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INCREASING THE RESILIENCE AND SECURITY OF SUPPLY OF PRODUCTION POST-COVID-19 - THE CASE OF MEDICAL AND PHARMACEUTICAL PRODUCTS

Jan Grumiller
Hannes Grohs
Christian Reiner



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“Increasing the resilience and security of supply of production post-COVID-19”- The Case of Medical and Pharmaceutical Products

Project “Increasing resilience and security of supply of production post-COVID-19: from
global to regional value chains?”

Jan Grumiller, Hannes Grohs (ÖFSE)
Christian Reiner (Lauder Business School)



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ABBREVIATIONS

AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH
API	Active pharmaceutical ingredients
ASF	African swine fever
BASG	Bundesamt für Sicherheit im Gesundheitswesen
BMSGPK	Federal Ministry of Social Affairs, Health, Care and Consumer Protection
CEP	Certificate of Suitability of Monographs of the European Pharmacopoeia
CPA	Corona SARS-Cov-2 Pandemie Atemschutzmasken
EC	European Commission
EEA	European Economic Area
EKO	Erstattungskodex
EMA	European Medicines Agency
EU	European Union
EUR	Euro
FDF	Final dosage form
FDI	Foreign direct investment
GVCs	global value chains
HS Code	Harmonised System Codes
ICU	Intensive care unit
IPR	Intellectual Property Right
LMWH	Low-molecular weight heparin
M&A	Mergers and acquisition
MDR	Medical device regulation
NCA	National competent authorities
OECD	Organisation for Economic Co-operation and Development
PPE	Personal protective equipment
R&D	Research and development
TNC	Transnational corporation
UFH	Unfractionated heparin
USD	US Dollar
WTO	World Trade Organization

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EXECUTIVE SUMMARY

The COVID-19 pandemic has exposed the fragility of medical product and pharmaceutical global value chains (GVCs). Against this background, debates on various policies to increase the resilience of these supply chains intensified. However, there is currently no consensus on which policies are required to ensure supply security for 'critical' or 'essential' products in the European Union (EU), and even the definition of these products is the subject of a debate.

This report presents a detailed analysis of the medical products and pharmaceutical GVCs in order to foster our understanding of their vulnerabilities and to identify potentials for increasing their resilience. Given the large diversity of products within the medical and pharmaceutical sectors, the report presents a selection of three case studies on representative products for each of the two sectors/GVCs: (i) respirators, (ii) examination gloves and (iii) ventilators for medical products, and (a) penicillin (antibiotic), (b) paracetamol (analgesic), and (c) heparin (anticoagulant) for pharmaceuticals. The effects of COVID-19 on medical and pharmaceutical GVCs were distinct: most countries in the EU faced shortages of various critical medical products in early 2020, with negative effects on patients and health care workers. In contrast, COVID-19 induced shortages of pharmaceutical products were, so far and with a few exceptions, rare and with very limited negative effects for patients. Having said that, the COVID-19 pandemic highlighted already existing and potential new vulnerabilities for various pharmaceutical products in the EU.

The key criteria regarding the vulnerability of the medical and pharmaceutical supply chain include (i) the degree of globalization and import dependency; (ii) the potential to substitute the product (without harming patients); (iii) the degree of globalization and import dependency of the substitutes; (iv) the degree of concentration (i.e. the number of supplier firms); (v) the degree of regional diversification (i.e. the number of supplying countries/different regions); (vi) the complexity of the GVC; and (vii) the likelihood of supply challenges for critical inputs.

Medical products include a broad range of product categories, ranging from low-complexity products such as bandages, syringes or Personal Protective Equipment (PPE), i.e. medical gloves or respirators, to high-complexity products e.g. for magnetic resonance imaging. Given these large differences between products, the governance structures of these chains also differ: Producer-driven chains (i.e. producers are the powerful players) are typical for more complex medical devices, while market-driven chains (i.e. the transactions are not very complex, the transactions can be easily codified, and the suppliers have the capabilities to produce PPE without significant input from the buyers) are common for PPE products.

Even though sophisticated medical products to a large extent continue to be produced in the EU and the US, lower-value and high-volume products (such as face masks/respirators or examination gloves) that have become of crucial importance during the COVID-19 pandemic have been increasingly outsourced. The degree of globalization and concentration of production however differs between the various products.

The main challenge for medical product supply chains was the sudden surge of demand during the pandemic. For respirators and examination gloves, the geographic concentration of production in China and Malaysia increased the vulnerability of the GVCs. China, the main producer of respirators, was the first country affected by COVID-19 and seized respirators produced in China for domestic use, while also increasing production for exports in the period March-April 2020. The main limitation to the upsurge of respirator production in Asia, Europe and the US was the short supply of meltblown non-woven fabric, the critical input for respirators. Export bans, logistical problems and shortages of packing because of company shutdowns in the pulp and paper industry also added to the problem.

Regarding examination gloves, the extreme geographical concentration of production 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. In contrast to respirators, there are no reports on export bans of medical gloves from Malaysia. However, other parts of the supply chain, such as the packaging suppliers, failed due to shutdowns.

The situation for ventilators differs. The industry is dominated by three European lead firms, which together account for roughly 60 % of the global ventilator market, and 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. 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. 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.

Depending on their characteristics, **pharmaceutical products** consumed in the EU are linked to two distinct GVCs: a producer-driven GVC for higher-value branded products and a buyer-driven GVC for lower-value generics. In general, the vulnerabilities of generics GVCs are much higher since production for generic products has increasingly been outsourced in the last decades, in particular to China and India. In addition, for many generic products there are only a few suppliers of active pharmaceutical ingredients (APIs), the key and often large-scale intermediate production step for pharmaceutical products, adding to the vulnerability of the supply chain.

The EU has a relatively large pharmaceutical sector, but produces mainly high-value, small volume and high-complexity APIs. The EU is thus highly import dependent for high-volume, low-value and low-complexity APIs, which includes critical products such as various antibiotics, analgesics, and more. 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 the EU, COVID-19 induced pharmaceutical shortages were limited, but the crisis and threat of shortages due to shutdowns in China and limitations of cross-border trade reignited an already ongoing debate: for various reasons, including the increasing globalization of production, shortages of pharmaceutical products in the EU have become an significant problem in the last decade.

The analysis of the three product-specific case studies underlines this general perspective, but also reveals important product specific differences. The case of off-patent analgesics (paracetamol) highlights the vulnerabilities created through outsourcing and the high degree of EU import dependency, in particular with regard to APIs. While this is also true for most antibiotics, 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. Off-patent antibiotics/penicillin and analgesics/paracetamol, in addition, are also characterized by a relatively high degree of concentration of suppliers (i.e. only few suppliers exist for specific products) as well as geographical concentration. This is the result of pressures on prices, financialization processes, and the importance of economies of scale. In addition, potential substitutes of these two pharmaceutical products are characterized by similar vulnerabilities.

In contrast, there continues to be a relatively large-scale production of heparin in the EU given the local/regional availability of inputs and the pronounced supply-chain vulnerability due to its input-dependence on porcine mucosa. 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) and the continued threat of input-shortages has shed light on these challenges.

In sum, the analysis of the medical products and pharmaceutical GVCs and the six case studies suggests the **following key policy options** for increasing supply-chain resilience: (i) promoting reshoring through financial and other incentives; (ii) increase stockpiling on the national or EU level; (iii) increasing the resilience of supply chains by incentivizing diversification of suppliers and regions; (iv) innovation policy, especially to change production methods; (v) adapt regulations and institutions to accelerate market entry of new producers; (vi) reform public procurement of the health sector to implement strategic purchasing policies; and (vii) support the creation of industrial commons to foster the adaptability of EU production capabilities during the next crisis that may require a not yet known set of products.

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 importance of economies of scale, any strategy needs to (a) aim for coordination at the EU level, (b) take into account the particularities of all identified critical products, and (c) develop a mix of policies for each of the identified products/product-groups.

In general, the policy debate on increasing supply chain resilience is particularly relevant for previously outsourced generic APIs in the case of pharmaceuticals and PPE in the case of medical products. Given the high cost of reshoring and stockpiling, fostering the resilience of (global) supply chains through regulatory measures that increase the number of suppliers and supplying regions is the most important policy option for most pharmaceutical and medical products. Increasing the resilience of supply chains through supplier and regional diversification will be particularly important in case of medical devices such as ventilators, since these products are generally already produced in the EU.

For selected critical products re- and nearshoring as well as stockpiling will also be necessary. It will have to be assessed on a case-by-case basis, which policy options are preferable. In general, stockpiling is preferable for products with high durability and relevance in cases of emergency, for instance, medical gloves and other PPE. Though costly, reshoring might be preferable for products that cannot be easily stored and may be required in large quantities during emergencies, such as certain antibiotics and analgesics. Medical gloves, for example, are difficult to reshore given the importance of economies of scale in production and the lack of regional availability of critical inputs such as latex. In such instances, stockpiling is likely a more cost-efficient option to improve supply security. In contrast, reshoring and the reservation of surge capacities is more feasible in the case of respirators and meltblown production, as was shown during the COVID-19 pandemic.

Complementary to reshoring, stockpiling of selected generic APIs may be a more cost-efficient solution compared to stockpiling FDFs. This presupposes, however, the existence of EU FDF production capacities.

Given the large economies of scale and the importance of an effective supplier network involved in generic production, re- or nearshoring strategies are comparatively cost-intensive. Nonetheless, re- and nearshoring may be of crucial importance to ensure the security of supply for selected pharmaceuticals. In this context, reshoring strategies could also target specific pharmaceutical clusters and associated supplier networks (e.g. Paracetamol, Diclofenac, Aspirin and Ibuprofen have similar supplier networks). In certain instances, such as vaccine production, to reserve local surge capacity is also an option. In addition, some potentially critical generics (e.g. penicillin or heparin) continue to be produced in the EU on a relatively large scale. However, the case penicillin highlights the fragility of EU production without government support, and the case of heparin shows that increasing EU capacities may be necessary nonetheless, given the repeated global supply shortages.

ZUSAMMENFASSUNG

Die COVID-19-Pandemie hat die Anfälligkeit globaler Wertschöpfungsketten (GVCs) für Medizinprodukte und Pharmazeutika offengelegt. Vor diesem Hintergrund haben sich die Debatten über verschiedene wirtschaftspolitische Maßnahmen zur Erhöhung der Resilienz von Lieferketten intensiviert. Allerdings herrscht aktuell keine Einigkeit darüber, welche Maßnahmen zur Gewährleistung der Versorgungssicherheit für ‚kritische‘ oder ‚essenzielle‘ Produkte in der Europäischen Union (EU) erforderlich sind, und selbst die Definition dieser Produkte ist Gegenstand der Diskussion.

Der vorliegende Report präsentiert eine detaillierte Analyse der GVCs medizinischer und pharmazeutischer Produkte mit dem Ziel ein besseres Verständnis für ihre Vulnerabilitäten zu schaffen und so Potenziale zur Erhöhung ihrer Resilienz zu identifizieren. Angesichts der großen Produktvielfalt innerhalb des Medizin- und Pharmasektors präsentiert der Report drei Fallstudien zu repräsentativen Produkten für jeden der beiden Sektoren bzw. GVCs: (i) Beatmungsgeräte, (ii) medizinische Handschuhe und (iii) Beatmungsgeräte für medizinische Produkte und (a) Penicillin (Antibiotikum), (b) Paracetamol (Analgetikum) und (c) Heparin (Antikoagulans) für pharmazeutische Produkte. Der Schwerpunkt der Analyse der medizinischen und pharmazeutischen GVCs unterscheidet sich, da sich die COVID-19-Pandemie auf die Produkte unterschiedlich auswirkte: Die meisten Länder in der EU waren Anfang 2020 mit Engpässen bei verschiedenen kritischen medizinischen Produkten konfrontiert. Dies hat zu negativen Auswirkungen auf PatientInnen und MitarbeiterInnen des Gesundheitswesens geführt. Im Gegensatz dazu waren COVID-19-induzierte Engpässe bei pharmazeutischen Produkten bisher – mit einigen wenigen Ausnahmen – selten und mit sehr begrenzten negativen Auswirkungen für PatientInnen. Die COVID-19-Pandemie hat jedoch bereits bestehende sowie potenzielle Vulnerabilitäten für verschiedene pharmazeutische Lieferketten in der EU aufgezeigt.

Zu den wichtigsten Kriterien für die Anfälligkeit medizinischer und pharmazeutischer Lieferketten zählen: (i) der Grad der Globalisierung und die Importabhängigkeit, (ii) das Potenzial, das Produkt (ohne Nachteil für PatientInnen) zu substituieren, (iii) der Grad der Globalisierung und die Importabhängigkeit der Substitute, (iv) der Grad der Konzentration (d. h. die Anzahl der Zuliefererfirmen), (v) der Grad der regionalen Diversifizierung (d. h. die Anzahl der Zuliefererländer/verschiedener Regionen), (vi) die Komplexität der GVC und (vii) die Wahrscheinlichkeit von Lieferproblemen kritischer Inputs.

Medizinische Produkte umfassen eine breite Palette von Produktkategorien, die von Produkten mit geringer Komplexität wie Verbänden, Spritzen oder persönlicher Schutzausrüstung (*personal protective equipment*, PPE; d. h. medizinischen Handschuhen oder Atemschutzmasken) bis hin zu hochkomplexen Produkten, z. B. für die Magnetresonanztomographie, reichen. Angesichts dieser großen Unterschiede zwischen den Produkten unterscheiden sich auch die Governancestrukturen der Lieferketten: *producer-driven* GVCs (d. h. die produzierenden Unternehmen sind die mächtigen Akteure) sind typisch für komplexere medizinische Geräte, während *market-driven* GVCs (d. h. Transaktionen sind nicht sehr komplex, Transaktionen können leicht kodifiziert werden, und Lieferanten können die Produkte ohne nennenswerte Inputs der Käufer produzieren) für PPE-Produkte üblich sind.

Auch wenn komplexere Medizinprodukte nach wie vor zu einem großen Teil in der EU und den USA produziert werden, sind Produkte mit geringerem Wert und größeren Produktionsvolumina (wie z. B. Gesichtsmasken, Atemschutzmasken oder medizinische Handschuhe) zunehmend ausgelagert worden. Diese Produkte waren im Zuge der COVID-19-Pandemie von entscheidender Bedeutung. Der Grad der Globalisierung und Konzentration der Produktion ist jedoch bei den verschiedenen Produkten unterschiedlich.

Die größte Herausforderung für die Lieferketten medizinischer Produkte war der plötzliche Anstieg der Nachfrage während der Pandemie. Bei Atemschutzmasken und medizinischen Handschuhen erhöhte zudem die geografische Konzentration der Produktion in China und Malaysia die Vulnerabilität der GVCs. China, der wichtigste globale Produzent von Atemschutzmasken, war als erstes Land von COVID-19 betroffen.

China konfiszierte zu Beginn der Krise einerseits in China produzierte Atemschutzmasken für den Inlandsgebrauch, und erhöhte andererseits die Produktion für den Export im Zeitraum März-April 2020. Die wichtigste Einschränkung für eine Aufstockung der Produktion von Atemschutzmasken in Asien, Europa und den USA war das knappe Angebot an *Meltblown*-Vliesstoff (Schmelzgeblasener Vliesstoff), dem entscheidenden Input für Atemschutzmasken. Exportverbote, logistische Probleme und Engpässe bei der Verpackung aufgrund von Betriebsstilllegungen in der Zellstoff- und Papierindustrie trugen ebenfalls zu den Problemen bei.

Bei medizinischen Handschuhen stellt die extreme geografische Konzentration der Produktion in Malaysia ein erhebliches Clusterrisiko dar. Sollte die Produktion in Malaysia aus irgendeinem Grund zusammenbrechen, würde dies zu gravierenden Engpässen auf den Weltmärkten führen. Insbesondere da der Aufbau neuer Produktionslinien extrem kostspielig ist und 2-4 Jahre erfordert. Die Möglichkeit zum schnellen Aufbau neuer Kapazitäten in Krisenzeiten ist somit stark begrenzt. Anders als bei Atemschutzmasken gibt es keine Berichte über Exportverbote für medizinische Handschuhe aus Malaysia. Allerdings sind andere Teile der Lieferkette, wie z. B. die Zulieferung von Verpackungsmaterial, aufgrund von Lockdowns und Produktionsstopps, ausgefallen.

Anders stellt sich die Situation bei Beatmungsgeräten dar. Die Branche wird von drei europäischen Leitunternehmen dominiert, die zusammen etwa 60 % des Weltmarktes für Beatmungsgeräte ausmachen. Know-how sowie Produktionskapazitäten sind somit innerhalb der Grenzen der EU-27 vorhanden. Die Zulieferfirmen dieser Unternehmen sind jedoch über die ganze Welt verstreut. Der Ausbau der Produktionskapazitäten von Beatmungsgeräten während der COVID-19-Pandemie war begrenzt, da der Automatisierungsgrad gering ist und das kurzfristige Einstellen von Arbeitskräften mit dem entsprechenden Know-how eine Herausforderung darstellte. Der strenge regulatorische Rahmen sowie die Komplexität von Beatmungsgeräten schafften zudem Eintrittsbarrieren für neue, unerfahrene Unternehmen. Just-in-time-Produktion und Single-Sourcing sind weitere Ursachen für die Vulnerabilität der Lieferketten. Zudem konzentriert sich die Herstellung einiger Inputs auf nur einen Zulieferbetrieb. So war einer der Hauptgründe für Verzögerungen bei der Produktion von Beatmungsgeräten die vorübergehende Schließung eines großen asiatischen Chip-Herstellers.

Die in der EU konsumierten **pharmazeutischen Produkte** sind grundsätzlich an zwei unterschiedliche GVCs geknüpft: an eine *producer-driven* GVC für höherwertige Markenprodukte und einer *buyer-driven* GVC für Generika mit geringerem Wert. Im Allgemeinen sind die GVCs für Generika deutlich anfälliger, da die Produktion von Generika in den letzten Jahrzehnten zunehmend nach China und Indien ausgelagert wurde. Darüber hinaus gibt es für viele Generika nur wenige Lieferanten von pharmazeutischen Wirkstoffen (*active pharmaceutical ingredients*, APIs), dem wichtigsten Zwischenproduktionsschritt für pharmazeutische Produkte, was die Anfälligkeit der Lieferkette zusätzlich erhöht.

Die EU weist einen relativ großen pharmazeutischen Sektor auf. Sie produziert aber hauptsächlich hochwertige, kleinvolumige und hochkomplexe APIs. Die EU ist daher in hohem Maße von Importen für großvolumige und weniger komplexe APIs mit niedrigem Wert abhängig. Zu diesen gehören kritische Produkte wie verschiedene Antibiotika, Analgetika und weitere. Die APIs für viele dieser Produkte werden in der EU zu fertigen Darreichungsformen (*finished dosage forms*, FDFs) weiterverarbeitet, weshalb Importe von FDFs in die EU eine vergleichsweise geringe Rolle spielen.

In der EU hielten sich die COVID-19-bedingten Engpässe pharmazeutischer Produkte in Grenzen, aber die Krise und die Gefahr von Engpässen aufgrund von Produktionsstillständen in China und Einschränkungen des grenzüberschreitenden Handels haben eine bereits laufende Debatte neu entfacht: Aus verschiedenen Gründen, darunter die zunehmende Globalisierung der Produktion, sind Engpässe bei pharmazeutischen Produkten in der EU im letzten Jahrzehnt zu einem bedeutenden Problem geworden.

Die Analyse der drei produktspezifischen Fallstudien unterstreicht diese allgemeine Einschätzung. Sie zeigt aber auch wichtige produktspezifische Unterschiede auf. Der Fall der patentfreien Analgetika (Paracetamol) verdeutlicht die starke Abhängigkeit der EU insbesondere beim Import von Wirkstoffen und die Vulnerabilitäten, die durch Outsourcing und Offshoring entstehen. Während dies auch für die meisten Antibiotika gilt, zeigt der Fall von Penicillin und der verbleibenden im großen Umfang produzierenden und vertikal integrierten Produktionsanlage in Österreich, dass es auch Ausnahmen von der Regel gibt. Patentfreie Antibiotika/Penicillin und Analgetika/Paracetamol sind darüber hinaus durch einen relativ hohen Konzentrationsgrad der Zulieferfirmen (d. h. es gibt nur wenige Zulieferfirmen für bestimmte Produkte) sowie eine geografische Konzentration gekennzeichnet. Die Ursachen hierfür sind im zunehmenden Preisdruck, Finanzialisierungsprozessen und der großen Bedeutung von Skaleneffekten zu finden. Zusätzlich sind die Lieferketten der potenziellen Substitute dieser beiden pharmazeutischen Produkte durch ähnliche Vulnerabilitäten gekennzeichnet.

Im Gegensatz dazu wird Heparin in der EU nach wie vor in relativ großem Maßstab hergestellt, da die Inputs auf lokaler/regionaler Ebene verfügbar sind und die Lieferkette aufgrund der Inputabhängigkeit von *porcine mucosa* sehr anfällig ist. Die Abhängigkeit von tierischen Inputs erhöht die Komplexität des Supply-Chain-Managements, insbesondere im Zusammenhang mit verschiedenen Tierkrankheiten. Der jüngste Ausbruch der Afrikanischen Schweinepest und die anhaltende Gefahr von Input-Engpässen haben diese Herausforderungen verdeutlicht. Die Besonderheiten von Heparin und die produktspezifischen Vulnerabilitäten der Lieferkette unterstreichen auch die Notwendigkeit von produktspezifischen Maßnahmen, um die Resilienz der Lieferketten zu erhöhen.

Die Analyse der GVCs für medizinische und pharmazeutische Produkte und der sechs Fallstudien führt uns zusammenfassend zu folgenden **zentralen wirtschaftspolitischen Empfehlungen** zur Erhöhung der Resilienz von Lieferketten, auch wenn sich die Potenziale für die jeweiligen Produkte unterscheiden: (i) die Förderung von Reshoring durch verschiedene Anreize; (ii) die Erhöhung der Lagerhaltung auf nationaler oder EU-Ebene; (iii) die Schaffung von Anreizen zur Diversifizierung von Zulieferfirmen und Regionen; (iv) eine Anpassung der Innovationspolitik, insbesondere zur Erhöhung der Förderungen sowie Änderung von Produktionsmethoden; (v) die Anpassung von Regulierungen und Institutionen zur Beschleunigung des Markteintritts neuer Hersteller; (vi) die Reform des öffentlichen Beschaffungswesens im Gesundheitssektor zur Umsetzung strategischer Einkaufspolitik; und (vii) die Stärkung der *industrial commons*, um die Anpassungsfähigkeit der EU-Produktionskapazitäten während der nächsten Krise zu fördern, die vermutlich eine noch nicht bekannte Reihe von Produkten erfordert.

In Anbetracht der großen Anzahl potenziell ‚kritischer‘ Medizinprodukte und Pharmazeutika (die je nach Definition von mehreren Dutzend bis zu mehreren Tausend reicht) und der Bedeutung von Skaleneffekten in der Produktion, muss jede Strategie (a) auf eine Koordinierung auf EU-Ebene abzielen, (b) die Besonderheiten aller identifizierten kritischen Produkte berücksichtigen und (c) einen Mix von Maßnahmen für die jeweiligen identifizierten Produkte/Produktgruppen entwickeln.

Im Allgemeinen ist die politische Debatte zur Erhöhung der Resilienz von Lieferketten besonders für zuvor ausgelagerte generische Wirkstoffe bei Arzneimitteln und PPE bei Medizinprodukten relevant. Angesichts der hohen Kosten für Reshoring und die strategische Bevorratung ist für die meisten pharmazeutischen und medizinischen Produkte die Förderung der Resilienz (globaler) Lieferketten durch regulatorische Maßnahmen, die zu einer Diversifizierung der Zulieferunternehmen und -regionen führen, die wichtigste wirtschaftspolitische Option. Die Erhöhung der Resilienz von globalen Lieferketten ist insbesondere bei medizinischen Geräten wie Beatmungsgeräten von Bedeutung, da diese Produkte in der Regel bereits in der EU hergestellt werden.

Für ausgewählte kritische Produkte sind auch strategische Bevorratung sowie Re- und Nearshoring erforderlich. Welche wirtschaftspolitischen Maßnahmen konkret vorzuziehen sind, muss von Fall zu Fall überprüft werden. Im Allgemeinen ist die strategische Bevorratung für Produkte mit hoher Haltbarkeit und hoher Relevanz im Krisenfall sinnvoll,

z. B. bei medizinischen Handschuhen und anderen PPE. Reshoring ist zwar kostspielig, kann jedoch für Produkte in Frage kommen, die nicht einfach zu lagern sind und in Notfällen in großen Mengen erforderlich sind, z. B. bestimmte Antibiotika und Analgetika. Andererseits ist die Produktion von medizinischen Handschuhen aufgrund der in der Produktion vorhandenen Skaleneffekte und der mangelnden regionalen Verfügbarkeit kritischer Inputs wie Latex eher schwierig in die EU rückzuverlagern. In solchen Fällen ist die Bevorratung wahrscheinlich eine kostengünstigere Option zur Verbesserung der Versorgungssicherheit. Im Gegensatz dazu ist Reshoring und die Haltung von Reservekapazitäten für den Krisenfall bei Atemschutzmasken und bei der Produktion von Meltblown-Vliesstoff einfacher darstellbar, wie sich auch während der COVID-19-Pandemie gezeigt hat.

Ergänzend zu Reshoring kann die strategische Bevorratung ausgewählter generischer APIs eine kostengünstigere Lösung sein als die Bevorratung von FDFs. Dies setzt jedoch das Vorhandensein von EU-FDF-Produktionskapazitäten voraus.

Angesichts der großen Skaleneffekte und der Bedeutung eines effektiven Lieferantennetzwerks für die Generikaproduktion sind Re- oder Nearshoring-Strategien vergleichsweise kostenintensiv. Dennoch kann ein Re- und Nearshoring von entscheidender Bedeutung sein, um die Versorgungssicherheit für ausgewählte Arzneimittel zu gewährleisten. In diesem Zusammenhang könnten Reshoring-Strategien auch auf bestimmte pharmazeutische Cluster und zugehörige Lieferantennetzwerke abzielen (z. B. haben Paracetamol, Diclofenac, Aspirin und Ibuprofen ähnliche Lieferantennetzwerke). In bestimmten Fällen, z. B. bei der Herstellung von Impfstoffen, ist ebenfalls die Haltung von lokalen Reservekapazitäten anzudenken. Darüber hinaus werden einige potenziell kritische Generika (z. B. Penicillin oder Heparin) weiterhin in relativ großem Umfang in der EU hergestellt. Der Fall Penicillin unterstreicht jedoch die Fragilität der EU-Produktion ohne staatliche Unterstützung, und der Fall Heparin zeigt, dass angesichts der wiederholten globalen Versorgungssengpässe eine Erhöhung der EU-Kapazitäten trotzdem erforderlich sein kann.

