

Text Comparison:

Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting and the **Compilation of Proposed Amendments to the International Health Regulations (2005)** submitted by States Parties in the context of Decision WHA75(9)

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This text comparison was developed by the Global Health Centre in mid-March 2023 after the WHO published the Zero draft of the WHO CA+ and compilation of proposed amendments to the IHR (2005). The Zero Draft of the WHO CA+ is used as the basis for comparison using a chapter-by-chapter approach (see green table cells), with a consequent review of the proposed amendments to the IHR (2005) to include all relevant articles and annexes. The text from the proposed amendments to the IHR (2005) is attributed to the Member State(s) in brackets [].

The text formatting within the proposed amendments to the IHR (2005) section follows this legend:

LEGEND FOR IHR (2005) PROPOSED AMENDMENTS

~~Strikethrough~~ = delete existing text

Underlined and bold = new text proposed

(...) = existing text in the IHR for which proposals for amendments were not submitted and thus omitted from this compilation

Zero Draft of the WHO CA+

Proposed Amendments to the IHR (2005)

Chapter 1: Introduction		
<p>Article 1. Definitions and use of terms</p>	<p>1. For the purposes of this WHO CA+:</p> <p>(a) “genomic sequences” means the order of nucleotides identified in a molecule of DNA or RNA. They contain the full genetic information that determines the biological characteristics of an organism or a virus;</p> <p>(b) “pandemic” means the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe</p>	<p>Article 1 Definitions</p> <p>1. For the purposes of the International Health Regulations (hereinafter “the IHR” or “Regulations”):</p> <p>(...)</p> <p>“health products” include therapeutics, vaccines, medical devices, personal protective equipment, diagnostics, assistive products, cell- and gene-based therapies, and their components, materials, or parts.” [Eswatini on behalf the WHO Africa Region Member States]</p> <p>“health products” include medicines, vaccines, medical devices,</p>

	<p>morbidity and high mortality, and causing social and economic disruptions, all of which require effective national and global collaboration and coordination for its control;¹</p> <p>(c) “pandemic-related products” means products that may be needed for pandemic prevention, preparedness, response and/or recovery, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;</p> <p>(d) “persons in vulnerable situations” includes indigenous peoples, persons belonging to national or ethnic, religious or linguistic minorities, refugees, migrants, asylum seekers, stateless persons, persons in humanitarian settings and fragile contexts, marginalized communities, older people, persons with disabilities, persons with health conditions, pregnant women, infants, children and adolescents, and those living in fragile areas, such as Small Island Developing States;</p> <p>(e) “pathogen with pandemic potential” means...;</p> <p>(f) “One Health approach” means...;</p> <p>(g) “One Health surveillance” means...;</p> <p>(h) “infodemic” means...;</p> <p>(i) “inter-pandemic” means...;</p> <p>(j) “current health expenditure” means...;</p> <p>(k) “universal health coverage” means...; and</p> <p>(l) “recovery” means...</p>	<p><u>diagnostics, assistive products, cell and gene-based therapies, and other health technologies, but not limited to this course</u> [Malaysia]</p> <p><u>“health technologies and know-how” includes organized set or combination of knowledge, skills, health products, procedures, databases and systems developed to solve a health problem and improve quality of life, including those relating to development or manufacture of health products or their combination, its application or usage. “Health technologies” are interchangeably used as “health care technologies”.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p>(...)</p> <p>“standing recommendation” means non-binding [Bangladesh] advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;</p> <p>“temporary recommendation” means non-binding [Bangladesh] advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;</p>
<p>Article 2. Relationship with other international agreements and instruments</p>	<p>1. The implementation of the WHO CA+ shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. The WHO CA+ and other relevant international instruments, including the International Health Regulations, should be interpreted so as to be complementary, compatible and synergistic, and the WHO CA+ should be interpreted in a manner that promotes and supports the implementation and operationalization of the International Health Regulations and other relevant international instruments.² In the event that any part of the WHO CA+ addresses areas or activities that may bear on the</p>	

¹ The INB is encouraged to conduct discussions on the matter of the declaration of a “pandemic” by the WHO Director-General under the WHO CA+ and the modalities and terms for such a declaration, including interactions with the International Health Regulations and other relevant mechanisms and instruments. In this connection see Article 15.2 hereof

² The INB is encouraged to conduct discussions on the matter of making explicit the synergies and concrete complementarity of the WHO CA+ with the International Health Regulations and other relevant mechanisms and instruments

	<p>field of competence of other organizations or treaty bodies, appropriate steps will be taken to avoid duplication and promote synergies, compatibility and coherence, with a common goal of strengthened pandemic preparedness, prevention, response and health system recovery.</p> <p>2. The provisions of the WHO CA+ shall not affect the rights and obligations of any Party under other existing international instruments and shall respect the competencies of other organizations and treaty bodies.</p> <p>3. The provisions of the WHO CA+ shall in no way affect the right of Parties to enter into bilateral or multilateral instruments, including regional or subregional instruments, on issues relevant or additional to the WHO CA+, provided that such instruments are compatible with their obligations under the WHO CA+. The Parties concerned shall communicate such instruments to the Governing Body for the WHO CA+ through the Secretariat.</p>	
Chapter 2: Objective, guiding principles and scope		
Article 3. Objective	<p>The objective of the WHO CA+, guided by equity, the vision, principles and rights set out herein, is to prevent pandemics, save lives, reduce disease burden and protect livelihoods, through strengthening, proactively, the world's capacities for preventing, preparing for and responding to, and recovery of health systems from, pandemics. The WHO CA+ aims to comprehensively and effectively address systemic gaps and challenges that exist in these areas, at national, regional and international levels, through substantially reducing the risk of pandemics, increasing pandemic preparedness and response capacities, progressive realization of universal health coverage and ensuring coordinated, collaborative and evidence-based pandemic response and resilient recovery of health systems at community, national, regional and global levels.</p>	<p>Article 2 Scope and purpose The purpose and scope of these Regulations are to prevent, protect against, prepare, [India] control and provide a public health response to the international spread of diseases including through health systems readiness and resilience [Bangladesh] in ways that are commensurate with and restricted to public health risk all risks with a potential to impact public health, [India] and which avoid unnecessary interference with international traffic and trade, livelihoods, human rights, and equitable access to health products and health care technologies and know how. [Eswatini on behalf the WHO Africa Region Member States]</p>
Article 4. Guiding principles and rights	<p>To achieve the objective of the WHO CA+ and to implement its provisions, the Parties will be guided, inter alia, by the principles and rights set out below:</p> <p>1. Respect for human rights – The implementation of the WHO CA+ shall be with full respect for the dignity, human</p>	<p>Article 3 Principles 1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development. [India]</p>

<p>rights and fundamental freedoms of persons, and each Party shall protect and promote such freedoms.</p> <p>2. The right to health – The enjoyment of the highest attainable standard of health, defined as a state of complete physical, mental and social well-being, is one of the fundamental rights of every human being without distinction of age, race, religion, political belief, economic or social condition.</p> <p>3. Sovereignty – States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to determine and manage their approach to public health, notably pandemic prevention, preparedness, response and recovery of health systems, pursuant to their own policies and legislation, provided that activities within their jurisdiction or control do not cause damage to their peoples and other countries. Sovereignty also covers the rights of States over their biological resources.</p> <p>4. Equity – The absence of unfair, avoidable or remediable differences, including in their capacities, among and within countries, including between groups of people, whether those groups are defined socially, economically, demographically, geographically or by other dimensions of inequality, is central to equity. Effective pandemic prevention, preparedness, response and recovery cannot be achieved without political will and commitments in addressing the structural challenges in inequitable access to fair, equitable and timely access to affordable, safe and efficacious pandemic-related products and services, essential health services, information and social support, as well as tackling the inequities in terms of technology, health workforce, infrastructure and financing, among other aspects.</p> <p>5. Solidarity – The effective prevention of, preparedness for and response to pandemics requires national, international, multilateral, bilateral and multisectoral collaboration, coordination and cooperation, through global unity, to achieve the common interest of a fairer, more equitable and better prepared world.</p> <p>6. Transparency – The effective prevention of, preparedness for and response to pandemics depends on transparent, open and timely sharing, access to and disclosure of accurate information, data and other relevant elements that may come to light (including biological samples, genomic sequence data and clinical trial results), for risk assessment and control</p>	<p>(...)</p> <p><u>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.</u> [Bangladesh]</p> <p>3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease. <u>When implementing these Regulations, Parties and WHO should exercise precaution, in particular when dealing with unknown pathogens.</u> [Czech Republic on behalf of the Member States of the European Union]</p> <p>(...)</p> <p><u>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.</u> [Malaysia]</p> <p><u>New 6: Exchange of information between State Parties or between State Parties and WHO pursuant to the implementation of these Regulations shall be exclusively for peaceful purposes.</u> [Malaysia]</p>
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	<p>measures, and development of pandemic related products and services, notably through a whole-of-government and whole-of-society approach, based on, and guided by, the best-available scientific evidence, consistent with national, regional and international privacy and data protection rules, regulations and laws.</p> <p>7. Accountability – States are accountable for strengthening and sustaining their health systems’ capacities and public health functions to provide adequate health and social measures by adopting and implementing legislative, executive, administrative and other measures for fair, equitable, effective and timely pandemic prevention, preparedness, response and recovery of health systems. All Parties shall cooperate with other States and relevant international organizations, in order to collectively strengthen, support and sustain capacities for global prevention, preparedness, response and recovery of health systems.</p> <p>8. Common but differentiated responsibilities and capabilities in pandemic prevention, preparedness, response and recovery of health systems – All States are responsible for the health of their people, including pandemic prevention, preparedness, response and recovery, and previous pandemics have demonstrated that no one is safe until everyone is safe. Given that the health of all peoples is dependent on the fullest cooperation of individuals and States, all Parties are bound by the obligations of the WHO CA+. States that hold more resources relevant to pandemics, including pandemic-related products and manufacturing capacity, should bear, where appropriate, a commensurate degree of differentiated responsibility with regard to global pandemic prevention, preparedness, response and recovery. With the aim of supporting every Party to achieve the highest level of proven and sustained capacity, full consideration and prioritization are required of the specific needs and special circumstances of developing country Parties, especially those that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate capacities to respond to pandemics; and (iii) potentially bear a disproportionately high burden.</p> <p>9. Inclusiveness – The active engagement with, and participation of, all relevant stakeholders and partners across all levels, consistent with relevant and applicable international and national guidelines, rules and regulations (including those</p>	
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	<p>relating to conflicts of interest), is fundamental for mobilizing resources and capacities to support pandemic prevention, preparedness, response and health systems recovery.</p> <p>10. Community engagement – Full engagement of communities in prevention, preparedness, response and recovery of health systems is essential to mobilize social capital, resources, adherence to public health and social measures, and to gain trust in government.</p> <p>11. Gender equality – Pandemic prevention, preparedness, response and recovery of health systems will be guided by and benefit from the goal of equal participation and leadership of men and women in decision-making with a particular focus on gender equality, taking into account the specific needs of all women and girls, using a country-driven, gender responsive/transformational, participatory and fully transparent approach.</p> <p>12. Non-discrimination and respect for diversity – All individuals should have fair, equitable and timely access to pandemic-related products, health services and support, without fear of discrimination or distinction based on race, religion, political belief, economic or social condition.</p> <p>13. Rights of individuals and groups at higher risk and in vulnerable situations – Nationally determined and prioritized actions, including support, will take into account communities and persons in vulnerable situations, places and ecosystems. Indigenous peoples, persons belonging to national or ethnic, religious or linguistic minorities, refugees, migrants, asylum seekers, stateless persons, persons in humanitarian settings and fragile contexts, marginalized communities, older people, persons with disabilities, persons with health conditions, pregnant women, infants, children and adolescents, for example, are disproportionately affected by pandemics, owing to social and economic inequities, as well as legal and regulatory barriers, that may prevent them from accessing health services.</p> <p>14. One Health – Multisectoral and transdisciplinary actions should recognize the interconnection between people, animals, plants and their shared environment, for which a coherent, integrated and unifying approach should be strengthened and applied with an aim to sustainably balance and optimize the health of people, animals and ecosystems, including through, but not limited to, attention to the prevention</p>	
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	<p>of epidemics due to pathogens resistant to antimicrobial agents and zoonotic diseases.</p> <p>15. Universal health coverage – The WHO CA+ will be guided by the aim of achieving universal health coverage, for which strong and resilient health systems are of key importance, as a fundamental aspect of achieving the Sustainable Development Goals through promoting health and well-being for all at all ages.</p> <p>16. Science and evidence-informed decisions – Science, evidence and findable, accessible, interoperable and reusable data should inform all public health decisions and the development and implementation of guidance for pandemic prevention, preparedness, response and recovery of health systems.</p> <p>17. Central role of WHO – As the directing and coordinating authority on global health, and the leader of multilateral cooperation in global health governance, WHO is fundamental to strengthening pandemic prevention, preparedness, response and recovery of health systems.</p> <p>18. Proportionality – Due consideration should be given, including through regular monitoring and policy evaluation, to ensuring that the impacts of measures aimed at preventing, preparing for and responding to pandemics are proportionate to their intended objectives and that the benefits arising therefrom outweigh costs.</p>	
Article 5. Scope	The WHO CA+ applies to pandemic prevention, preparedness, response and health systems recovery at national, regional and international levels.	<p>Article 2 Scope and purpose</p> <p>The purpose and scope of these Regulations are to prevent, protect against, prepare, [India] control and provide a public health response to the international spread of diseases including through health systems readiness and resilience [Bangladesh] in ways that are commensurate with and restricted to public health risk-all risks with a potential to impact public health, [India] and which avoid unnecessary interference with international traffic and trade, livelihoods, human rights, and equitable access to health products and health care technologies and know how. [Eswatini on behalf the WHO Africa Region Member States]</p>

