

## **FIFTH MEETING**

**Wednesday, 25 January 2006, at 09:15**

**Chairman:** Mr M.N. KHAN (Pakistan)

### **TECHNICAL AND HEALTH MATTERS:** Item 4 of the Agenda (continued)

#### **Prevention and control of sexually transmitted infections: draft global strategy:** Item 4.6 of the Agenda (Document EB117/8 Rev.1)

Mr AITKEN (Director, Office of the Director-General) recalled the explanations given in the first meeting to the effect that logistic reasons had delayed the production of the draft strategy. There had appeared to be consensus, however, that the draft would be issued in electronic form around mid-February and, after a final round of electronic consultations among Member States, produced in final form in time for the Fifty-ninth World Health Assembly.

In response to questions from Dr SUWIT WIBULPOLPRASERT (Thailand), he explained that the delay had been caused by the unforeseen consecutive scheduling of two major meetings – the current session of the Board and the Conference of the Parties to the WHO Framework Convention on Tobacco Control. Every effort would be made to avoid a recurrence of such circumstances in the future.

Mr MAHMOOD (alternate to Dr Ali Mohammed Salih, Iraq), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that any interventions in the area of the prevention and control of sexually transmitted infections must be culture-sensitive, and urged that Member States from his Region should be represented in all technical consultations on that issue. WHO should also develop tools that were applicable and adaptable to the specific cultural contexts of all countries. WHO support at all stages of adopting the strategy, including advocacy, adaptation, planning, capacity building, implementation and monitoring and evaluation remained crucial, since the area of sexually transmitted infections was underserved in many countries, particularly in the public sector. Countries also required assistance in the form of tools to create and foster partnerships between the public and the private sectors in that regard.

Dr HANSEN-KOENIG (Luxembourg) expressed regret that it would not be possible to discuss the draft global strategy at the current session, as it would certainly have provided useful input to the discussion on HIV/AIDS and the health-related Millennium Development Goals. The proposed procedure should enable the draft strategy to be discussed at the forthcoming Health Assembly.

She regretted, too, the removal from the agenda of a related item on women's health and gender issues, on which a draft strategy should also be elaborated for early discussion by the Board. Women after all accounted for 50% of the world's population and were most vulnerable, and should not be neglected by WHO.

Dr BRUNET (alternate to Professor Houssin, France), endorsing the comment by the previous speaker, said that issues relating to sexually transmitted infections and women's health were too closely related to the Millennium Development Goals and WHO's role in attaining them to be shelved for logistic reasons. Dealing with such issues in an appropriate manner was a matter of priority.

Mrs PHUMAPHI (Assistant Director-General), noting the concerns expressed about the delay in presenting the draft strategies on sexually transmitted infections and gender, agreed that action

against HIV/AIDS and sexually transmitted infections would be strengthened through both strategies. She thanked Member States for their support and for making experts available for the development of the draft strategy on sexually transmitted infections. Special care had been taken in the consultation process to ensure that the approach in the draft strategy was culture-sensitive and adaptable and hence usable by all countries. The draft strategy would be available electronically for final consultations and subsequent revision and submission to the forthcoming Health Assembly.

She assured the members for France and Luxembourg that women's health was taken very seriously. A gender strategy was being developed; the reason why consultations were being prolonged was to ensure that all cultural settings and sensitivities were duly taken into account.

Dr ANTEZANA ARANÍBAR (Bolivia) accepted the explanations, observing that the important point was that the draft strategy that would be submitted to the Health Assembly should reflect the relevant resolutions and the concerns of Member States, including those expressed at the current meeting by the members for France and Luxembourg.

The CHAIRMAN said that he took it that the Board wished to note the report and agreed that the item should be placed on the agenda of the Fifty-ninth World Health Assembly. The Secretariat would organize an electronic consultation with Member States on the draft strategy, which would be issued in electronic form shortly and, in the light of comments received and those made at the current session, would present a revised draft to the forthcoming Health Assembly.

**It was so agreed.**

**Smallpox eradication: destruction of variola virus stocks:** Item 4.7 of the Agenda (Document EB117/33)

Dr SHINOZAKI (Japan) said that, while the threat of bioterrorism remained a pressing issue, the ultimate goal was the total eradication of the variola virus worldwide through the destruction of stocks held in laboratories. He understood that the WHO Advisory Committee on Variola Virus Research and the Secretariat were properly monitoring the fruitful progress of research activity. Reports should be updated regularly and care taken to ensure their impartiality.

Dr OROOJ (alternate to Mr M.N. Khan, Pakistan), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the impressive research results contributed significantly to an understanding of smallpox virus. The broad research agenda covered increasingly complex scientific issues. Research activities were not time-limited and many were of limited public health significance. Their continuation obviously delayed destruction of the remaining stocks of smallpox virus. The research agenda should be confined to essential issues and the Board should set a time limit for completion of the studies so that remaining stocks of smallpox virus could be destroyed.

