World Health Organization

Reference document: proposed amendments and technical recommendations

The table below provides an overview of the amendments to the International Health Regulations (2005) (IHR) that have been proposed in accordance with decision WHA75(9), and the technical recommendations thereon made by the Review Committee regarding Amendments to the IHR ("Review Committee"). It has been prepared at the request of some Member States during the second meeting of the Working Group on Amendments to the International Health Regulations (2005), 20–24 February 2023 (see the report of the second meeting contained in document A/WGIHR/2/10).

The column on the left shows the text of the proposed amendments as presented in the Article-by-Article compilation (document A/WGIHR/2/7). The column on the right shows the summary of proposed amendments and technical recommendations of the Review Committee, as they appear in the Review Committee's report (document A/WGIHR/2/5).

This overview table is not intended to replace the proposed amendments to the IHR in the original submission.

Proposed amendments in accordance with decision WHA75(9)	Technical recommendations of the Review Committee regarding Amendments to the IHR
PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES	
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 international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;	***Summary of proposed amendments*** Two proposed amendments introduce somewhat similar definitions for a new term "health products". One proposed amendment introduces a definition for another new term "health technologies and know-how". One proposed definition to "health products" is that it includes "therapeutics, vaccines, medical devices, personal protective equipment, diagnostics, assistive products, cell- and gene-based therapies, and their components, materials, or parts." This definition of "health products" is proposed together with the proposed definition for "health technologies and know-how," with the latter encompassing "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 used interchangeably as 'health care technologies.'" A separate proposed definition of "health products" includes "medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies, but not limited to this course". The two definitions of "health products" are similar in scope, but the latter introduces flexibility and also concision, and moreover touches on aspects of the above definition on "health technologies and know-how". Lastly, two other amendments propose to delete the word "non-binding" from the definitions of both "standing recommendations" and "temporary recommendations". ***Technical recommendations*** In relation to the proposed amendments to introduce new terms in Article 1, the Committee notes that the proposed definitions for the new terms are introduced in relation to related amendments proposed to Articles 2, 13, 15, 16, 43, 44, as well as to the two new Articles 13A and the new Annex 10.

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	Should the Regulations be amended to address issues relevant to the definitions proposed, the Committee emphasizes the importance of a standard, consistently used, and well-considered definition in this regard, as proposed amendments to other articles of the Regulations refer to a similar concept but using different terms, such as "medical countermeasures," "technologies and know-how," and "health care products." In relation to the two proposed amendments to remove the word "non-binding" from the definitions of "temporary" and "standing recommendations", the Committee notes that on a plain reading the proposed change would not affect the current understanding of the definition of standing or temporary recommendations as merely advice that is not mandatory. However, given that substantial proposals were made in relation to WHO recommendations in other related articles, the proposed amendments to these definitions could be understood as aiming to change the nature of these recommendations from non-binding to binding, and giving a binding effect to WHO recommendations and requests as proposed in other articles. That change would require a fundamental reconsideration of the nature of recommendations and the process for their adoption and implementation. The Committee further notes that during a public health emergency of international concern the recommendations may work better if they are not mandatory and advises against changing the nature of recommendations. In addition to the proposed amendments to Article 1, some of the proposed amendments to other articles have introduced new terms that may also require a definition under Article 1. These terms are flagged in the relevant technical recommendations to the respective articles. The Committee notes the importance of ensuring clarity of definitions in the relevant global health instruments under the auspices of WHO, including in particular in the WHO pandemic accord. In this connection, due regard should be given to the development of definitions within the WGIHR and the INB
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Article 2 Purpose and scope	
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	***Summary of proposed amendments***

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diseases **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**.	Four amendments propose to extend the purpose and scope of the Regulations in the following ways: • add "to prepare" to the purpose; • introduce "health systems readiness and resilience" as a specific focus of the actions related to protection, control and public health response; • broaden the scope from "public health risks" to "all risks with a potential to impact public health"; and • add to the requirement to avoid unnecessary interference with traffic and trade the elements of "livelihoods, human rights, and equitable access to health products and health care technologies and know how". ***Technical recommendations*** Adding preparedness to the scope reinforces the functions of the Regulations related to building core capacities in an on-going manner, in the absence of outbreaks or events, during so-called "peace time". The proposed addition of "including through health systems readiness and resilience" refers to core capacity requirements that should be in place. The Review Committee is mindful that Annex 1 paragraph 1 states: "States Parties shall utilize existing national structures and resources to meet their core capacity requirements, 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." Moreover, Article 5 paragraph 3 and Article 13 paragraph 3 oblige WHO to assist a State Party in improving core capacities when requested to do so. This may well lead to the view that the current scope of the Regulations is reinforced by this proposed amendment, without further broadening or limiting it. The Committee notes that the concept of health systems resilience is introduced in further proposed amendments to other articles, including in those proposed to Annex 1 and the new Annex 10. However, the meaning of health system readiness and resilience if introduced in Article 2, may need to be defined in Article 1, or require alternative wording conveying a similar meaning.

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	The Committee considers that the proposed amendment to replace "public health risk" with "all risks with a potential to impact public health" may not increase the clarity of this Article. Public health risks are already defined in Article 1 and the definition fully encompasses the desire of States Parties for the "all-hazard approach" envisioned in the 2005 revision of the Regulations. The proposal to include avoiding unnecessary interference with human rights reinforces and potentially extends the current scope, and, as some Committee members indicated, is aligned with other provisions in the Regulations, such as current Articles 3, 32 and 42. Some interventions implemented for outbreak control, such as isolation, quarantine, social distancing, or school closure, limit the enjoyment of human rights and/or fundamental freedoms. They should only be imposed in accordance with the principles of legitimacy, necessity and proportionality, which means, inter alia, on a temporary basis and to the extent necessary. The proposal to include avoiding unnecessary interference with livelihoods potentially extends the current scope of the Regulations, but may be considered to be included in the proposed reference to human rights above. Some Committee members considered that the proposal to avoid unnecessary interference with "equitable access to health products and health-care technologies and know-how" extends the scope of the Regulations. However, other Committee members indicated that such explicit reference to products might be implicit within the existing reference to "international traffic and trade". Moreover, proposed amendments to other articles may depend on this proposed amendment to the scope. If any of the following terms are included in amendments to this Article, they should also be defined in Article 1: health system readiness, health system resilience, equitable access, health products, health-care technologies, livelihoods, and know-how.
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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**	***Summary of proposed amendments*** The six amendments propose to expand this Article 3 in the following ways:

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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.**	• add equity, inclusivity, coherence and solidarity as principles, either to replace the reference to dignity, human rights and fundamental freedoms, or as an additional paragraph; • introduce as a principle the concept of common but differentiated responsibilities and respective capabilities, taking into account available finances and technologies, either as an addition to paragraph 1 or as a new paragraph; • introduce the precautionary principle; and • add a new paragraph requiring that information should be exchanged exclusively for peaceful purposes. ***Technical recommendations*** The Committee strongly recommends the retention of the existing text "full respect for the dignity, human rights and fundamental freedoms of persons" as an overarching principle in the first paragraph, and notes that the concepts of human rights, dignity and fundamental freedoms are clearly defined within the framework of treaties to which many of the States Parties to the Regulations have adhered. The inclusion of human rights in Article 3 of the current International Health Regulations (2005) was a major improvement on the previous 1969 Regulations.[1] The reference to "respect for dignity, human rights and freedoms of persons" works not only as an overarching principle in Article 3, but also as a concrete reference point in the operationalization of all articles concerning public health response, response measures, additional health measures and recommendations. The introduction of the concept of common but differentiated responsibilities and respective capabilities in paragraphs 1 and 2 and new paragraph 5 should be analysed in depth and considered with care. The Committee notes the responsibility of all States Parties to apply the Regulations under Article 3, paragraph 3. The Committee acknowledges the origin of this concept in environmental law, in particular the international legal regime on climate change, and supports the spirit of the proposal,

[1] International Health Regulations (1969), 3rd ed., World Health Organization, 1983 (available at: https://apps.who.int/iris/bitstream/handle/10665/96616/9241580070.pdf?sequence=1&isAllowed=y, accessed 18 January 2023).

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	which is intended to give normative significance and implications to the profound differences between the respective resources and capacities of States Parties. At the same time, some Committee members questioned whether the concept of common but differentiated responsibilities and respective capabilities can be factually and conceptually applicable to public health risks and events that may constitute a PHEIC, and whether the purpose of the concept could be captured in different ways. Other than rejections (Article 61), reservations (Article 62) and extensions (Articles 5 and 13), the Regulations do not explicitly provide for differentiated responsibilities of States Parties. The Committee recognizes that implementation of the Regulations is in the mutual interest of all States Parties. The Committee acknowledges that there are differences across States Parties in, among others, the level of social and economic development (e.g. small island developing States), which can influence the level of implementation of the Regulations in some circumstances. The Committee notes that overcoming these differences in capacities requires cooperation among all States Parties. The Committee also notes that, as referred to in the proposed amendment to paragraph 1 and new paragraph 5, inclusivity, coherence and particularly equity and solidarity are important principles underpinning the Regulations, and also reflect important lessons from the COVID-19 pandemic.[1] These concepts can be understood as principles underlying Chapter IX of the United Nations Charter and the WHO Constitution, referred to in paragraph 2 of this Article. The notion of "coherence" requires a definition. The Committee considers that the proposed amendments to include text on equity, inclusivity, coherence and solidarity would make a constructive contribution to the framework of the Regulations and would support improved implementation. Many proposed amendments to other articles operationalize, in particular, the concept of equity with different objectives and consequences: some adjust or modify existing obligations; others create new obligations for States Parties and/or WHO. Alignment and clear definitions are necessary to ensure feasibility and understanding.

[1] See document A75/20, containing a report on strengthening the global architecture for health emergency preparedness, response and resilience, May 2022. Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_20-en.pdf, accessed 18 January 2023.

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	The proposed addition of precaution to paragraph 3 should be analysed in depth and considered with care. Measures in the Regulations are meant to be evidence-based, which may preclude or at least limit the application of precaution; however, uncertainties during an outbreak response may require action in the absence of evidence or with insufficient evidence. The concept does not seem to have a commonly accepted definition (other than to a certain extent in environmental law).[1] The Committee notes that Article 5 paragraph 7 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures[2] may provide a potentially useful clarification. The new paragraph 6 proposes that information must only be exchanged for peaceful purposes. Information exchange under the Regulations can only occur within the purpose of the Regulations: to prevent the international spread of diseases. This amendment, therefore, is unnecessary. The proposed requirement is also implicit in the United Nations Charter. If States Parties want to adopt this amendment it could be better placed, either in paragraph 2 as a general statement, or as an introduction to Part II of the Regulations.
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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.**	***Summary of proposed amendments*** There are two sets of proposed amendments to this Article. One set aims to clarify the fact that a National IHR Focal Point is an entity, not a person, and would oblige States Parties to enact or adapt legislation to support their functioning and resourcing. Another set of proposals would impose an obligation on States Parties to establish an entity responsible for the overall implementation of the Regulations, not only the

[1] See the following useful resources: Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights (https://www.icj.org/wp-content/uploads/1984/07/Siracusa-principles-ICCPR-legal-submission-1985-eng.pdf, accessed 18 January 2023); The precautionary principle. UNESCO; 2005 (https://unesdoc.unesco.org/ark:/48223/pf0000139578, accessed 25 January 2023); and Report of the United Nations Conference on Environment and Development. Rio Declaration on Environment and Development, United Nations General Assembly, 1992. Document A/CONF.151/26 (Vol. 1) (https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf, accessed 25 January 2023).

[2] Available at: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm, accessed 18 January 2023.

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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."	"health measures" as required of the "competent authority". The institutional positioning, organization and functioning of such an authority would be a matter of sovereignty, with each State Party designing it as they saw fit. Contact details would be shared with WHO, in the same way that contact details of National IHR Focal Points are shared and regularly updated. ***Technical recommendations*** The Committee supports the proposed amendments related to National IHR Focal Points and considers that the proposals bring greater clarity to their role and further support their functioning. The proposed amendment to establish a "National IHR competent authority" would establish a new function, which could be discharged by a new entity. Thus, this Article would encompass three functions: the National IHR Focal Point; the competent authorities as defined in Article 1, with the specific functions as delineated in Article 22; and a function of a "National IHR Competent Authority", as recommended by the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response, which would be responsible for the implementation of and reporting on all the State Party's obligations under the Regulations. The Committee notes that there are potentially inherent inconsistencies between the definition of "competent authority" in Article 1, which seems to imply a broader role of such authority since it is defined as "an authority responsible for the implementation and application of health measures under these Regulations" and the functions outlined in Article 22, which seem to narrow the role of the "competent authority" to measures at points of entry and in relation to conveyances and conveyance operators. To clarify these distinctions, it may be beneficial to restructure this Article into three paragraphs: one on National IHR Focal Points, bringing together the proposals to clarify their role; one on competent authorities, as defined in Article 1 and delineated in Article 22; and one on "National IHR Competent Authorities". To avoid potential confusion with the "competent authority" as already defined in Article 1, the Committee suggests replacing "National IHR Competent Authority" with "National Authority". Furthermore, to ensure clarity and consistency, text similar to the proposals related to the National IHR Focal Points could be added to further support the "National Authority" with the necessary legislation, and to establish obligations related

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	to sharing contact details with WHO, and subsequent updates. Lastly, the Committee suggests deleting the last part of proposed Article 1bis, after the "overall implementation of the IHR", since it is not clear to whom the "National Authority" would be accountable, and it may not be feasible in all States Parties to ensure accountability. Amending this Article may require amendments also of Article 1 in the following ways: revising the definition of National IHR Focal Point to further clarify that it is an entity and not a person; revising the definition of "Competent Authority"; and adding a definition for "National Authority".
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
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.**	**A. Capacity review mechanism (UHPR)** ***Summary of proposed amendments*** One proposed amendment to paragraph 1 introduces a provision for the surveillance capacity to be periodically reviewed through a mechanism, referred to as "Universal Health Periodic Review", which is to replace the Joint External Evaluation that has been used by some States Parties on a voluntary basis since 2016. ***Technical recommendation*** The following considerations by the Committee are based on the understanding that the proposed amendments referring to a "Universal Health Periodic Review" are, in fact, referring to the "Universal Health and Preparedness Review (UHPR)", which is an initiative launched by WHO in 2021 as a voluntary, transparent, Member State-led peer review mechanism, that aims to establish a regular intergovernmental dialogue between Member States on their respective national capacity for health emergency preparedness.[1]

[1] See: https://www.who.int/emergencies/operations/universal-health---preparedness-review#:~:text=Universal%20Health%20%26%20Preparedness%20Review&text=The%20Universal%20Health%20and%20Preparedness,capacities%20for%20health%20emergency%20preparedness, accessed 23 January 2023.

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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**	The Committee understands the spirit of this provision in enhancing mutual accountability and transparency in the implementation of the Regulations. Article 54.1 provides for the Health Assembly to decide on the reporting and functioning of the Regulations, and the Committee understands that this reporting may potentially include monitoring and evaluation mechanisms. Following resolution WHA61.2 (2008),[1] which decided on a single annual report on the implementation of the Regulations for both States Parties and the Director-General, the Secretariat developed the State Party Annual Reporting tool (SPAR), which is currently the only obligatory reporting mechanism for States Parties.[2] The Joint External Evaluation has been and continues to be one of the voluntary approaches, as part of the broader WHO International Health Regulations Monitoring and Evaluation Framework.[3] At the time of writing this report, the Universal Health and Preparedness Review has not yet been endorsed by Member States and is still undergoing pilot testing. WHO has established a Technical Advisory Groupon the matter[4] and has supported pilot testing in four countries.[5] Introducing a new obligatory review mechanism and replacing a voluntary mechanism such as the Joint External Evaluation with a mandatory mechanism, which, at this stage, is still in its pilot phase, would introduce inflexibility to future reporting (among other reasons, because as a Committee we cannot predict how States may engage with and buy into the Universal Health and Preparedness Review in future). The Committee notes that while the proposed mechanism is striving to promote transparency and accountability, the inclusion in a legally binding instrument of a peer-review mechanism which is currently in a pilot phase is premature.

[1] Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA61-REC1/A61_Rec1-part2-en.pdf, accessed 23 January 2023).

[2] Available at: States Parties Self-Assessment Annual Reporting (who.int), accessed 23 January 2023.

[3] Available at: https://extranet.who.int/sph/ihr-monitoring-evaluation, accessed 23 January 2023.

[4] Website of the Technical Advisory Group (TAG) for Universal Health and Preparedness Review (UHPR); (https://www.who.int/groups/technical-advisory-group-for-universal-health-and-preparedness-review#cms, accessed 23 January 2023).

[5] Universal Health and Preparedness Review Technical Advisory Group meeting report No. 4, July 2022; (https://www.who.int/publications/m/item/universal-health-and-preparedness-review-technical-advisory-group-meeting-report-18-July-2022, accessed 19 January 2023).

