Securing Medical Supply Chains in a Post-Pandemic World





Reliable medical supply chains are a cornerstone of resilient health systems. In the context of this report, medical supply chains refer to the flows of goods and services from production to distribution, and ultimately to final consumption (or use) of a medical product by patients, health professionals or healthcare institutions. Each product supply chain is unique, as products are often made up of many different components sourced and produced across different sites and countries and involving many stakeholders. A supply chain failure occurs when supply cannot meet demand for a product marketed in a given country. Shortages of medicines were common and increasing in frequency prior to the COVID-19 pandemic. The pandemic imposed immense strain on already stretched supply chains, impacting population access to a range of essential medical products (such as antibiotics, anaesthetics, face masks and respirators). Medical product shortages can have major implications on health and societies – e.g. delayed treatment and diagnoses, strain on already stretched healthcare systems, increased healthcare costs, loss of productivity, to name a few. Their proliferation has drawn policy attention and prompted calls for action to strengthen medical supply chains – both routinely and in anticipation of the next health crisis.

Medical supply chains are complex and increasingly internationalised

Medical product supply chains are complex and often spread across multiple locations, in different countries, even different continents (Figure 1). They involve many stakeholders. While there may be similarities in the organisation of some supply chains, particularly for medicines, each product supply chain is unique. Medical device supply chains exhibit greater variability than those of medicines, and often use multiple suppliers of components, some of which are specific to individual devices, while other components are used to produce non-medical goods.

Production Process Primary manufacturing Secondary manufacturing (intermediates, API, excipients) (FPP including packaging) Affiliate 1 Affiliate 1 Contractor 1 Contractor 1 Suppliers of raw materials Contractor 2 Contractor 2 Affiliate 2 Affiliate 2 **CDMO CDMO** Distribution Process Hospitals Community pharmacies Marketing Wholesalers / **Patients Authorisation Holders** distributors Internet pharmacies Other dispensers Foreign countries

Figure 1. The complexity of pharmaceutical supply chains

Note: Dotted vertical lines represent the possibility of an international border. API: active pharmaceutical ingredient; FPP: finished pharmaceutical product; CDMO: contract development and manufacturing organisation.

Source: Figure 1.1 in OECD (2024), Securing Medical Supply Chains in a Post-Pandemic World, https://doi.org/10.1787/119c59d9-en.

In the last decades, medical supply chains have become more internationalised, albeit with a degree of geographical concentration in the manufacturing of some finished pharmaceutical products and active pharmaceutical ingredients. Global trade in pharmaceuticals increased 10-fold over the past 30 years, reaching USD 900 billion in 2022 (Figure 2), and intermediate inputs (e.g. active pharmaceutical ingredients) now account for half of these movements of goods by value, likely much more by volume. Over the past 30 years, global trade in medical devices has increased 7-fold in value, reaching a total of USD 700 billion in 2022 (Figure 2), of which one-third are intermediate goods, one-third are finished products, and approximately one-third are capital goods (durable equipment).

The internationalisation of medical supply chains has played an important role in the development of capacities to produce more affordable medicines and medical devices, while also providing flexibility to producers and governments to source essential medical products. In the European Union (EU), Japan and the United States, the foreign share in value added of final consumption of finished pharmaceutical products accounted respectively for 35%, 26% and 49% in 2019 (Figure 3).

Pharmaceuticals Medical devices Final products (includes packaged medicines) ■ Intermediate inputs Intermediate inputs Capital goods USD billion USD billion 1 000 1 000 900 900 800 800 700 700 600 600 500 500 400 400 300 300 200 200 100 100

Figure 2. World trade in pharmaceutical products and medical devices, by end use in value (1995-2022)

Source: Based on Panel A of Figures 1.2 and 1.9 in OECD (2024), Securing Medical Supply Chains in a Post-Pandemic World, https://doi.org/10.1787/119c59d9-en.

