

French Presidency of the Council of the European Union: Leem calls for a Europe-wide health policy that protects, guides and acts

The French President has set out the details of France's ambitions and roadmap for the country's six-month Presidency of the Council of the European Union. The Pharmaceutical Companies of France have taken this opportunity to stress the urgency of learning lessons from the health crisis and setting Europe on an ambitious course for healthcare.

While the French President asserted his ambition for a *"more sovereign, more united and more democratic"* Europe at a press conference yesterday evening, Leem is keen to draw attention to the health challenges that characterise our continent today.

"The French Presidency of the Council of the European Union comes at a key moment for learning the lessons of the health crisis which has been impacting people and national economies around the world for almost two years now", says Leem Chairman Frédéric Collet.

Learning lessons from the health crisis

The Covid-19 pandemic has revealed a number of weaknesses in the ability of Europe to respond to a health crisis of this magnitude, and to ensure the extent of coordination and evidence-based decision-making essential at all levels to address the pandemic and its consequences effectively. Key lessons to be learned from the pandemic:

- The importance of keeping borders open to ensure the continued supply of essential pharmaceutical products to the patients who need them most
- The need for reliable data on the actual level of demand for pharmaceutical products as the basis for effective planning and management of manufacturing and the supply chain
- The need for shared guidelines intended to ensure the continuity of clinical trials during the pandemic
- The need for effective preparedness mechanisms to combat emerging infectious diseases

On all these points, Leem, which represents pharmaceutical companies operating in France, assures the French government and the institutions of the European Union of the support of the industry, which employs more than 620,000 people across the EU, including around 100,000 in France.

The priorities and challenges for a European Health Union

Given the level of demand for healthcare, and the heightened global competition that now exists around innovation and manufacturing, the next few months must see the emergence of a European health industry model that protects its people, provides guidance and takes action.

- **A Europe that protects:** Pharmaceutical companies have welcomed the proposals brought forward by the European Commission to strengthen the ability of Europe to prepare effectively for, and respond effectively to, public health threats by extending the roles of the EMA and ECD, and creating a European Health Emergency Preparedness & Response Authority (HERA) tasked with addressing these and other weaknesses. However, pharmaceutical companies are also focused particularly on specific aspects of the way in which solutions proposed by the Commission are implemented, to prevent the risk of them being counter-productive, at the same time as guaranteeing the effectiveness of a system in which these companies play a major role.

“A Europe that protects is a Europe that extends the power of its institutions in matters of health in general, and pharmaceuticals in particular, especially during health crises. France must support extending the role of a stronger and more united Europe; a Europe that really supports its health industry to become a world leader in innovation. Doing so requires closer harmonisation between the health policies of Member States, without compromising their sovereign powers”, analyses the Leem Chairman.

- **A Europe that guides:** More than at any previous time, France must step up its leadership in terms of understanding the challenges involved in upgrading the manufacturing capacity of a Europe-wide health industry. It is important that this strategy becomes integral to the ongoing work of the Commission on developing a strategic roadmap for the pharmaceutical industry under the dual leadership of France and Germany.

In this context, France occupies an important position on two issues: the first is combating discontinuities in supply, which can only be achieved effectively within the framework of inclusive European debate; the second relates to the policies around reshoring, which must be designed at continental level, rather than strictly national levels. If they are not, then the European offer will lose all coherence, with manufacturing being randomly distributed around Europe.

“The implementation of a shared manufacturing policy for products in no way challenges the globalisation of production, which is the only way we have of responding effectively to the explosion in global demand”, continues Frédéric Collet. “Which is why France must press for the rollout of a pharmaceutical manufacturing roadmap by the European Commission. This roadmap would allow Europe to assert the strategic importance of the pharmaceutical industry in Europe, and promote better and faster patient access to pharmaceutical products.

- **A Europe that acts:** Maintaining a regulatory, scientific and economic environment that favours and encourages the development of pharmaceutical products is imperative if we are to meet the public health challenges of the future. Any weakening in the regulation of pharmaceutical products could deprive Europe of an essential innovation research and development resource that benefits patients, at the same time as compromising the competitiveness of its pharmaceutical industry.

Against a background of intensifying international competition, Leem requests the French authorities to pay particularly close attention to the following three issues:

- The reopening of the European pharmaceutical regulation by the Commission, which must not have the effect of weakening European research and development capabilities.
- The revision of the paediatric and orphan pharmaceuticals regulations (provided for in the European pharmaceutical strategy), which must not result in the continent becoming unattractive in terms of extremely important therapeutic needs that have yet to be met.
- The development of a common health product assessment process, which provides France with an opportunity to export its methodology and expertise.

“The Covid-19 crisis has reminded us that an ecosystem which encourages research in Europe is essential for addressing the twin issues of independence and health security. In this respect, the Commission's pharmaceutical strategy represents an opportunity to put the pharmaceutical industry back at the heart of Europe's health and innovation challenges”, emphasises the Leem Chairman.

French Presidency of the Council of the European Union: an opportunity for France to elevate its health priorities to the European level

In conclusion, the Leem welcomes with interest the ambition expressed by the French President to increase cooperation, particularly with African countries, under which a health agenda would enable a much faster rollout of more robust structures for the production of vaccines and the development of primary healthcare systems.

The pharmaceutical industry organisation also welcomes France's ambition to *“build a European growth model”,* which, in the words of the President, will involve *“building strong and integrated industry sectors, with particular emphasis on health”,* which are envisioned as *“sectors of dense technology that will generate growth and jobs”.*

Our pharmaceutical companies intend to play a driving and contributory role in learning the lessons of the health crisis, rearming Europe to cope effectively with health threats, boost its innovation and production capacities, continue and consolidate efforts to deliver the harmonisation required for greater agility and - lastly - to establish the continent as a model in addressing the key challenges of public health.

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