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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."**	Moreover, it is unclear to the Committee why a reporting mechanism with a broad scope of capacities assessment, such as is currently proposed within the Universal Health and Preparedness Review, would only be introduced in Article 5, which is concerned only with surveillance capacity. At the same time, the Committee notes that there are proposals to also amend Article 54, as well as proposals for new articles on compliance and accountability, which provide for more flexibility and broader approaches to be used by States Parties to ensure accountability and compliance (see analysis of the related articles in Part IX). In conclusion, further mechanisms related to reporting on the implementation of the Regulations should arguably be addressed via Article 54, using flexibilities in this Article. Potentially, if the Health Assembly decides to endorse reporting on the Universal Health Periodic Review, then these sets of proposed amendments concerning the Periodic Review may be considered. **B. Assistance in capacity building for surveillance** ***Summary of proposed amendments*** Proposals related to the last part of paragraph 1 of this Article introduce obligations for WHO, including the regional offices, to provide or facilitate provision of technical assistance, including financial resources to develop, strengthen and maintain core capacities. These proposals link the findings of the proposed review mechanism discussed under section A above, with obligations on the part of WHO and its regional offices to provide technical and financial assistance. Furthermore, the proposals for amending paragraph 3 introduce obligations for both, "developed" States Parties and WHO to assist "any" State Party to strengthen and maintain the core capacities. ***Technical recommendation*** In the interests of streamlining and economizing the text of the Regulations, any proposals related to cooperation, collaboration and assistance are arguably better placed under Article 44 and should be aligned with the other proposals for amendments to Article 44. The rationale provided for these amendments – to ensure through cooperation and collaboration that all countries can, and do, in fact, develop, strengthen and maintain

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	core capacities – is consistent with the scope of the Regulations and with the role of WHO, as enshrined in its Constitution.[1] Notwithstanding the proposed amendments to Article 3 (e.g. including reference to common but differentiated responsibilities), introducing the obligation of assistance by high-income countries may create a tension with the existing principle of universal application provided for under Article 3, however it may be aligned with Article 44. Finally, as a structural concern, the Committee notes that the pre-emptive offering of assistance as opposed to the accepted/established formulation of "upon request" may require further discussions among the WGIHR and States Parties, in alignment with Article 2 of the WHO Constitution which requires WHO "to assist governments, upon request, in strengthening health services." The Committee notes that there is currently no definition provided under the Regulations for "developed" and "developing" countries, and States Parties must furthermore consider whether this language is future-proof. **C. Decision on capacity deadline extension by the Health Assembly** ***Summary of proposed amendments*** The proposal to amend paragraph 2 extends the time lines provided by this paragraph for allowing extensions of deadlines to fulfill obligations in paragraph 1, by introducing the obligation of the Director-General to refer the issue for decision by the Health Assembly. ***Technical recommendation*** The IHR Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation[2] (Review Committee on Second Extensions) was mandated to advise the Director-General on progress made in implementing this Article, and specifically on requests from States Parties on second extensions (2014–2016) for establishing the core capacities as specified by Annex 1 of the Regulations. It could thus be argued that the deadlines envisioned by this paragraph

[1] Basic Documents, 49th edn., 2020 (https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=6, accessed 19 January 2023).

[2] Document EB136/22 Add.1; 2015 (available at: https://apps.who.int/gb/ebwha/pdf_files/EB136/B136_22Add1-en.pdf, accessed 19 January 2023).

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	have expired. However, the proposed amendments would apply to any new States Parties, and if adopted as such, would be holding any new State Party to the Regulations to a different standard of decision making than previous States Parties. The Committee notes that there are many proposals to amend the capacities required of States Parties in Annex 1 of the Regulations. Annex 1 specifies the details of core capacity for surveillance and response as set out in Articles 5 and 13 (which are themselves also the subject of proposed amendments); as well as designated points of entry as set out in Article 19 (which is itself also the subject of proposed amendments). Articles 5, 13 and 19 also specify the time frames within which States Parties must develop, strengthen and maintain these core capacities – within five years, with the possibility of an extension of two years, and, in exceptional circumstances, a further extension of two years. A number of the proposed amendments to Annex 1 represent a potentially significant expansion in the nature and scope of the obligations. In this light, the Committee recommends that if amendments are to be made to the substantive obligations in Annex 1, States Parties should also consider whether or not any amendments should be subject to any time frame requirement. The Committee is mindful that the Review Committee on Second Extensions concluded that, "The work to develop, strengthen and maintain the core capacities under the Regulations should be viewed as a continuing process for all countries".[1] **D. Early warning criteria and criteria for risk assessment** ***Summary of proposed amendments*** In paragraphs 4 and 5, the proposed amendments have included the requirement for WHO to collect information regarding events, and to assess these events "on the basis of risk assessment criteria" that are to be regularly updated and agreed with States Parties. One proposal introduces a specific request for WHO to handle information

[1] Review Committee on Second Extensions (2014); Report (https://apps.who.int/gb/ebwha/pdf_files/EB136/B136_22Add1-en.pdf, accessed 19 January 2023); adopted through resolution WHA68.5 (2015) (https://apps.who.int/gb/ebwha/pdf_files/WHA68-REC1/A68_R1_REC1-en.pdf#page=37, accessed 19 January 2023).

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	received under this paragraph "not with an outside party" but only with States Parties, unless such information is already public under Article 11. ***Technical recommendation*** These proposals raise managerial and operational issues for WHO concerning raising the alert for public health risks. The Committee notes that while multiple States Parties have proposed the requirement for WHO to develop early warning criteria for assessing the risk, it is essential to maintain flexibility in different circumstances. The Committee notes that States Parties already have access to regularly updated information on the secure WHO Event Information Site platform. The postings on the platform related to a series of criteria constitute a form of risk assessment and alert. The Committee also notes that WHO has developed the manual "Rapid Risk Assessment of Acute Public Health Events" to guide national authorities and WHO staff in conducting rapid risk assessment related to any type of hazard, and is using a similar approach in conducting its risk assessments for events with the potential to become a PHEIC.[1] The Committee recommends that States Parties refer to relevant existing systems and manuals, such as those referenced above, to inform discussions about the proposed amendments. Further clarification regarding the proposed terminology and the relationship to Annex 2 is needed. There is currently no definition of "risk assessment" or "early warning" in the Regulations, and arguably new definitions to this effect, under Article 1, may be required if some form of amendment encompassing this grouping of amendments is adopted. At the same time, a fundamental question is at what level of detail the development of a definition of risk assessment is suitable for inclusion in the Regulations. The Committee notes that any inclusion of criteria or other definitional issues creates the potential for an inflexible and context insensitive framework which may have unintended negative consequences.

[1] WHO Manual for rapid risk assessment of acute public health events; 2012 (https://www.who.int/publications/i/item/rapid-risk-assessment-of-acute-public-health-events, accessed 19 January 2023.)

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	Finally, this grouping of amendments on the concept of "early warning" needs to be examined with proposals for amending Article 12, in relation to establishing an "intermediate level of alert or a regional level of alert." **E. Central coordinating authority of the health sector in surveillance and response** ***Summary of proposed amendments*** A new paragraph 5 proposes to explicitly emphasize and consolidate the central place of the health sector (i.e. health authorities) as the principal coordinating sector for interagency activities related to surveillance and response. ***Technical recommendation*** This proposed amendment is constructive as it aims to promote improved coordination of surveillance and response activities by putting the health sector at the centre of the coordination. However, this provision may be too prescriptive for countries and may not reflect their differing internal government structures, division of responsibility and resource levels. If States Parties would like to pursue this provision, it might be better placed with the proposal in Article 4 to designate a "national authority" responsible for the implementation of all States Parties' obligations under the Regulations.
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
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**	**A. Application of Annex 2 and communication to WHO** ***Summary of proposed amendments*** This grouping of proposed amendments to paragraph 1 refers to establishing the time interval in which States Parties must assess events occurring within their territory by using the decision instrument in Annex 2. One set proposes that this delay is specified at the beginning of the phrase, while another set introduces it at the end of the first phrase: within 48 hours of/after National IHR Focal Points receiving information about the event. In addition, another set of proposed amendments add, in the first line of paragraph 2, the words "by the most efficient means of communication available" as a qualifier to the obligations of States Parties to continue to communicate with WHO after notification.

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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**	***Technical recommendation*** These proposed amendments effectively reiterate obligations already existing in Annex 1 A paragraph 6(a) for States Parties to have capacities "to assess all reports of urgent events within 48 hours". However, it should be noted that the obligations for events assessment are for the State Party, and the National IHR Focal Points are only the conduit of communication with WHO. Therefore, the assessment of an event by a State Party, including within a set time frame, is not necessarily subject to the receipt of event-related information by the National IHR Focal Point. This grouping of amendments enhances the clarity of a crucial obligation that matters for the alert function of the Regulations and may require a minor rewording for clarifying its placement and whether to use "within 48 hours" or "48 hours after". The addition in the first line of paragraph 2 does not seem necessary since it is already mentioned in paragraph 1. This time line notwithstanding, it should be made clear that those who are unable to do so, or who exceed this 48 hour window, should do so as quickly as possible afterwards. **B. Notification by WHO to relevant international bodies** ***Summary of proposed amendments*** This grouping of proposed amendments to the latter part of paragraph 1 aims to expand the list of intergovernmental organizations to whom WHO should, in its turn, notify events – according to notifications received from States Parties – in addition to the one already listed, the International Atomic Energy Agency (IAEA), adding, "the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE),[1] the United Nations Environment Programme (UNEP) or other relevant United Nations entities". ***Technical recommendation*** The intent of this grouping of amendments is understandable, as the aim seems to be to support information sharing for events that may be within the purview/involving the

[1] On 28 May 2022, the Organisation founded as the Office International des Épizooties (OIE), then known as World Organisation for Animal Health (OIE), announced its change of name to World Organisation for Animal Health (WOAH), (https://www.woah.org/en/the-world-organisation-for-animal-health-launches-its-refreshed-brand-identity/#:~:text=From%20today%2C%20the%20Organisation%20previously,OMSA%20in%20French%20and%20Spanish, accessed 20 January 2023).

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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.**	competencies of other organizations and may be particularly relevant for applying the "One Health approach".[1] Of note, in addition to the Quadripartite Memorandum of Understanding signed by FAO, WOHA (formerly OIE), UNEP and WHO in April 2022,[2] a mechanism for coordination and collaboration between three organizations was established in 2006 – the Joint FAO-OIE(WOAH)-WHO Global Early Warning System for health threats and emerging risks at the human-animal-ecosystems interface (GLEWS+),[3] This mechanism already provides for joint risk assessments and formulates risk management options. Concerning the formulation of "relevant national and UN entities" the Committee considers there is a lack of clarity, as it is unclear which other United Nations entities are concerned by this provision. Additionally, the Committee regards as prudent conducting consultations with any intergovernmental organizations and international bodies whose name is intended to be mentioned in a prospective amendment of the Article. As a further consistency concern, the addition of immediately notifying "relevant national entities" is not required, as this is already provided for in Article 11. **C. Sharing of genetic sequence data (GSD)** ***Summary of proposed amendments*** A large grouping of amendments proposed in paragraph 2 by several States Parties introduce the obligation of States Parties to share with WHO GSD (although different wording is used in different proposals), as well as in some cases, to also share additional data. One proposed amendment further qualifies this obligation by linking it to capacities of States Parties and the prevailing national legislation. Another proposal in a new paragraph 3 states that GSD shall not be required, and makes the sharing of GSD conditional upon the existence of an operational mechanism for access and benefits sharing agreed by States Parties. Lastly, one proposal at the end of paragraph 2

[1] Available at (https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health, accessed 20 January 2023).

[2] Available at (https://www.who.int/news/item/29-04-2022-quadripartite-memorandum-of-understanding-(mou)-signed-for-a-new-era-of-one-health-collaboration, accessed 20 January 2023).

[3] Available at (http://www.glews.net/, accessed 20 January 2023).

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	introduces an obligation for WHO to share information received under this paragraph with all States Parties within the context of research and for risk assessment purposes. ***Technical recommendation*** The Committee acknowledges the importance and rationale of rapid access to GSD, as in today's world such data becomes increasingly relevant for the rapid identification and characterization of pathogens and the development of response measures. The Committee also notes, as mentioned in several proposals for amendments, the need for all countries to access in an equitable manner the response measures developed during a public health event. The Committee therefore recommends that States Parties outline a coherent, principled, efficient and pragmatic multilateral mechanism for GSD and benefit-sharing. In this regard consideration should be given to coherence with the Nagoya Protocol to the Convention on Biological Diversity which many States Parties to the International Health Regulations (2005) are also parties to. The Committee also discussed the Pandemic Influenza Preparedness (PIP) Framework as an example of multilateral collaboration in this area.[1] Furthermore, a standardization of terminology may be warranted (e.g. genomic vs. genetic sequencing data; the Committee recommends the use of "genetic sequence data"). The grouping of amendments that mandate States Parties the sharing of GSD are generally appropriate, and the formulation "genetic sequence data if available" appears to be the clearest. However, the Committee notes that the sharing of GSD currently occurs through public databases which are not governed by WHO but are accessible to WHO. Also, GSD-sharing through these databases is not directly associated with States Parties (national authorities) as such. Regarding the proposed amendments to add additional information, notably "epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent", the Committee considers that this additional information request may impose an additional burden on reporting, and thereby hinder feasibility.

[1] Available at (https://apps.who.int/gb/pip/pdf_files/pandemic-influenza-preparedness-en.pdf, accessed 20 January 2023).

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	The proposal that makes the duty of sharing conditional upon availability, as well as prevailing national legal frameworks, may create challenges for States Parties during negotiations, whereby they must decide whether the obligation of sharing GSD is subject to no limits other than availability and national law. Finally, the proposal introducing an obligation of WHO to share with all States Parties information received under Article 6 in accordance with modalities to be adopted by the Health Assembly, and with the aim of fostering event-related research, raises questions of consistency with the scope and purpose of the Regulations. This is because the proposal limits the sharing of information to responding to, and assessment and research, in relation to a public health risk under Article 11. The Committee notes that, currently, the International Health Regulations (2005) is an instrument concerned with the international spread of disease and primarily its potential impact on travel and trade. However, the proposed text appears to promote research while simultaneously imposing a procedural requirement that may defer, delay or simply render this amendment obsolete. **D. Non-disclosure by WHO of notified information to parties engaged in conflict** ***Summary of proposed amendments*** The proposal in a new paragraph 3 prevents WHO from disclosing information notified under Article 6 to parties engaged in conflict. ***Technical recommendation*** This proposal lacks clarity as it is unclear what kinds of circumstances this provision is intended to address, and it also raises feasibility concerns. At a more fundamental level, this provision raises an inconsistency with the Principles of the Regulations as outlined in Article 3, in particular the "universal application" of the Regulations, irrespective of the role of the States Parties in other international spheres. In addition, as provided for by Article 11, it is not possible to exclude some States Parties from information exchanged by WHO.

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	E. Application of Article 45 to Article 6 ***Summary of proposed amendments*** Another new paragraph 3 proposes that provisions of Article 45 apply to notifications made pursuant to Article 6. ***Technical recommendation*** Although the proposed amendment is consistent with the Regulations, it is not necessary since Article 45 already applies to all flows of information between States Parties and WHO, and between States Parties alone.
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
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).	***Summary of proposed amendments*** The proposed amendment introduces the obligations of States Parties to make available to WHO, as appropriate, "microbial and genetic material and samples" related to the notified event and proposes that this is done in a timely manner. The State Party proposing this amendment noted that the proposed amendment is "without prejudice to further discussions and reflection on where to allocate this issue between the Regulations and the pandemic agreement". ***Technical recommendation*** The proposed amendment introduces a reference to "samples", which was not included in similar proposals to amend Article 6. The Committee notes that genetic material and samples are important for events that may constitute a PHEIC. However, requiring the sharing of samples and the transfer of genetic material to WHO may raise issues of the mandate, capabilities and liabilities of WHO. At the same time, the aspect of benefit sharing needs to be addressed in the light of provisions of the Convention on Biological Diversity and its Nagoya Protocol. The Committee considers the proposal to require the sharing of materials and samples "not later than (…) hours after such material and samples become available" to be impractical and possibly not feasible given legal requirements and logistics. Should this

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	proposal be retained, the Committee advises that a potentially more useful wording would be that such sharing should happen "as soon as possible". Given that most of the effect of this proposed amendment is provided for in Article 6, to which Article 7 already refers, it is largely duplicative and therefore largely redundant. If this proposed amendment is to proceed, consistent terminology should be used across all information types listed in Articles 6 and 7, including in relation to the issue of access and benefit sharing.
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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.	***Summary of proposed amendments*** The proposed amendments specify the circumstances in which consultation must occur and provide a time frame for the exchange of information. ***Technical recommendation*** The Committee notes that, as a practical matter, Article 8 is seldom explicitly applied. The proposed amendments render the operative term "may" in Article 8, into a "shall". In so doing, the provision may enhance clarity by creating a legal obligation with certainty. However, the Committee is of the view that this change transforms the current basis for an informal consultation into a compulsory consultation, but only in certain limited circumstances where there is insufficient information, thereby fundamentally changing the nature of Article 8, and may result in events which would otherwise be communicated to WHO not being brought to its attention by States Parties. The Committee is aware of situations where a State Party has considered using Article 8 for events for which there was sufficient information to complete the decision instrument, but the result was three "no" answers and one "yes" answer. This meant the event was not notifiable under Article 6, but none the less the State Party enjoyed the flexibility to exercise discretion as to whether to communicate it to WHO via Article 8. This flexibility may be beneficial for both the consulting State Party and WHO for situational awareness purposes.

