

# **Report of the Review Committee regarding amendments to the International Health Regulations (2005)**

## **Report by the Director-General**

The Director-General has the honour to transmit to the Working Group on Amendments to the International Health Regulations (2005) the report of the Review Committee regarding amendments to the International Health Regulations (2005) (see Annex) in accordance with decision WHA75(9) (2022).

## ANNEX

## Contents

Acknowledgements .....	5
Preface .....	6
Acronyms and abbreviations .....	9
Executive summary .....	10
1. Introduction and background .....	12
2. Methods of work.....	13
3. General considerations regarding the proposed amendments.....	15
Key values underpinning some of the proposed amendments to the International Health Regulations (2005).....	16
Equity, solidarity and international cooperation .....	16
Trust and transparency .....	18
Sovereignty .....	18
General considerations on some of the proposed amendments to the provisions that operationalize the International Health Regulations (2005) .....	19
Surveillance.....	19
Notification and information sharing .....	19
Rapid public health responses .....	20
Support to improve health system capacities, including financial and technical assistance .....	20
Digital information and data protection .....	21
Countering misinformation and disinformation.....	21
Accountability, compliance and implementation.....	21
Reflections on the broader governance landscape in which the amendment process is taking place.....	22
4. Article-by-article/annex-by-annex analysis and technical recommendations .....	25
PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES .....	25
Article 1 – Definitions.....	25
Article 2 – Purpose and scope .....	26
Article 3 – Principles.....	28
Article 4 – Responsible authorities .....	30
PART II – INFORMATION AND PUBLIC HEALTH RESPONSE .....	31
Article 5 – Surveillance.....	31
Article 6 – Notification .....	36
Article 7 – Information-sharing during unexpected or unusual public health events .....	39
Article 8 – Consultation .....	40

Article 9 – Other reports .....	41
Article 10 – Verification .....	41
Article 11 – Provision of information by WHO .....	43
Article 12 – Determination of a public health emergency of international concern (PHEIC).....	45
Article 13 – Public health response.....	49
NEW Article 13A – Access to health products, technologies and know-how for public health response .....	52
NEW Article 13A – WHO-led international public health response .....	54
<b>PART III RECOMMENDATIONS .....</b>	<b>57</b>
Article 15 – Temporary recommendations .....	57
Article 16 – Standing recommendations.....	59
Article 17 – Criteria for recommendations .....	59
Article 18 – Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels .....	60
<b>PART IV – POINTS OF ENTRY .....</b>	<b>61</b>
Article 19 – General obligations .....	61
<b>PART V – PUBLIC HEALTH MEASURES.....</b>	<b>61</b>
Article 23 – Health measures on arrival and departure.....	61
Article 24 – Conveyance operators.....	62
Article 27 – Affected conveyances .....	63
Article 28 – Ships and aircraft at points of entry .....	64
Article 31 – Health measures relating to entry of travellers .....	64
<b>PART VI – HEALTH DOCUMENTS.....</b>	<b>65</b>
Article 35 – General rule.....	65
Article 36 – Certificates of vaccination or other prophylaxis .....	66
<b>PART VIII – GENERAL PROVISIONS.....</b>	<b>67</b>
Article 42 – Implementation of health measures .....	67
Article 43 – Additional health measures.....	68
Article 44 – Collaboration and assistance.....	69
New Article 44A – Financial mechanism for equity in health emergency preparedness and response .....	71
Article 45 – Treatment of personal data.....	71
<b>PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE.....</b>	<b>72</b>
Article 48 – Terms of reference and composition (Emergency Committee) .....	72
Article 49 – Procedure (Emergency Committee).....	73
New Article 53A – Establishment of an Implementation Committee .....	75

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New Chapter IV – The Compliance Committee with new Article 53bis Terms of reference and composition, new Article 53ter Conduct of business and new Article 53quater Reports.....	75
New Article 54bis – Implementation .....	75
PART X – FINAL PROVISIONS .....	77
Article 54 – Reporting and review .....	77
Article 56 – Settlement of disputes .....	78
ANNEX 1 .....	79
ANNEX 2 .....	83
ANNEX 3 .....	85
ANNEX 4 .....	86
ANNEX 6 .....	87
ANNEX 8 .....	88
NEW ANNEX 10 .....	89
Appendix 1.....	90
Appendix 2.....	92

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The Committee also thanks the following States Parties that submitted amendments to the International Health Regulations (2005): Armenia, Bangladesh, Brazil, Czech Republic (on behalf of the Member States of the European Union), Eswatini on behalf of the Member States of the WHO African Region, India, Indonesia, Japan, Malaysia Namibia, New Zealand, Republic of Korea, Russian Federation (on behalf of the Member States of the Eurasian Economic Union), Switzerland, United States of America, and Uruguay (on behalf of the Member States of the Southern Common Market).

The Committee thanks all Member States, representatives of United Nations technical agencies and other stakeholders who participated in the three meetings of the Review Committee organized in accordance with Article 51.2 of the Regulations.

## PREFACE

### **Focus on the fundamental importance of preparedness, effective response, and equity**

It has been our utmost privilege to serve Member States and WHO in reviewing the more than 300 amendments to the International Health Regulations (2005) submitted by Member States. We realize that the task for Member States is complex and vitally important, and failure is not an option. **Now is the best opportunity we will have in a generation to fundamentally strengthen how the world prevents, prepares for, responds to, and recovers from public health emergencies of international concern.**

We are over **3 years into a pandemic that is unprecedented in our lifetimes**, with an estimated global toll of 15 million excess deaths and wide-ranging and continuing impacts throughout societies. The international community has learned a great deal about how the International Health Regulations (2005) function in a public health emergency of international concern of historic proportions. **The COVID-19 pandemic revealed deep inadequacies in the global health architecture at the national and global levels, including shortcomings of the Regulations.**

We recognize that States Parties are also engaged in a parallel process of drafting and negotiating a WHO “pandemic agreement”. **Yet the International Health Regulations (2005) are currently the only near-universal instrument for global health security that the world has.** That is why bold and effective reforms to the Regulations are so vital, as is coordination between the two negotiating processes.

We wish to leave senior decision-makers with a singular message: focus on the fundamentals. Capture this unique moment of possibility. Be bold in thinking and in action. Develop and prioritize amendments to the International Health Regulations (2005) that will fundamentally improve global public health protection and help create a more equal, just and resilient world – and a better prepared one.

We urge States Parties to assess proposed amendments by considering their “effectiveness” as the most important guiding consideration. That is, ask yourselves and each other: how can amended International Health Regulations (2005) materially advance the goals of prevention, preparedness and response in a manner that leaves no one behind?

In this report, the Committee has identified key shared values that underpin the proposed amendments to the Regulations: (1) equity, solidarity and international cooperation; (2) trust and transparency; and (3) sovereignty. Building on these values, the Chair and Vice-Chair offer the following blueprint:

#### ***1. Strengthen health system capacities for better preparedness***

Every country should strengthen existing requirements for core capacities under the International Health Regulations (2005) and **consider expanding these wider health system capacities, including One Health.** They should also promote mutual and shared responsibilities for these functions, including funding, technical assistance and evaluation.

#### ***2. Leave no one behind***

The International Health Regulations (2005) imply the values of equity, solidarity and international cooperation in their inclusion of universal application, human rights and obligations on international cooperation and assistance. Negotiations on the proposed amendments to the International Health

Regulations (2005) offer an opportunity to strengthen and extend core equity and human rights protections, incorporating internationally recognized standards.

Shared responsibility recognizes that the best way to keep people in each country safe is to keep people in all countries safe. But more than this, it is a value rooted in justice and equity, that we endeavour to ensure the health of people everywhere not only for our own health and safety, but for theirs as well. The revised International Health Regulations (2005) should, wherever possible, further embody these values of international law.

### ***3. Align incentives for international cooperation***

The current incentive structures of the International Health Regulations (2005) are misaligned. States Parties that adhere to their requirements under the Regulations by quickly notifying WHO of public health events, by being fully transparent with their data, or by quickly sharing the full scope of their scientific understanding of a disease are sometimes penalized by unjust travel and trade restrictions. Amending the Regulations' incentive structure should encourage, rather than punish, full transparency and compliance.

### ***4. Ensure early and accurate notification***

Speed during the early stages of a potential public health emergency is of utmost importance. It may mean the difference between a local outbreak and a global pandemic. Notification to WHO has frequently been delayed, including during COVID-19. The International Health Regulations (2005) should better incentivize and facilitate rapid notification and comprehensive reporting.

### ***5. Promote the full sharing of scientific information***

Decisions should be rooted in scientific principles and the best available scientific evidence at every stage. While open science is not currently part of the International Health Regulations (2005), their chief aim will be advanced with the full and open exchange of all relevant scientific information. The amended Regulations should promote open and full exchange of all relevant scientific data. The corollary to this is the equally fulsome exchange of benefits that may be derived from such data. One of these essential values should not be traded for the other.

### ***6. Embed principles of good governance***

The International Health Regulations (2005) should promote good governance – that is, transparency, accountability and inclusive participation. Without transparency, public health decision-making may be ineffective or even grounded in misinformation. Without accountability – to fellow States and to national populations – national and international responses to disease outbreaks will be less effective. And only through inclusive, participatory decision-making, can governments be certain that they are meeting the needs of their entire populations, particularly those who are marginalized. States also may consider how advances in technology, including information and communications technology, could contribute to enhanced transparency and accountability.

### **7. *Improve implementation of and compliance with the International Health Regulations (2005)***

Strengthening implementation of and compliance with the Regulations is vital to the success of any reform. While States' failures to give full effect to the Regulations may have been most extensive during COVID-19, they have occurred since the Regulations were first adopted. The amended Regulations should seek to encourage and facilitate implementation and compliance.

If we fail to act now in fundamentally strengthening the International Health Regulations (2005), the consequences may be severe.

History will look to these negotiations and WHO Member States' willingness to prevent, or at least better manage, another global tragedy like COVID-19, the impacts of which could have been reduced with robust and effective national responses supported by international legal instruments and institutions. The global community demands bold action from the world's governments to advance collective health security and equity through revisions to the International Health Regulations (2005). Such bold action will help keep future generations safer, promote equity and human rights, and advance social and economic prosperity.

States Parties and WHO must then rise to meet the moment and make the International Health Regulations (2005) fit for purpose in the twenty-first century.

Dr Patrick Amoth

Chair, Review Committee regarding  
Amendments to the International Health  
Regulations (2005)

H.E. Ambassador Juan José Gómez Camacho,  
Mexico

Vice-Chair, Review Committee regarding  
Amendments to the International Health  
Regulations (2005)

January 2023



**ACRONYMS AND ABBREVIATIONS**

FAO	Food and Agriculture Organization
GSD	genetic sequence data
IAEA	International Atomic Energy Agency
IHR	International Health Regulations (2005)
INB	Intergovernmental Negotiating Body
OIE	World Organisation for Animal Health
PHEIC	public health emergency of international concern
PIP	Pandemic Influenza Preparedness
PoE	point-of-entry
SARS	Severe acute respiratory syndrome
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WARN	World Alert and Response Notice
WGIHR	Working Group on Amendments to the International Health Regulations (2005)
WOAH	World Organisation for Animal Health
WTO	World Trade Organization
UNEP	United Nations Environment Programme

## EXECUTIVE SUMMARY

The Review Committee regarding amendments to the International Health Regulations (2005) (the Committee) was convened by the Director-General at the Seventy-fifth World Health Assembly through decision WHA75(9) (2022), in accordance with Article 50, paragraphs 1(a) and 6 of the Regulations. The Committee's sole purpose is to provide technical recommendations to the Director-General on proposed amendments to the Regulations submitted by States Parties, pursuant to decision WHA75(9), and consistent with decision EB150(3) (2022). The decision further requested the Review Committee to submit its report to the Director-General by mid-January 2023, with the Director-General communicating it without delay to the Working Group on Amendments to the International Health Regulations (2005) (WGIHR). A final package of targeted amendments will be presented by WGIHR for consideration by the Seventy-seventh World Health Assembly in 2024, in accordance with Article 55 of the Regulations.

