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IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (IHR)

Introduction

1. The purpose of this document is to present a report on the status of the implementation of the International Health Regulations (hereafter referred to as IHR or the Regulations). The document also informs the Directing Council about the recommendations made by Member States of the Region of the Americas during the formal Regional Consultation on the *Draft WHO Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response* (Annex B), held in Miami, United States of America, on 1-3 August 2016.

2. This report: *a)* updates the information presented in 2015 to the 54th Directing Council *(1)* and, selectively, the information presented to the 158th Session of the Executive Committee in June 2016 *(2)*; *b)* focuses on activities undertaken by States Parties and the Pan American Sanitary Bureau (PASB) in response to the Public Health Emergency of International Concern (PHEIC) related to Zika virus; and *c)* highlights issues requiring concerted action by States Parties in the Region of the Americas for the future application and implementation of the Regulations.

Background

3. The International Health Regulations, adopted by the Fifty-eighth World Health Assembly in 2005 through Resolution WHA58.3,[1] constitute the legal framework that, among others, defines national core capacities, including at points of entry, for the management of public health events of potential or actual national and international concern and related procedures.

[1] The text of the International Health Regulations (Resolution WHA58.3) is available at: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf.

Update on Progress Achieved

4. The Pan American Health Organization (PAHO) serves as the World Health Organization (WHO) IHR Contact Point for the Region of the Americas and facilitates the management of public health events through established communication channels with the National IHR Focal Points (NFP). In 2015, all 35 States Parties in the Region submitted an annual confirmation or update of contact details for their NFPs. In 2015, routine connectivity tests performed between the WHO IHR Contact Point and the NFP in the Region were successful for 30 of the 35 States Parties (86%) by e-mail and for all 35 States Parties by telephone.

5. In the period from 1 January to 31 December 2015, a total of 99 public health events of potential international concern were identified and assessed in the Region. For 59 of the 99 events (60%), national authorities, including through the NFP on 44 occasions, were the initial source of information. Verification was requested and obtained for 25 events identified through informal or unofficial sources. Of the 99 events considered, 45 (45%), affecting 22 countries and territories in the Region, were of substantiated international public health concern. The largest proportion of these 45 events was attributed to infectious hazards (34 events; 76%), and the etiology most frequently recorded was Zika virus (15 events). The remaining 11 events of substantiated international public health concern were attributed to the following hazard categories: zoonosis-related (5), food safety (2), product-related (2), chemical (1), and radiation-related (1).

6. Significant public health events that affected, or had public health implications for, States Parties in the Americas from 1 January 2015 to 8 April 2016 are highlighted below:

a) Since the IHR Emergency Committee regarding the international spread of poliovirus (Polio IHR EC) first met in April 2014, with subsequent determination by the Director-General of WHO that the international spread of **wild poliovirus** constituted a PHEIC, the Polio IHR EC has met on eight additional occasions. During its most recent meeting in May 2016, the committee concluded that the spread of wild poliovirus, together with the circulating vaccine-derived poliovirus (cVDPV), still constitutes a PHEIC. Temporary recommendations were refined and extended for a further three months with a focus on specific subsets of countries, none of which are in the Americas. PAHO continues to advise that States Parties in the Americas apply the recommendations of the Technical Advisory Group on Vaccine-preventable Diseases to maintain the Americas free of wild poliovirus.

b) The **Middle East respiratory syndrome coronavirus** (MERS-CoV) began to spread in 2012, and as of 20 March 2016 nearly 1,700 laboratory-confirmed cases, including over 600 fatalities, had been reported to WHO. Confirmed cases of MERS-CoV infection have been reported by 26 States Parties worldwide, including 13 with documented local transmission, and with the Kingdom of Saudi Arabia accounting for approximately 80% of the cases. In response to the spread

of MERS-CoV, the Director-General convened the IHR Emergency Committee concerning Middle East respiratory syndrome coronavirus (MERS-CoV IHR EC), and the committee met 10 times between July 2013 and September 2015. The advice provided by the MERS-CoV IHR EC, disseminated to all States Parties, did not lead to the determination of a PHEIC by the Director-General.

c) Following the notification to WHO of the first **Ebola virus disease** (EVD) cases in Guinea in March 2014, the outbreak rapidly spread to the neighboring countries of Liberia and Sierra Leone and spiraled out of control. This led to the convening, on 6 August 2014, of the IHR Emergency Committee regarding the Ebola outbreak in West Africa (EVD IHR EC) and, upon its advice, to the determination by the Director-General of the EVD outbreak in West Africa as a PHEIC. As of 8 April 2016, there have been over 28,600 cases and more than 11,300 deaths in the three West African countries. With the recognition that new EVD clusters will continue to occur in these West African countries due to the reintroduction of the virus from survivors, in January 2016 they were declared Ebola-free by WHO. Based on the advice formulated by the EVD IHR EC at its ninth meeting on 29 March 2016, the Director-General terminated the PHEIC, also implying the termination of related temporary recommendations, including those applying to States Parties in the Americas.

d) Following the notification to WHO, in January 2016, of a **yellow fever** (YF) outbreak detected in Luanda, Angola, in December 2015, a rapid increase in the number of cases with extensive geographical spread was observed. Within Angola, over 3,800 suspected and confirmed cases, including over 480 deaths, were reported as of 29 July 2016. YF cases epidemiologically linked to the outbreak were detected in Brazil (1), China (11), Kenya (2), and especially the Democratic Republic of Congo (DRC), where further local transmission occurred; as of 3 August 2016, over 2,000 confirmed and suspected cases, including 95 deaths, were reported in the DRC. Following the mobilization of nearly 33 million doses of YF vaccine for mass immunization campaigns, the outbreak in Angola was receding as of 29 July 2016, but the event was still unfolding in the Democratic Republic of Congo. In 2016, additionally, non-epidemiologically linked YF outbreaks and cases were reported in the African Region and in the Americas, where cases of YF were reported in Brazil (1), Colombia (2), and Peru. An outbreak in Peru's Junín Region that started in March 2016 had produced 50 cases by 22 July 2016, including 17 deaths. In response to the YF outbreaks in Central Africa, on 19 May 2016 the Director-General convened the IHR Emergency Committee on yellow fever (YF IHR EC). The advice provided by the YF IHR EC, disseminated to all States Parties, did not lead to the determination of a PHEIC by the Director-General.

e) The **Zika virus** is a vector-borne virus transmitted, similar to the dengue and chikungunya viruses, by *Aedes aegypti* and *Aedes albopictus* mosquitoes. Following its reemergence in the Western Pacific Region in 2007, a case of autochthonous transmission of the virus was confirmed in Easter Island, Chile, in 2014. In February 2015, health authorities in Brazil began investigating cases of

rash illness in the country's northeastern states, which approached nearly 7,000 by the end of April 2015. The investigation led to the laboratory confirmation of autochthonous transmission of Zika virus in May 2015, representing the first documented transmission on the continental platform of the Americas. Reports by Brazilian health authorities concerning the unusual increase in cases of Guillain-Barré syndrome (GBS) in adults and microcephaly in newborns in the areas where autochthonous transmission of Zika virus was established were shared with the international community through the secure Event Information Site for NFP (EIS) in July 2015 and October 2015, respectively.

- The rapid spread of Zika virus in the Americas and beyond, accompanied by growing evidence of a spatial-temporal association with increases in the number of cases of GBS and microcephaly in newborns, led to the convening, on 1 February 2016, of the IHR Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations (Zika IHR EC). Upon its advice, the Director-General determined the event to be a PHEIC. Temporary recommendations issued, including recommendations resulting from two additional meetings of the Zika IHR EC on 8 March and 14 June 2016, have focused on:

  i. The intensification of concerted international research efforts to further corroborate the now widespread scientific consensus that Zika virus is a cause of microcephaly and GBS. The need for rapid and transparent sharing of the outcomes of research efforts was emphasized.

  ii. The implementation of control measures comprising of: *a)* surveillance, which also includes the development of a case definition for "congenital Zika infection," as well as rapid and transparent information sharing; *b)* vector control measures; *c)* risk communication targeting women of childbearing age and pregnant women, along with dissemination of information on the risk of sexual transmission; preparedness of health services for antenatal counseling, management of pregnancies at risk for Zika virus infection and related birth outcomes, and, in the longer term, management of the consequences; *d)* and travel advice focusing on pregnant women and safe sexual practices (no travel or trade restrictions with countries and territories experiencing Zika virus transmission were deemed to be warranted).

  iii. Actions to be taken by States Parties hosting mass gathering events, including the XXXI Summer Olympics and Paralympic Games, to be held in Rio de Janeiro, Brazil, 5 August-21 September 2016, as well as by States Parties with travelers to and from the XXXI Summer Olympics and Paralympic Games.

- As of 11 August 2016, 45 countries and territories in the Americas had confirmed autochthonous vector-borne transmission of Zika virus. Five countries have cases of sexually transmitted Zika virus infection. Ten

countries and territories have reported cases of congenital syndrome associated with Zika virus infection. Brazil accounts for the vast majority of these congenital syndrome cases (96%), with over 1,800 cases reported. Sixteen countries and territories in the Region have confirmed Zika virus infection in at least one GBS case, and ten of them have also reported increases in GBS cases.

7. At the end of 2015, PASB substantially intensified activities to support States Parties in responding to the introduction of Zika virus in the Region. These efforts culminated in December 2015 with the activation of an Organization-wide Incident Management Structure (IMS), including the release of funds from the PAHO Epidemic Emergency Fund. During the following months, the PASB IMS, in close coordination with the equivalent structure established at WHO headquarters in February 2016, triggered the release of the WHO Contingency Fund for Emergencies and the rollout of activities outlined in the Strategy for Enhancing National Capacity to Respond to Zika Virus Epidemic in the Americas *(3)*. The strategic framework revolves around the following elements: *a)* timely monitoring of the evolution of the epidemic in its multifaceted aspects; *b)* risk reduction through vector control; *c)* enhancement of response capacity with a focus on health services (including blood safety), risk communication, and mass gatherings; and *d)* development of a regional research agenda on Zika virus to address the growing gaps in knowledge.

8. Within the framework outlined above, activities undertaken by PASB as of 8 April 2016 include (updated information is provided under Item 7.4 of the provisional agenda of the 55th Directing Council):

a) The intensification of resource mobilization and coordination efforts with international partner organizations and agencies, including multiple United Nations agencies,[2] the Inter-American Development Bank, the World Bank, and WHO headquarters.

b) The development and dissemination of PAHO technical guidelines and epidemiological updates providing inputs to documents developed by WHO headquarters.

c) The organization of virtual meetings with national competent authorities and professionals from different disciplines to address continuously emerging new technical issues related to the spread of Zika virus.

[2] International Atomic Energy Agency (IAEA); International Civil Aviation Organization (ICAO); Joint United Nations Program on HIV/AIDS (UNAIDS) Office for the Coordination of Humanitarian Affairs (OCHA); UN-HABITAT (United Nations Centre for Human Settlements); United Nations Children's Fund (UNICEF); United Nations Development Group for Latin America and the Caribbean (UNDG-LAC); United Nations Development Program (UNDP); United Nations Educational, Scientific and Cultural Organization (UNESCO); United Nations High Commissioner for Refugees (UNHCR); United Nations Population Fund (UNFPA); UN Women; and World Food Program (WFP).

d) The provision of face-to-face training on laboratory services, entomological surveillance and vector control, monitoring of pregnant women, and risk communication at the national, subregional, and regional levels.

e) The deployment of multidisciplinary technical field missions to 22 countries and territories, in some cases on multiple occasions, involving the mobilization of over 70 staff and experts, including through the Global Outbreak Alert and Response Network (GOARN). The expertise represented in the in-country mission teams spanned several technical areas: antenatal care, clinical management, entomology and vector control, epidemiology, health and laboratory services, neonatology, neurology, public health, risk communication, and radiology. Several missions related to preparations for the XXXI Summer Olympics and Paralympic Games.

f) The distribution of reagents to 20 countries for detection of Zika virus by polymerase chain reaction (PCR), including an instrumental partnership with the United States Centers for Disease Control and Prevention (US CDC).

g) The organization of expert consultations on laboratory services, vector control, clinical surveillance, health services, and ethics.

h) The coordination of research efforts, including organization of the meeting "Towards the development of a Research Agenda for Characterizing the Zika Virus Outbreak and its Public Health Implications in the Americas," held in Washington, D.C., 1-2 March 2016.

i) The development of a dedicated PAHO portal on the Zika virus, presenting information tailored to a variety of audiences.[3]

9. While the introduction of Zika virus in the Americas is enabling a better understanding of the full spectrum of disease caused by this virus, over 600 million people in the Region are living in areas at risk for transmission of the virus, and its spread could pose a significant burden to public health and to health systems as a whole. Although sexual transmission of Zika virus might eventually assume a more prominent role in shaping the evolution of the Zika epidemic, integrated vector control remains the cornerstone for mitigating the impact of vector-borne diseases.

