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Social Security Financial Act for 2026

MARKET INSIGHTS SERIES

Key implications for pharmaceutical companies

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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

Economic regulation of drugs

1. **National Health Insurance Expenditure Target** (ONDAM)
2. Expansion of the **basket of reference countries** for drug pricing
3. Introduction of **new taxes**
4. **Clawback** ("Safeguard clause")

Other measures

5. Measures to boost **generics**, **hybrids** and **biosimilars**
6. **Retail pharmacists' legal rebates**
7. Dispensing of **unused medicines** by hospital pharmacies

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-of-pocket** expenditure
  - Ensuring the stability of **hospital tariffs**

Implications

- 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

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

With the 2026 LFSS, the CEPS[1] 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

Implications

- **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

[1] *Economic Committee on Healthcare Products*

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

3 Introduction of new taxes (1/2)

Key measures

Supplementary contribution (Article 28)

- For **all drugs**, **excluding**:
  - Generics
  - Originators under TFR[1] 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

Implications

- Increased **tax pressure** on pharmaceutical companies, as this new contribution adds to existing taxes:
  - Basic contribution[2]
  - Additional contribution[3]
  - M contribution[4]
- Risk of **delays** or **limitations** in **launching innovative drugs** in France

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

[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

Implications

- Risk of significant **financial penalties** in case of non-compliance 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

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

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	Rationale	Implications
Setting a cap on expenditure for 2026 (Article 28) ▪ **M amount** (for drugs): **€ 22.10 B** ▪ **Z amount** (for medical devices): **€ 2.16 B**	▪ **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)	▪ 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: – **Generics[1]** – **Biosimilars[2]** – **Hybrids[2]**	▪ **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

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

[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)

Implications

- **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

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

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

5 Measures to boost generics, hybrids and biosimilars

Key measures

Article 87

- Implementation of the **third-party payment** mechanism for **hybrids** and **biosimilars**
- **Biosimilars** authorized to be **prescribed in INN**
- **Capped reimbursement base**[1] in case of unjustified non-substitution:
  - Adjustment period[2] for the reimbursement base **reduced** from 2 years to **1 year** for **generics**
  - Adjustment period[2] 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**

Implications

- 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

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

[1] At the level of the generic, hybrid, or biosimilar with the highest price which belongs to the same group of substitutable medicines –
[2] From the date of publication in the Official Gazette of the price of the first reimbursed generic, first hybrid or first biosimilar

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 TFR**[1]
  - **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)

Implications

- 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

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

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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

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Best regards

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