The Committee was convened by the WHO Director-General on 6 October 2022 and functioned in accordance with the WHO Regulations for Expert Advisory Panels and Committees.<sup>1</sup> The Committee was composed of 20 members, selected and nominated by the Director-General from the International Health Regulations (2005) Roster of Experts, covering a wide range of expertise and reflecting an adequate gender and geographical representation (see Appendix 1 for details). Dr Patrick Amoth from Kenya was selected as the Committee's Chair, supported by Vice-Chair Ambassador Juan José Gómez Camacho from Mexico, and Rapporteur, Dr Clare Wenham from the United Kingdom of Great Britain and Northern Ireland. The experts worked in their personal capacity and not as representatives of their countries or employers.

The Committee conducted its work from 6 October 2022 to 15 January 2023, supported by the WHO Secretariat. Three in-person meetings in Geneva and three virtual meetings spanned a total of 25 days. Between meetings, members of the Committee worked individually and in subgroups and communicated by email. In accordance with Article 51, paragraph 2, the Committee held three open meetings at WHO headquarters with designated representatives from WHO Member States, States Parties to the International Health Regulations (2005), the United Nations and its specialized agencies and other intergovernmental organizations and nongovernmental organizations in official relations. These meetings took place on 25 October 2022, 1 December 2022 and 12 January 2023.

In total, more than 300 individual amendments were proposed by 16 States Parties (some on behalf of groups of countries). The proposed amendments relate to 33 of the 66 articles contained in the Regulations and to five of the nine annexes; in addition, six new articles and two new annexes were proposed. The proposed amendments as submitted by States Parties are available on the WGIHR website,<sup>2</sup> together with an article-by-article compilation of all proposed amendments.

The Committee's work progressed in three sequential readings of the full set of the proposed amendments. Each proposed amendment or grouping of amendments was analysed according to the criteria listed within the Committee's Terms of Reference: appropriateness, clarity, consistency and feasibility. Other considerations included, *inter alia*: whether the issues addressed by the proposed amendment(s) were consistent with other WHO instruments and other relevant international legal instruments; whether the proposed amendment(s) would require new definitions under Article 1 of the Regulations; whether the proposed amendment(s) would identify gaps or new elements for the

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<sup>1</sup> WHO Basic Documents 2020 ([https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf), accessed 17 January 2023).

<sup>2</sup> [https://apps.who.int/gb/wgihre/e\\_wgihre-1.html](https://apps.who.int/gb/wgihre/e_wgihre-1.html), accessed 17 January 2023.

consideration of States Parties; and whether the proposed amendment(s) would require additional mechanisms for monitoring and compliance.

The Committee agreed from the outset that an overarching consideration was to ensure that its findings and recommendations would be practical and useful for the members of the WGIHR.

The Committee encountered several limitations to the development of its technical recommendations. Most significant was the short time frame allowed for completion of the Committee's mandate and preparing its report. A second limitation in adopting a consistent methodology arose from the extreme diversity of proposed amendments, which range from limited technical changes to substantial additions and revisions, and even to entire new articles and annexes.

The Committee agreed to balance the methodological template with the desire to consider each proposed amendment in its own right. Despite some inevitable challenges, the Committee aimed, as far as possible, to reconcile consistency of analysis with a reflection of the different intentions and purposes of particular amendments, based, when applicable, on the rationale offered by the States Parties concerned. This approach was also used in assessing overlapping proposals with a similar purpose.

The more than 300 proposed amendments submitted by States Parties reflect an imperative to strengthen the Regulations to improve the prevention of, preparedness for, and response to, public health events with risks of international spread and public health emergencies of international concern (PHEICs).

During their article-by-article analysis, the Committee noted that multiple proposed amendments relate to values such as equity, solidarity, international cooperation, trust and transparency, and sovereignty. The Committee understands the importance of these values which underpin the implementation of the Regulations, and presented their related considerations in Chapter 3 under the heading "Key values underpinning some of the proposed amendments to the IHR". Chapter 3 also includes the Committee's overview of the proposed amendments concerning provisions that operationalize implementation of the Regulations, as well as some considerations in relation to the context in which the amendment process is taking place.

Chapter 4 presents the Committee's detailed analysis of each article or annex to which proposed amendments were submitted. This chapter includes over 70 pages of detailed analysis, connecting the proposed amendments to other related proposals, and identifying terms that may require definitions should the proposed amendments be adopted. This analysis is presented in the following format: a short description of the original article; a summary of the proposed amendments; and its technical recommendations.

All members of the Committee are grateful for the opportunity to serve on the Committee in their capacity as experts and hope their analysis will be duly considered by States Parties to the International Health Regulations (2005) as they embark on discussing these proposed amendments in the WGIHR. The Committee remains ready to be reconvened should the Director-General require its technical recommendations during or at the end of the WGIHR discussions, before submitting the package of proposed amendments to the Seventy-seventh World Health Assembly.

## 1. INTRODUCTION AND BACKGROUND

The Review Committee regarding Amendments to the International Health Regulations (2005)<sup>1</sup> (the Committee) was convened by the Director-General at the request of the Health Assembly in decision WHA75(9),<sup>2</sup> and in accordance with Article 50, paragraphs 1(a) and 6 of the Regulations. The Committee's sole purpose was to provide technical recommendations to the Director-General on proposed amendments to the Regulations submitted by States Parties, pursuant to decision WHA75(9) and consistent with decision EB150(3).<sup>3</sup> Decision WHA75(9) further requested the Review Committee to submit its report to the Director-General by 15 January 2023, with the Director-General communicating it without delay to the WGIHR,<sup>4</sup> also established pursuant to the same decision. A final package of targeted amendments will be presented by the WGIHR for consideration by the Seventy-seventh World Health Assembly in 2024, in accordance with Article 55 of the Regulations.

The Committee was convened by the WHO Director-General on 6 October 2022 and functioned in accordance with the WHO Regulations for Expert Advisory Panels and Committees.<sup>5</sup> The Committee was composed of 20 members, selected and nominated by the Director-General from the International Health Regulations (2005) Roster of Experts, covering a wide range of expertise and reflecting an adequate gender and geographical representation (see Appendix 1 for details). Dr Patrick Amoth from Kenya was selected as the Committee's Chair, supported by Vice-Chair Ambassador Juan José Gómez Camacho from Mexico, and Rapporteur Dr Clare Wenham from the United Kingdom of Great Britain and Northern Ireland. The experts worked in their personal capacity and not as representatives of their countries or employers. Meeting reports for the Committee's meetings are available on its website.<sup>6</sup>

The remainder of the report is structured as follows: Chapter 2 presents the method of work developed and used by the Committee, pursuant to their terms of reference; in Chapter 3 the Committee provides some general considerations in relation to the proposed amendments, placing them in the broader context in which the process of amending the Regulations is taking place; Chapter 4 presents an article-by-article/annex-by-annex analysis of the proposed amendments and the Committee's technical recommendations; finally, Appendix 1 contains the list of Committee members, and Appendix 2 their Terms of Reference.

The full set of proposed amendments as submitted by States Parties is available on the WGIHR website, together with an article-by-article compilation of all proposed amendments.<sup>7</sup>

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<sup>1</sup> International Health Regulations (2005), 3rd ed., World Health Organization; 2016; (<https://www.who.int/publications/i/item/9789241580496>, accessed 18 January 2023).

<sup>2</sup> Decision WHA75(9) ([https://apps.who.int/gb/ebwha/pdf\\_files/WHA75/A75\(9\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(9)-en.pdf), accessed 18 January 2023).

<sup>3</sup> Decision EB150(3), 2022 (available at: [https://apps.who.int/gb/ebwha/pdf\\_files/EB150-REC1/B150\\_REC1-en.pdf#page=30](https://apps.who.int/gb/ebwha/pdf_files/EB150-REC1/B150_REC1-en.pdf#page=30), accessed 18 January 2023).

<sup>4</sup> [https://apps.who.int/gb/wgihre/e\\_wgihr-1.html](https://apps.who.int/gb/wgihre/e_wgihr-1.html), accessed 18 January 2023.

<sup>5</sup> WHO Basic Documents 2020 [https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf).

<sup>6</sup> [https://www.who.int/teams/ihr/ihr-review-committees/review-committee-regarding-amendments-to-the-international-health-regulations-\(2005\)](https://www.who.int/teams/ihr/ihr-review-committees/review-committee-regarding-amendments-to-the-international-health-regulations-(2005)), accessed 18 January 2023.

<sup>7</sup> [https://apps.who.int/gb/wgihre/e\\_wgihr-1.html](https://apps.who.int/gb/wgihre/e_wgihr-1.html), accessed 18 January 2023.

## 2. METHODS OF WORK

The Committee conducted its work from 6 October 2022 to 15 January 2023, supported throughout by the WHO Secretariat. Three in-person meetings in Geneva and three virtual meetings spanned a total of 25 days. Between meetings, members of the Committee worked individually and in subgroups, and communicated by email.

In accordance with Article 51 paragraph 2, the Committee held three open meetings at WHO headquarters with designated representatives from WHO Member States, States Parties to the International Health Regulations (2005), the United Nations and its specialized agencies and other intergovernmental organizations and nongovernmental organizations in official relations. These meetings took place on 25 October 2022, 1 December 2022 and 12 January 2023.

In total, more than 300 individual amendments were proposed by 16 States Parties (some on behalf of groups of countries). The proposed amendments relate to 33 of the 66 articles contained in the Regulations, and to five of the nine annexes; in addition, six new articles and two new annexes were proposed.

The Committee's work progressed in three sequential readings of the full set of the proposed amendments.

**First reading:** In their first reading during the first face-to-face meeting from 24 to 28 October 2022, the Committee reflected on all the proposed amendments in an unstructured but comprehensive discussion. The first reading revealed several areas of consensus among Committee members, as well as matters requiring further in-depth study and deliberation. The amendments were organized by the Secretariat in individual files for each article or annex, using the following template: the original text of the article; the text of the proposed amendments, codified by the submitting State(s) Party(ies) and using a single format (bold and underlined fonts for newly proposed text, and strikethrough for text to be deleted); the rationale provided by the submitting State(s) Party(ies); and the overall assessment for all proposed amendments. These files were made available to all Committee members in an online secure platform, established and maintained by the WHO Secretariat. After the first reading, through the Secretariat, the Committee requested further clarification regarding the rationale or the proposed text from nine of the States Parties submitting proposed amendments.

**Second reading:** The Committee undertook a second reading, using the above-mentioned files, through online meetings held on 16–17 November and 22–23 November, as well as at an in-person meeting in Geneva from 28 November to 2 December. The second reading consisted of a structured analysis of each article and annex to which amendments had been proposed, building on the comments and considerations provided by members during the first reading. The Committee worked simultaneously in parallel smaller groups, each of which provided a preliminary assessment of groups of articles or annexes.

