SIXTY-NINTH WORLD HEALTH ASSEMBLY

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COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE SIXTH MEETING

Palais des Nations, Geneva
Wednesday, 25 May 2016, scheduled at 18:30

Chairman: Ms T. KOIVISTO (Finland)

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COMMITTEE A

SIXTH MEETING

Wednesday, 25 May 2016, at 18:40

Chairman: Ms T. KOIVISTO (Finland)

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Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: Item 14.2 of the agenda (documents A69/22, A69/22 Add.1 and A69/22 Add.2)

The CHAIR OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK 2016 REVIEW GROUP said the Review Group was undertaking a first review of the Pandemic Influenza Preparedness (PIP) Framework. Recent outbreaks of communicable diseases including influenza had underscored the vulnerability of many countries to public health emergencies that threatened global health security. The emergence of another influenza pandemic was inevitable, and Member State preparedness was therefore vital. The PIP Framework had been founded on the key principles of virus and benefit sharing on an equal footing; and transparent and inclusive implementation. The Review Group had had three overarching questions to answer: What had the PIP Framework achieved since its adoption? How well had it helped the world prepare for a pandemic? What were the challenges and possible solutions?

The Review Group had spoken to key stakeholders and had invited Member States and other stakeholders to in-person consultations. The PIP Framework aimed to increase pandemic influenza preparedness through an innovative public-private partnership. Information received thus far showed that implementation was proceeding steadily and effectively and all stakeholders had worked together to improve global preparedness for an influenza pandemic. Industry manufacturers had paid 95% of partnership contributions and WHO had secured advance access to three times more pandemic vaccines and antivirals than in 2009, through Standard Material Transfer Agreements 2. She described ongoing capacity-building activities under the PIP Framework, including the detection, monitoring and sharing of viruses with pandemic potential; analysing and sharing viruses for risk assessment; disease burden studies; strengthening regulatory capacity; planning for deployment of pandemic supplies; and efficient risk communication during a pandemic. The PIP Framework had received extraordinary commitment from: Member States, which continued to provide financial and political support to the essential work of public health laboratories; industry, which had contributed funding and provided real-time access to life-saving pandemic vaccines and other pandemic material; and civil society, which had contributed to discussions on how to strengthen the initiative. The Global Influenza Surveillance and Response System was the backbone of the PIP Framework and Member States should ensure the systematic and timely sharing of all viruses with pandemic potential in that System for essential risk assessment. The benefit-sharing mechanism had demonstrated its effectiveness, although it faced the challenges of real-world implementation, including barriers to the timely shipping of viruses. Clues to the emergence of the next pandemic virus could be missed if viruses were not shared in the Global Influenza Surveillance and Response System. Payment of partnership contributions must continue or improve as the sustainability of the system required equity and fairness.

The Review Group had considered goals and processes shared with other WHO programmes and instruments such as the International Health Regulations (2005) and the Global Action Plan for Influenza Vaccines, noting the relevance of the IHR Review Committee recommendation on sharing

of genetic sequence data. Some of the important work under the Global Action Plan for Influenza Vaccines could continue after its conclusion. It remained to be seen whether the PIP Framework or the Global Influenza Surveillance and Response System could or should be considered specialized instruments under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. The Review Group was monitoring the situation through the PIP Framework Secretariat acknowledging the mandate of that body to study the potential public health implications of the Nagoya Protocol and make appropriate recommendations. Pandemic preparedness was a cross-cutting, multidisciplinary issue and an effective response to a major infectious health risk required solidarity between Member States, industry, public health laboratories, civil society and donors. The PIP Framework worked with all stakeholders and was therefore a model for cooperation.

Ensuring the PIP Framework remained relevant was a key overarching issue, given the difficulty in maintaining focus on one disease against competing public health emergencies. Pandemic influenza preparedness supported global preparedness for other communicable diseases and the PIP Framework was likely to provide several indirect benefits including ongoing projects in Member States. Successful preliminary outcomes had driven discussions on expanding the PIP Framework to include seasonal influenza, which would have implications for the Framework, and on using it as a model for other infectious pathogens. Influenza viruses caused seasonal and epidemic outbreaks and were a constant pandemic threat. Viruses were studied for severity, transmissibility and population immunity to assess risk based on seasonal virus analysis, and pandemic vaccine production capacity was based on successful seasonal vaccine production capacity. Several linkages therefore supported expanding the Framework to all influenza viruses posing a risk to human health, provided that did not overburden the Global Influenza Surveillance and Response System laboratory network, and following a review of benefit sharing implications. Expanding the PIP Framework to other pathogens or using it as a model for the sharing of other pathogens was an interesting but complicated option that raised considerable challenges. The Review Group had instead highlighted principles that could be shared, such as that of equal footing, and discussions on accounting for the specific characteristics of specific pathogens.

