TWN Info Service on Health Issues (Mar24/06)
11 March 2024
Third World Network

WHO: Revised pandemic instrument text onerous, inequitable for developing countries

11 March, New Delhi/ Kochi (Nithin Ramakrishan and K M Gopakumar) – The Revised Draft Negotiating Text of the pandemic instrument imposes onerous and inequitable obligations on developing countries.

Text-based negotiations are to commence for the first time based on this revised draft negotiating text (Revised Draft) during the upcoming 9th session of the WHO Intergovernmental Negotiating Body (INB).

The session will take place at the WHO Headquarters in Geneva from 18 to 28 March in a hybrid mode. The INB Bureau aims to conclude the negotiations on the pandemic instrument prior to the 77th session of the World Health Assembly (WHA) scheduled for May this year.

The Revised Draft dated 7th March 2024 was developed by INB Bureau, with the support of WHO Secretariat and was circulated on 8th March 2024 late evening. It is an updated version of the Bureau's Proposal for Negotiating Text dated 30th October 2023 which was discussed during INB7 and INB8. At INB8, countries were particularly stopped from proposing textual suggestions. They were only supposed to make conceptual remarks on the proposed draft negotiating text.

Based on what has been captured by the Bureau and the WHO Secretariat from the INB discussions, the draft negotiating text was revised within a week (1-7 March) and circulated on 8 March midnight. The translated version of the text into other UN languages is not yet out.

Though there has been no formal adoption of a negotiating text in the INB so far, according to the INB Co-chairs, INB9 will begin the real text-based negotiations, The Bureau itself has declared their text proposals as the default negotiating text and WHO Member States are forced to negotiate on the said text, without an opportunity to ensure their proposals are incorporated into the text.

The Bureau along with the WHO Secretariat has been managing the process to keep the textual content as limited as possible to arrive at a consensus before May 2024, the deadline set for themselves by a group of enthusiastic delegations and the WHO Secretariat.

The Revised Draft proposes onerous and inequitable obligations on developing countries in the following areas, with a strong emphasis on State obligations to conduct surveillance:

1. *Expanding surveillance obligations beyond public health;*
2. *Information sharing obligations with no effective data governance;*
3. *Conversion of non-negotiated standards and guidelines into legal norms;*
4. *Over reliance on unregulated and unaccountable multi stakeholder initiatives;*
5. *No legal certainty in access to health products and technologies;*
6. *Proposals for a weak access and benefit sharing system;*
7. *Lack of sustainable financial assistance*

Expanding surveillance obligations beyond public health

Proposals on Articles 4 and 5 require States Parties to establish a massive surveillance infrastructure to monitor the emerging or re-emerging pathogens, including animal pathogens. This marks a departure from the IHR obligations, which obligate State Parties to maintain the capacity to *detect, assess, notify and report disease or an occurrence that result in potential diseases.* The draft negotiating text proposals shift the IHR approach i.e surveillance of events (manifestation of disease or an occurrence that creates a potential for disease) to pathogens and make surveillance and reporting a routine activity. Thus, there is a paradigm shift in the nature of surveillance.

Article 4.3.a of the Revised Draft commits States Parties to conduct *"coordinated multisectoral surveillance: (i) detect and conduct risk assessments of emerging or re-emerging pathogens, including pathogens in animal populations that may present significant risks of zoonotic spillover, in accordance with the International Health Regulations (2005); and (ii) share the outputs of relevant surveillance and risk assessments within their territories with WHO and other relevant agencies;".*

Moreover, under other paragraphs of Articles 4 and 5, the States Parties are supposed to undertake further surveillance in areas like antimicrobial resistance and on environmental factors, and human activities that result in zoonotic spillovers.

For example, Article 4.3 (g) states: "*… vector-borne disease surveillance and prevention: develop, strengthen and maintain capacity to conduct risk assessments of vector-borne diseases that may lead to pandemic situations*;".

There is also an attempt to neutralise the very limited provisions on technical assistance related to surveillance capacity under Article 5 of the IHR. Article 5.1 states: "*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.*"

Article 5.3 states that *"WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article"*.

