

**Appendix to the submission of proposed amendments to the International Health Regulations (IHR) (2005), pursuant to decision WHA75(9) of the World Health Assembly, by the Czech Republic, the current Presidency of the Council of the European Union, as a State Party to the IHR and in coordination with the European Union, and on behalf of the Member States of the European Union:**

**Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden, as State Parties to the IHR (2005).**

## **Explanatory notes**

Further to the submission of the proposed amendments on 30 September 2022, we are pleased to communicate short explanatory elements for each of the proposal submitted.

### **1. Article 3 - Principles**

The objective of the proposed amendment is to introduce a precautionary approach in the International Health Regulations (IHR) by giving the possibility to WHO and States Parties to issue and implement precautionary measures when scientific evidence about an emerging and probable high risk pathogen is lacking or uncertain. Such precautionary measures must be applied in accordance with the other provisions of the IHR, in particular with Articles 2 and 43 of the IHR.

### **2. Article 6 - Notification, Article 7 - Information-sharing during unexpected or unusual public health events and Annex 1:**

The COVID-19 pandemic has shown how crucial it is to ensure that epidemiological and clinical data, as well as microbial and genomic data, materials and samples, are shared as rapidly as possible at the global level after the detection of an event caused by an infectious agent.

The objectives of the proposed amendments to Article 6 and Annex 1 are:

- to extent the scope of the information that should be communicated to WHO, following the notification by a State Party of an event which may constitute a public health emergency of international concern, by including a requirement to notify in particular epidemiological and clinical data, as well as microbial and genomic data and while ensuring the protection and security of personal data;
- to ensure that the information received by WHO is made available to all State Parties, and can be widely used for related research and assessment;
- to ensure that State Parties have the required capacities to report such information at the appropriate level of healthcare response.

Likewise, the objective of the proposed amendments to Article 7 is to extend the scope of the information that needs to be provided to WHO, by including a requirement to share with WHO the microbial and genetic material and samples related to the notified event.

3. Article 11 - Exchange of information (new proposed title):

The proposed amendments aim at enabling information on health alerts to be shared more rapidly and more widely. In particular, the objectives of the proposed amendments are:

- to add a requirement that WHO shall inform all States Parties, and relevant international and regional organizations, of all event-related information and data, including any public health information not resulting from notifications or consultations, provided that its validity is appropriately assessed by WHO;
- to add a requirement that WHO shall provide a secure and reliable platform for the exchange of information among WHO and States Parties;
- to ensure that such a platform allows for interoperability with relevant data information systems.

4. Article 12 - Determination of a public health emergency of international concern and of a regional or intermediate public health emergency of international concern (new proposed title)

The current alert system, as established under the IHR, is sometime perceived as too restrictive, due the binary nature of the determination (an event either is, or is not, a public health emergency of international concern). The objective of the proposed amendment is to remedy this situation by introducing the possibility for the Director-General to determine that an event constitutes a regional public health emergency of international concern or an intermediate public health emergency of international concern (“yellow light”). The introduction of the categories of regional as well as intermediate PHEICs aims to take into account that there can be a regional component to a “yellow light” event, and that both the regional element as well as intensity need to be seen as interlinked. We would welcome the guidance of the IHR RC on how to further define such an intermediate alert.

This would raise awareness of the situation at national, regional and international level when an event of concern requires enhanced coordination at regional or international level to limit or slow down the spread of the disease, but does not fully meet the criteria for a public health emergency of international concern.

5. Article 15 - Temporary recommendations

The COVID-19 pandemic has shown that the governance of global response could benefit from stronger coordination underpinned by concise technical guidance and advice. The temporary recommendations issued by WHO following advice from the Emergency Committee are an internationally accepted and well-established mechanism to inform response interventions. The objective of the proposed amendment is to strengthen the role of the temporary recommendations issued by WHO and to facilitate their implementation by promoting the adoption of more specific, concise and tailored recommendations.

## 6. Article 23 - Health measures on arrival and departure

There is currently no standardized and international recognized electronic system to allow for safe and secure data transfer between passengers and the competent health authorities of a State Party for contact tracing purpose, in case of a reported infectious disease.

