World Health Organization

SIXTY-FIFTH WORLD HEALTH ASSEMBLY **A65/A/PSR/11**
COMMITTEE A **24 August 2012**

PROVISIONAL SUMMARY RECORD OF THE ELEVENTH MEETING

Palais des Nations, Geneva
Saturday, 26 May 2012, scheduled at 09:30

Chairman: Dr L.Z. DUKPA (Bhutan)

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ELEVENTH MEETING

Saturday, 26 May 2012, at 09:35

Chairman: Dr L.Z. DUKPA (Bhutan)

1. THIRD REPORT OF COMMITTEE A (Document A65/55)

Dr JIDDAWI (United Republic of Tanzania), Rapporteur, read out the draft third report of Committee A, noting that it contained a draft decision on WHO reform, under agenda item 12. Paragraph (19) of that decision, as contained in the report, was incomplete. The paragraph should read:

> "to request the Director-General to report, through the Executive Board at its 132nd session, to the Sixty-sixth World Health Assembly, on progress in the implementation of WHO reform on the basis of a monitoring and implementation framework."

The CHAIRMAN said that, subject to that correction, the Committee wished to adopt the report.

The report was adopted.

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

Consultative Expert Working Group on Research and Development: Financing and Coordination: Item 13.14 of the Agenda (Documents A65/24 and A65/24 Corr.1) (continued from the fourth meeting, section 2)

Ms CHILDS (MSF International), speaking at the invitation of the CHAIRMAN, said that the recommendations of the Consultative Expert Working Group on mechanisms to stimulate research and development should be supported. In order for those mechanisms to be successful, an overarching framework was needed, in the form of a binding convention, to ensure that priorities were set, funding was secured and innovation led to access. Unmet needs included: new treatments for drug-resistant tuberculosis and life-threatening drug-resistant infections; new treatments and diagnostic tools for kala azar, Chagas, and sleeping sickness; and vaccines that did not need to be refrigerated and could be administered without an injection. The fragile progress of the past had depended on donor philanthropy and corporate social responsibility. What was now needed was a sustainable solution, based on multilateral action, to ensure that innovation was able to deliver products which were immediately affordable and accessible. MSF International's involvement with the Drugs for Neglected Diseases initiative had shown that research and development of medicines could be made more efficient through the use of open knowledge innovation models or by delinking research and development costs from the price of products. She urged the Secretariat and Member States to initiate without delay the process of designing a new and sustainable global framework for medical research and development priorities.

Mr OTTIGLIO (International Federation of Pharmaceutical Manufacturers and Associations), speaking at the invitation of the CHAIRMAN, welcomed the emphasis placed in the report on the need to stimulate research and development on Type II and Type III diseases, where funding was

inadequate. Members of his organization had undertaken 93 research and development projects in 2011, three quarters of them through collaborative ventures. As current projects progressed into clinical trials, greater attention should be paid to the regulatory infrastructure in developing countries where the trials might take place. Member States should carefully evaluate all the available options highlighted in the report, while taking into account the complexity and ongoing evolution of pharmaceutical innovation. Any successful model should recognize the need for prioritization, effectiveness and sustainability, with the aim of increasing innovation, and improving access to high quality, safe and effective medicines.

Mr MAHAMA (CMC – Churches' Action for Health), speaking at the invitation of the CHAIRMAN, said that the patent system had failed to deliver medications for many of the conditions affecting people in developing countries. The system aimed to recover investment costs by charging high prices for medicines, which meant that the poor were denied access to those medicines and pharmaceutical companies did not invest in innovation for diseases of the poor. It was therefore essential to delink prices from research costs. The proposed convention on research and development would help to mobilize resources, manage the allocation of funds, coordinate public and private efforts, and ensure continuing policy development; it would also give concrete expression to the global community's moral obligation. He called on Member States to adopt the recommendations of the Consultative Expert Working Group with all urgency.

Dr KIENY (Assistant Director-General) thanked Member States and nongovernmental organizations for their useful comments.

The CHAIRMAN said that the drafting group established at the fourth meeting had produced a revised draft resolution, which read:

> The Sixty-fifth World Health Assembly,
>
> PP1 Having considered the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG);[1]
>
> PP2 Recalling resolution WHA63.28 which requested the Director-General, inter alia, to establish the CEWG in order to take forward the work of the Expert Working Group earlier established under resolution WHA61.21, and to submit the final report to the Sixty-fifth World Health Assembly;
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> PP3 Further recalling resolutions WHA59.24, WHA61.21 and WHA62.16,
>
> 1. WELCOMES the analysis of the CEWG report and expresses its appreciation to the Chair, Vice-Chair and all the members of the Working Group for their work;
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> 2. URGES Member States:[2]
>
> (1) to hold national level consultations among all relevant stakeholders in order to discuss the CEWG report and other relevant analyses resulting in concrete proposals and actions;
>
> (2) to participate actively in the meetings at regional and global level referred to in this resolution;

[1] Documents A65/24; Annex and A65/24 Corr.1.

[2] And, where applicable, regional economic integration organizations.

(3) to implement, where feasible, in their respective countries, proposals and actions identified by national consultations;
(4) to establish and/or strengthen mechanisms for improved coordination of research and development (R&D)[1] in collaboration with WHO and other relevant partners, as appropriate;

3. CALLS UPON Member States,[2] the private sector, academic institutions and nongovernmental organizations to increase investments in health research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases;

4. REQUESTS regional committees to discuss at their 2012 meetings the report of the CEWG in the context of the implementation of the global strategy and plan of action on public health, innovation and intellectual property[3] in order to contribute to concrete proposals and actions;

5. REQUESTS the Director-General to hold an open-ended Member States[2] meeting in order to analyse thoroughly the report and the feasibility of the recommendations proposed by the CEWG, taking into account, as appropriate, related studies. The meeting will also take into account the results from national consultations and regional committee discussions and develop proposals or options relating to (1) research coordination, (2) financing and (3) monitoring of R&D expenditures,[4] to be presented under a substantive item dedicated to the follow up of the CEWG report at the Sixty-sixth World Health Assembly, through the Executive Board at its 132nd session.

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

1. Resolution:	Consultative Expert Working Group on Research and Development: Financing and Coordination
2. Linkage to the Programme budget 2012–2013 (see document A64/7 http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_7-en.pdf)	
Strategic objective(s): 11	Organization-wide expected result(s): 11.1
How would this resolution contribute to the achievement of the Organization-wide expected result(s)?	
Access to essential medicines and medical technologies is a fundamental pillar of national medicine policies. Research and development of new medicines and technologies for effectively tackling the diseases that disproportionally affect developing countries is critical to improving access. It is also very important that new technologies, when developed, are affordable. Currently, spending on research and development is insufficient, and even when new medicines are developed they are not affordable. This resolution will support discussions and consultations among Member States on the feasibility of the	

[1] In the context of this resolution R&D shall refer to health research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.

[2] And, where applicable, regional economic integration organizations.

[3] Resolutions WHA61.21 and WHA62.16.

[4] As defined in the Global strategy and plan of action on public health, innovation and intellectual property.

recommendations of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, in particular those concerning a binding global instrument, aimed at enhancing sustainable funding for research and development and ensuring that the resulting products and technologies are affordable.

Does the programme budget already include the products or services requested in this resolution? (Yes/no)

No.

3. Estimated cost and staffing implications in relation to the Programme budget

(a) Total cost

Indicate (i) the lifespan of the resolution during which the Secretariat's activities would be required for implementation and (ii) the cost of those activities (estimated to the nearest US$ 10 000).

