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

Final Report

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Managementsamenvatting (NL)

Recente ontwikkelingen zoals de COVID-19 pandemie en Brexit 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 Verenigde Staten (VS) 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 vaccins, andere vaccins, 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 instrumenten zich in de volgende categorieën: financieel, wet- en regelgeving, productie, marketing en infrastructuur.

Vijf casussen zijn in meer detail geanalyseerd:

- Wetgeving die de productie van PBM in de VS stimuleert;
- Opschaalbare productiecontracten afgesloten door de Duitse overheid om (pandemische) mRNA vaccinproductie 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 in wisselende mate succesvol geweest in het realiseren van productie dichtbij huis

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

1. De VS slaagde erin om voor PBM minder afhankelijk te worden van andere landen door het implementeren van ‘reshoring’-beleid. De kosten van dit beleid zijn echter hoog en de baten hangen grotendeels af van de, hoogst onzekere, toekomstige vraag naar PBM.
2. De Duitse regering heeft contracten afgesloten met vaccinproducenten om ervoor te zorgen dat zij productie van mRNA vaccins snel kunnen opschalen. Zodat er 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 mRNA vaccins gegarandeerd en wordt voorkomen dat bij productie van vaccins opnieuw opgestart moet worden. Op de lange termijn bestaat echter het risico dat de investering voor stand-by-capaciteit niet nodig was geweest of dat tekorten op een goedkopere manier voorkomen hadden kunnen worden.
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)

Samengevat werken de beoordeelde beleidsinstrumenten op drie manieren:

1. Reshoring-beleid (zoals dat van de VS en Frankrijk) gericht op het aantrekken van (buitenlandse) producenten die momenteel niet actief zijn in de respectievelijke landen.
2. Beleid gericht op het behouden of vergroten van de lokale (schaalbare) productiecapaciteit door producenten financieel te ondersteunen of te navigeren in regelgevende processen (zoals de voorbeelden uit Duitsland, het VK en Oostenrijk). Deze beleidsinstrumenten zijn voornamelijk gericht op het behouden van huidige producenten en het stimuleren om hun productiecapaciteit (schaalbaar) uit te breiden.
3. Ander beleid, zoals R&D-fondsen, om een bloeiend startup-klimaat te stimuleren. Dit beleid is vooral gericht op onderzoek en ontwikkeling, maar kan ook bijdragen aan lokale productie.

De effectiviteit van het de instrumenten is onderzocht vanuit het perspectief van leveringszekerheid. Het effect van een geisoleerd instrument is echter lastig om exact te bepalen, omdat de effectiviteit afhankelijk is van veel verschillende factoren die buiten de scope van dit onderzoek vallen, denk daarbij aan het vestigingsklimaat van een land en geopolitieke situaties.

Ondersteuning van lokale (schaalbare) productie is eenvoudiger dan reshoring

Het stimuleren van (schaalbare) uitbreiding door producenten die al in een land aanwezig zijn, is over het algemeen makkelijker dan proberen om nieuwe productie (terug) te halen naar een land. Nadeel is echter dat landen zich hiermee beperken tot de productie die lokaal reeds aanwezig is. De casus uit Oostenrijk laat zien dat de lokale productie kan worden uitgebreid door samenwerking tussen industrie en overheid. Voor Nederland zou dit echter niet mogelijk zijn op het gebied van antibiotica, aangezien Oostenrijk de laatste grootschalige antibioticafabriek in Europa heeft. Om het gebruik van beleid ter ondersteuning van lokale (schaalbare) productie te optimaliseren, is het raadzaam om inzicht te krijgen in 1) welke medische producten kritisch zijn en daarom lokaal geproduceerd moeten worden en 2) of deze producten al op grote schaal in Nederland en/of in de EU worden geproduceerd. Als aan de tweede voorwaarde is voldaan, is het raadzaam om, in Europees verband, een strategie te volgen om de lokale productie te behouden en te vergroten.

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 door het inzetten van beleidsinstrumenten, er productiecentra - die naar lagelonenlanden waren verplaatst - weer terug verplaatst worden dichterbij huis, ook wel bekend als ‘reshoring’. 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, daarbij daalt ook de CO2-uitstoot als gevolg van minder transport. Daarnaast stellen westerse landen stellen strengere eisen aan vervuiling en arbeidsomstandigheden dan veel Aziatische landen waar nu veel van de productie van medische producten plaatsvindt, zoals China, India en Maleisië. Zo heeft de Europese Unie een industriële strategie om de transitie naar een groene en digitale economie te leiden.

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. In een studie van het CPB wordt geconcludeerd dat er een ernstig risico bestaat van overgangskosten en verstoring van toeleveringsketens als er op grote schaal beleid van reshoring zou worden gevoerd. Reshoring zou ook geopolitieke spanningen kunnen veroorzaken, bijvoorbeeld als gevolg van importtarieven, waardoor de voordelen van de wereldhandel teniet zullen worden gedaan.

Het nastreven van reshoring is daarmee een politieke beslissing waarbij de voordelen van de wereldhandel niet mogen worden onderschat.

Managementsamenvatting (NL)

Dicht bij huis produceren is één van de manieren waarop de leveringszekerheid kan worden verbeterd en moet altijd worden vergeleken met andere opties

Dicht bij huis produceren moet worden gezien als een van de alternatieven om de aanvoer van medische producten veilig te stellen. Experts geven aan dat maatregelen zoals reshoring om de leveringszekerheid te bevorderen vaak niet het meest economisch effectief zijn. Het is daarom belangrijk om de mogelijkheden die productie dichtbij huis bieden altijd te vergelijken met de kosten en baten van andere opties, zoals het vergroten van de leveringszekerheid door het aanhouden van extra voorraden. Ook moet worden opgemerkt dat dit onderzoek betrekking had op de productie van medische producten. Productie is echter slechts een deel van de toeleveringsketen. Ook andere delen van de keten kunnen naar Nederland worden gehaald, zoals distributeurs van producten (die niet produceren, maar doorverkopen).

Daarbij komt dat productie dichtbij huis niet gelijk staat aan betere leveringszekerheid. Producenten in Nederland exporteren een deel van hun producten en leveren deze niet uitsluitend aan Nederlandse zorginstellingen en consumenten. Leveringszekerheid door productie dichtbij huis ontstaat doordat het eenvoudiger is om contact te leggen tussen de zorginstelling/gebruiker en de producent en zo een goede relatie op te bouwen. Wanneer risico's optreden die de beschikbaarheid van producten onzeker maakt, is het vaak eenvoudiger om afspraken te maken met Nederlandse producenten dan met buitenlandse producenten en gezamenlijk op te treden om knelpunten bij de beschikbaarheid van producten op te lossen.

Als de Nederlandse overheid lokale productie wenselijk acht, is het verstandig om dit op Europees niveau na te streven

Voor Nederland is het stimuleren van productie dichtbij huis extra uitdagend, omdat er op dit moment beperkte producenten van medische producten zijn. Daarnaast geven producenten aan dat ze niet primair naar Nederland 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 de landen hebben een veel grotere afzetmarkt waardoor het makkelijker is om rendement op investeringen te realiseren.

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, als onderdeel van de *'2020 New Industial Strategy: building a stronger Single Market for Europe's Recovery*'. Soortgelijke trajecten kunnen ook ingezet worden voor andere medische producten.

Managementsamenvatting (NL)

Parallel en aanvullend aan Europese inspanningen zou de Nederlandse overheid beleid kunnen maken voor het behouden en uitbreiden van de huidige productiecapaciteit

Hoewel het verstandig is om productie dichtbij huis op Europees niveau na te streven, kunnen parallel en aanvullend aan de Europese aanpak ook Nederlandse initiatieven vormgegeven worden.

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 te 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 stimuleert om niet alleen te onderzoeken en te ontwikkelen, maar ook te produceren in Nederland;
- Als overheid contracten sluiten met producenten van gewenste medische producten om productiecapaciteit (schaalbaar) in Nederland te behouden.

Bovenstaand beleid is gericht op het behouden en eventueel uitbreiden van de productiecapaciteit van de huidige bedrijven. Deze maatregelen worden kosten effectiever beschouwd dan reshoring-beleid. Als bovenstaande maatregelen echter onvoldoende zijn, zou reshoring kunnen worden nagestreefd voor de meest kritieke medische producten, eerst op EU-niveau en ten tweede op nationaal niveau, hoewel dit waarschijnlijk erg duur zou zijn.

Wanneer reshoring naar Nederland wenselijk is, is het van belang om te beoordelen hoe Nederland in vergelijking met andere Europese landen waarde kan toevoegen aan het veiligstellen van productiecapaciteit of het innoveren van productie. Ook moet rekening worden gehouden met de beperkingen om de productie naar Nederland terug te halen, zoals de krappe arbeidsmarkt en beperkende (milieu)regelgeving (waaronder stikstofwetgeving). Als aan de randvoorwaarden is voldaan, kan de overheid een samenwerking aangaan met marktpartijen om een plan op te zetten om de productie terug te brengen, waarbij uiteraard rekening moet worden gehouden met randvoorwaarden ten aanzien van staatssteun.

