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US and EU secure vaccine production on home soil

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The deployment of a safe and effective vaccine for Covid-19 will be central to lifting containment measures. In a bid to speed up vaccine deployment, governments are entering into 'Advance Purchase Agreements' (APAs) with vaccine companies to secure access to vaccine doses. We document and compare the vaccine procurement strategies of the US and the EU. Most notably, we find that both the US and the EU only secure vaccine doses from developers whose (contracted) production facilities are based in US or EU territory, respectively. Securing vaccine production on home soil is crucial in a crisis because of the ability of governments to implement export restrictions; vaccines produced in a different jurisdiction may be blocked from exiting the region. Thus, only governments who can secure local production will be able to provide a vaccine quickly.

The global Covid-19 pandemic is unprecedented in scale. The deployment of a safe and effective vaccine - while there is no guarantee that one will be found - will be central to dampening major surges in infections and resuming normal economic activity. Private companies are hesitant to assume the risk and to make the large upfront investment required to successfully push a vaccine through clinical trials and on to the market. Consequently, governments are actively stepping in. Governments are entering into 'Advance Purchase Agreements' (APAs) with leading vaccine companies to secure access to a specified amount of vaccine doses. It is expected that some of the vaccines entering into production will not prove to be effective or fully safe; however, by pre-ordering doses governments decrease the risk for companies while speeding up and increasing production.

We document and compare the vaccine strategies of the US (Operation Warp Speed) and the EU (the Emergency Support Instrument). In particular, we analyze the timing and identity of vaccine projects/companies that have secured contracts with either the US government or European Commission (EC).[1,2] We find that while the US started to secure doses earlier than the EU, the EU has caught up. Most notably however, we find that both the US and the EU only secure vaccine doses from developers whose (contracted) production facilities are based in US or EU territory, respectively. Therefore, we observe a clear pattern of governments taking steps to secure vaccine doses that can be produced on home soil. Thus, US and EU governments clearly believe that securing local vaccine production capacity is key.

US Operation Warp Speed

Operation Warp Speed (OWS), which was announced in early April 2020, is a public–private partnership, initiated by the US administration, to facilitate the development, manufacturing, and distribution of Covid-19 vaccines, therapeutics, and diagnostics. For vaccines, the stated goal of OWS is to deliver 300 million doses of a safe, effective Covid-19 vaccine to US citizens by January 2021. As of the end of August 2020, OWS has backed six vaccine candidates.

[1] Whereas some individual countries within the EU have made moves to secure separate contracts, increasingly the purchase of vaccines for Europe is being coordinated by the European Commission. We also note that for other regions, notably China, the data is too sparse to provide an accurate picture.

[2] The data we use is collected from public sources: the vaccine trackers of the Milken Institute (available online) and London School of Hygiene & Tropical Medicine (available online), and the US clinical trials database (available online). Manufacturing and APA data is hand-collected from press releases/webpages of the companies and US and EU institutions, as well as newspaper articles.