Genetic sequence data had assumed an increasingly prominent role in influenza research and vaccine production due to advances in genomics. Broad discussions had been held with industry, genetics databases and civil society to decide how best to handle genetic sequence data under the PIP Framework. The PIP Advisory Group would assess the work done and attempt to offer a way forward on the issue. Health crises were unavoidable and affected vulnerable populations. It was therefore critical that countries establish systems, practices and procedures to ensure equitable access to life-saving supplies; that the weakest countries received support to strengthen capacities to prepare for and respond to public health emergencies; that the world was prepared for health emergencies; and that the Review Group received stakeholder input to ensure successes and challenges were understood.

The representative of CHINA commended the Organization's efforts to promote the PIP Framework and described steps taken in his country to implement it, including the signing of a Standard Material Transfer Agreement and sharing of viruses and information.

The representative of BRAZIL said that recent cases of pandemic influenza A(H1N1) in Brazil had exemplified the importance of an effective PIP Framework, particularly in sharing influenza strains. The PIP Framework had been successful in enabling virus sample and benefit sharing on an equal footing and establishing a positive, dynamic relationship between the public and private sectors. He agreed that the PIP Framework review should be comprehensive, transparent and independent, and involve Member States, to assess successes and areas for improvement. It was crucial that implementation of the PIP Framework adapted to technological changes. He was pleased that the equal footing principle was highly prioritized by the Review Group, and that the Review Group was studying the evolving aspects of technology, particularly genetic sequence data of viruses. The PIP

Framework and other mechanisms should apply to new genetic sequencing methodologies and treat them as material biological samples.

The representative of SOUTH AFRICA said that partnership contributions had helped target countries to develop capacities to detect and monitor novel influenza and other respiratory pathogens. She commended WHO for promoting the expansion of global seasonal influenza vaccine production and called on the Organization to continue its leadership in facilitating new technologies and research to ensure the required number of doses. She commended production agreements reached with vaccine manufacturers, progress towards a web portal, and financial and technical data reporting. However, few members of target populations in low- and middle-income countries could afford influenza vaccines. As high influenza vaccine coverage was important for pandemic preparedness, it was vital that all Member States implemented measures to fulfil the requirements under the PIP Framework. Her Government was committed to strengthening the Global Influenza Surveillance and Response System.

The representative of VIET NAM appreciated the support provided to developing countries to increase influenza vaccine production capacity through access to technology and hoped that would continue under the PIP Framework. Sample sharing mechanisms needed to be reviewed, as did the right of countries to consult on the use of samples and assess influenza virus mutations. WHO should provide information on influenza vaccine efficacy and safety, prepare vaccine stockpiles and prioritize high-risk countries. He described steps taken by his country to prepare for pandemic influenza, including vaccine development and surveillance.

The representative of the ISLAMIC REPUBLIC OF IRAN was concerned that disbanding the Global Influenza Surveillance and Response System and grouping influenza with other diseases with pandemic potential would jeopardize any pandemic or seasonal influenza response. He encouraged WHO to recognize the System's value in mitigating seasonal influenza and events during an influenza pandemic. He appreciated the Organization's support to his country in influenza vaccine production; however, more technical assistance was needed to complete that process. WHO should more effectively engage countries with good surveillance and response capacities and contribute to burden estimation and surveillance studies supporting vaccine production and response assessment.

The representative of IRAQ called for epidemiological surveillance to be fully integrated into laboratory surveillance; and said WHO should facilitate the exchange of expertise within and between regions. He also requested that focus be placed on the Organization's role in joint research and in the development of national action plans; ensuring the sustainability of materials and other requirements for influenza prevention and control and facilitating the incorporation of pandemic preparedness into primary health care.

The representative of JAPAN said that timely sample sharing was essential to ensure a prompt response to a global pandemic influenza and the PIP Framework had recently played an extremely important role to this end. The Secretariat, the PIP Framework Advisory Group and other relevant bodies needed to analyse and monitor outcomes and allocations of partnership contributions to ensure their appropriate and effective use in line with the Advisory Group's recommendations. Sharing data in the spirit of the PIP Framework was important, although genetic sequence data needed to be handled with special caution. The Secretariat and the Advisory Group should strive for greater transparency and fairness in their leadership, and in that context should continue consultations with Member States and relevant industries. The 2016 PIP Framework review would ensure the efficiency and effectiveness of that Framework, which should be aligned with other WHO emergency programmes. WHO should focus on seasonal influenza preparedness as the foundation of pandemic

preparedness. The PIP Framework and the Global Influenza Surveillance and Response System should be fully integrated into the new WHO Health Emergencies Programme.

The representative of the DOMINICAN REPUBLIC said the recommendations proposed by the Review Group would require open access to genetic sequence data without undue restrictions for scientific research. The products and benefits of genetic sequence data should also be shared. He described recent steps taken by his country to implement the PIP Framework, including exchanging genetic sequence data through the FluNet platform and working with PAHO to improve the application of new case definitions. He emphasized the relationship between the PIP Framework and the International Health Regulations (2005) and, recognizing that developing countries required the Organization's help to strengthen laboratory, surveillance and monitoring capacities, he welcomed the upcoming visit to his country.

