SIXTH MEETING

Thursday, 19 May 2011, at 09.25

Chairman: Dr H. MADZORERA (Zimbabwe)

1. SECOND REPORT OF COMMITTEE A (Document A64/54 (Draft))

Dr KULZHANOV (Kazakhstan), Rapporteur, read out the draft second report of Committee A**.**

The report was adopted.

2. TECHNICAL AND HEALTH MATTERS: Item 13 of the Agenda (continued)

Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: Item 13.1 of the Agenda (Documents A64/8, A64/8 Corr.1 and A64/8 Add.1) (continued from the fifth meeting, section 2)

Dr KIMANI (Kenya) welcomed the Pandemic Influenza Preparedness Framework and its institutionalization of a legal regime to enhance equitable access to essential vaccines, antiviral medicines and diagnostic kits, especially for lower-income countries. In the past, problems had arisen when developing countries had been unable to access vaccines developed from virus samples they had shared. He commended the commitment of the industrial sectors concerned to collaboration with the Secretariat and Member States for better pandemic influenza preparedness.

Kenya continued to be at risk of influenza and other emerging infectious diseases by virtue of its strategic location as an international travel and trade hub. As one of the first countries in Africa to have confirmed cases of pandemic influenza A (H1N1) 2009, it continued to support other countries in the African Region through laboratory testing. Sentinel surveillance sites had been established and more were planned. The International Health Regulations (2005) had been incorporated into integrated disease surveillance and response. All viral isolates were shared with the WHO Collaborating Centres in Atlanta (United States of America) and Melbourne (Australia) for quality control, quality assurance and inclusion in the viral strains bank, used for determining vaccine strains. He expressed appreciation to WHO and partners for support and asked other agencies to further support Kenya's national capacity for handling pandemic influenza.

Lack of consensus on one preambular paragraph of the draft resolution (document A64/8, Attachment 3) should not stall the adoption of the Framework for the sharing of influenza viruses and access to vaccines and other benefits, and he therefore supported its proposed deletion.

Mr SIHASAK PHUANGKETKEOW (Thailand), welcoming the consensus reached on the Pandemic Influenza Preparedness Framework after several years of negotiation, said that the Framework would provide a solid basis for scaling up international cooperation on pandemic preparedness. More predictable cooperation and partnership would result in better preparedness for future pandemics. He welcomed the establishment of a financing mechanism, based on annual partnership contributions, which would be crucial in enabling the Secretariat to support the

strengthening of surveillance, laboratory, and vaccine development and production capacities for countries in need.

He emphasized WHO's key role in facilitating the transfer of technology. If the Framework was adopted, WHO should expeditiously conduct negotiations on the details of benefits to be provided by entities outside the WHO Global Influenza Surveillance and Response System. His country trusted the Director-General to ensure that access to essential technologies would be included in overall benefit sharing. Without access to technology, developing countries would face tremendous difficulties in expanding vaccine production capacity.

Expressing appreciation to various donors who had supported the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply, he drew attention to the need to enhance local demand for seasonal influenza vaccines, in particular among health workers and high-risk population groups. Domestic demand would help to maintain the capacity built up for pandemic preparedness, making the system sustainable in the long term.

Pandemic preparedness was a work in progress. The Framework would be reviewed and revised as Member States continued to learn from experience. Thailand would cooperate fully and contribute to the global preparedness system.

Professor AZAD (Bangladesh) said that pandemic (H1N1) 2009 had highlighted the urgent need to finalize a mechanism for sharing viruses and other benefits, and he therefore welcomed the agreement on the Framework. He keenly awaited implementation of the WHO Global Pandemic Influenza Action Plan to increase Vaccine Supply, with its strategies to build new production facilities in developing countries and for the transfer of technology, skills and know-how.

Bangladesh had successfully managed the first wave of pandemic (H1N1) 2009 through various interventions. Stemming panic had been the highest priority. Staff had been trained and deployed throughout the country, and isolation facilities had been established at district level and below. Oseltamivir production had begun locally for domestic use and export, and Bangladesh was working with WHO to produce vaccines. Modern diagnostic facilities had also been established. Through its National Influenza Centre, Bangladesh was already examining the disease burden of seasonal influenza and would incorporate seasonal influenza vaccination into its Expanded Programme on Immunization if necessary. Its National Influenza Centre was ready, in principle, to share influenza isolates with other WHO international reference centres worldwide. He recommended that financial and technical assistance should be given to Bangladesh and other developing countries to help them to build capacity to respond to future pandemics.

