29 BRIEFING PAPER

Increasing security of supply for critical medical and pharmaceutical goods in the EU: lessons from the COVID-19 pandemic

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List of Abbreviations

AGES	Austrian Agency for Health and Food Safety
APIs	Active pharmaceutical ingredients
ASF	African swine fever
EC	European Commission
ENVI	European Parliament's Committee on the Environment, Public Health and Food Safety
EP	European Parliament
EU	European Union
EUR	Euro
FDF	Finished dosage forms
GDP	Gross domestic product
GVCs	Global value chains
HS code	Harmonised System code
KSM	Key starting materials
OECD	Organisation for Economic Co-operation and Development
PPE	Personal protective equipment
R&D	Research and development
WHO	World Health Organisation

Abstract

This Briefing Paper examines the resilience of the medical product and pharmaceutical global value chains. Based on this assessment, policy recommendations are presented to increase supply security, including measures to improve the resilience of supply chains, and to expand stockpiling. We also highlight that industrial policy measures to promote reshoring should play a more important role, and that coordination on the EU-level is necessary. Given the large differences between products and supply chains within and between sectors, policies need to be tailored to specific products and product groups. Finally yet importantly, repercussions of EU policy on the Global South also need to be taken into account.

Keywords: supply chain resilience, reshoring, pharmaceuticals, medical products, COVID-19

1. Introduction[1]

The COVID-19 pandemic has exposed the vulnerability of medical product and pharmaceutical supply chains. Most countries in the European Union (EU) 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 were, so far and with a view 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 EU. 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 briefing paper discusses policy options to increase the supply security through measures that improve the resilience of supply chains, expand stockpiling and promote reshoring.

2. The resilience of the medical product and pharmaceutical global value chains

2.1. 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., medical 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 (Hamrick/Bamber 2019). R&D represents the highest value-added stage of the value chain, whereas, in most instances, manufacturing delivers the lowest value-added.

In the last decades, outsourcing and offshoring processes had important effects on the structure of the medical product GVC. Outsourcing and offshoring to lower-cost countries has been more pronounced in the case of low-tech medical products, but it is also on the rise in case of 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. 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.[2] In contrast, Malaysian-based Hartalega is a leading global producer of examination gloves with no manufacturing plants outside of Malaysia.[3]

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

[1] This briefing paper is based on Grumiller et al. (2021)
[2] See https://www.3m.com/3M/en_US/company-us/about-3m/history/ (04.11.2020)
[3] See https://hartalega.com.my/about-us/ (04.11.2020)

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.

The medical product sector in the EU continues to be rather large, amounting to over 32 000 manufacturers that employ almost 730 000 people in 2020 (MedTech Europe 2020). Overall, the EU medical products trade surplus amounted to EUR 84.6 billion in 2019 (Eurostat 2020). The EU also had a trade surplus in most of the sub-categories with particular importance for the COVID-19 crisis or similar future pandemics (see Figure 1). However, import values are also large, highlighting import dependencies for specific products or inputs. This is particularly true for medical consumables (EUR 50.4 billion imports in 2019, excl. intra-EU trade), medical devices and equipment (EUR 19.6 billion) and protective garments and the like (EUR 17.7 billion) (ibid.).