Thus, the State Parties can seek WHO's assistance to fulfil obligations under Article 5.1. However, this might be neutralised through the proposal under Article 4.4 (b), which states: *"… develop, strengthen and maintain pandemic prevention capacities to complement the core capacities for surveillance, prevention and response as set out in the International Health Regulations (2005)*". Thus, it proposes to create an obligation or the implementation of IHR surveillance capacity without any reference to Article 5.3 on assistance.

As explained below there is no guaranteed assistance to implement obligations on the proposed multisector surveillance.

Obligations on information sharing with no effective data governance

As seen above, in Article 4.3.a.ii, States Parties are required to share the "outputs of relevant surveillance and risk assessment within their territories" with "WHO and other relevant agencies". In IHR 2005, a State Party has to report an event to WHO, only when the State Party concerned comes to a conclusion based on an assessment that the event might constitute a public health emergency of international concern.

However, under the Revised Draft, there is no such condition. Although the word "relevant" qualifies the word surveillance in Article 4.3.a, it is clear that outcomes of the surveillance itself should be reported, not just information which is found relevant after risk assessment. The data has to be shared not only with WHO but also with other relevant agencies. This is not even limited to intergovernmental agencies. At the same time, there is no limitation as to how this data or information will be used, processed or further shared.

Under paragraph 3.b of Article 4, States Parties are obliged to contain public health events at source, and paragraph 3.c of Article 4 obliges States Parties to take measures to prevent zoonotic spillovers. This means States Parties can take sanitary and phytosanitary measures on the consumable goods or persons coming from countries that reported information. However, there are no safeguards proposed to address any economic or livelihood loss that may be caused by such preventive actions.

Further, the developing country States Parties would be under tremendous pressure from powerful actors to share data collected through multisectoral surveillance. This is very clear from Article 6.4 which states: "*The Parties shall identify and promote relevant international data standards and interoperability that enable timely sharing of public health data for preventing, detecting and responding to public health events.*"

The phrase "public health data for preventing, detecting and responding to public health events" is too broad, and captures all data emerging from various surveillance obligations under Articles 4 and 5.

Conversion of non-negotiated standards and guidelines to legal norms

The Revised Text contains many proposed obligations for States Parties to implement various guidelines, which are currently optional. The proposed negotiating text does not name these existing guidelines or tools. It uses the term "guidelines, tools" etc., and these are often developed without the participation of States Parties. Thus, the proposal is forcing States Parties to undertake obligations of which they are not aware of the content as well as implications.

For instance, Article 4.3.e of the Revised Draft reads: *"… zoonotic spillover and spillback prevention: (i) identify settings and activities that create or increase the risk of disease emergence and re-emergence at the human animal-plant-environment interface; (ii) take measures to reduce risks of zoonotic spillover and spillback associated with these settings and activities, including measures aimed at safe and responsible management of wildlife, farm and companion animals, in line with relevant international standards and guidelines;".*

Apart from these provisions, the paragraphs in Article (4.3.d., 4.3.h and 4.4.c) are also using the clause applying relevant international standards and guidelines. Examples of these guidelines include FAO guidance on a value chain approach to animal disease risk management; FAO technical guidelines on rapid risk assessment for animal health threats; a guide to implementing the One Health Joint Plan of Action at the national level.

The problem with this kind of the language is that the provisions shift discretionary and voluntary guidelines to what is akin to a legal obligation. Although powerful countries could continue to treat these standards and guidelines as voluntary, developing countries could be forced through bilateral and multilateral funding agreements to adhere by such guidelines, citing this obligation. Further, it is also not clear that these guidelines or tools cover only existing ones, or the wording could include future guidelines and tools. In short, developing countries are asked to undertake obligations without any informed understanding on the nature and implications of such obligations.

