## SECOND MEETING

**Monday, 18 January 2010, at 14:35**

**Chairman:** Dr S. Zaramba (Uganda)

### 1. REPORT OF THE PROGRAMME, BUDGET AND ADMINISTRATION COMMITTEE OF THE EXECUTIVE BOARD: Item 3 of the Agenda (Document EB126/3)

Dr DAHL-REGIS (Bahamas), speaking in her capacity as Chairman of the Programme, Budget and Administration Committee, highlighted the issues in the Committee's report that were not on the agenda of the Board. Those included progress on WHO's management reforms, including the challenges that lay ahead in implementing the Global Management System and the new accounting system, the International Public Sector Accounting Standards; the Programme budget 2008–2009; the report of the Office of Internal Oversight Services; implementation of internal and external audit recommendations; and the reports of the Joint Inspection Unit. She would report the Committee's discussion of items on the Board's agenda as those items were taken up.

Dr KABULUZI (Malawi), speaking on behalf of the Member States of the African Region, welcomed the contribution of the Global Management System to enhanced budgetary controls, standardization of processes, increased transparency and improved access to information. It was not yet being widely used, and continuing efforts should be made to make it user-friendly as it was being extended to other regions, for example his own. He supported the requests for additional analysis regarding the system's costs, benefits and impact on all the Organization's work. The urgent situation regarding field staff security and the safety of headquarters premises emphasized the need for further discussion of the issue compounded with rapid action. He welcomed the thorough screening and a strict selection process for the appointment of members of the Independent Expert Oversight Advisory Committee. The African Region should be represented on the Committee, if possible.

### 2. TECHNICAL AND HEALTH MATTERS: Item 4 of the Agenda

**Implementation of the International Health Regulations (2005):** Item 4.2 of the Agenda (Documents EB126/5 and EB126/INF.DOC./1)

The CHAIRMAN drew attention to the report contained in document EB126/5, which described the Secretariat's activities and the procedures for convening the IHR Review Committee in early 2010. An update on the pandemic influenza A (H1N1) 2009 virus had been provided in document EB126/INF.DOC./1. In view of the close link between the International Health Regulations (2005) and the international response to the pandemic (H1N1) 2009, he suggested that the Board consider the situation concerning the pandemic under item 4.2 despite the fact that the Board had decided to postpone its consideration of item 4.1, on pandemic influenza preparedness, until later in the session. He took it that that arrangement was acceptable to the Board.

**It was so agreed.**

Dr FUKUDA (Special Adviser to the Director-General on Pandemic Influenza), giving a brief update on the current situation, recalled that pandemic influenza infections had first been reported in late April 2009. On 25 April 2009, the Director-General had declared a public health emergency of international concern, and by late May 2009, the Organization had received laboratory confirmation of infections in more than 48 countries and territories. By 11 June 2009, the infections had spread sufficiently for the Director-General to declare a pandemic, namely phase 6 under the pandemic preparedness guidance. By 1 July 2009, 120 countries and territories had reported confirmed infections; at present, that number had risen to about 208. In the northern hemisphere, virus transmission had started in May 2009, with a new surge of infections beginning in August 2009. In North America, peak activity had lasted for 10 to 15 weeks. In the southern hemisphere, virus transmission had been reported in many countries by June 2009.

The current situation in the southern hemisphere was one of sporadic infections but no large community outbreaks; in Africa, the most active transmissions were in northern countries, with data suggesting that western Africa had been largely spared; in North and South America, transmission had been declining or relatively low of late; and in Asia and Europe, transmission was still widespread but declining overall. Most infections resulted in uncomplicated influenza illness, not requiring specialized medical care. Most deaths were caused by severe viral pneumonia: unlike seasonal influenza, the pandemic virus directly attacked the lungs in severe cases. In about 25% of pneumonia cases there was a secondary bacterial infection, usually streptococcal. Among people who developed severe disease or died, up to 80% had underlying conditions, pregnancy being a major predisposing factor, although asthma, heart disease and diabetes, among others, were also implicated.

Severe cases and deaths had occurred in previously healthy young adults and children. Although young adults seemed to have been most often infected, the highest rates of admission to hospital – at least twice more than in other age groups – occurred in children under five years of age. The highest rates of death were among 50 to 60 year olds.

With regard to the impact on health-care systems, visits to outpatient clinics had increased in many countries, but it was not clear how many of the patients were merely worried or truly sick. Overall hospital admissions were generally not excessive although the rates of admission for younger people in particular were high. The most important finding, however, was that intensive-care units had been under the most pressure: about 4 to 15 times more patients than usual. Because many of the patients were young, they often spent fairly long periods in intensive care.