1 INTRODUCTION

Amongst many other repercussions, the COVID-19 pandemic has exposed the fragility of global production processes in medical goods and pharmaceuticals. The media were full with reports on supply shortages of facemasks, protective gear and respirators. Governments and public bodies in the EU have been struggling to secure the quantities of these goods required for public health systems to stay operational. World market prices for some of these products were skyrocketing, and supply chain disturbances through export taxes, confiscations, theft, and lack of adherence to quality standards increased.

Against this background, the organization of production in these and other sectors has become increasingly scrutinized by both policy-makers and the public. Calls for geographically more diversified production chains and for more local production, respectively, have intensified, as security of supply concerns have regained in importance relative to efficiency and cost considerations. Both the sectoral coverage and the instruments applied to support such a reorganization of production remain however contested. Some commentators go so far as to actively promote across-the-board de-globalization of production in the aftermath of the COVID-19 crisis, while others argue for a more nuanced approach according to the strategic importance of a sector, involving a mix of policy instruments including local production, tighter mandatory storage policies, public procurement conditionalities for companies to diversify their sourcing strategies, and other instruments.

The following report presents a more detailed analysis of the medical products and pharmaceutical global value chains (GVCs) in order to arrive at a better understanding of the respective supply chain vulnerabilities and potentials for increasing their resilience. Given the large diversity of products within the medical and pharmaceutical sectors, the report presents three product specific case studies for each of the two sectors/GVCs: (i) respirators, (ii) examination gloves and (iii) ventilators for medical products, and (a) penicillin (antibiotics), (b) paracetamol (analgesic), (c) heparin (anticoagulant) for pharmaceuticals. The case studies include an analysis of the respective product specific GVCs, supply chain vulnerabilities, potentials for increasing their resilience, and (if applicable) policies during the COVID-19 pandemic. The focus of analysis of the medical and pharmaceutical GVCs, respectively, differs slightly, because the effects of COVID-19 on the respective case studies were also distinct: most countries in the European Union (EU) were faced with shortages of various critical medical products in early 2020, with negative impacts on health care workers, patients, and the general public alike. In contrast, COVID-19-induced shortages of pharmaceutical products were so far and with a few exceptions rare, and negative effects on patients remained circumscribed. Instead, the COVID-19 pandemic highlighted already existing and potential new vulnerabilities as well as import dependencies for various pharmaceutical products. The report concludes by developing product and GVC specific policy recommendations.

The field research and interviews for this report were conducted from August to November 2020.

2 MEDICAL PRODUCTS

The GVCs of medical products are not usually in the limelight and most of the companies in the sector are only known to industry insiders. Before the COVID-19 pandemic set in, markets for most of these products worked smoothly, delivery times were short and delays the exception. All this changed in the first quarter of 2020, with seemingly dull products such as medical gloves or ventilators making headlines because of their importance for protecting health care workers. A combination of economic and political factors interrupted global value chains of medical products and triggered a shortage of medical devices in rich and poor countries alike. In Italy, one of the worst affected countries, health care workers suffered from high rates of infection and mortality due to a lack of personal protective equipment, and estimates for the US suggested the need for triage because of insufficient supply of ventilators (Ranney et al. 2020; Truog et al. 2020). As a result, prices for goods deemed essential to treat COVID-19 patients skyrocketed as governments competed to get hold of as much equipment as possible. Bown (2020) for instance reports that, based on trade data, export prices for respirators and surgical masks from China surged by 182 % from February 2020 to March 2020.

To understand the dynamics, causes and implications of these developments, this section presents empirical findings from three case studies on the GVCs of the following products: (i) respirators, (ii) examination gloves and (iii) ventilators. All of these products have played an important role in fighting the pandemic and varying degrees of shortages occurred. To contextualize the case studies, a general overview of the main characteristics and trends of the GVC of medical devices is provided.

Medical products for this section are defined as all medical equipment with the exception of pharmaceuticals. Hence, they include a broad range of product categories (Hamrick/Bamber 2019). On the one end of the spectrum are relatively less complex products such as bandages, syringes or Personal Protective Equipment (PPE). PPE is defined as “equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses.”¹ It includes items such as medical gloves, respirators, coveralls or safety glasses. PPE are mostly single-use products and the GVC is highly cost driven. On the other end of the spectrum are technically complex products such as MRI scanner machines or ventilators. We refer to these sophisticated capital goods as medical devices in order to distinguish them from PPE-like products. Medical devices can be utilized for several years and represent large long-term investments. While these commonly used definitions are based on economic logic (i.e. the characteristics of the products), legal terminology and regulations differ from their economic counterparts to some degree. For example, examination gloves are certified as both a medical device and a PPE, and products classified by economists as PPE because they display commodity-like characteristics are medical devices according to the medical device regulations of the EU. In order to avoid confusion, usage of the regulatory terminology is made with explicit reference to the regulation.

The market for medical products is a global growth market. Between 2002 and 2016, global imports of medical products increased by 227 % with even higher growth rates in upper and lower middle-income countries (382 % and 454 % respectively). By comparison, total imports of the world economy grew by about 147 % over the respective time-period. High-income countries still account for the largest share of medical imports (81 % in 2016) with the EU-15 being the major buyer of global production followed by North America and East-Asia-Pacific (Hamrick/Bamber 2019).

¹ <https://www.osha.gov/personal-protective-equipment>, 04.11.2020.

2.1 The Global Value Chain of Medical Products

Figure 1 shows the main elements of the GVC of medical products (in a broad sense). The first stage, research and development (R&D), is followed by manufacturing and assembly, distribution, sales and after-sales services. By the logic of the smile curve, R&D delivers the highest value-added whereas manufacturing is the lowest value-added stage of the value chain. The R&D process of medical devices is complex and time-intensive because each element and functionality of a product must receive regulatory approval by the authorities in the relevant markets. Investment in R&D is much more important for complex medical devices as compared to PPE. Typically, the R&D department is located in advanced economies providing the necessary human capital and the benefit of knowledge spillovers from universities or related firms.

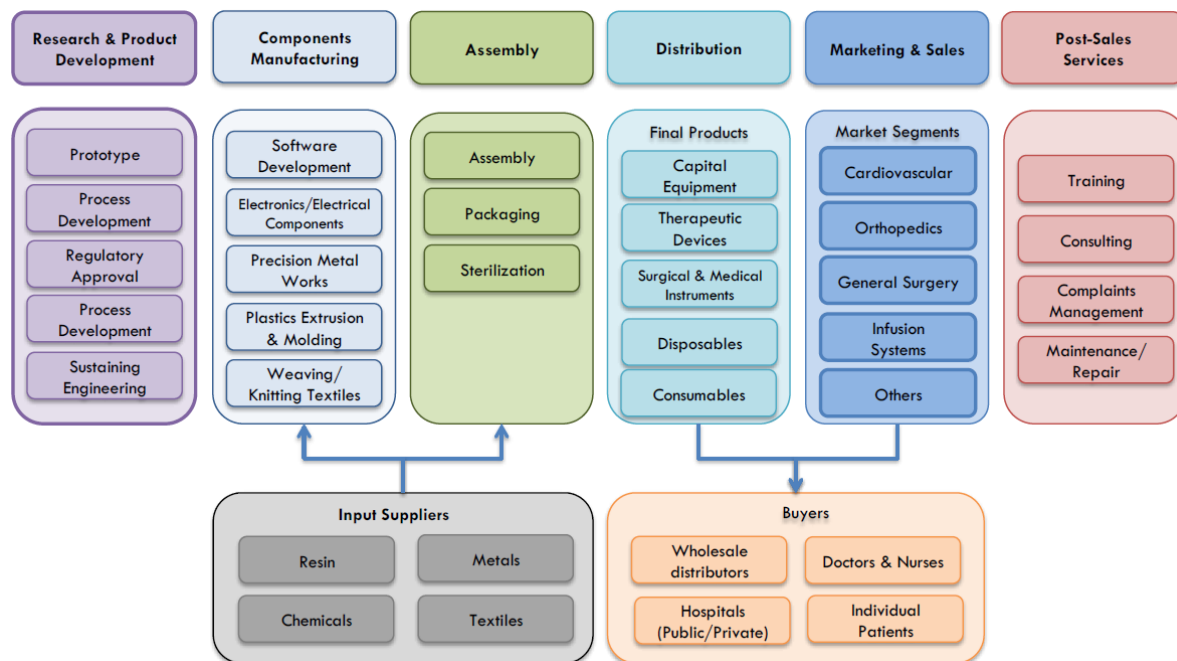
Depending on the type of product, the production process includes advanced IT elements such as software development or more general industrial competencies such as weaving and knitting textiles. Cost, quality, regulatory factors, lead-time and the protection of intellectual property and knowledge are the main parameters in the manufacturing of medical devices (Brocca et al. 2017). Lead firms limit their production to a handful of locations to monitor the production processes closely. Compared to other industries, the process of outsourcing and offshoring to lower-cost countries has been relatively slow because of the need to deliver high and consistent quality in line with demanding regulatory frameworks (Bamber et al. 2020). The production being offshored mainly pertains to low-tech mass-produced medical goods. While medical device companies have traditionally been vertically integrated to protect intellectual property, outsourcing to contract manufacturers is on the rise. The same holds true for just-in-time production and single sourcing – both strategies are thought to increase efficiency and reduce costs (McKinsey & Company 2013; Asian Development Bank 2020). One important reason for these dynamics is mounting cost pressures from public buyers who try to cope with rising health care costs and austerity policies (KPMG 2018; Harrington 2015; Brocca et al. 2017).

The main final buyers of medical devices in Europe are public hospitals or associations of hospitals at the regional or federal level. PPE is distributed to hospitals via wholesale distributors such as Lohman & Rauscher or Hartman. Complex products such as ventilators are sourced directly from the medical device producer. Interviews revealed that buyers have only limited knowledge of the actual organization of production processes, which limits their capacity to evaluate potential risks in the supply chain. A further negative factor during the pandemic is the recent change in purchasing behavior by hospitals towards just-in-time inventories and sourcing from fewer vendors to reduce costs (Gereffi 2020; Vecchi et al. 2020). This of course mirrors the effort to introduce just-in-time production by the suppliers and illustrates the cost pressure on diverse actors in the medical device value chain.

After-sales services such as training and maintenance are crucial for complex capital equipment. For instance, producers of ventilators offered advice on how to use ventilators for more than one patient.² Technologically advanced devices are not maintained by hospital staff but by external service teams from the producer.

² https://www.hamilton-medical.com/en_AE/E-Learning-and-Education/Knowledge-Base/Knowledge-Base-Detail~2020-04-09~Using-one-ventilator-for-multiple-patients~34aeb5b0-a67f-4c4a-aec3-a4dbdd16a2c2~.html, 04.11.2020.

Figure 1: GVC of medical devices



Source: Hamrick/Bamber 2019

The value chains of medical devices are producer-driven, i.e. the producers are the powerful players (Hamrick/Bamber 2019). They have the competence and the resources to organize global production networks and to make sure that the devices adhere to a complex set of public and private standards. A small number of multinational lead firms dominate the GVC for medical devices. Every firm from the top 10 firms (by revenue) is located in either the US or Europe. Traditionally, these firms have been highly vertically integrated, but this has changed in the last years.

Regarding the value chain of PPE, the governance structure is less clear-cut because the power of buyers is higher due to the commodity-like characteristics of the products, the relatively low technological competencies and the intensive price competition. In addition, innovation is far less important than in the medical device GVC. Perhaps the most appropriate characterization of the PPE chain is as market-driven, i.e. the transactions are not very complex, the transactions can be easily codified, and the suppliers have the capabilities to produce PPE without significant input from the buyers. The lead firms in the PPE chains are from both developed and emerging economies. 3M, for instance, a major US firm founded in 1902 with operations in 70 countries and selling more than 60,000 different products in 200 countries, produces face masks in Europe, Asia and the US.³ Hartalega, on the other hand, is a leading global producer of medical gloves in Malaysia and with no manufacturing plants outside Malaysia.⁴ This illustrates the diversity of lead firms and producers in the PPE chain.

Geography and trade interdependencies

Overall, the geography of the GVC for medical devices is still dominated by production locations 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. Their dominance is highest in the therapeutics market (72.6 %) and lower in the consumables segment, including items such

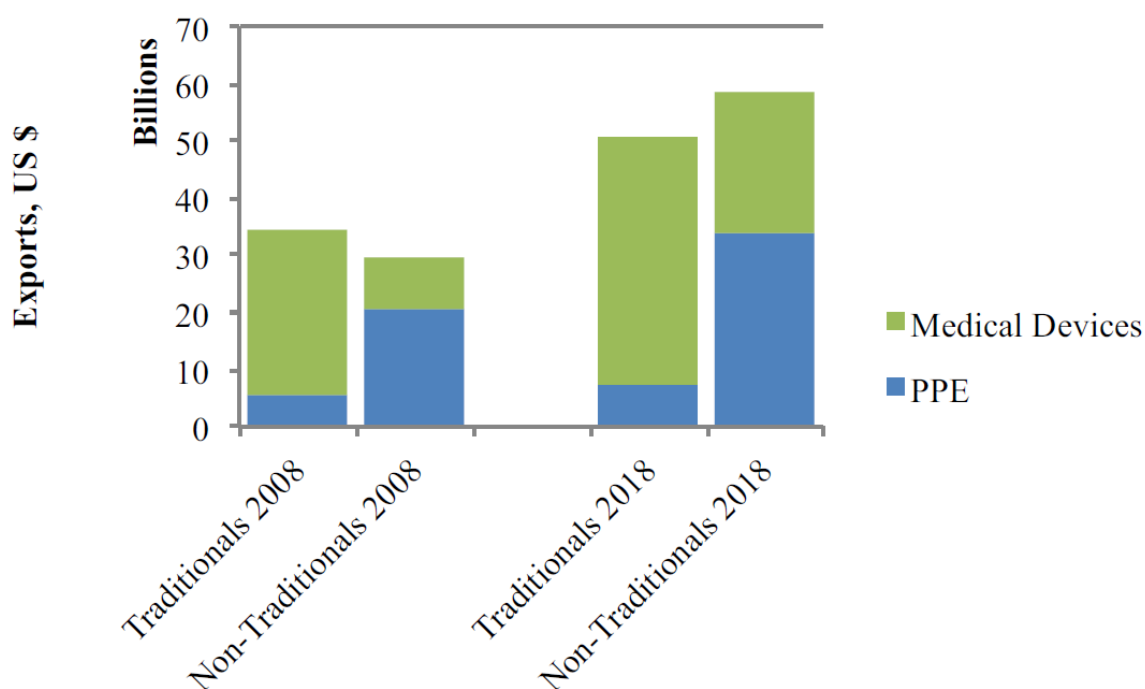
³ https://www.3m.com/3M/en_US/company-us/about-3m/history/, 04.11.2020.

⁴ <https://hartalega.com.my/about-us/>, 04.11.2020.

as bandages or dressings (59 %). Having said that, several emerging economies have entered the chain via offshore manufacturing. Exports from countries such as China, Malaysia, Mexico, Singapore, Costa Rica and the Republic of Korea grew much faster than the average.

The global exports of COVID-19 goods are concentrated in a small number of countries with about 85 % of all exports coming from just 20 countries. The top-5 exporters are Germany, the USA, Switzerland, China and Ireland (OECD 2020). Figure 2 shows the changing geography for of the GVC of medical products related to combat COVID-19, i.e. a subset of all medical products as defined by HS-2002 codes and the World Customs Organization. In the diagram a differentiation is made between traditional suppliers (the USA, Germany ...) and non-traditional exporters (China, Mexico, ...) as well as between medical devices and PPE. The growth in exports in the decade 2008-2018 was driven mainly by rising health care expenditures in emerging and developing economies as well as by population-aging trends in the developed countries. In 2008, exports were still dominated by the traditional exporters but in 2018 the emerging non-traditionals exported almost USD 60 billion, i.e. about USD 10 billion more than traditional exporters. In particular, their share in PPE exports has risen to about 80 %. While developed, traditional exporters are specializing in medical devices, non-traditional exporters focus on PPE. However, this pattern is set to change with non-traditionals starting to export larger shares of medical devices.

Figure 2: Exports of medical devices and personal protective equipment (PPE), 2008 and 2018



Note: * Traditional exporters: USA, Germany, Japan, the Netherlands, United Kingdom, France, Belgium, Italy, Canada.
 ** Non-traditional exporters: China, Mexico, Ireland, Malaysia, Vietnam, Costa Rica, Thailand, Singapore, Israel, Taiwan, China.
 *** HS-Codes: PPE: 630790, 9020, 900490, 392620, 401511, 401519, 611610, 6216, 6505, 6210; Medical Devices: 902212, 901890, 901920, 901819.

Source: Bamber et al. 2020

China stands out from this list of non-traditional countries due to its vast domestic market and growing demand for medical devices and an ambitious industrial policy aimed at building up a globally competitive medical device industry and reducing the dependence

on imports. Medical devices figure prominently in the industrial policy strategy “Made in China 2025” with the aim of increasing domestic content of advanced medical devices to 70 % (Congressional Research Service 2020). An important instrument is to instruct local hospitals to buy domestically produced medical devices from Chinese firms (Collins 2019). So far the strategy seems to be successful and the medical device sector is characterized by sweeping upgrading dynamics: FDI projects in China changed from being dominated by low-value added activities towards high-value added activities and the exports of medium-to high-tech medical devices have been out weighing low-tech exports since 2012 (Torsek 2018). Companies such as Mindray, founded in 1991 and domiciled in Shenzhen, managed to become a lead firm and the shortages during the pandemic enabled Chinese firms to enter European markets in areas such as ventilators, a market segment which had previously shunned Chinese products (Kamp 2020).

Chinese manufacturers are especially vital for medical products related to COVID-19 (Bown 2020). Indeed, the dependence on China for critical medical supplies is perhaps one of the most relevant economic insights of the pandemic. For instance, before COVID-19 about 60 % of all protective garments and face masks were produced in China (Bown 2020) and the dependence of the US on China even increased during the pandemic because its economy recovered faster than that of the US (Zeiger 2020). According to Gereffi (2020), China will continue to play a crucial role in the GVC of medical products simply because of its huge and growing market.

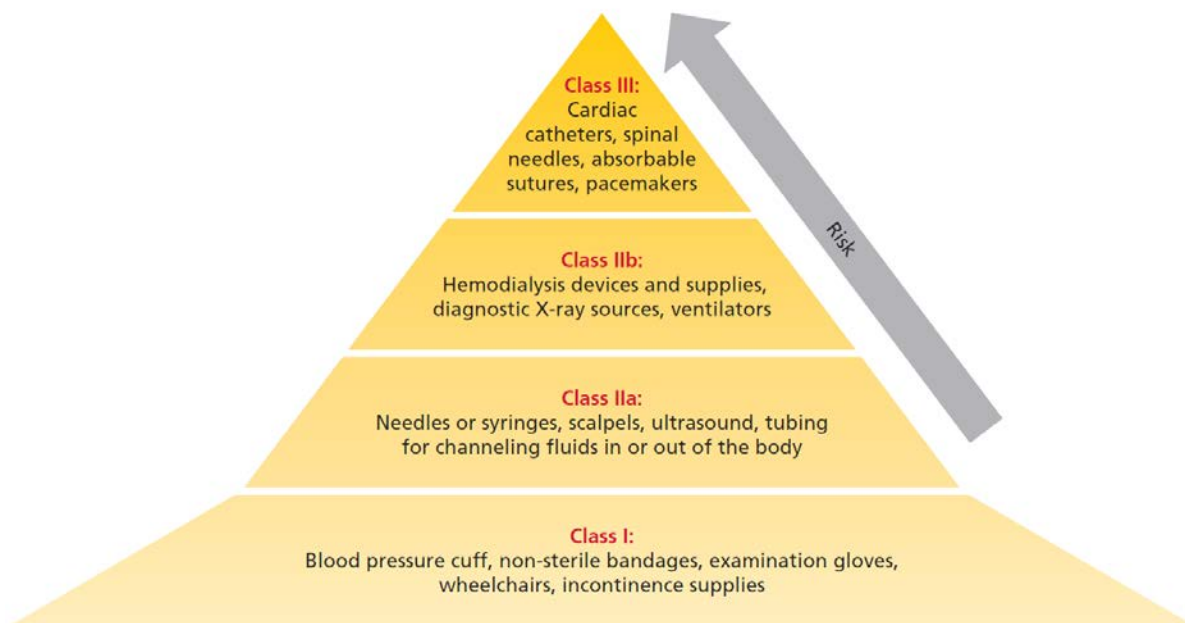
Yet it would be misleading to interpret the dependencies as one-sided. Actually, the interdependencies between countries in trading PPE and medical devices are quite pronounced. Countries tend to be both importers and exporters of PPE and medical devices. Germany, for example, imports EUR 0.72 for every euro of exports of COVID-19 related goods (OECD 2020).

EU regulation

The structure and dynamics of the GVC of medical products are strongly shaped by regulatory issues. Standards aim to ensure the safety and quality of medical products, and public and private standards have a strong impact on how firms develop, design, produce and distribute their products. The strictness of the standards increases with the potential hazards associated with the malfunctioning of the respective medical product. Figure 3 illustrates the different classes of regulation of medical devices according to medical device regulations in the EU.⁵ Ventilators are class IIb, examination gloves are class I and medical face masks are classified as Type I and Type II depending on the bacterial filtration efficiency. Even though regulation for PPE is less strict than for medical devices, regulation matters a great deal also for PPE production. In the EU, regulation is mainly driven by the work of the European standardization organizations CEN and CENELEC as well as by the European Commission, which traditionally strives for the harmonization of standards to deepen the single market. In 2017, two new regulations (MDR 2017/745) entered into force, thereby replacing the old regulation after a phase-in period and providing a new and more challenging regulatory framework for the medical device sector. An interviewee argued that the increasing costs of compliance with the new regulation will lead to the exit of SMEs in the medical device sector, thereby increasing the dependence of imports from low-cost locations.

⁵ There will be some changes to this scheme with the new EU medical device regulation 2017/745 which will come into force in 2021.

Figure 3: Regulation of medical devices in the EU according to the level of risk



Source: Harrington 2015

While medical devices are regulated by medical device standards, PPE are also regulated by standards specific for PPE. For instance, gloves used in hospitals are regulated by the medical device regulation (EN455, class I) and the PPE regulation (EN374, class III). Of importance are so-called notified bodies, i.e. public or private institutions designated by the EU, which evaluate the conformity of products with stipulated standards.⁶ The main elements of standards include technical documentation, controls or clinical trials (depending on the type of product) and proof of the biocompatibility of materials.

The most important private standard is the ISO standard 13485. The standard came into force in 2003 and nowadays all factories producing medical devices for developed markets must be certified according to ISO 13485. Such a certification is costly, time-consuming and, in a period of supply shortages, a potential barrier for alternative suppliers to enter the market.

During the pandemic, standards have become even more important. On the one hand, quality standards need not be compromised, especially with low-quality counterfeit goods flooding global markets for essential supplies. On the other hand, since new products are necessary to increase production, the certification process must be accelerated and the close cooperation between certifying bodies and firms is of utmost importance. Companies will be reluctant to sell products until they are certified due to liability issues. Several measures have been taken by the EU and national governments to deliver these goals. First and foremost, the European Commission defined new rules which enabled member states to set up fast-track procedures for assessing and certifying new medical equipment.⁷ In addition, the EU has adopted decisions on harmonized standards (HS) which will grant conformity of devices with the relevant directives on medical devices. Due to the challenges of COVID-19, the European Commission postponed the introduction of the MDR by one year until May 2021.⁸ In order to utilize the potential of 3-D-printing to

⁶ https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en, 04.11.2020.

⁷ <https://www.dekra-product-safety.com/en/dekra-tests-assesses-ventilators-covid-19>, 04.11.2020.

⁸ <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/neue-eu-verordnungen-mdr-ivdr/umsetzung-mep-regulierung-update.html>, 04.11.2020.

supply spare parts or equipment for new products invented to fight the pandemic, the Commission adopted assessment procedures for 3D printed products to be used in a medical context for COVID-19.⁹ European standardization bodies and ISO started to make the relevant standards for COVID-19 goods available free of charge so that interested companies wishing to start production can have access to the standards.¹⁰ At the national level Austria, for instance, has set up two public test laboratories for evaluating whether PPE is in line with standards and has introduced temporal rules that have helped national producers of PPE to sell their products to hospitals.

2.2 Case Study 1: Respirators

Masks should help prevent the spread of COVID-19. Basically there are three different types of masks which are of relevance during the pandemic: (i) face masks, (ii) surgical masks and (iii) respirators. Face masks or mouth-nose masks had to be worn on public transport or in supermarkets during most of the first year of the pandemic and can be made from different materials such as cotton or viscose; there are no specific regulations for these masks.

Before COVID-19, surgical masks and respirators were cheap mass products for healthcare workers. While surgical masks are loose fitting and block splashes and droplets, they are designed to protect patients during an operation from germs and viruses disseminated by doctors and nurses. Respirators, on the other hand, have a close facial fit and protect the health workers from infections by patients. This functionality is the reason why respirators experienced the greatest shortage of all mask types during the pandemic. Respirators must have FFP2 (EU) or N95 (US) protection levels (i.e. about 95 % of very small particles are blocked) to effectively shelter health workers when they treat COVID-19 patients. Typically, surgical masks and respirators are disposable products, and the protective effect lasts for several hours only. FFP2 masks, for instance, should be changed every 4 hours. FFP2 masks are not only used by health workers but also by workers who must deal with toxic matter, and in normal times the market for industrial use is much larger than for medical use (Gereffi 2020). According to EU regulation, surgical masks are a medical device and regulated by the norm EN1486, whereas respirators are classified as PPE (because their main function is to protect the wearer) and the norm EN149 applies. In what follows, we focus on respirators with a protection level as defined by FFP2.