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	In summary, the Committee recognizes that there is a grey area where a State Party may make an assessment with uncertain conclusions, but which nevertheless requires timely, accurate information during that stage. One way that States Parties may avoid limiting the information that leads to a consultation, is by changing "shall" to "should," and by omitting the rest of the amendments proposed to this Article.
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
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**	***Summary of proposed amendments*** One proposed amendment to paragraph 1 of this Article removes the obligation for WHO to consult and to verify the information with the State Party in whose territory the event allegedly occurs. The second proposed amendment for a new paragraph 3 introduces the possibility for WHO to advise States Parties on criteria and modes of processing and treating health information. ***Technical recommendation*** This Article and proposed amendments need to be read in conjunction with Articles 10 and 11 and the related proposed amendments. The presumed intention of the proposed amendment to paragraph 1 is to accelerate the risk assessment by WHO. However, WHO still requires accurate information in order to conduct its risk assessment. In removing the requirement for WHO to verify the information it has received from other reports with the State Party in which the event allegedly occurs may reduce the availability of relevant information for WHO's consideration and may also affect the relationship between WHO and the State Party. There may also be feasibility concerns, since without engaging with the State Party it may not be possible to obtain authoritative information about the event. One more issue that arises when removing consultations with States Parties is how to prevent negative consequences of disinformation and misinformation. A possible softening of the amendment may be to remove only the text about "... before taking any action", and in so doing offer WHO the ability to act on the basis of other reports where the situation is urgent and requires immediate action. A further issue not addressed in

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	the existing text or in the amendments relates to requirements for WHO to take reasonable steps to protect the confidentiality of its source(s). The second amendment lacks clarity as to exactly what is being proposed, for example, the nature of recommendations is unclear and presumably it applies to information related to paragraph 2, rather than verification under paragraph 1. In addition, the reference to WHO using guidelines for the handling of health information is feasible, but probably unnecessary, as WHO will refer to these guidelines as appropriate to the circumstances.
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
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	***Summary of proposed amendments*** The 11 proposed amendments specify time frames for WHO to request verification of an event from States Parties, and propose changes related to the obligations of both WHO and States Parties in relation to the offer of collaboration, inter alia, obligations of States Parties to accept or decline such offers of collaboration and to justify any rejections thereof. ***Technical recommendation*** The intent of the proposed amendments appears to be to put further parameters around the event verification process, in particular to encourage more timely information exchanges between both WHO and States Parties in relation to the verification of events. However, some of the amendments are too detailed and prescriptive and would mean unnecessary increased workloads both for States Parties and for WHO. WHO receives many reports and monitors many events and public health risks simultaneously. Introducing an obligation for WHO to offer to collaborate with the State Party for every instance within 24 hours may be unrealistic and would not be compatible with the time frame for States Parties to respond to WHO, as set out in paragraphs 2.(a) and 2.(b). The alternative formulation of "as soon as possible" may be preferable. Conversely, many events and public health risks are within the capacity of States Parties to address themselves and collaboration may simply not be required.

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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.~~	In paragraph 2, the reference to Article 9 should not be deleted, as this provision also supports verification processes. In new paragraph 3 bis, the 24/48-hour time frames are likely to be unrealistic as in many instances a State Party may need to go through several steps in order to consider, get sign-off at appropriate levels of government, and respond to an offer of collaboration. Factors including governance of the subnational level/s and intersectoral considerations, as well as the evolving nature of the event and new information about response priorities, may also make short time frames impractical. One of the proposed amendments to paragraph 4, while still qualified by the "... when justified by the magnitude of the public health risk", removes the discretion (changing "may" to "shall") for WHO to share information with other States Parties, and in so doing, reduces flexibility for WHO to take account of the wider circumstances. The amendment removing the requirement for WHO to take account of the views of the States Parties in whose territory the event is occurring may speed the process up, but potentially at the expense of long-term trust between WHO and States Parties. Overall, the amendments are clear and are intended to promote transparency and the timely exchange of information and assistance in acting upon an event that constitute a PHEIC. However, there may be unintended negative consequences, such as the hindrance of good faith collaboration and trust, which make many of the amendments unfeasible. This includes the proposals to impose prescriptive time frames for making and considering offers of assistance, the consequences of not accepting offers of collaboration, and removing the requirement to take account of the views of the State/s Party/ies in whose territory/ies the event is occurring. Verification is a technical process and should be separate from "take it or leave it" requirements for the consideration of offers of collaboration. Many of the amendments have the net effect of making this Article punitive in nature rather than genuinely collaborative, and this may be counterproductive.

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PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
Article 11 Provision of information by WHO	
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	***Summary of proposed amendments*** One proposed amendment to the title of Article 11 places emphasis on the exchange, rather than just provision, of information. The proposed amendments to paragraphs 1 and 2 would enlarge the scope of event-related information that WHO is required to share with States Parties and would include information that is available in the public domain, whose "validity" is supposed to be "appropriately assessed" by WHO. Some of the proposed amendments aim at increasing the exchange of information between States Parties, including by requiring WHO to facilitate this exchange via the Event Information Site platform, and one amendment to paragraph 2 places the responsibility on WHO to determine the necessity of sharing the information to support States Parties' risk assessments. One amendment in paragraph 1 proposes to replace the current reference to relevant "intergovernmental" organizations as recipients of information from WHO, with "international and regional" organizations, and one amendment proposes to add "United Nations" organizations. A new paragraph 3 proposes to ensure that information is only exchanged and used for peaceful purposes and limits the handling of information to entities not engaged in conflict. The two proposals for a new paragraph 5 introduce similar amendments that would require specific reporting on activities under this Article. ***Technical recommendation*** In relation to the proposal to replace the current title, the Committee considers that the current title adequately covers the content of the Article and the proposed amendments, should they be accepted. The proposed amendments are generally consistent with the intended aim of Article 11, in as much as they mostly aim at increasing the flow of information from WHO to and among States Parties. The reversal in the first sentence of paragraph 2 of a negative to a positive obligation for WHO, in particular, signals that the default position would be

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(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.	sharing information rather than holding it in confidence; this is strengthened by the replacement in paragraph 3 of an obligation to consult the State Party concerned with an obligation to simply inform it. The Committee notes the qualifier proposed by one amendment in paragraph 1 to the effect that WHO will assess the validity of available information before sharing it; this seems an important safeguard considering the amount of unverified information available through the internet and social media. Regarding the two overlapping proposals for a new paragraph 5, the language proposed is generally clear. The Committee is of the view that it is important to frame WHO's reporting requirements to the Health Assembly under Article 54 and not to limit its application to the possible occurrence of a PHEIC, which may complicate the assessment by WHO. The Committee is also of the view that it is preferable to avoid references that are too detailed as they may become obsolete in the future. In this case with regard to the reference to the Event Information Site in paragraph 1, the Committee suggests using the following formulation: "For this purpose, WHO shall facilitate the exchange of information between States Parties and ensure a secure and reliable platform (...)", without mentioning the name of the current platform, which may change in the future. Some of the proposed amendments are tied to those proposed to Article 10 with the purpose of strengthening the obligation of States Parties to verify, assess and communicate events and WHO's function to inform States Parties of situations warranting public health measures. New paragraph 5 is also linked consistently to the goal of strengthening accountability revealed by the proposed amendments to Articles 53 and 54. The reference in paragraph 2 (a) to public health emergency of regional concern and intermediate public health alert is relevant only if the related proposed amendments to Article 12 are accepted. The requirement in proposed new paragraph 5 for WHO to report to the Health Assembly "on all activities under this Article" would be an unrealistic requirement in terms of resource implications and the volume of information. The Committee is of the view that WHO should enjoy some flexibility in assessing the importance of information to report under this paragraph. The reference to "interoperability with relevant data information system" in the amendment to paragraph 2 raises the cross-cutting issue of ensuring the relevance of the

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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.**	Regulations in the light of evolving technological developments, as well as the feasibility of introducing specific requirements in the light of their resource implications for many States Parties. Similar references appear in other proposed amendments, including digitized data, for example, to Articles 35 and 36 as well as Annex 6, and would benefit from a general discussion by States Parties about the role of WHO in the harmonization of data sharing. Overall, the proposed amendments pursue the important goal of increasing and strengthening WHO's role as a purveyor of public health information, increasing transparency including to the public, and encouraging and facilitating the direct exchange of such information among States Parties. They would also increase WHO's accountability for complying with obligations to verify information through reporting to the Health Assembly.
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
Article 12 Determination of a public health emergency of international concern	
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	**A. Potential PHEIC, public health emergency of regional concern or intermediate level of alert** ***Summary of proposed amendments*** The proposed amendment to the title introduces the concepts of a public health emergency of "regional concern" and an "intermediate health alert". A proposed amendment to paragraph 2 introduces the concept of a "potential or actual" PHEIC. Several proposals for a new paragraph 6 introduce provisions related to the possibility of the Director-General determining a public health emergency of regional concern or an intermediate level of alert (one proposal referring specifically to a recommendation of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response to issue a World Alert and Response Notice), or a regional level of alert, as well as provisions for the Director-General to report to the Health Assembly on actions taken following the determination of a PHEIC. Several proposals for a new paragraph 7 introduce the possibility of a Regional Director determining whether an event constitutes a public health emergency of regional

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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	concern, "either before or after the notification of the event", to provide related guidance for the region, and an obligation for the Director-General to inform all States Parties. ***Technical recommendation*** In relation to a "potential PHEIC", the Committee understands the motivation to improve alerting, but it is unclear what criteria would inform the assessment of such a potential PHEIC. The Committee notes that the definition of a PHEIC, as per Article 1, is "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease; and (ii) to potentially require a coordinated international response". Therefore, the potentiality is already embedded in the definition of a PHEIC. The Committee also notes that the advance notice the Director-General gives to States Parties about his convening of the Emergency Committee in relation to such an event may effectively serve the same purpose. In relation to with "intermediate level of alert" or "intermediate health alert" or "intermediate PHEIC" the Committee is of the view that an intermediate alert may give the Director-General more tools for bringing acute events to the attention of States Parties. However, there is limited or mixed evidence from other intermediate emergency alert mechanisms, or scalar alert mechanisms in other spheres of emergency governance, whether such an introduction would improve engagement and response from States Parties.[1] Given that WHO already provides ongoing/updated advice on "public health risks" and events through the Event Information Site, this in effect fulfils the function of an intermediate alert. Furthermore, either determination may be challenging to communicate publicly, as something more than a public health risk, or an event, but less than a PHEIC, although they may become one. If the concept of an "intermediate alert" is to be pursued, the Committee notes the terminology of a World Alert and Response Notice (WARN) as

[1] Wenham, C., Kavanagh, M., Phelan, A., Rushton, S., Voss, M., Halabi, S. et al. Problems with traffic light approaches to public health emergencies of international concern. The Lancet, 2021; 397(10287), 1856-1858.

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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**	proposed by the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response and recommends in any case that a clear terminology must be defined for such an alert in Article 1. In relation to proposals for "regional public health emergencies", the Committee notes that the WHO regions are not geographically coherent with regions used by other international organizations and entities and may therefore not be directly relevant for event management. One proposal adopts the same procedures for the determination of a regional public health emergency as those provided for the determination of a PHEIC , while the other sets out no criteria or process. Neither proposal provides for any consequences of such a regional emergency, other than the issuing of guidance. The Committee notes that WHO is already empowered through its Constitution to issue guidance on any matter within its competence, so this proposal adds little to current mandates. As the existing Article 12 provisions for a PHEIC can be, and have been, used for events of regional significance (Ebola virus disease and Zika virus) it is unclear what, if any, additional benefit these proposals provide, while potentially leading to greater fragmentation of response mechanisms. The Committee is aware of initiatives within other institutions to declare regional health emergencies, and the WGIHR should consider how such mechanisms may complement or challenge the functioning of the PHEIC more broadly.[1] **B. Consultation with States Parties and convening the Emergency Committee** ***Summary of proposed amendments*** Proposed amendments to paragraph 2 remove the obligation of the Director-General to consult with the State Party in whose territory the event occurs and the obligation to convene an Emergency Committee. The proposal to delete paragraph 3 further removes the condition of consensus within 48 hours between the Director-General and the State Party in whose territory the event arises regarding the PHEIC status before convening the Emergency Committee.

[1] An example is the Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health, 2022 (available at: https://eur-lex.europa.eu/eli/reg/2022/2371/oj, accessed 23 January 2023).

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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**	One proposed amendment to paragraph 4 introduces the obligation of the Director-General to consider additional information submitted by other States Parties or available in the public domain or otherwise available under Articles 5–10. ***Technical recommendation*** Proposed amendments in paragraph 2 dilute the consultation requirements with the State Party in whose territory the event occurs, by removing the obligation of the Director-General to convene an Emergency Committee, and by removing the agreement between the Director-General and the State Party. It is unclear what the purpose is of the proposed amendments to eliminate the consultation with the State Party in whose territory the event occurs, since under the provisions of Article 48 these States Parties are required to have one representative among the members of the Emergency Committee. Excluding this consultative step can result in sovereignty concerns from the State Party in whose territory the event occurs. The proposal in paragraph 4 to include "other States Parties" in the consultation process with the Director-General when considering whether an event constitutes a PHEIC raises the issue of which States Parties can be counted as "other". In most pre-PHEIC situations several countries may be exposed. Moreover, consultations with multiple States Parties take resources and time and could delay the process of determining a PHEIC and response measures. One set of proposed amendments removes the distinction between whether or not the affected State Party agrees with the Director-General's preliminary assessment that an event constitutes a PHEIC. This would likely have the effect of speeding up the process and enhancing the authority of the Director-General to make such a determination. One interpretation of this proposed amendment is that it may also remove the opportunity for the Emergency Committee to advise the Director-General as to whether or not the event constitutes a PHEC (as well as providing advice on proposed temporary recommendations). At present, this aspect of the Emergency Committee's role can be activated by the State Party in whose territory the event occurs via paragraph 3 of this Article. In addition, WHO, only having to "seek to consult" with the affected State Party, makes for a weaker, but probably quicker, process, and means that WHO is not delayed if the affected State Party is unresponsive.

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<u>health emergency of regional concern, the Director-General shall inform all States Parties.</u>	Deleting this paragraph could be seen to leave the Emergency Committee only with the role of advising the Director-General on "appropriate temporary recommendations". In this respect the removal of paragraph 3 should not dilute the role of the Emergency Committee. The Committee is of the view that paragraph 4 still applies, irrespective of the proposed removal of paragraph 3, since paragraph 4 specifies the elements that the Director-General must consider in determining whether an event constitutes a PHEIC, and these elements also include the advice of the Emergency Committee. Therefore, the Committee sees little change to the current provisions and their application since even if the proposal is approved, the Emergency Committee will still have an important role in the determination of a PHEIC. The Committee advises, however, that it is not necessary to strike out paragraph 3. **C. Termination of a PHEIC** ***Summary of proposed amendments*** Proposed amendments to paragraph 5 related to ending the PHEIC introduce the step of consultation with "relevant States Parties", and one other proposed amendment introduces the possibility for the Director-General to convene a review committee to advise on issuing standing recommendations after the termination of a PHEIC. ***Technical recommendation*** The proposal seems confusing since the Director-General currently has an obligation to convene the Emergency Committee to seek its advice in relation to the termination of a PHEIC. In addition, removing the requirement to consult with just the originating State Party and replacing it with the broader formulation of "relevant States Parties" may potentially bring many more States Parties into the picture and in so doing confuse and delay proceedings. The meaning of "relevant" is also unclear, as it could mean either all other States Parties with cases, and/or neighbouring States Parties, and/or States Parties with direct flights, and/or any other range of relevant considerations. The Committee is of the view that convening a review committee to consult on potential standing recommendations could be an option for events that still require a coordinated response but may not meet the rest of the criteria for a PHEIC. Such considerations have been contemplated, albeit not yet acted upon, in relation to the PHEICs involving poliomyelitis and COVID–19.