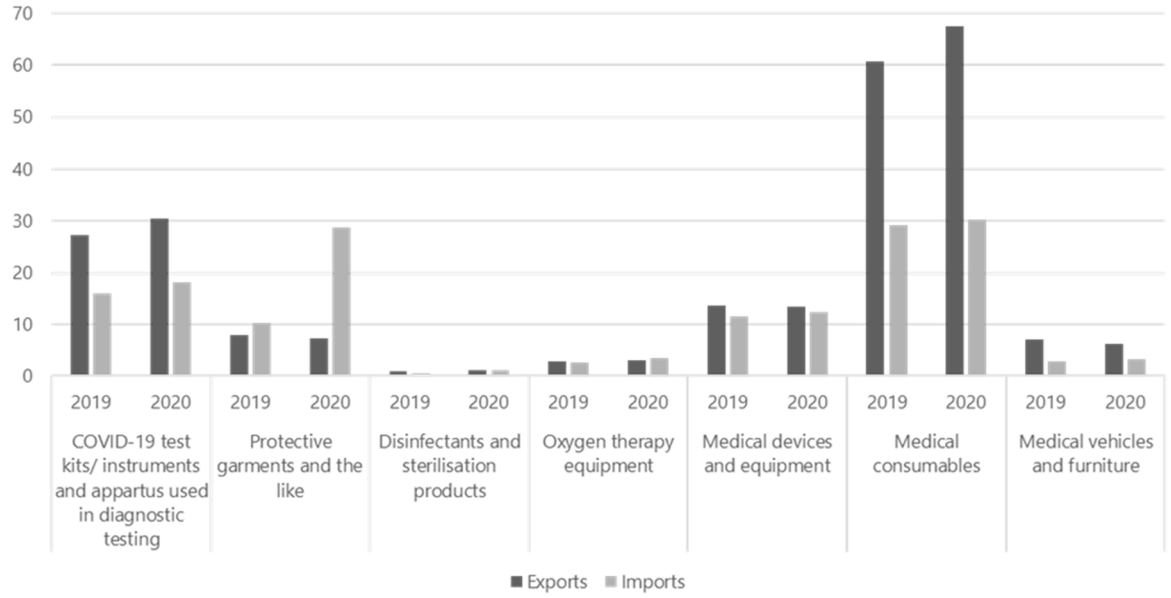
Before the COVID-19 pandemic, supply chains for most medical products worked smoothly, delivery times were short, and delays the exception. The pandemic mostly affected the medical product supply chains relevant for fighting the pandemic, in particular PPE. With the exception of ventilators, medical devices played a minor role in fighting the pandemic. The sudden surge in demand for medical products such as medical gloves, facemasks, respirators and ventilators triggered by the outbreak of SARS-CoV-2 led to supply and production bottlenecks for these products. In addition, prices skyrocketed as governments competed to get 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).

Figure compares EU exports and imports between the first halves of 2019 and 2020, highlighting the impact of the COVID-19 pandemic. Imports of protective garments and similar products increased by 185 % (EUR 18.7 billion), an increase that can largely be attributed to the 1 462 % growth of facemask imports (from EUR 1.1 billion to EUR 17.2 billion). Even though imports increased across all medical product categories, the effect was weaker in categories such as disinfectants and sterilisation products (74 %, or EUR 0.45 billion), oxygen therapy equipment (31 %, or EUR 0.8 billion), and medical devices (6 %, or EUR 0.74 billion) (Eurostat 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 examination 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 meltblown 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 2020).

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 examination 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 examination 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.

Figure 1: Comparison of EU exports and imports of medical products in the first halves of 2019 and 2020, in billion EUR



Source: Eurostat 2020
Note: Data refers to the period January to July 2019 and 2020, respectively (excl. intra-EU trade).

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.[4] Thus, know-how as well as productive capabilities are available within the borders of the EU-27. However, the suppliers of these firms are scattered around the world (Netland 2020). The surge capacity of the ventilator producers was limited because automation is low and hiring workers with the relevant skills at short notice is not an easy task. The strict regulatory framework as well as the complexities of ventilators create barriers to entry for new, inexperienced producers (Azmeh 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.

2.2. 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 GVCs (Busfield 2020; Fernandez/Klinge 2020; Haakonson 2009; Zeller/Van-Hametner 2018). In particular off-

[4] Source: https://www.nzz.ch/wirtschaft/weltweit-hat-es-zu-wenig-beatmungsgeraete-ld.1549108?reduced=true (04.11.2020)

patent, low-value, low-complexity products have been increasingly offshored and outsourced 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 the significant economies of scale and scope in production.

Today, pharmaceutical products consumed in high-income countries are linked to a producer-driven GVC[5] 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., branding), but outsource most of the manufacturing process to a global network of suppliers.

