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#### IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS

##### Introduction

1. This document reports on the application and implementation status of the International Health Regulations (IHR or “the Regulations”) and compliance therewith (1). The report covers the period from 1 July 2019 to 30 June 2020, complementing the information provided in Document A73/14, presented to the 73rd World Health Assembly in May 2020 (2). The current report reviews activities undertaken by States Parties and the Pan American Sanitary Bureau (PASB) in response to acute public health events, including public health emergencies of international concern (PHEIC), as well as activities for the purpose of capacity building. Finally, it highlights issues requiring concerted action by States Parties in the Region of the Americas and by PASB to enhance future application and implementation of the Regulations and compliance with them.

2. This document needs to be considered in the context of the ongoing COVID-19 pandemic.<sup>1</sup> It is closely related to Document CD58/6, COVID-19 Pandemic in the Region of the Americas (3), and the associated proposed resolution. It is also aligned with Resolution WHA73.1, COVID-19 Response (4), which, if implemented, might shape the future application and implementation of the Regulations and compliance therewith.

##### Background

3. The IHR were adopted by the 58th World Health Assembly in 2005 through Resolution WHA58.3 (5). They constitute the legal framework that, *inter alia*, defines national core capacities, including at points of entry, for the management of acute public health events of potential or actual national and international concern, as well as related administrative procedures.

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<sup>1</sup> Information about the ongoing COVID-19 pandemic is available on the WHO website at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019> and on the PAHO website at <https://www.paho.org/en/topics/coronavirus-infections/coronavirus-disease-covid-19-pandemic>.

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## **Situation Analysis**

### ***Acute Public Health Events***

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 with the National IHR Focal Points (NFP) through established communication channels. In both 2019 and 2020, all 35 States Parties in the Region submitted the annual confirmation or update of contact information for their NFPs, along with an updated list of national users of the secure WHO Event Information Site for National IHR Focal Points (EIS). As of 30 June 2020, 109 users from all 35 States Parties and 52 PASB staff had the credentials to access the WHO EIS portal. In 2019, routine tests of connectivity between the WHO IHR Contact Point and the NFPs in the Region were successful for 33 of the 35 States Parties (94%) by telephone, and for 32 States Parties (91%) by email.

5. The analysis presented below, concerning acute public health events of potential or actual national and international concern, exclusively focuses on those events not related to the COVID-19 pandemic (which includes Multisystem Inflammatory Syndrome in Children). From 1 July 2019 to 30 June 2020, 74 acute public health events of potential international concern were identified and assessed in the Region, representing 25% of the events considered globally over the same period. Fifty (68%) of those events were identified before the first COVID-19-related alert was published on the WHO EIS portal on 5 January 2020. The number of events identified and assessed for each of the States Parties in the Americas is presented in the Annex. For 44 of the 74 events (59%), national authorities (including through the NFPs on 29 occasions) were the initial source of information. Verification was requested and obtained for all but one of the 19 events identified through media sources.

6. Of the 73 events for which the final designation status is known or could be verified, 52 (71%) events, affecting 23 States Parties and three territories in the Region, were of substantiated international public health concern, representing 21% of such events determined globally. A large majority of these 52 events were attributed to infectious hazards (37 events, or 71%). The etiologies most frequently recorded for these 37 events were dengue fever (8 events), malaria (5 events), and yellow fever (4 events), all arthropod-borne diseases. The remaining 15 events of substantiated international public health concern were associated with product-related hazards (9 events), the human-animal interface (2 events), disasters (1 event), and food safety (1 event); for two events the etiology remained undetermined. Over the period considered, of the 52 new events published globally on the WHO EIS portal, 7 (13%) concerned States Parties in the Americas.

7. Besides the COVID-19-related PHEIC,<sup>2</sup> on 23 June 2020, following the twenty-fifth meeting of the IHR Emergency Committee, the Director-General of WHO determined that the spread of wild poliovirus and circulating vaccine-derived poliovirus continues to constitute a PHEIC.<sup>3</sup> On 26 June 2020, following the eighth meeting of the IHR Emergency Committee, the Director-General of WHO determined that the Ebola virus disease outbreak in the Democratic Republic of the Congo no longer constitutes a PHEIC.<sup>4</sup> Additional information about acute public health events of significance or with implications for the Region of the Americas is published and updated on the PAHO website.<sup>5</sup>

### ***Core Capacities of States Parties***

8. In May 2018, the WHO Secretariat offered to States Parties a revised tool (6) to facilitate the submission of their IHR Annual Report to the World Health Assembly, as mandated by Article 54 of the Regulations, Resolution WHA61.2 (7), and Decision WHA71(15) (8). Like its predecessor, the revised tool exclusively focuses on States Parties' core capacities. While its use remains entirely voluntary, it has been widely utilized by States Parties worldwide, as reflected by the information submitted to the World Health Assembly in 2019 and 2020, also publicly available through the WHO e-SPAR portal.<sup>6</sup>

9. In 2020, 29 (83%) of the 35 States Parties in the Region of the Americas submitted their IHR Annual Report to the 73rd World Health Assembly. Antigua and Barbuda, Barbados, Belize, Bolivia, Grenada, and Haiti did not comply with this obligation. Possibly due to the demands imposed on national authorities by the COVID-19 pandemic, the submission rate observed in 2020 in the Region is the second lowest since 2011, when the management of IHR Annual Report data was systematized by the WHO Secretariat. Since 2011, 10 States Parties have consistently submitted their IHR Annual Reports to the World Health Assembly each year: Canada, Colombia, Costa Rica, Dominica, Ecuador, Guyana, Honduras, Jamaica, Mexico, and the United States of America. Information on the degree of compliance with this commitment on the part of the remaining States Parties is presented in the Annex.