Ms SILVA DO RASARIO (Sao Tome and Principe) said that there had been 65 confirmed cases of pandemic (H1N1) 2009 infection and one death in her country. Without WHO's support for training, provision of medicines and vaccines, the situation could have been much worse. Only by preparing and responding appropriately to emergencies such as pandemic influenza could death and suffering be avoided. The Framework met those needs perfectly. She expressed support for the draft resolution, but suggested that a new subparagraph be added to paragraph 4, requesting that a report should be submitted every two years to the Health Assembly on progress in the implementation of the resolution.

Mr OTAKE (Japan) supported the draft resolution as amended by the delegate of Australia. Rapid sharing of influenza virus specimens was indispensible to the response to influenza pandemics. The Framework would play a significant role in that regard, but whether it functioned properly would depend entirely on the details of its implementation, to be discussed further by the Advisory Group referred to in section 7 of the Framework, on governance and review. It was to be hoped that the Advisory Group would conduct its work transparently and fairly. At the same time, the opinions of industry, which was an interested party and a direct stakeholder, should be appropriately reflected.

Dr DAULAIRE (United States of America) said that the Framework, an historic document finalized after sometimes difficult negotiations, would improve pandemic preparedness and response, facilitate the rapid sharing of virus samples and help to increase laboratory and vaccine production capacities in developing countries. Pandemic (H1N1) 2009 had highlighted the need for rapid and transparent sharing of viruses with pandemic potential and related data, such as viral genetic sequences, as a crucial part of global preparedness and response efforts. The WHO Global Influenza Surveillance and Response System served as a vital tool for risk assessment and global response as well as for capacity building for preparedness for future epidemics and pandemics. An essential component of the Framework was preserving and enhancing cooperation and partnerships between WHO and other stakeholders, including manufacturers and civil society, to safeguard public health.

He asked the Legal Counsel whether, in paragraph 1 of the draft resolution, the phrase "in accordance with Article 23 of the Constitution" should be inserted after the word "adopts" in order to make it clear that the Health Assembly had the authority to adopt the Framework. That wording was consistent with that in previous resolutions, such as resolution WHA63.16.

He urged Member States to redouble their efforts to develop and implement short-, medium- and long-term strategies to enhance pandemic influenza preparedness and to increase influenza vaccine manufacturing capacity in developing countries. He supported the Framework and the draft resolution.

Dr HWOAL (Iraq), underlining the need to take stock following pandemic (H1N1) 2009, said that countries should have the right to conduct studies on pandemic influenza, and to obtain the necessary vaccines without being restricted to dealing with particular pharmaceutical companies, in which regard WHO had a role to play. Information on pandemic influenza and related factors should be pooled, so that it could be monitored by WHO. The pandemic situation in different regions should be monitored continuously and comparisons drawn where possible. Technical advice should be provided to take account of new developments. Countries' capacities to study pandemic influenza should be strengthened, as should their institutional capacity, particularly with regard to vaccine production. Incidence of influenza, particularly influenza A (H1N1), should be reviewed periodically. Supplies of vaccine and laboratory staff to produce them were needed. The International Health Regulations (2005) should be implemented so that future pandemics could be tackled or even prevented, and effective partnerships should be established with all relevant stakeholders.

Mr CHANDRAMOULI (India) welcomed the Framework and expressed appreciation for the contributions of all involved and the commitments made by the pharmaceutical industry. The Framework must be implemented, and the details of such implementation should be worked out by the Director-General and the Advisory Group. Some elements should enter into force immediately, with others following in 2012. The Framework should be implemented in letter and spirit and the "equal footing" principle should guide all concerned in the discharge of their obligations. India was committed to making the Framework a success.

Dr SALEH (Egypt), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that pandemic (H1N1) 2009 had demonstrated the need for cooperation among all international organizations. The fact that the pandemic had originated in Mexico and been caused by the H1N1 strain had come as a surprise to many, as attention had previously focused on avian influenza A (H5N1), then prevalent in Asia and Europe. When the pandemic had been announced by the Director-General, the countries of the Region had made a political commitment to draw up preparedness plans, following WHO's guidance, but various weaknesses had become apparent. Some countries had insufficient laboratory capacity to deal with the pandemic, and the Secretariat's support

to the Region, including training and assistance from diagnostic teams, had therefore been much appreciated.

Vaccine distribution in the Region should have been more equitable. Wealthier countries had secured sufficient supplies, but poorer countries had been unable to do so, in some cases receiving vaccines only once they were no longer needed. The importance of exchanging samples had been highlighted. The availability of reagents and diagnosis capacity should be improved. Information should be pooled, through WHO collaborating centres and the WHO Global Influenza Surveillance and Response System, facilitating adequate preparation of vaccines for future pandemics so that lives could be saved and the threat to global health minimized. Information and samples from seasonal influenza outbreaks should also be pooled. It was to be hoped that adequate supplies of influenza vaccine would be available at reasonable prices in the future.