There was generally a good match between the vaccines being used and the viruses circulating. Viruses from people with severe as opposed to mild illness showed no consistent genetic differences. Sometimes mutation occurred and prompted speculation as to whether it was a marker for severe disease, but no such evidence had yet been borne out. One recently identified mutation had been proved to occur in a minority of viruses and it was impossible to determine whether it had a major effect on the behaviour of the viruses. Most of the viruses remained sensitive to oseltamivir and zanamivir, although about 200 cases of viruses resistant to oseltamivir had been reported. Small clusters of resistant viruses had been reported in the United Kingdom of Great Britain and Northern Ireland, the United States of America and Viet Nam, but no widespread increase in resistant viruses was so far evident.

Pandemic influenza viruses had replaced seasonal influenza viruses in nearly all countries. Meetings were to be held soon to determine the content of influenza vaccines, and a major question that scientists would be asking was what patterns of transmission could be expected for late 2010.

Pandemic infections were occurring in many countries, but decreasing overall. The highest transmission activity was in northern Africa, central and eastern Europe and southern Asia. The second wave of infection had peaked very early in some parts of the northern hemisphere. There was much speculation as to whether another wave of infection would occur in 2010 and what combination of viruses would be seen – would seasonal viruses return or be replaced by pandemic influenza viruses?

As to the availability of pandemic vaccines, by conservative estimates, more than 265 million doses had already been distributed, and about 175 million of those had been administered. Safety

monitoring had been unusually high, and coordination on reporting unusually intense. Even with especially careful scrutiny, no unusual safety issues had been reported.

Under WHO's vaccine initiative, 200 million doses had been pledged by a number of governments, foundations and manufacturers, something that the Organization greatly appreciated. Among the vaccines available worldwide, six had been prequalified by WHO and three more were under assessment. WHO and its partners were working to assist 95 countries, 86 of which had requested vaccine donations, and 32 had signed formal agreements with the Organization. Fourteen of those countries had finalized deployment and vaccination plans; vaccines had been deployed and received in two countries and used in one. It was expected that another 15 countries would receive vaccines before the end of January 2010.

The DIRECTOR-GENERAL recalled that the Sixty-first World Health Assembly in 2008 had requested the Secretariat to begin work in preparation for the first review of the functioning of the Regulations, which would be duly undertaken. Several Board members had requested the Secretariat to undertake an assessment of the current influenza pandemic. It was to be hoped that such a review would also serve to assess the performance of the Regulations. Once she had listened to comments from the Board, she would make proposals on action to be taken with respect to the reviews of both the Regulations and pandemic (H1N1) 2009.

Sir Liam DONALDSON (United Kingdom of Great Britain and Northern Ireland) said that Member States must be neither intimidated nor driven into a situation of complacency by the recent suggestions in the media that the Organization and national health ministries had overreacted to the pandemic. It was not of practical relevance to compare mortality from the current pandemic to previous influenza pandemics and seasonal influenza outbreaks, since, for the first time in history, countermeasures including a vaccine had been available during the pandemic rather than after the peak had passed. Consequently, irrespective of the perceived severity of the pandemic, further spread could be combated and individuals around the world protected. The current strain of influenza, as with all seasonal strains, would drift and cause more serious outbreaks over time and hence the relevance of long-term protection.

Sub-Saharan Africa was particularly vulnerable to the pandemic influenza A (H1N1) 2009 virus because of three main factors: the high proportion of people under the age of 25 years, the age group shown to be most vulnerable in developed countries; the prevalence of comorbidities, given that chronic respiratory diseases, including tuberculosis, and immunosuppression due to such factors as untreated HIV infection had been shown to be risk factors of severe disease and mortality in developed countries; and the low level of income, given that studies in aboriginal populations that had been affected thus far had suggested that the least economically developed countries could potentially suffer a four-fold inflation in mortality ratios. He emphasized continued and strong precautionary action concerning the possible spread of the pandemic to vulnerable countries.

Dr KÖKÉNY (Hungary), speaking on behalf of the Member States of the European Union, said that the candidate countries Croatia, The former Yugoslav Republic of Macedonia and Turkey, the countries of the Stabilisation and Association Process, and potential candidates Albania, Bosnia and Herzegovina, Montenegro and Serbia, and also Ukraine, the Republic of Moldova and Armenia, expressed support for the statement made by the previous speaker.

He urged the Secretariat to disseminate information on the impact and benefits of the Regulations and national public health measures. The Regulations had proved to be an adequate legal framework to manage the global response to the current pandemic; the IHR Emergency Committee had advised the Director-General appropriately; and the WHO networks had exchanged and disseminated information effectively. The network of National IHR Focal Points, however, should be consolidated further in order to become fully operational. That network and the WHO IHR Contact Points were being increasingly used for rapid communication of public health information: direct, immediate and continuous access to WHO experts had been useful in responding to public health risks and emergencies. The European Union supported the proposed procedures for convening the IHR

Review Committee in February 2010, which would provide technical advice to the Director-General and would propose ways of better implementing the Regulations. Continuous performance review of the decision instrument referred to in Annex 2 to the Regulations would also be useful.