10. All 29 States Parties that submitted their IHR Annual Report to the 73rd World Health Assembly compiled the report through a multidisciplinary and multisectoral effort, including face-to-face or virtual meetings in 26 States Parties (90%).

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<sup>2</sup> Information about the IHR Emergency Committee for the COVID-19 pandemic can be accessed on the WHO website at: [https://www.who.int/ihr/procedures/ihr\\_committees/en/](https://www.who.int/ihr/procedures/ihr_committees/en/).

<sup>3</sup> Information about the IHR Emergency Committee for ongoing events and context involving the transmission and international spread of poliovirus is available on the WHO website at: [https://www.who.int/ihr/ihr\\_ec\\_2014/en/](https://www.who.int/ihr/ihr_ec_2014/en/).

<sup>4</sup> Information about the IHR Emergency Committee for the 2018 Ebola virus disease outbreak is available on the WHO website at: [https://www.who.int/ihr/procedures/ihr\\_committees/en/](https://www.who.int/ihr/procedures/ihr_committees/en/).

<sup>5</sup> See Epidemiological Alerts and Updates, available at: <https://www.paho.org/en/epidemiological-alerts-and-updates>.

<sup>6</sup> The WHO Electronic State Parties Self-Assessment Annual Reporting Tool (e-SPAR) is a web-based platform available at: <https://extranet.who.int/e-spar>.

11. For all 13 core capacities, the average regional scores are close to or above 60%, with the lowest average score (59%) for radiation emergencies and the highest average score (79%) for laboratory. For all 13 core capacities, the average regional scores for the Americas are above the global averages.

12. Nevertheless, the status of the core capacities across subregions remains heterogeneous. As presented in the Annex, the highest average subregional scores for all 13 core capacities are consistently observed for North America, while the lowest average scores are registered in the Caribbean subregion for six core capacities (legislation and financing, zoonotic events and the human-animal interface, surveillance, human resources, chemical events, and radiation emergencies); in Central America for two core capacities (IHR coordination and NFP functions, and food safety); and in South America for five core capacities (laboratory, National Health Emergency Framework, health service provision, risk communication, and points of entry).

13. Historical data and trends concerning the status of core capacities from 2011 to 2018 are publicly available on the WHO Global Health Observatory web page.<sup>7</sup> Because of the introduction of the revised tool, however, comparison over time of most current data—at regional, subregional, and national levels, including States Parties’ abilities to maintain core capacities—is limited to 2019 and 2020, and to the 28 States Parties that submitted their IHR Annual Report in both those years in a format allowing for analysis.<sup>8</sup> The Annex presents scores on core capacities for each State Party based on reports submitted to the 73rd World Health Assembly in 2020.

14. Comparing the average regional scores of 2020 with those of 2019, for 11 of the 13 core capacities, variations are in the range of 5 percentage points. Increases in average regional scores above 5 percentage points are observed for food safety (+6%) and National Health Emergency Framework (+7%). When the individual States Parties’ scores of 2020 are compared with those of 2019, 22 (79%) of the 28 States Parties show the ability to maintain or improve their scores for at least 10 of the 13 core capacities.<sup>9</sup> While all 28 States Parties indicate the ability to maintain or make progress in food safety, the lowest degrees of ability are reported for the following core capacities: National Health Emergency Framework, health service provision, chemical events, and radiation emergencies (21 States Parties), followed by zoonotic events and the human-animal interface (20 States Parties).

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<sup>7</sup> The WHO Global Health Observatory web page is available on the WHO website at: <http://apps.who.int/gho/data/node.main.IHR00ALLN?lang=en>.

<sup>8</sup> States Parties that could not be included in the analysis are Antigua and Barbuda, Barbados, Belize, Bolivia, Grenada, Guyana, and Haiti.

<sup>9</sup> States Parties that, for any given core capacity and for the two years considered, have reported the lowest possible score according to the tool were not considered as having the ability to maintain that core capacity.

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15. The Program Budget of the Pan American Health Organization 2020-2021, adopted through Resolution CD57.R5 (9, 10), includes, under Outcome 23 and its Output 23.2,<sup>10</sup> indicator 23.2.a: “Number of countries with national action plans developed for strengthening International Health Regulations (2005) core capacities.” It should be emphasized that, as indicated in Document CSP29/INF/6 (2017) (11), the wide variation across States Parties with respect to both the maturity of their health systems and the status of their application and implementation of the IHR makes it necessary to overcome the one-size-fits-all concept of a “dedicated national IHR plan.” Similar concerns were expressed by the Independent Oversight and Advisory Committee (IOAC) for the WHO Health Emergencies Programme (12) in its report presented to the 146th Session of the WHO Executive Board in 2020 (13). Therefore, the status of indicator 23.2.a is appraised by extrapolating information provided by States Parties in their IHR Annual Reports under the legislation and financing core capacity.

16. Of the 29 States Parties that submitted their IHR Annual Reports to the 73rd World Health Assembly, 11 (38%) indicated that budgets are distributed in a timely manner and executed in a coordinated fashion. Also, 18 (62%) of the 29 States Parties indicated that an emergency public financing mechanism that allows structured reception and rapid distribution of funds for responding to public health emergencies is in place across relevant sectors.

