World Health Organization

SECOND MEETING OF THE WORKING GROUP ON AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005)
Provisional agenda item 6

A/WGIHR/2/7
6 February 2023

Article-by-Article compilation of proposed amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022)

The Working Group on Amendments to the International Health Regulations (WGIHR) at its first meeting on 14–15 November 2022 decided that "the Secretariat shall also publish online an article-by-article compilation of the proposed amendments, as authorized by the submitting Member States, in the six official languages, without attribution of the proposals to the Member States proposing them.".[1]

In furtherance of the WGIHR's decision above, this document provides an article-by-article compilation of the proposals for amendments to the International Health Regulations (IHR) (2005) submitted in accordance with decision WHA75(9) (2022).

Proposed amendments are presented as follows:

- ~~Strikethrough~~ = proposal to delete existing text
- **Underlined and bold** = proposal to add text
- (…): existing text in the IHR (2005) in relation to which no proposals for amendments were submitted and which is therefore omitted from the compilation

The compilation is not intended to replace the proposed amendments to the IHR (2005) in the original submission.

[1] Document A/WGIHR/1/5.

ARTICLE BY ARTICLE COMPILATION OF PROPOSED AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005) SUBMITTED BY STATES PARTIES IN THE CONTEXT OF DECISION WHA75(9)[1]

Legend

~~Strikethrough~~ = delete existing text

Underlined and bold = new text proposed

(…) = existing text in the IHR for which proposals for amendments were not submitted and thus omitted form this compilation

Article 1 Definitions

1. For the purposes of the International Health Regulations (hereinafter "the IHR" or "Regulations"):

(…)

"health products" include therapeutics, vaccines, medical devices, personal protective equipment, diagnostics, assistive products, cell- and gene-based therapies, and their components, materials, or parts."

"health products" include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies, but not limited to this course

"health technologies and know-how" includes organized set or combination of knowledge, skills, health products, procedures, databases and systems developed to solve a health problem and improve quality of life, including those relating to development or manufacture of health products or their combination, its application or usage. "Health technologies" are interchangeably used as "health care technologies".

(…)

"standing recommendation" means ~~non-binding~~ advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;

"temporary recommendation" means ~~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

[1] This compilation is published following the agreements at the first meeting of the Working Group on amendments to the International Health Regulations (2005), as per document A/WGIHR/1/5.

international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;

Article 2 Scope and purpose

The purpose and scope of these Regulations are to prevent, protect against, **prepare,** control and provide a public health response to the international spread of disease**s including through health systems readiness and resilience** in ways that are commensurate with and restricted to ~~public health risk~~ **all risks with a potential to impact public health**, and which avoid unnecessary interference with international traffic ~~and~~ trade, **livelihoods, human rights, and equitable access to health products and health care technologies and know how**.

Article 3 Principles

1. The implementation of these Regulations shall be ~~with full respect for the dignity, human rights and fundamental freedoms of persons~~ **based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development**.

(…)

2 bis. The States Parties shall develop and maintain capacities to implement the Regulations in accordance with their Common But Differentiate Responsibilities and Respective Capabilities (CBDR-RC), availability of international financial assistance and shared technological resources, and in this regard, primary preference shall be given to the establishment of functioning public health systems resilient to public health emergencies.

3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease. **When implementing these Regulations, Parties and WHO should exercise precaution, in particular when dealing with unknown pathogens.**

(…)

New 5. The State Parties shall implement theseRegulations on the basis of equity, solidarity as wellas and in accordance with their common but differentiated responsibilities and respective level of development of the State Parties.

New 6: Exchange of information between State Parties or between State Parties and WHO pursuant to the implementation of these Regulations shall be exclusively for peaceful purposes.

Article 4 Responsible authorities

1. Each State Party shall designate or establish a**n entity with the role of** National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations. **WHO shall provide technical assistance and collaborate with States Parties in capacity building of the National IHR focal points and authorities upon request of the States Parties.**

1bis. In addition, each State Party should inform WHO about the establishment of its National Competent Authority responsible for overall implementation of the IHR that will be recognized and held accountable for the NFP's functionality and the delivery of other IHR obligations.

NEW (1bis) States Parties shall / ALT **may enact or adapt legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and function of then entity with a role of National IHR Focal Point in implementing the obligations under these Regulations.**

(…)

4. States Parties shall provide WHO with contact details of their National IHR Focal Point and **National IHR Competent Authority** and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article."

Article 5 Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. **Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of the Article 44. This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism , in replacement of the Joint External Evaluation that began in 2016 . Such review shall** / ALT **Should such review identify resource constraints and other challenges in attaining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities.**

2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances, and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall ~~make the decision~~ **refer the issue to World Health Assembly which will then take a decision on the same**, taking into account the technical advice of the Committee established under Article 50 (hereinafter the "Review Committee"). After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

3. **Developed State Parties and** WHO shall assist **any** States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.

4. WHO shall collect information regarding events through its surveillance activities and assess **on the basis of risk assessment criteria regularly updated and agreed with State Parties** their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate **not with an outside party but member states**

4. (New wording) –WHO shall collect information regarding events through its surveillance activities and assess, through periodically updated assessment and risk criteria agreed with Member States, their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate";

New para 5: WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of known or unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate.

New 5. WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate. The risk assessment shall indicate, based on the best available knowledge, the level of risk of potential spread and risks of potential serious public health impacts, based on assessed infectiousness and severity of the illness.

New para 5. "Strengthen the central role of national health authorities in management and coordination with political, intersectoral, interministerial and multilevel authorities for timely and coordinated surveillance and response in accordance with the international health risk indicated by the IHR, thereby consolidating the central role of national health authorities in multilevel management and coordination."

Article 6 Notification

1. Each State Party, **within 48h after the Focal Point receives information about the event shall assess events occurring within its territory** by using the decision instrument in Annex 2, **within 48 hours of the National IHR Focal Point receiving the relevant information** . Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), **the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant UN entities,** WHO shall immediately notify the ~~IAEA,~~ **relevant national and UN entities**.

2. Following a notification, a State Party shall continue to communicate to WHO **by the most efficient means of communication available** timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including **genetic sequence data** , case definitions, laboratory results, **epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent, genome sequencing data if available**, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease ~~and~~ the health measures ~~employed~~ **implemented and other related information as per request of WHO** , **genome sequence data** ; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern**, with regards to the sharing of genetic sequence data it will depend on Member States' capacity and prevailing national legislation. With the aim of fostering event related research and assessment, the WHO**

shall make the information received available to all Parties in accordance with modalities to be adopted by the Health Assembly.

3. For better clarity, the provisions of Article 45 shall apply to notifications made pursuant to this Article.

New 3. No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing.

New 3: Upon receiving notification from a State Party, WHO shall not transfer the public health information received pursuant to paragraph 1 of this provision, and other information as defined in paragraph 2 of this provision to establishments, personals, non-state actors or any recipient whatsoever engaging directly or indirectly with conflict and violence elements. WHO shall also handle the information in a manner designed to avoid such actors accessing the information, directly or indirectly.

Article 7 Information-sharing during unexpected or unusual public health events

(…)

2. Following a notification pursuant to Article 6 of an event caused by an infectious agent, a State Party shall make available to WHO the microbial and genetic material and samples related to the notified event, as appropriate, not later than (…) hours after such material and samples become available. Note: The proposal for Article 7 is offered without prejudice to further discussion and reflection on where to allocate this issue between the IHR and the pandemic agreement).

Article 8 Consultation

In the case of events occurring within its territory not requiring notification as provided in Article 6, ~~in particular those events for which there is insufficient information available to complete the decision instrument~~, a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. **However, where available information is insufficient to complete the decision instrument in Annex 2, a State Party shall keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures within 72 hours of the National IHR Focal Point receiving the relevant information**. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.

Article 9: Other Reports

1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. ~~Before~~

~~taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end,~~ WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.

(…)

3. (New wording) In the recommendations made to the States Parties regarding the collection, processing and dissemination of health information, WHO could advise the following:

(a) To follow the WHO guidelines on criteria and analogous modes of processing and treating health information

Article 10 Verification

1. **Within 24 hours of receiving the information,** WHO shall request, ~~in accordance with Article 9~~ **as soon as possible or within a specific time** verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.

2. Pursuant to the foregoing paragraph ~~and to Article 9~~ , each State Party, when requested by WHO, shall verify and provide:

(a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;

(b) within 24 hours, available public health information on the status of events referred to in WHO's request; and

(c) information to WHO in the context of an assessment under Article 6, including relevant information as described **in paragraphs 1 and 2 of** that Article.

3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall**, as soon as possible or within a specific time** offer **within 24 hours** to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

3bis. Within 24 hours of receiving a WHO offer of collaboration, the State Party may request additional information supporting the offer. WHO shall provide such information within 24 hours. When 48 hours have elapsed since the initial WHO offer of collaboration, failure by the State Party to accept the offer of collaboration shall constitute rejection for the purposes of sharing available information with States Parties under Paragraph 4 of this section.