The representative of BAHRAIN said the report reflected the progress made in the fight against pandemic influenza. He described measures implemented in Bahrain to reinforce pandemic influenza preparedness and strengthen laboratory capacity, including the establishment of a National Influenza Centre to promote virus and benefit sharing.

The representative of the REPUBLIC OF KOREA acknowledged the Secretariat's effort to strengthen pandemic influenza preparedness and response. His country contributed to virus sharing, but said stronger advocacy for Standard Material Transfer Agreements 2 was needed to ensure standard materials were delivered transparently and efficiently.

The representative of PARAGUAY said that the PIP Framework was highly relevant for her country and its surveillance system, given the latent risk of a potential influenza pandemic. Continued support from WHO was therefore crucial for laboratory and surveillance capacity-building. Support was needed to incorporate virus sequencing and antiviral drug resistance monitoring as routine practice in countries without that infrastructure. Regional exchange strategies for influenza viruses with pandemic potential should be strengthened, and agile and secure strain exchange mechanisms were needed. Ensuring access to vaccines in future pandemics was vital, particularly in countries with small populations. This required flexible financing mechanisms, especially in developing countries. Surveillance systems should be continuously improved and assessed by a team of international experts, one of whom should originate from the Region of the Americas given the similar needs of countries in the region.

The representative of EGYPT said that as developing countries were most affected by seasonal influenza epidemics, WHO should increase technical and financial support to those countries by implementing the PIP Framework; improving sustainability and laboratory capacity to analyse genetic sequence data; introducing new technologies; providing competent staff; enacting vaccine policy; and ensuring cost effectiveness. Given the lack of knowledge of the PIP Framework among smaller vaccine manufacturers, WHO should strengthen its PIP Framework advocacy plan, which her Government would support. Finally, she asked whether vaccine stockpiles were sufficient to cover upcoming influenza seasons and potential pandemics, and how the fair distribution of vaccines would be monitored.

The representative of PANAMA expressed her country's commitment to national capacity-building in preparedness and response to potential high-risk public health events; the global fight against polio and smallpox; and the Global Action Plan on Antimicrobial Resistance, and welcomed technical support from WHO, PAHO, CDC and other agencies. Countries needed to promote migrant health, which was difficult given migrants' unusual and temporary situation. Timely response to their

health needs, especially among irregular migrants, required resources at all levels and better monitoring from United Nations specialized agencies.

The representative of THAILAND suggested extending the PIP Framework and benefit sharing to cover seasonal and potential pandemic influenza viruses. Partnership contributions should be increased according to inflation and yearly running costs; extended to cover research and development bodies using and benefiting from biological materials; and used to strengthen seasonal influenza vaccine production capacities in developing countries.

The representative of MEXICO commended the information that had been provided on the many areas covered by the PIP Framework, and praised the wide variety of approaches discussed, particularly innovative partnerships with the private sector. He urged countries to continue cooperating with WHO to strengthen epidemiological surveillance capacities to ensure viruses were efficiently identified in the event of pandemic. Early warning was the best way to ensure preparedness.

The representative of CANADA said that future implementation of the PIP Framework would be affected by issues such as genetic sequence data handling, new technologies and linkages with the International Health Regulations (2005) and other global agreements. The outcomes from the 2016 review would inform future efforts, particularly on genetic sequence data of virus samples and benefit sharing, and improve global implementation of the PIP Framework while considering virus sharing realities.

The representative of SWAZILAND, speaking on behalf of the Member States of the African Region, acknowledged the global consultation undertaken on the PIP Framework. He endorsed the financial report on the use of partnership contributions, and welcomed the allocation of 70% of those contributions to building laboratory and surveillance capacities, which would enhance detection and monitoring capacities for influenza and other respiratory viruses. Countries would therefore be able to report to WHO using virological and epidemiological data from event-based surveillance. Despite the designation of National Influenza Centres in Zambia and the United Republic of Tanzania, significant geographic and funding gaps remained a challenge in the Region. He appreciated the increase in global vaccine production capacity; the number of developing countries with approved vaccines; and the availability of dose-sparing technologies. Public-private partnerships and agreements with other academic and research institutions under the PIP Framework provided access to vaccines, antivirals and other pandemic material. Information on the PIP Framework should be shared with all stakeholders. Vaccine-related genetic sequence data should be widely shared; however, Member States should also consider regulatory matters and intellectual property, monitoring methods, biosecurity and biosafety. All countries in his Region remained committed to influenza monitoring and surveillance, enhancing preparedness, further harmonization with existing mechanisms at all levels, and continued advocacy to strengthen preparedness, sharing of influenza viruses and access to vaccines and other benefits.