Ms EPHREM (Canada) said that the Framework, the result of four years of collaboration, was an important example of how governments, multilateral organizations and industry could find innovative ways of improving global pandemic influenza preparedness. Considerable work, diligence and governance would be required to ensure effective implementation of the Framework. It was gratifying that Member States were committed to its use as the prime instrument for access to and benefit from pandemic influenza biological materials.

Dr AL NASSER (Kuwait) emphasized prevention grounded in epidemiological surveillance and monitoring. Laboratories must be equipped; supplies of vaccines must be made available. It was important to be able to access antiviral medicines in good time and to organize national information campaigns. He called on all parties to work together to ensure that antiviral medicines and reagents were made available promptly to control future pandemics.

Dr AL HAJERI (Bahrain) said that her Government had attached priority to combating pandemic influenza, providing financial and other support for activities such as vaccine preparation. In cooperation with WHO and other partners, Bahrain had set up a laboratory equipped to diagnose pandemic influenza and other diseases; the laboratory would be brought into service shortly, allowing for isolates to be identified, examined and shared, in accordance with the Framework and WHO's principles. She welcomed the Secretariat's work on pandemic influenza preparedness, particularly virus sharing and vaccine production.

Mr LARSEN (Norway) said that the Framework represented an important and innovative agreement and a victory for public health, international solidarity and global health diplomacy under the auspices of WHO. The negotiations had highlighted the strategic link between global health and foreign policy. Pandemic (H1N1) 2009 had demonstrated the importance of WHO and the need to improve global preparedness and ensure a more coordinated response based on public health risks and needs. The Framework, which brought together governments, civil society and industry in a unique public–private partnership, provided a good basis for such efforts, and should be implemented as a matter of urgency, under the continued leadership of the Director-General. The sharing of viruses and benefits must be made to work in practice. The Framework's focus on transparency and close monitoring of implementation and compliance was particularly welcome, and the review planned for 2016 would allow for adjustment to reflect changing needs and new scientific developments.

He expressed support for the draft resolution, as amended by the delegate of Australia.

Mr SILBERSCHMIDT (Switzerland) welcomed the finalization of the Framework after four years of negotiations that had proved that WHO could move global health forward. Although Switzerland had signed the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, it considered the Framework to be the

only instrument that would apply to influenza viruses with pandemic potential, in terms of both virus and benefit sharing.

The next challenge was implementation by Member States, which should support the Secretariat in its work, and by public and private partners. Although the Framework was a major advance towards global preparedness, he recalled the message from the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009: the world was not sufficiently prepared for the next pandemic. Vaccine would be produced too late and in too little quantity for any country. Research must therefore be promoted as a priority and thorough preparedness plans drawn up. He supported the draft resolution, subject to the deletion of the fifth preambular paragraph.

Mr MEI Yang (China) expressed appreciation for the cooperative spirit shown by all parties to negotiations on the Framework, especially on the issues of government responsibility, company contributions and benefit sharing, demonstrating international solidarity to meet a public health challenge that posed a huge threat to humanity. China supported the adoption of the Framework and would fulfil its responsibilities and obligations in that respect. Future consultations should be based on the principles of equality, fairness and transparency, and countries should shoulder common but differentiated responsibilities, according to their level of development and prevention needs, in order to generate effective implementation plans. Countries with intellectual property in the area of vaccine development should make greater commitments to intellectual property transfer to help developing countries improve vaccine research and development, so that they could lower costs and obtain affordable vaccines to protect the health of their populations.

Dr GOUYA (Islamic Republic of Iran), emphasizing the gap between global need and existing global capacity in preparing for a severe influenza pandemic or similar emergency, welcomed the Framework, which should lead to wider availability of vaccines, antiviral medicines and diagnostic kits, along with greater equity in dealing with the next pandemic. The Framework should facilitate access by developing countries to other benefits, such as knowledge sharing, transfer of technology and know-how to produce vaccines and other products. He urged all Member States and other stakeholders to give priority to and actively support the wide implementation of the Framework and to consider providing adequate resources to that end.

Dr CHISTYAKOVA (Russian Federation), acknowledging the leading role of WHO in coordinating international efforts to strengthen pandemic influenza preparedness and applauding the Director-General's work to improve monitoring, strengthen national influenza vaccination programmes and expand vaccine production capacity, welcomed the Framework. Her country fulfilled its international obligations with regard to access to vaccines and other benefits. In 2010, the Russian Federation had transferred a sublicence to WHO for the manufacture of influenza vaccine. An important part of its contribution to global pandemic preparedness efforts was cooperation with countries in eastern Europe and Central Asia for capacity building. The Russian Federation would participate actively in implementing the Framework.

