



## **IGBA Comments on Selected Provisions of the 30 October 2023 *Proposal for negotiating text of the WHO Pandemic Agreement***

IGBA welcomes the opportunity to provide comments to the 30 October 2023 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.

IGBA welcomes inclusion of the proposed new Article 10 on “sustainable production”, which, in part, reflects IGBA’s perspectives on “sustainable procurement”, outlined in both “IGBA Perspectives on Pandemic Accord (Zero Draft – April 2023)”<sup>1</sup> and “Key Comments and Proposals by IGBA on Selected Provisions of the Zero Draft of the Pandemic Accord May 2023”<sup>2</sup>. IGBA also underscores the importance of elements of Articles 13 and 14 for the ability of the generic and biosimilar medicines industry to respond quickly and equitably to future pandemics.

The broad definition of ‘pandemic-related products’ results in the potential for many of the Pandemic Agreement’s provisions to apply to a large cohort of medicines, with associated potential for market disruption. IGBA encourages the Intergovernmental Negotiating Body to consider experiences of the generic and biosimilar medicines industry during the COVID-19 pandemic when developing provisions impacting the sustained and equitable availability of off-patent medicines. In particular, due consideration is requested of the dual role of States as procurers and regulators; the optimal structuring of procurement systems capable of balancing patient access with sustainable production; potential unintended consequences of new efforts to coordinate pharmaceutical supply; the criticality of unimpeded cross-border movement of medicines; and the fundamental importance of strong, efficient, and flexible regulatory systems. IGBA’s general observations are presented first and proposed amendments for consideration in the subsequent table.

Ensuring the lessons learned from the COVID-19 pandemic are built upon for the benefit of people worldwide is a priority for IGBA. 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.

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<sup>1</sup> See [here](#).

<sup>2</sup> See [here](#).

### **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](http://www.igbamedicines.org)



## I. General Comments:

### 1. Broad scope of 'pandemic-related products'

We note that the current definition of 'pandemic-related products' as drafted is very broad, including without limitation any therapeutics or medicines that are needed for pandemic prevention, preparedness and response. We concur that a broad definition is warranted based on the experience of generic and biosimilar medicines manufacturers during the COVID-19 pandemic, which showed that demand fluctuated for medicines beyond antivirals intended to directly treat COVID-19, such as medicines used in hospital ICUs to support patients on ventilators and antimicrobials to address associated opportunistic infections.

We note, however, that the breadth of this definition may create a challenge in the execution of various Articles, including Article 10. It is unreasonable and unproductive for every nation to seek to produce all 'pandemic-related products', particularly as such products may vary depending on the characteristics of any given pandemic – i.e., a pandemic targeting mainly the respiratory system will likely need different products than a pandemic impacting the gastro-intestinal system. Maintaining production at national, and even regional, level for all potential 'pandemic-related products' would likely be an inefficient use of resources. We would therefore urge consideration of a differentiated approach to Article 10, whether through a more targeted approach to the scope of national production considering a small cohort of medicines likely to be needed regardless of the type of pandemic and for which suitable production capacity does not already exist globally, or instead a stronger focus on eliminating the limitations on cross-border movement of medicines that created supply disruptions during the COVID-19 pandemic.

### 2. The pharmaceutical procurement system and the twofold role of the State:

We note that for medicines, in most cases the State simultaneously fulfils two roles: one as regulator, the other as pharmaceutical procurer. As a regulator, it is in the State's interest to foster an appropriate regulatory environment for companies to register quality, safe, effective medicines and participate in a competitive market. As pharmaceutical procurer, it is in the State's interest to devise pricing and procurement policies that reflect both the needs of the State and the population it represents, and the sustained availability of medicines considering the



complexities of the medicines supply chain and market economics. Such policies should include a strategic component of economic sustainability and be flexible enough to mitigate and swiftly react to supply chain disruptions.

Procurement systems have a direct impact on the sustainability of production. Whether procurement is managed locally, regionally or at global level, procurement policies have direct market shaping impact. In the best case, procurement policies can support sustainable production and equitable access to affordable medicines. In the worst case, procurement policies can result in lack of viability for ongoing production, jeopardizing “timely, fair and equitable access to safe, effective, quality and affordable [medicines],” the main purpose of Article 10.

We have noted previously that procurement systems focused only on lowest pricing encourage the concentration of supply and increase the risk of supply disruption. The risk that this imposes on the medicines supply chain and trade is directly counter to the intention of the Pandemic Agreement to build more resilient health systems and supply chains and enable equitable access and sustained production.

We note that the concept of building procurement systems to support sustained production and supply is established in some regions. For example, the European Commission has made a series of recommendations 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.

The policy solutions for sustained production proposed in Article 10 are focused on maintaining and expanding local production, coordination between international organizations, and licensing and transfer of know-how, without directly mentioning the criticality of sustainable procurement models.

