

## **PRESS RELEASE**

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### **Meeting with the healthcare industries**

**Sylvie Retailleau**, Minister for Higher Education and Research, **François Braun**, Minister for Health and Prevention, **Roland Lescure**, Minister Delegate with responsibility for Industry and **Olivier Becht**, Minister Delegate with responsibility for Foreign Trade, Economic Attractiveness and French Nationals Abroad, met this morning at Bercy with more than 90 French and foreign healthcare businesses on improving France's economic attractiveness.

Laurent Saint-Martin, Chief Executive Officer at Business France; Thomas Courbe, Director General of the Businesses Directorate; Philippe Bouyoux, President of the French Economic Committee for Healthcare Products; Lise Alter, Managing Director of the French Healthcare Innovation Agency; Franck Von Lennep, Director of the French Social Security System; Christelle Ratignier-Carbonneil, Director General of the National Agency for the Safety of Medicines and Healthcare Products; Dominique Le Guludec, President of the French National Authority for Healthcare; Fabienne Bartoli, Director General of the French National Authority for Healthcare; and Didier Samuel, President and Chief Executive Officer of INSERM (the French National Institute for Health and Medical Research) all participated in this meeting, which reminded us that the healthcare industries are a vital link in our healthcare system, developing innovative solutions for the benefit of all patients. France is therefore committed to making healthcare sovereignty and healthcare innovation strong priorities.

**To this end, the Prime Minister, Elisabeth Borne, launched on January 25, 2023 an interministerial mission tasked with making proposals to the government on improving the regulatory and funding mechanisms for healthcare products.**

This is vital, not only for strengthening our industrial competitiveness, but also for ensuring the availability of essential healthcare products and fast-tracking patient access to innovations. The regulation and funding policy for healthcare products is, in fact, at the crossroads of concerns about access to care (enabling patients to benefit from the best treatments, particularly innovative ones, as well as more mature but essential products for French people), industrial concerns (allowing us to support innovation, particularly French businesses, preserving our industrial fabric in critical mature products and guaranteeing the economic attractiveness of the French market), but also financial concerns, the sustainability of our social protection system being an important issue for the future. Against a backdrop of very strong growth in expenditure, driven in particular by an ageing population and advances in therapeutic treatment, an effective regulatory framework is crucial.

The unstable geopolitical environment, current inflation levels and the need to guard against supply tensions require us to re-examine the relevance and acceptability of existing mechanisms. In addition, concerns about relocating the production of the most critical products must be better taken into account, as well as, more generally, questions regarding

the economic attractiveness of the French market, at a time when industrial key players are expressing their fears when faced with a risk of gradual relocation or closure of certain manufacturing units.

The Ministers also recalled that, in accordance with the Prime Minister's commitments, **a meeting will be organized this autumn, to assess the impact of the measures put in place in 2023** and consider the opportunity for an adjustment within the framework of the part amendment to the French Social Security Budget Bill (LFSS) for 2024.

**Concerning the fight against shortages, the government is fully mobilized to preserve French people's access to essential medicines throughout the country.**

A steering committee meeting held on February 2, 2023 with François Braun, the Minister for Health and Prevention, and Roland Lescure, the Minister Delegate with responsibility for Industry, laid the foundation for a new strategy in terms of prevention and supply management. A new roadmap should be finalized by June 2023.

**The ministers were also able to explain the application of article 65 of the Social Security Budget Act for 2022, also known as the "industrial criterion".**

This is an important tool in the face of weakening supply chains. Eligible products are those for which it is necessary to secure the supply, either because of their innovative nature, or because of the existence of shortages – or risks of disruptions – in the supply of comparators in the same therapeutic class. The guarantees provided by the operator to secure this supply, particularly in terms of industrial establishment, will be evaluated. The advantage granted to eligible products will consist of an increase in their net price.

All these actions aimed at encouraging industrial and innovation projects, by French and foreign businesses operating on French soil, and fast-tracking patient access to innovations and essential healthcare products were at the heart of this morning's discussions, in which more than 90 leading businesses in the pharmaceutical, medical device and diagnostic sectors participated.