Over reliance on unregulated and unaccountable multistakeholder initiatives

Interestingly at almost every part of the Revised Text, right from pandemic prevention and one health approach to sustainable financing, including provisions on equitable access to health products, there is significant reliance on multistakeholder initiatives. These multistakeholder initiatives are often camouflaged in the negotiating text using the terms alliances, networks, partners, mechanisms etc.

For instance, Article 4.2.b reads: *"The Parties shall undertake to cooperate in support of relevant global and/or regional initiatives aimed at preventing pandemics, in particular those that improve surveillance, early warning and risk assessment; promote evidence-based actions, risk communication and community engagement; and*

identify settings and activities presenting a risk of emergence and re-emergence of pathogens with pandemic potential".

Article 13.1 reads: *"The Global Supply Chain and Logistics Network (the Network) is hereby established. The Network shall be developed, coordinated and convened by WHO in partnership with the Parties and other relevant international and regional stakeholders, and shall be guided by the principles of equity, transparency, inclusivity, timeliness, fairness and consideration of public health needs.*"

Article 19.2 reads: "*The Parties shall, upon request, facilitate the provision of technical assistance and support for those Cooperating Parties that have requested such assistance or support, in particular developing countries, either bilaterally or through relevant regional and/or international organizations.*"

Article 20.1.b read: *"The Parties commit to working together to strengthen sustainable financing for health emergencies as well as for pandemic prevention, preparedness and response. In this regard, each Party, within the means and resources at its disposal, shall mobilize financial resources through all sources, including existing and new bilateral, sub-regional, regional and multilateral funding mechanisms, to assist in particular developing country Parties, in the implementation of the WHO Pandemic Agreement, including through grants and concessional loans".*

Interestingly none of these provisions are backed by provisions that ensure accountability, transparency, due diligence and efficient performance of the responsibilities entrusted to these entities. There is no remedy provided to the States Parties or its people in case these multistakeholder entities or arrangements fail to perform in a reasonable and fair manner. As mentioned above the Revised Text does not even name any of these alliances, initiatives, networks, partnerships etc. and yet ask developing countries to undertake obligations to collaborate with them, like signing a blank cheque.

No legal certainty in access to health products and technologies

Articles 9, 10, 11, and 13 fail to provide assured access to health products, sticking instead to a business-as-usual approach. The absence of guaranteed technology transfer for pandemic-related products, particularly those funded by the public, to diversify production facilities is notable. Instead, the proposed approach involves establishing a distribution network that procures products primarily from WHO prequalified producers and suppliers, potentially leading to further concentration in the production and supply of pandemic-related goods.

While Article 9 addresses research and scientific collaboration, it suggests obligating States Parties to formulate national policies incorporating provisions in government-funded research and development agreements to ensure global access to health products during international public health emergencies and pandemics (Article 9.6). However, States Parties are granted the freedom to determine these provisions, offering a broad spectrum of options without obligating them to include provision or clauses promoting

diversified production in developing countries. Furthermore, none of the options specify assistance to developing countries.

Article 10 proposes that States Parties provide support, maintain and strengthen production facilities at national and/or regional levels, particularly in developing countries. However, there is no guaranteed provision to provide technology to such facilities. What is there is a promise under Article 10 (c), i.e. to "*facilitate the transfer of relevant technology, know-how, and licenses pooled in relevant mechanisms (as referred to in Article 11), including during interpandemic times, to ensure the sustainability of the facilities referred to in subparagraph 2(a)*;".

Article 11 does not outline a specific mechanism to pool technologies from various sources and share them with the production facilities identified by the States Parties, resulting in minimal accountability, predictability, and sustainability in the flow of technologies to manufacturers in developing countries.

Article 13 introduces the Global Supply Chain and Logistics Network (the Network), but its operations and relationship with the Governing Body of the Pandemic Agreement remain unclear. There are no safeguards specified to ensure the performance of the Network and its participating entities. The Network is also not required to procure from the production facilities referenced in Article 10 (production facilities at national and/or regional levels, particularly in developing countries).

Thus Articles 9, 10, 11 and 13 are merely a set of aspirational provisions which do not guarantee equitable access to any pandemic-related product.