(i) 1 year (covering the period 2012–2013)

(ii) Total: US$ 1 370 000 (staff: US$ 370 000; activities: US$ 1 000 000)

(b) Cost for the biennium 2012–2013

Indicate how much of the cost indicated in 3 (a) is for the biennium 2012–2013 (estimated to the nearest US$ 10 000).

Total: US$ 1 370 000 (staff: US$ 370 000; activities: US$ 1 000 000)

Indicate at which levels of the Organization the costs would be incurred, identifying specific regions where relevant.

Headquarters and regional offices.

Is the estimated cost fully included within the approved Programme budget 2012–2013? (Yes/no)

No.

If "no", indicate how much is not included.

US$ 1 370 000

(c) Staffing implications

Could the resolution be implemented by existing staff? (Yes/no)

No.

If "no" indicate how many additional staff – full-time equivalents – would be required, identifying specific regions and noting the necessary skills profile(s), where relevant.

For the secretariat of the open-ended Member States meeting: one staff member at grade P.3 and one staff member at grade G.4 for one year.

4. Funding

Is the estimated cost for the biennium 2012–2013 indicated in 3 (b) fully funded? (Yes/no)

No.

If "no", indicate the funding gap and how the funds would be mobilized (provide details of expected source(s) of funds).

US$ 1 370 000; source(s) of funds: funding proposals will be sent to selected Member States and donor agencies.

Dr KIENY (Assistant Director-General) drew attention to an error in the text of the report on financial and administrative implications of the draft resolution. The correct text of paragraph 2 would read as follows: "This resolution will support discussion and consultations among Member States on the feasibility of the recommendations of the report of the Consultative Expert Working Group on

Research and Development: Financing and Coordination, aimed at enhancing sustainable funding for research and development and ensuring that the resulting products and technologies are affordable."

Dr VIROJ TANGCHAROENSATHIEN (Thailand), introducing the revised draft resolution, compared the work of the drafting group, which he had chaired, to the process of birthing a baby, with the Committee as natural parents, the drafting group as midwives, and the Director-General and her staff as foster parents and babysitters of a new draft resolution. Agreement on the text had been reached by consensus.

The CHAIRMAN said that, in the absence of any objection, he took it that the Committee wished to approve the draft resolution.

The draft resolution was approved.[1]

Dr DAULAIRE (United States of America) thanked the chairman of the drafting group for serving as its chief obstetrician. The degree of consensus reached on the resolution in such a short time had set a new standard for future drafting groups. There had been a commendably focused commitment among drafting group members to ensuring that new, appropriate and affordable products could be made available to people in need around the world. Noting the Assistant Director-General's explanation of the error in the report on the financial and administrative implications, he requested that the document be reissued with the necessary correction.

Ms SCHJØNNING (Denmark), speaking on behalf of the European Union and its Member States, commended the leadership displayed by the chairman of the drafting group. The lack of research and development in the area of health products of benefit to developing countries was a serious problem that needed to be addressed. The process of reinforcing and expanding the initiatives already in place should go hand in hand with the preparation of decisions to be taken at the Sixty-sixth World Health Assembly. The Secretariat should provide advice and support to help identify the most appropriate and cost-effective sequencing of decisions, options and actions in a budget-constrained environment. The European Union was also prepared to consider the possibility of early deliverables.

Dr GAMARRA (Paraguay), speaking on behalf of the members of the Union of South American Nations, thanked the chairman of the drafting group for his wisdom, patience and leadership in the difficult hours leading up to the birth of the draft resolution. All the members of the group had made substantive contributions to the discussions, and the Secretariat had provided valuable support by preparing documentation in a timely manner. The spirit of Geneva had prevailed, making it possible to reconcile diverging positions and achieve a consensus.

Ms MATSOSO (South Africa) congratulated the chairman of the drafting group on his skilful guidance of the work on the draft resolution, and recalled that he had previously also made an invaluable contribution to the drafting of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Dr EL OAKLEY (Libya), speaking on behalf of the Member States of the Eastern Mediterranean Region, thanked the chairman of the drafting group for making the impossible possible.

[1] Transmitted to the Health Assembly in the Committee's fourth report and adopted as resolution WHA65.22.

Dr MALECELA (United Republic of Tanzania) thanked the chairman for his skilful leadership and good humour in guiding the work of the drafting group in difficult circumstances. She commended the spirit of compromise that had prevailed in the group.

The DIRECTOR-GENERAL thanked the Member States, who were the natural parents of the resolution, and the members of the Consultative Expert Working Group, who were its surrogate parents. As a foster parent of the text, she was mindful of the need for efficiency and effectiveness and considered that time and resources should not be wasted. She would strive to ensure that the resolution served to facilitate the building of a fairer world, which was the goal of WHO in the 21st century.

Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: report on the work of the Advisory Group: Item 13.9 of the Agenda (Document A65/19)

Dr AL-TAAE (Iraq), speaking on behalf of the Member States of the Eastern Mediterranean Region, welcomed the report of the Advisory Group and the establishment of a framework for sharing influenza viruses, which would assist in the preparation of pandemic guidelines. It was important to promote research in relation to virus sharing and access to vaccines and to establish partnerships in different countries. The decision to use 70% of resources for preparedness and 30% for response was well founded, as it would make it possible to strengthen global partnerships, build necessary institutional partnerships, and improve capacity building in countries and regions. The Pandemic Influenza Preparedness Framework was a major step forward.

Dr CHAND (Nepal), speaking on behalf of the Member States of the South-East Asia Region, welcomed the support given by WHO to the Pandemic Influenza Preparedness Framework, which was an important initiative for countries in his Region. Implementation of the Framework would benefit national, regional and global public health, and promote equity in the sharing of influenza viruses and the associated benefits. Sharing of benefits should be based on levels of development. There were great variations in States' preparedness and response capacity, as well as in the degree to which each State was affected by avian influenza (A/H5N1). In his Region, six cases of avian influenza had been reported in Bangladesh, 129 in Indonesia, one in Myanmar and 25 in Thailand. The risk of the disease spreading to other countries, within and outside the Region, had led several south-east Asian countries to develop capacity to produce influenza vaccine. Those States might therefore benefit from the transfer of appropriate technology.

Although the Pandemic Influenza Preparedness Framework had been adopted one year earlier, standard material transfer agreements (SMTAs) between the Global Influenza Surveillance and Response System and other entities did not appear to have come into effect, and he requested the Director-General to indicate a time frame for operationalization. SMTA 2 negotiations should be accelerated, starting with at least one type of virus or manufacturer by the end of 2012. Noting that the interim mechanism for virus transfer to third parties was in place, he asked the Director-General to report back to the Sixty-sixth, Sixty-seventh and Sixty-eighth World Health Assemblies on the progress of SMTA 2 negotiations. He asked whether any manufacturers had made contributions to WHO in relation to pandemic influenza preparedness. Consideration should be given to establishing a mechanism to enable the needs of Member States to be communicated directly to the Advisory Group, so that informed decisions could be taken on the allocation of benefits and technology transfer. He asked the Secretariat to update Member States on a more regular basis regarding the status of Advisory Group recommendations and the status of virus sharing.

Dr KUDO (Japan) said that, when an influenza pandemic occurred, it was essential to respond by sharing pandemic virus specimens quickly. The Pandemic Influenza Preparedness Framework would play a crucial role, but its effectiveness would depend on the feasibility of its detailed application. The amount of companies' partnership contributions should be set on the basis of the

views of industries, as key stakeholders in the Framework. Their nature and capacities should be reflected appropriately, as described in the Framework document.

