

NINTH MEETING

Thursday, 21 January 2010, at 18:15

Chairman: Dr E. SEDYANINGSIH (Indonesia)

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

Tuberculosis control: Item 4.11 of the Agenda (Document EB126/14)

- **Progress and long-term planning**
- **Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis**

Mr PRASAD (adviser to Ms Sujatha Rao, India) said that an estimated 131 000 cases of multidrug-resistant tuberculosis had emerged in his country in 2007 alone. India accounted for almost one fifth of the annual global incidence of tuberculosis: the need to expand diagnostic and treatment services under the DOTS Plus strategy was urgent. His Government aimed to introduce treatment for patients who were still sputum-positive after supervised re-treatment (category IV patients) across the country by 2010, and provide access to laboratories for quality-assured diagnosis of multidrug-resistant pulmonary tuberculosis by 2012. By that time, the country should have the capacity to diagnose and treat 32 000 cases of multidrug-resistant tuberculosis per year.

The Revised National Tuberculosis Programme was consistently meeting the international targets for global tuberculosis control and cooperated with the national HIV programme in areas with high rates of coinfection. The Government was revising upwards the targets for case detection and treatment success; it aimed for universal access to prevention, diagnostic and treatment services. It was in contact with health-care providers in the private and corporate sectors as well as nongovernmental organizations, faith-based organizations and the Indian Medical Association through public-private mixed schemes and other mechanisms. It was promoting the rational use of first-line and second-line tuberculosis medicines, and had imposed severe penalties for the sale of such medicines without a valid prescription. Pharmaceutical manufacturers were encouraged to participate in quality assurance through the Green Light Committee. The national programme procured tuberculosis medicines from suppliers holding the WHO certification for good manufacturing practices. The pre-dispatch testing of medicines was mandatory, and independent laboratories had been recruited for post-dispatch testing. He called upon WHO to strengthen the prequalification mechanism.

The Government planned to expand capacity by creating 43 laboratories accredited for the diagnosis and monitoring of multidrug-resistant tuberculosis, and equipped with advanced technologies. Laboratories currently using culture systems and undertaking drug susceptibility testing, in both the public and the private sectors, would be accredited in order to increase capacity.

Dr BIRINTANYA (Burundi), speaking on behalf of the Member States of the African Region, said that the HIV/AIDS pandemic had exacerbated the epidemic of tuberculosis, already a serious public health problem in the Region. The Region had been notified of 9000 cases of multidrug-resistant tuberculosis from more than 30 countries between 2007 and 2008; and seven countries had already notified cases of extensively drug-resistant tuberculosis. The cure rate of only 75% could be attributed to shortcomings in the implementation of the DOTS strategy, with many patients failing to complete treatment or being lost to follow-up.

The Region lacked diagnostic capacity: 36 countries could diagnose drug-resistant tuberculosis, but only two had the facilities for diagnosis of extensively drug-resistant tuberculosis and 12 countries had no facilities for diagnosing multidrug-resistant tuberculosis. There were shortages of second-line medicines in some countries. The Regional Office had set up a surveillance system to monitor drug resistance; organized regional and national courses on multidrug-resistant tuberculosis; and provided support for some laboratories. Rapid surveys of multidrug-resistant and extensively drug-resistant tuberculosis had been conducted, and 10 countries had obtained second-line medicines at reduced prices. At its last session, the Regional Committee for Africa, in resolution AFR/RC59/R2, called upon Member States to strengthen their public health laboratories and adopt measures against infectious diseases, especially multidrug-resistant and extensively drug-resistant tuberculosis.

Developing countries, especially in Africa, needed more technical and financial support to combat tuberculosis and coinfection with HIV, whose increased incidence had been recorded. They needed to strengthen their technical and human capacity for the diagnosis of multidrug-resistant and extensively drug-resistant tuberculosis. Second-line medicines should be supplied free of charge. Follow-up activities and drug-resistance monitoring should be incorporated in national programmes, and awareness-raising activities should be conducted in communities.

Dr ABDI (Somalia) said that the Beijing Call for Action on Tuberculosis Control and Patient Care and the Health Assembly, in resolution WHA62.15, demanded urgent action. Only eight countries in the Eastern Mediterranean Region had conducted drug-resistance surveys. According to WHO's fourth global report on drug resistance,¹ the prevalence of multidrug resistance in the Region was 2% in new tuberculosis cases and 35.3% in re-treated cases. There were an estimated 25 475 multidrug-resistant cases in the Region every year.

At its fifty-sixth session in October 2009, the Regional Committee for the Eastern Mediterranean, in resolution EM/RC56/R.10, called for the implementation of national strategic plans for the management and care of multidrug-resistant and extensively drug-resistant tuberculosis; mandatory notification of such cases under the International Health Regulations (2005); the sale of tuberculosis medicines by accredited public and private providers only; and the strengthening of national drug regulatory authorities to ensure that national pharmaceutical manufacturers produced tuberculosis medicines of assured quality. A five-year regional strategic plan was currently being devised to provide universal access to diagnosis and treatment for multidrug-resistant and extensively drug-resistant tuberculosis by 2015.

Mrs BUGROVA (adviser to Dr Starodubov, Russian Federation) observed that the collective response was beginning to yield results. Indicators of global tuberculosis incidence were beginning to fall, and the global cure rate of 87% exceeded the target figure.

As the report indicated, most of the funding for tuberculosis programmes in the European Region went to the Russian Federation. The Government had strengthened the State's tuberculosis monitoring system: almost all laboratories throughout the country had modern equipment and facilities for rapid diagnosis. Testing of smear-positive cases for drug resistance had reached a coverage rate of 82%, and an average reduction of 4% in the prevalence of multidrug-resistant tuberculosis had been achieved in pilot areas of the country. Russian experts, in collaboration with WHO, had developed a reliable and effective mechanism for the implementation of antituberculosis measures. The Government had succeeded in monitoring the tuberculosis situation effectively, and was willing to share its experience with others.

Her Government was increasing the funding of tuberculosis programmes, and planned to allocate 10 000 million roubles for the purchase of second-line medicines in the period to 2015. She commended the coordinating role of the Secretariat, which had provided technical assistance in monitoring the tuberculosis situation and drafted international standards.

¹ Document WHO/HTM/TB/2008.394.

Dr TAKEI (adviser to Dr Omi, Japan) commended the Secretariat's work on tuberculosis globally, but expressed concern about the slow progress being made in the African and European regions. Japan was willing to share its experience; actions had included financial support for a network of tuberculosis laboratories and technical support for the development of human resources in the Western Pacific Region. Between 2000 and 2007, the prevalence of tuberculosis in that Region had decreased by 4.5% annually and mortality by 3.7% annually.

