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Study on security of supply of medical products: production close to home

Draft report

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25-06-2022

Managementsamenvatting (NL)

Recente ontwikkelingen zoals de COVID-19 pandemie en de oorlog in Oekraïne benadrukken dat de leveringszekerheid van medische producten niet langer vanzelfsprekend is. Nederland en ook de Europese Unie wil structureel – los van een crisis – minder kwetsbaar en afhankelijk zijn van een beperkt aantal landen of leveranciers. Verschillende facetten kunnen bijdragen aan het borgen van leveringszekerheid, zoals ook het produceren dicht(er) bij huis.

Voorliggend rapport beschrijft de resultaten van onderzoek in opdracht van het Ministerie van Volksgezondheid, Welzijn en Sport (VWS) naar stimuleren van leveringszekerheid door productie dichtbij huis. In dit onderzoek is onderzocht welke (beleids-)instrument in Europa en de USA actief zijn en hoe (effectief) deze productie dichtbij huis stimuleren.

Om (beleids-)instrumenten te identificeren is eerst een overzicht gemaakt van productielocaties in westerse landen voor de volgende vijf productcategorieën: persoonlijke beschermingsmiddelen (PBM), COVID vaccines, vaccines, medicijnen en medische apparatuur. Vervolgens is aanvullend onderzoek gedaan naar de landen waarin een (relatief) hoog aantal productielocaties geïdentificeerd zijn. Met als resultaat inzicht in (beleids-)instrumenten in de volgende acht landen: VS, Duitsland, Frankrijk, VK, België, Zwitserland, Italië en Spanje.

Verschillende type (beleids-)instrumenten zijn onderzocht, die allen bij kunnen dragen aan de keuze om in een bepaald land te produceren. Daarbij onderscheiden we financiële, wet en regelgeving, productie, marketing en infrastructuur.

Vijf casussen zijn in meer detail geanalyseerd:

- Wetgeving dat de productie van PBM in de USA stimuleert;
- Opschaalbare productiecontracten afgesloten door de Duitse overheid om (pandemische) vaccin productie te garanderen;
- Beleid van de Franse overheid om industriële projecten in de medische sector te ondersteunen die bijdragen aan onderzoek en lokale productie van medische producten;
- Kapitaalsubsidies van de Britse overheid om ontwikkeling en productie van medische technologie te stimuleren;
- Financiële steun om de productie van penicilline in Oostenrijk te behouden.

De onderzochte (beleids-)instrumenten zijn wisselend succesvol geweest in het realiseren van productie dichtbij huis

Op basis van de onderzochten casussen kan geconcludeerd worden dat er effectieve (beleids-)instrumenten zijn om lokale productie te stimuleren. De werkzaamheid varieerde per casus:

1. De VS slaagde erin om minder afhankelijk te worden van andere landen voor PBM door het implementeren van ‘reshoring’-beleid. De kosten van reshoring zijn echter hoog en de baten hangen grotendeels af van de, hoogst onzekere, toekomstige vraag naar persoonlijke beschermingsmiddelen.
2. De Duitse regering is van plan om contracten te sluiten met vaccinproducenten om ervoor te zorgen dat er snel genoeg vaccins kunnen worden geproduceerd voor de Duitse bevolking als de COVID-19-pandemie aanhoudt of een nieuwe pandemie uitbreekt. Op korte termijn is hiermee de toegang tot vaccins gegarandeerd. Op de lange termijn is het echter een risico om een aanzienlijk bedrag te betalen voor stand-by-capaciteit die misschien niet nodig is.
3. De Franse overheid lijkt effectief in het aantrekken van (buitenlandse) fabrikanten om (algemene) medicijnen in Frankrijk te produceren. Relatief kleine financiële steun van de Franse overheid resulteerde in grote investeringen door (buitenlandse) farmaceutische bedrijven. Het is echter onduidelijk in hoeverre deze investeringen het gevolg zijn van beleid dat specifiek is gericht op farmaceutische bedrijven of het resultaat zijn van de brede her-industrialisatiepolitiek van het land.
4. Het VK heeft beleid om de binnenlandse productie van medische hulpmiddelen te stimuleren, maar deskundigen vrezen desondanks dat producenten het VK zullen verlaten. Met name kleinere producenten zijn niet in staat het hoofd te bieden aan de wet- en regelgevingsproblemen die voortvloeien uit de Brexit.
5. De Oostenrijkse regering slaagde erin een deal te sluiten met een particulier bedrijf om de productie van actieve farmaceutische ingrediënten voor penicilline in Oostenrijk veilig te stellen.

Managementsamenvatting (NL)

Reshoring heeft voordelen, maar deze voordelen hebben een aanzienlijke prijs en staan haaks op de economische principes van globale handel

De casestudies laten zien dat reshoring werkt. Met investeringen in productiecentra, importbeperkingen, actieve samenwerking tussen overheden en producenten en overheidssteun zetten producenten de stap om in het betreffende land te gaan produceren. De leveringszekerheid van de producten die lokaal geproduceerd worden neemt daarmee toe. Reshoring heeft ook als bijkomend voordeel dat het de transportkosten verlaagt, die momenteel snel stijgen.

Aan de andere kant hebben landen die investeren in reshoring van de productie van medische producten vaak een breder industriebeleid dat niet primair gericht is op leveringszekerheid, maar gericht is op het aantrekken van bedrijvigheid in algemene zin en het creëren van banen. Het is onzeker of een reshoring-beleid met een lager budget, dat alleen gericht is op leveringszekerheid, in een land als Nederland op grote schaal zou kunnen werken.

Reshoring-beleid is vooral kostbaar als er weinig tot geen economische voordelen zijn, wat het geval zou kunnen zijn in Nederland omdat de werkloosheid (althans momenteel) laag is. Een ander nadeel van het toepassen van reshoring-beleid (op grote schaal) is dat het de geopolitieke balans van vrijhandel kan verstoren. Als steeds meer landen de voorkeur geven aan lokale productie, nemen de voordelen van de globale handel af.

Als de Nederlandse overheid reshoring-beleid wenselijk acht, is het verstandig om reshoring op Europees niveau na te streven

Voor Nederland is het stimuleren van productie dichtbij huis extra uitdagend, omdat producenten aangeven niet primair naar Nederland te kijken om de Europese markt te betreden, maar juist naar landen als Duitsland en Frankrijk. Deze landen hebben (net als Nederland) een goed investeringsklimaat met veel R&D en gekwalificeerd personeel. Maar Duitsland en Frankrijk hebben een veel grotere afzetmarkt, waardoor het behalen van rendement op investeringen makkelijker wordt.

Vanuit het perspectief van Nederland kan beleidsontwikkeling om de productie van kritieke medische producten dichter bij huis te brengen het beste op EU-niveau worden gedaan, in plaats van door elke individuele lidstaat. Productiecentra in omringende landen zouden ook medische producten voor Nederland kunnen produceren zonder dat elke lidstaat hoeft te investeren in het aantrekken van productiecentra. De productie is weliswaar minder dicht bij huis, maar de risico's met betrekking tot de leveringszekerheid zijn kleiner in vergelijking met bijvoorbeeld China of India.

Het is raadzaam om op EU-niveau een scan uit te voeren naar de productie van medische producten die wel of niet (voldoende) aanwezig is in de Europese Unie. Aanvullend kan onderzocht worden welke productie van medische producten eventueel naar Europa kan worden teruggehaald. De Europese Commissie werkt al aan het verminderen van de afhankelijkheid en het verbeteren van de beschikbare capaciteit voor een breed scala aan producten, waaronder geneesmiddelen. Soortgelijke trajecten kunnen ook ingezet worden voor andere medische producten.

Naast Europese inspanningen zou de Nederlandse overheid zich kunnen inspannen voor het behouden en uitbreiden van de huidige productiecapaciteit of het terughalen van de productie van de meest kritische medische producten

Gezien de verschillende mogelijkheden om de productie dicht bij huis te stimuleren en de randvoorwaarden die daarvoor nodig zijn, lijken de volgende manieren om de huidige productie te stimuleren het beste passen in de Nederlandse context:

- Zorgen dat producenten die al in Nederland produceren blijven, door ervoor te zorgen dat wordt voldaan aan de voorwaarden die producenten nodig hebben om te blijven;
- Zorgen voor een bloeiend startup klimaat dat ook stimuleert om niet alleen te onderzoeken en te ontwikkelen, maar ook te produceren in Nederland;
- Aangaan van contracten met producenten van gewenste medische producten om de productiecapaciteit in Nederland te behouden.

Bovenstaand beleid is gericht op het behouden en eventueel uitbreiden van de productiecapaciteit van de huidige bedrijven. Tegelijkertijd zou reshoring iets kunnen zijn dat Nederland zou kunnen nastreven voor de meest kritische medische producten, hoewel het waarschijnlijk erg duur is.

Executive summary (EN)

Security of supply of medical products has became an point of attention due to recent developments such as The COVID-19 crisis, the war in Ukraine and the departure of the United Kingdom from the European Union. The Netherlands and the European Union want to be structurally – apart from a crisis – less vulnerable and dependent on a limited number of countries or suppliers. This study, commissioned by the Dutch Ministry of Health, Welfare and Sport (VWS) aims to investigate policy instruments that stimulate local production in western countries. With this purpose, policies measures in several European countries and the USA are identified, and an assessment is made on how (effectively) they stimulate local production.

In order to achieve the goals set out for this study, first an overview of the current production centers in western countries is made for the following five product groups: personal protection equipment (PPE), COVID vaccines, non-COVID vaccines, medicines and medical devices. From there, additional research is conducted on countries that are home to a (relatively) high number of production locations for a certain medical product. This results in insights into policy instruments in the following eight countries: USA, Germany, France, UK, Belgium, Switzerland, Italy and Spain.

Several types of policies are examined which could drive the production centers to operate at the current location: financial, regulatory, production, marketing and infrastructure support. Subsequently, a deeper dive is performed into five selected cases:

- Legislation that stimulates reshoring PPE production to the United States;
- Scalable production contracts used by the German government to secure (pandemic) vaccine production;
- Support of the French government for industrial projects in the medical sector to increase domestic R&D and production of medical products;
- Capital grands that aim to encourage development and manufacturing of MedTech products within the United Kingdom
- Financial aid to maintain the production of penicillin in Austria.

The investigated policies have been successful to varying degrees

Based on the five case studies that were assessed, it can be concluded that there are effective ways to boost domestic production capacity, but the efficacy varies:

1. The USA became less dependent on other countries for PPE products by implementing reshoring policies. However the costs of reshoring are high and benefits largely depend on future demand for PPE, which is uncertain and cannot be predicted.
2. The German government is planning to sign contracts with vaccine producers to ensure that enough vaccines can be produced quickly for the German population if the COVID-19 pandemic persists or a new pandemic breaks out. On short term, access to vaccines is secured and might help the country navigate through a flare up of COVID-19. In the long term, however, it's a risk to pay a significant amount of money for stand by capacity that might not be necessary.
3. The French government seems to be effective in attracting (foreign) manufacturers to produce (general) medicines in France. Relatively small financial support by the French government resulted in large investments by (foreign) pharmaceutical companies. However, it is unclear to what extent these investment are a result of the policies specifically aimed at pharmaceutical companies or whether they are the result of large-scale reindustrialization policies of the country.
4. The UK has policies in place to stimulate domestic production of medical devices, however, experts expect that these incentives are not sufficient and that producers will leave the UK, because SMEs are not able to meet regulatory challenges that result from Brexit.
5. The Austrian government was successful in striking a deal with a private company to secure production of active pharmaceutical ingredients for penicillin in Austria.

Executive summary (EN)

Reshoring has benefits, but these benefits come at a significant price and reshoring goes against some economic principles

The case studies show that reshoring works. With investments in production centers, restrictions on import, active cooperation between governments and producers and government support to navigate regulatory processes, producers take the step to produce in the country concerned. In this way, these countries have an advantage over other countries when medical products are scarce. Reshoring also has an added benefit of lowering transportation costs, that are currently rising rapidly.

on the other hand, countries that invest in reshoring production of medical products often have a broader industrial policy that is not primarily focused on security of supply, but that is focused on attracting business activity in a general sense and create jobs. It is uncertain whether a reshoring policy with a lower budget, focusing only on security of supply, could work on a large scale in a country like the Netherlands.

Reshoring policies are especially costly when there are little to no economic benefits, which could be the case in the Netherlands, because unemployment (at least currently) in the Netherlands not an issue. Another disadvantage of applying reshoring policies (on a large scale) is that it could upset the geopolitical balance of free trade. If more and more countries start preferring local production, the benefits from global trade will diminish.

If the Dutch government deems reshoring desirable, it would be wise to pursue reshoring on a European level

For the Netherlands, stimulating production close to home is extra challenging, because producers indicate that they do not primarily look to the Netherlands to enter the European market, but rather to countries like Germany and France. These countries (just like the Netherlands) have a good investment climate with a lot of R&D and qualified personnel, but the countries have a much larger sales market, which makes it easier to effectuate return on investments.

From the perspective of the Netherlands, policy making to bring production of critical medical products closer to home can best be done on the EU-level rather than by each individual member state. Production centers in neighboring countries could produce medical products for the Netherlands also without each member state having to invest in attracting production centers. Production may be less close to home, but the risks regarding security of supply are in reduced in comparison to - for example - China or India.

It is advisable to carry out a scan at EU-level of what kind of production of medical products is and what is not (sufficiently) present in the European Union and what kind of production of medical products can and cannot be reshored to Europe. The European Commission is already working on reducing dependencies and improving capacity for a wide range of products, including pharmaceuticals. Similar trajectories could also be induces for other medical products.

Apart from European efforts, the Dutch government could put effort in maintaining and expanding current production capacity or reshoring the most critical medical products

Given the different options to stimulate production close to home and the preconditions that this requires, it seems that the following ways to stimulating current production are most fitting for the Dutch context:

- Ensuring that producers who already produce in the Netherlands stay, by making sure that the conditions that producers need to stay are met;
- Ensuring that there is a flourishing start-up climate that is also stimulating to not only research and develop, but also produce in the Netherlands;
- Sign contracts with current producers of desired products to maintain production capacity.

The above policies are aimed at maintaining and possibly expanding production capacity of current businesses. At the same time, reshoring could be something that the Netherlands could pursue for the most critical medical products, although it would likely be very expensive.

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1. Introduction and methodology

This report provides insight into the policy instruments in several EU-countries and the US which stimulate local production

Background information

Security of supply of medical products has became an point of attention due to recent developments such as The COVID-19 crisis, the war in Ukraine and the departure of the United Kingdom from the European Union. The Netherlands and the European Union want to be structurally – apart from a crisis – less vulnerable and dependent on a limited number of countries or suppliers.

Various aspects can contribute to guaranteeing security of supply and supply chain resilience. For example, with smart purchasing strategies and/or sustainable and innovative production close to home, dependency from other countries can be reduced.

This document is written from the perspective of the Netherlands. Three studies are conducted commissioned by the Dutch Ministry of Health, Welfare and Sport (VWS) in the field of medical products to formulate policies aimed at strengthening the security of supply. All of these studies follow a different approach on security of supply:

1. insight into the production and supply chains of some medical products (from raw material, including necessary substances / semi-finished products / technologies to the final product, including logistics and distribution);
2. increasing security of supply by stimulating production close to home;
3. stimulating security of supply through smart purchasing strategies.

This report describes the results of the second study.

Goal of the study

This study aims to investigate policy instruments that stimulate local production in western countries. With this purpose, policies measures in several European countries and the USA are identified, and an assessment is made on how (effectively) they stimulate local production. With this study, insights are created on several policy instruments and whether they would be effective in the Netherlands.

Research questions

This report focuses on the following research questions:

- Which western countries are home to production hubs for medical products?
- Are there policy instruments that stimulate production in those western countries?
  - What are the policy instruments that apply in the selected countries?
- How effective are these policy instruments in stimulating production close to home?
  - What costs and benefits are associated with the policy instruments?
- Which recommendations can be made about the policy instrument to stimulate production close to home within the Dutch context?