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 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 centres 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 centres 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) mRNA 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 signed contracts with vaccine producers to ensure that production of mRNA vaccines can be scaled up quickly so that enough vaccines can be produced for the German population if the COVID-19 pandemic persists or a new pandemic breaks out. In short term the policy by the German government secures access to mRNA vaccines. This might help the country navigate through a flare up of COVID-19. In the long run, however, there is a risk that the investment for standby capacity would not have been needed or that shortages could have been prevented in a cheaper way.
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)

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

1. Reshoring policies (such as those is the USA and France) aimed at attracting (foreign) producers that are not currently active in the respective countries.
2. Policies aimed at maintaining or increasing local (scalable) production capacity by supporting producers financially or in navigating regulatory processes (such as those in Germany, the UK and Austria). These policies are predominantly aimed in retaining current producers and incentivizing them to expand or maintain their production capacity.
3. Other policies, such as R&D funds, in order to stimulate a flourishing start-up climate. These policies mainly focus on research and development, however can also contribute to local production.

The effectiveness of the instruments has been studied from the perspective of security of supply. The effect of an isolated instrument, however, is difficult to determine precisely, because its effectiveness depends on many different factors that fall outside the scope of this study, such as the business climate of a country and geopolitics situations.

Supporting local (scalable) production is easier than reshoring

Stimulating expansion by producers that are already present in a country is overall easier then trying to bring new production (back) to a country. Downside is however that countries are limited to the production that is present locally. The case study from Austria shows that local production can be expanded by collaboration between industry and government. However for the Netherlands this wouldn't be possible for antibiotics as Austria is home to the last large-scale antibiotics plant in Europe. In order to optimize the use of policy supporting local (scalable) production it is advised to create insights in 1) which medical products are critical, and therefor should be produced locally and 2) whether these products are already produced on large scale in the Netherlands or EU. If the second condition is met, it is advised to pursue a (EU) strategy to keep and increase local production.

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

The case studies on France and the USA show that by deploying policy instruments production centres – which had been relocated to low-wage countries in the first place – are being relocated closer to home, also known as 'reshoring'. With investments in production centres, 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 decreasing carbon footprint and lowering transportation costs, that are currently rising rapidly. 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.

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 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 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 full 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.

Executive summary (EN)

The results from a study by the CPB concludes that there's a serious risk of transition costs and disturbance of supply chains if reshoring policies would be implemented. Reshoring could also cause geopolitical tensions, for example caused by tariffs or reshoring policies, will nullify the benefits of global trade.

Reshoring is therefor a political decisions in which the benefits of global trade should not be underestimated.

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

Production close to home should be seen as one of the alternatives among other ways to secure the supply of medical products. 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 the costs and benefits of other options, such as increasing security of supply by keeping additional stocks.

It should also 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 (who do not produce, but resell).

In addition, production close to home does not necessarily equate to better security of supply. Producers in the Netherlands export some of their products and do not supply them exclusively to Dutch healthcare institutions and consumers. Security of supply through production close to arises from that it is easier to establish contact between the healthcare institution/consumer and the producer and thus to build up a good relationship. When risks occur that make the availability of products uncertain, it is easier to make arrangements with a producer with whom you have a good relationship and to take joint action to solve product availability bottlenecks.

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

For the Netherlands, stimulating production close to home is extra challenging, because there are currently limited producers of medical products. Besides 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 increase production of critical medical products closer to home can best be done on the EU-level rather than by each individual member state. Production centres in neighbouring countries could produce medical products for the Netherlands also without each member state having to invest in attracting production centres. 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 as part of the '2020 New Industrial Strategy: building a stronger Single Market for Europe's Recovery'. Similar trajectories could also be followed for other medical products.

Executive summary (EN)

Parallel and complementary to European efforts, the Dutch government could make policy aimed at maintaining and expanding current production capacity

Although it is advisable to pursue production close to home at the European level, Dutch initiatives can also be undertaken in parallel, complementary to the European approach.

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;
- As a government, enter into contracts with manufacturers of desired medical products to maintain (scalable) production capacity in the Netherlands.

The above policies are aimed at maintaining and possibly expanding production capacity of current businesses. These measures are deemed more cost effective than reshoring policies. However, if the above measures are insufficient, reshoring could be pursued for the most critical medical products, first on the EU level and second on the national level, 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 labour market and limiting (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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KPMG

1. Introduction and methodology

This report provides insight into the policy instruments in several EU-countries and the USA 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 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 less 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 which may help 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, policy 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 increasing security of supply for medical products 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. To achieve the goals set out for this study, first an overview of the current production centres 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 centres 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 desk research. This extensive desk research 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 desk research was conducted and interviews were held with two experts from Germany and UK, two producers of medical products (PPE and medical devices) that operate internationally and a policy advisor in the USA in order to obtain a more in-dept understanding of the selected cases. The intention was to speak to more people to explore the cases in greater depth and gain a better understanding of the effectiveness of the policies. However, the response to these requests has been limited. Mainly because in most countries projects to improve security of supply are still in their infancy and/or part of the political debate

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 the type of policy (such as reshoring and scalable production locations) and the different product types and countries they apply to. 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 desk research 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 in securing supply for medical products 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 context on the Dutch industry policy and findings about foreign policies to stimulate production close to home. 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.

In annex A, a (non-exhaustive) overview of production hubs and policy measures per county is added. Annex B provides a long list of policy measures per country.

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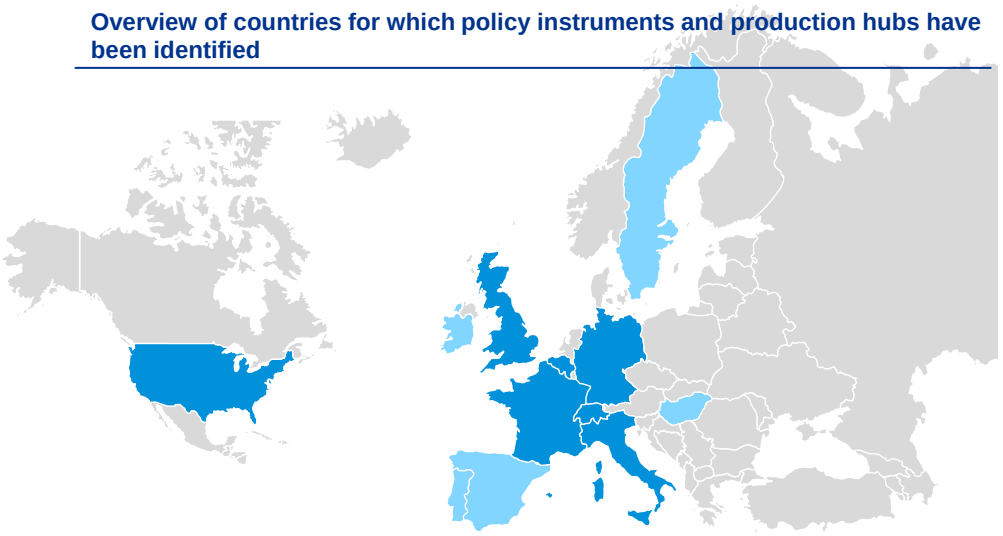
2. Policies that stimulate production close to home

Production centres 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 centres 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 centres 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 centres 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 advertising
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 centres 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 centres for medical products in western countries. For eight countries (USA, Germany, France, UK, Belgium, Switzerland, Italy and Spain), an overview is provided in annex A on the production centres 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 centres 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 B.

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 in annex A and B has therefore been compiled by extensive desk research, combining publicly available information regarding individual manufacturers and individual policy instruments. The overviews 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.

Reading guide

On the next page, we first provide some context on industrial policy of the Netherlands. On the pages thereafter we summarize (based on annex A and B) the insights about policies from other countries.

Dutch industry policy focuses on developing industry and becoming a world leader in sustainability

The Dutch government aims to incentivize the industry to further develop and become more sustainable

In a recent letter with reference 22266731 to the House of Representatives (In Dutch: 'Kamerbrief') the Ministry of Economic Affairs describes the policy of the Dutch government regarding the development of the Dutch industry (including production facilities) in the Netherlands. In summary, the policy of the Dutch government consists of three goals:

1. To adequately mitigate (security) risks resulting from vulnerabilities of the Netherlands and the EU in industrial sectors - for example, risky dependency on one or a few countries - and to retain openness as much as possible.
2. To become a world leader in making industry sustainable.
3. To retain a significant industrial base as part of a diversified economy, in which industrial production remains 10-15% of Dutch GDP.

This research, in which we investigate how security of supply of medical products can be improved with production close to home, is in line with the first goal: to mitigate (security) risks from dependency of production in other countries.

Dutch policies to incentivize the industry consists of incentives, standards and pricing, to encourage industry to make adjustments

As mentioned in the coalition agreement 2021 – 2025 of the Dutch government, lessons learned from the COVID-19 crisis such as the importance of cooperation, decompartmentalization and new (digital) ways of working, will be used to prepare the Netherlands for future health crises. This means an (European) commitment to, among other things, self-sufficiency for generic medicines and medical appliances and establishing care reserves in consultation with experts.

Examples of Dutch policy instruments to improve security of supply of medical products are funds for CO2 reduction and innovation, education of the workforce, the IPCEI Health subsidy scheme and the National Growth Fund (in Dutch: Nationaal Groeifonds).

The goal of the IPCEI Health subsidy scheme is to achieve a combination of large scale projects that strengthen the European health sector. Strengthening the European health sector can be done by for example innovation of production technologies and production processes for raw materials and medicines as well as innovating a greener, more sustainable solution. By participating in the IPCEI Health subsidy scheme, the Netherlands wants to contribute to an enhanced security of supply of medicines and thus be better prepared for a (new) health crisis.