The EU has a relatively large pharmaceutical sector with an annual production value of roughly EUR 275 billion (~2 % of EU GDP) in 2019, employing almost 800 thousand people (EFPIA 2020). The EU produces mainly FDFs and high-value, small volume and high-complexity APIs. The sector is thus highly import dependent for high-volume, low-value and low-complexity APIs (e.g. various antibiotics and analgesics). The APIs for many of these products are further processed in the EU to final dosage forms (FDFs), which is why imports of FDFs to the EU play a comparatively minor role. In 2019, the EU imported EUR 11.1 billion and exported EUR 7.4 billion of APIs, generating a trade deficit of EUR 3.7 billion for APIs. The API trade deficit is particularly pronounced for hormones, prostaglandins, thromboxanes and leukotrienes (HS code 2937; EUR 2.3 billion) and antibiotics (HS code 2941; EUR 1.7 billion) (Eurostat 2020). The EU particularly imports high volume APIs from Asia, while maintaining production capacities for smaller volume and complex APIs (MundiCare 2020). For FDFs, the EU imported EUR 42.2 billion and exported EUR 118.3 billion, generating a significant trade surplus (EUR 76.1 billion) against the rest of the world (Eurostat 2020).

In contrast to medical products, the pharmaceutical shortages 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 the EU have become a significant problem over the last decade. 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). In addition, a forthcoming study by the Organisation for Economic Co-operation and Development (OECD) 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. The causes of shortages are complex and include production and quality problems, a sudden surge in demand, parallel imports and others. However, policy makers have often overlooked the major structural cause of pharmaceutical shortages: globalized and decentralized production networks.

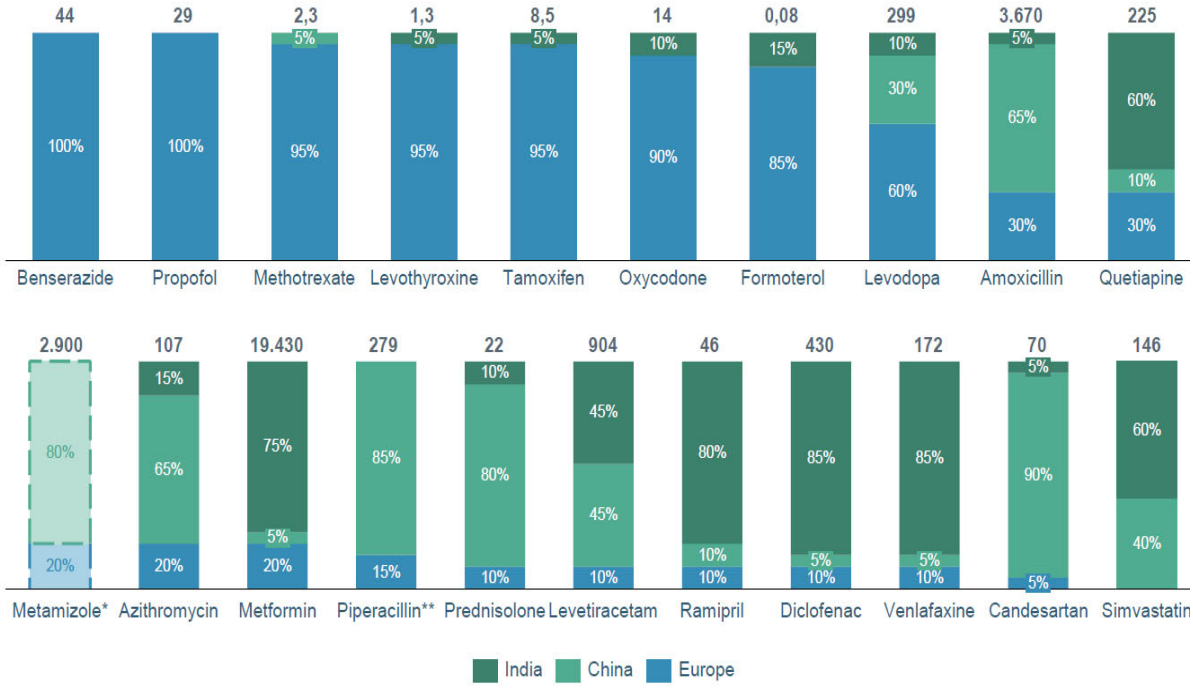
From an EU perspective, the vulnerability of the generics GVC is much higher, compared to the producer-driven GVC, due to the greater degree of offshoring, outsourcing and thus import-dependency (Figure 2). In addition, for many generic products there are only a few