In both the public and private sectors, maintenance of high standards of therapy under the DOTS strategy by all providers was the mainstay of the fight against tuberculosis, including multidrug-resistant and extensively drug-resistant forms. Research and development were also needed, with in particular better laboratory workforces, training, and monitoring and evaluation, as well as affordable tools for diagnosis and treatment for use in developing countries.

Tuberculosis control programmes should contribute to the strengthening of health systems. Without a robust financing system or appropriate human resources, achieving the Millennium Development Goals and other health targets would be difficult. The Director-General and the Regional Directors had provided powerful leadership for the strengthening of health systems. The Secretariat should continue to operate vertical prevention programmes, such as the tuberculosis programme, alongside horizontal measures to strengthen health systems. He emphasized surveillance of tuberculosis in priority countries.

Dr REN Minghui (China)¹ commended the Secretariat's work on tuberculosis prevention and treatment. His Government's tuberculosis policy was guided by the Global Plan to Stop TB 2006–2015. By the end of 2005, China had achieved 100% DOTS coverage, and currently had a cure rate of more than 85% and a case detection rate of 79%. The Government was particularly interested in the quality and effectiveness of DOTS treatment and in research and development for new diagnostic tools, vaccines and medicines, particularly for developing countries. More attention should be paid to prevention and treatment of tuberculosis, especially among migrants and people with HIV. The international community should provide funding to support countries with a high burden of tuberculosis. WHO should increase its collaboration in that area with other partners, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Ms VAN WOERSEM (Netherlands)¹ welcomed the report and commended the global leadership of the Stop TB Partnership, including WHO, in the fight against tuberculosis. She shared the concerns described in the report: in particular, Member States should not rely solely on the Stop TB Partnership or the Global Fund to help them to reach their targets under the Global Plan to Stop TB 2006–2015. Lack of funding and technical challenges were not the only problems. Member States would need to develop their infrastructure, emphasize community interventions, strengthen links with other programmes, particularly those on HIV/AIDS, and target groups that were hard to reach.

She expressed support in particular for the Regional Office for Europe. The Millennium Development Goals were achievable in the European Region only if countries reassessed their approaches and cooperated in strengthening national and cross-border tuberculosis programmes. She commended the Secretariat's work on impact measurement: the principle "know your epidemic" was relevant not only for HIV/AIDS, but for all programmes that targeted specific diseases.

Dr GHEBREHIWET (International Council of Nurses), speaking at the invitation of the CHAIRMAN, said that his organization was active in several areas of tuberculosis control, including case detection; implementing WHO's new policy on tuberculosis control in health-care facilities, congregate settings and households;² improving integrated care for patients coinfecting with tuberculosis and HIV; and supporting universal access to diagnosis, treatment and care. In

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

² Document WHO/HTM/TB/2009.419.

collaboration with partners, his organization had been building global nursing capacity in the area of tuberculosis. In its “training of trainers” approach, nurses experienced in tuberculosis and HIV care were trained to pass on their knowledge to colleagues in local health facilities. Since 2005, his organization had trained 752 nurses in 14 countries with a high burden of tuberculosis in Africa, Asia and eastern Europe: those nurses had then trained more than 16 000 others. The programme would be extended and its broad stakeholder approach could make a substantial difference.

Dr NAKATANI (Assistant Director-General) said that he was greatly encouraged by the commitment expressed by speakers. Progress was being made towards the achievement of Millennium Development Goal 6 (Combat HIV/AIDS, malaria and other diseases), and the incidence of tuberculosis had been in decline since 2004, albeit slowly. Those gains would be lost without successful responses to multidrug-resistant and extensively drug-resistant tuberculosis and coinfection with HIV. The Global Plan to Stop TB 2006–2015 covered six main areas, particularly HIV coinfection and multidrug-resistant tuberculosis, but it would not be easy to find effective medicines and organize procurement and laboratory services. It would be essential to strengthen health systems by involving all health-care providers, empowering communities and people with tuberculosis, and promoting research. The most vital priority of all was to achieve high-quality DOTS treatment.

The Board noted the report.

Viral hepatitis: Item 4.12 of the Agenda (Document EB126/15)

The CHAIRMAN, introducing the item, drew attention to the draft resolution proposed by Brazil, which read:

The Executive Board,
Having considered the report on viral hepatitis,¹

RECOMMENDS to the Sixty-third World Health Assembly the adoption of the following resolution:

The Sixty-third World Health Assembly,

Having considered the report on viral hepatitis and the proposal therein for the establishment of a world day for the struggle against viral hepatitis;

Taking into account the fact that some 2000 million people have been infected by hepatitis B virus and that about 350 million people live with a chronic form of the disease;

Considering that hepatitis C is responsible for most of the severe cases of hepatitis, and that in about 80% of those cases the infection becomes chronic;

Considering the seriousness of viral hepatitis as a global public health problem and the need for advocacy to both governments and populations for action on health promotion, disease prevention, diagnosis and treatment;

Recalling that one route of transmission of hepatitis B and C viruses is parenteral and that the Health Assembly in resolution WHA28.72 on utilization and supply of human blood and blood products recommended the development of national public services for blood donation and in resolution WHA58.13 agreed to the establishment of an annual World Blood Donor Day, and that in both resolutions the Health Assembly recognized the need for safe blood be available to blood recipients;

¹ Document EB126/15.

Reaffirming resolution WHA45.17 on immunization and vaccine quality which urged Member States to include hepatitis B vaccines in national immunization programmes;

Considering the proposal of WHO to reduce the liver cancer mortality rates and that viral hepatitides are responsible for 5% to 10% of cases of liver cancer;

Recognizing the need for actions to be taken to reduce the incidence of and to control viral hepatitides, to improve diagnostics and to institute treatment in all regions,

1. RESOLVES that 19 May shall be designated as the World Day for the Struggle against Viral Hepatitis in order to provide an opportunity for education and greater understanding of viral hepatitis as a global public health problem, and to stimulate the strengthening of preventive and control measures of this disease in Member States;

