





By Alexander Conway | February 2023



Introduction

The debate about industrial policy has risen to the top of the EU and the global agenda since the Russian invasion of Ukraine, which compounded the supply-chain shocks caused by COVID-19 and further exacerbated an increasingly tense and politicised global relations and trade. US-China tensions and protectionist tendencies across the world have prompted the need to identify, mitigate, and counter geopolitically motivated disruptions to critical trade links and value-chains, and for industry and government to work with one another to manage these changes and risks.

This paper will outline two broad trends which are impacting on the pharmaceutical industry both globally as well as within the Single Market and Ireland: a shift in the ethos of European health policy and a focus on strategic autonomy. It concludes with an assessment of the reframing of the concept of industrial policy in response to pressing challenges to the global competitiveness of European industry.

Shifts in European Health Policy Ethos from Efficiency to Security

A broad trend for European health sector regulation has been the COVID-19 pandemic which marked both a conceptual shift in how health was conceived of within the EU, and around the globe, as well as an institutional shift within the Union. One observable trend in the broad re-conceptualisation of the traditional market model for healthcare products and services is the switch from the previous emphasis on improving efficiency in terms of delivery, costs, and production to an emphasis on health as a critical public good whose potential supply can be disrupted in a globalised interconnected world. In the new approach, a premium is placed upon ensuring the security of supply, rather than the efficiency of delivery. This shift is perhaps best understood as a corrective response to a market failure in ensuring the supply of health goods for the Single Market and falls under the ambit of strategic autonomy as outlined by French President Macron's vision of a "Europe which protects" in response to meeting citizen demand.¹

A related development is the rebalancing of competency for health policy within the EU in favour of the European Commission rather than Member States. The establishment of Health Emergency Preparedness and Response Authority (HERA)² in September 2021 as a Directorate-General within the European Commission firmly centres authority and competence to coordinate Member States' health preparedness and crisis response measures under the remit of the Commission, although there is a legal exemption for the harmonisation of national health policies.³ While Member States do retain a degree of influence over HERA as participants in both its Board and the Advisory Forum, the ultimate budget and operation of HERA is in the Commission's gift, and the centripetal tendency of HERA is to de facto coordination of EU health policies. A knock-on implication of this development in the wake of the COVID-19 pandemic and public demand for greater intervention in the health sector is perceived by some as the increasing demonstrable influence of the European Commission philosophy embodied in the "precautionary principle", which privileges preventative actions to pre-empt crises, rather

1 <u>'There is an unprecedented crisis because of the war. The answer is a powerful Europe' | International | EL PAÍS En-</u> glish Edition (elpais.com), L'Europe qui protège : "Cela ne se fera jamais." Vraiment ? | Élysée (elysee.fr)

2 <u>The EU's Open Strategic Autonomy in the Field of Pharmaceuticals - Overcoming import dependencies for antibiotics</u> <u>through the EU authority HERA (swp-berlin.org)</u>

3 Art. 168 (5) TFEU - EUR-Lex - 12008E168 - EN - EUR-Lex (europa.eu)



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than reactive responses.⁴ This underscores the institutional development away from the previous dominance of a more "reactive" approach and brings a more "proactive" strand to equal prominence. HERA has two strategic strands, one which is based on preparedness and focuses R&D to develop new medical measures to counter pandemics, equipment, and chemical antidotes to emerging pandemics and a second which is an emergency response capacity. The latter envisages the activation of swift emergency response for the monitoring, procurement and purchase of raw materials and medical countermeasures.

European Strategic Autonomy

The EU goal of securing its strategic autonomy for critical goods and materials is particularly relevant for strategically significant pharmaceutical products and raw materials.⁵ COVID-19 and US-China tensions have highlighted the vulnerability of supply-chains for key therapeutics and medical devices, as the trade in certain products was instrumentalised for geopolitical goals, and triggered a call in 2021 to identify and eliminate risks for the supply of European healthcare goods though a so-called "systemic" industrial policy for fundamental medicines.⁶ The improvement of the resilience of EU pharmaceutical supply and production is at the core of the EU's Pharmaceutical Strategy across the entirety of pharmaceutical supply- and value-chains.⁷ It emphasises mitigating dependencies, improving competitiveness, and opening up further scope for public-private partnerships and the prospect of increased public intervention. This could prove to be a boon in terms of greater investment in the sector, both in new production and redundancy capacities. However, it could present potential risks which could constrain actors in this sector by including potentially onerous public procurement regulations or possible export restrictions to certain markets or firms.

At the core of this EU goal of "open strategic autonomy"⁸ lies a fundamental tension. On the one hand, strategic autonomy is conceived of as ensuring that the Union can act independently of other actors to secure its own interests, while simultaneously ensuring that free and fair global trade is not unduly disrupted or rendered uncompetitive. The consequent challenge for the EU and its Member States is how best to balance security of supply while maintaining the economic competitiveness of European pharmaceutical and medtech firms is an increasingly contested international environment.

