

22 January 2024

IGBA Support for a WHO Pandemic Agreement

The generic and biosimilar medicines industry globally, represented by the International Generic and Biosimilar medicines Association (IGBA), supplies the overwhelming majority of prescription medicines to patients worldwide, and strongly supports ongoing multilateral efforts to achieve a robust WHO Pandemic Agreement. The IGBA is deeply concerned about delays in the negotiations and the potential for WHO Member States to fail to reach an agreement. The experience of the generic and biosimilar medicines industry during the Covid-19 pandemic underscores the necessity for WHO Member States to urgently advance this process and commit to principles of cooperation, solidarity, and equity in a future pandemic. This focus on addressing the core challenges that constrained equitable access to medicines during the COVID-19 pandemic is vital to enable optimization of available industrial resources to sustainably address patient needs. Never again should the world experience a global pandemic where medicines are stopped at borders, expire in government stockpiles, and otherwise fail to reach patients in need, wherever they may live.

Building on lessons learned during the Covid-19 pandemic is critical to achieve fit-for-purpose solutions for the future, including identifying ways to increase equitable access and resilience of healthcare systems. IGBA's experience from the start of the Covid-19 pandemic has underlined the importance of solidarity and global health partnership for the benefit of patients' access to medicines. The WHO and IGBA immediately set up a dialogue in early 2020 to share real-time information about medicine shortages, emerging patient needs and the manufacturing response of our industry. We shared information about demand surges, supply chain disruptions and border closures, and engaged constructively to find solutions to supply medicines for patients. IGBA and its members worked closely with WHO and Member States to increase the output of prioritized medicines, including for Covid-19 therapeutics and related products. Throughout the pandemic, we took a clear and principled position in favor of solidarity could be improved for future pandemics, and why the IGBA has been a strong supporter of efforts to negotiate the WHO Pandemic Agreement.

Our comments and suggestions for the WHO Pandemic Agreement have been fully consistent with our support for global solidarity, with the needs of people at the center. We strongly reaffirm the importance of multisectoral collaboration to safeguard human health and build stronger, more resilient healthcare systems. We encourage further progress on "sustainable production" in the draft Agreement to fully reflect the most meaningful elements for securing availability of medicines and enabling the generic and biosimilar medicines industry to respond quickly and equitably to future pandemics. We also highlight the importance of ensuring that the definition of pandemic-related products is coherent with the objective of accomplishing equitable availability of off-patent medicines. We encourage negotiators to avoid clauses that might favor artificial restrictions to the access of these medicines throughout the Agreement. In alignment with the

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.

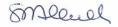


solidarity and equitable access objectives of the Agreement, we welcome due consideration for the dual role of States as procurers and regulators, including the optimal structuring of procurement systems capable of balancing patient access with sustainable production; potential unintended consequences of new efforts to coordinate pharmaceutical supply; the criticality of unimpeded cross-border movement of medicines; the fundamental importance of strong, efficient, flexible regulatory systems for greater solidarity; and improved demand forecasting through cooperation between governments and manufacturers.

The IGBA is ready and willing to engage with negotiators, stakeholders and all relevant multilateral institutions to facilitate a successful WHO Pandemic Agreement. We note with concern that some issues have led to delays in reaching consensus and may threaten the viability of the negotiations. While we do not have the expertise to address all of these matters, the perspectives of the generic and biosimilar medicines industry may be helpful in identifying a path forward, including related to scaling up manufacturing for demand surges, limiting all forms of export restrictions for medicines, and finding a balanced way forward on intellectual property right protections. This Agreement is of great importance for patients everywhere to access the medicines they need, and we are prepared to assist the WHO and Member States in taking pragmatic steps forward to achieve this common objective.

Yours truly,

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Adrian van den Hoven Chair International Generic and Biosimilar Medicines Association.

Susana Almeida Secretary General International Generic and Biosimilar Medicines Association.