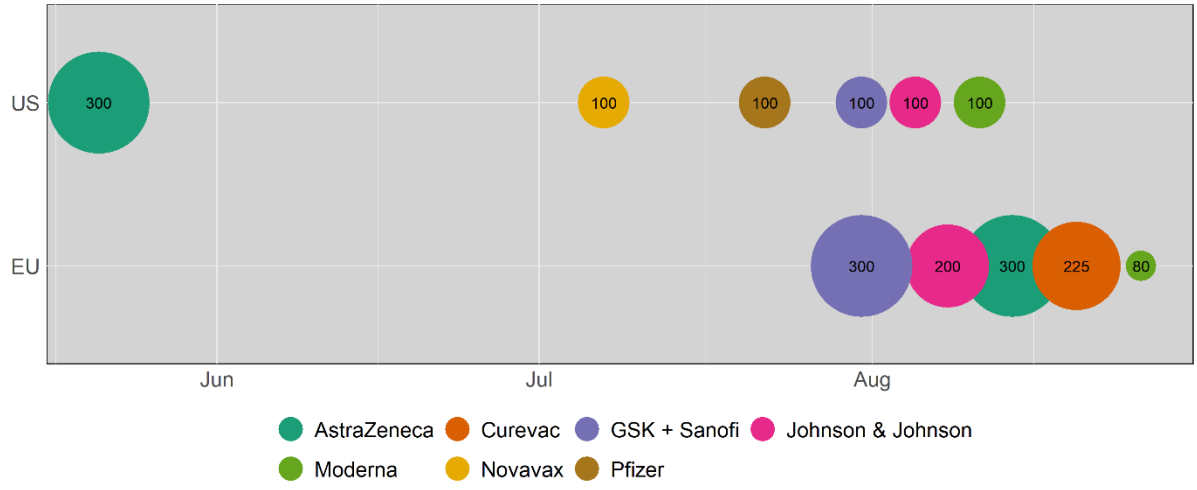
EU Emergency Support Instrument

The EU's Emergency Support Instrument (ESI), also announced in April 2020, is the EU's main tool to help Member States address the coronavirus pandemic. The two main pillars of the EU's stated strategy are to secure vaccine doses through 'advance purchase agreements' (APAs) and to adapt EU regulation to accelerate the development and authorization of Covid-19 vaccines. [3] As of the end of August, the EU has entered into APAs with five vaccine developers/manufacturers.[4]

Vaccine doses secured by the EU and the US

As of end of August 2020, there are 35 vaccine candidates that are currently undergoing phase 1, phase 2 or phase 3 clinical trials.[5] Figure 1 shows the principal companies of these vaccine candidates that have either secured an APA or entered into negotiations to set up an APA in order to supply a specific number of doses to either the US or the EU.[6]

Figure 1: Vaccine doses secured by the EU and the US over time



Notes: Bubble size and label represents amount of pre-purchased doses in millions. Last updated: 30.08.2020

[3] European Commission website (available online)
[4] European Commission website (available online)
[5] The standard innovation process consists of a preclinical phase, focused on research and testing of a drug *in vivo* and *in vitro*, and three phases of clinical development with testing in humans. Phase 1 typically tests the initial safety and tolerability on small sample of individuals. In Phase 2, involving up to 100 patients, therapeutic efficacy and dosage is tested. Phase 3 entails large scale trials with thousands of individuals, usually randomized, aimed at establishing safety and efficacy of a drug. If the drug shows promise in Phase 3 clinical trials it can apply to be approved by the relevant authority, and conditional on approval, the drug can be launched on market.
[6] Many vaccines are being developed and manufactured by consortia. In this brief, we define 'principal company' as the largest private firm involved per vaccine candidate. Each principal company is linked to one specific vaccine candidate. An exception is the joint vaccine of GSK and Sanofi. GSK and Sanofi formally formed alliance and pooled resources for the development of the Covid vaccine.

It is evident that the US started contracting with companies much earlier than the EU - beginning of May vs. end of July - through a large contract with AstraZeneca for 300 million doses. Several smaller contracts followed in July and August. The EU started contracting with companies later but has now overtaken the US in terms of number of secured doses. As of August 31st 2020, the US has secured deals with six companies for a total of 800 million doses. The EU has secured deals with five companies for a total of 1105 million doses.[7] The two are now roughly equal at around 2.5 secured doses per capita.

Further, the US and the EU are contracting with a number of the same companies: AstraZeneca, GSK and Sanofi, Johnson & Johnson and Moderna. Additionally, the US has contracted with Pfizer and Novavax, while the EU has secured doses from CureVac. All these companies have their headquarters in either the US (Johnson & Johnson, Moderna, Pfizer, Novavax) or in Europe (AstraZeneca, GSK, Sanofi, Curevac). Neither jurisdiction has concluded contracts for vaccines developed by China, despite the fact that China has the largest number of vaccine candidates that are in advanced stages of clinical trials.[8]

Contracts are concluded after local production capacity is secured

APAs are typically concluded between governments and vaccine companies once the vaccine has passed the preclinical stage. Indeed, for all vaccine candidates, apart from that of GSK and Sanofi, agreements were secured once the vaccine was already in clinical trials.[9]