By exploring international policies and assessing promising policies, conclusions about production close to home are drawn for the Netherlands

Methodological approach

1. In order to achieve the goals set out for this study, first an overview of the current production centers in western countries is made for the following five product groups: personal protection equipment (PPE), COVID vaccines, non-COVID vaccines, medicines and medical devices. From there, additional research is conducted on countries that are home to a (relatively) high number of production locations for a certain medical product. This results in insights into policy instruments in the following eight countries: USA, Germany, France, UK, Belgium, Switzerland, Italy and Spain.
2. Several types of policies are examined which could drive the production centers to operate at the current location: financial, regulatory, production, marketing and infrastructure support. Subsequently, a deeper dive is performed into five selected cases regarding a specific product group in a specific country, to assess these on multiple aspects. This assessment provides insights into the costs and benefits of the policy instrument together with its effectiveness in bringing production close to home.
3. These insights are structured through an assessment framework, to be able to compare the pros and cons of the different options.
4. These insights result in conclusions about policies to stimulate production close to home in the Netherlands.

Research methods

In order to be able to formulate reliable and supported answers to the research questions, a structured analysis of articles was carried out on the basis of extensive deskresearch. This extensive deskresearch provided insights into both the production locations as well as the policy instruments of western countries. Even though a large amount of production hubs and policy instruments were identified, this report doesn't provide an exhaustive overview of the production of medical products nor the policy instruments applied in the selected countries.

Based on the identified policy instruments, five case studies were selected. This was done based on certain criteria, such as an interest in policy types (reshoring and scalable production locations) and different product categories. Additional deskresearch was conducted and interviews were held with two experts from Germany and UK and two producers of medical products (PPE and medical devices) that operate internationally in order to obtain a more in-dept understanding of the selected cases.

In addition, the five cases were evaluated with a predetermined assessment framework. This framework was developed to create insights into the relative value of each policy instrument and to evaluate whether (elements of the) cases can valuable in the Dutch context.

Periodic coordination has taken place with employees from VWS and draft results were discussed. Insights from these different sources, perspectives and stakeholders were compared and contrasted to create the insights incorporated in this report.

1 Exploring policies and production hubs

Broad exploration of policies and production hubs in eight countries. In total, 90+ policies and 240+ production hubs have been identified

2 Selecting cases and in-depth analysis

In consultation with VWS, selection of five cases based on interest in particular policy types (reshoring and scalable production locations) and pertaining to different product types and countries. The following cases were selected:

1. Legislation encouraging reshoring of PPE production to the USA
2. Scalable manufacturing contracts used by the German government to secure production of (pandemic) vaccines
3. Support from the French government for industrial projects in the medical sector to increase domestic R&D and production of medical products
4. Capital grants to promote the development and production of MedTech products in the UK
5. Production of penicillin in Austria

Additional deskresearch and interviews were conducted to gain a more thorough understanding of the selected cases

3 Assess cases by applying an assessment framework

By applying an assessment framework to the cases, we mapped out what policies are effective and would fit in the Dutch context. The following criteria were used:

1. Costs of the policy
2. Effect on production close to home and/or supply chain security
3. Innovation
4. Environmental effects
5. Distinctive capability
6. Fit with Dutch/EU context

4 Draw conclusions

Based on insights from the various analyses, conclusions are drawn on how the Netherlands can promote security of supply with production close to home

Reading guide

In chapter 2, the report starts with an overview of the production hubs of the medical products and the related policy instruments per country. In chapter 3 we dive deeper into the five selected cases of policy instruments stimulating the production of medical products in a specific country.

The next chapter consists of an assessment of the selected cases to evaluate the costs of the policy, their effectiveness, the environmental effects and their fit with the Dutch context, among others things, to decide whether (elements of) this policy would be effective to introduce in the Netherlands.

Finally, the last chapter formulates conclusions and some recommendations for possible policy options within the Dutch context in order to increase production close to home.

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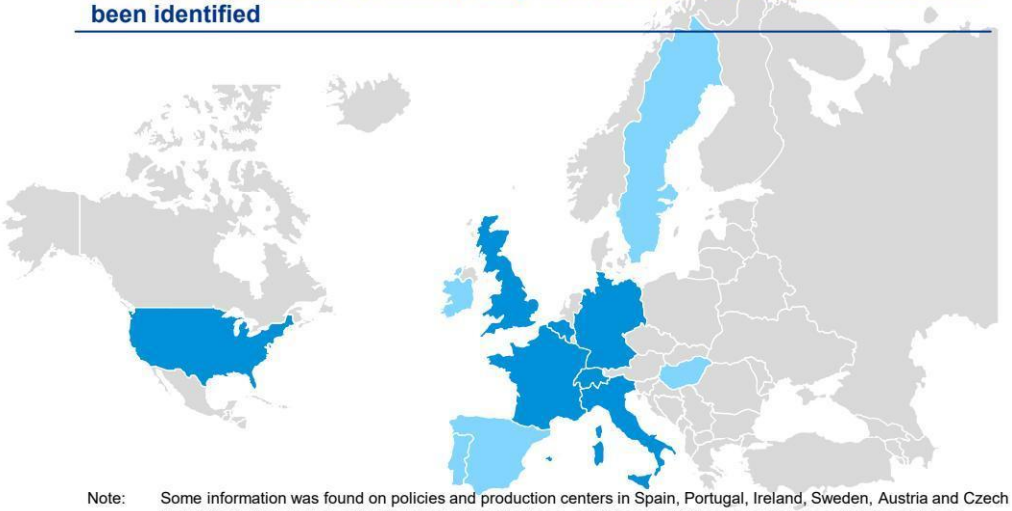
2. Overview of production hubs and policy measures per county

Production centers and policy instruments in western countries are identified based on publicly available information

Overview of countries for which policy instruments and production hubs have been identified



Note: Some information was found on policies and production centers in Spain, Portugal, Ireland, Sweden, Austria and Czech Republic that is reported on in this report. However these countries weren't in scope when research was done on production hubs and policies. The information about production centers and policies in these countries is therefor limited.

Policy types

The policies identified in this study are categorized by their nature. Note that most policies have a financial element, when possible they were assigned to subcategories as shown.

Policy type	*Description*	*Example*
Financial support	Policy aimed at financially supporting producers	Tax benefit, R&D investment
Regulatory support	Policies aimed at supporting producers to navigate regulatory processes	Fast-track program, relieving of liability
Production support	Cooperation between government and production centers to promote production	Public-Private Partnerships (PPP), investment in production capacity
Marketing support	Policies aimed at simplifying the marketing of manufactured products	Unrestricted price setting and advertizing
Infrastructure support	Policy aimed at simplifying the transport of manufactured products	Public infrastructure (such as airports) that are certified for transport of products

This chapter describes an overview of production centers and policy instruments per country

In order to identify policy instruments that support production close to home, research has been carried out to locate production centers for medical products in western countries. For eight countries (US, Germany, France, UK, Belgium, Switzerland, Italy and Spain), an overview is provided on the production centers located in these country's and what the country's policies are for stimulating production close to home. A distinction is made between the five different types of medical products that are in scope and five different types of policies, as shown on the left. In total, 245 production centers and 95 policy instruments are summarized. An overview of all identified policy instruments with a more detailed description of the policy instrument is described in annex A.

The overview production hubs and policy instruments in these countries is not exhaustive, but gives a perspective on the medical products that are produced per country and how the national governments stimulate production

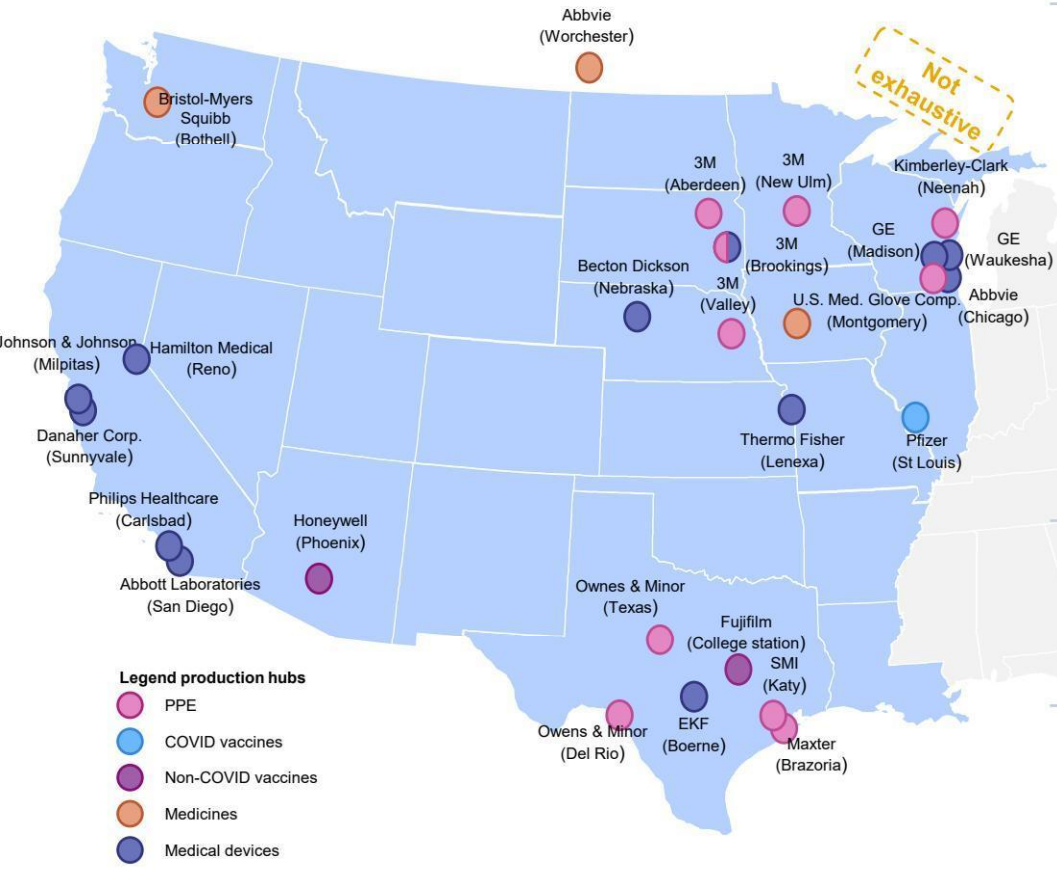
A complete overview of the manufacturers involved in the production of medical products in a country is often not publicly available. With exceptions such as the production of COVID vaccines in Europe, as this has been closely monitored in recent years.[1] Also, countries often apply different and complex policy schemes in their strategy to stimulate local production and increase the security of supply.

The information on the following pages has therefore been compiled by extensive deskresearch, combining publicly available information regarding individual manufacturers and individual policy instruments. The overviews on the following pages are therefore by no means exhaustive. However, they do give a perspective on the types of producers that are active and the types of products that are available.

The overviews could be further complemented by an additional search for producers and policy measures in the respective countries. In this report they were merely used to select interesting cases to follow up on in chapter 4.

Overview of production hubs and policies in the USA (1/2)

Production hubs



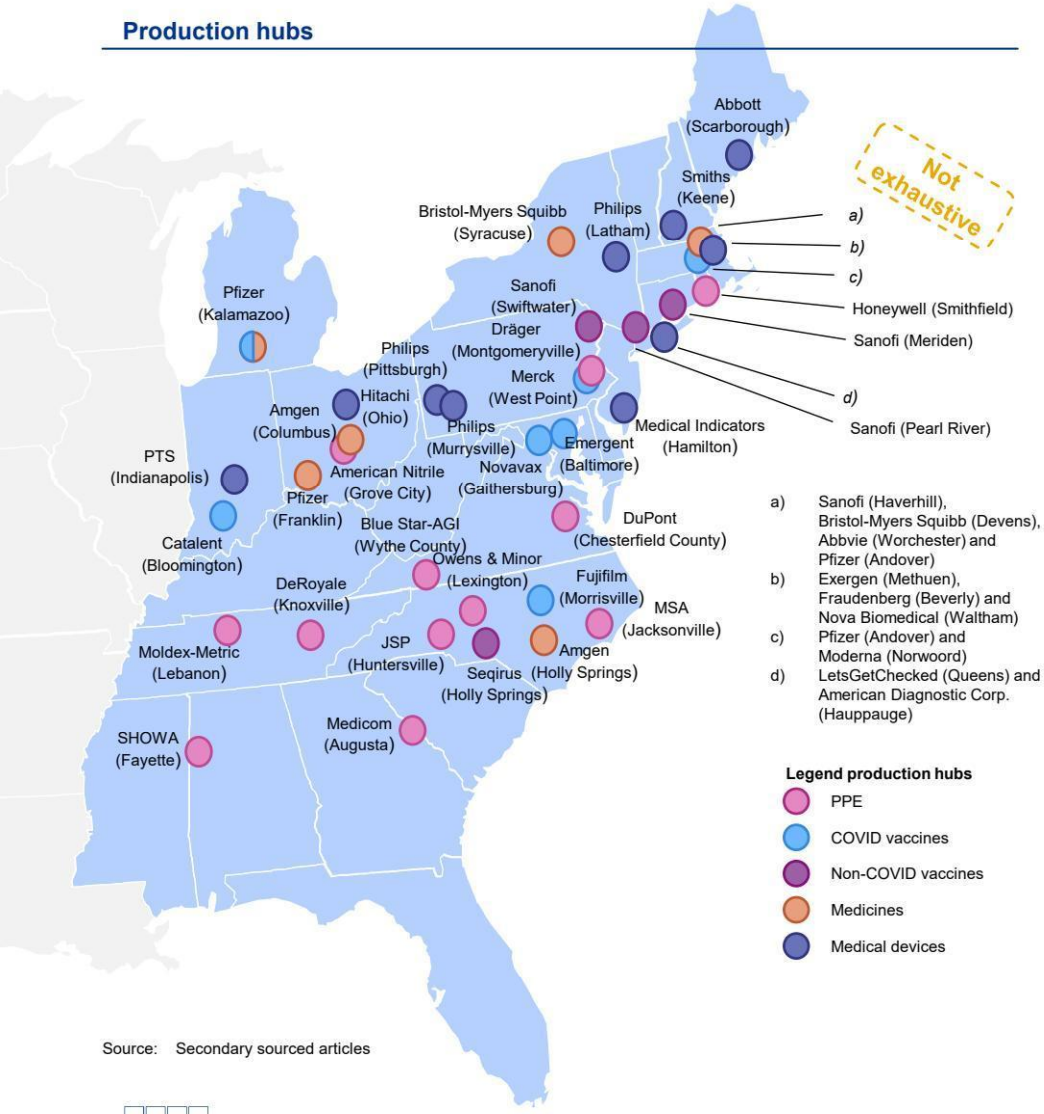
Summary of policy instruments in US

Support type	Policy	Applicable to
Financial support	Financial assistance or loans to the SMEs in medical device sector, through its SBA agency	Medical devices
	R&D tax credit to companies developing / improving medical devices or advancing pharma technology, on the basis of certain conditions	Medical devices Medicines
	30% tax credit for new investments in advanced manufacturing equipment used to manufacture medicines and medical devices in the country	Medical devices Medicines
	Domestic Medical and Drug Manufacturing Credit offers a 10.5% credit on net income from the sale of active pharmaceutical ingredients and medicines	Medicines
	Manufacturers in the Washington state are exempted from sales and use tax on machinery/equipment used directly in manufacturing or R&D	All
	Government sponsored R&D tax credit is offered to businesses that develop or improve products, processes, or formulas. The qualifying costs are wages, raw materials, and other costs.	All
Regulatory support	Payor Communication Task Force to facilitate communication between device manufacturers and payors to shorten the time between FDA approval or clearance	Medical devices
	Fast track program helping to facilitate the development and expedite the review of new drugs that treat a serious medical condition and fill unmet medical needs	Medicines
Production support	Bipartisan legislation to strengthen efforts for onshore production of PPE in the USA, by requiring the Defense Logistics Agency to issue long-term contracts for American-made PPE	PPE
	OWS, a partnership between HHS and the Defense department, to accelerate the development of multiple COVID vaccines. It also helps in addressing the manufacturing challenges	COVID vaccine

Source: Secondary sourced articles

Overview of production hubs and policies in the USA (2/2)