Dr SHANGULA (Namibia), speaking on behalf of the Member States of the African Region, acknowledged the work of the WHO Advisory Committee on Variola Virus Research and other reported research results. He recalled the concerns expressed at the Fifty-eighth World Health Assembly about the proposed expression of variola virus genes in other orthopoxviruses<sup>1</sup>. He drew attention to the decision taken and concerns raised by health ministers at the fifty-fifth session of the Regional Committee for Africa, including their request that the issue should be a substantive agenda item rather than an item for information at the current Board session. The Regional Committee, noting the temporary retention of the variola virus for research purposes in the Russian Federation and the United States of America, was concerned about security and proposed that the variola virus stocks

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<sup>1</sup> Document WHA58/2005/REC/3, summary record of the seventh meeting, section 4.

should be retained in a secure place within WHO and be entrusted to Member States. The ministers remained opposed to the proposed expression of variola virus genes in other orthopoxviruses on account of the risks of laboratory accidents, deliberate release or bioterrorism and the risks posed by more dangerous forms of the virus that might emerge. The group welcomed the decision of the Advisory Committee to withdraw that recommendation in its entirety. The ministers were likewise concerned about the composition of the Advisory Committee and suggested that it should be reviewed to ensure balanced representation, with the inclusion of experts from developing countries. It also proposed a balanced and broader representation of advisers and observers to the Committee. The fundamental issue was the eventual destruction of the remaining stocks of the variola virus rather than the expansion of research. The condition for temporary retention of the variola virus stocks was that approved research would remain outcome-oriented and time-limited and that its findings would be periodically reviewed. It would appear from the report that most of the essential research requiring the use of live variola virus had been concluded. It was therefore time to consider whether the benefits of destruction of the remaining stocks did not far outweigh those of continued research, and to reach global consensus on the timing of the destruction of existing stocks, setting a new date for their destruction.

The Member States of the African Region therefore proposed that the Director-General should be requested to broaden the representation of the WHO Advisory Committee on Variola Virus Research in keeping with Regulation 3 of the Regulations for Expert Advisory Panels and Committees and relevant Health Assembly resolutions, and to resolve the issue of the representation of advisers and observers to the Committee. They undertook to identify qualifying experts and to inform the Director-General accordingly. They further proposed that an open-ended intergovernmental working group should be established to work on a draft resolution addressing the foregoing issues and any others that might be raised by other Member States. The working group should start its work with immediate effect and present a draft resolution to the Fifty-ninth World Health Assembly.

Mr GUNNARSSON (Iceland) said that, as the member for Japan had pointed out, further study of the variola virus might be required if the need arose for a new vaccine. In the past, laboratories in the Nordic countries would have been able to produce such a vaccine. For that purpose, it would be useful to know whether the research findings would remain in the public domain or would be patented by commercial companies.

Dr BRUNET (alternate to Professor Houssin, France) supported the view expressed by the member for Iceland. Could the Secretariat confirm the present composition of the Advisory Committee, which ought to be taken into account if it was expanded in future? It would be premature to decide to terminate research. He endorsed the objective of eventual total eradication of smallpox, but that would only be achieved when the remaining stocks of variola virus had disappeared completely, even from the laboratories in which it was currently retained. However, the time was not yet ripe to destroy the stocks. In the framework of ongoing research, further testing was needed of diagnostic methods that distinguished between infection with variola virus and other orthopoxviruses. If smallpox were to reappear, the initial diagnosis would have such far-reaching implications that a differential diagnosis would have to be absolutely reliable. Work to improve the primate model of human smallpox should also be continued, to make way for the development of antiviral treatments. The second- and third-generation vaccines also needed to be improved, in order to have available a lower-risk vaccine for immunocompromised people. In many countries there was a significant proportion of such patients, owing to the prevalence of HIV, and they were at significant risk from the existing vaccines.

Dr SUWIT WIBULPOLPRASERT (Thailand) observed that the Health Assembly had agreed retention of the existing stocks of live virus up to, but not later than, 2002. Four years later, no serious attempt was being made to set a date for final destruction. Rather than continually seeking to buy time on the issue, the Board should move forward by supporting the proposal of the member for Namibia

for more balanced representation on the Advisory Committee, and for the establishment of an open-ended working group to set a time-limit for the destruction of the virus.

Mr SHUGART (Canada) said that the retention of the virus in the repositories should be determined by means of a scientific peer review assessment, in the light of the public health benefits, with the ultimate goal of destroying the remaining stocks. The present uncertainty about the value of continuing research mirrored the uncertainty inherent in the science itself. Canada continued to seek clear guidance from WHO and the experts available to it, given the nature of risks, as the report made clear. He agreed with the member for Japan that the report was valuable and that its approach should be followed in future reports. That would help the Board to exercise due vigilance with regard to the public health benefits of further research using the live virus.

Dr NYIKAL (Kenya) concurred that a clear time-limit should be set for destroying the virus, whether in line with a recommendation from the proposed working group or in the light of the research findings themselves. The process of appointing members of the Advisory Committee, which should have a broader membership, should be explained. He agreed with the members for France and Iceland that the Board should seek clear guidance on how the research findings would be owned and used.

Ms HALTON (Australia) said that the issue was difficult because research was, by definition, an imprecise science. In such a new area caution was highly desirable, and it would be premature to set a timetable for destroying the virus as long as fundamental questions remained unanswered. The secure maintenance of the stocks was naturally high among the concerns of members of the Board and mentioned in the report. The two laboratories had a very important responsibility in that regard; they also had to ensure enough transparency in their work to reassure the Board as a whole. The research should therefore be allowed to continue to its natural end-point on the topics mentioned in the report, especially on sequence analysis and the development of diagnostic assays and second- and third-generation vaccines. Work on other areas mentioned in the report, such as the use of animal models and development of potential antiviral drugs, might also be warranted. The report also showed an awareness of the potential dangers of mixing genetic material from highly pathogenic organisms, particularly in respect of other orthopoxviruses. She agreed with the remarks of previous speakers about the need for improved transparency in the appointment of members of the Advisory Committee.

The CHAIRMAN recalled that resolution WHA55.15 had authorized the further retention of the existing stocks of live virus on the understanding that all approved research would remain “outcome-oriented and time-limited” and be periodically reviewed. However, the consequences of the virus being released could be catastrophic. The Board’s decision must be properly balanced.

