

12 A new pharma industrial policy for Europe? Lessons from COVID-19

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1 Introduction¹²³

This chapter draws out lessons for industrial policy in the European Union from the COVID-19 vaccine experience. It reviews the process of development of safe and efficient vaccines and the issue of vaccine procurement.

The emergence of new efficient vaccines in record time has been a great success of public and private international cooperation. However, credit should go to the United States's 'Operation Warp Speed', from which Europe should learn important lessons.

This chapter also discusses how to improve the tradeoff between innovation and affordability, a challenge which is growing with the emergence of new, costly therapies thanks to the progress of science. In particular, opportunities should be taken in relation to the new role of the European Commission as representative of the 27 EU countries in price negotiations with pharmaceutical companies.

2 Vaccine development, authorisation and production¹²⁴

The COVID-19 crisis and the question of vaccine development have been instructive in terms of what needs to improve in the EU. The

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124 This section is partly based on Aghion *et al* (2020).

crisis revealed the weaknesses of the US social system compared to Europe, and the mismanagement of the pandemic by the Trump Administration. Nonetheless, together with Congress, the Trump Administration pursued a determined and aggressive strategy to: (i) ensure US leadership in vaccine R&D, and (ii) secure supplies of future vaccines for US citizens.

Although the European Commission took the lead in negotiating advance purchase agreements with vaccine manufacturers on behalf of the 27 EU countries, and decided to provide loans to European biotechs engaged in vaccine development through the European Investment Bank, it fell short in terms of matching the US effort to incentivise vaccine innovation. This was because of a lower level of financial investment and insufficient coordination of research and innovation funding schemes (reflecting the more decentralised nature of R&D and health policies in Europe).

2.1 General considerations

Considering the race for a successful ‘global product’, a natural question concerns the optimal degree of competition and coordination. For COVID-19 vaccines, we observed an interesting mix of the two: although political authorities in China initially denied the upcoming disaster, Chinese scientists have been very open about their research results. In fact, the first vaccines to be authorised could be developed rapidly because Chinese scientists had published the genetic sequence of the virus as soon as it was deciphered, allowing universities and private firms, large and small, to compete aggressively to be the first in the race for a vaccine, with the help of private, and especially state, funding sources.

From the perspective of world welfare, the cooperation/open science part is obviously good. As for the competition on vaccine development, things are more subtle: on the one hand, more financial effort overall is good since it saves lives and accelerates exit from costly lockdowns. On the other hand, is there a risk of money being ‘wasted’

in funding more than 100 vaccine projects, including advance building of production facilities? As discussed by Bolton and Farrell (1990), in “*times of war*”, speed is essential, and more coordination is preferable to “*fine-tuning for the most efficient option*,” if such an optimal solution comes significantly later. We can, however, safely conclude that speed has not been hampered, given the rush we observed. If anything, the risk to be worried about concerned ‘cutting corners’ in excessively fast approval of vaccines that might not be safe or effective enough. But that risk appears to have been dealt with successfully, since more than 13 billion vaccine doses had been administered worldwide by February 2023, with few adverse side-effects. Authorisation bodies (Food and Drug Administration (FDA) in the US, European Medicines Agency (EMA) in the EU, etc) thus showed they were able to combine speed and safety.

2.2 *The US versus the EU*

As is well-known, the US is a clear leader in biotech innovation (see evidence summarised in Aghion *et al*, 2020). Moreover, it set up an articulated US-centric COVID-19 strategy – Operation Warp Speed (OWS) – which took advantage of the complementarity between developing vaccines and securing advanced supplies. It thereby brought together the two phases of negotiations with private entities, while relying on the combined expertise and financial weight of existing federal instruments, in particular the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA). This gave the US a first-mover advantage.

Congress allocated almost \$10 billion to OWS, of which more than \$6.5 billion was allocated to BARDA and \$3 billion for NIH research. By September 2020, BARDA had distributed more than \$11 billion to more than 40 companies to fund the development of COVID-19 vaccines, diagnostic, therapeutics, rapidly deployable capabilities and others (see Aghion *et al*, 2020).

