World Health Organization

EIGHTH MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE

18 February 2024

Proposal for negotiating text of the WHO Pandemic Agreement

Chapter II, Article 14 *with refined textual proposals*

Chapter II. The world together equitably: Achieving equity in, for and through pandemic prevention, preparedness and response

Article 14. Regulatory Systems Strengthening

1. Each Party shall strengthen its national and/or regional regulatory authority responsible for the approval or authorization of [pandemic emergency response-related products], including through technical assistance and/or cooperation with WHO and relevant organizations, as appropriate, with the aim of ensuring the quality, safety, and efficacy of such products.

2. Each Party shall take steps to ensure that it has legal, administrative, and financial frameworks necessary for:
   a) emergency regulatory authorizations and approvals for [pandemic emergency response-related products] and/or, as appropriate, regulatory reliance processes aimed at the timely approvals and authorizations of such products, as well as systems to provide oversight of the quality, safety, and efficacy of those products, and
   b) taking actions to prevent, detect, and respond to substandard and falsified versions of such products including having mechanisms for notifying relevant regional or global rapid alert systems when such substandard or falsified products are confirmed.

3. Each party shall, in accordance with national laws, with the aim of enhancing transparency and regulatory reliance, make publicly available online and keep updated in a timely manner:
   a) information on national and, if applicable, regional regulatory processes for authorizing or approving use of [pandemic emergency response-related products] and
   b) information on the [pandemic emergency response-related products] that it has authorized or approved and its rationale for such decision(s), including the evidence, analysis of data, and other information on which the decision was based.

   The Parties request that WHO compile and maintain on its website links to Parties' websites containing such information.

4. Each Party shall, in accordance with national laws, encourage manufacturers[1], as appropriate, to generate and submit in a timely manner relevant data and diligently pursue regulatory authorizations and/or approvals of [pandemic emergency response-related products] with WHO listed authorities, other priority authorities, and WHO.

5. Each Party shall consider:
   a) adopting regulatory reliance processes in its national regulatory frameworks for use during [pandemic emergencies] incorporating principles from relevant guidelines such as the WHO Good Reliance Practices Guidelines, among others.

[1] We will need a definition that includes sponsors and marketing authorization holders as part of a definition for manufacturers.

b) providing support to help strengthen national regulatory authorities and regional regulatory systems' ability to respond to pandemic emergencies, on mutually agreeable terms and as appropriate, through efforts such as technical assistance, capacity building, training, and information exchange consistent with applicable law.

6. The Parties shall work together to develop and support strategies for strengthening WHO processes for Emergency Use Listing, Prequalification and any other relevant processes for recommending the use and continued regulatory oversight of [pandemic emergency response-related products].

7. Each Party shall consider adopting and implementing, when practicable and consistent with national law and procedures, guidance and technical documents concerning medical products developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF) or their successor organizations.