4. If the State Party does not accept the offer of collaboration **within 48 hours**, WHO ~~may~~ **shall**, when justified by the magnitude of the public health risk, **immediately** share with other States Parties

the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO~~, taking into account the views of the State Party concerned.~~

Article 11 ~~Provision of information by WHO~~ ***~~Exchange of information~~***

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant **UN and** ~~intergovernmental~~ **international and regional** organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive **or which is available in the public domain,** / ALT **or which is otherwise available and whose validity is appropriately assessed by WHO** and which is necessary to enable States Parties to respond to a public health risk. WHO ~~should~~ **shall** communicate information to other States Parties that might help them in preventing the occurrence of similar incidents. **For this purpose, WHO shall facilitate the exchange of information between States Parties and ensure that the Event Information Site For National IHR Focal Points offers a secure and reliable platform for information exchange among the WHO and States Parties and allows for interoperability with relevant data information systems.**

2. WHO shall use information received under Articles 6, ~~and~~ 8 and ~~paragraph 2 of Article~~ 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall ~~not~~ make this information generally available to other States Parties, ~~until such time as~~ **when**:

(a) the event is determined to constitute a public health emergency of international concern, **a public health emergency of regional concern, or warrants an intermediate public health alert**, in accordance with Article 12; or

(b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or

(c) there is evidence that:

(i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or

(ii) the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or

(d) the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures.

(e) WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments.

3. WHO shall ~~consult with~~ **inform** the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

New 3 bis: State Parties receiving information fromWHO pursuant to this provision shall not use it for conflict and violence purposes. State Parties shall also handle theinformation in a manner designed to avoid establishments, personals, non-state actors or any recipient whatsoeverengaging

directly or indirectly with conflict and violence elements, from accessing such information,directly or indirectly.

4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO ~~may also~~ **shall** make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.

New 5. WHO shall annually report to the Health Assembly on all activities under this Article, including instances of sharing information that has not been verified by a State Party on whose territory an event that may constitute a public health emergency of international concern is or is allegedly occurring with States Parties through alert systems.

New para 5 – The Director-General shall report to the World Health Assembly on all activities under this article as part of their report pursuant to Article 54, including instances of information that has not been verified by a State Party in accordance with article 10.

Article 12 Determination of a public health emergency of international concern ***public health emergency of regional concern, or intermediate health alert***

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.

2. If the Director-General considers, based on an assessment under these Regulations, that a **potential or actual** public health emergency of international concern is occurring, the Director-General shall **notify all States Parties and seek to** consult with the State Party in whose territory the event arises regarding this preliminary determination **and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee")**. If the Director-General **determines that the event constitutes a public health emergency of international concern,** ~~and the State Party are in agreement regarding this determination~~, the Director-General shall **notify all the States Parties**, in accordance with the procedure set forth in Article 49, seek the views of ~~the Committee established under Article 48 (hereinafter the~~ "Emergency Committee") on appropriate temporary recommendations.

~~3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.~~

4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:

(a) information provided by the State Party**, by other States Parties, available in the public domain, or otherwise available under Articles 5–10**;

(b) the decision instrument contained in Annex 2;

(c) the advice of the Emergency Committee;

(d) scientific principles as well as the available scientific evidence and other relevant information; and

(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

4bis. The PHEIC declaration is not designed to mobilise funds in the case of an emergency event. The Director-General should use other mechanisms for this purpose.

5. If the Director-General, following consultations with the **Emergency Committee and relevant States Parties** ~~the State Party within whose territory the public health emergency of international concern has occurred~~, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49. **If there is still a need for recommendations, he should consider convening the Review Committee to advise on issuing standing recommendations in accordance with Articles 16 and 53.**

New para 6: Where an event has not been determined to meet the criteria for a public health emergency of international concern, but the Director-General has determined it requires heightened international awareness and a potential international public health response, the Director-General, on the basis of information received, may determine at any time to issue an intermediate public health alert to States Parties and may consult the Emergency Committee in a manner consistent with the procedure set out in Article 49.

New para 6: Where an event has not been determined to meet the criteria for a public health emergency of international concern, but the Director-General has determined it requires heightened international awareness and preparedness activity, the Director-General, on the basis of information received, may determine at any time to issue a World Alert and Response Notice to States Parties and may seek advice from the Emergency Committee in a manner consistent with the procedure set out in Article 49.

NEW (6) The Director-General, if the event is not designated as a public health emergency of international concern, based on the opinion/advice of the Emergency Committee, may designate the event as having the potential to develop into a public health emergency of international concern, communicate this and the recommended measures to States parties in accordance with procedures set out in Article 49.

New para 6. The Director-General may determine that an event constitutes a regional public health emergency of international concern or an intermediate public health emergency of international concern and provide guidance to the Parties as appropriate. Such determination shall be in accordance with the process set out in this Article for the determination of a public health emergency of international concern.

New 6. Immediately after the determination of PHEIC, the activities of WHO in relation to such PHEIC shall be in accordance with the provisions of these Regulations. The Director General shall report all the activities carried out by WHO, including references to the corresponding provisions of these Regulations pursuant to Article 54.

New 7. A Regional Director may determine that an event constitutes a public health emergency of regional concern and provide related guidance to States Parties in the region either before or

after notification of an event that may constitute a public health emergency of international concern is made to the Director-General, who shall inform all States Parties.

New 6. Immediately after the determination of PHEIC, the activities of the WHO in relation to such PHEIC, including through partnerships or collaborations, shall be in accordance with the provisions of these Regulations. The Director General shall report all the activities carried out by WHO, including references to the corresponding provisions of these Regulations in pursuance to Article 54.

New 7. In case of any engagement with non-State actors in WHO's public health response to PHEIC situation, WHO shall follow the provisions of Framework for Engagement of Non-State Actors (FENSA). Any departure from FENSA provisions shall be consistent with paragraph 73 of FENSA.

New 7. A Regional Director may determine that an event constitutes a public health emergency of regional concern or issue an intermediate health alert and implement related measures to provide advice and support for capacity-building to States Parties in the region either before or after notification of the event. If the event meets the criteria for a public health emergency of international concern after the notification of the event that constitutes a public health emergency of regional concern, the Director-General shall inform all States Parties.

Article 13 Public health response

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities. **Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of the Article 44.**

2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall ~~make the decision~~ **refer the issue to World Health Assembly which will then take a decision on the same**, taking into account the technical advice of the Review Committee. After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

2bis. WHO shall provide to State Parties standardized forms for collaboration in the implementation of collaboration as provided in paragraph 1(a) of the Article 44 to facilitate State Parties' mutual collaboration essential for the effective implementation of public health response.[1]

[1] In revised submission received on 28 October 2022, the submitting State Party proposes the following edits to 2bis: **2bis. WHO shall provide to States Parties standardized forms for facilitating the implementation of collaboration as provided in paragraph 1(a) of Article 44 to facilitate States Parties' mutual collaboration, which is essential for the effective implementation of public health response.**

3. ~~At the request of a State Party~~, WHO shall ~~collaborate~~ **articulate clearly defined assistance to a State Party offer assistance to a State Party** in the response to public health risks and other events by providing technical guidance**, health products, technologies, know-how, deployment of civil medical personals,** and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary**, and if required cooperate with said Member State in seeking support and international financial assistance to facilitate the containment of the risk at source. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which the WHO shall share with other States Parties. WHO will also share any request for assistance by the affected State party that could not be met by WHO.**

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it ~~may~~ **shall** offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.**

5. When requested by WHO, States Parties ~~should~~ **shall** provide, to the extent possible, support to WHO-coordinated response activities**, including supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics, and vaccines, for effective response to PHEIC occurring in another State Party's jurisdiction and/or territory, capacity building for the incident management systems as well as for rapid response teams. Any State Party unable to fulfil such requests shall inform the reasons for the same to WHO and the Director General shall include the same in the report submitted to WHA under Article 54 of these Regulations. , including supply of health products and technologies especially diagnostics and other devices, therapeutics, and vaccines for effective response to PHEIC.**

(…)

New 7. Measures taken by States Parties shall not create barriers to or compromise the abilities of the other States Parties to effectively respond to public health emergency of international concern, unless exceptional circumstance warrant such measures. States Parties whose abilities to respond are affected by the measures taken by other State party shall have the right to enter into consultation with the State Party implementing such measures to find a solution at the earliest considering the country interest.

New 7. In case of any engagement with non-State actors in WHO's public health response to PHEIC situation, WHO shall follow the provisions of Framework for Engagement of Non-State Actors (FENSA). Any departure fromFENSA provisions shall be consistent with paragraph 73 of FENSA.

NEW Article 13A WHO Led International Public Health Response

1. States Parties recognize WHO as the guidance and coordinating authority of international public health response during public health Emergency of International Concern and undertake to follow WHO's recommendations in their international public health response.

