

THE SOCIAL SECURITY FINANCE BILL & MEDICINES THE BASICS

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As we prepare for the Social Security Finance Bill (PLFSS) for 2025, it is important to understand how its contents will impact the French public's access to the medicines they need.

An explanation

THE PLFSS What is its purpose?

■ The Social Security Finance Bill provides a unique opportunity to discuss France's national medicines policy; a policy that can potentially improve the lives of all citizens, provided the right decisions are made.

■ Every autumn, the Government uses this draft legislation to plan the Social Security budget allocated to meet the needs of the French population during the year ahead. Its ultimate aim is to ensure that every euro spent makes an effective contribution to promoting the health and wellbeing of French citizens.

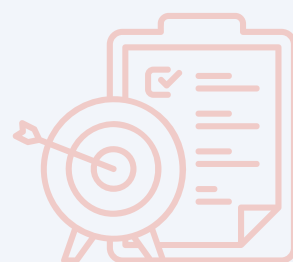
■ The decisions made when preparing the PLFSS — covering the budget for reimbursable medicines, price cuts, the conditions governing patient access to medicines and tax measures specific to the pharmaceutical industry — have a major impact on the sustainability of the companies concerned.

■ If pharmaceutical companies become no longer viable, how will they continue to supply the necessary medicines to the French population?

■ In 2023, the interministerial task force on the Financing and Regulation of Health Products concluded that it was absolutely essential to reinvent the pharmaceutical industry economic model. The current model, which is suffocating companies, is no longer aligned with the changing nature of healthcare needs and the emergence of major therapeutic innovations in France.

A responsible cost savings plan

At a time when the French national health insurance scheme must make up a shortfall of €10 billion, we recognise the pressing urgency of budgetary responsibility and committed involvement of all stakeholders. **Which is why we are proposing a responsible cost savings plan for medicines and solutions designed to simplify the system and make it more efficient.**



KEY STAKEHOLDERS AND MILESTONES OF THE PLFSS



The Directorate for Social Security (DSS) sets out the core principles of the budget and associated cost savings measures



Health authorities (via interface committees)

APRIL

—

MAY

—

JUNE

—

JULY

—

AUGUST

—

SEPTEMBER

—

OCTOBER

—

NOVEMBER

—

DECEMBER

—

JANUARY

—

FEBRUARY

—

MARCH

← 1 JUNE

Publication of Section 1 of the PLFSS regarding implementation of the LFSS (Social Security Finance Act) for the previous year

BEGINNING OF OCTOBER

The 1st official version of the PLFSS text



END OF NOVEMBER

Parliament votes on the PLFSS



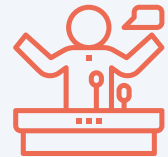
END OF DECEMBER

The LFSS is published in the Official Journal



Pharmaceutical companies (any contentious administrative appeals)

The Matignon (PM's office) and Elysée (President's office) teams arbitrate



The National Assembly and Senate debate the bill



Members of Parliament (work on amendments)

DURING DECEMBER The Constitutional Council ratifies the law

(in its entirety or after overruling specific provisions)



ONDAM, and the challenge of controlling expenditure

The National Health Insurance Expenditure Target (ONDAM) is set annually in the Social Security Finance Act.

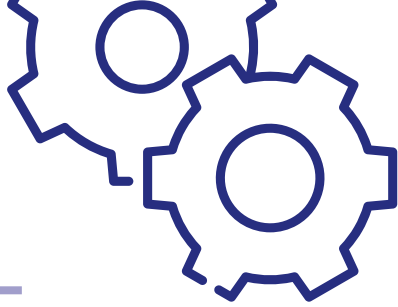
Understanding the ONDAM is key to grasp how healthcare resources are planned and used to ensure that the healthcare needs of the

French population are met fairly and efficiently.

Every year, the Government decides how many billions of euros it will devote to the Social Security budget, and how it will allocate that total to pay the salaries of healthcare professionals, ensure the smooth running of hospitals and reimburse patients for the money they spend on medicines. The size of this national piggy bank

grew by 3.1% year on year between 2010 and 2022.

However, growth in medicines-related expenditure over the same period remained more restrained. Medicines accounted for 12% of all healthcare expenditure 15 years ago; the figure today is below 9%. When you consider how healthcare needs can only continue to increase as people live longer and the level of disease chronicity rises, there is clearly a problem here!



GOAL

To regulate expenditure on medicines

The State has a responsibility to ensure that the budget set in the Social Security Financing Act is not overshot.