The EU, instead, pursued a less-coherent strategy overall, and with

fewer financial resources invested directly in candidate vaccines. And while it looked more ‘benevolent’ than the US in terms of vaccine development, pushing for worldwide cooperation, through the Coronavirus Global Response, the Coalition for Epidemic Preparedness Innovations (CEPI) and the ‘ACT-Accelerator’ (see details in Aghion *et al*, 2020), it has been ‘EU-centric’ when trying to secure vaccine supplies for its member states and citizens. This strategy did not exploit sufficiently the complementarity involved in the process, which adds to the problematic complexity of funding sources (European budget, European Investment Bank (EIB), member states, etc).

By September 2020, there were more than 130 candidate vaccines in preclinical evaluation and 30 candidate vaccines in clinical evaluation. Among these 30 candidates, 13 received support from BARDA, CEPI and/or the EU/EIB (see Aghion *et al*, 2020). Among these, three received support from both BARDA and CEPI (University of Oxford, Moderna and Novavax), one received support from both CEPI and the EIB (CureVac), and one received support from BARDA and EIB (BioNTech). In all these cases, BARDA consistently provided higher funding amounts.

It is moreover striking that BARDA spent \$8.69 billion out of its \$10.8 billion on the five vaccines that were approved, as of December 2021, by the FDA and/or EMA (BioNTech-Pfizer, Moderna, AstraZeneca, Johnson and Johnson and Novavax). And obviously the funding did not go only to US companies, since AstraZeneca and BioNTech (which is the company that received BARDA funding, not Pfizer) are European. In fact the remaining \$2.07 billion went to Sanofi, a French company, whose vaccine developed together with GSK received EMA approval in late 2022.

It is also interesting that a very significant chunk of the funding went to biotech companies Moderna and Novavax, and BioNTech. This confirms the importance of smaller firms in health innovation. That said, the success of the BioNTech-Pfizer alliance also shows the value of a close association with a big pharma company for scaling up the downward development and the production phases, even if Moderna’s

performance was quite impressive. And it is striking that, of the ‘big four’ pre-COVID-19 vaccine players – MSD, GSK, Sanofi and Pfizer – only the last emerged as a ‘winner’ of this race, and only thanks to its alliance with BioNTech.

Coming back to OWS, as stressed in 2020 by Moncef Slaoui¹²⁵, who was appointed OWS Chief Scientific Officer, there was a conscious decision to concentrate funding on three different technologies and two projects per technology (or ‘dual sourcing’): BioNTech/Pfizer (Germany/US) and Moderna (US) for the mRNA technology, Johnson and Johnson (US) and Oxford/AstraZeneca (UK/Sweden) for the viral vector technology, and Novavax (US) and Sanofi/GSK (France/UK) for the protein subunit technology.

It is hard not to consider OWS as an overwhelming success of ‘industrial policy’, bringing together, as stressed by Slaoui: (i) significant public money, (ii) competences from the whole ‘ecosystem’: universities, BARDA, NIH, FDA, biotech companies, big pharma, and even the US Army, and (iii) a small unified decision-making structure to speed things up, at arm’s length from politics. Of course, there was quite some luck: the most successful technology, mRNA, was readily available, thanks to years of research efforts (which, as argued by Veugelers (2021) had not benefited before COVID-19 from the support it deserved). And the vaccines turned out to be even more successful than what could have been expected. But still, this episode was a great success, which other jurisdictions should definitely try to learn from.

2.3 For an integrated EU treatment and vaccine development strategy

Europe (especially when adding the United Kingdom and Switzerland to the EU) is strong in health, with its universities, biotech companies, big pharma companies and public money, which is ample although

125 See Jean-François Munster, ‘Moncef Slaoui au «Soir»: «Avec les vaccins, on va pouvoir contrôler cette pandémie», *Le Soir*, 26 December 2020, <https://www.lesoir.be/345671/article/2020-12-26/moncef-slaoui-au-soir-avec-les-vaccins-va-pouvoir-controler-cette-pandemie>.

scattered (the EU being rightly seen as a regulatory giant but a budgetary dwarf). It is coordination that is suboptimal.

