# Public comment to the Office of Global Affairs

# regarding the proposed amendments

# to the International Health Regulations.

**My comments are summarized under the two following points:**

**POINT #1: Article 21 of the WHO Constitution limits the authority of the World Health Assembly to adopt regulations in regards to only 5 categories.**

**POINT #2: The Joint Resolution passed by Congress and signed by President Truman on June 14, 1948 clearly stated that the United States would be under no obligation to enact legislation to implement any WHO decisions.**

**POINT #1:**

**Article 21 of the WHO Constitution limits the authority of the World Health Assembly to adopt regulations in regards to only 5 categories.**

> *"Article 21 of the World Health Organization's Constitution gives the Health Assembly the authority to adopt regulations that are limited to only 5 categories…*
>
> *Article 21*
>
> *The Health Assembly shall have authority to adopt regulations concerning:*
>
> *(a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;*
>
> *(b) nomenclatures with respect to diseases, causes of death and public health practices;*
>
> *(c) standards with respect to diagnostic procedures for international use;*
>
> *(d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;*
>
> *(e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce."*

Basic Documents Article 21 (pages 12-13)

**Under the guidelines set forth in Article 21 of the World Health Organization, the World Health Assembly does NOT have the authority to adopt regulations that would…**

1. Place any obligations or responsibilities upon member nations, regardless of their relative capabilities or "differentiated responsibilities"
2. Require or restrict the use of any medical product, therapy or treatment
3. Override member nation's health care decisions
4. Finance, control, direct or govern the member nations' response to any outbreak of disease or other "emergency"
5. Finance, control, direct or govern the "recovery" of the health care systems of member nations' after an outbreak of disease or other "emergency"
6. Require access to personal health information in the form of a vaccine certificate, prophylaxis certificate, testing certificate or recovery certificate
7. Require member nations to meet core requirements within their own health care systems
8. Require member nations to provide universal health care or health coverage
9. Require expenditures within member nations
10. Require the exchange of pathogens or genetic information from one nation to another or from one nation to the WHO
11. Require one member nation to assist any other member nation, financially or otherwise
12. Establish any form of "financial mechanism" to redistribute wealth from one member nation to another
13. Establish or maintain local production and/or distribution facilities
14. Devise or implement an allocation plan or mechanism to regulate the logistics and distribution of medical products
15. Control the pricing or distribution of products and/or services
16. Seek to require or raise funding via the regulatory authority in Article 21
17. Require member nations to respond to WHO dictates
18. Oversee the member nations implementation of or compliance with regulations
19. Censor information or opinion in any way
20. Require nations to manufacture and provide pandemic response products
21. Require nations to help other nations or insist upon an "obligation of duty to cooperate"
22. Demand changes to intellectual property laws
23. Require nations to build core capacities
24. Censor speech, the press, or opinions or comments on social media or any other platform
25. Set clinical guidance or treatment protocols

**POINT #2:**

**The Joint Resolution passed by Congress and signed by President Truman on June 14, 1948 clearly stated that the United States would be under no obligation to enact legislation to implement any WHO decisions.**

> *"In adopting this joint resolution, the Congress does so with the understanding that nothing in the Constitution of the World Health Organization in any manner commits the United States to enact any specific legislative program regarding any matters referred to in said Constitution."*
>
> https://uscode.house.gov/statviewer.htm?volume=62&page=442

**THEREFORE,**

**ALL OF THE PROPOSED AMENDMENTS LISTED BELOW MUST NOT BE ACCEPTED OR SUPPORTED BY THE DELEGATES TO THE WORLD HEALTH ORGANIZATION.**

Article 3 Principles

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

Article 3 Principles

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

Article 4 Responsible authorities

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

**Article 4 Responsible authorities**

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

Article 4 Responsible authorities

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

Article 5 Surveillance

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

Article 5 Surveillance

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

Article 6 Notification

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

Article 6 Notification

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

Article 7 Information-sharing during unexpected or unusual public health events2.

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

Article 8 Consultation

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

Article 10 Verification

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

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

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

(c) information to WHO in the context of an assessment under Article 6, including relevant information

Article 11 Exchange of information

New 3 bis: State Parties receiving information fromWHO pursuant to this provision shall not use it for conflict and violence purposes. State Parties shall also handle the information in a manner designed to avoid establishments, personals, non-state actors or any recipient whatsoever engaging directly or indirectly with conflict and violence elements, from accessing such information,directly or indirectly.