2. WHO shall carry out an assessment of the availability and affordability of the heath products such as diagnostics, therapeutics, vaccines, personal and protective equipment and other tools required for responding to public health emergencies of international concern, including the potential increase in supply resulting form the surge and diversification of production and in cases of expected shortage of supply, WHO shall develop and allocation plan for health products so as to ensure equitable access to people of all States Parties.

3. WHO shall, in its allocation plan for health products, inter alia identify and prioritize the recipients of health products, including health workers, frontline workers and vulnerable populations, and determine the required quantity of health care products for effective distribution to the recipients across States Parties.

4. Upon request of WHO, States Parties with the production capacities shall undertake measures to scale up production of health products, including through diversification of production, technology transfer and capacity building especially in the developing countries.

5. Upon request of WHO, States Parties shall ensure the manufacturers within their territory supply the requested quantity of the health products to WHO or other States Parties as directed by WHO in a timely manner in order to ensure effective implementation of the allocation plan.

6. WHO shall develop and maintain a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required for responding to the potential public health emergencies of international concern. Within two years of the entry into force of this provision, WHO shall develop this database for all PHEICs declared so far, including for the diseases identified in the IHR 1969.

7. In accordance with the provisions of these Regulations and in particular Article 13A (1), shall collaborate with other international organizations, and other stakeholders consistent with the provisions of FENSA, for responding to public health emergency of international concern. WHO shall report all its engagement with other stakeholders to the Health Assembly. The Director-general shall provide documents and information relating to such engagements upon request of States Parties.

New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response

1. Immediately after the determination of a public health emergency of international concern under Article 12, the Director General shall make an immediate assessment of availability and affordability of required health products and make recommendations, including an allocation mechanism, to avoid any potential shortages of health products and technologies pursuant to Article 15 or 16 as appropriate.

2. States Parties shall co-operate with each other and WHO to comply with such recommendations pursuant to paragraph 1 and shall take measures to ensure timely availability and affordability of required health products such as diagnostics, therapeutics, vaccines, and other medical devices required for the effective response to a public health emergency of international concern.

3. States Parties shall provide, in their intellectual property laws and related laws and regulations, exemptions and limitations to the exclusive rights of intellectual property holders to facilitate the manufacture, export and import of the required health products, including their materials and components.

4. States Parties shall use or assign to potential manufacturers, especially from developing countries, on a non-exclusive basis, the rights over health product(s) or technology(ies), when the same is/are obtained in the course of research wholly or partially funded by public sources, and is/are identified as required health product(s) or technology(ies) to respond to a PHEIC, with a view to ensure equitable, timely availability and affordability through diversification of production.

5. Upon request of a State Party, other States Parties or WHO shall rapidly cooperate and share relevant regulatory dossiers submitted by manufacturers concerning safety and efficacy, and manufacturing and quality control processes, within 30 days. The dossiers received by a requesting State Party shall be solely used by their regulatory authorities and manufacturers designated by the requesting State Party for the purposes of accelerating the manufacture and supply of product(s) or technology(ies) as well as expediting their regulatory approval. Requesting State Party shall take measures to prevent designated manufacturer(s) from disclosing such information to a third-party(ies) except for the purposes of producing and supplying any materials or components to the manufacturer(s) under a contract with non-disclosure provisions.

6. WHO shall take measures to ensure availability and accessibility through the local production of required health products including:

(a) develop and publish a list of required health products,

(b) develop and publish specifications for the production of required health products,

(c) develop appropriate regulatory guidelines for the rapid approval of health products of quality including development of immunogenicity co-relative protection (ICP) for vaccines,

(d) establish a database of raw materials and their potential suppliers,

(e) establish a repository for cell-lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines,

(f) review and regularly update WHO Listed Authorities so as to facilitate appropriate regulatory approvals,

(g) any other measures required for the purposes of this provision.

7. The States Parties shall take measures to ensure that the activities of non-state actors, especially the manufacturers and those claiming associated intellectual property rights, do not conflict with the right to the highest attainable standard of health and these Regulations and are in compliance with measures taken by the WHO and the States Parties under this provision, which includes:

(a) to comply with WHO recommended measures including allocation mechanism made pursuant to paragraph 1.

(b) to donate a certain percentage of their production at the request of WHO.

(c) to publish the pricing policy transparently.

(d) to share the technologies, know-how for the diversification of production.

(e) to deposit cell-lines or share other details required by WHO repositories or database established pursuant to paragraph 5.

(f) to submit regulatory dossiers concerning safety and efficacy, and manufacturing and quality control processes, when called for by the States Parties or WHO.

Article 15 Temporary recommendations

1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, **or the event has a potential to become PHEIC,** the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.

2. **Temporary recommendations should be as evidence-based, concise and operational as possible, and refer to existing guidance and international technical standards, when appropriate**. Temporary recommendations may include **the deployment of expert teams, as well as** health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic **and recommendations on the access and availability of health products, technologies, and know-how, including an allocation mechanism for their fair andequitable access**.

(…)

New Para 2 bis: Temporary recommendations should be evidence based as per real time risk assessment of a potential or declared PHEIC, and the immediate critical gaps to be addressed for an optimal public health response, that shall be fair and equitable. The recommendations based on these assessments shall include:

(a) support by way of epidemic intelligence surveillance, laboratory support, rapid deployment of expert teams, medical countermeasures, finance as well as other requisite

health measures to be implemented by the State Party experiencing the Public Health Emergency of International Concern, or

(b) prohibitive recommendations to avoid unnecessary interference with international traffic and trade.

(…)

Article 16 Standing recommendations

WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic **and recommendations on the access and availability of health products, technologies, and know how, including an allocation mechanism for their fair and equitable access**. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

Article 17 Criteria for recommendations

When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:

(a) the views of the States Parties directly concerned;

(b) the advice of the Emergency Committee or the Review Committee, as the case may be;

(c) scientific principles as well as available scientific evidence and information;

(d) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;

(e) relevant international standards and instruments;

New para (e1): Equitable access to and distribution of medical countermeasures i.e. vaccines, therapeutics and diagnostics for optimal public health response.

(f) activities undertaken by other relevant intergovernmental organizations and international bodies; and

(g) other appropriate and specific information relevant to the event.

With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations imposed by urgent circumstances.

Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels

1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:

- no specific health measures are advised;
- review travel history in affected areas;
- review proof of medical examination and any laboratory analysis;
- require medical examinations;
- review proof of vaccination or other prophylaxis;
- require vaccination or other prophylaxis;
- place suspect persons under public health observation;
- implement quarantine or other health measures for suspect persons;
- implement isolation and treatment where necessary of affected persons;
- implement tracing of contacts of suspect or affected persons;
- refuse entry of suspect and affected persons;
- refuse entry of unaffected persons to affected areas; and
- implement exit screening and/or restrictions on persons from affected areas.

2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:

- no specific health measures are advised;
- review manifest and routing;
- implement inspections;
- review proof of measures taken on departure or in transit to eliminate infection or contamination;
- implement treatment of the baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;
- the use of specific health measures to ensure the safe handling and transport of human remains;
- implement isolation or quarantine;

- seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful; and

- refuse departure or entry.

- **ensure mechanisms to develop and apply a traveller's health declaration in international public health emergency of international concern (PHEIC) to provide better information about travel itinerary, possible symptoms that could be manifested or any prevention measures that have been complied with such as facilitation of contact tracing, if necessary**

New para 3: In developing recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate.

New 3. In Issuing such recommendation: The WHO should consult with other relevant international organization such as ICAO, IMO, WTO to avoid unnecessary interference with international travel and trade, such as the movement of essential health care workers and medical products and supplies.

New 4. In implementing such recommendation: State Parties shall take into consideration their obligations under relevant international law when facilitating essential health care workers movement, ensuring protection of supply chains of essential medical products in PHEIC, and repatriating of travellers.

NEW (3) Where States parties impose trave and/or goods and cargo restrictions, WHO may recommend that these measures not apply to movement of health personnel travelling to the State Party)ies) for a public health response and to the transport of medical immunobiological products needed for a public health response.

New 3. In developing temporary recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate. Additionally, temporary recommendations should allow for the appropriate exemption of essential health care workers and essential medical products and supplies from travel and trade restrictions.

New 4: In implementing health measures pursuant to these Regulations, including Article 43, States Parties shall make reasonable efforts, taking into account relevant international law, to ensure that:

(a) contingency plans are in place to ensure that health care worker movement and supply chains are facilitated in a public health emergency of international concern;

(b) travel restrictions do not unduly prevent the movement of health care workers necessary for public health responses;

(c) trade restrictions make provision to protect supply chains for the manufacture and transport of essential medical products and supplies; and

(d) the repatriation of travelers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases.

Article 19 General obligations

Each State Party shall, in addition to the other obligations provided for under these Regulations:

(a) ensure that the capacities set forth in Annex 1 for designated points of entry are developed within the timeframe provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;

(b) identify the competent authorities at each designated point of entry in its territory; and

(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.

