

Generics, biosimilars & hybrids development

MARKET INSIGHTS SERIES

Conditions for a dynamic and sustainable development in France

November 2025

Generics, biosimilars and hybrids are essential to patient care, the sustainability of the French healthcare system and the economic balance of retail pharmacies

Main contribution of generics, biosimilars and hybrids

€ 2.8 B¹

annual savings for the French healthcare system

- As the main contributors to the control of healthcare spending, these drugs represent a guarantee of **budgetary efficiency**...
- ... and should not be **sacrificed** to absorb the **inflationary cost** of innovative drugs

+28 million

patients treated with affordable drugs

- Patient access to drugs with an average ex-factory price limited at **€ 0.16 per generic tablet**...
- .. and this, most often for drugs of **major therapeutic interest** (representing over 70% of generic companies' portfolio)

28%

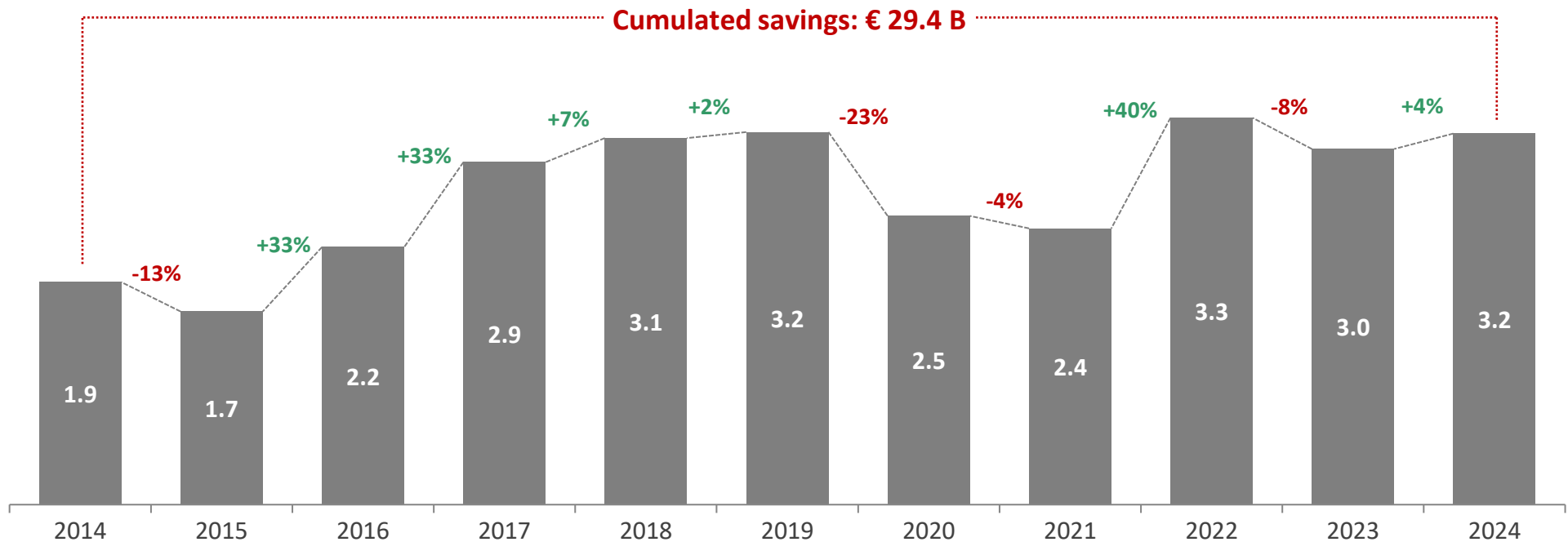
of retail pharmacies' average gross margin

- **Significant contribution** to the **economic balance** of retail pharmacies...
- ... supporting the **fight** against the **worsening** of **medical deserts**...
- ... and thus, **ensuring a better access to drugs for patients**

Cumulated savings generated by generics amounted to 29.4 B between 2014 and 2024, corresponding to an average annual saving of € 2.7 B