Disrupting the Single Market Level-Playing Field?

These developments could distort the level-playing field established by the Single Market. Increased public economic intervention into strategic industries and sectors, through state aid and subsidy programmes, as well as policies to counter economic coercion, dumping, and unfair practices all have an impact. This marks a shift away from "invisible" market-led economic policies towards "visible" ones where public authorities intervene to support certain firms or sectors, such as healthcare or pharmaceuticals in order to manage trade and secure strategic concerns.⁹ As this scenario could create distortions within the Single Market, several measures have been proposed to counter this:

⁴ Art 191 TFEU - EUR-Lex - 12016E191 - EN - EUR-Lex (europa.eu)

^{5 &}lt;u>The EU's Open Strategic Autonomy in the Field of Pharmaceuticals - Overcoming import dependencies for antibiotics</u> <u>through the EU authority HERA (swp-berlin.org)</u>

⁶ EU draws up plans to stockpile scarce medicines | Financial Times (ft.com)

^{7 &}lt;u>A pharmaceutical strategy for Europe (europa.eu)</u>

⁸ Communication on the Trade Policy Review (europa.eu)

⁹ Free Trade Is Dead. Risky 'Managed Trade' Is Here. (foreignpolicy.com)



- One is the prospect of a common financing vehicle or "European Sovereignty Fund", possibly delivered via the European investment Bank (EIB), to reinforce the EU's industrial capacity.¹⁰ As first outlined in President von der Leyen's 2022 State of the Union address,¹¹ this would aim to reinforce the economic resources needed for research, innovation, and strategic projects at the EU level for industrial policies. This proposal will be further explored in the European Commission's mid-term review of the Multiannual Financial Framework (MMF) budget, ahead of negotiations for the next seven-year tranche which will begin under Ireland's Council of the EU Presidency tenure in 2026.
- Other measures include Important Projects of Common European Interest (IPCEIs) which may facilitate investment into cross-border innovation, research, and infrastructure projects within the Single Market.¹² Ireland's application to participate in an Important Project of Common European Interest (IPCEI) on Health¹³ is of particular relevance for facilitating the levels of investment necessary for developing advanced pharmaceutical R&D and innovation capacities within Ireland.¹⁴

The measures mooted above to achieve these goals essentially amount to an EU-wide regime of effective state aid supports for critical or strategically sensitive industries and could pose potential challenges for smaller EU Member States like Ireland. However, given the presence of critical industries like the pharmaceutical and semiconductor sectors, Ireland could also potentially stand to benefit significantly from European-level strategic investment programmes such as the proposed European Sovereignty Fund. This situation begs the question as to how to best preserve economic competitiveness while ensuring that EU and Irish firms are not left-behind in a state-aid race-to-the-top and that the supply of critical goods and materials continue to flow. One notable development is that the retreat of globalisation has recontextualised the importance of geography for countries like Ireland on the periphery of Europe, due to the potential costs of global protectionist measures, like the US Inflation Reduction Act (IRA)¹⁵ for an economy so closely intertwined with the US and UK, particularly in the pharmaceutical sector.

Considering that the Stability and Growth Pact (SGP) debt and deficit rules have been effectively suspended since the onset of the COVID-19 pandemic, what would the de facto return of state aid in Europe mean for smaller Member States unable to match the fiscal firepower of larger countries? For example, France and Germany together account for 77% of national state aid across the EU since the temporary suspension of SGP frameworks,¹⁶ and this will have considerable long-term legacy impacts for their competitiveness within the Single Market.

EU leaders are addressing the fact that the former economic model is no longer a guarantee of the

10 Going big for EU industry - POLITICO

12 EUR-Lex - 52021XC1230(02) - EN - EUR-Lex (europa.eu)

¹¹ State of the Union Address by President von der Leyen (europa.eu)

¹³ Launch of an IPCEI on Health Announced During the Ministerial Conference 'Towards an Independent, Competitive and Innovative European Healthcare Sector' - French Presidency of the Council of the European Union 2022 (europa. <u>eu)</u>

^{14 &}lt;u>health-ipcei-call-scope-and-criteria.pdf (enterprise.gov.ie)</u>

¹⁵ https://www.govinfo.gov/content/pkg/PLAW-117publ169/uslm/PLAW-117publ169.xml

^{16 &}lt;u>Letter_EVP_Vestager_to_Ministers_Economic_and_Financial_Affairs_Council__Competitiveness_Council_aressv398731.pdf (politico.eu)</u>



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Union's future prosperity. In the post COVID-19 context, the European health industry landscape will be defined by US-China trade competition tensions and the broader philosophy of greater strategic autonomy in the EU. This suggests that critical industries like the pharmaceutical sector face significant challenges as the EU strikes a strategic balance in the trade-offs between external openness and internal autonomy.