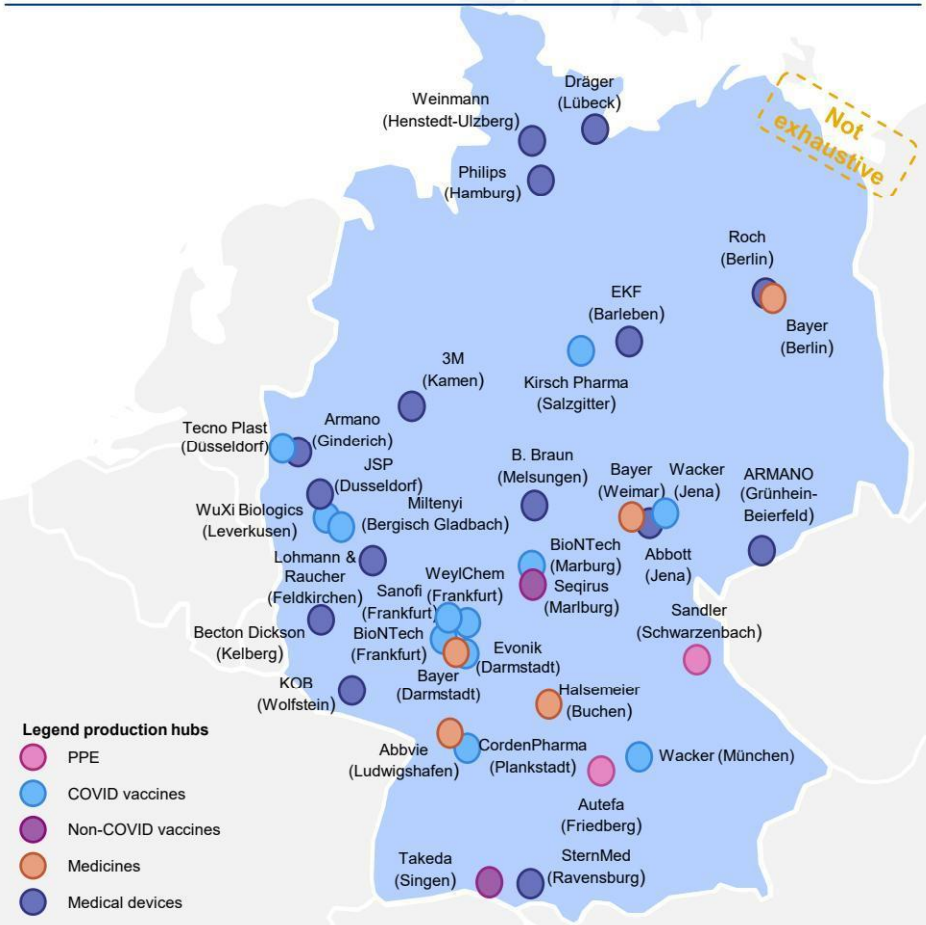
Production hubs



Source: Secondary sourced articles

Overview of production hubs and policies in Germany

Production hubs



Source: Secondary sourced articles

Summary of policy instruments in Germany

Support type	*Policy*	*Applicable to*
Financial support	Direct grants for new business, on the basis of the company's size and location in the country	All
	Debt financing for established medical device companies with continuous cash flow and loans for working capital financing	Medical devices
	Cash incentives for investors, while setting up production units, in the form of non-repayable grants applicable to co-finance investment-related expenditures	All
	Innovation funding program to fund SMEs for their innovation programs/projects such as drug development	All
	Government announced €750 million program to develop and manufacture COVID-19 vaccines including €250 million to expand vaccine production capacities for the future	COVID vaccines
	Cash incentives in the form of grants applicable to investment expenditures such as new buildings and machinery	All
	Government's funding program to invest in facilities to produce FFP2/3 masks and medical masks certified in line with European standards	PPE
Production support	Plans for investment of nearly €2.8 billion to secure local production capacities in order to supply vaccines through 2029	COVID vaccines Non-COVID vaccines
	Planning to ensure 600-700 million doses capacity and expecting different types of vaccines contracts with several firms	COVID vaccines Non-COVID vaccines
Marketing support	Allows pharmaceutical companies to freely set prices for their products for the initial 12 months following the approval from European Commission	Medicines

Overview of production hubs and policies in France

Production hubs

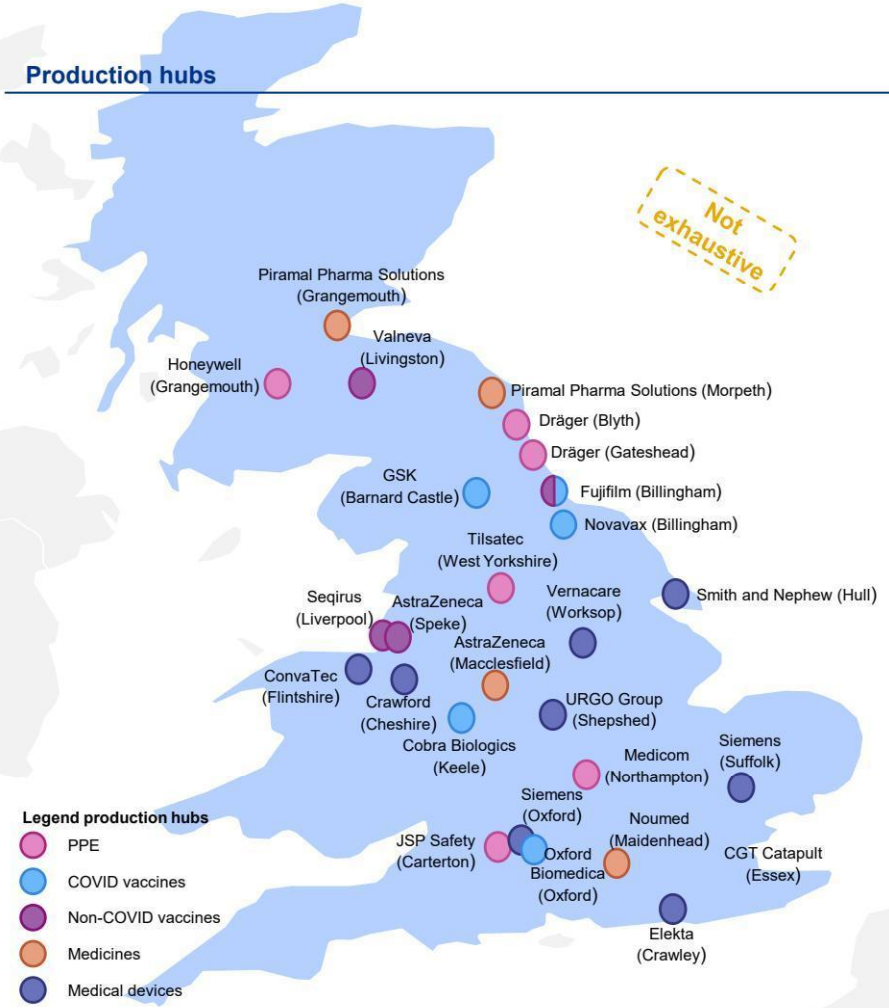
Source: Secondary sourced articles

Summary of policy instruments in France

Support type	Policy	Applicable to
Financial support	Support in terms of grants, interest-free loans, and reduced purchased prices for real estate up to €0.2 million over three years, at regional level	All
	Tax exemptions for setting up business in an urban free zone (100% for first 5 years, 60% the 6th year, 40% the 7th year, and 20% the 8th year)	All
	Government launched €300 million funding initiative for projects which will increase the production of COVID-19 vaccines in the country	COVID vaccines
	Government pledged €200 million to support domestic R&D and manufacturing of medicines, amid COVID-19; also, planning to bring back certain medicine production facilities to the country	Medicines
	Interest-free loans to attract Indian companies' investments into the country which are willing to expand across Europe[b]	All
	R&D tax credit of 30% of eligible R&D expenses to encourage greater research efforts of firms	All
	Government unveiled future investment plans and has reported an innovative medical devices plan as part of the France 2030 initiative, in support of the medical devices industry	Medical devices
	VAT rate reduced to 5.5% instead of 20%, and limiting the sales price of critical medical equipment or supplies suitable for combating the COVID-19	All
Production support	Government plans to ramp up production of face masks and ventilators and to fund the purchase of these products with a €4 billion boost to the state health budget during the pandemic	Medical devices PPE

Overview of production hubs and policies in the UK

Production hubs



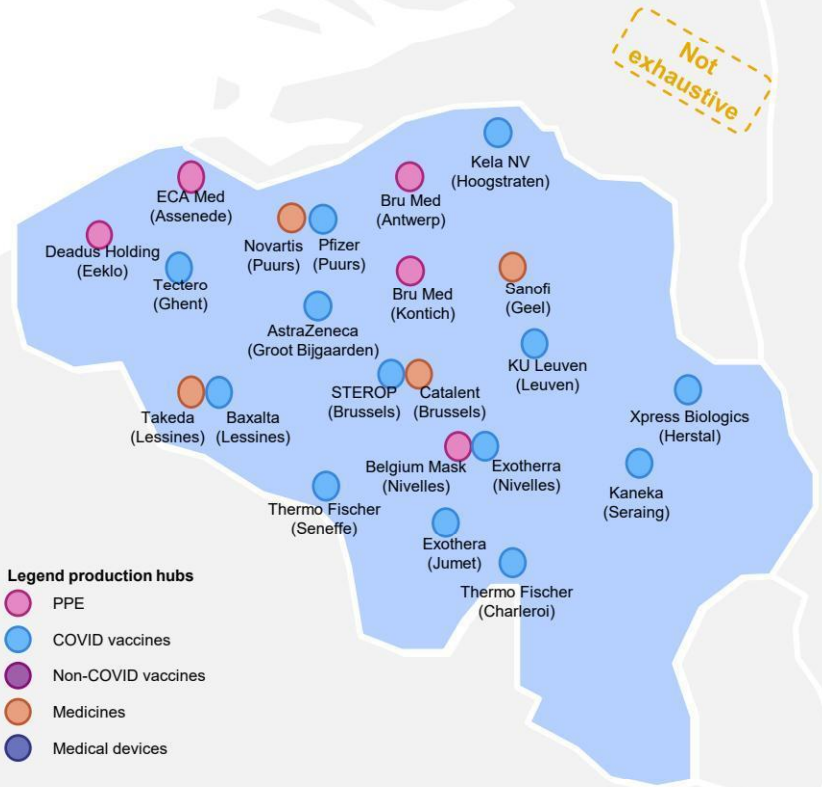
Summary of policy instruments in UK

Support type	*Policy*	*Applicable to*
Financial support	Enterprise investment scheme to help companies raise €5.9 million annually and a maximum of €14.1 million over the company's lifetime	All
	Tax credit scheme for the SMEs in cash repayment or reduction in their corporation tax up to 33% of their R&D spending	All
	Under super-deduction tax allowance, claims of up to 25% of the amount invested by firms in machinery/equipment for two years from April 2021 is available	All
	Government granted funds to various firms to increase manufacturing of critical medical items such as vaccine ingredients and PPE	PPE COVID vaccines Non-COVID vaccines
	Vaccine Task Force unit, having huge funds, supports the country's long-term vaccine strategy of developing and producing vaccines for COVID-19 and for any future pandemics	COVID vaccines Non-COVID vaccines
	Availability of funding scheme of €23.6 million for life sciences companies, including medicines, diagnostics, and MedTech manufacturers to expand their manufacturing in the country	Medical devices Medicines
	Government invested €117.9 million to scale up COVID-19 vaccine and gene therapy manufacturing capacities, mainly to respond to COVID-19 and future pandemics	COVID vaccines
	Government provided a €23.6 million funding to the medicine manufacturing sector to improve the industry's supply chains	Medicines
Regulaotry support	Launched Health Technology Regulatory and Innovation Program, funded by Innovate UK. This will help HealthTech SMEs faster navigate the regulatory process	Medical devices

Source: Secondary sourced articles

Overview of production hubs and policies in Belgium

Production hubs



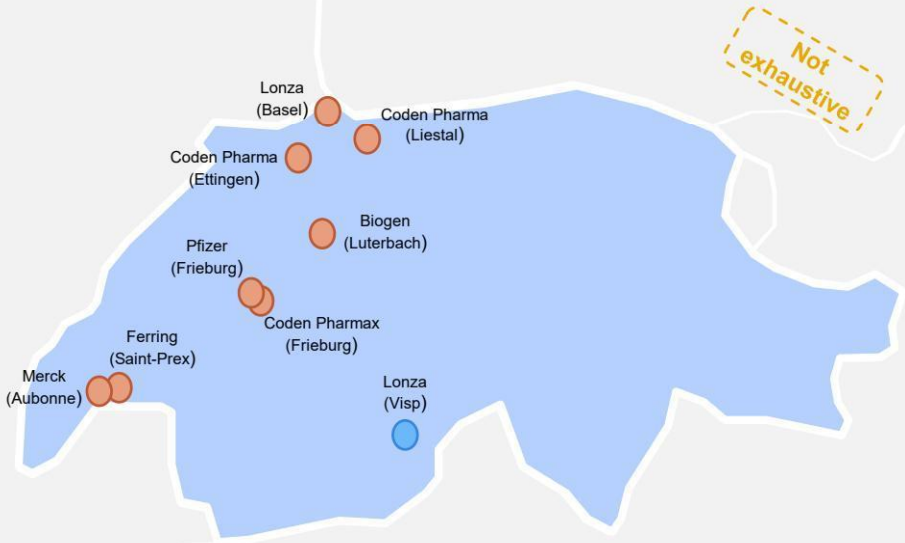
Source: Secondary sourced articles

Summary of policy instruments in UK

Support type	*Policy*	*Applicable to*
Regulatory support	Support to the producers such that the initial manufacturers of reprocessed products will not be held liable for any negative consequences of reprocessed products	PPE
Financial support	Government reduced VAT to 6% from 12% on masks along with the relaxation on employment taxes amid pandemic	PPE
	Availability of R&D tax schemes in which the companies can opt for tax credits deductible from the corporate income tax due	All
	Guarantee Scheme of the Flemish government for up to €1.5 million to obtain credit from banks for certain SMEs and certain large companies	All
	Availability of incentives under innovation deduction scheme providing deduction of 85% on the qualifying net IP income, effectively reducing the related maximum effective tax rate	All
	Availability of annual subsidies for advancing SMEs' business and financial assistance for supporting their innovative projects by the support agency	All
	Adopted €21 million Belgium scheme to support the production of COVID-19-relevant medical products, equipment, technologies, and raw materials in the Flemish region	All
	SME financing act which aims to facilitate access to bank finance for SMEs; this also helps in improving access to credit for the SMEs	All
Infrastructure support	Belgium has two airports which are certified for transporting medicines and vaccines for the distribution purposes of manufacturers	COVID vaccines Non-COVID vaccines Medicines
Production support	Government, academia, and health and biotech industry's representatives pledged to further strengthen the country's position in biopharma R&D and production	Medicines COVID vaccines Non-COVID vaccines

Overview of production hubs and policies in Switzerland

Production hubs



Legend production hubs

- PPE
- COVID vaccines
- Non-COVID vaccines
- Medicines
- Medical devices

Summary of policy instruments in Switzerland

Support type	*Policy*	*Applicable to*
Financial support	Incentives to companies investing substantially in R&D and production, such as: rental expense relief program for new companies; provisions for scientific or technical R&D of up to 20% of the taxable profit per year	All
	Under the BaseLaunch accelerator program, funding of up to €0.5 million for highly innovative biopharma projects is available; also provides access to its partners, global biopharma & investors, and network	Medicines
	Tax holiday at the federal and/or cantonal level for up to 10 years for establishment or relocation of businesses in the country	All
	Patent box regime offering relief in taxes for qualifying income from patents and patent equivalent rights of up to 90%	All
Regulatory support	Faster application procedure for obtaining a license of new pharmaceutical products from Swissmedic agency; an accelerated admission procedure is also possible at the request of the manufacturer or the distribution company.	Medicines

Source: Secondary sourced articles

Overview of production hubs and policies in Italy

Production hubs

Source: Secondary sourced articles

Summary of policy instruments in Italy

Support type	*Policy*	*Applicable to*
Financial support	Benefit of 50% tax credit on additional expenses (incremental credit) to companies that increase their R&D expenditure during 2017-2020, with an annual ceiling of EUR 20 million	All
	Government introduced tax breaks of 20% for companies conducting R&D for innovative drugs, including COVID-19 vaccines, provided they grant non-exclusive licenses	Medicines COVID vaccines
	Interest-free loans of up to 80% of relevant costs for projects between €0.1 million and €1.5 million under Smart & Start Italia Scheme (for less than five years old small-sized innovative start-ups)	All
	Tax benefit for legal entities amounting to 30% of the investments made in innovative start-ups and SMEs	All
	Italian aid scheme of €50 million to support production and supply of medical devices, such as ventilators and personal protection equipment	Medical devices PPE