Re-industrialization, healthcare sovereignty, decarbonization, market access, economic regulation, innovation, translational research, economic attractiveness and support for exports were all the subject of discussions between ministers and participating businesses. Everyone is committed to making France the leading innovative and sovereign European country in healthcare.

**This event was ultimately an opportunity to take stock of the operational deployment of the "France 2030" healthcare component, known as "Healthcare Innovation 2030".**

Unveiled by President Emmanuel Macron on June 29 and October 12, 2021, "Healthcare Innovation 2030" provides for a set of legislative and regulatory measures, as well as €7.5 billion to make France the most innovative and sovereign nation for healthcare in Europe. It is the result of a broad consultation carried out with the Strategic Council for the Healthcare Industries (CSIS). The aim is to support the transformations of our healthcare system, for the benefit of all French people, by producing innovative treatments, while ensuring the security of supply of essential products.

"Healthcare Innovation 2030" aims to help people "live better", by preventing illnesses or loss of autonomy, by providing better care and combating emerging infectious diseases, to "better produce" on French soil the medicines and medical devices that our country needs, to "better understand" life and diseases, and to better share knowledge of life sciences. It will take the form of actions to foster excellence and make France a leader in highly innovative healthcare products, strengthen the economic attractiveness of France, fast-track relocation, promote access to the market and create solid, productive and lasting co-operation.

It includes several strategic axes:

**1. Supporting the excellence of our biomedical research**, notably through the creation of world-class bioclusters and new university hospital research institutes. More than €1.2 billion is dedicated to biomedical research, with the aim of:

- Creating bioclusters (grouping of laboratories, research centers, care centers and businesses working in healthcare) on a global scale: the “Biocluster” call for expressions of selective interest, with a budget of €300 million, has already selected an initial winner: the Paris Saclay Cancer Cluster (PSCC).
- Supporting research projects with strong potential for rapid transfer to industry or society: University Hospital Research (RHU) projects. The projects will be selected in spring 2023 (€160 million).
- Developing University Hospitals Centers of Excellence (IHU). The call for projects, worth €300 million, closed on November 7, 2022. The selection of IHUs is underway.
- Strengthening our healthcare research through the funding of the French clinical research infrastructure network (F-CRIN) infrastructure, biobanks and new cohorts to monitor the evolving needs of patients over the long term and discover new treatment pathways (€200 million).
- Funding the renewal of our healthcare research infrastructures (€100 million) and attracting young researchers of the best international standing to the country (€80 million).
- Funding research programs led mainly by the French National Institute for Health and Medical Research (INSERM), particularly on mental health, the health of women and couples, biotherapies (with the French Atomic Energy and Alternative Energy Commission (CEA)) and digital healthcare (with the National Institute for Research in Digital Science and Technology (INRIA)) to make use of healthcare data and to build the technological building blocks required to develop the prevention and care system, and emerging infectious diseases, to become a leader in Europe and anticipate health crises.

**2. Investing in the three areas of tomorrow to produce biotherapies, to go further in terms of digital healthcare and fight against emerging infectious diseases (EID) and nucleated red blood cell (NRBC) threats.**

To date:

- As part of the strategy relating to infectious and emerging diseases and NRBC threats (€750 million), 15 projects have been deployed following the call for expressions of interest launched in 2021. An evolving list of priority pathogens guides the submission of calls for projects applications. Four industrialization projects have received support, two projects have been selected to strengthen training in the field of EIDs, and two Priority Research and Equipment Programs (PEPR) have been launched. In addition, the strategy will soon support demonstration and validation platforms for EID countermeasures (files currently being evaluated).
- As part of the digital healthcare strategy (€650 million), sixty winners have already received funding to develop reliable digital innovations, demonstrate their clinical and medical-economic value and support testing in third-party settings. A call for projects has also just been launched to strengthen the medical imaging sector and initial training in digital healthcare has been made compulsory from the start of the 2024 academic year for twelve medical and paramedical professions.

- The “biotherapies and bioproductions” strategy (€800 million) has supported more than 30 innovation projects (biotechnologies and bioprocesses) led by Biotechs, two industrialization projects and three training projects (notably engineers with dual expertise). In addition, France Biolead has been launched, which will bring together all the key players in bioproduction in France and will contribute, in conjunction with the Healthcare Innovation Agency (AIS), to strengthening the structuring of the sector.