Although the Advisory Group had held closed meetings, he requested the Group to consider making its materials available publicly once meetings were over, in order to ensure transparency. The total amount of partnership contributions for 2012 was some US$ 28 million, estimated as 50% of the operating costs of the Global Influenza Surveillance and Response System; however, no specific plan had yet been laid out to indicate how the total requirement of US$ 57.4 million would be obtained. It would be difficult to obtain contributions from industry without providing sufficient explanation. Allocating 70% of partnership contributions to preparedness and the remainder to pandemic response seemed reasonable.

Miss ORATHAI WALEEWONG (Thailand), welcoming the consensus reached on the Framework, commended the Advisory Group and other partners for their commitment to finalizing negotiations and requested the Secretariat to implement the Framework to achieve a fair, transparent, equitable, efficient and effective system. Although the process of finalizing the standard material transfer agreement 2 (SMTA 2) was complicated, time consuming and difficult, it was a stepping stone to implementation of the Framework. She therefore encouraged the Director-General to accelerate work in that regard and urged recipients of pandemic influenza preparedness biological materials outside the Global Influenza Surveillance and Response System to contribute to finalizing the SMTA 2 negotiations.

While it was clear that research must continue, it was also clear that certain research, which could generate more dangerous forms of the influenza virus, had the potential to pose a serious threat to the public. In the absence of a global or national regulatory mechanism, such high-risk research should be carried out only after all significant public health risks and benefits had been identified and thoroughly reviewed. Research facilities, biological material repositories and data management should operate to internationally acceptable standards in order to maximize benefits and guard against risks to public health. She urged WHO to work with research sponsors, Member States and other key parties towards developing a research regulation mechanism.

Pandemic influenza preparedness would continue to be a work in progress, as the Framework remained under development. Thailand was fully committed, and would contribute, to global preparedness. She stressed that mistrust and legal difficulties should not be allowed to hamper the global public health movement.

Mrs SMIRNOVA (Russian Federation), expressing appreciation to the Advisory Group for its work, welcomed the Organization's flexibility in its efforts to finalize the SMTA 2 negotiations, particularly with respect to the interim process for transferring pandemic influenza preparedness biological materials. Parties would be required to adhere to the spirit of a mechanism for sharing viruses and benefits on the basis of mutual trust and equity, so as to safeguard global public health. SMTA 2 negotiations should be finalized promptly through legal and other consultations, and preventive measures should be a priority to ensure that countries were prepared for pandemics. The Secretariat should also be flexible with regard to allocating resources on the basis of the prevailing epidemiological situation.

Ms SCHJØNNING (Denmark), speaking on behalf of the European Union and its Member States, said that the acceding country Croatia, the candidate countries Turkey, the former Yugoslav Republic of Macedonia, Montenegro, Iceland and Serbia, the countries of the Stabilisation and Association Process and potential candidates Albania and Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova, Armenia and Georgia, aligned themselves with her statement.

She commended the Advisory Group and the Secretariat for the progress made in implementing the Framework, which marked an important step towards an efficient Global Influenza Surveillance and Response System and would enhance international public health and laboratory collaboration. She

supported the proposal that, over the coming five years, 70% of partnership contributions should be used for pandemic preparedness and 30% for response. Capacity building and technology transfer for vaccine production were essential elements of preparedness, but the decision on how to allocate resources for preparedness in order to develop sufficient capacity in all regions should be left to the Director-General, based on advice from the Advisory Group.

Building on integrated surveillance and response capacities in developing countries would be essential for strengthening pandemic influenza preparedness globally, and she welcomed work on a classification system to determine, on the basis of public health system capacities and epidemiological and economic criteria, which countries would benefit from contributions. She particularly welcomed the proposal that core capacities under the International Health Regulations (2005) should be one of the classification criteria.

Endorsing the view of the Advisory Group on SMTA 2 negotiations, she underscored the need for a practical, balanced and uniform interim process so that materials could continue to be transferred outside the Global Influenza Surveillance and Response System, but without losing the incentive to conclude final agreements with industry swiftly. She urged the Secretariat to speed up work to that end and to report frequently to Member States on progress achieved, and affirmed the European Union's willingness to cooperate in further work, including the Framework review scheduled for 2016.

Ms WISEMAN (Canada) said that a robust and dynamic Advisory Group was key to implementing the Framework. Finalizing SMTA 2 negotiations was essential in order to ensure full virus sample sharing under the Framework. Her Government would be pleased to play its part, recognizing that the Secretariat needed human and financial resources to achieve that goal, including legal support.

Dr WU Liangyou (China), expressing appreciation to WHO for its efforts to establish a transparent, fair and reasonable Framework, said that the rapid response of Member States and the Secretariat to the outbreak of pandemic (H1N1) 2009, including the prompt sharing of viruses, had enabled his country to produce vaccine quickly and to vaccinate key groups. With WHO support, his Government had made remarkable progress in surveillance and preparedness. The Chinese Center for Disease Control and Prevention had served as the WHO Collaborating Centre since 2010, and China would continue to support and actively participate in global surveillance and share viruses and benefits. Where possible, it would also make donations to the international vaccine reserve. He suggested that partnership contributions should be determined, taking into account each individual company's capacity.

Mrs ESCOREL DE MORÃES (Brazil) said that the Advisory Group was right to prioritize partnership contributions and SMTA 2 negotiations, both of which were of fundamental importance for the functioning of the Framework. The Advisory Group had a key role to play in determining the contributions to be made by individual companies and others and in establishing rules for resource allocation, which could serve as a good example for discussions on WHO reform.

SMTA 2 negotiations should be finalized and the agreements implemented rapidly, as such agreements would provide the essential basis for producing vaccines and sharing benefits. A reasonable level of benefits should be provided, including the sharing of knowledge, technology and know-how with developing countries, with a view to increasing and diversifying vaccine production capacity. She congratulated the Advisory Group on the transparent manner in which it was maintaining a dialogue with industry.

The Framework was intended to strengthen cooperation between Member States and should be implemented fairly, efficiently and transparently, favouring those that had less, including those that would not have the capacity to respond with their own means in the event of a pandemic. Brazil attached great importance to the pandemic influenza preparedness process because it highlighted the

critical importance of making the dynamics of decision-making within WHO more democratic and set an example for current and future negotiations.

Dr DOUA (Côte d'Ivoire), welcoming the equitable approach to benefit sharing encouraged in the report of the Advisory Group, said that sentinel surveillance for influenza at 19 sites across his country allowed monitoring of changes in the virus and enabled Côte d'Ivoire to participate in collaborative activities with WHO. He reaffirmed the principle of equitable access to vaccines and universal access to medicines at affordable prices and expressed support for both the transfer of appropriate technologies and the necessary technical support to ensure a sustainable supply of vaccines.

Given the multifaceted nature of the fight against pandemic influenza, his Government was committed to doing its part by sharing clinical and virus samples from its laboratories. WHO should establish a framework to improve access to vaccines for people in Africa, and should also work on tracing systems for samples and viruses. He expressed appreciation to the Secretariat and to other Member States for their support in strengthening epidemiological and microbiological surveillance, and requested further technical, material and financial support to improve pandemic preparedness.