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	D. PHEIC as trigger to mobilize funds ***Summary of proposed amendment*** A new proposed paragraph 4bis specifies that the determination of a PHEIC is not designed to mobilize funds and proposes that the Director-General should use another mechanism for this purpose. ***Technical recommendation*** The Committee understands that the determination or continuation of a PHEIC should be based on the criteria outlined in Article 1 in the definition of a PHEIC, and on the elements outlined in paragraph 4 of this Article. As such, the need to mobilize funds does not seem to constitute a criterion for determination of the PHEIC, and therefore the proposed amendment seems unnecessary. However, as the determination of a PHEIC is supposed to be a call to arms for greater alert and response, it would be useful for relevant financing mechanisms within the global health architecture to be more engaged in the determination process, so as to adequately support the international response coordinated by WHO when it is most needed. **E. Reporting and engagement with non-State actors** ***Summary of proposed amendments*** Two similar proposals for a new paragraph 6 introduce an obligation for the Director-General to report on all activities carried out by WHO in relation to the PHEIC, while one of them also proposes that WHO activities in relation to the PHEIC must be in accordance with the provisions of the International Health Regulations (2005). One other proposed new paragraph 7 introduces an obligation for WHO to follow provisions of the Framework of Engagement with Non-State Actors. ***Technical recommendation*** The proposals for WHO's activities to be in accordance with the provisions of the Regulations is tautological, as this would apply anyway. Requiring the Director-General to report "... all the activities carried out by WHO" under Article 54 is not feasible as it would create a significant reporting burden and require additional resourcing for WHO. The proposal to require WHO to follow the provisions of the Framework of Engagement with Non-State Actors is understandable, but also tautological as WHO must use this Framework anyway.

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PART II – INFORMATION AND PUBLIC HEALTH RESPONSE	
Article 13 Public health response	
Paragraphs 1, 2 and 2bis	
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**	***Summary of proposed amendments*** One proposed amendment to paragraph 1 introduces an obligation for developed States Parties and WHO to offer assistance to developing States Parties for the full implementation of this Article, in pursuance of Article 44. In paragraph 2, one proposal replaces the Director-General's obligation to make a decision regarding extensions for establishing core capacities not exceeding two years, with an obligation to refer this issue to the Health Assembly for its decision. A new paragraph 2bis proposes an obligation for WHO to provide to States Parties "standardized forms" to support collaboration under Article 44.1(a). ***Technical recommendation*** The proposal in paragraph 1 would impose a new obligation on developed States Parties to offer assistance. Notwithstanding the caveat of "(...) depending on the availability of (...)", high- or even middle-income countries may also have concerns about such an open-ended obligation, which may imply that all developed States Parties must offer assistance to all developing States Parties. With regard to the proposal in paragraph 2, this would reduce the autonomy of the Director-General and hold any future States Parties requesting such second extensions to a different decision-making process than the original cohort of requestors. It may also delay and complicate the process for the requesting States Parties. It is both feasible and constructive for WHO to develop standardized forms to support collaboration under Article 44.1(a) for areas such as diagnostics and sharing of biological samples, surveillance, contact tracing, and conveyances. However, it may be less feasible for other, more complex forms of collaboration. The Committee notes that, for more complex matters the use of model memoranda of understanding may constitute more suitable alternatives. The Committee recommends that States Parties consider the new paragraph 2bis and other proposals, aimed at strengthening collaboration, together with other proposed amendments to Article 44.

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Article 44 to facilitate State Parties' mutual collaboration essential for the effective implementation of public health response.[1]	
Paragraph 3	
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.**	***Summary of proposed amendments*** One proposal removes the condition "at the request of a State Party" for WHO to collaborate in the response to public health risks; two proposals seek to replace WHO's obligation to "collaborate" with a different wording – either "articulate clear assistance" or "offer assistance" to a State Party. One proposal specifies that in addition to providing technical guidance, WHO is also required to provide "health products, technologies, know-how, deployment of civil medical personals". Another proposal adds the obligation for WHO, if required, to also collaborate "in seeking support and international financial assistance to facilitate the containment of the risk at source". One proposal introduces an obligation for the State Party to accept or reject the offer of assistance from WHO within 48 hours, and if the offer is rejected, the obligation for the State Party to provide to WHO the rationale for rejection. One last proposal introduces the obligation for WHO to share the requests of assistance which WHO cannot meet, although it does not specify with whom. ***Technical recommendation*** The obligation for States Parties to accept or justify rejecting WHO's offer of assistance may undermine the sovereignty of the State Party concerned and risks undermining the purpose and spirit of genuine collaboration and assistance. It is the prerogative of States Parties to request or accept assistance, not to be the recipient of unsolicited offers, accompanied by an obligation to justify the refusal and an unrealistic time frame in which to respond. Furthermore, the proposal that WHO share the rationale for rejection, while intended to promote transparency, may not be conducive to an atmosphere that fosters collaboration. It could be interpreted as a default approach of mistrust to States Parties that reject offers of assistance.

[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.**

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	Receiving, considering and then deciding whether to accept or reject an offer of assistance (including developing a rationale for rejection) particularly for such a consequential offer, within 48 hours, would likely be challenging for many States Parties. Requiring WHO to make such offers for all public health risks, which arise frequently, will create a significant and unpredictable additional workload for WHO. In many instances States Parties do not necessarily need assistance from WHO. Additionally, deleting the word "collaboration" and replacing it with "assistance" or offer of assistance, removes the flexibility provided by the concept of collaboration, which is a much broader term that may or may not include assistance. The proposal that, if requested by a State Party, WHO shall cooperate to seek financial assistance seems feasible and constructive but is limited only to actions to contain the risk at its source, which would preclude such assistance being for other reasons which may be relevant to the event at hand.
Paragraphs 4 and 5	
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**	***Summary of proposed amendments*** One proposed amendment to paragraph 4 reiterates the change proposed in paragraph 3 from what is currently only the possibility for WHO to collaborate during a PHEIC to an obligation (by replacing the word "should" with "shall"). Another proposal repeats the same amendment proposed in paragraph 3 regarding the obligation of States Parties to accept or reject offers of assistance from WHO. In addition, another proposed amendment introduces an obligation for States Parties to "facilitate short-term access" (presumably to WHO) for on-site risk assessments, and if access is denied, an obligation to provide a rationale for this denial. Paragraph 5 includes a similar proposal as in paragraph 3, replacing the current possibility with an obligation of States Parties to provide support to response activities coordinated by WHO, by replacing the word "should" with the word "shall". Another proposal further specifies that the support to WHO should include the supply of health products, personal protective equipment, vaccines and therapeutics for a PHEIC occurring in another State Party's jurisdiction, as well as capacity-building for incident management systems and for rapid response teams. If States Parties are unable to provide this support, they are obliged to inform WHO and provide the rationale for this;

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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. (…)	and this rationale is to be included in the annual report on implementation under Article 54. ***Technical recommendation*** Regarding the proposal in Paragraph 4 to change "WHO may offer ... further assistance" to "shall offer", the Committee believes there is a case to be made for retaining discretion for WHO to offer such assistance. Even in the event of a PHEIC, a State Party may not automatically require further offers of assistance. Subsequent amendments reiterate the requirement for the State Party to accept or reject the offer within 48 hours, including a rationale for rejection, to be shared by WHO with other States Parties. The same comments as in paragraph 3 apply to this amendment as well. The proposal regarding on-site assessments would support transparency and risk assessment. The majority of the Committee considers this amendment to be clear and feasible, in particular given that the requirement for on-site assessments must be in compliance with a State Party's national law. However, some Committee members also consider that this amendment poses challenges for the sovereignty of States Parties. The Committee recommends considering an alternative formulation by replacing "shall" with "should". The proposal to change the existing requirement that States Parties "should [when requested by WHO] to the extent possible, support WHO-coordinated response activities" to "shall" arguably improves the clarity of the expectation, in effect, removing any hint of discretion and making it mandatory. The two amendments adding a non-exhaustive list of health products that such support might include also improves clarity but may move the provision in the direction of excessive detail. One is limited only to PHEICs occurring in another State Party's jurisdiction, which may limit its applicability, and its rationale is not self-evident. The other is arguably the more feasible of the two as it has no such limitations. The amendment concerning States Parties "unable to fulfil such requests" would potentially incentivize the provision of support and associated transparency, but conversely may also make WHO less likely to request such support, mindful of the possible adverse consequences for the State Party so requested.

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Paragraph 7	
<u>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.</u> **<u>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.</u>**	***Summary of proposed amendments*** One proposed new paragraph 7 adds that response measures implemented by States Parties to a PHEIC must not compromise the ability of other States Parties to respond, and if they do, the affected State Party may consult the State Party concerned to find a solution. The other new paragraph 7 reiterates the proposal in Article 12 regarding WHO's obligation to follow the provisions in the Framework of Engagement with Non-State Actors in its response to a PHEIC. ***Technical recommendation*** The proposed paragraph regarding a formal avenue for States Parties adversely affected by the response measures of another State Party is both clear and feasible – it only creates a right to consult. If invoked, but the "consultation" is unsuccessful, it could be a precursor to invoking Article 56 (Settlement of disputes). In the Committee's view this proposal might be better located in Article 43, as it relates to additional measures. Furthermore, Article 56 could be amended to cross refer to this and/or vice versa. The other proposed new paragraph 7 is arguably unnecessary because WHO must use the Framework of Engagement with Non-State Actors irrespective of the Regulations. In addition, incorporating the Framework by reference in this way lacks flexibility should it subsequently be amended or replaced by a new policy.
NEW Article 13A WHO Led International Public Health Response	
See text of the proposed article below	***Summary of proposed amendments*** This proposed new Article seeks, among other things, to (re)iterate the leading role of WHO in the public health response (as per the title). The Article goes further, however, in attributing to WHO several obligations that it does not currently have under the International Health Regulations (2005), including: to conduct an assessment of availability and affordability of "health products"; to develop an allocation and prioritization plan in the event that such an assessment reveals shortages in supply; and to direct States Parties to increase and diversify production and distributive functions for health products within individual States.

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	The Article further mandates WHO to establish a database "containing details of the ingredients, design, know-how, and manufacturing process or any other information required to facilitate manufacturing of health products" required to respond to potential PHEICs, and to maintain the database for all past PHEICs, as well as diseases identified in the International Health Regulations (1969). The final paragraph emphasizes the importance of compliance with WHO's Framework of Engagement with Non-State Actors. ***Technical recommendation*** At the outset, the Committee notes that much of this proposed new Article is aligned with the spirit of proposed amendments in the other proposed new Article 13A. This proposal covers multiple distinct themes/topics which may be more clearly and appropriately addressed in separate Articles. The emphasis on WHO's leading role in the public health response while appropriate, may not be necessary, as this understanding is already embedded in both the Regulations and in the WHO Constitution. This proposal also renders mandatory the temporary and standing recommendations addressed under Articles 15 and 16. The State Party making this proposal has also provided corresponding proposals to change the definitions of temporary and standing recommendations under Article 1 to render them coherent with new proposals in paragraph 1 of this proposal for a new Article 13A. More fundamentally, it remains unclear how WHO could discharge the unprecedented set of new responsibilities attributed to it relating to health products and know-how under this proposed amendment, as these may arguably exceed its constitutional mandate. In order to be legally feasible, this amendment will require coherence with States Parties' relevant national laws and other international obligations. Further clarity on mechanisms of action and the duties of States Parties in relation to WHO's new obligations, as described below, may help to strengthen this proposed amendment. To render the obligation clearer, States Parties may wish to consider the amendment's time-limited scope, which takes effect after the determination of a PHEIC.
Title and paragraph 1 – WHO's leading role in public health response	
NEW Article 13A WHO Led International Public Health Response	The proposed title of this amendment, "WHO Led International Public Health Response," may not reflect the content in other paragraphs that accompany this Article,

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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.	which deal with a host of health product distribution and manufacturing matters that appear in other proposed amendments. The title of the other proposal for a new Article 13A ("Access to Health Products, Technologies and Know-How") is more appropriate and in line with the spirit of paragraphs that follow. Paragraph 1 is somewhat thematically repetitive of existing provisions in other instruments/resolutions (e.g. the emphasis on WHO's role in the international public health response draws, inter alia, from WHO's constitutional mandate under Article 2 and resolution WHA58.3 (2005)). It may therefore be unnecessary. Finally, it is unclear whether reference to "WHO's recommendations" in this paragraph refers to WHO's authority to issue non-binding recommendations under Articles 15 and 16, or whether other forms of recommendations are envisioned. If indeed recommendations under Articles 15 and 16 are the targets of this addition in paragraph 1, the addition would be incoherent with the existing Regulations, as it would render these recommendations mandatory, whereas they were intended to be non-binding. The Committee notes that the same State Party that proposed this new Article, has also put forward amendments to the definitions of temporary and standing recommendations, which propose removing the reference to "non-binding" in these definitions. If read in conjunction with this newly proposed Article, the proposed amendments to remove "non-binding" could be seen as a desire to make the temporary and standing recommendations binding, and therefore legally coherent with Article 13A, paragraph 1. Similar to this proposal, paragraph 1 in the other proposal for a new Article 13A also makes explicit reference to Articles 15 and 16, and paragraph 2 creates a mandatory obligation on States to cooperate according to Articles 15 and 16. But this other proposal for a new Article 13A does not seem to be linked to corresponding proposals to change the definitions of temporary or standing recommendations under Article 1. Irrespective of legal coherence, changing temporary and standing recommendations into binding obligations may raise questions of feasibility. At this moment it is still unclear how to assess "compliance" with temporary recommendations issued during PHEICs, since they are defined as non-binding advice. No standing recommendations have ever been issued under the Regulations. To mitigate this feasibility concern, States Parties may wish to adopt the proposed alternate language of "use best endeavours" or maintain the original language "undertake to follow".

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Paragraphs 2 to 5 – Health products and technologies	
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.**	The Committee notes that this proposed set of amendments are part of a package of proposed amendments to Articles 2 and 3, aiming to enhance coherence between this provision and the rest of the Regulations. In addition, other proposed amendments to Article 44 and the addition of a new Article 44A are also coherent with the spirit of this proposal. Several States Parties have proposed a definition for "health products" or "know-how" to be included in Article 1.
Paragraph 6 – Database of health product ingredients, know-how etc.	
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.	The proposed mandate for WHO to 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" may be helpful but would require additional resourcing from States Parties to WHO. It remains unclear from this paragraph which entities would help WHO populate this database,

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	given that much of the information called for in this database is not in the public domain but rather privately held by entities operating within States Parties. Presumably, WHO would need the help of States Parties to render this database operational, but there is no corresponding obligation on States Parties to help WHO in this regard. In that same vein, the effectiveness of such a database would be limited by the various laws and agreements that govern proprietary commercial data and patents, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and domestic intellectual property laws of individual States. A possible softening of this amendment may be to limit this provision to the extent allowed by "States Parties' relevant national laws and obligations under international law". It remains unclear whether such a database would be publicly accessible, or available only to States Parties.
Paragraph 7 – Non-State actors	
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.	The mention of the Framework of Engagement with Non-State Actors in paragraph 7 is also partially redundant, given that WHO must in any case abide by it. A minor point of clarity is that the first sentence in this paragraph is missing a "subject" (that is, WHO, States Parties, or both, or others?). The concern regarding the oversight of non-State actors also appears in the proposed amendments to Article 42. The latter amendment may more efficiently capture the spirit and intention of paragraph 7 while avoiding the redundancy of mentioning the Framework of Engagement with Non-State Actors, a policy instrument subject to more frequent, periodic revision (and potential replacement) by the Health Assembly. In conclusion, the two proposals for a new Article 13A are similar, but a distinction between the provisions is that one proposal is explicitly operationalized upon determination of a PHEIC, consequently limiting the circumstances under which WHO authorities may take effect. Questions of feasibility and appropriateness are inevitable in both proposals, as they introduce unprecedented obligations, as well as powers for WHO to direct States and non-State actors. For instance, the new functions for WHO to "assess availability and affordability" may be impractical. Noting that "affordability" is a relative and much more complex concept than "cost", these proposals effectively give WHO the authority to instruct States to "undertake to scale up production" of health

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	products and to supply the requisite health products according to an "allocation plan". It is not readily apparent whether States could be in a position to do so, without altering their domestic regulation of private actors operating in their territory. The Committee notes that the spirit of these Articles may be driven by the recent experience of WHO's coordinating role in the Access to COVID-19 Tools (ACT) Accelerator and more specifically the COVAX facility, under which WHO acted, in concert with other intergovernmental and international bodies, to allocate vaccines, diagnostics and therapeutics in accordance with a set of prioritization criteria. Nevertheless, the COVAX facility remained a voluntary mechanism, and States pooled funds into the mechanism to enable it to procure health products from non-State actors, rather than obliging States to direct non-State actors within their jurisdiction to scale up production.
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**	***Summary of proposed amendments*** This proposed new Article addresses a range of considerations pertaining to the availability and affordability of health products, technologies and know-how. It goes further than the other proposed new Article 13A WHO-led international public health response in that it imposes obligations on States Parties as well as on WHO and it introduces a more robust final paragraph concerning the role and regulation of non-State actors. ***Technical recommendation*** This proposed new Article would benefit from clarity and consistency in the use of terms that connote health products and know-how. WHO recommendations, as currently stated under Articles 15 and 16, were not envisioned for the purposes of establishing a medicines allocation mechanism or otherwise directing States Parties on increasing access to health products. Should such functions be contemplated for temporary and/or standing recommendations, additional amendments will be needed for the definitions of these recommendations under Articles 1, 15 and 16. A high degree of specificity in functions accorded to WHO and States Parties in enhancing the availability and accessibility of health products and technologies, as well as the regulation of such goods, will require careful consideration regarding feasibility and

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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,**	appropriateness, as well as consistency with the scope of the Regulations and with other international and domestic legal frameworks. In relation to paragraph 1, the Committee recognizes the critical importance of ensuring that health products are affordable and available to every State Party. However, the requirement in paragraph 1 for the Director-General to make an "immediate assessment of availability and affordability of required health products" may not be feasible due to the magnitude of such a list implied by the proposed amendment and the very high workload imposed on WHO during the initial stages of determining a PHEIC . As with the other proposed new Article 13A, further clarity is needed from this provision in order to fully understand what is meant by "availability and affordability." These terms are relative and complex under international law and warrant further consideration. The Committee notes the proposals for adding definitions under Article 1 for "health products" and "health technologies and know-how", but within this new Article, slightly different variations of the terms are used: "health products and technologies," "health products," "health products or technologies," "technologies, know-how" and so on. To enhance clarity and consistency, the Committee recommends that one or two expressions be clearly defined in Article 1 and used throughout the amendments, should they be adopted. The Committee has concerns regarding the proposal in paragraph 1 to use Article 15 (temporary recommendations) for the purposes of establishing an "allocation mechanism." Temporary recommendations, as defined under Article 1, are "non-binding advice and do not authorize WHO to direct States. Temporary recommendations may also be "risk-specific", that is, individualized to areas or States with particular risk profiles. A different mode of authority may be required to establish an allocation mechanism. The Committee notes that the proposed amendment to Article 17 may be more feasible, as it requires WHO to take into account "equitable access to and distribution of medical countermeasures i.e. vaccines, therapeutics and diagnostics for optimal public health response" when issuing, modifying or terminating temporary or standing recommendations. The proposed mandatory nature of temporary recommendations for the purposes envisaged in paragraphs 1 and 2 are addressed in greater detail in the technical recommendations for the proposed new Article 13A WHO-led international public heath response.

