INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

International Generic and Biosimilar medicines Association
C/O Dyn SA
Rue de Cornavin, 11
1201 Geneva-Switzerland

DEPARTMENT OF COMMERCE
Bureau of Industry and Security
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Subject: **IGBA Submission to the Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.**

Following the U.S. Commenting Guidance:

1 Introduction

The International Generic and Biosimilar medicines Association (IGBA), with members in Argentina, Australia, Brazil, Canada, European Union, India, Japan, Jordan, Malaysia, Mexico, Montenegro, Morocco, Serbia, South Africa, Taiwan and the United States, emphasizes that any disruption to the existing supply chains, such as the imposition of tariffs or non-tariff trade barriers, would adversely impact patient access to treatments, exacerbate existing medicine shortages and threaten the continuous availability of medicines/therapies, including essential and critical medicines. Such disruptions would also undermine the sustainability of the generic and biosimilar medicines industry that is the main provider of affordable medicines in the U.S. Ensuring the continuity and sustainability of generic and biosimilar medicines' supply is a key element not only for patient health but also for well-functioning economies, the independence and security of countries, and resilient societies.

In the United States, 9 out of every 10 prescriptions filled are for generic drugs.[1] Despite being used to fill 90% of all prescriptions in the U.S., generic drugs represent only 13% of total prescription drug costs[2]. Maintaining robust competition in the marketplace promotes the availability of generic drugs, helping to lower treatment costs and increase healthcare access for more patients.

2 Background

The IGBA is the global voice of the generic and biosimilar medicines industries[3]. Committed to improving patients' access to quality-assured, safe, and cost-effective medicines[4], the IGBA closely monitors regulations that impact finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, key starting materials, and derivative products of those items.[5] These areas are of significant relevance to ensuring sustainable and equitable access to treatments in the United States.

The IGBA appreciates the opportunity to contribute to this consultation and seeks to specifically highlight aspects related to the prevention of drug shortages and the preservation of widespread access to safe, affordable medicines. A resilient and reliable generic medicines supply chain is vital for safeguarding patient health, strengthening the U.S. healthcare system and achieving U.S. national security objectives. In response to the Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, the IGBA seeks to provide insights informed by our experience and engagement with international supply chains. The IGBA will focus on questions (iii), (viii), (ix), and (x) with the aim of contributing constructively to the discussion on mitigating potential impacts on drug availability and ensuring continued access to affordable treatments for U.S. patients.

3 Answers to specific investigation questions

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients

Generic and biosimilar companies that are part of the IGBA association membership are reliable trusted suppliers who have consistently cooperated with the U.S. government to address and mitigate shortages in the past, including during the first Administration of President Trump.

Tariff pressure for both domestic and foreign manufacturers of generic medicines will test their already low margins. Any disruptions to production in the already fragile generic injectable markets are likely to result in shortages. According to different studies by the U.S. Food and Drug Administration (FDA) and the United States Pharmacopeia (USP), the U.S. market is already exposed to structural shortages of these medicines[6].

It is therefore critical to consider the different characteristics between high margin originator products and lower margin generic and biosimilar medicines. While tariffs may provide a strong incentive for increasing U.S. manufacturing of brand-name drugs, they might not do the same for older, off-patent generic drugs, which represent over 90% of U.S. prescriptions by volume yet only a small share of spending.

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance

The U.S. government should introduce policies to incentivize investment in manufacturing to better diversify production while preserving the integrity of trade to avoid shortages that would

lead to undesirable impacts on patients' access to life-saving medicines. A resilient and reliable supply chain would have a better chance to ensure patients' access to medicines.

Any support for manufacturing should include measures to encourage multisource competition.[7, 8] Some hospital purchasing groups have for example introduced more modern tendering policies that include security of supply criteria in order to reduce the risk of shortages in the U.S. This was also an approach recommended by the U.S. FDA under President Trump's first Administration.[9] Some of the measures outlined in the recent Executive Order Lowering Drug Prices By Once Again Putting Americans First[10], conducive to balanced intellectual property systems, and accelerating approval of generic and biosimilar medicines, might also prove effective.