Dr DÍAZ (Chile) said that his country had complied with the resolutions of the Executive Board and the Health Assembly on the subject of pandemic influenza preparedness. It had formulated both a national influenza prevention and control policy and a national preparedness and response plan and had always supported virus sharing, which was a field in which WHO coordination and leadership had achieved positive results. He urged the Advisory Group to focus in particular on availability of vaccines and sharing of viruses and benefits, including identification of exactly which benefits were to be shared, and requested the Secretariat to maintain and strengthen mechanisms for disseminating viral epidemiology information, specifically with regard to the swine-origin triple reassortant influenza A(H3N2) and avian influenza A(H5N1) viruses, so as to improve preparedness and mitigate their pandemic potential.

Dr DAULAIRE (United States of America), expressing support for the Organization's efforts to strengthen global pandemic influenza surveillance and response, said that his Government remained strongly committed to the Pandemic Influenza Preparedness Framework and looked forward to its implementation, in accordance with the consensus already achieved. The Framework had broken new ground on a number of levels, requiring adaptation to new procedures for the operation of the Global Influenza Surveillance and Response System and challenging the Secretariat to engage with Member States and civil society, including manufacturers, in new ways. The progress made thus far was encouraging.

It was important to keep the Global Influenza Surveillance and Response System in operation during the transition period in implementing the Framework. The Secretariat had provided guidance for the interim period and had interacted well with the Advisory Group, industry and other elements of civil society. It was particularly satisfying that stakeholders had been involved in Advisory Group meetings, a practice that should continue. Active consultation with civil society, including industry, was an integral part of Framework implementation. He welcomed the initiation of SMTA 2 negotiations with industry, noting that questions had already been raised by stakeholders concerning the implementation of the Framework during the interim period preceding the conclusion of those negotiations.

The budgetary challenges faced by WHO should not be ignored: it was the joint responsibility of Member States to ensure that the Secretariat could meet its responsibilities with respect to the Framework and he encouraged Member States to provide necessary human and financial resources. His Government stood ready to do its part.

Dr Ho-Sheng WU (Chinese Taipei) said that experience had shown the importance of virus sharing and access to vaccines for pandemic influenza preparedness. As the vaccine manufacturer in Chinese Taipei was capable of producing vaccine for internal use, it hoped to be included in preparedness efforts. A Global Influenza Surveillance and Response System self-assessment would be welcome, as would WHO support to build influenza surveillance and laboratory capacity in developing countries. Some countries might require further technical or financial support from WHO to implement the Framework. Chinese Taipei would be pleased to share its experience. Highlighting the importance of stockpiles of pre-pandemic vaccines, he expressed support for Advisory Group efforts to establish an international stockpile of vaccines for avian influenza A(H5N1) and other viruses with pandemic potential. Chinese Taipei would contribute more in that respect, provided that its vaccine manufacturer was approved by WHO.

Mr DURISCH (Stichting Health Action International), speaking at the invitation of the CHAIRMAN, and on behalf of the Berne Declaration, the Third World Network and the People's Health Movement, expressed disappointment that, in the year since the adoption of the Framework, not a single SMTA 2 had been signed, even though biological materials had been exchanged with recipients outside the Global Influenza Surveillance and Response System. That situation had also affected full implementation of existing SMTAs within the Global Influenza Surveillance and Response System. It would be interesting to know whether the contributions due from manufacturers under the Framework had already been made and how much each manufacturer would contribute; additional information on the activities envisaged with respect to preparedness under the proposed 70%–30% division of partnership contributions would also be welcome. Pandemic preparedness should encompass building influenza surveillance and laboratory capacity and vaccine manufacturing capacity in developing countries. In the interests of equity and transparency, he suggested that the Secretariat should make available to the public the annual reports of the Advisory Group and information on partnership contributions made by manufacturers, including the use thereof.

Dr FUKUDA (Assistant Director-General), welcoming the support provided by Member States for the process of negotiating and implementing the Framework, said that it had indeed broken new ground and helped to democratize discussions within the Health Assembly and among Member States. The Secretariat was working towards full implementation as quickly as possible, but the process was complex and full of challenges. Significant progress had been made over the last year: the Advisory Group had held three meetings, with substantive discussions on SMTAs, including the finalization of SMTA 2, and partnership contributions, and efforts had been made to disseminate information and raise awareness, including the publication of a handbook on the Framework in all six official languages and the creation of a dedicated section on the WHO web site. He welcomed calls for the reports of the Advisory Group to be made more widely available and committed to doing so.

Formal discussions with three of the largest vaccine manufacturing companies on SMTA 2 arrangements had started well. The companies recognized the importance of the Framework and had expressed full support for its implementation. Discussions would be extended to other companies, including manufacturers in developing countries and manufacturers of diagnostic equipment and antiviral medicines. Realistically, however, the pace of negotiations was limited by the size of the Secretariat and the availability of legal support. The problem was being discussed with Member States.

The first US$ 28 million of partnership contributions was due in 2012, and the Secretariat was engaged in discussions with industry on how individuals contributions should be apportioned. Based on the principle of fairness, the amount each company was asked to provide should reflect what materials they received through the Framework and their market share. The Executive Board, at its 131st session, would consider whether the Director-General's proposal that 70% of the partnership contribution should be allocated to preparedness and 30% to response, was reasonable.

Responding to points raised by the delegates of Thailand and the United States of America, he said that a matter of concern to WHO and Member States was ensuring that research using viruses with pandemic potential was done under the safest possible conditions. The Secretariat hoped to convene a meeting on the subject later in 2012 or early 2013.

With regard to the allocation of partnership contributions, he said that the Advisory Group had recognized the need to build capacity in countries where it was needed most, and the Secretariat would work closely with the Group to that end. On the issue of the interim process for transferring pandemic influenza preparedness materials before the finalization of SMTA 2, he welcomed calls for flexibility. Companies receiving materials had been asked to agree to enter into discussions on concluding an SMTA 2. The aim was to ensure that viruses and other materials could continue to be shared for public health purposes during the interim period.

The DIRECTOR-GENERAL said that the speed with which the Framework could be implemented depended on several factors. Member States had expressed the desire for a transparent, fair process driven by a representative group of countries. Three meetings of the Advisory Group established for that purpose had already been organized, and the Group had provided beneficial advice, particularly for SMTA 2 discussions. She hoped that industry would likewise make its contribution to the process. The issue of partnership contributions placed WHO in a difficult situation, given the potential for conflicts of interest to arise, and the advice of the Advisory Group was particularly valuable in that respect. While acknowledging civil society calls for more progress to be made, she emphasized that the Secretariat could not compromise on fairness and transparency for the sake of speed. Progress depended partly on how many staff were available, and legal expertise was vital. She welcomed the financial and legal support provided by the Governments of Canada and the United States of America, but said that more was still needed. She reaffirmed the Secretariat's commitment to implementing the Framework.

The Committee noted the report.

Implementation of the International Health Regulations (2005): Item 13.7 of the Agenda (Documents A65/17, A65/17 Corr.1, A65/17 Add.1, A65/17 Add.2 and A65/17 Add.3)

The CHAIRMAN, introducing the item, said that informal consultations had already begun on the draft resolution contained in document A65/17 Add.2, the financial and administrative implications of which were set out in document A65/17 Add.3. Pending the results of those consultations, he invited general comments on the implementation of the International Health Regulations (2005).

Mr SKOTHEIM (Norway) said that, in order to save time, he would submit the full text of his statement to the Secretariat in writing.