The analysis of the proposed amendments for individual articles and annexes conducted in these smaller groups aimed to address the following elements, which the Committee tried to follow consistently, while recognizing that this was not always feasible, particularly with regard to the newly proposed articles and annexes:

- A summary of the current article or annex.

- A summary of the proposed amendment(s) to the article or annex, including where possible, a grouping by themes of the amendments which were similar in spirit and objective, even if proposed by different States Parties.
- An analysis of each proposed amendment or grouping of amendments according to the criteria listed within the Committee's Terms of Reference (see Appendix 2):
  - **Appropriateness** – whether the proposed amendment(s) would be suitable for achieving the intended purpose of this article and/or the International Health Regulations (2005) more broadly.
  - **Clarity** – whether the proposed amendment(s) would enhance the clarity of the article or annex.
  - **Consistency** – whether the proposed amendment(s) would be in line with the scope, in accordance with Article 2, principles in accordance with Article 3, or other articles of the Regulations, as well as within the scope of Article 21(a) of the WHO Constitution, the provision under which the Regulations were adopted. Since amendments were also proposed to Articles 2 and 3, the Committee considered the possibility of consistency between a proposed amendment and these proposed revisions to the scope and/or purpose of the Regulations.
  - **Feasibility** – whether the proposed amendment(s) would be feasible, in operational and legal terms, as well as with regard to resource implications for WHO.
  - **Other considerations** – the Committee considered, inter alia, (1) whether the issue addressed by the proposed amendment(s) was consistent with other WHO instruments, and other relevant international legal instruments, as appropriate; (2) whether the proposed amendment(s) would require new definitions under Article 1 of the Regulations; (3) whether the proposed amendment(s) would identify gaps or new elements for the consideration of States Parties; and (4) whether the proposed amendment(s) would require additional mechanisms for monitoring and compliance.

This preliminary assessment resulted in a set of technical recommendations on the proposed amendment(s) for each article or annex. Where the clarity and/or consistency of the proposed amendment(s) would benefit from minor rewording, suggestions were provided. The Committee agreed from the outset that an overarching consideration was to ensure that its findings and recommendations would be practicable and useful for the members of the WGIHR.

**Final reading:** In their final reading, which took place from 20 December 2022 to 6 January 2023, the Committee members reviewed and provided feedback on the shared platform on the preliminary assessments of each article and annex, and further refined the drafts of the preliminary assessments, as well as their technical recommendations.

The Committee finalized their technical recommendations and agreed on the final report during the last face-to-face meeting from 9 to 13 January 2023. The final analysis is presented in the following format for each article: a short description of the original article; a summary of the proposed amendments; and the technical recommendation of the Committee.

For some articles, the Committee notes that there were proposals addressing a similar theme but with different wording or with different modalities for operationalization. These proposals were grouped by theme and addressed together under the same subheading. For other articles, if there were multiple proposals made for the same paragraph and these could not be grouped under a similar theme, the analysis is presented paragraph by paragraph.

For the two newly proposed Articles 13A, a separate analysis is provided for each Article. For the newly proposed Articles 53, 53 bis-quater and 54bis, since these three Articles proposed a similar topic (compliance/implementation/reporting) but with different ways of operationalization, the Committee considered these proposed new Articles in a single analysis.

Although initially the Committee members drafted their analysis using the related States Parties' codes for each proposed amendment, the final analysis does not attribute the proposed amendments to the States Parties submitting them, in line with the way the article-by-article compilation of proposed amendments was published, following the decision of the WGIHR at its first meeting on 14–15 November 2022.

### **Challenges**

The Committee encountered several challenges in the development of its technical recommendations. Most significant was the short time frame for completion of the Committee's mandate and development of the report: the Committee was tasked with reviewing more than 300 amendments and developing consensus on the technical recommendations pertaining to these proposals within less than 100 days, a time frame compounded by challenges in scheduling meetings across many time zones.

A second challenge was the extreme diversity of the proposed amendments, which ranged from limited technical changes to substantial additions and revisions and even to entire new articles and annexes. The Committee agreed to balance the methodological template with the desire to consider each proposed amendment on its own merit.

Despite some inevitable challenges, the Committee aimed, as far as possible, to reconcile consistency of analysis with a reflection of the different intentions and purposes of particular amendments, based when applicable on the rationale offered by the States Parties concerned. This approach was also used in assessing overlapping proposals with a similar purpose.

### **3. GENERAL CONSIDERATIONS REGARDING THE PROPOSED AMENDMENTS**

The International Health Regulations (2005) were developed and adopted under Article 21(a) of the WHO Constitution.<sup>1</sup> They provide legal obligations and operational requirements for WHO and States Parties to prevent, protect against, control and provide a public health response to the international spread of disease. These public health requirements and objectives must be considered while avoiding unnecessary interference with international traffic, trade and human rights; and recognizing their universal application for the protection of all people of the world.

The COVID-19 pandemic revealed many shortcomings in the global health security architecture of which the Regulations are only one, albeit a critical, part. The challenges faced during the COVID-19

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<sup>1</sup> WHO Constitution, 1946 (available at: <https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1>, accessed 18 January 2023).

pandemic have been well documented through a range of expert analyses.<sup>123</sup> Notably for the analysis of this Committee, the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response (Review Committee on COVID-19) concluded that there are fundamental gaps in the implementation of and compliance with the Regulations.

The more than 300 proposed amendments submitted by States Parties reflect a major imperative to strengthen the Regulations to improve the prevention of, preparedness for, and response to, public health events with risk of international spread and PHEICs. Many proposed amendments also relate to the aim of improving and operationalizing equity as a vital global value.

The first section below provides an overview of the Committee's understanding of how the proposed amendments relate to key values underpinning the Regulations. The next section provides some general considerations about the proposed amendments related to the specific provisions that operationalize the Regulations. Lastly, in this Chapter, the Committee presents its views in relation to the broader governance landscape in which the amendment process is taking place.

## **Key values underpinning some of the proposed amendments to the International Health Regulations (2005)**

### **Equity, solidarity and international cooperation**

Several proposed amendments aim to address equity and solidarity, as well as international cooperation. The Committee acknowledges the need for a significant role for these key values within the Regulations, but there were divergent views among the Committee members as to whether their purpose and scope, as provided in Article 2, can accommodate all equity-related amendments.

Although the term “equity” is not used in the Regulations, this value is crucial to the promotion of global health to the extent that it guides the international response to public health risks, events that may constitute a PHEIC, and a PHEIC itself. As stated in Article 3, the Regulations are guided by the principle of their “universal application for the protection of all peoples of the world from the international spread of disease”, and their implementation requires respect for the “dignity, human rights and fundamental freedoms of persons”. The Regulations are further framed by the WHO Constitution, which has as its central objective the “attainment by all peoples of the highest possible level of health”.<sup>4</sup> The promotion of equity is underscored in amendments proposed to the purpose and scope of the Regulations, as well as to its principles. Moving beyond purpose, scope and overarching principles, the proposed amendments also seek to operationalize equity through specific provisions, some of which would build on and modify existing obligations, while others would introduce new obligations on both

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<sup>1</sup> Document A74/9 Add.1, containing the report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response, 2021; ([https://apps.who.int/gb/ebwha/pdf\\_files/WHA74/A74\\_9Add1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_9Add1-en.pdf), accessed 18 January 2023).

<sup>2</sup> COVID-19: Make it the Last Pandemic, Main Report of the Independent Panel for Pandemic Preparedness and Response (IPPPR), 2021 (available at: [https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic\\_final.pdf](https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf), accessed 18 January 2023).

<sup>3</sup> Document A75/16 containing the report by the Independent Oversight and Advisory Committee (IOAC) transmitted to the 75th World Health Assembly, 2022 ([https://apps.who.int/gb/ebwha/pdf\\_files/WHA75/A75\\_16-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_16-en.pdf), accessed 18 January 2023).

<sup>4</sup> WHO Constitution, 1946 (available at <https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1>, accessed 22 January 2023).



States Parties and WHO. The Committee sees merit in this dual, overarching and operationalizing approach.

WHO Member States recognized that equitable protection against the international spread of disease cannot be achieved without solidarity and cooperation among States Parties and the international community more broadly.<sup>1,2</sup> This Committee recalls the conclusion of the Review Committee on COVID-19 that the Regulations are as effective as States Parties enable them to be. Therefore, the Committee looks upon equity, solidarity and cooperation as key values that underpin the Regulations, and as instruments to be operationalized for the Regulations' successful functioning.

Several proposed amendments also impose shared but differential obligations between high- and lower-income States. These proposals, which introduce terms derived from the proposed concept of "common but differentiated responsibilities" as encountered in environmental law, will require careful analysis, given the goal of the universal application of the Regulations under Article 3. They were not designed to address more pervasive issues exposed by COVID-19, for example, the persistent and gross disparities in access to life-saving medical countermeasures, including not only diagnostics, personal protective equipment, treatments, medical devices and vaccines, but also the commodities necessary for the manufacturing, packaging and distribution of such countermeasures.

Inequities in access to medical countermeasures were manifested in myriad ways during the pandemic, in particular through pre-purchase agreements by high-income countries that resulted in vaccine scarcity, and unaffordable prices charged by patent holders whose stockpiled vaccine doses eventually expired before they ever reached individuals, including health workers.

Existing structural barriers to equitable access became even more evident during the COVID-19 pandemic, including intellectual property rights, the absence of diversified regional manufacturing capacities, and delays in technology transfer. Some States Parties view these and other barriers to equity in the COVID-19 response as issues that can be meaningfully addressed through amendments to the Regulations.

In particular, some proposed amendments would introduce obligations to ensure access to necessary medical countermeasures, some of which attribute new functions to WHO and would require adequate financing if adopted. These proposed amendments will also require attention being paid to the regulation of non-State actors and jurisdiction related considerations. These amendments call for a nuanced analysis of their coherence with States Parties' existing obligations in other domains of international law, which are briefly further elaborated below.

The Committee is of the view that equity as a value and principle extends well beyond access to medical countermeasures, knowledge and technology transfer. Some Committee members see a potential role for greater inclusion within the proposed amendments to help address the unequal experiences of the

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<sup>1</sup> See, for instance, Health Assembly resolutions issued by States during the COVID-19 pandemic; see also WHO Constitution the United Nations Charter Art. 56.

<sup>2</sup> In addition to the conclusions of the reports referenced in footnotes 11, 12 and 13, equity, solidarity, international cooperation and related themes were deemed critically important to the COVID-19 pandemic response in Health Assembly resolution WHA73.1 (2020); available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA73-REC1/A73\\_REC1-en.pdf#page=25](https://apps.who.int/gb/ebwha/pdf_files/WHA73-REC1/A73_REC1-en.pdf#page=25), accessed 22 January 2023; and United Nations General Assembly resolutions A/RES/74/270 (2020); available at: <https://undocs.org/en/A/RES/74/270>, accessed 22 January 2023; and A/RES/74/274 (2020); available at: <https://undocs.org/en/A/RES/74/274>, accessed 22 January 2023).

international spread of disease due to gender, race, locality, age, disability, sexuality, indigeneity and other vulnerabilities.

