



PRESS RELEASE

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New method, new framework, new roadmap...
A breakthrough CSIS to restore the attractiveness of France

The Strategic Council for the Healthcare Industries (Conseil stratégique des industries de santé: CSIS) held today and attended by the Prime Minister and four members of the government¹ marks a turning point in the process of dialogue between the French state and pharmaceutical companies.

Dedicated to boosting the attractiveness of France - and the development of healthcare solutions for tomorrow, this 8th CSIS was unlike its predecessors both in terms of content and method. Leem highlights that this CSIS went beyond a simple declaration of intentions to a true process of implementation of a number of major substantive decisions for the country.

Substantive, deliverable and measurable

Rarely since its creation in 2004 has this exclusive forum for dialogue between central government and healthcare industry stakeholders led to such operational measures. Leem recognises and congratulates the commitment of the coordinators who were able to provide the impetus required to make this a very different kind of CSIS ready to address all the issues faced by the industry (regulation, patient access to innovative therapies, assessment, industry attractiveness, etc.) with no preconditions, and to ensure a high quality of dialogue with the government.

As a result, Leem supports the measures announced today by the 8th CSIS, which echo some of the expectations it expressed during the 2017 presidential election campaign.

Over and above the measures adopted by the CSIS, this meeting marks a tangible expression of recognition by governmental bodies of the essential contribution made by healthcare companies to national economic development, and their ability to create jobs and drive innovation at a regional level.

Innovative in its method, this CSIS has been equally innovative in ensuring effective monitoring of the measures, with the introduction of meaningful guidance and a supervisory body reporting directly to the Prime Minister.

¹ **Agnès Buzyn**, Minister for Solidarity and Health, **Frédérique Vidal**, Minister for Higher Education, Research and Innovation, **Jean-Baptiste Lemoyne**, Secretary of State to the Minister for Europe and Foreign Affairs, and **Delphine Gény-Stephann**, Secretary of State to the Minister for the Economy and Finance.

Leem hopes and expects that this supervisory body will pay close attention to consistency in public-sector initiatives. Only too often before, the CSIS has suffered from a contradiction between the political intentions expressed and their substantive translation into reality.

The presence at this 8th CSIS of 30 global heads of leading pharmaceutical companies marks not only a resurgence of interest in France among decision-makers, but also their high expectations of the country's manufacturing and healthcare policy.

Necessary and urgent reforms to:

1. Ensure rapid patient access to innovative therapies

The decisions reached today are primarily intended to **improve patient access to innovative therapies**. The government is committed to reducing the lead time for patient access to newly marketed drugs, and has set the target of **ensuring compliance with the 180-day lead time set by the European directive**. French lead times are among the longest in Europe, putting France currently in 18th place, with an average of 530 days between market authorisation (MA) and the publication of a price in the *Journal Officiel*, which marks the point at which patients actually have access to the product (compared with 106 days in Germany and 111 in the UK).

In terms of providing rapid patient access to the most innovative products, the government has also committed to **extending the Temporary Authorisation for Use (ATUs) – a mechanism that facilitates early access to innovation – to include extension of therapeutic indications**. The current ATU mechanism is reserved exclusively for initial therapeutic indications and is no longer appropriate for current clinical developments, especially in cancer treatment.

Lastly, by opening up a workstream to **reform the drug assessment process**, the government clarifies its ambition to make the criteria for drug reimbursement clearer and more efficient.

2. Support the research drive

Against a background of intense European and global competition around the challenges of healthcare product research and manufacture, the CSIS intends to reposition France for inward investment in healthcare with a series of major decisions: accelerating clinical trial authorisation procedures, creating a Health Data Hub to optimise the use of nationally available health data, developing a sector of excellence for biotechnology and innovative therapy drugs...

3. Boost the attractiveness of France in the health industries sector

This CSIS has made clear its intention to break with the short termism of recent years by adopting a 3-year forward view on regulatory parameters, providing pharmaceutical companies in France with a more predictable and stable operating framework, thereby making the country more attractive in terms of health-related inward investment.

Leem is also delighted to welcome an end to the over-transposition of European directives.

Strong signals at an international level...

The announced reform of the drug assessment process, accompanied by a timetable, by the extension of the ATU mechanism, the reduction in the lead time for clinical trial implementation, and the policy goal of reducing the lead time for patient access to innovative therapies, constitute strong signals of the determination of France to regain its European leadership in the life sciences.

...subject to a return to reasonable growth

Leem is only too well aware of the constraints that continue to exert downward pressure on balancing the public accounts, particularly in terms of health expenditure. Pharmaceutical companies contribute half of all health expenditure savings, despite the fact that their products account for only 15% of health insurance costs.

As a proactive contributor to the healthcare system transformation initiated by the Prime Minister, Leem is calling for a relaxation in the budgetary constraint imposed on pharmaceutical companies and a return to reasonable growth, which is an essential prerequisite for France to regain its attractiveness for inward investment.

“Leem welcomes the spirit of reform embraced by the government, which has sent out strong and encouraging signals for the industry”, analyses Patrick Errard, Chairman of Leem. “This CSIS lays the foundations for a far-reaching transformation in the process of dialogue between the French state and the industry. These are undoubtedly substantive announcements that can become rapidly operational, but above all they constitute a long-term roadmap for an industrial policy that will reinstate France as a centre of innovation and excellence in health going forward. We will work closely with the French state to ensure that the measures announced at this CSIS are implemented as quickly and efficiently as possible. Nevertheless, we will continue as strongly as ever to make the case for a return to growth, which is the essential prerequisite to ensuring that France regains its rightful position in the community of innovative nations”.

Read the full CSIS 2018 press pack at www.leem.org

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