Reports on Core Capacities in States Parties

10. States Parties Annual Reports submitted to the World Health Assemblies between 2011 and 2016 showed steady improvements at the regional level in all core capacities. However, the status of the core capacities across the subregions continues to be heterogeneous, with the lowest scores consistently registered in the Caribbean subregion. When the States Parties Annual Reports in their current format were instituted for reporting to the Sixty-fourth World Health Assembly in 2011, the response rate was

[3] The Zika virus PAHO portal is available at: http://www.paho.org/hq/index.php?option=com_content&view=article&id=11585&Itemid=41688&lang=en.

51% (18 of 35 States Parties); in 2016, for the first time, the response rate was 100%, with all 35 States Parties in the Americas reporting to the Sixty-ninth World Health Assembly. This should be regarded as an achievement, one that signals an increased sense of ownership of the Regulations by States Parties as well as their willingness to be mutually accountable. Over this six-year period, 12 States Parties systematically complied with respect to annual submission of reports: Antigua and Barbuda, Barbados, Canada, Colombia, Costa Rica, Dominica, Ecuador, Guyana, Honduras, Jamaica, Mexico, and the United States. Information on the degree of compliance with this commitment among the remaining States Parties is presented in Annex A.

11. When the most recent reports are compared with the States Parties Annual Reports submitted to the Sixty-eighth World Health Assembly (2015), variations in regional average scores are in the range of 10 percentage points in the case of all capacities other than points of entry, for which a 18 percentage point improvement was registered. With the exception of the capacities to respond to events associated with chemical (57%) and radiation-related (55%) hazards, the regional average score for all remaining capacities is close to or above 75%; the highest score is for surveillance (92%). Annex A also presents a summary of the States Parties Annual Reports to the Sixty-ninth World Health Assembly.

12. PAHO conducted ad hoc missions to review the IHR implementation status in two of the United Kingdom Overseas Territories in the Americas: the Cayman Islands and the Turks and Caicos. In the overseas territories of the Kingdom of the Netherlands, the progress made is noteworthy in terms of legal and operational arrangements for the application and implementation of the IHR, as crystallized in a mutual agreement among the Netherlands, Aruba, Curaçao, and Sint Maarten.

13. To support institutional and intersectoral strengthening efforts in States Parties in the Region, PAHO has continued its joint activities with other international specialized agencies and organizations. Regional initiatives were conducted with: *a)* the International Civil Aviation Organization (ICAO), within the framework of the Collaborative Arrangement for the Prevention and Management of Public Health Events in Civil Aviation (CAPSCA), at its Sixth Americas Meeting held in Panama in September 2015 (the Seventh Americas Meeting will be held in Mexico in September 2016); *b)* the International Air Transport Association (IATA), with activities focusing on certification and recertification of national professionals with respect to international shipments of samples; *c)* and the Food and Agriculture Organization (FAO) at the annual regional meeting of the International Food Safety Authorities Network (INFOSAN), held in Mexico in October 2015. Subregional activities were conducted with the International Atomic Energy Agency (IAEA); for example, the first coordination meeting of the Strengthening Cradle-to-Grave Control of Radioactive Sources project in IAEA Member States in the Caribbean subregion was held in Jamaica in April 2016. Activities at the national level were conducted with ICAO within the framework of the CAPSCA project, including visits to the major international airports of Bolivia, Colombia, Panama, Paraguay, and the United States, and with the World Organization for Animal Health (OIE) intersectoral workshop in Costa Rica.

14. As of 8 April 2016, 484 ports in 27 States Parties in the Region of the Americas were authorized to issue Ship Sanitation Certificates *(4)*. Ten additional ports were authorized in eight overseas territories of France, the Netherlands, and the United Kingdom. As of the same date, no information had been provided to the WHO Regional Offices regarding the status of the WHO Procedures for voluntary certification of designated airports and ports already submitted to the States Parties on two occasions.

15. In the absence of rejections and/or reservations notified by States Parties to the Director-General by the set deadline (11 January 2016), the amendment of Annex 7 of the Regulations—recognizing that one single dose of yellow fever vaccine is sufficient to confer lifelong protection—entered into force in July 2016 *(5)*. As per Resolution WHA68.4 *(6)*, aimed at guaranteeing a participatory process in mapping areas at risk for yellow fever transmission, the Scientific and Technical Advisory Group on Geographical Yellow Fever Risk Mapping (GRYF) was established in December 2015. It consists of experts from five countries in the Region: Argentina, Brazil, Panama, Trinidad and Tobago, and the United States. As of 8 April 2016, 19 of the 35 States Parties (54%) had provided contributions to the 2016 update of the WHO publication International Travel and Health *(7)*.

16. As of 8 August 2016, the IHR Roster of Experts included 395 experts, 111 of whom are from the Region of the Americas, including seven designated by six of the 35 States Parties (Barbados, Brazil, Mexico, Peru, United States of America, Venezuela).

17. The recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation *(8)*, adopted by the Sixty-eighth World Health Assembly through Resolution WHA68.5 *(9)*, mandate that the Secretariat should develop a new monitoring and evaluation scheme with the active involvement of WHO regional offices that will be subsequently proposed to all States Parties through the WHO governing bodies' process. They further specify that implementation of the IHR should now advance to a more action-oriented approach to periodic evaluation of functional capacities.

18. In compliance with these recommendations, the WHO Secretariat developed a Concept Note *(10)* outlining a proposed post-2016 IHR monitoring and evaluation framework revolving around four components: self-assessment, after-action review of public health events, simulation exercises, and external evaluations. The Concept Note was submitted to the scrutiny of Member States in the six WHO Regions at the Regional Committee meetings in 2015. As noted in the Final Report to the 54th Directing Council *(11)*, as well as in the report by the Regional Committees to the 138th Executive Board *(12)*, the proposed IHR monitoring and evaluation framework was regarded by Member States as a solid basis to build upon and to be finalized for consideration and approval by the Sixty-ninth World Health Assembly, per the timeline presented in the Concept Note itself and in compliance with Article 54 of the Regulations.

19. To facilitate the revision and finalization of the IHR monitoring and evaluation framework, the WHO Secretariat organized the Technical Consultation on Monitoring

and Evaluation of Functional Core Capacity to Implement the International Health Regulations (2005) in Lyon, France, on 20-22 October 2015 *(13)*, with the participation of experts from Barbados, Brazil, and the United States. Subsequently, there has been relatively limited progress in terms of finalizing the IHR monitoring and evaluation framework to be presented to the Sixty-ninth World Health Assembly, with resources devoted by the WHO Secretariat primarily going to coordinating with partners (e.g., the Global Health Security Agenda (GHSA)) in the development of a tool related to only one of the four components: the Joint External Evaluation Tool.[4] Since May 2016, PASB: *a)* has conducted an external evaluation mission to Belize, involving experts from Canada, Chile, Suriname, IAEA headquarters, and PAHO staff; *b)* has participated in a self-evaluation in Peru, conducted under GHSA auspices; and *c)* has supported the US CDC in conducting an external evaluation in Haiti to inform the implementation of funds available under the GHSA umbrella. The United States has hosted an external evaluation of its own IHR implementation.

20. A revised version of the Concept Note, with the title "The International Health Regulations (2005): Monitoring and Evaluation Framework," was published on 18 May 2016 as an Annex to Document A69/20 *(14)* and presented to the Sixty-ninth World Health Assembly, 23-28 May 2016. The four components of the IHR Monitoring and Evaluation Framework have been renamed as follows: Annual Reporting, After-Action Review, Simulation Exercises, and Joint External Evaluation. The Assembly was requested to "note the report."

21. The "Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response" *(15)*, including 12 recommendations, was published on 13 May 2016. Since some of the 12 recommendations formulated by the Review Committee (EVD IHR RC), also encompassing the IHR Monitoring and Evaluation Framework, proved controversial, they were not adopted through an Assembly Resolution. Therefore, per point 2 of Decision WHA69(14) *(16)*, the Sixty-ninth World Health Assembly decided to defer to the six WHO Regional Committees in 2016, including the 55th Directing Council of PAHO/68th Session of the Regional Committee of WHO for the Americas, the consideration of a draft global implementation plan for the recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response (Draft Plan). The formal consultation for the Region of the Americas took place in Miami, United States, from 1 to 3 August 2016.

Action Necessary to Improve the Situation

22. As the Zika virus continues to spread, it is becoming clear that its transmission has multifaceted public health and ethical implications and challenges, in the short and long terms, at both national and regional levels, spanning disciplines and sectors. Similar to the EVD outbreak in West Africa, the spread of Zika virus is testing the application of

[4] The Joint External Evaluation Tool is available, in English and French, at http://www.who.int/ihr/publications/WHO_HSE_GCR_2016_2/en/, and http://www.who.int/ihr/publications/WHO_HSE_GCR_2016_2/fr/ respectively

the IHR and, once again, emphasizing that countries' ability to respond to rapidly emerging and evolving risks requires resilient health systems that feature essential public health functions—the core capacities detailed in Annex 1 of the Regulations—as an intrinsic and sustainable component. PASB is taking action across its departments to conceptually frame and operationally translate the application and implementation of IHR provisions in the context of health systems. The document Resilient Health Systems (Item 4.5 of the provisional agenda of the 55th Directing Council) constitutes a first step.

23. Similarly, as with the dengue epidemics in the Region over the past 30 years and the establishment of chikungunya virus transmission in all countries and territories of the Americas where *Aedes aegypti* is present over a 12-month period, the Zika virus epidemic is offering the opportunity to revive vector control efforts outlined in the Strategy for Arboviral Disease Prevention and Control (Item 4.12 of the provisional agenda of the 55th Directing Council).

24. The formal Regional Consultation, which examined the 12 recommendations of the EVD IHR RC and the Draft Plan, provided critical information to inform the deliberations of the 55th Directing Council and, by extension, to equip States Parties in the Americas with tools to influence the strategic and operational approaches that will shape the future of the application and implementation of the IHR at a global level. For this purpose, in light of the conclusions of the meeting, further internal consultations within PASB identified a decision as the most appropriate tool. The draft decision for the consideration of the Directing Council is presented in Annex C).

Action by the Directing Council

25. The Directing Council is invited to *a)* review the information provided in the report on the implementation of IHR in the Region, and *b)* provide comments on the Director-General's *Draft WHO Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response*, which will inform the development of a final version of the implementation plan for the consideration of the WHO Executive Board at its 140th session in January 2017. Furthermore, the Council is invited to consider adoption of the draft decision in Annex C.

