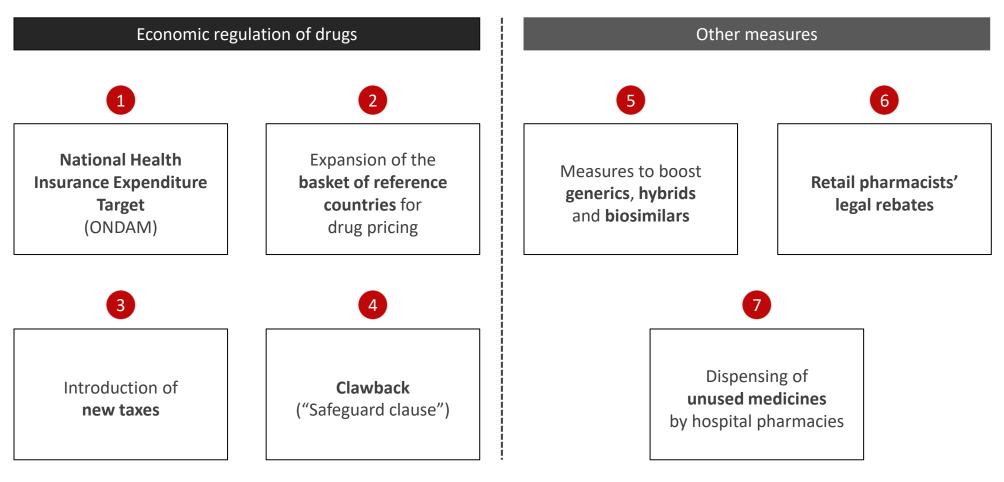


December 2025



Smart Pharma Consulting presents in this paper its analysis of the key implications for pharmaceutical companies of the Social Security Financial Act (LFSS) for 2026

Introduction



Sources: LFSS 2026 (December 16, 2025) – Smart Pharma Consulting analyses



The limited growth of the ONDAM (+3.2%) increases pressure on drug prices, reducing pharmaceutical companies' profitability and potentially limiting patient access to innovation

1 National Health Insurance expenditure target (ONDAM)

Key measures

Article 109

 For 2026, the National Health Insurance Expenditure Target (ONDAM) has been set at
 € 274.4 B, representing a
 +3.2% increase vs. 2025

Rationale

- ONDAM set at a higher level than initially planed (+€ 3 B) to preserve access to healthcare through:
 - Containing patient out-ofpocket expenditure
 - Ensuring the stability of hospital tariffs

- Despite its approved increase, the ONDAM is likely to remain below actual needs due to:
 - Growing needs linked to population ageing
 - Rise in chronic diseases
 that mechanically drive an expenditure growth of
 ~5% per year
- Risk that drugs bear almost the entire burden of cost containment through price regulation, for which the National Health Insurance has planned a € 1.7 B saving



With the 2026 LFSS, the CEPS¹ is expanding its reference basket, no longer limited to European countries, but now including all countries with comparable market characteristics

2 Expansion of the basket of reference countries for drug pricing

Key measures

Article 88

- The CEPS negotiates drug prices considering several criteria, including prices in other countries
- Whereas the reference basket of countries previously considered was limited to European countries...
- ... it is now open to all countries with comparable market characteristics

Rationale

 Strengthening of healthcare expenditure control, with the CEPS having the possibility to negotiate prices by considering markets where prices may be lower

- Increased pressure on prices, as pharmaceutical companies can no longer rely solely on the European market to justify their prices
- Risk of delays or limitations in launching innovations in France if the negotiated price becomes too low compared to other strategic countries
- Required adaptation of market access strategies (e.g., through implementing international price monitoring)

Sources: LFSS 2026 (December 16, 2025) - Smart Pharma Consulting analyses



The introduction of the supplementary contribution risks further reducing the attractiveness of the French market for pharmaceutical companies

Introduction of new taxes (1/2)

Key measures

Supplementary contribution (Article 28)

- For all drugs, excluding:
 - Generics
 - Originators under TFR¹ or with a price below a threshold defined by decree
- For 2026, the rate is set at:
 - 6.45% of sales (for pharmaceutical companies with sales > € 50 M)
 - 4.01% of sales (for pharmaceutical companies with sales < € 50 M)

