What does the COVID-19 crisis tell us about the European healthcare manufacturing value chain?

The current discussions on the lack of medical equipment in the context of the COVID-19 crisis in Europe trigger a debate on the optimal organisation of the medical devices value chain and Europe's industrial resilience in a globally optimised time-to-market value chain. In dealing with this new situation, Europe does not have to launch completely new initiatives, but is able to expand existing policies of analysis and support of what it calls 'Strategic Value Chains'. This will allow to emerge stronger from the current Crisis and to be better prepared for health emergencies of the future.

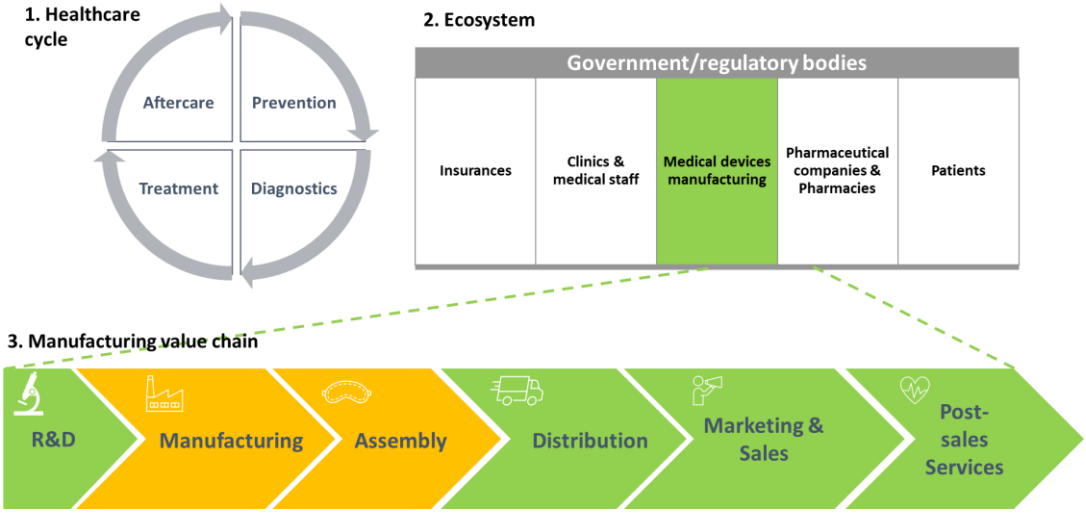
Medical Face Masks raising attention to the risks related to the global value chain

The hot topic of March 2020, the global Medical Face Masks market[1], clearly illustrates the increasing need of giving the healthcare manufacturing sector further attention. Face surgical masks, are classified as Class I (sterile) – low risk medical device according to the Medical devices Regulation[2], which due to the surge of demand across the globe have seen price increases of more than 10 times the pre-crisis prices in the US.[3]

The medical devices manufacturing value chain & COVID-19 market challenges

All medical supply is linked to four stages of the healthcare cycle: prevention, diagnostics, treatment, and aftercare. The ecosystem of stakeholders defining the supply, formats, and demand of products ranges from governments/regulatory bodies to insurances, clinics and medical staff, pharmaceutical companies, and patients to medical devices manufacturers. The sector is currently valued at least €7 500 million.[4]

Figure 1 The medical devices manufacturing value chain and its healthcare ecosystem



Source: Ecorys (2020) based on DG GROW (2017) Refurbishment of Medical Equipment and Torsekar, Mihir. "China Climbs the Global Value Chain for Medical Devices." Journal of International Commerce and Economics, February 2018. https://www.usitc.gov/journals

Despite an ever-increasing market for medical products over the last decades, advanced economies decided to outsource their production to cheaper locations. In the case of Europe, this trend is illustrated by the more than €16 billion difference between the value added of EU27 (excluding the

[1] NOTE: Masks are only one recent example. In case of alternative pandemics also productions of e.g. antibiotics might cause similar challenges.

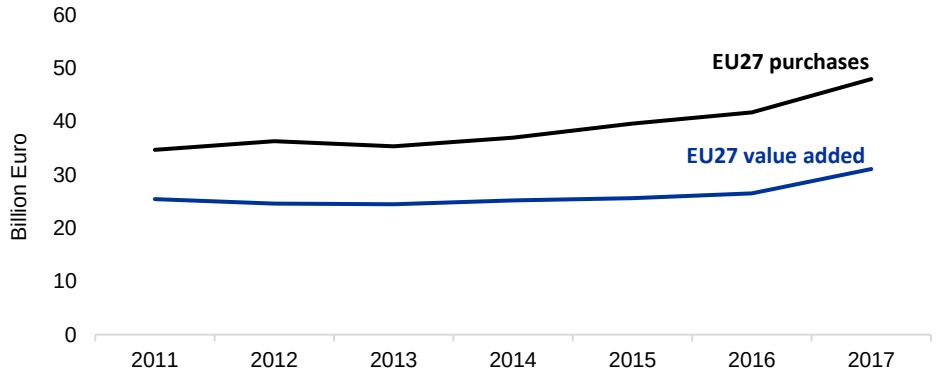
[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC

[3] https://www.newsweek.com/supplier-charging-7-per-face-mask-that-typically-costs-58-cents-hospital-ceo-says-1493106

[4] Industry Research(2020): GLOBAL MEDICAL FACE MASKS MARKET RESEARCH REPORT 2020

United Kingdom) manufacturing of medical instruments and supplies and the total EU27 market demand of those. Originally, these aspects focused on the sole parts of manufacturing and assembly, which are considered as low added value parts of the value chain. The 'factory of the world', China, has however recently also strongly expanded its role towards other high-end components of the value chain. This shift is reflected in the types of FDI made during this time. From 2009 through 2017, the majority of investments were geared towards R&D, distribution, marketing and sales, and post-market services.[5]

Figure 2 Value added and total purchases in Manufacture of medical and dental instruments and supplies



Source: Ecorys (2020) based on Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

This further increased a strong reliance on China for the supply of protective equipment that is indispensable for halting the current pandemic or any sudden and unexpected health emergencies. Even though, China relaunched its production after the total shutdown of February 2020, and large-scale producers can produce up to 500 000 masks per day, nowadays countries from all over the world are desperately ordering tens of millions of N95 masks from different suppliers in parallel. This is creating an inscrutable market picture. As oversight is lacking, the Chinese government might claim a large share of the production for its own demand at one point. Moreover, the rush in production seems to have hampered quality of the masks delivered to Europe. [6]

As a consequence, Europe is trying to get its share on the world market for medical equipment to fight the current pandemic by paying 'whatever it takes' while mobilising local production capacities. The latter is supported by actions such as the provision of free access to standards for masks[7] or the mobilisation of European industrial clusters and exchange of experience and matching supply and demand on the COVID-19 Response Forum of the European Cluster Collaboration Platform[8].

Adjusting policy initiatives to leverage Europe's resilience

As part of its adjustment to the current situation, the EU has decided to postpone the deadline for full application of the Medical Devices Regulation (MDR) by one year. Maintaining the current regulatory framework under the existing Directive (93/42/EEC)[9] aims to reduce compliance and administrative burden increase the speed of production of goods required for responding to the current crisis.

[5] Torsekar, Mihir. "China Climbs the Global Value Chain for Medical Devices."
Journal of International Commerce and Economics, February 2018. https://www.usitc.gov/journals
[6] Clingendael (2020): Taking back responsibility A joint effort to increase the production of medical masks in Europe
[7] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_502
[8] https://www.clustercollaboration.eu/forum/covid-19-response-forum
[9] See https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

Unclear impacts of the MDR

With the entry into force of the regulation in its existing form, the scope of the definition of medical devices would be wider and the updated classification and additional requirements (e.g. in relation to traceability) will be stricter. This is expected to strengthen the internal market and promote standardisation of EU production of medical devices. However, when it comes to players outside of Europe whose main focus lies in different markets and in particular SMEs, these additional requirements could lead to reduced interest in the EU market. The key question is, what would the EU's production capabilities be with the MDR in force and how could the EU respond to such a crisis under a less agile legislation.

As part of its 'New Industrial Strategy for Europe', the European Commission is expected to publish a Pharmaceutical Strategy, to be adopted in the fourth quarter of 2020[10]. The strategy will focus on strengthening the availability, affordability, sustainability, and security of supply of pharmaceuticals in the EU in view of the challenges emerged from the outbreak of COVID-19[11].

Both, the adjustment of the timeline for the MDR and the Pharmaceutical Strategy show the ambition to move into the right direction. What is important now, in fact, is that Europe continues to move from managing the crisis to an agile approach of streamlining further planned policy initiatives to the changing demands. Making use of existing mechanisms and drawing the right conclusions from previous crises, will allow Europe to emerge stronger from the current Crisis. Therefore, we argue that European policy makers also in non-directly health related policy initiatives do not have to completely launch new actions but can build on what has already been started.