### **Trust and transparency**

Several proposed amendments recognize the importance of strengthening the sharing, with WHO and other States Parties, of key scientific and epidemiological information as rapidly and transparently as possible. Speed and transparency in relation to the prevention of, preparedness for, detection and assessment of, and response to the international spread of disease are of paramount importance, and international cooperation is a cornerstone of an effective emergency response.

The Committee recognizes that historically, and, in particular, during the COVID-19 pandemic, States Parties that shared information in an open and transparent manner were often penalized, for example, through the imposition of travel or trade restrictions. The Committee believes that there should be no disincentives for full cooperation in sharing scientific information that could improve responses when there is a public health risk before or during PHEICs.

In recent years, the use of genetic sequence data (GSD)<sup>1</sup> has become invaluable for surveillance, risk assessment, response and ongoing research purposes, alongside other epidemiological and surveillance information and pathogen sample sharing. The Committee notes that there is convergence across proposed amendments on the sharing of GSD, with some making it conditional on having access to benefits deriving from their use.

In the Committee's assessment, both are essential: the rapid and reliable sharing of information, including pathogen samples and GSD, could be enhanced by guarantees for the equitable sharing of benefits arising from the use of such resources. At the same time, a purely bilateral relationship between access to pathogen samples and GSD and the sharing of benefits derived from them is detrimental to the global response. A pre-arranged multilateral model of access and benefit-sharing that mandates fast access to information, as well as fair, timely and equitable access to the benefits from their use (e.g. diagnostics, therapeutics and vaccines) may prove more promising.

In this regard, the Pandemic Influenza Preparedness (PIP) Framework, adopted by the World Health Assembly in 2011,<sup>2</sup> although developed for a specific situation and not yet fully tested in practice, in the absence of an influenza pandemic since its adoption, stands as an important example of how creativity, innovation and solidarity can help States Parties move past diverging interests, towards incorporating shared and mutual responsibilities for sharing critical public health information in protecting the world against the international spread of disease.

### **Sovereignty**

Article 3 of the International Health Regulations (2005) recognizes that “States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.” Many other provisions of the Regulations similarly embed – either

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<sup>1</sup> The term “genetic sequence data” (GSD) is used in the publication “Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032”. Geneva: World Health Organization; 2022: (available at: <https://www.who.int/publications/i/item/9789240046979>, accessed 18 January 2023).

<sup>2</sup> Resolution WHA 64.5, 2011 (available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA64-REC1/A64\\_REC1-en.pdf#page=21](https://apps.who.int/gb/ebwha/pdf_files/WHA64-REC1/A64_REC1-en.pdf#page=21), accessed 18 January 2023).

implicitly or explicitly – respect and recognition for the sovereignty of States Parties, including articles related to notification, reporting and response to public health events that are or may constitute a PHEIC.

Although the proposed amendments do not explicitly reference sovereignty, assessments of proposed amendments will depend upon their implications for the sovereignty of States Parties. Some proposed amendments show an increasing understanding of shared and mutual responsibilities. These aspects are particularly relevant to provisions under Article 43 (see detailed analysis in Chapter 4, Part VIII).

The sovereignty of States Parties remains foundational to the Regulations. As with the revisions nearly 20 years ago that led to the International Health Regulations (2005), proposed amendments to them will require careful balancing between a State Party's sovereign right to take the actions necessary to protect its population against a public health risk, while recognizing their mutual vulnerabilities and responsibilities, and the imperative of international cooperation and solidarity, which are key enablers of effective Regulations.

The Committee considers that the international framework for preventing, preparing for and responding to public health risks is most effective when individual States are strengthened to perform their duties with shared trust and responsibility, as sovereign Parties to, and custodians of, the Regulations. The values mentioned above should be regarded as complementary rather than opposing elements of Regulations that are fit to counter contemporary public health risks.

## **General considerations on some of the proposed amendments to the provisions that operationalize the International Health Regulations (2005)**

### **Surveillance**

A pathogen may be circulating for many months before its detection, consequently seeding the disease in many locations. The ability to rapidly detect circulating pathogens is vital for ensuring that a timely response is launched, so as to prevent the international spread of disease. Modern surveillance systems are moving from traditional retrospective data systems towards real time “data for action” systems, and from a system that is disease-oriented towards one that is pathogen-oriented. The proposed amendments reflect this change and seek to strengthen the pivotal role of surveillance and detection, to be able to promptly detect an emerging and/or re-emerging public health risk or other health event as soon as possible, including through One Health approaches.

Beyond the desire for enhanced surveillance capacities, some amendments call for a more proactive approach rooted in precaution, particularly in relation to surveillance and early reporting. This would enable decision-makers to take measures necessary to safeguard human health when there was incomplete, uncertain or evolving scientific evidence. This would mean that in a new health event, States Parties and WHO would be required to be more responsive when deciding whether to follow an event closely, when to report to WHO, and when to implement relevant public health measures.

### **Notification and information sharing**

The proposed amendments re-emphasize the importance of States Parties reporting a potential PHEIC to WHO as soon as possible, and introduce further details about how best to do this, with what mechanism, and in what time scale.

The Committee recognizes that in practice various disincentives discourage the reporting of potential PHEICs to WHO. Yet delaying reporting events that may constitute a PHEIC poses a major risk of the

international spread of diseases, can affect trust and could spur travel or trade restrictions based on rumours, rather than on scientific evidence. Finding the right balance will be key. This reaffirming of attention to rapid notification and information sharing appears as a normative recommitment by States Parties to the principles of transparency and trust.

### **Rapid public health responses**

The COVID-19 pandemic once again highlighted the challenges of issuing, modifying and implementing temporary recommendations in relation to a PHEIC, as well as the categorization of recommended health measures, as the Review Committee on COVID-19 also concluded. Shortcomings in the implementation of WHO temporary recommendations are in part due to a lack of health system capacities, but in many cases appear to have been more about the prioritization of other social or economic objectives. It is imperative for global health security that there are robust response mechanisms both within States and globally to deploy a rapid and effective response.

Many of the proposed amendments consider mechanisms to improve the response to emerging PHEICs, including a clear time frame in which a response should be initiated. Other proposed amendments encourage States Parties to request and accept international support in all areas of preparedness and response. Some amendments seek to impose unsolicited assistance on States Parties, and obligations to provide justification for any rejection of such support. Finally, some proposed amendments call for a broader health system approach for an effective response, including universal health coverage, access to medical countermeasures, risk communication, community engagement and broader social support to communities.

The Committee understands the intention of proposed amendments to address these gaps and provides a detailed analysis and technical recommendations for all the proposed amendments in Chapter 4. Although the Committee agrees that a broader health system approach would improve preparedness and response, it will also be important to carefully consider whether these proposed amendments fit into the overall scope of the Regulations, which, in turn, depends on whether the scope is redefined as part of the amendment process.

### **Support to improve health system capacities, including financial and technical assistance**

The spirit of Article 44 is that States Parties should bear mutual responsibility to one another to meet the obligations of the International Health Regulations (2005) and provide bilateral and multilateral support in preparedness and response to public health risks and events. Thus, many proposals seek to facilitate and elaborate on the types of assistance required under the Regulations.

Several suggested amendments propose more defined and expanded responsibilities for high-income countries to support low- and middle-income countries in meeting their core capacities, including surveillance, detection and response. Many proposals were also addressed to WHO on providing technical support, its technical role under the Regulations, and more generally.

In line with the core values of equity and solidarity, the Committee strongly supports greater collaboration and assistance in support of implementation of the Regulations. Resource constraints have impeded many States in developing and maintaining core capacities under the International Health Regulations (2005). While there are some good examples of bilateral financing efforts for increasing health system capacity, this has clearly not been comprehensive enough to date to plug the gaps in implementation of the Regulations. Noting the resource limitations of WHO and its functions, such

financing should be coordinated by WHO, but sourced from other sectors of the multilateral landscape, and should aim to become sustainable in the long term, seeking to avoid a model based on grants or donations.

### **Digital information and data protection**

Traditionally, health documents, including certificates and other data shared under the Regulations, have been in paper form. Many States Parties are moving towards digitalized data, which can improve authenticity, accuracy and efficiency, as well as facilitate exchanges among national authorities. Under modern data protection principles, information should be accurate, secure, private, and not shared beyond what is necessary for core public health purposes. There is also the aim of interoperability, which means that data systems should, wherever possible, be compatible and have the capacity for seamless exchange across different technological platforms.

Several proposed amendments address health documentation and their digitalization. This might include, for example, the maritime health declaration or passenger certificates for prophylaxis and vaccination. Some States Parties have proposed targeted amendments to include, inter alia, digital certificates or certificates with a quick response (QR) code.

The Committee agrees with the need to bring the Regulations from the analogue into a digital age, as mentioned in the report of the Independent Panel for Pandemic Preparedness and Response cited earlier, and that digitalization should be used wherever possible. Its members also recognizes that some States Parties may not currently have full capacity and that interoperability may not yet be possible. It will therefore be important to ensure flexibility within the Regulations on this aspect and to devise agile processes to update technical requirements in future. “Future proofing” the Regulations to accommodate potential future technologies for secure and accurate sharing of vital information is necessary, while ensuring that amendments do not inadvertently “lock in” specific current formats to the exclusion of potential future ones.

### **Countering misinformation and disinformation**

During the COVID-19 pandemic, multiple sources of inaccurate, spurious misinformation and disinformation from a range of political, social and cultural sources hindered a meaningful public health response. Misinformation and disinformation can also undermine public trust in health agencies and impede public confidence in, and compliance with, governmental or WHO guidance. In particular, the rapid growth of anti-vaccination messages promulgated through social media posed a significant challenge to managing the associated response. A balance is needed between ensuring more accurate scientific information on one hand and freedom of speech and the press on the other. How to strike that balance while navigating global policy and national regulatory landscapes will be an ongoing challenge. The Committee also suggests that the Working Group on Amendments to the International Health Regulations (2005) might consider how misinformation and disinformation may relate to obligations for WHO to verify information coming from sources other than States Parties.

### **Accountability, compliance and implementation**

Since the revision of the International Health Regulations in 2005, the question of compliance and accountability has been frequently raised by States Parties, scholars and independent expert committees, including the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response and the Independent Panel for Pandemic Preparedness and Response,

cited above. At present, other than Articles 54 and 56 there are few provisions in the Regulations that help ensure compliance and accountability for failing to live up to States' obligations.

Three newly proposed articles introduce provisions related to strengthening compliance with the Regulations, improving their overall implementation, and holding States Parties accountable for that. The challenge remains how best to implement compliance and accountability mechanisms to ensure that States Parties are able to meet their obligations and build mutual trust, as well as promote an effective and equitable implementation of the Regulations. Proposals include, strengthening reporting mechanisms to provide regular progress updates; mobilizing technical and financial assistance in support of implementation; and creating avenues for Member State dialogue to promote compliance and accountability. The Committee supports improved implementation and compliance monitoring for the Regulations, but holds divergent views as to what modality may be most effective while also aligning with sovereignty imperatives.

### **Reflections on the broader governance landscape in which the amendment process is taking place**

Several proposed amendments call for a more empowered WHO. When the Regulations were revised in 2005, following the outbreak of severe acute respiratory syndrome (SARS) and concerns over influenza H5N1, WHO was given an unprecedented tool for managing the international spread of disease, which included: the ability to determine a PHEIC; the ability to use other ("unofficial") sources of information; and the ability of the Director-General to issue non-binding temporary and standing recommendations to States Parties.