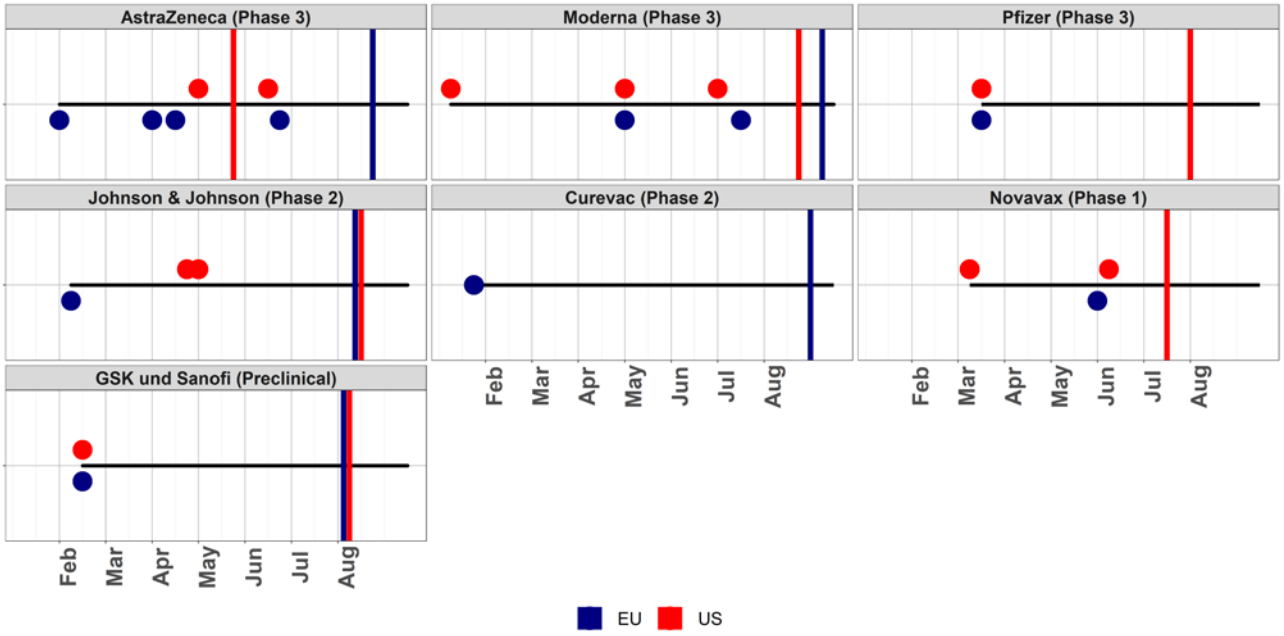
Furthermore, all companies involved in APAs have some initial manufacturing capacity and, apart from GSK/Sanofi and Curevac, companies add additional capacity later on as they progress through the stages of development by concluding contracts with vaccine manufacturers (see Figure 2). All principal companies, apart from Curevac, have now secured manufacturing capacity for their vaccine candidate in both the US and EU.

Most notably, both the US government and European Commission only make contracts with companies who have proven manufacturing capacity on US and EU territory, respectively, and have made clear that this capacity will be used to supply vaccines for the 'local deals.'[10] This observation is perhaps

[7] These doses include only the initial batches of vaccines ordered by the governments and do not consider additional optional doses built-in in some of the agreements.
[8] As August 31st 2020, Chinese entities are developing 10 vaccines, with three in Phase 3 trials. Chinese and Russian authorities have already approved vaccines for use. However, in both cases, this comes at the expense of skipping Phase 3 trials, and thus there is a lack of evidence for safe deployment.
[9] Given that GSK and Sanofi are two established vaccine producers, their proven track record may be the reason why the APA with GSK and Sanofi was concluded earlier on in the process.
[10] For example, the companies GSK and Sanofi issued a statement that the vaccine doses ordered through the EU deal would be manufactured in European countries including France, Belgium, Germany, and Italy (available online).

best illustrated by Curevac who, at this point, only has manufacturing capacity in the EU and has so far only secured an APA with the EU. Furthermore, given that both Pfizer and Novavax now also have manufacturing capacity on European territory, it should not come as a surprise if the European Commission makes a deal with these companies in the future.