Dr MANZUR (Paraguay), welcoming the Framework, reaffirmed his country's commitment to providing biological materials obtained from cases of human infection to WHO Collaborating Centres rapidly and systematically, whenever that was viable. The model standard material transfer agreements annexed to the Framework clearly set out the obligations of the parties. Materials should be accompanied by the clinical and epidemiological information necessary for risk assessment. He requested WHO to continue providing, through its collaborating centres and without charge to national influenza centres, noncommercial diagnostic reagents and test kits to identify and characterize clinical

influenza samples so that reports could be submitted and appropriate measures taken. He also requested WHO to provide continued support for strengthening the capacity of laboratories serving as national influenza centres. He expressed support for the draft resolution, subject to the deletion of the fifth preambular paragraph.

Ms EKEMAN (Turkey) said that, although the experience of avian influenza A (H5N1) and pandemic (H1N1) 2009 had not been easy, it had been educational, demonstrating the need for a rapid, equitable, transparent and collective global response in the event of a pandemic. It had also made clear the need for absolute predictability. The Framework would provide the necessary structures to respond adequately to future pandemics, and the technical agreements reached should help to mobilize public support and combat scepticism about the effectiveness of the system. The Secretariat and Member States had again demonstrated their collective political will and commitment to overcome differences of opinion and focus on the underlying issue of public health. She particularly welcomed industry's recognition of corporate social responsibility and its agreement to undertake certain tangible commitments. The open and collaborative attitude of industry had been crucial to the compromise achieved. Attention must now turn to implementing the Framework and honouring the commitments assumed, building upon the success of the negotiations. She supported the draft resolution.

Dr McMILLAN (Bahamas) expressed appreciation for efforts made to ensure vaccine availability, diagnostic capability and antiviral medicine stockpiles for use in developing countries and countries affected by pandemics at affordable prices. The coordinating mechanisms used by WHO and PAHO during pandemic (H1N1) 2009 had reduced morbidity and mortality in the Bahamas.

Regional difficulties persisted with regard to identifying novel influenza viruses and other viral etiologies; the Caribbean region relied primarily on laboratory capacity at the Caribbean Epidemiology Centre. For a region comprising many small island developing States, regional cooperation was imperative, alongside the necessary in-country capacity for rapid response. She acknowledged human resource development activities sponsored by PAHO, but noted that maintaining current knowledge and capacity levels would require further training.

She expressed support for the draft resolution, with the deletion of the fifth preambular paragraph, and requested the Director-General to continue providing support to enhance preparedness and response mechanisms and expand regional and global networks, as the movement of people and trade across borders would continue to challenge public health systems. As a recipient of the benefits of sharing viruses and other technologies, the Bahamas requested those in a position to provide support to continue to do so, to the benefit of developing Member States.

Dr RUSLI (Malaysia) said that, given its commitment to share on an equal footing influenza viruses of human pandemic potential, Malaysia continued to support the WHO Global Influenza Surveillance and Response System by sending representative isolates to WHO Collaborating Centres for reference and research on influenza and for advanced antigenic and genetic analysis. Like all developing countries that contributed to the Network, Malaysia was concerned that benefits from the use of viruses should be shared fairly and equitably in support of public health. She therefore welcomed the Framework, which should provide a coherent, coordinated and unified global approach to ensuring that influenza viruses were available to the System for monitoring and developing vaccines, and for benefits such as antiviral medicines, technical knowledge and enabling developing countries to access such benefits more equitably. She supported the draft resolution, with the deletion of the fifth preambular paragraph. It was to be hoped that all concerned would implement and adhere to the Framework in order to prepare for future pandemics.

Mrs TOELUPE (Samoa) welcomed the Framework and expressed support for the draft resolution, with the deletion of the fifth preambular paragraph. She expressed appreciation for WHO's

assistance in facilitating access to vaccines, improved surveillance and laboratory capacity enhancement. She further acknowledged the support received from many development partners in the area of pandemic influenza preparedness.

Mr ROSALES LOZADA (Plurinational State of Bolivia) welcomed the conclusion of the negotiations on the Framework. He did not oppose the adoption of the Framework, but reiterated his country's concerns with regard to the lack of prohibition of the patenting of the influenza biological material and parts thereof shared with entities outside the WHO Global Influenza Surveillance and Response System, as set out in document A64/8 Corr.1.