The main raw materials for respirators are petroleum oil, metal and paper pulp. The most sophisticated input is electret non-woven fabric (aka meltblown), which provides the filtering functionality of the mask and is made of propylene. Propylene is produced from petroleum oil but new techniques are being tested to use biological waste instead. The respirator is coated with textiles which absorb moisture (inner layer) and protect against splashes (outer layer). Compared to the non-woven fabric, these textiles are low-tech mass products. The layers are put together by ultrasonic welding, nose strips and ear loops are added and the masks are sterilized before they are packaged in cardboard boxes.

The dominant firms in the production of respirators are mainly headquartered in North America (3M (US), Honeywell (US), Presitge Ameritech (US), Moldex (US), Medicom (Canada) or in Asia (Makrite (Taiwan, Chian), Shanghai Dasheng Health Products Manufacture Company (China)).¹¹ For Austria, the German company Dräger is an important producer of masks with production sites in Sweden and South Africa. An interviewee stressed the importance of buying from well-established companies with a

⁹ <https://ec.europa.eu/docsroom/documents/40562>, 04.11.2020.

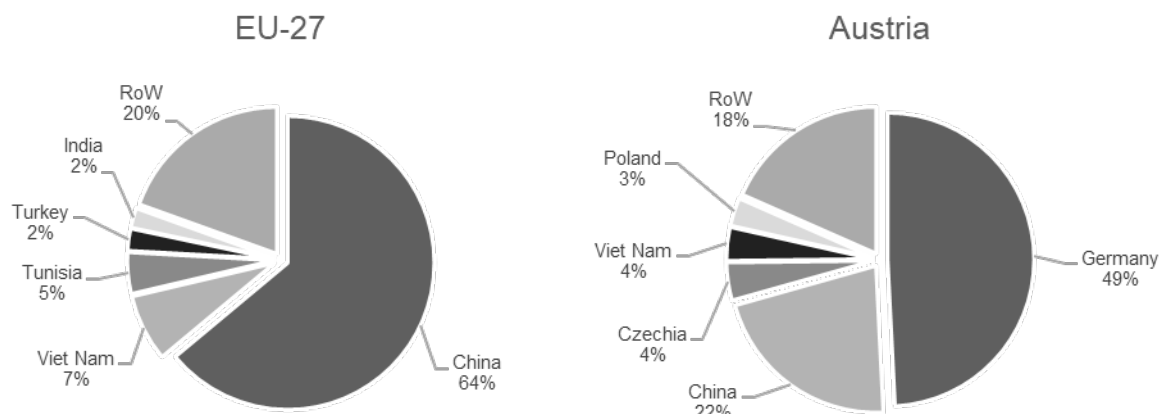
¹⁰ https://ec.europa.eu/commission/presscorner/detail/en/ip_20_522, 04.11.2020.

¹¹ <https://blog.technavio.com/blog/top-10-n95-mask-manufacturers>, 04.11.2020. See also Bamber et al. (2020).

reputation for high quality because testing the masks is difficult and time consuming. Typically, these leading companies have multiple production sites in developed and developing economies, with China being the main hub and producing about 50 % of world output before the pandemic (OECD 2020). Before the pandemic set in, there were several production sites of respirators in Europe and the US but no major ones in Germany and literally none in Austria.¹² For instance, Innovatec, a German firm and the main European producer of meltblown, exported most of its output to mask producers in France, the Netherlands and Turkey.¹³ Meltblown is produced by a limited number of companies in China (45 % of global production), US (15 % of global production) and by the German firms Sandler and Innovatec¹⁴, which has an estimated market share of 50 % in Europe.

Figure 4 shows the origins of European and Austrian imports of masks. Accounting for 64 % of all imports, China is by far the most important source for the EU-27, followed by other low wage countries such as Vietnam or Turkey. No OECD economy is under the top-5 import countries. Austria imports about half of its masks from Germany and 22 % from China directly. Having said this, it is likely that imports from Germany are actually from China (see above). Firstly, German trade data show that China is the dominant import source for masks. Secondly, trade data may mask the actual origin of goods. For instance, if a German company produces its masks in a factory in China and imports these masks, then they are recorded as an import from China. If this company re-exports some of the masks to Austria, then Austrian trade statistics may register them as German imports. Hence, Figure 4 is likely to understate the dependence of Austria on Chinese imports.

Figure 4: EU-27 and Austrian import shares of face masks and respirators, Top 5 importers, 2019



Note: Data include facemasks (excl. paper surgical masks), textile facemasks, without a replaceable filter or mechanical parts, including surgical masks and disposable facemasks made of non-woven textiles. This includes the masks known as N95 Particulate Respirators. HS codes: 6307 90 10, 6307 90 982. Data should be interpreted with caution because the HS codes may include products which are not related to COVID-19.

Source: Eurostat 2020 (DS-1180622)

¹² Generally, it is very difficult to find out where production actually occurs. For different reasons companies refrain from providing this information and buyers also have a quite limited knowledge on this question.

¹³ https://www.handelsblatt.com/unternehmen/mittelstand/familienunternehmer/christian-kloeber-und-daniel-krumme-wie-die-corona-pandemie-den-vliesproduzenten-innovatec-ins-rampenlicht-rueckt/25887850.html?ticket=ST-2231224-szMbY2a154jrkBHyg6fT-ap6_04.11.2020.

¹⁴ https://apnews.com/article/health-global-trade-virus-outbreak-pandemics-fresno-02a0542e8a05176bd5d79757134bc277_04.11.2020.

An evaluation of the vulnerability of a GVC should also consider the production locations of the investment goods because they are critical when it comes to increasing the production potential in periods of crisis (surge capacity). Oerlikon Nonwoven (CH)¹⁵ and Reifenhäuser Recofil (DE)¹⁶ are leading the production of high-technology machines for meltblown. The less sophisticated machines for producing masks are manufactured in countries such as China, France, Germany or the United States (OECD 2020). According to interviews, economies of scale are more important for the production of meltblown than for the manufacturing of respirators.

Vulnerability of the supply chain and political as well as corporate responses

Simply speaking, the main challenge has been the immediate surge in demand in a market that is very stable in normal times. The geographic concentration of production is surely one factor among others increasing the vulnerability of the GVC of respirators. China, the main producer, was the first country affected by COVID-19. As a result, China did three things: It began to import masks from other countries at the beginning of 2020, seized the masks produced in China for domestic use and increased production so that they were able to hike exports of masks by more than 1000 % in the period March-April 2020 as compared to one year before (Fuchs et al. 2020).

The main limitation to the upsurge of production in Asia, Europe and the US was the short supply of non-woven fabric, the critical input for respirators. This bottleneck developed due to the fact that meltblown production lines need specialized, sophisticated and capital-intensive investments, requiring a lead-time of half a year before new production capacity becomes available. It is not possible to repurpose other machinery or 3D-printers to produce meltblown. Several additional factors exacerbated the shortages: (i) export bans, (ii) logistical problems, (iii) shortages of packaging because of company shutdowns in the pulp and paper industry (Asian Development Bank 2020; OECD 2020; Interviews).

Due to the severe shortages, political and corporate actors launched several initiatives that have the potential to fundamentally change the GVC of respirators. Together they are likely to reduce the dependence on imports from Asia, but it is still uncertain how sustainable the new projects are.

The main actions by politicians differed from country to country. In the following, we will mainly concentrate on Europe and Austria. They included (i) export bans, (ii) intensified efforts to procure masks as well as a change in the strategy of public procurement, (iii) subsidies for new production lines of meltblown and masks (in Germany), (iv) regulatory adjustments, (v) quality control and (vi) stockpiling. These actions are of course not unique but can be observed for other PPE and medical devices as well. Yet, due to the severity of the respirator shortages, the government intervened more strongly in the market for respirators. The European Commission provided guidance on regulatory issues, joint procurement of medical products as well as 100 % financing of stockpiles of FFP2 and FFP3 masks (rescEU medical reserve).¹⁷ The shelf life of masks is around 5 years (Interviews).

Several companies, mainly from the textile sector but also newcomers to the market, started to produce face masks in several European countries in the first half of 2020. A non-exclusive list of investment projects in large European economies is as follows: Honeywell invested in a new production line in Scotland; Medicom and Dräger set up new production facilities in France; Mondi, Dräger and other firms launched new production

¹⁵ <https://www.oerlikon.com/manmade-fibers/en/>, 04.11.2020.

¹⁶ <https://www.reicofil.com/en/pages/company>, 04.11.2020.

¹⁷ https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1709, 04.11.2020.

lines in Germany.¹⁸ Innovatec and Sandler have both invested in new production lines for meltblown and in August 2020 Sandler inaugurated a new production line for nonwovens for face masks¹⁹, illustrating the time-lag in setting-up a new meltblown production line. The overall impression suggests that almost every European country has invested in new production capacities without striving for a coordinated European approach. This of course, raises the question of economic sustainability once the pandemic is over. Indeed, Dan Reese, president of Prestige Ameritech, the largest domestic maker of medical N95 respirators in the USA, recalls the H1N1 flu outbreak in 2009/10, when his company increased capacity but ended up near-bankrupt after the pandemic had subsided.²⁰

The main new producers in Austria are Hygiene Austria LP GmbH (a joint venture between the companies Palmers Textil AG and Lenzing AG), Vprotect (an initiative by textile firms from Vorarlberg led by the Grabher Group) and Aventrium, a company with no prior experience in the production of face masks. In addition to respirators according to the CPA standard (CPA stands for “Corona SARS-Cov-2 Pandemie Atemschutzmasken”), they also produce face masks for everyday use of households and firms. Vprotect offers reusable respirators while Hygiene Austria and Ventrion produce single-use masks. Borealis is the only company in Austria that can produce meltblown, although its production capacity is quite limited because the machine used is only suitable for R&D activities and not for mass production. The company Grabher Group has had to import the meltblown from Germany but plans to invest in a meltblown production line. It is unclear whether the companies will be able to compete with Chinese prices once the pandemic is over. Interviews suggest that public procurement needs to adapt to support domestic production, i.e. quality, environmental issues and security of supply concerns should increase public buyers’ willingness to pay. Yet there is some pessimism about this happening. Firstly, the behavior of buying cheap single-use products from China is quite entrenched in cash-strapped public institutions. Secondly, the public buyers refrained from providing any long-term contracts (which would be against European law according to interviewees) to secure the viability of domestic producers also beyond the pandemic. Thirdly, some mask producers complained that they did not receive substantial government contracts so far. Indeed, domestic production was mainly exported to other European countries, while the government seemed to prefer (cheaper) products from Asia, once they were available again.²¹

In line with recommendations from the EU, the Austrian Federal Ministry for Digital and Economic Affairs set up a simplified and accelerated certification procedure for respirators. Certification of a FFP 2 mask according to EN149 would take several months. Hence, the Ministry decreed the introduction of a new category of face masks, namely so-called CPA masks. These masks are subject to a simplified certification process with test values being taken from the EN149 for FFP 2 masks and they receive no CE marking. As a result, CPA masks have similar properties as FFP2 masks but from a legal standpoint cannot be declared as FFP2. The usage of CPA certified masks is restricted to health personal during the pandemic and must be procured by a public institution.²² The US government followed another strategy by granting a waiver of liability for selected companies and products. For

¹⁸ There are some reports on problems with new market entrants regarding quality and delivery time: <https://www.daserste.de/information/wirtschaft-boerse/plusminus/sendung/swr/masken-ausschreibungen-100.html>, 04.11.2020.

¹⁹ <https://www.sandler.de/en/news/details/new-production-line-formally-inaugurated>, 04.11.2020.

²⁰ <https://apnews.com/article/health-global-trade-virus-outbreak-pandemics-fresno-02a0542e8a05176bd5d79757134bc277>, 04.11.2020.

²¹ <https://www.derstandard.at/story/2000120240561/oeffentliche-hand-kauft-schutzmasken-nicht-bei-heimischen-herstellern>, 04.11.2020.

²² https://www.wko.at/branchen/handel/foto-optik-medizinproduktehandel/NEU_Infoblatt-med.-Schutzausruestung_5.pdf, 04.11.2020.

example, 3M wanted to supply US produced industrial face masks to hospitals but industrial and medical masks are produced according to different standards. Hence, 3M asked the Trump administration for a liability waiver (which was granted by the government) without which the conversion of masks would have been too risky for 3M due to looming lawsuits (Gereffi 2020).

Further regulatory action related to procedures and allowances for the reuse of respirators.²³ In order to evaluate the quality of masks and their suitability for reuse, the government set up two test laboratories, one with the military forces and the other with the Federal Office of Metrology and Surveying. However, these two institutions do not certify respirators, as the private Viennese company OETI is the notified body for PPE in Austria. OETI tested and certified all new respirator models introduced during the pandemic by Austrian companies. The lack of testing facilities for respirators in Austria at the beginning of the crisis (i.e. before the two testing facilities were established) led to a time delay in the development of respirators in the case of one Austrian producer (Interviews). As a result, the company had to resort to the services of the German company DEKRA in the early phase of the pandemic.

2.3 Case Study 2: Examination gloves

About 96 % of all disposable gloves are used in the medical sector; the remainder mainly in the food sector. Medical gloves are disposable and classified as personal protective equipment, i.e. they should protect the wearer from the spread of infection or illness during medical procedures and examinations. Medical gloves are disposable and changed after every treatment or after a specific brief time period (30 min in the case of chemotherapy gloves²⁴). Therefore, large volumes of medical gloves are needed every day in hospitals, clinics and homes for the elderly.²⁵ The shelf life of examination gloves is about three years (Interviews). Three different types of medical gloves can be differentiated: (i) examination gloves, (ii) surgical gloves, and (iii) medical gloves for handling chemotherapy agents (chemotherapy gloves).²⁶ In what follows, we focus on examination gloves, which are the least sophisticated product among the three different types. Basically, the products are considered as homogenous once they receive the certifications and it is very difficult for the producers to differentiate their products. As a result, price sensitivity of buyers is substantial.

Examination gloves are typically certified twice. Firstly, they are certified as a medical device (they are Category I according to the medical device regulation EN455) and secondly they are also certified according to the PPE directive 2016/425.²⁷ Examination gloves can be made of natural rubber latex or synthetic materials (nitrile, vinyl). The latter is important because people can be allergic to natural latex. Most of the examination gloves are made of latex or nitrile, vinyl is less important; the nitril segment displays the highest growth rates (Interviews).

Production of medical gloves is an expanding business with growth rates of about 5-7 % annually (Interviews). Considering the large disparities in glove consumption between developed and emerging economies, high growth rates are likely to persist well into the future. For instance, while approximately 200 gloves are used per capita in Austria or Germany, the respective numbers for China and India are four and one.²⁸

²³ https://www.bmas.de/SharedDocs/Downloads/DE/Thema-Arbeitsschutz/einsatz-schutzmasken-einrichtungen-gesundheitswesen.pdf?__blob=publicationFile, 04.11.2020.

²⁴ <https://www.ons.org/sites/default/files/PPE%20Use%20With%20Hazardous%20Drugs.pdf>, 04.11.2020.

²⁵ According to an estimate from 2016, 150 billion pairs of gloves are produced every year (Bhutta and Santhakumar 2016).

²⁶ <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gloves>, 04.11.2020.

²⁷ https://www.sempermed.com/fileadmin/img/sempermed/pdf_dateien/Sterile_examination_gloves_folder.pdf, 04.11.2020.

²⁸ <https://seekingalpha.com/article/4231751-defensive-growth-opportunities-in-growing-medical-glove-market>, 04.11.2020.

The current structure of the industry emerged in the 1980s when growth dynamics were ignited due to concerns about transmissible diseases in the context of the HIV virus (Bhutta/Santhakumar 2016). High growth rates and intensified price competition propelled the offshoring of production from Europe and the US to South-East Asia. Against this trend, in the 1980s Sempermed invested in a production line for surgical gloves in Wimpasing, Austria. According to interviews, this is the sole remaining manufacturing plant of medical gloves in high-income countries. After this early growth period, a consolidation of the industry set in and the number of companies decreased from about 200 in 1990 to 45 in 2009 and 20-30 in 2020 with just about 8 companies dominating the industry (ibid.; Interviews). Sempermed, while important for the Austrian market, is a relatively small player in the industry.

Depending on the type of examination glove, either latex or petroleum (for vinyl or nitrile) are the main raw materials used in production. In addition, several chemicals such as chlorine gas or calcium nitrate are needed. In the case of latex, the production process proceeds as follows (Bhutta/Santhakumar 2016): (i) latex is mixed with other chemicals; (ii) the former is immersed in the latex solution and (iii) vulcanized under high temperatures; (iv) the gloves are removed from the formers (aka stripping). Because of the intensive use of chemicals and high temperatures, working conditions in the medical glove industry are notorious for occupational accidents and health problems. Cheap labor is vital as the production processes have not changed significantly in the last decades, a lot of workers are required and automation is rather limited. Having said this, economies of scale based on large assembly lines and rising minimum efficient scales of production matter a great deal (Interviews)²⁹. For instance, the factories of the dominant players in the industry have assembly lines of 2 km length and they produce billions of gloves per year.

At the end of the production process, the quality must be tested and medical gloves are sterilized before packaging. Research and Development are of rather low relevance; the main innovations are due to the introduction of new materials. The latest radical innovation in this regard was the launch of nitrile gloves in 2005 by Hartalega, a Malaysian firm and the technological leader in the industry (Interviews).³⁰

Due to dismal working conditions, most of the workers in the Malaysian glove sector (the largest producer in the industry) are migrants from countries such as Indonesia or Bangladesh. There are recurring reports of forced labor in the medical glove industry.³¹ In July 2020, the US Customs and Border Protection barred medical gloves from a Malaysian company due to suspicion of operating with forced labor.³²

The geographical concentration of examination glove production is substantial: About 60 % of global production is in Malaysia. Thailand (ca. 17 % market share), China (ca. 7 %), Indonesia (ca. 5 %) and smaller countries like Sri Lanka or Taiwan are the other main producers (Yazid/Yatim 2014). There are literally no production lines in North America, Japan or Europe. The Sempermed plant in Austria manufactures surgical gloves but not examination gloves. The surge of Malaysia to industry dominance happened in the 1980s as production was offshored to Asia. A number of locational advantages can explain the development of Malaysia as the leading production location: (i) the warm weather reduces energy costs for the vulcanization process; (ii) cheap labor, especially migrant labor (see above); (iii) proximity to rubber tree plantations; (iv) government incentives; (v) after the initial relocation phase in the 1980s, external economies due to the clustering of

²⁹ Yazid/Yatim (2014) report output numbers of gloves per hour per line in the Malaysian rubber glove industry: 1988: 3,000; 2002: 20,000; 2012: 45,000.

³⁰ <https://hartalega.com.my/about-us/>, 04.11.2020.

³¹ <https://edition.cnn.com/2020/09/11/business/malaysia-top-glove-forced-labor-dst-intl-hnk/index.html>, 04.11.2020.

³² <https://www.reuters.com/article/us-malaysia-glove-labour-idUSKCN24U2E3>, 04.11.2020.

glove manufacturers, related suppliers and infrastructure have reinforced the industry dominance of Malaysia.

All major glove producers are from Malaysia. The firms are typically not subsidiaries of lead firms headquartered in the US or the EU, but managed by domestic tycoons and are listed on Asian stock exchanges. Top Glove is the number one in the industry; 18,000 employees produce ca. 25 % of global output and 39 out of its 44 factories are in Malaysia (four in Thailand and one in China). Its production capacity consists of 711 production lines and amounts to about 73 billion gloves per annum. The company is vertically integrated in the sense that it operates latex concentration plants, chemical plants, a glove-former factory and packaging material factories.³³ Hartalega, a Malaysian company, was established in 1988. The company is capable of manufacturing 39 billion gloves a year and is the number two in the industry.³⁴ YTY (founded in 1988 in Malaysia) and Supermax (founded in 1987 in Malaysia) and Kossan (founded in 1979 in Malaysia) are also members of the club of major disposable glove producers. Sempermed operates one plant in Malaysia (Kamunting) since its takeover of Latexx Partners in 2012. A new production line for examination gloves was added in the years 2014-2016.³⁵

Regarding the geography of raw materials, more than 85 % of global rubber is produced in the ASEAN countries, with Thailand and Indonesia accounting for more than 60 %. Malaysia must import roughly 80 % of its latex to produce examination gloves (Daly et al. 2017). The machinery is produced in developed and emerging economies. Some mechanical engineering firms are from Malaysia or China but there are also companies from the US or Europe that produce mechanical parts for the production lines of gloves. For instance, DipTechSystems in Ohio or Faigle in Hard (Austria) produce machines and high-performance plastic parts respectively.³⁶

Figure 5 shows the import shares of gloves to Europe (left panel) and Austria (right panel). The data for Europe reflect the dominance of Asian producers, with Malaysia accounting for 45 % of all imports. Austria imports most of its gloves from Germany and direct imports from Malaysia are only 10 %. There are two explanations for this result: Firstly, the data includes other items in addition to medical gloves because there is no singular HS code for these products. Secondly, and much more important, Austria buys medical gloves from vendors in Germany, which previously imported them from Asia.

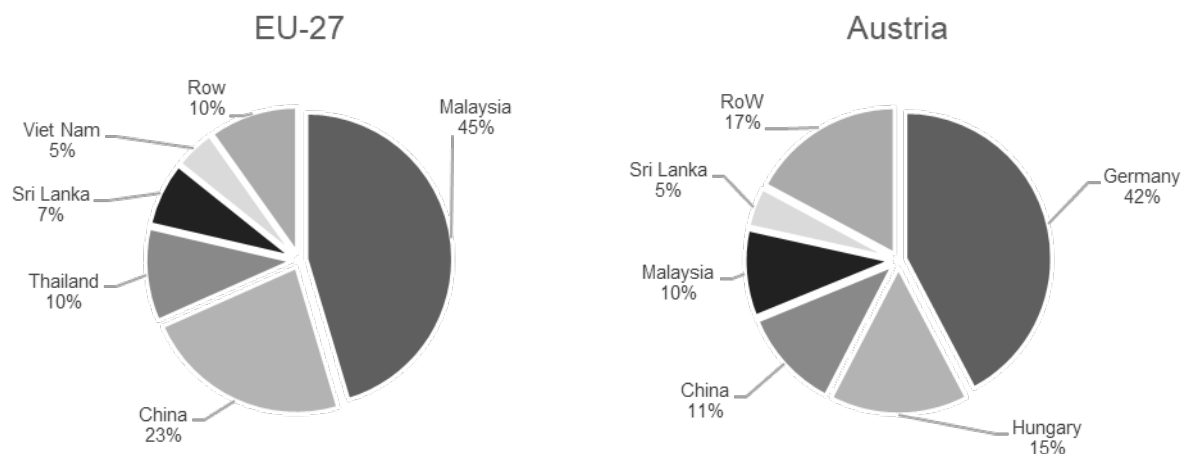
³³ https://www.topglove.com/App_ClientFile/7ff8cb3f-fbf6-42e7-81da-6db6a0ab2ef4/WebEvent/UploadItem/EventDocument/1d49d167-2836-4a93-8210-ff181f26cc64_en.pdf, 04.11.2020.

³⁴ <https://hartalega.com.my/about-us/>, 04.11.2020.

³⁵ [https://www.sempermed.com/news/presseaussendungen/details/?cHash=39a265a5150b5547306a85dbed45a572&tx_ttnews\[tt_news\]=1139](https://www.sempermed.com/news/presseaussendungen/details/?cHash=39a265a5150b5547306a85dbed45a572&tx_ttnews[tt_news]=1139), 04.11.2020.

³⁶ <https://www.faigle.com/en/press/100-million-disposable-medical-gloves-a-day/>, 04.11.2020.

Figure 5: EU-27 and Austrian import shares of gloves, Top 5 importers, 2019



Note: Data include surgical rubber gloves (Code 4015 11 00), other rubber gloves (4015 19 00), knitted or crocheted gloves which have been impregnated or covered with rubber (6116 10 20), textile gloves that are not knitted or crocheted (6216 00 00).

Source: Eurostat 2020 (DS-1180622)

Vulnerability of the supply chain and political as well as corporate responses

Geographical concentration of production in Malaysia represents a substantial cluster risk. If for any reason production in Malaysia collapses, severe shortages will occur on global markets. This finding is further strengthened by a second factor, namely the long lead time of a new production line for medical gloves. Setting up a new production line requires a huge capital investment and a time horizon of 2-4 years. As a result, the surge capacity in periods of crisis is very limited. However, Malaysian firms have overcapacities and they commence production in unused factories during a pandemic and close them once the crisis is over. According to an interviewee, this is also how they reacted during the SARS-epidemic in 2003.

There are no reports on export bans of medical gloves from Malaysia but other parts of the supply chain, such as the packaging suppliers, failed (Interviews). The reason was that shutdowns to prevent the spread of the virus reduced production in several segments of the manufacturing sector in Malaysia, one of the hardest hit countries in Southeast Asia.³⁷ Just-in-time production is a strategic aim of glove producers (Interviews). Yet, except for packaging, inputs were delivered on time.

Demand for gloves increased tremendously due to COVID-19. An infectious disease specialist from the New York University School of Medicine reported that she needed six times more gloves than normal.³⁸ As a result, prices of examination gloves surged during the pandemic. Before that, 1,000 pair of gloves traded for about USD 23 while during the pandemic the price increased to roughly USD 80. New customers must pay even more (up to USD 100-150) (Interviews).

Having said this, there was no comparable shortage of examination gloves as compared to respirators. In Austria for instance, the Austrian Red Cross, which oversaw the procurement of PPE in the early phase of the pandemic, purchased 60 million medical gloves from Sempermed and delivery was made without significant delays. Faigle, the Austrian producer of components for glove-making machines, offered its help to procure examination gloves from China but since no critical shortage existed, policy makers

³⁷ <https://www.reuters.com/article/us-health-coronavirus-malaysia-packaging-idUSKBN21C11W>, 04.11.2020.

³⁸ <https://www.reuters.com/article/us-health-coronavirus-malaysia-packaging-idUSKBN21C11W>, 04.11.2020.

declined the proposal (Interviews). This corroborates the finding of no critical shortages of medical gloves in Austria.

As a result, governments are much less active in the glove market as compared to the mask market. For instance, the only identifiable initiative of the Austrian government was the organization of four flights to transport gloves from the Sempermed production site in Malaysia to Austria.³⁹ There have been no initiatives to relaunch a European production of medical gloves and no investments by firms. There is some discussion about a new production line in the US, but so far no major investment has been announced.⁴⁰ Given that the cluster risk is a result of the geographical concentration of the industry, this complacency is perhaps somewhat surprising.