Dr TANGI (Tonga) pointed out that the Health Assembly delegates who had adopted resolution WHA52.10 had already been replaced by a new generation, who in turn were being advised by scientists in laboratories. There was no obvious end to the process. It was in the nature of scientific work on any topic that those engaged in it preferred to continue, and, in so doing, raised fresh questions to which they then sought answers. A new generation of scientists would invariably produce new research proposals. The Board’s members, as the policy-makers, should set for the present generation of scientists a definite time-limit, perhaps eight years, in which to pursue their research.

Mrs MTSHALI (South Africa)<sup>1</sup> recalled that it was almost 26 years since the global eradication of smallpox had been agreed upon in resolution WHA33.3. Subsequent Health Assembly resolutions on the subject of the variola virus stocks had agreed to their temporary retention for approved

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

research, with a view to their eventual destruction. The excellent results in terms of the efficacy of second- and third-generation vaccines, especially the evidence that suggested fewer adverse effects in children and immunocompromised people, were encouraging, and she was pleased to note that the Advisory Committee did not see any need, on scientific or regulatory grounds, to use live variola virus in order to assess smallpox vaccines; she was also pleased to note the conclusion that no further research requiring access to live virus was considered essential for the purpose of sequence analysis of variola virus DNA. The Committee had found no scientific justification for performing further research on the hybrid viruses in the United States collection, nor was it believed that any additional research using live variola virus was required for the purpose of diagnostic assays. Owing to the requirements for regulatory approval of antiviral agents in the United States of America, further work might require the use of live variola virus. Such work should therefore be expedited to eliminate the use of live virus. She supported the Committee's recommendation for an urgent review of all current research proposals, in order to indicate the essential research that still required the use of live variola virus, and thus the timing for the destruction of the stocks. In the light of resolution WHA55.15 and the reported research accomplishments, she encouraged the Board to support the proposal to establish an open-ended intergovernmental working group to draft a resolution on those issues. She requested the Director-General to put additional measures in place to strengthen the biosafety of the storage and research facilities.

Dr STEIGER (United States of America)<sup>1</sup> said that, as policy-making organs, the Health Assembly and the Executive Board had made a correct decision in establishing an Advisory Committee to define a research agenda and review the research periodically, while retaining stocks of the live virus in the two authorized repositories. It was not the right time to change that decision. He welcomed the report's conclusions on antiviral drugs, second- and third-generation vaccines, genomic sequencing of the virus strains and the development of new diagnostic tools, and agreed with the members for Australia and France that it would be premature either to decide on destroying the stocks or to set an arbitrary date or timetable for completing the programmes of scientific research, which should be allowed to continue to their natural conclusion. There was a need for greater transparency, a matter in which his country and others had been at fault. However, they had nothing to hide, and the scientists involved would be available in the coming months for briefings, which would be arranged in consultation with the Member States of the African Region. With regard to biosafety, in late 2005 both the United States of America and the Russian Federation had called for additional inspections, and were working in full cooperation with WHO to ensure that the repositories remained absolutely safe. His country was also eager to address the issue of representation on the Advisory Committee, and had already worked with the Secretariat to find additional experts from Africa and other parts of the world. His country had also been assisting other countries to develop their capacity for manufacturing their own vaccines, and was prepared to continue that work.

Mr CHESTNOV (Russian Federation),<sup>1</sup> observing that smallpox remained a potential threat to the entire world community, said that his country would continue its cooperation on the subject with all interested partners. The research centres in his country and in the United States of America were conducting research into smallpox under the aegis of WHO: each year, the Advisory Committee reviewed the research undertaken and made adjustments where necessary. In order to achieve all the objectives set, work should continue on developing a more effective and safer smallpox vaccine, and on improving diagnostic methods. Effective antiviral drugs should also be produced, animal models developed, and the virus genome and pathogenesis studied further. The Russian Federation understood the concerns expressed, including those of the African Member States, about the need for greater transparency. It would welcome better representation of countries on the Advisory Committee, and the provision of more information about the research undertaken, as a confidence-building measure.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

WHO should provide a comprehensive report on the results of its inspections of the repositories, in order to reassure the international community that all the steps necessary for the safe retention of the virus were being taken. The Russian Federation looked forward to receiving the support of the international community, including the African countries, to continue working with the live virus in the interests of mankind as a whole.

Dr CHAN (Assistant Director-General), acknowledging the long history of the debate on the destruction of the virus, said that, while destruction had always been recognized as the end point, the decision to embark upon that action must be taken with great care.

In reply to the question by the member for France regarding the composition of the Advisory Committee, she explained that the Secretariat was doing its utmost to ensure geographical and gender representation and balance. The subject was highly technical, but the criteria for the selection of experts were transparent: experts needed to have relevant laboratory and public health expertise in the field of orthopox infections, including field and laboratory experience of smallpox before eradication, and relevant expertise in the field of orthopoxvirus research was also important; expertise in the fields of biosafety and biosecurity, and field experience relevant to communicable diseases prevention, emergence, intervention and control, were also required. The Advisory Committee and its subcommittees were WHO committees, and, in their deliberations, took into account the relevance of the live virus from the public health perspective in order to ascertain the public health benefits of the recommended research. The Advisory Committee consisted of 19 members, of whom three were from the African Region, three from the Region of the Americas, one from the Eastern Mediterranean Region, seven from the European Region, two from the South-East Asia Region, and three from the Western Pacific Region. WHO also sought to maintain a geographical balance among the 35 advisers; currently one expert was from the African Region, 14 were from the Region of the Americas, 17 from the European Region, one from the South-East Asia Region and two from the Western Pacific Region, but none from the Eastern Mediterranean Region. There was also one observer from the Region of the Americas. Geographical representation had improved in recent years. WHO would continue to do its utmost to work with the regions to find experts with the relevant expertise and improve representation further. She thanked South Africa for its assistance in that regard.

