WHAT DOES THE FUTURE HOLD FOR EUROPE'S PHARMACEUTICAL INDUSTRY?

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Since his speech at the Sorbonne in September 2017, during which President Macron voiced his clear position on European sovereignty, France has played the card of European health over the long term, drawing on some of its own success stories including its national plans for rare diseases and cancer. And given the current health and economic crisis, affirming a policy of sovereignty and investment at European level will help to consolidate the progress of the National Recovery and Innovation 2030 plans.

This is a determining moment for the health industries in general, and for Europe's competitiveness and attractiveness in a context of global competition. The pharmaceutical industry has become a strategic sector for Europe and for European sovereignty, as reconfirmed in the speech given by the President of the French Republic on 10 December. For the EU's health industries, which generate 260,000 jobs and over 35 billion euros in R&D investment, this will translate into growth and innovation.

THE FPEU[1] IS BEGINNING AT A UNIQUE MOMENT, AFTER ALMOST TWO YEARS OF COVID CRISIS

Freed, due to the crisis, of a binding framework, the Member States have engaged in cooperations and practical approaches that must continue. It was France that led the four-country alliance between France, Germany, Italy and the Netherlands to initiate the EU-wide vaccine procurement strategy from June 2020, before DG Health took up the reins. The Union has also stepped up its transformation, with for example the EU4Health programme, an ambitious ▶

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▶ EU response to Covid-19 aimed at making strategic investments to complement the policies of EU countries. Finally, the course of the crisis has shown the importance of relations **between politicians and industry** for increasing the long-term resilience of health systems.

In this respect, and as we have seen during the crisis, **France has resolutely pushed ahead with and for Europe,** as a frame of reference for structural decisions and with a certain pragmatism. From an industrial perspective, the French recovery has helped increase production capacity for health products, and even encouraged relocation to Europe, with for example the symbolic case of paracetamol.

This pragmatism and sense of rapid action must continue under the FPEU. A lot will boil down to rapid execution. As Europe builds its Health Union, in a context of increasing global competition, what can France do to **align health policies with those of technological, industrial and health sovereignty?**

The action taken by France is a step in the right direction, it is helping to **strengthen European cooperation** in terms of preparing for and managing cross-border health crises. The ambitious and pragmatic American BARDA[2] must serve as a model to be transposed into European values, a benchmark for developing simple tools. HERA[3] should be able to set clear priorities for guiding research programmes and investments, while envisaging how pharmaceutical companies and public authorities might **co-finance and anticipate** the discovery and manufacture of treatments and vaccines. The EU FAB initiative, which is the "industrial arm" of HERA, will mobilise investment for emergency and backup production capacity. This will work if the amounts set aside are ambitious and the investment conditions clearly defined.

Still from an industrial perspective, IPCEI Health (Important Project of Common European Interest in the field of health) will be decisive in creating possible incentives in each Member State. France, through its Ministry of Industry, was able to move quickly with its launch of an IPCEI Health. And it was at the instigation of France that Ursula von der Leyen as President of the European Commission, Chancellor A. Merkel and President Macron announced this IPCEI in May 2021. The mobilisation of the other Member States will prove essential for rapid reporting in the first weeks of the FPEU given the international competition, and a European model will quickly become necessary to attract and boost investment in the research and development of medical technologies, such as mRNA, bioproduction and digital technologies, and to encourage their development in Europe.

Health sovereignty will go hand in hand with that of data and digital solutions, crucial for tomorrow's medical challenges and technologies. Faced with the temptation to turn to the USA or China for solutions, Europe must give research teams – including clinical teams, start-ups and manufacturers, professionals and health systems – the means to safely deploy and use health data. Real World Evidence (RWE) studies will provide new knowledge on the use of treatments beyond evaluation periods.

The main challenges involve storage on European servers, interoperability and the harmonisation of legislation within Europe. The European market must be less fragmented ▶

when it comes to using data – the work undertaken by the European Commission on the future European Health Data Space (EHDS) will prove crucial in this respect. France can develop a digital sovereignty strategy, building on the experience of its Health Data Hub (HDH), which supports the development of Real World Data (RWD) by providing centralised access to public health data.

In addition, the Pharmaceutical Strategy for Europe, currently under review, addresses the issues of i**nnovation and access** with the revision of the legislation on orphan and paediatric medicines, **the issue of availability** of medicines and health products "for all patients in the European Union", and that of **better European coordination.**

How can we meet these requirements while accelerating the discovery and production of treatments within the internal market?

To cope with the challenge of tackling **drug shortages,** Europe must introduce several measures, including the introduction of EU packaging, a digital leaflet and better mapping of raw material producers. This will require effective coordination between Member States to secure the essential drugs needed today and for treating patients tomorrow.

In terms of **managing rare diseases, incentives for innovation and support for paediatric research,** France has pushed to reopen the legislation but has lacked clarity on its objectives, even though the regulation has had the expected effects: pooling of knowledge, more targeted public research funding, and setting up of innovative policies and systems such as registries and incentives for investment for developing cutting-edge therapies. France has a legitimate interest in pushing courageously for a revision that will safeguard the effectiveness of this regulation. Europe must accelerate and harmonise assessments to **increase access to innovative medicines** for all patients in the EU, rather than rely on restrictive criteria and launch obligations which, in any case, go against the different public health needs and medical practices of the Member States.

The health of European citizens holds a central place in the construction of Europe and in the EU's response to the crisis, which has demonstrated that dramatic and rapid progress is possible if there is political momentum and ambition. Similar ambition is now expected from the FPEU, to continue, among other things, the construction of the Health Union. Rapid reporting under the IPCEI and speedier action to create an ambitious and rapidly operational HERA will fuel the movement already underway in favour of greater health and industrial sovereignty, and will further increase EU competitivity allowing it to rapidly develop the most promising technologies and the treatments of tomorrow. ■

(1) FPEU: French Presidency of the European Union
(2) The Biomedical Advanced Research and Development Authority (BARDA) provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies such as chemical, biological, radiological and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza (PI) and emerging infectious diseases (EID).
(3) European Health Emergency Preparedness and Response Authority.