With the National Growth Fund, the government will invest €20 billion between 2021 and 2025 in projects that ensure long-term economic growth. This also allows the Dutch government to continue to invest in, for example, the healthcare, education and in the necessary measures against climate change.

In addition, the Dutch government aims to align with the European industrial policy. In order to connect, the Netherlands invests in European industrial projects, such as investments in the semiconductor industry.

An important condition for the industrial policies to have effect is that there is sufficient space, both literally and figuratively

In a literal sense, industry requires sufficient physical space for production facilities.

In a figurative sense, industry requires predictable and appropriate regulations that guarantee safety of people that work at the facilities and live near facilities. Also environmental implications of production facilities should be taken into account and sufficient qualified workforce should be available.

Foreign 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 identified in this research (appendix A) were put in place during or in the aftermath of the COVID-19 pandemic. These policies are mainly focused on PPE and vaccine production.
- Germany has focused on ensuring sufficient (scalable) capacity as an aftermath of the COVID-19 pandemic. The German government has invested in R&D and wants to ensure that vaccine producers have sufficient production capacity to supply vaccines for any future outbreaks.
- A dichotomy can be recognized in the policies. Part of the policies are aimed at maintaining current production, another part is aimed at transferring a business operation that was moved overseas back to the country from which it was originally relocated (reshoring).
- Policies aimed at attracting industry in a general sense, use among others reshoring as a means. Various cases in this research consider reshoring policies such as 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.

Reshoring and local production

Location decisions of manufacturing firms are among the most debated topics in the international business and supply chain management fields. Boosted by the opportunities created by increasing globalization, these decision generally concern offshoring strategies. For years, the trend has been to optimize 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.

In the past few years, companies operating in different industries have decided to (partially) reverse their previous manufacturing offshoring decisions and have transferred their production activities back home. This phenomenon is referred to as reshoring.[(2)]

For this study a broader definition of reshoring or stimulating local production is used, since no research is done to whether or not the production originally belonged in a certain country. This broader definition includes the practice of transferring a business operation that was moved overseas for economic reasons back to a western country. Within this definition also policies that stimulate local production, which was not offshored in the first place, are included.

Varying policies and strategies 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 centres 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 five policy instruments in the context of five countries.

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 should include varying policy instruments
- The case studies should include at least an example of reshoring and scalable production capacity;
- The case studies should include a dispersion between the types of medical products that the policy instrument (mainly) influences;
- The case studies should include a dispersion between western countries that the cases apply to.

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

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

As stated a lot of factors influence whether a policy adds value to a country or not, we analysed 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.

The selected cases 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 USA 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 USA.

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.

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 grants 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. Financial aid to maintain penicillin production 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 centres, but over the years – 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 Austria is secured, while production in many other countries was cut back over the years.

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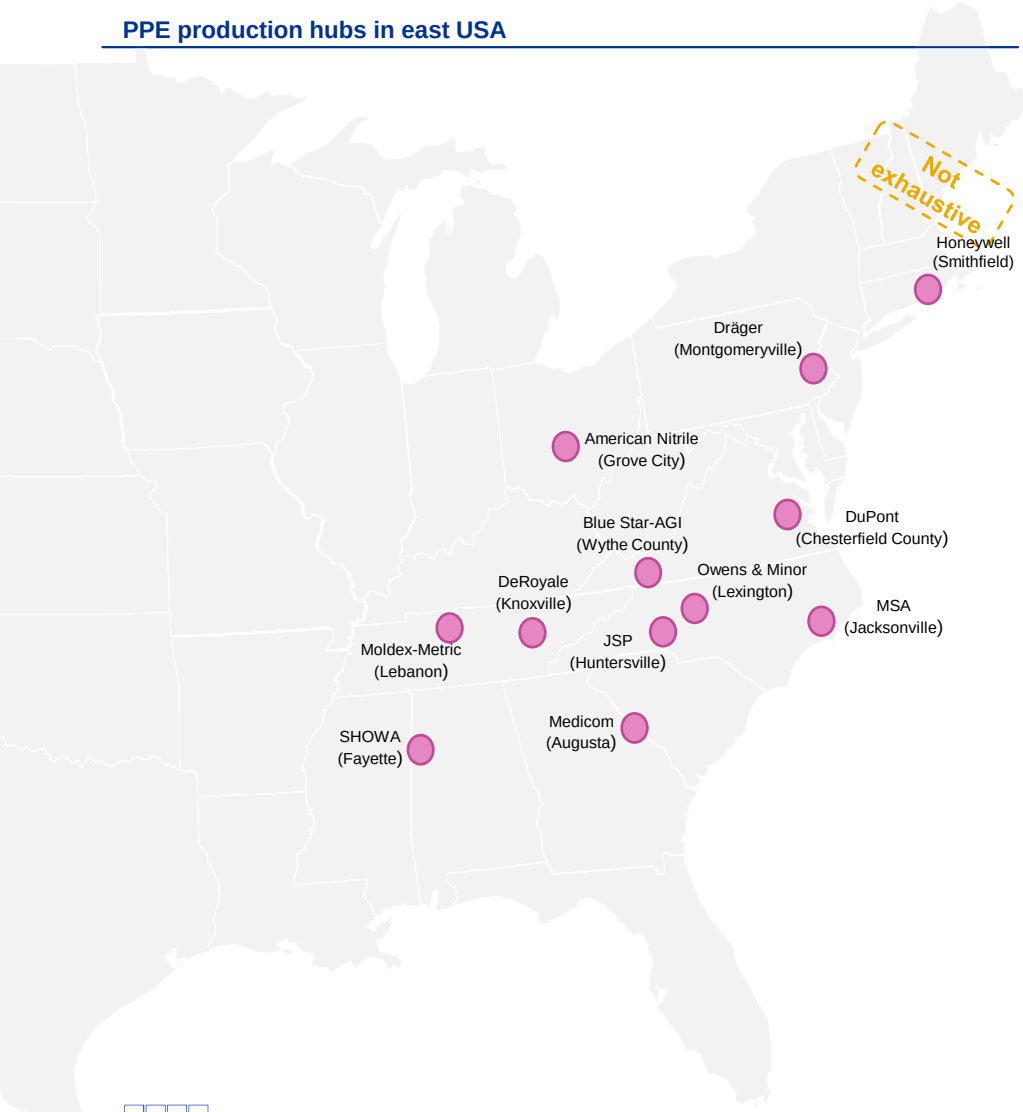
Legislation that stimulates reshoring PPE production to the USA

The USA are home to 20% of the Medical PPE market in 2019

PPE production hubs in east USA



Before the COVID-19 pandemic, the USA was a leading medical PPE production market

The PPE market has several sub-industries, including healthcare, construction and chemicals. In 2019, the USA medical PPE production market was estimated to amount to ~USD 8 billion, in turn accounting for ~20% of the global medical PPE market size in 2019 (excluding gloves)*. The countries with the highest production of medical PPE were China, USA 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.(3)

Although the USA was, in 2019 a major manufacturer - accounting for ~20% of the global production - it relied heavily 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, Eye Protection and Hand Hygiene. Gloves are excluded.

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

Case description[4]

Policy description	The USA 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 PPE to be domestically manufactured. Contracts entered into by the Departments of Homeland Security, Health and Human Services, Defence, 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. Contracting with local producers is unlikely to become mandatory. However, it is likely that a 'comply or explain' principle will be applied. This means that if PPE is not purchased from local producers, the buyers will have to provide a justification for this.
Date of implementation	The act was introduced in the Senate of the United States Congress in April 2021, but has yet to be implemented.
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 Défense, the Secretary of Education, and the Secretary of Veterans Affairs. The Secretaries are the advisory bodies to the president of the United States.

The COVID-19 pandemic forced the USA 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 USA government (not exhaustive):

- financial support for local supply chain operators through the U.S. International Development Finance Corporation (DFC);
- the use of the Defense Production Act to push manufacturers to increase production;

Besides increased production, temporary export bans on PPE ensured that the locally produced medical products were available to use by the local health care sector. During the pandemic the Federal and state governments have rapidly became the largest buyers of 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, 5]. This Act is part of the Build America, Buy America (BABA) Act, the main purpose of which is to create jobs.

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 USA reshoring policies[6]

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 fulfil 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.

"The Made In America Office is just in its infancy, especially related to PPE. Our primary focus right now it to draft a report for congress about how we aim to pursue the goals of the Make PPE in America Act. However, this report is already overdue. The only results from the policy so far is that the Act has brought awareness to the benefits of local production."

Policy advisor at Made In America Office, 2022

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, the country does not depend on production facilities and transport from other countries. However, it is uncertain if, when and for how long this will occur again.
- Additionally, reshoring production to the USA creates 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 labour 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.

Overall, the costs of reshoring are high whereas the benefits largely depend on future demand for PPE. Also, creating policy on reshoring and oversight does require recourses, i.e. the employees of the 'Made in America Ofiice'

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 itself are ineffective, they do make the USA less dependent on other economies and/or countries.

Providing State aid to favour local producers might disturb 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. Some exceptions are allowed, such as giving developing countries special access to the market or raise barriers against products that are considered to be traded unfairly from specific countries. And in services, countries are allowed, in limited circumstances, to discriminate. But the agreements only permit these exceptions under strict conditions.[7] Therefore scrutiny is to be expected when applying large scale reshoring policies in a non-crisis / un-justified situation.