Chapter 3: Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems

<p>Article 6. Predictable global supply chain and logistics network</p>	<p>1. The Parties, recognizing the shortcomings of the preparedness for and response to the COVID-19 pandemic, agree on the need for an adequate, equitable, transparent, robust, agile, effective and diverse global supply chain and logistics network for pandemic prevention, preparedness, response and recovery.</p> <p>2. The WHO Global Pandemic Supply Chain and Logistics Network (the "Network") is hereby established.</p> <p>3. The Parties shall support the Network's development and operationalization, and participate in the Network, within the framework of WHO, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic. In that regard, the Parties shall:</p> <p>(a) determine the types and size of products needed for robust pandemic prevention, preparedness and response, including costs and logistics for establishing and maintaining strategic stockpiles of such products, by working with relevant stakeholders and experts, guided by scientific evidence and regular epidemiological risk assessments;</p> <p>(b) assess anticipated demand for, and map sources of, manufacturers and suppliers, including raw materials and other necessary inputs, for sustainable production of pandemic-related products (especially active pharmaceutical ingredients), including manufacturing capacities, and identify the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms and in-kind contributions, as well as promoting transparency in cost and pricing of all elements along the supply chain;</p> <p>(c) develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;</p> <p>(d) map existing delivery and distribution options, and establish or operationalize, as appropriate, international consolidation hubs, as well as regional staging areas, to</p>	<p>Article 13 Public health response</p> <p>3. At the request of a State Party, [United States of America] WHO shall collaborate articulate clearly defined assistance to a State Party [India] offer assistance to a State Party [USA] in the response to public health risks and other events by providing technical guidance, health products, technologies, know-how, deployment of civil medical personals, [Malaysia] 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. [Uruguay on behalf of MERCOSUR] 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. [United States of America] 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. [India]</p> <p>5. When requested by WHO, States Parties should shall [Eswatini on behalf the WHO Africa Region Member States] 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 fulfil such requests shall inform the reasons for the same to WHO and the Director General shall include the same in the report submitted to WHA under Article 54 of these Regulations. [Eswatini on behalf the WHO Africa Region Member States], including supply of health products and technologies especially diagnostics and other devices, therapeutics, and vaccines for effective response to PHEIC. [Malaysia] (...)</p> <p>New 7. Measures taken by States Parties shall not create barriers to or compromise the abilities of the other States Parties to effectively</p>
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	<p>ensure that transport of supplies is streamlined and uses the most appropriate means for the products concerned; and</p> <p>(e) develop a dashboard for pandemic-related product supply capacity and availability, with regular reporting, and conduct regular tabletop exercises to test the functioning of the Network.</p> <p>4. The Parties commit not to impose regulations that unduly interfere with the trade in, or of, pharmaceutical raw materials and ingredients, mindful of the need for unhindered access to pandemic-related products.</p> <p>5. The Parties commit to safeguard the humanitarian principles of humanity, neutrality, impartiality and independence, and to facilitate the unimpeded access of humanitarian staff and cargo. The commitment to facilitate such access is understood to be legally binding and to apply in all circumstances, consistent with humanitarian principles.</p> <p>6. The Parties, working through the Governing Body for the WHO CA+, shall take all appropriate measures to establish and start functioning of the Network no later than XX. It is understood that giving effect to this Article immediately upon adoption of the WHO CA+ shall be considered pursuant to, and within the meaning of, Article 35 of the WHO CA+.</p>	<p><u>respond to public health emergency of international concern, unless exceptional circumstance warrant such measures. States Parties whose abilities to respond are affected by the measures taken by other State party shall have the right to enter into consultation with the State Party implementing such measures to find a solution at the earliest considering the country interest.</u> [Bangladesh]</p> <p><u>NEW Article 13A WHO Led International Public Health Response</u> [Bangladesh]</p> <p><u>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.</u></p> <p><u>2. WHO shall carry out an assessment of the availability and affordability of the health products such as diagnostics, therapeutics, vaccines, personal and protective equipment and other tools required for responding to public health emergencies of international concern, including the potential increase in supply resulting from the surge and diversification of production and in cases of expected shortage of supply. WHO shall develop and allocation plan for health products so as to ensure equitable access to people of all States Parties.</u></p> <p><u>3. WHO shall, in its allocation plan for health products, inter alia identify and prioritize the recipients of health products, including health workers, frontline workers and vulnerable populations, and determine the required quantity of health care products for effective distribution to the recipients across States Parties.</u></p> <p><u>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.</u></p> <p><u>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.</u></p> <p><u>6. WHO shall develop and maintain a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate</u></p>
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		<p><u>manufacturing of health products required for responding to the potential public health emergencies of international concern. Within two years of the entry into force of this provision, WHO shall develop this database for all PHEICs declared so far, including for the diseases identified in the IHR 1969.</u></p> <p><u>7. In accordance with the provisions of these Regulations and in particular Article 13A (1), shall collaborate with other international organizations, and other stakeholders consistent with the provisions of FENSA, for responding to public health emergency of international concern. WHO shall report all its engagement with other stakeholders to the Health Assembly. The Director-general shall provide documents and information relating to such engagements upon request of States Parties.</u></p> <p><u>New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>1. Immediately after the determination of a public health emergency of international concern under Article 12, the Director General shall make an immediate assessment of availability and affordability of required health products and make recommendations, including an allocation mechanism, to avoid any potential shortages of health products and technologies pursuant to Article 15 or 16 as appropriate.</u></p> <p><u>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.</u></p> <p><u>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.</u></p> <p><u>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</u></p>
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		<p><u>a) to comply with WHO recommended measures including allocation mechanism made pursuant to paragraph 1.</u></p> <p><u>b) to donate a certain percentage of their production at the request of WHO.</u></p> <p><u>c) to publish the pricing policy transparently.</u></p> <p><u>d) to share the technologies, know-how for the diversification of production.</u></p> <p><u>e) to deposit cell-lines or share other details required by WHO repositories or database established pursuant to paragraph 5.</u></p> <p><u>f) to submit regulatory dossiers concerning safety and efficacy, and manufacturing and quality control processes, when called for by the States Parties or WHO.</u></p> <p><i>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p><u>New para 3: In developing recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate.</u> [India]</p> <p><u>New 3. In issuing such recommendation: The WHO should consult with other relevant international organization such as ICAO, IMO, WTO to avoid unnecessary interference with international travel and trade, such as the movement of essential health care workers and medical products and supplies.</u> [Indonesia]</p> <p><u>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.</u> [Indonesia]</p> <p><u>NEW (3) Where States parties impose travel and/or goods and cargo restrictions, WHO may recommend that these measures not apply to movement of health personnel travelling to the State Party(ies) for a public health response and to the transport of medical immunobiological products needed for a public health response.</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>New 3. In developing temporary recommendations, the Director-General shall consult with relevant international agencies</u></p>
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		<p><u>such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate. Additionally, temporary recommendations should allow for the appropriate exemption of essential health care workers and essential medical products and supplies from travel and trade restrictions.</u> [United States of America]</p> <p><u>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:</u></p> <p><u>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;</u> <u>b) Travel restrictions do not unduly prevent the movement of health care workers necessary for public health responses;</u> <u>c) Trade restrictions make provision to protect supply chains for the manufacture and transport of essential medical products and supplies; and</u> <u>d) The repatriation of travelers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases.</u> [USA]</p> <p>Article 44 Collaboration and assistance</p> <p>1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request,</u> to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.</u> [Indonesia]</p> <p><u>(f) (new) facilitating the provision of equitable access to medical countermeasures.</u> [Indonesia]</p> <p><u>New (e) providing equitable access to health products such as diagnostics, therapeutics, vaccines, PPE equipment and other tools</u></p>
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		<p><u>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</u> [Bangladesh]</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries</u> upon request, to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>New (e) training health and supportive workforce in the implementation of these Regulations;</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>New (f) the facilitation of accessibility and affordability of health products, including sharing of technologies and know-how, establishment and maintenance of the local production and distribution facilities.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>New (d) in providing equitable access to health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general public of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans and production capacity.</u> [Bangladesh]</p> <p>ANNEX 1</p> <p>A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]</p> <p>[1-4]</p> <p>5. At the intermediate public health response levels The capacities: (...)</p> <p><u>(vi) supply of affordable health care products and technologies, including through effective management of emergency supply chains.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>(e) to conduct research on cause and origin of disease, symptoms, transmission roots, progression of diseases, diagnosis methods,</u></p>
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		<p><u>effective prevention and control of the risks etc.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>(f) To coordinate, supervise and ensure the provision of prompt and quality health care to affected persons with available resource.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>(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.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>(...)</u> 6. At the national level [...]</p> <p><i>Public health <u>preparedness</u></i> [India] <i>response.</i> The capacities [...]</p> <p><u>(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.</u></p> <p><u>(e) Establish co-ordinating mechanism</u> [India] to provide direct liaison <u>collaboration</u> [India] with other relevant government ministries, sub-national level entities, Country office and Regional Office of WHO, other stakeholders including NGOs and civil society; [India]</p> <p><u>(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.</u> [India]</p> <p><u>(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;</u> [India]</p> <p><u>(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);</u> [India]</p>
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		<p><u>(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.</u> [India]</p> <p><u>(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;</u> [India]</p> <p><u>(j) Capacity to research, manufacture and deploy quickly medical countermeasures/ health products to respond to the health event</u> [India]</p> <p><u>(k) For sustainable financing to develop core capacities and respond to health emergencies.</u> [India]</p>
<p>Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how</p>	<p>1. The Parties recognize that inequitable access to pandemic-related products (including but not limited to vaccines, therapeutics and diagnostics) should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed.</p> <p>2. The Parties, working through the Governing Body for the WHO CA+, shall strengthen existing and develop innovative multilateral mechanisms that promote and incentivize relevant transfer of technology and know-how for production of pandemic-related products, on mutually agreed terms, to capable manufacturers, particularly in developing countries.</p> <p>3. During inter-pandemic times, all Parties commit to establish these mechanisms and shall:</p> <p>(a) coordinate, collaborate, facilitate and incentivize manufacturers of pandemic-related products to transfer relevant technology and know-how to capable manufacturer(s) (as defined below) on mutually agreed terms, including through technology transfer hubs and product development partnerships, and to address the needs to develop new pandemic-related products in a short time frame;</p> <p>(b) strengthen coordination, with relevant international organizations, including United Nations agencies, on issues related to public health, intellectual property and trade, including timely matching of supply to demand and mapping manufacturing capacities and demand;</p>	<p><u>New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>1. Immediately after the determination of a public health emergency of international concern under Article 12, the Director General shall make an immediate assessment of availability and affordability of required health products and make recommendations, including an allocation mechanism, to avoid any potential shortages of health products and technologies pursuant to Article 15 or 16 as appropriate.</u></p> <p><u>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.</u></p> <p><u>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.</u></p> <p><u>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</u></p>