The representative of INDONESIA praised the level of support provided through partnership contributions to improve event-based epidemiological and virological surveillance and maintain key achievements and capacities. Recipient countries should also develop exit strategies to ensure sustainability of national capacity. She was concerned that projected global vaccine production capacity would not meet requirements in the event of a pandemic and urged the Director-General to encourage the sharing of benefits, including technology, to improve production capacity. She appreciated efforts made by the PIP Framework Secretariat to negotiate with international influenza vaccine manufacturers and diagnostic companies to ensure global protection in an influenza pandemic. All Member States should comply with all PIP Framework mechanisms, and the 2016 PIP Framework

review should be fair, transparent and equitable. She reiterated the importance of including the sharing of genetic sequence data of viruses in the PIP Framework.

The representative of the RUSSIAN FEDERATION noted the significant progress made through the implementation of the PIP Framework, including increased laboratory capacity at the global and national level through the expansion of the WHO reference laboratory network and increased global influenza vaccine production capacity. Research into innovative influenza vaccines should be stepped up. Work on the conclusion of agreements to allow developing countries access to vaccines and antivirals had intensified; WHO experts and legal consultants should help to encourage manufacturers to sign Standard Material Transfer Agreements. It was important that the WHO Technical Working Group promptly complete its guidance on optimal characteristics for a genetic sequence data sharing system, which could potentially be used to manufacture vaccines and other products. The guidance should consider legal and scientific aspects and the consequences for public health and the biosecurity of new developments in synthetic biology linked to the creation and use of influenza viruses with pandemic potential. She underscored the need for a more thorough, transparent and inclusive analysis of the implementation of the PIP Framework by the Review Group and supported the Advisory Group's recommendations to the Director-General on the scope and terms of reference for the 2016 review.

The representative of the UNITED STATES OF AMERICA noted that some countries and National Influenza Centres were experiencing a lack of funding and government commitment. She urged WHO and partners to continue prioritizing global influenza preparedness and response, which had proved vital to collective global health security efforts. Her Government would continue to collaborate with WHO to strengthen the PIP Framework in areas such as genetic sequence data handling and harmonizing the PIP Framework with existing global health instruments. She commended the multistakeholder consultation undertaken as part of the 2016 PIP Framework review.

The representative of the UNITED REPUBLIC OF TANZANIA said that although partnership contribution funds received by Tanzania had been directed at strengthening influenza response, surveillance and response systems had been strengthened overall. The Review Group should consider how to increase awareness of the PIP Framework so it could be effectively implemented alongside other initiatives including the Global Health Security Agenda. It should address the slow funding flow that led to delays in workplan activities in some countries and consider expanding the PIP Framework model to include other infectious diseases.

The representative of TUNISIA noted the efforts to conclude agreements with producers of genetic material. The role of WHO under the PIP Framework should be to strengthen national laboratory capacities, particularly the level of security under which virological analyses were undertaken, and to equip laboratories with new technologies such as those for genetic sequencing. It was also important to carry out research on the influenza disease burden to design effective national vaccination policies. WHO regional offices should continue to provide support to national efforts.

The representative of ZAMBIA noted the different measures taken by her Government to combat influenza, including designation of a National Influenza Centre and a strengthened surveillance system. Recognizing the ongoing review of the PIP Framework, she expressed support for that Framework.

The observer of CHINESE TAIPEI said that the PIP Framework should be the basis for addressing novel and seasonal strains of the influenza virus and the sharing of viruses and other materials on an equal footing, and urged all partners to support it. In Chinese Taipei, future outbreaks would be addressed by increasing vaccination coverage and production capacity.

The representative of the WORLD MEDICAL ASSOCIATION, speaking at the invitation of the CHAIRMAN, recognized the many concerns that arose during influenza outbreaks, and said physicians should have access to reliable information through pre-established channels. All stakeholders should be involved in the development of national preparedness plans, with governments ensuring access to vaccines, and health-care professionals delivering frontline services. Health system strengthening was essential, as the provision of all health services should be maintained even during an outbreak. Finally, lessons should be learned from the Ebola virus disease epidemic on patient management and the need for deaths to be investigated.

The EXECUTIVE DIRECTOR ad interim (Outbreaks and Health Emergencies) welcomed Member States' support for the PIP Framework and thanked Dr Kaseba-Sata (Zambia) for her work as Chair of the Review Group. The Secretariat was actively engaged in advocacy for further Standard Material Transfer Agreements 2 and had already assigned 4 vaccine manufacturers, 41 academic research institutes and 1 diagnostic producer, with a further 7 agreements being considered. Furthermore, the rumour regarding the disbandment of the Global Influenza Surveillance and Response System was untrue. WHO greatly valued its significance and would continue to ensure its central role. He noted the requests for a range of technical assistance from the Organization on the burden of disease, vaccine production and access to new technologies. With regard to transparency, the Advisory Group had webcast its proceedings, met face-to-face with missions and rapidly produced reports, but WHO welcomed any further suggestions on how to improve. In relation to the quantity of vaccines available for pandemic influenza, he recognized that substantially more was available than 10 years previously, but that quantity was still not sufficient. Work would continue on increasing the proportion of the vaccine available to WHO and on ensuring it could go further, for instance, through dose-sparing approaches. Lastly, genetic sequence data was a complex issue but one of central importance on which progress would be made.