New (d): The development of "bi-national" contingency plans with minimum content for the inclusion in plans of action where two countries share a border, for public health emergencies of international concern (PHEIC).

Article 23 Health measures on arrival and departure

1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, **whether in paper based or digital format,** on arrival or departure:

(a) with regard to travellers:

(i) information concerning the traveller's destination so that the traveller may be contacted;

(ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations **including documents containing information for a lab test in digital or physical format including documents containing information on a laboratory test for a pathogen and/or information on vaccination against a disease, including those provided at the request of the State Party in digital /electronic form**; and/or

(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;

(b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.

(…)

New 6. Documents containing information concerning traveller's destination (hereinafter Passenger Locator Forms, PLFs) should preferably be produced in digital form, with paper form as a residual option. Such information should not duplicate the information the traveller already

submitted in relation to the same journey, provided the competence authority can have access to it for the purpose of contact tracing. The Health Assembly may adopt, in cooperation with the International Civil Aviation Organization (ICAO) and other relevant organisations, the requirements that documents in digital or paper form shall fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in such documents. Documents meeting such requirements shall be recognized and accepted by all Parties. Specifications and requirements for PLFs in digital or paper form shall take into account existing widely used systems established at the regional or international level for the issuance and verification of documents. Parties which are low and lower middle-income countries shall receive assistance in accordance with Article 44 for the implementation of this provision.

Article 24 Conveyance operators

1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:

(a) comply with the health measures recommended by WHO and adopted by the State Party;

(b) inform travellers of the health measures recommended by WHO and adopted by the State Party for application on board; and

(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.

(d) implement quarantine promptly on board as necessary.

(…)

Article 27 Affected conveyances

1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:

(a) disinfect, decontaminate, disinsect or derat the conveyance, as appropriate, or cause these measures to be carried out under its supervision; and

(b) decide in each case the technique employed to secure an adequate level of control of the public health risk as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority determines that other methods are as safe and reliable.

The competent authority may implement additional health measures, including isolation of the conveyances, **and demand the conveyance operators, the pilot in command of the aircraft or the officer in command of the ship to take practicable measures on the conveyances** as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.

Article 28 Ships and aircraft at points of entry

(…)

2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused *free* **or a controlled** *pratique* by States Parties for public health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of *free* **or a controlled** *pratique* to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.

(…)

4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control as early as possible before arrival at the port or airport of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board as soon as such illnesses or public health risks are made known to the officer or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority. **The competent authority for the port or airport which received information pursuant to this paragraph may notify the health measures applicable to a ship or an aircraft as necessary.**

Article 31 Health measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis **whether in paper based or digital format**:

(a) when necessary to determine whether a public health risk exists;

(b) as a condition of entry for any travellers seeking temporary or permanent residence;

(c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or

(d) which may be carried out pursuant to Article 23.

(…)

Article 35 General rule

No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they

meet the requirements set out in Article 23. **Digital health documents must incorporate means to verify their authenticity via retrieval from an official web site, such as a QR code.**

2. Health documents may be produced in digital or paper form, subject to the approval by the Health Assembly of the requirements that documents in digital form have to fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in the health documents. Health documents meeting the conditions approved by the Health Assembly shall be recognized and accepted by all Parties. Specifications and requirements for certificates in digital form shall take into account existing widely used systems established at the international level for the issuance and verification of digital certificates. Parties which are low and lower middle-income countries shall receive assistance in accordance with article 44 for the implementation of this provision.

Article 36 Certificates of vaccination or other prophylaxis

1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations, or to recommendations and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.

2. A traveller in possession of a certificate of vaccination or other prophylaxis issued in conformity with Annex 6 and, when applicable, Annex 7, shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.

3. Other types of proofs and certificates may be used by Parties to attest the holder's status as having a decreased risk of being the disease carrier, particularly where a vaccine or prophylaxis has not yet been made available for a disease in respect of which a public health emergency of international concern has been declared. Such proofs may include test certificates and recovery certificates. These certificates may be designed and approved by the Health Assembly according to the provisions set out for digital vaccination or prophylaxis certificates, and should be deemed as substitutes for, or be complementary to, the digital or paper certificates of vaccination or prophylaxis.

Article 42 Implementation of health measures

Health measures taken pursuant to these Regulations**, including the recommendations made under Article 15 and 16,** shall be initiated and completed without delay **by all State Parties**, and applied in a transparent**, equitable** and non-discriminatory manner. **State Parties shall also take measures to ensure Non-StateActors operating in their respective territories comply with such measures.**

Article 43 Additional health measures

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:

(a) achieve the same or greater level of health protection than WHO recommendations; or

(b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33, provided such measures are otherwise consistent with these Regulations.

Such measures **shall be based on regular risk assessments, provide a proportionate response to the specific public health risks, be reviewed on a regular basis and** shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would ~~achieve~~ attain the ~~appropriate~~ **highest achievable** level of health protection.

2. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:

(a) scientific principles;

(b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies; and

(c) any available specific guidance or advice from WHO.

3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.

New 3 bis. A State Party implementing additional health measures referred to in paragraph 1 of this Article shall ensure such measures generally do not result in obstruction or cause impediment to the WHO's allocation mechanism or any other State Party's access to health products, technologies and knowhow, required to effectively respond to a public health emergency of international concern. States Parties adopting such exceptional measures shall provide reasons to WHO.

4. After assessing information **and public health rationale** provided pursuant to paragraph 3**, 3bis** and 5 of this Article and other relevant information **within two weeks**, WHO ~~may request that~~ **shall make recommendations to** the State Party concerned ~~reconsider~~ **to modify or rescind** the application of the **additional health** measures **in case of finding such measures as disproportionate or excessive. The Director General shall convene an Emergency Committee for the purposes of this paragraph.**

(…)

6. ~~A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article.~~ **Recommendations made pursuant to paragraph 4 of this Article shall be implemented by the State Party concerned within two weeks from the date of recommendation. State Party concerned may approach WHO, within 7 days from the date of recommendations made under paragraph 4 of this Article, to reconsider such recommendations. Emergency Committee shall dispose the request for reconsideration within 7 days and the decision made on**

the request for reconsideration shall be final. The State Party concerned shall report to the implementation committee established under Article 53A on the implementation of the decision.

7. Without prejudice to its rights under Article 56, any State Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution. **Parties taking measures pursuant to paragraphs 1 and 2 of this Article shall endeavour to ensure that such measures are compatible with measures taken by other Parties in order to avoid unnecessary interference with international traffic and trade while ensuring the highest achievable level of health protection. To this end, at the request of the Director-General or of any Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article, Parties so requested shall undertake consultations either bilaterally, multilaterally or at the regional level as the case may be. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measures and to find a mutually acceptable solution. The Director-General or WHO Regional Directors on his or her behalf shall:**

(a) facilitate those consultations and propose modalities for their conduct;

(b) review the evidence and information supplied by the Parties;

(c) provide his or her views on the necessity and proportionality of the measures in question and, as appropriate, make suggestions or proposals on a mutually acceptable solution;

(d) report to the Health Assembly on the conduct and outcome of consultations, with particular regard to general challenges and problems revealed by them.

(…)

Article 44 Collaboration and assistance

1. States Parties shall ~~undertake to~~ collaborate with **and assist** each other**, in particular developing counties States Parties, upon request,** ~~to the extent possible~~, in:

new (a) strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organizations;

(a) the detection and assessment of, and response to, events as provided under these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations **and in particular as provided in Annex 1**;

(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and **to establish an international financial mechanism for providing financial assistance to developing countries in the development, strengthening and maintenance of core capacities required under these Regulation sand functioning health systems resilient to the public health emergencies.**

(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;

(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.

(e) (new) collaborating with each other, with WHO, the medical and scientific community, laboratory and surveillance networks, to facilitate timely, safe, transparent and rapid exchange of specimens and generic sequence data for pathogens with the potential to cause pandemics and epidemics or other high-risk situations, given the relevant national and international laws, regulations, commitments and principles, including, as appropriate, the Convention on Biological Diversity, the Pandemic Influenza Preparedness Framework, and the importance of rapidly securing access to human pathogens for public health preparedness and taking response measures

(f) (new) strengthening cooperation and establishing mechanisms for upgrading coordinating and explaining in contiguous territories programs on health issues that are recognized of being common interest in terms of appropriate response to health risks and emergencies of international concern

(g) (new) developing recommendations and guidance on the use of the digital technologies to improve and modernize communication for preparedness and response to health emergencies, including to better meet the obligations of these Rules

(h) (new)in countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information

(i) (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.