<p>(c) encourage entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms, licences to capable manufacturers, notably from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic response product research, development and production, in particular for pre-pandemic and pandemic-related products; and</p> <p>(d) collaborate to ensure equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities.</p> <p>4. In the event of a pandemic, the Parties:</p> <p>(a) will take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;</p> <p>(b) will apply the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement;</p> <p>(c) shall encourage all holders of patents related to the production of pandemic-related products to waive, or manage as appropriate, payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so; and</p> <p>(d) shall encourage all research and development institutes, including manufacturers, in particular those receiving significant public financing, to waive, or manage as</p>	<p><u>equitable, timely availability and affordability through diversification of production.</u></p> <p><u>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 thirdparty(ies) except for the purposes of producing and supplying any materials or components to the manufacturer(s) under a contract with non-disclosure provisions.</u></p> <p><u>6. WHO shall take measures to ensure availability and accessibility through the local production of required health products including:</u></p> <p><u>a) develop and publish a list of required health products.</u> <u>b) develop and publish specifications for the production of required health products.</u> <u>c) develop appropriate regulatory guidelines for the rapid approval of health products of quality including development of immunogenicity co-relative protection (ICP) for vaccines.</u> <u>d) establish a database of raw materials and their potential suppliers.</u> <u>e) establish a repository for cell-lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines.</u> <u>f) review and regularly update WHO Listed Authorities so as to facilitate appropriate regulatory approvals.</u> <u>g) any other measures required for the purposes of this provision.</u></p> <p><u>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:</u></p> <p><u>a) to comply with WHO recommended measures including allocation mechanism made pursuant to paragraph 1.</u></p>
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	<p>appropriate, royalties on the continued use of their technology for production of pandemic-related products.</p> <p>5. For purposes of this Article, “capable manufacturer” refers to an entity that operates in a manner that is consistent with national and international guidelines and regulations, including biosafety and biosecurity standards.</p>	<p><u>b) to donate a certain percentage of their production at the request of WHO.</u> <u>c) to publish the pricing policy transparently.</u> <u>d) to share the technologies, know-how for the diversification of production.</u> <u>e) to deposit cell-lines or share other details required by WHO repositories or database established pursuant to paragraph 5.</u> <u>f) to submit regulatory dossiers concerning safety and efficacy, and manufacturing and quality control processes, when called for by the States Parties or WHO.</u></p> <p><u>Article 44 Collaboration and assistance</u></p> <p>1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request, to the extent possible,</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.</u> [Indonesia] <u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p>(i) (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries</u> upon request, to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p>
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		<p><u>(c) (New) implementation of the timely, secure and transparent exchange of samples and genetic sequence data of pathogens capable of causing pandemics and epidemics or other high-risk situations, taking into account relevant national and international legal provisions, rules, obligations and principles, including these Regulations, as appropriate, the Convention on Biological Diversity, and the importance of rapid access to information on human pathogens for public health preparedness and response;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>New (d) the formulation of laws and other legal and administrative provisions for the implementation of these Regulations;</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>New (f) the facilitation of accessibility and affordability of health products, including sharing of technologies and know-how, establishment and maintenance of the local production and distribution facilities.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>New Annex 10</u> <u>OBLIGATIONS OF DUTY TO COOPERATE</u> [Eswatini on behalf the WHO Africa Region Member States],</p> <p><u>2. WHO and States Parties collaborating and assisting with each other shall:</u> <u>(a) with regard to surveillance capacities:</u> <u>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;</u> <u>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.</u></p>
<p>Article 8. Regulatory strengthening</p>	<p>1. The Parties shall strengthen the capacity and performance of national regulatory authorities and increase the harmonization of regulatory requirements at the international and regional level, including, as applicable, through mutual recognition agreements.</p> <p>2. Each Party shall build and strengthen its country regulatory capacities and performance for timely approval of pandemic-related products and, in the event of a pandemic, accelerate the process of approving and licensing pandemic-related products for emergency use in a timely</p>	<p><u>New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>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</u></p>

	<p>manner, including the sharing of regulatory dossiers with other institutions.</p> <p>3. The Parties shall, as appropriate, monitor and regulate against substandard and falsified pandemic-related products, through existing Member State mechanisms on substandard and falsified medical products.</p>	<p><u>approval. Requesting State Party shall take measures to prevent designated manufacturer(s) from disclosing such information to a thirdparty(ies) except for the purposes of producing and supplying any materials or components to the manufacturer(s) under a contract with non-disclosure provisions.</u></p> <p><u>6. WHO shall take measures to ensure availability and accessibility through the local production of required health products including:</u></p> <p><u>c) develop appropriate regulatory guidelines for the rapid approval of health products of quality including development of immunogenicity co-relative protection (ICP) for vaccines.</u></p> <p><u>e) establish a repository for cell-lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines.</u></p> <p><u>f) review and regularly update WHO Listed Authorities so as to facilitate appropriate regulatory approvals.</u></p>
<p>Article 9. Increasing research and development capacities</p>	<p>1. The Parties recognize the need to build and strengthen capacities and institutions for innovative research and development for pandemic-related products, particularly in developing countries, and the need for information sharing through open science approaches for rapid sharing of scientific findings and research results.</p> <p>2. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received:</p> <p>(a) promote the free, public dissemination of the results of publicly and government-funded research for the development of pandemic-related products;</p> <p>(b) endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms;</p> <p>(c) ensure that promoters of research for pandemic-related products assume an appropriate level of the associated risk;</p>	<p><u>New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>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.</u></p> <p><u>Article 44 Collaboration and assistance</u></p> <p>1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request,</u> to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.</u> [Indonesia]</p>

<p>(d) promote and incentivize technology co-creation and joint venture initiatives; and</p> <p>(e) establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies.</p> <p>3. Parties shall increase the transparency of information about funding for research and development for pandemic-related products by:</p> <p>(a) disclosing information on public funding for research and development of potential pandemic-related products and provisions to enhance the availability and accessibility of the resulting work, including freely available and publicly accessible publications and public reporting of the relevant patents;</p> <p>(b) making it compulsory for manufacturers that receive public funding for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics, taking into account the extent of the public funding received; and</p> <p>(c) encouraging manufacturers that receive other funds, external to the manufacturer, for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics.</p> <p>4. Each Party should encourage non-State actors to participate in and accelerate innovative research and development for addressing novel pathogens, pathogens resistant to antimicrobial agents and emerging and re-emerging diseases with pandemic potential.</p> <p>5. The Parties shall establish, no later than XX, with reference to existing models, a global compensation mechanism for injuries resulting from pandemic vaccines.</p> <p>6. Pending establishment of such global compensation mechanism, each Party shall, in contracts for the supply or purchase of pandemic-related products, endeavour to exclude</p>	<p><u>New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>1. A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to achieve the following purposes:</u></p> <p><u>(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate.</u></p> <p>ANNEX 1</p> <p>A. CORE CAPACITY REQUIREMENTS FOR <u>DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p>5. At the intermediate public health response levels</p> <p>The capacities:</p> <p><u>(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.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p>6. At the national level</p> <p><i>Public health preparedness [India] response.</i> The capacities: [...]</p> <p><u>(j) Capacity to research, manufacture and deploy quickly medical countermeasures/ health products to respond to the health event</u> [India]</p> <p><u>New 7. At the Global level, WHO shall strengthen capacities to:</u> [India]</p> <p><u>d. Facilitate research, technology transfer, development and timely distribution of health products to manage public health emergencies.</u> [India]</p> <p>New Annex 10</p>
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<p>buyer/recipient indemnity clauses of indefinite or excessive duration.</p> <p>7. In the conclusion of contracts for the supply or purchase of pandemic-related products, each Party shall endeavour to exclude confidentiality provisions that serve to limit disclosure of terms and conditions.</p> <p>8. Each Party shall, as applicable, implement and apply international standards for, oversight of and reporting on laboratories and research facilities that carry out work to genetically alter organisms to increase their pathogenicity and transmissibility, in order to prevent accidental release of these pathogens, while ensuring that these measures do not create any unnecessary administrative hurdles for research.</p> <p>9. The Parties are encouraged to promote and strengthen knowledge translation and evidence-based communication tools and strategies relating to pandemic prevention, preparedness, response and recovery, at local, national, regional and international levels.</p> <p>10. The Parties acknowledge the need to take steps, individually and collectively, to develop strong, resilient national, regional and international clinical research ecosystems. In that regard, the Parties, as appropriate, commit to:</p> <p>(a) fostering and coordinating clinical research and clinical trials, including, as appropriate, through existing coordination mechanisms;</p> <p>(b) ensuring equitable access to resources (funding or in-kind), clinical research and clinical trials, so that resources are deployed optimally and efficiently;</p> <p>(c) supporting transparent and rapid reporting of clinical research and clinical trial results, to ensure evidence is available in a timely manner to inform national, regional and international decision-making; and</p> <p>(d) disclosing disaggregated information, for instance by gender and age, to the extent possible and as appropriate, on</p>	<p><u>OBLIGATIONS OF DUTY TO COOPERATE</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>2. WHO and States Parties collaborating and assisting with each other shall:</u></p> <p><u>(a) with regard to surveillance capacities:</u></p> <p><u>i. identify, assess and update the listing of technologies for the surveillance on a periodic basis;</u></p> <p><u>ii. identify, assess and update the listing of best practices related to organization structure and surveillance network;</u></p> <p><u>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;</u></p> <p><u>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;</u></p> <p><u>v. facilitate adaptation of the best-practices to the national and cultural contexts of the States Parties.</u></p> <p><u>(b) With regard to response capacities:</u></p> <p><u>i. develop various guidelines and protocols for prevention, control and treatment of the diseases, including standard treatment guidelines, vector control measures;</u></p> <p><u>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;</u> (...)</p> <p><u>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;</u></p> <p><u>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.;</u></p> <p><u>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;</u> (...)</p>
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	the results of clinical research and clinical trials relating to pandemic prevention, preparedness, response and recovery.	<p><u>ix. carry out research and building capabilities for implementing of the regulations including the product development;</u> <u>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.</u> <u>xi. building and maintaining IHR facilities in points of entry and its operations.</u></p>
<p>Article 10. WHO Pathogen Access and Benefit-Sharing System</p>	<p>1. The need for a multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with pandemic potential and genomic sequences, and benefits arising therefrom, that applies and operates in both inter-pandemic and pandemic times, is hereby recognized. In pursuit thereof, it is agreed to establish the WHO Pathogen Access and Benefit-Sharing System (the “PABS System”) under this WHO CA+. The Parties are mindful that the PABS System, or parts thereof, could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed. The terms of the PABS System shall be developed no later than XX with a view to their provisional application consistent with Article 35 hereof.</p> <p>2. The PABS System shall cover all pathogens with pandemic potential, including their genomic sequences, as well as access to benefits arising therefrom, and ensure that it operates synergistically with other relevant access and benefit-sharing instruments.</p> <p>3. The PABS System shall include the following elements and shall be regulated as follows: Access to pathogens with pandemic potential</p> <p>(a) Each Party, through its relevant and authorized laboratories, shall, in a rapid, systematic and timely manner:</p> <p>(i) provide pathogens with pandemic potential from early infections due to pathogens with pandemic potential or subsequent variants to a laboratory recognized or designated as part of an established WHO coordinated laboratory network; and (ii) upload the genomic sequence of such pathogens with pandemic potential to one or more publicly accessible databases of its choice. For purposes hereof, “rapid” shall be understood to mean within XX hours from the time of identification of a pathogen with pandemic potential;</p>	<p><u>Article 6 Notification</u></p> <p>2. Following a notification, a State Party shall continue to communicate to WHO <u>by the most efficient means of communication available</u> [United States of America, New Zealand] timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible <u>including genetic sequence data</u> [United States of America, New Zealand], case definitions, laboratory results, <u>epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent</u> [Czech Republic on behalf of the Member States of the European Union], <u>genome sequencing data if available</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union], source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed <u>implemented and other related information as per request of WHO</u> [Czech Republic on behalf of the Member States of the European Union], <u>genome sequence data</u> [Indonesia]; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern, <u>with regards to the sharing of genetic sequence data it will depend on Member States’ capacity and prevailing national legislation</u> [Malaysia]. <u>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.</u> [Czech Republic on behalf of the Member States of the European Union]</p> <p><u>3. For better clarity, the provisions of Article 45 shall apply to notifications made pursuant to this Article.</u> [Czech Republic on behalf of the Member States of the European Union]</p> <p><u>New 3. No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of</u></p>