The proposed amendments to Article 23 aim at:

- providing a clear legal basis in the IHR allowing for the use of Passenger Locator Forms in digital form, provided that the two proposed conditions of an agreement on the technical requirements and their endorsement/adoption by the Health Assembly are achieved;
- providing common technical standards, with appropriate safeguards against falsification and while ensuring data protection, and
- setting out the conditions for the recognition of the common technical standards, taking into account the legal provisions applicable across countries, as well as the need of low and lower middle income countries for capacity-building and technical cooperation, in line with Article 44 of the IHR.

## 7. Article 35 - General rule, Article 36 - Certificates of vaccination or other prophylaxis and Annex 6 - Vaccination, prophylaxis and related certificates

A concern expressed during the COVID-19 pandemic has been the absence of clarity in the IHR on global standards for the use of digital vaccination certificates required for international travel.

The proposed amendments to Article 35 and Annex 6 aim at:

- providing a clear legal basis in the IHR for the use of digital certificates, thereby enabling travellers to use them in the same situations where paper-based certificates are accepted. This would provide certainty for the use of digital credentials in the future, provided that the two proposed conditions of an agreement on the technical requirements and their endorsement/adoption by the Health Assembly are achieved;
- providing common technical standards, with appropriate safeguards against falsification and while ensuring data protection, and
- setting out the conditions for the recognition of the common technical standards, taking into account the legal provisions applicable across countries, as well as the need of low and lower middle income countries for capacity-building and technical cooperation, in line with Article 44 of the IHR.

The proposed amendments to Article 36 aim at allowing States Parties the possibility to recognize test certificates and recovery certificates as an alternative or as a complementary tool to vaccination certificates.

## 8. Article 43 - Additional health measures

The COVID-19 pandemic has shown the need to improve and facilitate consultations and coordination among countries on the implementation of national health measures, such as border closures, visa suspensions or vaccination, testing and quarantine requirements.

The proposed amendments to Article 43 aim at:

- ensuring that additional health measures implemented by States Parties are based on strong and regular risk assessments, reviewed on a regular basis and that they are strictly proportionate to the specific public health risks;
- fostering consultations and discussions between States Parties on their respective risk management approaches, to avoid unnecessary disruptions to international traffic and trade;
- tasking WHO with a more active role in facilitating these discussions and in encouraging Parties to engage in such discussions, by providing a forum for consultations, reviewing the public health rationale of national measures and reporting to the Health Assembly on the conduct, outcomes and challenges of the consultations.

#### 9. Article 44 - Collaboration and assistance

The objective of the proposed amendments to Article 44 are to strengthen the implementation of the IHR by improving the provision of technical assistance and capacity building.

The proposed amendments aim in particular at:

- strengthening the integration of regional coordination in the IHR;
- facilitating the provision of technical assistance by mandating the WHO Secretariat, in cooperation with other relevant international organizations, such as the quadripartite organizations, to provide support in the organisation of technical assistance and capacity building initiatives and actions, so as to allow for a better operationalization of the provisions of article 44.

The proposed reporting requirement aims at increasing the political importance and highlight given to collaboration and assistance activities and at facilitating the sharing of best practices.

#### 10. Article 48 - Terms of reference and composition

The proposed amendments aim at:

- Ensuring a more diverse representation of the Emergency Committee;
- Ensuring that the experts of the Emergency Committee receive appropriate support and training, including through the WHO Academy.

#### 11. Article 49 - Procedure

The objectives of the proposed amendments are:

- to strengthen the decision-making process for the determination of a public health emergency of international concern by improving the Emergency Committee meetings' output, through the standardisation of its agenda, leading to more specific and focused advice to the Director General;
- to strengthen the position of the Emergency Committee by ensuring that its recommendations are presented to relevant WHO bodies dealing with health emergency prevention, preparedness and response. The reference in brackets to the Standing Committee on Health Emergency Prevention, Preparedness and Response is not a

reflection of disagreement within the EU. The brackets are put, pending the start of the work of the SCPPR and its review, as per decision EB 150(6)<sup>1</sup>.

## 12. Article 54 bis - Implementation

An often-heard criticism of the IHR is that they suffer from low implementation and compliance and that States Parties are not sufficiently invested at a political level in their implementation.

The objectives of the new proposed article is:

- to promote the effective implementation of the IHR, by entrusting the Health Assembly with this task;
- defining the different functions of the Health Assembly in order to perform this new task;
- establishing, as an expert committee, a Special Committee to assist the Health Assembly in performing its functions.

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<sup>1</sup> [https://apps.who.int/gb/ebwha/pdf\\_files/EB150/B150\(6\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(6)-en.pdf)