In 2022, the Health Assembly initiated additional reforms to strengthen WHO's role in global health, such as increased commitments to assessed contributions to ensure more sustainable financing for the Organization, and the placing of the proposed pandemic accord under the auspices of WHO, with a view towards using the pandemic accord to strengthen the institution itself, as well as global health security and equity.

Many of the proposed amendments to the Regulations follow in this vein and seek equally to strengthen the Organization and its role in the management of public health risks and events that may lead to a PHEIC. Among them are: proposals for WHO to have an increased and supportive role in surveillance and response to PHEICs and other events; proposals to make it easier for WHO to perform multiple new roles, including playing a coordinating function within the response phase of a PHEIC; and proposals to expand its role not only to provide technical guidance and coordination, but as part of this, to assess the availability of medical and non-medical countermeasures and determine their global distribution when planning a response.

The Committee is cognizant that proposed amendments to the Regulations are just one part of broader reforms and efforts across the landscape of pandemic preparedness and response. The Committee's mandate is to provide technical advice on the proposals submitted for targeted amendments to the Regulations, but it also notes the importance of strong coordination and synergy with the various instruments, institutions and processes across the current landscape of public health emergency and pandemic preparedness and response. These include, but are not limited to:

- the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (pandemic accord);<sup>1</sup>
- the establishment of an Executive Board Standing Committee on Health Emergency Prevention, Preparedness and Response;<sup>2</sup> and
- the development of the Universal Health and Preparedness Review (UHPR).
- In addition, there are related processes under way in other institutional settings, such as:
  - the “Pandemic Fund” hosted by the World Bank;<sup>3</sup>
  - the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol);<sup>4</sup>
  - the negotiations under the auspices of the World Trade Organization (WTO) in relation to proposed waivers of provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);<sup>5</sup> and
  - the United Nations General Assembly High-level meeting on pandemic prevention, preparedness and response.<sup>6</sup>

To function effectively as a collective landscape for the prevention and mitigation of the threats posed by emerging and re-emerging infectious diseases, proposed amendments to the Regulations should be considered in the light of the wider global health architecture.

The Committee also notes that not all States Parties to the International Health Regulations (2005) are party to the same institutions and instruments. With that in mind, the Committee has been cognizant of

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<sup>1</sup> Available at: <https://inb.who.int/>, accessed 18 January 2023.

<sup>2</sup> Decision EB151(2), 2022 (available at: [https://apps.who.int/gb/ebwha/pdf\\_files/EB151-REC1/B151\\_REC1-en.pdf#page=15](https://apps.who.int/gb/ebwha/pdf_files/EB151-REC1/B151_REC1-en.pdf#page=15), accessed 18 January 2023).

<sup>3</sup> Available at: <https://www.worldbank.org/en/programs/financial-intermediary-fund-for-pandemic-prevention-preparedness-and-response-ppr-fif>, accessed 18 January 2023.

<sup>4</sup> Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 8(b), entered into force 12 October 2014 (available at: <https://www.cbd.int/abs/text/default.shtml>, accessed 18 January 2023).

<sup>5</sup> Available at: [https://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/trips_e.htm), accessed 18 January 2023.

<sup>6</sup> See United Nations General Assembly resolution 76/301 (2022) (available at: <https://documents-dds-ny.un.org/doc/UNDOC/GEN/N22/584/35/PDF/N2258435.pdf?OpenElement>, accessed 18 January 2023).

the ongoing work of the INB for a WHO pandemic accord. Because the content of this new instrument is, at the time of drafting this report, not yet established (only a conceptual zero draft was published while the Committee was in session) the Committee is unable to comment on how this new instrument may or may not relate to the proposed amendments to the Regulations. However, the simultaneous processes driven by Member States of negotiating a pandemic accord and amending the Regulations allow a reflection on how best the proposed amendments should be addressed.

The proposed methodology foresaw considerations of consistency across other international agreements. The Committee recognizes the very real risk of issues being missed if each concurrent process defers the issue to the other, and if there is no cohesion and interaction between the INB and the WGIHR. The WGIHR and the INB are both crucial to improving the global health security architecture, and while outcomes remain uncertain, each must be ambitious but realistic in what it can achieve, and each without the other, is incomplete.

Simultaneously, States Parties are seeking more systematic monitoring and analysis across the health and broader socioeconomic sectors. Although not always explicitly stated, some amendments relate to the development and use of the Universal Health and Preparedness Review. However, as the process remains in the pilot phase, has not as yet been agreed by the Health Assembly, and its spirit could arguably be accommodated within the existing provisions of Article 54, we remain cognizant that the Universal Health and Preparedness Review should not be expressly embedded into the Regulations so as to better future proof the instrument.

Outside WHO, there are broader efforts to improve financing for pandemic preparedness and response. Recent efforts within the World Bank to establish the Pandemic Fund seek to support implementation of the Regulations. However, the fund is still evolving, and, moreover, is currently under-capitalized, and, therefore, as a new financial instrument it cannot be exclusively relied upon within amendments to the Regulations in order to future proof any proposed changes. Financing for core capacities must be addressed more comprehensively within the global health architecture.

At WTO, negotiations continue in relation to waivers to the Agreement on Trade-Related Aspects of Intellectual Property Rights, given the tensions this has demonstrated during COVID-19 and access to medical countermeasures, vaccines and technological know-how. Clearly any changes to the Regulations to include equity in this regard would need to be considered within this forum simultaneously. The Committee notes that WTO and WHO share almost 80% of their Member States. Health and trade are not mutually exclusive and there are imperatives within the trade regime to prioritize public health.<sup>1</sup> Consequently, the Committee encourages States Parties to build stronger health–trade policy coherence, including through avenues within WTO to prioritize public health.

Finally, the Committee draws attention to the potential overlap in proposed amendments to the Regulations on access to GSD and equitable sharing of benefits derived from their use and the Convention on Biological Diversity and its Nagoya Protocol,<sup>2</sup> as well as ongoing debates in the

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<sup>1</sup> Doha Ministerial Declaration, November 2001; ([https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm), accessed 18 January 2023).

<sup>2</sup> In accordance with its Arts. 4.3 and 4.4, the Nagoya Protocol does not apply where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol.



Conference of the Parties to the Convention on access and benefit sharing frameworks governing digital sequence information.<sup>1</sup>

Negotiations to amend the Regulations should be cognizant of broader reform efforts across the global health security landscape. The very nature of these ongoing simultaneous processes, if coordinated and harmonized, gives the Committee cause for optimism that the combination of these transformational reforms will lead to a safer and more equitable world.

#### **4. ARTICLE-BY-ARTICLE/ANNEX-BY-ANNEX ANALYSIS AND TECHNICAL RECOMMENDATIONS**

##### **PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES**

###### *Article 1 – Definitions*

Article 1 presents more than 60 definitions developed for the purposes of the Regulations, which, unless otherwise specified, includes the annexes thereto.

###### *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*

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<sup>1</sup> The Committee notes that in December 2022, COP15 adopted the Kunming-Montreal Global Biodiversity Framework, with Parties deciding to establish a multilateral mechanism for benefit-sharing from the use of digital sequence information (available at: <https://www.cbd.int/article/cop15-final-text-kunming-montreal-gbf-221222>), accessed on 25 January 2023).

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.

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.

### *Article 2 – Purpose and scope*

As set out in Article 2, the scope of the Regulations comprises all events related to the international spread of disease. The purpose (goal or target) of the Regulations is to “prevent, protect against, control and provide a public health response to the international spread of disease”. Actions and interventions, however, are limited in three ways to staying within the scope of the Regulations: they are tied to events whose international spread poses public health risks; they must be proportional to the actual level of risk; and they must avoid unnecessary interference with international traffic and trade.

Although Article 2 frames the whole of the Regulations, it relates particularly to Article 5 paragraph 1, Articles 6, 13, 15, 16, 42 and 43, and Annexes 1 and 2.

#### *Summary of proposed amendments*

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.

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.

### *Article 3 – Principles*

Article 3 describes the general principles that should guide the interpretation and implementation of the Regulations. It refers to the protection of all people from the international spread of disease; to dignity, human rights and fundamental freedoms; and to the Charter of the United Nations and the Constitution of WHO. In addition, the sovereign right of States Parties is acknowledged to implement national health policies through national legislation, as long as the purpose of the Regulations is respected.

#### *Summary of proposed amendments*

The six amendments propose to expand this Article 3 in the following ways:

- 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.<sup>1</sup> 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,

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<sup>1</sup> 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).

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, 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.<sup>1</sup> 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.

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).<sup>2</sup> The Committee notes that

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<sup>1</sup> See document A/75/20, 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](https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_20-en.pdf), accessed 18 January 2023.

<sup>2</sup> 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](https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf), accessed 25 January 2023).

Article 5 paragraph 7 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures<sup>1</sup> 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.

#### *Article 4 – Responsible authorities*

Article 4 obliges States Parties to establish a National IHR Focal Point as the permanent conduit of communication between States Parties and WHO IHR Contact Points. The National IHR Focal Point is defined in Article 1 as “the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations”. Article 4 also obliges States Parties to establish “the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations”.

#### *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 “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

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<sup>1</sup> Available at: [https://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm), accessed 18 January 2023.

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 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*

Article 5 requires States Parties to develop, strengthen and maintain the surveillance capacity to detect, assess, notify and report events as specified in Annex 1, and sets out the associated deadlines for meeting these obligations, as well as obligations to establish an implementation plan to meet these obligations, and to report annually to WHO on their implementation. It also requires WHO to assist States Parties and, upon request, to develop, strengthen and maintain these capacities. Lastly, it provides a mandate for WHO’s global surveillance function and for the assessment of potential international spread of diseases, as well as their potential interference with international traffic. It relates the use of such information to the provisions of Articles 11 and 45 and Annex 1 A.

The assessment of proposals for amendments to this Article are grouped into five themes: A. A capacity review mechanism (referred to as “the Universal Health Periodic Review”); B. Assistance in capacity building for surveillance; C. A decision on capacity deadline extension by the Health Assembly; D. The establishment of early warning criteria and criteria for risk assessment; and E. Central coordinating authority of the health sector in surveillance and response. Each theme is analysed separately below.

#### **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.<sup>1</sup>

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),<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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 Group on the matter<sup>5</sup> and has supported pilot testing in four countries.<sup>6</sup> 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. 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.

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<sup>1</sup> 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.

<sup>2</sup> Available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA61-REC1/A61\\_Rec1-part2-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA61-REC1/A61_Rec1-part2-en.pdf), accessed 23 January 2023).

<sup>3</sup> Available at: States Parties Self-Assessment Annual Reporting (who.int), accessed 23 January 2023.

<sup>4</sup> Available at: <https://extranet.who.int/sph/ihr-monitoring-evaluation>, accessed 23 January 2023.

<sup>5</sup> 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).

<sup>6</sup> 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).



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 core capacities – is consistent with the scope of the Regulations and with the role of WHO, as enshrined in its Constitution.<sup>1</sup>

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.

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<sup>1</sup> Basic Documents, 49th edn., 2020 ([https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf#page=6](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=6), accessed 19 January 2023).

## 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<sup>1</sup> (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 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”.<sup>2</sup>

## 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

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<sup>1</sup> Document EB136/22 Add.1; 2015 (available at: [https://apps.who.int/gb/ebwha/pdf\\_files/EB136/B136\\_22Add1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB136/B136_22Add1-en.pdf), accessed 19 January 2023).