Figure 2: The timing of APAs, development stage and secured manufacturing capacity



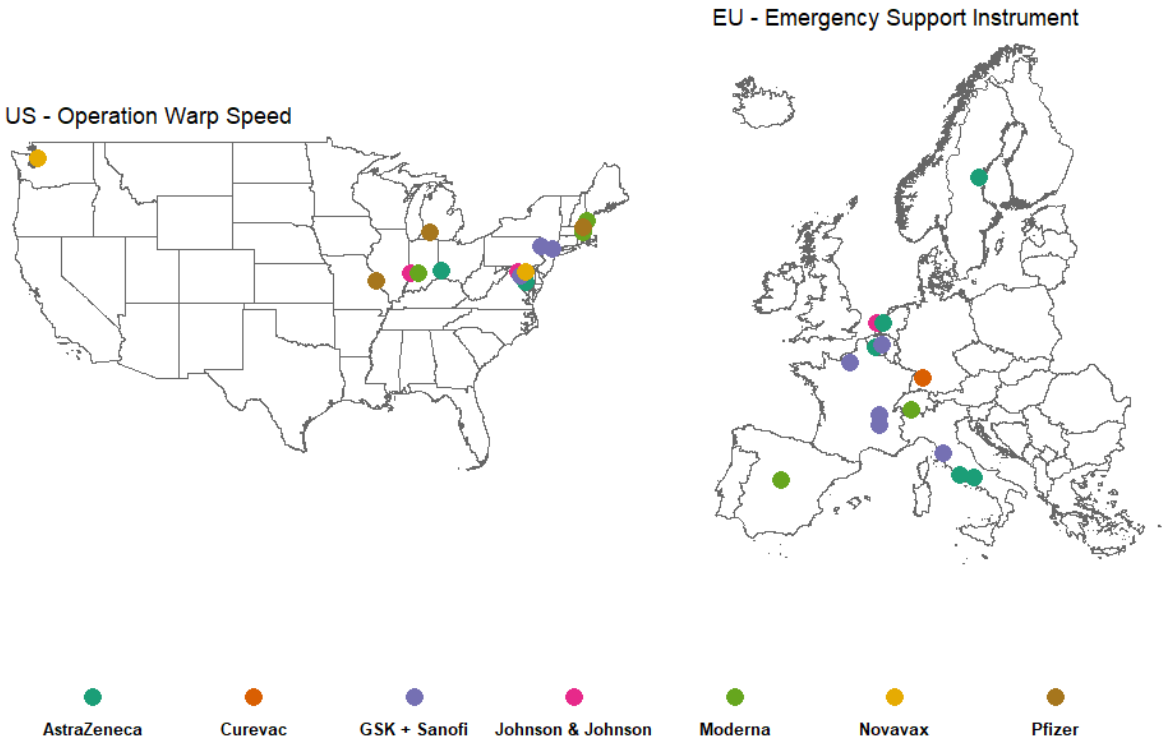
Notes: The heading indicates the principal company for the vaccine candidate and, in brackets, the current phase, which aligns with the phase in which the APA(s) was concluded. The beginning of the black line indicates the start date of the vaccine project. A blue (red) dot at the beginning indicates that the company itself has capacity in the EU (US). Further blue (red) dots indicates that a company has secured additional production capacity in the EU (US). The blue (red) vertical line shows the start date of the APA agreement with the EU (US). Last updated: 30.08.2020.

The location of manufacturing facilities

All vaccine candidates contracted by the US government and all production facilities tied to these projects are on US soil. Similarly, all vaccine candidates contracted by the European Commission and all production facilities tied to these projects are on EU soil (see Figure 3). As discussed above, the US and EU governments have thus far only concluded APAs for vaccines where local production is possible. Within the US, manufacturing facilities are primarily located in the east of the country. Within

Europe, the manufacturing facilities linked to the secured doses are located in Belgium, France, Germany, the Netherlands, Italy, Switzerland, Sweden and Spain.