Article 13 Public health response

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

Article 13 Public health response

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

Article 13 Public health response

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

Article 13 Public health response

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

Article 13 Public health response

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

NEW Article 13A WHO Led International Public Health Response

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

NEW Article 13A WHO Led International Public Health Response

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

NEW Article 13A WHO Led International Public Health Response

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

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

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

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

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

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

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

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

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

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

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

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

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

c) to publish the pricing policy transparently.

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

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

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

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

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

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

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

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

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

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

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

Article 24 Conveyance operators

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

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

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

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

(d) implement quarantine promptly on board as necessary.

Article 35 General rule

No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23. Digital health documents must incorporate means to verify their authenticity via retrieval from an official web site, such as a QR code.

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

Article 42 Implementation of health measures

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

Article 43 Additional health measures

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

Article 43 Additional health measures

6. Recommendations made pursuant to paragraph 4 of this Article shall be implemented by the State Party concerned within two weeks from the date of recommendation. State Party concerned may approach WHO, within 7 days from the date of recommendations made under paragraph 4 of this Article, to reconsider such recommendations. Emergency Committee shall dispose the request for reconsideration within 7 days and the decision made on the request for reconsideration shall be final. The State Party concerned shall report to the implementation committee established under Article 53A on the implementation of the decision.

Article 43 Additional health measures

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

paragraph 1 or 2 of this Article, Parties so requested shall undertake consultations either bilaterally, multilaterally or at the regional level as the case may be. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measures and to find a mutually acceptable solution. The Director-General or WHO Regional Directors on his or her behalf shall:

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

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

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

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

Article 44 Collaboration and assistance

1. States Parties shall collaborate with and assist each other, in particular developing counties States Parties, upon request, in:

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 49 Procedure

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

Article 56 Settlement of disputes

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

**The vast majority of ANNEX 1 places obligations upon member states to maintain "core capacities"**

ANNEX 1

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

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

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

**including with regard to:**

(a) their surveillance, reporting, notification, verification, response and collaboration activities; and (b) their activities concerning designated airports, ports and ground crossings.

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

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

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

The capacities:

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

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

(c) to implement preliminary control measures immediately.

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

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

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

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

5. At the intermediate public health response levels

**The capacities:**

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

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

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

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

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

(ii) clinical guidance and treatment guidelines;

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

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

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

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

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

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

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

**New 5. Building capacities**

of the state parties (community level/ intermediate level) after consulting with concerned member state

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

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

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

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

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

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

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

6. At the national level

Assessment and notification.

**The capacities:**

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

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

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

Public health preparedness response.

**The capacities:**

(a) Establish governance structure to manage a potential or declared Public Health Emergency

of International concern.

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

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

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

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

(e) Establish co-ordinating mechanism to provide direct liaison collaboration with other relevant

government ministries, sub-national level entities, Country office and Regional Office of WHO, other stakeholders including NGOs and civil society;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**New 7. Health System Capacities:**

States shall develop health systems capacities with a view to achieve resilience against health emergency outbreaks, including through

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

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

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

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

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

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

(vii) financing solutions avoiding catastrophic burdens in the housesholds, (viii) national planning and leadership.

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

**New 7. Health Systems Capacities:**

in accordance with principle 2bis,

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

States Parties need to build, develop and maintain health systems capacities resilient to public health emergency of international concern as stated below:

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

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

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

(iv) Health information systems: establishment and maintenance of institutional mechanism in charge

of health statistics, synthesis of data from different sources and validation of data from population-based and facility-based sources, periodic health systems performance assessment, health systems resource tracking, immunization coverage and periodic burden of disease studies and its dissemination, subject to national sovereignty of the State Parties and privacy of personal data

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

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

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

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

1. At all times

**The capacities:**

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

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

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

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

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

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

**The capacities:**

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

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

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

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

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

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

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

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

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

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

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

**New Annex 10 OBLIGATIONS OF DUTY TO COOPERATE**

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

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

(a) with regard to surveillance capacities:

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

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

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

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

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

(b) With regard to response capacities:

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

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

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

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

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

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

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

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

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

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

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

(c) With regard to legal assistance:

i. take into consideration the socio-economic conditions of the States Parties concerned; ii. adopt legal and administrative arrangements to support public health response;

iii. train implementation of such legal instruments.