Therefore a renewed EU support strategy for the development and commercialisation of innovative technologies is desirable. This could be extended to other areas, for example, defence-related technologies, on the model of the Defense Advanced Research Projects Agency (DARPA) in the US, which, strikingly, has been instrumental also in a number of non-defence innovations. This should not be a renewed industrial policy amounting to ‘picking one winner’. As in the case of COVID-19 vaccines, the BARDA-DARPA model mixes top-down and bottom-up approaches, in which government funds finance competing teams that work on making new technologies operational¹²⁶. Once selected by the government, team leaders have full autonomy in deciding how to organise the research process and who to involve in that process. The various teams will typically compete not only within Europe, but also on a more global scale, with the US but also China. So, this is about competition-friendly industrial policy, as advocated by Aghion *et al* (2015).

Interestingly, by the end of 2020, the European Union had launched HERA, the Health Emergency Response and Preparedness Authority, with explicit reference to BARDA and the US innovation ecosystem. Let us see to what extent it can help in boosting European innovation in healthcare.

Let us end this section with three remarks. First, since speed is often crucial, flexibility has been key to the success of BARDA. This pleads for relaxing typical EU political constraints about *juste retour*, seven-year budgets and (near) unanimity voting rules. Second, BARDA has taken a global view, so funding should not be exclusively restricted to EU entities; in particular, despite Brexit, joining forces with the UK makes particular sense, given its academic and industrial expertise in the area (the same is true for defence). Third, the US success was not limited to BARDA. Pooling more resources at the EU level to create an EU

126 See Veugelers (2021) for a discussion of the various dimensions of this ecosystem.

equivalent of the NIH is worth considering. And the US has been able to use the leverage of the Defense Production Act to request private firm cooperation with OWS (not to mention the help of the US Army). The lessons of this US success are thus wide-ranging.

3 Securing supplies and setting up delivery systems

COVID-19 vaccines provided an opportunity for the European Commission to centralise discussions with vaccine producers in order to obtain sufficient vaccine supplies at an appropriate price.

The Commission was criticised in the first months of 2021 for insisting too much on low prices in their contractual negotiations with vaccine producers, and not enough on speed of delivery, in a world where the opportunity cost of delaying the recovery was huge. This criticism is not unfair, and countries including Israel, the UK and the US did get ahead of the EU in vaccination in the first half of 2021. This was particularly true in the first quarter of 2021. In this respect, while the UK and the US benefited from their close links with, respectively, AstraZeneca and Pfizer and Moderna to accelerate purchases, Israel showed that one does not have to be involved in R&D or production to be the first in terms of purchases: paying a high price is enough (Israel also allowed Pfizer/BioNTech to analyse in detail the impact of vaccination on the Israeli population, thereby contributing to global knowledge). Indeed, Israel seems to have paid between \$47 and (more than) \$100 – respectively around €38 and €81 at the time – for two doses of the Pfizer/BioNTech vaccine¹²⁷, much more than the €24 the EU paid for the same vaccine (the EU also paid less than €4 for two doses of the AstraZeneca vaccine and €36 for two doses of the Moderna vaccine in the original contracts signed by the Commission (these numbers are contractually meant to be secret but were disclosed in a tweet by the Belgian secretary of state for budget).

After the first quarter of 2021, EU vaccination took off and many

127 Stuart Winer, 'Israel has spent \$788m on vaccines, could double sum — Health Ministry', *Times of Israel*, 16 March 2021, <https://www.timesofisrael.com/israel-has-spent-788m-on-vaccines-could-double-that-in-future-health-ministry/>.

western EU countries overtook the US, the UK and Israel in vaccination rates. And the Commission intervention favoured equal treatment between member states, while earlier a group of four countries (France, Italy, Germany and the Netherlands) had decided to join forces and bargain only for themselves. Thanks to the Commission, everyone agreed ultimately to go for centralised EU-wide bargaining.