17. The IHR Monitoring and Evaluation Framework (IHR-MEF) (14) includes one mandatory component, namely the State Party Annual Report, and three voluntary ones: After-Action Review of Public Health Events, Simulation Exercises, and Voluntary External Evaluations. The voluntary components are embedded in the PAHO Program Budget 2020-2021 (9). In December 2019, PASB formally communicated to States Parties in the Caribbean subregion that, to streamline and make truly complementary the components of the IHR-MEF, Voluntary External Evaluations would be conducted based on the State Party Annual Report. This approach is fully aligned with the subsequent recommendation of the IOAC, which called on the WHO Secretariat to adopt a more streamlined process for IHR monitoring and evaluation purposes (15).

18. During the period covered by this report, in the context of the IHR-MEF and of the Biennial Work Plans 2020-2021 jointly developed by the PAHO/WHO Representative Offices and national authorities, PASB has supported Argentina and the Dominican Republic in hosting Voluntary External Evaluations based on the Joint External Evaluation (JEE) tool (16). Toward this end, PASB worked in close collaboration with the International Atomic Energy Agency (IAEA) and the World Organization for Animal Health (OIE). States Parties that have hosted Voluntary External Evaluations are listed in the Annex.

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<sup>10</sup> Outcome 23: “Health emergencies preparedness and risk reduction: Strengthened country capacity for all-hazards health emergency and disaster risk management for a disaster-resilient health sector.” Output 23.2: “Countries and territories enabled to strengthen capacities for emergency preparedness.”

19. According to the States Parties Annual Reports submitted to the 73rd World Health Assembly, 10 of 29 States Parties (34%) have tested, reviewed, and updated at least one of the instruments that constitute their National Health Emergency Framework. Over the period covered by this account, PASB, across its different levels, has supported national authorities in conducting Simulation Exercises, as well as After-Action Reviews of Public Health Events in the Bahamas, Brazil, and Peru. Additionally, PASB organized the Caribbean Sub-regional Workshop on After-Action Reviews and Simulation Exercises, Port of Spain, Trinidad and Tobago, 19-21 November 2019, with the participation of professionals from 13 States Parties and eight territories. Activities related to After-Action Reviews were carried out thanks to financial support provided by the government of the Netherlands.

20. Over the period from 1 July 2018 to 23 October 2019, to support efforts by national authorities to advance in the continuous process of enhancing public health preparedness, PASB conducted regional, subregional, multicountry, and country missions and workshops. These focused on, among other topics: *a)* the early warning function of the surveillance system; *b)* NFP functions (including an IHR NFPs Regional Meeting held in Brasilia, Brazil, 21-23 October 2019); *c)* laboratory diagnostics and public health laboratories; *d)* infection prevention and control; *e)* rapid response teams; and *f)* all-hazard response functions.<sup>11</sup> Several capacity-building activities were carried out with financial support provided to PASB by the governments of Brazil and the United States of America.

21. The collaboration between PASB and IAEA is continuing within the framework of several large-scale projects focusing on the Caribbean subregion. As of 30 June 2020, Saint Kitts and Nevis and Suriname remain the only two States Parties in the Americas that have not sought IAEA membership.<sup>12</sup> Similarly, PASB is continuing its collaboration with the National Institute for Public Health and the Environment of the Netherlands and with Public Health England to address the needs of the Dutch and British overseas territories, respectively. In March 2020, the Universidad del Desarrollo in Santiago, Chile, was designated as WHO Collaborating Centre for the International Health Regulations (WHO CC CHI-23).<sup>13</sup>

### ***Administrative Requirements and Governance***

22. During the period of this report, 492 ports in 28 States Parties in the Region of the Americas, including one landlocked State Party (Paraguay), were authorized to issue the Ship Sanitation Certificate.<sup>14</sup> Nine additional ports were authorized in six overseas territories of France, the Netherlands, and the United Kingdom.

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<sup>11</sup> Document CD58/6, COVID-19 Pandemic in the Region of the Americas, presents an exhaustive description of capacity-building activities supported by PASB in the context of the pandemic.

<sup>12</sup> The list of IAEA Member States is available on the IAEA website at: <https://www.iaea.org/about/governance/list-of-member-states>.

<sup>13</sup> Additional information on the WHO CC CHI-23 is available on the WHO website at: <https://apps.who.int/whooc/Detail.aspx?zHwhM62gLkY0g4NkxEmhsg==>.

<sup>14</sup> The list of ports authorized to issue the Ship Sanitation Certificate is available on the WHO website at: [https://www.who.int/ihr/ports\\_airports/portslanding/en/](https://www.who.int/ihr/ports_airports/portslanding/en/).

23. As of 30 June 2020, the IHR Roster of Experts included 417 professionals, 94 of whom are from the Region of the Americas. They include experts designated by 10 of the 35 States Parties in the Region: Argentina, Barbados, Brazil, Canada, Cuba, Mexico, Nicaragua, Paraguay, Peru, and the United States of America.

24. In 2020, 18 (51%) of the 35 States Parties in the Region responded to the global survey for updating the WHO publication, *International Travel and Health*, concerning *inter alia* requirements for proof of vaccination against yellow fever as a condition for granting entry and/or exit to international travelers. At the time of this writing, such requirements have not yet been published on the WHO website. In the context of the COVID-19 pandemic, it is worth noting that, pursuant to Articles 35 and 36 and Annexes 6 and 7 of the Regulations, no health documents other than the International Certificate of Vaccination or Prophylaxis, with proof of vaccination against yellow fever, can be required by States Parties as conditions for granting travelers entry and/or exit.

