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The French Social Security Finance Bill (PLFSS) for 2022

Following the second reading of the bill in the National Assembly, Leem welcomes a PLFSS consistent with the announcements made by the French President

The PLFSS currently passing through parliament has been eagerly awaited by the pharmaceutical industry, since it constitutes one of the first opportunities to deliver on the announcements made by the President at the Strategic Council for the Health Industries (CSIS) on 30 June this year.

Leem notes that this most recent CSIS - entitled *Innovation Santé 2030* (Healthcare Innovation 2030) - confirmed the strategic importance of the pharmaceutical industry, and expressed the ambition of central government to establish France as the European leader in health innovation and sovereignty by 2030. This ambition has its roots in the Covid-19 crisis, which has highlighted both the strengths and weaknesses of the French healthcare ecosystem.

These are the reasons why, on completion of the second reading in the National Assembly, Leem welcomes a draft legal text that gives substance to the majority of the measures announced at the CSIS, most of which are intended to improve patient access to medicinal products, and restore the attractiveness of France for inward investment by the industry.

In terms of **patient access to medicinal products**, Leem particularly welcomes:

- **The reform of the direct access system.** Introduced on an experimental basis, this reform will give patients access ASMR (improvement in actual benefit) I to IV treatments as soon as the HAS (national authority for health) has made its recommendations. This far-reaching transformation of the current system, which complements the major reform to the early access mechanism introduced in the LFSS for 2021, should allow France to shorten the lead time of patient access to the treatment they need, and achieve convergence with the best performing European countries, such as Germany.

- **Broadening the criteria governing the addition of medicinal products to the *liste en sus* (supplementary list).** This list provides the opportunity to fund innovative and costly medicines independently of hospital resources to prevent creating unequal patient access across the country. Until now, the scope of this scheme was limited to ASMR I, II and III pharmaceuticals, which excluded many cutting-edge products essential for effective therapeutic strategies. From now on, ASMR IV drugs will be

eligible for inclusion in this list, and therefore direct reimbursement by the *Assurance Maladie* (national health insurance system).

- **Updating of the organisational structure of *Comités de Protection des Personnes* (CPP - equivalent to Institutional Review Boards in the US and Ethics Committees in the UK) with the aim of boosting the attractiveness of France for inward investment in clinical research**. The move will be funded by an increase in the revenue-based tax paid by pharmaceutical companies.

On the subject of **industrial attractiveness**, Leem stresses:

- **The option for the Healthcare Products Pricing Committee (CEPS) to take the location of production sites into account when setting the prices of medicinal products.** This text consolidates the terms of the framework agreement signed by Leem and CEPS on 5 March 2021 regarding the price stability of products that have attracted, or will attract, inward investment in the European Union, and more specifically in France.

- **The increase in CSIS credits.** These clawback credits are made available to companies that have invested in pharmaceutical manufacturing and/or research in the European Union. The current Social Security Finance Bill proposes to double their value.

"*This PLFSS gives France the resources it needs to achieve its ambition of regaining its status as Europe's leading country in terms of health",* says Leem President Frédéric Collet. *"More particularly, our pharmaceutical companies welcome the government's desire to improve access to medicinal products at a time when we are seeing the emergence of an unprecedented wave of therapeutic innovations"*.

Additionally, Leem notes that the M rate for reimbursed expenditure is to be set at 2.2%, again in accordance with the decisions announced by the French President.

At the same time, it also highlights the fact that although the net budget for medicinal products is significantly higher than last year, the historic increase in the safeguarding clause and rebates will once again make pharmaceuticals a main contributor to the healthcare cost-control policy.

"French patient access to innovative therapies and essential pharmaceutical products, and the need to give our manufacturing base back its competitive edge, demand that we keep up a sustained effort to deliver growth and adapt our funding mechanisms. This situation calls for structural responses that go far beyond simply annual budgeting", concludes Frédéric Collet.

As a result, Leem continues to call for the rapid establishment of a regulatory monitoring body, as announced by the French President at the 2021 CSIS.

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