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security

As recognized by the Senate Committee on Finance (2024)[11], generic drugs comprise the majority of medications in shortage at any given point. According to the U.S. Generic & Biosimilar Medicines Savings Report (2024)[12] published by the Association for Accessible Medicines (AAM) in September 2024, the percentage of shortages in the US affecting generics was 84% and shortages were more common for lower priced drug products (the percentage of shortages for drugs priced at $1/unit or less was 56%). The increase in generic drug shortages is closely correlated with unsustainably low prices, new government policies that harm generic competition, supply chain challenges, as well as regulatory and manufacturing challenges.

Shortages occur due to market conditions and policies that deflate the price of generic medicines below reasonable levels. If price falls below the break-even point, the most efficient manufacturer may have to exit the market, leading to a loss in supply. Even shortages due to manufacturing issues can be explained by economic forces that threaten the sustainability of the generic medicines industry as a whole; if the manufacturer elects to stay in a price-deflated market, lost revenues could lead to foregoing investment in facilities, contributing to greater risk for future manufacturing problems[13].

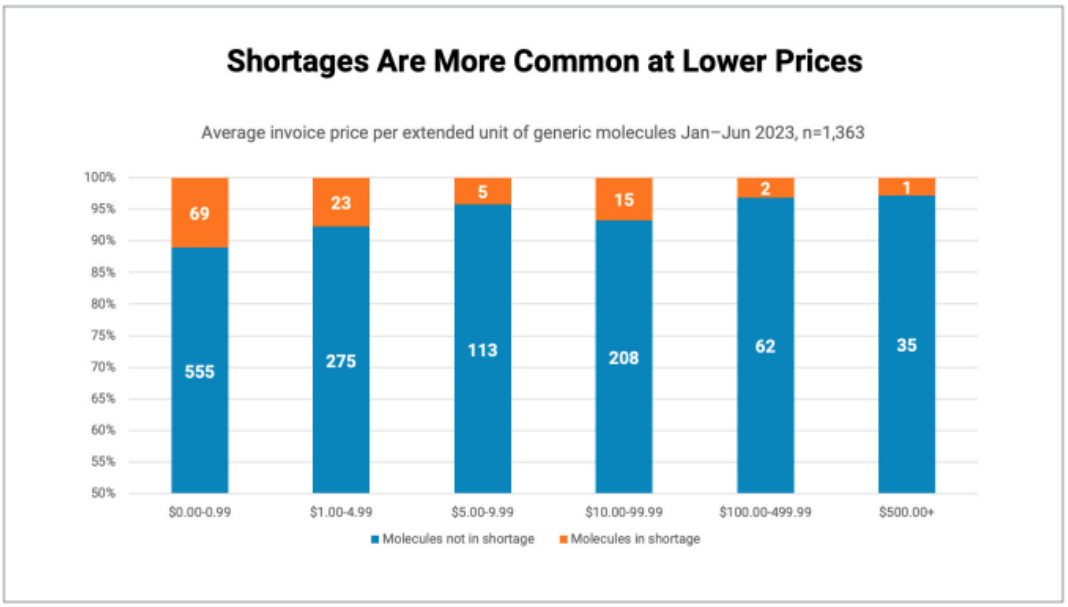

Figure 1 – Shortage percentage as a function of average invoice price per extended unit of generic molecules (January to June 2023, n=1363)[iError! Marcador no definido.].

As noted by the U.S. FDA in their *Drug Shortages: Root Causes and Potential Solutions* Report (2019)[9]: manufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns. Current contracting practices contribute to a "race to the bottom" in pricing. Introducing disruptions such as difficulties obtaining raw materials and unstable or unpredictable market demand can result in shortages of critical medicines.

The USP has cautioned that absent significant market and policy interventions, the current drug shortage trends will probably continue or intensify and has highlighted the necessity of policy reforms, including those designed to promote the sustainability of the generic medicines industry, to reinforce supply chain resilience.