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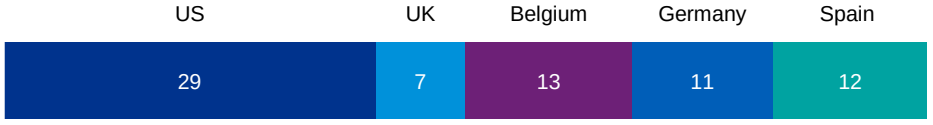
Scalable production contracts used by the German government to secure (pandemic) vaccine production

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[8]



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 labour 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, with respect to producing world-leading research, use new knowledge and educate researchers, relative to other countries such as the UK, the USA and the Netherlands.[9] 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.[10] Lastly, the German industry is regarded as an industry with one of the highest quality standards. Germany also has a high labour productivity, but also high labour costs.[11]

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. [12]
- 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. [12]

German's health care system is a hybrid system

To understand the context of the policy instrument implemented by the German government, which is elaborated on the next page, it is good to mention that Germany's health care system exists out of a hybrid system. Where on the one hand they have a public system run by the government, and on the other hand a private system where people can choose to purchase their own health insurance.

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

Case description [13, 14]

Policy description	Germany signed contracts worth 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 signed 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 pandemic preparedness contracts contain agreements on the production and delivery of vaccines to the federal government. The companies will maintain the ratcheted-up production capacities created during the COVID-19 pandemic. In the event of an urgent situation where large demand is necessary, production can thus be scaled up as quickly as possible. The contracts grant the government access rights to the companies' production capacities. The terms on which the total 2,861 billion is paid out to producers are not known based on publicly available information.
Date of implementation	The procurement process started in June of 2021. Contracts were signed in April of 2022.
Governing body	The Center for Pandemic Vaccines and Therapeutics (ZEPAI) represents the Federal Republic of Germany as the contracting authority.

"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. In addition Germany is investing in pandemic preparedness in the long run. To ensure that enough vaccines (mRNA, vector and protein vaccines) 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 until 2029 for supplying the country with vaccines in future outbreaks. [13]

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 all made (joint) bids to the German government in order to get a contract.

CureVac and GSK will receive an annual standby fee to reserve domestic mRNA vaccine manufacturing capacity until 2029. Following a set up period of two years the five year contract will enable production of up to 80 million mRNA vaccine doses. A similar contract to secure another 80 million vaccines is announced with BioNTech. Wacker and CordenPharma presented a joint bid in which they cover the entire manufacturing chain for mRNA vaccines between them, with most steps in Germany and if not, within the EU. Also these companies will receive stand by fee from 2024 onwards, after creating the necessary capacity to produce up to a 100 million doses a year.[14] Following the pandemic preparedness agreement Wacker recently announced they will be expanding their Biotech's site in Halle and it will establish a new biotechnology centre in Munich, which is scheduled to be operational in 2024.[15]

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.

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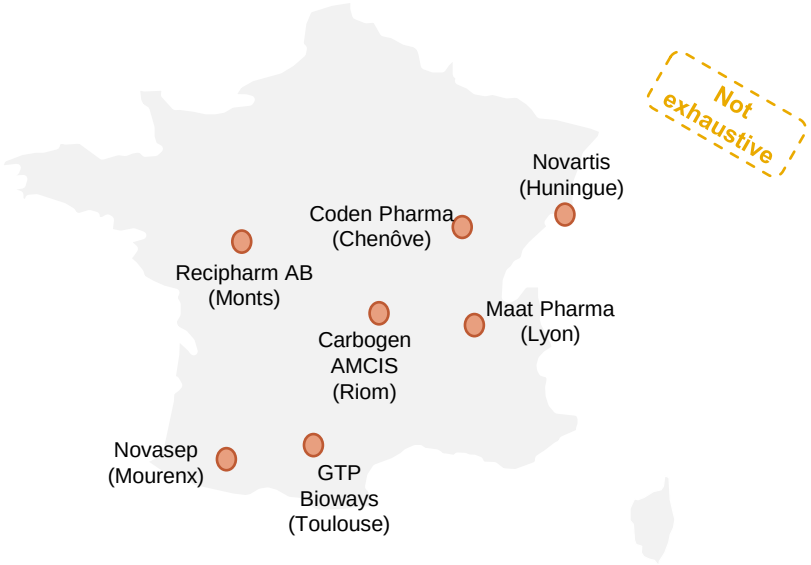
Support of the French government for industrial projects in the medical sector to increase domestic R&D and production of medicines and medical products

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[16]

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 generic 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.[16] 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.[17] As a result, 80% of the active pharmaceutical ingredients used by European drug makers are sourced from India and China.[18] For example, there have not been production plants active in France (or Europe) since 2008 to produce the active ingredient for paracetamol.[17]

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.[17]
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.[17]

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 in different sectors. It also opened up 323 new manufacturing sites in 2021 across the country, showing an increment of 62% year-on-year growth.[19]
These projects were mainly new factories and expansions of existing sites and not primarily focused on medical products.[19] This is (partly) due to a broader government program aimed at the rapid construction of factories.[20]

The public health care system offers universal coverage for all citizens

Enrollment in France's statutory health insurance system is mandatory. The system covers most costs for hospital, physician, and long-term care, as well as prescription drugs. The insurance system is funded primarily by payroll taxes (paid by employers and employees), a national income tax, and tax levies on certain industries and products.

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

Case description[21, 22]

Policy description	French government supports industrial projects in the medical sector to increase both the domestic R&D and domestic production of medical products (including medicines). 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	Companies can submit a proposal to the French authorities describing how they can strengthen the production of medical products (including medicines) in France. The French authorities then review them and determine whether to grant funding. This funding is focused on the first stage of production (R&D and production in small batches). Applicants must meet, among others, the following conditions: 1) the work as part of the project must be carried out in France, 2) the project must be innovative and realize new value chains in France or Europe, 3) the product must be in the first phase of development (and therefore not be mass produced yet) and 4) the production process must be logically linked to the supply chain of medical products in France or Europe.
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.

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

During the COVID-19 pandemic, France suffered from shortages of generic medicines.[23] As a result, the French government started more specific projects (as part of the broader reindustrialization policy) to bring production of medical products (including medicines) to France. The government wants to achieve this by financially supporting industrial projects in the medical sector to increase domestic R&D and production of medical products. In June 2020, the French government pledged to support domestic manufacturing of medical products and has supported 166 industrial projects with a total public support of EUR 683 million since.[24] Among the projects, 25 projects are in the context of the fight against COVID-19. Examples are vaccines and other preventive treatments, healing treatments (excluding vaccines), generic medicines and medical equipment.[25]

Despite high labour 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.[26] 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. In a joint statement health minister Oliver Véran and junior economy minister Agnès Pannier-Runacher stated that talks were underway with French pharmaceutical companies Seqens, Upsa and Sanofi to ensure that “within three years, France will be able to produce, package and distribute paracetamol".[27] France uses both national as European innovation funding tools to support French health industry projects.[28]

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 grants 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.(29)

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.(30)

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 able 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.(31)

Health care in the UK is mainly provided by the National Health Service, a public body

Though the public system dominates healthcare provision, private health care and alternative treatments are available for those willing and able to pay.

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

Case description[32]

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. The project can be for the upgrade, expansion or establishment of new manufacturing facilities. In particular, applications that include the adoption of innovative technologies are welcomed, such as scalable manufacturing and flexible manufacturing (enabling product switching).
Date of implementation	From April 2021 a similar fund was open: Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF) which was succeeded in March 2022 by the LSIMF.
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.'

A wide range of (medical) companies benefit from the available funds[33]

The LSIMF is the successor to the Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF). Which was also established to help grow and strengthen the UK's medicines and diagnostics manufacturing industry by encouraging companies to use new technologies, and to build or expand facilities throughout the country. Next to research grants £60 million was available to help expand life sciences manufacturing in the UK. Since MDMTF is closed it is public which companies are awarded funding through the MDMTF:

— *Ortho Clinicals Diagnostics UK*, which will expand its innovative biological diagnostic product lines, at its Pencoed, Wales site

— *Custom Pharmaceuticals Limited*, which plans to build a new facility in Brighton that will create capacity to manufacture and develop difficult to handle, high potency medicines for the UK NHS and export biopharmaceuticals market

— *Randox Laboratories,* which will build a new large-scale manufacturing facility in Northern Ireland

— *Piramal Healthcare*, which will undertake a facilities upgrade at their Morpeth site in Northumberland, where they develop and manufacture a broad range of pharmaceutical products including generic, clinical trial scale, and commercialized medicines

— *AstraZeneca*, which plans to use new technologies in a continuous manufacturing plant at their Macclesfield, Cheshire site that will result in faster production and reduced waste

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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

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.[34, 35]

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.[36]

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

The geopolitical dimension of medicine shortages increased significantly over the years. Around 80% of the total active pharmaceutical ingredients are sourced from China and India. Additionally, China and India are the largest producers of the world's penicillin, accounting for 90%. Which makes the EU increasingly dependent on non-EU countries - mainly India and China - when it comes to the production of active pharmaceutical ingredients, chemical raw materials and medicines.[37]

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. Developing and introducing innovative manufacturing technology for both active pharmaceutical ingredients (APIs) and finished dosage forms (FDFs).[38] The Austrian government will put up about one third (USD ~60 million) of the investment. The government primarily supports new process technology to produce API for penicillin products at Kundl. "Sandoz commits to related penicillin API production in Europe for the next 10 years, despite fierce global price competition, particularly from China," the CEO of Sandoz says.