<p>(b) The PABS System will be consistent with international legal frameworks, notably those for collection of patient specimens, material and data, and will promote effective, standardized, realtime global and regional platforms that promote findable, accessible, interoperable and reusable data available to all Parties;</p> <p>(c) Access shall be accorded expeditiously by the laboratory recognized or designated as part of an established WHO coordinated laboratory network, subject to conclusion of a Standard Material Transfer Agreement, developed for the purposes of the PABS System, with the recipient in accordance with subsection (i) below. Any such access shall be subject to applicable biosafety and biosecurity rules and standards, and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;</p> <p>(d) Recipients of materials shall not claim any intellectual property or other rights that limit the facilitated access to pathogens with pandemic potential, or their genomic sequences or components, in the form received; and</p> <p>(e) Access to pathogens with pandemic potential protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws.</p> <p><i>Fair and equitable benefit-sharing</i></p> <p>(f) The Parties agree that benefits arising from facilitating access to pathogens with pandemic potential shall be shared fairly and equitably in accordance with the provisions of the PABS System. Accordingly, it is understood that production of pandemic vaccines or other pandemic related products, irrespective of the technology, information or material used, implies use of pathogens with pandemic potential, including the genomic sequence;</p> <p>(g) Facilitated access shall be provided pursuant to a Standard Material Transfer Agreement, the form of which shall be set out in the PABS System and that shall contain the benefit-sharing options available to entities accessing pathogens with pandemic potential; and</p>	<p><u>benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing.</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>Article 7 Information-sharing during unexpected or unusual public health events</u> (...) <u>2. Following a notification pursuant to Article 6 of an event caused by an infectious agent, a State Party shall make available to WHO the microbial and genetic material and samples related to the notified event, as appropriate, not later than (...) hours after such material and samples become available.</u> 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). [Czech Republic on behalf of the Member States of the European Union]</p> <p><u>NEW Article 13A WHO Led International Public Health Response</u> [Bangladesh] <u>6. WHO shall develop and maintain a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required for responding to the potential public health emergencies of international concern. Within two years of the entry into force of this provision, WHO shall develop this database for all PHEICs declared so far, including for the diseases identified in the IHR 1969.</u></p> <p><u>Article 44 Collaboration and assistance</u> 1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request,</u> to the extent possible; [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p>
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	<p>(h) Such options shall include, but not be limited to: (i) real-time access by WHO to 20% of the production of safe, efficacious and effective pandemic-related products, including diagnostics, vaccines, personal protective equipment and therapeutics, to enable equitable distribution, in particular to developing countries, according to public health risk and need and national plans that identify priority populations. The pandemic-related products shall be provided to WHO on the following basis: 10% as a donation and 10% at affordable prices to WHO; (ii) commitments by the countries where manufacturing facilities are located that they will facilitate the shipment to WHO of these pandemic-related products by the manufacturers within their jurisdiction, according to schedules to be agreed between WHO and manufacturers.</p> <p><i>Recognition of the PABS System as a specialized international instrument</i></p> <p>(i) The PABS System, adopted under the WHO Constitution, is established with a view to its recognition as a specialized international access and benefit-sharing instrument within the meaning of the Nagoya Protocol;</p> <p>(j) Upon adoption, each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures to give effect to such recognition at the domestic level and/or with respect to its relations with all other States and regional economic integration organizations, as appropriate; and</p> <p>(k) The Parties shall support the further development and operationalization of the PABS System, including appropriate governance mechanisms, and participate in its operation, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic.</p> <p>4. The Parties, working through the Governing Body for the WHO CA+, shall develop and finalize additional elements and tools necessary to fully implement, operationalize and sustain the PABS System, no later than XX.</p>	<p><u>(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.</u> [Indonesia]</p> <p><u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries</u> upon request, to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States], in:</p> <p><u>(c) (New) implementation of the timely, secure and transparent exchange of samples and genetic sequence data of pathogens capable of causing pandemics and epidemics or other high-risk situations, taking into account relevant national and international legal provisions, rules, obligations and principles, including these Regulations, as appropriate, the Convention on Biological Diversity, and the importance of rapid access to information on human pathogens for public health preparedness and response;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p>ANNEX 1</p> <p>A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]</p> <p>4. At the local community level and/or primary public health response level The capacities:</p> <p>(b) to report all available essential information immediately to the appropriate level of healthcare response. At the community level, reporting</p>
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		<p>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, [Czech Republic on behalf of the Member States of the European Union] sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed; and</p> <p><u>New 5. Building capacities of the state parties (community level/ intermediate level) after consulting with concerned member state</u> [India]</p> <p><u>(b) Laboratory networks including that for Genomic sequencing and diagnostics to accurately identify the pathogen/ other hazards.</u> [India]</p> <p>6. At the national level <i>Public health preparedness [India] response.</i> The capacities:</p> <p>(b) to provide support through specialized staff, laboratory analysis of samples, genome sequencing [Russian Federation on behalf of the Member States of the Eurasian Economic Union] (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);</p> <p><u>(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.</u> [India]</p> <p><u>(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):</u> [India]</p> <p><u>(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.</u> [India]</p> <p><u>New 7. At the Global level, WHO shall strengthen capacities to:</u> [India]</p> <p><u>c. Facilitate sharing of Biological materials and genetic sequencing data and transparent subject to equitable access to benefits derived therefrom.</u> [India]</p>
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Chapter 4: Strengthening and sustaining capacities for pandemic prevention, preparedness, response and recovery of health systems