He emphasized that the challenges of public health alerts and emerging diseases demanded: intensified implementation of the Regulations in all States Parties; strengthened capacities for disease surveillance, and early-warning and rapid-response systems; and the sustainable integration of those into general public health surveillance strategies. The Organization should guide and support States in that endeavour in order to ensure coherence between national and worldwide measures. He stressed that such comprehensive and prompt response required WHO to strengthen relations with other international and intergovernmental organizations, especially those active in the transport sector, and expressed support for the establishment of a collaborative framework with FAO and OIE.

Mr HOUSSIN (France) said that the revised Regulations, seen functioning on a large scale in 2009, had proved satisfactory. He commended the role of WHO during the pandemic and the rapid publication of its initial recommendations, even if the scope of certain measures, such as those concerning quarantine and the use of thermal cameras in airports, had not always been adequately defined.

At least five years would be needed to build the capacities of a fully operational system. However, every effort must be made to consolidate the National IHR Focal Points; to continue building capacities, particularly with respect to laboratories and diagnosis, in which area the WHO Office in Lyon could play an essential role; to publish guidelines; and to support Member States in implementing the Regulations, notably in preparing a list of diseases necessitating disinsection, preparing minimum standards for the National IHR Focal Points and laboratories, describing procedures for issuing ship sanitation certificates and intensifying anti-vectoral activities. The IHR Review Committee must draw lessons from the pandemic but also pursue those other aspects linked to implementation of the Regulations.

Professor HAQUE (Bangladesh), anticipating the first comprehensive review of the Regulations at the Sixty-third World Health Assembly, said that the context of virus pandemics emphasized the importance of implementing the Regulations. Noting that the current pandemic had been the first human influenza pandemic since 1968, he expressed support for the statement by the member for the United Kingdom that vigilance was essential since the virus was sure to mutate: the Organization must provide guidance in that respect. The report highlighted progress in the implementation of the Regulations; its finding that many emerging diseases originated in the interaction between humans and animals demonstrated the importance of effective cooperation between the health sector and the food, agriculture, livestock and poultry sectors. Strengthening the capacities of laboratories in developing countries was also vital. The report acknowledged that points of entry into countries, particularly ground crossings, remained a serious weakness: just how public health capacities could be improved in order to address that problem required consideration. He urged the Organization to continue assisting countries such as his own in implementing the Regulations.

Dr MOHAMED (Oman) said that the pandemic had been of such proportions in the Eastern Mediterranean Region that countries had not always been able to respond on an individual basis. Nevertheless, official health measures had been introduced, not always successfully, and decisions amended as necessary. Between 6% and 7% of his country's population had access to vaccines; vaccines were in stock but had not yet been distributed. It was essential that States that did not have the capacity to tackle the pandemic, for example with respect to pulmonary or respiratory conditions, should be provided with vaccines. Although in some countries in the Region specialized medical care and admission to hospital had limited the number of deaths, the mortality rate had remained relatively high. He expressed surprise that the Secretariat had received requests for vaccines from many developing countries when other developed countries had returned unused stocks of vaccines. Vaccines and care must be provided where needed, and every effort made to avoid viral mutations, as had occurred during previous pandemics. He asked for statistics to be provided on the number of

vaccines that had been distributed and not administered, and therefore perhaps discarded, and for clarification of predictions for 2010.

Dr GIMÉNEZ (Paraguay) said that the Regulations had proved adequate for the global, regional and national response to the current pandemic; the guidelines provided by WHO, PAHO and other regional health organizations and the efforts of national health ministries, had further mitigated the impact of the pandemic. Those experiences should lead to a strengthening of systems in preparation for such events in the future. The increased public confidence in health institutions that had resulted from communication between health ministries and the general public must be preserved. Although vaccination was the main tool for preventing the spread of the pandemic, complementary measures had also had a considerable impact on health indicators in his country: a significant reduction in mortality over the winter had been attributed to communication and prevention measures through public and private institutions including the Ministry of Education. He noted that a second outbreak of the pandemic could coincide with the current dengue epidemic in the Region of the Americas and thus strain health systems. Finally, he shared the concern expressed by previous speakers regarding access to medicines, especially oseltamivir, and to vaccines.

Dr OMI (Japan) pointed out that the low mortality rate associated with pandemic influenza in Japan had been due to the provision of antiviral medicines; the high level of public awareness; and to the lengthy suspension of schools, an important factor in weakening the transmission of the virus.

Mr OTAKE (alternate to Dr Omi, Japan) expressed appreciation of WHO's leadership in the implementation of the Regulations; they had promoted global sharing of information following the outbreak of pandemic (H1N1) 2009. Member States should establish or improve national systems and ensure functioning Regulations. Noting that operational preparedness varied among States, he recommended the use of simple and effective indicators in monitoring and responding to global health emergencies. He trusted that the Secretariat would continue its efforts to improve the implementation of the Regulations.