Annexes

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Annex A
Summary Table: States Parties Annual Reports to the 69th World Health Assembly (Core Capacities Scores in Percentages)

State Party	Requested and Obtained 2012-2014 Extension	Requested and Obtained 2014-2016 Extension	Number of Annual Reports Submitted from 2011 to 2016 (6-year period)	Legislation Policy Financing	Coordination and NFP Communication	Surveillance	Response	Preparedness	Risk Communication	Human Resources	Laboratory	Points of Entry	Zoonotic Events	Food Safety Events	Chemical Events	Radiation Emergencies
Antigua and Barbuda	yes	yes	6	100	100	100	82	73	86	100	100	97	100	100	85	23
Argentina	yes	no	5	50	73	80	100	100	86	100	90	83	100	80	69	62
Bahamas	yes	yes	4	75	83	100	70	0	71	40	96	97	67	27	54	8
Barbados	yes	yes	6	100	90	95	82	100	100	80	96	100	100	80	77	69
Belize	yes	yes	5	25	63	75	88	52	57	40	45	83	89	53	38	8
Bolivia (Plurinational State of)	yes	yes	5	100	90	75	76	53	57	40	91	91	89	67	23	77
Brazil	no	no	5	100	100	100	100	100	100	100	96	100	100	100	92	100
Canada	no	no	6	100	100	95	100	100	100	100	100	100	100	100	100	100
Chile	no	no	5	75	83	90	94	61	100	40	66	97	100	93	54	77
Colombia	no	no	6	100	90	85	81	100	100	60	80	97	89	80	77	77
Costa Rica	no	no	6	100	100	100	69	71	100	80	86	97	100	100	46	54
Cuba	yes	no	5	100	100	100	100	100	100	100	100	100	100	100	100	100
Dominica	yes	yes	6	50	100	80	78	60	100	40	43	80	100	100	15	15
Dominican Republic	yes	yes	5	75	90	75	58	81	71	40	80	88	100	47	38	77
Ecuador	yes	yes	6	100	100	95	83	91	86	80	86	94	100	93	62	100
El Salvador	yes	no	5	100	100	100	100	90	86	100	100	100	100	100	54	85
Grenada	yes	yes	4	100	83	95	69	33	86	60	49	49	100	67	46	15
Guatemala	yes	no	5	50	83	100	94	80	100	100	100	88	100	87	77	69
Guyana	yes	yes	6	100	100	95	100	100	100	100	100	94	100	53	62	0

Summary Table: States Parties Annual Reports to the 69th World Health Assembly (Core Capacities Scores in Percentages) *(cont.)*

State Party	Requested and Obtained 2012-2014 Extension	Requested and Obtained 2014-2016 Extension	Number of Annual Reports Submitted from 2011 to 2016 (6-year period)	Legislation Policy Financing	Coordination and NFP Communication	Surveillance	Response	Preparedness	Risk Communication	Human Resources	Laboratory	Points of Entry	Zoonotic Events	Food Safety Events	Chemical Events	Radiation Emergencies
Haiti	yes	yes	4	0	46	100	70	26	100	40	96	17	67	27	38	0
Honduras	yes	yes	6	100	80	95	76	50	57	60	81	88	100	87	38	62
Jamaica	yes	yes	6	50	90	90	100	92	71	60	86	88	78	87	77	85
Mexico	yes	no	6	100	70	95	94	100	100	100	100	100	100	100	100	100
Nicaragua	yes	no	5	100	83	100	87	100	100	100	86	100	100	60	0	0
Panama	yes	yes	5	75	100	95	88	60	71	40	96	94	89	60	15	31
Paraguay	yes	yes	4	100	100	95	94	43	100	80	76	91	89	47	69	92
Peru	yes	yes	4	100	100	100	94	90	100	80	100	24	100	100	69	100
Saint Kitts and Nevis	yes	yes	4	100	100	80	58	33	86	20	87	71	67	80	0	0
Saint Lucia	yes	yes	5	75	56	70	69	25	86	40	83	74	89	60	23	0
Saint Vincent and the Grenadines	yes	yes	5	75	63	80	66	53	43	80	0	0	0	0	0	0
Suriname	yes	yes	5	50	83	90	100	100	71	40	86	97	67	87	62	0
Trinidad and Tobago	yes	yes	5	50	56	95	76	71	71	20	81	83	89	87	62	77
United States	no	no	6	100	100	100	100	100	100	100	60	100	100	100	100	100
Uruguay	yes	no	2	100	100	95	94	90	100	20	56	100	100	100	69	62
Venezuela (Bolivarian Republic of)	yes	yes	4	100	90	95	100	100	86	100	90	97	100	93	100	85

Summary Table: States Parties Annual Reports to the 69th World Health Assembly (Core Capacities Scores in Percentages) *(cont.)*

Caribbean* (n=15)	70	81	90	81	61	82	57	77	75	81	67	49	27
Central America (n=7)**	86	91	95	82	76	84	74	90	94	98	77	38	54
South America* (n=10)**	93	93	91	92	83	91	70	83	87	97	85	68	83
North America** (n=3)**	100	90	97	98	100	100	100	87	100	100	100	100	100

* Caribbean subregion includes: Antigua and Barbuda, Bahamas, Barbados, Belize, Cuba, Dominica, Grenada, Guyana, Haiti, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, and Trinidad and Tobago.

** Central America subregion includes: Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and Panama.

*** South America subregion includes: Argentina, Bolivia (Plurinational State of), Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela (Bolivarian Republic of).

**** North America subregion includes: Canada, Mexico, and United States.

Annex B

REGIONAL CONSULTATION

ON THE DRAFT WHO GLOBAL IMPLEMENTATION PLAN FOR THE RECOMMENDATIONS OF THE REVIEW COMMITTEE ON THE ROLE OF THE INTERNATIONAL HEALTH REGULATIONS (2005) IN THE EBOLA OUTBREAK AND RESPONSE

Purpose

1. The purpose of this Annex is to present, in Appendix I, the report of the formal Regional Consultation on the Implementation of the International Health Regulations (hereafter referred to as IHR or the Regulations), organized by the Pan American Sanitary Bureau (PASB) in Miami, United States, 1-3 August 2016. The consultation was held in preparation for the 55th Directing Council/68th Session of the Regional Committee of WHO for the Americas, following support expressed by the 158th Session of the Executive Committee for such a meeting in light of Document CE158/INF/5, Add. I *(1).*

2. This document provides the basis for States Parties in the Americas, through the 55th Directing Council/68th Session of the Regional Committee of WHO for the Americas, to comply with Decision WHA69(14) of the Sixty-ninth World Health Assembly *(2)*.

3. Therefore, this document also constitutes the basis for States Parties in the Americas to offer their feedback to the WHO Secretariat on:

a) The *Draft WHO Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response* (hereafter referred to as Draft Plan, Appendix II), through the considerations elaborated for each of the 12 recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response (EVD IHR RC) *(3)*. The WHO Secretariat shared the Draft Plan with PASB on 22 July 2016 and invites the WHO Regional Committees 2016 to provide their comments *"to inform the development of a final version of the implementation plan for the consideration of the Executive Board of WHO at its 140th session, in January 2017"* (hereafter referred to as Final Plan);

b) The IHR Monitoring and Evaluation Framework is presented as Appendix III to this Annex B.

4. In line with Document CE158/INF/5, Add. I, this document additionally serves to inform the deliberations by the 55th Directing Council regarding Governing Bodies mechanisms that can be activated to influence the strategic and operational approaches

that will shape the future of the application and implementation of the IHR at global level, starting with the 140th session of the Executive Board of WHO in January 2017.

Appendixes

References

1. Pan American Health Organization. Implementation of the International Health Regulations (IHR) [Internet]. 158th Session of the Executive Committee of PAHO; 2016 June 20-24; Washington, DC. Washington, DC: PAHO; 2016 (Document CE158/INF/5, Add. I) [cited 2016 August 12]. Available from: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=35119&Itemid=270&lang=en

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4. World Health Organization. Implementation of the International Health Regulations (2005): Annual report on the implementation of the International Health Regulations (2005) [Internet]. 69th World Health Assembly; 2016 May 23-28; Geneva. Geneva: WHO; 2016 (Document A69/20) [cited 2016 August 12]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_20-en.pdf

Appendix I

Report of the Formal Regional Consultation on the Draft WHO Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response

Miami, United States, 1-3 August 2016

Objectives

1. The objectives of the Formal Regional Consultation (hereafter referred to as the meeting) were:

a) To consider the relevance for the Americas of each of the 12 recommendations by the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response (EVD IHR RC);

b) To provide comments and suggestions on the *Draft Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response* (hereafter referred to as Draft Plan, Appendix II);

c) To define, where applicable and in anticipation of the development of an IHR Regional Plan, key actions for implementation of the recommendations and of the Draft Plan in the Region;

d) To provide suggestions on PAHO and/or WHO Governing Bodies mechanisms to be activated in order to convey, in the most effective manner, the position of States Parties in the Americas to the WHO Governing Bodies.

2. While the objectives of the meeting were fully aligned with those outlined in Document CE158/INF/5, Add. I, they had to be adjusted by taking into account the Draft Plan, which was shared by the WHO Secretariat with the Pan American Sanitary Bureau (PASB) on 22 July 2016.

Participants

3. Each of the 35 States Parties in the Region was invited to designate two officials with the following profiles to participate in the meeting:

a) A government official with intra- and intersectoral IHR application and implementation coordinating function, familiar with national IHR-related operational and administrative arrangements, and with thorough knowledge and understanding of IHR provisions and related WHO Governing Bodies documents;

b) A government official from the Ministry of Health's External/International Relations Office or from the Ministry of Foreign Affairs, familiar with WHO and PAHO Governing Bodies processes and procedures and, ideally, with experience of direct participation.

4. Twenty-nine (29) States Parties were represented at the meeting. Cuba, Dominica, El Salvador, Haiti, St. Kitts and Nevis, and Venezuela were unable to attend. Additionally, professionals from the Region, members of the IHR Roster of Experts, were mobilized by PASB to facilitate the working group sessions together with PAHO staff from four departments. The meeting also benefited from the participation of staff from PAHO/WHO Representative Offices and from WHO headquarters.

Methods of work

5. The work methodology adopted for the meeting primarily revolved around facilitated discussions in working groups, with feedback provided in plenary sessions. Recommendation 1 ("*Implement rather than amend the IHR"*) of the EVD IHR RC was addressed in plenary at the end of the meeting. Simultaneous interpretation in the four official PAHO languages was provided in the plenary sessions and during selected working group sessions.

Structure of the report

6. The report is structured around the 12 recommendations of the EVD IHR RC, capturing for each of them: *a)* considerations regarding the recommendation; *b)* comments on the Draft Plan to inform the development of a final version of the plan for the consideration of the Executive Board of WHO at its 140th session, in January 2017 (hereafter referred to as Final Plan); and *c)* relevance for the Region and prospective regional actions. Recommendation 1 is addressed at the end of the report, otherwise recommendations are addressed in order.

Recommendation 2: Develop a Global Strategic Plan to improve public health preparedness and response *[Encompassed by Draft Plan's Area of Action 1: Accelerating country implementation of the International Health Regulations (2005)]*

Considerations regarding the recommendation

7. There was overall consensus that there is value in developing a Global IHR Strategic Plan and Regional Offices IHR Operational Plans.

8. While it was recognized that there might also be value in having dedicated National IHR Action Plans, there is wide heterogeneity across States Parties with respect to the administrative setup of the health system (e.g., federal States as opposed to small island States); the degree of robustness of the health system's functions, allowing for the maintenance of core capacities as essential public health functions truly integrated into the health system; as well as the maturity of intersectoral and interministerial

coordination mechanisms, allowing for a common understanding of responsibility shared across the different sectors under the IHR, integrated planning, effective use of resources, and operational arrangements. Additionally, while some countries might not have National IHR Action Plans as such, they might have plans submitted with their request for the 2014-2016 extension.

Comments on the Draft Plan to inform the development of the Final Plan

9. With respect to the scope, the Final Plan should specify that the Global IHR Strategic Plan will focus on national core capacities as essential public health functions, corresponding to Area of Action 1 in the Draft Plan, and will also include selected items pertinent to Recommendation 6, corresponding to Area of Action 4 in the Draft Plan.