(f) (new) facilitating the provision of equitable access to medical countermeasures

New (e) providing equitable access to health products such as diagnostics, therapeutics, vaccines, PPE equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general population of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans

2. WHO shall collaborate with **and promptly assist** States Parties, **in particular developing countries** upon request, ~~to the extent possible~~, in:

(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and

(c) (New) implementation of the timely, secure and transparent exchange of samples and genetic sequence data of pathogens capable of causing pandemics and epidemics or other

high-risk situations, taking into account relevant national and international legal provisions, rules, obligations and principles, including these Regulations, as appropriate, the Convention on Biological Diversity, and the importance of rapid access to information on human pathogens for public health preparedness and response;

(d) (New) application of digital technologies to improve and upgrading communications for health emergency preparedness and response, including through the development of an interoperability mechanism for secure global digital exchange of health information;

(e) (New) countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information;

(f)(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 **and Annex 6 through the financial mechanism established under Article 44A and to establish an international financial mechanism for providing financial assistance to developing countries State Parties for the said purpose**;

(g) (New) support to States Parties in enhancing reporting capabilities in accordance with the requirements of these Regulations, including the simplification and harmonization of reporting processes by States Parties;

(h) (New) facilitation of the development of national public health emergency response plans by developing, disseminating and updating policy documents and technical guidance, training materials, data and science to enable response;

(i) (New) strengthening the capacity of Focal Points, including through regular and targeted training events and workshops, consultations;

(j) (New) ensuring that differences in contexts and priorities among different States Parties, respect for their sovereignty, including health system strengthening, are taken into account when developing recommendations and supporting their implementation by WHO in order to improve pandemic preparedness and effective response for public health emergencies.

New (d) the formulation of laws and other legal and administrative provisions for the implementation of these Regulations;

New (e) training health and supportive workforce in the implementation of these Regulations;

New (f) the facilitation of accessibility and affordability of health products, including sharing of technologies and know-how, establishment and maintenance of the local production and distribution facilities.

New (d) in providing equitable access to health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general public of all countries in order, as well as in prioritizing access to such health

products for health workers of all countries in rolling out distribution plans and production capacity.

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies **and if undertaken shall be reported to Health Assembly through the report submitted under Article 54**.

New 4. WHO shall develop an evaluation matrix for assessing the contributions of States Parties to the international coordination of public health preparedness and response to health emergencies and shall make the results of such assessments publicly available within five years of entry into force of the provision, and thereafter every three years

New 4. The WHO, in collaboration with other international organizations as appropriate, shall provide assistance in the organization of the collaboration provided for in this Article, with particular regard to the needs of the Parties which are low or lower-middle income countries. The Parties and WHO shall report on the results obtained to the Health Assembly at least every two years.

New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response

1. A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to achieve the following purposes:

(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;

(ii) strengthening of Health Systems including its functioning capacities and resilience;

(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate.

(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised;

2. The WHA shall make arrangements to implement the above-mentioned provisions, within 24 months of the adoption of this provision, reviewing and taking into existing availability of funds and WHO arrangements for health emergency preparedness and response and whether they shall be maintained. Every four years thereafter, the WHA shall review the financial mechanism and take appropriate measures to improve the functioning of the mechanism. WHA shall also ensure that the financial mechanism functions under the guidance of and be accountable to States Parties, which shall decide on its policies, programme priorities and eligibility criteria.

Article 45 Treatment of personal data

(…)

2. Notwithstanding paragraph 1, States Parties may **disclose to only internal and relevant personnel** and process **and disclose** personal data where essential for the purposes of assessing and managing a public health risk. **In the case where disclosure of personal data is essential for such purposes, State Parties should obtain consent from the State Party which provided the information. When processing and/or disclosing personal data,** State Parties, in accordance with national law, and WHO must ensure that the personal data are:

(a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose;

(b) adequate, relevant and not excessive in relation to that purpose;

(c) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and

(d) not kept longer than necessary.

(…)

New Para 4: WHO receiving personal data, and States Parties receiving personal data from other States Parties, shall process the data in a manner such that the data is not duplicated or stored without the permission of the provider States Party.

Article 48 Terms of reference and composition

1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:

(a) whether an event constitutes a public health emergency of international concern, **based on Articles 1, 2 and 12.4."**;

(b) the termination of a public health emergency of international concern; and

(c) the proposed issuance, modification, extension or termination of temporary recommendations.

2. The Emergency Committee shall be composed of experts **free from the conflict of interests selected** by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization, **as well as Regional Directors from any impacted region**. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable **age, gender, and** geographical representation **and gender balance and require training in these Regulations before participation. The WHO, including through the WHO Academy, shall provide them with support as appropriate.** ~~At least one member~~ **Members** of the Emergency Committee should ~~be an~~ **include at**

least one expert nominated by ~~a~~ **the** State Party within whose territory the event arises**, as well as experts nominated by other affected States Parties. For the purposes of Articles 48 and 49, an "affected State Party" refers to a State Party either geographically proximate or otherwise impacted by the event in question**.

3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts **free from the conflict of interests** to advise the Committee.

Article 49 Procedure

(…)

2. The Director-General shall provide the Emergency Committee with ~~the~~ **a detailed** agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance**. The agenda should include a recurrent set of standard items for consideration of the Emergency Committee aimed at ensuring specificity, completeness and coherence of the advice provided.**

(…)

3 bis If the Emergency Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Emergency Committee's report.

3 ter The composition of the Emergency Committee and its complete reports shall be shared with Member States.

4. The Director-General shall invite **affected States Parties, including** the State Party in whose territory the event arises to present ~~its~~ **their** views to the Emergency Committee. To that effect, the Director-General shall notify ~~to it~~ **States Parties of** the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party **in whose territory the event arises** ~~concerned, however~~, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.

(…)

6. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public **including the reasons behind such recommendations.**

7. **Affected** States Parties ~~in whose territories the event has occurred~~ may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.

8. After the declaration of a public health emergency of international concern, the Emergency Committee should present its recommendations to relevant WHO bodies dealing with health emergency prevention, preparedness and response, such as the Standing Committee on Health Emergency Prevention, Preparedness and Response.

Article 53A - Establishment of an Implementation Committee

The State Parties shall establish an Implementation Committee, comprising of all States Parties meeting annually, that shall be responsible for:

(a) Considering information submitted to it by WHO and States Parties relating to their respective obligations under these Regulations, including under Article 54 and through the IHR monitoring and Evaluation framework;

(b) Monitoring, advising on, and/or facilitating provision of technical assistance, logistical support and mobilization of financial resources for matters relating to implementation of the regulations with a view to assisting States Parties to comply with obligations under these Regulations, with regards to

(1) development and maintenance of IHR core capacities;

(2) cooperation with WHO and State Parties in responding to outbreaks or events.

(c) Promote international cooperation and assistance to address concerns raised by WHO and States Parties regarding implementation of, and compliance with, obligations under these Regulations in accordance with Article 44;

(d) Submit an annual report to each Health Assembly

NEW Chapter IV (Article 53 bis-quater): The Compliance Committee

53 bis Terms of reference and composition

1. The State Parties shall establish a Compliance Committee that shall be responsible for:

(a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;

(b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;

(c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and

(d) Submitting an annual report to each Health Assembly describing:

(i) The work of the Compliance Committee during the reporting period;

(ii) The concerns regarding non-compliance during the reporting period; and

(iii) Any conclusions and recommendations of the Committee.

2. The Compliance Committee shall be authorized to:

(a) Request further information on matters under its consideration;

(b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;

(c) Consider any relevant information submitted to it;

(d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and

(e) Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.

3. The Members of the Compliance Committee shall be appointed by States Parties from each Region, comprising six government experts from each Region. The Compliance Committee shall be appointed for four-year terms and meet three times per year.

53 ter. Conduct of business

1. The Compliance Committee shall strive to make its recommendations on the basis of consensus.

2. The Compliance Committee may request the Director-General to invite representatives of the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions, where appropriate to address a specific issue under consideration. Such representatives, with the consent of the Chairperson, make statements on the subjects under discussion.

53 quater Reports

1. For each session, the Compliance Committee shall prepare a report setting forth the Committee's views and advice. This report shall be approved by the Compliance Committee before the end of the session. Its views and advice shall not commit WHO, States Parties, or other entities and shall be formulated as advice to the relevant State Party.

2. If the Compliance Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.

3. The Compliance Committee's report shall be submitted to all States Parties and to the Director-General, who shall submit reports and advice of the Compliance Committee, to the

Health Assembly or the Executive Board, as well as any relevant committees, for consideration, as appropriate.

Article 54 Reporting and review

1. States Parties and the Director-General shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly.

2. 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 first such review shall take place no later than five years after the entry into force of these Regulations.

3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.

New 4. Apart from providing information to the State Parties and reporting to the Health Assembly in this Article, WHO shall maintain a webpage/ dashboard to provide the details of the activitiescarried out under the various provisions of these Regulations including Articles 5(3), 12, 13(5), 14, 15, 16, 18, 43, 44, 46, and 49.

New Article 54 bis – Implementation[1]]

1. The Health Assembly shall be responsible to oversee and promote the effective implementation of these Regulations. For that purpose, Parties shall meet every two years, in a dedicated segment during the regular annual session of the Health Assembly.