Dr MELNIKOVA (alternate to Dr Starodubov, Russian Federation) said that the Regulations had provided for access to information, risk assessment and possible coordinated action to global threats to public health, and proven their effectiveness following the outbreak of pandemic influenza. In regard to the pandemic influenza A (H1N1) 2009 virus, she looked forward to regular updates from the Secretariat and continued technical support to Member States.

She welcomed WHO's development of global partnerships with other international and intergovernmental organizations with a view to coordinating possible emergencies and particularly in the area of transport.

Introduction of the Regulations in her country had encouraged improved epidemiological surveillance and laboratory diagnostics; strengthened response to outbreaks of disease; and enabled modernization of specialized mobile brigades. Her Government had been implementing the Regulations and was using information from WHO to prevent the spread and transmission of the virus. It was also assisting several members of the Commonwealth of Independent States in monitoring the influenza outbreak.

The Secretariat should inform States Parties of the methods, indicators and criteria that would be used to review the functioning of the Regulations, and of progress in their implementation. Its work on future implementation of the Regulations should focus on the technical issues identified in the report contained in document EB126/5.

Dr DJIBO (Niger), speaking on behalf of the Member States of the African Region with regard to pandemic influenza, said that the pandemic influenza A (H1N1) 2009 virus had taken the world by surprise. By December 2009, some 14 000 cases of the virus had been reported in the African Region and there had been 80 deaths. Since the first case in the Region, the Secretariat had provided Member States with guidance regarding management, control and surveillance, highlighting early identification

and effective communication. Public health messages on prevention and control had been circulated to all Member States, and a system established for the daily reporting of suspected and confirmed cases. The integrated regional preparedness and response plan developed for an avian influenza pandemic had been revised accordingly. By the end of July 2009, 21 Member States in the Region had finalized their preparedness and response plans. The Regional Committee for Africa had adopted a resolution urging all Member States to continue integrated disease surveillance, to apply the Regulations and to contribute to the African Public Health Emergency Fund.

African countries faced challenges in managing effectively the current influenza pandemic, including the low level of public awareness of health issues, insufficient planning and preparation, inadequate monitoring and surveillance systems, poor infection control in health facilities, and limited efforts to mobilize resources.

Intellectual property rights were at the heart of the concerns of the African Member States. Pharmaceutical companies and laboratories fixed the prices of vaccines and determined research and development priorities. Accordingly, WHO's support was essential to provide African countries with access to the technologies, medicines and vaccines necessary to respond to pandemic influenza.

Dr GOPEE (Mauritius), speaking on behalf of the Member States of the African Region on the implementation of the Regulations, said that more than one third of Member States had started to revise their national guidelines for integrated disease surveillance and response in order to incorporate the Regulations. Seventy-two laboratories in 45 countries and 13 laboratories in 12 countries were participating in external quality assurance schemes for microbiology and influenza respectively. With the technical support of WHO, health ministries were raising awareness of the Regulations and their implications. The Regional Office had helped to develop a checklist for monitoring core capacities for surveillance and response; and Cameroon and Sierra Leone had already conducted an in-depth assessment of their core capacities and developed action plans.

All countries had designated a National IHR Focal Point, and a briefing for all focal points in the African Region had been held. Almost 40% of Member States complied with the requirement to notify or otherwise reported events to WHO using the mechanism provided under the Regulations. In addition, several countries were using the IHR Event Information Site and had established communication channels with other relevant sectors. Ten of the 33 countries with sea ports had provided a list of ports authorized to issue ship sanitation certificates, and exemption certificates and extensions for ship control.

Although 36 countries had submitted annual reports to the Secretariat by February 2009, problems remained in increasing implementation of the Regulations, including delays in revising technical guidelines and tools for Integrated Disease Surveillance and Response; delays in assessing core capacities and compliance with requirements; untimely notification of events constituting a public health emergency of national or international concern; and the high turnover of National IHR Focal Points. Technical support from WHO was thus urgently required.

Ms TOELUPE (Samoa) said that WHO's response to the pandemic (H1N1) 2009 had been effective and appropriate and had demonstrated the value of the Regulations in guiding national response. Samoa looked forward to the convening of the IHR Review Committee, and trusted that the country feedback provided through National IHR Focal Points would contribute significantly to its work.

Welcoming WHO's activities to facilitate reporting by States Parties, she noted that the response rate to the 2008 and 2009 questionnaires was low, and supported WHO's promotion of global partnerships. States Parties should be kept informed of any new access to the IHR Event Information Site granted to non-national focal points, in order to assist local response and operational relationships. She commended WHO's efforts to assist States Parties in fulfilling core capacity requirements under the Regulations; developing countries should be given priority in that regard.