2. URGES Member States:

- (1) to apply integrated methods for the prevention and control of viral hepatitis through multisectoral collaboration among health and educational institutions and associated participation of nongovernmental organizations and civil society;
- (2) to incorporate in their specific contexts the policies, strategies and tools recommended by WHO in order to define and implement preventive actions, diagnostic measures and the provision of assistance to the population affected by viral hepatitis;
- (3) to institute or strengthen national programmes for the prevention and control of viral hepatitis which have as their main elements health promotion, diagnosis, surveillance and the follow-up and treatment of people affected by viral hepatitis;
- (4) to assign national and international resources, either human or financial, for technical support in order to provide local populations with the most advanced and suitable means to meet the needs of local epidemiological situations;
- (5) to establish, as necessary, national legislative mechanisms for the use of the flexibilities stated in the Agreement on Trade-Related Aspects of Intellectual Property Rights in order to promote access to specific pharmaceutical products;¹
- (6) to use all necessary administrative and legal means in order to promote access to preventive, diagnostic and treatment technologies;
- (7) to elaborate monitoring and evaluation tools of public policies on viral hepatitis in order to check the efficacy of preventive, diagnostic and treatment actions;
- (8) to implement and/or improve epidemiological surveillance systems in order to generate reliable information for guiding prevention and control measures;
- (9) to promote the celebration of 19 May each year as the World Day for the Struggle against Viral Hepatitis;

3. REQUESTS international organizations and financial institutions:

- (1) to provide support for building capacity in developing countries for increasing the use of reliable diagnostic and treatment methods suitable to local epidemiological situations;

¹ The WTO General Council in its Decision of 30 August 2003 (i.e. on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health) decided that ‘“pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.’

- (2) to assign resources for the prevention and control of viral hepatitis, providing support to countries in a equitable manner to provide technical assistance in the most efficient and suitable manner;
4. REQUESTS the Director-General:
- (1) to establish the necessary guidelines needed by Member States to establish the policies, strategies and tools for the prevention and control of viral hepatitis;
 - (2) to provide the necessary support to the development of scientific research related to the prevention, diagnosis and treatment of viral hepatitis;
 - (3) to adopt measures for more precisely estimating the prevalence of viral hepatitis in the world;
 - (4) to support Member States in conducting events to celebrate the World Day for the Struggle against Viral Hepatitis;
 - (5) to report to the Sixty-fifth World Health Assembly, through the Executive Board, on the implementation of this resolution.

The financial and administrative implications for the Secretariat of the draft resolution were:

1. Resolution Proposal for the establishment of a world day for the struggle against viral hepatitis	
2. Linkage to programme budget	
Strategic objective:	Organization-wide expected result:
1. To reduce the health, social and economic burden of communicable diseases.	<p>1.1 Policy and technical support provided to Member States in order to maximize equitable access of all people to vaccines of assured quality, including new immunization products and technologies, and to integrate other essential child-health interventions with immunization.</p> <p>1.4 Policy and technical support provided to Member States in order to enhance their capacity to carry out surveillance and monitoring of all communicable diseases of public health importance.</p> <p>1.5 New knowledge, intervention tools and strategies that meet priority needs for the prevention and control of communicable diseases developed and validated, with scientists from developing countries increasingly taking the lead in this research.</p>
(Briefly indicate the linkage with expected results, indicators, targets, baseline)	
The resolution is consistent with the expected result. Indicators specific to prevention of viral hepatitis will be designed as needed.	
3. Budgetary implications	
(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US\$ 10 000, including staff and activities)	
US\$ 30 million are needed for the next five years. Of this amount, one third (US\$ 10 million) is needed at headquarters for global planning and coordination between stakeholders, global policy guidance, and the provision of support to regional and country offices; two thirds (US\$ 20 million) are needed for support activities at regional and country levels.	

<p>(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US\$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)</p> <p>Total costs are estimated at US\$ 6 million per year.</p> <p>(c) Is the estimated cost noted in (b) included within the existing approved Programme budget for the biennium 2010–2011?</p> <p>The Organization's hepatitis prevention activities involve a number of technical units. It is difficult to know the true amount of resources available for these activities as they may not be directly identified in the Programme budget and may, for example, be covered under references to blood safety, injection safety, food safety, cancer prevention, child immunization or treatment of opportunistic infections in HIV/AIDS.</p>
<p>4. Financial implications</p> <p>How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?</p> <p>Additional funding from voluntary contributions is expected through active resource mobilization.</p>
<p>5. Administrative implications</p> <p>(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)</p> <p>Currently, most activities are performed at headquarters (policy and technical guidance, global advocacy and stakeholder coordination, and fund-raising) and in two WHO regions (Eastern Mediterranean and Western Pacific).</p> <p>(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below</p> <p>No.</p> <p>(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)</p> <p>At headquarters, at least two additional staff (full-time equivalents) will be required in the professional category, together with one staff member (full-time equivalent) in the general service category. During the biennium 2010–2011, one additional staff member (full-time equivalent) will be needed in the professional category in each of three regional offices (plus administrative support); during the biennium 2012–2013, three more staff (full-time equivalents) will be needed for the other regional offices (plus administrative support). A total of eight staff (full-time equivalents) will therefore be required in the professional category, together with three or four staff (full-time equivalents) in the general service category. In at least 10 countries, a dedicated national programme officer will be needed.</p> <p>(d) Time frames (indicate broad time frames for implementation of activities)</p> <p>The global programme will be expanded into the African, European, and Eastern Mediterranean regions in 2010, and into all regions during the biennium 2010–2011.</p>

Mr DE ALMEIDA CARDOSO (adviser to Dr Buss, Brazil) recalled that 2000 million people were infected with hepatitis B virus, despite an effective vaccine being available, and hepatitis C virus, against which there was no vaccine. Infection with hepatitis viruses was associated with complex cultural, socioeconomic and environmental factors. Prevention and control measures therefore required considerable commitment from governmental and nongovernmental organizations, health professionals, communities and other partners. The designation of a world day for the struggle against viral hepatitis would give impetus to national programmes and campaigns.

The draft resolution provided guidelines for research and development to improve access to technology for the prevention and control of viral hepatitis, particularly in developing countries and

vulnerable populations. As several amendments had been proposed in informal discussions, he suggested that its consideration be postponed until a revised text was available.

Dr GOPEE (Mauritius), speaking on behalf of the Member States of the African Region, said that the Region was home to 50 million carriers of hepatitis B virus. Hepatitis B and C viruses were even more prevalent and more infectious than HIV, leading to high morbidity (liver cirrhosis and liver cancer) and high mortality. In millions of cases every year they were transmitted through unsafe injection practices. Furthermore, the probability of transmission through the transfusion of unscreened or poorly screened blood was high; and contamination of medicine vials was a more serious cause of nosocomial infection than had previously been believed.