<sup>2</sup> Review Committee on Second Extensions (2014); Report ([https://apps.who.int/gb/ebwha/pdf\\_files/EB136/B136\\_22Add1-en.pdf](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](https://apps.who.int/gb/ebwha/pdf_files/WHA68-REC1/A68_R1_REC1-en.pdf#page=37), accessed 19 January 2023).

for WHO to handle information 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.<sup>1</sup> 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.

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

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<sup>1</sup> 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.)

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.

#### *Article 6 – Notification*

This Article places an obligation on States Parties to notify WHO of events that may constitute a PHEIC, using the decision instrument in Annex 2. The Article also lists the event-related information that States Parties are required to share with WHO at the time of and after the notification of the event.

The proposals of amendments to this Article are grouped and analysed according to five themes: A. Application of Annex 2 and communication to WHO; B. Notification by WHO to relevant international bodies; C. Sharing of genetic sequence data; D. Non-disclosure by WHO of notified information to parties engaged in conflict; and E. Explanation of linkages between Article 45 and Article 6.

### **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.

#### *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),<sup>1</sup> 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 competencies of other organizations and may be particularly relevant for applying the “One Health approach”.<sup>2</sup>

Of note, in addition to the Quadripartite Memorandum of Understanding signed by FAO, WOAH (formerly OIE), UNEP and WHO in April 2022,<sup>3</sup> 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+),<sup>4</sup> 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 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.

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<sup>1</sup> 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).

<sup>2</sup> Available at ([https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health,](https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health) accessed 20 January 2023).

<sup>3</sup> 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,](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).

<sup>4</sup> Available at (<http://www.glews.net/>, accessed 20 January 2023).

### *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.<sup>1</sup> 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.

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.

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

**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.

**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.

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

Article 7 specifies that any unexpected or unusual public health event shall be brought to WHO’s attention, irrespective of its origin or source. It reiterates the duty to apply the provisions of Article 6 in full in so doing.

*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 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.

#### *Article 8 – Consultation*

Article 8 provides a discretion for States Parties to consult with WHO about public health events that do not meet the criteria for a notification under Article 6 and Annex 2. This provision supports the opening of dialogue between the States Parties and WHO – it is not limited to events for which there is insufficient information (e.g. where answers to parts of the decision instrument in Annex 2 may be “yes”, but the final answer to reporting is “no”).

#### *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.

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.



### *Article 9 – Other reports*

The Article allows the possibility for WHO to take into account reports from other sources than notification and to assess such reports and communicate the information to the State Party in which the event allegedly occurred. It also reiterates the obligation of WHO to consult and attempt to verify the information with the State Party in whose territory the event is allegedly occurring, in accordance with procedures of Article 10, before taking any action based on such reports.

#### *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 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.

### *Article 10 – Verification*

Article 10 mandates WHO to request States Parties to verify information from sources other than notifications or consultations about events, and sets the time frame for States Parties to respond to such a request for verification. This Article also provides that, when WHO receives information about an event that may constitute a PHEIC, the Organization is obliged to offer to collaborate with the States Parties concerned in assessing the potential for international disease spread, possible interference with international traffic, and the adequacy of control measures. Such activities may include collaboration

with other standard-setting organizations, and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. Lastly, if the WHO offer of collaboration is not accepted, the Article offers WHO the possibility to share the information available with other States Parties, when justified by the magnitude of the public health risk, while considering the views of the State Party concerned. This Article is linked to Articles 6, 8, 9 and 12.

### *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.

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.

#### *Article 11 – Provision of information by WHO*

Article 11 includes provisions related to WHO’s obligations to use and share information about events and public health risks that come to its attention under Articles 5 to 10. WHO is required to use the information received under Articles 5 to 10 for verification, assessment and assistance purposes. WHO is also required to share information about public health events with States Parties and relevant intergovernmental organizations, in confidence, following verification and consultation with States Parties in whose territory the events occur. This sharing of information is subject to specified conditions, such as a PHEIC, evidence of international spread, situations when control measures are unlikely to be successful, lack of operational response capacities, or the need for international control measures. WHO may make such information available to the public if there is already information in the public domain.

This Article is the basis on which WHO developed the Event Information Site platform, a secure online platform to share information with National Focal Points and relevant intergovernmental organizations. Currently, the platform is not interactive – while WHO can post information on that platform, its users cannot proactively interact either with WHO or among themselves, for example, States Parties cannot post notifications and cannot exchange information.

#### *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 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 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.

*Article 12 – Determination of a public health emergency of international concern (PHEIC)*

This Article specifies the process, criteria and authority for the Director-General to determine whether an event constitutes a PHEIC, and the provisions related to terminating it. The Article places emphasis on consultation with the State Party in whose territory the event occurs, and the obligation of the Director-General to seek the views of an Emergency Committee, while also stating that the ultimate decision to make the determination of a PHEIC remains with the Director-General, who shall consider a series of elements, including the advice of the Emergency Committee, the decision instrument in Annex 2, the risks to human health, the risk of international spread, and the risk of interference with international traffic. The Article does not specify in detail the conditions for terminating a PHEIC other than consultation of the Director-General with the State Party within whose territory the PHEIC occurs and with the Emergency Committee.

The proposals for amending this Article can be grouped in five categories: A. Potential PHEIC, public health emergency of regional concern and intermediate level of alert; B. Consultation with States Parties and convening an Emergency Committee; C. Termination of a PHEIC; D. PHEIC as a trigger for resource mobilization; and E. Reporting and engagement with non-State actors.

As a general observation, in this Article some of the proposed amendments seek to streamline the process for determining a PHEIC whereas others may have the opposite effect, in other words, in this Article the Committee noted conflicting proposals.

**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 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.<sup>1</sup> 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 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

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<sup>1</sup>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.

consider how such mechanisms may complement or challenge the functioning of the PHEIC more broadly.<sup>1</sup>

## **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.

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 PHEIC (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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<sup>1</sup> 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).

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.

### **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.

### *Article 13 – Public health response*

Article 13 requires States Parties to develop, strengthen and maintain the capacity to respond promptly and effectively to public health risks and PHEICs as specified in Annex 1. It also sets out the associated deadlines for meeting these obligations, as well as obligations to establish an implementation plan to meet these obligations, and to report annually to WHO on their implementation. It mandates WHO to assist States Parties, upon request, in the response to public health risks, and, in the event that a PHEIC is determined, to offer further assistance to directly affected and other States Parties. It also empowers WHO to request any State Party to provide support to response activities coordinated by WHO.

There are multiple amendments proposed to Article 13, but they cannot be grouped by themes, hence for this article the proposals will be addressed paragraph by paragraph.

## **Paragraphs 1, 2 and 2bis**

### *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.

## **Paragraph 3**

### *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.

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**

### *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; 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.

## **Paragraph 7**

### *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 – Access to health products, technologies and know-how for public health response*

### *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 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 health response.

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<sup>1</sup> and the decisions taken by WTO Member States, such as the Doha Declaration on the TRIPS Agreement and Public Health,<sup>2</sup> 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.

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<sup>3</sup> 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.

#### *NEW Article 13A – WHO-led international public health response*

##### ***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

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<sup>1</sup> WTO website ([https://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/trips_e.htm), accessed 20 January 2023).

<sup>2</sup> WTO website ([https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm), accessed 20 January 2023).

<sup>3</sup> Available at: <https://www.who.int/initiatives/who-listed-authority-reg-authorities>, accessed 20 January 2023.

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.

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**

The proposed title of this amendment, “WHO Led International Public Health Response,” may not reflect the content in other paragraphs that accompany this Article, 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”.

### **Paragraphs 2 to 5 – Health products and technologies**

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.**

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, 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**

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 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.

## **PART III RECOMMENDATIONS**

### *Article 15 – Temporary recommendations*

Article 15 provides a mandate for the Director-General to issue temporary recommendations following the determination of a PHEIC and establishes that these recommendations are to be reviewed within three months before they automatically expire. These recommendations concern either a single State Party experiencing a PHEIC or States Parties in general. Article 15 needs to be read in conjunction with Articles 12, 17 and 49.

### *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 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.

### *Article 16 – Standing recommendations*

This Article offers the possibility for the WHO Director-General to issue standing recommendations of appropriate health measures for routine or periodic application, in accordance with the provisions of Article 53, which requires the Director-General to convene a Review Committee to advise him/her on such recommendations. Standing recommendations may be applied for specific ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. This Article needs to be read in conjunction with Articles 50 and 53.

#### ***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.

### *Article 17 – Criteria for recommendations*

Article 17 establishes a list of criteria for the Director-General’s decision-making relating to Articles 15 and 16.

#### ***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 diagnostics, to include all potential future countermeasure needs and innovations. This amendment would also benefit from a definition of “medical countermeasures” in Article 1.

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

This Article provides a non-exhaustive list of possible recommendations (temporary or standing) that the Director-General can issue, aimed at persons and/or goods and conveyances.

***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.

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.

## **PART IV – POINTS OF ENTRY**

### *Article 19 – General obligations*

This Article presents State Parties' general obligations at points of entry and refers specifically to requirements to develop the capacities set forth in Annex 1, to identify the competent authorities at points of entry, and to provide WHO upon request with relevant data concerning sources of infection or contamination at points of entry, which could result in international spread of disease.

#### ***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”.

## **PART V – PUBLIC HEALTH MEASURES**

### *Article 23 – Health measures on arrival and departure*

This Article includes provisions related to the health measures that States Parties may require for public health purposes, upon arrival or departure, with regard to travellers.

#### ***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:

- 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”.

### *Article 24 – Conveyance operators*

This Article includes provisions related to States Parties’ obligations to ensure that conveyance operators comply with health measures recommended by WHO and adopted by States Parties, inform their travellers about these measures, and keep conveyances free of sources of infection. It refers to more specific provisions pertaining to conveyances and conveyance operators listed in Annexes 4 and 5.

### ***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.”

### ***Article 27 – Affected conveyances***

This Article provides for actions that the competent authorities may take on board affected conveyances.

### ***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 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.”

#### *Article 28 – Ships and aircraft at points of entry*

This Article includes provisions concerning States Parties’ obligations in relation to permissions for ships and aircraft at points of entry.

##### *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.

##### *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.

#### *Article 31 – Health measures relating to entry of travellers*

This Article includes provisions related to the health measures for travellers that may be required by States Parties upon entry, and the conditions for such requirements.

##### *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, 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*

This Article states that, as a general rule, no health documents, other than those provided for under the Regulations or in recommendations issued by WHO, shall be required in international traffic. It also states 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. Lastly, it states that the competent authority may request travellers to complete contact information forms, and it refers to the related provisions in Article 23.

### ***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 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.

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.

#### *Article 36 – Certificates of vaccination or other prophylaxis*

This Article stipulates that the vaccines and prophylaxis administered to travellers, and the related certificates, must conform to the provisions of Annex 6 and Annex 7 for specific diseases, and that a traveller in possession of a certificate issued in conformity with the provisions of Annex 6 and, when applicable, Annex 7, must not be denied entry.

### *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 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*

This Article sets out general principles for the implementation of health measures taken pursuant to the Regulations, which must be initiated without delay and applied in a transparent and non-discriminatory manner.