Savings for the National Health Insurance Fund generated by retail generics

In € B¹



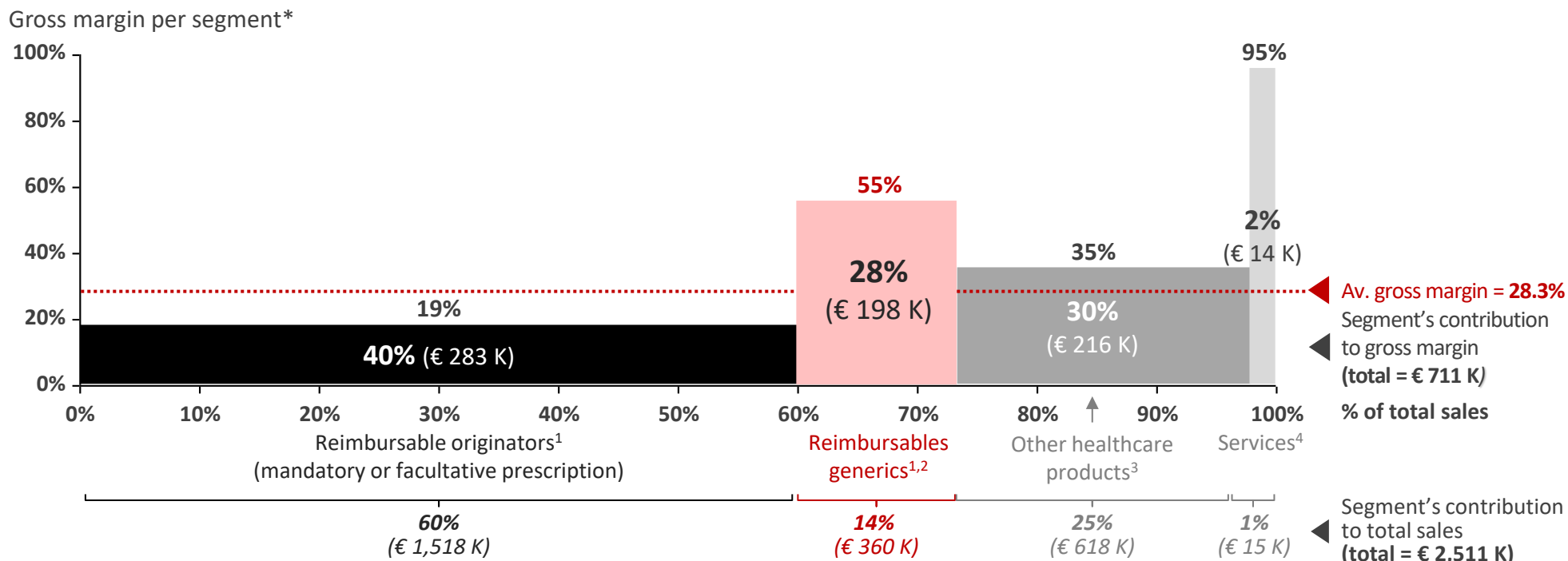
Generics, biosimilars and hybrids could generate up to ~ € 4 B annual savings between 2026 and 2030, provided that additional measures to support their penetration are implemented

Sources: GEMME – GERS – Smart Pharma Consulting estimations and analyses

¹ Estimations based on ex-factory prices, which corresponds approximately to the amount reimbursed by the Social Security (for reimbursable drugs)

In 2024, reimbursable generics contributed to ~28% of retail pharmacies' average gross margin, though they only accounted for ~14% of their sales

Retail pharmacies' average gross margin breakdown (2024)



By 2030, generics, biosimilars and hybrids could account for up to one third of retail pharmacies' profits, highlighting the strategic relationship between retail pharmacies and drug suppliers

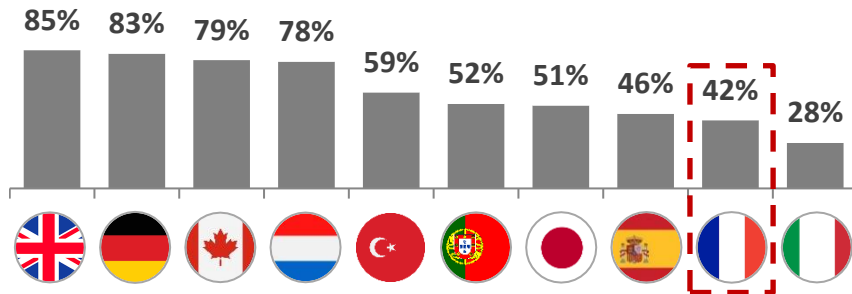
Sources: CGP Experts Comptables (2025) – Smart Pharma Consulting estimations and analyses

