

France

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

2023

About ATMP, whose prices are high (higher than flat-rate amount granted to hospital – still awaiting), questions of access and long-term financing sustainability arise. A new financing model has been implemented by sharing the financing risk between the company and the health insurance company. This model is still based on a negotiation between the manufacturer and CEPS, but with the addition of two parameters: staggered payments, and payment based on real-life results.

(LFSS 2023, art. 54)

→ Awaiting implementation

2022

In order to limit the risks of shortages and to increase the security of supply of the market, it is necessary to encourage the relocation in Europe of the production of the most critical active ingredients. Security of supply is now a criterion that could be taken into account in setting the price of a drug.

(LFSS 2022, art. 65)

OTHER CHANGES

2022

Biosimilars substitution : community pharmacists are allowed to substitute a prescribed biological product with its biosimilar within a positive list and under certain conditions (no formal objection by the prescriber, patient and prescriber to be informed). So far the list includes 2 molecules : filgrastim, pegfilgrastim.

(LFSS 2022, art. 64)

Full implementation pending ministerial order on pharmacist margins

2021

Before the early access reform in July 2021, companies had to pay rebates at the end of the negotiation with the CEPS. This led to situations where companies had to pay significant amounts if the drug remained in derogatory access for a long period. The early access reform provides for annual rebates according to a defined scale, allowing companies to pay the rebates in advance and in fact to spread the payments over several years.

SPECIAL TOPIC:

Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

New measures to tackle medicines shortages to be implemented in 2023

New Road map on shortage prevention and strategy/ to be implemented in June 2023, including:

- critical drug list to be established
- strategic drug production relocation plan (France 2030 plan). See also above the implementation of the industrial criteria in price settings in 2022
- better information for patients

The National drug safety agency (ANSM) will prepare, by June, a plan for winter epidemics aiming at securing stocks, foster the availability of data and anticipating tensions.

Preparation of a "White plan" ("Plan blanc") to be activated in case of a future major disruption of supply.

Price measures to adjust for inflation

- the framework agreement between CEPS and LEEM, more precisely the article 28, expands the conditions for price increases, which can be individual, or for a therapeutic class. It may concern essential product, product with production relocalisation, or public health reasons. The quantum of price increase takes into account in particular, increase in product cost of operating documented by the manufacturer.
- a moratorium on price decreases for generics ; targeted price increases for generics produced in Europe in return of a security of supply.