### *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.

### *Article 43 – Additional health measures*

Article 43 grants States Parties the authority to adopt health measures that go beyond WHO recommendations or that are otherwise prohibited by other provisions in the Regulations. The Article also introduces substantive and procedural conditions for the legitimacy and legality of those measures and provides for consultation among the States Parties concerned and with WHO in relation to the introduction and application of additional measures that significantly interfere with international traffic, and their public health rationale.

#### *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 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 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.

#### *Article 44 – Collaboration and assistance*

This Article includes provisions requiring States Parties to cooperate with each other and with WHO. This Article is relatively general and focuses on bolstering public health capacities, facilitating compliance with obligations under the Regulations, and mobilizing financial resources. These commitments can be implemented through various channels, including bilaterally and through international organizations.

#### *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 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.

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.

*New Article 44A – Financial mechanism for equity in health emergency preparedness and response*

***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.

***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.

*Article 45 – Treatment of personal data*

Article 45 includes provisions related to the handling of health information and personal data for the purpose of assessing and managing public health risks.

### *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 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)*

Article 48 requires the Director-General to establish an Emergency Committee to advise him/her on whether an event constitutes a PHEIC, on the issuance of temporary recommendations and on the termination of a PHEIC. It also includes requirements for the composition of the Emergency Committee. This Article should be read in conjunction with Article 49 on the functioning of the Emergency Committee, Article 47 on the IHR Roster of Experts, which is the main source of expertise for the Emergency Committee, and Articles 12 and 15 concerning the determination of a PHEIC, its termination and related temporary recommendations.

### *Summary of proposed amendments*

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,<sup>1</sup> which contain explicit references, in Rule 4.2, to several principles underpinning the establishment of

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<sup>1</sup> 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](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=160), accessed 24 January 2023).



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.

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.

#### *Article 49 – Procedure (Emergency Committee)*

Article 49 includes provisions related to the obligations of the Director-General concerning the establishment and functioning of the Emergency Committee.

#### *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.

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.<sup>1</sup>

### *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 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

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<sup>1</sup> 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).

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.

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 53bis Terms of reference and composition, new Article 53ter Conduct of business and new Article 53quater Reports*

*New Article 54bis – Implementation*

*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 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 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*.<sup>1</sup> 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))

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<sup>1</sup> 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](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=160), accessed 24 January 2023).

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. 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.<sup>1</sup>

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.

## **PART X – FINAL PROVISIONS**

### *Article 54 – Reporting and review*

This Article includes provisions for reporting on the implementation of the Regulations as agreed by the Health Assembly and for regular reviews of the functioning of the Regulations.

#### ***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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<sup>1</sup> See document EB151/2022/REC/1 and decision EB151(2).

### *Article 56 – Settlement of disputes*

This Article includes provisions for settlements of disputes between States Parties or between States Parties and WHO. This Article has not been invoked since the entry into force of the Regulations in 2007.

#### *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 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**

Annex 1, referred to in Articles 5, 13 and 19, specifies the core capacity requirements that States Parties are obliged to develop.

Given the link between Annex 1 and relevant Articles of the Regulations, amendments to Annex 1 need to be evaluated together with the proposed amendment to Articles 5, 13 and 19, and where necessary to other provisions of the Regulations, such as those set forth in Articles 2 and 44 and the new Annex 10.

There are several proposed amendments to the title of Part A of Annex 1. One adds “disease detection” while another adds “health emergency” to the term “core capacity”. The Committee acknowledges the underlying intention to emphasize the importance of detection and the need for better responses to health emergencies. However, the Committee believes that the proposed aspects of disease detection are already covered by the Regulations and are thus unnecessary. The Regulations require State Parties’ surveillance not only of disease, but more broadly, of public health risks and PHEIC. Article 5, concerning surveillance, refers to the “capacity to detect, assess, notify and report events in accordance with these Regulations”. The Regulations require States Parties to undertake surveillance and response prior to a health emergency, rather than waiting for it. Therefore, there is no need to specify “health emergency” here.

The proposed amendments to this Annex are grouped and analysed according to seven themes: A. Capacities beyond surveillance; B. Health products, technology, know-how and materials as part of a public health response; C. Genomic sequence data and other data; D. Assistance from States Parties; E. Assistance from WHO; F. Health system capacities; and G. Point-of-entry capacities.

**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 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*

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, 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.

## **G. Point-of-entry capacities**

### *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.

## ANNEX 2

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

Annex 2 provides an algorithm for States Parties to use when deciding to notify WHO of events that may constitute a PHEIC, in line with the provisions of Article 6, according to four questions (Is the public health impact of the event serious? Is the event unusual or unexpected? Is there a significant risk of international spread? And is there a significant risk of international travel or trade restrictions?) It also provides a set of examples to assist in the interpretation of decision instrument criteria.

*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 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.<sup>1</sup> After the current Regulations were adopted through resolution WHA58.3,<sup>2</sup> 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.

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<sup>1</sup> See resolution WHA48.7.

<sup>2</sup> See resolution WHA58.3.

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 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 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**

Annex 3 presents a model ship sanitation certificate to be used for the Ship Sanitation Control Exemption Certificate and the Ship Sanitation Control Certificate, as referred to in Articles 20 and 39.

*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 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**

Annex 4 provides the technical requirements for conveyance and conveyance operators, as referred to in Article 24.

#### *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**

This Annex includes provisions related to the international certificate of vaccination and prophylaxis that should be provided for all travellers as proof of vaccination or prophylaxis if required by States Parties.

#### *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.

## ANNEX 8

### **MODEL OF MARITIME DECLARATION OF HEALTH**

Annex 8 includes the model of maritime declaration of health, which relates to the specific obligations for shipping operators and the actions by States Parties presented in Article 37. A maritime declaration of health must be completed and submitted to the competent authorities by the masters of ships arriving from foreign ports. The model contains a general part related to the ship, and a part entitled “health questions” related to persons on board.

#### *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 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***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 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.

## Appendix 1

**LIST OF MEMBERS OF THE REVIEW COMMITTEE**

	<b>Name and nationality(ies)</b>	<b>Affiliation</b>
1.	Mohammad ABDELFAHATTAH Egypt	Undersecretary for Preventive Affairs, Preventive Medicine Sector, Ministry of Health and Population, Cairo, Egypt
2.	Obijiofor AGINAM Nigeria	Principal Visiting Fellow, United Nations University, International Institute for Global Health, Kuala Lumpur, Malaysia Adjunct Research Professor of Law and Legal Studies, Carleton University, Ottawa, Canada Visiting Research Fellow, United Nations University, Institute on Comparative Regional Integration Studies, Bruges, Belgium
3.	Mohannad AL-NSOUR Jordan	Executive Director, Eastern Mediterranean Public Health Network (EMPHNET), Amman, Jordan
4.	Patrick AMOTH <b>(Chair)</b> Kenya	Acting Director General for Health, Ministry of Health, Nairobi, Kenya
5.	Lucille BLUMBERG South Africa	Deputy Director at the National Institute for Communicable Diseases (NICD), National Health Laboratory Service, and founding head of the Division of Public Health Surveillance and Response (stepped down after the third meeting, Pretoria, South Africa)
6.	Gian Luca BURCI Italy, Switzerland	Adjunct Professor of international law and Academic Adviser in the Global Health Centre, Graduate Institute of International and Development Studies, Geneva, Switzerland Director of the joint LLM on Global Health Law and Governance, Graduate Institute of International and Development Studies, Geneva, Switzerland, and Georgetown Law School, Washington DC, United States of America
7.	Cherita DAVIS-MOXEY The Bahamas	Lead, Planning & Policy Unit, Ministry of Health & Wellness, The Bahamas
8.	Andrew FORSYTH New Zealand	Manager, Public Health Strategy, Ministry of Health, New Zealand
9.	H.E. Ambassador Juan José GÓMEZ-CAMACHO <b>(Vice-Chair)</b> Mexico	Senior Fellow, Foreign Policy Institute, School of Advanced International Studies, Johns Hopkins University, Washington DC, United States of America
10.	Lawrence GOSTIN United States of America	Professor, Founding O'Neill Chair in Global Health Law, and Faculty Director, O'Neill Institute for National and Global Health Law, Georgetown University, Director, WHO Collaborating Center on National and Global Health Law, Washington DC, United States of America
11.	Roojin HABIBI Canada	Research Fellow, Global Strategy Lab, York University, Toronto, Canada Fellow, Canadian International Council Lecturer, Lincoln Alexander School of Law, Toronto Metropolitan University, Toronto, Canada
12.	George HARINGHUIZEN The Netherlands	Chief Legal Officer, Centre for Infectious Disease Control, National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands
13.	Hani JOKHDAR Saudi Arabia	Deputy Minister for Public Health, Ministry of Health, Riyadh, Saudi Arabia

14.	Yang LIU China	Assistant Professor, Law School, and Director of the Center for Global Law and Strategy, Law and Technology Institute, Renmin University of China, Beijing, China
15.	Rana SAFDAR Pakistan	Chief, Field Epidemiology & Disease Surveillance Division, National Institute of Health, Islamabad, Pakistan
16.	Aalisha SAHUKHAN Fiji	Head of Health Protection, Ministry of Health and Medical Services, Suva, Fiji
17.	Sandhya Dilhani SAMARASEKERA Sri Lanka	Consultant Community Physician, Quarantine Unit, Ministry of Health, Colombo, Sri Lanka
18.	Vyacheslav SMOLENSKIY Russian Federation	Deputy Head, Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rosпотребнадзор), Moscow, Russian Federation
19.	Sunita SREEDHARAN India	Lawyer and Registered Patent Agent, New Delhi, India
20.	Clare WENHAM (Rapporteur) United Kingdom of Great Britain and Northern Ireland	Associate Professor of Global Health Policy, Department of Health Policy, London School of Economics and Political Science, London, United Kingdom of Great Britain and Northern Ireland

## Appendix 2

**TERMS OF REFERENCE OF THE REVIEW COMMITTEE REGARDING AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005)****1. Introduction**

The IHR Review Committee regarding amendments to International Health Regulations (2005) (IHR or Regulations)<sup>1</sup> (hereafter the “IHR Amendments RC”) is convened pursuant to Articles 50.1.(a)<sup>2</sup> and 47 of the IHR, as well as decision WHA75(9).<sup>3</sup>

This Review Committee will function in accordance with the WHO Regulations for Expert Advisory Panels and Committees,<sup>4</sup> and will provide its report to the WHO Director-General (DG) no later than mid-January 2023.

Its sole purpose is to provide technical recommendations to the Director-General on amendments proposed to the IHR, as decided by the Health Assembly in decision WHA75(9).

This document provides an overview of the mandate of this Review Committee, its scope of work and terms of reference, composition, conduct of business, timelines, and methods of work.

**2. Mandate of the IHR Amendments RC**

Following the Executive Board decision EB150(3),<sup>5</sup> through decision WHA75(9), the World Health Assembly decided:

(2) with respect to targeted amendments to the International Health Regulations (2005):

(a) to continue the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, with a revised mandate, including as appropriate and if agreed within each region, the rotation of the Bureau, and name (the “Working Group on Amendments to the International Health Regulations (2005)” (WGIHR)) to work exclusively on consideration of proposed targeted amendments to the International Health Regulations (2005), consistent with decision EB150(3) (2022), for consideration by the Seventy-seventh World Health Assembly in 2024;

(b) to request the Director-General to convene a Review Committee on the International Health Regulations (2005) (IHR Review Committee), as early as possible but no later than 1 October 2022, in accordance with Part IX, Chapter III, of the International Health

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<sup>1</sup> IHR 3rd Edition: <https://www.who.int/publications/i/item/9789241580496>.