Sandoz produces enough penicillin products at Kundl to potentially meet all current Europe-wide demand. Kundl is the Sandoz competence centre for antibiotic FDFs and the focal point of its European antibiotics manufacturing network.[39]

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 USA 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.[38]

The negotiations between Sandoz and the Austrian government were initiated by Sandoz. The Austrian government uses funding from a basic program[40]

The Austrian government is using funds from the basic program of the FFG (the national funding institution for business-related research and development in Austria) to support the project. The government funding consists of annual amounts, with conditions attached. The exact conditions are currently unknown and are defined annually.

The nation of Austria has a two-tier health care system

All individuals receive publicly funded care, but they also have the option to purchase supplementary private health insurance. Some individuals choose to completely pay for their care privately.

"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 centre 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 [parent company of Sandoz] 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

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Summary of lessons learned from the case studies

The case studies show three types of policy instruments used to support or increase local production

Reshoring policies aimed to attract (foreign) producers to manufacture in western countries

The reshoring policies as analysed in the USA and France cases are aimed at attracting foreign producers to move their manufacturing (back) to the western country. This was done by financial aid from the government and/or guarantees on local contracts. However both policy instruments are part of a larger strategy deployed by the government, therefore it's difficult to pinpoint the exact impact.

The policy instrument in the USA will require covered Secretaries to issue long-term contracts for American-made PPE when implemented. The policy is not yet effective, so it is unclear to what extent the policy will increase local production. However benefits arise from this policy instrument because what is locally produced is locally used. Given the fact that the USA government is one of the largest buyers of PPE the policy is expected to have a high impact in supporting local producers.

Also the French policy instrument is relatively new, implemented in 2020. But since the policy is part of a larger strategy of reindustrialization there have been quite some positive effects in terms of new openings of production plants. 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.

Both reshoring case studies show that security of supply increases, simply because dependence on other countries decreases. However policies aimed at reshoring come with significant costs and can potentially disrupt the global market. Besides country specific aspects, such as the size can determine the success of the policy. Since the Netherlands is a small country compared to the USA and France, it is likely to benefit less from similar policies. Additionally, the Netherlands is economically highly dependent on global trade. Reshoring opportunities in the Dutch context therefore mainly arise on the European level.

Policies aimed at increasing local (scalable) production by financial support aim at retaining current producers

The policies used in Germany, UK and Austria are aimed at increasing (scalable) local production by financially supporting producers that are already present in the countries. The effects and magnitude of the policy instruments used differ between the cases.

The policy introduced in Germany is, compared to the other cases, costly. On the other hand it does grant a fair amount of supply chain security for mRNA, vector and protein vaccines. In the short term, since there's a reasonable chance 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.

The Netherlands could also conclude such contracts to secure production of certain scarce products. There is a risk of concluding expensive contracts that would not have been necessary afterwards. On the other hand, the benefits can also be high if the production capacity proves to be much needed. It is a policy consideration whether the benefits in different possible scenario's outweigh the costs that are involved in any scenario.

In the UK, the goal of the policy is much broader than only increasing the supply of several medical product groups. However the effects of the investment made by the government are marginal compared to the annual turnover in UK's health industry.

Driving long term competitiveness, the Austrian government agreed upon investing in a penicillin production plant which was already present. The goal is to stay competitive and therewith prevent dependency on import from other countries. This policy instrument can also be applied for existing production plants in the Netherlands, as long as complied to EU State Aid regulation.

Stimulating innovations and supporting projects, for example with R&D funds, in the medical sector to achieve a flourishing start-up climate

Lastly, the UK case is a good example of investing in the R&D of the country, which is again part of the larger policy to create economic opportunity among others. One of the goals, as mentioned, is to deploy cutting-edge innovations. With the investment by the LSIMF companies are encouraged to deploy at scale in commercial manufacturing. Also here, it is hard to draw a conclusion on the effects, however the Dutch and UK climate are similar and the policy could fit in Dutch context. The difference is that the Netherlands is bound by EU State Aid regulation, in contrast to the UK.

4. Assessment of the foreign policies

Using an assessment framework in order to compare the different policy instruments

The policy instrument as described on the previous pages are assed 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. However due to the nature of some policy, such as the date of implementation or the absence of a cost-benefit analysis, the assessment is limited to information publicly available and expert opinion.

The policy instruments are assessed on several relevant criteria

On the following pages, the policy instruments from the five case studies are analysed 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 and/or the impact on supply chain security of medical products.
- *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 seems to align 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.

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 costs of the policy are unknown, because the policy has yet to be implemented. However, some cost drivers are identified: — Higher costs of products, because of, among others, higher labour cost in the USA compared to Asia. — Long-term contracts with relatively high prices	EUR 2.861 billion is reserved to ensure vaccine producers have sufficient capacity for any future outbreaks from 2022 up to 2029. Contracts grants the government access rights to the production capacities, while paying an annual stand-by fee	EUR 683 million to increase domestic R&D and production of medical products with the aim to make it attractive for domestic and foreign manufacturers to produce medicines in France	The LSIMF will provide £60 million in capital grants for investment in the manufacture of human medicines, medical diagnostics and MedTech products with the aim to encourage companies ready to deploy their emerging technologies at scale in commercial manufacturing.	The Austrian government contributed a one time USD ~60 million of the total USD 175 million investment needed to expand the production plant.
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 and/or the impact on supply chain security of medical products	Medium: The policy provides long-term security to companies interested in domestic production, this grants them a competitive advantage over producers abroad. However in the long run it creates a disbalance between supply and demand in the market.	High: Local producers must have enough capacity to supply the German market with locally produced vaccines for any future outbreaks until 2029.More then 250 million doses of mRNA vaccines are secured until 2029	High: The acceleration of the reindustrialization of France has been evident, with a recorded increase of 62% in 2021, accounting for 323 new manufacturing sites. More than half of these, namely 166, represent manufacturers producing medicines.	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 labour productivity pave the way for (innovative) vaccine production hubs.	Medium: A combination of investments in R&D and investments in bringing back production of generic medicines, might make production of generic 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 USA are more stringent than in Asian countries.	Medium/Low: The policy does not explicitly stimulate sustainable production, however, it is to be assumed that environmental regulations in Germany are more stringent than in Asian countries	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 generic 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.	Medium/Low: The policy does not explicitly stimulate sustainable production, however, it is to be assumed that environmental regulations in Austria are more stringent than in Asian countries

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 seem to align with the desire to stimulate global trade.	Medium: The Dutch government could sign contracts with current producers of vaccines in the Netherlands, to maintain or increase production capacity. However, the Dutch government aims to collaborate on a European level regarding securing supply of vaccines and not necessarily secure supply for the Netherlands primarily.	Low: The French policy is part of a strategy to expand the industrial sector. The Dutch strategy, however, has been to focus on making the industrial sector more innovative and greener rather than expanding the sector. Therefore the impact of this policy in the Dutch context is expected to be lower.	High: Grants for R&D for medical products are already in place in the Netherlands and could be extended with a focus on security of supply.	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 increasing local production in three ways:

1. Reshoring policies (such as those is the USA and France) aimed at attracting (foreign) producers that are not currently active in the respective countries.
2. Policies aimed at maintaining or increasing local (scalable) production capacity by supporting producers financially or in navigating regulatory processes (such as those in Germany, the UK and Austria). These policies are predominantly aimed in retaining current producers and incentivizing them to expand or maintain their production capacity.
3. Other policies, such as R&D funds, in order to stimulate a flourishing start-up climate. These policies mainly focus on research and development, however can also contribute to local production.

All of the assessed policies have pros and cons, highly dependent on the nature of the policy and the context of the country. There does not seem to be a 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 policies that stimulate reshoring of production back to the EU. On the next page a more extensive analysis based on our research of the possible fit of the policy instruments in the EU and Dutch context is provided.

Policies to increase domestic production are effective, but the way they fit in the Dutch context varies

The case studies include policy instruments aimed at increasing domestic production capacity of medical products. These policies are efficient to a different degree to bring production (back) to a country, but they come with downsides. Part of these downsides arise from the local context. Below we reflect on the potential for (large scale) policies to increase production capacity in the Dutch / EU context.

Current use of reshoring and the potential in the Dutch context

Activities in reshoring production that used to be present Europe is currently of modest proportions. It happens mainly as a result of companies experiencing problems with the quality of the outsourced activities, costs that 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 labour 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 the need for additional local labour force should be taken into account.(41)

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.(42) For example during the COVID-19 pandemic when demand for protective equipment was high, the western world relied heavily on suppliers in China, who were confronted with a sudden increase in the domestic and foreign demand for protective products that they could not meet.

Reshoring production that used to be in Europe or more specifically in the Netherlands therefore sounds like a logical step 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 analysed the developments since the abolishment of mutual tariffs in 1994 and China joining the WTO in 2001. The study concluded that:

- European consumers benefit from 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, for example caused by 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, because production facilities have to be build up in Europe.

Therefore the CPB questions whether less geopolitical dependency outweighs the costs that it comes with. This is a political decision in which the benefits of global trade should not be underestimated.