A possible reason for this passive stance of governments is that industry insiders consider the idea of European production as not being economically viable (Interviews). This assessment is based on the following facts: Firstly, production costs in Europe would be substantially higher due to (i) higher wages, (ii) higher energy costs or capital costs to insulate production facilities so that higher temperatures are possible, (iii) transport costs to import latex from Asia and (iv) stricter environmental and labor regulations. According to one estimate, production costs in Europe would be two times higher than in Asia (Interview). Automation may reduce the difference in production costs between Europe and Asia, but the costs of the investment would still be substantial, and risk-averse investors are unlikely to undertake this investment considering the danger of oversupply after the pandemic (Interviews). Secondly, the market is very price-sensitive and quality competition beyond certification is almost absent. Sempermed, for instance, tried to differentiate its “Green Glove” from competitor products by using more sustainable production methods. Yet, the “Green Glove” has remained a niche product, thereby demonstrating the limited willingness of buyers to pay for additional product characteristics as well as the quality standards set by regulation (Interviews). According to the interviews, absent a substantial change in the purchasing behavior of hospitals and clinics, i.e. a higher willingness to pay, no European production is likely to be set up. This change, however, is deemed rather unlikely and the actions of policy makers are considered as short-lived, lacking long-term commitments such as guaranteed purchases of certain volumes by public institutions. Cost pressure will incentivize public buyers to buy medical gloves from Asia, irrespective of whether European products provide additional benefits (Interviews).

A trader of examination gloves reported a diversification of its supplies as a result of the changing market conditions. Instead of two suppliers, the company buys its products now from eight suppliers (Interviews). A further implication of the COVID-19-crisis was that the scheduled sale of Sempermed was put on hold because of the pandemic. Yet, as of January 2021 the plan is postponed and possibly subject to a review under the new investment control act⁴¹ (Interviews).⁴² As a result, the future of the last production line of medical gloves in Europe and Austria, respectively, is at risk. Yet, it should be stressed once again that this production line does only produce the more expensive surgical gloves. The higher profit margins in this market segment may explain the persistence of this production site in Europe. In addition, the size of the production line is just 200 meters, 10 times smaller than of comparable facilities in Malaysia.

³⁹ https://www.sempermed.com/news/presseaussendungen/details/?tx_ttnews%5Btt_news%5D=2341&cHash=e4c7638c47981ccc0cba0668ac173d0f, 04.11.2020.

⁴⁰ <https://www.rubbernews.com/article/20110819/NEWS/308199993/howe-glove-manufacturing-reappearing-in-u-s>, 04.11.2020.

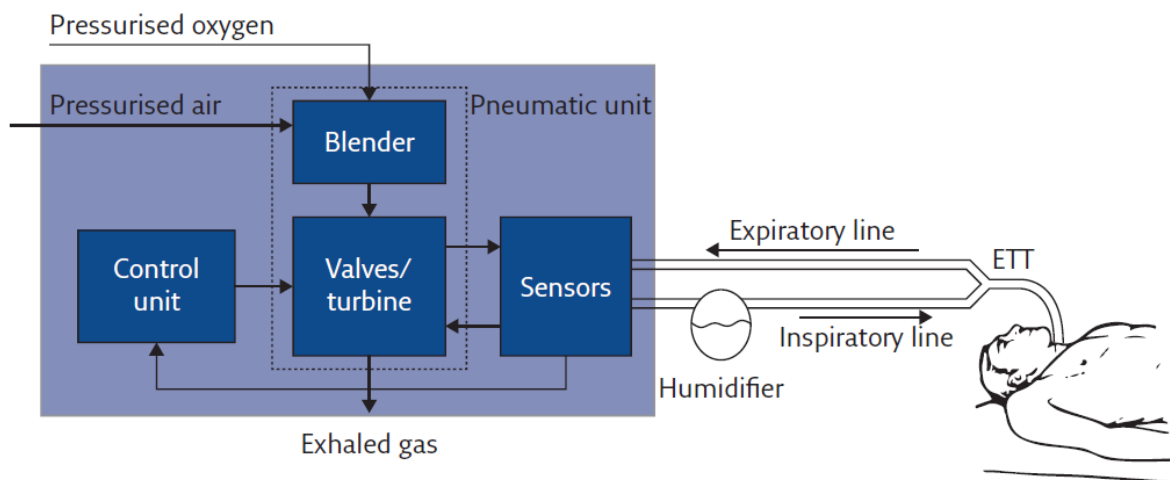
⁴¹ https://trade.ec.europa.eu/doclib/docs/2020/september/tradoc_158955.pdf, 12.01.2021.

⁴² <https://www.sn.at/wirtschaft/oesterreich/staat-koennte-verkauf-der-semperit-medizinsparte-verhindern-91996057>, 12.01.2021.

2.4 Case Study 3: Ventilators

The main function of ventilators is to help ease the task of breathing. According to one estimate at the beginning of the pandemic, 30 % of all hospitalized COVID-19 patients needed ventilation.⁴³ Since their invention in the first half of the twentieth century, ventilators have become increasingly complex and technology-intensive medical devices (Dellaca et al. 2017). Nowadays, a ventilator is made up of about 700 components, including mechanical and electronical devices as well as computer code (Netland 2020). Figure 6 shows a stylized representation of the main elements of a ventilator. In addition to the ventilator, equipment such as ventilator masks or helmets, tubes or filters are needed. These accessories are also medical devices and subject to regulatory oversight (MDCG 2020).

Figure 6: Main elements of a ventilator



Source: Dellaca et al. 2017

Major steps in the development included the use of electronic components in the 1970s and microprocessors in the 1980s. Both enabled the ever more accurate monitoring of the ventilation process and of the health condition of the patient by using sensors. The process of ventilation is intricate due to the danger of ventilation-induced lung injury (VILI), i.e. ventilation must be carefully planned and executed considering the individual situation of the patients (Dellaca et al. 2017).

There are different types of ventilators (MDCG 2020): (i) ventilators for intensive care, (ii) home healthcare ventilators, (iii) ventilators for emergency and transport and (iv) anaesthetic ventilators.⁴⁴ The latter are of relevance to treat COVID-19, and the case study concentrates on this segment. The ventilation process can be either invasive or noninvasive and depending on the chosen option, different equipment is needed. For instance, noninvasive ventilation necessitates a mask or helmet. The sole buyers of ventilators for intensive care units are hospitals.

Since ventilators are designed to prevent respiratory failure, they can mean the difference between life or death. However, in case of malfunction they can be a source of harm and as a result, the regulatory framework provides strict and very detailed norms (93/42/EEC (MDD)) (ibid.). Within the Medical Device Directive (MDD), ventilators fall into Class IIb, the second highest class in terms of risk for patients.

⁴³ <https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-9-impact-of-npis-on-covid-19/>, 04.11.2020.

⁴⁴ <https://www.philips.co.in/healthcare/solutions/ventilation>, 04.11.2020.

Nowadays, ventilators used in hospitals are replaced about every fifteen years. This creates a steady and projectable demand and the market is characterized by low volatility. Even though ventilators are sophisticated products, price sensitivity of buyers is rather high. Over time, the price of a ventilator fell from EUR 50,000 to about EUR 10,000. In the last years the nominal prices have been constant, i.e. falling in real terms (Interview). According to buying agents from hospitals, price competition between producers is intense and the quality of the products is perceived as relatively homogenous (Interviews). Buying decisions by hospitals are based on price (accounting for 60 %) and quality (accounting for 40 %). But given the rather small quality differences, the price is likely to dominate the decision-making process. Until now, reliable delivery has not been included as a criteria in tenders because, before the pandemic, deliveries were on time and delivery time was short (4-6 weeks). While hospitals do usually not buy PPE directly from the producer, they do so in the case of ventilators. Post-sale services are important because repair and maintenance is undertaken by the producer. The operating company of five hospitals in a medium-sized Austrian region buys between 5 and 10 ventilators per year on average; a tender for 30 ventilators is perceived as large.

Considering the very different components of a ventilator, companies from a wide array of industries are supplying components. For some of these suppliers, producing parts for ventilators is just a small niche market. Chip makers, for instance, are important for the sensors but most chips are not produced for medical devices (Interviews). Medical devices need to be manufactured in sterile and clean-room conditions, every producer must be registered with relevant regulators and certified by ISO 13485 (Bamber et al. 2020; Ogrodnik 2020). For instance, there are more than 20 producers of ventilators in China, but only eight are certified to sell their products in Europe.⁴⁵ The different components are produced in a complex chain of suppliers and assembled by lead firms of the ventilator chain such as Dräger or Hamilton. Following Kaplinsky and Morris (2016), the production process follows the model of a vertically specialized value chain: The companies in the GVC concentrate on their core competencies and outsource non-core activities. Different elements of the ventilator can be produced in parallel and are assembled at the final stage. This process shows some similarity to the production of automobiles or cellphones.

Technically, ventilators are not the most complex machinery. But the subtleties of breathing and ventilation require intensive testing procedures of new ventilators and may impede the rapid development of new ventilators by unexperienced companies (Interviews). For instance, the Swedish company Getinge needs around two years to develop a new ventilator model.⁴⁶ The development of ventilators calls for a close cooperation between medical device companies, hospitals and medical doctors as well as the relevant regulatory body. Economies of scale at the level of the lead firms seem to be relevant but not crucial. This is at least one implication of the very different size of producers: Hamilton (15,000 ventilators per year), Getinge (10,000 ventilators per year), Löwenstein Medical (1,500 ventilators per year). Producers of specialized niche products, such as ventilators for surgical operations, can be competitive with just 30 employees.⁴⁷ Digitization of the production process is limited because the number of units produced is rather small.⁴⁸

⁴⁵ <https://www.bloomberqqint.com/global-economics/carmaker-ventilator-plans-are-virus-test-for-global-trade>, 04.11.2020.

⁴⁶ <https://www.bloomberg.com/opinion/articles/2020-04-08/carmaker-ventilator-plans-are-virus-test-for-global-trade>, 04.11.2020.

⁴⁷ See for instance the company Carl Reiner in Vienna: <https://www.carlreiner.at/>, 04.11.2020.

⁴⁸ While a small car producer such as BMW produces about 2.5 Mio. cars per year, the largest manufacturers of ventilators have an output of ca. 10,000 per annum.

Structure and geography

The GVC of ventilators is producer-driven, i.e. the lead firms are the producers who possess the competencies and resources to develop, design, produce and assemble the ventilators. The vertical integration of the companies is limited, as about 80 % of the components are sourced from suppliers (Interview). Lead firms' R&D and in-house production is typically in the same country as the headquarters.

The industry is dominated by three European lead firms, which together account for around 60 % of the global ventilator market (see Table 1). The two leading US companies, Vyaire Medical and General Electrics (GE), have market shares below 5 %, and with the exception of Medtronic there is no other producer from a low wage country. Yet for Austrian hospitals, GE is an important source of supply, perhaps because its ventilators are rather cheap (Interviews). There are no Austrian producers of ventilators, which are typically used in ICU (intensive care unit). But the SME Carl Reiner produces specialized ventilators for surgical operations, which can also be used for intensive care patients with additional equipment (hardware and software) (see below). Regarding suppliers, the company Infineon in Carinthia has announced to produce chips for ventilators as a response to the rising demand during the pandemic.⁴⁹

Table 1: Top 5 firms in the ventilator industry by market share, 2019

Company	Country	Market share (%)
Getinge	Sweden	22
Hamilton	Switzerland	22
Dräger	Germany	16
Mindray	China	10
Medtronic	Ireland	5

Source: <https://www.nzz.ch/wirtschaft/weltweit-hat-es-zu-wenig-beatmungsgeraete-ld.1549108?reduced=true>, 04.11.2020.

The geographical pattern of the lead firms reflects the historical development of the industry, the high relevance of competencies in medicine and engineering as well as the relatively low importance of labor costs. While the lead firms are located in a small number of countries, suppliers are scattered all over the globe and there can be as many as “*nine layers of subcontractors in dozens of different countries*” (Netland 2020). Dräger, for example, sources components from Europe, the US, Asia, Australia and New Zealand.⁵⁰ Yet, sourcing patterns can be intricate if a ventilator producer buys products from, say, a Swiss firm when this firm has its production site in Sri Lanka (Interviews). There are no numbers available to provide an overall picture of the dependence on Asia. Simple components, such as hoses for ventilators, are produced on a fully-automated production line in Switzerland⁵¹ and Chinese producers of ventilators also depend on suppliers from around the world.⁵²

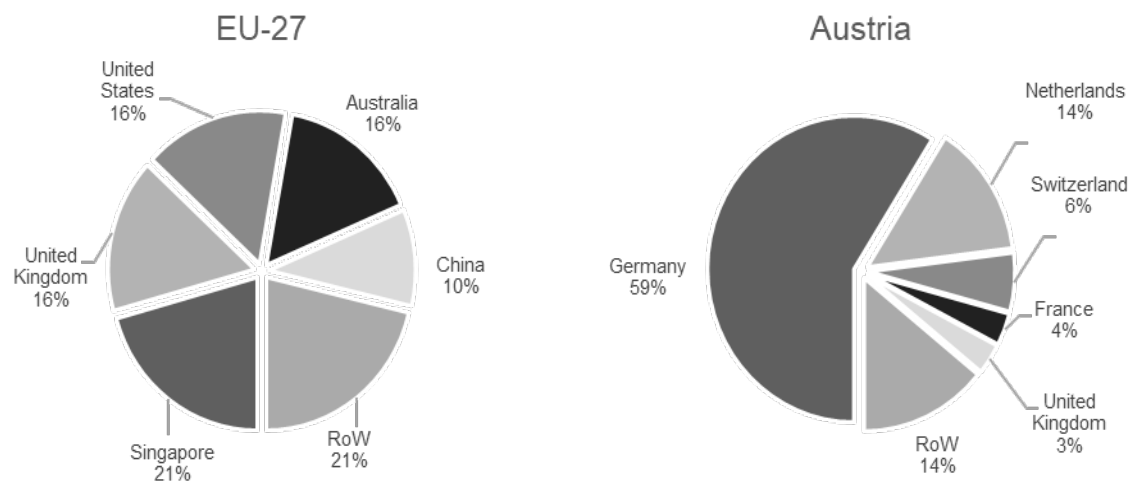
⁴⁹ <https://www.sn.at/wirtschaft/welt/grossauftrag-fuer-infineon-38-millionen-chips-fuer-beatmungsgeraete-85509919>, 04.11.2020.

⁵⁰ <https://www.ft.com/content/2f2845b3-a1ed-44cb-90af-e04d8d712403>, 04.11.2020.

⁵¹ <https://www.nzz.ch/wirtschaft/weltweit-hat-es-zu-wenig-beatmungsgeraete-ld.1549108?reduced=true>, 04.11.2020.

⁵² <https://www.nzz.ch/wirtschaft/beatmungsgeraete-made-in-china-fuer-europa-ld.1550951?reduced=true>, 04.11.2020.

Figure 7: EU-27 and Austrian import shares of ventilators, Top 5 importers, 2019



Note: Oxygen therapy equipment and pulse oximeters: Respirators for intensive and sub-intensive care, medical ventilators (artificial respiration apparatus), oxygen tents (HS code 9019 20 00).

Source: Eurostat 2020 (DS-1180622)

Figure 7 shows imports to the EU-27 and Austria. Since the main producers are in Europe, the overall import dependence should be limited. More than 50 % of the imports are from Singapore, UK or the US; China is the only low-wage country among the top-5 importers. Austria's imports are dominated by Germany and the Netherlands⁵³; there are no substantial trading relationships with low-wage countries.

Vulnerability of the supply chain and political as well as corporate responses

According to estimates of the Society of Critical Care Medicine, the US needs about 960,000 ventilators but only 200,000 are available to treat COVID-19 patients.⁵⁴ The NHS estimated an additional need of 30,000 ventilators; the same number was stated by the Governor of New York (Azmeah 2020). To put this last number into perspective, it is useful to consider the following: In 2019, the global annual production of ventilators for ICU amounted to about 50,000; the largest producers had an annual output of around 10,000 units.⁵⁵ In the early phase of the spread of COVID-19, the German government ordered 10,000 ventilators from Dräger, the annual output of the company. Delivery times of ventilators increased from 2 weeks to 8-12 weeks or even longer, depending on the situation in the country. The producers of ventilators prioritized orders from countries with a higher incidence of COVID-19 (Interview).

But the early projections turned out to be overestimates of actual needs. One of the main factors which explains the reduced need of ventilators is a change in the treatment of COVID-19 patients. At the start of the pandemic, patients received invasive ventilation relatively early. New insights showed that it is better to avoid intubation as long as possible and use other, less invasive techniques to help people breathe (Interview). These new ways of treatment reduced the demand for ventilators substantially. Indeed, in April 2020 the UK government ordered several industry consortia, which had started to manufacture ventilators to stop production, because there were stockpiles of unused ventilators.⁵⁶

⁵³ Philips Respironics, another ventilator producer, is from the Netherlands. This may explain some of the 14% import share of the Netherlands with Austria.

⁵⁴ <https://www.bloomberg.com/opinion/articles/2020-04-08/carmaker-ventilator-plans-are-virus-test-for-global-trade>, 04.11.2020.

⁵⁵ <https://www.nzz.ch/wirtschaft/weltweit-hat-es-zu-wenig-beatmungsgeraete-ld.1549108?reduced=true>, 04.11.2020.

⁵⁶ <https://www.theguardian.com/business/2020/apr/27/uk-to-halt-several-ventilator-projects-after-fall-in-demand>, 04.11.2020.

An analysis of the structure of the ventilator GVC suggests a low dependence of Europe on foreign lead firms, since the major firms are European firms and they all have their major production sites in Europe. In times of crises, this can be considered an advantage from a European perspective: Know-how and productive capabilities are available within the borders of the EU-27. Yet the surge capacity of the ventilator producers is limited because automation is low and hiring workers with the relevant skills with 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 (Azmeah 2020).

In the case of Austria, having no national notified body for the certification of medical devices presents a further weakness. Before 2016, the TU Graz and the TÜV Austria fulfilled this important systemic function. They were however closed due to the higher demands on notified bodies demanded by the new Medical Device Regulation (MDR 2017/745). Instead of upgrading the existing notified bodies, policy makers decided to shut them down. Since then, Austrian medical device companies must consult firms from other EU countries for certification. But, during a crisis, small Austrian firms may be treated differently by notified bodies in foreign countries than large domestic producers, and the national response to a pandemic is may be less proactive than what would be possible if a national notified body were in place. Fortunately, the foundation of a new notified body in Austria under the umbrella of Quality Austria is underway (Interviews).

Just-in-time production and single sourcing are further sources of vulnerability. There are several components which are produced by just one supplier. The reason for this is a combination of the small size of the industry and the high degree of specialization of certain elements. In addition, all the major producers of ventilators source selected critical inputs (e.g. chips for the sensors) from the same single 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. Because of the high specialization and the need to source products from certified producers, switching to alternative suppliers in the short run was impossible. A further specialized component with only a handful of suppliers are oxygen membranes needed for mechanical ventilation.⁵⁷

National governments and the EU reacted to the ventilator shortage in the following ways: (i) regulatory adjustments to speed up the production of ventilators (for the certification of new ventilators as well as of spare parts produced by 3-D printing); (ii) coordinating and motivating the building of industry consortia; (iii) diplomacy to prevent exports bans of critical components and (iv) stockpiling.

Hospitals tried to increase their capacity by stockpiling old ventilators which would be discarded under normal circumstances. One Austrian hospital signed a lease agreement with a private company for home healthcare ventilators which are needed after the patient leaves the ICU. In case of very scarce ventilator capacities (such as in Northern Italy or New York), several hospitals started to use one ventilator for two patients. But producers such as Hamilton declined to support this strategy: *“As a medical device manufacturer, Hamilton Medical assumes an extremely high level of responsibility for patient and user safety. Their safety can only be guaranteed when the devices are used as intended, i.e., one patient per device. Non-intended usage of our ventilators for multiple patients may lead to unpredictable complications.”*⁵⁸

The surge capacity of ventilator production was provided by three different sources: Firstly, ventilator producers increased their production. For example, the Swedish company Getinge has increased its production capacity by 160 % compared to 2019.⁵⁹ Secondly,

⁵⁷ <https://www.bloombergquint.com/global-economics/carmaker-ventilator-plans-are-virus-test-for-global-trade>, 04.11.2020.

⁵⁸ https://www.hamilton-medical.com/de_AT/E-Learning-and-Education/Knowledge-Base/Knowledge-Base-Detail~2020-04-09~Using-one-ventilator-for-multiple-patients~34aeb5b0-a67f-4c4a-aec3-a4dbdd16a2c2~.html, 04.11.2020.

⁵⁹ <https://news.getinge.com/us/getinge-to-further-increase-production-capacity-of-ventilators-in-2020>, 04.11.2020.

ventilator companies cooperated with firms from other branches and the military to shore up the ventilator market. Automobile firms in particular participated in these industry consortia, with the most famous project being the so-called “VentilatorChallenge” in the UK. After initial problems, a group of diverse firms such as Airbus, Ford, Microsoft, Rolls-Royce and two medical device companies successfully supplied almost 13,500 ventilators to the NHS from 19.3.2020-5.7.2020. The consortium produced already established and certified ventilator models and sourced their inputs from 22 different countries.⁶⁰ In Italy, Siare Engineering International Group, the only national ventilator company, joined forces with the military to produce 2,000 ventilators in four months; the normal output would be 640 units.⁶¹ This project also succeeded in achieving the target set by the government.⁶²

The third way to accelerate ventilator production was undertaken by industry newcomers with a background in engineering as well as technical universities. Compared to the machines produced by the ventilator companies, the new models have fewer functions and the technique is simplified. They are best thought of as low-cost emergency ventilators, i.e. they are designed for periods such as the COVID-19 pandemic. For instance, the ETH Zurich developed such an emergency ventilator based on an open source project from the MIT. With Swiss government support, it is planned to produce the ventilator in the Ukraine and to export it to other developing countries.⁶³

In Austria there were two noteworthy projects. Firstly, the company Carl Reiner redeveloped its specialized ventilators for use in intensive care units. Being in the business of ventilation for decades, the company was able to adapt its machines with software and hardware elements within several weeks. In addition, there was no need for new regulatory procedures as the company already possesses all the necessary certificates. However, after having developed the upgrade in part because governments urged the company to do so, no public buyer has so far placed any orders with the company (as of October 2020).

Secondly, the company Hage, a producer of special-purpose machines with no prior experience in the field of medical devices, developed an emergency ventilator with 3-D printing technologies. Together with the Medical University Graz, Hage developed a prototype but did not receive the necessary certificates. The lack of a notified body in Austria aggravated the difficulties in this process (see above). However, it would have been possible to set up an accelerated procedure in line with EU regulation.⁶⁴ But the relevant authority in Austria (AGES) did not exploit this legal option and so the project ended without a marketable product. Currently, the TU Graz is further developing the ventilator and seeks to obtain a certificate in the next years.

Compared to countries such as Switzerland or the Netherlands⁶⁵, the performance of the public sector in Austria in supporting the surge capacity of ventilator production is regarded as somewhat disappointing by several interviewees.

⁶⁰ <https://www.ventilatorchallengeuk.com/>, 04.11.2020.

⁶¹ <https://www.reuters.com/news/picture/army-joins-the-production-line-as-ventil-idUSKBN2180JU>, 04.11.2020.

⁶² <http://www.siare.it/en/covid-19-lung-ventilators/>, 04.11.2020.

⁶³ <https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-79668.html>, 04.11.2020.

⁶⁴ <https://www.dekra.co.jp/en/press-local-1664/>, 04.11.2020.

⁶⁵ <https://osf.io/mn7xq/>, 04.11.2020.

2.5 Conclusions and Policy Recommendations

The GVC of the three products exhibits pronounced differences in terms of governance and geography (see Table 2). Hence, the prospects for reshoring are also diverse. Regarding face masks, reshoring processes have already occurred during the early phase of the pandemic. To be more precise, this development does not reflect reshoring in a narrow sense but instead the investment in additional production capacities in the EU and the US without reducing production in countries such as China. As a result, the global production potential of face masks has increased significantly. Several months after the outbreak of COVID-19, Austria has three mask producers and a machine to manufacture meltblown, while having none of these in the last decades. The question is whether the new producers have a sustainable business model for the time after COVID-19 as well. Indeed, the danger of oversupply and tough price competition is real, and the activities of some new domestic mask companies may be rather short-lived.

Gloves are rather unlikely to be reshored, despite the cluster risk due to their concentration in essentially one country, namely Malaysia. Much higher labor and energy costs, lack of raw materials such as latex, tighter environmental regulation and very high upfront costs are all factors, which inhibit investment in new glove production sites in Europe. Indeed, there has been no public discussion about the option of European glove production and policy makers did not provide any incentive to support such plans. In such instances, strategic stockpiling is likely the most effective policy to increase supply security.

While suppliers are scattered all over the planet, leading ventilator producers are concentrated in Europe. Hence, reshoring is not really a suitable strategy, at least for the industry as a whole and from a European perspective. The main vulnerability seems to be due to single sourcing and this problem stems from the high specialization and relatively low volumes of output. Incentivizing ventilator firms to diversify away from single suppliers and stress testing the entire GVC are perhaps more reliable strategies. Concerning stockpiling, all three products are suitable (their respective shelf life last for several years) and there were initiatives at the national and EU level to build up strategic reserves. In addition, the Austrian Federal Procurement Agency (BBG) has contracted firms whose inventory is either in Austria or in neighboring countries. This should reduce the danger of being cut off from supplies due to export bans or other measures from foreign countries.

In addition to national production and stockpiling of specific goods, more systemic policy recommendations are as follows: (i) Set-up national laboratories and notified bodies to accelerate the market entry of new producers, products and spare parts in case of emergency. These facilities are also essential for evaluating the quality of foreign supplies. (ii) Centralize procurement of the health sector. This would have two advantages: Firstly, during a pandemic a more coordinated approach would be followed and price competition between domestic institutions reduced. Secondly, larger buyers might find it easier to integrate strategic elements in their purchasing behavior (such as environmental issues, reliable delivery, etc.). (iii) The surge capacity of an economy also depends on a diverse manufacturing sector, capable of producing different elements according to complex specifications, and its cooperation with technical and medical universities. Digital technologies (3-D printing) in combination with mechanical engineering form a powerful combination to shore up production in a wide array of product categories. This is important as the next crisis may require quite different solutions than COVID-19.