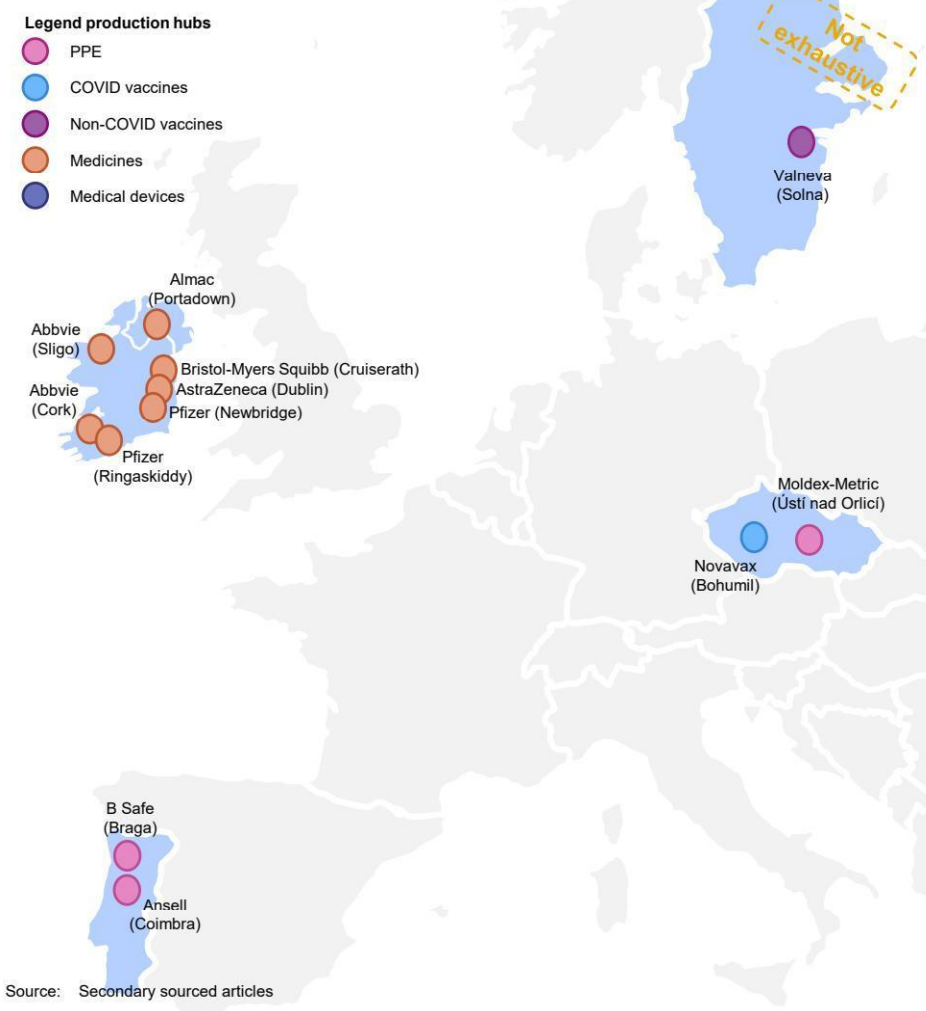
Overview of production hubs in Spain

Production hubs

Source: Secondary sourced articles

Overview of production hubs in other EU countries: Portugal, Ireland, Sweden and Czech Republic

Production hubs



Source: Secondary sourced articles

Listed on the left are some additional manufacturing hubs that were identified

- As part of the research into manufacturing hubs, we looked at the US, the UK and Europe. Based on the initial information we found, we selected the European countries for a more in-depth investigation, namely Germany, France, Belgium, Switzerland, Italy and Spain. Information on the production hubs in these countries is described on the previous pages.
- In addition to the European countries that we have investigated in more detail, we have identified a number of production hubs in other countries. The information on these countries is included here as additional information.

The country's approach to stimulate production close to home vary significantly. There is no silver bullet

In various ways, countries are making efforts to stimulate production close to home

Based on the identified policies and production hubs, some initial insights are presented below:

- The policies of different countries vary. There is not one policy that all countries implement to improve production close to home. For example, one country may be more focused on increasing a country's pandemic preparedness (Germany), another country may want to position itself as a leader in the production of certain product categories (Switzerland), and others may see increasing the production of medical products as part of a larger effort to generally increase domestic production (France and the USA).
- Many of the policies were put in place during or in the aftermath of the COVID-19 pandemic. These policies are mainly focused on PPE and vaccine production.
- A dichotomy can be recognized in the policies. Part of the policies are aimed at maintaining current production, another part is aimed at attracting producers that formerly did not produce in the respective country (reshoring).
- Policies aimed at reshoring are often part of broader programs to attract industry in a general sense, such as the reshoring policies in the USA, Switzerland and France.
- The policies identified are largely financial in nature. These policies aim to make it more attractive for manufacturers to produce in the country, relative to production in low-wage countries.

The results show that there is no silver bullet to stimulate production close to home

In some countries, when a policy is implemented to produce a certain product, many production centers are identified, such as Switzerland, which produces many medicines, and the USA, which produces many medical devices. However, no silver bullet emerges from which to conclude what is effective in promoting manufacturing close to home, because the approach among the countries vary significantly. The analysis on the previous pages is also not exhaustive. Further research is needed to determine the effectiveness for each policy in the specific context. In the next chapter we assess the effectiveness of 5 measures from 5 countries.

KPMG

3. Case studies on foreign policies to stimulate production close to home

In order to get a better understanding of the identified policy we performed a deep dive into specific cases

This chapter provides a more in depth analysis of five cases in which policy instruments are used to stimulate production closer to home.

Out of all the identified production hubs and policy instruments a selection was made for cases to further follow up on. This was done based on a few criteria:

- The case studies have to include an example of reshoring (the practice of transferring a business operation that was moved overseas back to the country from which it was originally relocated) and scalable production capacity;
- Dispersion between the types of medical products that the policy instrument (mainly) influences;
- Dispersion between western countries that the cases apply to.

Based upon the criteria above five cases were selected for further research:

- Legislation that stimulates reshoring PPE production to the United States;
- Scalable production contracts used by the German government to secure (pandemic) vaccine production;
- Support of the French government for industrial projects in the medical sector to increase domestic R&D and production of medical products;
- Capital grands that aim to encourage development and manufacturing of MedTech products within the United Kingdom
- Financial aid to maintain the production of penicillin in Austria.

The case studies provide insight in relevant context of the country, the policy instrument and the costs and benefits from a societal point of view.

All of the following cases start with a description of relevant, country specific, context in which the policy was implemented. Given the interaction between multiple factors that can influence a decision to produce in a certain country, it is vital to get insights on the context of a country to asses the effect and potential of the policy instrument.

Next the cases provide more in dept insights in specific policy measures used, and their cost and benefits for society. This insights are based on deskresearch and expert interviews.

As stated a lot of factors influence whether a policy adds value to a country or not, we analyzed literature on effectiveness on different types of policies in order to provide insights on the cost and benefits. Although this gives an indication of the potential of a policy instrument and its main pitfalls, this study doesn't include a analysis of causation between policy instruments and production in a certain country.

The next page provides an overview of the selected case studies, the policy instruments used and the main considerations to perform additional research on these cases.

In consultation with VWS, cases are selected that are promising and provide insight into policies in different countries regarding different products.

1. Legislation that stimulates reshoring PPE production to the USA

Case description

—The US introduced bipartisan legislation to strengthen efforts for onshore production (reshoring) of PPE in the country: Make PPE in America Act. This policy requires government entities to issue long-term contracts for American-made PPE.

Goal of the policy instruments

—To reduce or remove dependency of the country on other economies for PPE products.

—In addition to ensuring supply for PPE for the country, it is expected to also help in creating jobs in the US.

Considerations to include as a case

—The case has a strong focus on reshoring.

2. Scalable production contracts used by the German government to secure (pandemic) vaccine production

Case description

—Germany is planning to spend up to EUR 2.86 billion to ensure sufficient capacity from vaccine manufacturers to supply vaccines for any future outbreaks through 2029.

—In the next step, it will sign pandemic readiness agreements with the five companies.

Goal of the policy instruments

—These contracts will give the government access rights to the companies' production capacities if the pandemic persists or a new pandemic breaks out.

Considerations to include as case

—The German policy is an example of scalable production capacity that VWS is investigating as one of the possible options for the Netherlands to be able to increase the production capacity of vaccines or other medical products when there is a shortage.

3. Support of the French government for industrial projects in the medical sector to increase domestic R&D and production of medical products

Case description

—French government supports industrial projects in the medical sector to increase domestic R&D and production of medical products. The French government has supported industrial projects with a total value of EUR 1.42 billion, of which EUR 683 million is state aid.

Goal of the policy instruments

—Job creation and boost economy.

—To reduce dependency of foreign production of medicine.

—To attract foreign investments in the French economy.

Considerations to include as a case

—The case has a strong focus on increasing domestic production and R&D of medicines.

4. Capital grands that aim to encourage development and manufacturing of MedTech products within the UK

Case description

—The Life Sciences Innovative Manufacturing Fund (LSIMF) is part of the Global Britain Investment Fund, of which £354 million will support life sciences manufacturing.

—The LSIMF will provide £60 million in capital grants for investment in the manufacture of: human medicines (drug substance and drug product), medical diagnostics, MedTech products.

Goal of the policy instruments

—Creating economic opportunity.

—Deploying cutting-edge innovations.

—Increasing health resilience.

—Minimizing impact on the environment.

Considerations to include as a case

—The case involves different aspects of production of medical devices, including financial and regulatory aspect.

—The UK has a considerable medical technology industry. A large part of medical technology companies in the UK are SMEs.

5. Production of penicillin in Austria

Case description

—In 2020 Sandoz agreed with the Austrian government to invest more than USD 175 million combined to build a production plant, having Sandoz stay active for the upcoming 10 years to produce penicillin.

—The Austrian government will put up about one third (USD ~60 million) of the investment made by Sandoz.

Goal of the policy instruments

—The investment by the Austrian government in the production of penicillin in Austria is driven by Sandoz' competitive considerations to compete more successfully with Chinese and Indian producers.

Considerations to include as a case

—Europe was once home to major antibiotics production centers, but over the year – due to competition from Chinese and Indian firms – production from companies in Italy, Germany and the Netherlands exited or was cut back.

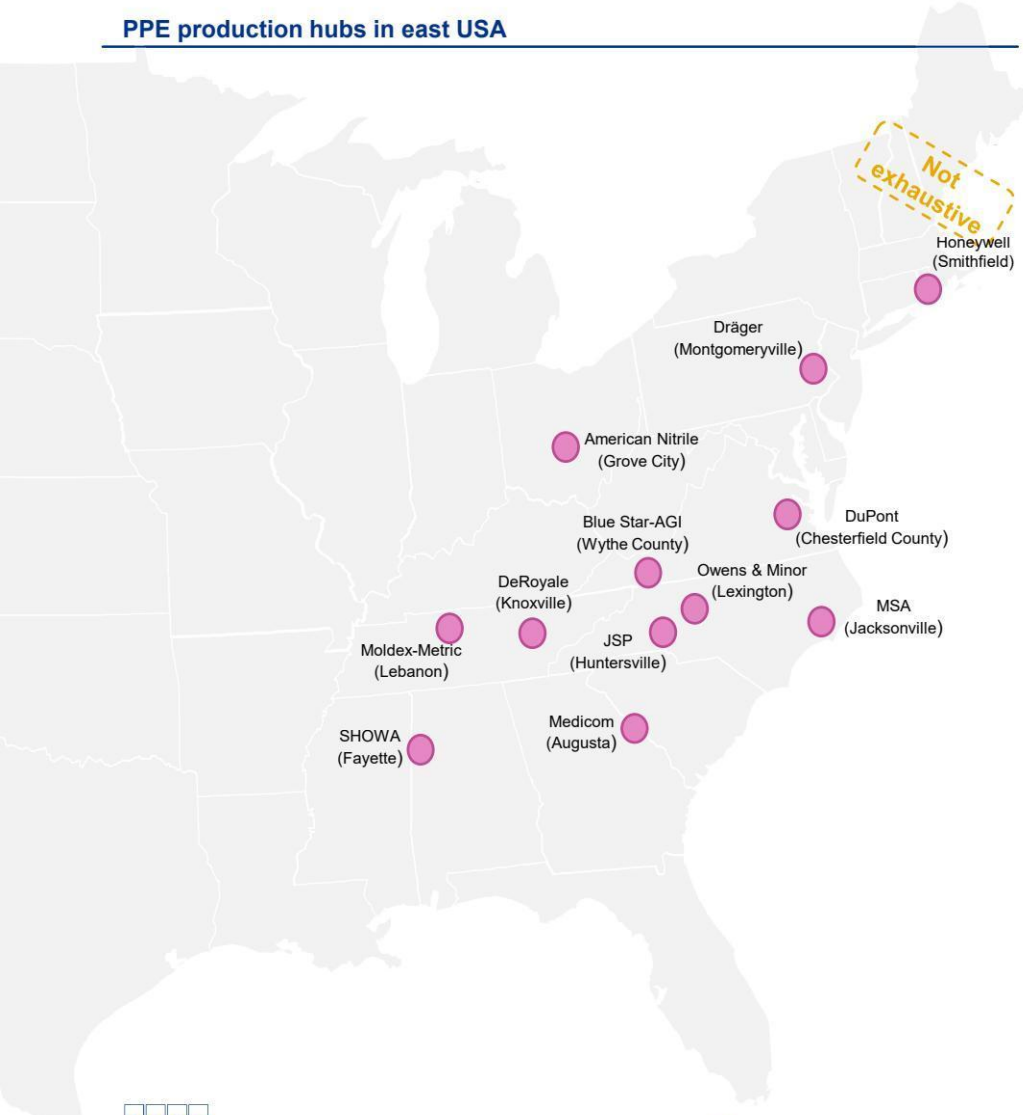
—By investigating the case, insights can be derived on how production in Austia is secured, while production in many other countries was cut back over the years.

KPMG

Legislation that stimulates reshoring PPE production to the USA

The USA are home to 33% of the Medical PPE market in 2019

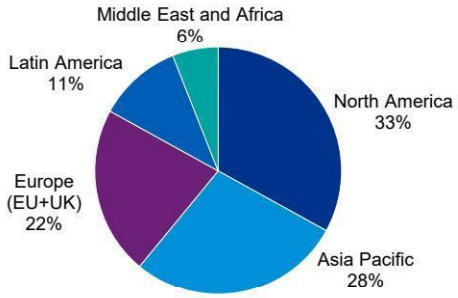
PPE production hubs in east USA



Before the COVID-19 pandemic, North America was leading the medical PPE market

In 2019, the US medical PPE market was estimated to amount to ~USD 8 billion, in turn accounting for 15% of the total PPE market size in 2019. The PPE market has several sub-industries, including healthcare, construction and chemicals. The countries with the highest production of medical PPE were China, US and Germany, each with different export dynamics: while China was the biggest exporter worldwide, the USA exported mainly across North and Latin America and Germany served almost exclusively European countries[2]

Medical PPE market share in 2019 (%)



Although the USA was, in 2019 a major manufacturer - accounting for ~20% of the global production of every category of medical PPE* apart from gloves - it relied heavily reliant on imports to meet domestic demand. For example, the USA was the largest importer of masks and coveralls (imports of USD 360 million in 2019, mostly from China) and the second largest importer of gloves (imports of USD 450 million in 2019, mostly from Malaysia).

* Categories include but are not limited to: Face Masks, Gowns and overalls, Gloves, Eye Protection and Hand Hygiene.

Make PPE in America Act stimulates reshoring of production to the USA

Case description[3]

Policy description	The US introduced bipartisan legislation to strengthen efforts for onshore production (reshoring) of PPE in the country: Make PPE in America Act. This policy requires government entities to issue long-term contracts for American-made PPE.
Goal of the policy instrument	1) To reduce or remove dependency on other economies and/or countries for medical PPE products. 2) Also the policy is expected to create jobs in the USA.
Operating mechanism	The bill requires procurement contracts for PPE to be long-term and for domestically manufactured. Contracts entered into by the Departments of Homeland Security, Health and Human Services, Defense, Education, or Veterans Affairs for the procurement of PPE must be for a duration of at least three years, including a base period and all option periods, to incentivize investment in the production of PPE, and materials and components of PPE, in the United States.
Date of implementation	The act was introduced in the Senate of the United States Congress in April 2021
Governing body	The policy applies to all “covered Secretaries”, meaning the Secretary of Homeland Security, the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of Education, and the Secretary of Veterans Affairs.