2. The Health Assembly shall take the decisions and recommendations necessary to promote the effective implementation of these Regulations. To this effect, it shall:

(i) consider, at the request of any Party or the Director-General, any matter related to the effective implementation of these Regulations and adopt recommendations and decisions as appropriate on the strengthening of the implementation of these Regulations and improvement of compliance with their obligations;

(ii) consider the reports submitted by Parties and the Director-General pursuant to Article 54 and adopt any recommendation of a general nature concerning the improvement of compliance with these Regulations;

(iii) regularly assess the implementation of the Regulation by Parties and establish a strengthened review mechanism to that effect, with the aim of continuously improving the implementation of the Regulations by all Parties. In particular, the WHO and its Regional offices, upon request of a Party, which is a low or lower-middle income country, shall

[1] Note from the State Party submitting the proposal: The proposal for Article 54 bis is without prejudice to the discussions on the governance structure of the Pandemic Agreement. Such institutional elements would need to be considered in a complementary fashion.

provide or facilitate technical support and assist in the mobilization of resources aimed to implement the recommendations of such a review mechanism to that Party;

(iv) promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes, as well as policies, legislation and other measures by Parties;

(v) cooperate as appropriate with relevant WHO bodies, in particular those dealing with health emergency prevention, preparedness and response;

(vi) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as referred to in Article 14, as a means of strengthening the implementation of these Regulations;

(vii) oversee the implementation by the Secretariat of its functions under these Regulations, without prejudice to the authority of the Director-General under Articles 12, 15 to 17 and 47 to 53;

(viii) consider other action, as appropriate, for the achievement of the objective of the Regulations in the light of experience gained in its implementation.

3. A Special Committee on the IHR is hereby established, as an expert committee. The Special Committee shall have (…) members, appointed in a manner to ensure equitable regional representation and gender balance. The Special Committee shall assist the Health Assembly in discharging the functions set out in this Article and report to the Assembly.

4. The Special Committee shall meet at least (once a year/ twice a year/ every two years/…).

Article 56 Settlement of disputes

(…)

6. WHO must communicate all complaints by Member States regarding additional measures that have not been notified by any of them or recommended by the Organization;

7. Member States that apply the measures referred to in the preceding paragraph must inform WHO in a timely manner of the scientific justification for their establishment and maintenance and WHO must disseminate this information;

8. The World Health Assembly must have the opportunity to study the reports of the Review Committee on the relevance and duration of the measures and other data referred to in (a) and (b) included in this paragraph 6 and make recommendations regarding the relevance and continuity of the additional health measures.

ANNEX 1

A. CORE CAPACITY REQUIREMENTS FOR **DISEASE DETECTION,** SURVEILLANCE AND **HEALTH EMERGENCY** RESPONSE

1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations **to identify public health risks**, **in accordance with principle 2bis** including with regard to:

(a) their surveillance, reporting, notification, verification, response and collaboration activities; and

(b) their activities concerning designated airports, ports and ground crossings.

New 1 bis. Developed Countries States parties shall provide financial and technological assistance to the Developing Countries States Parties in order to ensure state-of-the-art facilities in developing countries States Parties, including through international financial mechanism as envisaged in Article 44.

(…)

3. States Parties and WHO shall support assessments, planning and implementation processes **in building, strengthening, developing and maintaining the core capacities requirements under this Annex in accordance with Article 44. The support of States Parties and WHO shall be in accordance with Annex 10.**

New 4. State (s) whose existing/ and or strengthened national structures and resources are not able to meet the core capacity requirements within time frame stipulated under para 2, shall be supported by WHO to fill gaps in critical capacities for surveillance, reporting, notification, verification, response.

4. At the local community level and/or primary public health response level.

The capacities:

(a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and

(b) to report all available essential information immediately to the appropriate level of healthcare response. At the community level, reporting shall be to local community healthcare institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, **microbial, epidemiological, clinical and genomic data,** sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed; and

(c) to implement preliminary control measures immediately.

(d) to ensure infrastructure, personnel, technologies and access to health-care products especially PPE, diagnostics and other devices, therapeutics, and vaccines and the necessary logistics for their distribution;

(e) to engage and promote people's participation such as promotion of awareness and cooperation with control and response measures, social and welfare assistance to affected persons etc;

(f) to provide prompt and quality health care to affected persons, with the available resources

(g) Implement prevention measures to reduce or contain the disease outbreaks with available resources.

5. At the intermediate public health response levels

The capacities:

(a) to confirm the status of reported events and to support or implement additional control measures; and

(b) to assess reported events immediately and, if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

(c) to detect and identify the responsible pathogen(s), investigate the cause, and assess the preliminary risk.

(d) to provide support to the local community level or primary health care response level, including

(i) laboratory support for detection, diagnosis and epidemiological investigation;

(ii) clinical guidance and treatment guidelines;

(iii) facilitation of field level public health interventions, if necessary.

(iv) assessment of the social and cultural context of populations at risk, gaps and rapid needs and schemes for enhancing capacities as mentioned in paragraph 4(e);

(v) information dissemination through socio-culturally appropriate messages and risk communication management;

(vi) supply of affordable health care products and technologies, including through effective management of emergency supply chains.

(e) to conduct research on cause and origin of disease, symptoms, transmission roots, progression of diseases, diagnosis methods, effective prevention and control of the risks etc.

(f) to coordinate, supervise and ensure the provision of prompt and quality health care to affected persons with available resource.

(g) to assist in self-sufficiency of emergency medical teams, provide logistics and field support to response teams including secure and comfortable accommodations, functional and secure working spaces and equipment, communications capabilities, safe staff transport and effective fleet management.

New 5. Building capacities of the state parties (community level/ intermediate level) after consulting with concerned member state

(a) Collaborative surveillance networks to quickly detect public health events at human animal-environmental interface including zoonotic spills and Anti-Microbial resistance within the territory of the State Party;

(b) Laboratory networks including that for Genomic sequencing and diagnostics to accurately identify the pathogen/ other hazards.

(c) Health emergency response systems to co-ordinate and implement public health response including surge capacity and state party response capacities.

(d) Health workforce development to identify, track, test and treat to contain/ control the outbreak/ public health event

(e) Support for a Health information management system to report all available essential information immediately to the appropriate level of health-care response, depending on organizational structures. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed;

(f) to assess and verify reported events immediately. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

(g) Leverage of communication channels to communicate the risk, countering misinformation and dis-information.

6. At the national level

Assessment and notification. The capacities:

(a) to assess all reports of urgent events within 48 hours; and

(b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

(c) to isolate, identify, sequence and characterize pathogens, under appropriate biosafety conditions.

*Public health **preparedness** response*. The capacities:

(a) Establish governance structure to manage a potential or declared Public Health Emergency of International concern.

(a) to determine rapidly the control measures required to prevent domestic and international spread;

(b) to provide support through specialized staff, laboratory analysis of samples**, genome sequencing** (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);

(c) to provide on-site assistance as required to supplement local investigations;

(d) to provide a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;

(e) **Establish co-ordinating mechanism** to provide ~~direct liaison~~ **collaboration** with other relevant government ministries, **sub-national level entities, Country office and Regional Office of WHO, other stakeholders including NGOs and civil society**;

(d) Leverage digital technology for collaborative surveillance networks, forecasting, laboratory networks including that for genomic sequencing, health emergency response systems, supply chain management and risk communication.

(e) to develop epidemiological intelligence to assess potential public health emergency of regional or international concern and determine rapidly the control measures required to prevent domestic and international spread;

(f) to support outbreak investigations, laboratory analysis, genomic sequencing of samples (domestically or through collaborating centres) and for quick and timely transportation of biological materials. logistical assistance (e.g. equipment, supplies and transport);

(g) to support timely exchange of biological materials and genetic sequence data to WHO, entities under WHO and other State Parties subject to equitable sharing of benefits derived therefrom.

(h) Work force development to provide emergency medical teams and specialized Rapid Response Teams including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern;

(j) Capacity to research, manufacture and deploy quickly medical countermeasures/ health products to respond to the health event

(k) For sustainable financing to develop core capacities and respond to health emergencies.

(f) to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;

(g) to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern; and

(h) to provide the foregoing on a 24-hour basis.

(i) to make available affordable health products and any other response materials

(j) to access and absorb technologies and knowhow for the production of health care products including diagnostics, therapeutics and vaccines ensuring their timely availability and distribution to the local community level/primary health care response level and intermediate levels

(k) to develop clinical guidance, tools, methods and means to meet the specific logistical needs of medical facilities, cold chain management, and laboratories at local community level and/or primary health care response level and intermediary levels.

(l) to invest in development of infrastructure, and capacity building of local community level and/or primary health care response level, and intermediary levels to implement control and response measures, including health care services.

(m) to provide logistics and field support to response teams including secure and comfortable accommodations, functional and secure working spaces and equipment, communications capabilities, safe staff transport and effective fleet management.

(n) to coordinate, supervise and evaluate the provision of prompt and quality health care to affected persons with the available resource.

(o) to ensure the implementation of available prevention measure(s) to prevent further transmission, prevent avoidable morbidity, mortality and disability.