Dr AL-TAAE (Iraq) said that Iraq considered the International Health Regulations (2005) to be a key part of global health partnership and had taken several measures to implement them nationally, including establishing within the Ministry of Health a steering committee and focal points. Legislation and workplans had been developed or strengthened for the implementation of the Regulations across all sectors; particular issues of concern had been addressed and monitoring and evaluation strategies had been developed. His Government's priorities included halting the transmission of communicable diseases, developing procedures to ensure food safety, scaling up joint management, planning, monitoring and evaluation measures across all ministries. It would continue to incorporate the requirements of the Regulations into key areas of health, including control of communicable diseases, health of travellers, and food and medicines.

Dr HEMMATI (Islamic Republic of Iran) said that the threat posed by pandemic (H1N1) 2009 had provided countries with the opportunity to evaluate their preparedness for public health emergencies of international concern. All Member States should use the International Health Regulations (2005) core capacity monitoring framework to develop and strengthen their core capacities in order to ensure that they would be able to deal successfully with future public health emergencies. To address the challenges that remained in implementing the Regulations, additional interregional collaboration mechanisms were needed, as was further technical support from WHO to strengthen capacity in areas such as human resources, surveillance and cross-border health activities.

Ms POLL (Costa Rica) said that the Regulations were fundamental to monitoring health at all land, air and sea borders. Her country's Ministry of Health had been responsible for implementation, supported by other sectors and PAHO, and significant progress had been made. Core capacities had been assessed, and improvement and contingency plans had been established. Subnational monitoring plans had also been developed at points of entry. The country was thus well prepared to respond to any public health event of international concern. Efforts had also included the production of guidelines for dealing with specific situations, including coordinating the notification and management of emergencies relating to contaminated food and to bioterrorism, and for communication of risk when transferring a patient from one country to another. Her delegation called on the international community and on the Secretariat to continue supporting countries in implementing the Regulations and sustaining the progress already made.

Ms SCHJØNNING (Denmark), speaking on behalf of the European Union and its Member States, said that the acceding country Croatia, the candidate countries Turkey, the former Yugoslav Republic of Macedonia, Montenegro, Iceland and Serbia, the countries of the Stabilisation and Association Process and potential candidates Albania and Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova, Armenia and Georgia aligned themselves with her statement. The International Health Regulations were the core instrument for improving global health security, and she strongly encouraged all States Parties to collaborate actively in ensuring full implementation of the Regulations, particularly strengthening and maintaining the required core capacities. The Health Assembly should continue to monitor progress.

As the June 2012 deadline approached, a review was needed to determine the extent to which the core capacities had been implemented and what action was needed in order to overcome remaining challenges to full and effective implementation. There was a clear need to keep implementation of the Regulations high on the international health agenda, and the European Union therefore urged the Secretariat to formulate a post-2012 workplan for guidance, training and assessment of States Parties' implementation of the core capacities, so as to ensure that the Regulations remained the common leading instrument for global health security.

Dr DÍAZ (Chile) reaffirmed his Government's commitment to enhancing its human, physical and financial resources in the health sector in order to implement the Regulations. By June 2012, Chile would have fulfilled 93% of the core capacity requirements under the Regulations and would continue to work towards full compliance by improving point-of-entry surveillance and response capabilities and developing intersectoral contingency plans. The Government did not intend to request an extension of the deadline. It was willing to share its experience with other Member States in order to further global implementation of the Regulations.

Ms ALI (Maldives), speaking on behalf of the Member States of the South-East Asia Region, said that, while significant progress had been made in strengthening core capacities in the Region, the level of implementation was uneven among countries and across capacities. Fulfilling the requirements of the Regulations demanded policy and action in non-health sectors and greater

commitment and partnership at the national, regional and global levels. WHO should have an increased role in advocacy and facilitating dialogue.

Meeting the core capacity requirements by the June 2012 deadline would be a challenge, and most Member States in the Region would be applying for a two-year extension. Achieving full compliance within that extension period would require realistic implementation plans, with political commitment at the country level and continued technical and financial support from WHO and other partners. WHO support would be particularly welcome in regard to conducting full assessments of core country capacities and developing guidelines and ensuring the availability of contingency funding for public health emergencies. The current financial constraints faced by WHO and the low level of donor and partner support were matters of concern, especially as the full implementation of the Regulations required financial investment beyond the capacity of developing countries. Urgent action was needed to resolve the issue of funding if the deadlines for implementation were to be met.

Mr ROLLIANSYAH SOEMIRAT (Indonesia) said that it was vitally important to strengthen core capacities and develop national plans for the implementation of the International Health Regulations as a means of achieving global health security. Her Government had established a national committee on implementation of the Regulations but recognized that there were many areas where capacity still needed strengthening. It had therefore applied for an extension of the deadline to mid-2014.

Dr RAMSARAN (Guyana), speaking on behalf of the member countries of the Caribbean Community, said that an analysis of core capacity levels had shown clear regional differences in current strengths and weaknesses; intensified efforts were required from countries, the Secretariat and the regional offices to eliminate those regional variations. The capacity of the countries of the Caribbean Community to respond to chemical and radionuclear events was currently weak but, through support from PAHO and the Caribbean Epidemiology Centre, subregional plans had been formulated for strengthening systems of regulation, detection and response to such events. Individual country action plans would allow for national responses involving not just the health sector but all stakeholders. Other subregional activities included the development of a training curriculum on inspection of ships and aircraft; courses on port health, which could be offered online; and workshops on strengthening legislation and collaboration with ICAO and IAEA in order to build core capacities.

Dr SA'A (Cameroon) said that, despite facing a number of challenges, his Government had made significant progress in strengthening the core capacities required under the International Health Regulations. He commended the Secretariat's development of indicators and tools to be used in the annual monitoring of implementation of the Regulations. It was to be hoped that continued Secretariat support would be provided to help countries attain their core capacities by the extended deadline of mid-2014.

Mr NEVES SILVA (Brazil) emphasized that all countries must remain committed to assessing and developing their core capacities for surveillance and response to public health emergencies and to implementing the Regulations. The Secretariat should ensure that the necessary support was provided to countries. His Government had complied with the requirements set out in Annex 1 of the Regulations and had carried out an assessment of capacities at the subnational level and developed a plan to strengthen them further. It remained committed to supporting other countries in the implementation process in a spirit of South–South cooperation.

Dr HAO Yang (China) said that the implementation of the Regulations had greatly contributed to the development of capacities for assessment, surveillance and response to public health emergencies. His Government was continuing to strengthen core capacities and, to that end, had held training workshops and ensured real-time communication with WHO. He underscored the need for all

States Parties to improve their core capacities for assessment, notification and response to public health emergencies. WHO had provided valuable support and tools to countries in recent years for monitoring capacity building at subnational level. States Parties should respond to the relevant WHO questionnaires with a view to determining whether they could meet the June 2012 deadline for fulfilling the core capacity requirements.

Mrs SMIRNOVA (Russian Federation) observed that although many Member States had made progress towards achieving the core capacities required under the Regulations, others had more to do and would need to take action within a relatively short space of time. It was very important for countries requesting an extension to identify gaps, formulate clear national plans to eliminate them and mobilize all necessary resources to that end. Some countries, particularly those with limited resources, would doubtless need support from WHO and other partners, but there must be a clear understanding of what support was required.

The Russian Federation had developed a methodology for implementing the Regulations and applied it at national level. Steps were being taken to modernize the national laboratory network, enhance intersectoral cooperation, and formulate and implement training programmes for experts. National standards and methodologies had been aligned with the Regulations. By the deadline set, all core capacities would be in place. Her Government stood ready to provide scientific and human resources to assist other States Parties in building and strengthening their core capacities. She welcomed the guidelines produced by the Secretariat thus far and requested that guidance also be prepared on port certification procedures.