### **3. The multiple functions of a unifying body:**

IGBA welcomes international efforts to address the global issue of medicine supply, particularly to avoid disruptions and shortages impacting patients. The proposed WHO Supply Chain and Logistics (SCL) Network could be a helpful mechanism to aggregate information about supply and demand of ‘pandemic-related products’ and increase coordination, however, the Network would also have a profound impact on product markets and potentially destabilize supply if not operationalized successfully. We would urge the Parties to this agreement consider private sector perspectives in development of the Network, particularly perspectives from suppliers of ‘pandemic-related products’ on the anticipated impacts of various provisions on sustained production and supply.

Some of the elements we would particularly call to attention are:

- a. The obligations created by Article 13 bind Member States, yet the provisions can only be made effective by collaboration from industry. For the moment, many questions remain about the methods to estimate—or determine—costs and volumes of supply (Art. 13.2), and to



- map and anticipate demand (Art. 13.3). Meeting these obligations may require Member States to adjust national legal and regulatory frameworks; we would urge all Parties to consider good practices of consultation with all impacted stakeholders, including private sector.
- b. Stockpiling requirements (Art. 13.3(d)) may prove contrary to the aim of tackling shortages and increasing access to medicines in pandemic events. Stockpiling can run counter to the objective of enabling fair and equitable access and can instead protect access for certain populations while creating an artificial shortage for others. Stockpiling may also run counter to Article 13.4 on the reduction in waste of pandemic-related products. 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 access. Stockpiling provisions should be carefully assessed, including with cost-benefit analyses, and consider the potential for disruptions to global supply.
  - c. While greater coordination in demand planning may be helpful, too much intervention in supply and demand matching may impact competition and the functioning of global product markets. Any action that alters the conditions of the market risks favoring some actors over others and may lead to unintended outcomes. The degree of intervention should be defined under the scope of specific global health goals, with defined metrics and clear accountability among stakeholders.



## II. Proposed changes to the text:

| 30 Oct 2023 draft text of selected provisions   | Key Comments and Proposals  |
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| <b>Chapter II. The world together equitably: Achieving equity in, for and through pandemic prevention, preparedness and response.</b>   |   |
| <b>Article 10. Sustainable production</b>   |   |
| <p>1. The Parties, with a view to achieving a more equitable geographical distribution of the global production of pandemic-related products, and increasing timely, fair and equitable access to safe, effective, quality and affordable pandemic-related products, thereby reducing the potential gap between supply and demand at the time of a pandemic, shall:</p> | <p>There are key enablers of sustainable production of off-patent medicines that are not currently included in Article 10, specifically, regulatory reliance and the promotion of globally harmonized regulatory requirements, balanced intellectual property systems aside from licensing, well-functioning procurement systems that support sustained availability, and avoidance of trade barriers that create supply chain disruptions. Reference to other relevant articles, such as Article 14 on regulatory systems, would be appropriate in Article 10, paragraph 1, to provide more context to the precursors of sustainable production. We would also underscore that geographic location of production is only one part of a much broader issue, and would suggest that Article 10, paragraph 1 instead focus on the core goal of a more resilient and sustainable supply of pandemic-related products.</p> <p>Furthermore, Article 10 may benefit from an additional paragraph that explicitly calls for the development of frameworks and principles guiding procurement systems that enable supply security and sustainable production.</p> <p><b><u>Proposed variation:</u></b></p> <p>1. The Parties, with a view to achieving <b>a more resilient and sustainable supply a more equitable geographical distribution of the global production</b> of pandemic-related products, and increasing timely, fair and equitable access to safe, effective, quality and affordable pandemic-related products, thereby reducing the potential gap between supply and demand at the time of a pandemic, shall:</p> |



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|  | <p><b><u>Proposed variation:</u></b></p> <p>To amend Article 10.1 by including a new letter g) that may read as follows:</p> <p><i>“[...] g) develop policy frameworks and principles for the negotiation of procurement agreements to achieve the highest possible supply security of quality-assured pandemic-related products and products included in WHO's Essential Medicines List in categories deemed strategic for potential pandemics ; [...]”</i></p>   |
| <p>(a) take measures to identify and maintain production facilities at national and regional levels, as well as to facilitate the production, as appropriate, and in furtherance of the provisions of Article 13 herein, of pandemic-related products therein;</p>   | <p>The goal of sustainable production should be reliable availability, not necessarily related to geographic location of production, as duplication of production will not always be optimal, efficient, or entail any benefit to resilience. Per article 3.10, preparedness measures should be based on science and evidence.</p> <p><b><u>Proposed variation:</u></b></p> <p>(a) take measures to identify and maintain <b>adequate</b> production facilities <b>at national and regional levels, as well as</b> to facilitate the production <b>at scale sufficient to meet global demand</b>, as appropriate, and in furtherance of the provisions of Article <b>13 and 14</b> herein, of pandemic-related products therein.</p> |
| <p>(b) take measures to identify and contract with manufacturers other than those referenced in paragraph 1(a) of this Article, for scaling up the production of pandemic-related products, during pandemics, in cases where the production and supply capacity of the production facilities does not meet demand;</p> | <p>Paragraph 1(a) of this article references "facilities", not manufacturers, therefore, reference in paragraph 1(b) to "manufacturers other than those referenced in paragraph 1(a) of this Article)" is unclear. Many manufacturers have multiple facilities, across geographies and with a variety of products. Given the broad definition of 'pandemic-related products', the scope of this paragraph is unclear. Suggest clarifying terminology or providing definitions. Alternatively, if the above proposed edits to paragraph 1(a) are accepted, paragraph 1(b) may be stricken.</p>  |



