INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

IGBA Comments on Selected Provisions of the 13 March 2024 *Proposal for negotiating text of the WHO Pandemic Agreement*

As the international representative organization of the generic and biosimilar medicines industry, IGBA joins the WHO and Member States in reaffirming the importance of multisectoral collaboration to safeguard human health and build stronger, more resilient health systems. In an open letter concerning the International Negotiating Body (INB) negotiations of the Pandemic Agreement, dated January 2024, our association expressed it support to having an international legal instrument for the achievement of access to cost-effective, quality-assured, safe, and effective medicines. With the aim to take part of the public debate, in the framework of the 9th meeting of the INB, we would respectfully like to present a new round of observations.

The triple call for a definition of the 'Pandemic-related products'—and the want of a better approach in their achievement during the negotiations—; for an understanding at an international level of the dual role of the State as a regulator and as a procurer; and for strong, efficient and flexible regulatory systems, is a comment that remain valid in any round of observations. In IGBA's views, great progress has been made by the addition of Article 13(bis), as a separate conversation on the procurement of medicines is much needed. The article could further benefit from the inclusion of considerations regarding the criticality of unimpeded cross-order movement of medicines, the inclusion of pharmaceutical products including pandemic-related products in Article 13(bis).1, and especially the inclusion of multi-winner awards in tendering processes, both at a national level as in pooled procurement mechanisms. Additionally, great progress is also being achieved by the inclusion of new text in paragraphs 6, 7, and 8 in Article 14, regarding regulatory convergence and reliance. Enabling generic and biosimilar medicines to prepare a single data package globally, acceptable in all jurisdictions—what we call Single Global Development—would support more timely and equitable access to affordable therapies.

As the originally defined deadlines approach and the debate approaches, the IGBA wants to highlight the importance of achieving an international legal instrument capable of expanding access to medicines. To this end, we appreciate the consideration of our input in this critical endeavor with such consequence for global health and sustained patient access to affordable, safe, and high-quality medicines.

About IGBA:

The International Generic and Biosimilar medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. Adopting a patient centric approach, IGBA works to improve patients' access to quality-assured, safe, and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders. For more details, regarding IGBA and its members, see the IGBA website at: www.igbamedicines.org

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I. General Comments:

1. **The question of definitions:** Since its first conception in the Zero Draft, the Pandemic Accord has made great progress, and has steadily advanced towards its completion. Some issues, such as a lack of fundamental definitions, including for "Pandemic Related Products, "Pathogen with pandemic potential", among others, have persisted throughout the process. The IGBA insists, as it has done in former rounds of observations, that a clear definition, if not of the products subject to these provisions, at least of the process, implied parties, and methodologies for their determination, is fundamental for the effective implementation of a Pandemic Accord. Equipping the industry with this clarity is of the utmost importance to move forward with clear and achievable goals and objectives.
2. **The Supply Chain and Logistics Network:** The IGBA welcomes efforts to minimize uncertainty in supply and demand fluctuations. This is recognized as a key activity in the preservation of flow continuity, and consequently, of supply chain resiliency. However, to some of the comments we presented in former rounds of comments, we now add new observations on the following topics:
    a. **Extended participation in the network:** As the voice of the pharmaceutical off-patent sector, IGBA reinforces its commitment to contribute to the provision of safe, effective, quality-assured, and cost-effective pharmaceutical alternatives. In this guise, IGBA remains observant of developments within the new disposition of the network, now including "other relevant and regional stakeholders" as partners in the process. For IGBA, it is important to understand what the expectations of this network are regarding these parties. The IGBA welcomes further clarification on their nature and their role (as mentioned by Art. 13 (a)).
    b. **The determination of drug product attributes is privy to regulatory authorities:** The IGBA recognizes the importance of identifying the types of pandemic-related products and estimating the quantities needed (Art. 13.4.(a)) in a crisis. The IGBA also recognizes the value of identifying the sources of safe, effective, and quality assured pandemic-related products, including raw materials, and of having a tool for the monitoring of this information. In this line, the IGBA welcomes any clarification of the foreseen processes to satisfactorily accomplish these activities. As an association grouping active players in the market, the IGBA must bring back to mind the fact that the determination of drug product attributes, namely safety, quality, and efficacy, remains privy to regulatory

authorities. Any mechanism to identify pandemic-related products and estimate needed quantities must be strictly observant of the preservation of competition within markets.

3. **The question of national procurement and medicines distribution:** As stated in former rounds of comments, the IGBA welcomes an article dealing directly with the procurement of medicines. This is an important link in the supply chain, with a direct impact on drug product availability and access to medicines. Addressing issues such as irrational stockpiling, shelf lives, and expedited procedures for donations, the article is pointing in the right direction. We believe that this version of the article could be greatly enhanced by the inclusion of clauses considering a multi-winner approach to tendering processes, both at the national as well as the regional level. Inflexible national legal frameworks for contracting, uncertain conditions for manufacturers, and the clash between trade agreement clauses related to government procurement, are additional points that, should them be addressed by this article, would lead to enhanced access to cost-effective, safe, quality-assured, effective medicines to the global populations.

