

# IMPROVING SECURITY OF SUPPLY FOR CRITICAL PRODUCTS IN THE GLOBAL NORTH AND SOUTH POST-COVID-19: THE CASES OF MEDICAL AND PHARMACEUTICAL GOODS

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## INTRODUCTION<sup>1</sup>

The COVID-19 pandemic has exposed the vulnerability of medical product and pharmaceutical supply chains. Most countries in the Global North, including the United States of America (US) and member states of the European Union (EU), as well as in the Global South faced shortages of various critical medical products in early 2020, with negative effects on patients and health care workers (Ranney et al. 2020; Truog et al. 2020). In contrast, COVID-19 induced shortages of pharmaceutical products (excl. vaccines) were, so far and with a few exceptions, rare and with very limited negative effects for patients. Nonetheless, the COVID-19 pandemic highlighted already existing and potential new vulnerabilities for the security of supply of various pharmaceutical products in the Global North and South. Against this background, debates on various policies to promote strategic autonomy and increase supply security of so-called critical products intensified. Based on an analysis of the medical product and pharmaceutical global value chains (GVCs), this contribution discusses the policy implications of the COVID-19 crisis in the Global North and South. The article also highlights that policies to increase supply security in the Global North may have adverse effects on economic development and supply security in the Global South.

## THE RESILIENCE OF THE MEDICAL PRODUCT AND PHARMACEUTICAL GLOBAL VALUE CHAINS

### MEDICAL PRODUCTS

Medical products, i.e. medical equipment excluding pharmaceuticals, cover a wide range of different product categories (Hamrick/Bamber 2019). They include

products with limited complexity such as bandages, syringes and Personal Protective Equipment (PPE) (e.g., surgical gloves, facemasks, coveralls or safety glasses), and technically complex medical devices such as MRI scanners or ventilators. The main segments of the medical products GVC include (i) research and product development (R&D); (ii) components manufacturing; (iii) assembly; (iv) distribution; (v) marketing and sales; and (vi) post-sales services (ibid.). R&D represents the highest value-added stage of the value chain, whereas, in most instances, manufacturing delivers the lowest value-added.

From the perspective of the Global North, outsourcing and offshoring processes had important effects on the structure of the medical product GVC in recent decades. Outsourcing and offshoring to lower-cost countries in the Global South has been more pronounced in the case of low-tech medical products, but it is also on the rise for more complex medical devices (Bamber/Fernandez-Stark/Taglioni 2020). In the latter case, this is reflected in the increased hiring of contract manufacturers and the pursuit of strategies such as just-in-time production and single sourcing, which aim to reduce costs and increase efficiency (Ebel et al. 2013; Park et al. 2020). However, this does not change the fact that the GVC for medical devices is still dominated by a small number of multinational lead firms primarily based in the EU and the US. These two regions account for more than 50 % of the exports in all segments of the medical device sector (UN Comtrade 2021). The lead firms in the PPE chains, in contrast, are highly diverse and from the Global North and the Global South. For example, 3M is a major US firm with operations in 70 countries, selling more than 60 000 different products across 200 countries, including facemasks in Europe, Asia and the US.<sup>2</sup> In contrast, Malaysian-based Hartalega is a leading global producer of surgical gloves with no manufacturing plants outside of Malaysia.<sup>3</sup>

Given the large differences between products, the governance structures of medical product GVCs also differ. Producer-driven chains in which the producers themselves are the powerful firms structuring the GVC are typical for more complex medical devices (Hamrick/Bamber 2019). Market-driven chains (i.e. chains in which the transactions are not very complex and can be easily codified, and the suppliers have the capabilities to produce without significant input from the buyers), in contrast, are common for PPE products.