<p>Article 11. Strengthening and sustaining preparedness and health systems' resilience</p>	<p>1. The Parties recognize the need for resilient health systems, rooted in universal health coverage, to mitigate the shocks caused by pandemics and to ensure continuity of health services, thus preventing health systems from becoming overwhelmed.</p> <p>2. The Parties are encouraged to enhance financial, technical and technological support, assistance and cooperation, in particular to developing countries, to strengthen health emergency prevention and preparedness consistent with the goal of universal health coverage. The Parties shall strive to accelerate the achievement of universal health coverage.</p> <p>3. The Parties are encouraged to establish global, regional and national collaborative genomics networks that are dedicated to epidemiological genomic surveillance and the global sharing of emerging pathogens with pandemic potential.</p> <p>4. Each Party shall, in accordance with national law, adopt policies and strategies, supported by implementation plans, across the public and private sectors and relevant agencies, consistent with relevant tools, including, but not limited to, the International Health Regulations, and strengthen and reinforce public health functions for:</p> <p>(a) continued provision of quality routine and essential health services during pandemics, including clinical and mental health care and immunization, with a focus on primary health care and community-level interventions, and management of the backlog of and waiting lists for the diagnosis and treatment of, and interventions for, other illnesses, including care for patients with long-term effects from the pandemic disease;</p> <p>(b) strengthening human resource capacities during inter-pandemic times and during pandemics;</p> <p>(c) surveillance (including using a One Health approach), outbreak investigation and control, through interoperable early warning and alert systems;</p> <p>(d) sustained laboratory capacity for genomic sequencing, as well as for analysing and sharing such information;</p>	<p>Article 3 Principle 2 bis. <u>The States Parties shall develop and maintain capacities to implement the Regulations in accordance with their Common But Differentiate Responsibilities and Respective Capabilities (CBDRRC), 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.</u> [Bangladesh]</p> <p>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. <u>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[Malaysia]. This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism [United States of America], in replacement of the Joint External Evaluation that began in 2016 [ROK]. 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</u> [United States of America].</p> <p><u>New para 5: WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of known or unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate.</u> [India]</p> <p><u>New 5. WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate. The risk assessment shall indicate, based on the best available knowledge, the level of risk of potential spread and</u></p>
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	<p>(e) prevention of epidemic-prone diseases, and emerging, growing or evolving public health threats with pandemic potential, notably at the human-animal-environment interface;</p> <p>(f) post-emergency health system recovery strategies;</p> <p>(g) strengthening public health laboratory and diagnostic capacities, and national, regional and global networks, including standards and protocols for infection prevention and control, and public health laboratory biosafety and biosecurity; and</p> <p>(h) creating and maintaining up-to-date, universal platforms and technologies for forecasting and timely information sharing, through appropriate capacities, including building digital health and data science capacities.</p>	<p><u>risks of potential serious public health impacts, based on assessed infectiousness and severity of the illness.</u> [US, New Zealand]</p> <p><u>Article 15 Temporary recommendations</u> <u>New Para 2 bis: Temporary recommendations should be evidence based as per real time risk assessment of a potential or declared PHEIC, and the immediate critical gaps to be addressed for an optimal public health response, that shall be fair and equitable. The recommendations based on these assessments shall include:</u> <u>(a) support by way of epidemic intelligence surveillance, laboratory support, rapid deployment of expert teams, medical countermeasures, finance as well as other requisite health measures to be implemented by the State Party experiencing the Public Health Emergency of International Concern, or</u> <u>(b) prohibitive recommendations to avoid unnecessary interference with international traffic and trade.</u> [India]</p> <p><u>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</u> <u>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:</u> <u>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;</u> <u>b) Travel restrictions do not unduly prevent the movement of health care workers necessary for public health responses;</u> <u>c) Trade restrictions make provision to protect supply chains for the manufacture and transport of essential medical products and supplies; and</u> <u>d) The repatriation of travelers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases.</u> [United States of America]</p> <p><u>Article 44 Collaboration and assistance</u> 1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member</p>
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		<p>States] each other, <u>in particular developing countries States Parties, upon request, to the extent possible,</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>new (a) strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organizations;</u> [Czech Republic on behalf of the Member States of the European Union]</p> <p>(a) the detection and assessment of, and response to, events as provided under these Regulations;</p> <p>(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 <u>and in particular as provided in Annex 1</u> [Bangladesh];</p> <p>(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and <u>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.</u> [Bangladesh]</p> <p><u>(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.</u> [Indonesia]</p> <p><u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(f) (new) strengthening cooperation and establishing mechanisms for upgrading coordinating and explaining in contiguous territories</u></p>
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		<p><u>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</u></p> <p><u>(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.</u></p> <p><u>(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</u></p> <p><u>(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</u></p> <p><u>confidence building measures and engagement of community participation in both agenda setting and implementation.</u></p> <p><u>New 7 . At the Global level, WHO shall strengthen capacities to:</u></p> <p>[India]</p> <p><u>a. Provide policy document, guidelines, operating procedures epidemic intelligence, forcasting tools for managing public health emergency of international concern</u></p> <p><u>b. Use evaluation framework in finding critical gaps and support such state parties in attaining the core capacities.</u></p> <p><u>c. Facilitate sharing of Biological materials and genetic sequencing data and transparent subject to equitable access to benefits derived therefrom.</u></p> <p><u>d. Facilitate research, technology transfer, development and timely distribution of health products to manage public health emergencies.</u></p> <p><u>e. Counter misinformation and disinformation</u></p> <p><u>f. Co-ordinate with UN agencies, academia, non-state actors and representatives of civil society.</u></p> <p><u>g. Ensure sustainable financing for managing health emergencies.</u></p> <p>3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease. <u>When implementing these Regulations, Parties and WHO should exercise precaution, in</u></p>
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<p>Article 12. Strengthening and sustaining a skilled and competent health and care workforce</p>	<p>1. Each Party shall take the necessary steps to safeguard, protect, invest in and sustain a skilled, trained, competent and committed health and care workforce, at all levels, in a gender-responsive manner, with due protection of its employment, civil and human rights and well-being, consistent with international obligations and relevant codes of practice, with the aim of increasing and sustaining capacities for pandemic prevention, preparedness and response, while maintaining essential health services. This includes, subject to national law:</p> <p>(a) strengthening in- and post-service training, deployment, remuneration, distribution and retention of the health and care workforce, including community health workers and volunteers; and</p> <p>(b) addressing gender disparities and inequalities within the health and care workforce, to ensure meaningful representation, engagement, participation and empowerment of all health and care workers, while addressing discrimination, stigma and inequality and eliminating bias, including unequal remuneration, and noting that women still often face significant barriers to taking leadership and decision-making roles.</p> <p>2. The Parties are encouraged to enhance financial and technical support, assistance and cooperation, in particular to developing countries, to strengthen and sustain a skilled and competent health and care workforce at the national level.</p> <p>3. The Parties shall invest in establishing, sustaining, coordinating and mobilizing an available, skilled and trained global public health emergency workforce that is deployable to support Parties upon request, based on public health need, in order to contain outbreaks and prevent an escalation of small-scale spread to global proportions.</p> <p>4. The Parties will support the development of a network of training institutions, national and regional facilities and centres of expertise in order to establish common guidance to enable more predictable, standardized, timely and systematic</p>	<p>particular when dealing with unknown pathogens. [Czech Republic on behalf of the Member States of the European Union]</p> <p>Article 13 Public health response</p> <p>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.[Malaysia]</p> <p>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</p> <p>New 3. In Issuing such recommendation: The WHO should consult with other relevant international organization such as ICAO, IMO, WTO to avoid unnecessary interference with international travel and trade, such as the movement of essential health care workers and medical products and supplies. [Indonesia]</p> <p>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. [Indonesia]</p> <p>New 3. In developing temporary recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate. Additionally, temporary recommendations should allow for the appropriate exemption of essential health care workers and essential medical products and supplies from travel and trade restrictions. [United States of America]</p> <p>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:</p> <p>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;</p>
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	<p>response missions and deployment of the aforementioned public health emergency workforce.</p>	<p><u>b) Travel restrictions do not unduly prevent the movement of health care workers necessary for public health responses;</u> <u>c) Trade restrictions make provision to protect supply chains for the manufacture and transport of essential medical products and supplies; and</u> <u>d) The repatriation of travelers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases.</u> [United States of America]</p> <p><u>Article 44 Collaboration and assistance</u> 1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request, to the extent possible,</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in: <u>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.</u> [Bangladesh] <u>New (d) in providing equitable access to health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general public of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans and production capacity.</u> [Bangladesh] 2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries</u> [Eswatini on behalf the WHO Africa Region Member States], upon request, to the extent possible [Bangladesh, Eswatini on behalf the WHO Africa Region Member States], in: <u>(i) (New) strengthening the capacity of Focal Points, including through regular and targeted training events and workshops, consultations;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p>
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<p>Article 13. Preparedness monitoring, simulation exercises and universal peer review</p>	<p>1. Each Party shall undertake regular and systematic capacity assessments in order to identify capacity gaps and develop and implement comprehensive, inclusive, multisectoral national plans and strategies for pandemic prevention, preparedness and response, based on relevant tools developed by WHO.</p> <p>2. Each Party shall periodically assess the functioning, readiness and gaps of its preparedness and multisectoral response, logistics and supply chain management, through appropriate simulation or tabletop exercises, that include risk and vulnerability mapping. Such exercises may consist of after-action reviews of actual public health emergencies that can support identifying gaps, share lessons learned and improve national pandemic prevention, preparedness and response.</p> <p>3. The Parties will convene multi-country or regional tabletop exercises every two years, with technical support from the WHO Secretariat, with an aim to identify gaps in multi-country response capacity.</p> <p>4. Each Party shall provide annual (or biennial) reporting, building on existing relevant reporting where possible, on its pandemic prevention, preparedness, response and health systems recovery capacities.</p> <p>5. The Parties shall develop and implement a transparent, effective and efficient pandemic prevention, preparedness and response monitoring and evaluation system, which includes targets and national and global standardized indicators, with necessary funding for developing countries for this purpose.</p> <p>6. The Parties should establish, regularly update and broaden implementation of a universal peer review mechanism to assess national, regional and global preparedness capacities and gaps, by bringing nations together to support a whole-of-government and whole-of-society approach to strengthen national capacities for pandemic prevention, preparedness, response and health systems recovery, through technical and financial cooperation, mindful of the need to integrate available data and to engage national leadership at the highest level.</p>	<p>Article 5 Surveillance</p> <p>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. <u>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.[Malaysia]. This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism [United States of America], in replacement of the Joint External Evaluation that began in 2016 [ROK]. 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 [United States of America].</u></p> <p>4. WHO shall collect information regarding events through its surveillance activities and assess <u>on the basis of risk assessment criteria regularly updated and agreed with State Parties</u> [India, Russian Federation on behalf of the Member States of the Eurasian Economic Union] their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate <u>not with an outside party but member states</u> [India]</p> <p><u>4. (New wording) –WHO shall collect information regarding events through its surveillance activities and assess, through periodically updated assessment and risk criteria agreed with Member States, their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate”; [Uruguay on behalf of MERCOSUR]</u></p> <p><u>New para 5. “Strengthen the central role of national health authorities in management and coordination with political, intersectoral, interministerial and multilevel authorities for timely and coordinated surveillance and response in accordance with the international health risk indicated by the IHR, thereby consolidating the central role of national health authorities in multilevel management and coordination.” [Uruguay on behalf of MERCOSUR]</u></p>
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	<p>7. The Parties shall endeavour to implement the recommendations generated from review mechanisms, including prioritization of activities for immediate action.</p>	<p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR <u>DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p>(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;</p> <p><u>New Annex 10</u> <u>OBLIGATIONS OF DUTY TO COOPERATE</u> [Eswatini on behalf the WHO Africa Region Member States] <u>2. WHO and States Parties collaborating and assisting with each other shall:</u> <u>(a) with regard to surveillance capacities:</u> <u>i. identify, assess and update the listing of technologies for the surveillance on a periodic basis;</u> <u>ii. identify, assess and update the listing of best practices related to organization structure and surveillance network;</u></p>
<p>Article 14. Protection of human rights</p>	<p>1. The Parties shall, in accordance with their national laws, incorporate non-discriminatory measures to protect human rights as part of their pandemic prevention, preparedness, response and recovery, with a particular emphasis on the rights of persons in vulnerable situations.</p> <p>2. Towards this end, each Party shall:</p> <p>(a) incorporate into its laws and policies human rights protections during public health emergencies, including, but not limited to, requirements that any limitations on human rights are aligned with international law, including by ensuring that: (i) any restrictions are non-discriminatory, necessary to achieve the public health goal and the least restrictive necessary to protect the health of people; (ii) all protections of rights, including but not limited to, provision of health services and social protection programmes, are non-discriminatory and take into account the needs of people at high risk and persons in vulnerable situations; and (iii) people living under any restrictions on the freedom of movement, such as quarantines and isolations, have sufficient access to medication, health services and other necessities and rights; and</p>	<p><u>Article 2 Scope and purpose</u> The purpose and scope of these Regulations are to prevent, protect against, prepare, [India] control and provide a public health response to the international spread of diseases <u>including through health systems readiness and resilience</u> [Bangladesh] in ways that are commensurate with and restricted to public health risk <u>all risks with a potential to impact public health</u>, [India] and which avoid unnecessary interference with international traffic and trade, <u>livelihoods, human rights, and equitable access to health products and health care technologies and know how</u>. [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>Article 3 Principles</u> 1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons <u>based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development</u>. [India]</p>

	<p>(b) endeavour to develop an independent and inclusive advisory committee to advise the government on human rights protections during public health emergencies, including on the development and implementation of its legal and policy framework, and any other measures that may be needed to protect human rights.</p>	<p><u>NEW Article 13A WHO Led International Public Health Response</u> [Bangladesh] <u>3. WHO shall, in its allocation plan for health products, inter alia identify and prioritize the recipients of health products, including health workers, frontline workers and vulnerable populations, and determine the required quantity of health care products for effective distribution to the recipients across States Parties.</u></p> <p><u>Article 44 Collaboration and assistance</u> <u>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</u> [Bangladesh]</p> <p><u>New (d) in providing equitable access to health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general public of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans and production capacity.</u> [Bangladesh]</p> <p><u>Brazil proposes a model for the evaluation and notification of events that may constitute PHEIC for countries to replace Annex 2: [Brazil]</u> <u>4. Social and Economic Relevance - whether the event affects vulnerable populations, has high social impact and/or poses a risk to international travel or trade</u> [Brazil] <u>4.1. Does the event affect vulnerable populations?</u> [Brazil]</p>
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Chapter V. Coordination, collaboration and cooperation for pandemic prevention, preparedness, response and health system recovery