### **Actions Necessary to Improve the Situation**

25. Although the current COVID-19 pandemic, which originated in the People's Republic of China and is caused by SARS-CoV-2 virus, is unprecedented in its dynamics and in the magnitude of its multidimensional impact, in its very initial stages it mirrored the 2002-2003 Severe Acute Respiratory Syndrome (SARS) outbreak, which originated in the same country and was caused by SARS-CoV virus. It was that earlier outbreak that triggered the intergovernmental process leading, in 2005, to the adoption of the current IHR by the World Health Assembly. The COVID-19 pandemic embodies the acute public health event with international implications for which the world has been preparing, or attempting to prepare, over the past two decades. It appears to test the application of virtually all provisions of the Regulations, which were conceived and developed for the collective management of occurrences of this very nature.

26. Article 54 of the IHR states, "The Health Assembly shall periodically review the functioning of these Regulations. To that end it may request the advice of the Review Committee, through the Director-General." The 73rd World Health Assembly in 2020, through Resolution WHA73.1 (4), has requested the Director-General of WHO to evaluate and review, *inter alia*, "the functioning of the International Health Regulations (2005) and the status of implementation of the relevant recommendations of previous IHR Review Committees." Pursuant to this Resolution, on 9 July 2020, WHO announced the formation of the Independent Panel for Pandemic Preparedness and Response (IPPR), whose mandate is to evaluate the world's response to the COVID-19 pandemic.<sup>15</sup> The resolution proposed in Document CD58/6, COVID-19 Pandemic in the Region of the Americas (3), is in alignment with and complements this request.

27. To better contextualize the points of reflection offered in this section, the following four paragraphs provide a historical overview, with relevant references, of the analyses and

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<sup>15</sup> The news release is available on the WHO website at: <https://www.who.int/news-room/detail/09-07-2020-independent-evaluation-of-global-covid-19-response-announced>.

reviews of the application, implementation, and compliance with the Regulations conducted to date.

28. In 2011, in its report to the 64th World Health Assembly (17), the recommendations of which were endorsed through Resolution WHA64.1 (18), the IHR Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 concluded that “the world is ill-prepared for a severe pandemic or for any similarly global, sustained and threatening public health emergency.”

29. In 2015, in its report to the 136th Session of the WHO Executive Board (19) and the 68th World Health Assembly (20), the recommendations of which were endorsed through Resolution WHA68.5 (21), the IHR Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation concluded that, although considerable progress had been made in implementation of the IHR, States Parties worldwide still faced significant challenges. In its conclusions, the Review Committee emphasized that *a)* the work to develop, strengthen, and maintain the core capacities under the IHR should be viewed as a continuing process for all countries, and *b)* the implementation of the IHR should advance beyond “implementation checklists” to a more action-oriented approach. The Committee also stressed that “core capacities [...] are essential public health functions.”

30. In 2016, in its report to the 69th World Health Assembly (22), the IHR Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response emphasized that “the global response to Ebola, the failures of which mirrored those documented during the 2009 response to the influenza A (H1N1) pandemic, highlighted flaws in the operational mechanisms and strategic framework of the International Health Regulations (2005) (IHR), which function to improve global solidarity to protect public health.” The Review Committee further stated that “consideration must now be given to ensuring realistic and practical ways forward to further strengthening its implementation.” While the recommendations formulated by the Review Committee were not adopted by the World Health Assembly, the Committee’s overarching conclusions remain highly relevant:

- a) “The failures in the Ebola response did not result from failings of the IHR themselves, but rather from a lack of implementation of the IHR [...] [The IHR] provide the backbone to any future response to a public health threat [and] amendments to the IHR text are not required.”
- b) “The IHR must be, and be seen to be, equitable across countries [...].”
- c) “Implementation of the IHR should not be seen as an end point in a process, but rather as a cycle of continuous improvement in public health preparedness, in which the development and maintenance of IHR core capacities are embedded in essential health systems strengthening.”



- d) “Full implementation of the IHR [...] cannot be achieved in a very short timeframe because of the systemic improvement required [...]. It is imperative to [...] roll-out an overarching global strategic improvement plan [...]. [This plan] must deliver significant improvements [...] within the first three years, but [...] it may take 10 years to deliver the health systems strengthening that is needed.”

31. Together with the approach to monitoring the application and implementation of the Regulations and compliance with them, the strategic plan mentioned above in *d*) has been the object of repeated regional consultations across the six WHO regions (11, 23-25). It has also been the focus of intense debates during sessions of the PAHO and WHO Governing Bodies from 2015 to 2018 (21, 26-29). In 2018, through Decision WHA71(15), the 71st World Health Assembly decided that “the five-year global strategic plan [...] does not create any legally binding obligations for Member States” (8, 30).

32. As highlighted in its Interim Report on WHO’s Response to COVID-19: January-April 2020 (15), the IOAC has called for an independent assessment of the performance of both Member States and the WHO Secretariat in responding to the COVID-19 pandemic. The IOAC has also offered recommendations for tackling salient and recurrent themes that have emerged from past reviews of IHR application, implementation, and compliance— issues that, to date, have been either dismissed or unsatisfactorily addressed by both States Parties and the WHO Secretariat, including through the WHO Governing Bodies.

33. The COVID-19 pandemic has put to test virtually all of the IHR provisions. At the same time, at the level of States Parties, the pandemic has also shined a spotlight on aspects of the national response—especially at critical junctions of its evolution to date—that had not been highly visible before. These issues need to be carefully factored into any review of the application and implementation of, and compliance with, the IHR. They include:

- a) Leadership of the national response at the highest possible institutional level;
- b) Rapid and complex decision making in a context of acute and dynamic uncertainties, in particular with respect to the adoption of community-wide social distancing measures, and in the absence of any guidance from either PASB or the WHO Secretariat;
- c) Sustained activation of whole-of-government and whole-of-society response actions and interventions, which, over time, have often magnified geopolitical as well as internal political tensions;
- d) Rapid mobilization and negotiation of national financial and human resources;
- e) Response coordination mechanisms overcoming, in terms of their breadth, scope, and—paradoxically—simplicity, any model anticipated in existing, documented arrangements for national preparedness and response;

- f) Reactive, adaptive, and innovative actions, conducted over an extremely short period of time, with the potential to drive and shape a sustainable transformation of the national health system as a whole—from public health practice to the reorganization of health services, increased independence of the supply chain, and use of technology for health.