However, it is important to mention that drugs cannot be immediately manufactured when shortages occur: the supply chains have lead times of 6 to 12 months, and no manufacturer knows if the prices in the market will cover the costs.

Competition, particularly between originators and competing generic and biosimilar medicines manufacturers, is essential in order to keep public health budgets under control and to increase access to medicines to the benefit of patients. It is essential for patients' health to maintain a balanced and equitable system for medicine innovation and competition. Specific instances of Intellectual Property Rights abuse/ misuse, as well as pricing and reimbursement policies are also areas of concern. The removal of such barriers will reduce costs for the development of generic and biosimilar medicines and ensure that such products can be traded freely and enter markets without delay[14].

(x) any other relevant factors

Generic and biosimilar medicines play a pivotal role in healthcare systems, providing access to affordable treatment options for a wide range of diseases. Their production depends on complex, globally integrated supply chains, involving the sourcing of active pharmaceutical ingredients (APIs), excipients, and other essential components as well as the manufacturing of finished products across multiple countries. Disruptions to this network, including tariffs, can significantly impact the availability and affordability of these critical life-saving medicines. This is especially concerning as off-patent medicines manufacturers operate in a highly competitive market with a limited capacity to absorb additional costs[15].

4 Proposed recommendations

The IGBA presents the following points for policy consideration:

- **Any disruption to the existing supply chains**, such as the imposition of tariffs or other trade remedies, **could negatively impact patients' access to life saving treatments**, exacerbate existing **drug shortages**, and threaten the **sustainability of the generic and biosimilar industry**, which differs from that of the high value brand manufacturers.
- **Subsequent-entry (generic and biosimilar) medicines are different from first-entry (branded) medicines.** Generics and biosimilars are safe, effective, quality-assured, affordable versions of medicines. Because of this, they are fundamental for widespread access to life-saving treatments. But this also means that cost structures are different, which leaves generics and biosimilars in more vulnerable situations vis-à-vis supply chain shocks. Policy measures should be careful not to affect the sustainability of subsequent-entry product markets, as this would have direct consequences for patients' access to medicines.
- **Intellectual property systems should be balanced and provide timely access to competition.** Policymakers should recognize that a thriving off-patent medicines sector is an integral part of the innovation system. Regulatory, IP, and market access rules need to be designed considering their possible interplay, to prevent their possible (mis)use. Their proactive review and adaptation is necessary to address loopholes leading to competition delays. Robust patent offices that grant quality patents to protect true innovation are needed**¡Error! Marcador no definido.**.
- **Supply chains should be diverse, reliable and resilient, nationally and abroad.** A main policy goal is to ensure product availability, so patients' access to safe, effective, cost-effective, and quality-assured medicines is not hindered.

5 Conclusions

Generic and biosimilar medicines are essential for ensuring widespread, equitable access to life-saving therapies and are a cornerstone of health systems. Their continued availability depends on resilient and diversified supply chains, sustainable market conditions, and well-balanced regulatory and intellectual property frameworks. To avoid generating root causes of drug shortages and safeguard long-term supply, policies must encourage multisource competition, support targeted investments in manufacturing, and avoid generating pricing pressures that threaten the viability of producers. A strong and competitive off-patent medicines sector is not only crucial for lowering healthcare costs but also for enhancing the resilience and security of national and global healthcare systems.

However, it is important to mention that drugs cannot be immediately manufactured when shortages occur: the supply chains have long lead times, and no manufacturer knows if the prices in the market will cover the costs.

Competition, particularly between originators and competing generic and biosimilar medicines manufacturers, is essential in order to keep public health budgets under control and to increase access to medicines to the benefit of patients. It is essential for patients' health to maintain a balanced and equitable system for medicine innovation and competition. Specific instances of Intellectual Property Rights abuse/ misuse, as well as pricing and reimbursement policies are also areas of concern. The removal of such barriers will reduce costs for the development of generic

and biosimilar medicines and ensure that such products can be traded freely and enter markets without delay[14].

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