Vaccination with a safe and effective vaccine against hepatitis B had been integrated into the national immunization programmes of 45 of the 46 countries in the African Region. The Secretariat should collect the necessary evidence and develop policies for the screening and treatment of hepatitis B and C in the African Region, taking into account the constrained resources. Surveillance of trends in incidence and risk factors was also needed. WHO should appeal to pharmaceutical manufacturers to reduce the prices of medicines for the treatment of hepatitis, as they had done for HIV/AIDS. At present, the cost of treatment was prohibitive for many African countries.

Participants from some 20 sub-Saharan African countries at the second “Hepatitis B and C - the African Experience Exchange Conference” (Mauritius, 2–4 April 2009) adopted a declaration urging African States to scale up the diagnosis, prevention, treatment and care of hepatitis B and C and to strengthen health systems in order to promote universal access to treatment and care.

The CHAIRMAN suggested that consideration of the draft resolution be postponed until the next morning, when a revised text incorporating the proposed amendments would be available.

Sir Liam DONALDSON (United Kingdom of Great Britain and Northern Ireland) recommended that, in the interests of time and efficiency and bearing in mind the Board’s heavy workload, every effort should be made to finish work on the item at the current meeting.

Mr DE ALMEIDA CARDOSO (adviser to Dr Buss, Brazil) explained that his proposal would enable the Board to work more quickly and efficiently with a clean text containing all the proposed amendments.

The DIRECTOR-GENERAL suggested that the debate on the agenda item should continue while a revised text containing all the proposed amendments was being prepared.

It was so agreed.

Dr AWAD (adviser to Dr Abdi, Somalia), speaking on behalf of the Member States of the Eastern Mediterranean Region, noted that viral hepatitis, although a growing concern for public health, had long remained on the margins of other competing health priorities. His Region was facing a silent epidemic of viral hepatitis, especially hepatitis B and C. Hepatitis A and E were also endemic in some countries. The financial cost of treating patients and the opportunity cost to health services were staggering. Current global efforts to implement prevention and control measures remained fragmented; and a comprehensive and coordinated strategy must be adopted in order to protect future generations from infection. Viral hepatitis posed a serious problem in developing countries but, in an era of global migration, the burden was shared by all nations. Clear leadership and strategic direction were needed with a timeline and framework in which countries could work towards specific goals. The Regional Committee for the Eastern Mediterranean had adopted resolution EM/RC56/R.5 at its fifty-sixth session (Cairo, 3–6 October 2009); that set a regional target for reduction in prevalence of chronic hepatitis B virus infection to less than 1% among children below five years of age by 2015. He called on the Secretariat to continue providing technical and strategic guidance to Member States for the prevention and control of viral hepatitis.

Dr MELNIKOVA (adviser to Dr Starodubov, Russian Federation), confirming the serious and growing burden of viral hepatitis, said that her country had taken many steps in accordance with WHO's guidelines. As part of a national strategy on prevention and treatment, more than 50 million children, teenagers and adults up to the age of 55 years had been vaccinated in a mass immunization programme over several years. As a result, the prevalence of acute cases of hepatitis B had been reduced to sporadic levels in most areas of the country. In order to prevent transmission through contaminated blood products, programmes were in place to screen donors and record the information obtained in a database. Her country was well aware of its need to improve treatment of patients chronically infected with hepatitis B and C viruses, and had increased its purchases of antiviral medicines. Programmes to educate the public on prevention of infection with hepatitis B and C viruses and HIV were targeting people with high-risk behaviour in particular, resulting in a fall in the morbidity rate for viral hepatitis. However, despite widespread vaccination, mutant and drug-resistant forms of the viruses were emerging, and an international monitoring system and comprehensive global strategy were needed. She commended the Secretariat's technical support to Member States, especially for expanding immunization programmes, and requested regular updates on results achieved. She supported the draft resolution, but proposed that wording should be added to subparagraph 3(2) to in order emphasize that immunization and public information campaigns were the most effective forms of prevention.

Dr ABDESSELEM (Tunisia) requested the addition of a paragraph to the draft resolution emphasizing the importance of the use of safe, disposable syringes for vaccination, as a way of preventing infection with hepatitis B and C viruses.

Professor ADITAMA (alternate to Dr Sedyaningsih, Indonesia) commented that most carriers of hepatitis B virus lived in developing countries, mainly in South-East Asia and the Far East. Indonesia's carrier rate was about 10%. The disease must be recognized urgently as a public health priority in order to reduce morbidity and mortality rates, to save on related public health expenditures, and raise the awareness of health officials about the need for prevention programmes. Hepatitis B vaccination must be made more accessible and affordable in regions endemic for the disease and universal access to affordable treatment of hepatitis B and C must be ensured. Improved surveillance should be prioritized, along with systems for detecting hepatitis, including blood screening. Support should be strengthened for research aimed at preventing and managing the disease. The Secretariat should provide Member States with technical support for defining national prevention and control strategies with clear goals and timelines, and to ensure surveillance, immunization and treatment. Indonesia wished to cosponsor the draft resolution, which should lay foundations for solid global cooperation.

Dr GIMÉNEZ (Paraguay), noting the report's acknowledgement of support from the GAVI Alliance in the introduction of the hepatitis B vaccine, wished to acknowledge also the fundamental role of PAHO's Revolving Fund for Vaccine Procurement in the Region of the Americas. He supported the draft resolution, but requested the addition of wording that would emphasize the vaccination of health professionals and better institutional safety measures.

Dr TAKEI (adviser to Dr Omi, Japan), noting that the new Japanese Government was giving higher priority to viral hepatitis, expressed support for the proposal to establish a world day for the struggle against viral hepatitis and thus strengthen prevention and control through multisectoral collaboration. The draft resolution covered several potentially controversial issues relating to intellectual property, and, in the interests of avoiding protracted discussions in that respect, he proposed the deletion of subparagraphs 5 and 6 of paragraph 2.

Dr MUÑOZ (Chile) expressed support for the draft resolution, noting that he would have liked to see a final version before commenting on it. Parenteral transmission of hepatitis viruses was a serious problem in developing countries, which had not only to ensure safe blood transfusions but also

the ethical duty to treat patients who had contracted hepatitis C through transfusion of unscreened blood. Given the current cost of treatment to prevent cirrhosis following infection, a paragraph should be added on the possible use of the flexibilities provided for by international intellectual property treaties in order to facilitate access to medicines.

Dr DODDS (Canada) welcomed the draft resolution, which would contribute to raising awareness of the global challenges posed by viral hepatitis. She supported the proposal to designate 19 May as World Hepatitis Day. Canada was working with Brazil and other Member States to consolidate the draft resolution. A comprehensive approach to prevention, management and research was essential, with a particular focus on hepatitis B and C.