An excellent spirit of cooperation existed between the Secretariat and States Parties, and among States Parties themselves, in fulfilling national obligations under the Regulations, exemplified by WHO's immediate response to requests for assistance in response to the pandemic (H1N1) 2009, and

by the assistance provided to many Pacific island States by States Parties in the early sharing of information, technical advice and laboratory testing.

Ms SUJATHA RAO (India) commended the Secretariat for its efficient handling of the pandemic (H1N1) 2009, and welcomed the assistance her country had received in containing the spread of the virus. India had 1.5 million vaccine doses for the vaccination of health workers, and vaccines produced domestically were likely to be available by the end of March 2010. The closure of schools in her country had helped to interrupt transmission of the virus. Her country had had the third highest number of deaths from the virus, but reflected the trend in other countries of patients with existing conditions more likely to succumb to the virus. Oseltamivir had so far proven effective, and care was being taken to ensure that resistance to that drug did not develop.

To be listed as a country fulfilling the obligations under the Regulations, a high level of performance regarding core capacities and clear public health outcomes were required: considerable technical assistance would have to be given to enable countries to achieve those objectives within the time frame provided. India, for its part, had designated a National Centre for Disease Control as the National IHR Focal Point, and state and district level focal points were currently being designated. A new public health emergencies act would be drawn up to facilitate the implementation of the Regulations.

Dr DODDS (Canada) said that her country was committed to full compliance with the Regulations by June 2012 and to international collaboration to reduce the global impact of the pandemic influenza A (H1N1) 2009 virus. Welcoming the strong leadership shown by WHO in helping to manage the pandemic, Canada looked forward to reflecting upon the global response to the pandemic, to sharing lessons learnt in order to better prepare for, and respond to, future threats to global public health. Only two out of the 95 countries that WHO was supporting had received vaccines, emphasizing a need for further progress in pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits. Canada was prepared to draft a text to facilitate the Board's discussion of that issue.

Dr KWON Jun-wook (alternate to Professor Sohn Myongsei, Republic of Korea) highlighted the need to evaluate the implementation of the Regulations in the context of pandemic (H1N1) 2009. The high-level consultation on new influenza A (H1N1) held during the Sixty-second World Health Assembly in 2009 had provided Member States with a valuable opportunity to share experiences, and assist in their response to the situation. WHO should hold a similar meeting at the forthcoming Health Assembly to promote continued learning, collaboration and vital exchange.

Mr PEHNI DATO SUYOI (alternate to Mr Osman, Brunei Darussalam) expressed concern that, as the perceived severity of the pandemic (H1N1) 2009 decreased, populations had begun to believe that vaccination was not necessary, and he therefore welcomed suggestions on how to combat that belief. Despite support from the Organization's regional offices in the implementation of the Regulations, technical challenges included: the implementation of the broad scope of the Regulations, which required both public health surveillance and response in health and other sectors; the elaboration of plans to strengthen core public health capacities at points of entry, especially ground crossings; and dealing with events such as those caused by noncommunicable diseases or chemical and irradiation accidents.

Dr ABDESSELEM (Tunisia), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the implementation of the Regulations represented a major achievement in international communication and response. The importance of transparent reporting in critical health situations had been seen particularly during the pandemic (H1N1) 2009. He urged the Organization to defend the economic interests of Member States that suffered as a result of other States' reactions to the Regulations' implementation. He asked the Organization to provide technical assistance for continued implementation of the Regulations, notably in monitoring early warning

systems, in order to complete implementation by June 2012. He emphasized the evaluation of lessons learnt from the pandemic (H1N1) 2009.

Dr VALLEJOS (Peru) said that access to influenza viruses and the subsequent vaccines had always been the subject of controversy between countries with the technological capacity to produce vaccines and those suffering the effects of a pandemic, in three main areas: the Standard Material Transfer Agreement; benefit sharing; and intellectual property rights. He therefore supported the proposals made by WHO to establish a model framework for the transfer of biological material between WHO laboratories and to define governing principles for sharing benefits with influenza vaccine manufacturers.

Dr REN Minghui (China)[1] noted that the pandemic (H1N1) 2009 had demonstrated the effectiveness of the Regulations for the first time. The Organization should review the lessons learnt, with particular regard to the review committee, coordination of States' control measures, and communication between WHO and States Parties, in order to further improve the implementation of the Regulations. During the pandemic, his country had strengthened its laboratory surveillance network and the capacity of the National Influenza Centre. He thanked WHO, as well as the Governments of Canada, Mexico and the United States of America, for the timely sharing of the H1N1 virus in order to enable the development and subsequent distribution of a vaccine. He requested that the Secretariat provide up-to-date information on the monitoring tool referred to in paragraph 19 of document EB126/5. Furthermore, he suggested that the differing resources and capacities of States Parties should be taken into account when developing indicators for the implementation of the Regulations.