1998 2001 2004 2007

2010 2013 2016

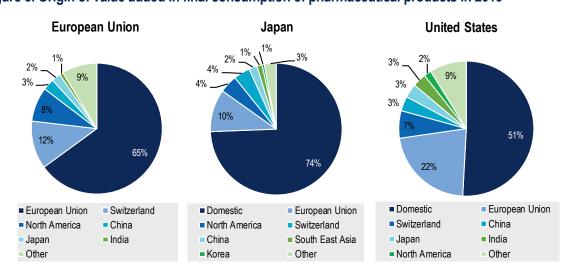


Figure 3. Origin of value added in final consumption of pharmaceutical products in 2019

2010 2013 2016

2001 2004 2007

Source: Based on Figure 1.5 in OECD (2024), Securing Medical Supply Chains in a Post-Pandemic World, https://doi.org/10.1787/119c59d9-en.

The COVID-19 pandemic exacerbated existing shortages of medical products

Shortages of medicines were already common and increasing prior to COVID-19. Across OECD countries, medicine shortages mainly affect older, off-patent medicines, and are particularly prevalent among central nervous system, cardiovascular and anti-infective medicines. Empirical evidence on the underlying root causes of shortages is lacking, partly due to country differences in shortage reporting requirements and the lack of reliable and comparative data. Nonetheless, manufacturing and quality issues are the most frequently reported reasons (50-60%), while "commercial issues" are often cited in generic markets where competitive price pressures are sometimes intense. The contribution of the nature of distribution chains in local or national shortages has not been established empirically, although one study in the EU found that around 8% of shortages are reportedly due to distribution issues. Further empirical analyses are needed, at local or regional level, to confirm these findings in different contexts.

Until recently, shortages of medical devices received less attention than medicine shortages. Nevertheless, several sources of risk to medical device supplies have been identified by experts and industry representatives, including reforms to the European Union's medical device and in-vitro-diagnostic (IVD) regulation; competition with other sectors for raw materials and electronic components; and recently, significant inflation in the costs of inputs. Data on shortages of medical devices and IVDs and their causes are scant, however, as reporting requirements are less stringent than for medicines.

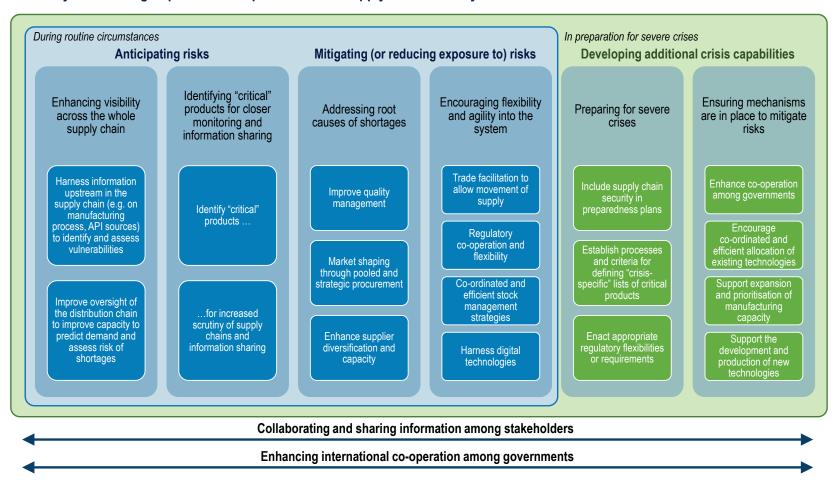
The resilience of medical product supply chains in the face of severe crises has been tested on several occasions. For example, large surges in demand occurred with the H1N1 and COVID-19 pandemics, and in the latter, these were coupled with significant disruptions in manufacturing and trade restrictions, together exacerbating the pre-existing issues. During the initial stages of the COVID-19 pandemic, there were shortages of key medicines, testing reagents, and personal protective equipment. This global crisis showed that even though internationalisation and complexity cannot be seen as the root cause of shortages or disruptions in medical supply chains, they have implications for the transmission of shocks, and interdependencies among producing and consuming economies. Nevertheless, despite being severely stressed during these periods and facing several shortages, medical product supply chains demonstrated considerable resilience.