With regard to the issue of biosafety, WHO had recently conducted an additional inspection of the facilities and was satisfied that the biosafety and biosecurity measures at the two repositories were consistent with international best practices.

The Secretariat would be guided by the Board regarding the suggestion by the member for Namibia concerning the establishment of an open-ended intergovernmental working group. As indicated in paragraph 17 of the report, much progress had been made in recent years, but there was still much work to be done. The Committee had perceived an urgent need to review all proposals for further research, and the deadline for submission of research proposals had been set for the end of January 2006. The review process had already started, and proposals would be examined to ensure that they remained in line with the relevant Health Assembly resolutions.

Dr ANTEZANA ARANÍBAR (Bolivia), supported by Dr ALI MOHAMMED SALIH (Iraq), expressed concern that the criteria for the selection of experts were likely to exclude scientists from the poor and least developed countries. Consideration might therefore be given to appointing experts from such countries to the Advisory Committee and its subcommittees to enable them to improve their knowledge and expertise.

Dr CHAN (Assistant Director-General), in response to a request for further clarification from Mrs MTSHALI (South Africa),<sup>1</sup> said that WHO did not have a P4 laboratory to allow it to be the custodian of live virus stocks. She would need to consult colleagues before replying to the question on the patent issue.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

Dr NYIKAL (Kenya) pointed out that research on the variola virus differed from other research, in that it was of interest to every country. When the issue of patents was considered, it should not be forgotten that the whole world had a stake in the research.

Dr SHANGULA (Namibia) asked whether the authority over the viruses was held by the States in which those viruses were located or whether WHO had any authority over the stocks.

Mr BURCI (Legal Counsel), replied that the situation was not clear-cut. Following the eradication of smallpox it had been decided that countries holding the live virus would give their stocks to a limited number of laboratories that had secure locations. The documentation available to WHO setting out the terms under which countries had given their stocks either to the laboratory in the United States of America or that in the Russian Federation was not complete. In cases where countries had given stocks “in trust” for WHO, the Organization would, arguably, have some measure of control and authority over those viruses; in other cases, terms had not been specified, and it was not clear whether those countries wished to retain legal title. At the present juncture, therefore, he was unable to give a definitive answer but would endeavour to provide a more substantive response at a later meeting if the Board so wished.

Dr CHAN (Assistant Director-General) said that, in her previous intervention, she had been responding to the suggestion that the two repositories should be housed in a WHO laboratory. WHO itself did not have a P4 laboratory; however, the two laboratories holding the repositories met the very high requirements for biosafety and biosecurity.

Dr SUWIT WIBULPOLPRASERT (Thailand) said that the question put by the member for Namibia raised another question concerning submission of viruses by Member States of WHO, including severe acute respiratory syndrome and avian influenza virus. At least three conditions should obtain in such situations: first, WHO would ensure that the viruses were kept securely out of the reach of bioterrorists; secondly, the viruses would be used for appropriate research to benefit humankind; and thirdly, if the viruses were used to produce vaccines, the countries that had submitted them and developing countries that lacked the capacity to produce them would be given access.

There seemed to be no problem with the first condition, even though it appeared that WHO had no practical control, but only a moral influence, over the laboratories that were storing the viruses. As to the second and third conditions, clarification was needed as to whether viruses submitted to WHO would be used for research to benefit all countries. Would countries that needed the vaccines produced receive them? The Secretariat should provide clear information on mechanisms to ensure that the second and third conditions would be met.

Mr LEÓN GONZÁLEZ (Cuba)<sup>1</sup> said that he was surprised by the Assistant Director-General’s comment regarding WHO’s lack of control over stocks of virus that were retained in two locations. It raised a further question as to the extent of such control and what WHO was able to do to ensure that the products of research were really used to benefit all. Since the Legal Counsel was going to provide further information on that subject, perhaps he could also explain what means could be used to enhance the Organization’s control over the viruses, including possible action by the Health Assembly.

Dr STEIGER (United States of America)<sup>1</sup> recalled that, at the initiative of the Health Assembly and the Board, WHO had created a smallpox vaccine reserve, which as a result of work done on the virus had created a stock of vaccine specifically for the use of developing countries in an emergency.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

His Government, the Government of Canada and many others had made additional contributions, whether physically or through a virtual commitment, of vaccine stocks out of their national stockpiles in order to augment the physical reserve held in Geneva.

Dr CHAN (Assistant Director-General), responding to the question by the member for Thailand, said that influenza virus isolates had been submitted to four WHO collaborating centres which had high standards of biosafety and biosecurity. Every year, those laboratories helped to develop the prototype vaccine for influenza, which was distributed to manufacturers free of charge through WHO. As to developing countries, discussions were currently under way on providing Viet Nam with prototype vaccine from WHO collaborating centres on the understanding that they could produce the vaccine safely at recognized facilities. As to research, where viruses were required for developing diagnostics, WHO would try to make them available. It must be emphasized, however, that the quantity of viruses submitted to WHO was small, and the demand was high.