Dr SADRIZADEH (Islamic Republic of Iran),¹ noting that hepatitis B virus infection early in life was associated with the highest risk of chronic infection and therefore premature death from liver cancer, said that most Member States had introduced hepatitis B vaccine into their immunization programmes. In his country, hepatitis B vaccination had been fully integrated into primary health-care services since 1993, and 98% of infants were fully vaccinated by their first birthday. Persons at risk were routinely vaccinated, and adolescents born between 1989 and 1992 had been the target of a catch-up immunization strategy.

Dr REN Minghui (China),¹ noting that the prevalence of viral hepatitis was high in China, expressed support for the draft resolution but wanted to propose several amendments. Greater emphasis should be placed on hepatitis B vaccination as a prevention measure and on ensuring access to vaccination for neonates, children and people at high risk. Strengthened health promotion should contribute to controlling the spread of hepatitis C and E viruses. Public health measures to control viral hepatitis should be integrated with those to deal with other viruses, such as HIV, in order to make best use of resources. The Secretariat should set global targets for viral hepatitis control, assist in identifying specific national targets and encourage Member States to boost funding in that respect. It should also lead in the elaboration of guidelines for the management of viral hepatitis. He suggested that it should be left to individual Member States to decide the date on which they wished to mark world hepatitis day: 19 May was not an appropriate date in China as it was currently the national day for persons with disabilities.

Ms BLACKWOOD (United States of America)¹ pointed out that the report did not contain a proposal for the establishment of a world day for the struggle against viral hepatitis, as was erroneously stated in the preamble to the draft resolution; that reference should be corrected. She supported the proposal by the member for Japan to delete subparagraphs 2(5) and 2(6).

Mr GORE (International Alliance of Patients' Organizations), speaking at the invitation of the CHAIRMAN and noting that the Alliance represented the interests of some 365 million patients in 200 member groups, said that, as president of the World Hepatitis Alliance and a hepatitis patient himself, he was speaking for the 500 million people infected with hepatitis B and C viruses (one twelfth of the world's population) and the many millions more at risk of infection and disease. Hepatitis B and C were often described as silent diseases as they could remain undiagnosed for many years, allowing carriers unknowingly to infect others. Too often, silence also characterized the response to the diseases. Many of the one million or so deaths each year linked to chronic viral hepatitis were preventable. Viral hepatitis had been overlooked and, despite the many excellent examples of national hepatitis programmes, infectious diseases as prevalent as hepatitis B and C required a global response. He urged the Board to adopt a resolution on viral hepatitis that would recognize the need for action;

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

ensure that WHO provided leadership and technical assistance, and identified a global strategy; and call on Member States to adopt targets and take specific action to prevent and control hepatitis B and C.

Mr COMMAR (Australia),¹ noting that hepatitis B and C viruses could be transmitted through blood and plasma supplies, said that the Organization should focus on the safety and quality objectives of national drug systems. Education on prevention for high-risk groups and improvements to ensure safe blood supplies in countries that currently did not undertake screening activities were crucial to reducing the spread of viral hepatitis. He proposed two amendments to the draft resolution: the insertion at the end of subparagraph 2(2) of the phrase “including strengthening adverse events reporting systems that capture transfusion transmitted infections”; and the insertion at the end of subparagraph 4(1) of the phrase “including national policies for strengthening regulation and enhancing safety and quality of blood and plasma”.

Dr FUKUDA (Assistant Director-General) agreed that viral hepatitis was a major public health problem that entailed a long list of challenges relating to, among other things, behavioural change, blood supply, the use of safe needles and access to vaccines. As such, several clusters in the Secretariat dealt with the matter. The draft resolution would encourage the adoption of an integrated approach, and every effort would be made to respond to the calls for leadership, coordination and provision of technical support to Member States.

The DIRECTOR-GENERAL noted that the proposed amendments were being incorporated into a consolidated text which, when ready, would be distributed for the Board’s consideration. She suggested that, at that point, those members who had suggested further amendments during the current discussion should propose them again for incorporation. Consideration of the item should therefore be resumed when the consolidated text became available.

The CHAIRMAN said that he took it that the Board agreed with the approach suggested by the Director-General.

It was so agreed.

(For adoption of the resolution, see summary record of the thirteenth meeting, section 1.)

Leishmaniasis control: Item 4.12 of the Agenda (Document EB126/16)

Mr PRASAD (India) acknowledged WHO’s efforts in achieving a substantial reduction in the price of five medicines for the treatment of leishmaniasis, and stressed that those medicines should be included in national control programmes at the reduced price. He called for more information on the state of progress of research into vaccines, diagnostics and new, less toxic medicines. According to a recent report,² in 2008 total funding for leishmaniasis had amounted to US\$ 57.74 million, including US\$ 18.96 million for antiprotozoal agents and research, US\$ 5.23 million for vaccine research, and US\$ 5.76 million for diagnostics. However, there had been limited funding for the development of vector-control products. He urged more countries to support research on leishmaniasis.

Dr DOS RAMOS (Sao Tome and Principe), speaking on behalf of the Member States of the African Region, said that cutaneous leishmaniasis had been detected in at least 26 countries in the Region, although the actual extent of areas endemic for the disease was unknown. Strategies adopted

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

² Moran M et al. *Neglected disease research & development: new times, new trends*. G-FINDER report. Sydney, Australia, The George Institute for International Health, 2009.

to reduce the incidence of leishmaniasis following the adoption of resolution WHA60.13 included early diagnosis and rapid treatment; use of insecticide-treated bednets; and programmes to educate the public about the clinical signs of the disease and related treatment.

The African Region was planning a consultative meeting that would cover strategies and national control programmes, the mapping of epidemiological data, and information on outbreaks, morbidity burden, and availability of medicines.

She urged the Secretariat and Member States to continue their efforts to reduce morbidity rates related to leishmaniasis.

Dr AL HAJ HUSSEIN (alternate to Dr Said, Syrian Arab Republic), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that, since the adoption of resolution WHA60.13, progress had been made to raise awareness about the regional burden of leishmaniasis. In 2008 some 100 000 cases of cutaneous leishmaniasis and 5000 of visceral leishmaniasis in the Region were reported, nearly two thirds from Afghanistan, Morocco, Saudia Arabia and the Syrian Arab Republic. A regional meeting (Sharm-el-Sheikh, Egypt, 27–29 October 2009) had further reviewed control strategies of cutaneous leishmaniasis in the Region.

Interventions to build regional capacity had included: the training of health personnel from Afghanistan, Iraq and in other countries endemic for the disease; further training to cope with the outbreak in southern Sudan; the establishment of a harmonized regional system for surveillance, data collection and analysis; and the creation of the Leishmaniasis Mediterranean and Middle East Network, a platform for sharing knowledge online.

