FRANCE

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Pharmacist margins (biosimilars)
Since July 2024, pharmacists' remuneration margins have been aligned for the dispensing of biosimilars and originator medicines, with calculations based on the price of the originator.
Arrêté du 5 juillet 2024

CHANGES IN REIMBURSEMENT

Co-payments on each medicine package :
Since 31 march 2024, it has increased from 0,5€ to 1€ (capped at 50€ per year per insured person).

OTHER CHANGES

Biosimilar substitution by pharmacist
The list of biologics a pharmacist can substitute is to be extended automatically one year after the first biosimilar of a reference group (including originators and their biosimilars) is listed for reimbursement. This period has been reduced from two to one year in the Social Security budget law for 2025 (LFSS, article 77) to increase biosimilar uptake. Pharmacists will be allowed to substitute within that group, unless the national medicines agency (ANSM) issues a contrary opinion before the end of this one-year period. Substituting a biosimilar should not result in additional costs for health insurance.

Biosimilars - payment for performance for pharmacists: according to biosimilar market share**,** *to be defined in 2025*

Biosimilars - gain sharing model for community prescribers
In 2025, gain sharing is set for only one year at 50%, (so far for ranibizumab, tocilizumab, ustekinumab). It was previously set over 3 years (at lower and degressive rates).

AGLP1: reinforced prescription for community prescribers since February 2025 to limit misuse
Implementation of a "prescription support" that allows the prescribers to verify if their prescription complies with the reimbursable indications of the medication.
There is a high level of reimbursement (one third) outside of the reimbursable indications, even though there are supply tensions. This system was therefore created to ensure that prescriptions for certain classes of drugs comply with the reimbursable therapeutic indications and the marketing authorization .The objective is to enhance the proper use of certain widely used health products that present a risk of misuse through *a priori* checks on a few fundamental criteria of the reimbursed indications.
Medicines included in the scope (so far): sémaglutide (Ozempic®), dulaglutide (Trulicity®), liraglutide (Victoza®), exenatide (Byetta®).
Other therapeutic classes or medical devices may be included.

Measures to address and/or mitigate medicines shortages
A drug shortage roadmap is set for 2024-2027, including Social security law for 2025 provisions. Main measures

- The national regulatory agency (ANSM), in charge of monitoring Security of supply and drugs shortages has activated the "winter plan" (for the second year). It aims to secure supply of 13 medicines forms (mainly paediatric) and focuses on antibiotics, fever medications, corticosteroids, asthma medication; a weekly updated dashboard is available here : https://ansm.sante.fr/dossiers-thematiques/plan-hivernal
- A white plan" that could be activated by the Minister of Health in case of emergency:
  - allowing community pharmacies to produce drugs (allowed ones)
  - controlled antibiotics dispensation : supply by units (instead of packages)could be made compulsory; antibiotics could be delivered only if a rapid test is carried out (by the pharmacist) and positive (angina, cystitis)
- Measures to maintain mature medicines on the market : reinforced obligation for a company that plans to stop production to find a buyer (otherwise it risks financial penalty), for drugs of major therapeutic interest (around 6 000 drugs), in addition to the obligation to notify ANSM 1 year before production stops
- Measures to support production relocation
- List of Medicines of Major Therapeutic Interest (MITM) published by ANSM in December 2024: medicines for which treatment interruption could be life-threatening or significantly impact patients due to disease severity. Manufacturers must implement shortage management plans, maintain a safety stock (2 months, or 4 months for high-risk medicines), and report any supply risks to ANSM. Measures like informing healthcare professionals, prioritizing distribution, adjusting supply chains, or importing alternatives may be required. Failure to comply can result in sanctions, including inspections, injunctions, or financial penalties.

SPECIAL TOPIC:
Current advances in HTA
(for EU Member States: Implications from EU-HTA Regulation)

For EU Member States:

On 11 January 2022 the EU-Regulation 2021/2282 on health technology assessment (HTAR) was published and applies since 12 January 2025. It promotes a streamlined HTA process through Joint Clinical Assessments in the EU and stipulates the use of common assessment methodologies along the HTA pathway.

Briefly outline the HTA process in your country, including whether and how the process is linked to pricing and/or reimbursement decisions.

In France, HTA process is conducted by the Haute Autorité de Santé (HAS), primarily through its Transparency Committee. The committee evaluates the clinical benefit (SMR) and the clinical added value (ASMR) of a medicine to inform reimbursement eligibility and pricing negotiations. While the SMR is used by the ministers to determines whether a drug should be reimbursed, the ASMR rating influences price setting in negotiations with the pricing committee (CEPS) among other criteria set in the law. The decision to include the medicine on the positive reimbursement list is made by the Ministry of Health (published in the Official Journal).

What are the implications of the EU-HTA Regulation on your country's existing HTA or other assessment system(s)?

Companies must still submit a reimbursement application. HAS continue to assess health technologies according to its established guidelines. Clinical data provided at the European level will not be re-requested at the national level. However, if new data become available since the publication of a JCA, they shall be filed in the national file; if necessary, HAS can request additional data from the company.

What institutional, procedural or methodological changes have been required to ensure alignment with the Regulation?

Application for early access made after the marketing authorisation granting must comply with the HTA-R i.e. can't include data already submitted to the HTA-R CG.