<sup>2</sup> Chapter III – The Review Committee; Article 50 – Terms of reference and composition: 1. The Director-General shall establish a Review Committee, which shall carry out the following functions:

(a) make technical recommendations to the Director-General regarding amendments to these Regulations; [...]

<sup>3</sup> Decision WHA75(9), [https://apps.who.int/gb/ebwha/pdf\\_files/WHA75/A75\(9\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(9)-en.pdf).

<sup>4</sup> WHO Basic Documents 2020, [https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf).

<sup>5</sup> Decision EB150(3), [https://apps.who.int/gb/ebwha/pdf\\_files/EB150/B150\(3\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(3)-en.pdf).

Regulations (2005), in particular Article 50, paragraphs 1(a) and 6, with particular attention to be paid to the fulfilment of the letter and spirit of Article 51, paragraph 2, to make technical recommendations on the proposed amendments referred to in subparagraph (c) below, with a view to informing the work of the WGIHR;

(c) to invite proposed amendments to be submitted by 30 September 2022, with all such proposed amendments being communicated by the Director-General to all States Parties without delay;

(d) to request the WGIHR to convene its organizational meeting no later than 15 November 2022, and to coordinate with the process of the Intergovernmental Negotiating Body (INB)<sup>1</sup> to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, including through regular coordination between the two Bureaus and alignment of meeting schedules and workplans, as both the International Health Regulations (2005) and the new instrument are expected to play central roles in pandemic prevention, preparedness and response in the future;

(e) to request that the IHR Review Committee submit its report to the Director-General no later than 15 January 2023, with the Director-General communicating it without delay to the WGIHR;

(f) to request the WGIHR to establish a programme of work, consistent with decision EB150(3), and taking into consideration the report of the IHR Review Committee, to propose a package of targeted amendments, for consideration by the Seventy-seventh World Health Assembly, in accordance with Article 55 of the International Health Regulations (2005).

### 3. Scope of work and terms of reference of the IHR Amendments RC

Pursuant to Article 50.1.(a) of the IHR, the “Review Committee [...] shall carry out the following functions: (a) make technical recommendations to the Director-General regarding amendments to these”.

As of 30 September 2022, the following 14 States Parties submitted proposals for amendments to the IHR, of which four did so also on behalf of other States Parties – Armenia; Bangladesh; Brazil; Czech Republic on behalf of the Member States of the European Union; Eswantini on behalf the WHO African Region Member States; India; Indonesia; Japan; Namibia; New Zealand; Russian Federation on behalf of the Member States of the Eurasian Economic Union; Switzerland; United States of America; and Uruguay on behalf of MERCOSUR.

Specifically,<sup>2</sup> the technical recommendations by the IHR Amendments RC shall be based on, address, and document in the final report the following:

(i) **Analysis** of each of the proposed amendments to the IHR submitted no later than 30 September 2022, in terms of:

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<sup>1</sup> Information on the work of the INB is available at: <https://apps.who.int/gb/inb/>.

<sup>2</sup> Regulations Item 4.9 in WHO Regulations for Expert Advisory Panels and Committees, [https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf).

- Consistency across proposed amendments in case multiple proposals are submitted to the same article;
- Pertinence vis-à-vis the purpose and scope of the IHR, as defined in Article 2;
- Pertinence vis-à-vis the article intended to be amended;
- Consistency with the Constitution of WHO;
- Consistency, where applicable, with other provisions contained in the article intended to be amended;
- Consistency with any other provisions of the IHR;
- Compatibility and consistency with provisions of other relevant WHO frameworks and relevant international legal instruments under the auspices of other intergovernmental and international organizations, such as:
  - the Pandemic Influenza Preparedness (PIP) Framework;<sup>1</sup>
  - the International Food Safety Authorities Network (INFOSAN, under the auspice of the Food and Agriculture Organization (FAO) and WHO);<sup>2</sup>
  - the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS);<sup>3</sup>
  - Convention on Biological Diversity (CBD), relevant legal instruments of the following UN agencies: International Atomic Energy Agency (IAEA), International Civil Aviation Organization (ICAO), International Maritime Organization (IMO), Organization for the Prohibition of Chemical Weapons (OPCW), United Nations Human Rights Council (HRC), United Nations Office for Disarmament Affairs (UNODA), World Organization for Animal Health (OIE), World Trade Organization (WTO);
- Compatibility and consistency with the Working Draft of a WHO Convention, Agreement, or other International Instrument on Pandemic Prevention, Preparedness and Response (Document A/INB/2/3);<sup>4</sup>
- Considerations about appropriate mechanisms allowing for the monitoring of compliance with the article intended to be amended;

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<sup>1</sup> Information about the Pandemic Influenza Preparedness (PIP) Framework is available at: <https://www.who.int/initiatives/pandemic-influenza-preparedness-framework>.

<sup>2</sup> Information about the FAO/WHO International Food Safety Authorities Network (INFOSAN) is available at: <https://www.who.int/groups/international-food-safety-authorities-network-infosan>; and <https://www.fao.org/food-safety/emergencies/infosan/en/>.

<sup>3</sup> Information about the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS) is available at: <https://www.who.int/who-global-surveillance-and-monitoring-system>.

<sup>4</sup> Document A/INB/2/3, [https://apps.who.int/gb/inb/pdf\\_files/inb2/A\\_INB2\\_3-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb2/A_INB2_3-en.pdf).

- Identification, where applicable, of other related Articles of the Regulations that would also need to be amended in order for the article intended to be amended to be applicable, so that the integrity and robustness of the IHR are maintained and/or strengthened.

**(ii) Proposals for reformulation and/or clarification** – e.g., recommendations for potential rewording, rephrasing, inclusion of cross-references to other relevant articles of the IHR, inclusion of compliance monitoring elements – and/or consolidation, if/when necessary, of the text of the article intended to be amended, as well as of the text of any other article of the Regulations that needs amendments for the article intended to be amended to be applicable. Such proposals shall ensure the internal consistency, integrity, and robustness of the text of the IHR, as well as the compatibility and consistency with any other relevant international legal instrument under the auspices of intergovernmental and international organizations. Each of the above-mentioned proposals for reformulation and/or refinement by the IHR Amendments RC shall be accompanied by its rationale, including the reason/s why amendments proposed by States Parties have not been totally or partially retained, or have been reallocated to an article different from the one initially intended to be amended.

**(iii) Analysis of the remaining provisions of the IHR** – for provisions that were not subject to proposals for amendments – to identify internal inconsistencies, inconsistencies vis-à-vis other international legal instruments.

**(iv) Overall consistency analysis, including of definition of terms** – to advise on definitions of terms, either new or existing terms the meaning of which might be changed following the proposed amendments, to ensure clarity and consistency; as well as to advise on whether the inclusion, in the text of the IHR, of an explicit taxonomy related to the nature of amendments (e.g., targeted amendments, conforming amendments, technical adjustments, updates, “reopening the instrument”) is warranted and, if so, to formulate a proposal in that respect.

#### 4 Composition of the IHR Amendments RC

The selection and appointment of the Members of the IHR Amendments RC comply with the application of the WHO Regulations for Expert Advisory Panels and Committees<sup>1</sup> and Article 50 of the Regulations, based on the specific Terms of Reference outlined above.

In addition to considerations related to maintaining of gender and geographical balance, the areas of expertise represented in the IHR Amendments RC encompass national and international health governance; international health law, including human rights; and health emergency preparedness and response, and the affiliations of the Members spans from the governmental sector to the academia and non-profit sector.

Some of the Members selected had expressed their interest in being appointed to the IHR Roster of Experts through the open “Call for expression of interest: International Health Regulations (2005) Roster of Experts” launched by the WHO Secretariat in April 2022. The final list of the Members of this Review Committee will be published on the WHO website after the conclusion of the first meeting of the IHR Amendments RC.

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<sup>1</sup> Regulations Items 4.1-4.7 in WHO Regulations for Expert Advisory Panels and Committees, [https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf).

## 5. Conduct of business of the IHR Amendments RC

The conduct of business of the IHR Amendments RC will comply with the application of the WHO Regulations for Expert Advisory Panels and Committees (including the Rules of Procedure in their Annex) and Articles 51 and 52 of the Regulations, encompassing, inter alia, rules related to the private nature of the Committee's meetings, and the report of the Committee.<sup>1</sup>

Pursuant to Article 51.2, "The Director-General shall invite Member States, 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. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote."

## 6. Timeline of the work of the IHR Amendments RC

The timeline of work of the IHR Amendments RC is set by decision WHA75(9) as follows:

- **30 September 2022:** deadline for the submission of proposed amendments to the IHR.
- **1 October 2022:** Deadline for the DG to convene the IHR Amendments RC. The proposed schedule of the IHR Amendments RC meetings is below:
  - 6 October 2022: closed virtual meeting to elect Chair, Vice-Chair, and Rapporteur of the IHR Amendments RC, and define the Methods of Work;
  - **24–28 October 2022: face-to-face meeting** (5 days, Geneva, Switzerland), with, a one day meeting, on 27 October 2022, with Member States, United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO, in accordance with Article 51.2 of the IHR, which will also include presentations of rationale for amendments proposed by States Parties, and, if needed, additional discussions of the IHR Amendments RC with each State Party that has proposed amendments;
  - 16–17 November 2022: closed virtual working meeting;
  - **28 November–2 December 2022: face-to-face meeting** (5 days, Geneva, Switzerland) for report drafting purposes, with, at least, one day meeting with Member States, United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO, the Bureau of the Bureau of the Intergovernmental Negotiating Body (INB),<sup>2</sup> and the WGIHR;
  - 15–16 December 2022: closed virtual working meeting;
  - **9–13 January 2023: face-to-face meeting** (5 days, Geneva, Switzerland) for finalization of the report, with, at least, one day meeting with Member States, United

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<sup>1</sup> Regulations Items 4.12-4.15 in WHO Regulations for Expert Advisory Panels and Committees, [https://apps.who.int/gb/bd/pdf\\_files/BD\\_49th-en.pdf](https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf).

<sup>2</sup> Information about the Intergovernmental Negotiating Body (INB) is available at: <https://apps.who.int/gb/inb/>.



Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO, the Bureau of the INB, and the WGIHR.

- **15 November 2022:** Deadline for the WGIHR to convene its first organizational meeting;
- **15 January 2023:** Deadline for the IHR Amendments RC to submit its report to the DG, noting that the DG shall communicate it without delay to the WGIHR.
- **15 December 2023:** The Review Committee remains “dormant” during 2023, and it will be reconvened in December 2023, to review the package of amendments agreed by the WGIHR, with a view to submit its final technical recommendations to the DG before mid-January 2024.
- **January 2024:** WGIHR submits their final package of proposed amendments to the DG who will communicate them to all States Parties in accordance with Article 55.2, for the consideration of the Seventy-seventh World Health Assembly.

## 7. Methods of work of the IHR Amendments RC

The IHR Amendments RC will meet virtually and in person – see timeline above.

The Secretariat of the Review Committee will be provided by the IHR Secretariat, under the oversight of the Assistant Director-General on Health Emergencies Preparedness (ADG/WEP) and will include one focal person from each of the six WHO Regional Offices, to ensure alignment, coordination and consistent approach in support of the RC.

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