The Committee noted the reports.

Smallpox eradication: destruction of variola virus stocks: Item 14.3 of the agenda (document A69/23)

The representative of EGYPT said that a deadline had still not been set for destruction of variola virus stocks, despite convening a Scientific Working Group and an Independent Advisory Group on public health implications of synthetic biology technologies related to smallpox to provide evidence for that decision to be made. Given that WHO guidelines prohibited the use of a recreated variola virus in the development of diagnostics and vaccines, it was absolutely mandatory that existing stocks be destroyed. As the completion and review of ongoing projects on antiviral agents against smallpox would take three years, the deadline for destruction of existing stocks should be established as quickly as possible.

The representative of THAILAND said that strengthening public health emergency preparedness and response, including ensuring vaccine supply, was the first line of defence against any emerging disease outbreaks and against bioterrorism. She noted with concern the delay in agreeing a deadline for the destruction of existing variola virus stocks and requested that the issue be discussed at the Seventieth World Health Assembly. Furthermore, manufacturers of smallpox vaccines should be obliged to contribute to the global stockpile. It was also important to apply the lessons learned from the PIP Framework to pandemic smallpox preparedness.

The representative of AUSTRALIA said his Government supported the recommendation to enhance the technical capacity of the Advisory Committee on Variola Virus Research to include new technologies and synthetic biology, and commended the review of WHO's recommendations

concerning the synthesis and use of variola virus DNA. Carefully managed stocks of live variola virus should be retained for the further development of countermeasures and caution should be exercised in making a decision on the destruction of those stocks. He supported the proposal to include a substantive item on the destruction of variola virus stocks on the provisional agenda of the Seventy-second World Health Assembly.

The representative of NAMIBIA, speaking on behalf of the Member States of the African Region, was concerned by repeated delays in setting a date for the destruction of existing variola virus stocks despite previous agreement. She sought assurance that no undue risks would arise from that delay, and requested ongoing reporting on inspections of the variola virus repositories. In light of the evolving nature of the risk of re-emergence of smallpox, she urged WHO to investigate reports on the re-emergence of monkeypox in Africa, which could impact ongoing research. She welcomed the proposal to include members with appropriate expertise in new technologies on the Advisory Committee and the recommendation that three years be granted to complete ongoing research projects.

The representative of the RUSSIAN FEDERATION supported continued work to create a mechanism for rapid access to WHO's emergency stockpile of smallpox vaccine, but said discussions should be conducted more openly, and noted that the question of whether WHO should establish an emergency stockpile of drugs for smallpox treatment remained open. The variola virus stocks held in the Russian Federation had been used to produce means for diagnosing, preventing and treating smallpox which could be supplied to WHO if required. He supported the conclusions and recommendations of the 17th meeting of the Advisory Committee, including the need to create a network of laboratories dealing with smallpox diagnostics which did not need live variola virus and to expand expert knowledge in the fields of laboratory biosecurity and diagnostics. The terms of reference of the Advisory Committee were broad enough to include the area of synthetic biology technology. If the Advisory Committee decided to recruit additional members with expertise in new technologies, the Russian Federation would put forward a candidate.

The representative of the UNITED STATES OF AMERICA, noting the information on synthetic creation of variola virus provided by the Independent Advisory Group, said the destruction of variola virus stocks could no longer be considered irrevocable. In that light, changes should be made to preparedness and response plans. All appropriate research should be completed prior to any decision on destruction of stocks. Therefore, the Advisory Committee should immediately consider new research to protect against the risk that the variola virus could be synthetically created, altered or misused. Additional experts in the fields of synthetic biology and emerging biotechnology should be added to the Advisory Committee. Finally, the Health Assembly should reconsider the agenda item on destruction of variola virus stocks in five years, or whenever it warranted revisiting. Furthermore, his Government welcomed the biannual inspections of the two WHO repository laboratories, and the transparent nature of inspection reports.

The representative of NORWAY said that his Government would not support a decision on the destruction of variola virus stocks at the current Health Assembly. Given the need to further study the implications of synthetic biology relating to smallpox, he was in favour of including smallpox and the destruction of variola virus stocks on the provisional agenda of the Seventy-second Health Assembly.

The representative of IRAQ said that all research should continue under the sponsorship of WHO, to ensure progress towards global health security.