Figure 3: The location of manufacturing facilities



Notes: The dots indicate manufacturing locations of principal companies that have concluded an APA with the US (left panel) and the EU (right panel), respectively. Last updated: 30.08.2020.

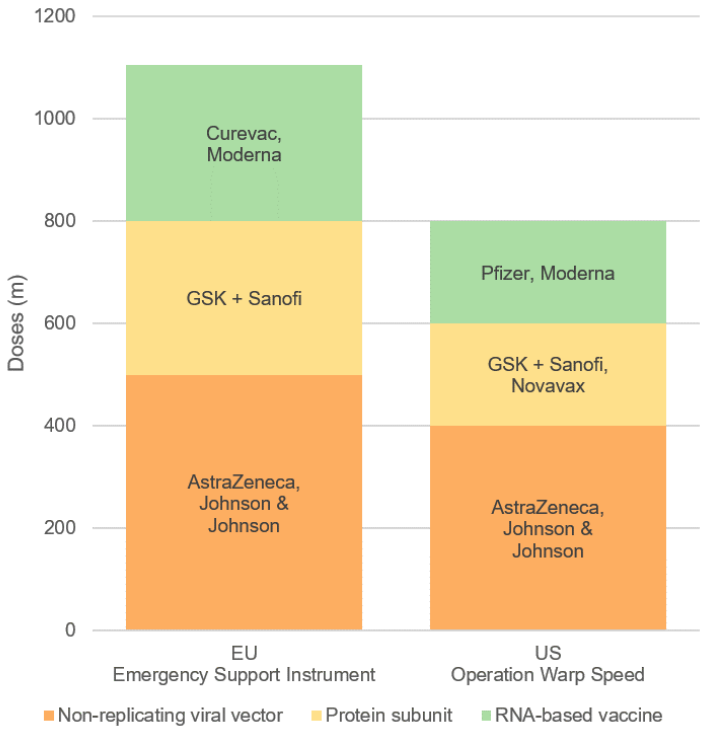
Total number of vaccine doses secured by vaccine type

Looking at the total volume of vaccine doses secured by the US and the EU as of August 31, 2020, broken down by vaccine type, the EU has overtaken the US in terms of the absolute number of doses secured (Figure 4). Both the US and EU hold a diversified portfolio of vaccines in terms of type. Three types currently make up their portfolio: non-replicating viral vector vaccines, protein subunit vaccines and RNA-based vaccines.

Currently, it is unclear which vaccine will elicit the best immune response and provide lasting protection, hence it makes sense for governments to hedge their bets by contracting with companies that employ different vaccine technologies. However, the fact that we see governments holding a portfolio of vaccines is most likely less due to an explicit strategy to support different technology types, and more a consequence of the fact that governments are contracting with front runners in the vaccine

race or traditional top vaccine companies. Several other technologies are under development but have so far not been involved in APAs with the US or EU governments as they are not front runners in the race or are under development by China.

Figure 4: Total number of vaccine doses secured, by vaccine type



Conclusion: Local production ensures vaccine supply security

Both the US and EU governments mainly secure vaccine doses from companies that are already conducting clinical trials and whose contracted production facilities are located in the US or the EU - and not somewhere else entirely, for example in China. This strategy of contracting with manufacturers who commit to produce the vaccine on *home soil* makes sense given the ability of governments to implement export restrictions in a crisis. In theory, a vaccine can either be imported or produced locally. However, experiences during the early days of the Covid-19 pandemic have already shown that when a health crisis hits, relying on imports might be a tricky strategy. Already in March, countries indicated that they would give preference to their own needs, when France and Germany imposed limits on the export of protective medical equipment such as face masks.[11] Furthermore, local production lowers the costs to deploy a vaccine quickly: manufacturing close by minimizes stability issues associated with biological products and reduces cold-chain requirements and logistical issues. Hence,

[11] See report in the New York Times, available online.

the ability of governments to secure sufficient local production capacity is of crucial importance, and indeed we see that this is a key component of both the US and the EU's vaccine deployment strategy.

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