10. Additionally, the Final Plan should specify:

a) The mechanisms through which the Global IHR Strategic Plan will be aligned and articulated with related existing Global Plans (e.g., for antimicrobial resistance);

b) How the Global IHR Strategic Plan will be implemented in the context of the recently established WHO Health Emergencies Programme, and, more specifically, how this would relate to the WHO Health Emergencies Programme Results Framework and Budget Requirements 2016–2017,[1]

c) How the development of the Global IHR Strategic Plan will inform and be articulated with WHO's planning cycles (e.g., five-year Global IHR Strategic Plan and Biennial Work Plans) and, more specifically, how this would relate to the WHO Health Emergencies Programme Results Framework and Budget Requirements 2016–2017;

d) The factors that would make the proposed cascade of plans a sustainable approach for application of the Regulations.

11. States Parties indicated that the development of the Global IHR Strategic Plan may offer an opportunity for the WHO Secretariat to model intersectoral coordination by concrete example. Therefore, the Final Plan should clearly outline the process through which a strategic alignment with other relevant international agendas and organizations (e.g., International Atomic Energy Agency, World Organization for Animal Health, etc.) will be ensured throughout the development of the Global IHR Strategic Plan. It was recognized that establishing efficient intersectoral coordination mechanisms remains challenging in many States Parties. Therefore, the alignment of the Global IHR Strategic Plan with other international organizations and initiatives would facilitate advocacy and mutual accountability of the different sectors of national level. The alignment process at global level is regarded as especially critical for the Region in areas of work related to the management of chemical and radiation-related hazards.

[1] http://www.who.int/about/who_reform/emergency-capacities/emergency-programme-framework-budget.pdf?ua=1

12. Although a bottom-up approach would be preferable, there was agreement that a top-down approach, not necessarily reflecting States Parties' needs or priorities, may be the most efficient means to advance the planning process at both WHO Secretariat and national levels, with the Global IHR Strategic Plan guiding the development of the Regional Offices IHR Operational Plans and national plans. However, it was strongly asserted that the development of the Global IHR Strategic Plan should be participatory. Toward that end, the Final Plan should present in detail the process that will be adopted for its development, explicitly indicating the mechanisms for the involvement of States Parties.

13. Similarly, the Final Plan should indicate that an equally participatory process will be adopted for the development of the Regional Offices IHR Operational Plans, making clear that these should focus on operationalization of the strategic lines delineated by the Global IHR Strategic Plan.

14. Because of the diversity across States Parties, in the Region and beyond, the Final Plan should explicitly state that the development of the Global IHR Strategic Plan will take into account the heterogeneity of country contexts and hence will allow a flexible approach to planning national activities relevant to States Parties' compliance with IHR provisions—beyond the model of a single National IHR Action Plan—as part of strategies for overall health systems strengthening.

15. Therefore, the Final Plan should indicate that National IHR Action Plans as such will not constitute the foundation of the Global IHR Strategic Plan, as the need to develop them will vary across States Parties. On one hand, it was recognized that National IHR Action Plans might add value in some countries—for example, by boosting the health systems strengthening process, fostering intra- and intersectoral coordination, overcoming existing barriers to interministerial national planning processes, mobilizing external resources, and strengthening the National IHR Focal Points (NFPs) in countries where they have the mandate to coordinate IHR-related activities. On the other hand, it was recognized that in some States Parties, the activities needed to comply with IHR provisions are already partially or fully integrated into existing institutional planning and intersectoral coordination mechanisms; in such settings the introduction of National IHR Action Plans might represent a setback and could even undermine functioning institutional arrangements (see also Recommendation 10).

16. The Final Plan, and by extension Global IHR Strategic Plan, should explicitly state that, regardless of the diversity of IHR-related national planning processes, requirements that States Parties report on the status of implementation and application of the IHR will only be bound to the rollout of the prospective IHR Monitoring and Evaluation Framework.

Relevance for the Region and prospective regional actions

17. Actions related to this recommendation that would benefit States Parties in the Region include: (i) the identification of approaches to secure the political commitment of the Ministers of Health to guarantee sustainability; (ii) the identification of effective ways to engage with subregional integration mechanisms and development partners to promote alignment of their plans, projects, and initiatives with national plans and Regional Offices IHR Operational Plans, in order to avoid duplications that will ultimately impose a burden on States Parties; (iii) actions to facilitate sharing of best practices with respect to the application and implementation of the IHR across all relevant sectors; (iv) provision of support to update national legislation beyond the health sector; (v) maintaining and strengthening the NFPs, since in some settings they might constitute the only tool with which to maintain the continuity and focus of actions in the face of changes in government and shifts in priorities.

Recommendation 3: Finance IHR implementation, including to support the Global Strategic Plan *[Encompassed by Draft Plan's Area of Action 1: Accelerating country implementation of the International Health Regulations (2005)]*

Considerations regarding the recommendation

18. It was recognized that resources are scarce and hence priorities need to be set. The concept of using milestones as incentives could help to develop logic models.

Comments on the Draft Plan to inform the development of the Final Plan

19. The Final Plan should specify that the Global IHR Strategic Plan will include a budget, with a related timeline for actions.

20. It was noted that sectors beyond health have only limited involvement in the integrated planning for IHR-related activities. Also, adding to the challenges experienced by the Ministries of Health in financing those activities, the financial contribution of other sectors is suboptimal or nonexistent. The involvement of the Ministries of Finance is needed throughout the planning process, especially with regard to its interministerial aspects.

21. Therefore, for future consideration in the development of the Global IHR Strategic Plan, the Final Plan should clearly outline the strategic approach that the WHO Secretariat intends to adopt in order to facilitate the mobilization of national financial resources. This can contribute to national ownership of the Regulations and to accountability across sectors, which in turn will promote sustainability. Considering that resources are limited, the Final Plan should indicate the extent to which the Global IHR Strategic Plan addresses criteria for setting priorities.

22. Similarly, the Final Plan, and by extension the Global IHR Strategic Plan, should present a conceptual framework representing the core capacities detailed in Annex 1 of

the IHR as essential public health functions in the context of the health system as a whole (see also Recommendation 10). It should also specify that models for costing and budgeting of areas of work needed for State Party compliance with IHR provisions will encompass the diversity of planning approaches in the different national contexts—going beyond a single National IHR Action Plan—and across sectors.

Relevance for the Region and prospective regional actions

23. The development of Regional Offices IHR Operational Plans was regarded as an opportunity for PASB to reshape its resource mobilization approach to adequately cater for States Parties' needs.

Recommendation 4: Increase awareness of the IHR, and reaffirm the lead role of WHO within the UN system in implementing the IHR *[Encompassed by Draft Plan's Area of Action 2: Strengthening WHO's capacity to implement the International Health Regulations (2005)]*

Considerations regarding the recommendation

24. Concerns were expressed about potential duplications that could emerge at the level of the United Nations (UN) system. These related in particular to the fact that WHO's leadership role in managing public health emergencies is not sufficiently emphasized. WHO was regarded as the sole UN agency with the potential to promote integration and sustainability in this regard.

Comments on the Draft Plan to inform the development of the Final Plan

25. The recommendation and the Draft Plan are not fully aligned, since in the Draft Plan WHO's leadership seems to fade away further.

26. It was suggested that while WHO's efforts to involve and coordinate with the UN system may add value, these activities also entail the risk that the UN could take over WHO's decision-making process, potentially superseding the deliberations of the WHO Governing Bodies.

27. Although the prospective role of the Inter-Agency Standing Committee (IASC) in infectious disease emergencies might have value, the information provided in the Draft Plan regarding IASC's and WHO's roles was regarded as insufficient, insofar as the proposed operational arrangements are unclear. Therefore, the Final Plan should make explicit the expected strategic positioning of WHO within the UN system for the management of health emergencies and should outline the operational details.

28. It was noted that WHO experienced challenges when it participated in the process of shaping the UN's 2030 Agenda for Sustainable Development, and that despite WHO's effort to give prominence to health issues, those related to the IHR became diluted in the

Agenda. In light of this experience, the Final Plan should be expanded to present WHO's strategy for influencing the UN 2030 Agenda.

Relevance for the Region and prospective regional actions

29. No actions for the Region related to this recommendation were proposed.

Recommendation 5: Introduce and promote external assessment of core capacities *[Encompassed by Draft Plan's Area of Action 3: Improving the monitoring and evaluation of and reporting on core capacities under the International Health Regulations (2005)]*

Considerations regarding the recommendation

30. The recommendation is not regarded as appropriate because:

a) It is internally inconsistent with other sections of the Report of the EVD IHR RC;

b) It undermines the application of Article 54 of the IHR and the implementation of Resolution WHA68.5;

c) It ultimately conflicts with the deliberations of the Regional Consultations, through the WHO Regional Committees in 2015, regarding the IHR Monitoring and Evaluation Framework (hereafter referred to as the Framework) in terms of content, Governing Bodies' path, and timeline set by the WHO Regional Committees in 2015, anticipating the approval of the Framework by the Sixty-ninth World Health Assembly in May 2016.

31. The expectation that the Framework would be considered for approval by the Sixty-ninth World Health Assembly, as per Article 54, was not met. Instead, a revised version of the Framework (Appendix III of this document) was presented as an annex to Document A69/20, which, as per action requested by the Assembly, was only "noted." Moreover, the Framework presented to the Assembly was not consistent with Recommendation 5 of the EVD IHR RC, whose Report was presented in Document A69/21.

32. It was noted that, while monitoring and evaluation activities constitute good public health practice, the efforts of States Parties and the WHO Secretariat in this regard should not represent a priority; rather, the focus of the WHO Secretariat should shift to more substantial capacity-building activities at national level, aimed at improving sustainability. It was also noted that the volume of information about States Parties available to the WHO Secretariat, including data from numerous on-the-ground assessments, might not have been used appropriately to inform country cooperation activities.

33. It was stressed that while monitoring and evaluation activities are important to ensure mutual accountability among States Parties, the primary beneficiaries of such

efforts should remain States Parties themselves. It was also emphasized that the State Party Annual Report, in the format used over the past six years, has created an atmosphere of comparison by indirectly ranking States Parties.

Comments on the Draft Plan to inform the development of the Final Plan

34. IHR Monitoring and Evaluation should not be included in the Final Plan.

35. The IHR Monitoring and Evaluation Framework should be presented for consideration and approval by the 140th session of the WHO Executive Board, and subsequently to the Seventieth World Health Assembly in 2017, as a stand-alone document as indicated by the WHO Regional Committees in 2015.

36. While it was noted that at present, in compliance with Article 54, States Parties are required to report to the World Health Assembly on an annual basis by Resolution WHA61.2, the broad content and processes encompassed by the Framework should be adopted by Resolution. This did not happen for the annual reporting scheme currently in place, a situation that caused several controversies and challenges for States Parties in the Americas. The coexistence of mandatory and voluntary components in the Framework was deemed compatible with the approval of the Framework by Resolution. The Framework presented in Document A69/20 includes one mandatory component, Annual Reporting, and three voluntary components, Joint External Evaluation, After-Action Review, and Simulation Exercises.

37. The IHR Monitoring and Evaluation Framework presented in Document A69/20 was regarded as not satisfactory. Therefore, it should undergo a further round of review, through the WHO Regional Offices, before being put forward to the WHO Governing Bodies in 2017. Toward this end, the following suggestions are offered:

a) The document should be a policy document, focusing on the principles according to which monitoring and evaluation will take place and on the roles and responsibilities of States Parties and the WHO Secretariat. It should not detail operational aspects. Considering the diversity of States Parties, it was stressed that operationalization should be determined by the WHO Regional Offices and that States Parties should be granted flexibility to ensure that the Framework will be beneficial at national level;

b) The document should clearly state how the information produced by the application of its different components will be used by the WHO Secretariat to inform its country cooperation activities;

c) The document should be reviewed giving due consideration to concerns and suggestions from the Regional Consultation held in 2015.