Policies must strengthen supply chains now and in anticipation of future crises

Companies are responsible for and have an interest in ensuring the reliable supply of their products, and, in most cases, they deliver. The proliferation of shortages, however, has drawn policy attention and prompted calls for action. In the context of global supply chains, policy action is challenging and should be complemented by international co-operation and co-ordination, as well as collaboration with the private sector. Supply chains are complex adaptive systems with no single point of control, especially when they span across a large number of countries.

Although sound evidence of the effectiveness or cost-effectiveness of policy options is not always available, policy makers can consider several options. Foundational policies should be implemented routinely to enhance overall medical supply chain security – to both anticipate and mitigate risks of shortages. Additional capabilities, that go beyond these foundational policies, are needed to prepare for and mitigate risks in the event of severe crises. Figure 4 outlines the analytical framing of such policies.

Figure 4. Analytical framing of policies to improve medical supply chain security



Note: API active pharmaceutical ingredient. "Routine circumstances" refers to routine or "business as usual" situations in which minor or major supply disruptions occur absent a major crisis. Severe crises refer to major events (e.g. pandemic, other type(s) of major events or health threats).

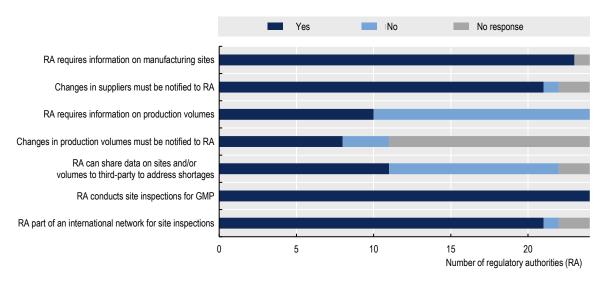
Source: Figures 2.1 and 3.1 in OECD (2024), Securing Medical Supply Chains in a Post-Pandemic World, https://doi.org/10.1787/119c59d9-en.

Risks of shortages must be better anticipated and assessed

> Enhance visibility and harness information across the whole supply chain

Today, regulators lack information on upstream supply chains to assess their vulnerability, and mainly rely on manufacturers to notify them of shortages or potential risks of shortages. What happens in distribution chains is even less clear. As a first step, policy makers should consider how to harness information already reported to regulators by manufacturers to identify and assess points of vulnerability in manufacturing supply chains (Figure 5). On the distribution side, implementing track-and-trace systems building on unique identifiers already required in many countries for medicines (to fight fraud) and high-risk medical devices (for materio-vigilance and real-world performance assessment) would enable better monitoring of supply, demand, and available stocks; characterisation of the nature and scope of notified shortages in real-time; and the organisation of effective (re)allocation of available stocks.

Figure 5. Visibility of manufacturing supply chains of medicines by 24 regulatory authorities



Note: GMP Good Manufacturing Practices.

Source: Based on Table 2.1 in OECD (2024), Securing Medical Supply Chains in a Post-Pandemic World, https://doi.org/10.1787/119c59d9-en.

Identify "critical products" for closer monitoring and information sharing

For "critical products" – e.g. essential medicines with vulnerable supply chains – closer monitoring of volumes and flows should be established in partnership with suppliers.

In general, achieving better visibility requires more routine collection of granular, real-time information on the structure, content, and status of medical supply chains, and investments in data infrastructure and analytics – both by firms and governments. Better anticipation of risks also requires information sharing between stakeholders, which should be permitted where appropriate and necessary.

Risks of shortages must be mitigated

Identify and address root causes of shortages

The reduction of shortage risks should also be a key priority and rests on a better identification of root causes to better address them.

To address quality issues, public authorities need to require manufacturers to maintain quality management systems meeting the highest established standards and to monitor their implementation. International efforts are ongoing in this space; for example, seven regulatory agencies have already implemented guidelines to improve manufacturer's quality risk management of medicines as recommended by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

In some market segments, excessive pressure on prices is suspected to lead to degradation of quality standards, product withdrawals and market exits, as well as concentration of supply to achieve economies of scale. Here, public policies should focus on more strategic procurement to contribute to market shaping that is more conducive to reliable supply chains.