Table 2: Indicative assessment and summary of supply chain vulnerabilities of selected medical products⁺

	Respirators	Examination gloves	Ventilators
Degree of EU import-dependency	**	***	*/**
Degree of regional diversification (incl. substitutes)	*/**	*	**
Complexity of the supply chain	*/**	*	***
Likelihood of supply shortages for critical inputs (in <i>normal</i> times)	*	*	*
Key bottlenecks	<p>The main limitation to the upsurge of production in Asia, Europe and the US was the short supply of non-woven fabric, the critical input for respirators</p> <p>Lack of testing facilities for respirators in Austria at the beginning of the crisis</p> <p>Export bans and logistical problems</p> <p>Shortages of packaging because of company shutdowns in the pulp and paper industry</p>	<p>Geographical concentration of production in Malaysia represents a substantial cluster risk</p> <p>There are literally no production lines of examination gloves in Europe</p> <p>Setting up a new production line requires a huge capital investment and a time horizon of 2-4 years. As a result, the surge capacity in periods of crisis is very limited.</p>	<p>Surge capacity of the ventilator producers is limited because automation is low and hiring workers with the relevant skills with short notice is not an easy task</p> <p>The strict regulatory framework as well as the complexities of ventilators create barriers to entry for new, inexperienced producers</p> <p>Lack of a notified body for the certification of medical devices in Austria</p> <p>Just-in-time production and single sourcing</p>

+ Except for the likelihood of supply shortages, the evaluation refers to developments during the first wave of COVID-19. Since then, several changes occurred. For instance, the import dependency regarding respirators was reduced and European production capacities for non-woven fabric were installed. As a result, the supply chain vulnerability of respirators is now lower as compared to the beginning of the pandemic in early 2020. Yet, it remains an open question whether the new European production lines for respirators will remain economically viable once the pandemic is over.

Note: Indicative assessment based on expert-interviews: * = low, ** = medium, *** high.

Source: Own elaboration

3 PHARMACEUTICAL PRODUCTS

The COVID-19 pandemic has highlighted the fragility and vulnerabilities of the pharmaceutical supply chain. At the end of March 2020, the European University Hospital Alliance warned that hospitals are rapidly running out of essential drugs for COVID-19 patients, in particular drugs necessary to treat intensive care patients, including muscle relaxants, sedatives and pain-killing drugs (EUHA 2020). The threat of shortages at the time were related to the lack of sufficient stocks as well as to export-bans within and outside the EU. As a result, the European Commission issued guidelines to tackle these shortages, calling to lift export-bans and avoid national stockpiling, increase and reorganize production, ensure optimal use in hospitals, consider alternative medicines, optimize sales in pharmacies, and more (EC 2020a). In addition, the export bans implemented by a major global supplier of medicines, India, were lifted soon after their enactment following international pressure from the US and other buyers.⁶⁶

Apart from the at least partially overwhelmed health systems and hospitals during the initial outbreak in early 2020, COVID-19-induced drug shortages in the EU were (so far) relatively rare. Instead, COVID-19 highlighted an already known problem: drug shortages in the EU are not a new phenomenon, and have become more frequent in the last decade(s). Already in 2017, the European Parliament has addressed the problems of medicine shortages in the EU.⁶⁷ According to a recent report prepared by the European Parliament's Committee on the Environment, Public Health and Food Safety, it is estimated that the number of shortages increased 20-fold between 2000 and 2018, and has increased 12-fold since 2008 (EP 2020a). In addition, a new OECD study on shortage notifications in 14 OECD countries between 2017 and 2019 showed that the number of notifications of expected or actual shortages increased by more than 60 % (OECD forthcoming). The drugs affected by these shortages include a large variety of products (esp. cancer treatments, antibiotics, vaccines, anesthetics and medication for hypertension, heart disease and disorders of the nervous system), which is why the reasons for these shortages also differ and may include manufacturing problems, quality issues, unexpected spikes in demand, parallel imports/exports and more (EP 2020a). However, it is now increasingly acknowledged that the increasing consolidation of the industry and outsourcing processes in the last decades, in particular with regard to low-value generic products, has added to the problem (Council of the EU 2019; EP 2020a).

In the following report, the structure and dynamics of the pharmaceutical GVC are discussed in order to highlight key reasons for the increasing supply chain vulnerabilities. Further, three product-specific GVCs are analyzed: (i) penicillin (antibiotic), (ii) paracetamol (analgesic), and (iii) heparin (anticoagulant). The analysis of product-specific GVCs underlines the importance to assess product-specific supply chain vulnerabilities and potentials for increasing their resilience. The section concludes by presenting a comparative analysis and policy recommendations.

⁶⁶ <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/govt-lifts-curbs-on-exports-of-formulations-made-from-paracetamol/articleshow/75196205.cms>, 04.11.2020

⁶⁷ https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html, 04.11.2020

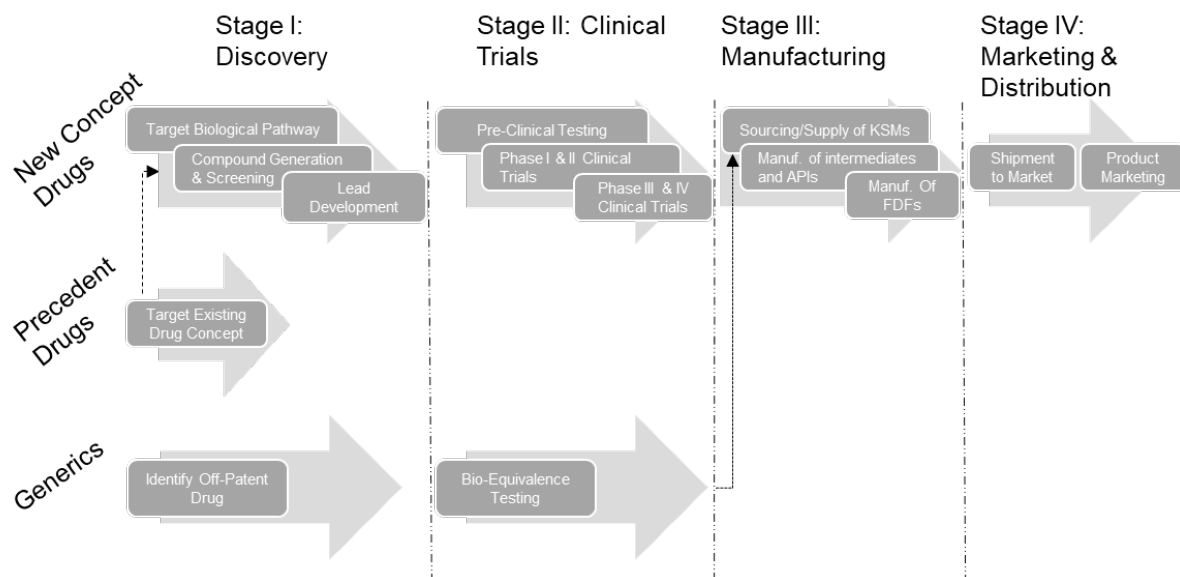
3.1 The Global Value Chain of Pharmaceutical Products

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, 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).

Within the pharmaceutical GVC, three types of drugs with different development paths can be distinguished (Figure 8): new concept, precedent, and generic/biosimilar drugs (Kedron/Bagchi-Sen 2012: 817; Wadhwa et al. 2008: 6). The former two are associated with branded products and pursued by originator manufacturers. New concept development represents a first attempt to treat chemical and biological reactions that cure diseases and is associated with the highest cost. Precedent development builds on existing drug concepts and requires less innovation and thus investments (Kedron/Bagchi-Sen 2012: 817). The generic development path – regardless if low or high-quality generics are produced – skips the first two stages of product development and is associated with the lowest cost (ibid.).

The current structure and dynamics of the pharmaceutical GVC need to be understood from a historical perspective. The pharmaceutical industry is a comparatively young industry and emerged as a research and development intensive manufacturing industry only during the second half of the 20th century building on new discoveries during and after the Second World War (Breitenbach/Fischer 2013: 6; Haakonsson 2009). Since then, the complexity and number of actors involved in the pharmaceutical GVC increased significantly (Zeller/Van-Hametner 2018: 535).

Figure 8: Three development paths of pharmaceutical products



Source: Own elaboration based on Kedron/Bagchi-Sen 2012: 818

From the beginning of the 1950s until the mid-1990s, the pharmaceutical industry quickly internationalized and became dominated by large and vertically integrated transnational corporations (TNCs) specialized on specific product types or diseases, based on different patent-portfolios (Haakonsson 2009). During this period, many TNCs also set up offshore subsidiaries in order to facilitate market access to (semi-)peripheral countries, sometimes

creating spillover effects that promoted the growth of domestic pharmaceutical industries based on counterfeited products and product imitation, respectively, a practice that often was in accordance with national law (for example in India, see Chaudhuri 2005; Sahu 2014). As a result, until the 1990s the pharmaceutical industry was characterized by two different types of value chains: a producer-driven and innovation-based GVC linked to the global core countries, and nationally organized value chains copying low-value pharmaceuticals for (semi-)peripheral countries (Haakonsson 2009).

Since the 1990s, a variety of processes led to increased internationalization, concentration and financialization of the pharmaceutical industry (*ibid.*; Zeller et al. 2014). The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement) and the establishment of the World Trade Organization (WTO) in 1995, resulting in the global harmonization of minimal requirements for protecting Intellectual Property Rights (IPRs), were key pillars for the further global expansion of pharmaceutical TNCs (Haakonsson 2009). In addition, the non-binding Pharmaceutical Tariff Elimination Agreement was reached in 1995 among the 22 most important pharmaceutical producer countries, most importantly EU member states, the US and Switzerland. The agreement has led to an elimination of tariffs on thousands of pharmaceutical intermediates, APIs and products (Helble 2012).

In parallel to the changing international regulatory environment, the pharmaceutical industry underwent a process of financialization entailing a radical shift in the business models of big pharma companies in the last two decades. Investments in financial activities and takeovers increased, and fewer resources were geared towards the means of production and product innovation. This resulted in a shareholder value orientation and higher levels of indebtedness of big pharma companies, rendering their business model dependent on capital markets and making them more vulnerable during economic crises (Busfield 2020; Fernandez/Klinge 2020; Montalban/Sakinç 2013).

The financialization processes and changing international regulatory framework furthered outsourcing and/or offshoring strategies and initiated a wave of mergers and acquisitions (M&As) of TNCs. M&As allowed TNCs to increase their economies of scale and scope in the context of high R&D costs, expand to new markets, and extend their expertise to new areas. The concentration further increased with a shift of the technology regime in the context of new research breakthroughs in the fields of biotechnology, “drug designs”, amongst others. In this context, large TNCs shifted their strategy and opened up to cooperation with innovative smaller biotech firms that in turn aim to benefit from strong global brands, marketing and distribution networks.

Outsourcing and offshoring processes particularly increased following the TRIPs agreement, the latter reducing the risk of lacking patent protections, but were also driven by the circumvention of national regulations and the decentralization of R&D (Haakonsson 2009). International competition and related pressure on prices and margins was particularly pronounced in the case of generics, furthering outsourcing and consolidation processes for these type of products. In addition, lower regulatory requirements (e.g. regarding environmental pollution) and governmental support for pharmaceutical manufacturers in the global (semi-)periphery were driving these processes (esp. in China and India). Large pharmaceutical TNCs also adjusted their strategies through increasingly relying on contract manufacturing for off-patent APIs and the outsourcing of clinical studies to specialized clinical research organizations (CROs) (*ibid.*).

As a result, the pharmaceutical GVC today is characterized by three different strands (Figure 9): (i) a **producer-driven GVC⁶⁸ for branded products**, 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), (ii) a **buyer-driven GVC⁶⁹ for quality generics**, (iii) and a “**non-driven**” (global) value chain dominated by national companies **for low-value generics** (ibid.).

Figure 9: A typology of pharmaceutical GVCs

		Branded products	Quality generics	Low-value generics
Parameters for differentiation of the three strands	End-markets	Industrial countries High income groups e.g. in India, China	Industrial countries Middle class groups in developing countries	Developing countries Government tenders Sub-Saharan Africa
	Products	Patented and global blockbusters	Life-style diseases Branded generics	Antiinfective, off-patent, tropical diseases
	Producers	Vertically integrated, research, marketing- intensive companies in Europe and US	Outsourcing by R&D and marketing intensive companies to low-cost production sites	Developing country- based companies, (some outsourcing within the strand)
	Research and development	In-house product development, some in- sourcing from biotech companies	In-house or outsourced process development, contract research	Some process development, and development of fixed- dose combinations
	Governance and entry barriers	Producer-driven Entry barriers: cost of R&D and marketing	Buyer-driven Entry barriers: international approvals	Not driven Entry barriers: price and WHO-quality

Source: Haakonsson 2009: 83

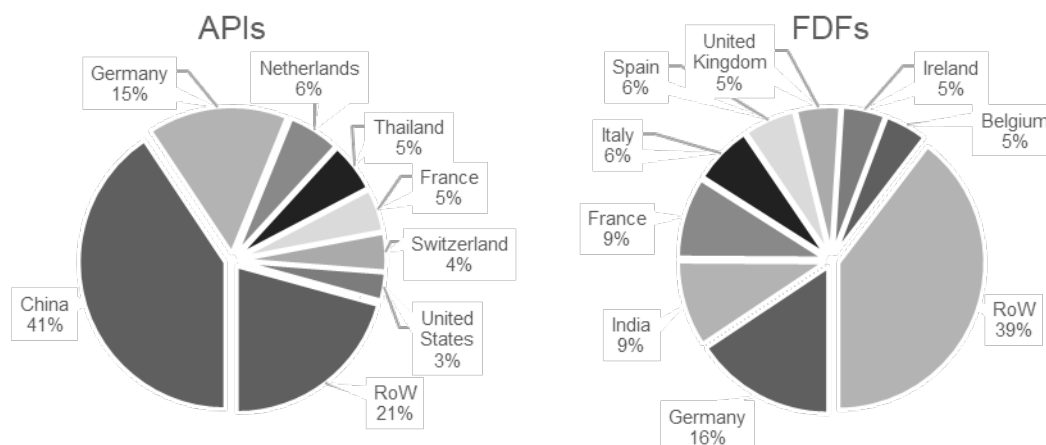
Geography and trade interdependencies

The growth and globalization of the pharmaceutical GVC and the particular importance of branded products in terms of value is also reflected in trade data. The global trade value of FDF pharmaceutical products (HS Code 3004) increased almost by a factor of 10 in the last three decades, from USD 39.4 billion in 1995 to USD 352.9 billion in 2019 (UN Comtrade 2020). Various EU countries (Figure 10) remain key players in the production and export of high-value on-patent APIs and FDFs, which is why the EU is generating a significant trade-surplus against the rest of the world. In addition, one third of global FDF pharmaceutical trade constitutes intra-EU trade. In contrast, the US is the major global importer of pharmaceuticals.

⁶⁸ Large (transnational) manufacturers dominating the coordination of production networks characterize producer-driven commodity chains (Gereffi 1994, 1995).

⁶⁹ A buyer-driven value chain is characterized by decentralized, globally dispersed production networks, coordinated by lead firms, which control activities that add “value” to products (e.g. design, branding), but often outsource all or most of the manufacturing process to a global network of suppliers (Gereffi 1994, 1995).

Figure 10: Global trade shares of APIs and FDFs by volume (2019)



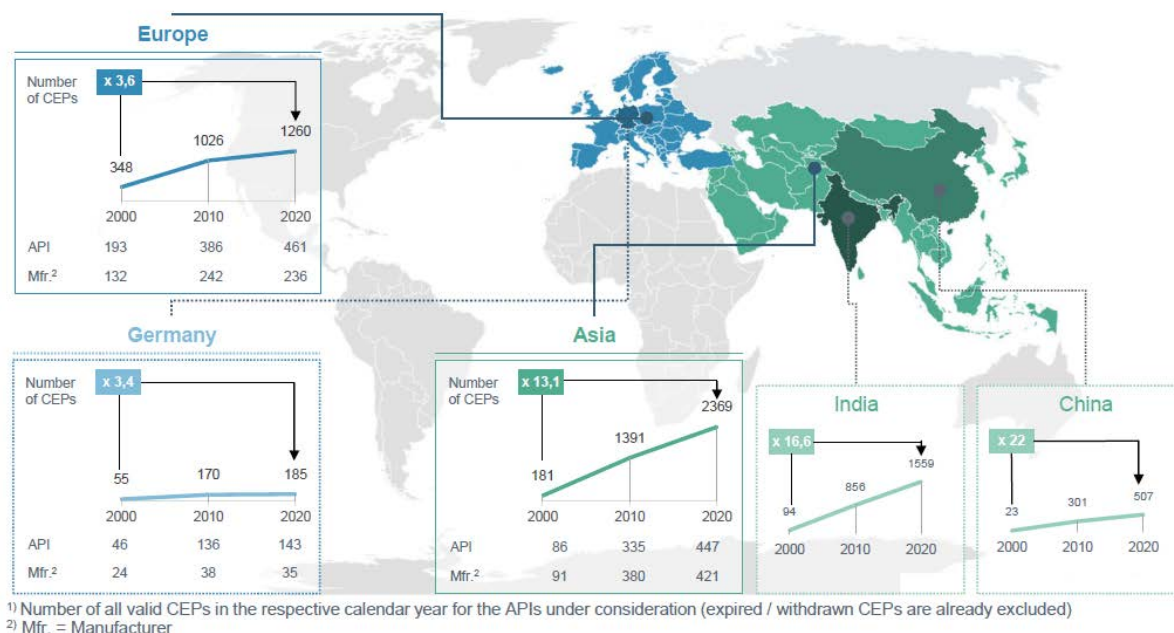
Notes: Including intra-EU-trade.

Source: UN Comtrade 2020 (WITS)

The increasing and crucial role of China and India for the pharmaceutical generics GVC is also reflected in the trade data, in particular since the mid-2000s. Today, China is the key global source of APIs for the global pharmaceutical industry. The trade value of these inputs amounts to USD 39.4 billion in 2019 and globally more than 40 % of these inputs by volume are sourced from China (HS codes 2936 to 2941) (Figure 10). Similarly, India is a key global supplier of low-value-generics and accounts for 9 % of global exports of dosified medicines in terms of volume (compared to 4% in value terms, in 2019) (Figure 10). Excluding intra-EU trade, India's share by volume increases to 22%, highlighting its dominant position in low-value generics trade (ibid.).

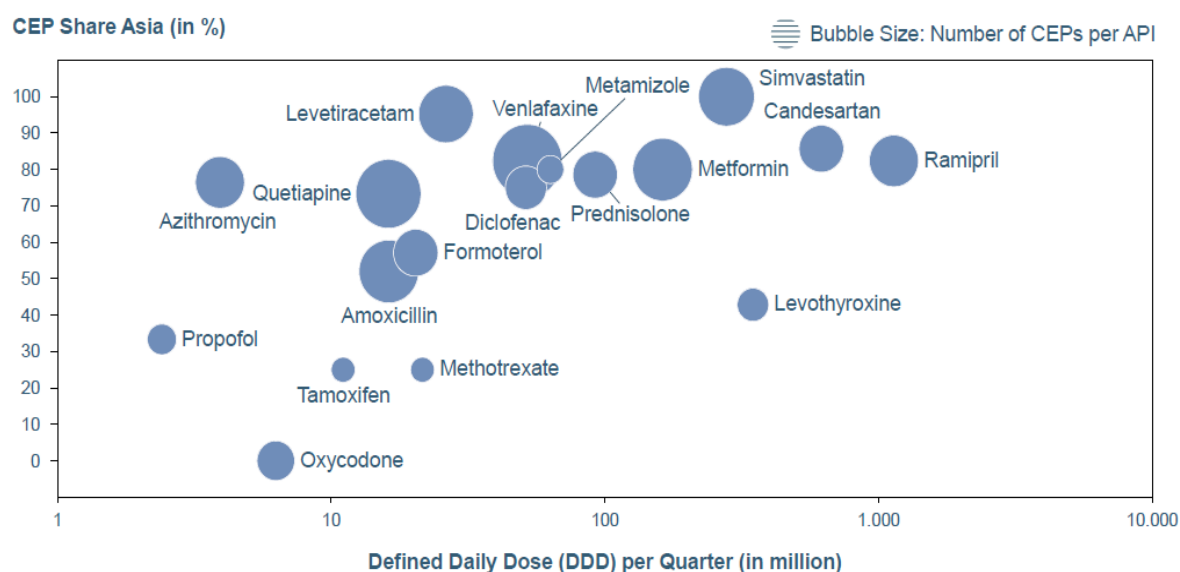
The growing importance of China and India as key global suppliers of APIs and FDFs in the generics pharmaceutical GVC also resulted in a changing and reduced role of the EU in pharmaceutical manufacturing. This change is reflected in the growing number of APIs with a Certificate of Suitability of Monographs of the European Pharmacopoeia (CEP), which complies with European regulatory requirements, in Asia from 181 in the year 2000 to 2,369 in 2020 (Figure 11). In Europe, the number of CEPs only increased from 348 to 1,260 during the same period. Similarly, the number of manufacturers increased from 91 to 421 in Asia, and only from 132 to 236 in Europe. In general, the share of Asian CEP holders for APIs increases with the production volume of APIs (Figure 12). In addition, global production of APIs is regionally highly concentrated in a few Indian and Chinese provinces (esp. Telangana, Maharashtra, Zhejiang, Jiangsu, Shandong) and industrial parks (cf. MundiCare 2020). Furthermore, there are only a few CEPs – and therefore manufacturers – worldwide for more than half of APIs (Figure 13), adding to potential supply bottlenecks. In light of the increasing enforcement of environmental regulations, labor regulations regarding working conditions, and increasing wages, in particular in China, outsourcing of pharmaceutical production to countries like Vietnam, Malaysia, Mongolia and Indonesia has started or is currently in consideration (Interviews).

Figure 11: Overview of CEPs, APIs, and manufacturers by region (2000-2020)



Source: MundiCare 2020

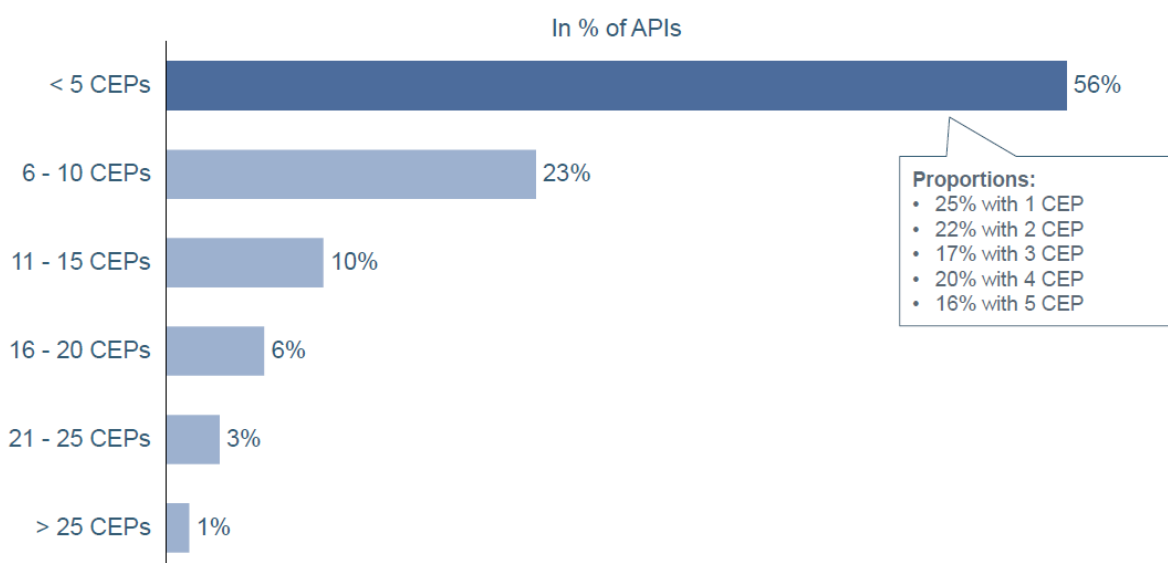
Figure 12: CEP share in Asia in relation to defined daily doses for selected APIs (2020)



¹) Number of all valid CEPs in the respective calendar year for the APIs under consideration (expired / withdrawn CEPs are already excluded)
²) API sample selected by defined daily dose Q4 2019 > 1 million DDD in retail (exclusion of: Piperacillin, Benserazide, Levodopa); n = 18

Source: MundiCare 2020

Figure 13: Overview share of APIs per group “CEPs per API” worldwide (2020)

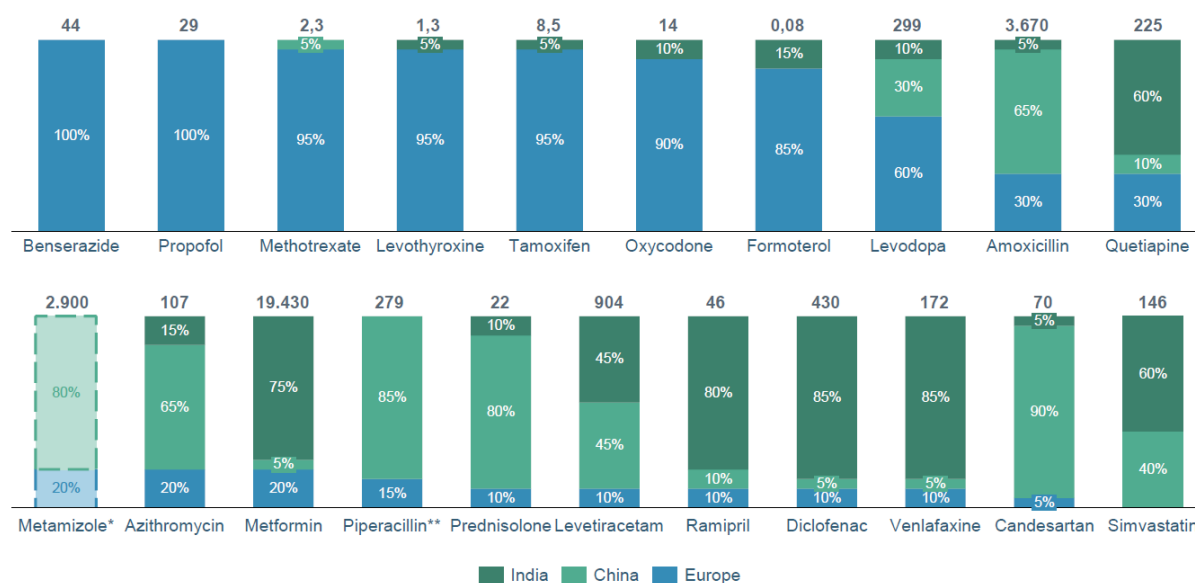


Source: MundiCare 2020

3.2 The EU's Pharmaceutical Industry, GVC Integration and Sector Regulation Today

In 2019, the pharmaceutical industry in the EU-27 had an annual production value of roughly EUR 275 billion (~2 % of EU GDP), employing almost 800 thousand people (EFPIA 2020). The EU's pharmaceutical industry focuses on producing high-value and on-patent products for local consumption and exports, and generally imports low-value and off-patent API and/or FDF products for further processing, local/regional consumption, or export. In 2019, the EU imported USD 11.5 billion and exported USD 5.9 billion APIs, generating a trade deficit of USD 5.6 billion for APIs. The API trade deficit is particularly pronounced for hormones, prostaglandins, thromboxanes and leukotrienes (HS code 2937; USD 3.7 billion), antibiotics (HS code 2941; USD 1.7 billion), and (pro-)vitamins (HS code 2936; USD 0,6 billion) (UN Comtrade 2020). For APIs, France, Germany, Spain and Italy have the largest number of manufacturers in the EU (MundiCare 2020). The EU particularly imports generic and high volume APIs from Asia, while maintaining production capacities for on-patent, smaller volume and complex APIs (Figure 14). FDF manufacturing of all varieties of APIs continues to be relatively large in the EU due to the existing regional API production and multi-purpose factories. For FDFs, the EU imported USD 42 billion and exported USD 106.5 billion, generating a significant trade surplus (USD 64.5 billion) against the rest of the world (UN Comtrade 2020).