38. With regard to the operationalization of two of the four components of the Framework presented to the Sixty-ninth World Health Assembly, the following suggestions were made:

a) The tool to be developed for Annual Reporting should: *a)* be shorter than the State Party Annual Report currently used; *b)* be based on a graduated scoring system, which should be consistent with the one used for the Joint External Evaluation; *c)* have content that differs from the Joint External Evaluation tool, since they are used for complementary purposes and the underlying methodologies are different; *d)* ensure coherence and continuity with the tool used for submission of the State Party Annual Report up to now, in order to maximize benefits and minimize controversies at national level.

b) The content of the current Joint External Evaluation tool is regarded as not necessarily aligned with IHR provisions and WHO existing guidelines, and it should therefore undergo considerable scrutiny. Efforts should be made to avoid duplications with the prospective Annual Reporting tool and to make them fully complementary.

It was noted that the tool does not take into account "access to certain core capacities" as an alternative to having capacity in-country, which is a concern for small countries. Also, it was stressed that Joint External Evaluations should be conducted by experts from the Region who have knowledge of the country's language and context. Concerns were expressed about the financial sustainability of the Joint External Evaluations.

While voluntarily hosting an external evaluation was regarded as a sign of transparency and commitment, uncertainties about its possible impact were expressed. Two of the States Parties that had hosted an evaluation under the auspices of the Global Health Security Agenda (GHSA) had opposite experiences: one expressed extreme satisfaction with benefits realized, while the other expressed serious concerns. In the latter case, the evaluation appeared to undermine existing intersectoral mechanisms put in place by ministerial decree to coordinate the application and implementation of the Regulations. It was noted that the EVD IHR RC, in its Report, recognized that *"with the GHSA also requesting reporting on IHR implementation from participating countries…[there is] potential for the creation of parallel systems that could be burdensome to countries."*

Relevance for the Region and prospective regional actions

39. Considering: *a)* the substantial contributions of States Parties and experts from the Americas to the development of the IHR Monitoring and Evaluation Framework; *b)* their effort through PAHO and WHO Governing Bodies for IHR related monitoring and evaluation activities to be implemented in a participatory manner and in compliance with World Health Assembly provisions and resolutions; and *c)* the anticipated benefits for States Parties, it is critical that IHR Monitoring and Evaluation Framework follow the

direction set by the Regional Committee of WHO for the Americas in 2015 (Document CD54/INF/4, Add. I) and that this be done independently from the Final Plan.

Recommendation 6: Improve WHO's risk assessment and risk communication *[Encompassed by Draft Plan's Area of Action 4: Improving event management, including risk assessment and risk communication]*

Considerations regarding the recommendation

40. The recommendation is regarded as not fully appropriate or consistent with IHR Article 12 or Annex 2, and it also affects the application of Annex 1.

41. The underlying spirit of the recommendation breaches one of the fundamental inspiring principles of the Regulations, namely that risk assessment is a continuous and reiterative process and, most importantly, a shared responsibility of States Parties and the WHO Secretariat.

42. The proposed creation of a new, additional structure, a standing advisory committee to advise the Director-General on risk assessment and risk communication, is regarded as unnecessary. It would duplicate the functions of the Emergency Committee and could generate delays in the overall risk assessment and response process. Additionally, it was noted that risk assessment and risk communication, while needing to be bridged, constitute two different disciplines, each of which needs to be addressed in its own right.

43. Although the establishment of an intermediate level of alert, called an International Public Health Alert (IPHA), would require amendment of the Regulations, its establishment could be supported by States Parties in the Region on condition that its purpose is duly explained and that an analysis of its implications for the regional and national levels is provided to States Parties.

44. Overall, the recommendation promotes a top-down approach to risk assessment, with the WHO Secretariat as the exclusive intended recipient of the recommendation. It disregards the fact that the efforts of the WHO Secretariat should focus on strengthening existing mechanisms that would be adequate if consistently activated and applied. Most importantly, it ignores the fact that resources of any kind should be invested where they are most needed: at national level.

Comments on the Draft Plan to inform the development of the Final Plan

45. The recommendation and the Draft Plan are not aligned, since the latter does not necessarily offer solutions to the issues targeted by the recommendation.

46. The Draft Plan does not approach the risk assessment process as a shared responsibility of States Parties and the WHO Secretariat, and in its current form it would not necessarily lead to the desired improvements.

47. Therefore, the Final Plan should indicate that the Global IHR Strategic Plan will strategically address the strengthening of the risk assessment process as a shared responsibility, with a bottom-up perspective.

48. In the context of rapidly changing national political landscapes, States Parties, irrespective of the performance and capacity of the technical level, including the NFPs, may not be prone to disclose information. In light of this, the Final Plan should set forth strategies for routinely advocating for the need for transparency at the political level.

49. The Final Plan should indicate that the Global IHR Strategic Plan will include strategic indications, backed by evidence, on how to improve the risk assessment at national level and the articulation with the WHO IHR Contact Points at Regional Office level. The Global IHR Strategic Plan should also explain how communication across the three organizational levels will be improved and, by extension, the global public health community kept informed about evolving public health events.

50. Considering that the continuous and reiterative risk assessment process takes place at the national level, the Final Plan should outline the best use of available financial resources toward this end, as well as, if possible, the modalities for allocation of these resources in the short term.

51. Taking into account that the Regulations already contain provisions for the WHO Secretariat to swiftly engage with States Parties experiencing unusual public health events (Article 10), the Final Plan should indicate that the Global IHR Strategic Plan will set forth more explicit epidemiological criteria for the WHO Secretariat to conduct "on-the-ground assessment." It should also specify the terms of engagement with States Parties where such an event is occurring, and provide a justification for using a top-down approach that might not satisfactorily and efficiently address subsequent response efforts in a rapidly evolving context.

52. The concerns expressed with respect to the proposal to establish a new standing advisory committee also apply to the Draft Plan's proposal to establish a scientific advisory group of experts for infectious hazards. The prospective functions of such a new structure remain unclear in the Draft Plan, and given the multi-hazard scope of the Regulations, focusing on infectious hazards is considered restrictive. Accordingly, the Final Plan should indicate that the focus of the Global IHR Strategic Plan will be on strengthening existing mechanisms rather than investing resources in the creation of an additional structure of uncertain sustainability—one that has, moreover, the potential to hamper the risk assessment process, which is dynamic by definition and needs to be operationally agile to inform an efficient response.

53. Although the Final Plan, and by extension the Global IHR Strategic Plan, must prioritize efficiency of alert and response operations and shift the focus from the WHO Secretariat to States Parties as a priority for the five-year time frame, consideration could be given at a later stage to the possible establishment of an advisory group of experts and

introduction of an IPHA level. A risk-grading approach to risk assessment might have value in informing public health actions at national level. It was emphasized that information on public health events shared by the WHO Secretariat through existing channels (e.g., the Event Information Site) could be more farsighted and better structured, with links to existing preparedness and response plans proactively highlighted. Such information should also be more explicit in terms of specific public health actions deemed appropriate for States Parties to take at specific points in time while an event is unfolding, before "declarations of emergency" typically switch public health actions to a reactive mode.

Relevance for the Region and prospective regional actions

54. Although no specific suggestions were made, and available guidance is generally regarded as sufficient, actions related to this recommendation within the Region revolve around strengthening the national risk assessment and risk communication capacities. In particular, it was stressed that risk perception at technical and political levels, within and between countries, might diverge. As a result, risk assessment informed by diverse criteria could lead to the adoption of public health measures that negatively impact entire geographic subregions (e.g., by depressing tourism in the Caribbean) and that are not justifiable on public health grounds. In this context, risk communication interventions might become exceedingly challenging.

Recommendation 7: Enhance compliance with requirements for Additional Measures and Temporary Recommendations *[Encompassed by Draft Plan's Area of Action 5: Enhancing compliance with the temporary recommendations under the International Health Regulations (2005)]*

Considerations regarding the recommendation

55. The recommendation exclusively focuses on temporary recommendations issued when a Public Health Emergency of International Concern (PHEIC) is determined. Therefore, its scope is restrictive with respect to Article 43, "Additional health measures." Public health measures for managing an unfolding event are dynamically adjusted and adopted as a result of the continuous and reiterative risk assessment process.

56. Although no provisions in the Regulations mandate the WHO Secretariat to proactively conduct the monitoring of potential additional health measures using informal sources of information, data accumulated since the entry into force of the Regulations in 2007, as part of epidemic intelligence activities mandated to the WHO Secretariat, demonstrate that States Parties also adopt additional health measures in response to events that do not constitute a PHEIC.

57. States Parties noted that the implementation of Article 43 is hampered by conflicting political and technical/scientific perspectives, with public risk perception and pressure often leading to the adoption of measures by political decision-makers, overriding scientific evidence.

58. Together with a lack of information about the modus operandi of the WHO Secretariat, it was noted that there is a lack of transparency and coherence in the way the Secretariat treats events occurring in different States Parties and possible additional measures adopted by third parties.

59. It was also noted that existing national legislation may prevent States Parties from complying with Article 43. States Parties and the WHO Secretariat may exert undue pressure on another State Party to lift measures it has adopted, either because the country is unprepared to manage a public health risk without putting at risk national security (e.g., States Parties that had transparently requested extensions) or because it is operating according to existing national quarantine laws.

60. An expert in international health law explained at length, and with examples, that the involvement of the World Trade Organization (WTO) in the settlement of disputes under the IHR, as proposed by the recommendation, is not a viable and realistic option. The same considerations also apply to the proposed issuance of standing recommendations. States Parties indicated that it is unclear how the health sector would trigger procedures that could escalate to the WTO.

61. It was noted that the recommendation calls for States Parties to engage with the private sector. However, while national authorities are already taking action in this respect, it is not necessarily feasible or possible for national authorities to exert an oversight function. As for the WHO Secretariat engaging with the private sector, it was noted that this would have to be done according to the Framework of Engagement with Non-State Actors (FENSA).

Comments on the Draft Plan to inform the development of the Final Plan

62. The Final Plan should explicitly broaden its scope and encompass additional health measures at all times, beyond a PHEIC, stressing the continuum underlying the management of public health events.

63. The Final Plan should clearly define the word “significant” in “significant interference” with travel and trade in Article 43.

64. The Final Plan should indicate that the process for development of a standardized process for the monitoring and management of additional measures, including the escalation pathway in cases of noncompliance, will be truly participatory, involving both States Parties and the WHO Secretariat. Details and timeline of this process should be presented.

65. Development of such a standardized process should seek to overcome the asymmetric treatment of different States Parties and hence improve transparency. The following suggestions were offered:

a) Criteria to be applied by States Parties and by the WHO Secretariat to determine whether a measure should or could be regarded as an additional measure should be explicit;

b) The process should encourage dialogue among States Parties and with the WHO Secretariat so as not to be perceived as punitive, which would further inhibit fluid communication. In particular, the process should promote bilateral dialogue. A fine balance between the rigidity of a standardized process and flexibility favoring dialogue will have to be reached in order to ensure consistency and transparency;

c) An option for States Parties to appeal should also be contemplated.

Relevance for the Region and prospective regional actions

66. Actions related to this recommendation at regional level include: (i) improving the risk analysis capacity at national level; (ii) catalyzing the communication between technical areas of the different institutional entities concerned with the IHR and the political level, including the Ministry of Health's External/International Relations Office and the Ministry of Foreign Affairs.

Recommendation 8: Strengthen National IHR Focal Points *[Encompassed by Draft Plan's Area of Action 1: Accelerating country implementation of the International Health Regulations (2005)]*

Considerations regarding the recommendation

67. The recommendation is regarded as relevant. However, the recommendation goes beyond the communication functions mandated to the NFPs by Article 4, referring instead to *"all of their mandatory* coordination *[…] functions."* It was recognized that the positioning and institutional structure of the NFPs (NFP functions carried out by an existing entity versus an NFP Office created ad hoc), as well as their legal status and the functions assigned to and/or performed by them, vary greatly across countries, within and beyond the Region.

68. The consolidation of these functions requires striking a fine balance with respect to the NFPs' institutional positioning, including considerations about whether and to what extent to prioritize institutional connectivity over technical expertise. Although there are substantial institutional differences between countries, based on part on their size, it is generally true that while a high institutional position for the NFPs may facilitate their access to the decision-making level, it may also jeopardize their continuity and operational communication by exposing them to political influence and political changes. Article 4 is one of the very few IHR provisions that clearly mandate the attribution of institutional functions.