Rationale

- Strengthening of healthcare expenditure control
- Targeting of contributions towards drugs that are most costly for the National Health Insurance

- Increased tax pressure on pharmaceutical companies, as this new contribution adds to existing taxes:
 - Basic contribution²
 - Additional contribution³
 - M contribution⁴
- Risk of delays or limitations in launching innovative drugs in France

¹ Reference Price – ² 0.20% of sales – ³ 1.60% of sales –

⁴ In the event of the activation of the safeguard clause



The 2026 LFSS introduces a tax on pharmaceutical companies delaying generics entry, penalizing dilatory practices to protect National Health Insurance expected savings

3 Introduction of new taxes (2/2)

Key measures

Tax on pharmaceutical companies artificially maintaining their commercial exclusivity (article 29)

- Tax charged to originator pharmaceutical companies delaying the entry of generics more than one year after patent expiry (e.g., filing patents on forms, dosages, processes, or combining active ingredients that do not provide any improvement in medical benefit)
- Tax of 3% of the drug's sales (even 5% in the event of a further offense within 5 years)

Rationale

- Accelerated availability of generics, considered as a major lever for controlling healthcare expenditure
- Sanction of practices aimed at artificially delaying competition
- Protection of the expected savings due to generics for the National Health Insurance

- Risk of significant financial penalties in case of noncompliance with the law
- Reputational risk for pharmaceutical companies...
- ... knowing that National Health Insurance may publicize the savings lost due to:
 - Unjustified delays in generics entry and/or...
 - ... a limitation of their penetration



The 2026 LFSS modifies the calculation method of the safeguard clause which is now based on reimbursed amounts and which excludes generics, biosimilars and hybrids from the calculation

4 Clawback – "Safeguard clause" (1/2)

Key measures

Setting a cap on expenditure for 2026 (Article 28)

- M amount (for drugs): € 22.10 B
- Z amount (for medical devices):
 € 2.16 B

Rationale

 Simplification of drugs regulation, with M and Z amounts now expressed as amounts reimbursed by the National Health Insurance (instead of net sales reported by pharmaceutical companies)

Implications

- Need for pharmaceutical companies to monitor actual reimbursements, not just their drug sales
- Better visibility re. the risk of triggering the "M contribution"

Exclusions from the calculation base of the safeguard clause (Articles 28 and 31)

- Exclusion of:
 - Generics¹
 - Biosimilars²
 - Hybrids²

- Targeting of contributions towards the drugs that are the costliest for the National Health Insurance...
- ... to avoid penalizing players that help generate savings for the National Health Insurance



 Shift of the M contribution to the detriment of innovative drugs reimbursed by the National Health Insurance

¹ From 2026, vs. a M contribution capped at 1.75% of reimbursed generics gross sales in 2025 – ² Exclusion of biosimilars and hybrids from the calculation base of the safeguard clause from 2025, resulting in a downward revision of the M amount for 2025 (€ 26.10 B set in Article 31 of the 2026 LFSS vs. € 27.25B planned in the 2025 LFSS)



The inclusion of a territoriality criterion aims to promote production within the European Union, thereby encouraging pharmaceutical sovereignty and securing supply chains

4 Clawback – "Safeguard clause" (2/2)

Key measures

Inclusion of a territoriality criterion in the calculation of the safeguard clause (Article 32)

- Introduction of a 3rd allocation criterion for the safeguard clause ("M contribution")
- The new allocation keys are as follows:
 - 50% based on pharmaceutical companies' sales
 - 30% based on their respective contribution to drugs expenditure growth
 - 20% based on the location of their products manufacturing

Rationale

- Valuation of local production within European Union countries to:
 - Promote industrial reshoring
 - Reduce dependence on imports
 - Ensure patient access to drugs in case of crisis (e.g., pandemic, supply disruption)

- Financial impact, which could lead some pharmaceutical companies to consider relocating part of their production ...
- ... to gain better control over their "M contribution"
- However, the potentially higher manufacturing costs in EU countries is likely to limit the industrial impact of this measure



The 2026 LFSS includes new measures aimed at boosting the adoption of generics, hybrids and biosimilars in order to contribute to savings for the National Health Insurance