Current use of scalable production capacity and the potential in the Dutch context

Contracts aimed at maintaining production capacity to secure the supply of certain products in the future (when there is a shortage) are rare. That is because buyers usually enter into contracts to purchase a product or service, not stand by capacity. The application of policies aimed at pandemic preparedness contracts as are described in the case of Germany, we have not seen in the Netherlands before.

There are, however, examples in the Netherlands where production capacity for other products was used for the production of scarce medical productions during the pandemic, such as Auping. Auping has used its production plants and capabilities for the confection of fabrics in different layers for the production of face masks instead of the production of mattresses that Auping is known for.

When flexibility of production capacity is required, it is generally more common for buyers to sign contracts with companies of sufficient size that supply the product to different customers and can therefore be more flexible and/or companies that have a strong financial position, so that they can buy (extra) raw materials and hire (extra) personnel if necessary.

In the context of preparing for a pandemic, it is conceivable that production capacity that can be scaled up when needed is beneficial for the Netherlands. The key question is whether it is worth the investment to maintain (stand by) production capacity to avoid the risk of shortages of a particular product when a pandemic occurs. The uncertainty of the product to even be required in a future pandemic should be taken into account as well. It is plausible that mRNA vaccines or masks, that were in high demand during the COVID-19 pandemic, won't be needed in a future pandemic.

Preferably, agreements about scalable production capacity are made at the European level. Keeping one or a few production centers on stand by that produce for many countries is more cost effective than keeping one or a few production centers stand by for one country.

Policies to increase domestic production are effective, but the way they fit in the Dutch context varies

Current use of investment in R&D to improve security of supply and the potential for the Dutch context

Stimulating R&D in the field of (production of) medical products from start-ups and stimulating its valorization is a way to promote production close to home from a entrepreneurial perspective. This is a common policy in the Netherlands. There are for example already policies in place to stimulate (circular) production of medical masks, such as the SBIR (Small Business Innovation Research) ‘Sustainable Masks for Healthcare' in which two companies are currently working on the development of (production of) masks in the Netherlands. This competition was an initiative of the Dutch Ministry of Health, Welfare and Sport (VWS). Such competitions could also be set up for innovation of (the production of) other medical products. The disadvantage of policies like the SBIR is that they are aimed at small companies and are therefore mainly limited to mostly low-value products.[43][44]

To stimulate the production of more high-value products in the Netherlands, consortiums of existing Dutch parties could be formed. The government could play a role in this, but should take European rules on state aid into account, as is done with the before mentioned National Growth Fund (in Dutch: Nationaal Groeifonds).

5. Conclusions and recommendations

Policies to encourage local production are successful to varying degrees, there is no 'silver bullet'

This study started with mapping out the different ways in which a selection of 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 optimize 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 intents to sign contracts with vaccine producers to ensure that production of mRNA vaccines can be scaled up quickly so that enough vaccines can be produced for the German population if the COVID-19 pandemic persists or a new pandemic breaks out. In short term the policy by the German government secures access to mRNA vaccines. This might help the country navigate through a flare up of COVID-19. In the long run, however, there is a risk that the investment for standby capacity would not have been needed or that shortages could have been prevented in a cheaper way.
3. The French government seems to be effective in attracting (foreign) manufacturers to produce (generic) 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 and a private company successfully closed a deal to secure production of active pharmaceutical ingredients for penicillin in Austria.

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

1. Reshoring policies (such as those is the USA and France) aimed at attracting (foreign) producers that are not currently active in the respective countries.
2. Policies aimed at maintaining or increasing local (scalable) production capacity by supporting producers financially or in navigating regulatory processes (such as those in Germany, the UK and Austria). These policies are predominantly aimed in retaining current producers and incentivizing them to expand or maintain their production capacity.
3. Other policies, such as R&D funds, in order to stimulate a flourishing start-up climate. These policies mainly focus on research and development, however can also contribute to local production.

The above shows that governments can invest in different phases of the product life cycle (research into products or production techniques, development, scaling up, innovation, etc.) to improve security of supply. Some measures focus early stages of the product life cycle, so that if a R&D trajectory is promising a product can go into production locally and perhaps, in the long term, mass production. Other measures focus on later stages to scale up production, innovate production or prevent production from scaling down.

The strategy that a government should apply depends on the (historical) context of a country and its current policy objectives. If production capacity used to be available but is not any more, reshoring may be appropriate. If production capacity is available in the country, upscaling production capacity may be suitable. If the country has no or little production capacity and aims to be more innovative, R&D funds could be used.

Supporting local producers that are already present is deemed easier than reshoring production to a certain country

Supporting local (scalable) production is easier than reshoring

Stimulating expansion by producers that are already present in a country is overall easier then trying to bring new production (back) to a country. Downside is however that countries are limited to the production that is present locally. The case study from Austria shows that local production can be expanded by collaboration between industry and government. However for the Netherlands this would be a longer road to walk than it was in the case of Austria, since the Dutch government would have to invest (for many different products) to bring new business activities to the Netherlands. This would likely be much more expensive. In order to optimize the use of policy supporting local (scalable) production it is advised to create insights in 1) which medical products are critical, and therefor should be produced locally and 2) whether these products are already produced on large scale in the Netherlands or EU. If the second condition is met, it is advised to pursue a (EU) strategy to keep and increase local production. It should be noted that the Netherlands is likely to benefit (in term of security of supply) from the Austrian government to secure penicillin production in Europe.

However if certain medical products are not or no longer produced in the Netherlands or EU but it is desirable to produce them locally, strategies can be implemented in order to bring (back) production to the Netherlands or EU: reshoring.

However also reshoring has benefits,…

The case studies on France and the USA show that by deploying policy instruments production centres – which had been relocated to low-wage countries in the first place – are being relocated closer to home, also known as ‘reshoring’. With investments in production centres, 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 decreasing carbon footprint and 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 centres. 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 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 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 full 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. The results from a study by the CPB concludes that there’s a serious risk of transition costs and disturbance of supply chains if reshoring policies would be implemented. Reshoring could also cause geopolitical tensions, for example caused by tariffs or reshoring policies, will nullify the benefits of global trade.

Reshoring is therefor a political decisions in which the benefits of global trade should not be underestimated.

Local production is preferably pursued on a European level, but there are options the Dutch government could consider nationally

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

Production close to home should be seen as one of the alternatives among other ways to secure the supply of medical products. 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 the costs and benefits of other options, such as increasing security of supply by keeping additional stocks.

It should also 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 (who do not produce, but resell)..

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

For the Netherlands, stimulating production close to home is extra challenging, because there are currently limited producers of medical products. Beside, producers that were interviewed indicated 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 increase production of critical medical products closer to home can best be done on the EU-level rather than by each individual member state. Production centres in neighbouring countries could produce medical products for the Netherlands also without each member state having to invest in attracting production centres. 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 reshore to Europe. The European Commission is already working on reducing dependencies and improving capacity for a wide range of products, including pharmaceuticals as part of the ‘2020 New Industrial Strategy: building a stronger Single Market for Europe’s Recovery’. Similar trajectories could also be followed for other medical products.

Apart from European efforts, the Dutch government could make policy aimed at maintaining and expanding current production capacity

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. For example by ensuring a good investment climate with a lot of R&D and qualified personnel and a regulatory environment that can be easily navigated. The Ministry of Health, Welfare and Sport (VWS) could collaborate with parties such as the Ministry of Economic Affairs and Climate Policy (EZK), the Netherlands Enterprise Agency (RVO) or InvestNL to ensure this;
- Ensuring that there is a flourishing start-up climate that is also stimulating to not only research and develop, but to also produce in the Netherlands. This can be pursued for example by establishing R&D programs, investing in start-ups and scale-ups or stimulating collaboration among academics and businesses;
- Sign contracts with current producers of desired products to maintain (scalable) production capacity.