69. In response to such concerns, several States Parties in the Region have created ad hoc NFP Offices, rather than attributing functions to existing institutional entities. For almost 10 years, the NFP Offices have reported facing the same challenges, including

complex intersectoral interactions with numerous coexisting coordination mechanisms, insufficient resources, overlaps with the emergency management structure, lack of legal recognition despite the need to extend their functions, and so on. These difficulties may signal the need for a thorough review of the institutional positioning and functions of NFPs in the Region.

Comments on the Draft Plan to inform the development of the Final Plan

70. Taking into account Article 4, the Final Plan should clearly define the NFP's minimum functions, and these will have to be incorporated in the Global IHR Strategic Plan. In particular, the scope of any intra- and intersectoral coordination function in relation to the application of the Regulations that may be implicit in Article 4 should be described in detail.

71. The Final Plan should be more specific in stating what the WHO Secretariat intends to strengthen at NFP level and what strategies it would use to do so, in particular with respect to legal issues, sustainability of NFP functions, and increasing political support. These will have to be reflected in the Global IHR Strategic Plan.

72. For all remaining components of the prospective Global IHR Strategic Plan, the Final Plan should provide indications on financial resources available at country level.

Relevance for the Region and prospective regional actions

73. Actions related to this recommendation were regarded as high priority for the Region.

74. Given the broad variation in capacities between Regions, any guidance document by the WHO Secretariat should be produced at regional level to ensure that the contents are appropriate for the context. This will help prevent setbacks in regions and States Parties where the NFPs' capacity is already well established and their functions well understood. Guidance to inform the development of operational processes would be welcome.

75. Annual regional NFP meetings were suggested to improve communication among NFPs and as a mechanism to exercise peer pressure.

76. The need for training NFPs was mentioned on several occasions. However, no specific suggestions were made on the areas and/or issues that would need to be targeted.

Recommendation 9: Prioritize support to the most vulnerable countries *[Encompassed by Draft Plan's Area of Action 1: Accelerating country implementation of the International Health Regulations (2005)]*

Considerations regarding the recommendation:

77. The criteria for defining vulnerability are unclear in the recommendation. Often vulnerability in this area of work is determined by economic criteria, but this is regarded as a restrictive and short-sighted approach. It was noted that PASB take into account both economic and non-economic criteria to define priority countries in the Americas. However, it is unclear how priority and vulnerability measures are linked.

78. It was stressed that assistance should be afforded to any country, regardless of its vulnerability ranking, that confronts circumstances where its public health capacities are exceeded.

79. It was noted that cross-border activities should be approached in a broader manner, beyond the question of ground crossings addressed by the Regulations. Accordingly, the WHO Secretariat should consider building on the approach developed by the International Organization for Migration (IOM). Cross-border working groups can be difficult to implement in times of crisis, when human resources are fully engaged in preparedness and response activities.

Comments on the Draft Plan to inform the development of the Final Plan

80. The recommendation and the Draft Plan are not aligned: the recommendation focuses on emergency situations, whereas the Draft Plan focuses on capacity building. Therefore, the Final Plan, and by extension the Global IHR Strategic Plan, should clarify the focus, and—should the capacity-building approach prevail—explain how the strategic approach would differ from that employed in other States Parties.

81. The Final Plan should specify the criteria that will be used to define "high vulnerability and low capacity" States Parties. These criteria will need to be captured in the Global IHR Strategic Plan.

82. The Final Plan, and by extension the Global IHR Strategic Plan, should more clearly state how the prospective support to be provided by the WHO Secretariat will articulate with the provision of support by partners under Article 44.

Relevance for the Region and prospective regional actions

83. Apart from the need for PASB to clarify how the criteria used to define priority countries in PAHO's planning processes relate to the criteria for vulnerability, no additional suggestions were made.

Recommendation 10: Boost IHR core capacities within health systems strengthening *[Encompassed by Draft Plan's Area of Action 1: Accelerating country implementation of the International Health Regulations (2005)]*

Considerations regarding the recommendation

84. While there was agreement that core capacities detailed in the IHR should be framed as and linked to essential public health functions, it was noted that the essential public health functions in their current iteration do not necessarily cover all the components related to IHR provisions across sectors. The recommendation does not indicate the conceptual framework invoked to substantiate it.

Comments on the Draft Plan to inform the development of the Final Plan

85. Considering that governance, human resources, financing, and legislation have been consistently cited by States Parties as major constraints to their ability to comply with and apply IHR provisions in a sustainable manner, the Final Plan, and by extension the Global IHR Strategic Plan, should present the conceptual framework underlying the actions proposed (see also Recommendation 3).

86. It is clearly understood that preparedness, early warning, and response functions can only be effective and sustainable if they are embedded in the health system as a whole. The Final Plan, and by extension the Global IHR Strategic Plan, should be explicit on the strategies envisaged to promote and trigger shifts from IHR core capacities to essential public health functions while maintaining sufficient political awareness regarding States Parties' rights and obligations vis-à-vis the international community under IHR provisions.

87. Similarly, there is a need for detailed presentation of strategies to bridge the gaps and integrate the work of Ministry of Health departments that apply the IHR on a daily basis with the work of other Ministry of Health departments and other sectors concerned with planning, financing, and human resources.

88. The Final Plan should indicate that the Global IHR Strategic Plan will capture the wide variation across States Parties with respect to the both maturity of their health systems and the status of their application and implementation of the IHR. This would help ensure that individual States Parties adopt the most appropriate model for integrating core capacities in their health systems, with particular emphasis on planning models to avoid setbacks where partial or full integration already exists (see also Recommendation 2).

Relevance for the Region and prospective regional actions

89. No actions for the Region related to this recommendation were proposed.

Recommendation 11: Improve rapid sharing of public health and scientific information and data *[Encompassed by Draft Plan's Area of Action 6: Rapid sharing of scientific information]*

Considerations regarding the recommendation

90. The recommendation is not regarded as fully appropriate, and there are doubts about its consistency with Articles 7 and 45 of the Regulations. The concepts of risk, emergency, and crises need to be better defined and the differences among them framed more clearly.

Comments on the Draft Plan to inform the development of the Final Plan

91. The Final Plan has to be explicit on the key policies and mechanisms established to govern the use of data/information that States Parties share with WHO.

92. These policies and mechanisms must be scrutinized by States Parties, and the processes to do so should be indicated in the Final Plan.

93. Confidentiality issues should also be addressed in the Final Plan, which should set forth specific conditions for invoking confidentiality and defining data as sensitive. An unusual health event detected in the private sector may not generate a signal, given concerns about breach of confidentiality. The same concerns would apply to the sharing of line listing by small States Parties.

94. Similarly, the Final Plan should include a definition of what "equal footing" means and should state explicitly that data providers and/or researchers on site must, at a minimum, be informed about the findings and conclusions of any study conducted using the data they provided.

Relevance for the Region and prospective regional actions

95. Actions related to this recommendation are regarded as high priority for the Region. In particular, States Parties in the Caribbean subregion would welcome further support from PASB for updating national legislation, including the development of a legislative framework governing the private sector.

Recommendation 12: Strengthen WHO's capacity and partnerships to implement the IHR and to respond to health emergencies *[Encompassed by Draft Plan's Area of Action 2: Strengthening WHO's capacity to implement the International Health Regulations (2005), and Draft Plan's Area of Action 5: Enhancing compliance with the temporary recommendations under the International Health Regulations (2005)]*

Considerations regarding the recommendation

96. Too many sub-items are addressed, some of them are unclear, and their pooling under a common heading seems inconsistent with the overall structure of the report. Therefore, a thorough analysis proved challenging.

97. Nevertheless, it was reiterated that when mandates are clear, activities aimed at disseminating knowledge and raising awareness about the IHR, as well as using the IHR to improve communication with other UN agencies and international organizations, do have value.

Comments on the Draft Plan to inform the development of the Final Plan

98. Although the reform of WHO work in emergencies was requested by Member States in the wake of the Ebola outbreak in West Africa, and the recent establishment of the WHO Health Emergencies Programme was supported by the Sixty-ninth World Health Assembly, concerns were expressed regarding the impact that the WHO Health Emergencies Programme may have on national institutions.

99. Therefore, the Final Plan should state clearly that, unless there is evidence that warrants a restructuring of national institutions because of deficiencies in essential public health functions, what States Parties might experience is a change in the way they interact with WHO on a day-to-day basis.

Relevance for the Region and prospective regional actions

100. There is a need for PASB to clearly communicate organizational changes to national authorities, to specify how these changes will likely affect the interactions with national authorities on a daily basis and during emergencies, and to outline the criteria and processes that would warrant the introduction of institutional changes at national level.

Recommendation 1: Implement rather than amend the IHR *("There is neither the need for, nor benefit to be drawn from, opening up the amendment process for the IHR, at this time.")*

101. Following thorough consideration of both the recommendation of the EVD IHR RC and the Draft Plan, there was agreement that, at present, amendment of the IHR is not warranted.

Conclusions

102. It was agreed that PASB would present the report of the meeting to the 55th Directing Council for its consideration and further actions to take forward the position of the Region to the WHO Governing Bodies.

103. PAHO staff indicated that they would identify the most appropriate Governing Bodies mechanisms and format to do so.

104. In preparation for the 140th session of the Executive Board of WHO, in order to consolidate consensus, within and beyond the Region, around the position expressed by States Parties in the Americas during the meeting, it was suggested that PASB should prepare an Information Note on this matter for dissemination through the Group of the Americas (GRUA).

Appendix II

Regional Committees 2016

Draft global implementation plan for the recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response

1. In May 2016, the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response presented its recommendations to the Director-General at the Sixty-ninth World Health Assembly.[1] The Health Assembly adopted decision WHA69(14) in which, inter alia, it requested the Director-General "to develop for further consideration of the Regional Committees in 2016 a draft global implementation plan for the recommendations of the Review Committee that includes immediate planning to improve delivery of the International Health Regulations (2005) by reinforcing existing approaches, and that indicates a way forward for dealing with new proposals that require further Member State technical discussions".[2] It also requested the Director-General to submit a final version of the global implementation plan for the consideration of the Executive Board at its 140th session.

Overview of the draft global implementation plan

2. The Review Committee made 12 major recommendations and 60 supporting recommendations. Its first recommendation was to "implement rather than amend" the International Health Regulations (2005). During the Health Assembly's deliberations on the Committee's report, however, a number of representatives of Member States expressed concern that some of the recommendations could in fact require revisions to the International Health Regulations (2005), although there were no detailed discussions on this specific group of recommendations. Accordingly, this draft global implementation plan proposes modalities and approaches for implementing the recommendations of the Review Committee in respect of which planning and implementation can start immediately. For other recommendations, it proposes a way forward. An overview of the relationship between the proposed areas of action of the draft global implementation plan and the recommendations of the Review Committee is provided in the Annex.

3. The six proposed areas of action of the draft global implementation plan are as follows:

- **Accelerating country implementation of the International Health Regulations (2005)** – this area addresses recommendations 2, 3, 8, 9 and 10 of the Review Committee.
- **Strengthening WHO's capacity to implement the International Health Regulations (2005)** – this area addresses recommendations 4 and 12 of the Review Committee, with the exception of recommendations 12.7 and 12.8.
- **Improving the monitoring and evaluation of and reporting on core capacities under the International Health Regulations (2005)** – this area presents the Director-General's proposal in response to recommendation 5 of the Review Committee.

[1] Document A69/21 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf).
[2] Document A69/DIV./3 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_DIV3-en.pdf).

- **Improving event management, including risk assessment and risk communication** – this area presents the Director-General's proposal in response to recommendation 6 of the Review Committee.
- **Enhancing compliance with the temporary recommendations under the International Health Regulations (2005)** – this area presents the Director-General's proposal in response to recommendation 7 of the Review Committee and supporting recommendations 12.7 and 12.8.
- **Rapid sharing of scientific information** – this area presents the Director-General's proposal in response to recommendation 11 of the Review Committee.

