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THE FRENCH SOCIAL SECURITY BUDGET FOR 2025

Guaranteeing access to medicines in France: proposals from pharmaceutical companies

The Government is currently preparing the Social Security Finance Bill (PLFSS) for 2025, which will then be submitted to Parliament for its approval. To ensure that everyone is able to receive the treatment they need, pharmaceutical companies are bringing forward a series of concrete recommendations designed to strike the right balance between protecting and perpetuating the French social welfare model, at the same time as enhancing sector attractiveness. We urge the public authorities to use the forthcoming PLFSS to implement a plan that will effectively control the safeguard clause and introduce measures to streamline access to new treatments for French patients. Fully aware of the constraints on public finances, we propose the introduction of a savings plan - to which we will contribute - to ensure that the necessary funding is available.

Campaigning for a Social Security Finance Bill that benefits the French population and boosts our competitiveness

Pharmaceutical companies have long contributed very significantly to national health insurance cost savings via the various regulatory mechanisms put in place by successive Social Security Finance Bills. Unfortunately, the scale of this effort is now undermining the financial sustainability of the industry, which finds itself caught in a financial vice between the highest level of taxation in Europe (with 5 industry-specific taxes that soak up 60% of company turnover) and prices that are 10% lower on average than in comparable European countries. This discrepancy is clearly illustrated in the results of the Barometer survey of France's attractiveness for inward investment in medicines[1].

If we are to provide an effective long-term response to healthcare needs, we need a medicines policy that is both ambitious in ways that benefit the people of France, at the same time as being sustainable for pharmaceutical companies. *"France must choose between championing taxation or championing healthcare, and this choice needs to be clearly reflected in the forthcoming social security budget"*, explains Leem Chairman Thierry Hulot.

Pharmaceutical companies are therefore calling for the introduction of an emergency measure that will **control and cap the safeguard clause**. Initially intended to secure a stream of industry funding to offset a rising demand for medicines, this clause has since metamorphosed into a cost-cutting policy that heavily penalises pharmaceutical companies of all sizes. In its findings of August 2023, the interministerial task force on the Financing and Regulation of Health Products condemned this situation, the impact of which may prove potentially detrimental for patient access to medicines.

- We are asking the public authorities to ensure that, in line with their previous commitment, **the safeguard clause be capped at €1.6 billion for 2024,** and **to start a process of gradual reduction, beginning with the PLFSS for 2025.**

- As recommended by the interministerial task force, **this gradual downward trend** (to €1 billion in 2025 and €750 million in 2026) **should ultimately culminate in a safeguard clause cap of €500 million for 2027**.

[1] Leem survey results presented in June 2024

- But if capping the safeguard clause is to be genuinely effective in revitalising our pharmaceutical companies and helping to restore the health sovereignty of France, **we must also halt the aggressive price-cutting race to the bottom.**

Because we understand the current budgetary constraints being felt by France and its welfare budgets, **we are proposing a responsible plan for reducing expenditure on medicines by €1.1 billion as part of ensuring the long-term viability of our system without penalising patients.**

Key measures of this savings plan:
- **Reducing the consumption of medicines** by promoting their proper use in accordance with the *Réduisons le volume* (Let's turn down the volume) campaign launched in spring 2024;
- **Early company settlement of national health insurance clawback payments**;
- **Access to a broader range of non-prescription medicines** (without delisting them for reimbursement if they continue to be prescribed).

Streamlining access to new treatments for French patients

The **French early access scheme remains excessively rigid and increasingly misaligned with the pace at which innovative therapies are emerging, thereby depriving French patients of priority access to potentially life-changing treatments.**
- The **average new medicine access lead time** for French patients is **527 days**[2], **compared with just 126 days** in Germany. And this lead time continues to grow.
- **37%** of new medicines authorised for use in Europe between 2019 and 2022 were still **not available in France** on 31 December 2023 (**compared with just 12% in Germany**).
- While **early access** marks a genuine step forward, it currently benefits only **127,000 patients**, when 13 million people in France are suffering from long-term conditions!
- **Fewer than 1 in 10 new medicines are manufactured in France, compared with 1 in 4 in Germany.** These figures clearly demonstrate that this scheme is stifling the flow of new innovations, just as it is for other existing treatments.

Reforming patient access procedures must therefore be prioritised at the same level as price regulation and taxation. To do so will have a tangible impact on the daily lives of patients, at the same time as benefitting the healthcare system as a whole by improving treatment and care, while avoiding further national health insurance expenditure.

"The people of France must be able to access the treatments they need now and in the future. This is our core mission as pharmaceutical companies. We are not asking for any special treatment: simply a sustainable fiscal and regulatory framework that allows us to deliver that mission, and fully embrace the innovations of tomorrow. By capping the safeguard clause, implementing a responsible cost savings plan and simplifying access procedures, France would be positioning itself to reconnect with a realistic, ambitious and visionary medicines policy", concludes Leem Chairman Thierry Hulot.

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[2] *Standard procedure and early access.*