Experiences of designing economic policy due to political challenges

COVID-19 will not be the first time economic policy is influenced by wider strategic and policy challenges. The reactions to the Ukraine war e.g., boosted the debate on European defence capabilities giving an important push to the establishment of the European Defence Fund (EDF). In its set-up, while promoting competitiveness of EU industry, it ultimately addresses Europe's lack of sovereignty in security and defence.[12]

A second example to draw from is the realisation of lagging behind on technological developments (IoT, Big Data etc.). Recently launched initiatives addressing data sovereignty as well as digital competences like data literacy can be seen as investments in competitiveness, but also in independence as they clearly aim to 'increase Europe's technological sovereignty in key enabling technologies and infrastructures for the data economy'.[13] Interestingly, the healthcare system was already addressed in the data strategy, where it states that *"A Common European health data space, which is essential for advances in preventing, detecting and curing diseases as well as for informed, evidence-based decisions to improve the accessibility, effectiveness and sustainability of the healthcare systems."*[14]

Focusing on the third dimension of defining Strategic Value chains

At the focus of our attention in widening existing policy initiatives towards incorporation of healthcare manufacturing policies is in our view the Strategic Forum for Important Projects of Common European Interest (IPCEI). The Strategic Forum describes strategic value chains (SVCs) as '*of systemic importance'* and acknowledges that they *'make a clear contribution to growth, jobs and*

[10] https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-a-pharmaceutical-strategy-for-europe

[11] COM (2020) 102 final: A New Industrial Strategy for Europe

[12] COM(2020) 102 final: A New Industrial Strategy for Europe

[13] COM(2020) 66 final: A European strategy for data

[14] COM(2020) 66 final: A European strategy for data

competitiveness'. Even though, in February 2019, the Strategic Forum selected with 'Smart Health' as one of the six[15] strategic value chains for Europe a health related sector, its definition of what is 'strategic' might differ from what we have learnt due to COVID-19. The third dimension of their characterisation (in addition to technological innovativeness and economic and market potential) – societal and political importance[16] – can and probably should also be interpreted as addressing issues such as health and safety of European citizens. For the future, one would expect therefore, that the manufacturing of healthcare products becomes another sector declared to be of strategic importance at a European level. In the past, Europe might have relied too much on the certainty that the sector was relatively price inelastic compared with the demand for other goods which are subject to more discretionary purchasing decisions during economic downturns.[17] However pandemics or natural catastrophes drastically impacting the demand and blocking trade routes have not been considered enough.

It is important to mention that the strategic nature of the manufacturing of healthcare products and particularly those of low value production differs with respect to the SVCs selected so far. It is strategic due to its health importance not to its potential economic prospects. This is why blind investments into recreation of basic manufacturing capabilities might not be the solution to the problem. Bruegel argues that "*while localisation of production for some specific goods might be necessary to prepare for pandemics, there are substantial advantages to keeping Europe's markets for medical goods open*"[18]. They argue that healthcare in the EU is already very costly, however "*precautionary stockpiling of non-perishable medical goods and provision of intensive-care beds and medical testing facilities do not need local production, and would have gone a long way to alleviate the shortages currently experienced*". Examples of stockpiling from the past have however been of mixed success. Health ministers of various Member States including France and Austria have been criticised for over-expenditure on masks in preparation of outbreaks such as SARS or A/H1N1 flu. In contrast, Belgium destroyed around 6 million FFP2 type face masks because they had exceeded their expiration date.[19] Nevertheless, the immediate reaction at European level, appears to follow the suggestion of Bruegel with the first ever creation of a rescEU stockpile to fight COVID-19.[20]

Neither stockpiling nor recreating launchable manufacturing capabilities for emergencies needs to be mutually exclusive solutions. A thorough understanding of the weaknesses and potential gaps of the value chain including emergency plans is fundamental in order to take informed policy decisions. Such a timely and informed approach would help shaping the right plans to avoid major glitches and shortages at times of similar crises in the future.

Relevant Ecorys work

Ecorys has conducted more than 40 industry studies for the European Commission over the last 15 years and analysed a broad variety of value chains ranging from classic industries (glass, ceramics, cements…) to new value chains such as hydrogen fuel cells or ocean energy.

For more information about our work in this area, please contact: andreas.pauer@ecorys.com

[15] The others are: Clean, connected, and autonomous vehicles; Low CO2 emissions Industry; Hydrogen technologies and systems; Industrial Internet of Things; Cybersecurity

[16] European Commission DG GROW (2018): Strengthening Strategic Value Chains for a future-ready EU Industry. Report of the Strategic Forum for Important Projects of Common European Interest

[17] SWD(2014) 216 final/2 PHARMACEUTICAL INDUSTRY: A STRATEGIC SECTOR FOR THE EUROPEAN ECONOMY

[18] https://www.bruegel.org/2020/04/eu-trade-in-medical-goods-why-self-sufficiency-is-the-wrong-approach/

[19] https://www.euractiv.com/section/all/short_news/brussels-mask-stocks-destroyed-without-replacement/

[20] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_476