Speaking at the 2023 World Economic Forum (WEF) in Davos, Commission President von der Leyen attempted to walk a fine line between assuring industry leaders that they would receive subsidised support, while assuaging concerns that the Single Market was becoming protectionist by emphasising the EU's "ambitious" pursuit of free trade agreements with Mexico, Chile, New Zealand, Australia, India, and Indonesia. These agreements are crucial both in securing access for critical inputs, like APIs, (active pharmaceutical ingredients), for the pharmaceutical sector, and the rare earths minerals and raw materials needed for the green transition, as well as facilitating broader trading relations with rising dynamic economies.

Defining a New Industrial Policy

The announcement at Davos by Commission President von der Leyen of a forthcoming EU Net-Zero Industry Act encapsulates the balancing act between openness and autonomy, in an attempt to retain the EU's industrial clout in the face of US and Chinese competition, while meeting climate targets. It has three main elements. A temporary loosening of direct state aid rules, simplified tax-break models for firms, and an accelerated implementation process for indirect subsidies and supports.¹⁷

The proposal is a direct riposte to Chinese and US measures. On the one hand, American legislation like the Inflation Reduction Act (IRA), (a US\$369bn green industrial subsidy package combined with low domestic energy costs and lenient regulation), and on the other, allegations of unfair Chinese state subsidies, industrial espionage, and economic coercion, pose a challenge to the Single Market's economic model. Furthermore, von der Leyen's ambition of a more cooperative approach to industrial policy, working together in concert with the United States to jointly address challenges rather than compete with one another, faces significant obstacles. It is not prima facie a given that respective EU and US monies earmarked for green industry subsidies would complement one another, nor that the question of attracting and retaining industrial production is a non-zero-sum game where both sides can benefit and retain facilities. A related concern is whether non-US firms would benefit equally from IRA support, or would they be relatively disadvantaged.

There is also divergence within the EU itself between those who see such measures as protectionist and anti-free trade, like Belgium, Sweden, and Germany, and the Netherlands warn that economic competitiveness cannot be based on permanent state aid which may fracture the Single Market.¹⁸ In this context Sweden, as the current President of the Council of the European Union, is expected to devote considerable attention to the issue of economic competitiveness while maintaining its role as an honest broker in the Council. In contrast, others in France, Italy, and Spain support greater state intervention, underscoring that what is needed is long-term coherent investment in critical strategic industries lest the EU be outpaced and left behind.¹⁹ In addition, there is concern that loosened state aid rules will disproportionately benefit bigger Member States with deeper pockets, like France and

¹⁷ Davos 2023: EU to counter U.S. climate game changer with own green deal | Reuters

^{18 &}lt;u>Vestager proposes 'urgent' state aid reforms to keep business in EU – POLITICO</u>

^{19 30} Years of the EU Single Market: A Referee for Fair Competition and a Coach for Economic Growth | LinkedIn



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Germany, leaving those smaller, less well-resourced Member States like Ireland effectively unable to compete.²⁰ However, the development of an instrument at EU level to address these disproportionate resources, such as the proposed European Sovereignty Fund could be seen as analogous to Cohesion Funding in terms of reinforcing the industrial base of the Single Market while limiting disruptions to the level-playing field of the Single Market.

Conclusion

Industrial policy is firmly back on the political agenda, and it is imperative that these new industrial policies are distinct from those of the past.²¹ A "systemic" industrial policy as proposed by Commission President, von der Leyen, envisages a horizontal strategy which would shift the structure of a fossil-fuel based, globalised just-in-time model towards one which meets the needs of a new economic era and support social and environmental goals and sustainable growth. Critical sectors like the health industry and pharmaceutical sector are emblematic of this shift, given their strategic value, complex and brittle supply-chains, and the capital intensity needed to sustain operations. By including competitiveness and sustainability in the definition of industrial policy, the EU could create a model which might defuse current disputes about whether EU industrial policy measures should be temporary or permanent.

Maintaining the resilience of the Single Market now relies on open strategic autonomy through diversifying international partnerships, creating industrial alliances, and reviewing strategic dependencies in sensitive sectors such as pharmaceuticals, where the EU is highly dependent on foreign suppliers. The challenge remains for governments and companies to ensure that industrial policy measures strengthen the EU's competitiveness in order to protect European interests at home while promoting them abroad.

^{20 &}lt;u>Brussels Playbook: Postcard from Thessaloniki – Czech election – Weber's euros – POLITICO</u> 21 <u>Industrial Policy for a Sustainable Growth Path (repec.org)</u>

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