The representative of GEORGIA stressed that smallpox remained a threat to the global community as vaccination campaigns had ceased and variola virus genetic sequencing had been completed. Public health preparedness should be strengthened by including synthetic biologists in the

Advisory Committee; and by improving diagnostics and treatment. Existing variola virus repositories should be maintained for the development of new countermeasures. WHO should conduct a review in five years – or whenever research goals or new developments warranted – to allow time for researchers to complete their work and for the Advisory Committee consider that new research. At the current time, he opposed the destruction of variola virus stocks, but said his Government would continue to work with WHO and Member States on the issue.

The representative of CANADA recognized the limited value of retaining stocks of variola virus but acknowledged that security concerns remained, particularly developments in synthetic biology. The Director-General should seriously consider the recommendations of the Independent Advisory Group and the Advisory Committee, and the latter should continue considering the implications of synthetic biology. Her Government supported the inspections of declared stocks, including the provision of technical experts as needed, and she looked forward to receiving the reports on the variola virus repositories.

The representative of ARGENTINA noted the Independent Advisory Group's recommendations on the need for increased preparedness and knowledge of biosafety and biosecurity given the possible synthesis and re-emergence of the variola virus. The Advisory Committee needed more expertise on new biotechnologies and synthetic biology, and it should expand its field of inquiry before considering the destruction of existing variola virus stocks.

The representative of the ISLAMIC REPUBLIC OF IRAN recalled decision WHA64.11 prohibiting genetic experiments on smallpox and three separate deadlines set by the Health Assembly for destroying remaining variola virus stocks, none of which had been met. All necessary research requiring live variola virus had been completed and any further studies would be of limited benefit to public health. WHO should therefore exercise leadership in destroying the remaining stocks, end authorization for new research involving the live variola virus, and guarantee universal and equitable access to all existing research outcomes. Genetic engineering of the variola virus must be prohibited and enforcement strictly monitored. Developments in synthetic biology did not change the fact that stocks should be destroyed, nor did the recommendation to revise the current rules on the use of synthetic material. WHO must immediately set a deadline for the destruction of variola virus stocks.

The representative of INDONESIA strongly supported the destruction of remaining variola virus stocks in order to achieve global health security. Given the importance of biosafety and biosecurity in the destruction process, WHO must provide support for a global notification system. He asked WHO to develop recommendations on synthetic biology technologies and assured the Health Assembly that no Indonesian institution would stock the variola virus.

The representative of the REPUBLIC OF KOREA recognized that advancements in synthetic biology had increased the risk that smallpox would re-emerge. More research in that area, as well as on diagnostic tests, animal models, new vaccines and antivirals would be needed, but prevention and response must remain priorities. Immediate destruction of variola virus stocks could reduce response capacities: a better decision could be made in four to five years, once sufficient research had been conducted. His Government would seek to incorporate the revised biosafety rules into national biosafety regulations.

The representative of CHINA noted that important progress had been made in the development of early and fast diagnostic methods, antivirals and new vaccines, which had led to the development of important safeguards. The pressing issue was how to effectively prevent the re-emergence of smallpox. She supported bringing experiments with live variola virus to completion as soon as

possible, quickly reaching a consensus on destroying stocks and strictly prohibiting artificially synthesized variola virus.

The representative of JAPAN, while sharing the goal of destroying variola virus stocks, supported continued research in order to develop countermeasures to a potential synthetic or enhanced strain, given the serious risk of the virus being used for bioterrorism. Appropriate experts should be included on the Advisory Committee. While progress should be reviewed in a timely and appropriate manner, flexibility was needed regarding the timing of the next review. A balanced approach would be required when deciding on the destruction of remaining variola virus stocks.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said it was essential to complete ongoing research and further consider the implications of synthetic biology before the Health Assembly should discuss the destruction of variola virus stocks, though it should be discussed within a maximum period of five years. She agreed that members with expertise on emerging biotechnologies and synthetic biology should be added to the Advisory Committee.

The EXECUTIVE DIRECTOR ad interim (Outbreaks and Health Emergencies) assured Member States that the forthcoming repository inspection reports would be made available on the Organization's website. He noted the comments welcoming the addition of new members with expertise on emerging biotechnologies to the Advisory Committee. Although the Secretariat had proposed not to reopen discussion on destruction of variola virus stocks until the Seventy-second World Health Assembly in 2019, the Advisory Committee would nonetheless continue to meet annually, and repositories would still be reviewed biannually. Recognizing the divergent views on when next to review the issue, he said the Secretariat's proposal of three years provided a middle ground and hoped it would be acceptable to the Health Assembly.

The representative of THAILAND said her proposal of including a substantive item on smallpox on the provisional agenda at the Seventieth World Health Assembly, rather than the Seventy-second had not been formally accepted or rejected. Waiting more than one year between reviews would put the world at greater risk. An alternative would be to include an annual progress report instead of a substantive item.

The DIRECTOR-GENERAL said that if new members were to be added to the Advisory Committee as requested, one year may not be enough time to deliver sufficient results to report back to the Health Assembly. She urged that a timeline of three years should be sufficient.