Before the COVID-19 pandemic, GVCs for most medical products supplying the Global North worked smoothly, delivery times were short, and delays the exception. The pandemic mostly affected the medical product supply chains relevant for fighting the pandemic, in particular PPE. With the exception of ventilators, medical devices played a minor role in fighting the pandemic. The sudden surge in demand for medical products such as surgical gloves, facemasks, respirators and ventilators triggered by the COVID-19 pandemic led to supply and production bottlenecks for these products. In addition, prices skyrocketed as governments competed to buy as much equipment as possible. For example, export prices for respirators and surgical masks from China increased by 182 % from February 2020 to March 2020 (Bown 2020).

Even though the sudden surge of demand during the pandemic was the main challenge for medical product supply chains, the pandemic also revealed product-specific vulnerabilities. In the case of respirators and surgical gloves, for example, the supply chain vulnerability is particularly related to the geographic concentration of production in China and Malaysia. China, the main producer of respirators, was the first country affected by the COVID-19 pandemic and seized masks produced in China for domestic use, while also increasing production and exports of masks in the period March-April 2020 (Fuchs et al. 2020). In terms of inputs, the main bottleneck to the upsurge of mask production in Asia, the EU and the US was the limited supply of melt-blown non-woven fabric. Export bans, logistical problems and shortages of packing because of company shutdowns in the pulp and paper industry also added to the problem (Asian Development Bank 2020; OECD 2020a).

For a variety of reasons, including climatic conditions necessary for production, access to raw materials, low wages, industrial policy support and more, the global production of surgical gloves is mostly concentrated in Malaysia (Yazid/Yatim 2014). While many Malaysian manufacturers

operated well within their emergency capacities, bottlenecks ensued during the first phase of the pandemic when shutdowns affected the supply of packaging. The geographic concentration of surgical gloves in Malaysia represents a substantial cluster risk. If for any reason production in Malaysia collapses, severe shortages will occur on global markets, in particular since setting up new production lines is extremely costly, requiring a time horizon of 2-4 years, and hence surge capacity in periods of crisis is limited.

Ventilators are a different example in terms of geographic dispersion of production and GVC vulnerability. Three European lead firms, which together account for roughly 60 % of the global ventilator market, dominate the industry.<sup>4</sup> However, the suppliers of these firms are scattered around the world (Netland 2020). The surge capacity of the ventilator producers was limited due to low levels of automation and the challenge of hiring workers with the necessary skills in the short term. The strict regulatory framework as well as the complexities of ventilators create barriers to entry for new, inexperienced producers (Azmeah 2020). Just-in-time production and single sourcing are further sources of vulnerability. Furthermore, several components are produced by just one supplier. As a result, one of the major reasons for delays in the production of ventilators was due to the temporary closure of a major Asian chip producer.

In contrast, most countries in the Global South – with the exception of producer countries, especially in the case of PPE – do not have production capacities and are import-dependent. In particular in the case of low- and lower-middle-income countries, the already weak healthcare infrastructure and low availability of medical products (esp. expensive medical devices such as ventilators) were the major challenges during the COVID-19 crisis. In sub-Saharan Africa, for example, most countries dispose of only a very limited number, and ten countries had no ventilators at all at the outbreak of the crisis (Maclean/Marks 2020). The bottleneck in the case of PPE was arguable a less severe problem due to the quick upsurge in global supply, e.g. in the case of medical gloves and masks, in particular by Malaysian and Chinese manufacturers.

## PHARMACEUTICALS

The pharmaceutical GVC can be divided into four key stages: (i) the discovery of new drugs through research

and development; (ii) clinical trials in order to approve new drugs; (iii) manufacturing of approved drugs, including (iii.a) the supply/sourcing of key starting materials (KSM), (iii.b) the production of intermediates and active pharmaceutical ingredients (APIs), and (iii.c) the production of the finished dosage forms (FDF) (e.g., pills or capsules) through the combination of APIs with excipients; and (iv) the marketing and distribution of drugs (Kedron/Bagchi-Sen 2012; Zeller/Van-Hametner 2018).