Dr AGOUDAVI (Togo), welcoming the Framework, said that pandemic (H1N1) 2009 had enabled Togo to strengthen its epidemiological surveillance system. A national steering committee had been set up to manage pandemic response and had met weekly, focusing in particular on points of entry. An influenza laboratory had been established at the National Institute of Hygiene and had identified 29 cases of pandemic influenza A (H1N1) 2009 virus infection between May 2010 and April 2011. Donations of oseltamivir, personal protective equipment and sampling equipment had been received through WHO. Vaccine donations had allowed just more than 10% of the population to be vaccinated, mainly among high-risk groups. Togo faced numerous challenges, including maintaining surveillance, especially at points of entry, and mobilizing resources to implement its national response plan, but the Framework would enable them to be tackled.

Dr JUNG Sung-hoon (Republic of Korea) expressed support for the Framework. His Government had completed construction of a vaccine production facility in early 2009 and begun production later in the year, thereby helping to control pandemic (H1N1) 2009. In order to increase influenza vaccine supply, many companies, particularly from developing countries, should be encouraged to manufacture influenza vaccine. As too many donations might deter small companies from producing vaccine, a flexible approach to donation should be adopted, in the light of companies' specific circumstances. Collaboration between Member States was crucial in responding rapidly and effectively to pandemic influenza, and the Secretariat should continue to play a leading role.

Mr SEAKGOSING (Botswana), noting that sporadic cases and seasonal outbreaks associated with pandemic (H1N1) 2009 continued to be reported, said that his Government had established a multisectoral national task force for overall coordination of pandemic influenza preparedness and response. Technical working groups had been responsible for developing and monitoring the implementation of the national preparedness and response plan, and had made progress in a range of areas. In particular, a vaccination campaign against pandemic (H1N1) 2009 had reached more than 80% of the population. No new case had been confirmed since the 32 reported to WHO during the pandemic. He expressed appreciation to WHO and other partners for their technical support and donations, including vaccines.

Supporting the draft resolution but with the deletion of the fifth preambular paragraph, he emphasized the need for immediate implementation of the Framework and urged the Director-General to develop a coordinated programme to enhance preparedness in the African Region.

Dr LEWIS FULLER (Jamaica) said that she could accept the draft resolution with the deletion of the fifth preambular paragraph, but if the paragraph were to be retained, she would prefer the opening word to be "Recognizing" rather than "Considering" and would favour retention of the word "international" before "specialized access". The text of the draft resolution placed more emphasis on the sharing of influenza viruses than on access to vaccines and other benefits. Accordingly, and in the light of the Jamaican experience during pandemic (H1N1) 2009, she proposed the insertion of a new

subparagraph before existing subparagraph 4(2) to read: "to set up mechanisms to facilitate access, by countries in need, to vaccines and antiviral medicines through appropriate and adequate stockpiling and fair and affordable pricing of these products." Jamaica intended to join the international public health community in implementing the Framework.

Dr EZAATI (Uganda) endorsed the position of the Australian delegation. His country had participated in the negotiations in the Open-ended Working Group and expected the effective, fair and equitable application of the Framework, guided by the Advisory Group, in the interests of improved global preparedness and response to future influenza pandemics. He endorsed the Framework and pledged his country's cooperation in its implementation.

Dr MIYAGISHIMA (Office International des Epizooties), speaking at the invitation of the CHAIRMAN, said that, in conjunction with FAO, his organization had for several years been operating an initiative, known as the OIE/FAO Network of expertise on animal influenza aimed at facilitating the exchange of scientific information on animal influenza viruses, including the sharing of epidemiological data and virus sequences. Pandemic (H1N1) 2009 had highlighted the importance of collaborative research on animal and human influenza. The OIE/FAO network had consequently built on its past experience to launch a new project designed to boost research on swine influenza, although the fact that swine influenza was not a notifiable animal disease in many countries posed something of a challenge. OIE welcomed WHO's ongoing participation in major meetings of the network and was committed, through that mechanism, to continue contributing useful data to WHO's vaccine composition consultations and facilitating the timely selection and production of vaccines for human use, including those against zoonotic strains of influenza virus.

Ms SHASHIKANT (CMC - Churches' Action for Health), speaking at the invitation of the CHAIRMAN, said that agreement on the Framework was a milestone, as it instituted terms and conditions for the sharing of influenza materials with a view to infusing equity into WHO's virus-sharing scheme. The amount of annual monetary contributions and in-kind contributions required of the industry could have been set higher. Further, the granting of non-exclusive licences at affordable royalties or royalty-free to developing countries should have been listed as a stand-alone mandatory benefit in order to facilitate sharing of the knowledge, technology and know-how needed by those countries to counter an influenza pandemic.