Long-term efforts were essential for reducing the burden of the disease. The Region's control strategy was based on active surveillance, prompt treatment and measures to prevent transmission, such as use of insecticide-treated bednets and rodent control. The strategy incorporated the recommendations arising from assessments made in the four most affected countries in 2009.

Dr GIMÉNEZ (Paraguay) welcomed the report, as leishmaniasis was one of the most neglected tropical diseases. In 2009, more than half the people affected by the disease in Paraguay had been children under the age of five years. It was vital that the medicines available to treat leishmaniasis were included in the national list of medicines and that access to treatment was expanded.

Dr SADRIZADEH (Islamic Republic of Iran)¹ also observed that leishmaniasis was one of the most neglected tropical diseases with few control tools available and no agreed strategy. Globally the trend of coinfection with the *Leishmania* parasites that caused visceral leishmaniasis and HIV was increasing ominously; that was changing the epidemiology and bringing visceral leishmaniasis to new geographical areas. Research was urgently needed, under the stewardship of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, into alternative and cheaper medicines and rapid and more reliable diagnostics. Mapping of the disease distribution and at-risk populations should be a priority at local levels, and integrated vector control had the potential to strengthen a multidisciplinary approach to prevention and control. His country would be pleased to share its experience in this regard with interested Member States.

Mrs FERNANDEZ DE LA HOZ (Spain),¹ also speaking on behalf of France and Italy, noted that leishmaniasis was present in more than 25 countries in the European Region, in some of which national control programmes were inadequate or non-existent and access to medicines was limited. Furthermore, coinfection with HIV was increasing. The Governments of France, Italy and Spain were providing political and financial support to the development of programmes in accordance with resolution WHA60.13; that included research in collaboration with developing countries into innovative treatment methods, improvement of existing networks, and activities in the veterinary

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

sphere related to transmission from animals to humans. She emphasized their readiness to continue working with the Secretariat in order to strengthen interregional collaboration networks, particularly in the Mediterranean region, Europe and central Asia; and to promote capacity building, research into innovative diagnostic tests, new medicines and vaccines for both canine and human leishmaniasis, and the establishment of national surveillance systems.

She urged governments and nongovernmental organizations to collaborate in order to help developing countries affected by the disease and to encourage pharmaceutical companies to continue to manufacture existing medicines and sell them at reduced prices.

Ms BLACKWOOD (United States of America)¹ said that her Government was committed to reducing the burden of neglected tropical diseases such as leishmaniasis. It was continuing to provide support for research on the topic, including, for instance, complications related to coinfection with HIV, the mechanisms of disease transmission, the development of safe and effective treatments and vaccines, and ecological and integrated vector management. She confirmed the previously mentioned and essential elements of a safe and effective control strategy for leishmaniasis.

Dr NAKATANI (Assistant Director-General) thanked speakers for their contributions. In response to the member for India, he said that no new combination of medicines or single-dose regimens had been developed, although results of trials of combinations of existing medicines were promising. He congratulated India and the Islamic Republic of Iran on their contributions to research in that area.

Monitoring was also an important aspect of the control of leishmaniasis, in particular in relation to coinfection with HIV. The next meeting of the Expert Committee on Leishmaniasis, scheduled for March 2010, would consider all of the aspects covered in the discussion.

The Board noted the report.

Global eradication of measles: Item 4.14 of the Agenda (Document EB126/17)

Dr DAHL-REGIS (Bahamas) commended the contribution of all parties to the significant progress towards the goal of the global eradication of measles. The reported reductions in mortality would be paralleled with decreases in morbidity. Further efforts should be devoted to the Western Pacific Region and she asked for an update on progress in the South-East Asia Region. She also asked whether an interim report on the independent analysis of cost-effectiveness mentioned in the report was available, and whether the lack of cost-effectiveness data had affected regional efforts. The report clearly demonstrated WHO's leadership role as a global public health authority.

Mr PRASAD (adviser to Ms Sujatha Rao, India) said that, in India, about 70% of children had been vaccinated against measles. The Government recognized the need to increase coverage and was seriously considering undertaking an additional catch-up round of immunization. The previous lack of catch-up vaccination had been the price that had to be paid for the global campaign to eradicate poliomyelitis, which had severely affected India's capacity to deliver routine immunization programmes. He encouraged the Secretariat to consider India's situation and provide support for developing a sustainable strategy for all routine immunizations.

Dr DJIBO (Niger), speaking on behalf of the Member States of the African Region, said that the Region had achieved the target of a 90% reduction in measles mortality rates three years before the target date, based on estimates for the period 2000–2006, mainly thanks to the combined efforts of Member States in implementing measures that had proved successful in the Region of the Americas.

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

As the report indicated, the goal of 2020 for elimination had been adopted by the Regional Committee for Africa; the Region was setting pre-elimination targets for 2012, and emphasizing improved coverage rates of first-dose measles vaccine. Measures that had been implemented included increased coverage rates of routine immunization, supplementary vaccination activities and the implementation of a monitoring system that included laboratory confirmation. However, challenges remained, including large-scale outbreaks in some countries, the lack of political commitment, and the limitations in health service accessibility and capacity for follow-up.

Dr MOHAMED (Oman), speaking on behalf of the Member States in the Eastern Mediterranean Region, said that significant progress had been made: the number of cases had decreased from 101 000 in 1977 to 7000 in 2008. However, certain countries, notably Afghanistan, Somalia and Sudan, continued to face a heavy burden of measles. In some countries, first-dose vaccination coverage in 2008 had reached 83%; however, problems affecting health systems, such as security, meant that, in 2009, there had been outbreaks of measles in Afghanistan, Iraq, the Libyan Arab Jamahiriya and Somalia. In some countries, government commitment had been lacking, foreign funding for vaccination programmes had been insufficient, and renewed financing was required.

Global eradication of measles was indeed possible. The countries of the Region that would not achieve the goal of eradicating measles by 2010 had taken steps, such as immunization campaigns and monitoring, towards that objective. Achieving the objective was a step-by-step process, and it was important that the objectives be reviewed every year.

Dr GIMÉNEZ (Paraguay) commended the report. Regarding the achievements of the Region of the Americas, he noted the two prerequisites for eradication of measles: the commitment of political and programme leaders at national level, and of the leadership of PAHO, to strengthen immunization programmes, together with the significant impact of the Region's Revolving Fund for Vaccine Procurement, which ensured equitable access to vaccines at fixed, affordable prices. Ensuring vaccination activities in border areas remained challenging: difficulties with surveillance, information-sharing and logistics had to be overcome. The latter point could add a strategic dimension to the Secretariat's report to the next Health Assembly.