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(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.**	Paragraphs 2 to 6 concern a set of measures that States Parties must take with the aim of rendering health products available and affordable. The Committee noted that many of the proposed amendments to this Article contain a great variety of measures, and recommends that further specificity be developed to clarify the intent. Paragraph 2 requires States Parties to cooperate with each other and with WHO to comply with any Article 15 or 16 recommendations to ensure the availability and affordability of health products needed for the response to a PHEIC. It is unclear to the Committee what it means to comply with non-binding recommendations as per Articles 15 or 16. Paragraph 4 may be helpful as it requires States to simply "take measures" to ensure affordability and availability. However, the Committee questions the feasibility of this obligation in the early phases of a PHEIC when information is either limited, incomplete or uncertain. The Committee notes that additional domestic legislation might need to be developed if the requested information is the property of private parties. The intention is good but in practice due to little information may not be feasible. The Committee acknowledges the importance and spirit of paragraph 3, which requires States Parties to impose exemptions and limitations on the exclusive rights of intellectual property holders in order to facilitate the manufacturing, export and import of health products. Some exemptions and limitations may not be out of harmony with existing flexibilities within the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights[1] and the decisions taken by WTO Member States, such as the Doha Declaration on the TRIPS Agreement and Public Health,[2] but justifying such flexibilities is a complex matter and may depend on the context. A threshold question is whether intellectual property matters should be addressed in the text of the Regulations or left for WTO discussions or other instruments. Similar concerns apply to paragraph 4, although this paragraph may also require standardized agreements from the beginning of the research pipeline for publicly funded health products to facilitate the arrangements proposed.

[1] WTO website (https://www.wto.org/english/tratop_e/trips_e/trips_e.htm, accessed 20 January 2023).

[2] WTO website (https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, accessed 20 January 2023).

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	Paragraph 5 presents significant challenges relating to the publication of manufacturers' regulatory dossiers, the contents of which are almost always secret, proprietary company data. Far greater clarity is required to enhance understanding of how this provision may be operationalized. Paragraph 6 introduces obligations on WHO to "take measures" to ensure the availability and accessibility "through local production" of "required health products." Yet at a preliminary level, it is not clear what these health products must be required for. Presumably, they are for a PHEIC, but this point could be made more clearly. The same comment applies to paragraph 6(a). More fundamentally, however, it is not clear what is meant in paragraph 6(b) by "specifications" for the production of these required health products, or "appropriate regulatory guidelines for the rapid approval of health products of quality" under 6(c). It may be inadvisable from a legal perspective to require that WHO develops such regulatory guidelines, as the liability in the event of a significant safety flaw that appears post-marketing of the product will then fall chiefly on the Organization. The requirement for WHO to develop a database of raw materials and suppliers (6(d)) raises feasibility concerns as there may be an endless list of raw materials and suppliers and it is unclear for whom WHO would be developing such a list. Similar concerns also arise with 6(f). Finally, it remains unclear whether a new 6(f) is needed, given that WHO will, in any case, regularly review the WHO Listed Authorities[1] so as to facilitate regulatory approvals. Moreover, as a policy initiative, the WHO Listed Authorities may be subject to name and other changes over a more frequent time period than future possible amendments to the Regulations. Paragraph 7 raises the same concerns as above regarding feasibility and appropriateness. Elsewhere, the Committee has noted that it may be possible to require States Parties to take measures to regulate non-State actors (e.g. the proposal for amendments to Article 42). However, it remains uncertain whether regulation of non-State actors can be feasibly carried out to cover the minutiae of details within this proposed amendment under the domestic context of individual States Parties.

[1] Available at: https://www.who.int/initiatives/who-listed-authority-reg-authorities, accessed 20 January 2023.

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Part III RECOMMENDATIONS	
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:**	***Summary of proposed amendments*** The six proposed amendments include, inter alia: • a proposal in paragraph 1 to expand the circumstances in which temporary recommendations can be issued to include an event that has the potential to become a PHEIC; • proposals in paragraphs 2 and in a new paragraph 2bis to include more details and prescriptions concerning the quality and content of the temporary recommendations. This includes a proposed addition to encourage temporary recommendations that are evidence-based, operational and based on real time risk assessment and that refer to existing guidance and international technical standards; • the possibility to include in the temporary recommendations the deployment of experts (paragraphs 2 and 2bis), recommendations on the "access and availability of health products, technologies, and know-how, including an allocation mechanism for their fair and equitable access" (paragraph 2), but also the provision of support "by way of epidemic intelligence surveillance, laboratory support, rapid deployment of expert teams, medical countermeasures, finance as well as other requisite health measures or prohibitive temporary recommendations to avoid unnecessary interference with travel and trade" (paragraph 2bis). ***Technical recommendation*** Before issuing temporary recommendations, WHO provides States Parties with informal and formal communication on risk assessment, information about the epidemiological situation through the Event Information Site platform and Disease Outbreak News and guidance on preparedness and response measures. As noted by the Committee in relation to Article 12, the concept of a potential PHEIC as a basis for issuing temporary recommendations is not clearly defined and may be problematic in practice. Furthermore, there are no thresholds or criteria offered for clarity and consistency between events; most events can potentially become PHEICs, thus diluting

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(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.** (…)	the normative effects of temporary recommendations in the event of a PHEIC. In effect, the Event Information Site platform functions similarly to the proposal for an intermediate or potential PHEIC. The Committee believes that the proposed changes would provide no added value. Concerning the proposal for evidence-based decision-making, the Committee notes that the role of evidence in formulating the temporary recommendations is clearly addressed in Article 17. The deployment of experts is part of the public health response, which is already dealt with in Article 13. The aim here is to introduce it specifically in the provisions related to the temporary recommendations. However, since the deployment of experts relates to operational issues (addressed by Article 13), this proposal is inconsistent with, and falls outside the scope of, Article 15, which is concerned solely with provisions related to the issuance of temporary recommendations, and not their content. The Committee considers health products, technologies and know-how to be critical for the health measures defined in the Regulations. An allocation mechanism for fair and equitable access is important and needs to be discussed in conjunction with the broader equity elements introduced by other proposed amendments. "Prohibitive recommendations" are not defined in Article 1 and this addition therefore does not add clarity to Article 15. However, it is important to balance this with potential interference to travel and trade, and the Committee is aware that border restrictions that were inconsistent with the temporary recommendations were implemented against countries that reported the new variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) known as Omicron to WHO. This proposal should be considered alongside Article 18 and the criteria for issuing temporary recommendations.

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Part III RECOMMENDATIONS	
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.	***Summary of proposed amendments*** The proposed amendment specifies that standing recommendations should also include recommendations on access to and the availability of health products, technologies and know-how, including an allocation mechanism for their fair and equitable access. ***Technical recommendation*** Article 16 has never been used but has been considered for use in relation to the PHEICs concerning poliovirus and the COVID-19 pandemic. The Committee notes that the proposed recommendations concerning the availability of health products, technology and know-how are a critical part of the public health response. An allocation mechanism for fair and equitable access is important and needs to be discussed in conjunction with the broader equity elements introduced by other proposed amendments.
Part III RECOMMENDATIONS	
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;	***Summary of proposed amendments*** The proposed amendment extends the list of criteria that the Director-General can consider when issuing temporary and standing recommendations to include equitable access to and distribution of medical countermeasures for optimal public health response. ***Technical recommendation*** This proposed amendment is in line with similar proposals to other Articles that address the issue of equitable access to countermeasures, and may be linked to the comparable amendments proposed in Articles 15 and 16. The Committee considers the second part of the phrase, which lists types of countermeasures ("vaccines, therapeutics and diagnostics"), to be future-limiting, and suggests keeping it broad by mentioning medical countermeasures, including, but not limiting them to vaccines, therapeutics and

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(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.	diagnostics, to include all potential future countermeasure needs and innovations. This amendment would also benefit from a definition of "medical countermeasures" in Article 1.
Part III RECOMMENDATIONS	
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	***Summary of proposed amendments*** The amendments include one addition to paragraph 2, four proposals for a new paragraph 3 and two for a new paragraph 4. They cover a number of issues, including: • collecting information on travellers for contact tracing; • considering which organizations should be consulted on the development of recommendations in order to avoid unnecessary interference with international travel and trade; • supporting the free movement of health workers and essential medical products; and • addressing the repatriation of travellers. ***Technical recommendation*** The first part of the proposal about passenger information is not clear. If the proposed mechanism only concerns affected persons as per Article 1, then the mechanisms described in Articles 30, 37 and 38 and Annexes 8 and 9 can be used. If it is to cover all passengers, this would be a challenge to feasibility.

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- 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**	The other amendments have a similar ultimate purpose: to avoid unnecessary interference with international travel and trade and, conversely, to facilitate essential travel and trade, or recommend that States Parties should exempt such travel and trade from restrictions, during a PHEIC. The proposals therefore address an important point that is not spelled out adequately in the Regulations. The requirement to consult with relevant international organizations for this purpose is also important but may require more time. To this end, the proposals are relevant, constructive and convergent and it may even be possible to suggest consolidation into a single text. The "shall" in the proposed new paragraph for the Director-General to consult relevant organizations should be changed to a "may". It should not be compulsory, as this could delay the process of making recommendations, which could be counterproductive to the response. Moreover, the organizations should not be specified; instead, the text should read as follows: "other international organizations/agencies as appropriate". This amendment would support the engagement of a more holistic range of actors. The intention to facilitate the movement of health workers and essential medical products is vital. The Committee notes that multiple proposals address this issue. Due consideration should be given to improving the language and, where needed, definitions should be developed under Article 1.

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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;**	

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(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.**	
PART IV – POINTS OF ENTRY	
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).**	***Summary of proposed amendment*** One proposed amendment adds to these requirements the obligation for States Parties sharing a border to develop "bi-national" contingency plans in the event of a PHEIC. ***Technical recommendation*** The Committee notes that the proposal is relevant but also redundant because the issue is already covered by two other Articles. Article 21, paragraph 2(a), addresses the possibility for States Parties sharing common borders to consider "entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 57". Article 57, paragraph 2, provides that nothing in the Regulations shall prevent States Parties from concluding special treaties or arrangements in order to facilitate the application of the Regulations with regard to "the health measures to be applied in contiguous territories of different States at their common frontier".

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PART V – PUBLIC HEALTH MEASURES	
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, **<u>whether in paper based or digital format,</u>** 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 **<u>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</u>**; 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. (…) **<u>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</u>**	***Summary of proposed amendments*** One proposed amendment to paragraph 1 specifies the format for the information that may be required for travellers, by adding "whether in paper based or digital format". In another set of proposed amendments to the same paragraph, travellers' health documents may also include information concerning a laboratory test and/or information on vaccination against a disease, either in digital or physical format. A new proposed paragraph 6 introduces a specific reference to passenger locator forms as part of the documents that may be required, and a preference for these to be in digital format. The same proposal also introduces the possibility for the Health Assembly, in cooperation with ICAO and other relevant organizations, to adopt interoperability requirements for documents issued in electronic format. These requirements should take into account existing systems that are widely used at the regional or international level for the issuance and verification of documents. Lastly, the proposal introduces an obligation to assist low- and lower-middle-income countries in accordance with Article 44 for the implementation of this provision. ***Technical recommendation*** While recognizing the importance of bringing the Regulations in line with modern technology, the Committee considers that the first proposed amendment related to the format of health documents (paper or digital) is better placed elsewhere, either in paragraph 1(a), or in other Articles related to health documents (e.g. Article 35). Regarding the proposal to introduce the possibility for health documents to include information related to laboratory tests, the Committee notes that this was a practice during the COVID-19 pandemic, within the context of the PHEIC and the related temporary recommendations. However, given that Article 23 applies to all situations, not only PHEICs, the Committee is concerned that such a requirement may overburden travellers, and may even raise ethical and discrimination-related concerns. Regarding the proposal for a new paragraph 6, the Committee considers the following:

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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.	• the specifications and requirements for passenger locator forms is a practical matter, and the Committee suggests changing the term "shall" to "should"; • the paragraph is too detailed when it refers to contact tracing purposes, since paragraph 1(a)(ii) of Article 23 already includes information that is used for practical contact tracing even if not mentioned by name: "to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival"; • it is unclear whether the Health Assembly is the most appropriate body to define requirements for digital health documents or whether this responsibility should be entrusted to the Director-General; and • it appears that the paragraph introduces an open-ended obligation that "…low and lower-income countries shall receive assistance in accordance with Article 44" and the wording is not clear. Several proposed amendments to Article 44 need to be considered in relation to the obligations of States Parties to cooperate and provide assistance. Member States should consider consistent terminology between developing and developed vs low- and lower-middle-income countries. Overall, the proposed new paragraph 6 is too specific to be feasibly realized by all States Parties. Therefore, the Committee suggests streamlining this proposed new paragraph, for example, as follows: "Wherever possible, States Parties should provide information in an accurate and secure digital format". Lastly, the Committee recommends examining these proposed amendments in conjunction with Articles 31, 32, 35 and 36 and Annexes 6 and 7, as well as with the related proposed amendments thereto. Should any of these amendments be retained, definitions should be provided in Article 1 for the terms "information", "digital" and "report".

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PART V – PUBLIC HEALTH MEASURES	
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.** (…)	***Summary of proposed amendments*** The proposed amendment adds the obligation for conveyance operators to implement quarantine on board as necessary. ***Technical recommendation*** The Committee agrees that the proposed amendment addresses an important issue, i.e. the ability of conveyance operators to implement quarantine on board, when necessary. However, the spirit of the proposed amendment seems to already be covered in Article 24, paragraph 2, which refers to Annex 4, which provides specific technical requirements for conveyances and conveyance operators. Section A.1(c) of Annex 4 provides that conveyance operators "shall facilitate application of other health measures under the Regulations". Moreover, as defined in Article 1, "health measures" refer to procedures to prevent the spread of disease or contamination, and "quarantine" refers to actions aimed at preventing the spread of disease or contamination. Lastly, when it comes to regulating the conveyance operator, the State Parties need to consider limits of international law of jurisdiction as well. If the amendment is to be retained, the Committee suggests that a general reference to health measures, instead of only quarantine, should be included, since it is more comprehensive and the conveyance operators need to have the capacity to implement all sorts of health measures, not only quarantine. Therefore, the Committee proposes an alternative wording: "Implement evidence-based health measures, including isolation and quarantine, promptly on board as necessary."
PART V – PUBLIC HEALTH MEASURES	
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	***Summary of proposed amendments*** One proposed amendment to paragraph 1 introduces an additional action for the competent authority to "demand the conveyance operators, the pilot in command of the

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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.	aircraft or the officer in command of the ship to take practicable measures on the conveyances". ***Technical recommendation*** The Committee considers the proposed amendment to be redundant, since Article 27, paragraph 1, already refers to the possibility for the competent authority to implement additional health measures. Hence, there is no need to specify that the competent authority must "demand" the conveyance operators to "take practicable measures". It is also unclear what "practicable measures" refer to. The Committee notes that States Parties' ability to regulate is subject to the international law of jurisdiction. Depending on the location of conveyance, State Parties may or may not have the legal power to fulfil their newly proposed obligation. The Committee notes a similar proposed amendment to Article 24, with regard to an obligation for States Parties to ensure that conveyance operators "implement quarantine promptly on board as necessary". It seems that these two proposals seek to address the same concern, i.e. the absence of a specific reference to quarantine as a desirable measure to be implemented on board affected conveyances. If the proposed amendment is to be retained, the Committee suggests that consideration is given to including the word "quarantine" in Article 27, paragraph 1, as follows: "The competent authority may implement additional health measures, including isolation and quarantine of the conveyances, as necessary, to prevent the spread of disease."
PART V – PUBLIC HEALTH MEASURES	
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	***Summary of proposed amendments*** Two proposals for amendments to paragraph 2 introduce the concept of "controlled *pratique*" in addition to the existing concept of *free pratique*, which is defined in Article 1. Another proposed amendment to paragraph 4 introduces the possibility for the competent authority to notify the health measures applicable to a ship or aircraft as necessary.