As discussed by Dewatripont (2022), vaccination rates went up with little variance across most EU countries in the first months of 2021. Until May 2021, only Bulgaria was significantly slower than the other EU countries. During the course of May and June, some other eastern EU countries, including Romania, Slovakia, Poland and Czechia, also started to lag the rest of the pack. Other EU countries stayed close together until June, when divergence started to grow. But by this time, vaccine hesitancy had become the key constraint, not vaccine availability or logistical challenges. Joint European purchases therefore ensured equity between EU member states, a success which explains why HERA was subsequently tasked to buy monkeypox vaccines for most EU countries.

4 Insufficient public leverage on the innovation/affordability tradeoff of new drugs

The COVID-19 vaccine experience also offers lessons on this innovation/affordability tradeoff.

4.1 Excessive prices?

While the European Commission was criticised in the first half of 2021 for insisting excessively on low COVID-19 vaccine prices (instead of speed of delivery), containing prices of booster shots and improved COVID-19 vaccines could be a concern in the future. In this respect, the words of Frank D'Amelio, the Chief Financial Officer of Pfizer were not very reassuring: "In short, D'Amelio explained that Pfizer expects its COVID vaccine margins to improve. Under one pandemic supply deal, Pfizer is charging the US \$19.50 per dose, D'Amelio said, which is

‘not a normal price like we typically get for a vaccine—\$150, \$175 per dose. So, pandemic pricing’¹²⁸.

This should remind authorities of the need to avoid rents above competitive rates of returns for vaccines and treatments. The question of high prices has become an even bigger issue at a time when accelerating scientific progress opens up new opportunities, for example with gene therapies (and mRNA could provide another boost to this trend), which is both very promising and challenging. For example, Fischer *et al* (2019, 2022) reported several cases of treatments approved by the FDA and/or EMA since 2018 costing between \$373,000 and \$2,100,000 per patient, for diseases affecting 1000 to more than 10,000 patients in Europe and the US. Since this increasing trend is going to persist, it is important to find ways to keep public health budgets under control, while ensuring that useful innovation can flourish.

In its official strategy documents, the European Commission (2021) has recognised this challenge, and has therefore stressed the need to ensure access to affordable medicines for patients, and to address unmet medical needs, in the areas of antimicrobial resistance and rare diseases in particular. In this respect, the Commission has stressed four strands of policy: (i) enhancing competition; (ii) working with national authorities to exchange information on sustainable health systems, pricing, cost-effectiveness, payment, procurement policies and affordability; (iii) enhancing transparency through guidelines on how to calculate the R&D costs of medicines; and (iv) using the annual European Semester cycle of economic policy coordination to assess national health systems and issue country-specific recommendations to ensure their accessibility, efficiency and sustainability.

While these are useful avenues, more could be done. Of course, while Pfizer, BioNTech and Moderna have been making good money,

128 Eric Sagonowsky, ‘Pfizer eyes higher prices for COVID-19 vaccine after the pandemic wanes: exec, analyst’, *Fierce Pharma*, 23 February 2021, <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst>.

typical discussions about innovation in pharma in general pit critics of high prices and returns against industry advocates who stress the cost and risk of innovation. Obviously, economists would naturally assume that inducing private R&D to take place, especially in the *ex-ante* less 'attractive' areas of 'neglected' diseases (rare diseases, several infectious diseases, complex diseases like Alzheimer's, where industry is seen to be not active enough), requires the researcher/innovator to anticipate the (discounted) net benefit $(B - C)$ of innovation to exceed $(B - C)^*$, the net benefit of other potential uses of the innovator's resources. Policy can act in particular on the gross benefit B (which is the result of price negotiations with funders after authorisation) and also on the cost C ¹²⁹.