¹ Incl. dispensation fees – ² Incl. cooperation agreements – ³ OTC products, medical device, food supplements, para-pharmacy – ⁴ Incl. conventional missions, Covid-19 vaccination, antigen testing

There is significant room for improvement in the development of generics and biosimilars in France

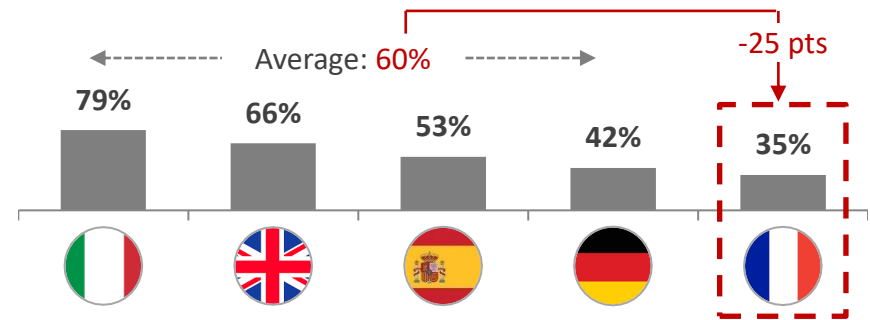
International comparison of penetration rates

Generics' penetration in volume (2023)
(% of reimbursable retail market)



- To **increase** the share of generics in France, which is lower than in many OECD countries, the following measures should be implemented:
 - **Broaden the current, overly restrictive definition** of generics
 - **Increase the prescription** of substitutable drugs and generics by physicians, which is still too limited

Biosimilars' penetration in volume (2024)¹
(% of retail biologic groups repertory)



- To reach a biosimilars penetration at the level of the other Euro-5 countries, **four major measures**, which have proven to be successful for generics, could be considered:
 1. Authorize **substitution** at biosimilars entry date
 2. Implement the **third-party payment mechanism** to promote the use of biosimilars
 3. Authorize **prescribing** by INN² only
 4. Launch a **national information campaign**

Sources: OECD – GEMME – Court of Auditors – Smart Pharma Consulting analyses

¹ Based on a study realized by the GEMME in June 2025 on the penetration rate of 13 commercialized retail biologic groups – ² International Nonproprietary Name

Though generics, biosimilars and hybrids play a major role in limiting healthcare spending, current and potentially future regulations are putting their sustainability at risk

Main economic threats to generics, biosimilars and hybrids

**Significant
price
cuts**

**Overwhelming
sectorial taxation**
(e.g.: clawback¹, additional tax)

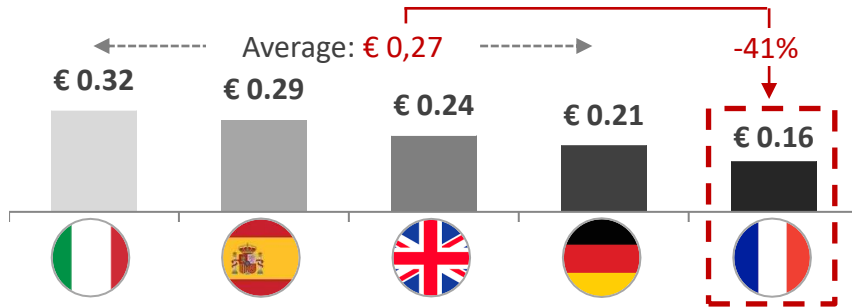
**Introduction
of national
tendering procedures**

**Financial penalties in the event
of non-compliance with safety
stocks requirements**

To achieve savings, French authorities should focus on increasing the penetration of generics, biosimilars and hybrids rather than lowering their prices