Area 1. Accelerating country implementation of the International Health Regulations (2005)

4. In order to accelerate the country-level implementation of the International Health Regulations (2005), in keeping with the recommendations of the Review Committee, WHO will give priority to actions to:

- develop a 5-year global strategic plan, which builds on regional efforts and lessons learned, to improve public health preparedness and response, to be presented to Member States at the Seventieth World Health Assembly, in May 2017, followed in turn by the development or adaptation of relevant regional action plans;
- develop national 5-year action plans based on the global strategic plan and relevant regional action plans;
- prioritize WHO support to countries with high vulnerability and low capacity, based on objective assessments of national core capacities (see Area 3);
- mobilize financial resources to facilitate the implementation of the International Health Regulations (2005) at the global, regional and national levels;
- support and further strengthen the work of the National IHR Focal Points; and
- systematically link the building of core capacities under the International Health Regulations (2005) with health systems strengthening.

5. WHO proposes that the final version of the global implementation plan for the recommendations of the Review Committee should serve as the basis for the global strategic plan to improve public health preparedness and response. The global strategic plan would be implemented through the new WHO Health Emergencies Programme,[1] the results framework[2] for which includes all the relevant elements for supporting the six areas of action covered by the draft global implementation plan.

6. Under this draft global implementation plan, countries with the highest vulnerability and lowest capacity would be prioritized for WHO in-country capacity building activities. WHO will also work with partners to mobilize technical and financial assistance to countries with high vulnerability and low capacity for the assessment of their core capacities and the development and implementation of national action plans to address gaps and weaknesses as rapidly as possible.

[1] Document A69/30 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_30-en.pdf).

[2] WHO Health Emergency Programme results framework and budget requirements 2016–2017, 16 May 2016 (http://www.who.int/about/who_reform/emergency-capacities/emergency-programme-framework-budget.pdf?ua=1).

7. WHO will work with countries to encourage the allocation of domestic financial resources to the national action plans for the development and maintenance of the core capacities for surveillance and response, as agreed in the Addis Ababa Action Agenda of the Third International Conference on Financing for Development.[1] WHO will develop models for the costing of and budgeting for the national action plans, in the context of broader national health systems strengthening plans. It will support States Parties in mobilizing and tracking international financial and in-kind support for national action plans by further enhancing and maintaining WHO's Strategic Partnership Portal.

8. WHO will accelerate action to strengthen the capacity of the National IHR Focal Points to use the International Health Regulations (2005), including by calling for the National IHR Focal Points to play a more prominent role in the broader national public administration, within and beyond the health sector. In addition, WHO will accelerate the development or revision of standard operating procedures for and guidelines on the role of National IHR Focal Points and make recommendations on empowering National IHR Focal Points with adequate resources and the authority to carry out their obligations, including through the adoption of appropriate national legislation with respect to the functions of National IHR Focal Points. It will strengthen its work to maintain a strong network of National IHR Focal Points by holding regular regional and global meetings for training purposes and for sharing lessons learned to accelerate the use of the International Health Regulations (2005) on a day-to-day basis.

9. WHO will further strengthen the operational links between its work in health systems strengthening and the new WHO Health Emergencies Programme, paying particular attention to ensuring a joint programme of work in the development of national action plans and in the implementation of capacity-building activities in the areas of human resources for health, health financing and health system resilience. This will have a beneficial impact on health security, through the development of core capacities under the International Health Regulations (2005), on the attainment of the Sustainable Development Goals, and on universal health coverage.

Area 2. Strengthening WHO's capacity to implement the International Health Regulations (2005)

10. The new WHO Health Emergencies Programme will substantially strengthen the capacity of the Organization to implement the International Health Regulations (2005). Under the new Programme, the number of personnel dedicated to the Regulations and preparedness capacity building will be considerably increased at all three levels of the Organization, including and especially in countries with high vulnerability and low capacity. Country health emergency preparedness in the context of the International Health Regulations (2005) is one of the major elements of the results framework for the new Programme, which includes outputs on the monitoring, evaluation and assessment of core capacities for all hazards emergency risk management, the development of national plans and critical core capacities for health emergency preparedness and the provision of secretariat support for the implementation of the International Health Regulations (2005).

11. In the context of the new Programme, WHO will enhance its coordination and collaboration on health emergencies with other entities and agencies both within and outside the United Nations system. To promote the International Health Regulations (2005) and their full implementation, WHO will build on its preliminary work to include in the remit of the

[1] United Nations General Assembly Resolution A69/313 Available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/69/313.

United Nations Secretary-General's Special Representative for Disaster Risk Reduction a mandate to act as an advocate for the International Health Regulations (2005) to ensure that they are well understood and positioned prominently across sectors in both governments and in international organizations, and that their ongoing implementation is closely monitored. This would serve to improve global awareness and recognition of the Regulations and would be a powerful signal from outside WHO about their importance for national governments and not just for ministries of health.[1]

12. The Inter-Agency Standing Committee is the primary mechanism for the interagency coordination of international humanitarian assistance and is convened by the United Nations Emergency Relief Coordinator of the United Nations Office for the Coordination of Humanitarian Affairs. On 7 June 2016, the Standing Committee's Principals concurred on the use of the mechanisms of the Standing Committee and the United Nations Office for the Coordination of Humanitarian Affairs to coordinate the international response to large-scale infectious emergencies, under the strategic and technical leadership of WHO. The United Nations Office for the Coordination of Humanitarian Affairs and WHO will lead the drafting of standard operating procedures for the work of the Standing Committee in infectious disease emergencies with the aim of having a draft document by the end of September 2016. Progress in this regard will be among the issues reported to the global health crises task force that has been established by the United Nations Secretary-General to monitor and support implementation of the recommendations of the High-level Panel on the Global Response to Health Crises.[2]

13. The new WHO Health Emergencies Programme also establishes a number of mechanisms to further strengthen WHO's partnership work in respect of the implementation of the International Health Regulations (2005), particularly in collaboration with the Global Outbreak Alert and Response Network, the members of the Global Health Cluster and a range of expert networks. In June 2016, the Steering Committee of the Global Outbreak Alert and Response Network agreed to further strengthen the Network to enhance the WHO's capacity for surveillance, risk assessment and risk communication.

Area 3. Improving the monitoring and evaluation of and reporting on core capacities under the International Health Regulations (2005)

14. Following the adoption of Health Assembly resolution WHA61.2, requesting States Parties to report annually on the implementation of the Regulations,[3] the reporting instrument for conducting annual self-assessments and annual reporting by States Parties, was the WHO's Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties.[4] The annual reporting process involved the assessment of the implementation of eight core capacities and the development of capacities at points of entry and for Regulations-related hazards, notably biological (zoonotic, food safety and other infectious hazards), chemical, radiological and nuclear, based on Annex 1 to the International Health Regulations (2005).

15. The Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation recommended in 2014 moving "from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent

[1] See document A69/21, Annex, supporting recommendation 4.1 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf).
[2] See document A69/30, para. 13 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_30-en.pdf).
[3] WHA Resolution WHA61.2 (http://apps.who.int/iris/bitstream/10665/23569/1/A61_REC1-en.pdf).
[4] http://www.who.int/ihr/publications/checklist/en/.

experts."[1] A concept note[2] outlining a revised approach was discussed by the WHO Regional Committees in 2015, and a revised International Health Regulations (2005) monitoring and evaluation framework was noted by the Sixty-ninth World Health Assembly.[3] That framework has four components: annual reporting, joint external evaluation, after-action review and/or simulation exercises.

16. The Secretariat, with input from partners, has developed a joint external evaluation tool[4] as one of the four components of this new framework for the monitoring and evaluation of the International Health Regulations (2005). The tool has been used in 10 countries as of July 2016. It contains 19 areas grouped under four main headings: "Prevent", "Detect", "Respond" and "Other IHR-related hazards and Points of Entry". The new monitoring and evaluation framework proposes that all countries conduct at least one external evaluation every four years.

17. The Director-General proposes that States Parties should continue to conduct self-assessments for the purpose of annual reporting to WHO on the achievement of core capacities under the International Health Regulations (2005). The Director-General further proposes that the new monitoring and evaluation framework should be used by all States Parties to assess their core capacities and, on a voluntary basis, can be used to complement the information contained in annual self-assessments, with particular attention being paid to the experience gained and lessons learned from voluntary, external evaluations. For consistency within the new monitoring and evaluation framework, it is proposed that, after 2016, the annual reporting tool should follow the same format as the joint external evaluation tool for those elements of the annual report on the self-assessment that are included in the joint external evaluation tool.

Area 4. Improving event management, including risk assessment and risk communication

18. Central to the WHO Health Emergencies Programme is a new single, unified set of procedures across the three levels of the Organization for conducting rapid risk assessments in response to newly detected public health events. The new procedures will involve a systematic assessment of the hazard, exposure, vulnerability and capacities, in order to determine whether an event constitutes a low, medium, high or very high risk of amplification and international spread. The results of these risk assessments will be made publicly available, in addition to their dissemination through the current WHO processes, and, in the case of high and very high-risk events, will be directly and immediately communicated to the United Nations Secretary-General, the National IHR Focal Points and the Principals of the Inter-Agency Standing Committee.

19. The WHO Health Emergencies Programme will initiate within 72 hours an on-the-ground assessment when notified of a high threat pathogen (for example, human-to-human transmission of a novel influenza virus), clusters of unexplained deaths in high-vulnerability, low-capacity settings, and other events deemed appropriate at the discretion of the Director-General. When feasible, the Programme will engage partner agencies with relevant expertise to assist in such risk assessments. The outcomes will be communicated to the Director-

[1] Document A68/22 Add.1, Annex 1 (http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_22Add1-en.pdf).
[2] http://www.who.int/ihr/publications/concept_note_201507/en/.
[3] Document A69/20, Annex (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_20-en.pdf).
[4] http://www.who.int/ihr/publications/WHO_HSE_GCR_2016_2/en/.

General within 24 hours of completion of the assessment, together with recommendations of the Programme on risk mitigation, management and response measures as appropriate.[1]

20. The Director-General will establish a scientific advisory group of experts for infectious hazards to help guide the Organization's work in evaluating and managing new and evolving public health risks, as well as its broader work in the identification, characterization and mitigation of high-threat pathogens.

Area 5. Enhancing compliance with the temporary recommendations under the International Health Regulations (2005)

21. In the context of a public health emergency of international concern under the International Health Regulations (2005), WHO has monitored on an ad-hoc basis the additional measures taken by States Parties that went beyond the temporary recommendations issued by the Director-General in terms of travel and trade. Going forward, WHO will establish a standardized process to identify, collate and monitor such additional measures, and to systematically engage with the relevant States Parties to verify the reported measures, understand the basis for their implementation and, if inappropriate, request that they be rescinded.

22. WHO will maintain a publicly accessible repository of public health measures adopted by countries in response to public health emergencies of international concern, including recommendations for travellers. Based on the data in the repository, the WHO Secretariat will publicly report on the additional measures through the WHO website and to the Health Assembly as part of WHO's regular reporting on implementation of the International Health Regulations (2005). WHO will establish a follow-up system with countries reporting additional measures, and consider the development of standard operating procedures for escalating cases of non-compliance.

Area 6. Rapid sharing of scientific information

23. The Director-General has, in 2016, established new WHO policies and mechanisms, in the context of public health emergencies, for sharing line-listed data with appropriate entities for the purposes of epidemiologic studies and mathematical modelling to facilitate understanding of and the response to emergencies, and for ensuring rapid access to new information and data from public health studies and clinical trials to allow the timely application of such data in a response.

24. The findings, deliberations and recommendations of the Pandemic Influenza Preparedness Framework 2016 Review Group will inform the next phase of WHO's work to enhance the sharing of genetic sequence data for other pathogens.