The COVID-19 pandemic forced the US into action

In order to meet the increased demand during the pandemic, local PPE production was scaled up (e.g. a 10x for masks, ~5x for face shields). This increase in local manufacturing has been supported by several measures by the US government (not exhaustive):

- financial support for local supply chain operators through the DFC;
- the use of the Defense Production Act to push manufacturers to increase production;
- export bans on PPE.

Next to these short-term measures to handle the demand peak, more long-term policies are implemented in order to secure the availability of medical PPE.

Stimulating onshoring production to secure availability of medical PPE

In order to become less reliant on foreign countries for PPE, the USA introduced bipartisan legislation to strengthen efforts for onshore production (reshoring). This was done by introducing the ‘Make PPE in America Act’. This bill requires procurement contracts for personal protective equipment (PPE) to be long term and for domestically manufactured PPE[4].

The legislation, passed by the Homeland Security & Governmental Affairs Committee of the Senate in April 2021, was introduced by Ohio Republican Senator Rob Portman and Michigan's Democrat Senator Gary Peters. On passing the legislation the Senators said:

"Reshoring production will ensure American workers, health care professionals, and more, have the PPE they need as the economy continues to reopen. Domestic production of PPE supplies also will create American manufacturing jobs and ensure that America is better prepared for the next pandemic."

Policies that stimulate reshoring are successful in bringing production closer to home, however, may also introduce inefficiencies that might outweigh the benefit

Lessons learned from previous US reshoring policies [5]

Already in 2018-19 tariffs imposed by the Trump administration caused an acceleration of the reshoring and nearshoring manufacturing trend that was already growing as wages and costs rose in China. However, much of this reshoring was driven by high tech manufacturing returning home; commoditized goods, such as masks, gowns, and generic drugs were still able to be cheaply produced in China and did not reshore in response to the Trump administration's policies. This indicates that The United States will be unable to bluntly "tariff" its way into reshoring the medical supply industry due to the nature of the commoditized goods it is trying to bring home. A more complex system of subsidies for domestic manufacturers would be required to accomplish that goal, which would have to be sustained over time, even if there is not another similar global health crisis for decades.

Reshoring capacity may be possible with the right subsidies program, but it may not be sustainable without significant and unnecessary inefficiencies. During the H1N1 epidemic in 2009, the nation's remaining PPE manufacturers saw an increase in demand for their goods; many invested in further domestic capacity, anticipating demand for their goods being needed again. However, this glut of supply overran the U.S. market, and caused healthcare systems to stockpile the cheap equipment in 2010, depressing demand in the following year and causing significant harm to domestic manufacturers. This inability to flex surge capacity in the U.S.' domestic production indicates the key problem with reshoring: the capacity needed to fulfill demand created by a pandemic can't be sustained after the initial demand wears off. Under normal circumstances, the United States has enough domestic production capability to flex its capacity slightly in response to small outbreaks, but not to a major epidemic or pandemic outbreak. It is also still generally cheaper to manufacture PPE goods abroad, due to their commoditized nature.

Analysis of costs and benefits of the Make PPE in America Act

The main benefits are:

- The policy is aimed at reducing production dependencies on foreign economies/countries. The main benefit therefore arises when there (again) is a global shortage of PPE; however, it is uncertain if, when and for how long this will occur again.
- Reshoring production to the USA creates additional jobs within the area of production.
- Also, depending on the raw materials used to make the product, it can reduce global transport and logistic movements.

The costs consist of:

- Inefficiencies such as the additional labor costs in the USA compared to, for example, Asian countries.
- An increase in medical PPE will, if the demand stays steady, drive down the prices of the product. Therefore, the government will be paying a price higher than the market price when entering into long-term contracts.
- Providing State aid to favor local producers disturbs the global market. Under normal circumstances the World Trade Organization (WTO) regulates the market under the principle as non-discrimination, open trade and fair competition. Therefore scrutiny is to be expected when applying reshoring policies in a non-crisis / un-justified situation.

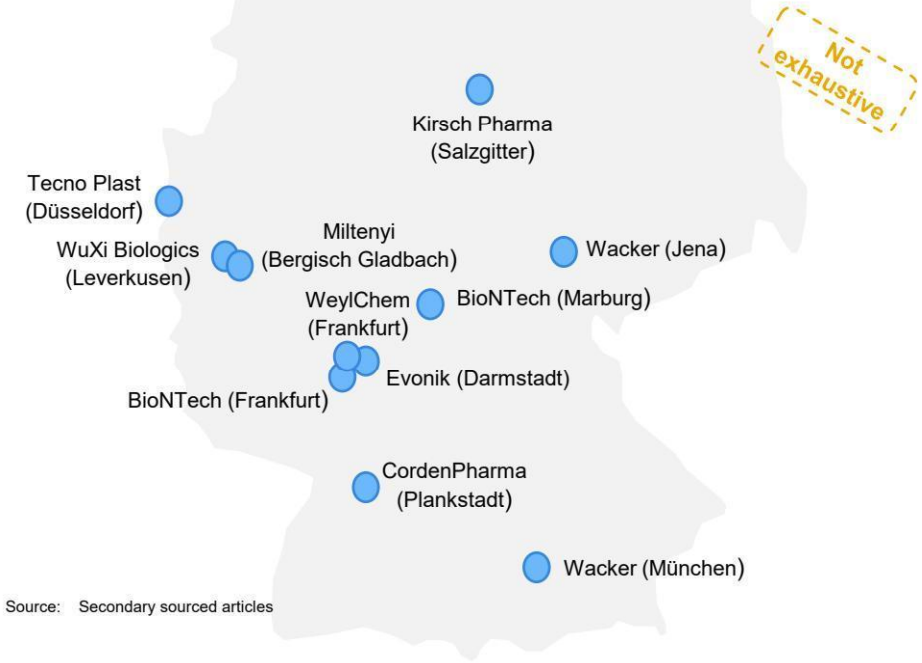
Overall, the costs of reshoring are high where's the benefits largely depend on future demand for PPE. Therefore reshoring PPE production facilities might not be the most cost effective way of securing local supply. This does not mean, however, that reshoring policies by it self are ineffective, they do make the USA less dependent on other economies and/or countries.

KPMG

Scalable production contracts used by the German government to secure (pandemic) vaccine production

Germany is home to multiple COVID-19 vaccine production hubs due to strong presence of biotechnology clusters and a stimulating government

Covid-19 vaccine production hubs in Germany



Source: Secondary sourced articles

Number of vaccine production hubs in Germany compared to other countries[6]

Note: The European Union is home to a total of 88 covid-19 production hubs . Belgium, Germany and Spain are home to the most production hubs Europe.

There are multiple COVID-19 vaccine production hubs in Germany; most of these also have their origin in Germany

Germany is one of the countries with the most COVID-19 production hubs in Europe. Almost all of the identified COVID-19 production hubs in Germany have German roots, with the exception of Tecno Plast, an Indian-origin company that produces packaging for COVID-19 vaccines, and WuXi Biologics, a Chinese-origin company which produces vaccines for AstraZeneca.

High-quality industry standards, close cooperation between science and industry, and high labor productivity pave the way for (innovative) vaccine production hubs

The production hubs originated in Germany because of many research and development (R&D) initiatives that are pursued in Germany. Germany has a high R&D expenditure relative to other countries such as the UK, the USA and the Netherlands.[7] Also close cooperation between science and industry contributes to an attractive R&D landscape. In a total of 30 biotechnology clusters, research is being done on new innovative biotechnical products, among which research on vaccines.[8] Lastly, the German industry is regarded as an industry with one of the highest quality standards. Germany also has a high labor productivity, but also high labor costs.[9]

The government funded research on COVID-19 vaccines and invested in the expansion of production capacity

- In May 2020, at the end of the first wave of the pandemic, Germany announced a program for the development and manufacturing of vaccines against COVID-19 amounting to EUR 750 million. [10]
- EUR 500 million was invested in funding of research for vaccine development in Germany and EUR 250 million was invested in expanding production capacities for a future COVID-19 vaccine.[10]

To maintain the ratcheted-up production capacity of COVID-19 vaccines, the German government plans to spend up to EUR 2.861 billion until 2029

Case description

Policy description	Germany plans to spend up to EUR 2.861 billion to ensure that vaccine producers have sufficient capacity to supply vaccines for any future outbreaks until 2029. The German government plans to sign contracts with BioNTech, CureVac/GSK, Wacker/CordenPharma, Celonic and IDT.
Goal of the policy instrument	Ensuring that enough vaccines can be produced quickly for the German population if the covid-19 pandemic persists or a new pandemic breaks out.
Operating mechanism	The contracts will maintain the ratcheted-up production capacities created during the COVID-19 pandemic by paying the production companies an annual standby fee. The contracts grant the government access rights to the companies' production capacities.
Date of implementation	The pandemic preparedness agreements with the five companies have yet to be signed. This is currently work in progress.
Governing body	The Ministry of Economics concludes the agreements on behalf of the Ministry of Health.

"Germany historically has a strong chemical industry which formed the base of todays pharmaceutical industry. Stimulating local production not only secures the availability of vaccines but might also be strategically and politically interesting in order to maintain economic power."

Professor of Health Economics, 2022

Germany is actively preparing for a new pandemic and/or a flare up of COVID-19 by securing local vaccine production

As described on the previous page, the German government invested in the development of vaccines and scale-up of production capacity during the COVID-19 pandemic. At the time of writing this report (June 2022), the number of infections in Germany is low. The large share of the German population is vaccinated, which contributes to the low number of infections.

However, the extend in which Germany is prepared for a future outbreak of the coronavirus or any other another pandemic is uncertain. New variants of the coronavirus or new viruses may lead to the need for future vaccination, using vaccines that could be similar to current covid-19 vaccines but could also require different technology to be effective against the virus.

To ensure that enough vaccines (of any kind) can be produced quickly for the German population if the covid-19 pandemic persists or a new pandemic breaks out, the German government announced plans to spend up to EUR 2.861 billion to secure local production capacity for supplying the country with vaccines in future outbreaks through 2029.

Stand by fees do secure quick access to vaccines when needed however questions can be asked about the sustainability of this policy

The German government plans to sign pandemic preparedness agreements with five companies, namely BioNTech, CureVac/GSK, Wacker/CordenPharma, Celonic and IDT. These companies will receive a standby fee in order to maintain ratcheted-up vaccine production capacities.

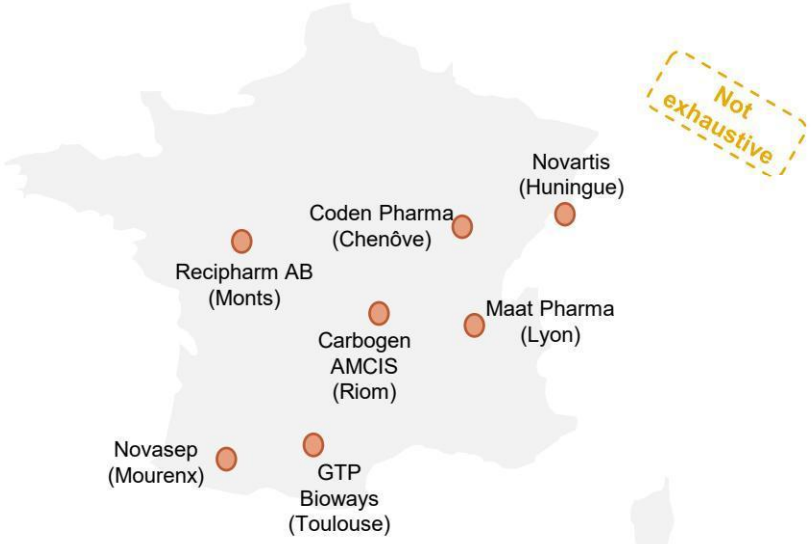
In the short term, when there's a reasonable chances that there will be demand for these production capacities, this policy might be beneficial from a societal perspective. Access to much needed vaccines is secured and might help the country navigate through a flare up of COVID-19. In the long term however it's a risk to pay a significant amount of money for stand by capacity that might not be necessary.

KPMG

Support of the French government for industrial projects in the medical sector to increase domestic R&D and production of medical products

French government stimulates production of (generic) medicines close to home as part of wider plans to reindustrialise France

(General) medicine production hubs in France



List of European countries with the most production of pharmaceuticals[11]

Country	*Pharmaceutical production in million EUR*
Switzerland	54.305
France	**35.848**
Italy	34.000
Germany	33.158
UK	23.039
Ireland	19.305
Belgium	17.547
Spain	15.832
Denmark	14.391
Sweden	9.840
Netherlands	6.180

France is a production hub for medicines in Europe, but most of the general medicines are no longer produced in France.

With a production value of EUR 35.8 billion, France is Europe's second largest producer of medicines.[11] With multinationals such as Sanofi, France is also a major global player in the field of medicine production. However, producers, such as Sanofi, have followed a years-long strategy to outsource production abroad to free up capital and escape France where costs are high and labour laws tough.[12] As a result, 80% of the active pharmaceutical ingredients used by European drugmakers are sourced from India and China.[13] General medicines, such as paracetamol, have not been produced in France (or Europe) since 2008.[12]

The French government wants to promote production of (generic) medicines close to home

Governments are increasingly concerned about dependence on imports from China and India, among others, when exports were banned at the beginning of the COVID-19 pandemic.[12]

Therefore, the French government is planning to increase the domestic production of medicines. French President Macron mentioned paracetamol as one of the medicines he would like to see fully produced in France again.[12]

The French policy to promote the production of medicines is part of wider plans to reindustrialize France

- France witnessed acceleration of reindustrialization in the country which led to 460 foreign industrial projects (up 50%) and generated over 15,000 jobs. It also opened up 323 new manufacturing sites in 2021 across the country, showing an increment of 62% y-o-y growth.[14]
- This is (partly) due to a government program aimed at the rapid construction of factories.[15]

French government is investing to bring production to France as part of wider reindustrialization of the country

Case description

Policy description	French government supports industrial projects in the medical sector to increase domestic R&D and production of medical products. The French government has supported industrial projects with a total value of EUR 1.42 billion, of which EUR 683 million is state aid.
Goal of the policy instrument	1. Job creation and boost economy. 2. To reduce dependency of foreign production of medicine. 3. To attract foreign investments in the French economy.
Operating mechanism	The policy of the French government aims to make it attractive for domestic and foreign manufacturers to produce medicines in France, for example by subsidizing industrial projects or designating production sites.
Date of implementation	June 2020
Governing body	Ministry of the Economy, Finance and the Recovery in collaboration with Ministry of Health and Solidarity and Ministry of Higher Education, Research and Innovation.

France is the leading European destination for industrial projects and R&D investments

— France is undergoing a reindustrialization of its economy. Since 2004, France has invested heavily in stimulating production of different kinds of products.[16] From 2018 till 2020, France was the leading European destination for industrial investment projects.[17]

In 2020, plans to reindustrialize coincided with shortages due to the covid-19 pandemic

During the COVID-19 pandemic, France suffered from shortages of general medicines.[18] As a result, the French government started more specific projects (as part of the broader reindustrialization policy) to bring medicine production to France. In June 2020, the French government pledged to support domestic manufacturing of medicines and has supported 166 industrial projects with a total public support of EUR 683 million since.[19]

Despite high labor costs and tougher regulations, producers are willing to invest in France as a production location

France has a Strategic Committee for the Health Industries and Technologies (CSF) that is working on drafting and implementing an action plan identifying industry projects that could be relocated to France, taking into account their socio-economic feasibility, environmental and social externalities, as well as the eligibility criteria for national and European support measures.[20] As a result of the wider French policies, many different pharmaceutical companies such as Sanofi, Pfizer, GlaxoSmithKline, Merck KGaA, and Bristol Myers Squibb, are reported to plan investments in France. An example of one of these projects is to bring the production of active ingredients for paracetamol to France. This is being done in cooperation with Seqens, Upsa and Sanofi.[21]

The policy seems effective in interesting (foreign) manufacturers to produce in France.

Relatively small financial support by the French government resulted in large investments by (foreign) private parties and multiple pharmaceutical companies that plan additional investments. However it is unclear which reindustrialization policy contributed significantly to those developments.