<p>Article 15. Global coordination, collaboration and cooperation</p>	<p>1. The Parties recognize the need to coordinate, collaborate and cooperate, in the spirit of international solidarity, with competent international and regional intergovernmental organizations and other bodies in the formulation of cost-effective measures, procedures and guidelines for pandemic prevention, preparedness, response and recovery of health systems, and to this end shall:</p> <p>(a) promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness, response and recovery by means that include establishing appropriate governance arrangements;</p> <p>(b) support mechanisms that ensure global, regional and national policy decisions are science and evidence-based;</p> <p>(c) develop, as necessary, and implement global policies that recognize the specific needs, and ensure the protection of, persons in vulnerable situations, indigenous peoples, and those living in fragile environments or areas, such as Small Island Developing States, who face multiple threats simultaneously, by gathering and analysing data, including data disaggregated by gender, to show the impact of policies on different groups;</p> <p>(d) promote equitable gender, geographical and socioeconomic status, representation and participation, as well as the participation of youth and women, in global and regional decisionmaking processes, global networks and technical advisory groups;</p> <p>(e) ensure solidarity with, and prevent stigmatization of, countries that report public health emergencies, as an incentive to facilitate transparency and timely reporting and sharing of information; and</p> <p>(f) facilitate WHO with rapid access to outbreak areas within the Party's jurisdiction or control, including through the deployment of rapid response and expert teams, to assess and support the response to emerging outbreaks.</p> <p>2. Recognizing the central role of WHO as the directing and coordinating authority on international health work, and mindful of the need for coordination with regional organizations, entities in the United Nations system and other intergovernmental organizations, the WHO Director-General</p>	<p>Article 5 Surveillance</p> <p>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. <u>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.</u> [Malaysia]. <u>This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism</u> [United States of America], <u>in replacement of the Joint External Evaluation that began in 2016</u> [ROK]. <u>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</u> [United States of America].</p> <p>4. WHO shall collect information regarding events through its surveillance activities and assess <u>on the basis of risk assessment criteria regularly updated and agreed with State Parties</u> [India, Russian Federation on behalf of the Member States of the Eurasian Economic Union] their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate <u>not with an outside party but member states</u> [India] <u>4. (New wording) –WHO shall collect information regarding events through its surveillance activities and assess, through periodically updated assessment and risk criteria agreed with Member States, their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate”;</u> [Uruguay on behalf of MERCOSUR] <u>New para 5. “Strengthen the central role of national health authorities in management and coordination with political, intersectoral, interministerial and multilevel authorities for timely and coordinated surveillance and response in accordance with the international health risk indicated by the IHR, thereby consolidating</u></p>
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	<p>shall, in accordance with terms set out herein, declare pandemics³.</p>	<p><u>the central role of national health authorities in multilevel management and coordination.</u> [Uruguay on behalf of MERCOSUR]</p> <p>Article 10. Verification</p> <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall, <u>as soon as possible or within a specific time</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union] <u>offer within 24 hours</u> [United States of America, supported by New Zealand] to collaborate with the State Party 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. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p><u>3bis. Within 24 hours of receiving a WHO offer of collaboration, the State Party may request additional information supporting the offer. WHO shall provide such information within 24 hours. When 48 hours have elapsed since the initial WHO offer of collaboration, failure by the State Party to accept the offer of collaboration shall constitute rejection for the purposes of sharing available information with States Parties under Paragraph 4 of this section.</u> [United States of America]</p> <p>4. If the State Party does not accept the offer of collaboration <u>within 48 hours</u> [United States of America], WHO may <u>shall</u> [United States of America], when justified by the magnitude of the public health risk, <u>immediately</u> [United States of America] share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned. [United States of America]</p> <p>Article 13. Public health response</p> <p><u>NEW Article 13A WHO Led International Public Health Response</u></p> <p><u>6. WHO shall develop and maintain a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required for responding to the</u></p>
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³ Reference is made to footnote 3 (Article 1), which invites the INB to propose and consider the development of modalities and terms for this provision. A/INB/4/3

		<p><u>potential public health emergencies of international concern. Within two years of the entry into force of this provision, WHO shall develop this database for all PHEICs declared so far, including for the diseases identified in the IHR 1969.</u> [Bangladesh]</p> <p><u>2bis. WHO shall provide to State Parties standardized forms for collaboration in the implementation of collaboration as provided in paragraph 1(a) of the Article 44 to facilitate State Parties' mutual collaboration essential for the effective implementation of public health response.</u> [Japan]</p> <p>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. <u>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.</u> [United States of America]</p> <p><u>Article 44 Collaboration and assistance</u></p> <p>1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request,</u> to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>new (a) strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organizations;</u> [Czech Republic on behalf of the Member States of the European Union]</p> <p>(a) the detection and assessment of, and response to, events as provided under these Regulations;</p>
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		<p>(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 <u>and in particular as provided in Annex 1</u> [Bangladesh];</p> <p>(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and <u>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.</u> [Bangladesh]</p> <p><u>(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing:</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.</u> [Indonesia]</p> <p><u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries</u> [Eswatini on behalf the WHO Africa Region Member States], upon request, to the extent possible [Bangladesh, Eswatini on behalf the WHO Africa Region Member States], in:</p>
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		<p>(f)(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 and Annex 6 [Indonesia] <u>through the financial mechanism established under Article 44A</u> [Eswatini on behalf the WHO Africa Region Member States] and to establish an international financial mechanism for providing financial assistance to developing countries State Parties for the said purpose [Bangladesh];</p> <p><u>(i) (New) strengthening the capacity of Focal Points, including through regular and targeted training events and workshops, consultations;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(j) (New) ensuring that differences in contexts and priorities among different States Parties, respect for their sovereignty, including health system strengthening, are taken into account when developing recommendations and supporting their implementation by WHO in order to improve pandemic preparedness and effective response for public health emergencies.</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>1. A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to achieve the following purposes:</u></p> <p><u>(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;</u></p> <p><u>(ii) strengthening of Health Systems including its functioning capacities and resilience;</u></p> <p><u>(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate.</u></p> <p><u>(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised;</u></p> <p><u>2. The WHA shall make arrangements to implement the above-mentioned provisions, within 24 months of the adoption of this provision, reviewing and taking into existing availability of funds and WHO arrangements for health emergency preparedness and response and whether they shall be maintained. Every four years</u></p>
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		<p><u>thereafter, the WHA shall review the financial mechanism and take appropriate measures to improve the functioning of the mechanism. WHA shall also ensure that the financial mechanism functions under the guidance of and be accountable to States Parties, which shall decide on its policies, programme priorities and eligibility criteria.</u></p> <p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]</p> <p>1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations <u>to identify public health risks</u> [India], <u>in accordance with principle 2bis</u> [Bangladesh] 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.</p> <p><u>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.</u> [Bangladesh]</p> <p>5. At the intermediate public health response levels</p> <p><u>New 5.</u> <u>(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;</u> [India]</p> <p>6. At the national level, <i>public health preparedness</i> [India] <i>response. The capacities:</i> <u>(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.</u> [India]</p> <p><u>(e) Establish co-ordinating mechanism</u> [India] to provide direct liaison</p>
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		<p><u>collaboration</u> [India] with other relevant government ministries, <u>sub-national level entities, Country office and Regional Office of WHO, other stakeholders including NGOs and civil society;</u> [India]</p> <p><u>New 7 . At the Global level, WHO shall strengthen capacities to:</u> [India]</p> <p><u>a. Provide policy document, guidelines, operating procedures epidemic intelligence, forecasting tools for managing public health emergency of international concern</u></p> <p><u>b. Use evaluation framework in finding critical gaps and support such state parties in attaining the core capacities.</u></p> <p><u>c. Facilitate sharing of biological materials and genetic sequencing data and transparent subject to equitable access to benefits derived therefrom.</u></p> <p><u>d. Facilitate research, technology transfer, development and timely distribution of health products to manage public health emergencies.</u></p> <p><u>e. Counter misinformation and disinformation</u></p> <p><u>f. Co-ordinate with UN agencies, academia, non-state actors and representatives of civil society.</u></p> <p><u>g. Ensure sustainable financing for managing health emergencies.</u></p> <p><u>NEW ANNEX 10</u></p> <p><u>OBLIGATIONS OF DUTY TO COOPERATE</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>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.</u></p>
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<p>Article 16. Whole-of-govern-ment and whole-of-societ-y approaches at the national level</p>	<p>1. The Parties recognize that pandemics begin and end in communities and are encouraged to adopt a whole-of-government and whole-of-society approach, including to empower and ensure communities' ownership of, and contribution to, community readiness and resilience for pandemic prevention, preparedness, response and recovery of health systems.</p> <p>2. Each Party shall establish, implement and adequately finance an effective national coordinating multisectoral mechanism with meaningful representation, engagement and participation of communities.</p> <p>3. Each Party should promote effective and meaningful engagement of communities, civil society and non-State actors, including the private sector, as part of a whole-of-society response in decisionmaking, implementation, monitoring and evaluation, as well as effective feedback mechanisms.</p> <p>4. Each Party shall develop, in accordance with its national context, comprehensive national pandemic prevention, preparedness, response and recovery plans pre-, post- and inter-pandemic that, inter alia:</p> <p>(i) identify and prioritize populations for access to pandemic-related products and health services;</p> <p>(ii) support timely and scalable mobilization of multidisciplinary surge capacity of human and financial resources, and facilitate timely allocation of resources to the frontline pandemic response;</p> <p>(iii) review the status of stockpiles and surge capacity of essential public health and clinical resources, and surge capacity in production of pandemic-related products; (iv) facilitate rapid and equitable restoration of public health capacities following a pandemic; and</p> <p>(v) promote collaboration with non-State actors, the private sector and civil society.</p> <p>5. Each Party will take steps to address the social, environmental and economic determinants of health, and vulnerability conditions that contribute to the emergence and spread of pandemics, and prevent or mitigate the socioeconomic impacts of pandemics, including but not limited</p>	<p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>New Article 5.</u> <u>Building capacities of the state parties (community level/ intermediate level) after consulting with concerned member state [India]</u></p> <p><u>(e) Support for a Health information management system to report all available essential information immediately to the appropriate level of health-care response. At the community level, reporting shall be to local community health-care 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, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed.</u> [India]</p> <p><u>New 7.</u> <u>Health Systems Capacities: in accordance with principle 2bis, States Parties need to build, develop and maintain health systems capacities resilient to public health emergency of international concern as stated below</u> [Bangladesh]:</p> <p><u>(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.</u> [Bangladesh]</p>
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	<p>to, those affecting economic growth, the environment, employment, trade, transport, gender equality, education, social assistance, housing, food insecurity, nutrition and culture, and especially for persons in vulnerable situations.</p> <p>6. Each Party should strengthen its national public health and social policies to facilitate a rapid, resilient response, especially for persons in vulnerable situations, including mobilizing social capital in communities for mutual support.</p>	
<p>Article 17. Strengthening pandemic and public health literacy</p>	<p>1. The Parties commit to increase science, public health and pandemic literacy in the population, as well as access to information on pandemics and their effects, and tackle false, misleading, misinformation or disinformation, including through promotion of international cooperation. In that regard, each Party is encouraged to:</p> <p>(a) promote and facilitate, at all appropriate levels, in accordance with national laws and regulations, development and implementation of educational and public awareness programmes on pandemics and their effects, by informing the public, communicating risk and managing infodemics through effective channels, including social media;</p> <p>(b) conduct regular social listening and analysis to identify the prevalence and profiles of misinformation, which contribute to design communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust; and</p> <p>(c) promote communications on scientific, engineering and technological advances that are relevant to the development and implementation of international rules and guidelines for pandemic prevention, preparedness, response and recovery of health systems, based on science and evidence.</p> <p>2. The Parties will contribute to research and inform policies on factors that hinder adherence to public health and social measures, confidence and uptake of vaccines, use of appropriate therapeutics and trust in science and government institutions.</p> <p>3. The Parties shall promote science and evidence-informed effective and timely risk assessment, including the uncertainty of data and evidence, when communicating such risk to the public.</p>	<p>Article 44 Collaboration and assistance</p> <p>1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request, to the extent possible,</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p><u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(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</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries,</u> upon request, to the extent possible [Bangladesh, Eswatini on behalf the WHO Africa Region Member States], in:</p> <p><u>(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;</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p><u>(e) (New) countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other</u></p>

