INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Key Comments and Proposals by IGBA on Selected Provisions of the Zero Draft of the Pandemic Accord
May 2023

Zero draft text of selected provisions	Key Comments and Proposals
Chapter I. Introduction	
Article 1. Definitions and use of terms	
(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;	Comments: 1. The definition of "pandemic-related products" is critical for the determination of the exact content of several obligations arising from the Zero Draft. 2. From the perspective of manufacturers and suppliers, the treatment of pandemic-related products, as compared to non-pandemic-related products, may be different in many respects. 3. Clarity is needed on the process by which a product qualifies as a “pandemic-related product”, including who determines this product list, cadence for review and revision of the list, and criteria for determining product inclusion. Such transparency is essential for proper planning by manufacturers and suppliers in compliance with the obligations set forth by the Accord. Proposal: To include under "Article 5. Scope", the process for determining “pandemic-related products”, including who will be responsible for determining the list of products to be considered "pandemic-

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 member associations, see the IGBA website at: www.igbamedicines.org.

	related products", how often this list will be reviewed, and what criteria will be used to determine such qualification. We would request that such process include consultation of relevant stakeholders and experts, including impacted manufacturers and suppliers.
Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems	
Article 6. Predictable global supply chain and logistics network	
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: (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 (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; […]	Comments: 1. We appreciate the recognition in Article 6.3(a) that stakeholder consultation is a key component of ensuring resilient supply of relevant medicines and health products. As stated in Article 6.3 (a), we call for the assessment in Article 6.3(b) to also involve "working with relevant stakeholders and experts", to ensure the Parties consult relevant stakeholders on these critical elements. 2. We appreciate the focus on "sustainable production" and note that procurement systems have a direct impact on the sustainability of production. Whether procurement is managed locally, regionally or at global/multilateral level, procurement policies have direct market shaping impact and can result in lack of viability for ongoing production, jeopardizing supply of relevant products. 3. We note that experience has shown that a procurement system focused only on pricing, and not on other aspects such as supply security and quality-assured products, among others, encourages the concentration of supply, driven by reaching economies of scale and the need for the lowest available raw material and manufacturing costs. The risk that this imposes on the medicines supply chain and trade is directly counter to

	the intention of the Pandemic Accord to build more resilient health systems and supply chains. Negotiators are urged to consider inclusion of a recognition that procurement considering criteria beyond price is an essential component of health system resiliency.[1] 4. This approach has precedence as best practice in procurement system management. In 2022, the European Commission made a series of recommendations[2] related to the public procurement of medicines. These included (i) applying the "Most Economically Advantageous Tender" ("MEAT") criteria which considers criteria beyond price, and (ii) awarding contracts to multiple winners instead of pursuing a single-winner approach, when it is advisable to secure supply. These measures aim to create a well-defined mix of criteria for procurement and avoid overreliance on a single manufacturer, which can lead to shortages in the market.[3] 5. Regarding promoting transparency of cost, this should only apply where relevant, technically feasible and compliant with competition laws and principles. Proposal: To amend Article 6.3 (a) as follows:: "[…] the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms and in-kind contributions, **that shall consider the market shaping impact of procurement**

[1] See IGBA (2023), IGBA Perspectives on Pandemic Accord (Zero Draft – April 2023), available here.
[2] European Commission (2022), Study on Best Practices in the Public Procurement of Medicines, available here.
[3] See also IQVIA (2022), From Regulated Prices to Prices Set in Tenders, available here; Maniadakis N, Holtorf AP, Otávio Corrêa J, Gialama F, Wijaya K. Shaping Pharmaceutical Tenders for Effectiveness and Sustainability in Countries with Expanding Healthcare Coverage. Appl Health Econ Health Policy. 2018, available here; WHO (2016), Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region, available here.

	criteria and incorporate sustainability of supply of quality-assured products, including award criteria beyond price and avoiding single-winner contracts, as well as promoting transparency in cost and pricing, where relevant, technically feasible and compliant with competition laws and principles; […]
Article 8. Regulatory strengthening	
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. 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 manner, including the sharing of regulatory dossiers with other institutions.	1. We support the identification of the need for greater harmonization of regulatory requirements and practices to facilitate the entry of medicines into markets around the world. Negotiators are urged to further strengthen the focus on regulatory efficiency to achieve timely, equitable access to health products, including through a recognition of the importance in advancing single global development of generic and biosimilar medicines.[4] 2. There is growing consensus among regulatory authorities and normative bodies that reliance among regulators is an important tool for consideration in advancing regulatory efficiency, in addition to harmonization, convergence and capacity building of national regulatory authorities, and shifting, to the extent possible, to digital tools. 3. The Pan American Health Organization (PAHO) has expressed that "[w]hile harmonization and convergence have been pursued for many years by international initiatives, the use of reliance is an emerging trend as a strategy to bring efficiencies to regulatory systems and of interest for regulatory systems strengthening".[5] 4. The WHO has emphasized that it "[…] supports reliance among regulators to make the best use of available

[4] IGBA (2023), op. cit.

[5] See PAHO (2018), REGULATORY RELIANCE PRINCIPLES: CONCEPT NOTE AND RECOMMENDATIONS, available here.

	resources and expertise. This principle allows leveraging the output of other regulators whenever possible while placing a greater focus at national level on value-added regulatory activities. The purpose of the Good Reliance Practices (GRelP)[6] is to promote a more efficient approach to regulation, thereby improving and expediting access to quality-assured, effective and safe medical products".[7] 5. According to WHO's Good Reliance Practices[8] "[i]f no public assessment reports are available or when additional information of a confidential nature is required, the manufacturer should provide an assessment report when available to them. If the relying NRA requests non-public assessment reports from a reference agency, **they may be provided with the consent of the manufacturer,** if necessary".[9] Proposal: To amend Articles 6.1 and 6.2 as follows:: " 1. The Parties 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 **regulatory reliance** and mutual recognition agreements, **and shifting, to the extent possible, to digital tools**. 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 manner, including the sharing of regulatory dossiers with other

[6] WHO (2021), Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations, available here.
[7] See WHO Publishes new guidance to promote Strong, Efficient and Sustainable Regulatory Systems, available here.
[8] WHO (2021), op. cit.
[9] Emphasis added.

	institutions **provided the consent of the applicant has been obtained**.”