Figure 14: Estimated share of supply for European demand of APIs by region



*) Estimation. Data basis limited: **) API mainly in combination with Tazobactam (exclusively produced in Asia).

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

Source: MundiCare 2020

The EU pharmaceutical market is exceptional since demand for pharmaceuticals is not linked to direct consumer choices due to regulations and large institutional buyers (Kedron/Bagchi-Sen 2012: 816). EU member states have bidding systems or negotiation processes in place that determine which pharmaceuticals will be reimbursed by state funded insurance funds. Consumers, in addition, are generally not allowed to choose their prescribed medicines, but physicians prescribe drugs approved by national competent authorities (NCAs).

EU legislation demands a relatively high degree of coordination among member states given that rules and requirements regarding the authorization and monitoring of medicines are harmonized. The coordination among member states rests upon a broad network of 50 regulatory authorities from the 31 European Economic Area (EEA) countries, the European Commission (EC) and in particular the Directorate General for Health and Food Safety (DG SANTE), and the European Medicines Agency (EMA)⁷⁰ (EMA 2016). Market authorization procedures in the EU may be conducted either by the EMA, or by NCAs through mutual recognition procedures. Based on scientific assessments by EMA's scientific committees, the EC takes binding decisions on the EU's authorization of medicines. Additionally, the EC proposes or amends legislation for the pharmaceutical sector, adopts implementing measures and ensures the application of EU law.⁷¹ Even though the coordination on the EU level is high regarding authorization procedures and related quality and safety requirements of medicines, pricing and reimbursement of medicines takes place at the member state level in correspondence with the respective national health care systems (see the example of Austria below).

In light of the shifting challenges for the EU pharmaceutical and health care sectors, and in particular in light of the COVID-19 pandemic, various initiatives on the EU level may

⁷⁰ The EMA was established in 1995 and bundles expertise through its scientific committees, working parties, and scientific advisory groups (EMA 2016). An independent Management Board with 36 members governs EMA. The EMA staff, which is overseen by an Executive Director, carries out the agency's daily operations. EMA's tasks include the evaluation, supervision and pharmacovigilance (safety monitoring) of medicines. With its committees and working groups it provides guidelines and scientific advice to support medicine developers and companies to work in line with EU requirements (see <https://www.ema.europa.eu/en/about-us/who-we-are>, 04.11.2020).

⁷¹ <https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-institutions>, 04.11.2020.

have important implications for the future development of the EU pharmaceutical sector and its supply chains. Most importantly, the recently published (November 2020) Pharmaceutical Strategy for Europe (2020c) by the EC encompasses four strategic pillars: (i) addressing unmet needs of patients; (ii) improving access to affordable medicines for patients; (iii) promoting a competitive and innovative European pharmaceutical industry; and (iv) enhancing the resilience of the pharmaceutical supply chains. The latter aims to build the EU's *open strategic autonomy* in the pharmaceutical sector by diversifying production and supply chains, promoting strategic stockpiling, and increasing production and investment in Europe. This flagship initiative on open strategic autonomy includes a revision of the pharmaceutical legislation by 2022 to enhance the security of supply through earlier notification of shortages, stricter obligations for supply and transparency, enhanced transparency of stocks and improved EU coordination and mechanisms to manage and avoid shortages. The strategy also initiates a *structured dialogue* with the actors in the pharmaceutical GVC, including manufacturers, public authorities, research communities, Non-Governmental Organisations, etc., in order to assess the vulnerabilities of the GVC and to discuss other potential options for improving supply security, such as reshoring. The strategy, thus, remains vague with regard to the promotion of reshoring in the EU pharmaceutical sector.

In addition, with the EU4Health Programme, part of the Next Generation EU recovery plan, the EU also aims to improve the availability of medicines (EC 2020b), but the measures so far remain relatively abstract. Members of the European Parliament have, in addition, called for financial incentives to increase API production in the EU and create an EU contingency reserve of medicines with strategic importance (EP 2020b).

3.3 The Case of Austria

The Austrian pharmaceutical sector is relatively young, has a relatively large share of medium-sized firms, and of firms established during the 2000s (Zeller et al. 2014). In 2018, 101 firms with sales of EUR 5.1 billion, and more than 15 thousand employees were active in the production of pharmaceuticals (Statistik Austria 2018). Similar to global dynamics, the Austrian pharmaceutical sector increasingly internationalized in the context of growing foreign direct investment (FDI) inflows into the sector, in particular during the 2000s (Zeller et al. 2014: 32ff; 36ff.). Pharmaceutical FDI outflows are focused on the EU, and have been increasingly geared towards Eastern- and South-Eastern European countries.

In Austria, the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) is the key authority regulating the pharmaceutical and health care sectors, but various other institutions like the Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES), the Bundesamt für Sicherheit im Gesundheitswesen (BASG), the Gesundheit Österreich GmbH (GÖG), amongst others, assist the Ministry in the management of the health and pharmaceutical sectors.

The Austrian healthcare system consists of the in-patient (public hospitals, private non-for-profit hospitals, private for profit hospitals) and out-patient sector. In the out-patient sector, the Austrian Reimbursement Code (Erstattungskodex, EKO) regulates which medicines are eligible for reimbursement and are subject to a special price mechanism that is linked to the calculation of EU average prices. Manufacturers applying for the inclusion of a medicine into the EKO have to submit the ex-factory and wholesale prices of the medicine in all EU Member states in which they already market the medicine.⁷² The Main Association

⁷² The EU average price is the arithmetic mean of prices, whereby special discounts and rebates are considered for various member states. If price data are available for only one or no EU Member State (Austria excluded), the Price Committee considers the price reported by the company to be the EU average price. In each of these cases, a re-evaluation of the average price takes place after several months.

of Austrian Social Security Institutions (HVB) decides whether specific medicines are included in the EKO based on the recommendation of the Pharmaceutical Evaluation Board (Heilmittel-Evaluierungskommission; HEK).⁷³ Following the decision of the HVB, the Austrian Social Security Institutions negotiate the reimbursement price for products included in the EKO with the respective companies. The EU average price is the key reference point of these negotiations. Special price regulations apply for successor products with the same active pharmaceutical ingredient (i.e. generic or biosimilar products).⁷⁴ The prices for medicines not included in the EKO are generally not regulated, but companies have to report ex-factory prices for new medicines and price changes to the BMSGPK, and the BMSGPK may initiate an official price-fixing process in case the reported prices are considered to be too high.⁷⁵ In Austria, wholesalers and pharmacies are remunerated via statutory mark-up schemes applicable to all medicines (BMSGPK 2019; Zimmermann/Rainer 2018: 11ff.).⁷⁶

The above discussed regulations do not apply for the Austrian in-patient sector, in which the purchasing of medicines is highly decentralized and negotiations take place between individual hospitals or hospital holdings (and their purchasing bodies) and companies. For medicines included in the EKO, the regulated price serves as a starting point of negotiations (ibid.: 17).⁷⁷

3.4 Resilience of the Pharmaceutical GVC and Case Studies

The key criteria regarding the vulnerability of product specific pharmaceutical supply chains include (i) the degree of globalization and import-dependency; (ii) the potential to substitute the product (without harming patients); (iii) the degree of globalization and import-dependency of the substitutes; (iv) the degree of concentration of the industry (i.e. the number of supplier firms); (v) the degree of regional diversification (i.e. the number of supplying countries/different regions); (vi) the complexity of the GVC; and (vii) the likelihood of supply shortages for critical inputs. Additional factors, like the political economic context of buyer/supplier countries and their political relations, are not considered within this study.

The generics pharmaceutical GVC generally has a much higher degree of vulnerability compared to branded products given the higher degree of global decentralization of production, the dependency on API/FDF imports, and the risk of API/FDF shortages in case of disturbances in cross-border trade. International competition and low prices/profit margins were not only the main driver in the outsourcing process (in the context of the above discussed institutional changes and financialization processes), but also led to the consolidation of suppliers and the ever-increasing exploitation of economies of scale and

⁷³ The HEK consists of health experts, the patient ombudsman, and representatives of insurance institutions, social partners, and public authorities.

⁷⁴ The price of the first generic successor product must be at least 50 % below the price of the original branded product, for which patent protection has expired. In the case of biosimilars the rate is 38 %. The second successor product again has to be priced below the first successor product (generics 18 %, biosimilars 15 %). Prices for the third successor product in relation to the second have to be 15 % respectively 10 % lower. In addition, the manufacturer of the original product is obliged to lower its price by at least 30 % within three months as soon as the first generic or biosimilar successor is included in the EKO. The market launch of a third generic or biosimilar product requires all existing licensees of the product to reduce their prices to the price of the third product. Further successors must offer discounts of at least EUR 0.10 in order to be included in the EKO.

⁷⁵ If the Ministry refrains from doing so, the proposed price will automatically be granted (Zimmermann/Rainer 2018). However, should a specific pharmaceutical (regardless of type of packages and strength) under the free pricing scheme exceed a sales value of EUR 750,000 within 12 consecutive months at the expense of the Austrian health insurance institutions, the Main Association of Social Insurance Institutions notifies the Pricing Committee, which is chaired by the BMSGPK, other ministries, and social partners (ibid.). The Pricing Committee then determines an EU average price within eight weeks. Is the EU average price lower than the indicated price, the respective company has to repay the differential amount from the time the threshold was exceeded.

⁷⁶ The value added tax on pharmaceuticals in Austria is 10 percent

⁷⁷ Reimbursement of the costs for medicines takes place via lump sums, which are refunded by insurances to hospitals based on diagnosis-oriented case groups.

scope. As indicated above (Figure 13), the global supply of more than half of APIs often rests on the shoulders of only a few suppliers, contributing to the supply chains' vulnerability.

In the last decade, supply shortages of pharmaceuticals increased significantly. A recent OECD study on shortage notifications in 14 OECD countries between 2017 and 2019 showed that the number of notifications of expected or actual shortages increased by more than 60 % (OECD forthcoming). Even though the number of notifications varied widely across countries, in part due to differences in the notification systems, the study suggests that shortages were mostly non-country specific (i.e. only 11 % of the reported substances were missing in only one country). The most affected drugs were off-patent generics, and included medicines targeting the nervous system (analgesics, anesthetics, and antidepressants; 25 %), cardiovascular pharmaceuticals (19 %; esp. antihypertensive), and anti-infectives for systemic use (10 %; esp. antibiotics) (ibid.).

As a result, a task force on the availability of authorized medicines for human and veterinary use (TF AAM) at the EMA and the Heads of Medicines Agency (HMA) to investigate shortages and supply chain disruptions was set up in 2016.⁷⁸ The main goal is to decrease supply shortages, in particular through improving EU coordination (e.g. a pilot program for creating network of single points of contact across the EU–SPOC Network). Since 2016, the EMA also publishes information on medicine shortages in the EU.⁷⁹

In Austria, AGES also reported a strong increase of pharmaceutical shortages in the last decade and in particular since 2016/17 (Figure 15). In 2009, AGES only reported two incidents, but already 77 in 2016. Afterwards, the incidents increased significantly to 146 in 2017 and 323 in 2019 (AGES 2020). The product categories largely resemble OECD averages, with medicines targeting the nervous system (15 %), cardiovascular pharmaceuticals (21 %), and anti-infectives (14 %) being among the most affected drugs (OECD forthcoming). According to interviews, shortages in Austria almost exclusively affect generic products that are generally not re-exported/imported. Following the strong increases of shortages in Austria, AGES initiated a task force on medical shortages, including key Austrian stakeholders, in 2019. In addition, a new regulation (Sicherstellung der Arzneimittelversorgung) that requires market authorization holders to report potential shortages of more than two to four weeks (depending on its severity) to a register run by the BASG was implemented early 2020.⁸⁰ The BASG, in turn, may implement export restrictions for affected products.

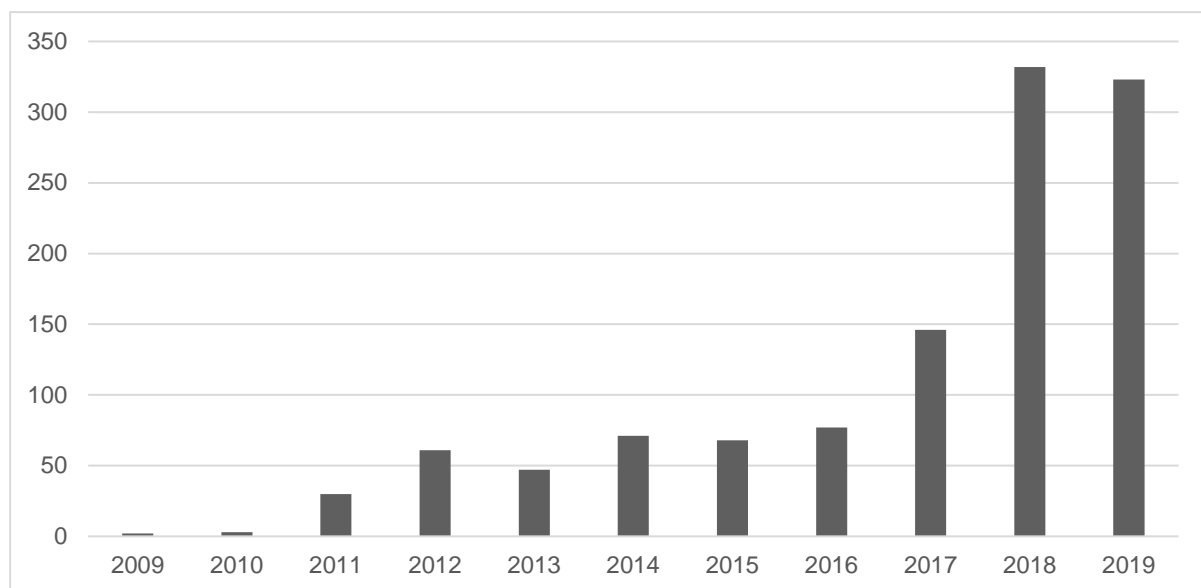
In the following, three pharmaceutical product case studies are presented, in order to highlight the product specific differences regarding supply chain vulnerabilities and potential policy measures to increase their resilience (Table 3): (i) antibiotics/penicillin, (ii) analgesics/paracetamol, and (iii) anticoagulants/heparin. The case studies have a particular focus on off-patent products and thus generic GVCs (in particular in the case of penicillin and paracetamol), but on-patent/branded products are also included in the analysis in particular in the case of heparin. The generic antibiotics and analgesics GVCs of off-patent and low-complexity products are characterized by a high degree of outsourcing, with limited production remaining in the EU. However, the case study of penicillin serves as an exception to the rule due to remaining EU/Austrian production. The case study of heparin, a biopharmaceutical/biosimilar, has many particularities due to its linkages with the livestock sector, highlighting the importance to consider product-specific dynamics in developing strategies to improve the resilience of the pharmaceutical GVC.

⁷⁸ <https://www.hma.eu/522.html>, 04.11.2020.

⁷⁹ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue>, 04.11.2020.

⁸⁰ <https://www.ris.bka.gv.at/eli/bgbl/II/2020/30>, 04.11.2020.

Figure 15: Reported incidents of pharmaceutical shortages in Austria (2009-2019)



Note: Numbers increased with the introduction of the electronic reporting system in 2018.

Source: AGES 2020

Table 3: Indicative assessment and summary of supply chain vulnerabilities of selected pharmaceutical products

	Penicillin (antibiotics)	Paracetamol (analgesics)	Heparin (anticoagulants)
Degree of EU import-dependency	*/**	***	**
Substitutable	*/**	***	*/**
EU import-dependency for substitutes	***	***	**
Degree of consolidation (incl. substitutes)	***	**/**	*/**
Degree of regional diversification (incl. substitutes)	*/**	*/**	**
Complexity of the supply chain	*/**	*/**	**
Likelihood of supply shortages for critical inputs	*	*	***
Potential key bottlenecks	<p>High degree of import dependency for various other antibiotics (with the exception of penicillin).</p> <p>Regional concentration of the production of penicillin and substitutes in China/India, but remaining large scale and vertically integrated penicillin production in the EU/Austria.</p> <p>For some antibiotics, only few (sometimes only one) companies/factories supply the global market with APIs.</p>	<p>Extremely high degree of import-dependency for paracetamol and substitutes.</p> <p>Regional concentration of production for paracetamol and substitutes in China (APIs)/India (FDFs).</p> <p>Only few firms supply the global market with APIs.</p>	<p>Likelihood of supply shortage for critical input is extremely high (porcine mucosa) due to African swine flu and other diseases.</p> <p>Regional concentration of production in China, but remaining/increasing production in the EU.</p>

Note: Indicative assessment based on expert-interviews: * = low, ** = medium, *** high.

Source: Own elaboration

3.4.1 Case Study 1: Penicillin

This section presents a case study on antibiotics based on the example of (generic) penicillin. Production of generic penicillin/antibiotics is of particular importance, given that new and on-patent penicillin/antibiotics are generally classified as reserves (i.e. they are limited in use in order to prevent antibiotic resistances). Even though there are differences between various antibiotics regarding the scale of existing EU production and import-dependency, the differences between the governance structure of the penicillin GVC and other antibiotics GVCs are relatively minor.

Penicillin is a group of β -lactam antibiotics including products that are among the most used antibiotics globally and in the EU. In the EU, β -lactam penicillin accounts for roughly 44 % of all consumed antibacterials for systemic use (ECDC 2019).⁸¹ The structure and dynamics of the penicillin GVC has similar characteristics with the above-discussed buyer-driven generic GVC, but also some particularities. Penicillin production is highly capital-intensive, digitalized, greatly benefits from economies of scale, and can be differentiated in natural fermentation, semi-synthetic, and synthetic. In the case of penicillin, semi-synthetic production is of particular importance and includes (i) the sourcing and manufacturing of inputs, in particular producing strains of the *Penicillium chrysogenum* mold in large stainless steel tanks; (ii) the production of intermediate products (e.g., benzylpenicillin and 6-aminopenicillanic acid) through chemical processes such as fermentation and hydrolysis; and (iii) the manufacturing of semi-synthetic penicillin (e.g., Amoxicillin, Ampicillin, and others) through different chemical processes. Other antibiotics have a similar supply chain, but they differ in terms of intermediate and final API products (e.g., 7-aminocephalosporanic acid that is used to produce cephalosporin-antibiotics like Cefuroxim and others). (iv) Similar to other pharmaceuticals, the API is then used as an input for FDF production.

Likewise to the above discussed dynamics in the generics GVC that include institutional changes and financialization processes, international competition and pressure on prices and margins in the last decades have been strong in the case of off-patent antibiotics such as off-patent penicillin.⁸² As a result, the production of generic penicillin has been increasingly outsourced from the US and the EU to China (with a focus on APIs) and India (with a focus on FDFs). GlaxoSmithKline also operates a large penicillin manufacturing site (producing mostly amoxicillin) in Singapore, which is particularly important for EU imports. The outsourcing process of APIs was generally more pronounced, and FDF production to some extent remained in the EU in particular due to the remaining EU pharmaceutical industry focusing on high-value branded products.

The cost-competitiveness of large-scale Chinese antibiotic API production also outcompeted Indian API manufacturers, which is why countries like India (with a large pharmaceutical sector) are also highly dependent on antibiotic/penicillin API imports today. Given these competitive pressures on prices, the industry has become increasingly consolidated and in some instances, only one company globally supplies specific antibiotic/penicillin APIs on a significant scale. For example, only four suppliers of the benzathine penicillin G (BPG) API exist globally, and in particular in the global semi-periphery there have been repeatedly reported shortages of BPG (e.g. during syphilis outbreaks) (Cogan et al. 2018). The combination of Piperacillin/Tazobactam, in addition,

⁸¹ The daily consumption per inhabitant in Austria is roughly 40% below EU average due to the high rate of consumption in many Southern and Eastern European countries (ECDC 2019). β -lactam penicillin nonetheless accounts for roughly 40% of all consumed antibiotics.

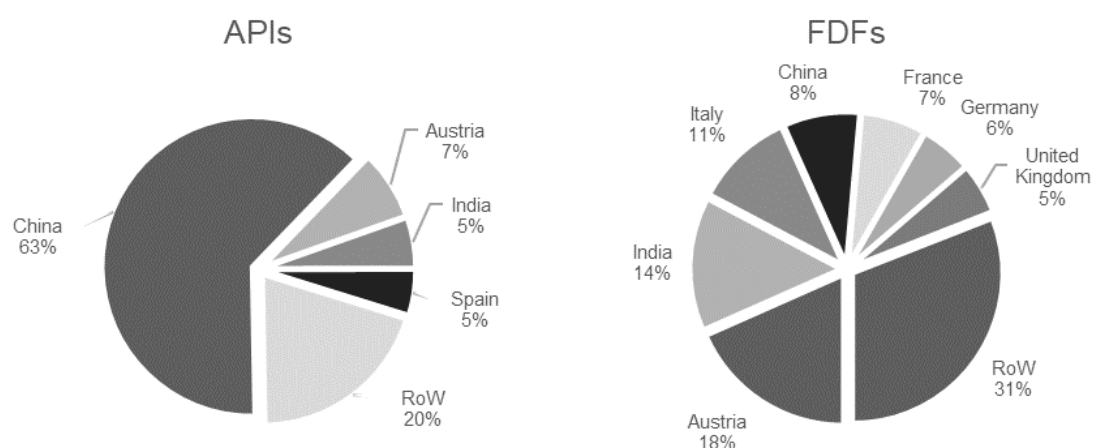
⁸² Firms' interviewed during the study did not share their margins; however, they stated that profits for one dosage of penicillin are only a few cents at current price levels. Roland Berger (2018) estimated that manufacturers receive roughly 16 eurocent, and 6 eurocent after the deduction of discounts for health insurance funds for a daily dosage of cephalosporine.

is only produced in Asia and global supply particularly depends on one company. For exports to the EU and the US, API and FDF manufacturers generally engage in contract manufacturing for large buyers.

In the EU-27, Sandoz (a Novartis division) operates the only remaining large-scale and vertically integrated manufacturing site of penicillin varieties today and is located in Austria. This manufacturing site supplies primarily the EU market with oral penicillin varieties and also engages in contract manufacturing for various brands. Until recently, the strategic management of Novartis has also contemplated to relocate the last remaining vertically-integrated production facility of penicillin in the EU to Asia, given the challenge to produce profitable in the EU in light of low-priced imports. In the context of the shifting discourse during the COVID-19 pandemic of 2020 and the revival of debates on supply chain vulnerabilities and supply-dependency on China, the Austrian government intervened and signed a declaration of intent to secure, expand, and modernize local production by pledging over EUR 50 million of a total of EUR 150 million investment. Out of the EUR 50 million, EUR 25 million are to be financed by research funding facilities, EUR 5 million by the federal state of Tyrol, and EUR 20 million by the EU and the Important Projects of Common European Interest (IPCEI) facility. An additional vertically-integrated penicillin manufacturing site (esp. amoxicillin) is operated by GSK in the UK.

This general structure of the penicillin GVC is also reflected in the trade data (Figure 16). In 2019, global trade of penicillin APIs and FDFs accounted for USD 1.7 billion and USD 2.7 billion, respectively. In 2019, China accounted for 63 % of global penicillin API exports (HS 294110) by volume and 48 % by value, followed by Austria (7 % and 6 %, respectively) (UN Comtrade 2020).⁸³ The differences between value and volume data is explained by the large scale of low-value penicillin production in China. Global penicillin FDF exports (HS 300410)⁸⁴, in contrast, are regionally more diversified and include Austria (18 % by volume; 9 % by value), India (14 %; 11 %), Italy (11 %; 12 %), China (8 %; 3 %), and various other (EU) countries such as France, Germany and the UK.

Figure 16: Global trade shares of penicillin APIs and FDFs by volume (2019)



Note: Data reflects import data. APIs include HS code 294110; FDFs include HS code 300410, including penicillin and streptomycins.