Nevertheless, the Framework should contribute to better pandemic preparedness. The benefit levels might at some stage be reconsidered and improved. She called on the Secretariat and Member States to ensure that both the Framework and the accompanying Standard Material Transfer Agreements were implemented in a manner that protected and promoted public health and furthered the objectives of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

Professor Shan-Chwen CHANG (Chinese Taipei) said that, in 2009, Chinese Taipei had obtained pandemic (H1N1) 2009 vaccine strains from a number of sources, including WHO Collaborating Centres. With help from Japan, the United Kingdom and the United States of America, it had been able to manufacture enough pandemic (H1N1) 2009 vaccines to launch a mass vaccination programme and successfully control the outbreak. In the light of that experience, it welcomed the Framework for the sharing of influenza viruses and access to vaccines and other benefits. It also supported the establishment of an international stockpile of vaccines for influenza A (H5N1) and other influenza viruses with human pandemic potential, and was willing to increase its contribution to the production of such vaccines. Given that influenza vaccine production capacity remained insufficient worldwide, especially in developing countries, it welcomed the consensus reached in the Open-ended Working Group on a global arrangement under which countries would share influenza virus samples

in exchange for access to affordable medicines derived from those samples. Lastly, it looked forward to opportunities to participate in the global efforts to promote sharing of influenza vaccines and access to vaccines and other benefits.

Dr FUKUDA (Assistant Director-General), replying to the points raised, said that the reservations expressed by the delegate of Bolivia had been acknowledged and the Jamaican proposal noted. There appeared to be a strong consensus on the need to ensure effective implementation of the Framework through the efforts of Member States, civil society, industry and the Secretariat. The Secretariat was fully aware of the scope of the Framework and of its responsibility for its implementation, to which it would dedicate its efforts.

Mr SOLOMON (Office of the Legal Counsel), referring to the amendment proposed by the delegate of the United States to paragraph 1 of the draft resolution, said that there were several precedents, such as resolutions WHA63.16, WHA51.7 and WHA34.22, for the inclusion of a reference to Article 23 of the WHO Constitution so as to indicate the basis of the Health Assembly's authority to make recommendations to Members.

The DIRECTOR-GENERAL expressed her thanks to all those who had contributed to the discussion. The Framework was indeed an unprecedented achievement in the field of public health and a milestone for WHO. The wisdom, flexibility and diplomacy demonstrated by Member States in the interests of public health and global solidarity had served as the catalyst for that achievement in a spirit of compromise and political commitment to strengthening pandemic influenza preparedness as a collective responsibility. Many individuals had played vital roles in steering WHO towards such an historic achievement, and she paid tribute to the co-Chairs of the Open-ended Working Group, Ambassador Gomez-Camacho (Mexico) and Ambassador Angell-Hansen (Norway), with the support of José Ramón Lorenzo Dominguez (Mexico) and Sissel Hodne Steen (Norway), and the Chair and Vice-Chairs of the Intergovernmental Meeting on Pandemic Influenza Preparedness, as well as to Australia, Brazil and India for their important intersessional work conducted with the aim of facilitating the discussion of Member States. Those who had worked tirelessly behind the scenes in support of the co-Chairs also deserved special recognition and her Secretariat staff was likewise to be commended for its work. The successes achieved would have been unattainable without the efforts of National Influenza Centres, WHO Collaborating Centres and Essential Regulatory Laboratories. In that connection, she stressed that, as provided for in the Framework, no laboratory in the system would seek to claim any intellectual property rights over biological materials. She looked forward to the implementation of the Framework and to working with the Advisory Group. She also looked to Member States for further advice and guidance, as well as for both human resources and financial support, with a view to satisfactory implementation of the Framework within the shortest possible time frame.

The CHAIRMAN invited the Committee to consider the draft resolution as amended.

Dr PÁVA (Hungary) requested further time to consult on the new proposals for amendment of the text.

Mr SOLOMON (Office of the Legal Counsel), responding to queries from Mr SILBERSCHMIDT (Switzerland), confirmed that the amendment proposed by the delegate of the United States had no new legal implications since the Framework constituted a recommendation under Article 23 of the Constitution and the inclusion of a reference to Article 23 would merely clarify that point. Moreover, the Standard Material Transfer Agreements would be legally binding contracts.

Dr DAULAIRE (United States of America) said that additional negotiations would be needed in order to establish mechanisms of the kind called for in the new subparagraph to paragraph 4 proposed by the delegate of Jamaica. The proposed wording did not, therefore, serve the interests of immediate approval of the text.

Dr KEINHORST (Germany), supported by Ms SEDYANINGSIH (Indonesia), asked the delegate of Jamaica to consider withdrawing the proposal since the mechanisms concerned were provided for under section 6 of the Framework.

Dr LEWIS FULLER (Jamaica) said that section 6 of the Framework set out in Attachment 2 to document A64/8 gave no precise indication of who would be responsible for ensuring the availability of vaccines and antiviral medicines at affordable prices. However, having received a personal assurance from the Director-General that she herself would assume that responsibility, she agreed to withdraw the proposed amendment..

