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on behalf of the Member States of the WHO African Region

IHR 2005 Targeted Amendments Proposals **Submitted by Eswatini on behalf of the WHO Africa Region Member States**[1]

Contents

[1]Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cabo Verde, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, South Africa, South Sudan, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

Note:

1. Text in bold represents "textual insertion/addition" proposed by Africa Group
2. Text in bold with strikethrough represents "textual deletions" proposed by Africa Group
3. Normal Text represents the already existing texts as available in IHR 2005.
4. Word "New" is added to the Paragraph/Article Number when an entirely new paragraph or provision is proposed.

PROPOSED AMENDMENTS BY THE AFRICA GROUP

I. Africa Group Proposal: *Article 1 Definition*

…

"health measure" means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;

"health products" include therapeutics, vaccines, medical devices, personal protective equipment, diagnostics, assistive products, cell- and gene-based therapies, and their components, materials, or parts.

"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".

"ill person" means an individual suffering from or affected with a physical ailment that may pose a public health risk;

…

Description:
Africa Group proposes to include the definition for "health products" and "health technologies and know-how" in Article 1 on Definitions, since the phrases will be repeatedly used in the provisions intending to improve equity in international public health response to Health Emergencies. The use of the above phrase "health products" is consistent with the use of language in various WHO Resolutions and UN Documents as well as public health approaches to health emergency response.

II. Africa Group Proposal: Article 2 - Purpose and scope

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate

with and restricted to public health risks, 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**.

Description:
The proposal to change the text in Article 2 is to clarify the mandate to "avoid unnecessary interference with international traffic and trade" applies to those measures that affect equitable access to and supply of health products required for the response to the international spread of disease as well.

III. Africa Group Proposal: Article 4 - Responsible authorities

It is recommended to introduce a provision under this section on training and capacity building of National IHR Focal Points, since the COVID-19 pandemic has revealed several challenges in terms of preparedness and response particularly in many LMICs.

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

IV. Africa Group Proposal: Article 6 – Notification

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 benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing.

V. Africa Group Proposals: Article 12 – Determination of a Public Health Emergency of International Concern

New 6. Immediately after the determination of PHEIC, the activities of the WHO in relation to such PHEIC, including through partnerships or collaborations, shall be in

accordance with the provisions of these Regulations. The Director General shall report all the activities carried out by WHO, including references to the corresponding provisions of these Regulations in pursuance to Article 54.

New 7. In case of any engagement with non-State actors in WHO's public health response to PHEIC situation, WHO shall follow the provisions of Framework for Engagement of Non-State Actors (FENSA). Any departure from FENSA provisions shall be consistent with paragraph 73 of FENSA.

Description:

The new paragraphs are proposed for bringing accountability and visibility of WHO Response to a PHEIC. These paragraphs are proposed within Article 12 to enhance the importance of the declaration of PHEIC and to keep WHO and Member States reminded that their activities and response measure to a public health event is very much linked to the determination of PHEIC by WHO under IHR 2005

VI. Africa Group Proposal: Article 13(5) Public health response – WHO Coordinated Response Activities

5. When requested by WHO, States Parties ~~**should**~~ **shall** provide, to the extent possible, support to WHO-coordinated response activities**, including supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics, and vaccines, for effective response to PHEIC occurring in another State Party's jurisdiction and/or territory, capacity building for the incident management systems as well as for rapid response teams. Any State Party unable to 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.**

Description:

Article 13(5) of IHR 2005 is one of the most potential provisions of IHR 2005 which can deliver against equity challenges. It provides for a better possibility of having a legally binding, and internationally coordinated public health response to PHEIC. Currently, the text of Article 13(5) is weak with usage of the verb "should" and the phrase "to the extent possible". The proposed amendments bring address these weaknesses.

VII. Africa Group Proposal: New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response

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.

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.

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.

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.

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

6. WHO shall take measures to ensure availability and accessibility through the local production of required health products including:

a) develop and publish a list of required health products,

b) develop and publish specifications for the production of required health products,

c) develop appropriate regulatory guidelines for the rapid approval of health products of quality including development of immunogenicity co-relative protection (ICP) for vaccines,

d) establish a database of raw materials and their potential suppliers,

e) establish a repository for cell-lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines,

f) review and regularly update WHO Listed Authorities so as to facilitate appropriate regulatory approvals,

g) any other measures required for the purposes of this provision.