On the other hand, there is no reason, for either $(B - C)$ or $(B - C)^*$, to be above competitive returns. However, evidence indicates that, while biotech firms earn on average a $(B - C)$ that is higher than (risk-adjusted) market-consistent rates of return (having in fact a higher risk more than compensating their *ex-post* high return), big pharmaceutical companies have for decades earned annual risk-adjusted rates of return that are 3 percent in excess of the market (see Thakor, 2015).

This is partly linked to the lobbying power of big pharma companies, especially in the US, where prices have been high since George W. Bush convinced Congress to prevent Medicare from negotiating drug prices (see Danzon, 2018). This adds to the problem of generally weak competition today, which has led big firms to earn high returns,

129 Note that neglected diseases have a number of specificities as far as this inequality is concerned: (i) B will typically be low when the potential market is small, either in terms of number of cases (eg rare diseases), or of low 'ability to pay' (diseases affecting poor countries); (ii) on the other hand, since low patient numbers reduce the threat to public budgets, higher prices per patient can at times be obtained, which raises B ; (iii) as for C , it can be higher when the disease is complex (eg Alzheimer's); (iv) on the other hand, some neglected diseases can benefit from a fair amount of public funding, which lowers C , and finally (v) authorisation on the basis of lower sample sizes for randomised controlled trials, typical for rare diseases, lowers C again.

even leading to adverse macroeconomic consequences (see, for example, the discussion in Aghion *et al*, 2021). In this respect, one should reiterate that industrial policy should be competition-friendly, as stressed by Aghion *et al* (2015) and as successfully managed by OWS.

Moreover, not only is the equilibrium (B – C) 3 percent per year too high, but evidence points to an authorisation bias against ‘truly creative’ innovation through an excessive reward of ‘marginal’ innovation.¹³⁰ Fojo *et al* (2014) looked at US evidence on cancer therapies and stressed the unintended consequences of expensive marginal therapies that earn higher risk-adjusted returns than more innovative ones, and are unsurprisingly pursued by for-profit pharma companies. This indicates a flaw in the authorisation/pricing process for new therapies, since by making marginal innovation more lucrative, one raises the opportunity cost (B – C)* of engaging in truly innovative research. Industrial policy should try and address this problem.

4.2 Improving the innovation/affordability tradeoff

Unsurprisingly, the COVID-19 vaccine experience has generated debates about the distribution of the rewards of innovation between private companies and the public sector.

4.2.1 Improving bargaining positions

In fact, the emergence of the European Commission as a negotiator on behalf of the 27 EU countries echoes efforts by groups of EU countries to join forces in price negotiations with drug companies. Belgium, the Netherlands, Austria, Ireland and Luxembourg were the first such group¹³⁰. Other initiatives are the Valletta group of southern European countries, the Nordic pharmaceuticals forum and the Visegrad group¹³¹.

130 See <https://beneluxa.org/>.

131 Francesca Bruce, ‘Europe’s Biggest Multi-Country Access Alliance Picks Up The Pace’, *Pink Sheet*, 28 July 2021, <https://pink.pharmaintelligence.informa.com/PS144710/Europes-Biggest-Multi-Country-Access-Alliance-Picks-Up-The-Pace>.

The goal of such initiatives is to put these countries in a better position to require more transparency about R&D, manufacturing and distribution costs of the drug.

Truly meaningful impact would however require further coordination. The COVID-19 vaccine episode should provide an opportunity to go more generally towards EU-wide coordination of negotiations with pharma companies, to limit their ability to put states in competition. Kyle (2007) showed in particular that new drugs are introduced earlier in jurisdictions that pay higher prices, which is in line with the priority given to Israel by Pfizer. One should therefore not draw the wrong lessons from the European COVID-19 negotiation: it should constitute a precedent worth building on in order to improve the bargaining power of European member states with pharma companies.