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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.**	***Technical recommendation*** The term "controlled *pratique*" is not defined under the Regulations. It may create confusion, since according to Article 28, paragraph 2, the granting of *free pratique* can already be subject to inspection or other measures to prevent the spread of infection or contamination. The proposed amendment to paragraph 4 requires further clarification of terms. The term "competent authority" is defined in Article 1 as an "authority responsible for the implementation and application of health measures under these Regulations". At the same time, Article 22 sets out the obligations of competent authorities and includes, among other things, an obligation under paragraph 1(i) to "communicate with the National IHR Focal Point on the relevant public health measures taken pursuant to these Regulations". The proposed amendment introduces the possibility for officers in command of ships or pilots in command of aircraft to be informed by the competent authority of the port or airport of the applicable health measures for the ship or aircraft, in view of the information provided by these officers. This provision, however, already appears in Article 28, paragraph 4, and paragraph 5(a) and (b). In addition, Article 27, paragraph 1, also contains a provision stating that the competent authority may implement additional health measures for affected conveyances.
PART V – PUBLIC HEALTH MEASURES	
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) (a) when necessary to determine whether a public health risk exists;	***Summary of proposed amendments*** The proposal for an amendment to paragraph 1 specifies that proof of vaccination or other prophylaxis can be either paper-based or in digital format. ***Technical recommendation*** The Committee agrees with the broad intent of the proposal, which is to encourage bringing the Regulations up to date with technological advancements and recognizing that not all States Parties have the capacity to provide information in digital format. While acknowledging that the Regulations should be future proof to include other possible formats, the Committee also considers that the information provided,

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(b) (b) as a condition of entry for any travellers seeking temporary or permanent residence; (c) (c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or (d) (d) which may be carried out pursuant to Article 23. (…)	irrespective of the format, should be accurate and secure. The Committee suggests considering rephrasing the proposed amendment to read: "whether in paper-based, digital or other possible formats".
PART VI – HEALTH DOCUMENTS	
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**	***Summary of proposed amendments*** One proposed amendment to the single paragraph of this Article adds a requirement that digital documents must incorporate means for verification of their authenticity. Another proposed amendment introduces a new paragraph 2, which contains detailed provisions related to health documents. Similar proposals have been introduced to Article 23, and related proposals made to Article 36 and to Annex 6. The new paragraph 2 introduces (similarly to the proposed amendments to Article 23) the requirement for the Health Assembly to approve the requirements that health documents in digital format have to fulfil with regard to interoperability of information technology platforms. The Health Assembly should also approve safeguards to reduce the risk of abuse and security of personal data. The proposal then introduces the obligation for States Parties to recognize health documents that meet these requirements. While the first part of the proposed new paragraph gives the Health Assembly the authority to decide on the requirements that health documents in digital format should fulfil, the proposal introduces the obligation for specifications and requirements for "certificates" (not health documents) in digital format to take into account "existing widely used systems established at the international level for the issuance and verification of digital certificates". Lastly, the new paragraph 2 repeats the same proposal as in Article 23, new paragraph 6, that "low- and lower-middle-income

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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.	countries" shall receive assistance in accordance with Article 44 for the implementation of this provision. ***Technical recommendation*** Regarding the proposed amendment to the original paragraph (Article 35 currently contains only one paragraph), the Committee recognizes the importance of ensuring the accuracy and security of the information included in health documents. However, it also recognizes that such a provision may be difficult to implement for States Parties that lack the technology to develop digital documents in the first place and to incorporate means of verification into such documents. The new paragraph 2 (partially repeated in proposed amendments to Article 23) addresses a legitimate concern related to the proliferation of different national certificates, which can disrupt international travel, as experienced during the COVID-19 pandemic. The proposal is aimed at ensuring the harmonization and mutual acceptance of health documents that met certain criteria. The Committee recognizes that the harmonization of documents required for international travel, and the goal of mutual global recognition of travel documents to ensure consistency and confidence in the validity of such health documents, should be encouraged and supported. Annex 6 provides such a standardized example in the form of the model international certificate for vaccination and prophylaxis, which has been used since the entry into force of the Regulations in 2007. However, some aspects of the proposals seem internally inconsistent, since, on the one hand, the new paragraph 2 would reaffirm the Health Assembly's authority to decide on the technical specifications that health documents in digital format must fulfil, while, on the other, it introduces an obligation for such specifications and requirements to follow established systems. Introducing an obligation for States Parties to recognize the health documents of other States Parties may pose many practical difficulties, especially considering that domestic legislation concerning privacy and personal information protection differs from one State Party to the next. Another concern, depending on how the amendments are implemented, is the appropriate level of protection of personal data under the applicable regional and international instruments.

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	The proposal that "low- and lower-middle-income countries" shall receive assistance for the implementation of this provision is similar to the proposal in Article 23, new paragraph 6, and the same recommendation applies. In general, while the interoperability of information technology platforms among States Parties is desirable, it is not currently achievable. The Committee notes that authority to approve requirements for mutual recognition of documents lies with States Parties through the Health Assembly or with the Director-General through technical guidelines. These proposals have to be read in conjunction with the proposed amendments to Article 36 concerning certificates of vaccination and prophylaxis. There is also a need to ensure consistency with Article 5 on surveillance and Article 45 on treatment of personal data, among others. As a general observation, the Committee recommends that the multiple proposals for amendments related to the digitalization of health information should be addressed in one single article and be harmonized with the provisions of Annexes 6 and 7.
PART VI – HEALTH DOCUMENTS	
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**	***Summary of proposed amendments*** A new paragraph 3 offers the possibility for States Parties to use "other types of proofs and certificates" 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". The proposal also maintains that such certificates may include test certificates and recovery certificates, and that such certificates "may be designed and approved by the Health Assembly". ***Technical recommendation*** It is unclear how the specifications and requirements for such "other types of proofs and certificates" would be formulated and by whom, since the proposal only mentions a possibility for the Health Assembly to design and approve such certificates. It is also unclear whether "substitutes for" and "complementary to" are to be used interchangeably. This matters because the meaning is different. The proposal that such

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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.	certificates may include test certificates and recovery certificates should be read in conjunction with the proposed amendments to Article 23, paragraph 1(a), introducing laboratory tests and/or information on vaccination as part of the information that may be required of travellers.
PART VIII – GENERAL PROVISIONS	
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.**	***Summary of proposed amendments*** The proposed amendments expand the scope of Article 42 in three ways: by making specific reference to recommendations made under Articles 15 and 16 (temporary and standing recommendations); by adding "equitable manner" to the way in which the health measures must be applied; and by adding an obligation for States Parties to ensure that non-State actors also comply with these measures. ***Technical recommendation*** The proposed amendment to include a reference to temporary and standing recommendations seems to make application of these recommendations obligatory, whereas current Article 42 only refers to health measures as having to be applied in a transparent and non-discriminatory manner. Temporary or standing recommendations may include other advice in addition to health measures and defined in Article 1 as "non-binding advice". The inclusion of the equity principle in the application of health measures and the obligation to ensure compliance by non-State actors strengthen the spirit of the Article. However, non-State actors are not parties to the Regulations. The Committee is concerned that the proposed amendment goes too far in implying that States Parties must oblige, through legislation or other regulatory measures, non-State actors to comply with measures under the Regulations. While the reference to compliance by non-State actors strengthens the spirit of Article 42, there may be feasibility limits due to the regulatory powers of States under national and international law.

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PART VIII – GENERAL PROVISIONS	
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	***Summary of proposed amendments*** The proposed amendments have three broad aims: to strengthen the requirement for health measures to be based on a risk assessment and not unnecessarily obstructive or restrictive; to tighten the procedure to ensure that those requirements are met; and to provide for a consultation procedure to find mutually acceptable solutions in case of problems concerning the implemented measures. Several amendments introduce new sets of conditions for the adoption of national health measures, such as "risk assessments" and "proportionate responses to specific public health risks" and require such measures to avoid any impediment to another State Party's access to "health products, technologies and know-how". Other proposed amendments also create greater requirements for States Parties to justify the measures they adopt, by emphasizing the goal of the "highest achievable" level of health protection, instead of an "appropriate level of health protection", as currently formulated under Article 43. In a marked departure from the existing operationalization of Article 43, some States Parties have also proposed pathways for ensuring greater compliance with the provisions of this Article, for instance, through bilateral, multilateral or regional consultations, or binding reviews by the Emergency Committee. ***Technical recommendation*** The proposed amendments in general reflect a legitimate concern to strike a better balance between implementing health measures at the national level and avoiding disproportionate and unnecessary repercussions for other States Parties. The proposals in paragraphs 4 and 6 establish a quasi-judicial process with tight deadlines and binding effects for recommendations, with the Emergency Committee having the final authority to decide on the appropriateness of health measures. This Committee is concerned that these proposals may unduly impinge on the sovereignty of States Parties and give binding effects to what are supposed to be recommendations. Moreover, it remains unclear which types of recommendations are considered under this proposed

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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**	amendment, since the Regulations only define temporary and standing recommendations in Article 1. The proposal in paragraph 7 to develop a consultation mechanism among States Parties concerned, and for WHO to support such a mechanism, responds to the need for a practical and swift resolution of problems raised by the implementation of national health measures that significantly interfere with international traffic. The proposal to ensure that States Parties' measures are compatible with those taken by other States Parties may be impracticable when multiple other States Parties may be taking multiple inconsistent measures. The Committee notes that the proposed amendments under Article 56 also include mechanisms in this regard. The Committee also notes that this proposed amendment would introduce obligations for WHO Regional Directors that are not currently included in the Regulations. The Committee finds that a number of proposals lack clarity. It is unclear for the Committee how the reference in paragraphs 1 and 7 to "the highest achievable" level of health protection would be achieved, since such a reference seems subjective and potentially unattainable. In paragraph 3bis, the reference to a WHO "allocation mechanism" cross-refers to the proposals contained in the new Article 13A and a related amendment to Article 16. The relevance of the proposed amendment to paragraph 3 can only be assessed in connection with the proposals for these other Articles. In relation to the proposal to introduce "risk assessments", the Committee reiterates the technical recommendation provided in Part D concerning the proposed amendments to Article 5 and the absence of a definition of "risk assessment", including whether such a definition is advisable. If the references to the Emergency Committee in paragraphs 4 and 6 are accepted, this will necessitate a revision of the terms of reference of the Emergency Committee set out in Article 48. The proposal to amend paragraph 6 to remove the periodic self-review of measures that have not been challenged by a State Party may result in the unnecessary continuation of additional measures even if not challenged by another State. Party. The proposed amendments, in particular those to paragraphs 4 and 6, aim to make States Parties that adopt national measures more attentive with regard to the necessity and proportionality of these measures. The Committee supports the intention of the

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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.** (…)	proposed amendments but is of the view that the procedure envisaged therein may be too prescriptive. The amendments also raise resource implications for WHO and States Parties, for example, with regard to more stringent requirements to provide evidence for their measures within tight deadlines, and for WHO to support the consultation process envisaged and to provide reports to the Health Assembly on the conduct and outcome of such consultations, as proposed in paragraph 7.

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PART VIII – GENERAL PROVISIONS	
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**	***Summary of proposed amendments*** Multiple, and at times overlapping, amendments have been proposed, some of which are linked to similar proposals made for other Articles, such as Articles 4, 5 and 6, and Annex 1 and new Article 13A. The general intent is to add much more specificity, breadth and detail to the obligation of WHO and States Parties to cooperate and assist in order to achieve equity, strengthen national core capacities, and share information and other resources, such as pathogens, genetic sequences and benefits. Some of the amendments also aim to increase transparency and accountability, for instance, through the creation by WHO of an evaluation matrix and reporting to the Health Assembly. ***Technical recommendation*** In paragraph 1, the proposed amendments introduce "assist" as an operative verb, in particular with regard to developing States Parties. That verb is missing in the original text of Article 44, except in the title. The Committee supports the affirmative idea of tangible assistance and, moreover, emphasizes that such assistance should be viewed as an act of mutual responsibility to fulfil this Article. Alternative formulations in this regard may be considered to convey this sense of partnership and mutual responsibility. Given the emphasis put on assistance in the chapeau of paragraph 1, by adding the verb "assist" and removing the qualifier "undertake to", States Parties may wish to reflect on the desirability of retaining the existing wording of "to the extent possible" at the end of that paragraph. With regards to the proposed amendments to paragraph 1(c) to establish a new financial mechanism, the Committee refers to its comments under Article 44A. New subparagraphs 1(e) and 2(c) introduce specific collaboration in the form of the exchange of pathogen samples and GSD. Although the issue of access to benefits derived from the use of shared pathogens is not specifically mentioned in these proposals, the Committee notes that the broader issue of pathogen and benefit sharing recurs in several amendments, particularly with regard to Article 6. The Committee acknowledges the importance of both information sharing (including biological

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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**	specimens and GSD) and access to benefits derived from the use of shared pathogens. Both principles are vital but do not need to be implemented in a transactional manner. Strong language in the Regulations to support each idea would advance the aims of States Parties for improved information exchange and more equitable sharing of the benefits arising from such exchange. In addition, this proposal raises the issue of consistency with the Convention on Biological Diversity, the related Nagoya Protocol and the PIP Framework. As already mentioned in the analysis of Article 6, the PIP Framework has not yet been used in practice and does not include provisions related to the sharing of GSD (only biological materials, such as influenza viruses with pandemic potential); therefore its relevance to the issue of access to and sharing of benefits relates mainly to the model for benefit sharing offered by the Standard Material Transfer Agreements. However, the proposed amendment already includes reference to "relevant national and international law, commitments and principles", and in the interest of future-proofing the Regulations, States Parties may wish to retain this reference and omit the explicit reference to the other instruments mentioned above. New subparagraphs 1(e) and 1(f) require States Parties to either facilitate or provide equitable access to medical countermeasures. This point is also raised in the new subparagraph 2(d) with regard to WHO. The Committee broadly supports the principle of equitable access. The key issues are whether equitable access falls within the scope of the Regulations and, if so, where it should be placed in the Regulations, and how it should be operationalized and evaluated. In this regard, the Committee notes that both versions of the new Article 13A consider in detail the question of equitable access to health products. The numerous proposed amendments to paragraphs 2 and 3 introduce many new functions for WHO to fulfil, which would have serious implications for WHO in terms of human, financial and other resources. Subparagraph 2(d) raises the issue of digital technologies and the development of an interoperability mechanism to exchange health information. The Committee supports the spirit of this proposal, which reflects the need to take technological developments into account, but this proposal needs to be read in conjunction, and reconciled, with similar proposals made in Articles 23, 35 and 36.

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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**	Strengthening the capacity of the National IHR Focal Points, as proposed in the new subparagraph 2(i), is also proposed in Article 4 and may be more appropriately dealt with in that Article to avoid repetition. The requirement for WHO, in the new subparagraph 2(f), to facilitate "accessibility and affordability" of health products would be difficult to implement if expressed in such general terms. The proposed role for WHO under the new paragraph 4 requires further clarification as to whether it should act as a negotiator or facilitator of collaboration, or whether it should only aim to coordinate the collaboration. The Committee notes that many of the proposed amendments to Article 44 address issues that may also warrant consideration as part of the Intergovernmental Negotiating Body (INB) process.

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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**	

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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.**	
PART VIII – GENERAL PROVISIONS	
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;**	***Summary of proposed amendments*** A new Article 44A proposes the establishment of a financial mechanism to support developing countries in strengthening core capacities and health systems, building research and development capacities, and addressing health inequities. The proposed new Article also provides deadlines for the establishment of the mechanism and reviews of the mechanism by the Health Assembly.