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Capital grands that aim to encourage development and manufacturing of MedTech products within the UK

The UK has a strong life science industry underpinned by a powerful research landscape and high-quality science base

Medical devices production hubs in the UK

Historically, the UK has supported the R&D of life sciences, resulting in a strong health and life sciences industry

The UK has one of the strongest and most productive health and life sciences industries globally, with a turnover of GBP 80 billion and supporting 256,000 jobs, underpinned by a powerful research landscape and high-quality science base.[22]

Already in 2000, the UK government proposed an enhancement to the small and medium enterprise (SME) tax incentives. The SME scheme started in 2000 with a rate of relief amounting to 150% of eligible expenses. In 2008, this rate was raised to 175%, and increased further to 200% in 2011 and 225% in 2012. On top of that, the 2011 Budget Document introduced a 'Patent Box' policy, which grants a reduced 10% rate of corporate tax for profits arising from patents.

A study by the University of Oxford states that the UK R&D tax incentive scheme that is gradually becoming more generous, has cost the UK government more than GBP 1 billion in foregone corporation tax revenue annually. The same study, however, shows a robust 18-23% increase in R&D spending after the enterprises in the treatment group became eligible for this tax incentive. Therefore concluding that the UK R&D tax incentive scheme has been successful in generating a considerable amount of additional R&D spending by the business sector.[23]

Multiple policies are in place that stimulate and keep the production of medical devices in the UK

Case description[24]

Policy description	The Life Sciences Innovative Manufacturing Fund (LSIMF) is part of the Global Britain Investment Fund, of which £354 million will support life sciences manufacturing. The LSIMF will provide £60 million in capital grants for investment in the manufacture of: — human medicines (drug substance and drug product) — medical diagnostics — MedTech products The policy encourages applications from companies ready to deploy their emerging technologies at scale in commercial manufacturing.
Goal of the policy instrument	1. **Creating economic opportunity** through investments that will provide high-wage, high-skilled jobs. 2. **Deploying cutting-edge innovations** (at both pilot and commercial scale) which can be embedded in either the product itself or the manufacturing process. 3. **Increasing health resilience**, either through increased domestic capacity or by providing flexible capabilities that can be re-deployed in some way in a future health emergency. 4. **Minimizing impact on the environment**, which might include reduction in input resources or using alternative input materials to become more sustainable or support the government's net zero target.
Operating mechanism	Manufacturing projects for all type of medical devices that are located in the UK and have a total investment value of more than £12 million can apply for the capital grants.
Date of implementation	April 2021 and renewed in March 2022.
Governing body	Department for Business, Energy & Industrial Strategy and the Office for Life Sciences.

Policies are in place to support domestic production

In addition to the tax support that the UK government historically provides to life science, companies are now also stimulated to produce domestically. At introduction of the policy, UK Life Sciences Minister Nadhim Zahawi said:

'Our life sciences sector is world leading and its incredible response to COVID-19 has reminded us of the crucial importance of the sector to the UK. I am thrilled to see this fund opening for applications and would encourage companies to make the most of the opportunity to expand their operations and create good jobs as we build back better from the pandemic.'

The UK market for medical devices is threatened by regulatory changes

In addition to policies increasing domestic production, the UK is faced with challenges in keeping producers and products in the UK market.

The UK's regulatory landscape for HealthTech is changing, and manufacturers will need to prepare for a UK sovereign regulatory system. This is because the Medicines and Healthcare Products Regulatory Agency (MHRA) is currently consulting on the future regulation of medical devices and invitro diagnostics in the UK. Besides, companies looking to sell into the EU market must adhere to the new medical device regulations (MDR) and impending invitro diagnostic medical device regulations (IVDR). This may lead to some UK companies finding their products no longer meet the regulatory requirements to be sold within the EU.

If SMEs are not enabled to meet regulatory challenges, there is a risk that innovators will be unable to commercialize their ideas and the UK could lose out on vital investment in the HealthTech sector. In order to mitigate risks, a GBP 7 million funding program is set up to support UK SMEs to help meet their regulatory needs.[25]

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Production of penicillin in Austria

The Austrian government agreed upon investing in a penicillin production plant to drive long-term competitiveness of European production for key antibiotics

"This plan is a great example of government and the private sector working closely together to protect the long-term interests of patients in Europe and beyond. Antibiotics are the backbone of modern medicine and our facility in Kundl, Austria is the hub and center of the last remaining integrated production chain for antibiotics in the western world. This joint investment will help to keep it that way."

CEO of Pharmaceutical Production Plant, 2020

"Novartis is committed to sustain a resilient and competitive supply chain for the essential medicines in its' active markets. I am proud that Novartis is leveraging its market-leading manufacturing expertise to enable Sandoz to further strengthen supply of these vital medicines, and we can build upon the high manufacturing and quality standards at the Kundl (Austria) site and further deepen its vertical integration."

Global Head of Novartis Technical Operations, 2020

Austria's pharmaceutical industry is one of the largest in the world per capita due to large R&D investments

Austria has one of the highest per capita expenditures on pharmaceuticals worldwide, with a turnover of USD 8.1 billion and supporting 18,000 jobs, which follows from three reasons: (1) growing demand from an aging population; (2) nearly 100% of the population is covered by social health insurance; (3) cost constraints inherent to Austria's public insurance system.[26] [27]

This sector is characterized by the intensity of research, where in 2014 around 100 specialized biotech firms invested around 70% of their total revenue in research.[28]

Largest part of the active pharmaceutical ingredients are sourced from India and China, which makes a production plant in Austria stand out even more

Around 80% of active pharmaceutical ingredients are sourced from China and India, due to a vast aging population and increases in chronic diseases among other. They are the largest producers of the world's penicillin, accounting for 90%.[29]

However, in 2020 Sandoz agreed with the Austrian government to invest more than USD 175 million combined in its site in Kundl, Austria, Europe's last large-scale antibiotics plant. This investment grants that Sandoz stays active for the upcoming 10 years to produce penicillin, "despite fierce global price competition, particularly from China," the CEO of Sandoz says.[30] The Austrian government will put up about one third (USD ~60 million) of the investment.

The joint plans are to drive long-term competitiveness of European production for key antibiotics in Europe

The investment is one of the several ongoing investments in the US and Europe to shore up local drug manufacturing. Sandoz intends to strengthen the long-term competitiveness of its integrated antibiotic manufacturing operations, developing and introducing innovative manufacturing technology for both active pharmaceutical ingredients and finished dosage forms.[30]

(a) Austria - Pharmaceuticals (trade.gov)
(b) Facts and Figures (advantageaustria.org)
(c) Life sciences in Austria | Invest in Austria
(d) Medicine shortages in the EU: causes and solutions
(e) Sandoz to shore up Europe's last antibiotics plant (acs.org)

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4. Assessment of the foreign policies

An assessment framework is used in order to compare the different policy instruments

The policy instrument as described on the previous pages are assess on multiple aspects in order to compare the pros and cons of the different options. This assessment provides insights into the costs and benefits of the policy instrument together with its effectiveness in bringing production close to home.,

The policy instruments are assessed on several relevant criteria

On the following pages, the policy instruments from the five case studies are analyzed by scoring relevant criteria. The criteria used are the following:

- *Costs of the policy:* The (expected) costs that are associated with the policy
- *Effect on production close to home and/or supply chain security:* The extent in which the policy improves production close to home. That is how many additional (domestic) production capacity results from the policy
- *Innovation:* The extent in which the policy stimulates innovative production and/or new or improved products
- *Environmental effects (including circularity of production):* The extent in which the policy stimulates sustainable production and reduces environmental impacts. For example, circular production, or a decrease in global logistic movements
- *Digital:* The extent to which the policy (or production close to home as a result of the policy) contributes to the embedding of digital solutions in products and/or production processes
- *Distinctive capability:* The extent to which the policy is unique in the European context and would distinguish the Netherlands from other European countries
- *Fit with Dutch context:* The extent to which the policy aligns with the Dutch or EU context and legislations

The assessment framework is displayed on the following pages. For all policies, a brief explanation of the rating is provided. The assessment is done relative to the other policy instruments.

Assessment of the policies to stimulate production close to home (1/2)

Assessment criteria	Explanation of criteria	Case 1: USA	Case 2: Germany	Case 3: France	Case 4: UK	Case 5: Austria
Costs of the policy	The (expected) costs that are associated with the policy	The exact cost of the policy is unknown, however, some cost drivers are identified: — Additional labor cost of USA compared to Asia — Long-term contracts with relatively high prices — Countermeasures by trade partners / organizations, in order to protect their local production.	EUR 2.861 billion from 2022 up to 2029.	EUR 683 million.	The LSIMF will provide GBP 60 million in capital grants.	The Austrian government contributed USD ~60 million of the total USD 175 million investment
Effect on production close to home and/or supply chain security	The extent to which the policy improves production close to home. That is how many additional (domestic) production capacity results from the policy	High: The policy provides long-term security to companies interested in domestic production, this grants them a competitive advantage over producers abroad.	High: Local producers must have enough capacity to supply locally produced vaccines for any future outbreaks until 2029.	High: The French government has supported 166 industrial projects.	Medium/Low: UK health industry accounts for a turnover of GBP 80 billion and supporting 256,000 jobs, underpinned by a powerful research landscape and high-quality science base. GBP 60 million additional capital grants can therefore be considered a marginal contribution.	High: The collaboration between the Austrian government and Sandoz successfully guaranteed the production of penicillin in Austria
Innovation	The extent to which the policy stimulates innovative production and/or new or improved products	Medium: Producing in a highly developed country might stimulate innovation, as knowledge is widely available. However, producers are given a vast amount of security when it comes to income and turnover, which might take away from the incentive to innovate in a more competitive market.	High: High-quality industry standards, close cooperation between science and industry, and high labor productivity pave the way for (innovative) vaccine production hubs.	Medium: A combination of investments in R&D and investments in bringing back production of general medicines, might make production of general medicines more innovative.	High: One of the policy's goals is to deploy cutting-edge innovations either embedded in the product itself or in the manufacturing process.	Medium/High: Sandoz says it will invest the money over 5 years to strengthen the facility's competitiveness and introduce new manufacturing technology.
Environmental effects (including circularity of production)	The extent to which the policy stimulates sustainable production and reduces environmental impacts. For example, circular production or a decrease in global logistic movements	Medium/Low: The policy does not explicitly stimulate sustainable production, however, it is to be assumed that environmental regulations in the US are more stringent than in Asian countries.	No explicit mention of environmental effects on products and/or production processes.	Medium/high: The environmental and social externalities are taken into account for the projects that could be reshored to France. Environmental legislation is more strict in France than in countries were general medicines are currently produced, such as China and India.	Medium/high: One of the policy's goals is to minimize impact on the environment, which could include reduction in input resources or using alternative input materials.	No explicit mention of environmental effects on products and/or production processes.

Assessment of the policies to stimulate production close to home (1/2)

Assessment criteria	Explanation of criteria	Case 1: USA	Case 2: Germany	Case 3: France	Case 4: UK	Case 5: Austria
Distinctive capability	The extent to which the policy is unique in the European context and would distinguish the Netherlands from other European countries	Low: The EU prohibits State Aid unless exceptionally justified.[31] Direct subsidies or income guarantees for local producers would therefore only be possible if open to all of the EU and not for individual member states.	Medium: Signing contracts to maintain ratcheted-up production capacity is not new. However, to sign these kinds of contracts for vaccine production is new.	Medium: France is one of the countries that has a focus on (re)industrialization of the economy and aim to keep or extend their domestic production of medicines. Other countries are Germany and Switzerland.	Medium: The Netherlands, like the UK, has a powerful research landscape and high-quality science base, however, the impact of this policy on achieving this landscape is marginal.	High: Austria is home to Europe's last large-scale antibiotics plant therefore it is highly distinctive.
Fit with Dutch context	The extent to which the policy aligns with the Dutch or EU context and legislations	Low: The EU, and in particular the Netherlands, are economically dependent on global trade. Measures that disturb the free market do not align with the desire to stimulate (global trade). On the next page, a more extensive analysis of reshoring policy in the EU/Dutch context is provided.	High: The Dutch government could sign contracts with current producers of vaccines in the Netherlands, to maintain or increase production capacity.	Low: The French policy is part of a broader strategy to industrialize. However a broad strategy on industrial policy is not mentioned in the Dutch 'Coalitieakkoord.'	Medium: Given the similarities of the UK and Dutch climate, the policy measure would fit within the Dutch context. However, the Netherlands (contrary to the UK) is bound by EU State Aid regulations.	Medium: Austria has kept production in the EU rather then reshoring it. Since the Netherlands isn't home to (large) antibiotics manufacturing plants it doesn't have this option. However for manufacturing plants that do exist in the Netherlands this could be applied.

In summary, the assessed policies are effective in two ways:

1. Reshoring policies (such as those is the USA and France) are effective to attract (foreign) producers that are not currently active in the respective countries.
2. Other policies, such as R&D funds, contracting producers to maintain their production capacity, and supporting producers financially or in navigating regulatory processes (such as those in Germany, the UK and Austria), are predominantly effective in retaining current producers and incentivizing them to expand or maintain their production capacity.

All of the assessed policies have pros and cons, highly dependent on the nature of the policy and the context of the country. There's no silver bullet to secure supply by means of policy to stimulate local production.

For the Dutch and EU context policies aimed at retaining current producers and incentivizing them to expand or maintain their production capacity rank higher than to policies that stimulate reshoring of production back to the EU. On the next page a more extensive analyses of reshoring policy in the EU and Dutch context is provided.

Research shows that although reshoring is effective in securing supply, however the impact on global trade should not be underestimated

Current use of reshoring in the Netherlands

Activities in reshoring production to the Netherlands, is currently of modest proportions. It happens mainly as a result of companies experiencing problems with the quality of the outsourced activities, or the costs are higher than expected, or because companies respond to new production techniques. When companies decide to retrieve certain production, the government can facilitate and create conditions that make this easier. The main condition is that there is sufficient knowledge, expertise and availability within the labor force. For the time being, employment effects are limited because the scale of reshoring is likely to be small and the production brought back is often highly automated or robotized. However when considering reshoring as a policy it is much needed to consider the need for additional local labor force.[32]

Potential for reshoring of medical products to the Netherlands / EU

A recent study by the Netherlands Bureau for Economic Policy Analysis (CPB) illustrate the interdependency of the EU and in specific the Dutch economy with China.[33] This was clearly shown during the COVID-19 pandemic. The western world relied, for protective equipment in particular, on suppliers from China, who were confronted with a sudden a sudden increase in the domestic and foreign demand for protective products.

Reshoring therefore sounds like a logical step to take in order to secure the supply of critical products and become less depended on other economies. However there are downsides, especially when it results in geopolitical tensions. The CPB analyzed the developments since the abolishment of mutual tariffs in 1994 and China joining the WTO in 2001. The study concluded that:

- European consumers benefit form increased trade with China, it resulted in more diversity of products, available for (significantly) lower prices;
- Export to China has increased which is beneficial for European economies;
- Geopolitical tensions, caused by for example tariffs or reshoring policies, will nullify the benefits of global trade.
- In addition there's a serious risk of transition costs and disturbance of supply chains if reshoring policies would be implemented. I.e. because production facilities have to be build up within Europe.

Therefore the CPB questions whether less geopolitical dependency outweighs the costs that it comes with. These are political decisions in which the benefits of global trade should not be underestimated.

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5. Conclusions and recommendations

Policies to encourage production close to home are successful to varying degrees

This study started with mapping out the different ways in which foreign countries stimulate production close to home and learn about effective ways the Dutch government could implement similar policies. In this chapter we draw the conclusions.

Many countries encourage production close to home with different policies

For years, the trend has been to optimes supply chains by global trade, in order to lower costs by moving production away from Europe to low-wage countries. This has created risks with regard to security of supply. That is why many countries currently put emphasis on stimulating production close to home.

In this study 94 policies from 8 countries were identified from which five case studies were derived to assess the efficacy of policies that aim to stimulate production close to home.

