

IGBA Releases Report on Factors Affecting the Supply of Generic Medicines

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Contact: Info@igbamedicines.org

The <u>International Generic and Biosimilar medicines Association (IGBA</u>) today released a report identifying key factors affecting the security of the global supply of generic prescription medicines.

The <u>report</u> reflects progress made by the joint WHO-IGBA Drug Shortages Workstream, comprised of WHO thought leaders, global generic manufacturers and IGBA's member associations, to support efforts to mitigate shortages of essential medicines and supply chain capacity, particularly in lower- to middle-income countries.

"Across the Globe, generic pharmaceutical manufacturers continue to work closely with our partners in government and the pharmaceutical supply chain to mitigate and prevent drug shortages. Today's report reflects the industry's collective experience and offers policy makers solutions to help ensure patients have access to the affordable prescription medicines they need," said Jim Keon, Chair IGBA WHO-IGBA Drug Shortages Workstream and President of the Canadian Generic Pharmaceutical Association (CGPA).

The report identified five factors impacting the security and supply of generic medicines:

- 1. **Procurement practices:** Procurement is an important instrument to encourage price competition and supply sustainability. Highly centralised procurement practices can leave hospitals exposed to localized shortages and can have broader impacts across markets.
- 2. **Consolidation within the manufacturing supply chain:** Global over-reliance on a limited number of ingredient suppliers creates vulnerabilities in the supply chain, and limits the ability of companies to adapt to gaps in supply.
- 3. **Regulatory hurdles and lack of global alignment:** Country-specific regulatory requirements contribute to product discontinuations, portfolio rationalization, and, ultimately, shortages.
- 4. **Impact of local policy changes on a global industry:** Local policies to influence product supply and ingredient sourcing decisions, even when targeted to other markets like chemicals and foods, can limit options and increase costs in the broader pharmaceutical supply chain.
- 5. **Barriers to rapid reallocation across borders:** Domestic policies and regulatory differences can undermine efficient product allocation across markets to ensure equitable supply.

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.



Today's report reinforces that increased global cooperation is needed to enable generic medicines to be developed and approved on the basis of the same clinical and scientific evidence. Increasing international convergence, harmonization and regulatory reliance will reduce barriers to market access and lower costs for manufacturers, resulting in increased supply due to more competition.

"While measures to enhance local manufacturing and supply chain diversification are important, it is clear that pricing and procurement practices play a key role in the viability of current markets and the number of suppliers," Keon added. "More than anything, manufacturers need fair and predictable pricing to maintain current investments and strengthen supply."

Overall, the WHO aims to improve the availability and quality of information from medicines supply chains, shortage reporting and other innovative areas to reduce the negative impact of suboptimal supply chain performance. The IGBA will continue to work with the WHO to advance their strategic priorities related to drug shortages as a part of their joint 2022-2024 Collaboration Plan.