34. Although in a minority of States Parties in the Region, some of these phenomena have led the national response along undesirable paths, overall the current situation offers the opportunity to boost States Parties' confidence in steering the application, implementation, and compliance with the IHR. Most importantly, it may lead to sustained investments in health to break, once and for all, the panic-and-then-neglect cycle that has characterized the aftermath of acute public health events over the past 15 years.

35. The following paragraphs elaborate on issues that have repeatedly been pinpointed as undermining the relevance of the IHR as a tool for global governance and propose strategies for addressing these issues. However, the proposed actions can only be effective if they are *a*) collegially enabled by States Parties and by the WHO Secretariat through the WHO Governing Bodies, and *b*) undertaken through the transparent facilitation and leadership of the WHO Secretariat as custodian of the Regulations. Some of the issues are related to the level of awareness and in-depth knowledge of the text of the Regulations among States Parties and the WHO Secretariat (e.g., composition of the IHR Emergency Committees, drafting of temporary recommendations related to a PHEIC). It would be imperative for the IHR Review Committee related to the COVID-19 pandemic—which, in addition to the IPPR, is expected to be convened by the WHO Secretariat pursuant to Resolution WHA73.1 (4)—to systematically, holistically, and unambiguously address the below issues, considering both the historical perspective and the ongoing response to the COVID-19 pandemic.

36. ***Information sharing by States Parties with the WHO Secretariat during acute public health events:*** As highlighted in reports to PAHO Governing Bodies over the past few years, a high volume and intensity of exchanges has been observed in the Region of the Americas during acute events. This has been maintained by most of the States Parties throughout the COVID-19 pandemic. However, during the pandemic, some States Parties in the Region have dramatically restricted and reduced the information they share in terms of both its timeliness and comprehensiveness. Therefore, items aimed at rectifying this behavior, pursuant to relevant IHR provisions, have been included in the proposed resolution that is embedded in Document CD58/6, COVID-19 Pandemic in the Region of the Americas (3). Confidentiality of line listing shared by Small Island Developing States emerged again as an issue requiring clarifications in the context of the application of and compliance with IHR provisions. The suggestion by States Parties in the Americas to establish an internet-based interactive platform for reporting to the WHO Secretariat pursuant to IHR provisions should be given consideration (25). Such a platform is already used for international reporting by States Parties to the IAEA, through the Unified System

for Information Exchange in Incidents and Emergencies (USIE) portal,<sup>16</sup> and OIE, through the World Animal Health Information System (WAHIS) portal.<sup>17</sup>

37. ***Information sharing by the WHO Secretariat with States Parties during acute public health events:*** Over the past few years, the volume of information published by the WHO Secretariat on the WHO EIS portal has been increasing; its content has become slightly more elaborate in terms of risk assessment; and references to relevant WHO technical documentation are more systematically presented. The COVID-19 pandemic was characterized by very early postings on both the secure WHO EIS portal and the WHO public-facing website (5 January 2020) about the unfolding event in the People’s Republic of China.<sup>18, 19</sup> Subsequently, daily situation reports were published on the WHO public website.<sup>20</sup>

38. ***Temporary recommendations concomitantly issued with the determination of a PHEIC:*** Article 1 of the IHR defines “temporary recommendations” as “non-binding advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic.” Article 17 establishes the criteria that should underpin the formulation of those recommendations. Pursuant to Articles 12 and 15 of the IHR, temporary recommendations shall be issued by the Director-General of WHO when he/she determines that an acute public health event constitutes a PHEIC. Such recommendations may be modified or extended, as appropriate, throughout the event’s duration, with the cessation of their validity set out in Article 15. The Regulations have historically been portrayed as a “legally binding” text; however, Article 1 defines temporary recommendations as “non-binding advice.” The WHO Secretariat should provide clarification as to whether the contradiction is merely apparent (e.g., other IHR provisions override Article 1, or the text of the IHR as a whole is not legally binding) or is real. In the latter case, the resolution of the paradox through the appropriate tools is warranted. Reinforcing concerns highlighted by States Parties in the Americas in 2017 (25), the determination of the PHEIC in relation to the COVID-19 pandemic has shown, once again, the need for better transparency, for semantic clarity (e.g., use of the word “pandemic”; inconsistent wording over time), and for technical clarity (e.g., use of the word

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<sup>16</sup> Information about the USIE portal is available on the IAEA website at:

<https://iec.iaea.org/usie/actual/LandingPage.aspx>.

<sup>17</sup> Information about the WAHIS portal is available on the OIE website at:

<https://www.oie.int/en/animal-health-in-the-world/wahis-portal-animal-health-data/>.

<sup>18</sup> “Pneumonia of Unknown Cause – China,” WHO Disease Outbreak News, 5 January 2020. Available at:

<https://www.who.int/csr/don/05-january-2020-pneumonia-of-unknown-cause-china/en/>.

<sup>19</sup> “Novel Coronavirus – China,” WHO Disease Outbreak News, 12 January 2020. Available at:

<https://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/>.