		<p>ways of disseminating such information: [Russian Federation on behalf of the Member States of the Eurasian Economic Union]</p> <p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]z</p> <p>5. At the intermediate public health response levels The capacities:</p> <p><u>New 7 . At the Global level, WHO shall strengthen capacities to: [India]</u></p> <p><u>a. Provide policy document, guidelines, operating procedures epidemic intelligence, forecasting tools for managing public health emergency of international concern</u></p> <p><u>e. Counter misinformation and disinformation</u></p>
<p>Article 18. One Health</p>	<p>1. The Parties, recognizing that the majority of emerging infectious diseases and pandemics are caused by zoonotic pathogens, commit, in the context of pandemic prevention, preparedness, response and recovery of health systems, to promote and implement a One Health approach that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing instruments and initiatives.</p> <p>2. The Parties, with an aim of safeguarding human health and detecting and preventing health threats, shall promote and enhance synergies between multisectoral and transdisciplinary collaboration at the national level and cooperation at the international level, in order to identify, conduct risk assessment of and share pathogens with pandemic potential at the interface between human, animal and environment ecosystems, while recognizing their interdependence.</p> <p>3. The Parties will identify and integrate into relevant pandemic prevention and preparedness plans interventions that address the drivers of the emergence and re-emergence of disease at the humananimal- environment interface, including but not limited to climate change, land use change, wildlife, trade, desertification and antimicrobial resistance.</p>	<p><u>Article 6 Notification</u></p> <p>1. Each State Party, <u>within 48h after the Focal Point receives information about the event shall assess events occurring within its territory</u> [Russian Federation on behalf of the Member States of the Eurasian Economic Union] by using the decision instrument in Annex 2, <u>within 48 hours of the National IHR Focal Point receiving the relevant information.</u> [India, United States of America, New Zealand], Each State Party shall notify WHO, by the most efficient means of communication available... If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), <u>the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant UN entities,</u> WHO shall immediately notify the IAEA, <u>relevant national and UN entities.</u> [India, United States of America, New Zealand]</p> <p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]</p> <p>5. At the intermediate public health response levels The capacities:</p>

	<p>4. The Parties commit to regularly assess One Health capacities, insofar as they relate to pandemic prevention, preparedness, response and recovery of health systems, and to identify gaps, policies and the funding needed to strengthen those capacities.</p> <p>5. The Parties commit to strengthen synergies with other existing relevant instruments that address the drivers of pandemics, such as climate change, biodiversity loss, ecosystem degradation and increased risks at the human-animal-environment interface due to human activities.</p> <p>6. The Parties commit to strengthen multisectoral, coordinated, interoperable and integrated One Health surveillance systems and strengthen laboratory capacity to identify and assess the risks and emergence of pathogens and variants with pandemic potential, in order to minimize spill-over events, mutations and the risks associated with zoonotic neglected tropical and vector-borne diseases, with a view to preventing small-scale outbreaks in wildlife or domesticated animals from becoming a pandemic.</p> <p>7. Each Party shall:</p> <p>(a) implement actions to prevent pandemics from pathogens resistant to antimicrobial agents, taking into account relevant tools and guidelines, through a One Health approach, and collaborate with relevant partners, including the Quadripartite;</p> <p>(b) foster actions at national and community levels that encompass whole-of-government and whole-of-society approaches to control zoonotic outbreaks (in wildlife and domesticated animals), including engagement of communities in surveillance that identifies zoonotic outbreaks and antimicrobial resistance at source;</p> <p>(c) develop and implement a national One Health action plan on antimicrobial resistance that strengthens antimicrobial stewardship in the human and animal sectors, optimizes antimicrobial consumption, increases investment in, and promotes equitable and affordable access to, new medicines, diagnostic tools, vaccines and other interventions, strengthens infection prevention and control in health care settings and sanitation and biosecurity in livestock farms, and provides technical support to developing countries;</p>	<p><u>New 5. Building capacities of the state parties (community level/ intermediate level) after consulting with concerned member state [India]</u></p> <p><u>(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;</u></p> <p>6. At the national level <i>Public health preparedness</i> [India] response. The capacities:</p> <p><u>(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;</u> [India]</p> <p>(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</p> <p>(h) to provide the foregoing on a 24-hour basis.</p> <p><u>New Annex 10</u> <u>OBLIGATIONS OF DUTY TO COOPERATE</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>2. WHO and States Parties collaborating and assisting with each other shall:</u></p> <p><u>(b) With regard to response capacities:</u> <u>viii. establish multidisciplinary and multisectoral rapid response teams to respond to alerts and PHEIC, swiftly acting upon request from states parties;</u></p>
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	<p>(d) enhance surveillance to identify and report on pathogens resistant to antimicrobial agents in humans, livestock and aquaculture that have pandemic potential, building on the existing global reporting systems; and</p> <p>(e) take the One Health approach into account at national, subnational and facility levels in order to produce science-based evidence, and support, facilitate and/or oversee the correct, evidence-based and risk-informed implementation of infection prevention and control.</p>	
Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems		
<p>Article 19. Sustainable and predictable financing</p>	<p>1. The Parties recognize the important role that financial resources play in achieving the objective of the WHO CA+ and the primary financial responsibility of national governments in protecting and promoting the health of their populations. In that regard, each Party shall:</p> <p>(a) cooperate with other Parties, within the means and resources at its disposal, to raise financial resources for effective implementation of the WHO CA+ through bilateral and multilateral funding mechanisms;</p> <p>(b) plan and provide adequate financial support in line with its national fiscal capacities for: (i) strengthening pandemic prevention, preparedness, response and recovery of health systems; (ii) implementing its national plans, programmes and priorities; and (iii) strengthening health systems and progressive realization of universal health coverage;</p> <p>(c) commit to prioritize and increase or maintain, including through greater collaboration between the health, finance and private sectors, as appropriate, domestic funding by allocating in its annual budgets not lower than 5% of its current health expenditure to pandemic prevention, preparedness, response and health systems recovery, notably for improving and sustaining relevant capacities and working to achieve universal health coverage; and</p> <p>(d) commit to allocate, in accordance with its respective capacities, XX% of its gross domestic product for international cooperation and assistance on pandemic prevention, preparedness,</p>	<p>Article 5 Surveillance</p> <p>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. <u>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.[Malaysia]. This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism [United States of America], in replacement of the Joint External Evaluation that began in 2016 [ROK]. 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</u> [United States of America].</p> <p>Article 12 Determination of a public health emergency of international concern <u>public health emergency of regional concern, or intermediate health alert</u> [India, United States of America, Czech Republic on behalf of the Member States of the European Union]</p> <p>4bis. The PHEIC declaration is not designed to mobilise funds in the case of an emergency event. The Director-General should use other mechanisms for this purpose. [Switzerland]</p> <p>Article 13 Public health response</p> <p>3. At the request of a State Party, [United States] WHO shall collaborate [India, United States of America] articulate clearly defined assistance to</p>

	<p>response and health systems recovery, particularly for developing countries, including through international organizations and existing and new mechanisms.</p> <p>2. The Parties shall ensure, through innovative existing and/or new mechanisms, sustainable and predictable financing of global, regional and national systems, capacities, tools and global public goods, while avoiding duplication, promoting synergies and enhancing transparent and accountable governance of these mechanisms, to support strengthening pandemic prevention, preparedness, response and recovery of health systems, based on public health risk and need, particularly in developing countries.</p> <p>3. The Parties shall promote, as appropriate, the use of bilateral, regional, subregional and other appropriate and relevant channels to provide funding for the development and strengthening of pandemic prevention, preparedness, response and health system recovery programmes of developing country Parties.</p> <p>4. The Parties will facilitate rapid and effective mobilization of adequate financial resources, including from international financing facilities, to affected countries, based on public health need, to maintain and restore routine public health functions during and in the aftermath of a pandemic response.</p> <p>5. The Parties represented in relevant regional and international intergovernmental organizations and financial and development institutions shall encourage these entities to provide financial assistance for developing country Parties to support them in meeting their obligations under the WHO CA+, without limiting their participation in or membership of these organizations.</p>	<p><u>a State Party</u> [India] <u>offer assistance to a State Party</u> [United States of America] in the response to public health risks and other events by providing technical guidance 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, <u>and if required cooperate with said Member State in seeking support and international financial assistance to facilitate the containment of the risk at source.</u> [Uruguay on behalf of MERCOSUR] <u>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.</u> [United States of America] <u>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.</u> [India]</p> <p><u>Article 44 Collaboration and assistance</u></p> <p>1. States Parties shall undertake to [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] collaborate with <u>and assist</u> [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] each other, <u>in particular developing countries States Parties, upon request,</u> to the extent possible, [Bangladesh, Eswatini on behalf the WHO Africa Region Member States] in:</p> <p>(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and <u>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.</u> [Bangladesh]</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> [Eswatini on behalf the WHO Africa Region Member States] States Parties, <u>in particular developing countries</u> upon request, to the extent possible [Bangladesh, Eswatini on behalf the WHO Africa Region Member States], in:</p> <p>(f)(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 <u>and Annex 6</u> [Indonesia] <u>through the financial mechanism established under Article 44A</u> [Eswatini on behalf the WHO Africa Region Member States] <u>and to establish an international</u></p>
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		<p><u>financial mechanism for providing financial assistance to developing countries State Parties for the said purpose</u> [Bangladesh];</p> <p><u>New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>1. A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to achieve the following purposes:</u></p> <p><u>(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;</u></p> <p><u>(ii) strengthening of Health Systems including its functioning capacities and resilience;</u></p> <p><u>(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate.</u></p> <p><u>(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised;</u></p> <p><u>2. The WHA shall make arrangements to implement the above-mentioned provisions, within 24 months of the adoption of this provision, reviewing and taking into existing availability of funds and WHO arrangements for health emergency preparedness and response and whether they shall be maintained. Every four years thereafter, the WHA shall review the financial mechanism and take appropriate measures to improve the functioning of the mechanism. WHA shall also ensure that the financial mechanism functions under the guidance of and be accountable to States Parties, which shall decide on its policies, programme priorities and eligibility criteria.</u></p> <p><u>Article 53A - Establishment of an Implementation Committee</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>The State Parties shall establish an Implementation Committee, comprising of all States Parties meeting annually, that shall be responsible for:</u></p> <p><u>(b) Monitoring, advising on, and/or facilitating provision of technical assistance, logistical support and mobilization of financial resources for matters relating to implementation of the regulations with a view</u></p>
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		<p><u>to assisting States Parties to comply with obligations under these Regulations, with regards to</u> <u>(1) development and maintenance of IHR core capacities;</u> <u>(2) cooperation with WHO and State Parties in responding to outbreaks or events.</u></p> <p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>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.</u> [Bangladesh]</p> <p>6. At the national level Public health <u>preparedness</u> [India] response. The capacities: <u>(k) For sustainable financing to develop core capacities and respond to health emergencies.</u> [India]</p> <p><u>New 7. Health System Capacities: States shall develop health systems capacities with a view to achieve resilience against health emergency outbreaks, including through</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>(vii) financing solutions avoiding catastrophic burdens in the households</u> [Eswatini on behalf the WHO Africa Region Member States]</p> <p><u>New 7. Health Systems Capacities: in accordance with principle 2bis, States Parties need to build, develop and maintain health systems capacities resilient to public health emergency of international concern as stated below</u>[Bangladesh]:</p> <p><u>(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</u></p> <p><u>New 7 . At the Global level, WHO shall strengthen capacities to:</u> [India]</p> <p><u>g. Ensure sustainable financing for managing health emergencies.</u></p>
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Chapter VII. Institutional arrangements