Ms MATSOSO (South Africa) said that States Parties to the International Health Regulations needed to ensure a common interpretation of public health requirements, with uniform procedures for vaccine-preventable and epidemic-prone diseases in particular. Drawing attention to the section in the Secretariat's report (document A65/17) on yellow fever and the list of countries where it still occurred, she requested clarification on the proper interpretation of Annex 7, when read in conjunction with Article 31, paragraph 2, and Article 36 of the Regulations. All States Parties should adhere to their commitments under the Regulations, given their importance for controlling the spread of disease and protecting health.

Dr CHIN Zing Hing (Malaysia) expressed appreciation for the Secretariat's continued efforts to support countries in developing their core capacities under the International Health Regulations. While Malaysia had already attained its core capacities, it would continue to strengthen them in the areas of importance identified in the Asia Pacific Strategy for Emerging Diseases 2010, which also served as a strategy for compliance with the International Health Regulations (2005).

Dr DAULAIRE (United States of America) said that the International Health Regulations had proved their value in protecting the international community from the spread of public health threats across borders and it was therefore critically important, in the next two years, to intensify international efforts to build core capacities for the benefit of all Member States. His Government had taken several measures to ensure compliance with the Regulations, including through a trilateral, cross-sectoral plan with Canada and Mexico on preparing for and responding to pandemic influenza threats. He urged all countries to formulate similar plans to improve information-sharing and preparedness. The Secretariat should continue to work with Member States to ensure full compliance with the Regulations by mid-2014 and should also facilitate connections between countries and potential providers of support in the strengthening of national core capacities.

Ms BALAS (Germany) expressed appreciation for the Secretariat's support to Member States for the implementation of the Regulations, which had been an enormous task, but one that had contributed considerably to better global public health preparedness. Her Government had produced

legislation fulfilling the legal requirements of the Regulations and had worked hard to translate the requirements relating to airports, ports and ground crossings into national recommendations. It would be pleased to share those recommendations with other interested States Parties in order to support their own implementation efforts. The Secretariat should continue to support Member States in further developing their preparedness and response capacities in the post-2012 period.

Dr GORI MOMOLU (Equatorial Guinea) said that his Government had provided training to staff in various areas to help implement the Regulations throughout the country, including at points of entry, ports and airports. National surveillance and response capacity had been assessed and a plan of action developed. A national focal point had also been appointed for the management of health emergencies, and border personnel had received training on the notification of and response to such emergencies.

Mr LASKAR (Bangladesh) noted that although progress had been made on implementing the International Health Regulations (2005), many countries would not be able to meet the June 2012 deadline owing to technical and financial constraints. Bangladesh had made considerable progress in building capacity, particularly in relation to surveillance, management of public health emergencies of international concern, laboratory strengthening and the drafting of a new law to enforce the Regulations. However, additional financial, human and material resources were needed in order to ensure full compliance, particularly in the areas of infection control and prevention and the implementation of measures at border entry points. He urged the Secretariat to mobilize additional resources to support Member States in meeting the proposed extended deadline for implementation. Advocacy efforts should be strengthened with all stakeholders in order to raise awareness of the importance of the Regulations, and support should be provided to enable Member States to improve their border entry point capacities.

Dr JIMA (Ethiopia), speaking on behalf of the Member States of the African Region, said that, although significant progress had been made in the assessment of national core capacities in relation to surveillance and response, laboratory services and zoonotic events, many countries in the African Region had reported relatively low capacity in relation to human resources and the detection of chemical and radionuclear events. To date, 40 of the 46 African Member States had assessed their national core capacities for surveillance and response and had developed plans of action. Thirty had identified competent authorities to oversee the implementation of public health measures in line with the Regulations and 19 countries had assessed capacity at designated points of entry. However, in spite of the progress made, many African countries would not be able to meet the June 2012 deadline, mainly owing to lack of financial resources. The Secretariat had an important role to play in mobilizing resources and supporting Member States in accelerating the attainment of the core capacities, including assessment and enhancement of laboratory capacity; development of new tools to strengthen capacity at points of entry; and training of public health professionals. It was of particular importance to enable African Member States to attain the core capacities, given that many of the diseases with the potential to cause international health emergencies originated in the Region.

Dr IWATA (Japan) said that many Member States would not be able to fulfil the core capacity requirements by the agreed initial deadline and asked the Secretariat what support they could be given in that regard. Additional technical support should be provided to Member States to enable them to improve the detection of and response to chemical and radionuclear events and emergencies. The development of an enforcement mechanism would increase the operational effectiveness of the International Health Regulations (2005). Japan was continuing to strengthen its domestic system for implementation of the Regulations and stood ready to promote international cooperation, in collaboration with WHO, for the building of core capacities.

Dr SALALH (Egypt) said that his country was implementing the International Health Regulations and strengthening its human resources in that area. The Ministry of Health had developed a web site providing information on the country's core capacities, which might be useful to other Member States. Referring to the outbreak of *Escherichia coli* (E. coli) O104:H4 in Germany in 2011, he thanked WHO for the support provided to establish the source of the outbreak. Egypt had been wrongly alleged by some to be the source, which had led to significant economic losses as a result of reduction in trade. Countries and organizations should not implement restrictions or bans on the import of products without consulting and cooperating with the countries concerned, given the potential social and economic impact. WHO should maintain a leading advisory role in such matters.

Mr URQUIDO VELÁSQUEZ (Colombia) said that full compliance with the International Health Regulations and the strengthening of national core capacities were essential to national and international public health security. His Government had developed a programme to implement the Regulations, which included assessment of national core capacities; institution-building and allocation of resources at the local level to enhance monitoring and response capacities; strengthening of international and cross-border cooperation; support and technical support for port health; and strengthening of national communication links and networks for purposes of monitoring, risk assessment and reporting to WHO of events posing a potential risk to global public health. Member States must continue their efforts to apply the Regulations, which were an important instrument for the monitoring and management of public health and gave new meaning to the concept of national and global public health security.

Ms WISEMAN (Canada) said that her Government remained committed to collaborating with WHO and PAHO to support the implementation of the International Health Regulations, which continued to pose significant challenges for some Member States, a number of which would not meet the core capacity requirements by the June 2012 deadline. Considerable effort would be needed to ensure that national core capacity requirements were met by the new 2014 deadline. Partnerships would be important for stimulating progress, as would strong national focal point networks and the promotion of knowledge-sharing activities, which would encourage the exchange of public health information as well as resources and best practices.

Dr BENJAPORN PANYAYONG (Thailand) welcomed the progress made in strengthening implementation of the Regulations, but expressed concern at the slow progress made by some States Parties in building human resource capacity, especially in relation to chemical and radionuclear events. Multisectoral action and international collaboration were essential for the effective implementation of the Regulations; States Parties and the Secretariat should work together to promote the engagement of stakeholders at all levels. Multiple channels of communication should be promoted, including between national focal points and the Organization, as well as with formal and informal national, regional and transregional networks, in order to ensure a timely and effective response to public health emergencies of international concern. Regional and global networks should be supported and fostered; they had already proved to be effective in providing an immediate cross-border response to avian influenza A(H5N1). Field epidemiology training programmes, such as the ASEAN+3 Field Epidemiology Training Network, had contributed to the strengthening of human resources.