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(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.**	***Technical recommendation*** The Committee believes that sustainable financing for the development of core capacities and for the equitable implementation of the Regulations is a very important issue. The Committee is aware that the World Bank recently established the Financial Intermediary Fund, known now as the Pandemic Fund, to enhance financing for pandemic prevention, preparedness and response, for which WHO acts as Lead of the Technical Advisory Board, and has a role within the broader secretariat. At the time of writing, the Pandemic Fund has yet to launch a call for proposals and remains undercapitalized, in terms of both overall funding requirements and delivered versus pledged resources. The Committee notes a divergence of views as to whether WHO has a financing function. Article 2(d) of the WHO Constitution stipulates that one of the WHO mandatory functions is: "to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments", and Article 28, paragraph i, gives this function to the Executive Board: "to take emergency measures within the functions and financial resources of the Organization to deal with events requiring immediate action. In particular it may authorize the Director-General to take the necessary steps to combat epidemics, to participate in the organization of health relief to victims of a calamity and to undertake studies and research the urgency of which has been drawn to the attention of the Board by any Member or by the Director-General." The Committee notes that, under Article 44, WHO already has a role, in collaboration with States Parties, to mobilize financial resources, and cautions against creating an explicit financing function for WHO under the Regulations.
PART VIII – GENERAL PROVISIONS	
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	***Summary of proposed amendments*** The proposed amendments to paragraph 2 introduce specificities/limitations concerning to whom data can be disclosed and introduce the idea of obtaining consent for

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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.**	disclosing such information from the State Party providing it. A new paragraph 4 introduces an obligation for WHO to process and store data only with permission from the State Party providing the data. ***Technical recommendation*** The Committee understands the importance of ensuring that personal data are protected and not used for purposes unconnected with containing the spread of disease. At the same time, the Committee is of the view that the purpose of the Regulations is to encourage disclosure and the exchange of information necessary to contain the international spread of disease, while also maintaining the privacy of individuals in accordance with modern data protection principles and human rights principles. The Committee is of the view that the spirit of the amendment is already addressed in the original text of this Article and, for the same reasons, the proposed amendment to paragraph 2 and the proposed new paragraph 4 may not be in keeping with the scope and purpose of the Regulations.
PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE	
Article 48 Terms of reference and composition (Emergency Committee)	
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.	***Summary of proposed amendments***

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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.	The proposed amendments to paragraphs 2 and 3 introduce specific references to elements that need to be considered when composing an Emergency Committee: ensuring experts are free from conflict of interest; expressly including Regional Directors from any impacted regions; paying due regard to the principles of equitable age representation and gender balance among selected experts; training experts before they start their work as members of the Emergency Committee; and expressly including experts from the State Party on whose territory the event arises and experts from other affected States Parties. One proposal introduces a definition of "affected State Party" for the purpose of Articles 48 and 49. ***Technical recommendation*** As stated in Article 47, the IHR Roster of Experts, which is the source of expertise for the Emergency Committees, is established under the WHO Regulations for Expert Advisory Panels and Committees,[1] which contain explicit references, in Rule 4.2, to several principles underpinning the establishment of expert committees, including equitable geographical representation and gender balance. In addition, Rule 4.6 includes specific obligations for experts appointed to these committees to disclose all circumstances that could give rise to a potential conflict of interest. Therefore, the proposed amendments related to equitable geographical representation, gender balance and conflict of interest seem redundant. Regarding the proposed amendment concerning the inclusion of Regional Directors from impacted regions in the Emergency Committee, the Committee notes that in practice all Regional Directors or their representatives attend all meetings of the Emergency Committees as part of the WHO Secretariat, but not as members. Emergency Committee members are independent experts not serving with WHO and are meant to provide independent advice to the Director-General. Regional Directors are WHO staff members.

[1] Basic documents: forty-ninth edition (including amendments adopted up to 31 May 2019). Geneva: World Health Organization; 2020 (https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=160, accessed 24 January 2023).

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	An Emergency Committee is almost always composed under time pressure and the expected speed of work is high. Therefore, it may not be practicable to ensure training when appointing new members to an Emergency Committee. Members are appointed based on their technical capacities and expertise while respecting the diversity requirements mentioned above. There is potential merit in providing training in the Regulations for all participants, but this should be done when the Roster of Experts is compiled and not when under the time pressure of an Emergency Committee. In addition, mentioning the provider of such training (i.e. by the WHO Academy) is not appropriate for the future-proofing of the Regulations in relation to any potential organizational changes. The proposed definition of "affected State Party", with the criteria of geographic proximity or otherwise impacted by the event, seems to be in conflict with the existing criterion of equitable geographical representation of Emergency Committee members. In addition, "otherwise impacted" can be interpreted in many different ways, depending on the issue or event at hand, and may include many States Parties. The overall purpose of Article 48 must remain to create a fast operating, independent Emergency Committee, primarily based on content expertise and experience available through the IHR Roster of Experts and free from conflicts of interest.
PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE	
Article 49 Procedure (Emergency Committee)	
(…) 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.** (…)	***Summary of proposed amendments*** One proposed amendment to paragraph 2 introduces a reference to a detailed agenda that the Director-General must provide to the Emergency Committee, which should include elements to ensure the completeness, specificity and coherence of the advice provided. A new paragraph entitles any member of the Emergency Committee to express dissenting views and requires the Emergency Committee's report to the Director-General to include an explanation of such divergent views.

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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	Another new paragraph 3ter introduces a specific obligation for the composition of the Emergency Committee and its complete reports to be shared with States Parties. Proposed amendments to paragraph 4 introduce the notion of "affected States Parties", which must be invited to present their views to the Emergency Committee, and another proposal replaces the word State Party "concerned" with the words "in whose territory the event arises". A similar reference to "affected States Parties" is proposed in paragraph 7 to replace the more extended expression "in whose territories the event has occurred". In paragraph 6, a proposed amendment requires the Director-General, when communicating the recommendations to the public, to include the reasons behind such recommendations. Lastly, the proposed new paragraph 8 introduces a requirement for the Emergency Committee to present its recommendations to "relevant WHO bodies dealing with health emergency prevention, preparedness and response", and makes reference to the Standing Committee on Health Emergency Prevention, Preparedness and Response.[1] ***Technical recommendation*** As a general statement, the Committee notes that some of the proposed amendments are grounded in the related recommendations of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response, specifically in relation to ensuring more transparent sharing of documentation and the rationale for convening the Emergency Committee, and standardized information sharing following each meeting. Regarding the proposed amendment to paragraph 2 for a standardized agenda, it should be noted that the Emergency Committee is by default presented with an agenda by the WHO Secretariat, in accordance with the WHO Regulations for Expert Advisory Panels and Committees. This agenda includes: a procedural introduction by the WHO Secretariat; a presentation by the States Parties in whose territories the event occurs and by WHO; and a closed deliberative session of Emergency Committee members, who are to advise the Director-General on whether or not the event constitutes a PHEIC and

[1] For more information, see the Standing Committee on Health Emergency Prevention, Preparedness and Response webpage (https://apps.who.int/gb/scheppr/, accessed 24 January 2023).

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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.**	if so, what would be the appropriate temporary recommendations. The aim to ensure "specificity, completeness and coherence" seems relevant to ensure greater consistency between Emergency Committee meetings, which is important for the normative authority of the Committee process. However, the varying nature of health events may lead to different agenda items. The "should" might be changed to "may" to facilitate this. With regard to the new paragraph 3bis, it should be noted that the Regulations do not require a "report" from the Emergency Committee, but rather for the Committee to present "its views" to the Director-General, although in practice there is a report, as per the guidance set forth in the WHO Regulations for Expert Advisory Panels and Committees. The proposal to allow dissenting views to be expressed complies with Article 4, paragraph 12, and Rule 6 of the Annex to the WHO Regulations for Expert Advisory Panels and Committees. The Committee notes additionally that, for the protection of Emergency Committee members, who participate on the basis of their personal professional expertise and experience, it is of utmost importance that the opinions and statements are presented in the report anonymously. The proposed amendments related to the documentation of the proceedings and information sharing are redundant. The current practice, anchored in the WHO Regulations for Expert Advisory Panels and Committees, is that the composition of the Emergency Committee and the report of each meeting of the Committee to the Director-General are shared systematically with States Parties, National IHR Focal Points and other relevant entities of the United Nations system, before being made publicly available on the WHO website. It seems reasonable to provide the rationale for the temporary recommendations, but it should be clear that this remains the responsibility of the Director-General, who takes the final decision on temporary recommendations. The proposals introducing the notion of "affected States Parties" have been addressed already in the comments concerning Article 48. The proposal in the new paragraph 8 is inconsistent with the provisions of Articles 12, 15 and 49, which state that the final responsibility for determining a PHEIC and issuing temporary recommendations lies with the Director-General not with the Emergency Committee, which has only an advisory function.

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	The Committee notes that Article 50 includes a specific reference to the WHO Regulations for Expert Advisory Panels and Committees. For the sake of consistency between provisions related to the functioning of the Emergency Committee and the Review Committee, this Committee proposes that States Parties consider aligning the two Articles by adding the same reference to Article 49.
NEW Article 53A Establishment of an Implementation Committee	
NEW Chapter IV The Compliance Committee with NEW Article 53 bis Terms of Reference and Composition, NEW Article 53 ter Conduct of business and NEW Article 53 quater Reports	
NEW Article 54 bis Implementation	
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**	***Summary of proposed amendments*** The three sets of proposals relating to the establishment of a committee on the implementation of, or compliance with, the Regulations are examined together. These partially overlapping proposals aim to raise the Regulations' profile, energize States Parties' engagement and strengthen implementation of the Regulations. The proposals are trying to fill governance gaps in the current text of the Regulations and address three functions: reviewing progress, mobilizing support and assessing compliance. The new Article 53A proposes the establishment of an implementation committee with all States Parties as members. The committee would be responsible for assessing implementation based on existing information from the Regulations' monitoring and evaluation framework, and for monitoring, advising on and facilitating the provision of technical, logistic and financial support to develop core capacities and respond to health events. It would have the ability to call out States Parties for lack of compliance and would submit reports to the Health Assembly. The new Chapter IV (Articles 53bis–quater) proposes a new compliance committee composed of six government experts from each WHO region who would work by consensus, inviting other institutions to participate where relevant. The committee would be responsible for considering information from WHO and from States Parties related to compliance with obligations under the Regulations, for monitoring, advising and/or facilitating assistance on matters of compliance, and for promoting compliance. It would be authorized to request further information, undertake to collect its own

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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**	information, consider all information submitted to it, seek expertise as necessary and make recommendations to States Parties and to WHO about how to improve compliance (including through technical and financial support). This committee would submit its annual report to all States Parties and to the Health Assembly, through the Director-General. The new Article 54bis addresses implementation and would make the Health Assembly responsible for overseeing and promoting the effective implementation of the Regulations and giving it the authority to take decisions and make recommendations as necessary. The Health Assembly would also, inter alia, regularly assess the implementation of the Regulations by States Parties and establish a review mechanism to that effect. A dedicated meeting would be held every two years during the Health Assembly and a special expert committee would be established to support the Health Assembly in its implementation of the new provisions set out in the proposed amendment. ***Technical recommendation*** The Committee notes that current Article 53 covers procedures for standing recommendations, while current Article 54 covers reporting and review. The Committee considers that, in concert, the three intersecting proposals would be better located in Article 54. However, clarification is needed as to whether the proposed mechanisms are supplementary to the paragraphs related to reporting under Article 54, or whether they relate to the ways to implement that Article. All three proposals aim to enhance implementation of, and compliance with, States Parties' obligations under the Regulations. The Committee notes that the three proposed amendments underscore the importance of promoting improved implementation and compliance, including by creating a space for States Parties' deliberations and for gathering additional information. The three proposals, however, use different mechanisms for improving implementation and compliance, and each poses important operational and legal challenges. Regarding the "implementation committee" envisaged in the new Article 53A, where all States Parties are members, it is unclear whether this would be a committee of the Health Assembly (in which case, it should function in line with the respective Rules of

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(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**	Procedures of the Health Assembly), or a different type of committee, in which case it is unclear on what basis that "committee" would be established. The same consideration applies to the proposal in the new Article 54bis, where it is not clear under which rules the "special committee" would function. In addition, paragraph 2(vi) seems to provide additional functions to the Health Assembly (to "request, where appropriate, the services and cooperation of […] competent and relevant organizations […]"), and it is unclear whether this request for cooperation would involve organizations other than those included already in the agreements annexed to WHO's *Basic documents*.[2] Paragraph 2(iii) of this new Article proposes the establishment of a "review mechanism" to assess the implementation of the Regulations, but it is not clear how this mechanism would function. Paragraph 2(iii) also seems to imply that only low- and lower-middle-income countries are entitled to request technical assistance, which seems to be inconsistent with the WHO Constitution, which states that all countries are entitled to request and receive technical support from WHO. Similar considerations apply to the new Articles 53bis–quater, in which the proposal to establish a "compliance committee" seems to give significant powers to 36 appointed government experts, without clearly explaining the rules under which such a committee would function, whether as an expert committee under the WHO Regulations for Expert Advisory Panels and Committees or as a subsidiary body of the Health Assembly. In addition,, the Committee notes that the potential power given to the "compliance committee" proposed in Article 53bis–quater, to freely gather and use information, is far-reaching; some Committee members noted that (with the exception of the proposed subparagraph 2(b)) there is no requirement for the proposed compliance committee to verify information received from other sources with the State Party concerned, as is provided for, for example, in Article 9. The Committee agrees that it would be valuable to have enhanced provisions in the Regulations with regard to compliance and implementation. Realizing such provisions may take several forms. The Committee recommends that States Parties should seek common ground on what aspects of the Regulations require monitoring (e.g.

[2] Basic documents: forty-ninth edition (including amendments adopted up to 31 May 2019). Geneva: World Health Organization; 2020 (https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=160, accessed 24 January 2023).

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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.** ***New Article 54 bis – Implementation***3F[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;**	functioning, implementation of core capacities and other obligations), and through which modalities this can be best achieved. Furthermore, the three proposals would benefit from more clarity with regard to the functions and operations of an implementation/compliance committee, and related definitions of terms that may need to be included in Article 1. These proposals will also need to be considered in the light of the establishment by the Executive Board in 2022, through decision EB151(2), of the Standing Committee on Health Emergency Prevention, Preparedness and Response.[3] While the Committee recognizes the need to improve implementation and compliance monitoring mechanisms, all three of the proposed mechanisms are likely to carry an administrative cost for both States Parties and WHO.

[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.

[3] See document EB151/2022/REC/1 and decision EB151(2).

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(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 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**	

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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/…).**	
PART X – FINAL PROVISIONS	
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 Partiesand 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.**	***Summary of proposed amendments*** The proposed amendment introduces an obligation for WHO to maintain a webpage of activities carried out in relation to specific provisions of the Regulations under certain Articles. ***Technical recommendation*** The Committee acknowledges the importance of transparency and notes that WHO already reports or publishes information on activities in relation to specific Articles, either in real time or through the annual report to the Health Assembly on implementation of the Regulations. Maintaining a webpage, while potentially a good mechanism to improve transparency, may have substantial feasibility and resource implications, depending on the expected level of detail of such reporting. A webpage seems more of an operational mechanism and perhaps not best placed in an international law instrument. The specific reference to Article 43 raises particular concerns, because of the current ambiguity related to the reporting by WHO under this Article and the amendments proposed to that Article with regard to WHO's role. Such a detailed dashboard may push the reporting under Article 43 towards naming and shaming, if WHO is to publish information about States Parties not responding to WHO to rescind measures. The WGIHR may want to reflect on whether this is desirable.