New 7. Health System Capacities: States shall develop health systems capacities with a view to achieve resilience against health emergency outbreaks, including through

(i) state-of-art health care infrastructure and service delivery including scene care and pre-hospital services,

(ii) upgradation of tools and methods, trained health workforce with equitable representation of gender, cultural and linguistic groups,

(iii) fair and decent working conditions for health workers,

(iv) adoption of legal, administrative and technical measures to diversify and increase production of health products,

(v) improved distribution, and generic substitution for therapeutics,

(vi) information systems respectful of State Sovereignty over data and privacy of the personal data,

(vii) financing solutions avoiding catastrophic burdens in the housesholds,

(viii) national planning and leadership.

(ix) providing infrastructural facilities at points of entry including appropriate communication and transportation facilities.

New 7. Health Systems Capacities: in accordance with principle 2bis, States Parties need to build, develop and maintain health systems capacities resilient to public health emergency of international concern as stated below:

(i) health-care infrastructure and service delivery: improved number and distribution of health care infrastructure and facilities at the local community level, primary, secondary, and tertiary health care levels to the resilience levels as defined by WHO, including inpatient beds and outpatient visiting slots, geographical accessibility of sch facilities, providing general and specific services.

(ii) Upgradation of the health-care infrastructure and service: enhance the prompt and quality health care to the affected persons at the local community level and/or primary health care response level and to make available the state-of-the-art health care technologies, advanced tools and methods, acting in coordination with intermediate or national health response level.

(iii) Health workforce: improved number and distribution of trained health workers at local community level, primary, secondary and tertiary health care levels to the resilience levels as defined by WHO, including and equitable and gender specific, cultural, regional and linguistic representation, availability of generalists and specialists, and adequate yearly replenishment of reinforcement ratio.

(iv) Health information systems: establishment and maintenance of institutional mechanism in charge of health statistics, synthesis of data from different sources and validation of data from population-based and facility-based sources, periodic health systems performance assessment, health systems resource tracking, immunization coverage and periodic burden of disease studies and its dissemination, subject to national sovereignty of the State Parties and privacy of personal data

(v) Access to health products: assessment and enhancement of availability and affordability of listed health products including improved agility of the health products listing by national authorities, ease of adoption of legal, administrative and technical measures to diversify and increase production, and improve distribution and generic substitution.

(vi) Financing: health care service delivery during health emergencies shall not result in catastrophic payments, i.e that households shall not spent more than 10% of their total income on health

(vii) Leadership/governance: existence of national health strategy linked to national needs and priorities, including national medicines policy and health emergency preparedness and response plan, periodic updating of the same, and implementation – feedback – follow-up cycle, public confidence building measures and engagement of community participation in both agenda setting and implementation.

New 7. At the Global level, WHO shall strengthen capacities to:

(a) Provide policy document, guidelines, operating procedures epidemic intelligence, forecasting tools for managing public health emergency of international concern

(b) Use evaluation framework in finding critical gaps and support such state parties in attaining the core capacities.

(c) Facilitate sharing of Biological materials and genetic sequencing data and transparent subject to equitable access to benefits derived therefrom.

(d) Facilitate research, technology transfer, development and timely distribution of health products to manage public health emergencies.

(e) Counter misinformation and disinformation

(f) Co-ordinate with UN agencies, academia, non-state actors and representatives of civil society.

(g) Ensure sustainable financing for managing health emergencies.

B. CORE CAPACITY REQUIREMENTS FOR DESIGNATED AIRPORTS, PORTS AND GROUND CROSSINGS

1. At all times

The capacities:

(a) to provide access to (i) an appropriate medical service including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;

(b) to provide access to equipment and personnel for the transport of ill travellers to an appropriate medical facility;

(c) to provide trained personnel for the inspection of conveyances;

(d) to ensure a safe environment for travellers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms, appropriate solid and liquid waste disposal services and other potential risk areas, by conducting inspection programmes, as appropriate; and

(e) to provide as far as practicable a programme and trained personnel for the control of vectors and reservoirs in and near points of entry.

2. For responding to events that may constitute a public health emergency of international concern

The capacities:

(a) to provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;

New (b) to provide surveillance at point of entry and access to laboratory facilities for quick diagnosis of pathogens and other public health hazards.

(b) to provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities for their isolation, treatment and other support services that may be required;

(c) to provide appropriate space, separate from other travellers, to interview suspect or affected persons;

(d) to provide for the assessment and, if required, quarantine of suspect travellers, preferably in facilities away from the point of entry;

(e) to apply recommended measures to disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels including, when appropriate, at locations specially designated and equipped for this purpose;

(f) to apply entry or exit controls for arriving and departing travellers; and

(g) to provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travellers who may carry infection or contamination.

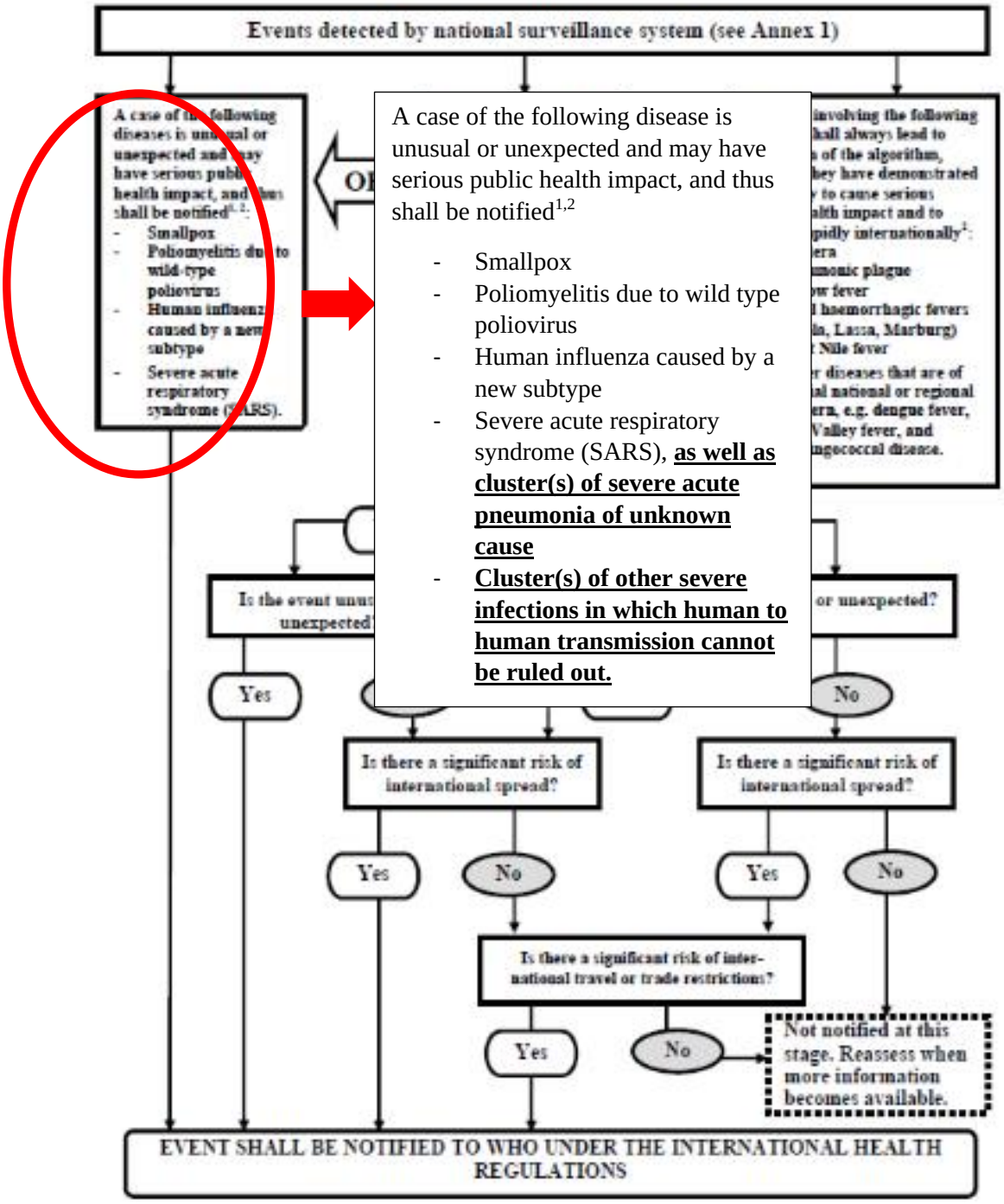
New (i) to develop the POE work force for surveillance and POE response.

New (j) Leverage digital technology for harmonising reporting capabilities and for uniform certification procedures / mutual trust framework / universal credential verification system.

