechnological products;
(2) to extend the assistance offered to Member States within the limits of existing resources to develop and to strengthen their national regulatory authorities and control laboratories so as to increase their competence in this area. Efforts to upgrade the quality of biological products should focus primarily on increasing the capabilities of national control authorities;
(3) to revise the approach to the development of requirements and guidelines for biologicals to ensure that the documents focus primarily on principles and essential elements that ensure the safety and efficacy of products. Details of specifications, assays, and processes could be provided as appendices, as appropriate;
(4) to review and update existing requirements and guidelines for biologicals and ensure that there is a mechanism to address and resolve rapidly scientific and medical inconsistencies in available documents;
(5) to expand WHO's interaction and collaboration with other agencies and increase the use of selected WHO collaborating centres and other organizations in the preparation and review of documents (including draft guidelines and requirements), and in the production of WHO international reference materials;
(6) to ensure that the decisions taken by the WHO Expert Committee on Biological Standardization are widely disseminated in a timely manner;
(7) to keep Member States informed of the development of new biological products and their potential value and application;
(8) to serve as the central resource for providing guidance on quality, efficacy and safety of biological products, when requested by a national control authority, and assist in promoting the exchange of information and "networking" of authorities;
(9) to review issues of potential conflict of interest and confidentiality as they relate to the application of WHO requirements and guidelines, including advice on the acceptability of vaccines intended for purchase by other organizations of the United Nations system;
(10) to convene an independent review of WHO's remit and activities in this field, particularly WHO's biologicals unit, covering *inter alia* how it interacts with other groups with related functions within WHO and externally, with a view to recommending action that will assist in the harmonization of standards and requirements, minimize duplication of activities and enable WHO to respond to scientific developments in a timely manner;
(11) to review the relations between WHO technical reports, requirements, and guidelines and World Trade Organization agreements, in particular, the Agreement on Technical Barriers to Trade, the Agreement on the Application of Sanitary and Phytosanitary Measures, and the Agreement on Trade-related Aspects of Intellectual Property Rights, as well as international trade in biological medicinal products, and to prepare a report on this issue for submission to the Executive Board at its 102nd session in May 1998.

Dr ANTEZANA (Assistant Director-General) recalled that the Forty-ninth World Health Assembly had recognized and endorsed the aim and intention of a draft resolution on quality of biological products moving in international commerce, and had recommended that the Director-General convene an ad hoc working group to study the technical and legal implications of that draft resolution, and report to the Executive Board. Document EB99/29 contained the recommendations of the group, which had met from 4 to 5 October 1996. Those recommendations were important not only from the scientific and technical point of view, but also...
from the institutional point of view in terms of strengthening national regulatory control authorities, particularly in developing countries, and of strengthening WHO activities in the field of biologicals, not only those in current use but also new products manufactured using modern biotechnology.

The recommendations contained in the report had been incorporated into the draft resolution before the Board in a way that fully reflected the opinions of members of the group. If adopted, the resolution would require some additional resources for its implementation. He paid tribute to the contribution made by WHO collaborating centres - particularly two in the United Kingdom of Great Britain and Northern Ireland, one in the Netherlands and one in Denmark - in sustaining the production and distribution of reference substances for biologicals and blood products; that contribution was vital in helping to meet the needs of developing countries.

Professor PICO (alternate to Dr Mazza) recalled that the draft resolution considered at the Forty-ninth World Health Assembly had been sponsored by 26 countries. The Director-General was to be commended for convening a group of such high-level experts in such a short time; he agreed that the technical and legal impact of its recommendations would be considerable.

He proposed that, at the end of the first preambular paragraph of the resolution contained in the draft resolution, the words "both in developed and developing countries" should be added. In the fifth preambular paragraph, after "technical assistance", the words "and in promoting resource mobilization" should be added, and the last phrase should read "WHO's coordinating and advocacy role is one of its most important functions". Lastly, in paragraph 2 a further subparagraph should be added, reading "(12) to support and assist developing countries in the necessary negotiation process with potential sources of science and technology and resource mobilization".

Dr NIGHTINGALE (alternate to Dr Boufford) commended the recommendations of the ad hoc working group which were in line with the spirit of the discussions held and decisions taken at the Forty-ninth World Health Assembly. The draft resolution now before the Board reflected both the intent of the draft resolution discussed at the Health Assembly and those recommendations. The amendments just proposed by the previous speaker took into account recommendation (9) listed in paragraph 8 of document EB99/29. Adoption of the resolution would set in motion a series of activities which would greatly enhance the work of WHO, and notably the work of the biologicals unit of the Division of Drug Management Policies. It would also strengthen national control authorities, and facilitate international use of, and trade in, biological products that were safe, effective and of good quality.

The requests being made to the Director-General were mostly without financial implication or indeed would produce savings. The review of WHO's functions related to biologicals, would involve short-term costs but potential substantial long-term savings. All the activities could be undertaken within current resources, though the allocations might require rearrangement. In short, the resource issue was not an impediment to the adoption of the draft resolution; it was rather a reason to endorse it.

The draft resolution, as amended, was adopted.

The meeting rose at 17:40.