Dr MELNIKOVA (adviser to Dr Starodubov, Russian Federation) expressed her country's support for WHO's strategy for the eradication of measles, which was a priority for her Government. Country-wide immunization of children and adults had reduced the morbidity rate to one reported case per million population – in line with WHO's goal for measles elimination. That experience reflected the importance of surveillance, public information and assessment of virus circulation. A molecular epidemiological approach with genotyping of strains of measles virus allowed monitoring of eradication of the disease; already, one previously endemic genotype was no longer circulating in the country. Although measles prevalence rates were low in the Russian Federation, the threat from imported strains and genotypes was recognized. She emphasized technical support for preventive measures in order to reduce morbidity and mortality to the level of the indicators given in the report.

Dr FENG Yong (China),¹ noting the many difficulties that remained, said that the Secretariat should increase both support and funding for the eradication effort. He also expressed the hope that other international organizations and foundations could make additional funding and technical support available to developing countries. His Government had already developed a national action plan for the period 2006–2012 and begun a vaccination programme in the provinces. As a result, for the period from January to November 2009 reported incidence had fallen nationally by 58.5% year on year. The plan being developed for the period 2010–2012 included an intensified programme of vaccination with the first dose of measles-containing vaccine, to be conducted nationally in 2010.

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

Dr NAKORN PREMSRI (Thailand)¹ commended the report. His country aligned itself with the goal of Member States in the South-East Asia Region, to eliminate measles by 2020; and fully supported the global eradication effort which contributed significantly to the achievement of Millennium Development Goal 4 (Reduce child mortality). However, he was concerned that efforts to eradicate measles globally constrained health systems in developing countries, particularly in resource-limited settings, and competed with work on other priority diseases such as influenza, malaria, dengue and poliomyelitis. He further emphasized that other factors could exacerbate outbreaks in the adult population, such as armed conflict, the movement of migrant workers and the location of populations that were hard to reach.

Strong political commitment, financial support and the continued support of global funding agencies would be crucial in view of the following: the current low rate, in countries in the South-East Asia Region, of coverage with the first dose of measles-containing vaccine (averaging 25% instead of the target of more than 90%); the information provided on the incremental cost of the vaccination strategy for measles eradication in Latin American and Caribbean countries (US\$ 244 million from 1994 to 2002); the estimated additional costs of vaccination in countries in the South-East Asia Region; and the heavy financing and manpower needed for measles surveillance. Measles mortality was rising, despite the availability of effective vaccines, and a global effort was needed with strong commitment from all partnerships and parties.

Ms DLADLA (South Africa)¹ welcomed the report and commended the leadership and support provided by the Secretariat, including the recommendations of WHO's technical support mission that had considered the outbreak of measles in her country in October 2009. She noted the challenges posed by inadequate access to, and low quality of, immunization services; poor quality of data on immunization coverage; and inadequate resources. A concerted effort would thus be needed if the African Region were to reach the target of measles elimination. She supported the global measles targets for 2015 together with the regional elimination target. Her Government was encouraged by the efforts of the African Region and committed itself to further collaboration in order to achieve the pre-elimination targets for 2012.

Ms BLACKWOOD (United States of America)¹ thanked the Secretariat for its report and said that she would respond to that document's request for strategic direction concerning the establishment of the next global measles goal.

The Centers for Disease Control and Prevention strongly supported the stepwise process proposed by the Secretariat, setting global measles targets for 2015 as milestones towards eradication. They appeared reasonable and achievable. However, numerous challenges underscored the need to conduct a thorough technical assessment and to establish realistic targets for sustaining current gains before setting future goals. As the member for Paraguay had said, the accomplishments of the Region of the Americas indicated that measles eradication was feasible; however, the fight against poliomyelitis had shown that regional successes were not necessarily easy to replicate. Although vaccine supply and logistics should be manageable with sufficient lead time and planning, there were concerns over financing, competing priorities and the platform of support for the next global eradication goal. Cost-effectiveness studies were under way. An essential lesson learnt from the poliomyelitis eradication programme was that realistic estimates of long-term costs were needed to ensure that donors had a more comprehensive understanding of their obligations.

Ms ATHERSUCH (Médecins Sans Frontières (MSF) International), speaking at the invitation of the CHAIRMAN, said that, despite the progress made, control of measles remained a major challenge in many countries. She therefore welcomed the call for new, ambitious targets for 2015. In 2008, her organization had vaccinated more than 1.9 million children and had treated 32 000 cases

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of measles in response to outbreaks. Additional investment and strong political will would be needed if the 2015 targets were to be attained.

Member States could take practical steps: programme monitoring and disease surveillance were crucial for assessing progress and validating elimination. Independent surveys were needed in order to evaluate immunization coverage, guide adjustments to immunization programmes, and determine the risks to specific populations; and assessments were needed to enable appropriate adjustments of age-group criteria and timing between campaigns.

The enlargement of the target group for measles immunization to five years of age, in accordance with the WHO/UNICEF Global Immunization Vision and Strategy, would be important, especially where there were cases or outbreaks of the disease. Further, supplementary activities would be needed where routine rates of coverage remained below 90% for the first dose. It was never too late to use vaccination in measles outbreaks. At times of high risk of outbreaks, the target group should be extended; and during outbreaks, measles treatment should be offered free of charge to encourage the seeking of care. Outbreak responses also provided an opportunity to provide the second dose to some and to use additional antigens, thereby increasing overall coverage under the Expanded Programme on Immunization. Member States should provide funds to enable the Secretariat to allocate additional support during responses to measles outbreaks. The introduction of new systems for vaccine delivery should be accelerated, for the benefit in particular of those populations that were hard to reach.

Ms MAFUBELU (Assistant Director-General) expressed appreciation for the comments made by Board members. She commended Member States' efforts to control measles. Eradication was achievable, but major challenges remained. It was crucial to protect all children against the disease, to maintain vigilance in the border areas of countries that had eliminated the disease and to share information, as outbreaks would continue for the time being. Effective routine immunization with high coverage and strong health systems were essential.

In answer to specific questions, she replied that there would be no interim report on the independent analysis of the cost and cost-effectiveness, whose results were expected in June 2010. The lack of cost-effectiveness data was not affecting regional efforts. The main problem faced by Member States was the lack of resources and the estimated shortfall in funding was around US\$ 60 million in 2010. WHO was working in partnership with and acknowledged the support being received from the Measles Initiative in securing additional resources. In the South-East Asia Region, with the exception of India whose situation had been described, all Member States were on track to attain their current measles targets of reduction in measles mortality.