These policies have been successful to varying degrees

Based on the five case studies that were assessed, it can be concluded that there are effective ways to boost domestic production capacity, but the efficacy varies:

1. The USA became less dependent on other countries for PPE products by implementing reshoring policies. However the costs of reshoring are high and benefits largely depend on future demand for PPE, which is uncertain and cannot be predicted.
2. The German government is planning to sign contracts with vaccine producers to ensure that enough vaccines can be produced quickly for the German population if the COVID-19 pandemic persists or a new pandemic breaks out. On short term, access to vaccines is secured and might help the country navigate through a flare up of COVID-19. In the long term, however, it's a risk to pay a significant amount of money for stand by capacity that might not be necessary.
3. The French government seems to be effective in attracting (foreign) manufacturers to produce (general) medicines in France. Relatively small financial support by the French government resulted in large investments by (foreign) pharmaceutical companies. However, it is unclear to what extent these investment are a result of the policies specifically aimed at pharmaceutical companies or whether they are the result of large-scale reindustrialization policies of the country.
4. The UK has policies in place to stimulate domestic production of medical devices, however, experts expect that these incentives are not sufficient and that producers will leave the UK, because SMEs are not able to meet regulatory challenges that result from Brexit.
5. The Austrian government was successful in striking a deal with a private company to secure production of active pharmaceutical ingredients for penicillin in Austria.

In summary, the assessed policies are effective in two ways:

1. Reshoring policies (such as those is the USA and France) are effective to attract (foreign) producers that are not currently active in the respective countries.
2. Other policies, such as R&D funds, contracting producers to maintain their production capacity, and supporting producers in navigating regulatory processes (such as those in Germany, the UK and Austria), are predominantly effective in retaining current producers and incentivizing them to expand or maintain their production capacity.

Reshoring works to bring production to a country, but given the disadvantages, it is questionable whether reshoring is desirable

Reshoring has benefits,…

The case studies on France and the USA show that reshoring works. With investments in production centers, restrictions on import, active cooperation between governments and producers and government support to navigate regulatory processes, producers take the step to produce in the country concerned. In this way, these countries have an advantage over other countries when medical products are scarce. Reshoring also has an added benefit of lowering transportation costs, that are currently rising rapidly.

Producing medical products in a western country usually has a positive effect on the innovation and environmental impact of the product and production process. Research and development (R&D) in western countries in the field of sustainable and innovative production is more likely to have a spill-over effect on production when they are physically closer to production centers.

Western countries also have stricter requirements for pollution and working conditions than many Asian countries where much of the production of medical products currently takes place, such as China, India and Malaysia. The European Union in particular has an industrial strategy to lead the transition to a green and digital economy.

…but these benefits come at a significant price and reshoring goes against some economic principles

On the other hand, countries that invest in reshoring production of medical products often have a broader industrial policy that is not primarily focused on security of supply, but that is focused on attracting business activity in a general sense and create jobs. Governments such as France and the USA invest billions annually in these types of projects.

It is also uncertain whether a reshoring policy with a lower budget, focusing only on security of supply, could work on a large scale in a country like the Netherlands. It is also difficult to predict which products will be in short supply in the future, as for instance a new pandemic may create shortages in a completely different type of medical product category. Reshoring policies therefore do not give a guarantee that supply is secured. For example, because shortages will occur anyway for products of which production is not reshored, or because raw materials (that are still sourced abroad) are scarce.

Reshoring policies are especially costly when there are little to no economic benefits, which could be the case in the Netherlands, because unemployment (at least currently) in the Netherlands not an issue.

Another disadvantage of applying reshoring policies (on a large scale) is that it could upset the geopolitical balance of free trade. If more and more countries start preferring local production, the benefits from global trade will diminish.

Reshoring is preferably pursued on a European level, but there are options the Dutch government could consider on a national level

Production close to home is one of the ways security of supply could be improved and should always be compared with other options

Reducing dependence on production in China, for example, has major disadvantages, as a recent study by CPB shows. Decoupling the supply chain from China could have consequences for the diversity of products and costs for producers.[33]

It should be noted that this study concerned the production of medical products. However, production is only one part of the supply chain. Other parts of the supply chain could also be brought to the Netherlands, such as distributors of products.

Production close to home should also be seen as one of the alternatives among others. Experts indicate that measures such as reshoring to promote security of supply are often not the most economically effective. It is therefore important to always compare the possibilities offered by production close to home with other options.

If the Dutch government deems reshoring desirable, it would be wise to pursue reshoring on a European level

For the Netherlands, stimulating production close to home is extra challenging, because producers indicate that they do not primarily look to the Netherlands to enter the European market, but rather to countries like Germany and France. These countries (just like the Netherlands) have a good investment climate with a lot of R&D and qualified personnel, but the countries have a much larger sales market, which makes it easier to effectuate return on investments.

From the perspective of the Netherlands, policy making to bring production of critical medical products closer to home can best be done on the EU-level rather than by each individual member state. Production centers in neighboring countries could produce medical products for the Netherlands also without each member state having to invest in attracting production centers. Production may be less close to home, but the risks regarding security of supply are in reduced in comparison to - for example - China or India.

It is advisable to carry out a scan at EU-level of what kind of production of medical products is and what is not (sufficiently) present in the European Union and what kind of production of medical products can and cannot be reshored to Europe. The European Commission is already working on reducing dependencies and improving capacity for a wide range of products, including pharmaceuticals.[34] Similar trajectories could also be induces for other medical products.

Apart from European efforts, the Dutch government could put effort in maintaining and expanding current production capacity or reshoring the most critical medical products

Given the different options to stimulate production close to home and the preconditions that this requires, it seems that the following ways to stimulating current production are most fitting for the Dutch context:

- Ensuring that producers who already produce in the Netherlands stay, by making sure that the conditions that producers need to stay are met;
- Ensuring that there is a flourishing start-up climate that is also stimulating to not only research and develop, but also produce in the Netherlands;
- Sign contracts with current producers of desired products to maintain production capacity.

The above policies are aimed at maintaining and possibly expanding production capacity of current businesses. At the same time, reshoring could be something that the Netherlands could pursue for the most critical medical products, although it would likely be very expensive.

When reshoring to the Netherlands is desirable it is important to assess how the Netherlands could add value to securing production capacity or innovate production in comparison to other European countries. Also, the constraints to reshore production to the Netherlands, such as the tight labor market and environmental regulations (including nitrogen legislation) should be taken into account.

If the preconditions are met, the government can establish a collaboration with market parties to set up a plan to reshore production in which constraints regarding state aid obviously should be taken into account.

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Annex A: Long list of identified policies

USA: Long list of identified policies (1/3)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Small business administration	Financial support	- SBA agency, created in 1953, provides comprehensive support to the small and medium enterprises (SMEs) including medical device manufacturers - The support is in the form of financial assistance or loans through commercial lenders and intermediaries	Existing	Yes			
CARES Act	Regulatory support	- This act incentivizes medical device manufacturers to produce and distribute medical devices by providing liability protection	New	Yes			
Business development program	Financial support	- This program provides grants, loans, and other economic assistance to businesses for projects that will create economic growth in Michigan - Criteria of a competitive business include those that will create jobs, provide investment, and that are expected to ultimately provide Michigan with a net return on their grant	Existing	Yes	Yes	Yes	Yes
Medical and health R&D support programs	Financial support	- Medical and health R&D investment in the US reached USD 245.1 billion in 2020, an 11.1% increase from 2019 - Federal government investment accounted for 25% of all U.S. medical and health R&D at USD 61.5 billion, with the National Institutes of Health (NIH) alone accounted for 20% (USD 48.9 billion) of all such investment in 2020	Existing	Yes	Yes	Yes	Yes
Payor Communication Task Force	Regulatory support	- Center for Devices and Radiological Health has established the Payor Communication Task Force to facilitate communication between device manufacturers and payors to potentially shorten the time between FDA approval or clearance and coverage decisions	Existing	Yes			
Tax credits schemes	Financial support	- Under this, the R&D tax credits by the companies working on developing new or improving medical devices or advancing pharma technology can be availed, basis their R&D comes under certain qualifying activities	Existing	Yes	Yes		
Site selection incentives	Financial support	- There are a variety of state and local incentives available to medical device manufacturing firms, depending on the geographic location, type of operation, investment, employment, and tax impact of the company's facilities - In the US, around USD 48.8 billion is spent annually on state and local incentives to attract new investments	Existing	Yes			
Biomedical Venture Fund	Financial support	- Michigan Biomedical Venture Fund (MBVF) invests in and supports life science start-up companies with U-M licensed intellectual property – including therapeutics, medical devices, diagnostics, and health IT - The MBVF is a collaborative effort between the U-M Medical School's Fast Forward Medical Innovation (FFMI) program and the U-M College of Engineering's Center for Entrepreneurship (CFE)	Existing	Yes			
Tax refund program	Financial support	- Texas Enterprise Zone Program (EZP) is a state sales and use tax refund program designed to encourage private investment and job creation in economically distressed areas of the state - Companies approved for Enterprise Zone designations are eligible to apply for refunds of the state sales and use tax they have paid during the designation period on qualified expenditures, up to their maximum allowable refund.	Existing	Yes	Yes	Yes	Yes

USA: Long list of identified policies (2/3)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Orphan Drug Act	Financial and marketing support	- This act of 1983 provides seven-year marketing exclusivity to sponsors of approved orphan products, a tax credit of 50% of the cost of conducting human clinical testing, and research grants for clinical testing	Existing		Yes		
Tax credit	Financial support	- 30% tax credit for new investments in advanced manufacturing equipment or machinery can be used in the US to manufacture medicines and medical devices	New	Yes	Yes		
Tax credit	Financial support	- Domestic Medical and Drug Manufacturing Credit offers a 10.5% credit on net income from the sale of active pharmaceutical ingredients and medicines	New		Yes		
Tax credit	Financial support	- Established in 1981, the government sponsored R&D tax credit is offered to businesses that develop, design, or improve product, processes, or formulas. The qualifying cost are wages, raw materials and supplies cost, and other costs	Existing	Yes	Yes	Yes	Yes
Fast track program	Regulatory support	- This process helps to facilitate the development and expedite the review of new drugs that treat a serious medical condition and fill an unmet medical need	Existing		Yes		
Sales and use tax exemption	Financial support	- Manufacturers in the Washington state are exempted from sales and use tax on machinery and equipment used directly in manufacturing or research and development	Existing	Yes	Yes	Yes	Yes
Emergency funding	financial support	- In 2020, the U.S. Department of Commerce's National Institute of Standards and Technology (NIST) awarded USD 50 million in emergency funding to support U.S. manufacturers in increasing the production of products such as PPE, and to recover from workforce and supply chain interruptions	New			Yes	
Investments	Financial support	- In the past year, Department of Health and Human Services (HHS) has invested USD 250 million in U.S.-based manufacturing of PPE and USD 950 million in manufacturing the supplies and equipment needed for vaccines, therapeutics, and diagnostic tests	New			Yes	Yes
Production grant	Financial support	- Massachusetts announced over USD 9.5 million in grants to boost production of PPE and other critical materials. It was made through the Manufacturing Emergency Response Team to 15 grantees, including Massachusetts manufacturers producing these items such as masks, gowns, ventilators, swabs, and testing materials	New			Yes	

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USA: Long list of identified policies (3/3)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Emergency funding	Financial support	- Coronavirus Preparedness and Response Supplemental Appropriations Act 2020, provides USD 8.3 billion in emergency funding for federal agencies to respond to COVID-19 - It funds the programs addressing the issues such as developing, manufacturing, and procuring vaccines and medical supplies; grants for state, local, and tribal public health agencies and organizations	New			Yes	Yes
CARES Funding	Financial support	- New York administration announced USD 2.3 million in federal CARES Act funding for four organizations to provide critical services to small and mid-sized manufacturers. The awardees will use these funds to assist companies in reshoring and rebuilding supply chains, adopting new technologies and enhancing resilience for future disruptions, and others	New	Yes	Yes	Yes	Yes
Grants	Financial support	- NIST awarded nearly USD 54 million in grants, under American Rescue Act, to 13 high-impact projects for R&D at 8 institutes in the Manufacturing USA network - The funds will be used in, using advanced manufacturing technologies, producing PPE and medical equipment; creating new and sustainable domestic supply chains; improve resilience in existing supply chains; and others	New	Yes		Yes	
Buy American Act	Production support	- This act mandates that a product must have a higher share (current level is 55%) of components made in the U.S. to qualify as Made in America. This threshold will go to 60% and will jump to 65% in 2024 before reaching to 75% in 2029 - This will create a framework to enable the government to set price preferences for critical products and components such as pharmaceuticals and others	New	Yes	Yes	Yes	Yes
Reshoring policy	Production support	- In 2020, U.S. Senators introduced bipartisan legislation to strengthen efforts for onshore production of PPE in the US, by requiring the Defense Logistics Agency (DLA) to issue long-term contracts for American-made PPE	New			Yes	
Vaccine compensation program	Regulatory support	- National Vaccine Injury Compensation Program (VICP) was created as the result of a federal law known as the National Childhood Vaccine Injury Act of 1986 - The law protects both the manufacturers of vaccines and the health care workers that administer them from liability in the rare case of vaccine-related injury or death	Existing				Yes
Operation warp speed (OWS)	Development support	- OWS, is partnership between HHS and Defense department, aims to accelerate the development of multiple COVID-19 vaccines. It also helps in addressing the manufacturing challenges	New				Yes

Germany: Long list of identified policies (1/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Tax credits schemes	Financial support	- Companies in Germany are eligible for up to EUR 1,000,000 annual research allowance, since 2020. If a company uses its own research staff, 25% of the wages and salaries, including tax-free social security contributions, are credited against the annual tax liability	New	Yes	Yes	Yes	Yes
Public funding	Financial support	- Germany offers direct grants for new business, basis company's size and location - The public funding in Germany can be classified as direct grants, public loans, public guarantees, and equity capital	Existing	Yes	Yes	Yes	Yes
Taxation policy	Financial support	- Government in Germany is keeping the tax rate low for the SMEs, including medical device companies, to reduce their tax burden - In August 2019, German Economy Minister announced the outlines of a plan to reduce the tax and regulatory burden on SMEs in Germany.	Existing	Yes	Yes	Yes	Yes
Project financing	Financial support	- Debt financing is available to established medical device companies with continuous cash flow and loans can be borrowed for working capital financing	Existing	Yes			
Labor incentives	Financial support	- Companies in the medical device sector can receive subsidies to help put together a workforce. This reduces operational costs incurred by the new businesses	Existing	Yes			
Competitive production	Financial support	- In terms of nominal unit labor costs, Germany has gained in productivity in the last decade - The labor cost difference between Germany and its neighbors in Eastern Europe has been reduced significantly - Since 2005, wages in manufacturing sector across most EU-28 countries has risen at average rate of 2.7%, while in Germany it only grew at 2.3%	Existing	Yes	Yes	Yes	Yes
Cash incentives program	Financial support	- While setting up production facilities, investors can take benefit of cash incentives provided in the form of non-repayable grants applicable to co-finance investment related expenditures such as new buildings, equipment or machinery	Existing	Yes	Yes	Yes	Yes
Price setting	Marketing support	- Pharmaceutical companies could freely set the prices of their products for the first 12 months following the approval by the European Commission	Existing		Yes		
Innovation funding program	Financial support	- It is the Central Innovation Program that provides funding to SMEs having business operations in Germany for their innovation programs/projects such as drug development	Existing	Yes	Yes	Yes	Yes

Germany: Long list of identified policies (2/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Development Funding	Financial support	- In May 2020, Germany announced program for the development and manufacturing of vaccines against COVID-19 amounting to EUR 750 million - EUR 250 million will go towards expanding production capacities for a future COVID-19 vaccine	New				Yes
Incentive program	Financial support	- Under the GRW program, formed in 1969, grants are mainly designed to reduce the investment costs for setting up new plant or building new business premises in certain regions	Existing	Yes	Yes	Yes	Yes
Cash Incentive and grants	Financial support	- Federal Ministry for Economic Affairs and Energy (BMWi) funding programme provides important incentives for SMEs to invest in new innovative facilities and products in order to establish competitive production capacities in Germany - Funding is provided for investment in facilities to produce FFP2/3 masks and medical masks certified in line with European standards - Manufacturers investing in mask production lines located in Germany can benefit from attractive financial incentives and cash grants including 30% cash grant for short-term availability of CE-compliant surgical masks and FFP2/FFP3 masks up to a maximum of EUR 10 million per applicant - Companies investing in the establishment of new, innovative and forward-looking facilities and products receive funding for up to 50% of their investment for the purchase of facilities and components and development work of their own	New			Yes	
Expansion subsidy	Financial support	'- German government subsidized the expansion of fleece production by local company Innovatec to boost production of face masks in the country - Innovatec invests more than 11 million euros (12.5 million U.S. dollars) in two new units for fleece production and could manufacture an additional 1,500 tons of fleece in the future, enabling the production of more than 1.5 billion face masks - Objective- Significantly expand production capacities for protective equipment in Germany and thus effectively reduce our dependence on imports	New			Yes	
Future contracts	Production support	- In 2022, Germany has announced plans to spend around EUR 2.86 billion to secure local production capacity for supplying the country with vaccines in future outbreaks through 2029	New				Yes
Reserve capacity plan	Production support	- Germany announced its aim to build up reserve capacity to fight against future pandemics and aims to ensure 600-700 million doses capacity. - Moreover, it expects contracts with several firms for different vaccine types which could be delivered across Europe and globe	New				Yes