Over the last decades, financialization, consolidation, concentration, offshoring and outsourcing processes significantly changed the pharmaceutical sector and related GVCs (Busfield 2020; Fernandez/Klinge 2020; Haakonsson 2009; Zeller/Van-Hametner 2018). In particular off-patent, low-value, low-complexity products have been increasingly offshored and outsourced from the Global North to China (esp. APIs) and India (esp. FDFs). Offshoring processes have in part been furthered by financialization processes and an increasing shareholder-orientation, but also by the increasing international competition and buyers focusing primarily on prices, and not on the security of supply or other factors such as sustainability standards. In addition, not only the number of multinational firms dominating the sector decreased due to mergers and acquisitions over time, but also the number of suppliers and supplying regions decreased due to significant economies of scale and scope in production.

Nonetheless, pharmaceutical production and export of high-value on-patent APIs and FDFs continues to be dominated by European countries such as Germany, the Netherlands, France, Italy, Spain and the United Kingdom. In addition, one third of global FDF pharmaceutical trade constitutes intra-European trade. In contrast, the US is the major global importer of pharmaceuticals. Since the mid-2000s, China and India emerged as key global suppliers of low-value and off-patent APIs and FDFs (generics). Despite the changes of the pharmaceutical GVCs, most countries in the Global South continue to be highly import-dependent for almost all pharmaceuticals.

For these reasons, pharmaceutical products consumed in high-income countries are a producer-driven GVC<sup>5</sup> for higher-value branded products and a buyer-driven GVC for lower-value generics (Haakonsson 2009). Buyer-driven GVCs are characterized by decentralized, globally dispersed production networks, coordinated by lead firms that control activities that add 'value' to products (e.g., by branding), but outsource most of the manufac-

turing process to a global network of suppliers. South-South value chains, on the other hand, tend to be dominated by manufacturers in the Global South, but they are also sometimes referred to as non-driven (i.e. no lead firm governs the chain) (cf. *ibid.*).

In contrast to medical products, pharmaceutical shortages in the Global North induced by the COVID-19 pandemic were limited. Instead, the crisis and threat of shortages due to shutdowns in China and limitations of cross-border trade, including the threat of export restrictions, reignited an already ongoing debate: shortages of pharmaceutical products in OECD (Organisation for Economic Co-operation and Development) countries have become a significant problem over the last decade. A study by the OECD (2020b) shows that the number of shortages in 14 OECD countries increased by 60 % between 2017 and 2019. In particular, medicines for cancer treatments, heart disease, nervous system disorders, hypertension, as well as antibiotics and vaccines were affected. In addition, according to a report by the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI), the number of pharmaceutical product shortages in the EU increased 20-fold between the years 2000 and 2018, and 12-fold since 2008 (EP 2020). The causes of shortages are complex and include production and quality problems, a sudden surge in demand, parallel imports, amongst others. However, policy makers have often overlooked the major structural cause of pharmaceutical shortages: globalized and decentralized production networks.

From a Global North perspective, the vulnerability of the generics GVC is much higher, compared to the producer-driven GVC, due to the greater degree of offshoring, outsourcing and thus import-dependency. In addition, for many generic products there are only a few suppliers or supplying regions of APIs – the key and often large-scale intermediate production step for pharmaceutical products – adding to the vulnerability of the supply chain (MundiCare 2020).

There are, however, major differences between products and regions. The cases of off-patent analgesics (e.g., paracetamol, ibuprofen, etc.) and antibiotics (e.g. cephalosporin), for example, highlight the vulnerabilities created through outsourcing and the high degree of EU import dependency – the key manufacturer of pharmaceuticals in the Global North – in particular with regard to critical inputs/APIs. Both product categories are characterized

by a relatively high degree of concentration of suppliers (i.e. only few suppliers exist for specific products/inputs) and geographical concentration. In addition, potential substitutes within these two pharmaceutical product categories are characterized by similar vulnerabilities.

