

04 Feb 2021 | News

# Viewpoint: Lessons from Operation Warp Speed can help overcome EU vaccines crisis

*As the problem of COVID-19 vaccines supplies so potently illustrates, it is time to rethink the EU's pandemic preparedness strategy. More support is needed for late stage clinical development and large scale manufacturing*

By [Professor Michel Goldman](#)



Michel Goldman, former executive director of the EU Innovative Medicines Initiative and professor emeritus at the Université Libre de Bruxelles.

Despite European Medicines Agency approval of three COVID-19 vaccines and the hundreds of millions of doses procured through advance purchase agreements negotiated by the European Commission, member states are facing a shortage of vaccine supplies and [falling behind](https://ourworldindata.org/covid-vaccinations) (<https://ourworldindata.org/covid-vaccinations>) Israel, the UK and the US in terms of vaccines coverage.

At this stage of the game, demand is bound to be outstripping demand, but in Europe that problem has been compounded by issues at manufacturing plants of both the Pfizer/BioNTech and AstraZeneca vaccines.

The first reaction of the EU Commission was to try and enforce what it saw as the contractual obligations of AstraZeneca, judging the company should export supplies from the UK, while at the same time taking measures to block COVID-19 vaccine exports from the EU, a move that was seen as threatening UK supplies of the Pfizer/BioNTech vaccine, sourced from a manufacturing facility in Belgium.

These measures are clearly insufficient to remedy the situation – especially since the shortage of AstraZeneca vaccine is due to a problem with scaling up the tricky bioprocess for generating the raw material.

In any case, the EU Commission cannot do much since health policies are the prerogative of member states.

Facing the anger of their citizens, some national governments, which previously supported the idea of the European Commission procuring vaccines for all EU27 countries, are now going their own way.

Hungary was the first EU member to break ranks, unilaterally approving the Sputnik V vaccine developed in Russia.

Surprisingly, Germany followed suit in approving and purchasing anti-SARS-CoV-2 antibodies for passive vaccination. Chancellor Angela Merkel also instructed regulators in the Paul Ehrlich Institute to support Sputnik V's developers in making an application for European Medicines Agency (EMA) marketing approval of the Russian vaccine.

## **Lack of coherence**

The row will go on, but it is already clear that European citizens are paying the price for insufficient support, at both an EU and member state level, for late phase clinical development and commercialisation of innovative vaccines technologies,

as I argue with Philippe Aghion and other colleagues [here \(https://voxeu.org/article/how-strengthen-european-industries-leadership-vaccine-research-and-innovation\)](https://voxeu.org/article/how-strengthen-european-industries-leadership-vaccine-research-and-innovation).

Ugur Sahin, co-founder of German biotech BioNTech, which with US pharma company Pfizer co-developed the first COVID-19 vaccine to be approved by EMA, had grant funding from EU Framework research programmes from 1998 to 2014.

But a lack of coherence between EU and national funding schemes hampers the implementation of an efficient strategy to ensure vaccine discoveries made with the support of EU programmes are translated into large scale industrial development across the EU.

Although vaccine research by Oxford University (where the AstraZeneca vaccine originated), BioNTech and Johnson & Johnson has been supported by the EU, clinical trials and manufacturing of COVID-19 vaccines have not.

Contrast this with Operation Warp Speed, launched in the US at the start of the pandemic with the involvement of several government organisations, including the Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health.

Yes, the success of this US initiative in delivering approved vaccines within the space of a year is partly related to its impressive budget. But it also rests on its super-efficient management under the two-headed leadership of Gustave Perna, a top officer of the US army, and Moncef Slaoui, former head of vaccines research at GlaxoSmithKline, an experienced industrialist with an exceptional track record in vaccine development.

As Slaoui underlined in a [recent interview \(https://www.sciencemag.org/news/2021/01/proud-vaccine-success-warp-speed-s-ex-science-head-talks-politics-presidents-and-future\)](https://www.sciencemag.org/news/2021/01/proud-vaccine-success-warp-speed-s-ex-science-head-talks-politics-presidents-and-future), a key principle of an efficient pandemic preparedness plan is to integrate and coordinate efforts across the value chain from basic research to large-scale manufacturing and distribution, and across public and private sectors. Building of vaccine manufacturing facilities that are on

standby to be mobilised in response to emerging infectious threats is probably the most important element, given – as the example of the AstraZeneca vaccine illustrates - rapid vaccine production at scale is a major challenge.

Whereas Operation Warp Speed received a dedicated budget of \$10 billion, the European Commission committed around €1 billion to COVID-19 research.

It is hard to make a direct comparison between US and EU funding, but the salient fact is that rather than concentrating its firepower, the overall EU budget [was scattered \(https://www.sciencemag.org/news/2021/01/proud-vaccine-success-warp-speed-s-ex-science-head-talks-politics-presidents-and-future\)](https://www.sciencemag.org/news/2021/01/proud-vaccine-success-warp-speed-s-ex-science-head-talks-politics-presidents-and-future) across a number of different instruments including the Horizon 2020 programme, the Coalition for Epidemic Preparedness Innovations, the European and Developing Countries Clinical Trials Partnership, the Innovative Medicines Initiative, the European Innovation Council, the European Institute of Innovation and Technology, the European Investment Bank and the European Structural and Investment Funds.

A more stark comparison is closer to home, with the UK Vaccines Taskforce, which assessed 240 vaccines projects before agreeing advance purchase agreements with seven companies, for vaccines then in the early stages of development. Rather than awarding the contracts and standing back, the taskforce has provided expertise and funding to scale up manufacturing.

The UK has also run a number of phase III vaccines trials, at scale and at pace. The UK phase III trial of US biotech Novavax's COVID-19 vaccine, which reported positive interim results last week, recruited 15,000 people, administering two doses to all the volunteers between September and November 2020.

As these examples illustrate, there is a need to rethink and reboot the EU's pandemic preparedness strategy. As a first move, Ursula von der Leyen has announced the formation of a European Health Emergency Response Authority (HERA), modelled on BARDA.

If the ambition is to emulate BARDA, a big enough budget and a reduction in red

tape, though necessary, will not be sufficient. Building on the lessons learned from the Innovative Medicines Initiative public-private partnership, it will be essential to adapt the legal framework governing EU public-private partnerships and ensure HERA is an autonomous empowered agency with a strong leadership.

It should be able to make long-term commitments and provide the necessary incentives to invest in risky competitive projects. First and foremost, HERA should dedicate sufficient resources to late stage clinical trials of vaccines and therapeutics and the building of manufacturing capacities.

Clearly, the European Union will need to follow a disruptive approach to make HERA fit-for-purpose. The time is now.

*Michel Goldman is former executive director of the EU Innovative Medicines Initiative*

*And professor emeritus at the Université Libre de Bruxelles*

*Brussels, Belgium*

[Health](#)[COVID-19](#)[Coronavirus](#)[Vaccines](#)[R&D policy](#)

*Never miss an update from Science | Business:*

Newsletter sign-up

## Related News

---



## UK seeks views on post-Brexit subsidy regime

04 Feb 2021



## Gabriel announces new panel to advise on ERA shake-up

04 Feb 2021



## EU declares a €4B research war on cancer

04 Feb 2021



## EU auditors to scrutinise Horizon 2020 Widening efforts

04 Feb 2021