

BELGIUM

Recent and planned developments in pharmaceutical policies 2022 – 2023

CHANGES IN PRICING

- 01.01.2022: Indexation of margin and delivery fee pharmacists
- 01.06.2022: Pre-indexation of margin and delivery fee pharmacists
- 01.10.2022: price alignment biologicals and biosimilars of etanercept
- 01.01.2023: indexation margin wholesalers and delivery fee pharmacist

CHANGES IN REIMBURSEMENT

- 01.01.2023: Monthly application of the reference reimbursement system, instead of every 3 months
- 2023: Reform and harmonisation of the different saving measures
- 2023: Start of the reform of the reimbursement procedures
- 2023: Start of the simplification of the conditional reimbursement

OTHER CHANGES

Start 2023:

Formal commitment of the prescribers for rational prescription of PPI, statins, antidepressants, antipsychotics, benzodiazepines, opioids, gabapentine, pregabalin

Start 2023:

Tackle Antimicrobial Resistance (AMR)

SPECIAL TOPIC:

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

1) Medicine shortages

Already existing:

- ✓ The Medicines Agency (FAMHP) analyses every notified shortage, using a decision tree.
 - In case of shortage of an essential medicine without alternative in Belgium, the responsible MAH can obtain a derogation to import and distribute its unavailable medicine (after approval of the FAMHP).
 - In case no solution can be found, a taskforce is put in place with experts to prioritize the indications and to find alternative treatments.
- ✓ A working group is in place, led by the FAMHP, together with pharmaceutical industry, NIHDI, Pricing Service, pharmacists, hospital pharmacists, patient organisations, wholesalers, sickness funds, ministry of health and parallel importers/distributors.
- ✓ Stock Monitoring Tool (2021): This tool is used for medicines that play an important role in the fight against COVID-19. This was first done manually, but in the meanwhile automated and will be expanded to other essential medicines.
- ✓ Regulation to allow substitution by pharmacists in case of shortages (2022).

2023:

- ✓ Export ban for essential medicines and obligation to notify export.
- ✓ Regulation to oblige the responsible company to compensate the extra costs due to critical shortages (not yet in place - ongoing).

2) Price increases:

Timeline:



Conditions and rejections: There are no specific conditions defined. The requests are analysed one by one, based on economic motivation and the prices in the other EU countries. Based on the motivation, a rejection is possible, but more often there will be a limitation of the price increase. Therefore, the prices in other EU countries are used (alignment to the price in a specific country or to the average price in the EU countries)

Price increases 2018 – 2022:

YEAR	2018	2019	2020	2021	2022
Number of accorded price increases for reimbursed medicines	22	28	99	167	97

Price level freezing: There are no measures in place to freeze the price levels of (all or certain groups of) medicines.

- 3) **Other measures related to current challenges:** increased (informal) collaboration with other countries on defining willingness-to-pay of high-priced medicines, ongoing development of exit-strategy for Managed Entry Agreements (eg in view of patent loss, alternatives on the market,...).