- Cross-country pooled procurement can be useful, for example to enhance prediction of demand and to secure supply for small markets that might not be supplied otherwise. The Pan-American Health Organization's revolving fund for the purchase of vaccines is a good example.
- Strategic public procurement approaches that consider criteria other than price alone can also
 relieve some pressure on prices while elevating the importance of supply security in decision
 making. The "most economically advantageous tender" (MEAT) criteria for public procurement
 recommended by the European Commission is a potential vehicle for more strategic procurement.
 Procurers of medical goods could also consider the diversification of supply as a rationale for
 splitting awards.

Diversification of supply may require further action. Re-shoring and near-shoring policies are high on the policy agendas of several countries seeking to reduce dependency on highly concentrated sources of certain raw materials, active pharmaceutical ingredients and finished products. These policies can expand production capacity, reduce concentration, and help meet increasing global demand. However, careful consideration should precede their implementation as they entail substantial cost. They should be focused on "critical products" as previously, ideally, defined at supranational level.

Encourage greater agility and flexibility

Policy action should also encourage greater agility and flexibility into the system, to reduce risks of potentially harmful supply disruptions.

- Trade facilitation and harmonisation of regulatory requirements for marketing authorisation would ease movements of medical goods. As an example, e-leaflets, in particular for hospitaladministered products, can facilitate re-allocation of products across countries with different languages and labelling requirements.
- Appropriate inventory strategies and co-ordinated stockpiling policies can help mitigate shortages
 due to spikes in demand and/or interruptions in supply chains in the short term but are of limited
 effectiveness in long-term disruptions. Countries have adopted a variety of strategies for
 stockpiling, with differences in the range of products, and in stock management and financing
 mechanisms. The proliferation of national stockpiling policies, however, can potentially worsen
 supply gaps. Regional and co-ordinated stockpiling may be an option for responding to short-term
 mismatches between supply and demand, by allowing swift re-allocation of stocks where they are
 most needed.

 Digital technologies, such as big data analytics and artificial intelligence, could be harnessed by all stakeholders to gain a better understanding of, and improve predictions of, supply and demand, as well as of movements of goods.

Additional capabilities must anticipate future severe crises

It became clear from the COVID-19 pandemic that countries need additional capabilities to prepare for and mitigate risks on medical supply chains in the event of a severe crisis. Governments have a central role in organising emergency supply chains and developing these capabilities in advance. Here, international co-operation and close collaboration between the private sector and governments are important to ensure a cohesive, collective, and efficient response. The importance of medical supply chain security and preparing for future crises is already recognised in international co-operation fora (e.g. G20 and G7 meetings, reforms of the International Health Regulations and the development of the new Pandemic Treaty, and initiatives at European Union level).

Prepare for more rapid responses

Preparedness plans, for pandemics and other shocks, should include specific measures to address medical supply chain issues that can be rapidly enacted. Stakeholders must work together to establish processes for defining lists of critical products specific to different emergency situations and putting in place mechanisms to monitor international and regional flows of these products. These lists could also be used for multi-country pooled procurement.

Countries should also agree on clear mechanisms to share critical medical products' supply and demand data, and on additional regulatory flexibilities or requirements such as rules refraining them from exacerbating supply chains issues through hoarding and export restrictions. Multilateral or regional trade agreements could – before the next crisis occurs – include provisions for co-operation in ensuring the continuity of supply of medical goods.

> Ensure mechanisms are in place to facilitate worldwide access to needed medical products

Policy makers should also ensure that mechanisms are in place to facilitate worldwide access and fair allocation of existing and newly developed technologies.

- Policy makers may need to support expanding production capacity in cases of surging demand and mandate the prioritisation of the medical sector for the supply of raw materials and electronic components. Preparing and implementing appropriate legislation in advance is critical to facilitating rapid responses.
- Governments may need to support the development of new vaccines and treatments in response
 to specific crises. In doing so, they should reinforce existing mechanisms to facilitate equitable
 access, such as knowledge sharing, voluntary licensing, and technology transfer, using
 mechanisms that can be activated immediately in the event of a crisis.

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