In the case of paracetamol, for example, there is a comparatively large number of API-producing companies, but global production is essentially limited to China and India due to the availability of a product-specific supplier ecosystem. Moreover, almost all API producers outside China are dependent on imports of intermediate inputs (para-aminophenol) from a few companies in China.<sup>6</sup> Similarly, there is no significant production of cephalosporin APIs in the EU, although the case of penicillin and the large-scale and vertically-integrated Sandoz production facility in Kundl/Austria remains the major exception to this rule. Amid rumors that production might be offshored, the Austrian government has negotiated a 50 million € support package under the condition that local production is continued for at least another 10 years.<sup>7</sup> The EU is, nonetheless, highly import-dependent for key semi-synthetic penicillin products such as Amoxicillin (MundiCare 2020).

In addition, the vulnerability of pharmaceutical supply-chains may have a variety of other product specific reasons. In the case of heparin, for example, the major problem is the input-dependence on porcine mucosa. For example, even though there continues to be significant EU production, given the local/regional availability of inputs, the EU continues to be dependent on imports from China and other countries. The dependence on animal inputs increases the complexity of the supply chain management, in particular in the context of various animal diseases. The recent outbreak of African swine fever (ASF) in China and elsewhere, and the continued threat of input shortages, highlight these challenges (McCarthy et al. 2020). The peculiarities of heparin and its product-specific supply chain vulnerabilities underline the need for product-specific policy approaches to increase the resilience of supply chains.

In contrast, limited access to high-priced medicines and medicine shortages are not a new phenomenon in the Global South, but a structural problem (WHO 2018), highlighting their – with some exceptions – lack of production capacities, import-dependencies, and lack of funding. Medicine shortages are thus related to a large variety of reasons, involving all types of different prod-

uct groups, including essential medicines (Acosta et al. 2019), and affect buyer-, producer- and non-driven value-chains. But in particular in the case of low- and lower-middle-income countries, the lack of medicines is not primarily a problem of value chain-specific vulnerabilities, but is related to the high cost of medicines and/or a weak infrastructure to treat diseases such as tuberculosis, malaria and HIV-related illnesses. But even in upper-middle income countries like Brazil, for example, an increasing incidence of syphilis led to a national shortage of penicillin due to a lack of global supply in recent years (ibid.). During the COVID-19 pandemic the import-dependency and lack of funding in the Global South had a particularly strong impact in the case of vaccines, since producer countries (such as the EU, USA, China, Russia, etc.) and financially powerful countries were able to access vaccines much earlier compared to most countries in the Global South (WHO 2021).

## POLICY IMPLICATIONS IN THE GLOBAL NORTH AND SOUTH

The vulnerability of medical product and pharmaceutical supply chains has reignited a policy-debate in the Global North and South on how to improve the security of supply for critical products. From a policy perspective, the main challenge is that there is a large variety of (potentially) critical products with different supply chain vulnerabilities, and it is yet not known which products will be needed during the next crisis, even though some products are likely to be more important than others. For this reason, there is not “one” solution to improve the supply-chain vulnerability of critical products, but policies need to be tailored towards product-specific vulnerabilities (e.g., input supply bottlenecks, single sourcing, regional clusters, likelihood of demand surges or export bans, etc.). In general, a mix of the following key policies tailored to the specific situation is likely to be implemented by different countries in order to increase supply-security.

### INCREASING GLOBAL SUPPLY-CHAIN RESILIENCE

Given the current situation, it is likely that most medical product and pharmaceutical companies will reevaluate their supply chain risk management, but the outcome of these internal evaluations remains uncertain. Even though it is likely that multinational firms will aim to reduce expo-

sure to shocks, for instance, through diversifying supplier networks, strengthening logistic systems and infrastructure, and improve their capacity to respond and recover, e.g., by increasing in-house stocks, enhancing the flexibility of production systems, or by creating cash-flow buffers, the scale and scope of these measures may be insufficient given their high costs (cf. MGI 2020). For this reason, it is possible that various countries in the Global North will introduce regulations for selected critical products to improve security of supply. For example, the pharmaceutical strategy of the European Commission (EC 2020) is likely to include some regulatory measures to this end, in particular with regard to transparency and monitoring mechanism. Similarly, the US government aims to strengthen supply chain resilience for various critical products, including APIs, through increasing supply chain transparency and incentives (The White House 2021). A major incentive for companies to restructure their supply chains may come from revised public procurement rules, which enable (public) buyers to give a stronger weight to security of supply issues in their purchasing decisions.