The Board noted the report.

Smallpox eradication: destruction of variola virus stocks: Item 4.15 of the Agenda (Document EB126/18)

Dr AWAD (adviser to Dr Abdi, Somalia), speaking on behalf of the Member States of the Eastern Mediterranean Region, welcomed the fact that the world had remained free from smallpox ever since the announcement by WHO in 1980 that it had been eradicated. The Eastern Mediterranean Region welcomed the progress made in health research involving variola virus. All essential research requiring live variola virus stocks for the purpose of sequencing and development of diagnostic tests and vaccines had been completed. Further sequencing was perhaps not justified from a public health perspective: accordingly, live variola virus stocks should no longer be retained for those purposes. The Secretariat kept an emergency stockpile of smallpox vaccines in case of need. For all those reasons, the Member States of the Eastern Mediterranean Region strongly recommended that a date for the destruction of variola virus should be set as soon as possible.

Dr KABULUZI (Malawi), speaking on behalf of the Member States of the African Region, recounted the history of WHO's work on smallpox eradication, as reflected in Health Assembly resolutions WHA52.10, WHA55.15, WHA55.16 and WHA60.1. He noted that the virus that caused

smallpox was believed to exist in places other than WHO-authorized repositories and that it could potentially be released deliberately to cause harm. Following the global eradication of smallpox, health workers had almost lost skills in smallpox diagnosis and treatment, including surveillance and case definition. Updated training was therefore needed. At least one member of the Advisory Committee on Variola Virus Research should be a representative of the African Region. With those comments, he endorsed the report on smallpox eradication.

Mr PRASAD (adviser to Ms Sujatha Rao, India) said that the retention of variola virus stocks with no definite time frame for their total destruction was a matter of concern, and Member States should reach a consensus on a proposed date for their destruction. The report was silent on whether all 10 Member States that had declared virus stocks in 1977 had provided further information on the legal status of ownership of stocks. He noted that an emergency stockpile of smallpox vaccine was safely stored, and supported the steps being taken to develop the vaccine reserve so that timely and adequate supplies could be made available to an affected country if the need arose. It was a matter of concern that advances in synthetic biology made it possible to synthesize a full-length variola virus genome. For that reason, he recommended that existing guidelines on work with live variola virus and with variola virus DNA should be evaluated.

Ms ARTHUR (alternate to Mr Houssin, France) requested clarification on the proposed laboratory network referred to in resolution WHA60.1; it seemed to be a step backwards as more than two centres would then hold stocks of variola virus, even if they were only samples. She expressed some concern about strains being stored in different laboratories, particularly as there was no mention of geographical distribution.

Priority should be given to reliable testing but there was also concern about long-term experimentation. The report had referred to sequencing activity within the two repositories but such work was not useful, particularly as the report stated that there was no justification for it from a public health perspective. Further transparency was needed in the report on what research was being conducted in that area.

Dr HOSSEIN NIEKNAM (Islamic Republic of Iran),¹ recalling resolution WHA59.10 and the recommendation contained therein to destroy the remaining stocks of variola virus, noted that the issue had been discussed annually for many years but no date had been set for their destruction. He therefore called for a fixed date to be set either by the Executive Board at its current session or by the Sixty-third World Health Assembly.

Dr NAKORN PREMSRI (Thailand)¹ welcomed the report's focus on research, in particular regarding the third-generation smallpox vaccine. The continuous global research effort on smallpox vaccine was welcome; however, the WHO smallpox vaccine stockpile of 32.6 million doses, together with the 27 million pledged doses, fell far short of the 200 million doses recommended by the Ad Hoc Committee on Orthopoxvirus Infections in 2004. He echoed concerns expressed by the Advisory Committee regarding the advances in technology for virus synthesis and synthetic biology, which could lead to illegal variola virus synthesis. Control procedures should be established for all repositories of variola virus and genome-sequencing laboratories. He reiterated the comments of earlier speakers concerning the threat of the existence of live variola virus. The only solution was the total destruction of the variola virus.

Dr RYAN (Global Alert and Response) thanked Member States for their continued support to the important regulatory process, despite the additional workload created by the pandemic H1N1 (2009). The establishment of the Advisory Committee on Variola Virus Research had led to oversight of

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research projects involving live variola virus, establishment of a vaccine stockpile, and standard operating procedures for use of that vaccine. The Advisory Committee had also evaluated new and promising antiviral agents and diagnostic tools. Regular inspections had been made of the two WHO collaborating centres, with the testing of a new protocol for standardized inspections. The Advisory Committee was also responsible for regulating the use of segments of variola virus DNA, and had developed an operational framework to handle an outbreak of smallpox. The current archives relating to the variola virus and the eradication of smallpox had been digitally recorded. A report of all actions would be presented at the Health Assembly in 2011.

The Advisory Committee had continued to act in the spirit of resolution WHA52.10, which stated that all research should be outcome-focused, health-oriented and time-limited, and had followed up on all activities requested in resolutions WHA49.10, WHA52.10 and WHA55.15. With regard to the request for a new date for destruction to be set, a full scientific review of all published and unpublished data, currently being drafted by the Advisory Committee, would be presented to the Health Assembly in 2011, following additional scrutiny by independent experts to be appointed by the Director-General. At the request of the Health Assembly, geographical representation on the Advisory Committee had been improved, including the invitation of experts from four African Member States, and the broadening of its public health expertise. He thanked the Governments of Canada and the United Kingdom of Great Britain and Northern Ireland, which had provided significant funds to purchase the vaccines being stockpiled by WHO, and the Governments of France, Germany, New Zealand and the United States of America, which had made pledges to provide 27 million doses. The number of doses did fall short of the recommended 200 million, but the existing 60 million doses would be adequate to respond to an emergency at the point of origin. He recognized the contribution of the Government of Switzerland, which had provided facilities for the safe stockpiling of the vaccines, and the Secretariat had worked with all parties to determine operational procedures for the release of those vaccines if required.

The development of technology had led to advances in genome sequencing, and the capacity to synthesize viruses was growing. While guidelines existed, they would require constant review as well as the independent oversight of all research. The Committee had worked, at the request of the Health Assembly, on increasing access to reliable diagnostics, and a review of capacity had been under way since November 2009. It would subsequently be for the Sixty-fourth World Health Assembly in 2011 to decide on future actions. In answer to the concern expressed by the member for France, he said that the proposed network of laboratories was intended solely to improve diagnostic capacity, and there was no intention to distribute variola virus.

The Board noted the report.

The meeting rose at 21:10.