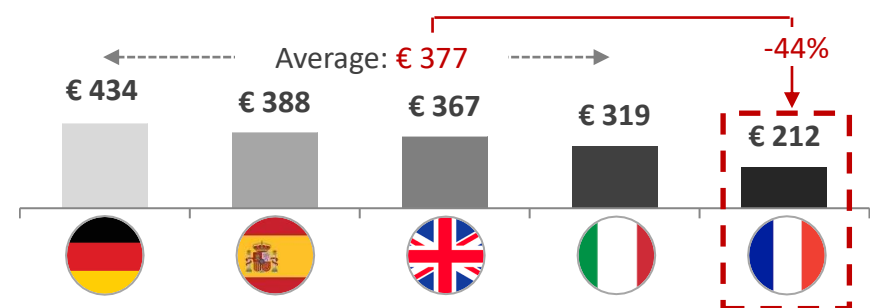
International comparison of prices

Average price of a **generic** tablet (2023)¹



- Over time, the regulation of substitutable drugs has resulted in **French average prices** being **more than 40% lower** than those observed in other Euro-5 countries
- For 2026, an **additional price cut on generics** of **€ 200 M** is being **considered** as part of the **2026 Social Security Financing Act Project (PLFSS)**, which would correspond to the 2021, 2022 and 2023 total cumulative price cuts

Average price of a **biosimilar** standard unit (2024)²



- For biosimilars, the **average price** set by the Government is also **lower** than in other Euro-5 countries
- These low prices, combined with the **rebates** granted to retail pharmacists to remain competitive, are **weakening biosimilars' suppliers...**
- ... as it has been the case for many years with generics suppliers

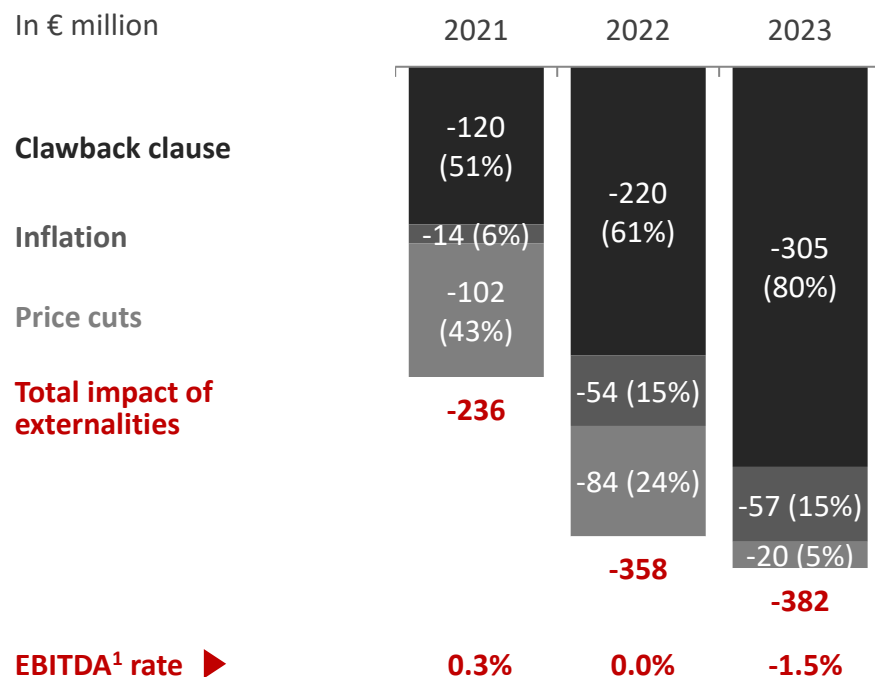
Sources : GEMME – Smart Pharma Consulting analyses

¹ Based on a study realized by the GEMME in January 2025, which compares the ex-factory price of 4,600 reimbursable generics –
² Based on a study realized by the GEMME in June 2025, which compares the ex-factory prices of 13 commercialized retail biologic groups

The development of generics, biosimilars and hybrids should no longer be financially penalized, as is currently the case with the clawback clause

Clawback clause

Impact of externalities on the profitability of generics suppliers on the retail reimbursable market



- **Generics suppliers** have been particularly **weakened** by the **clawback clause**, the amount of which has been **multiplied by 2.5** between 2021 and 2023...
- ... which contributed to generating a negative profitability of **-1.5% in 2023**
- Applying this contribution to generics, biosimilars and hybrids would not only be **unfair**, but also **illogical**...
- ... because the more savings suppliers generate, the more they are penalized
- The development of generics, biosimilars and hybrids should be based on a **predictable** and **sustainable economic model**, with an **exemption** from the **clawback clause**

Sources: GEMME – Smart Pharma Consulting

¹ Earnings Before Interest, Taxes, Depreciation and Amortization

Implementing national tendering procedures for generics and biosimilars is likely to disadvantage domestic production and increase the risk of drug shortages