Source: UN Comtrade 2020 (WITS)

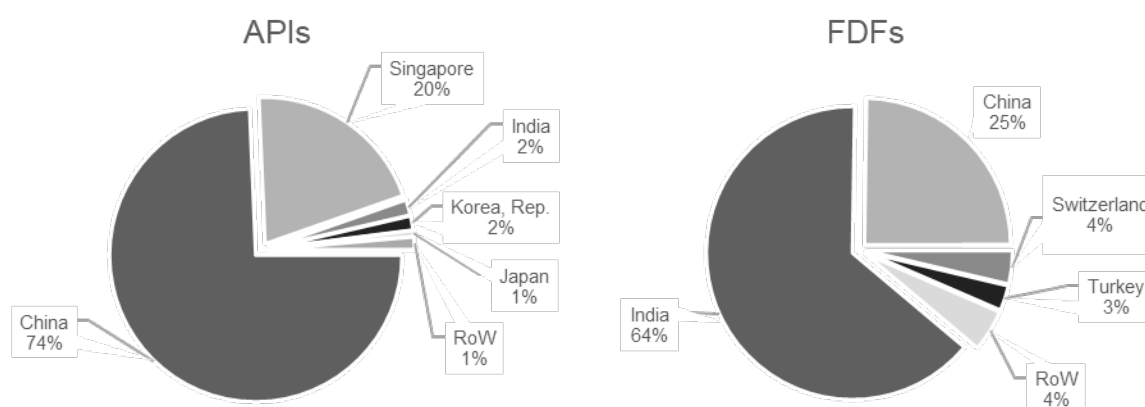
⁸³ Data reflects global imports.

⁸⁴ Data includes penicillin and streptomycin.

The EU has a large trade surplus for penicillin products given the comparatively large local production of (higher-value) penicillin. EU imports of penicillin (excl. intra EU trade) APIs and FDFs thus amount to USD 173 million and only USD 45 million in 2019, respectively, highlighting that the EU tends to import penicillin APIs for further processing to FDFs (UN Comtrade 2020). APIs are mostly imported from China (74 % share by volume; 53 % by value) and Singapore (20 %; 20 %), and FDFs are mostly imported from India (64 %; 58 %) and China (25 %; 30 %) (Figure 17). In contrast, exports of APIs and FDFs amounted to USD 47 million and USD 888 million, respectively.

Despite the trade surplus and remaining vertically integrated penicillin manufacturing facility in Austria, the EU remains highly dependent on penicillin API imports from Asia/China. For example, it is estimated that the EU imports 70 % of its yearly demand of Amoxicillin (3,670 tons), and 85 % of Piperacillin (279 tons) (Figure 14). The combination Piperacillin/Tazobactam, in addition, is only produced in Asia.

Figure 17: EU import shares of penicillin APIs and FDFs by volume (2019)



Note: Data reflects import data. APIs include HS code 294110; FDFs include HS code 300410, which includes penicillin and streptomycins.

Source: UN Comtrade 2020 (WITS)

Compared to other antibiotics, the EU import dependency on penicillin is relatively low due to the remaining large-scale manufacturing site in Austria. The EU's total trade deficit for antibiotic APIs (HS code 2941) excl. penicillin amounts to USD 1.5 billion. However, the EU has USD 3.2 billion trade surplus for antibiotic FDFs not containing penicillin or streptomycins (HS code 300420) due to USD 1.4 billion in imports and USD 4.6 billion in exports. This is because of the remaining antibiotic FDF manufacturing industry and the relatively higher-value of antibiotics produced in the EU.

Vulnerability of the supply chain and political as well as corporate responses

The high degree of outsourcing, consolidation, and the low degree of regional diversification explain the high vulnerability of the antibiotics GVC. Only the potential to – at least to some degree – substitute antibiotics with other products to some extent mitigates the problems, although also most substitutes suffer from similar fragilities. The vulnerability of the supply chain(s) became particularly apparent in light of shortages of Piperacillin/Tazobactam in 2016/17 due to the explosion of the key global supplying Chinese API factory at the time.⁸⁵ During the COVID-19 pandemic, in addition, India's

⁸⁵ <https://www.aerztezeitung.de/Politik/Lieferengpass-bei-PiperacillinTazobactam-296901.html>, 04.11.2020.
http://www.chinadaily.com.cn/china/2016-10/11/content_27018905.htm, 04.11.2020.

export ban on 26 APIs and related FDFs also included various antibiotics such as tinidazole and erythromycin, further highlighting the vulnerability of the generics antibiotic GVC (cf. DGFT 2020). However, penicillin is to some extent an exception in the EU antibiotics sector given the remaining vertically-integrated and large-scale production facility in Austria.

(i) Re- and nearshoring of antibiotics/penicillin manufacturing

The limited profitability of producing off-patent penicillin/antibiotics in the EU in light of increasing international competition and price-pressure was the main driver of outsourcing processes. The pressure on prices is of major concern in the debates regarding the potential of reshoring antibiotic API production to the EU (cf. Hosseini/Baur 2020). For example, a Roland Berger (2018) study argues that antibiotic production (cephalosporin) is currently economically not viable in Germany due to higher manufacturing costs and low prices, regardless whether the facility would produce for the German, EU, or world market. According to their estimates based on current price levels, production for the German market (approx. 100 tons p.a.) would generate an EBIT loss of EUR 55 million p.a.; and a yearly loss of EUR 78 million for the EU market (approx. 500 tons) (ibid.). Nonetheless, the case of Sandoz highlights that production of antibiotics is possible in certain instances, but it is clearly less demanding to preserve existing production capacities compared to the setting-up of new ones. In addition, the production of penicillin antibiotics (in particular aminopenicillin and amoxicillin) are likely to have a higher potential for economies of scale due to the larger global and EU demand.

(ii) Strategic stockpiling of antibiotic/penicillin APIs/FDFs

For the most used penicillin products,⁸⁶ the issue of long-term stockpiling is reduced due to the remaining manufacturing facility in Austria. However, increasing stocks of other antibiotic FDFs may be a necessary strategy. Increasing the stock of APIs for antibiotics would also be a potential option. API stocks for antibiotics would dramatically decrease warehousing costs and rely on EU manufacturing capacity of FDFs in case of emergency. An EU-wide warehousing strategy for antibiotic APIs would be more cost-effective given the large scale required for creating cost-effective storage and manufacturing capacities. Increasing stocks of FDF antibiotics, on the other hand, could be implemented more easily without EU coordination.

3.4.2 Case Study 2: Paracetamol

Paracetamol (derived from its chemical name **para-acetylamino**phenol⁸⁷) is used to treat pain and fever and belongs to the group of non-opioid analgesics. Non-opioid analgesics, and in particular paracetamol, are among of the most frequently used medicines in the EU today (cf. Hider-Mlynarz et al. 2018).

The paracetamol GVC can be divided into the following four key production steps: i) the sourcing of starting materials (esp. benzene from crude oil), which can differ depending on the manufacturing process (either chlorobenzene or nitrobenzene); (ii.a) the manufacturing of para-aminophenol (PAP)⁸⁸ as a final intermediate through different processing steps, depending on the input used; ii.b) the manufacturing of paracetamol APIs through the acetylation of PAPs; iv) the manufacturing of paracetamol FDFs (see

<https://www.gmp-compliance.org/gmp-news/explosion-of-an-api-manufacturing-site-supply-of-medicinal-products-endangered>, 04.11.2020

⁸⁶ Some penicillin API products are not produced in Austria.

⁸⁷ In the US, paracetamol is more commonly referred to as acetaminophen (para-acetylamino

⁸⁸ The great majority of PAP (more than 80 %) is used to manufacture paracetamol. Small amounts account to the rubber and cosmetic industry (in particular hair dyes) (Vinati Organics Limited 2016)

Mitchell/Waring 2000: 62f.; Vinati Organics Limited 2016: 5). The various inputs required to produce PAP/paracetamol⁸⁹ and byproducts sold for further processing⁹⁰ is the main reason why paracetamol production benefits from the proximity to these different industries. Given the similar starting materials (esp. benzene) for producing paracetamol and other APIs (e.g. Ibuprofen, Fexofenadin, Diclofenac, acetylsalicylic acid/Aspirin), there also exist major linkage potentials.

Paracetamol is a prime example of a low-value generic that has been outsourced in the last decades in the context of the above discussed globalization and financialization processes, and increasing price-competition from China and India.⁹¹ For a long time, three companies in the EU and the US – Hoechst-Celanese (USA), Mallinckrodt (USA), and Rhône-Poulenc (France) – dominated the paracetamol API market (Vinati Organics Limited 2016). As a result of increasing price-pressure, a series of M&A further consolidated the industry. In 1999, Rhône-Poulenc and the Hoechst AG – the German parent company of Hoechst-Celanese – merged to form Aventis (Breitenbach/Fischer 2013: 9). Rhône-Poulenc spun-off its pharmaceutical business to the newly formed company Rhodia. The paracetamol unit of Hoechst-Celanese was taken over by BASF (Vinati Organics Limited 2016: 5), only to be purchased by Rhodia in 2001, making Rhodia the second largest paracetamol producer in the world after the US company Mallinckrodt^{92, 93}

However, increasing competitive pressure from Chinese firms since the 2000s initiated the downfall of paracetamol API manufacturing (and similar APIs) in the EU and US. It is estimated that Chinese producers undercut Rhodia's prices by at least 30 %. As a consequence, Rhodia closed down its paracetamol production line in Louisiana (USA) in 2004 and outsourced its production to Wuxi (China). By the end of 2008, Rhodia also closed down its facility in Roussillon (France) and thus Europe's last manufacturing site of paracetamol.⁹⁴

Today, it is estimated that global paracetamol demand amounts to 150,000 to 160,000 tons a year (Yap 2020; Interviews), but only two paracetamol API manufacturers exist outside of China and India. Mallinckrodt continues to produce PAP and APIs in the US, with a capacity of roughly 15,000 tons, supplying the US market with a demand of 30,000 to 35,000 tons per year, and in particular Johnson & Johnson. However, due to a recent lawsuit the company has filed for Chapter 11 bankruptcy restructuring for all its US subsidiaries in October 2020. The Turkish company Atabay Pharmaceuticals, in addition, exports 4,000 tons of paracetamol APIs per year to European countries (Gandolfi/Stevensen 2014: 66). Interviews indicate however that the company is not an end-to-end producer and depends on PAP imports from China.

All other production sites of paracetamol APIs are located in China or India, dominating global supply PAP and paracetamol API supply. The largest manufacturers include the French company Novacyl (former Rhodia, now part of the French Seqens group), producing PAP with an annual capacity of 35,000 tons in Taizhou (China) and paracetamol

⁸⁹ E.g. benzene from crude oil refinery industry; chlorine, nitric acid, hydrogen, acetic anhydride/acetic acid and caustic lye from the chemical industry.

⁹⁰ E.g. ortho-nitro chloro benzene for the agriculture or dye industries, and acetic anhydride wash solutions for the sugar or mattress industries

⁹¹ Given the lack of trade data for paracetamol (paracetamol data is only available at the CN10 level), the following discussion focuses more on the changing structure, location, and production capacities of specific firms in order to assess the structure and dynamics of the GVC.

⁹² Mallinckrodt was acquired by Tyco International in 2000. In 2007, Tyco Healthcare separated from its mother company Covidien. In 2013, Mallinckrodt Pharmaceuticals again formed an independent company. <https://www.mallinckrodt.com/about/our-story/>, 04.11.2020.

⁹³ <http://www.pharmafile.com/news/end-line-european-paracetamol/>, 04.11.2020.

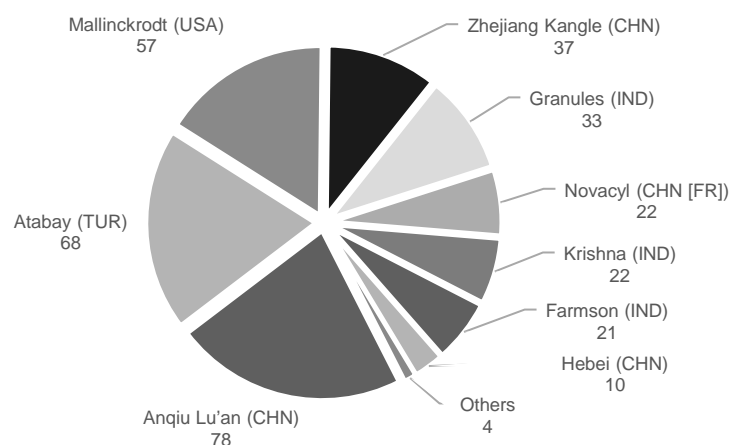
⁹⁴ <http://www.pharmafile.com/news/end-line-european-paracetamol/>, 04.11.2020.

APIs with a capacity of 8,000 tons per year in Wuxi (China).⁹⁵ The largest Chinese producer (Shandong province) is the vertical-integrated Anqiu Lu'an Pharmaceutical, with an annual capacity of 40,000 tons and an export-share of roughly 80 % (Yap 2020).⁹⁶ The Hebei Jiheng (Group) Pharmaceutical, in addition, has an annual API capacity of 25,000 tons.⁹⁷

China also outcompeted India with regard to PAP production, which is why India also depends on PAP imports from China today (Reji 2020). A recent report by the Confederation of Indian Industry and KMPG (2020) estimates that China's manufacturing costs for APIs is roughly 20 % lower compared to India. However, interviews indicate that India actually has a 15-20 % cost-advantage in API manufacturing compared to China for exports to the EU, in particular due to their efficiency in finishing processes for smaller batches. Important Indian players include the companies Granules India (18,000 tons of paracetamol per year) and Farmson Pharmaceutical Gujarat (25,000 tons of paracetamol and 19,200 tons of PAP per year).⁹⁸ During the COVID-19 pandemic, India announced to promote local PAP production (potentially cooperating with the Indian company Vinati) in order to decrease its dependency on China (Interviews).⁹⁹

EU demand for paracetamol is estimated to roughly 35,000 to 40,000 tons per year (Interviews). The EU imports paracetamol APIs for further processing or FDFs for direct consumption. Regarding API imports, the demand is largely met by the above discussed companies as indicated by the EudraGMDP database that lists all third country sites from which APIs are sourced (Figure 18). The EU has large paracetamol FDF manufacturing capacities, with at least 1-2 manufacturers in most member states, which is why API imports to the EU play a major role (Interviews). Interviews estimated the number of FDF manufacturers to 50-100, in particular due to the large number of contract manufacturers. In addition, larger FDF manufacturers also import APIs for global FDF exports.

Figure 18: Number of EudraGMDP entries for paracetamol APIs per EU production facility



Note: The data reflects the number of EU production sites importing from respective API manufacturers.

Source: EMA 2020

⁹⁵ <https://www.segens.com/en/locations/>, 04.11.2020.

⁹⁶ <http://www.luanpharm.com/english/cpml.asp>, 04.11.2020.

⁹⁷ <https://www.it-idc.com/About/>, 04.11.2020. No capacity data is available for Zhejiang Kangle Pharmaceutical.

⁹⁸ <http://www.granulesindia.com/about-us-our-facilities.php#our-alliances>, 04.11.2020. <http://www.farmson.com/about/about-us>, 04.11.2020. No capacity data is available for Sri Krishna Pharma. Megmani is a recently established vertically-integrated company.

⁹⁹ <https://www.bloomberg.com/news/articles/2020-04-13/india-to-boost-drug-ingredient-output-to-pare-china-s-dominance>, 04.11.2020

Vulnerability of the supply chain and potentials for rebalancing

The key vulnerability of the paracetamol supply chain is related to its (i) strong regional concentration in China and India, and (ii) relatively few suppliers of PAP/APIs. These vulnerabilities became particularly apparent during the COVID-19 crisis. On 3 March 2020, the Government of India implemented an export ban for a variety of APIs and formulations, including paracetamol (DGFT 2020). Concerns in the EU further increased following the reports from India that prices for non-opioid analgesics were rising by up to 70 % due to the challenging supply situation of Chinese APIs (Wallace 2020). In addition, for a short period it was believed that Ibuprofen should not be prescribed during a COVID-19 infection, ramping up paracetamol demand, in part due to stockpiling by individual households (Interviews). Interviews during this research project indicated that short-term paracetamol shortages were reported in almost half of EU countries. In the light of the lockdown and restrictions in India, EU's Commissioner for Health and Food Safety, Stella Kyriakides, wrote an open letter (April 2020) to representatives of the pharma industry arguing that there is a clear need to increase paracetamol production in the EU.¹⁰⁰

The potential policies to increase the resilience of the paracetamol GVC largely resembles the penicillin GVC, although they differ with regard to their feasibility/complexity:

- (i) *Promotion of re- and nearshoring of end-to-end or API paracetamol production (or other low-value generic analgesic such as Ibuprofen)*

Reshoring paracetamol to the EU could entail two scenarios: (a) reshore paracetamol API production, but continue to import PAP from China (or, in the near future, potentially from India); (b) build an end-to-end manufacturing facility in the EU.

In scenario a), initial investments of roughly USD 25 to 30 million would finance an API production facility of 10,000 tons, roughly a fourth of EU's yearly paracetamol demand.¹⁰¹ However, API production taking place in the EU would not decrease the input dependency and thus increase the resilience of the supply chain. Instead, the EU/manufacturers would need to contemplate whether to engage in stockpiling inputs (or FDFs) instead of paracetamol APIs to counter potential supply shortages in times of crisis. Despite this, such a scenario is currently widely discussed in the EU: In June 2020, the French President, Emmanuel Macron, announced that France aims to reshore the production of up to 30 pharmaceuticals,¹⁰² including paracetamol, within three years by pledging EUR 200 millions to co-finance production lines (Abboud/Peel 2020). Regarding paracetamol, the not yet finalized plan is that Seqens builds an API production line in France,¹⁰³ and Sanofi and UPSA, who currently sell about 90 % of paracetamol medicines in France, would commit to buying their product at a higher price (potentially 10 % above current import prices) for further processing (Domenech 2020). As of today, some of the companies have raised their concerns regarding the feasibility/profitability of the project and highlighted the need for government support (Abboud/Peel 2020). Furthermore, according the interviews, the EU API production facility of Seqens is currently (October 2020) not planned to be end-to-end, and would thus continue to depend on the above-mentioned PAP production facility of Seqens in China. Interviews also indicated that the Seqens production facility lacks price-competitiveness compared to its Chinese competitors, further adding to the limited economic feasibility of the project.

In scenario b), in contrast, the EU would not be dependent on importing key inputs/intermediates, thereby significantly increasing the resilience of the supply chain.

¹⁰⁰ <http://www.oeb.org.cy/wp-content/uploads/2020/04/Letter-from-Commissioners-Kyriakides-to-the-pharmaceutical-industries.pdf>, 04.11.2020.

¹⁰¹ Investment costs per ton would decrease with scale and increase with the technological sophistication (e.g. digitalization).

¹⁰² Companies can express their interest for producing specific APIs in France until the end of October 2020.

¹⁰³ Until the time of writing, it was not entirely clear whether the facility is planned to be end-to-end.

However, establishing a cost-efficient and vertically-integrated production facility is highly complex. According to interviews, the initial investment for a fully vertically-integrated production facility (including the inputs required to produce PAP, given the lack of EU capacities) is ten-fold the investments compared to API manufacturing, i.e. roughly USD 250-300 million for 10,000 tons. The high-cost of these investments are linked to the large variety of inputs required to produce PAP/paracetamol. The main challenge to achieve price-competitive operation, however, is the management of the supply chain and selling/disposal of byproducts, requiring linkages with various industries (e.g. crude oil refineries, and segments of the chemical, agriculture for inputs; and the dye, sugar, wine and/or mattress industries for the selling of byproducts) that only to some extent exist on a significant scale in the EU today. Given this complexity and required know-how, interviews during the research project indicated that a multinational pharmaceutical company engaged in paracetamol FDF manufacturing in the EU contemplates to cooperate with Indian PAP/API manufacturers to build a vertically-integrated manufacturing site in the EU. Given the large scale required to cost-efficiently produce PAP (and the required inputs), such a strategy is likely to include various APIs that have linkages in the production process (see above). Even though early cost-estimates see potential for cost-competitive operations in the long-term, largely due to the high cost of the current supply chain management (esp. inventory, logistics, long lead times), some subsidies will be required to incentivize such investments.

(ii) Stockpiling of PAP, APIs or FDFs

Increasing the stock of paracetamol in form of APIs or FDFs may also help to ensure sufficient supply of paracetamol in times of crisis. However, stockpiling of paracetamol is a challenge due the large volumes required. Similar to antibiotics, storage of APIs is likely to require more comprehensive logistics, but is also likely to be more cost-efficient in case of large-scale storages at the EU-level (see conclusion for a broader discussion on policy-recommendations). For example, a safety stock for three months would require roughly 10,000 tons of paracetamol APIs (~5 USD per kg equals to roughly USD 50 million in API inventory alone) in drums of 200 kg each (amounting to 50,000 drums), highlighting the significant cost associated with such a large-scale strategy (Interviews).

(iii) Substitute or limit consumption during shortages

In contrast to heparin and antibiotics/penicillin, “weak” analgesics such as paracetamol are rarely critical to treat patients. There are only few clinical situations, e.g. in case of intolerances to other analgesics or during pregnancy, in which paracetamol is difficult to substitute. And even though shortages of key substitutes such as Ibuprofen may occur at the same time (given the similarities of generics value chains), e.g. in case disturbances of cross-border trade, overall consumption of these weak analgesics may be reduced during shortages in order to ensure sufficient supply for patients with the greatest needs.

3.4.3 Case Study 3: Heparin

Heparin is a strongly charged polysaccharide used and produced as a medication since the 1940s (Schwarzmann-Schafhauser 2007). It has an inhibiting effect on blood clotting and is the preferred and most widely used parenteral anticoagulant/blood thinner in a variety of clinical situations (e.g., coronary syndromes, cardiopulmonary bypass, extracorporeal membrane oxygenation, venous thromboembolism). Heparin is second only to insulin in application as a biological drug (van der Meer et al. 2017). Both, on- and off-patent heparin products are widely used in the EU.

Heparin can be extracted from a variety of animals,¹⁰⁴ with heparin derived from swine (porcine intestinal mucosa) being by far the most common source since the outbreak of bovine spongiform encephalopathy (BSE, mad cow disease) during the 1990s. In addition, porcine heparin is also preferred due to a higher activity compared to bovine heparin. Today, only few countries such as Brazil, India and Argentina use bovine-derived heparin (ibid.).¹⁰⁵ Given its classification as a biological medicinal product, heparin is subject to special regulatory requirements in the EU (see EMA 2013).¹⁰⁶ Companies aiming at marketing their product in the EU thus need to prove that the mucosa is derived from animals fit for human consumption, requiring ante- and post mortem inspections in accordance with EU regulations (ibid.: 5).

Heparin can be distinguished into unfractionated heparin (UFH) and low-molecular weight heparins (LMWHs). LMWHs have a higher bioavailability and less side effects, which is why LMWHs are broadly prescribed for treatment and prevention of thromboembolic diseases (Vilanova et al. 2019). They are also crucial in many clinical instances (e.g. in case of long-term use during pregnancy, cancer patients with venous thromboembolism, and more).

The dependency on animal/porcine inputs has important implications for the dynamics and structure of the heparin GVC, which is why there are important differences compared to the other two case studies. The heparin GVC can be divided into the following key production steps (see van der Meer et al. 2017 for more details): (i) The production and supply of input, mostly mucosa¹⁰⁷ scrapped from porcine intestines and preserved for further processing, as a byproduct of the meat/sausage industry.¹⁰⁸ (ii) The production of various intermediate heparin products (such as raw, resin bound, partly purified, or crude heparin) and the final UFH or LMWH API (heparin sodium/calcium, or respective LMWH products such as enoxaparin sodium) through various processing steps, including – among others – the concentration and purification of heparin (van der Meer et al. 2017). LMWHs can be derived from UFHs by digestion or depolymerization of longer chains (Vilanova et al. 2019). It is estimated that 70 % of the APIs for UFHs are used to produce different LMWHs (ibid.). (iii) The manufacturing of FDF heparin (e.g. for infusions, injections or ointments).

China is the world's largest heparin supplier given that it has also the largest livestock (428 million in early 2019) and consumption of swine (USDA FAS 2020). It is estimated that 80 % of the world's heparin intermediates/APIs are sourced from China, producing over 30 trillion international heparin units¹⁰⁹ per year (Vilanova et al. 2019). In 2019, global trade of heparin accounted for USD 3.7 billion (HS code 300190).¹¹⁰ China accounted for 24 % of exports by value, followed by Singapore (19 %), France (16 %), and the United States (14 %). The latter three are also the main importers of heparin (France 27 %, Singapore 13 %, and United States 12 %) (UN Comtrade 2020, see Figure 19). The high share of Singapore is explained by the supply chain of the French company Sanofi, which produces

¹⁰⁴ E.g., porcine, bovine, ovine, dromedary, chicken, turkey, salmon, shrimps, clam (cf. van der Meer et al. 2017, Table 1)

¹⁰⁵ Bovine-derived heparin is also sometimes preferred for religious reasons.

¹⁰⁶ In 2013, the EMA (2013) published a Guideline on the use of starting materials and intermediates collected from different sources in the manufacturing of non-recombinant biological medicinal products. The guideline clarifies – amongst others – the definition of starting materials for heparin, since “[t]he multi-step manufacturing processes of biological substances have caused differences in the definition of ‘starting materials’ for the active substance manufacturing by both regulators and industry” (ibid.: 3).

¹⁰⁷ Besides mucosa, whole porcine intestines may also be used for heparin production.

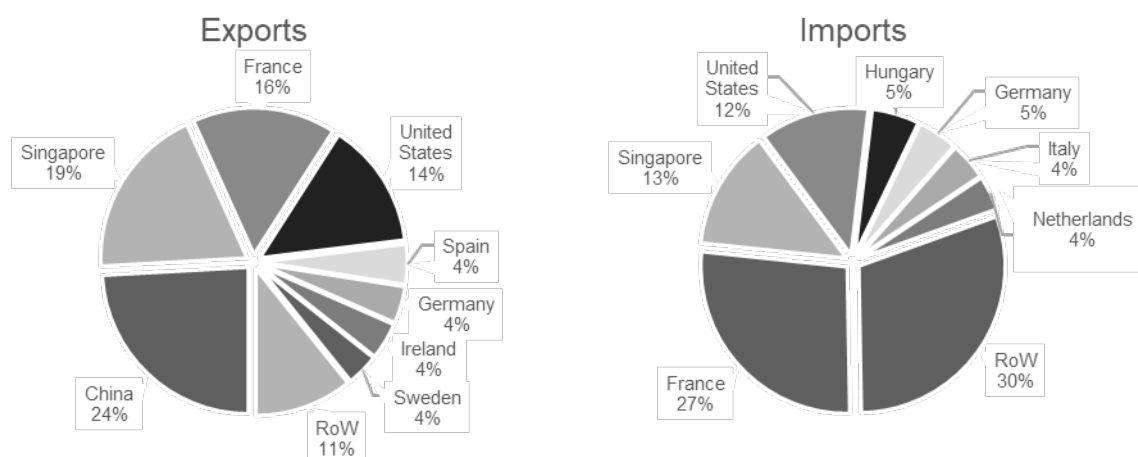
¹⁰⁸ For transportation, the mucosa is often hydrolyzed at the slaughterhouses and the heparin is loaded on an anion exchange resin.