<sup>20</sup> WHO coronavirus disease (COVID-19) situation reports are available at:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

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“containment”) in the formulation of temporary recommendations.<sup>21, 22, 23</sup> In alignment with the suggestions of States Parties in the Region (25) to rectify the above, as well as to avoid the introduction of an “intermediate level of alert” (referred to in para. 40 below), it would be sufficient to present each set of temporary recommendations in a standard format that includes:

- a) Overall strategy proposed by the WHO Secretariat to respond to the PHEIC that has been determined;
- b) For each of the criteria for determining a PHEIC, detailed in Article 12 of the IHR, specifications about how the WHO Director-General found the criterion to have been met;
- c) Assignment of all States Parties to different categories according to their level of risk, which would determine the specific subsets of recommended actions/interventions deemed adequate to trigger actions and raise a level of alertness or awareness commensurate with the risk attributed to each category;
- d) Each recommendation explicitly labeled as “issued,” “modified,” “extended,” or “terminated”;
- e) Recommendations explicitly linked to those enumerated under Article 18 of the Regulations;
- f) Each recommendation explicitly linked to IHR articles relevant to its implementation;
- g) Evidence supporting the formulation of each recommendation;
- h) Global supply chain challenges for the implementation of each recommendation, if applicable;
- i) Reference to relevant existing WHO recommendations;
- j) Reference to technical documents by the WHO Secretariat relevant to the implementation of each recommendation;

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<sup>21</sup> WHO statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 30 January 2020. Available at: [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

<sup>22</sup> WHO statement on the third meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), 1 May 2020. Available at: [https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19)).

<sup>23</sup> WHO statement on the fourth meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), 1 August 2020. Available at: [https://www.who.int/news-room/detail/01-08-2020-statement-on-the-fourth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/detail/01-08-2020-statement-on-the-fourth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19)).

- k) Specification, for each PHEIC and by subset of States Parties, of what would be regarded as an “additional health measure” pursuant to Article 43 the IHR;
- l) Mechanisms in place for monitoring States Parties’ compliance with the recommendations issued.

39. Considering the evolution over time of the content of the temporary recommendations issued in response to the COVID-19 pandemic, particularly those related to international traffic, clarifications are needed about the application of both the “precautionary principle” (31) and the “no regrets policy” (32) in the formulation of temporary recommendations.

40. **“Intermediate level of alert”:** A debate surrounding the introduction of an “intermediate level of alert,” as part of the acute public health event management cycle underpinned by the IHR, has been ongoing in the international public health arena since 2016 (22). This debate has intensified in the context of the COVID-19 pandemic. As was asserted by States Parties in the Americas in 2016, such a change is not warranted because *a)* the definition of PHEIC presented in Article 1 already allows for the possibility that an event may acquire broader international public health implications in the future; *b)* any decision-making process, including a potential one related to the determination of an “intermediate level of alert,” is intrinsically and ultimately binary, and it is not exempt from the application of the “precautionary principle” (31) and, in the case of the WHO Secretariat, of its “no regrets policy” (32); and *c)* the WHO Secretariat, through the WHO EIS platform, the formulation of temporary recommendations, and the WHO corporate risk communication mechanisms, already has the tools to improve both the predictability and the effectiveness of its communications regarding the potential international public health implications associated with events being reiteratively assessed.

41. **Procedures related to the IHR Emergency Committees:** States Parties in the Americas have expressed concerns about a lack of transparency in the operations of the IHR Emergency Committees (25). In particular, they have urged the WHO Secretariat to consistently include experts designated by a given State Party in the Roster of Experts, pursuant to Article 47, as members of the IHR Emergency Committee that is considering an acute public health event in that State Party.

42. **Strategic and Technical Advisory Group for Infectious Hazards (STAG-IH):** Invoking the recommendations formulated by the IHR Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response (22), in late 2018 the WHO Director-General established the STAG-IH<sup>24</sup>. In 2016 and 2017, States Parties in the Americas expressed concerns about the creation of such an additional body and warned of the risk of duplicating the functions of the IHR Emergency Committee and IHR Review Committees (24, 25). Those concerns turned out to be justified. Notwithstanding its terms of reference published on the WHO website, the STAG-IH has

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<sup>24</sup> The WHO web page on the STAG-IH is available at:  
<https://www.who.int/emergencies/diseases/strategic-and-technical-advisory-group-for-infectious-hazards/en/>.

formulated recommendations to States Parties in the context of two PHEIC: the Ebola virus disease outbreak in the Democratic Republic of the Congo, and the COVID-19 pandemic.<sup>25</sup> Furthermore, in a recent article in the *Weekly Epidemiological Record*, the STAG-IH advised the WHO Secretariat on the functioning of the IHR, even though IHR provisions confer this responsibility on the IHR Review Committee. (33).

43. ***National IHR Focal Points (NFP)***: Article 4 of the IHR delimits, the functions of the NFP exclusively concern communication. However, the WHO Secretariat has historically invested the NFP with functions beyond those mandated by Article 4, encompassing risk assessment related to acute public health events; decision making about outbreak response and health emergencies; intersectoral coordination; oversight and coordination of the implementation of the IHR as whole; and responsibility to comply with IHR-related reporting requirements to the World Health Assembly. As extensively documented by PASB in communications to the PAHO Governing Bodies over the past four years, such an approach has generated, at national level, institutional tensions, unwarranted institutional changes, and, ultimately, a biased sense of ownership and understanding of the Regulations, as well as their selective application. The role of the NFP during the COVID-19 pandemic—during which coordination of the national response has been handled at the highest possible institutional level, with a whole-of-government activation—has highlighted this issue. As recognized by States Parties in the Americas in 2016 and 2017 (24, 25), the institutional positioning of the NFP should be the object of a thorough review in order to *a*) strike the necessary balance between institutional connectivity, technical expertise, access to the decision-making level, and operational continuity, and *b*) ensure that NFP functions are carried out in the context of the activation of national emergency management mechanisms.