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| <p>(f) support public and private sector investments aimed at creating or expanding manufacturing facilities for pandemic-related products, especially facilities with a regional operational scope that are based in developing countries.</p>   | <p>Investment in production capacity should be prioritized where it can best improve equitable access, based on a broader consideration of enablers.</p> <p><b><u>Proposed variation:</u></b><br/>(f) support public and private sector investments aimed at creating or expanding manufacturing facilities for pandemic-related products, <b>situated to have the greatest impact on expanding access to such products. with a regional operational scope that are based in developing countries.</b></p>  |
| <p><b>Article 13. Global Supply Chain and Logistics Network</b></p>   |   |
| <p>1. The WHO Global Supply Chain and Logistics Network (the WHO SCL Network) is hereby established. The WHO SCL Network will operate within the framework of WHO, in partnership and collaboration with relevant international, regional and other organizations, and be guided by equity and public health needs, paying particular attention to the needs of developing country Parties.</p> | <p>The proposed WHO Supply Chain and Logistics (SCL) Network could be a helpful mechanism to aggregate information about supply and demand of ‘pandemic-related products’ and increase coordination, however, the Network would also have a profound impact on product markets and potentially destabilize supply if not operationalized successfully. We would urge the Parties to this agreement consider private sector perspectives in development of the Network, particularly perspectives from suppliers of ‘pandemic-related products’ on the anticipated impacts of various provisions on sustained production and supply.</p> |
| <p>(d) working with national authorities to establish and maintain national and/or regional stockpiles of various pandemic response-related products, as well as maintaining the relevant logistic capacities and assessing them at regular intervals, and specifying the criteria to ensure that stockpiling is used only to address public health needs;</p>                                  | <p>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.</p>                                       |



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|  | <p><b><u>Proposed Variation:</u></b><br/>(d) working with national authorities to <b>assess the benefit of establishing and maintaining coordinated <del>establish and maintain national and/or regional</del></b> stockpiles of various pandemic response-related products, as well as maintaining the relevant logistic capacities and assessing them at regular intervals, and specifying the criteria to ensure that stockpiling is used only to address public health needs <b>and does not disrupt global supply availability;</b></p>   |
| <p>3. The Parties shall support the WHO SCL Network’s development and operationalization and participate in the WHO SCL Network, including through sustaining it at all times. The terms of the WHO SCL Network shall include:</p>                     | <p><b><u>Proposed variation:</u></b><br/><b>To amend Article 13.3 by including a new letter l) that may read as follows:</b><br/><br/><b><i>“[...] l) In implementing the provisions outlined in clauses 13.3(a) through 13.3(k), parties shall exercise due diligence and caution to prevent any alteration of market conditions that could inadvertently favor certain actors over others. This includes ensuring that processes are transparent, equitable, and inclusive, thereby upholding the principles of fair competition and market neutrality that support a diverse and competitive market.</i>”</b></p> |
| <p>7. The Parties recognize that any emergency trade measures in the event of a pandemic shall be targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.</p> | <p>We underscore the criticality of paragraph Article 13(7), 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</p>  |





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|   | <p>to meet evolving global demand in a timely and efficient way. The strengthening of Article 13(7) to this effect would be welcome.</p> <p><b><u>Proposed Variation:</u></b><br/>7. The Parties <b>shall commit</b> <del>recognize</del> that any emergency trade measures in the event of a pandemic shall be targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains, <b>noting the criticality of free movement of pandemic-related products in enabling fair and equitable access.</b></p>  |
| <b>Article 14. Regulatory strengthening</b>   |  |
| <p>1. The Parties shall strengthen their national and regional regulatory authorities, including through technical assistance, with the aim of expediting regulatory approvals and authorizations and ensuring the quality, safety and efficacy of pandemic-related products.</p> | <p>We underscore the criticality of Article 14 for the sustained availability and equitable access to pandemic-related products, and all medicines and health products, and note the importance of Parties systematically progressing on these actions outside of a pandemic context.</p> <p><b><u>Proposed Variation:</u></b><br/>1. The Parties shall strengthen their national and regional regulatory authorities, including through technical assistance <b>and adoption and strengthening of digital tools and interoperable global data sharing platforms</b>, with the aim of expediting regulatory approvals and authorizations and ensuring the quality, safety and efficacy of pandemic-related products.</p> |