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

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

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

c) to publish the pricing policy transparently.

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

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

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

Description:

The new provision is proposed as an extension of Article 13 to address concerns relating to the equitable access to health products, by providing for technical assistance, technological transfer, providing for discipline for the behaviour of non-state actors, etc.

VIII. Africa Group Proposal: Article 43 - Additional health measures

….

New 3 bis. A State Party implementing additional health measures referred to in paragraph 1 of this Article shall ensure such measures generally do not result in obstruction or cause impediment to the WHO's allocation mechanism or any other State Party's access to health products, technologies and knowhow, required to effectively

respond to a public health emergency of international concern. States Parties adopting such exceptional measures shall provide reasons to WHO.

43.4. After assessing information **and public health rationale** provided pursuant to paragraphs 3**, 3 bis** and 5 of this Article and other relevant information **within two weeks,** WHO ~~**may request that**~~ **shall make recommendations to** the State Party concerned to ~~**reconsider,**~~ **modify or rescind** the application of **the additional health** measures **in case of finding such measures as disproportionate or excessive. The Director General shall convene an Emergency Committee for the purposes of this paragraph.**

…

43.6. ~~**A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article.**~~ **Recommendations made pursuant to paragraph 4 of this Article shall be implemented by the State Party concerned within two weeks from the date of recommendation. State Party concerned may approach WHO, within 7 days from the date of recommendations made under paragraph 4 of this Article, to reconsider such recommendations. Emergency Committee shall dispose the request for reconsideration within 7 days and the decision made on the request for reconsideration shall be final. The State Party concerned shall report to the implementation committee established under Article 53A on the implementation of the decision.**

Description:

The proposal for amendments in Article 43 is made to make Article 43 operational. IHR Review committee has noted that Article 43 is not operational, and this has caused several excessive travel measures during Covid19 response and many of them were also discriminatory on a racial basis. The proposals in Article 43 made above provide a proper platform to review unilateral health measures made by States.

IX. Africa Group Proposal: Article 44 - Collaboration and assistance

1. States Parties shall ~~**undertake to**~~ collaborate with **and assist** each other**, in particular developing country States Parties**, upon request, ~~**to the extent possible**~~, in:

2. WHO shall collaborate with **and promptly assist** States Parties, in particular developing **countries** upon request, ~~**to the extent possible**~~, in:

…….

(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 through the financial mechanism established under Article 44A;

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

(e) training health and supportive workforce in the implementation of these Regulations;

(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.

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies **and if undertaken shall be reported to WHO. The Director General shall publish such information in pursuance of the Article 54, including the Director General's report to the World Health Assembly and the dedicated webpage.**

New 4. Collaboration and Assistance under this Article shall include activities mentioned under Annex 10 of the Regulations and shall be monitored by the implementation committee established under Article 53A.

Description:

The proposal is made to strengthen the duty to cooperate. It also makes certain obligations of duty to cooperate further explicit. A proper linkage to provision on reporting, financial mechanism, and implementation committee is also suggested to make the Article operational.

X. Africa Group Proposal: New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response

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:

(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;

(ii) strengthening of Health Systems including its functioning capacities and resilience;

(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.

(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised;

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.

Description:

Lack of sufficient finance and funding both at the international and national level impedes the implementation of IHR obligations. Furthermore, when such a fund is created it should be accountable to WHO and its Member States, which shall decide on its policies, programme priorities and eligibility criteria for funds. In this regard a new Article 44 A is proposed. This also an extension of obligation to collaborate and assist in mobilizing financial resources under Article 44.

XI. Africa Group Proposal: Article 45 - Treatment of Personal Data

New Para 4: WHO receiving personal data, and States Parties receiving personal data from other States Parties, shall process the data in a manner such that the data is not duplicated or stored without the permission of the provider States Party.

Description:

The addition of a new Article 45 (4) brings in responsibility of recipient States Parties to handle personal data in the manner described therein, in accordance with the concept of national sovereignty over the data of its nationals.