Introduction of national tendering procedures

Social Security Financing Act Project (PLFSS) 2023

- The implementation of **national tendering procedures** for **generics** had been planned for the end of **2022**
- This measure, considered as **devastating** by **pharmacists' unions, VTOs¹** and **generic suppliers**, was ultimately rejected

Social Security Financing Act Project (PLFSS) 2026

- The **article 35** of the **PLFSS 2026** reintroduces the possibility of **multi-award national tenders** for a maximum period of **two years**, as part of a pilot program lasting up to **five years**
- This would apply to **mature retail generics** and **biosimilars**

- These tenders should include **environmental criteria** to **favor** products manufactured in **France** or **Europe**
- However, in practice, they are likely to be **won by the least expensive product...**
- ... thus, **disadvantaging domestic production**, which is usually more expensive¹
- Several examples demonstrate the limits of such a system (e.g., Denmark, the Netherlands, Belgium)
- The **European Court of Auditors' report** of September 2025 points out that national tendering procedures favor the **outsourcing of production to low-cost countries** and the **concentration of suppliers** in the global market, making countries using such policies more **dependent** and **vulnerable** in terms of drug supply

Sources: PLFSS 2023 – PLFSS 2026 – European Court of Auditors – Smart Pharma Consulting

¹ For example, the hourly cost of labor in 2024 was € 47 in France, € 32 in Italy, € 28 in Spain and € 7 in Bulgaria (source: Eurostat)

Stricter financial penalties in the event of non-compliance with safety stock requirements increase the risk of generics', biosimilars' and hybrids' shortages, thereby limiting patient access

Financial penalties in the event of non-compliance with safety stocks requirements

Social Security Financing Law (LFSS) 2025

- The **Social Security Financing Law (LFSS) 2025 tightened financial penalties** for non-compliance with safety stock requirements, increasing the penalty from **30% to 50% of the drug's turnover**
- For reference, since 2021, drug suppliers have been required to maintain safety stocks **covering at least two months of demand for any drug of major therapeutic interest (MITM)**, which account for over 70% of generic suppliers' portfolio
- This two-month period is **extended to four months** for molecules subject to **regular shortages or risks of shortages** over the previous two years
- Such financial penalties are likely to increase supply tensions, as they encourage pharma companies to:
 - **Prioritize securing their** stocks rather than supplying the retail market
 - **No longer compensate** other players' failures, so as not to risk falling below the safety stock requirement at any given moment
- The implementation of a **"flexicurity" system** would ensure better access to drugs for patients
- Such a system would allow stocks to be **temporarily under** the safety stocks requirements
- Without this system, pharma companies could **decide not to market** certain drugs, which would automatically **reduce access for patients**

To optimize the savings generated by generics, biosimilars and hybrids, it is important to support their penetration and preserve the financial situation of the involved stakeholders

Accelerate the development and protect profitability

GENERIC & HYBRIDS

- **Increase the number of substitutable drugs** (e.g., inhaled, hybrids) among the Repertory
- **Encourage physicians** to prescribe (more) substitutable drugs
- **Limit / moderate price cuts**

BIOSIMILARS

- **Apply to biosimilars the measures** that enabled generics to achieve an 85% penetration rate within the Directory
- **Launch an information campaign** on biosimilars for the general public

STAKEHOLDERS

- It would be **logical to exempt** generics, biosimilars and hybrids from the **M contribution and any new taxes¹**, as they contribute to savings for the healthcare system
 - The **strict implementation** of the **law on stock requirements** increases the **risk of drug shortages** in retail pharmacies and the associated **financial penalties** are an **important threat** for pharma companies
- The project of **national tendering** for generics and biosimilars would **weaken the suppliers** and **increase the risk of drug shortages**

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Market Insights Series

- The Market Insights Series has in common to:
 - Be well-documented with recent facts and figures
 - Highlight key points to better understand the situations
 - Determine implications for key stakeholders
- Each issue is designed to be read in less than 20 minutes and not to exceed 20 pages

Generics, biosimilars and hybrids

Conditions for a dynamic and sustainable development

- Generics, biosimilars and hybrids are essential drugs for patient care and the sustainability of both the French healthcare system and the retail pharmacies' network
- New threats endanger the current situation:
 - Regular and increasing authoritative price cuts
 - Overwhelming taxation (i.e., clawback, new specific taxes)
 - National tenders for generics and biosimilars
 - Financial penalties for failing to maintain safety stocks

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Best regards

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