[5] This GVC is dominated by vertically integrated EU and US TNCs. These firms produce within OECD countries and sell to OECD countries, as well as to other high-income groups in (semi-)peripheral 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).

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. 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, 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.

Figure 2: Estimated share of supply for European demand of APIs by region



Note: Above the pillar is the estimated European demand in tons.
Source: MundiCare 2020

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 from a few companies in China (para-aminophenol).[6] Similarly, there is no significant production of cephalosporin APIs in the EU, but the case of penicillin and the remaining large-scale and vertically-integrated production facility in Austria shows that there are also exceptions to the rule. The EU is, nonetheless, highly import-dependent for key semi-synthetic penicillin products such as Amoxicillin (Figure 2).

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-

[6] India is currently increasing efforts to promote para-aminophenol production.

dependence on porcine mucosa. 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.

3. Policy recommendations

The high vulnerability of medical product and pharmaceutical supply chains calls for policy interventions to improve supply security and strategic autonomy for critical products. The COVID-19 crisis also highlighted the necessity for a broad public discussion about which products are to be considered critical and how many resources our society is willing to invest into security of supply. Given the large amount of potentially 'critical' medical products and pharmaceuticals (ranging from various dozens to more than thousand, depending on the definition) and the large scale of production required for many of these products, any strategy to improve supply security needs to (a) take into account the particularities of all identified critical products/product-groups, (b) develop a mix of policies for each of the identified products/product-groups, and (c) aim for coordination at the EU level.

Based on our analysis of the medical products and pharmaceutical GVCs, policy-makers in the EU should contemplate the **following key policy options** for increasing supply-chain security. The best policy option for specific product groups will depend on the specific policy-goals (e.g. strategic autonomy, security of supply) and the vulnerability of the respective product groups' supply chains (e.g. likelihood of demand surges, export bans, supply bottlenecks etc.).

(i) Increase the resilience of global supply chains

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 remain uncertain. Even though it is likely that multinational firms will aim to reduce exposure 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, a regulatory framework that incentivizes or mandates specific measures in selected supply chains may be necessary. 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. A major incentive for companies to restructure their supply chains would 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.

(ii) Increase stockpiling

For medical products and pharmaceuticals, various stockpiling models are possible. The basic trade-off involved in stockpiling is between security of supply and cost-effectiveness. The more comprehensive the stocks of specific products, the higher the costs of storage and associated transactions. Given higher bargaining power, more centralized stockpiling will lead to lower sourcing costs, while it will increase logistics costs for management and distribution. For

larger-scale stockpiling programs, coordination at the EU level will be necessary, while smaller-scale storage models may be effectively organized at the national level.

Another issue relates to the governance model for stockpiling. The question arises, whether stocks should be managed by a public entity or by private operators, that is, manufacturers or traders. The first option would involve large upfront investments. The second option could build on existing structures, but requires a regulatory framework that stipulates precise storage obligations for private operators and possibly be complemented by financial compensation.

In the case of medical products, stockpiling PPE products is comparatively easy. The main problem are the required quantities in times of crisis, which is why stockpiling cannot be the only strategy. In the case of pharmaceuticals, stockpiling strategies also depend on the type of products to be stored, i.e. APIs, FDFs, or a mix of both. Storing APIs may be more cost-effective but is conditional upon technical feasibility and the availability of production capacities in the EU for processing APIs into FDFs. In many instances, the storage of imported FDFs may be preferable.