44. ***Additional health measures***: The scope and purpose of the IHR, as set out in Article 2, are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.” Therefore, by definition, public health measures, including those related to international traffic, in response to unfolding acute public health events should be dynamically adopted and adjusted as a result of a continuous and reiterative risk assessment process. During such process, the desirable level of evidence and/or information for decision making might not be available, and, hence, resorting to the precautionary principle becomes unavoidable. While some progress in the application of Article 43: Additional Health Measures, by both States Parties and the WHO Secretariat, has been observed over the past two years (e.g., inclusion of a section on additional health measures in the reports on IHR implementation presented to the World Health Assembly), this critical IHR provision remains controversial, poorly understood, and weakly complied with. At national level, as stressed by States Parties in the Americas in 2016 and 2017 (24, 25), these problems stem from conflicting political and technical/scientific perspectives, with public risk perception and pressure often leading to the adoption of measures that override scientific evidence. At the same time, the WHO Secretariat, while formulating temporary

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<sup>25</sup> Ibid.

recommendations in particular, has had difficulties in considering the full range of international traffic-related measures detailed in Article 18 and in issuing temporary recommendations commensurate with the risk of international spread. The COVID-19 pandemic has made this patent, together with the polarization of the positions of States Parties and the WHO Secretariat. In fact, only the sets of temporary recommendations issued on 1 May 2020<sup>26</sup> and 1 August 2020<sup>27</sup> contain an implicit recognition that the adoption of international traffic restrictions by States Parties is justified. Comprehensively tackling the future application, implementation, and compliance with Article 43 by the States Parties represents a major collective endeavor that will need to address matters related to legal interpretation and procedure, as well as Article 56: Settlement of Disputes.

45. **Essential public health functions:** Article 3 provides that “States have [...] the sovereign right to legislate and to implement legislation in pursuance of their health policies.” The recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation (20, 21) further state that “core capacities [...] are essential public health functions.” Nonetheless, the core capacities, which are detailed in Articles 5, 13, and 19-21 and Annex 1 of the Regulations, continue to be semantically and programmatically separated from the national health system as a whole. The effect of this is to hinder processes of national health system strengthening and transformation. In 2016 and 2017, States Parties in the Americas provided extensive and detailed suggestions intended to overcome the perception of the IHR as a separate discipline and thus erase the dichotomy between core capacities and essential public health functions (24, 25). The COVID-19 pandemic, which at national level has consistently triggered the activation of the health system in its totality, along with intersectoral interfaces, has revealed the artificial nature of that dichotomy.

46. **IHR monitoring and evaluation:** As extensively reported to PAHO Governing Bodies since 2011, the approach by the WHO Secretariat to the application, implementation, and compliance with Article 54: Reporting and Review, has been controversial. States Parties in the Americas have repeatedly expressed their technical and procedural concerns and have also formulated several related proposals (23-26, 28) that emphasize the following: *a)* the responsibility to demonstrate accountability should not fall exclusively on States Parties, but should be extended to the WHO Secretariat; *b)* IHR-related monitoring and evaluation should encompass all IHR provisions and should not be limited to those regarding core capacities; *c)* the inconsistencies, technical and with respect to IHR provisions, of the components and related metrics of the current IHR-MEF should

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<sup>26</sup> WHO statement on the third meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), 1 May 2020. Available at: [https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19)).

<sup>27</sup> WHO statement on the fourth meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), 1 August 2020. Available at: [https://www.who.int/news-room/detail/01-08-2020-statement-on-the-fourth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/detail/01-08-2020-statement-on-the-fourth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19)).

be addressed (14); d) States Parties should be the primary beneficiaries of the voluntary components of the current IHR-MEF, as opposed to the WHO Secretariat or stakeholders; e) there is an imperative need for the WHO Secretariat to guarantee that the approach to monitoring and evaluation of the Regulations is addressed by the World Health Assembly, as mandated by Article 54, and represents the result of formal and consultative iterations involving States Parties. The COVID-19 pandemic has demonstrated the largely foreseeable limitations of the current components of the IHR-MEF and their related metrics. This warrants an absolutely transparent and thorough reconsideration of the accountability mechanisms among parties with a view to making the IHR a relevant tool for global governance.

### **Action by the Directing Council**

47. The Directing Council is invited to take note of this report and provide any comments it deems pertinent

Annex

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## Annex

**Summary Table 1: States Parties Annual Reports to the 73rd World Health Assembly, Voluntary Components of the IHR Monitoring and Evaluation Framework, and Public Health Events of Potential International Concern<sup>1</sup>**  
(core capacities scores in percentages)

State Party	Mandatory State Party Annual Report														Voluntary External Evaluation (year conducted)	Number of acute public health events of potential international concern assessed (1 July 2019-30 June 2020) <sup>2</sup>
	Number of Annual Reports submitted from 2011 to 2020 (10-year period)	Legislation and financing	IHR coordination and National IHR Focal Point	Zoonotic events and the human-animal interface	Food safety	Laboratory	Surveillance	Human resources	National Health Emergency Framework	Health service provision	Risk communication	Points of entry	Chemical events	Radiation emergencies		
Antigua and Barbuda	9	-	-	-	-	-	-	-	-	-	-	-	-	-		1
Argentina	9	67	70	80	80	67	80	60	27	53	40	50	60	60	Yes (2019)	3
Bahamas	8	67	80	80	80	80	80	60	73	40	60	40	40	20		2
Barbados	8	-	-	-	-	-	-	-	-	-	-	-	-	-		0
Belize	6	-	-	-	-	-	-	-	-	-	-	-	-	-	Yes (2016)	0
Bolivia (Plurinational State of)	8	-	-	-	-	-	-	-	-	-	-	-	-	-		3
Brazil	9	100	100	100	80	100	100	100	73	40	80	60	100	100		7
Canada	10	93	100	100	100	100	100	100	100	100	100	100	100	100	Yes (2018)	1
Chile	9	80	80	80	100	80	80	60	73	67	60	70	80	80		4

<sup>1</sup> Acute public health events of potential international concern assessed in the overseas territories in the Americas of France, the Netherlands, and the United Kingdom are not reflected in Table 1.

