Proposed Amendments to the International Health Regulations That are Designed to Implement Global Digital Health Certificates

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

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

-Uruguay on behalf of the Member States of the Southern Common Market

* * * * *

Article 23: Health measures on arrival and departure

1. Para 1(a)(ii)

including documents containing information for a lab test in digital or physical format.

-India

* * * * *

Article 23: Health measures on arrival and departure

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

-Russian Federation on behalf of the Member States of the Eurasian Economic Union

Proposed Amendment

Article 23: Health measures on arrival and departure

New 6. Documents containing information concerning traveller's destination (hereinafter Passenger Locator Forms, PLFs) should preferably be produced in digital form, with paper form as a residual option. Such information should not duplicate the information the traveller already submitted in relation to the same journey, provided the competence authority can have access to it for the purpose of contact tracing.

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

-Czech Republic on behalf of the Member States of the European Union

* * * * *

Article 31: Health measures relating to entry of travellers

- 1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis whether in paper based or digital format:
- (a) when necessary to determine whether a public health risk exists
- (b) as a condition of entry for any travellers seeking temporary or permanent residence;
- (c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or
- d) which may be carried out pursuant to Article 23.
- -Indonesia

Proposed Amendment

Article 35: General rule

Digital health documents must incorporate means to verify their authenticity via retrieval from an official web site, such as a QR code.

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

* * * * *

Article 36: Certificates of vaccination or other prophylaxis

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

* * * * *

Article 44: Collaboration and assistance

- 2 (d) (New) application of digital technologies to improve and upgrading communications for health emergency preparedness and response, including through the development of an interoperability mechanism for secure global digital exchange of health information;
- -Russian Federation on behalf of the Member States of the Eurasian Economic Union

ANNEX 6: VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided
with an international certificate of vaccination or prophylaxis (hereinafter the "certificate") in the form
specified in this Annex or in any digital format as being used in the country. No departure shall
be made from the model of the certificate specified in this Annex.

-Indonesia

* * * * *

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

* * * * *

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

ANNEX 6 VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

Proposed draft: (1)

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

Conditions for digital documents:

Paper certificates must be assigned by the clinician indicating the administration of the vaccine or other prophylaxis, or by another duly authorized health professional. Digital certificates must incorporate a means to verify authenticity from an official web site, for example a QR code. (2)

- (1) Rationale: Necessary relaxation of emergency regime, the need to consider certification of vaccines approved in accordance with the normative framework of the country of origin in scenarios of voluntary vaccination using WHO-approved products in the research phase or products subject to very limited worldwide distribution, in WHO- declared IPHE settings, for international travel purposes.
- (2) Vaccination certificates for entry to and exit from national territory: Two scenarios for the data to be included on certificates:

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

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

Maximum scenario: Certification of vaccination history via QR code

- 1. Vaccination history is accredited in digital or paper format, via QR code
- 2. QR code directs to the official site of the country of origin to retrieve the vaccination information.
- -Uruguay on behalf of the Member States of the Southern Common Market (MERCOSUR)

* * * * *

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

Proposed amendment to this section:

- "To verify authenticity, scan on the official web site, the QR code or other verification method. Image of the QR code"
- -Uruguay on behalf of the Member States of the Southern Common Market (MERCOSUR)

ANNEX 6: VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

- 4. Certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature. Signatures and stamps may also be appended digitally by the clinician or the administering centre, or by the health authority on their behalf, in accordance with Article 35 and with the specifications and requirements approved and reviewed periodically by the Health Assembly.
- 8. A parent or guardian shall sign the certificate when the child **or a person with disability** is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person's mark and the indication by another that this is the mark of the person concerned. **Such signatures shall not be required on a vaccination certificate in digital form.**
- -Czech Republic on behalf of the Member States of the European Union

* * * * *

- 4. **For paper based format,** certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.
- 4bis For digital format, certificates must be presented with QR code that contains the information mentioned on the Model International Certificate of Vaccinations or Prophylaxis and should be aligned with any current guidelines or/and agreed by State Parties.
- 9. A parent or guardian shall sign the certificate when the child **or a person with disability** is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person's mark and the indication by another that this is the mark of the person concerned.
- -Indonesia

* * * * *

TECHNICAL RECOMMENDATIONS FROM THE FINAL REPORT OF THE IHRRC

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

"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 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 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."

* * * * *

Article 23: Health measures on arrival and departure

"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;"

"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."

* * * * *

Article 31: Health measures relating to entry of travellers

"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".

Article 35: General rule

"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."

"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."

"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

"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."

* * * * *

Article 44: Collaboration and assistance

"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."