Rare diseases would be a natural area for EU-wide intervention. One objective reason for high prices is of course the limited market size of each country. A pan-EU purchase would offer the prospect of higher sales, thereby making lower prices more sustainable for industry. One could even envisage advance market commitments, like with vaccines (Levin *et al*, 2021), which should ideally be coupled with a percentage of profits to be refunded by the company in case these turn out to be higher than expected.

EU-wide coordination of the organisation of statistically significant clinical trials, which does represent a key challenge for rare diseases, would also make sense. And the same is true for the necessary coordination of national research and development funding beyond EU R&D funding, along the lines of NIH funding, in order to maximise synergies, especially for rare diseases.

Finally, COVID-19 vaccines are an extreme example of the asymmetric timing of the financial costs and benefits of health innovation. Early stages of the process are heavily subsidized – in this case not only R&D but even production – but price negotiations, and especially renegotiations, happen later on and risk insufficiently rewarding earlier subsidies through subsequent price discounts in the case of

successful innovation. Public authorities should make their early support conditional on profit-sharing schemes in order to benefit from the upside of innovation.

4.2.2 Governance

Current healthcare innovation typically works as follows: its later stages are implemented by the private sector, often big pharmaceutical companies, which buy biotech firms, which are themselves built on publicly-funded research (universities, the NIH and BARDA in the US, etc). While this sequence is natural, achieving a fair distribution of the rewards of innovation is difficult in a system of large for-profit providers of new vaccines and therapies. The profit motive is a powerful driver with high rent-extraction costs, and economics has documented how information asymmetries and residual rights of control do allow producers to earn rents. One idea to limit these rents could be the introduction of common-good advocates on the boards of pharma companies. Another could be to transform (part of) them into 'benefit corporations', as advocated by Fischer *et al* (2019), so that shareholder value would stop being their overriding objective (an objective resulting from their legal charter and, since the 1980s, aggressively put into practice).

Change could be enacted by leveraging companies' corporate social responsibility. Concretely, payers could for example incentivise companies involved in expensive therapies to create *ad-hoc* subsidiaries for these activities and organise them according to the benefit corporation concept (Cummings, 2012) in order to subsequently obtain a B Corporation certification¹³². The benefit corporation declaration gives legal protection to companies to pursue social and environmental performance alongside value for shareholders. The boards of benefit corporations are required in their decision-making to consider other stakeholders in addition to shareholders. The application for B corporation certification further enhances accountability to social good, as the

132 See <https://bcorporation.net/>.

certification is done by an external third-party based on the company's verified performance on the B impact assessment, making the benefit corporation a certified B corporation.

By acquiring the status of certified B corporation, companies should be able to leverage the social impact of their pricing in their performance indicators, thus affording them the opportunity to bring their pricing down to a market-consistent level, in order to enhance their social performance.

Pushback is to be expected. But corporations themselves are increasingly recognising the need to generate long-term value for all stakeholders, instead of solely shareholders, and to shift their priorities from profit maximisation to optimising value creation, as demonstrated by the Business Roundtable 2019 Statement on the Purpose of a Corporation (Business Roundtable, 2019), to which several pharmaceutical companies are signatories. The next step would be for payers to consider making reimbursement of some therapies conditional on their commercialisation by certified B corporations. The greater objective should be a pricing policy that results from a credible alignment of the interests of industry, patients and payers.

5 Conclusion

This pandemic has been unique in its magnitude and should lead to a rethink of a number of features of the institutional system. In particular, the US OWS success should call for a strengthening of the EU biotech innovation system, not only through a BARDA-like HERA, but also through a better-coordinated EU health research budget similar to the NIH. More EU coordination on purchases is also desirable given the experience the European Commission has acquired in its contractual negotiations with vaccine producers. The objective should be to improve the terms of the innovation/affordability tradeoff. Given the magnitude of public funds poured into health innovation systems, society at large could obtain a larger share of successful innovation returns, without driving private players away from the market.

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