<sup>2</sup> Events related to the COVID-19 pandemic, including Multisystem Inflammatory Syndrome in Children, are not reflected in Table 1.

State Party	Mandatory State Party Annual Report														Voluntary External Evaluation (year conducted)	Number of acute public health events of potential international concern assessed (1 July 2019-30 June 2020) <sup>2</sup>
	Number of Annual Reports submitted from 2011 to 2020 (10-year period)	Legislation and financing	IHR coordination and National IHR Focal Point	Zoonotic events and the human-animal interface	Food safety	Laboratory	Surveillance	Human resources	National Health Emergency Framework	Health service provision	Risk communication	Points of entry	Chemical events	Radiation emergencies		
Colombia	10	80	70	80	80	67	60	60	67	67	40	100	60	60		3
Costa Rica	10	93	90	80	80	93	70	80	67	73	80	60	80	60		1
Cuba	9	53	20	60	100	100	80	80	100	100	100	100	60	60		3
Dominica	10	80	90	80	100	73	60	60	80	67	80	90	20	40		1
Dominican Republic	9	47	60	40	40	53	70	40	67	27	100	50	40	80	Yes (2019)	2
Ecuador	10	87	90	80	80	80	80	80	87	60	60	80	80	60		7
El Salvador	9	100	100	100	80	100	100	100	100	100	40	100	40	100		3
Grenada	5	-	-	-	-	-	-	-	-	-	-	-	-	-	Yes (2018)	1
Guatemala	9	67	40	40	40	80	70	60	73	33	40	60	40	40		2
Guyana	10	100	100	100	100	100	100	80	67	73	100	100	100	20		1
Haiti	7	-	-	-	-	-	-	-	-	-	-	-	-	-	Yes (2016, 2019)	2
Honduras	10	73	50	80	40	67	70	60	67	40	60	50	40	80		1
Jamaica	10	87	100	80	80	87	80	60	80	73	100	100	80	80		0
Mexico	10	80	100	60	80	80	100	80	87	87	80	80	80	80		11
Nicaragua	9	100	30	60	80	87	80	80	93	73	80	90	60	100		1
Panama	9	73	80	80	80	87	90	80	80	73	60	60	80	60		0
Paraguay	8	47	100	60	80	53	80	80	47	40	80	60	80	40		2

State Party	Mandatory State Party Annual Report														Voluntary External Evaluation (year conducted)	Number of acute public health events of potential international concern assessed (1 July 2019-30 June 2020) <sup>2</sup>
	Number of Annual Reports submitted from 2011 to 2020 (10-year period)	Legislation and financing	IHR coordination and National IHR Focal Point	Zoonotic events and the human-animal interface	Food safety	Laboratory	Surveillance	Human resources	National Health Emergency Framework	Health service provision	Risk communication	Points of entry	Chemical events	Radiation emergencies		
Peru	8	67	50	80	60	47	90	40	67	40	40	0	40	0	Yes (2015)	4
Saint Kitts and Nevis	8	33	80	60	80	67	60	40	47	60	40	40	40	20		0
Saint Lucia	8	60	90	80	80	87	70	80	80	60	60	90	40	20		1
Saint Vincent and the Grenadines	8	33	70	60	80	47	60	60	67	40	40	20	20	40		0
Suriname	9	80	70	60	80	73	20	80	53	53	80	30	40	20		1
Trinidad and Tobago	9	40	80	20	40	80	40	40	60	73	60	80	60	20		0
United States of America	10	100	100	80	100	100	100	60	100	100	100	100	80	80	Yes (2016)	5 <sup>3</sup>
Uruguay	6	93	90	80	80	87	90	80	93	73	100	80	60	80		0
Venezuela (Bolivarian Republic of)	9	73	90	60	80	67	90	80	53	60	20	100	40	100		7

<sup>3</sup> The figure includes acute public health events of potential international concern assessed in Puerto Rico.



**Summary Table 2: States Parties Annual Reports to the 73rd World Health Assembly:  
Regional and Subregional Averages  
(core capacities scores in percentages)**

Subregion	Legislation and financing	IHR coordination and National IHR Focal Point functions	Zoonotic events and the human-animal interface	Food safety	Laboratory	Surveillance	Human resources	National Health Emergency Framework	Health service provision	Risk communication	Points of entry	Chemical events	Radiation emergencies
<b>Caribbean* (n = 10)</b>	63	78	68	82	79	65	64	71	64	72	69	50	34
<b>Central America** (n = 7)</b>	79	64	69	63	81	79	71	78	60	66	67	54	74
<b>South America*** (n = 9)</b>	77	82	78	80	72	83	71	65	56	58	67	67	64
<b>North America**** (n = 3)</b>	91	100	80	93	93	100	80	96	96	93	93	87	87
<b>Region of the Americas (n = 29)</b>	74	78	72	78	79	78	70	73	64	68	70	60	59

\* 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, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela.

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

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