New (k) Standard SoPs for Infection prevention and control to be framed and implemented at all POEs

ANNEX 2

DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN



ANNEX 2

DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN

[The submitting State Party proposes the following model for the evaluation and notification of events that may constitute PHEIC for countries to replace Annex 2]

Events detected by national surveillance system:

Questions in four areas should be considered for the decision, evaluation and notification of events that may constitute a potential PHEIC:

l. Geographical scope/ risk of territorial spread

1.1 Has the event already been notified in more than one country?

l.2 Has the event already been flagged by more than one unit within the national health system?

1.3. Has the event been the subject of national alert or international alert (disease contained in a priority list of the IHR)?

1.4 Is there a risk of national or intonational spread?

2. Characteristics of the event- whether it is rare, reemerging, presents changes in its epidemiological profile and/or has serious health impact

2.l. Is the event unexpected or unusual?

2.2. Is the event the reemergence of a previously eradicated disease?

2.3. Were there changes in the epidemiological clinical profile (levels of incidence, mortality, lethality) or in the alert zone ("Corresponds to the area delimited by the endemic curve itself and by the upper limit in each time unit of the calendar year")?

2.4. Does the event present high pathogenicity, virulence and transmissibility?

2.5. Is the public health impact of the event serious?

3. Healthcare relevance - whether the event risks compromising the delivery of healthcare and/or poses a risk to health professionals

3.1. Does the event impair the delivery of healthcare services, for instance, because there is no treatment available or treatment requires the use of controlled medications?

3.2. Is there a significant increase in treatment provision or in hospitalizations?

3.3. Does the event affect healthcare professionals?

4. Social and Economic Relevance - whether the event affects vulnerable populations, has high social impact and/or poses a risk to international travel or trade

4.1. Does the event affect vulnerable populations?

4.2. Is it a disease or public health event with high social impact (which generates fear, stigmatization or social grievance)?

4.3. Does the event affect social interaction?

4.4. Does the event affect local tourism or has a high economic impact?

4.5. Is there a significant risk for international travelling or trade?

The risk must be evaluated in accordance to the aforementioned questions, with a value of 1 for Yes and 0 for No. The sum of the value of all responses will guide the Member State regarding the decision to notify the WHO, according to Art. 6 of the RSI.

For the risk level, the following scores were assigned:

LOW: Equal to or< 5 - Keep monitoring it internally

AVERAGE: 5 to 11 - Potential for spread between countries - Notify WHO according to

Art. 6 of the RSI

HIGH: > 11 -Potential PHEIC - Notify the WHO according to Art. 6 of the RSI

ANNEX 3

MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP SANITATION CONTROL CERTIFICATE

To verify authenticity, scan on the official web site or as a QR code.

Image of the QR code or other validation application.

Possibly include "international river vessels" in:

I. The title of the ship sanitation control certificate and control exemption certificate

II. The articles and annexes referring to the maritime declaration

III. All places where the word maritime occurs

ANNEX 4

TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND CONVEYANCE OPERATORS

(…)

3. Conveyance operators shall prepare in advance, where possible, a plan for taking appropriate measures required if evidence of a public health risk on board is found.

ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

When a public health emergency of international concern has been declared, for the purposes of entry and exit of international travellers in a scenario of voluntary vaccination using products still at the research phase or subject to very limited availability, vaccination certificates should be considered approved in accordance with the normative framework of the country of origin, including with reference to the model/format of certification and the vaccination schedule (type of vaccine and schedule).

Conditions for digital documents:

Paper certificates must be assigned by the clinician indicating the administration of the vaccine or other prophylaxis, or by another duly authorized health professional. Digital certificates must incorporate a means to verify authenticity from an official web site, for example a QR code.[1]

(…)

2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the "certificate") in ~~the~~ **digital or paper** form specified in this Annex **or in any digital format as being used in the country** . **International certificates may be issued in digital or paper form in accordance with Article 35 and with the specifications and requirements approved and reviewed periodically by the Health Assembly. Such specifications and requirements should enable flexibility in terms of their validation and acceptance taking into account applicable national and regional rules and the need for rapid modifications due to changing epidemiological contexts. In order to enhance transparency specifications and requirements should be based on open standards and implemented as open source. The paper certificates shall be issued in the form specified in this Annex**. No departure shall be made **in the paper certificates** from the model of the certificate specified in this Annex.

---

[1] Vaccination certificates for entry to and exit from national territory:
Two scenarios for the data to be included on certificates:

Minimum scenario:
Presentation of certificate/proof in paper format.
Irrespective of the format, the following data should be present:

1. **First name(s) and family name**
2. **No. of national identity document/passport**
3. **Type of vaccine: for example yellow fever, poliomyelitis, measles**
4. **Vaccine batch no. (optional, if available)**
5. **Date of administration**
6. **Place of administration (vaccinator)**
7. **Official stamp (or of the health professional or institution)**

Maximum scenario:
Certification of vaccination history via QR code

1. **Vaccination history is accredited in digital or paper format, via QR code**
2. **QR code directs to the official site of the country of origin to retrieve the vaccination information.**

Diseases in the process of elimination/eradication

3. Certificates under this Annex **or any digital format** are valid only if the vaccine or prophylaxis used has been approved by WHO **or/and by State Parties.**

4. **For paper-based format,** Certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature. **Signatures and stamps may also be appended digitally by the clinician or the administering centre, or by the health authority on their behalf, in accordance with Article 35 and with the specifications and requirements approved and reviewed periodically by the Health Assembly.**

4bis For digital format, certificates must be presented with QR code that contains the information mentioned on the Model International Certificate of Vaccinations or Prophylaxis and should be aligned with any current guidelines or/and agreed by State Parties

(…)

8. A parent or guardian shall sign the certificate when the child **or a person with disability** is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person's mark and the indication by another that this is the mark of the person concerned. **Such signatures shall not be required on a vaccination certificate in digital form.**

(…)

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

This is to certify that [name] ....., date of birth ....., sex .....,

nationality ....., national identification document, if applicable .....

whose signature follows …….....

has on the date indicated been vaccinated or received prophylaxis against:

(name of disease or condition) …….

in accordance with the International Health Regulations.

To confer authenticity when appropriate, scan the official site, such as the QR code or other verification method QR code image

ANNEX 8

MODEL OF MARITIME DECLARATION OF HEALTH

(…)

New 10) Is there a traveler without the required vaccination in Annex 7? If not….. If yes, please provide the details in the attached form. "To verify the authenticity by scanning the official site, such as QR code or other verification method QR code image

FORM ATTACHED TO THE MARITIME DECLARATION OF HEALTH MODEL

Include the column "Vaccination according to Annex 7"

NEW ANNEX 10

OBLIGATIONS OF DUTY TO COOPERATE

1. States Parties may request collaboration or assistance from WHO or from other States Parties in any of the activities mentioned in paragraph 2 or any other activities in which collaboration or assistance with regard to health emergency preparedness and response become necessary. It shall be obligation of the WHO and States Parties, to whom such requests are addressed to respond to such request, promptly and to provide collaboration and assistance as requested. Any inability to provide such collaboration and assistance shall be communicated to the requesting States and WHO along with reasons.

2. WHO and States Parties collaborating and assisting with each other shall:

(a) with regard to surveillance capacities:

(i) identify, assess and update the listing of technologies for the surveillance on a periodic basis;

(ii) identify, assess and update the listing of best practices related to organization structure and surveillance network;

(iii) train human resources to detect, assess and report events under these Regulations, as according to the lists developed and maintained under the above paragraphs;

(iv) facilitate sharing of technologies and know-how with States Parties in need, especially those technologies obtained in the course of research, wholly or partially funded by public sources;

(v) facilitate adaptation of the best-practices to the national and cultural contexts of the States Parties.

(b) With regard to response capacities:

(i) develop various guidelines and protocols for prevention, control and treatment of the diseases, including standard treatment guidelines, vector control measures;

(ii) assist in the development of infrastructure and capacity building for the successful implementation of protocols and guidelines and provide the same to the States Parties in need;

(iii) provide logistical support for the procurement and supply of health products;

(iv) develop and publish product development protocols for the materials and health products required for the implementation of above paragraphs, including all relevant details to enhance production and access to such products;

(v) develop and publish technical specifications of the health products, including details of technologies and knowhow with a view to facilitate local production of diagnostics, therapeutics and vaccines, including cell-lines, raw-materials, reagents, design of devices etc.;

(vi) develop and maintain an agile database of health product required for various health emergencies taking into account the past experiences and the needs of the future;

(vii) train health workers to respond with health emergencies, including in adaptation of best practices and using of required technologies and equipment;

(viii) establish multidisciplinary and multisectoral rapid response teams to respond to alerts and PHEIC, swiftly acting upon request from states parties;

(ix) carry out research and building capabilities for implementing of the regulations including the product development;

(x) facilitate sharing of technologies and know-how with States Parties in need, especially those technologies obtained in the course of research wholly or partially funded by public sources.

(xi) building and maintaining IHR facilities in points of entry and its operations.

(c) With regard to legal assistance:

(i) take into consideration the socio-economic conditions of the States Parties concerned;

(ii) adopt legal and administrative arrangements to support public health response;

(iii) train implementation of such legal instruments.

= = =