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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.**	***Summary of proposed amendments*** The proposed new paragraphs 6, 7 and 8 introduce three obligations: for WHO to communicate the complaints of States Parties regarding additional measures that were not notified; for States Parties to inform WHO in a timely manner about additional health measures and to provide the scientific justification for them; and for the Health Assembly to examine and make recommendations on the assessment of the Review Committee regarding the relevance and duration of these measures. ***Technical recommendation*** The term "additional measures" in the proposal lacks clarity. In Article 1, a "health measure" is defined as "procedures applied to prevent the spread of disease or contamination […]". Article 43, paragraph 1, defines an additional health measure as a health measure that either achieves the same or greater level of protection than WHO recommendations (including temporary recommendations), or is applied despite being otherwise prohibited by Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33. The proposed amendment introduces a set of obligations that already exists in similar form under paragraphs 3 and 5 of Article 43. These include a specific obligation for States Parties to provide WHO with the public health rationale and relevant scientific information regarding the additional health measures, and also to include the timeline by which States Parties are obliged to inform WHO of such measures. These proposals need to be examined in conjunction with the related proposal in Article 43, paragraph 7, for a forum for consultations for additional health measures that are adopted pursuant to Article 43, paragraphs 1 and 2, as well as the possible publication of these measures/consultations in a report to the Health Assembly. This suggests that there is some convergence among States Parties regarding the need for a platform to address disagreements arising specifically in relation to Article 43. The Committee considers that these proposed amendments are focused on creating a platform for discussion on a specific set of issues arising from the application of, or

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	compliance with, Article 43, but have little to do with the settlement of disputes. While the Committee encourages increased dialogue among States Parties as foreseen by Article 56, it recommends that further thought be given to the placement of these proposed amendments, which seem more closely related to the application of Article 43.
ANNEX 1 **A. Core capacity requirements for surveillance and response** **B. Core capacity requirements for designated airports, ports and ground crossings**	
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.**	**A. Capacities beyond surveillance** ***Summary of proposed amendments*** A number of proposals would extend States Parties' capacity requirements beyond surveillance to include, for example: infrastructure; personnel; technologies and access to health care products; health information systems; coordinating mechanisms; epidemiological intelligence; research; the manufacture and deployment of medical countermeasures; and sustainable financing. The capacity requirements relate to the local, intermediate and national levels. ***Technical recommendation*** The Committee recognizes that strengthening surveillance and, more broadly, preparedness are essential aims of the Regulations, and the proposals are intended to meet these aims. While these proposals reflect important lessons from the COVID-19 pandemic, collectively they would result in a significant change in the Regulations' scope and level of detail. Annex 1 covers States Parties' legal obligations and is limited to core public health capacities, rather than all health system capacities. The Committee notes that including the proposed requirements in Annex 1 may raise feasibility challenges. For example, not all States Parties may be able to assume responsibility for the "supply of affordable health care products". Some States Parties will have difficulty in reporting and reviewing within the time frame specified in Articles 5 and 13, given their level of development. The Committee also notes that the proposals require other States Parties and WHO to assist

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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;**	in building these capacities. State Parties should discuss this issue in the WGIHR to improve the feasibility of these requirements. Moreover, some requirements may be feasible for States Parties at the national level, but unfeasible at subnational levels where resources may be insufficient. Given the ambition of some of the proposed amendments, the Committee suggests that States Parties consider whether the chapeau to Part A of Annex 1 might be amended to reflect the caveat of the availability of resources in developing and maintaining the core capacities. **B. Health products, technology, know-how and materials as part of a public health response** ***Summary of proposed amendments*** Several proposals require States Parties, as part of their public health response, to provide health products, technology, know-how, materials, etc. ***Technical recommendation*** Given that these proposals correspond to related proposed amendments to Article 13, the Committee refers to its analysis of Article 13. **C. Genomic sequence data and other data** ***Summary of proposed amendments*** This group of proposed amendments requires States Parties to have, at the national, intermediate and local levels, the capacity to isolate, identify, sequence and characterize pathogens and to report GSD, and microbial, epidemiological and clinical data. ***Technical recommendation*** The Committee recognizes the need to update the Regulations in line with technological advances, and capacity to analyse GSD for the purpose of reporting is important. However, there may be feasibility challenges for some States Parties to fulfil this requirement in the given time frame, especially at the subnational level. **D. Assistance from States Parties** ***Summary of proposed amendments***

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(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;**	This group of proposed amendments would require State Parties, especially developed countries, to assist States Parties that do not meet the requirements set out in Annex 1, by providing finance, technology, health products, etc. ***Technical recommendation*** These proposals are to be read in conjunction with the proposed amendments to Articles, 3, 5, 13 and 44 and the new Annex 10. These proposals aim to achieve equity in capacity-building/maintenance, etc. by providing detailed arrangements at some levels. These proposals, if adopted, would change the nature and function of Annex 1, which currently specifies the requirements to fulfil the obligations set out in Articles 5, 13 and 19, thus providing the specificity needed to assess compliance with, and implementation of, the Regulations. The proposed amendments, by contrast, are intended to operate in the event of a State Party's failure to fulfil its obligations under Articles 5, 13 and 19, and to provide assistance to the relevant State Party. As a result, the incentive under Annex 1 changes, as the State Party that cannot meet the requirements in Annex 1 may benefit from assistance. While the Committee fully supports assistance between States Parties, this is already addressed by Article 44. For this reason, its inclusion in Annex 1 should be carefully considered. **E. Assistance from WHO** ***Summary of proposed amendments*** This group of proposed amendments would oblige WHO to support States Parties that lack critical capacities for surveillance, reporting, notification, verification and response. ***Technical recommendation*** The Committee notes that similar amendments are proposed to Article 44, paragraph 2, with related proposals concerning Articles 5 and 13. The Committee sees these proposals as a call for greater capacity for WHO. WHO may need significantly greater resources to fulfil such an obligation. Therefore, the proposals would not be feasible in the time frame provided by Articles 5 and 13. Other proposals require WHO to strengthen its own capacity. Since Annex 1 relates to the obligations in corresponding Articles, these proposals need corresponding amendment proposals to Article 5. The Committee notes that Article 5, paragraph 4,

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(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**	requires WHO to collect and assess information, but that Annex 1 does not specify that requirement. Moreover, the language could be improved to provide more detail. **F. Health system capacities** ***Summary of proposed amendments*** Some proposals require States Parties to develop and maintain health system capacities to achieve resilience against health emergencies in relation to, for instance, infrastructure, the health workforce, working conditions for health workers, health information systems, access to health products, financing, leadership and governance. ***Technical recommendation*** Some of the proposals lack clarity. Obligations may provide incentives, but it is the Committee's view that the State Parties' incentives are not the major problem. Health system capacity-building involves an array of complex factors, for example, resources available to States Parties and the regulation of private actors by States Parties. The Committee wishes to remind States Parties that effective mechanisms for channelling those concerns are critical if the proposals are to work. While some members of the Committee consider that wider health system capacities are within the current scope of the Regulations, as provided in Article 2, other members are of the view that the proposals may be contingent on corresponding amendments to Article 2. The Committee believes that health system resilience is a very important issue, which should be better addressed in international health law. The Committee notes that the Regulations do not address health system resilience in detail. Meanwhile, this important issue is under consideration by the INB, which is working towards a binding legal instrument regarding pandemics.

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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);	

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(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**	

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(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**	

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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:**	

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(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**	

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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.**	

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G. Point of entry capacities	
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.**	***Summary of proposed amendments*** These proposed amendments address: surveillance and access to quick diagnosis; developing a point-of-entry workforce for surveillance and point-of-entry response; leveraging digital technology; and introducing standard operating procedures for all points of entry. ***Technical recommendation*** The Committee notes that some of the proposals may face feasibility challenges, for example, concerning the use of digital technology. Some proposed requirements, for example, the establishment of a point-of-entry workforce, are already provided for in the Regulations. Many of the proposed amendments to Annex 1 would create significant new capacity requirements. In light of this, States Parties may wish to consider whether the time frames specified in Articles 5 and 13 for the development, strengthening and maintenance of such capacities would be reactivated or not.

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(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	
A case of the following disease is unusual or unexpected and may have serious public health impact, and thus shall be notified[1,2] - Smallpox - Poliomyelitis due to wild type poliovirus	***Summary of proposed amendments*** One proposed amendment to the left-hand column of the decision instrument introduces, in addition to the four diseases which require immediate notification (smallpox, poliomyelitis due to wild-type poliovirus, human influenza virus caused by a

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- Human influenza caused by a new subtype - Severe acute respiratory syndrome (SARS), **as well as cluster(s) of severe acute pneumonia of unknown cause** - **Cluster(s) of other severe infections in which human to human transmission cannot be ruled out.** **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")?**	new subtype and severe acute respiratory syndrome), a qualifier of the latter disease adding "cluster(s) of severe acute pneumonia of unknown cause", as well as a reference to "cluster(s) of other severe infections in which human to human transmission cannot be ruled out". Another proposed amendment seeks to expand the examples for informing the application of the decision instrument and proposes a scoring system to be used for the decision to notify WHO. ***Technical recommendation*** The Committee notes that the initial development of Annex 2 dates back to the end of the 1990s and early 2000s, following the adoption of resolution WHA48.7 (1995) on the revision and updating of the International Health Regulations.[1] After the current Regulations were adopted through resolution WHA58.3,[2] and prior to their entry into force in June 2007, Annex 2 was subject to an extensive piloting exercise, which led to further fine-tuning of the decision instrument. Regarding the proposal to introduce additional diseases in the decision instrument, the Committee is of the view that the reference to clusters of severe acute pneumonia of unknown cause is a useful addition in the light of the recent experience with COVID-19. However, the reference to "other severe infections" is quite broad and seems to prejudge the outcome of the assessment that States Parties in any case have to carry out under Article 6 and the rest of Annex 2. Regarding the other proposal aimed at entirely redefining the criteria for the assessment, the Committee notes that the purpose of Annex 2 is primarily to guide States Parties in assessing whether they should notify WHO with regard to events in their territories. At the same time, in accordance with Article 12, paragraph 4, the Director-General is also required to consider the decision instrument in determining whether an event constitutes a PHEIC. It is the view of the Committee that some of the proposals may enrich and complement the current criteria, while others seem to go beyond the purpose of Article 6 and the

[1] See resolution WHA48.7.

[2] See resolution WHA58.3.

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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**	current Annex 2 and may run the risk of delaying States Parties' notification and the assessment of the event by the Director-General. The absence of a specific rationale for such an extensive proposal has made the assessment by the Committee more difficult. The Committee has the following specific considerations regarding the proposal to replace Annex 2: With regard to considerations of the "geographical scope/risk of territorial spread", the Committee is of the view that criterion 1.2, dealing with events at the national level, may be a useful addition to the assessment that States Parties have to perform. Other criteria under that heading, such as 1.4 concerning the risk of national or international spread, seem to already be covered under Part III of the current Annex 2. The criteria set out under "Characteristics of the event- whether it is rare, reemerging, presents changes in its epidemiological profile and/or has serious health impact" seem to already be covered in Parts I and II of the current Annex 2 and the purpose of the proposed amendment is unclear. With regard to "Healthcare relevance - whether the event risks compromising the delivery of healthcare and/or poses a risk to health professionals", some of the proposed criteria, such as the risk to health professionals, are already covered in current Annex 2, but criteria 3.2 ("Is there a significant increase in treatment provision or hospitalization?") may be a relevant editorial change to Part I of the current Annex 2. The criteria set out under "Social and Economic Relevance - whether the event affects vulnerable populations, has high social impact and/or poses a risk to international travel or trade" raise important considerations about the social impact of an event, with particular regard to populations at risk, which may already be encompassed in Part I, Box 2, of the current Annex 2. However, certain considerations related to social and economic factors (for instance, the criteria proposed under 4.2, 4.3, and 4.4) go beyond the existing decision instrument and might not be relevant and practical for the purpose of initial notification. The Committee notes that, at the time of notification, subsequent social and economic implications might not be known. Moreover, Part IV of the current Annex 2 already takes into consideration significant risks to "international travel or trade restrictions". With regard to the proposal to introduce a scoring system, the Committee appreciates the need for an objective method for assessing events and that is indeed the purpose of

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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 2. At the same time, replacing the qualitative approach of current Annex 2 with a quantitative method would remove the qualitative weighting for each element, which it is vital for such decision-making. The Committee is concerned that the proposed amendment will decrease the sensitivity of the decision instrument and, hence, have a negative impact on the notification of health risks and events that might constitute a PHEIC. The Committee notes that using the proposed replacement for Annex 2 would see an event that: (1) is unexpected/unusual; (2) has a change in epi/clinical profile; (3) is serious; and (4) poses a risk of international spread that would score only four and would therefore warrant continued monitoring but would not meet the threshold for notification.
ANNEX 3 Model Ship Sanitation 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**	***Summary of proposed amendments*** The proposed amendments introduce the possibility of allowing authenticity to be verified through an official website or with a QR code. Also proposed is the possible inclusion of "international river vessels" in "the title of the ship sanitation control certificate and control exemption certificate; the articles and annexes referring to the maritime declaration; and all places where the word maritime occurs". ***Technical recommendation*** The Committee notes that "ship", as defined in Article 1, means a seagoing or inland navigation vessel on an international voyage, which covers the proposed wording in the amendment, "international river vessel". The Committee recognizes the need to keep up with technological developments and to future-proof the Regulations by allowing ship sanitation certificates in both paper-based and digital formats. However, authorized port officials may not have adequate facilities to enter data to be read by a QR code system or to upload data to a website. In addition, specifying "websites" and "QR codes" could be problematic in terms of future-proofing, as these technologies may be superseded. The Committee suggests that States Parties consider inserting the following sentence below the title: "This Certificate is to be produced in either paper-based, or paperless/digital/electronic, or any other possible forms, provided that the

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	paperless/digital/electronic or other possible forms are able to verify the authenticity and present all the information listed in this Annex when scanned/verified".
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.**	***Summary of proposed amendments*** One proposed amendment includes an obligation for conveyance operators to prepare in advance, where possible, a plan for addressing public health risks on board. ***Technical recommendation*** The Committee notes that Article 24 already includes reference to the obligation of conveyance operators to comply with health measures adopted by the State Party. It is thus the responsibility of the States Parties to ensure that conveyance operators are able to implement such measures. In addition, Article 27 includes specific provisions related to actions by the competent authority in case of evidence of a public health risk on board a conveyance. It is therefore unclear to what extent a "plan" to be developed by conveyance operators, as proposed by the amendment, would interfere with the provisions already included in Articles 24 and 27. The qualifier "where possible" will make it difficult to monitor compliance with such a provision, should this amendment be adopted.
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**	***Summary of proposed amendments*** The many amendments to this Annex relate to the digital format of the certificate and the necessary means of verification. ***Technical recommendation*** The comments made under Article 35 apply in general to Annex 6, for example, with regard to the feasibility of digital certificates in many countries, as well as not precluding future technological developments. Similar considerations apply to the feasibility of having the Health Assembly decide on the related technical requirements, since situations may change periodically at short notice.

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authorized health professional. Digital certificates must incorporate a means to verify authenticity from an official web site, for example a QR code.4F[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**	

[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

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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. 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.**	

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(…) 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"**	***Summary of proposed amendments*** The proposed amendment adds another question to the list of "health questions" in relation to the presence on board of ships of travellers "without the required vaccination in Annex 7", and an action to verify the authenticity of this vaccination by using a QR code verification method. The proposed amendment would also require a column to be added to the attachment to the model of maritime declaration of health entitled "Vaccination according to Annex 7". ***Technical recommendation*** Annex 7 states that States Parties "may" require proof of vaccination against yellow fever, or against any other disease for which specific recommendations are made under the Regulations, as well as proof of prophylaxis. In addition, Annex 4 requires conveyance operators to facilitate the application of health measures under the Regulations. Therefore, the provision concerning verification of proof of vaccination, if

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	required by the State Party where the conveyance arrives, is covered by Annexes 4 and 7. The proposed amendment to Annex 8 implies that the master of a ship carries out the verification of proof of vaccination, instead of the State Party. It is unclear to the Committee how this additional question on the maritime declaration will facilitate application of the Regulations. The issue of the digital format of vaccination cards is being addressed in other proposed amendments to Articles 31, 35 and 36 (see related comments).
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;**	***Summary of proposed amendments*** The proposed new Annex 10, in the Committee's understanding, would create obligations on States Parties to collaborate and cooperate between themselves and on WHO and States Parties to collaborate and cooperate with each other. ***Technical recommendation*** The Committee appreciates the spirit of the proposed new Annex and believes that there should be collaboration and assistance under the Regulations. Articles 13 and 44, as well as some of the proposed amendments to those Articles, speak to such collaboration and assistance and how they should be strengthened. The obligations set out in paragraph 1 of this proposed new Annex appear to be absolute and unconditional. The Committee notes that WHO currently publishes and updates many of the guidelines and protocols referred to in paragraph 2(a), as well as the medical products listing (pre-qualified medical products) and devices/technologies listing (Global Model Regulatory Framework for Medical Devices). The Committee further notes that many of the proposed amendments to paragraph 2 relate to core capacity gaps, which can be identified through the assessment tools developed by WHO. These tools can also be used by State Parties to identify how core capacities and response architecture need to be strengthened. If requested to provide assistance, it is unclear what steps WHO or States Parties should take. Some of the bullet points, such as paragraph 2(b)(iii) concerning the provision of logistical support, are more clearly related to international cooperation, while others, such as paragraph 2(b)(i) concerning the development of guidelines and protocols, seem to refer to measures to be implemented by individual States Parties. There are clear

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(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;**	resource constraints on the ability of any State Party or WHO to provide particular forms of assistance. In summary, the Committee supports the idea of full cooperation and collaboration between WHO and States Parties, but the proposed new Annex 10 would be difficult to implement. Overall, the Committee observes significant interlinkages between Articles 13 and 44 (and related proposed amendments) and the proposed new Annex 10, to the extent that this new Annex may be redundant. Moreover, in the current structure of the Regulations, the Annexes provide the technical components of the provisions in the main body of the Regulations. However, the proposed new Annex 10 goes well beyond that supporting function, containing provisions that exceed the scope of both the current Article 44 and the amendments proposed thereto.

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(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.**	

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