FRANCE

Recent and planned developments in pharmaceutical policies 2025/2026

CHANGES IN PRICING

- **Pharmacist margins : dispensing fees**

As of 1st january 2026, dispensing fees linked to age, for filling the prescription for patient younger than 3 years and older than 70 years has increased from 1,58€ to 1,68€.
All other dispensing-related fees remain the same in 2026.

- **External price referencing**

The social security financial law for 2026 financial law allows the pricing committee (CEPS) to consider non-European countries in contractual price reduction decisions (medicines and medical devices); *pending an amendment to the implementing act.*
Social Security Financing Law for 2026 (LFSS 2026, Art. 88)

CHANGES IN REIMBURSEMENT

The Social Security Financing Law for 2026 *("LFSS 2026")* includes measures to promote the uptake of biosimilar/hybrid medicines :

- **Biosimilar/hybrid dispensing against third-party payment (> 1st September 2026)**

Extension of the "third-party payment against generics" to substitutable biosimilar and hybrid medicines ➔ If a patients refuse biosimilars substitution (respectively hybrid), they may lose the benefit of third-party payment (direct reimbursement), meaning they must pay upfront and get reimbursed later.

- **Biosimilar reimbursement : possible copayment if the patient refuses substitution (> 1st September 2026)**

2 years after the first biosimilar arrival on the market, reimbursement will be based on the price of the most expensive biosimilar within the biological substitution group (that includes the reference drug and the biosimilars). ➔ If the patient refuses biosimilar substitution and there is a price difference between the reference drug and the most expensive biosimilar, the patient will bear the cost of that difference.

- **Generic/Hybrid reimbursement : possible copayment if the patient refuses substitution (> 1st September 2026)**

1 year after the first hybrid arrival on the market (instead of two years previously), reimbursement will be based on the price of the most expensive Generic (respectively hybrid) within the substitution group (that includes the reference drug and the generics, resp. hybrids). ➔If the patient refuses the hybrid substitution and there is a price difference between the reference drug and the most expensive generic (resp. hybrid), the patient will bear the cost of that difference.

All these measures include exemptions in cases where the prescriber has expressly excluded the possibility of substitution on the prescription, due to the patient's medical condition.

OTHER CHANGES

Biosimilars – INN prescribing

"From September 2026 onward, brand-name prescribing will no longer be mandatory, with INN-only prescribing introduced to facilitate substitution.
LFSS 2026, art 87

Direct access – experimentation extended

Two-year renewal of the experimental direct access system for certain medicines (not eligible for early access), introduced in 2023: medicines may be reimbursed following an HTA recommendation, prior to the completion of price negotiations. *LFSS 2026, art. 88.*

Safeguard clause modifications

The Social Security financing Law for 2026 introduces a new tax framework and narrows its scope. It establishes a tax targeting the artificial extension of commercial exclusivity, excludes biosimilar and hybrid medicines from the mechanism, and incorporates a territoriality criterion into its calculation. *LFSS 2026*

SPECIAL TOPIC:

Regulation, pricing and reimbursement of pharmaceutical combination products

Definition

The current framework agreement between the industry representatives ("LEEM") and the pricing Committee ("CEPS") defines combination products as "a **combination of at least two medicinal products that are listed, or intended to be listed, for reimbursement, and for which—at least for one of them—the marketing authorization and the Health Technology Assessment opinion require their use in combination for all or part of the treatment duration.**" *(framework agreement, article 15-d)*

The conventional negotiation may lead to not considering, as combination therapy within the meaning of this article, those specialties associated with one (or more) products whose cost is low.

Regulation, Pricing and Reimbursement

On 31 July 2024, LEEM and CEPS signed an amendment to the existing framework agreement, aimed at providing a clearer and more structured framework for the pricing of medicines used in 'combination therapies'. This amendment formalises a policy already implemented by the Committee, which involves using the overall cost of the combination therapy as the benchmark for pricing the negotiated medicinal product, provided that a therapeutic benefit is recognised for the combination as a whole.

The framework agreement sets out principles for the pricing of the combination products (that have MA). The net cost of a drug combination is determined in two steps. First, a reference cost is established based on identified comparator medicines, according to the rules of the framework agreement, using where necessary similar or cost-based comparators. Second, this cost is adjusted according to the added therapeutic value of the combination and other usual pricing criteria set out in the French Social Security Code.

The net price of the new medicinal product(s) or of the product(s) for the relevant indication is derived from the total cost allocated to the combination, taking into account, where applicable, treatment durations.

In the absence of information on comparative therapeutic benefit as specified by the HTA body ("HAS") in its opinions, the Committee will allocate value on an equivalent basis when determining the pricing conditions for combination therapy medicines.