<p>Article 20. Governing Body for the WHO CA+</p>	<p>1. A governing body for the WHO CA+ is established to promote the effective implementation of the WHO CA+ (hereinafter, the “Governing Body”).</p> <p>2. The Governing Body shall be composed of:</p> <p>(a) the Conference of the Parties (COP), which shall be the supreme organ of the Governing Body, composed of the Parties and constituting the sole decision-making organ; and</p> <p>(b) the Officers of the Parties, which shall be the administrative organ of the Governing Body.</p> <p>3. The COP, as the supreme policy setting organ of the WHO CA+, shall keep under regular review every three years the implementation and outcome of the WHO CA+ and any related legal instruments that the COP may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO CA+.</p> <p>The COP shall:</p> <p>(a) be composed of delegates representing Parties;</p> <p>(b) convene regular sessions of the Governing Body; the first of which shall take place not later than one year after the date of entry into force of the Convention, at a time and place to be determined by the WHO Secretariat, with the time and place of subsequent ordinary sessions to be determined by the COP upon a proposal of the Officers of the Parties;</p> <p>(c) convene special sessions of the Governing Body at such other times as may be deemed necessary by the COP, or at the written request of any Party, provided that, within 30 days of such a request being communicated to the Party/Parties by the Secretariat, it is supported by at least one third of the Parties; and</p> <p>(d) adopt its rules of procedure, as well as those of the other bodies of the Governing Body, which shall include decision-making procedures. Such procedures may include</p>	<p>Article 5 Surveillance</p> <p>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. <u>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.</u>[Malaysia]. <u>This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism</u> [United States of America], <u>in replacement of the Joint External Evaluation that began in 2016</u> [ROK]. <u>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</u> [United States of America].</p> <p><u>Article 53A - Establishment of an Implementation Committee</u> [Eswatini on behalf the WHO Africa Region Member States] <u>The State Parties shall establish an Implementation Committee, comprising of all States Parties meeting annually, that shall be responsible for:</u></p> <p><u>(a) Considering information submitted to it by WHO and States Parties relating to their respective obligations under these Regulations, including under Article 54 and through the IHR monitoring and Evaluation framework;</u> <u>(b) Monitoring, advising on, and/or facilitating provision of technical assistance, logistical support and mobilization of financial resources for matters relating to implementation of the regulations with a view to assisting States Parties to comply with obligations under these Regulations, with regards to</u> <u>(1) development and maintenance of IHR core capacities;</u> <u>(2) cooperation with WHO and State Parties in responding to outbreaks or events.</u> <u>(c) Promote international cooperation and assistance to address concerns raised by WHO and States Parties regarding</u></p>
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	<p>specified majorities required for the adoption of particular decisions.</p> <p>4. The Officers of the Parties, as the administrative organ of the Governing Body, shall:</p> <p>(a) be composed of two Presidents, four Vice-Presidents and two rapporteurs, serving in their individual capacity and elected by the COP for XX years; and</p> <p>(b) endeavour to make decisions by consensus; however, if efforts to reach consensus are deemed by the Presidents to be unavailing, decisions may be taken by voting by the President and Vice-Presidents.</p> <p>5. The Governing Body may further develop proposals for consideration by the WHO Executive Board, including to promote coordination and synergies between its Standing Committee on Health Emergency Prevention, Preparedness and Response and the Governing Body for the WHO CA+.</p>	<p><u>implementation of, and compliance with, obligations under these Regulations in accordance with Article 44:</u> <u>(d) Submit an annual report to each Health Assembly</u></p> <p><u>NEW Chapter IV (Article 53 bis-quater): [USA]</u> <u>The Compliance Committee 53 bis Terms of reference and composition</u></p> <p><u>1. The State Parties shall establish a Compliance Committee that shall be responsible for:</u></p> <p><u>(a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;</u> <u>(b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;</u> <u>(c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and</u> <u>(d) Submitting an annual report to each Health Assembly describing:</u></p> <p><u>(i) The work of the Compliance Committee during the reporting period;</u> <u>(ii) The concerns regarding non-compliance during the reporting period; and</u> <u>(iii) Any conclusions and recommendations of the Committee.</u></p> <p><u>2. The Compliance Committee shall be authorized to:</u></p> <p><u>(a) Request further information on matters under its consideration;</u> <u>(b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;</u> <u>(c) Consider any relevant information submitted to it;</u> <u>(d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and</u> <u>(e) Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.</u></p>
<p>Article 21. Consultative Body for the WHO CA+</p>	<p>1. A consultative body for the WHO CA+ (the “Consultative Body”) is established to provide advice and technical inputs for the decision-making processes of the COP, without participating in any decision-making.</p> <p>2. The Consultative Body will provide opportunity for broad, fair and equitable input to the COP for the decision-making processes of the COP. Further, the Consultative Body will provide opportunity for facilitation of implementation of COP decisions through modalities to be established by the COP. For the avoidance of doubt, it is understood that the Consultative Body will not participate in any decision-making, whether by consensus, voting or otherwise, of the COP.</p> <p>3. The Consultative Body shall be composed of (i) delegates representing Parties; and (ii) representatives of the United Nations and its specialized and related agencies, as well as any State Member thereof or observers thereto not Party to the WHO CA+. Further, representatives of any body or organization, whether national or international, governmental or nongovernmental, private sector or public sector, which is qualified in matters covered by the WHO CA+, may be admitted upon formal application, in accordance with terms</p>	

	<p>and conditions to be adopted by the COP, renewable every three years, unless at least one third of the Parties object.</p> <p>4. The Consultative Body shall be subject to the oversight of the COP, including rules of procedure adopted by the COP.</p>	<p><u>3. The Members of the Compliance Committee shall be appointed by States Parties from each Region, comprising six government experts from each Region. The Compliance Committee shall be appointed for four-year terms and meet three times per year.</u></p>
<p>Article 22. Oversight mechanisms for the WHO CA+ 1</p>	<p>The Governing Body, at its first meeting, shall consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of the WHO CA+ and also address cases of non-compliance.</p> <p>2. These measures, procedures and mechanisms shall include monitoring provisions and accountability measures to systematically address the achievement and gaps of capacities for prevention, preparedness, response and recovery of health systems, and the impact of pandemics, by means that include submission of periodic reports, reviews, remedies and actions, and to offer advice or assistance, where appropriate. These measures shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under the WHO CA+.</p>	<p><u>Article 54 Reporting and review</u> (...) <u>New 4. Apart from providing information to the State Parties and reporting to the Health Assembly in this Article, WHO shall maintain a webpage/ dashboard to provide the details of the activities carried out under the various provisions of these Regulations including Articles 5(3), 12, 13(5), 14, 15, 16, 18, 43, 44, 46, and 49.</u> [Malaysia]</p> <p><u>New Article 54 bis – Implementation</u> [Czech Republic on behalf of the Member States of the European Union]</p> <p><u>1. The Health Assembly shall be responsible to oversee and promote the effective implementation of these Regulations. For that purpose, Parties shall meet every two years, in a dedicated segment during the regular annual session of the Health Assembly.</u></p> <p><u>2. The Health Assembly shall take the decisions and recommendations necessary to promote the effective implementation of these Regulations. To this effect, it shall:</u></p> <p><u>(i) consider, at the request of any Party or the Director-General, any matter related to the effective implementation of these Regulations and adopt recommendations and decisions as appropriate on the strengthening of the implementation of these Regulations and improvement of compliance with their obligations;</u> <u>(ii) consider the reports submitted by Parties and the Director-General pursuant to Article 54 and adopt any recommendation of a general nature concerning the improvement of compliance with these Regulations;</u> <u>(iii) regularly assess the implementation of the Regulation by Parties and establish a strengthened review mechanism to that effect, with the aim of continuously improving the implementation of the Regulations by all Parties. In particular, the WHO and its Regional offices, upon request of a Party, which is a low or lower-middle income country, shall provide or facilitate technical support and</u></p>
<p>Article 23. Assessment and review</p>	<p>The Governing Body shall establish a mechanism to undertake, three years after the entry into force of the WHO CA+, and thereafter every three years and upon modalities determined by the Governing Body, an evaluation of the relevance and effectiveness of the WHO CA+, and recommend corrective measures, including, if deemed appropriate, amendments to the text of the WHO CA+.</p>	
<p>Article 24. Secretariat</p>	<p>1. A Secretariat for the WHO CA+ shall be provided by the Director-General of the World Health Organization.</p> <p>Secretariat functions shall be:</p> <p>(a) to make arrangements for sessions of the Governing Body and any subsidiary bodies and to provide them with services as required;</p> <p>(b) to transmit reports received by it pursuant to the WHO CA+;</p>	

	<p>(c) to provide support to the Parties, on request, in the compilation and communication of information required in accordance with the provisions of the WHO CA+;</p> <p>(d) to prepare reports on its activities under the WHO CA+ under the guidance of the Governing Body, and submit them to the Governing Body;</p> <p>(e) to ensure, under the guidance of the Governing Body, the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;</p> <p>(f) to enter, under the guidance of the Governing Body, into such administrative or contractual arrangements as may be required for the effective discharge of its functions; and</p> <p>(g) to perform other secretariat functions specified by the WHO CA+ and such other functions as may be determined by the Governing Body.</p>	<p><u>assist in the mobilization of resources aimed to implement the recommendations of such a review mechanism to that Party;</u></p> <p><u>(iv) promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes, as well as policies, legislation and other measures by Parties;</u></p> <p><u>(v) cooperate as appropriate with relevant WHO bodies, in particular those dealing with health emergency prevention, preparedness and response;</u></p> <p><u>(vi) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as referred to in Article 14, as a means of strengthening the implementation of these Regulations;</u></p> <p><u>(vii) oversee the implementation by the Secretariat of its functions under these Regulations, without prejudice to the authority of the Director-General under Articles 12, 15 to 17 and 47 to 53;</u></p> <p><u>(viii) consider other action, as appropriate, for the achievement of the objective of the Regulations in the light of experience gained in its implementation.</u></p> <p><u>3. A Special Committee on the IHR is hereby established, as an expert committee. The Special Committee shall have (...) members, appointed in a manner to ensure equitable regional representation and gender balance. The Special Committee shall assist the Health Assembly in discharging the functions set out in this Article and report to the Assembly.</u></p> <p><u>4. The Special Committee shall meet at least (once a year/ twice a year/ every two years/...).</u></p> <p>Article 56 Settlement of disputes (...)</p> <p><u>6. WHO must communicate all complaints by Member States regarding additional measures that have not been notified by any of them or recommended by the Organization;</u> [Uruguay on behalf of MERCOSUR]</p> <p><u>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;</u> [Uruguay on behalf of MERCOSUR]</p>
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