Further to the comments by the representative of the United States, she said that about five million doses were currently stockpiled in Geneva. Progress had already been made towards meeting the virtual commitment to a smallpox vaccine reserve of 200 million doses: France had already pledged five million doses, Germany two million, the United Kingdom of Great Britain and Northern Ireland four million and the United States of America 20 million. The stocks would be available for use by developing countries.

The DIRECTOR-GENERAL said that much, unfortunately, was left unsaid about vaccines and virus stocks. The virus strains in repositories in the Russian Federation and the United States of America were the only ones in known locations. The fact that some countries had stockpiled the vaccine and that WHO had millions of doses of it did not reflect fears about the natural re-emergence of smallpox but rather was an indication of the current times — one could not gamble.

Dr NYIKAL (Kenya) said that the news that vaccine was being stockpiled was a matter for concern. While it was reassuring to hear that some of the vaccine was intended for developing countries, the question arose to what extent those countries would be involved in the process.

The DIRECTOR-GENERAL said that both the WHO and the international vaccine stockpiles were intended to be deployed rapidly to developing countries in the event of need.

Mrs MTSHALI (South Africa)<sup>1</sup> said that there was some concern that stocks of the virus might exist outside the Russian Federation and the United States of America and that some live virus might be retained in other countries for purposes other than research. That concern should be clearly dealt with.

The CHAIRMAN said that it would be helpful if a list of the experts who were members of the WHO Advisory Committee on Variola Virus Research could be circulated to Board members. Even poor countries had enough expertise to participate in the Committee's work.

Mr AITKEN (Director, Office of the Director-General) suggested that the best course of action might be for the Secretariat to prepare a draft resolution. In advance of the Health Assembly, a working group open to all members and with interpretation in all six official languages would be convened in Geneva to examine the draft and make any necessary adjustments. The Director-General would submit the resulting text to the Health Assembly for its consideration.

**It was so agreed.**

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.



**The Board noted the report.**

**Sickle-cell anaemia:** Item 4.8 of the Agenda (Document EB117/34)

The CHAIRMAN drew attention to the draft resolution entitled Sickle-cell anaemia proposed by Angola, Belgium, Burkina Faso, Congo, Côte d'Ivoire, France, Guinea-Bissau, Kenya, Lesotho, Madagascar, Namibia, Rwanda, Senegal, South Africa and Sudan which read:

The Executive Board,  
Having examined the report on sickle-cell anaemia;<sup>1</sup>

RECOMMENDS to the Fifty-ninth World Health Assembly the adoption of the following resolution:

The Fifty-ninth World Health Assembly,  
Recalling resolution WHA57.13 on genomics and world health, and the discussion of the Executive Board at its 116th session on control of genetic diseases which recognized the role of genetic services in improving health globally and in reducing the global health divide;<sup>2</sup>

Recalling decision Assembly/AU/Dec.81 (V) of the Assembly of the African Union at its Fifth Ordinary Session;

Noting the conclusions of the 4th International African American Symposium on sickle-cell anaemia (Accra, 26-28 July 2000), and the results of the first and second international congresses of the International Organization to Combat Sickle-Cell Anaemia (respectively, Paris, 25-26 January 2002 and Cotonou, 20-23 January 2003);

Concerned at the impact of genetic diseases, and of sickle-cell anaemia in particular, on global mortality and morbidity, especially in developing countries, and by the suffering of patients and families affected by the disease;

Recognizing that the prevalence of sickle-cell anaemia varies between communities, and that insufficiency of relevant epidemiological data may present a challenge to effective and equitable management;

Deeply concerned at the absence of official recognition of sickle-cell anaemia as a priority in public health;

Recognizing the current inequality of access to safe and appropriate genetic services throughout the world;

Recognizing that effective programmes for sickle-cell anaemia must be sensitive to cultural practices, and appropriate for the given social context;

Recognizing that the management of sickle-cell anaemia raises specific ethical, legal and social issues that require appropriate consideration,

1. URGES Member States:

- (1) to develop, implement and reinforce in a systematic, equitable and effective manner national, integrated programmes for the management of sickle-cell anaemia, including dissemination of information, awareness-raising, and screening, such programmes being tailored to specific socioeconomic and cultural contexts and aimed at reducing the incidence, morbidity and mortality associated with this genetic disease;

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<sup>1</sup> Document EB117/34.

<sup>2</sup> See document EB116/2005/REC/1, summary record of the first meeting, section 4.

- (2) to develop their capacity to evaluate the situation regarding sickle-cell anaemia and the impact of national programmes;
  - (3) to intensify the training of specialist health professionals in high-prevalence areas;
  - (4) to develop and strengthen medical genetics services, within existing primary health care systems, in partnership with parent/patient organizations;
  - (5) to promote community education, including health counselling, and associated ethical, legal and social issues;
  - (6) to establish effective international cooperation in combating sickle-cell anaemia;
  - (7) in collaboration with international organizations, to support basic and applied research on sickle-cell anaemia;
2. REQUESTS the Director-General:
- (1) to increase awareness of the international community of the global burden of sickle-cell anaemia, including by launching a world sickle-cell anaemia day, and to promote equitable access to health services for prevention and management of the disease;
  - (2) to provide technical support and advice to national programmes of Member States through the framing of policies and strategies for prevention and management of sickle-cell anaemia;
  - (3) to support intercountry collaboration in order to expand the training and expertise of personnel and to support the further transfer of advanced technologies and expertise to developing countries;
  - (4) to continue WHO's normative functions in drafting guidelines on prevention and management of sickle-cell anaemia and fostering the establishment of regional groups of experts.