XII. Africa Group Proposal: New Article 53A - Establishment of an Implementation Committee

The State Parties shall establish an Implementation Committee, comprising of all States Parties meeting annually, that shall be responsible for:
(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;

(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

(1) development and maintenance of IHR core capacities;

(2) cooperation with WHO and State Parties in responding to outbreaks or events.

(c) Promote international cooperation and assistance to address concerns raised by WHO and States Parties regarding implementation of, and compliance with, obligations under these Regulations in accordance with Article 44;

(d) Submit an annual report to each Health Assembly

Comment:

The proposal is a for a committee of all Member States to discuss implementation and functioning of IHR annually. The proposal is equivalent to an annual conference of parties, and it can monitor and review both the implementation of IHR (2005), as well as new international instrument ensuring better coherence and complementarity between the implementation of two instruments.

XIII. Africa Group Proposals: Annex 1

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

…

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

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

The capacities:

…

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

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

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

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

5. At the intermediate public health response levels

The capacities:

…

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

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

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

(ii) clinical guidance and treatment guidelines;

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

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

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

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

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

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

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

6. At the national level

Assessment and notification. The capacities:

..

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

Public health response. The capacities:

…

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

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

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

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

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

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

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

New 7. Health System Capacities: States shall develop health systems capacities with a view to achieve resilience against health emergency outbreaks, including through

- **(i) state-of-art health care infrastructure and service delivery including scene care and pre-hospital services,**
- **(ii) upgradation of tools and methods, trained health workforce with equitable representation of gender, cultural and linguistic groups,**
- **(iii) fair and decent working conditions for health workers,**
- **(iv) adoption of legal, administrative and technical measures to diversify and increase production of health products,**
- **(v) improved distribution, and generic substitution for therapeutics,**

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

(vii) financing solutions avoiding catastrophic burdens in the housesholds,

(viii) national planning and leadership.

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

Description:

The proposals are made in consideration from the Member States discussions for strengthening Health Systems Capacities during the WGPR and INB. Also, few other amendments are proposed to Annex 1 in order to bring more clarity and details as to the response capacities required for effectively addressing the public health emergencies.

XIV. Africa Group Proposals: New Annex 10

OBLIGATIONS OF DUTY TO COOPERATE

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

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

(a) with regard to surveillance capacities:

i. identify, assess and update the listing of technologies for the surveillance on a periodic basis;
ii. identify, assess and update the listing of best practices related to organization structure and surveillance network;
iii. train human resources to detect, assess and report events under these Regulations, as according to the lists developed and maintained under the above paragraphs;
iv. facilitate sharing of technologies and know-how with States Parties in need, especially those technologies obtained in the course of research, wholly or partially funded by public sources;
v. facilitate adaptation of the best-practices to the national and cultural contexts of the States Parties.

(b) With regard to response capacities:

i. **develop various guidelines and protocols for prevention, control and treatment of the diseases, including standard treatment guidelines, vector control measures;**
ii. **assist in the development of infrastructure and capacity building for the successful implementation of protocols and guidelines and provide the same to the States Parties in need;**
iii. **provide logistical support for the procurement and supply of health products;**
iv. **develop and publish product development protocols for the materials and health products required for the implementation of above paragraphs, including all relevant details to enhance production and access to such products;**
v. **develop and publish technical specifications of the health products, including details of technologies and knowhow with a view to facilitate local production of diagnostics, therapeutics and vaccines, including cell-lines, raw-materials, reagents, design of devices etc.;**
vi. **develop and maintain an agile database of health product required for various health emergencies taking into account the past experiences and the needs of the future;**
vii. **train health workers to respond with health emergencies, including in adaptation of best practices and using of required technologies and equipment;**
viii. **establish multidisciplinary and multisectoral rapid response teams to respond to alerts and PHEIC, swiftly acting upon request from states parties;**
ix. **carry out research and building capabilities for implementing of the regulations including the product development;**
x. **facilitate sharing of technologies and know-how with States Parties in need, especially those technologies obtained in the course of research wholly or partially funded by public sources.**
xi. **building and maintaining IHR facilities in points of entry and its operations.**

(c) With regard to legal assistance:

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

Description:

New Annex 10 is proposed to bring more consistency in the discharge of obligations under Article 44 and it provides a non-exhaustive list of activities in which WHO and States Parties may collaborate.

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