Mr HOHMAN (United States of America)[1] commended the Organization's sharing of information relating to the pandemic (H1N1) 2009, and the development of evidence-based health measures and guidance in support of surveillance; clinical and pharmacological management; infection control; and individual and community measures. He further welcomed the Organization's efforts to ensure access to vaccines and antiviral medication. Further assistance would be needed in some States to develop core capacities for the full implementation of the Regulations, especially in non-health sectors, given their extensive scope. In addition, WHO should evaluate lessons learnt and any gaps in national public health capacity. He agreed with the comments made by the member for the United Kingdom on reviewing the response to the pandemic (H1N1) 2009.

Mrs ARRINGTON AVIÑA (Mexico)[1] said that the recent situation provided an ideal opportunity to evaluate the implementation and effectiveness of the Regulations, thereby defining gaps in capacity or areas to be strengthened. The pandemic (H1N1) 2009 had demonstrated that only measures such as the Regulations would be effective in establishing an international alert system and in ensuring global access to reliable information, allowing clear decisions to be made. Diseases previously confined to countries were having increasing international consequences and, as such, she welcomed the creation of the IHR Review Committee to further improve the measures. She reiterated her country's commitment to better preparedness, in collaboration with WHO.

Dr NAKORN PREMSRI (Thailand)[1] commended the continuing efforts to evaluate the implementation of the Regulations, but suggested such evaluations should not be delayed until the pandemic was over. The pandemic (H1N1) 2009 had demonstrated the importance of an accurate global reporting system, in particular the exchanges through National IHR Focal Points. Containment guidelines at points of entry should be reviewed, as had been suggested by the representative of China. He reaffirmed his country's commitment to implementing the Regulations.

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

Mr ROSALES LOZADA (Plurinational State of Bolivia)[1] said that his country had made significant progress in the implementation of the Regulations following recent dengue fever epidemics and the influenza pandemic. The recently created national liaison centre ensured collaboration between national, departmental and local management, as well as with the relevant international bodies, and was responsible for raising awareness of the Regulations on a national level. Capacities for the detection, verification, evaluation and notification of significant public health events were also being developed, as well as related rapid response teams. A national action plan to strengthen core capacities had been elaborated. Subsequent to that, national legislation would be reviewed to strengthen national preparedness and response.

Dr KESKİNKILIÇ (Turkey)[1] said that the implementation of the Regulations had been accelerated by the recent influenza pandemic, and, as a result, most countries should achieve full implementation by 2012. Only 56 experts had been included on the IHR Roster of Experts, and he urged Member States to complete that important list. Furthermore, he requested clarification with regard to the reference made in paragraph 18 of the report to measures taken by States that might interfere with international travel or trade. The Secretariat should evaluate the appropriateness of any such actions, as well as ensure their reporting, in particular during pandemic alert phase 6. He welcomed the monitoring tool being developed to evaluate the implementation of the Regulations, and looked forward to its universal application.

Dr FUKUDA (Special Adviser to the Director-General on Pandemic Influenza), responding to questions and comments, said that the pandemic influenza virus would inevitably mutate, and it was important to try to predict which influenza strains would be widespread in order to produce vaccines effectively. It was probable that further H1N1 influenza-related disease would be prevalent later in the year, in particular given that the H1N1 virus had all the characteristics of a long-term virus.

Based on current information, of the 265 million doses of vaccine that were thought to have been distributed worldwide, it was estimated that 175 million doses had actually been administered.

He welcomed the widespread recognition that the International Health Regulations (2005) had become the central mechanism for information exchange and cooperation and stressed the importance of continuing to improve them. With regard to the 2012 deadline for implementation of the Regulations, he noted that Member States could request an initial two-year extension by giving appropriate reasons for their request, and an additional two-year extension could then be granted in exceptional circumstances. Relating to the eight core capacities to be evaluated, 33 indicator variables were being field tested in 11 countries across the six regions, including India. Of those variables, it was expected that 20 would be reported to the next Health Assembly, and it had been suggested that the variables needed to be simpler overall.

The DIRECTOR-GENERAL endorsed the point made in connection with the response to pandemic (H1N1) 2009 that it was essential to guard against complacency. In doing so, however, it was also essential to strike a delicate balance with the need to avoid causing alarm. She did not subscribe to the widely held view that the pandemic influenza A (H1N1) 2009 virus caused a mild disease against which vaccination was unnecessary. On the contrary, she was concerned by that view and thus supported the many national efforts under way to promote vaccination. Communication relating to the pandemic was a key challenge for health authorities, whose efforts thus far were to be commended in the face of rapidly developing technologies that made it doubly difficult for the public to determine the reliability of the plethora of information available to it. It was therefore vital in those circumstances to identify best practices and lessons learnt in the area of communication.

She also attached great importance to zoonoses, which posed another challenge in so far as almost three quarters of the 40 diseases which had newly emerged in the past 30 years had originated

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

in the animal sector. On that score, WHO's work now largely complemented that of FAO and OIE, although there was still further room for improvement.