3. Fast-track the growth of startups and disruptive innovations by strengthening Bpifrance’s investment in healthcare.

4. Support industrial investment, at a national level and through European co-ordination, re-inforced by an **Important Project of Common European Interest (IPCEI)** (projects currently being examined by the European Commission).

5. Become the European leader in clinical trials, through regulatory simplifications, support for the structuring of organizations and financial support.

6. Create the **digital and innovative medical devices of tomorrow** and roll out those that already exist. To date, the “medical devices” plan has supported 11 industrialization projects to create the medical and in vitro diagnostic devices of tomorrow. It has also supported nearly 90 businesses in their market access efforts, with the establishment, in September 2022, of a “Regulatory Diagnostic” window to make it easier to obtain CE marking for products. A call for projects has also been launched to demonstrate the value of medical devices for collective use.

7. Create a strategic impetus and management structure for healthcare innovation: **the Healthcare Innovation Agency (HIA)**. The HIA, attached to the French General Secretariat for Investment, under the authority of the French Prime Minister, was launched in November 2022, to strengthen and revitalize our healthcare sector and facilitate patient access to innovations. It is notably responsible for:

- Managing, in conjunction with the ministries and operators concerned, the implementation of the “France 2030” health component.
- Co-ordinating work on healthcare foresight to define the future needs of the healthcare system and anticipate their impacts on the prevention and care system.
- Providing personalized support for innovative, strategic projects for France.
- Proposing measures to simplify and fast-track existing regulatory processes.

In this context and following on from the work already carried out under the leadership of the CSIS, the HIA will carry out priority work to fast-track clinical research and promote the development of innovations. **Starting in March, a working group, co-led with F-CRIN, will be launched to begin work on new clinical trial methodologies.** Two types of developments will be targeted: those impacting the conception and design of clinical studies and those affecting their operating mode (digitalization and decentralization of clinical trials to fast-track patient inclusion).

The aim will be to identify priority use cases. The working group, capitalizing on these analyses, and on previous work carried out, including that of the French National Authority for Healthcare, will aim to make the link with the work undertaken at the European and international level to ensure good co-ordination.

## About Business France

Business France is the national agency supporting the international development of the French economy, responsible for fostering export growth by French businesses, as well as promoting and facilitating international investment in France.

It promotes France's companies, business image and nationwide attractiveness as an investment location, and also runs the VIE international internship program.

Business France has 1,500 personnel, both in France and in 56 countries throughout the world, who work with a network of partners.

Since January 2019, as part of the reform of the state support system for exports, Business France has given private-sector partners responsibility for supporting French SMEs and mid-size companies in the following markets: Belgium, Hungary, Morocco, Norway, the Philippines and Singapore.

For further information, please visit: [www.businessfrance.fr](http://www.businessfrance.fr) @businessfrance

## Media contacts:

Office of Sylvie Retailleau, Minister for Higher Education and Research –  
[secretariat.communication@recherche.gouv.fr](mailto:secretariat.communication@recherche.gouv.fr)

Office of François Braun, Minister for Health and Prevention –  
[sec.presse.cabsante@sante.gouv.fr](mailto:sec.presse.cabsante@sante.gouv.fr)

Office of Roland Lescure, Minister Delegate with responsibility for Industry –  
[presse@industrie.gouv.fr](mailto:presse@industrie.gouv.fr)

Office of Olivier Becht, Minister Delegate with responsibility for Foreign Trade, Economic Attractiveness and French Nationals Abroad – [presse.comext@diplomatie.gouv.fr](mailto:presse.comext@diplomatie.gouv.fr)

General Investment Secretariat – [presse.sgpi@pm.gouv.fr](mailto:presse.sgpi@pm.gouv.fr)

Business France:

Séverine de Carvalho – Tel.: +33 1 40 74 73 88 – Mob.: +33 6 82 23 69 12 –  
[severine.decarvalho@businessfrance.fr](mailto:severine.decarvalho@businessfrance.fr)

Siham Morchid – Tel.: +33 1 40 73 30 74 – Mob.: +33 6 59 37 56 87 –  
[siham.morchid@businessfrance.fr](mailto:siham.morchid@businessfrance.fr)