¹⁰⁹ International units measure the action of the medication, and not its weight.

¹¹⁰ HS code 300190 includes heparin and its salts as well as glands and other organs, and other human or animal substances prepared for therapeutic or prophylactic uses. We use the HS code as a proxy for global heparin trade since the CN8 code at EU level for heparin and its salts (CN8 30019091) represents 93 % in the HS6 code. Data reflects global imports.

high-value heparin (esp. the LMWH enoxaparin) at its Aventis Pharma Manufacturing site in Singapore based on imported inputs.

Figure 19: Global trade shares of heparin and its salts by value (2019)



Note: Data reflects import data. HS code 300190 is used as a proxy for heparin and its salts [see footnote].

Source: UN Comtrade 2020 (WITS)

Compared to other generic products, heparin API and FDF production in the EU is relatively large given the scale of local and regional pork production and consumption (the EU had a livestock of 143 million swine in 2019) (EC 2019).¹¹¹ Some of the largest API manufacturers in the EU include Bioiberica (Headquarter in Spain),¹¹² Sanofi (France), and ROVI (Spain), but there also exist smaller manufacturers (e.g. Biofer, Italy). EU API manufacturers supply larger FDF manufacturers and/or are vertically integrated in FDF (contract) manufacturing. Some API manufacturers also engage in marketing their own FDF products. In addition, many firms import heparin APIs for further processing.

The overall business sentiment in the EU heparin subsector is generally positive, in particular with regard to LMWH heparins. In the last decade, investments by ROVI, Tönnies/Pharma Action,¹¹³ and others have increased the heparin production capacity in the EU (Pharma Action was sold to Bioiberica in 2017). ROVI, for example, highlighted the “enormous business potential” (ROVI 2020: 17) of its LMWH division (enoxaparin and bemiparin). Following ROVI’s investments in the last decade, and after the patent expiry of bemiparin/Hibor in the end of 2019, sales of the enoxaparin biosimilar increased from EUR 30.2 million in 2018 to EUR 80.9 million in 2019 (ibid.).¹¹⁴ The investor relation platform Edison (2019), in addition, estimated enoxaparin sales growth of ROVI to EUR 96.2 million by 2020 and EUR 125 million by 2021.

Nonetheless, the EU-27 had a trade deficit of USD 743 million¹¹⁵ vis-à-vis the world for heparin and its salts in 2019, importing USD 1.4 billion and exporting USD 677 million (Figure 20). The EU imports Heparin mostly from Singapore (47 %), China (31 %), and the United States (19 %). Again, the high share of Singapore is explained by the supply chain of Sanofi and its links with its Aventis Pharma Manufacturing facility. Likewise, Sanofi’s trade relations with Singapore inflate the number of EU exports. In 2019, France accounted for 72 % of EU heparin exports, 89 % of which go to Singapore (Eurostat 2020). Intra-EU trade, in addition, amounted to USD 679 million in 2019, reflecting the large share of local

¹¹¹ Heparin APIs may also be manufactured based on intermediate imports.

¹¹² Bioiberica is part of the German Saria Group, which in turn is part of the German Rethmann Group.

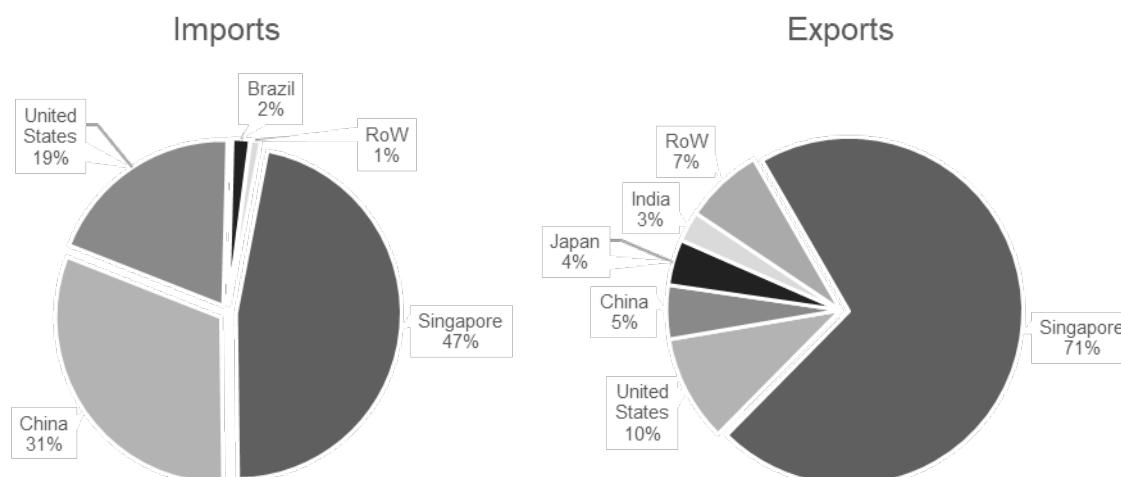
¹¹³ Tönnies is the largest swine meat company in Germany.

¹¹⁴ Data also includes exports.

¹¹⁵ Converted Euro values (average exchange rate for 2019, EUR 1 = USD 1.214)

production, with Germany (21 %), Sweden (20 %), Ireland (17 %), the Netherlands (12 %), Italy (11 %), and France (8 %) being the key exporters within the EU. In contrast, France (54 %) is by far the largest intra-EU importer, also reflecting its position as an exporter of intermediate products to Singapore (ibid.).

Figure 20: EU trade shares of heparin by value (2019)



Note: Data reflects CN8 30019091.
Source: Eurostat 2020

Vulnerability of the supply chain, political and corporate responses

The key vulnerabilities in the heparin GVC are (i) the dependency on animal inputs and the potential for bottlenecks due to a lack of input; and (ii) the regional concentration of input and API production in China. Even though heparin may be substituted by other anticoagulants, these substitutes may not be used interchangeably in many important clinical situations. Heparin, for example, is the anticoagulant of choice for cardiopulmonary bypass surgery and percutaneous ventricular support systems (i.e. circulatory assisting devices). LMWHs, in addition, are required for treating pregnant patients receiving long-term anticoagulation and cancer patients being treated for venous thromboembolism (see McCarthy et al. 2020; Vilanova et al. 2019).

In the last decade, the vulnerability of the heparin GVC has been repeatedly highlighted in the context of various swine diseases. In 2007, for example, the outbreak of porcine reproductive and respiratory syndrome in China massively reduced the availability and increased the price of swine and thus porcine mucosa. The following counterfeiting incident in 2008 was likely the result of these developments, resulting in the death of more than 80 and injury of hundreds of patients in the USA (Vilanova et al. 2019). Other examples include ban of a Chinese heparin manufacturers due to various issues in the production process (including contamination risk, unsatisfactory traceability, etc.).¹¹⁶

Since 2018, the outbreaks of African Swine Fever, a highly contagious and mostly fatal disease of pigs for which there are currently no medicines or vaccines, in China, Southeast Asia and other countries, has again increased concerns about the fragility of the supply chain.¹¹⁷ The outbreak resulted in the decimation of the Chinese swine-stock from 441 million in 2018 to 310 million in 2020 (USDA FAS 2020), again resulting in a sharp increase of prices and threats of insufficient input supply, thereby threatening global heparin supply.

¹¹⁶ <https://www.fiercepharma.com/manufacturing/chinese-heparin-maker-banned-by-ema-over-contamination-risks>, 04.11.2020.

¹¹⁷ ASF is no direct threat to humans.

As a result, the German manufacturer Fresenius Kabi, for example, started to ration heparin to buyers in July 2019 (particularly affecting the US), and Baxter International and Pfizer reported manufacturing disturbances in November 2019 (McCarthy et al. 2020). In January 2020, Pfizer raised the prices of heparin by 50 % to offset the increasing cost of the heparin API (Eaton 2020). However, the outbreak of ASF so far (September 2020) did not result in reducing the supply of heparin to patients in the EU, but the outbreak is not contained yet. In addition, ASF has also spread to Eastern Europe in the last decade, and in 2020 some cases were reported in Germany (wild boar) as well (ter Beek 2020).

The USA is particularly threatened by the potential heparin shortage given its even greater dependence on imports from China (roughly 60 % of crude heparin used in the USA is imported from China) and the ban of alternative heparin sources (e.g. bovine heparin) (Higgins 2019). As a result, the problem has raised concerns in the US Congress and some US-hospitals have started to ration heparin usage (Rosovsky et al. 2020).

There are various potential strategies to rebalance the supply chain and ensure supply for the EU market:

(i) Increasing local production of porcine heparin

Increasing local production of porcine heparin is a potential and economically viable option. The local/regional availability of swine and the profitability of investments in the last decade clearly highlight these potentials. Despite the higher cost-competitiveness of Chinese producers, EU production benefits from regional supply chains, and thus easier traceability (which is required by the EMA), and good track records in terms of quality that is valued by many buyers (Interviews). Nonetheless, the economic viability of EU production is higher in case of on-patent products (due to their higher prices), to some extent limiting this potential. Even though exact numbers are not accessible, the economic viability of local production is underscored by the investments of ROVI (see above) or Tönnies. Tönnies, for example, invested into heparin production (Pharma Action) in Germany, subsequently sold it to Bioiberica/Saria Group, who in turn announced to increase investments and capacities.¹¹⁸

Given the large scale production, increasing investments, and profitability of heparin production in the EU, as well as potential other options to rebalance to supply chain as discussed below, it is debatable whether local heparin production needs to be extended through industrial policy support. However, policy measures may be required in order to ensure a higher degree of local/regional production capacity.

(ii) Enhance supply chain diversification

In the heparin GVC, the high dependency on porcine inputs and API imports from China is a major reason for the supply chain vulnerability. This is particularly apparent in the US, which has a much higher import dependency compared to the EU. Nonetheless, and particularly given the threat of ASF, increasing the number of sourcing regions is crucial in order to improve the resilience of the heparin supply chain. This also implies that reshoring alone may not be sufficient to establish a resilient supply chain in the case of heparin, given that an outbreak of ASF or a similar disease in the EU may also threaten supply.

¹¹⁸ <https://www.aurea-a2.de/page.php?p=24398&n=24397%7C24398>, 04.11.2020.
<https://www.die-glocke.de/lokalnachrichten/kreisguetersloh/rheda-wiedenbrueck/heparinproduktion-wird-gesteigert-26ab9200-5773-4df0-8744-2217a20a46b7-ds>, 04.11.2020.
<https://www.westfalen-blatt.de/OWL/Kreis-Guetersloh/Rheda-Wiedenbrueck/3056466-Tochter-mit-Werk-in-Rheda-geht-an-spanisch-deutsches-Unternehmen-Toennies-verkauft-Pharmasperte>, 04.11.2020.

(iii) Increase local production/imports of bovine heparin or other alternatives

Increasing the usage of alternative heparin sources may be a potential option in case of an intensifying global ASF outbreak and porcine input shortages. In addition to heparin derived from porcine intestines, heparin may also be derived from various other animals. Bovine heparin is generally considered to be one of the best alternative sources, in particular given its large availability. The structure and biological activity profiles of bovine heparin, however, differs compared to porcine heparin (this is also true for other animal sources) (Keire et al. 2015). The major safety concern with bovine heparin, however, is the possible – but rare – presence of BSE infectious agents. In contrast, adverse effects have not been associated with the usage of bovine heparin, with the exception of potential challenges in cardiovascular surgery (ibid.).

(iv) Further research and development to promote alternative production methods

In the future, alternative heparin production methods may be a viable option. For example, the industrial production of heparin in cell culture may be possible in the future (Weiss et al. 2020). Further research and development will be necessary before this or other alternatives become a reality.

(v) Further research and development to find a treatment for ASF and other porcine diseases

As of today, there are no medicines to cure or vaccines to prevent ASF, even though there are potential new candidates (see e.g. Borca et al. 2020). As such, a potential way to combat porcine shortages would be to increase R&D efforts in combatting ASF.

(vi) Limit usage of heparin in times of shortages

The broad use of heparin for various clinical cases can be effectively reduced during times of shortages. McCarthy et al. (2020) and others, for example, suggest that heparin should be reserved for patients with the greatest need and that UFH should only be given in urgent or emergency cases. During the recent ASF-induced shortage threat in the US, for example, the Massachusetts General Hospital activated its emergency plan, successfully reducing the heparin use by 80 % within two months through clinical guidelines (see Rosovsky et al. 2020 for more details). Even though the specific case of one particular hospital should not be overestimated, it highlights that the use of heparin may be effectively reduced in times of shortages.

3.5 Conclusions and Policy Recommendations

The analysis of the pharmaceutical GVC and case studies on penicillin, paracetamol and heparin revealed similarities and differences regarding the vulnerability of the respective supply chains. The key criteria regarding the vulnerability of the pharmaceutical supply chain include (i) the degree of globalization and import dependency; (ii) the potential to substitute the product (without harming patients in a meaningful way); (iii) the degree of globalization and import dependency of the substitutes; (iv) the degree of concentration (i.e. the number of supplier firms); (v) the degree of regional diversification (i.e. the number of supplying countries/different regions); (vi) the complexity of the GVC; (vii) and the likelihood of supply challenges for critical inputs.

This study argued that supply chain vulnerability due to pandemics or other crises that constrain cross-border trade is particularly pronounced in the case of the highly globalized and low-value generic GVCs, but important differences exist between products. The case of off-patent analgesics (paracetamol) particularly highlighted the vulnerabilities created through outsourcing and the high degree of EU import dependency, in particular with

regard to APIs. While this is also true for most antibiotics, the case of penicillin and the remaining large-scale and vertically integrated production facility in Austria highlights that there are also exceptions to the rule. Off-patent antibiotics/penicillin and analgesics/paracetamol, in addition, are also characterized by a relatively high degree of concentration (i.e. only a few suppliers exist for specific products) and low degree of regional diversification, given the pressure on prices, financialization processes and the importance of economies of scale. In addition, the potential substitutes are characterized by similar vulnerabilities in both cases.

In contrast, there continues to be relatively large-scale production of heparin in the EU in light of the local/regional availability of inputs and the pronounced supply chain vulnerability due to its input dependence on porcine mucosa. 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 ASF and the continued threat of input shortages has highlighted these challenges. The case of heparin and product-specific supply chain vulnerabilities also underlines that increasing the resilience of GVCs requires product-tailored policies.

In sum, the analysis of the pharmaceutical GVC and the three case studies suggest the following key policy options for increasing supply chain resilience of pharmaceutical products: (i) promoting reshoring; (ii) increase stockpiling; (iii) increasing the resilience of supply chains, in particular through the diversification of suppliers and regions; and (iv) innovation policy. In certain instances, such as vaccine production, to reserve local surge capacity is also an option. The policy analysis in the context of this study does not include more horizontal policies for critical products, such as trade policy. Given the large amount of potentially 'critical' pharmaceuticals (ranging from various dozens to more than one thousand, depending on the definition) and the large scale nature of production/market required for most of these products (due to significant economies of scale), any strategy needs to (a) aim for coordination at the EU level, (b) take into account the particularities of all identified critical products, and (c) develop a mix of policies for each of the identified products/product-groups.

Near- and reshoring

The analysis of the different pharmaceutical GVCs and product-specific case studies highlighted that the debate on re- and nearshoring particularly concerns API production of off-patent and generic products, but also to some extent FDF manufacturing. In addition, the analysis of the case studies revealed important product-specific differences regarding the potential for reshoring. The case of off-patent antibiotics/penicillin and analgesics/paracetamol highlights that API manufacturing for these products in the EU is generally not profitable in light of international competition, price pressure, and buyers focusing on price and quality (and not supply chain resilience). Promoting API, and to a lesser extent FDF, production of these and many other off-patent and generic pharmaceuticals in the EU would thus require industrial policy measures such as subsidies, tax-incentives, and more. Given the importance of economies of scale and potential linkages in the manufacturing of different APIs (e.g. regarding required inputs from the chemical industry), and the large amount of potentially critical pharmaceuticals, reshoring strategies in the pharmaceutical sector need to be coordinated across the EU. In addition, promoting reshoring through industrial policy should target specific key/critical pharmaceuticals (and potentially specific API production clusters),¹¹⁹ given that it is unlikely and costly to re-/nearshore the production of "all" pharmaceuticals. Instead, a systemic approach needs to find a policy-mix of promoting reshoring, stockpiling, and other measures for different products.

¹¹⁹ Paracetamol, Diclofenac, Aspirin and Ibuprofen, for example, have similar supplier networks.

An additional option to direct industrial policy support is to promote buyer requirements regarding price, quality, supply chain resilience, and sustainability standards. This would allow for paying higher prices in order to ensure resilient supply chains and thus more regional production. Such a strategy would also promote nearshoring, and not only reshoring, processes. Again, such a strategy would require EU coordination in order to create sufficient demand for regionally produced products (i.e. adaptation of buyer requirements in Austria alone would hardly create sufficient incentives to relocate production to Europe). However, the differences between health systems in the EU and the different actors involved in buying decisions (esp. hospitals and health funds) impedes such a strategy. In addition, the higher prices of pharmaceuticals will result in higher expenditures of buyers and health insurance costs. The increase of healthcare costs would in turn depend on the range of products included, and the agreed additional mark-up for regionally produced products (which should differ for various products).

The inclusion of sustainability standards in buyer requirements could have particularly important effects on the pharmaceutical GVC, since it would reduce the price competitiveness of firms that lack environmental and labor standards. Sustainability standards would also impede strategies that aim to enhance competitiveness by outsourcing from China or India to countries with lower standards, such as Vietnam or Mongolia (for exports to the EU). The inclusion of sustainability standards would thus also increase the competitiveness of the EU industry for critical low-value products, potentially reducing the need for subsidies.

In the near future, the EU pharmaceutical strategy is likely to set the agenda in the EU for the years to come. In addition, national initiatives, e.g. the likely promotion of API manufacturing in France, will play an important role in this context, but it is so far unclear in how far these strategies will be coordinated at the EU level as well. Furthermore, various policy-independent private sector initiatives will also shape the future of the EU pharmaceutical sectors. For example, Sanofi announced the creation of a new company in the EU in February 2020, focusing on API manufacturing, through merging its six EU production sites into a standalone company to be headquartered in France (Sanofi 2020). Sanofi expects sales to reach USD 1 billion by 2022 and growth rates of 6 % p.a. (pre COVID-19-estimates).

Strategic stockpiling

Another option to increase the security of supply is stockpiling of pharmaceutical or intermediate products. The cost of stockpiling will differ with regard to its scale and scope, and depend on the answers to the following critical issues: (i) stockpiling on the EU or national levels?; (ii) inclusion of how many products (dozens to thousands)?; (iii) stockpiling to secure supply for which time period?; (iv) stockpiling of APIs for further processing, FDF for direct consumption, or a mix of strategies for different products?; (v) which actors should be involved in stockpiling (manufacturers, wholesale distributors, independent state entities, etc.) and under which conditions?; (vi) should stockpiling be centralized or decentralized in terms of warehouses? From a security of supply and cost-effectiveness perspective, the “best” stockpiling model will depend on its scale and scope. However, for larger-scale and longer-term stockpiling strategies, coordination at the EU level and stockpiling that includes a mix of API and FDF storage for different products is likely the best model. Smaller scale storage models may also be effectively organized at the national level.

Interviews during the research project revealed that the discussions are currently (October 2020) at an early stage (e.g. within the AGES task force and the EU pharmaceutical strategy). However, national strategies are currently a likely scenario. In Austria, 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 (they currently have stocks for roughly three weeks for products sold at pharmacies, given demand stability), expecting remuneration for their services.

Increase the resilience of (global) supply chains

Given the comparatively high cost of reshoring and strategic stockpiling, increasing the resilience of (global) supply chains is the most important policy intervention for most pharmaceuticals. In this context, measures that increase the number of supplying firms and regions for APIs or FDFs are particularly effective. This is because off-patent APIs are often supplied only by a few (and sometimes only one) suppliers and regions (in particular China). However, there are important product specific differences, even within specific product categories. Depending on the product, increasing the number of suppliers may be a challenge because it increases costs for buyers (due to supply chain management activities like quality assurance, etc.), but potentially also due to a lack of (so far) qualified suppliers. Given the concentration of off-patent API and FDF suppliers in Asia, in particular in China and India, the regional diversification of the value chain may be particularly challenging.

Given the current discussion, it is likely that most pharmaceutical companies will reevaluate their supply chain risk management, but the outcome of these internal evaluations are uncertain. Again, the major incentive for companies to restructure their supply chains would be buyers that give a higher weight to security of supply issues in their purchasing decisions. Depending on the specific requirements of buyers in the EU (regional production vs. regional diversification of suppliers), companies may be inclined to opt for regional diversification instead of regional production.

In contrast, imposing sourcing requirements on buyers would be very demanding given the need to develop product specific regulations that specify sourcing requirements for each input. In addition, companies may find it difficult to fulfill the specified requirements in the near term (e.g. lack of required supply).

Innovation policy

Innovation and R&D needs to be at the heart of any pharmaceutical strategy. In this study, innovation policy is only briefly discussed to highlight its potential to increase the resilience of supply chains. Promotion of R&D, ranging from lowering the environmental footprint to finding new input sources or manufacturing methods, may play a particularly important role in this regard. For example, the outsourcing of production in the EU was to some extent also a result of more stringent environmental standards and resulted in the outsourcing of “dirty industries” (e.g. antibiotics). Technological advances have improved the sustainability of production, and today, many products can be produced with much lower environmental impact. Similarly, the digitalization of production has reduced the labor-intensity of production, increasing the competitiveness of the EU industry relative to countries with lower wages and more labor-intensive manufacturing facilities for many products. Furthermore, R&D may fundamentally change specific supply chains, e.g. in case new sources for heparin can be found and the dependence on porcine mucosa can be reduced. Finally, enhancing and channeling R&D efforts to identify new drugs, e.g. new antibiotics, will be crucial in the future. Given the limited R&D investments of private actors in products with lower profitability, government regulations or incentives need to be strengthened.

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ANNEX

A. Interviews

All interviews were conducted in person or by telephone between August and November 2020 and supplemented by inquiries via email.

Table 4: List of interview partners – Case study medical products

Name	Type of institution/organization/company
Association of Medical Products	Chamber of Commerce
Association of Textile, Fashion, Shoe and Leather Industry	Chamber of Commerce
Austrian Red Cross	Non-Profit Organisation
Aventrium Health Care GmbH	Private company, producer of respirators
Borealis	Private company, producer of melt-blown and polypropylen
Carl Reiner	Private company, producer of ventilators
faigle Kunststoffe GmbH	Private company, producer of equipment for medical globe producers
Federal Ministry for Digital and Economic Affairs	Ministry
Goldhauben-Webe e.U.	Private company, producer of face masks
Hage Sondermaschinenbau	Private compancy, producer of high-tech machines for special purposes
Hamilton Medical AG	Private company, producer of ventilators
Landeskrankenanstalten-Betriebsgesellschaft - KABEG	Public hospital
Lohmann & Rauscher GmbH	Merchant (medical gloves)
mpö pfm GesmbH	Merchant (equipment for verntilators)
Oberösterreichische Gesundheitsholding GmbH (OÖG)	Public hospital
Semperit	Private company, producer of medical gloves
Sigmathek	Private compancy, producer of electronical equipment for automation
Technical University of Graz	Expert
Technomed GmbH	Merchant (medical gloves)
Vienna University of Economics and Business	Expert
vProtect Austria (Fa Grabher Group)	Private company, producer of respirators

Table 5: List of interview partners – Case study pharmaceutical products

All interviews were conducted in person or by telephone between August and November 2020 and supplemented by inquiries via email.

Name	Type of institution/organization/company
Austrian agency for health and food safety GmbH (AGES)	State institution
Austrian Chamber of Pharmacists	Industry association
Austrian Institute for Health Technology Assessment GmbH (AIHTA)	State institution
Anonymized multinational pharmaceutical company	Multinational pharmaceutical company
Anonymized pharmaceutical company	Pharmaceutical company
Association of Austrian pharmaceutical wholesalers (PHAGO)	Industry association
Association of the Austrian pharmaceutical industry (PHARMIG)	Industry association
European Chemical Industry Council (CEFIC) / European Fine Chemicals Group (EFCG)	Industry association
GlaxoSmithKline (GSK)	Multinational pharmaceutical company
Health Austria GmbH (GÖG)	State institution
Merck KGaA	Multinational chemical and pharmaceutical company
Organization for Economic Co-operation and Development (OECD) – ELS/Health Division	Multinational institution/Expert
Sandoz GmbH – Austria	Pharmaceutical company
University of Bremen	University/Expert
University of Manchester	University/Expert
Vienna nursing and patient advocacy (WPPA)	State institution

Die Autoren:

Jan Grumiller holds a PhD in economics and is a Researcher at ÖFSE. His research focusses on industrial policy and value chain analysis. He has worked on various commodity and food sectors (olive oil, mango, cocoa, seafood) and the textile and apparel industry, both in Africa (Cote d'Ivoire, Ghana, Mozambique) and Asia (Vietnam).

Hannes Grohs is an economist and Research Assistant at ÖFSE. He has participated in various GVC analyses and provided data assistance and desk research.

Christian Reiner studied economic geography, history, and economics at the University of Vienna and the University of Salzburg. He has a doctoral degree in economic geography (University of Salzburg) and experience in basic and applied empirical economic research (Vienna University of Economics and Business, Joanneum Research, Institute for Advanced Studies). Christian Reiner works as a senior scientist at the Lauder Business School and as a lecturer in economics, economic geography, and statistics at the University of Vienna, Modul University Vienna, University of Applied Sciences BFI Vienna and the FH Wien University of Applied Sciences of WKW. His fields of interest include regional economics and industrial organization. Mr. Reiner's research has added insights into the following topics: Structural change, growth policy, innovation, human capital mobility, industrial policy, green growth, and policy evaluation. He will be responsible for conducting research on the case studies in Work Package 2 of this project.

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