The Global South, in particular import-dependent countries, will tend to benefit from measures that increase global supply chain resilience, given that improved capacities to recover, larger in-house stocks or supply chain diversification will not only benefit countries in the Global North. However, since global lead firms are rarely located in the Global South and the market size of most economies in the Global South is small, the governments of most peripheral countries will struggle to incentivize or enforce stricter regulations to ensure supply chain resilience. For this reason, other measures such as stockpiling and building up local or regional production capacities will be even more critical in the Global South.

## STOCKPILING

It is likely that stockpiling measures for critical products will increase in the aftermath of the COVID-19 pandemic. For medical products and pharmaceuticals, various stockpiling models are possible (e.g., with regard to selected products, mode of governance, degree of centralization, public/private management, etc.) (see Grumiller et al. 2021 and Grumiller/Grohs 2021 for more details). The high cost of stockpiling implies that it is only feasible for selected products that are likely to be needed during potential crises.

For the Global South, stockpiling is particularly challenging, given low per capita incomes and the fact that a weaker infrastructure is often coupled with higher population numbers. For this reason, regional cooperation in order to lower investment costs per country and to improve the bargaining power of the buying entity could be a viable strategy, even though such a strategy could increase the cost of distribution and may involve coordination challenges between cooperating countries.

## PROMOTION OF LOCAL AND REGIONAL PRODUCTION CAPACITIES

The promotion of local production capacities, re- and nearshoring and a regionalization of the production of critical products could be potential outcomes of the COVID-19 pandemic. To improve their strategic autonomy, it is possible that many countries in the Global North promote reshoring for selected critical products, i.e. the relocation of production activities of previously offshored products back to the Global North. However, production for many of these products is currently not profitable in the Global North, which is why reshoring will most likely only occur if it is promoted by industrial policy measures such as direct subsidies or strategic purchasing policies by public buyers. Additionally, the possibilities for reshoring differ highly between and within sectors. For example, the build-up of local production for facemasks is comparatively easy to achieve, but reshoring for generic APIs is much more complex and hardly conceivable without massive state support. In the EU, for example, reshoring is yet to be discussed in the context of the EU's pharmaceutical strategy (EC 2020), even though France is already supporting reshoring initiatives on the national level (Abboud/Peel 2020). A new report by the US administration, in addition, clearly highlights that boosting local production for critical medicines will be incremental to improve the resilience of supply chains (The White House 2021).

From a Global South perspective, limited local production capacities for most critical products and in most countries/regions, and thus high import-dependencies, are key challenges. The lack of local and regional capacities has proven to be a particular disadvantage during the COVID-19 crisis, for example in the case of vaccines. For this reason, building up local or regional production capacities will be even more critical in the case of the Global South. Regional cooperation and the building-up of regional clusters are likely to be crucial in this context,

given the high capital intensity and economies of scale for many pharmaceutical and medical products.

The debates on the Global North's supply security for critical products as well as calls for reshoring also bear important implications for the Global South. For example, the attempt to increase supply security in high-income countries by (re)establishing or expanding local production can have very different effects on countries depending on their position in GVCs. For instance, reshoring of production can have a negative impact on income and employment levels in those countries currently producing the respective goods. The additional build-up of production in the Global North could also create overcapacities and reduce prices and thus the profitability of existing companies. A displacement of these companies is also conceivable. On the other hand, import-dependent countries, e.g. large parts of Sub-Saharan Africa, could benefit from policy-induced overcapacities if this reduces prices and procurement costs. In addition, some countries with geographical proximity to potential reshoring regions, such as North African states in the case of the EU, could benefit from nearshoring strategies of European companies (i.e. strategies that promote reshoring to regions close to the EU) and build up or expand production for EU export.