The European Commission's new Pharmaceutical Strategy (EC 2020) emphasizes the necessity to increase strategic stockpiling efforts. However, national strategies are currently also a likely scenario. For example, there are discussions within the Austrian Agency for Health and Food Safety (AGES) task force, but they are still at an early stage. Various stakeholders have expressed different preferences, often depending on their position within the value chain. For example, manufacturers tend to prefer stockpiling of selected APIs (for which processing capacities exist or can be easily established) and have voiced their concerns regarding mandatory stockpiling requirements for manufacturers. In contrast, wholesalers prefer the stockpiling of FDFs by enlarging their existing facilities or building new ones based on their know-how, but expect financial compensation for their services.[7]

(iii) Promote reshoring

To improve the strategic autonomy of the EU or specific member states for selected critical products, increasing the resilience of global supply chains and stockpiling may not suffice. For this reason, promoting reshoring, i.e. the relocation of production activities into the EU, for selected critical products may be a viable solution. However, production for many of these products is currently not profitable in the EU. Therefore, reshoring needs to be promoted by industrial policy measures such as direct subsidies or strategic purchasing policies by public buyers (e.g. selection of suppliers based on security of supply criteria or sustainability standards, and not only on the basis of price competition).

The possibilities for reshoring highly differ between and within sectors. For example, the build-up of local production for facemasks is comparatively easy to achieve. However, in this case the question of the sustainability of production after the COVID-19 pandemic arises. Reshoring for generic APIs, on the other hand, is much more complex and hardly conceivable without massive state support. Vertically-integrated production of paracetamol, for example, requires a complex supplier-network that is currently not available in the EU. For other products, such as examination gloves, climatic conditions but also the lack of local availability of essential inputs (esp. rubber) make the establishment of EU production seem very unlikely. Here, higher stockholding would be a possible alternative.

In the case of pharmaceuticals, and despite political pressure from some EU member states, in particular France (Abboud/Peel 2020), the EU pharmaceutical strategy (EC 2020) remains vague about promoting reshoring: the role of *reshoring* is yet to be discussed. For this reason, national initiatives, e.g. the likely promotion of API manufacturing in France, will also play an

[7] They currently have stocks for roughly three weeks for products sold at pharmacies, given demand stability.

important role, and it is so far unclear in how far these strategies will be coordinated at the EU level.

(iv) Support the creation of industrial commons

To foster the adaptability of EU production capabilities during the next crisis, which may require a not yet known set of products, the EU needs to support the creation or conservation of industrial commons, that is, the knowledge and capabilities that enable the EU to quickly build the required industrial capacities. This is critical since many important industrial production capacities were lost during the process of globalization through outsourcing and offshoring.

In addition, it is also important that regulations and institutions are adapted to accelerate the market entry of new producers and products in the times of crisis (without undermining product safety). The COVID-19 crisis highlighted, for example in the case of ventilators, that regulations pose a significant barrier for new medical products with high regulatory standards (Azmeh 2020).

4. The need for policy coherence for development

The debates on the EU's supply security for critical products as well as calls for reshoring bear implications for non-EU countries, including the Global South. The attempt to increase European supply security by (re)establishing or expanding local production can have very different effects on countries depending on their position in GVCs. For example, reshoring of production can have a negative impact on income and employment levels in the producing countries. The additional build-up of EU production 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. in 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 the EU, e.g. in North Africa, 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.

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, the EU should actively promote supply security of critical goods can be ensured 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 European development cooperation post-COVID-19.

5. Conclusion

The COVID-19 crises highlighted the necessity for a broad public discussion about which products are to be considered critical, which policies should be implemented for which product groups, and how many resources societies are willing to invest into security of supply. The large variety of 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 reshoring. Particularly with regard to 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 the EU level are necessary. The important implications of EU policies on the Global South also need to be taken into account.

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