Dr WINT (Jamaica) said that it should be made clear whether the subject was sickle-cell anaemia, sickle-cell disease or sickle-cell disorders, since sickle-cell anaemia was only one piece of the picture. In his country, the prevalence of sickle-cell disease was about 10%, and it led to severe morbidity, reduced quality of life and premature mortality. There was a need for more comprehensive programmes for prevention and control, encompassing early diagnosis, registration and follow-up of the individuals affected and the training of providers at both primary and secondary health-care levels to improve recognition and the care given. The recommendation on increased research activity was noteworthy, as was the progress reported in treatment, including bone marrow transplantation, which was seen as a potential cure, although in countries such as his own it remained only a dream.

He supported the draft resolution, but proposed the following amendments. In paragraph 1(1), the word "comprehensive" should be inserted before "national"; the words "prevention and" should be inserted before "management"; and "surveillance," should be inserted before "dissemination of information". In paragraph 1(3), the word "specialist" should be replaced by "all". Paragraph 1(6) was addressed more to the Director-General than to Member States; accordingly, it might be better to strengthen paragraph 2(3) by inserting the words "promote and" before "support intercountry collaboration". A new paragraph 2(5) should be added, to read: "to promote, support and coordinate the needed research on sickle-cell disorders in order to improve the duration and the quality of life of those affected by those disorders".

Dr RAHANTANIRINA (alternate to Dr Jean Louis, Madagascar), speaking on behalf of the Member States of the African Region, said that sickle-cell anaemia, one of the most common genetic diseases in the world, spared no country, and, owing to population movements and intermarriage, its prevalence was increasing. Moreover, the highest birth rate of homozygotes was found in the most impoverished countries, 230 000 to 240 000 children being born annually in Africa with sickle-cell

anaemia. In sub-Saharan Africa, the rate of healthy carriers (heterozygotes) was between 10% and 30% of the population in some countries. Paradoxically, optimal treatment was available only in countries where the disease was least common, once again demonstrating the North-South health disparity.

The expansion of referral centres had revealed that, with healthy living habits and ready access to care, many adult sufferers could be fully integrated into society and lead a normal family and professional life. In many developing countries, mortality rates for children and pregnant women remained high, and proper treatment was hampered by economic problems, and lack of information and training for health care providers, political decision-makers and the general population.

The First Ladies of the Central African Republic, Chad, Congo, Mali and Senegal had endeavoured through appeals and conferences to raise awareness about the disease. Those countries had launched an appeal at the Fifty-eighth World Health Assembly for the international community to intensify the fight against sickle-cell anaemia. The Member States of the African Region had accordingly requested the Director-General to include the current item on the Board's 117th session, with a view to consideration of the draft resolution by the Fifty-ninth World Health Assembly.

Referring to paragraph 2(1) of the draft resolution, she said that the launching of a world sickle-cell anaemia day might entail heavy expenditure. Accordingly, the Member States of the African Region suggested that the reference thereto should be replaced by a reference to the early inclusion of "Strengthening the fight against sickle-cell anaemia" as a topic for World Health Day. In paragraph 2(4), the words "with a view to elaborating regional plans" should be inserted after "sickle-cell anaemia".

Professor PEREIRA MIGUEL (Portugal) observed that the model national control programme developed in high-resource countries was clearly not appropriate for most low-resource settings, but that sickle-cell disorders should be covered by health service planning in all countries where they were common. Interventions undertaken in countries in the Mediterranean area with a high prevalence of haemoglobinopathies had demonstrated that prevention of acute forms was possible through the detection of individuals carrying the relevant genetic mutations and prenatal diagnosis.

Prevalence in Portugal was around 1% and a national control programme, established in 1984, covered genetic counselling to couples at risk, prenatal diagnosis, prevention, training of health professionals, dissemination of up-to-date information, research, and cooperation with patient-support organizations. Given its considerable experience, Portugal was willing to cooperate in the preparation of a global prevention and control strategy and to provide training for laboratory, clinical and primary health-care professionals from developing countries. Portugal therefore wished to be included as a sponsor of the draft resolution.

Dr SUWIT WIBULPOLPRASERT (Thailand) said that haemoglobinopathies were widespread, with sickle-cell anaemia in African and Mediterranean countries and thalassaemias in Asian countries. Thailand had intended to suggest that an agenda item on thalassaemia should be included on the agenda for the next sessions of the Board and Health Assembly. The technologies to prevent and treat such genetically inherited diseases were generally similar, however. He therefore proposed that all types of haemoglobinopathies should be considered under a single agenda item, entitled "Haemoglobinopathies: sickle-cell anaemia and thalassaemia", in order to reflect the global nature of the public health problems concerned and to avoid duplication of effort. He endorsed the proposal to select haemoglobinopathies as the theme for a future World Health Day and supported the draft resolution.

Dr KHALFAN (Bahrain), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that greater attention should be paid to blood disorders. In order to prevent sickle-cell anaemia, it was important to encourage the implementation, where facilities were available, of mandatory premarital genetic screening in high-risk communities; pre-pregnancy genetic screening in cases where premarital screening had not been undertaken; and pre-implantation genetic diagnosis

in cases of in vitro fertilization. Bahrain and Saudi Arabia had achieved good results with such measures.

WHO had a pivotal role to play in promoting services development, research and training for countries in greatest need. Activities should include the development of global and regional guidelines on the prevention and treatment of blood disorders, the promotion of collaboration among relevant institutions, with the establishment of networks and centres of excellence, and the provision of technical support to Member States. WHO should also promote the development of a quality control programme for biochemical, cytogenetic, haematological and molecular tests.

Speaking as the member for Bahrain, which had a high prevalence of sickle-cell anaemia, he said that his country wished to be included as a sponsor of the draft resolution.