Action by the Regional Committee

25. The Regional Committee is invited to provide comments on the Director-General's draft global implementation plan for the recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, to inform the development of a final version of the implementation plan for the consideration of the Executive Board at its 140th session, in January 2017.

[1] See document A69/30, paragraph 10 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_30-en.pdf).

Annex to Appendix II

Relationship Between the Proposed Areas of Action of the Draft Global Implementation Plan and the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response

Area of action of the draft global implementation plan	Corresponding recommendations of the International Health Regulations Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response
1. Accelerating country implementation of the International Health Regulations (2005). • Develop a global strategic plan to improve public health preparedness and response, and present this to Member States at the Seventieth World Health Assembly, in May 2017. • Prioritize WHO support to high vulnerability, low capacity countries, based on objective assessments. • Mobilize financial resources to facilitate the implementation of the International Health Regulations (2005) at the global, regional and national levels. • Support and further strengthen the National IHR Focal Points. • Link core capacities under the International Health Regulations (2005) with health systems strengthening.	**Recommendation 2:** Develop a global strategic plan to improve public health preparedness and response. **Recommendation 3:** Finance implementation of the International Health Regulations (2005), including to support the global strategic plan. **Recommendation 8:** Strengthen National IHR Focal Points. **Recommendation 9:** Prioritize support to the most vulnerable countries. **Recommendation 10:** Boost core capacities under the International Health Regulations (2005) within health systems strengthening.
2. Strengthening WHO's capacity to implement the International Health Regulations (2005). • Sustain WHO collaboration with the United Nations system. • Strengthen WHO capacity to implement the International Health Regulations (2005).	**Recommendation 4:** Increase awareness of the International Health Regulations (2005), and reaffirm the lead role of WHO within the United Nations system in implementing them. **Recommendation 12:** Strengthen WHO's capacity and partnerships to implement the International Health Regulations (2005) and to respond to health emergencies.
3. Improving the monitoring and evaluation of and reporting on core capacities under the International Health Regulations (2005).	**Recommendation 5:** Introduce and promote external assessment of core capacities.
4. Improving event management, including risk assessment and risk communication.	**Recommendation 6:** Improve WHO's risk assessment and risk communication.
5. Enhancing compliance with the temporary recommendations under the International Health Regulations (2005)	**Recommendation 7:** Enhance compliance with requirements for additional measures and temporary recommendations. **Recommendation 12.7:** WHO should collaborate with WTO […] to develop a prototype template for standing recommendations […]. **Recommendation 12.8:** WHO should encourage recognition of such standing recommendations in dispute settlement proceedings […].
6. Rapid sharing of scientific information	**Recommendation 11:** Improve rapid sharing of public health and scientific information and data.

Appendix III

Implementation of the International Health Regulations (2005): Annual report on the implementation of the International Health Regulations (2005) *(Annex to Document A69/20)*

The International Health Regulations (2005)

Monitoring and Evaluation Framework
Principles of the new IHR Monitoring and Evaluation Framework

1. The new IHR Monitoring and Evaluation Framework combines qualitative and quantitative approaches in an objective review process of the countries' actual capacities. It is proposed to conduct this monitoring and evaluation process through a four-year cycle anchored in the national health system review cycle and budget planning.

2. The new framework should promote accountability and transparency through accurate and timely reporting on the status of IHR implementation which will foster dialogue, trust and accountability among States Parties. Opportunities for improvements identified as a result of applying this framework should be translated into a national plan of action with timelines and resources for implementation. The national plan of action for IHR core capacity and country health emergency preparedness should be incorporated into the national budget cycle and aligned with the national strategic plan, rather than being independent of institutional planning. This continuing cycle of review process must facilitate linkages with other relevant sectors and ensure compatibility within existing national strategic plans; promote partnership at national and international levels; and engage with current and prospective donors and partners to complement domestic investment in health security.

The four components of the new IHR Monitoring and Evaluation Framework

3. The framework comprises four interrelated components, which are designed to identify gaps and opportunities for improvement. It is proposed that, within a four-year period, States Parties will systematically conduct the following activities.

Annual reporting

4. Annual reporting on implementation of the Regulations to the Health Assembly by States Parties is required under Article 54 of the Regulations. These reports must be made in accordance with resolution WHA61.2 (2008) on implementation of the Regulations. Annual reporting seeks to give a quantitative snapshot of the status of the core capacities across all countries. Recognizing the limitations of any self-administered tool, the current IHR monitoring questionnaire is to be complemented as frequently as possible by the other three elements. The questionnaire is also being revised to make it simpler and aligned with the Joint External Evaluation Tool.

Joint external evaluation

5. Joint external evaluation is intended to assess country capacity to prevent, detect, and rapidly respond to public health events under the Regulations. The purpose of the external evaluation is to introduce an independent expert measurement of a country's capacity and to measure progress in achieving capacities required under the Regulations.

6. External evaluation allows countries to identify the most urgent needs within their national plans; to prioritize opportunities for enhanced preparedness, detection and response capacity building including setting national priorities and allocating resources on the basis of objective findings; and to engage with current and prospective donors and partners, as appropriate. Transparency is an important element to attract and direct resources to where they are needed most.

7. Countries are encouraged, on a voluntary basis, to conduct at least one joint external evaluation every four years.

8. To conduct joint external evaluations in a standardized manner across States Parties, a Joint External Evaluation Tool has been designed by the Secretariat in collaboration with experts, States Parties and partners. The tool is organized so as to assess 19 technical areas.

After-action review and/or simulation exercise(s)

After action review

9. It is imperative to complement annual reporting by reviewing real-life experience of a public health event which can offer an opportunity to draw lessons and identify opportunities for improvement. The health event(s) for after-action review should be selected by States Parties, although technical advice can be provided by the Secretariat upon request. The information that is captured through the after-action review will be primarily qualitative and functional, and will be used to identify any areas for improvement through a national plan of action. This review can be a self-review (IHR national implementers) or a joint review (IHR national implementers and external national or international partners in partnership with a peer group from another country or with the Secretariat).

Simulation exercise(s)

10. When there is no suitable public health event to review, simulation exercises can serve as an alternative for testing the actual functioning of IHR core capacities. Exercises (national, regional or subregional) could also be specially designed when there is a need to test the performance of a particular functionality or technical area.

11. Countries are encouraged to conduct an after-action review or conduct simulation exercises at least once every four years.

Reporting to the World Health Assembly on progress in implementing the Regulations

12. According to the transparency and mutual accountability principles underlying the Regulations, it is proposed that the relevant reporting to the Health Assembly by the Secretariat will provide a summary of each country's assessment based on the new IHR Monitoring and Evaluation Framework. The Secretariat will establish dedicated pages on the WHO website to provide access, with the agreement of the country concerned, to the information contained in the annual report and/or in respect of any joint external evaluation mission, after-action review and/or simulation exercise conducted.

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

55th DIRECTING COUNCIL

68th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 26-30 September 2016

Provisional Agenda Item 4.8

CD55/12, Rev. 1
Annex C
Original: English

PROPOSED DECISION

IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (IHR)

(PP1) The 55th Directing Council, having reviewed the document entitled *Regional Consultation on the Draft WHO Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response* (Document CD55/12, Rev. 1, Annex B), presenting the report of the formal Regional Consultation held in Miami, United States, 1-3 August 2016;

(PP2) Having recalled Resolution WHA61.2 (2008), Decision CD52(D5) (2013), Resolution WHA68.5 (2015), Document CD54/FR (2015), Document EB138/4 (2016), Document A69/20 (2016), Document A69/21 (2016), Decision WHA69(14), and Document CE158/INF/5 (2016),

Decides:

(OP)1. To endorse the report of the formal Regional Consultation on the Implementation of the International Health Regulations and the Member States' comments on the *Draft Global Implementation Plan for the Recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response (hereafter the 'Draft Plan')*; with a request to WHO's Secretariat to include the recommendations of Member States of the Americas under the relevant agenda item to be presented to the Executive Board of WHO at its 140th session in January 2017, with particular emphasis on the following outcomes of the formal Regional Consultation:

a) the final plan should encompass the Areas of Action of the current Draft Plan, with the exception of Area of Action 3, and WHO should develop the Global IHR Strategic Plan separately, only addressing Areas of Action 1 and 4 of the current Draft Plan, in order to be presented to the Seventieth World Health Assembly in May 2017;

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b) the IHR Monitoring and Evaluation Framework corresponding to Area of action 3 of the current Draft Plan, should not be addressed in the Final Plan, and, as per Article 54, should be presented as a separate document for consideration and adoption by the Seventieth World Health Assembly in May 2017.

(OP) 2. To request the Director to:

a) transmit to the WHO Secretariat the report of the formal Regional Consultation in its entirety,

b) facilitate the preparations of Member States in the Americas for the 140th session of the Executive Board of WHO, in January 2017, with the dissemination of an Information Note on this matter to the Member States and to their Missions in Geneva.

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.8 - Implementation of the International Health Regulations

2. Responsible unit: CHA/IR

3. Preparing officer: Dr. Roberta Andraghetti

4. Link between Agenda item and Health Agenda for the Americas 2008-2017:
The topic of International Health Regulations (IHR) is most closely aligned to the Area of Action (h) in the *Health Agenda for the Americas 2008-2017* related to Strengthening Health Security. The IHR are explicitly mentioned as an opportunity for countries to strengthen public health capacities and to foster inter-country collaboration.

5. Link between Agenda item and the PAHO Strategic Plan 2014-2019:
The policy document is completely aligned with core strategic areas of the PAHO Strategic Plan 2014 – 2019, Championing Health: Sustainable Development and Equity, in particular *Category 5: Preparedness, Surveillance, and Response*. The Plan specifically notes the importance to 'ensure that all countries of the Region have the core capacities needed to fulfill their responsibilities under the IHR, which cover Legislation, policy, and financing; coordination and NFP communication; surveillance; response; preparedness; risk communication; human resources; laboratory; points of entry; zoonotic hazard; food safety; chemical hazard; radiation-related hazard. Outcome 5.1.1: *Number of States Parties meeting and sustaining International Health Regulation requirements for core capacities* was established to show the progress of States Parties in the Region towards the implementation of IHR.

6. List of collaborating centers and national institutions linked to this Agenda item:
WHO Collaborating Center for Implementation of IHR Core Capacities (Global Health Security Branch, Division of Global Health Protection, CDC), Ministries of Health, Ministries of Defense, Ministries of Agriculture, Ministries of Foreign Affairs; Ministries of Transport; Ministries of Energy.

7. Best practices in this area and examples from countries within the Region of the Americas:
As a Region, starting in 2014, the Americas have led the work at global level to reshape the approach to the monitoring and evaluation of the IHR, stressing the critical role of the PAHO and WHO Governing Bodies in the process.

Specific examples of best practices from countries include (but are not limited to) to following:

- Canada, Chile, Dominica, and El Salvador: institutionalization and emphasis in the sustainability of core capacities, while maintaining a flexible and intersectoral approach to preparedness;

- Brazil, Canada, Chile, United States: Functioning of the National IHR Focal Point Office;
- Canada, Costa Rica, Mexico, and United States: solid national reference laboratory;
- Brazil and Mexico: tailoring institutional training efforts to address needs (Epidemiology Training Program/EPISUS);
- Barbados: institutionalization of the Infection Prevention and Control Programme;
- Brazil and Mexico: architecture of the response structure, based on a solid command and control structure;
- Brazil, Canada, Colombia, and El Salvador: holistic and integrated approach to port health/international health;
- Caribbean countries taking actions to become members of the International Atomic Energy Agency (IAEA).

8. Financial implications of this Agenda item:

The work of the PAHO Secretariat in the implementation of the IHR is embedded primarily in Category 5 (Preparedness, Surveillance and Response) and in Category 4 (Health Systems – related to resilience in health systems) and in the corresponding budgetary allocation in programmatic areas within these categories. Sustained funding is needed to support the constant efforts by States Parties in the management of public health events of potential international concern, as well as to address the long term obligations, such as the establishment and maintenance of core capacities.

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