The representative of EGYPT supported the proposal made by the representative of Thailand. As the Advisory Committee met annually and the repositories were inspected biannually, there should be sufficient material for an annual report to the Health Assembly.

The representative of the UNITED STATES OF AMERICA, agreeing with the comments made by the representatives of Thailand and Egypt, noted that an annual progress report on smallpox was always submitted to the Health Assembly.

The representative of the ISLAMIC REPUBLIC OF IRAN agreed that a progress report should be submitted annually to keep the issue current and enable evidence-based decisions.

The EXECUTIVE DIRECTOR ad interim (Outbreaks and Health Emergencies) said it was clear that Member States favoured the submission of annual progress reports and the inclusion of a substantive agenda item as appropriate based on that progress.

The CHAIRMAN said she took it that the Committee noted the report and agreed that annual progress reports should be submitted to the Health Assembly and that a substantive agenda item should be included on the provisional agenda of the Seventy-second World Health Assembly.

It was so agreed.

Global action plan on antimicrobial resistance: Item 14.4 of the agenda (documents A69/24 and A69/24 Add.1)

The CHAIRMAN informed the Committee that footnote 1 to paragraph 15 in document A69/24 Add.1 should refer to paragraph 10 of the global action plan, not paragraph 11.

The representative of SRI LANKA supported the establishment of a global framework on antimicrobial resistance, but said that the growing use of antimicrobials in agriculture and veterinary medicine would pose serious challenges, as would their illegal production and availability without prescriptions. The public must be made aware of how antimicrobial resistance would affect the future treatment of infectious diseases; empowering communities would help to limit illegal production and indiscriminate use. While adhering to policies on the use of antimicrobials, the new WHO Model List Essential Medicines must be large enough to provide clinicians with enough choice. WHO should provide leadership in bringing together stakeholders so the problem could be attacked from all sides.

The representative of the NETHERLANDS, speaking on behalf of the European Union and its Member States, said that the candidate countries Turkey, the former Yugoslav Republic of Macedonia, Serbia and Albania, the country of the Stabilization and Association Process and potential candidate Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova and Georgia aligned themselves with her statement. Combatting antimicrobial resistance required concerted multisectoral action at all levels. The global action plan on antimicrobial resistance represented an important global consensus on action needed to combat antimicrobial resistance. Commending WHO's support for the development of national action plans, she welcomed work towards a global development and stewardship framework, which was vital to ensure that the issues of stewardship, innovation and access were balanced and should continue under WHO leadership with support from relevant actors. However, more concrete options for establishing the framework were needed, such as the development of a global prioritized list of antibiotics and the identification of research and development needs. She encouraged the Director-General to continue engaging with the United Nations Secretary-General to prepare for the United Nations General Assembly High-level Meeting on antimicrobial resistance, an event that called for active preparation and coordination from Member States and should be the basis of further work across United Nations agencies. She looked forward to proposals for future action following that Meeting.

The representative of PARAGUAY described measures to combat antimicrobial resistance in her country, including the antimicrobial resistance surveillance network, training and surveillance Technical support was needed from WHO to develop and monitor a national action plan, improve regulation of medicines, and develop mechanisms ensuring access to antimicrobials and other materials. The time frame mentioned in the global action plan on antimicrobial resistance should be extended to allow strategies and interventions to be fine-tuned and to ensure sustainable short- and medium-term results in all countries.

The representative of the UNITED REPUBLIC OF TANZANIA, noting efforts to develop a national action plan on antimicrobial resistance, supported efforts by WHO, FAO and OIE to develop a global package of activities to combat antimicrobial resistance under the global action plan. He encouraged countries that had not yet done so, to make use of the flexibilities under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to facilitate local production. He urged WHO to provide an effective international mechanism for antimicrobial resistance data exchange, to be linked with the WHO Global Observatory on Health Research and Development. Outcomes from the United Nations General Assembly High-level Meeting on antimicrobial resistance would boost the implementation of the global action plan by WHO and its Member States.

The representative of SENEGAL provided details on antimicrobial resistance measures implemented in his country, in particular the creation of a national list of bacteria and expansion of antimicrobial surveillance to include animal health. He encouraged the implementation of the "One Health" initiative in the fight against antimicrobial resistance.

The representative of the PHILIPPINES described measures adopted in the country's national action plan, which included multisectoral policies, national guidelines and programmes for the rational use of antimicrobial medicines and infection prevention and control, as well as research and development of new technologies. She supported the development of a global priority list of antibiotics under a global stewardship framework; but encouraged further consideration of awareness-raising and training, professional codes, regulatory mechanisms and funding mechanisms to subsidize essential antibiotics for poorer populations.

The representative of IRAQ called for a focus on supporting laboratory surveillance; considering epidemiological and demographic variables; developing an action plan on sentinel sites; and joint monitoring and assessment of national action plans on antimicrobial resistance. The Organization's role in capacity-building among staff and institutions should be strengthened, as should WHO country offices.