Dr BRUNET (alternate to Professor Houssin, France), speaking on behalf of the Member States of the European Union, expressed support for the draft resolution. Speaking as the member for France, he stressed that the amendments proposed by the member for Madagascar would reduce the financial implications of the resolution for WHO.

Dr SINGAY (Bhutan) endorsed the view that prevention and control of sickle-cell anaemia, which was prevalent in some Member States in the South-East Asia Region, should form part of general health services and programmes to combat all types of genetic blood disorders. WHO's efforts to update and disseminate information should encompass all such disorders. He supported the draft resolution.

Dr SHINOZAKI (Japan) welcomed the recognition by WHO of the significance of sickle-cell anaemia as a public health issue for many countries, especially in Africa. The Secretariat, other international organizations and donor countries should tackle a disease that had received little attention to date, partly because of its geographical distribution. He supported the draft resolution and endorsed the remarks made by the member for Thailand.

Dr ACHARYA (Nepal) said that sickle-cell anaemia had not been detected in Nepal. He supported the draft resolution and emphasized the need for preventive measures, including health education, genetic counselling, marriage counselling and prenatal diagnosis as well as collaborative research and capacity-building. He endorsed the views expressed by the members for Thailand and Bhutan regarding the need to combine efforts on all types of genetic blood disorders.

Ms VALDEZ (United States of America)<sup>1</sup> asked how the Secretariat intended to respond to the significant financial implications of implementing the draft resolution in the current biennium and over the lifespan of the resolution, given that there was no allocation to the area in the current programme budget.

Dr LE GALÈS-CAMUS (Assistant Director-General) agreed that there were clearly similarities among the measures needed to tackle the various haemoglobinopathies and that efficiencies would be gained by combining efforts, rather than concentrating on each form, as in the draft resolution before the Board. However, given the regional characteristics of the distribution of the diseases, and the diversity of the populations affected, strategies must be tailored to regional and national situations. The inclusion of all haemoglobinopathies would clearly have an impact on the financial implications of the draft resolution, in particular for the current biennium and in terms of support to the regional offices concerned, as well as on the speed and intensity with which activities could be introduced. She expressed appreciation for the offer of support from Portugal.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

Mr AITKEN (Director, Office of the Director-General) re-read the proposed amendments. Paragraph 1(1) would read: “to develop, implement and reinforce in a systematic, equitable and effective manner comprehensive national, integrated programmes for the prevention and management of sickle-cell anaemia, including surveillance, dissemination of information, ...”. In paragraph 1(3), the word “specialist” would be replaced by “all”.

He took it that the member for Jamaica would accept the rephrasing of paragraph 1(6) to read: “to promote effective international cooperation in combating sickle-cell anaemia;”.

The second phrase in paragraph 2(1) would read: “... including as part of a World Health Day, ...”. The beginning of paragraph 2(3) would read: “to promote and support intercountry collaboration ...”. Paragraph 2(4) would read: “to continue WHO’s normative functions in drafting guidelines on prevention and management of sickle-cell anaemia with a view to elaborating regional plans and fostering the establishment of regional groups of experts” and a new paragraph 2(5) would read: “to promote, support and coordinate the needed research on sickle-cell disorders in order to improve the duration and quality of life of those affected by those disorders”.

Dr SUWIT WIBULPOLPRASERT (Thailand) asked whether there was to be any decision regarding his proposal for the inclusion of all haemoglobinopathies under one agenda item. If that was not possible, he would propose that a new item on thalassaemia should be included on the agenda for the Board’s next session.

Dr LE GALÈS-CAMUS (Assistant Director-General) said that, if the scope of the draft resolution were to be expanded, it would be necessary to define precisely the range of diseases covered.

**The resolution, as amended, was adopted.<sup>1</sup>**

**Prevention of avoidable blindness and visual impairment:** Item 4.9 of the Agenda (Documents EB117/35 and EB117/35 Add.1)

The CHAIRMAN drew attention to the draft resolution set forth in paragraph 12 of the report.

Mr AITKEN (Director, Office of the Director-General) observed that the text of the draft resolution did not include the request contained in the resolution adopted by the Regional Committee for the Eastern Mediterranean at its fifty-second session in September 2005, namely, that the Director-General should make the item a priority area of work. That was a matter for the Health Assembly to decide when it considered the budget. He suggested that, to convey the essence of that request, the words “to give priority to this issue and” should be inserted after “REQUESTS the Director-General”, in paragraph 2 of the draft resolution.

Dr WINT (Jamaica) said that trauma was a significant cause of avoidable blindness in his subregion, particularly among young people, and should be mentioned in the draft resolution. In the fifth preambular paragraph, the word “families,” should be inserted before “communities”. With regard to paragraph 2, he supported the amendment suggested by the Secretariat, but questioned the need for the words “on request or as appropriate”. He proposed adding a new subparagraph to paragraph 2, to read: “(2) to monitor progress in the Global Initiative for the Elimination of Avoidable Blindness in collaboration with international partners and to report to the Health Assembly every three years”.

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<sup>1</sup> Resolution EB117.R3.

Mr GUNNARSSON (Iceland), expressing support for the draft resolution, said that blindness was an important issue, particularly since nine out of 10 blind persons lived in low-income countries. All members of the Nordic group of countries endorsed the amendment suggested by the Secretariat and hoped that the Health Assembly would soon make preventable blindness and visual impairment a priority area of work. It was his understanding that private funds were available for technical assistance in that area.