Proposals for a weak access and benefit sharing system

The proposal on pathogen access and benefit sharing (PABS) in Article 12 of the Revised Text effectively aims at making sharing of pathogens and their genetic sequence data (GSD) obligatory without any guaranteed fair and equitable benefit sharing.

The proposed benefit sharing from the manufacturers of pandemic-related products includes donation of 10% of real time production as well as another 10% of real time production at a not-for-profit price. Further, it also proposes monetary contribution from all commercial users of GSD and pathogens. However, it proposes no role for States Parties in formulating the standard material transfer agreements or data access contracts. Instead, the proposal is that the WHO Secretariat would draw up the legally binding document based on templates provided by States Parties. Thus, unlike the WHO Pandemic Influenza Preparedness Framework (PIP), there is no effective role for State Parties in finalising conditions for providing access to pathogens samples and related data.

Further, Article 12.3 (c) states: "*All users of GSD shall have legal obligations under PABS regarding benefit sharing*", but there is no legally binding agreement to regulate access to GSD of pathogens. The users will only be notified of the benefit sharing provisions of

GSD. No obligation is proposed for States Parties to ensure that GSD users comply with the above-mentioned assertion that all users have legal obligations.

The Revised Text also proposes that States Parties provide consent to share the samples and GSD outside of the WHO Coordinated Laboratory Networks (CLN) and sequence databases (SDBs) with "an electronic label of "PABS biological material" or "PABS GSD", in accordance with the provisions of the-Article 12 including on benefit sharing".

However, it is not clear whether this sharing with entities or persons outside the CLN and SDB will happen on the basis of legally binding agreements regulating the use of the materials and data and prescribing benefit sharing. What is proposed is only a notification of benefit sharing provisions within the PABS system. Article 12.5 states:

"*The Parties agree that WHO shall develop, in accordance with the relevant templates to be developed by the Parties, as referenced in paragraph 11 below, as well as consistent with the WHO regulations for study, scientific groups, collaborating institutions and other mechanisms of collaboration, legally binding terms of reference for the CLNs and SDBs with arrangements to notify the users of biological materials and GSD of the benefit-sharing provisions of the PABS system.*"

Lack of sustainable financial assistance

The proposed financial mechanism under Article 20 is more rhetorical than having any legal effect. The proposed financial mechanism under paragraph 3 aims "*to increase the effectiveness and efficiency of existing and future financial mechanisms, including by providing additional financial resources to strengthen and expand capacities for pandemic prevention, preparedness and response in Cooperating Parties, in particular in developing country Parties*".

However, the reality is that there would not be any binding effect because the existing mechanism is not legally bound to follow the directions from the proposed financial mechanism under Article 20.

Similarly, though a new fund ("pooled fund") is created, there is no obligation on developed countries to provide financial resources to the proposed pool fund under paragraph 4. This is a clear departure from the principle of common but differentiated responsibilities, one of the principles stated in Article 3.

There are long standing international agreements like the UN Framework Convention on Climate Change and the Convention on Biological Diversity (CBD) where developed countries undertook the obligation to provide financial resources to developing countries for implementation of the conventions. For instance, the CBD's Article 20.2 states: "*The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and*

the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria…"

Article 21.1 of the CBD separately provides for the following: "*Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance*".

It is also worth noting that irrespective of citing CBDR as a principle of the instrument under Article 3, there is no provision in the revised draft negotiating text to translate the principle into concrete deliverable. Though assistance to developing countries is mentioned in several articles of the Revised Text including Article 19 these articles do not place nay special obligations on developed countries, which have the financial and technical abilities to provide assistance.

Thus, the Revised Text proposed as the basis for text-based negotiations contains onerous obligations on surveillance and information without any corresponding concrete obligation to ensure access to health care or medicines to the people. Such proposals prolong and further deepen the inequity instead of delivering on equity in pandemic preparedness, prevention and response.

As such, starting textual negotiations without placing concrete suggestions to change the basic orientation of the text would result in the reinforcing, even worsening, the *status quo*.+