Following explanatory remarks by Dr KEINHORST (Germany), Ms STEEN (Norway), and Mr MARQUES DE LIMA (Sao Tome and Principe) concerning the wording of the new subparagraph 4(3) proposed by the delegate of Sao Tome and Principe, Dr YOUNES (Secretary) said that the subparagraph in question would read: "to report, on a biennial basis, to the World Health Assembly, through the Executive Board, on progress in the implementation of this resolution".

The draft resolution, as amended, was approved.[1]

Global immunization vision and strategy: Item 13.5 of the Agenda (Document A64/14)

Dr HWOAL (Iraq) said that, following the experience of pandemic (H1N1) 2009, countries had to have access to the latest research on pandemic influenza, and they should be able to exchange information and advice in the light of new findings generated in particular through continual analysis of the regional status of influenza A (H1N1). The use of vaccines, especially seasonal vaccines, should likewise be based on such research and analysis, as should the provision of necessary medicines and laboratory supplies. The right to obtain vaccines was another imperative. On that score, there should be no commercial monopoly and WHO must play an effective role. Capacity building for research purposes was another fundamental requirement, together with institutional capacity building for vaccine production. He looked forward to systematic improvements in all those areas in order to strengthen implementation of the International Health Regulations (2005) and the capacity of public health systems for coping with and preventing epidemics and crises. To that end, effective partnerships must be built with all concerned parties.

Mr CHIREH (Ghana) recalled that it was as a result of the extraordinary progress in the field of immunization that no child in Ghana had died from measles since 2003. Other vaccines provided under the Expanded Programme on Immunization had also significantly contributed to the reduction in childhood morbidity and mortality, and the introduction of a pentavalent vaccine in 2002 had further improved the health status of Ghanaian children. Ghana therefore proposed to introduce the pneumococcal and rotavirus vaccines into its Expanded Programme on Immunization and a second-

[1] Transmitted to the Health Assembly in the Committee's third report and adopted as resolution WHA64.5.

dose measles vaccine into its routine immunization programme. Plans were also under way to introduce the meningitis A conjugate vaccine in the northern part of the country. Those measures would put Ghana further on track towards the achievement of Millennium Development Goal 4 (Reduce child mortality). Committed as it was to the ownership and long-term sustainability of its immunization programme, Ghana would continue to contribute to the cost of vaccines with established budget lines. It appealed to donor partners, however, to step up their efforts in the fight against unnecessary deaths in developing countries from vaccine-preventable diseases.

Mrs BADJIE (Gambia) said that her country's efforts to protect its population against vaccine-preventable diseases had been productive. Indeed, it had been awarded a certificate by the GAVI Alliance for having maintained its coverage with three doses of diphtheria-tetanus-pertussis vaccine above 90% over the past five years. It had attained poliomyelitis-free status in 2004 and had conducted five rounds of national immunization days against the disease in 2010 and a further two in 2011, attaining coverage of more than 95% in each round. Immunization against yellow fever had been routinely provided since 1979, with an administrative coverage of 92% attained in 2010; the administrative coverage for measles was also 92%. Pneumococcal conjugate vaccine had been added to its Expanded Programme on Immunization in 2009 and the rotavirus and meningitis A vaccines would be introduced under its next comprehensive multi-year plan, which had been developed with WHO's technical and financial support. The main challenge concerned the availability of vaccines without the support of the GAVI Alliance. Gambia would nevertheless continue to ensure payment of the co-financing allocation to the GAVI Alliance.

Dr OBARA (Japan) fully recognized the importance of both the Global immunization vision and strategy to improving public health worldwide and to the strengthening and monitoring of health systems. Japan therefore welcomed the strategic direction for the Decade of Vaccines outlined in the report. It actively supported vaccination not only through work with WHO and UNICEF but also through bilateral assistance, Expanded Programme on Immunization activities and vaccine donation. It was actively cooperating with international organizations to eradicate poliomyelitis and, at the national level, it was working vigorously on measures to counter vaccine-preventable diseases. One domestic result of those measures had been a decline of 96%, from 2008–2010, in cases of measles, which it was seeking to eradicate by 2012.

Dr SHONGWE (Swaziland) welcomed the Global immunization vision and strategy 2006-2015 and the work to develop a global vaccine action plan. His Government's political commitment to achieving vaccine and immunization goals was evidenced by its procurement of all vaccines. He urged WHO to increase its support to the GAVI Alliance.