The above policies are aimed at maintaining and possibly expanding production capacity of current businesses. These measures are deemed more cost effective than reshoring policies. However, if the above measures are insufficient, reshoring could be pursued for the most critical medical products, first on the EU level and second on the national level, 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 labour market and limiting (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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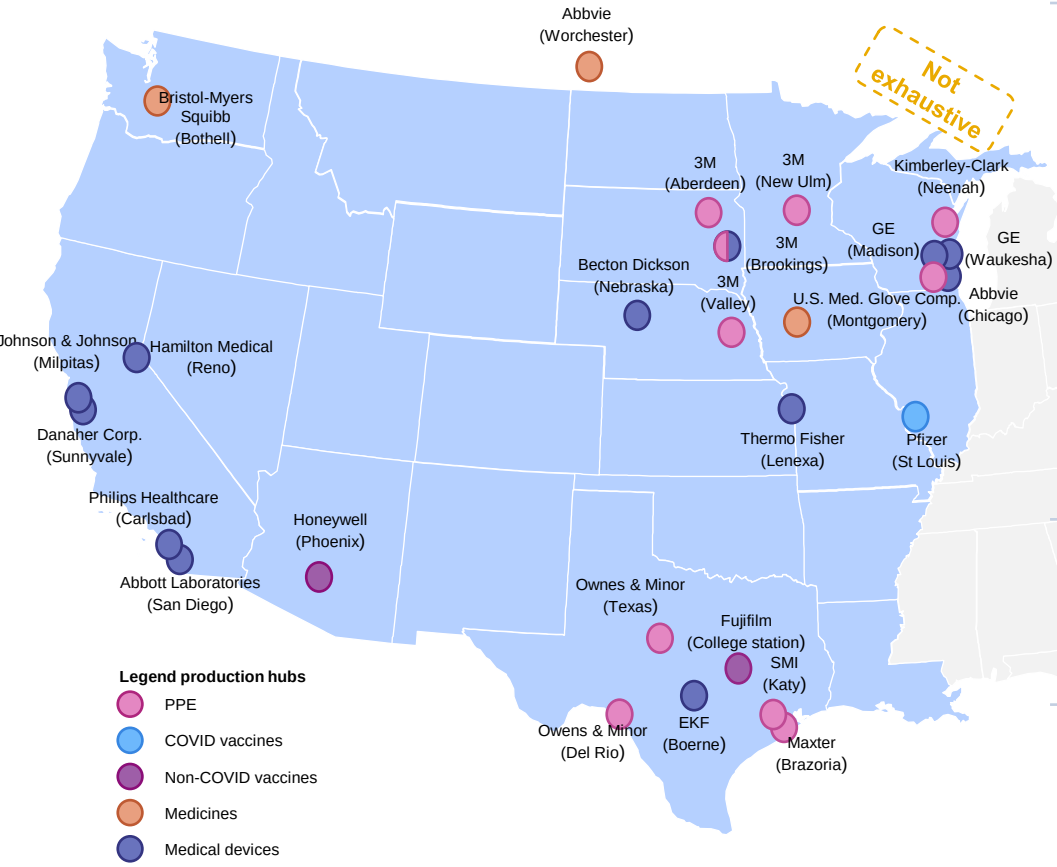
Annex A:Overview of production hubs and policy measures per county

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

Production hubs



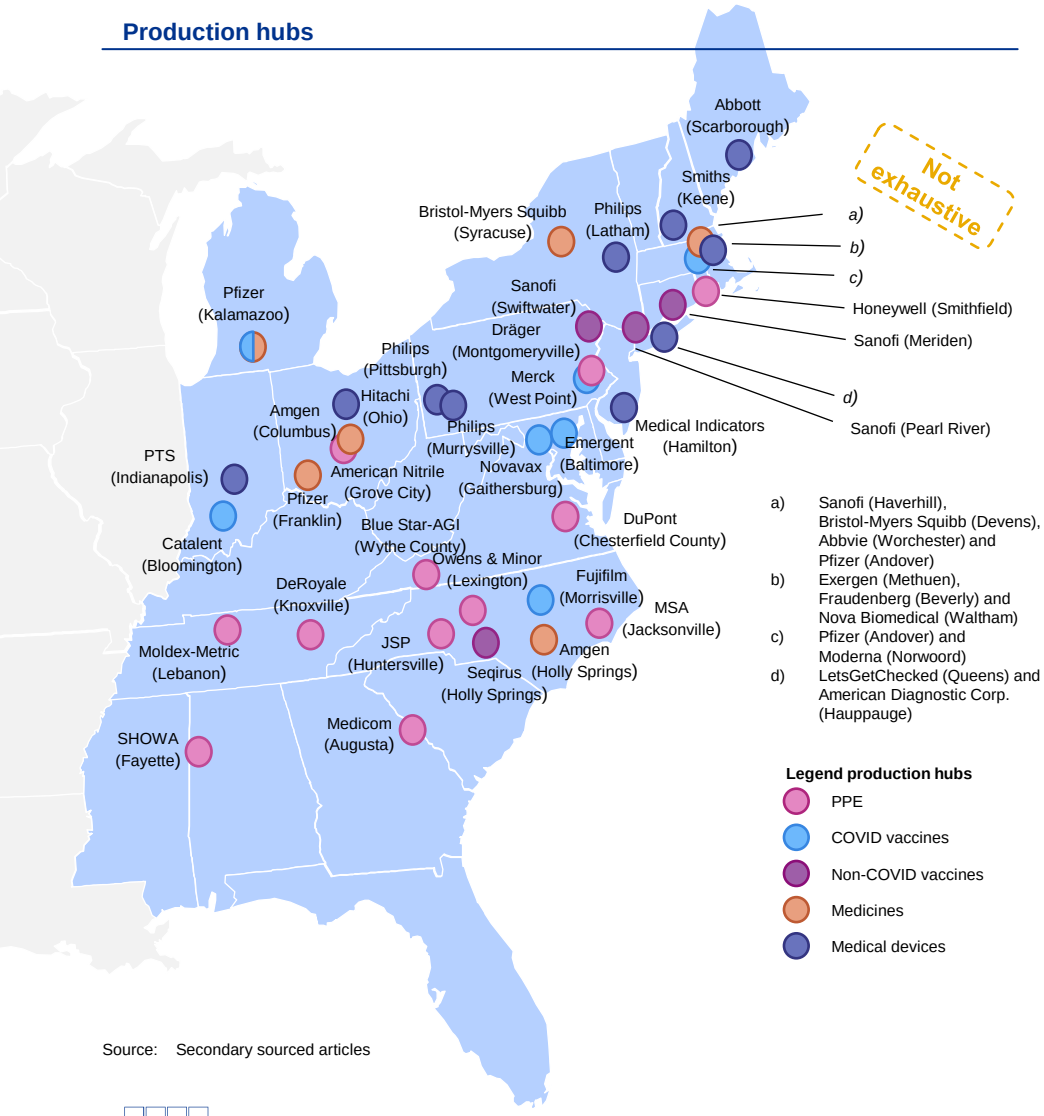
Summary of policy instruments in USA

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)