Dr LARIK (Pakistan) said that the International Health Regulations were essential to protect communities from cross-border infections. His country had completed the self-assessment questionnaire on the implementation of the Regulations and had taken a range of measures to improve port health, including the establishment of health clearance certificates, ship sanitation control certificates and ship sanitation exemption certificates that were periodically reviewed to ensure their effectiveness and alignment with international norms. National monitoring and surveillance systems had been established at all entry points in order to prevent cross-border transmission of yellow fever.

As a result, Pakistan was yellow fever-free. The provision of additional technical support would enable his country to be fully compliant with the Regulations, in particular with regard to laboratory strengthening, the implementation of early warning systems and the preparedness of public health professionals, especially in the context of radionuclear and chemical events. His country would be requesting an extension of the compliance deadline.

Dr ALLENDE (Paraguay), speaking on behalf of the member and associate member countries of the Common Market of the Southern Cone (MERCOSUR), said that MERCOSUR had designed an instrument to assess national core surveillance and response capacities, and PAHO had assisted in the migration of the data collected. However, the assessment did not include core capacities at points of entry. Noting that a number of guidelines and other important documents existed only in English, he urged the Secretariat to provide them in all of the six official languages of WHO.

Although States Parties to the Regulations were required to provide a rapid response to radionuclear and chemical events, that would not always be possible given the time required to analyse the necessary data and consult the relevant experts at all levels of government. Requests for information in relation to such events should be made directly to the highest ministerial authority, allowing it sufficient time to provide a comprehensive response. MERCOSUR countries had faced a number of challenges in implementing the Regulations, including lack of procedures for monitoring overall compliance and difficulties in defining the measures needed to address key aspects of implementation. The operational framework of the Regulations should be reviewed, including the definition of the functions of national communication networks and the feasibility of ensuring full compliance, including the financial implications. Full implementation of the Regulations would require a concerted effort on the part of all States Parties.

Dr BANGA-MINGO (Central African Republic) said that the International Health Regulations were an important instrument for preventing and controlling communicable diseases, which remained the most serious public health issue in many countries, including his own. With the support of WHO, his country had made some progress in applying the Regulations, for example by establishing an institutional and regulatory framework to facilitate implementation, by raising awareness, and by strengthening national core capacities and epidemiological surveillance activities. However, full implementation of the Regulations was hindered by a number of major challenges, including insufficient qualified human resources, lack of resources, and an inadequate technical platform to support the health system and laboratories in monitoring and surveillance activities. His Government was working to strengthen those areas and reinforce multisectoral partnerships in order to achieve compliance with the Regulations. Full implementation was also hindered by the apparent unwillingness of neighbouring countries to declare outbreaks of disease promptly and candidly, owing to the possible implications for trade and tourism. He encouraged all States Parties to adhere to the Regulations in order to facilitate the management of global public health risks and emergencies.

Dr Ho-Sheng WU (Chinese Taipei) encouraged the Secretariat to continue providing support to those countries that would not meet the national core capacity requirements by the mid-2012 deadline. Chinese Taipei had attained the minimum core capacity requirements and would willingly share its experience. It would also continue to work with the Secretariat and States Parties in detecting the emergence of infectious diseases and potential public health emergencies of international concern. He expressed support of the Secretariat's activities with global partners to monitor, assess and respond to important food safety-related events and looked forward to further international collaboration on health issues of global concern.

Dr FUKUDA (Assistant Director-General), thanking Member States for their comments, said the Secretariat had understood the interventions and that appropriate responses would be provided to the concerns raised.

The CHAIRMAN asked the Secretary to read out the amendments to the draft resolution contained in document A65/17 Add.2, as proposed by an informal drafting group.

Dr DAYRIT (Secretary) said that the amendments focused on four key areas: the difficulties in implementing the Regulations with regard to points of entry; the need for constructive engagement of stakeholders; the importance of regional and transregional networks; and the provision of an interim progress report to the 132nd session of the Executive Board. In preambular paragraph 4, "Member States" should be changed to "States Parties". Preambular paragraph 4bis should read: "Recognizing that there still exist difficulties to the implementation of International Health Regulations, especially regarding points of entry, including with respect to the operational understanding of International Health Regulations, which make it necessary to strengthen the capacities related to Annex 1.B". Preambular 4ter should read: "Recognizing the importance of having available tools and procedures for continuous monitoring of core capacities related to Annex 1.A and 1.B".

Preambular paragraph 5bis should read: "Recognizing the need to strengthen the role and capacity of States Parties and international organizations in effective implementation of IHR that requires constructive engagement of stakeholders in health and non-health sectors as well as regional and transregional networks of States Parties". Preambular paragraph 6 should read: "Recognizing that States Parties may, as provided for in the International Health Regulations (2005), report to WHO and obtain, on the basis of a justified need and an implementation plan, an extension of two years in which to fulfil their obligations, and acknowledging in particular the decision of the majority of the Member States of the African Region of WHO to seek such an extension". In paragraph 2 of the draft resolution, "Member States" should be changed to "States Parties" and a footnote should be inserted thereafter to read: "And, where applicable, regional economic integration organizations". Subparagraph 2(1) should read: "to ensure identification of remaining gaps including institutional, human and financial resources in the development, strengthening and maintenance of the core public health capacities required under the International Health Regulations (2005), including Articles 5 and 13 and Annex 1, in accordance with their national implementation plans".

Mrs ESCOREL DE MORÃES (Brazil), rising to a point of order, said that in view of the large number of amendments, a document containing the full text of the amended draft resolution should be prepared. Although the drafting group had reached consensus on the amendments, it was important for all Member States to see them and fully understand their implications.

The DIRECTOR-GENERAL said that the proposed amendments had already been translated into two official languages and the existing language versions could be made available to participants immediately. If Member States wished to have the text in all six official languages, she would recommend that the meeting be suspended and reconvened once all language versions were available.

The CHAIRMAN took it that the meeting should be suspended pending preparation of all six language versions of the amendments.

It was so agreed.

The meeting was suspended at 12:50 and resumed at 14:40.

The CHAIRMAN drew attention to a revised version of the draft resolution contained in document A65/17 Add.2, incorporating all the proposed amendments proposed by the draft group, and which read:

Further to the submission of the two reports on implementation of the International Health Regulations (2005) (documents A65/17 and A65/17 Add.1), the Health Assembly is invited to consider the following draft resolution.

The Sixty-fifth World Health Assembly,

PP1 Having considered the reports on implementation of the International Health Regulations (2005);[1]

PP2 Recalling resolution WHA58.3 on revision of the International Health Regulations, which underscored the continued importance of the International Health Regulations as the key global instrument for the protection against the international spread of disease, and which urged Member States inter alia to build, strengthen and maintain the capacities required under the International Health Regulations (2005) and to mobilize the resources necessary for that purpose;

PP3 Recalling that Articles 5.1 and 13.1 of the International Health Regulations (2005) provide that each State Party shall, as soon as possible but no later than five years from entry into force of the Regulations for that State Party, develop, strengthen and maintain the capacity to detect, assess, notify and report events, in accordance with the Regulations, as specified in Annex 1 therein, and to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in that Annex, and that the date for having these core public health capacities falls in June 2012 for all but a small number of States Parties which have later dates;[2]

PP4 Also recalling resolution WHA61.2 on implementation of the International Health Regulations (2005), which urged ~~Member States~~ **States Parties [secretariat]** to take steps to ensure that the national core capacity requirements specified in Annex 1 to the Regulations are developed, strengthened and maintained, in accordance with Articles 5 and 13 of the International Health Regulations (2005);

PP4bis Recognizing that there still exist difficulties to the implementation of International Health Regulations, especially regarding points of entry, including with respect to the operational understanding of International Health Regulations, which makes it necessary to strengthen the capacities related to Annex 1B [Argentina, Finland, Switzerland]

Recognizing the importance of having available tools and procedures for continuous monitoring of core capacities related to Annex 1A and 1B.