Dr BIRINTANYA (Burundi), speaking on behalf of the Member States of the African Region, said that three-dose diphtheria-tetanus-pertussis vaccination coverage in the Region had increased over the past decade to 85% overall and to more than 90% in 20 countries. Measles vaccination coverage had similarly risen to 86% in 26 countries and routine vaccination against yellow fever had been introduced in 23 countries. Vaccines against hepatitis B and *Haemophilus influenzae* type b had been introduced in the past two years and the hope was that, with support from the GAVI Alliance, the pneumococcal conjugate vaccine thus far introduced in three countries would eventually be available throughout the Region. The meningococcal A conjugate vaccine had also been launched in three countries. Other measures to counter vaccine-preventable diseases included the strengthening of surveillance networks and the African Vaccination Week initiative.

Infection with wild poliovirus, measles and yellow fever had nonetheless proved persistently difficult to contain in certain countries. Lack of finance was part of the problem; local resources were

often limited and international resources were unpredictable, particularly in times of economic crisis. He therefore strongly endorsed the Decade of Vaccines in the hope that it would prompt a new wave of international action in support of vaccination, which required strong political and financial commitment.

Professor LOUKOU (Côte d'Ivoire) said that measures taken in his country in the context of the Global immunization vision and strategy had resulted in an improvement in routine vaccination indicators since 2008; measles vaccination campaigns and awareness weeks had been organized; the *Haemophilus influenzae* type b and hepatitis B vaccines had been included in the Expanded Programme on Immunization to reduce child mortality; and the surveillance of invasive bacterial diseases and rotaviral diarrhoea had been strengthened through the establishment of a sentinel site network. The introduction of pneumococcal and rotavirus vaccines was also envisaged under the newly elaborated multi-year plan for 2011–2015. He supported the Decade of Vaccines and appealed for a resumption of the support that had been suspended during the country's recent crisis. Its vaccination activities could then be effectively pursued.

Mr FIFE (Norway) said that the lives of millions of children had been saved over the past decade by the accelerated introduction of new vaccines in the poorest countries and by reaching more children with immunization services. The development of a global vaccine action plan as part of the Decade of Vaccines was therefore a most welcome initiative for maintaining the necessary focus and commitment to vaccination. Norway's commitment to immunization activities was demonstrated by its high levels of official development assistance. It was one of the largest contributors to the GAVI Alliance and was working with partners with a view to fully funding the GAVI Strategy 2011–2015. Other beneficiaries of its support included the Global Polio Eradication Initiative and the Measles Initiative. The most cost-effective vaccination was that against measles and he therefore called for continued efforts to eliminate the disease. It was also worth noting that immunization was a centrepiece of the United Nations Secretary-General's Global Strategy for Women's and Children's Health.

Norway was working closely with partners to close the financing shortfall facing the GAVI Alliance. It was imperative, however, for all stakeholder groups to contribute to that endeavour in order to secure the lowest possible vaccine prices.

Dr SOE LWIN NYEIN (Myanmar), speaking on behalf of the Member States of the South-East Asia Region, agreed with the five overarching objectives referred to in the report. It was crucially important to strengthen routine immunization and standardize expanded programmes on immunization in the Region, where pentavalent vaccine was not available in all countries owing to financial constraints. More emphasis should also be placed on cross-border vaccine-preventable diseases and response, while financial sustainability for vaccine security must be explored with regional foundations, philanthropic organizations and interested partners. The Region was striving hard to achieve good-quality immunization and high rates of routine immunization coverage. WHO's technical collaboration and financial support was needed to provide for quick reviews or sentinel surveillance for the achievement of quality immunization. Member States had greatly benefited from the regular meetings of immunization programme managers, whose reports could well yield generic information for possible inclusion in the Region's work plan for the next biennium. He suggested that information derived from reports of other WHO expert groups and workshops on immunization might also be used to develop a technical compendium that would serve as a useful reference document for Member States.

Dr MELNIKOVA (Russian Federation) said that the considerable progress achieved in tackling vaccine-preventable diseases was in large part due to the activities of WHO and UNICEF in such areas

as accelerated immunization, child vaccination coverage and disease prevention. Vaccine accessibility was a particular problem in countries with underdeveloped health systems and insufficient resources to fund the high cost of vaccines. Her country therefore welcomed the Decade of Vaccines and supported the global vaccine action plan initiative which should serve to overcome the obstacles to the achievement of the aim of reducing global morbidity from vaccine-preventable diseases. Public support was essential to the success of any immunization programme. Mass immunization had enabled her country with its aim of becoming measles-free. Morbidity due to hepatitis B had also been reduced. All national strategies should incorporate the measures set forth in the Global immunization vision and strategy as a guarantee of success in the efforts to strengthen health systems and improve immunization programmes.

The meeting rose at 12:00

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