France: Long list of identified policies (1/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Equity incentive scheme	Financial support	- An equity incentive scheme was introduced in France in 2005 to make the country more lucrative to multinational companies	Existing	Yes	Yes	Yes	Yes
Investment initiatives	Financial support	- The French government has unveiled future investment plans and has reported innovative medical devices plan as part of the France 2030 initiative, in support of the medical devices industry	New	Yes			
Tax incentive scheme	Financial support	- The French Ministry of Equipment, Transport and Tourism, through its agency DATAR, offers a prime d'aménagement du territoire, which is an incentive scheme for businesses for all types setting up in 'special development' zones - Incentives involve tax breaks that means a partial exoneration from business taxes during the first five to seven years of the company's existence	Existing	Yes	Yes	Yes	Yes
Interest-free loans	Financial support	- Companies can get support from local authorities: grants, interest-free loans, reduced purchased prices for real estate up to EUR 200,000 over three years	Existing	Yes	Yes	Yes	Yes
Industry grants	Financial support	- The regional development bonus (PAT) in the industry and services sector aims to support companies, including medical devices, carrying out, in priority regions for regional development, programs having an impact on employment - PAT in the industry and services sector, a subsidy of a maximum of EUR 15,000 per job created is given, within the limits of the ceiling rates for regional aid	Existing	Yes	Yes	Yes	Yes
Tax credit	Financial support	- The research tax credit is in place since 1983, to encourage firms to make a greater research effort. The current R&D tax credit equals 30% of the eligible R&D expenses incurred during a year, upto EUR 100 million in eligible tax expenses	Existing	Yes	Yes	Yes	Yes
Tax exemptions	Financial support	- Setting up business in an urban free zone provides exemption from company taxes (100% for first 5 years, 60% the 6th year, 40% the 7th year, and 20% the 8th year	Existing	Yes	Yes	Yes	Yes

France: Long list of identified policies (2/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Interest-free loans	Financial support	- French government to offer zero percent loans to Indian companies willing to invest in France as part of financial incentives	-	Yes	Yes	Yes	Yes
R&D Investment	Financial support	- In 2020, French government pledged EUR 200 million to help domestic R&D and manufacturing of medicines amid COVID-19 - Further announced plans to bring back certain drug production facilities to France	New		Yes		
Project financing support	Financial support	- French government signed the manifesto for an Important Project of Common European Interest (IPCEI) on Health. It has also secured project financing of EUR 1.5 billion for the IPCEI on Health - The projects under are set to focus on three strategic areas: (i) developing innovative and greener technologies and production processes for manufacturing medicines; (ii) innovating with regard to strategic challenges; (iii) developing gene and cell therapies	New		Yes		
Purchase programme	Production support	- The French government funded the purchase of masks and ventilators with a EUR 4 billion boost to the state health budget amid pandemic	New	Yes		Yes	
Purchase programme	Financial Support	- France government sanctioned EUR 8 billion for national health system. This will be used to buy necessary material, including masks, as well as to fund exceptional compensations for health workers.	New	Yes	Yes	Yes	Yes
VAT reduction	Financial support	- Amendment of Finance Bill for 2020 to reduce VAT rate to 5.5% instead of 20%, and limit the sale price of Masks, Protective clothing and Products intended for personal hygiene and suitable for combating the COVID-19	Existing	Yes	Yes	Yes	Yes
Vaccine investment	Financial support	- In Feb 2021, France launched EUR 300 million for projects which will enable more production of COVID-19 vaccines in the country	New				Yes

UK: Long list of identified policies (1/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Enterprise Investment Scheme	Financial support	- This scheme launched in 1993-94, is a useful in enabling companies including manufacturing sector companies to raise GBP 5 million each year to a maximum of GBP 12 million in the company's lifetime	Existing	Yes	Yes	Yes	Yes
Health Technology Regulatory Innovation Program	Regulatory and financial support	- In Feb 2022, CPI and the Association of British HealthTech Industries (ABHI) have announced the GBP 7 million Health Technology Regulatory and Innovation Programme, funded by Innovate UK. This will help HealthTech SMEs to navigate the regulatory processes	Existing	Yes			
Elevate grant program	Financial support	- Oxfordshire Business Support (OBS) has created the Elevate Programme consisting of two funds for Oxfordshire SMEs to fund projects and activities related to job creation, start-up, and growth for small businesses in UK in the medical device industry	Existing	Yes			
R&D tax credit	Financial support	- The government backed tax credit scheme offers UK SME companies up to 33% of their R&D spend back in either a cash repayment or as a reduction in corporation tax	Existing	Yes	Yes	Yes	Yes
Tax deduction	Financial support	- Under super-deduction tax allowance, the company can claim back up to 25% for the amount invested in qualifying machinery and equipment for two years from 1 April 2021.	New	Yes	Yes	Yes	Yes
Tax incentive scheme	Financial support	- Introduced in 2000, the R&D Tax Relief Scheme is for the SMEs, and it aims to encourage their efforts in developing and improving new products and services	Existing	Yes	Yes	Yes	Yes
Tax credit	Financial support	- The pharma companies, including drug developers and manufacturers developing innovative ways to produce products, in the UK can claim up to 33% of the R&D expenditure as tax credits	Existing		Yes		
Investment scheme	Financial support	- In the UK, life sciences companies including medicines, diagnostics, and MedTech manufacturers can now apply for GBP 20 million fund to expand manufacturing in the country	New	Yes	Yes		
Low tax rates	Financial support	- Patent box legislation introduced in 2013 leads to lower corporation tax applied on profits attributable to certain UK patents - by 2017 the tax rates for such profits will be as low as 10%	Existing		Yes		

UK: Long list of identified policies (2/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Expansion funds	Financial support	- Manufacturing sector of the UK is set receive GBP 300 million of joint government and industry funding to boost manufacturing capabilities including using robotics, artificial intelligence, and augmented reality	New	Yes	Yes	Yes	Yes
Transformation fund	Financial support	- Medicine manufacturing industry is being given a GBP 20 million fund aimed at improving medicine supply chains and creating potentially thousands of skilled jobs. Moreover, these companies will be encouraged to build new factories and use new technologies	New		Yes		
Investment boost	Financial support	- Government announced investment to build a national vaccine center and invites manufacturers to apply for grant funding aimed at stimulating innovation and disruption - It would be investing GBP 131 million into the Vaccines Manufacturing and Innovation Centre (VMIC), a vaccine production facility being built in Oxfordshire	New				Yes
Sustainable Innovation fund	Financial support	- It is a GBP 200 million investment fund for supporting innovative projects by companies in the UK and help businesses recover from the pandemic impact - For instance, Petit Pli company was given GBP 84,065 grant from this fund to improve the design, antiviral functionality and circularity of the face mask product and boost production worldwide	New	Yes	Yes	Yes	Yes
Project funding	Financial support	- Greater Manchester Combined Authority (GMCA) maintains and develops a pipeline of projects submitted by applicants seeking funding from the Combined Authority's Core Investment Funds allocation - For instance, in June 2020, in a meeting of GMCA, the leaders agreed to approve a loan of up to GBP 1.4 million to Private White VC Ltd. to manufacture PPE for frontline services	Existing	Yes	Yes	Yes	Yes
Grants	Financial support	- Government granted GBP 15.9 million to chemical producer Croda to increase the capacity to produce key vaccine ingredients in the country - This will be creating more volume of ingredient and number of ingredients in jobs at the production site	New				Yes
Vaccine Task Force	Financial support	- The government established VTF in 2020 with a budget of billions of pounds with objectives of supporting the UK's industrial strategy by establishing a long-term vaccine strategy to prepare the UK for future pandemics, among others	New				Yes
Capacity expansion	Financial support	- The UK government invested extra GBP 100 million in a new state-of-the-art center to scale up COVID-19 vaccine and gene therapy manufacturing. It is expected to be vital for country's ability to respond to viruses like the COVID-19 and other potential future pandemics	New				Yes

Belgium: Long list of identified policies (1/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Guarantee scheme	Financial support	- The Guarantee Scheme of the Flemish government for up to EUR 1.5 million to obtain credit from banks is for companies including SMEs and large companies which cannot conclude a financing agreement due to a lack of sufficient guarantees	Existing	Yes	Yes	Yes	Yes
Direct grants	Financial support	- In June 2020, Commission adopted EUR 21 million Belgium scheme to support the production of coronavirus-relevant medical products, equipment, technologies and raw materials in the Flemish region in the form of direct grants	New	Yes	Yes	Yes	Yes
Tax incentive scheme	Financial support	- The innovation deduction is an incentive which provides for a deduction of 85% of the qualifying net IP income, effectively reducing the related maximum effective tax rate. It is applicable since 2016 to Belgian companies as well as foreign companies having a permanent establishment in the country	Existing	Yes	Yes	Yes	Yes
R&D tax credit	Financial support	- The country offers R&D tax credit in which the companies can opt for tax credits deductible from the corporate income tax due. The excess tax credits are carried forward and can be used considering certain limitations	Existing	Yes	Yes	Yes	Yes
Allowance scheme	Financial support	- In Wallonia region, SMEs or large companies can apply for investment allowance or grant which depends on certain conditions - There is also assistance availability which is co-financed by the EU as part of the ERDF for small and medium-sized enterprises - Companies can take advantage of property tax exemption under certain conditions	Existing	Yes	Yes	Yes	Yes
SME Financing Act	Financial support	- The Belgium law on SME financing, amended in 2017, aim to facilitate access to bank finance for SMEs. This act majorly seeks to improve access to credit for the SMEs	Existing	Yes	Yes	Yes	Yes

Belgium: Long list of identified policies (2/2)

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Lower interest rate	Financial support	- The European Investment Fund and Flemish promotional organization PMV have signed a guarantee that will lower the interest rates on PMV's 'corona loans' to Belgian SMEs - The guarantee covers a portfolio of EUR 110 million in loans by PMV, which is expected to benefit over 1,000 Belgian SMEs and entrepreneurs	New	Yes	Yes	Yes	Yes
Reprocessing policy	Regulatory support	- The Belgian Task Force on shortages, a working group set up by the Belgian Federal Agency for Medicines and Health Products to remedy the shortage of protective and medical equipment, has prepared a guidance on the reprocessing of these single-use products - The guidance follows FDA approach and provides that the initial manufacturers of reprocessed products will not be held liable for any negative consequences of reprocessed products	New			Yes	
VAT reduction	Financial support	- The government announced the reduction in VAT rate to 6% from 12%, extended for the masks amid pandemic. Apart from VAT measures, there is also be relaxation on employment taxes expected	New			Yes	
Infrastructure and location	Infrastructur e support	- Flander region is considered central location to various European markets and has top-notch infrastructure. Moreover, the manufacturers can leverage its two airports that are certified for transporting medicines and now vaccines for the distribution purposes	Existing		Yes		Yes
Growth aid	Financial support	- Flanders Innovation & Entrepreneurship (VLAIO) support agency provides two types of aid including the SME portfolio and the SME growth subsidies, to help Flanders-based SMEs develop and grow their business - It can provide assistance to SMEs in their development and allows to obtain annual subsidies of EUR 7,500, along with financial aid of EUR 25,000 per year per project on innovation, internationalization and transformation	Existing	Yes	Yes	Yes	Yes
Strong government intent	Production support	- In Oct 2020, representatives of the Belgian government, academia and the health and biotech industry signed at the initiative of Prime Minister Alexander De Croo a joint charter pledging to (further) strengthen Belgium's position in biopharma R&D and production.	New		Yes		Yes

Switzerland: Long list of identified policies

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Fast track procedure	Regulatory support	- It takes around 330 days to obtain a license for a new pharmaceutical product from the Swiss Agency for Therapeutic Products (Swissmedic), making it one of the fastest application procedures worldwide - At the request of the manufacturer or the distribution company, Swissmedic may also provide for an accelerated admission procedure, which usually takes around 140 days	Existing		Yes		
Low tax rates	Financial support	- The country has an average effective corporate-tax rate of just under 20%. Switzerland's overall corporate tax rate applied on corporate income before the federal, cantonal, and communal taxes is between 11 to 21.6%, depending on the business or corporate location	Existing	Yes	Yes	Yes	Yes
Financial incentives	Financial support	- Incentives to companies investing substantially in R&D and production, include such as: rental expense relief program for newly established companies; provisions for scientific or technical research and development in an amount of up to 20% of the taxable profit per year	Existing	Yes	Yes	Yes	Yes
BaseLaunch accelerator	Financial support	- This program offers funding of up to USD 500,000 for highly innovative biopharma projects and provides access to its partners, global biopharma & investors, and network	Existing		Yes		
Tax holiday	Financial support	- Tax holiday at the federal and/or cantonal level for up to 10 years is available if a new business is established or relocated to Switzerland, ultimately creating jobs and encouraging business innovation	Existing	Yes	Yes	Yes	Yes
Low tax rates	Financial support	- The patent box regime offers relief in taxes for qualifying income from patents and patent equivalent rights of up to 90%	Existing	Yes	Yes	Yes	Yes

Switzerland: Long list of identified policies

Policy/Act/Scheme/ Initiative	Support type	Description	Policy type	Medical devices	Medicines/ Pharma.	PPE	Vaccines
Italian Aid Scheme	Financial support	- The European Commission has approved a EUR 50 million Italian aid scheme to support the production and supply of medical devices, such as ventilators, and personal protection equipment, such as masks, goggles, gowns, and safety suits.	New	Yes		Yes	
Tax credit	Financial support	- To introduce tax breaks of 20% for companies conducting research and development for innovative drugs, including COVID-19 vaccines, provided they grant non-exclusive licenses - These companies will be entitled to a tax credit equal to 20% of the costs they incurred from June 2021 to December 2030 on condition that they commit to grant licenses to third parties in the European Economic Area	New		Yes		Yes
Tax incentive scheme	Financial support	- Investment by both individuals and legal entities towards innovative start-ups and innovative SMEs benefit from a substantial break on Italian income tax - The benefit amounts to 30% of the invested sum for both categories, up to EUR 1 million yearly for individuals, and to EUR 1.8 million for companies - The incentive also applies to investments in Italian venture capital funds, CIUs, and other entities that predominantly invest in innovative start-ups and SMEs	Existing	Yes	Yes	Yes	Yes
Tax credit	Financial support	- Companies that increase their R&D expenditure in the 2017-2020 period benefit from a 50% tax credit on their additional expenses (incremental credit), with an annual ceiling of EUR 20 million - It applies to basic research, industrial research and experimental development (including personnel expenditure, research agreements with other entities and IP costs)	-	Yes	Yes	Yes	Yes
Tax deduction	Financial support	- Patent Box is a fiscal regime consisting of a 50% reduction in corporate tax on income deriving from direct and indirect use of intangible assets (i.e. industrial patent rights, industrial design and models, know-how and copyrighted software) - In order to avail benefit, there must be a direct link between R&D activities, qualified IP and the resulting income	Existing	Yes	Yes	Yes	Yes
Smart & Start Italia Scheme	Financial support	- The scheme is for small-sized innovative start-ups (including life sciences and biotech) which are less than 5 years old - They can claim interest-free loans of up to 80% of relevant costs for projects between EUR 100k and EUR 1.5 million. The money can be borrowed in instalments over 24 months and then paid back over a 10-year period	Existing	Yes	Yes	Yes	Yes

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Annex B: List of interviewees

Appendix B: List of interviewees

The table below gives an overview of the people that have been interviewed for this study:

Function	Organization
Head of Connected Care Benelux	Philips
Commercial Manager Hospital Markets	3M
Prof of Health Economics	University of Munich (Germany)
Head of Inspection	Element (UK)

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Annex C: References

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