PP5 Further recalling resolution WHA64.1 on implementation of the International Health Regulations (2005), which urged Member States to support the implementation of the recommendations contained in the final report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009,[3] which in its first recommendation noted the need to accelerate implementation of the core capacities required by the Regulations;

[1] Documents A65/17 and A65/17 Add.1.

[2] The time frames for the States Parties which made reservations to the International Health Regulations (2005) (United States of America and India) are slightly later (entry into force for United States of America on 18 July 2007, and for India on 8 August 2007). The time frame was also later for Montenegro (entry into force 5 February 2008), which became a State Party after entry into force of the Regulations on 15 June 2007; and for Liechtenstein (which became a State Party in 28 March 2012). See States Parties to the International Health Regulations (2005) at http://www.who.int/ihr/legal_issues/states_parties/en/ *(accessed 21 May 2012).*

[3] Document A64/10.

PP5bis Recognizing the need to strengthen the role and capacity of States parties and International Organizations, in effective implementation of IHR, that requires constructive engagement of stakeholders, in health and non-health sectors as well as regional and trans-regional networks of States Parties [Thailand]-

PP6 Recognizing that ~~Member~~ States **Parties** may, as provided for in the International Health Regulations (2005), report to WHO and obtain, on the basis of a justified need and an implementation plan, an extension of two years in which to fulfil their obligations, **and acknowledging in particular the decision of the majority of the Member States of the Africa Region of WHO to seek such an extension [Ethiopia].**

1. AFFIRMS its renewed commitment to full implementation of the International Health Regulations (2005);

2. URGES States Parties[1]:

(1) to ensure identification of remaining **including institutional, human and financial resources [Thailand]** gaps in the development, strengthening and maintenance of the core public health capacities required under the International Health Regulations (2005), including Articles 5 and 13 and Annex 1, in accordance with their national implementation plans;

(2) to take the necessary steps to prepare and carry out appropriate national implementation plans in order to ensure the required strengthening, development and maintenance of the core public health capacities as provided for in the International Health Regulations (2005);

(3) to respect time frames stipulated in the International Health Regulations (2005) in Articles 5 and 13 and Annex 1 for undertaking and completing activities and communications relating to implementation of core capacity requirements and procedures concerning related extensions;

(4) to strengthen coordination and collaboration among **and within [EU] States Parties** intersectorally and multisectorally to develop, ~~and~~ establish **and maintain [Japan]** the core public health capacities and operational functions required under the International Health Regulations (2005);

(5) to further strengthen active collaboration among ~~Member~~ States Parties, WHO and other relevant organizations and partners as appropriate, by measures including the mobilization of technical ~~and,~~ financial **and logistical [Japan]** support for building core public health capacities, so as to ensure full implementation of the International Health Regulations (2005);

(6) to reconfirm their support to developing countries and countries with economies in transition upon their request in the building, strengthening and maintenance of the core public health capacities required under the International Health Regulations (2005);

3. REQUESTS the Director-General:

(1) to build and strengthen the capacities of WHO to perform fully and effectively the functions entrusted to it under the International Health Regulations (2005), in particular through strategic health operations that provide support to countries**, regional and trans-regional networks of States Parties [Thailand]** in detection, reporting and assessment of, ~~and~~ response to, **and capacity strengthening in [Thailand]** public health emergencies;

[1] and where applicable regional economic integration organizations

(2) to collaborate ~~with~~ **and assist [Canada, Eygpt]** States Parties through ministries of health as well as all other relevant ministries and sectors in the mobilization of technical support and financial resources to support building, strengthening and maintaining the core capacities required under the International Health Regulations (2005), **in particular those related to Annex 1B in relation to ports of entry core capacities [Argentina]** including technical support to help interested countries to assess their own needs and to make the business case for investment in implementing the Regulations, in accordance with national plans;

2bis to promote the engagement with relevant international organizations and stakeholders to strengthen their contribution towards effective IHR implementation [Thailand]

(3) to ensure the transparent sharing of information on progress of States Parties in the full implementation of the national core capacities required under the International Health Regulations (2005), so as to facilitate provision of appropriate support **including guidance and training [EU]** as needed, by posting the list of States Parties that have requested and received extensions to the initial deadline on the restricted WHO web site for National IHR Focal Points;

(4) to facilitate the provision of appropriate support between and among States Parties for the establishment of the national core capacities required under the International Health Regulations (2005) by posting a relevant summary of the country information collected through the IHR core capacity monitoring framework on the restricted WHO web site for National IHR Focal Points;

(5) to monitor the progress of each State Party that has received an extension to the initial deadline using the implementation plans submitted with the request for extension and the annual reports required under Articles 5.2 and 13.2 of the International Health Regulations (2005) from all States Parties receiving extensions;

(6) to monitor the maintenance of the national core capacities required under the International Health Regulations (2005) in all States Parties not requesting extensions to the deadline through the development of appropriate ~~indicators~~ **methods of assessing [EU]** of effective functioning of the established core capacities;

(7) to develop and publish the criteria to be used in 2014 by the Director-General, in conjunction with the advice of the Review Committee of the International Health Regulations (2005), when making decisions about the granting of any further extensions to the timeline for establishment of the national core capacities as provided for in Articles 5.2 and 13.2;

7bis to submit an interim progress report to the Sixty-sixth World Health Assembly through the Executive Board at its 132nd session [Canada].

(8) to report to the Sixty-seventh World Health Assembly, through the Executive Board at its 134th session, on progress made by States Parties and the Secretariat in implementing this resolution.

Dr DAYRIT (Secretary) said that there were a number of typographical errors in the document, including the following in particular: in subparagraph 2(1), the word “gaps” should be moved from the second line so that it appeared after the word “remaining” in the first line. In subparagraph 3(2), the words “ports of entry” should be changed to “points of entry”.

Mr ADMASU (Ethiopia) proposed that in the sixth preambular paragraph, the words “the majority of the” should be changed to “many” and the words “of the African Region of WHO” should be deleted.

Mr THOMSON (Switzerland) said that, in preambular paragraph 4, the words "Member States Parties" should be changed to "States Parties", in line with the language used in resolution WHA61.2. He also suggested that in subparagraph 3(1) in the French language version, "*des urgences de santé publique*" should be moved to the end of the paragraph.

Ms WISEMAN (Canada) suggested that in subparagraph 3(2) the word "with" should be inserted after the word "collaborate", in line with the original wording contained in document A65/17 Add.2.

Dr BANGA-MINGO (Central African Republic) suggested changing the words "*établir et appliquer*" to "*élaborer et mettre en oeuvre*" in subparagraph 2(2) of the French language version.

The CHAIRMAN said that he took it that the Committee wished to approve the draft resolution, with the proposed amendments.

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

3. FOURTH REPORT OF COMMITTEE A (Document A65/58)

Dr MALECELA (United Republic of Tanzania), Rapporteur, read out the draft fourth report of Committee A.

The CHAIRMAN said that, in the absence of any objections, he took it that the Committee wished to adopt the report.

The report was adopted.

4. CLOSURE

After the customary exchange of courtesies, the CHAIRMAN declared the work of Committee A completed.

The meeting rose at 14:55.

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[1] Transmitted to the Health Assembly in the Committee's fourth report and adopted as resolution WHA65.23.