With regard to the suggestions that the Secretariat should conduct a review of the pandemic (H1N1) 2009 situation, such a review was not entirely within the scope of the first review of the functioning of the Regulations to be considered by the Health Assembly which would not cover such issues as vaccination availability and distribution. Her proposal for the consideration of the Board was therefore to convene the IHR Review Committee to enable the examination of the global response to the pandemic and the identification of lessons to be learnt in such areas as information-sharing that could be used to inform the functioning of the Regulations.[1] Given the enormous scope of the requested review, she did not envisage its completion in the four months before the Sixty-third World Health Assembly in May 2010. In addition, the pandemic was not yet over. She therefore proposed to submit an interim report on the subject to the Health Assembly, in which regard she looked forward to technical input and expert guidance from Member States.

Noting the key concerns expressed in connection with the requirements under Annex 1 to the Regulations, she agreed that the pandemic (H1N1) 2009 should be used as a fast-track exercise to provide energy and momentum in assisting developing countries to develop their core capacities for surveillance and response. She also drew attention to the method for the selection of review committee experts outlined in paragraph 3 of the report and called on States Parties to submit nominations for experts; 193 were needed, but only 56 were currently listed on the Roster.

Sir Liam DONALDSON (United Kingdom of Great Britain and Northern Ireland) suggested that the proposed review would be a timely opportunity for revising the technical definition of the pandemic, which had proved to be a highly controversial issue and which was vital to maintaining credibility with the public and the media.

The DIRECTOR-GENERAL confirmed her intention to include as part of the review the question of a revised definition of the pandemic.

The CHAIRMAN said that he took it that the Board wished to accept the Director-General's proposal to conduct an interim review of the pandemic (H1N1) 2009.

**It was so agreed.**

**The Board took note of the report.**

**Public health, innovation and intellectual property: global strategy and plan of action:** Item 4.3 of the Agenda (Documents EB126/6 and EB126/6 Add.1)

Sir George ALLEYNE (Chairman of the Expert Working Group on Research and Development Financing) explained that document EB126/6 Add.1 contained an extended executive summary rather than the full report because the Expert Working Group had completed its work only on 3 December 2009, leaving no time to have the full report processed and translated from English into the other five official languages. Those versions should be available within six weeks.

He recalled the evolution and terms of reference of the Working Group, noting that the Health Assembly in resolution WHA61.21 had called for an examination of the current financing and coordination of research and development and formulating proposals for new and innovative sources of funding with which to stimulate it.

[1] Subsequently issued as document EB126/INF.DOC./3.

The 24 members from 23 countries, representing a wide range of disciplines, had held a year of virtual meetings and Internet-based public hearings. It had solicited and discussed submissions from governments and the public.

A wider discussion of the reasons for financing research and development had concluded that incentives stemmed either from the existence of a market for the output, or from the absence or failure of such a market, as was the case in many developing countries. In regard to the current financing of research and development, the Working Group had examined the public records of donor agencies; the publicly available records of the world's largest pharmaceutical companies; and those of private philanthropists. It had discovered that most of the funding was going to noncommunicable diseases, especially cancer; that no reliable method existed at the global level for tracking flows of resources to research and development; and hence no global means existed for monitoring the financing. The Working Group had found no evidence of coordination of research and development at the global level, especially for the Type II and III diseases which most frequently affected developing countries. No global mechanism existed for financing health research, innovation and development to produce new diagnostics, medicines and vaccines nor one to support health policy and health systems.

Essential criteria for proposals retained included: an impact on developing countries; financial clarity; and operational efficiency. Ten proposals had been short-listed: three mechanisms to increase research and development funding; five mechanisms for allocating the resultant funding; and two efficiency proposals to cut the costs of research and development across the board.

He drew particular attention to the report's recommendations on incentives for knowledge production; the relationship between research, funding and the disease burden; supporting efforts in research tracking; and the need to create a global coordination and funding mechanism for health research and innovation. The Working Group was also keen to see WHO consider promoting the local development of policies to stimulate research and development, together with the idea of facilitating regional collaboration and funding.

Concluding in regard to any concern caused by a letter circulated to the Executive Board by one of the Working Group members, he said that a member whose opinions differed from the rest should rightfully express them within that group.

The CHAIRMAN said that that incident was regrettable and agreed that dissenting views should be dealt with internally.

Ms SUJATHA RAO (India), emphasizing the mapping of global research and development activities in order to identify gaps and priorities, appreciated the support of the Quick Start Programme to such activities and to promotion of standard-setting in the area of traditional medicine, in which India had an inherent strength. She welcomed any steps taken under the Programme to develop and strengthen regulatory capacity, including safety, efficacy, quality and ethical review.

The report of the Expert Working Group confirmed the double burden of disease borne by the poor; indicated the inadequacy of research and development to address Type II and III diseases; and further confirmed that commercial incentives provided by intellectual property rights had not sufficiently improved either public health in developing countries or access to the benefits of innovations taking place in the developed world.