The implications of policies in the Global North to improve security of supply on the Global South must thus be considered from the onset. For example, if the EU is to fulfil its commitment to promote policy coherence for development, i.e., to account for development objectives in policies likely to affect countries in the Global South (EC 2019), it must consider these aspects when formulating any strategies on supply security. The EU should thus aim to mitigate potentially negative economic impacts on the Global South and enhance positive ones.

In addition, countries should actively promote supply security of critical goods on a global level. Since national strategies often gain the upper hand in times of global crises, lessons should be learned from the COVID-19 pandemic to increase the Global South's supply security of medicines and other critical goods. This may include expanding stockpiling efforts by international organizations such as the World Health Organization (WHO), the availability of crisis facilities at international financial institutions for the procurement of urgently needed goods, or medium- and long-term support for the development of national production and stockpiling capacities in the Global South. Clearly, measures to strengthen public

health should be given a higher priority in development cooperation post-COVID-19.

## SUPPORT THE CREATION OF INDUSTRIAL COMMONS

To foster the adaptability of production capabilities during the next crisis, which may require a not yet known set of products, countries in the Global North and South could aim to support the creation or conservation of industrial commons, that is, the knowledge and capabilities that enable countries to quickly build the required industrial capacities. From a Global North perspective, this is critical since many important industrial production capacities were lost during the process of globalization through outsourcing and offshoring. However, from a Global South perspective, the creation of industrial commons is particularly challenging given the weak industrial base in most countries.

## CONCLUSION

The analysis highlighted that the new debate on "GVC resilience" is driven by the challenges of the Global North, given that the Global South, in particular low- and lower-middle-income countries, have long suffered from medicine shortages, weak healthcare infrastructures and, thus, inadequate patient care. Nonetheless, the COVID-19 crisis underlined the necessity for broad public discussions at the global, regional and national levels on how to improve supply security, and in particular about (i) which products are to be considered critical, (ii) which policies should be implemented in which countries and regions and for which product groups, and (iii) how many resources societies are willing to invest into security of supply. The large variety of challenges, critical products and respective GVCs calls for a policy-mix, including policies to increase the resilience of supply chains, to support stockpiling efforts and to promote local/regional production capacities. Particularly with regard to the building-up of production capacities and reshoring, and given the challenge of high subsidy costs and the potential to benefit from the larger market and pronounced economies of scale in production, solutions on regional levels are necessary. The important implications of policies in the Global North on the Global South also need to be taken into account, in particular the potential adverse effects of reshoring.

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- 1 This contribution is based on Grumiller et al. (2021) and Grumiller/Grohs (2021).
  - 2 See [https://www.3m.com/3M/en\\_US/company-us/about-3m/history/](https://www.3m.com/3M/en_US/company-us/about-3m/history/) (04.11.2021)
  - 3 See <https://hartalega.com.my/about-us/> (04.11.2021)
  - 4 Source: <https://www.nzz.ch/wirtschaft/weltweit-hat-es-zu-wenig-beatmungsgeraete-ld.1549108?reduced=true> (04.11.2021)
  - 5 This GVC is dominated by vertically integrated EU and US TNCs (Transnational Corporations). These firms produce within high-income countries and sell to high-income countries (although the increasing role of small biotech firms and start-ups in drug development, as well as a large service industry in testing, stands in contrast to this overall structure).
  - 6 India is currently increasing efforts to promote para-aminophenol production.
  - 7 See <https://www.sandoz.at/news/media-releases/bundesregierung-und-novartis-bekennen-sich-zu-penicillin-produktion-kundl> (04.11.2021)