Measures to boost generics, hybrids and biosimilars

Key measures

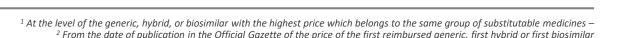
Article 87

- Implementation of the thirdparty payment mechanism for hybrids and biosimilars
- Biosimilars authorized to be prescribed in INN
- Capped reimbursement base¹ in case of unjustified nonsubstitution:
 - Adjustment period² for the reimbursement base reduced from 2 years to 1 year for generics
 - Adjustment period² created for hybrids (1 year) and biosimilars (2 years)

Rationale

- Health authorities' ambition to accelerate the penetration of:
 - Generics
 - Hybrids
 - Biosimilars...
- ... to increase the drug savings for the National Health Insurance

- Risk of **faster erosion** of **market share** for **originators**
- Acceleration of market uptake and...
- ... increase in market share of generics, hybrids, and biosimilars, whose substitution will be facilitated by these measures





If the capping of discounts provides greater predictability and security for pharmacies, however, uncertainty surrounding future provisions and the austerity context remains a source of concern

6 Retail pharmacists' legal rebates

Key measures

Article 37

- Review of maximum legal rebates and commercial or financial benefits of any kind granted by pharmaceutical companies to retail pharmacies
 - 40% of ex-factory price for generics, hybrids and originators under TFR¹
 - 20% of ex-factory price for biosimilars and reference biologics at the same price as biosimilars
 - 2.5% for other reimbursed drugs

Rationale

- Securing of the retail pharmacies remuneration model...
- ... to preserve the density of the territorial network
- Limitation of aggressive commercial practices by pharmaceutical companies
- Alignment of retail pharmacists' remuneration with healthcare authorities' substitution objectives for generics, hybrids, and biosimilars

Implications

- Strengthened price competition: need to offer competitive rebates to remain present in retail pharmacies
- Increased pressure on pharmaceutical companies' margins
- Enhanced monitoring of commercial compliance by authorities





Sources: LFSS 2026 (December 16, 2025) – Smart Pharma Consulting analyses

¹ Reference Price



The experiment provided for in Article 86 of the 2026 LFSS aims to secure access to medicines while reducing waste

7 Dispensing of unused medicines by hospital pharmacies

Key measures

Article 86

- Launch of an experiment
 authorizing hospital pharmacies
 to dispense certain unused
 medicines for a maximum
 period of 3 years
- A government evaluation report to Parliament is expected no later than 6 months before the end of the experimental period, to determine the relevance and, if applicable, the conditions for its generalization

Rationale

- Fight against drugs waste
 (estimated to range from € 0.6 B
 to € 1.7 B per year according to
 a report published by the Court
 of Auditors in September 2025)
- Improved access to drugs (~5,000 shortage or stock tension alerts in 2023 according to the same report of the Court of Auditors, representing an increase by 81% vs. 2021)

- Potential negative impact on sales of drugs subject to redistribution by hospital pharmacies
- Liabilities in case of adverse effects need to be clarified if an unused medicine is redistributed by a hospital pharmacy
- Additional information may be required to ensure traceability of batches redistributed by hospital pharmacies



Consulting firm dedicated to the pharmaceutical sector operating in the complementary domains of strategy, management and organization

Market Insights Series

- This series provides practical tools and recommendations to enhance the efficacy and efficiency of the most important activities or processes in place within pharma companies
- Our tools and recommendations are based on both:
 - Our consulting experience in the pharma sector
 - Our research for innovative, pragmatic and useful solutions
- Each issue is designed to be read in less than 20 minutes and not to exceed 20 pages

Social Security Financial Act for 2026 Key implications for pharmaceutical companies

- The Social Security Financial Act (LFSS) for 2026 was adopted by the National Assembly on December 16, 2025
- This paper outlines the main implications of the law for pharmaceutical companies in terms of:
 - Economic regulation of drugs (e.g., prices, taxes, clawback)
 - Measures to boost generics, hybrids and biosimilars
 - Legal rebates to retail pharmacists
 - Dispensing of unused medicines by hospital pharmacies

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching activities in advanced masters (ESSEC B-school)
 - Training activities for pharma executives
 - The publication of articles, booklets, books and expert reports
- Our publications can be downloaded from our website:
 - 43 articles
 - 75 position papers covering the following topics:
 - 1. Market Insights
- 5. Marketing

2. Strategy

- 6. Sales Force Effectiveness
- 3. Market Access
- 7. Management & Trainings
- 4. Medical Affairs
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny