



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

International Trade and Resilient Supply Chains of Medicines in a Post-Covid Era

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Context

The COVID-19 pandemic has emphasized the importance of resilient supply chains for medicines and pharmaceuticals, and has prompted a re-evaluation of the role of international trade in this regard in a post-pandemic era. The disruptions in the global supply chains of medicines during the pandemic, including shortages of critical medicines and raw materials, have highlighted the need for robust and adaptable supply chains that can withstand shocks and emergencies.

As the Covid-19 pandemic wanes in most parts of the world, the impact on individuals and communities has been enormous. In the tragic aftermath, nearly 7 million people died and nearly 750 million were infected.¹

The pandemic has brought to fore the importance of resilient supply chain for medicines and pharmaceuticals. The widespread disruption of supply chains and trade affected medicines at various levels, exacerbating shortages that existed prior to the pandemic for a variety of reasons.² As the impact on global supply chain continues, it has highlighted the need for robust and adaptable supply chain that can withstand shocks and emergencies and has further prompted a re-evaluation of the role of international trade in ensuring resilience of medicines supply chain capable of dealing with future pandemics, natural disasters, wars, etc.

Medicine shortages resulting from supply chain disruptions are not harmless to patients and healthcare systems, but generate, among other things, lack of adherence to therapies, aggravation of clinical conditions, preventable deaths and additional costs to the system.³

¹ See WHO information [here](#), accessed on 04.02.2023

² See Francas D. Global Pharmaceutical Supply Chains and Resilience Strategies: Overview and Implications of the Covid-19 Pandemic. Department of Transportation and Logistics, Heilbronn University, Germany, 2021, available [here](#); Socal MP, Sharfstein JM, Greene JA. The Pandemic and the Supply Chain: Gaps in Pharmaceutical Production and Distribution. *Am J Public Health*. 2021 Apr;111(4):635-639. doi: 10.2105/AJPH.2020.306138. Epub 2021 Jan 28. PMID: 33507805; PMCID: PMC7958046, available [here](#)

³ See Postma DJ, De Smet PAGM, Notenboom K, Leufkens HGM, Mantel-Teeuwisse AK. Impact of medicine shortages on patients - a framework and application in the Netherlands. *BMC Health Serv Res*. 2022 Nov 17;22(1):1366, available [here](#); Atif M, Sehar A, Malik I, Mushtaq I, Ahmad N, Babar ZU. What impact does medicines shortages have on patients? A qualitative study exploring patients' experience and views of healthcare professionals. *BMC Health Serv Res*. 2021 Aug 17;21(1):827, available [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 member associations, see the IGBA website at: www.igbamedicines.org.

Causes and possible policy solutions

Regarding the causes of the disruption of the medicines supply chains, there is a broad consensus that it was, among others, due to the surge in demand, the various restrictions inherent to the sanitary measures and lockdowns taken in different countries, but mainly to the high concentration of the supply of active ingredients and finished products in certain regions of the world.⁴

Given the mentioned concentration of supply in pharmaceutical sector, many governments have proposed varied measures to encourage reshoring⁵ or nearshoring⁶ of production capacities, with a special focus on essential medicines, in order to reduce dependence on third countries.⁷ There is also a certain consensus that success of reshoring policies so far to have been modest,⁸ and should therefore be complemented by other measures such as better monitoring of supply chain vulnerabilities, especially for essential medicines, stockpiling of active ingredients and finished products reserves, building emergency capacities, as well as promoting international cooperation.⁹ However, international cooperation can be achieved by ensuring uninterrupted flow of medicines and its components through improved international trade. This requires a holistic approach and global cooperation on various aspects that should lead to resilient supply chains and trade.

Initiatives

Several initiatives have been undertaken at global and regional level on achieving supply chain resilience. For example, the ongoing negotiation of the World Health Organisation's (WHO) "Pandemic Prevention, Preparedness and Response Accord" (referred to as the "Pandemic Accord") aims to establish a global framework through the WHO Global Pandemic Supply Chain and Logistics Network. The goal is to ensure more equitable distribution of counter-measures, such as vaccines, during pandemics, as well as to establish a global compensation scheme for vaccine injuries.¹⁰ The negotiation process is still in its early stages and is expected to undergo multiple adjustments. The accord also covers other topics related to building more resilient supply chains and healthcare systems. The negotiation process is mandated to be completed by 2024.¹¹

The ongoing negotiations acknowledges the importance of harmonizing regulatory requirements for easier market entry of medicines and balancing intellectual property rights. However, it lacks

⁴ See European Commission (2020), Pharmaceutical Strategy for Europe, available [here](#). Moosavi J, Fathollahi-Fard AM, Dulebenets MA. Supply chain disruption during the COVID-19 pandemic: Recognizing potential disruption management strategies. *Int J Disaster Risk Reduct.* 2022 Jun 1;75:102983. doi: 10.1016/j.ijdr.2022.102983. Epub 2022 Apr 22. PMID: 35475018; PMCID: PMC9027543, available [here](#); The White House (2021), BUILDING RESILIENT SUPPLY CHAINS, REVITALIZING AMERICAN MANUFACTURING, AND FOSTERING BROAD-BASED GROWTH, available [here](#), p. 207 ff.

⁵ Reshoring is a term used to explain the process of returning domestic product manufacturing from a foreign country back to the home country of where the business's products are sold.

⁶ Nearshoring is where a business moves its operations to a nearby country from one of greater distance. Nearshoring is a term that came out of the practice of offshoring, which is when companies move their product manufactured to a lower landed cost region than that of their native country.

⁷ See e.g. The White House, op.cit. at p. 242. OECD (2021), Global Value Chains: Efficiency and Risks in the Context of COVID-19, available [here](#)

⁸ European Parliament (2021), Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy, available [here](#)

⁹ See e.g. The White House, op.cit. at p. 240 ff.

¹⁰ Zero Draft available [here](#)

¹¹ To follow the negotiation see also [here](#)

emphasis on sustainable procurement systems for medicines. If the focus remains solely on price¹² and ignores other aspects such as supply security and quality assurance¹³, it may result in concentration of supply and trade risks in the supply chain, driven by economies of scale.¹⁴ In this context, in 2022, the European Commission made a series of recommendations¹⁵ 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.¹⁶ Another worth noting initiative is from the World Trade Organization (WTO). The WTO has a dedicated Global Supply Chains Forum, which discusses on how to strengthen global supply chains and collaborate further to make supply chains sustainable and inclusive.¹⁷ Furthermore, other cooperative frameworks are also in discussion such as Indo-Pacific Economic Framework (IPEF).¹⁸

Conclusions

As can be seen, achieving resilient supply chains of medicines is the top priority for governments, international institutions and businesses.

Covid-19 pandemic has provided us with an opportunity to rethink how to build a more resilient medicines supply chains. There is no silver bullet for this, but rather a variety of measures that must be implemented as globally as possible, as merely national solutions will always not be sufficient.

The Pandemic Accord points in the right direction, in the sense of a global approach, but it must be reinforced with other measures that have not yet been considered, such as those related to improving public procurement of medicines that encourages security of supply.

This is the time to move forward and act with agility, when the memories of the pandemic are fresh, so that all the suffering and losses are not in vain.

¹² According to some reports, approximately 83% of generic drug shortages in the EU today relate to products with daily prices of less than €0.10. Hernandez I, Hershey TB, Donohue JM. Drug shortages in the United States: are some prices too low? JAMA. 2020;323(9):819-820, available [here](#)

¹³ Regarding WHO, see [here](#). This is especially relevant in low- and middle-income countries.

¹⁴ See International Monetary Fund (2022), Rationalizing Pharmaceutical Spending, available [here](#)

¹⁵ European Commission (2022), Study on Best Practices in the Public Procurement of Medicines, available [here](#).

¹⁶ 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](#).

¹⁷ See WTO DG’s speech on Global Supply Chain Forum [here](#).

¹⁸ IPEF has 14 partner countries including Australia, Brunei, Fiji, India, Indonesia, Japan, Republic of Korea, Malaysia, New Zealand, Philippines, Singapore, Thailand, Vietnam & USA. Supply Chain and Resilient Economy is identified as one pillar out of four pillars.