The representative of KENYA said the burden posed by antimicrobial resistance required collective political, financial and technical commitment and support from WHO and other partners. He described steps taken in his country to combat antimicrobial resistance, with particular reference to multisectoral efforts at the national level to analyse the situation, to develop national policies and bodies on antimicrobial resistance, and to regulate the quality of antimicrobial medicines on sale. He reiterated the importance of involving Member States and all relevant stakeholders in the development of a balanced global development and stewardship framework. All Member States should develop and implement strong surveillance systems to detect antimicrobial resistance and foster collaboration and information exchange to combat it.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said that commitments made at the United Nations General Assembly High-level Meeting on antimicrobial resistance should accelerate implementation of the global action plan and the development of national action plans. Her Government would continue to work towards consensus on a global financing solution to address the causes of antibiotic market failure, and had pledged £265 million to improve laboratory capacity, diagnosis and antimicrobial resistance data and surveillance in low- and middle-income countries. She supported the call for the Director-General to update the United Nations Secretary-General on work done on the stewardship framework and to report the outcomes of the High-level Meeting and the Secretariat's recommendations for next steps to the Executive Board at its 140th session. Although WHO would still lead on health aspects, the approach taken to antimicrobial resistance enabled greater engagement with other United Nations

agencies including FAO, OIE and WTO, and so care should be taken in preparing for the High-level Meeting.

The representative of ICELAND drew attention to the reference to contaminated food as an important route of transmission of antimicrobial resistant bacteria in view of a recent document published by the European Centre for Disease Prevention and Control and the European Food Safety Authority. He supported the Organization's efforts to combat the spread of antimicrobial resistant bacteria through, inter alia, reducing the use of antimicrobial medicines in humans and animals and improving surveillance, diagnostics and public awareness of bacterial contamination and hygiene.

The representative of SOUTH AFRICA, recalling that stewardship could be seen as the responsible management of antimicrobials to improve patient outcomes while minimizing the development of resistance, a balanced stewardship framework was required, with input from FAO, OIE and industry stakeholders. A review of the WHO Model List of Essential Medicines was necessary and should identify which antibiotics should always be available and which should be reserved for targeted use. Restricting the use of second-line antimicrobial medicines to cases demonstrating confirmed first-line treatment failure, could be key in preventing widespread resistance.

The representative of GERMANY underscored the importance of the development of national action plans by Member States for the timely implementation of the global action plan on antimicrobial resistance, such as that adopted by her Government. Additionally, her Government would contribute €1.3 million for the implementation of the global action plan in 2016. The United Nations General Assembly High-level Meeting would increase awareness at the highest political level and she encouraged WHO to continue its leadership on the health aspects of antimicrobial resistance. Given the need to strengthen research, her Government would provide an additional €500 000 to the recently-launched Global Antibiotic Research and Development Partnership between WHO and the Drugs for Neglected Diseases Initiative and she encouraged others to do the same.

The representative of BRAZIL, noting that the complexity of antimicrobial resistance deserved serious reflection, said that WHO was in a position to provide a substantial contribution to the United Nations General Assembly High-level Meeting. Brazil had adopted measures to ensure the rational use of medicines and multisectoral action based on the global action plan. As many countries were still formulating national action plans, ongoing discussions on options for a global stewardship and development framework must not duplicate the global action plan. He emphasized that the "One Health" initiative did not mean that one size fit all, and encouraged WHO, FAO and OIE to continue working within their respective mandates and commitments. Monitoring, control and conservation of antibiotics should be balanced against their access and affordability, and he recalled the importance of awareness and infection prevention. Generic medicines should continue to be recognized as part of the solution, and TRIPS flexibilities should be reaffirmed as a legitimate resource tool to encourage the affordability, accessibility and early commercialization of relevant medicines. Proposals to include monitoring of antimicrobial resistance as an International Health Regulations (2005) obligation should be closely considered. Finally, he requested that "in the absence of risk analysis" be added to the end of paragraph 20 after "crop protection" in order to fully reflect the text of the global action plan for antimicrobial resistance.

The representative of CANADA said that given the multisectoral action required to combat the complex issue of antimicrobial resistance, the Government of Canada was working with provincial and territorial governments, key stakeholders and experts to develop a national action plan that considered the country's specific needs; however, the report had erroneously referred to Canada as a Member State with a completed national action plan, which required clarification with the Secretariat. She asked Member States to consider flexible, feasible and appropriate options for establishing a

global development and stewardship framework, taking into account the different circumstances and needs of different countries. The development of the framework should be phased to ensure its most critical elements received the most efficient consideration, even if that limited the initial scope. She stressed the need for a shared definition of "appropriate use" and for the issue of access to be included in all discussions on the framework.

(For continuation of the discussion, see the summary record of the seventh meeting, section 3.)

The meeting rose at 21:35.

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