Professor PEREIRA MIGUEL (Portugal) expressed support for the draft resolution, if amended to take into account the proposal of the Regional Committee for the Eastern Mediterranean. However, the actions requested of Member States should be limited to those set out in subparagraphs (1) and (2) of paragraph 1. Moreover, paragraph 1(2) should be amended to read “to provide support for these plans in the context of a comprehensive national health strategy in each country”. Portugal had extensive experience in programme and health strategy development in the area of preventable blindness and offered to share that experience with WHO.

Dr SOPIDA CHAVANICHKUL (adviser to Dr Suwit Wibulpolprasert, Thailand) supported the draft resolution as amended by Jamaica. She proposed that, in paragraph 2, the words “, as well as support for collaboration among Member States,” should be inserted after “Member States”.

Mrs LE THI THU HA (Viet Nam) said that, as a signatory to Vision 2020: The Right to Sight, her country supported the draft resolution as amended by Jamaica and Thailand and with the addition suggested by the Secretariat.

Dr ANTEZANA ARANÍBAR (Bolivia) commended the clarity and concision of the report and welcomed the inclusion in the draft resolution of a reference to the Vision 2020 initiative, which had created such high expectations at its launch. The goals and objectives of Vision 2020 were easily attainable, given the wide availability and the low cost of treatment of avoidable blindness and visual impairment. Member States needed to commit themselves to international cooperation and providing support for prevention programmes, as Portugal had done. His own country had received valuable support from Spain. He therefore fully supported the draft resolution with the addition suggested by the Secretariat and endorsed the remark by the member for Jamaica regarding the need to mention trauma as a cause of avoidable blindness.

Dr SINGAY (Bhutan) said that his country commended the three pillars of the Vision 2020 initiative, namely, reducing the burden of blindness; developing human resources and infrastructure; and advocacy, programme development and management. Bhutan fully supported the draft resolution as amended by the members for Jamaica and Thailand.

Dr KHALFAN (Bahrain), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that it had been estimated that more than 22 million people in his Region were visually impaired and six million were blind, cataract being the main cause of those conditions. Cost-effective solutions were available, but the countries most affected needed technical and financial support from the international community and WHO. Moreover, Member States needed to establish national prevention programmes and national Vision 2020 plans and prioritize the strengthening of primary and secondary eye-care services. A renewed global initiative was needed which would mobilize governments, communities and individuals and involve the private sector. The Member States of the Region therefore supported the draft resolution, and proposed that paragraph 2 should be amended so as to include a further request, to read: “REQUESTS the Director-General to take the necessary action to submit the prevention of blindness to the Fifty-ninth World Health Assembly”.

Ms GILDERS (alternate to Mr Shugart, Canada) welcomed the report and concurred with the proposed actions to respond to identified priorities for the prevention of avoidable blindness and visual

impairment. Through the Canadian International Development Agency, her country supported a number of blindness prevention and treatment programmes in developing countries. Canada endorsed the draft resolution and amendments and urged the Director-General to provide Member States with the necessary technical support for the prevention of avoidable blindness and visual impairment. Canada also appreciated the costing estimates.

Mr AZIZ (alternate to Dr Ali Mohammed Salih, Iraq) said that only 32% of the targeted countries had drafted a national Vision 2020 plan by August 2005. Recent figures suggested a decrease in global blindness, probably due to the initiative and its focus on the treatment of ocular infections. The impact of the initiative would be even greater if the remaining two thirds of targeted countries became involved. However, the chronic, noncommunicable diseases affecting eyesight such as cataract, glaucoma and diabetic retinopathy also needed to be tackled. Each country needed to identify the priorities that would enable it to reduce blindness and visual impairment and to mobilize human and financial resources to implement Vision 2020. Countries must show the necessary political will to ensure the success of the initiative.

Dr SHINOZAKI (Japan) commended WHO's leading role in avoidable blindness prevention. Blindness reduced the quality of life and had a significant economic impact on individuals and societies. His country supported the work of Vision 2020, such as increased commitment and the strengthening of human resources and technologies, and would support targeted countries by providing technical assistance in setting up national Vision 2020 plans. He endorsed the draft resolution with the amendments proposed.

Dr PHOOKO (Lesotho), expressing support for the draft resolution as amended, stressed that blindness and visual impairment were widespread on the African continent and that interventions had become costly because of limited facilities and infrastructure.

Dr ABDULLA (alternate to Dr Botros Shokai, Sudan) endorsed the request by the member for Bahrain that WHO should make the prevention of avoidable blindness and visual impairment a priority area of work. A joint study by WHO and the World Bank had suggested that interventions against blinding diseases, in terms of disability-adjusted life years gained, were as cost-effective as immunization, and had shown that the global productivity loss due to blindness was almost US\$ 28 000 million. The leading causes of avoidable blindness and visual impairment could be tackled by simple and cheap interventions that could enable blind people to resume economically active lives, thus reducing the substantial economic impact of blindness. Of the 37 million blind people worldwide, 17 million could be cured by a 15-minute operation with a 98% success rate, costing US\$ 50. It could be seen from document EB117/35 Add.1 that the total estimated costs of implementing the resolution were modest.

Dr TANGI (Tonga) welcomed the report and endorsed the request that WHO should make the prevention of avoidable blindness and visual impairment a priority area of work. Tonga was a signatory of the Vision 2020 initiative. He expressed his country's gratitude to Australia, Israel, New Zealand, the United States of America and the European Union for the voluntary work being carried out in Tonga by their specialists, and for the resources they supplied. To witness the gratitude of a person whose sight had been restored through cataract operations was truly a rewarding experience.

**The meeting rose at 12:50.**