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Proposed changes to the text:

8 March 2024 draft text of selected provisions	Key Comments and Proposals
Article 10. Sustainable and geographically diversified production	
(a) take measures, in cooperation with regional organizations, to provide support, maintain and strengthen production facilities at national and/or regional levels, particularly in developing countries, and to facilitate scaling up of production of pandemic-related products during emergencies, including through promoting and/or incentivizing public and private investment aimed at creating or expanding economically viable manufacturing facilities of relevant health products;	Production facilities represent one of several elements that must be fostered to enable sustainable production and support reliable availability. Support should targeted and extend to other elements of the supply chain. **Proposed variation:** *take measures, in cooperation with regional organizations, to provide support, maintain and strengthen **supply and distribution capacity, including** production facilities **as appropriate** at national and/or regional levels, particularly in developing countries, and to facilitate scaling up of production of pandemic-related products during emergencies, including through promoting and/or 12 incentivizing public and private investment aimed at creating or expanding economically viable manufacturing facilities of relevant health products;*
(b) facilitate the continuous and sustainable operations of the facilities referred to in subparagraph 2(a) of this Article, including through promoting transparency of relevant unprotected information on pandemic-related products and raw materials across the value chain;	It is not clear what is referred to by "relevant unprotected information." It is not clear how "transparency of relevant unprotected information" facilitates the continuous operations of production facilities. Per article 3.10, preparedness measures should be based on science and evidence. Other relevant provisions may be included as an exemplification of this important task of member states: **Proposed variation:**

	(b) facilitate the continuous and sustainable operations of the facilities referred to in subparagraph 2(a) of this Article, including through ***fostering an appropriate regulatory environment, ensuring conditions for market financial sustainability, and achieving the correct procurement conditions and supply chain resiliency.***
(d) take measures, and encourage international organizations, to establish long-term contracts and make investments, especially in developing countries' facilities preferably with a regional scope of operation, to ensure regular production of pandemic-related products produced by local and regional manufacturers;	For the sake of supply chain resiliency, this provision points in the right direction. It is equally important to guarantee that pandemic-related products are compliant with international regulations: **Proposed variation:** (d) take measures, and encourage international organizations, to establish long-term contracts and make investments, especially in developing countries' facilities preferably with a regional scope of operation, to ensure regular production of ***safe, effective, quality-assured, and cost-effective*** pandemic-related products produced by local and regional manufacturers;
3. Each Party shall promote public and private sector investments aimed at creating or expanding manufacturing facilities for pandemic-related products, especially regional manufacturers based in developing countries.	Investment in production capacity should be prioritized where it can best improve equitable access, based on a broader consideration of enablers. **Proposed variation:** Each Party shall promote public and private sector investments aimed at creating or expanding manufacturing facilities for pandemic-related products, especially regional manufacturers based in developing countries ***as appropriate based on evidence-driven feasibility assessment.***
Article 13. Supply Chain and logistics	
3. The Parties shall periodically review the operationalization of the Network, including the	Stakeholders, such as the private sector, are key players in the operation and success of the proposed Network and should be considered strategic partners.

support provided by Parties and other stakeholders during and between pandemics.	**Proposed variation:** *The Parties shall periodically review the operationalization of the Network, including the support **and perspectives** provided by Parties and other stakeholders during and between pandemics.*
4(f) collaborating with relevant national authorities and organizations/institutions, as appropriate, and taking into account national and regional circumstances to 17 establish, strengthen and maintain national, regional and/or international stockpiles of various pandemic-related products, including stockpiles earmarked for humanitarian settings, as well as to maintain related logistic capacities and assess them at regular intervals;	Stockpiling requirements may prove contrary to the aim of tackling shortages and increasing access to medicines in pandemic events. It is important to carefully consider the impact of stockpiling on pharmaceutical production, the potential for stockpiling to contribute to inefficiencies in supply allocation to meet evolving demand, and the potential for resulting product waste and lack of fair and equitable access. Stockpiling provisions should be carefully assessed, including with cost-benefit analyses, and consider the potential for disruptions to global supply. **Proposed variation:** collaborating with relevant national authorities and organizations/institutions, as appropriate, and taking into account national and regional circumstances to 17 establish***, and considering global supply availability,*** strengthen and maintain national, regional and/or international stockpiles of various pandemic-related products, including stockpiles earmarked for humanitarian settings, as well as to maintain related logistic capacities and assess them at regular intervals;
Article 13.*bis* National procurement- and distribution-related provisions	
1. Each Party shall publish the terms of its government-funded purchase agreements for pandemic-related products at the earliest reasonable opportunity and in accordance with applicable laws, and shall exclude confidentiality provisions that serve to limit such disclosure. Each Party shall also encourage [regional and global purchasing mechanisms] to do the same.	As the objective of the Pandemic Agreement (Art. 2) is to "prevent, prepare for, and respond to pandemics", the considerations in Art. 13(bis).1. should extend to the most comprehensive set of pharmaceutical categories, including pandemic-related products. **Proposed variation:** 1. Each Party shall publish the terms of its government-funded purchase agreements for **pharmaceutical products, including** pandemic-related products at the earliest reasonable opportunity and in accordance with applicable laws, and shall exclude

	confidentiality provisions that serve to limit such disclosure. Each Party shall also encourage [regional and global purchasing mechanisms] to do the same.
3. The Parties recognize the importance of ensuring that any emergency trade measures designed to respond to a pandemic are targeted, proportionate, transparent and 18 temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.	We underscore the criticality of paragraph Article 13.bis(3), noting the experience of generic and biosimilar medicines suppliers during the COVID-19 pandemic navigating border closures, export restrictions and other unnecessary barriers that impeded supply chains and limited equitable availability of pandemic-related products. The greatest benefit of this proposed Pandemic Agreement would be the commitment of all Parties to maintain unimpeded flow of pandemic-related products across borders to meet evolving global demand in a timely and efficient way. The strengthening of Article 13(7) to this effect would be welcome. **Proposed variation:** The Parties recognize the importance of ensuring that any emergency trade measures designed to respond to a pandemic are targeted, proportionate, transparent and 18 temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains, ***noting the importance of free movement of pandemic-related products in enabling fair and equitable access***.