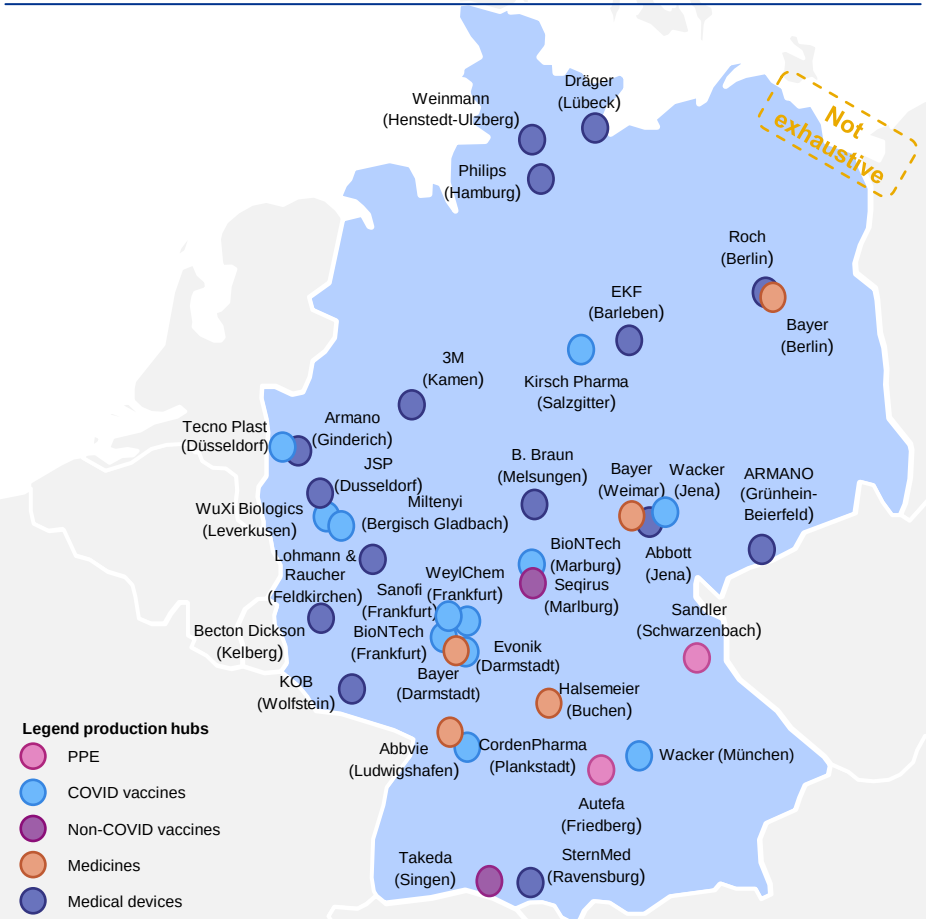
Production hubs



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

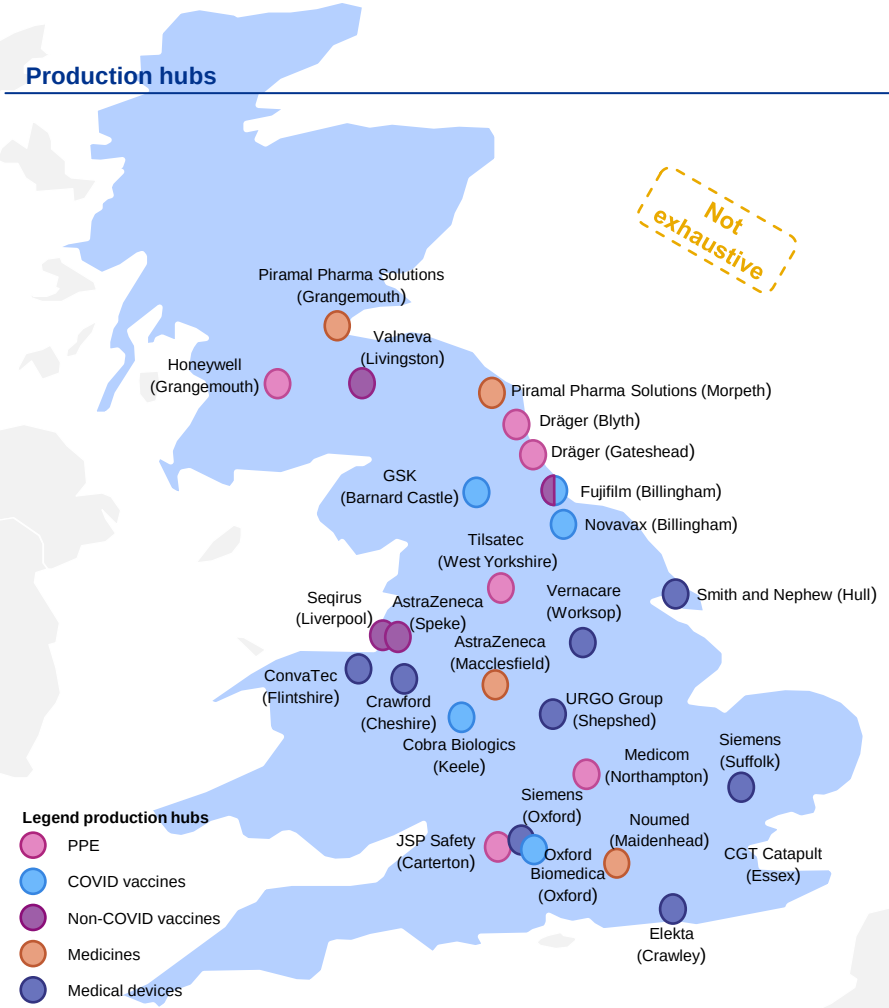
Source: Secondary sourced articles

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



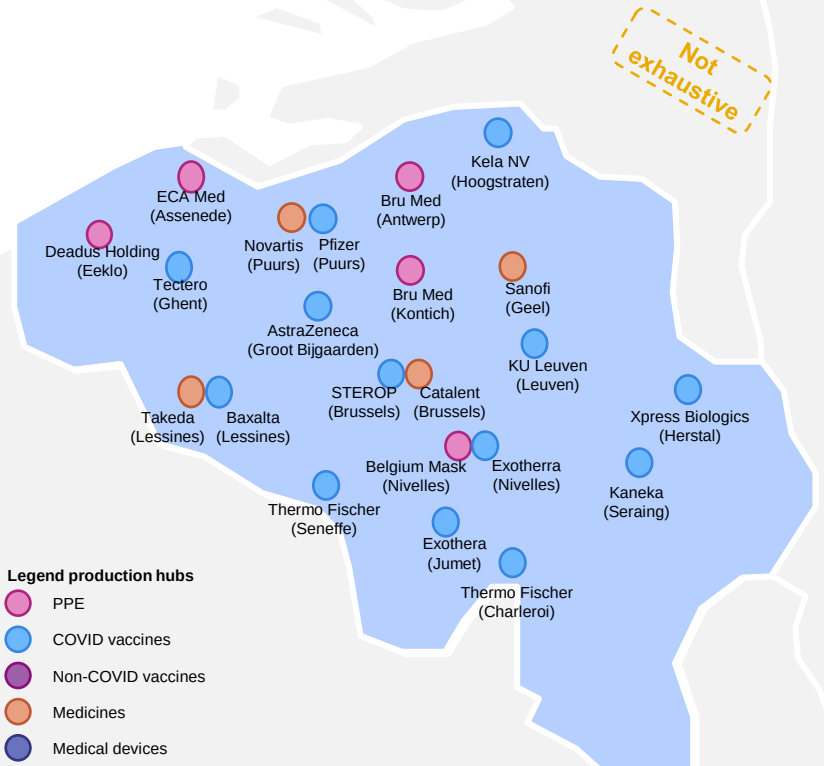
Summary of policy instruments in UK

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
Regulatory 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



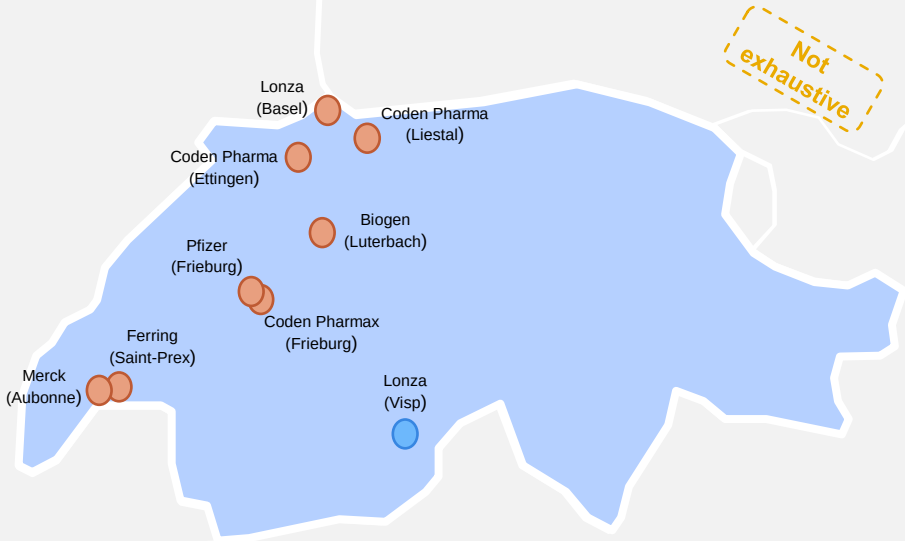
Source: Secondary sourced articles

Summary of policy instruments in Belgium

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

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

Source: Secondary sourced articles

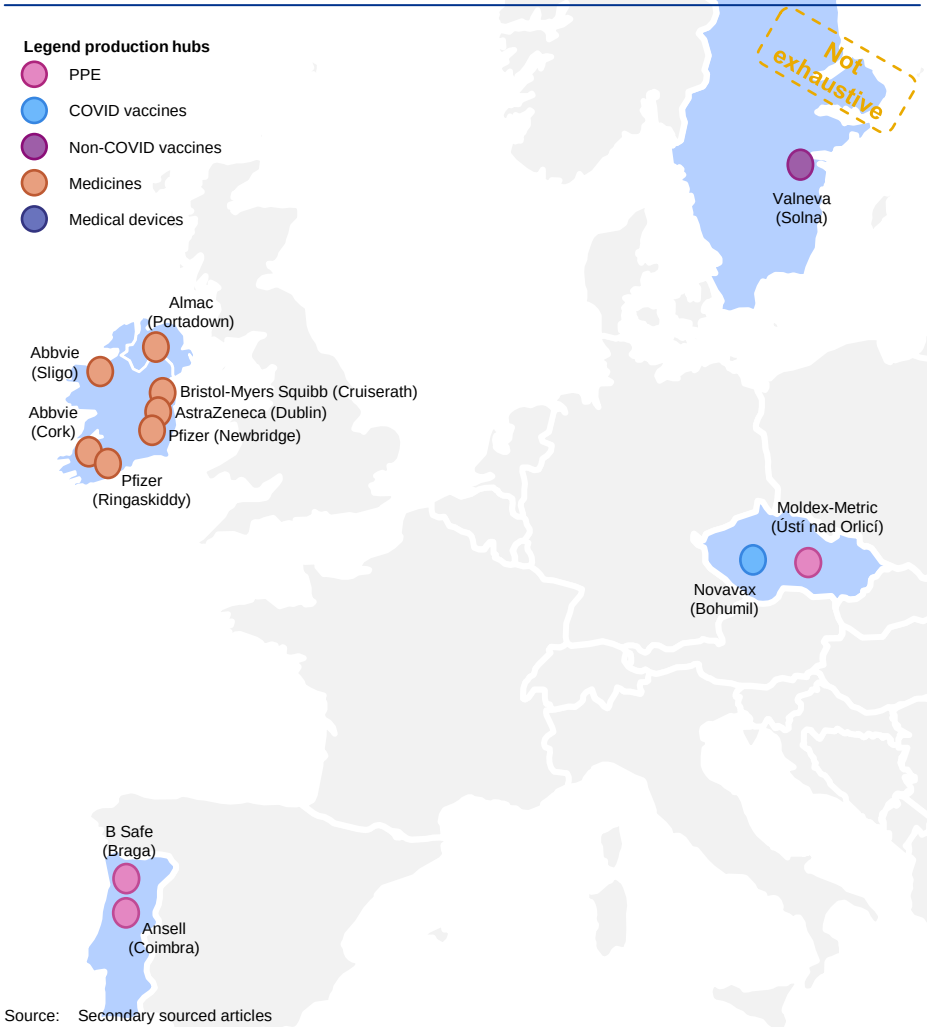
Overview of production hubs in Spain

Production hubs

Source: Secondary sourced articles

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

Production hubs



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.

Source: Secondary sourced articles

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Annex B: 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 USA 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	- Centre 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 USA, 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 Centre 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 USA 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	

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 USA, 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			
Labour 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 labour costs, Germany has gained in productivity in the last decade - The labour cost difference between Germany and its neighbours 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, up to 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 centre 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 centre 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 C: References

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