The Government has **four levers** for regulating the cost of medicines, all of which can be activated annually in the Social Security Finance Act.

- 1. Price cuts.** The lower the price of medicines, the lower the expenditure.
- 2. Clawback payments.** At the end of each year, pharmaceutical companies reimburse the State for a proportion of its expenditure on medicines.
- 3. Medical cost containment through prescription control.**

This mechanism encourages the proper prescription and use of medicines by doctors and patients: neither too much nor too little.

- 4. The safeguard clause.** If expenditure exceeds the preset threshold known as *Montant M*, pharmaceutical companies must repay a large proportion of the variance.

All these mechanisms are based on, and require, the active participation of pharmaceutical companies in achieving cost savings. In 2023, these measures enabled the State to collect more than €3 billion from pharmaceutical companies. **That figure makes us the greatest contributors to Social Security cost savings!**

Réduisons le volume



Au-delà de 5 médicaments par jour, surtout après 65 ans, demandez à votre médecin ou votre pharmacien si vous pouvez en prendre moins.*

*Arrêtez jamais votre traitement sans avis médical.

DE MÉDICAMENTS, C'EST MÉDICAMIEUX leem

les entreprises du médicament sociales unives

en savoir + sur leem.org/medicamieux

« Let's turn down the volume »

This year, French pharmaceutical companies launched a new action plan to reduce the excessive use of multiple medicines among the elderly through the use of awareness-raising information and support for healthcare professionals, combined with a public communication campaign.

The expectation is that this could save the national health insurance scheme €300 million annually.

Other similar initiatives are planned for the future, focusing on antimicrobial resistance and wastage of medicines.

The margin squeeze, imposed by the combination of having the lowest prices in Europe, but the highest level of taxation, continues to significantly penalise the growth of pharmaceutical companies in France :

■ France overtaxes its pharmaceutical industry: 60% of annual income, 88% of which relates to taxes specific to our industry.

■ At the same time, it imposes prices that are on average 10% lower than in comparable European countries.

Focus on the safeguard clause

The safeguard clause began with a perfectly good intention: to avoid any budget overrun as a result of higher than expected demand for medicines from French patients. To achieve this goal, pharmaceutical companies are required to make a financial contribution to ensure that everyone can be treated appropriately without compromising the accounts of the national health insurance scheme.

In 2015, this contribution equated to only 1% of pharmaceutical

company turnover; today, the proportion is 6%...

The amounts demanded have now become unsustainable for manufacturers: €1.6 billion per year.

And it applies to all companies, regardless of size, and is based on their market share and year-on-year growth, ignoring their profitability or otherwise!

The unpredictability of the amount demanded, poses real problems for budgetary management in pharmaceutical companies.

Towards a meaningful and effective **Social Security Finance Bill**

→ There can be no health sovereignty without economic sustainability!

→ To return to its essential purpose, the PLFSS must put in place the conditions required to ensure that pharmaceutical companies continue to provide French citizens with access to the treatments they need, and to do so as quickly as possible.

→ The essential pre-condition is that companies can continue to invest in the ongoing development and manufacture of medicines in France.

→ An economic environment that provides incentives and protects patients means:

1. A fair regulatory system that enables the national health insurance scheme to balance its books without penalising pharmaceutical companies :

- **Make the safeguard clause sustainable:** it has an important role to play, but the amount demanded of companies has exploded. As explained in the report of the interministerial task force on the Financing and Regulation of Health Products, the maximum acceptable level is €500 million.
- **End the margin squeeze** imposed by the combination of Europe's highest taxation and lowest medicine prices.

2. A voluntary contribution made by companies to the cost savings measures applied by the National health insurance scheme, as part of ensuring the long-term future of the French healthcare system:

- **Incorporate the cost saving proposals brought forward by pharmaceutical companies in the PLFSS**, these include stronger measures to ensure the proper use of medicines and the delisting of certain products (medicines available simultaneously with and without prescription).
- **Treat pharmaceutical companies as healthcare stakeholders in their own right**, and treat medicines as an investment for the healthcare system.

3. Simplify procedures to boost efficiency and accelerate patient access to new medicines:

- **Remove all unnecessary stages** from early access procedures and the data collection associated with them.
- **Simplify the HAS therapeutic value assessment** by adopting the EU Joint Clinical Assessment (this reform will apply from 1 January 2025).
- Promote practical solutions for public and private **data sharing**.