However, the report contained no road map or guidance for greater access to the technologies already available for addressing the disease burdens of developing countries, which included the areas of diagnostics, classification and therapies for diseases that were expensive to treat. Indeed, high costs and encumbrances relating to intellectual property rights were responsible for greatly impeding access to medicines. WHO had a core mandate as a catalyst for facilitating delivery and should seek to obtain royalty-free licences for the benefit of developing countries in accordance with mutually agreed terms and conditions. It should also support those countries in use of the flexible options to which they were entitled under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

An incentive structure was needed to stimulate research and development of knowledge and technologies to address the problems of developing countries. The tracking of resources was essential to understanding the distribution and coordination of the necessary financing. The creation of a

coordination and funding mechanism for global health research and innovation which targeted new drugs, vaccines, diagnostics and prioritized the health conditions of the poor was a welcome recommendation. It nevertheless fell far short of the decisive plan needed to augment research into Type II and III diseases.

She drew attention to the most recent report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, submitted to the Human Rights Council in March 2009, notably in respect to access to medicines and intellectual property rights. She suggested that the Special Rapporteur should be invited to present to the Sixty-third World Health Assembly his findings on the role of intellectual property rights in promoting public health and access to medicines. She took it that the Secretariat had noted that two privileged draft documents of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property had been published on an Internet web site.

She suggested further needs: to outline a mechanism for the funding of research and development by developed countries; to avoid unfairly placing the burden of research and development on certain developing countries; to design mechanisms to redress the limitations on access to medicines imposed by intellectual property rights; to fund and facilitate such access in the developing world; and to match resources with the technologies available for dealing with public health needs. Further dialogue on those issues could take place during the intersessional period before the Sixty-third World Health Assembly.

Mrs ESCOREL DE MORAES (Brazil) said that her Government attached great importance to the global strategy and plan of action on public health, innovation and intellectual property and to the commitments of resolution WHA61.21, to tackle health inequities. Emphasizing the duties of States to protect human rights to the highest possible standards of health, she called on the international community, led by the Member States and Secretariat to implement the global strategy. Brazil, a co-founder of UNITAID, was contributing financial resources to support the strategy.

The global strategy provided for countries with different levels of development to act in solidarity, with tools to channel resources to the health sector, thereby ensuring access to affordable medical products and fostering capacity building, technical cooperation and technology transfer. Access to medicines was critical: they must not be treated like other commercial goods. The cost of research and development must be separated from the price. The TRIPS agreement needed to be interpreted and implemented in a manner that supported the duty of States to protect public health by fully applying its flexibilities, and with the political and tactical support of WHO.

The Board must give guidance to the Secretariat on the question of ensuring access to affordable medicines, including generics; and patients had to be informed on all their options regarding medicines and treatment. Brazil would share its experiences in providing free and universal treatment to people with HIV/AIDS. Her country supported South–South cooperation programmes, especially capacity building, research and innovation in the health sector and, crucially, broader access to medicines for poor populations.

The report contained in document EB126/6 should have entered into greater detail; addressed aspects beyond research, development and innovation; provided greater focus on intellectual property and access to medicines and health products by developing countries; provided links between indicators of the plan of action and the activities undertaken; and detailed relevant regional forums, courses and seminars, such as those carried out in the Americas in 2009.

In addition, she requested more information on WHO's work with other organizations and experts regarding development of a diagnostic workbook on trade and health; current examinations of the barriers to the use of innovative technologies in resource-limited settings; the terms of the technology transfer for the production of a monoclonal antibody cocktail for the treatment of rabies; and the independent ethics committee mentioned in the report. In the context of the establishment by UNITAID of a voluntary patent pool and WHO's contribution to that process, the Board might consider suggesting to the Health Assembly that the Secretariat should become its host and manager.

In regard to the report by the Working Group, she was concerned about an apparent contradiction between the work of the Commission on Intellectual Property Rights, Innovation and Public Health and the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property regarding the impact of intellectual property rights on research and development. The Working Group appeared to have reintroduced rejected elements such as tax exemptions and its discussions had not specifically centred on poor countries, as requested in the global strategy. The report did not contain references to source documents; it did not clearly identify the criteria used to select proposals that met the needs of developing countries; and it laid the responsibility for establishing new financing mechanisms on governments and consumers without reference to the contribution of the private sector. Regarding the latter, she would have appreciated proposals for a tax on profits remitted by non-domestic pharmaceutical companies to their overseas parent companies.

In the light of the urgent need to implement the global strategy, she seconded the proposals by the member for India that the Director-General should convene intergovernmental consultations before the next Health Assembly in order to examine the recommendations of the document and that she should invite the Special Rapporteur of the Human Rights Council to address the Health Assembly.

**The meeting rose at 17:45.**

(For continuation of the discussion, see summary record of the third meeting, section 2.)