Belgium

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

- **Since 01.2024**: Reference system has been extended to biologicals, so price cut for originals upon arrival of biosimilar
- **Since 01.2025**: Indexation of maximum co-payment:

Category	A/Fa (vital specialities)	B/Fb (therapeutically important)		C (symptomatic treatment)	Cs (comfort treatment, f.e. allergy)	Cx (comfort treatment, f.e. contraception)
		Preferentially assured (P.A.)	Regularly assured (R.A.)			
Max. (EUR)	No co-payment	**8,30 €** (< 60 units) **10,20 €** (> 60 units)	**12,50 €** (< 60 units) **15,50 €** (> 60 units)	**10,20** € (P.A.) **15,50 €** (R.A.)	No max	No max

- **Since 01.2025**: Dispensing fee for pharmacists 5,22 € (was 5,06 €) + slight increase of economical margin

General remark:
Federal elections in June 2024 and long negotiations to find a coalition, so no 'major' changes in pricing regulation

CHANGES IN REIMBURSEMENT

Implemented:

- **Since 07.2024**: Change in quorum Commission for Reimbursement (presence required of 16 voting members instead of 18)
- **Since 07.2024**: Lump sum will cover 100% of the reimbursement for medicines for patients in hospital
- **Since 04.2025**: Patient groups will be heard during evaluation by the Commission for Reimbursement (non-voting member). They will act as an external expert during assessment

Ongoing:

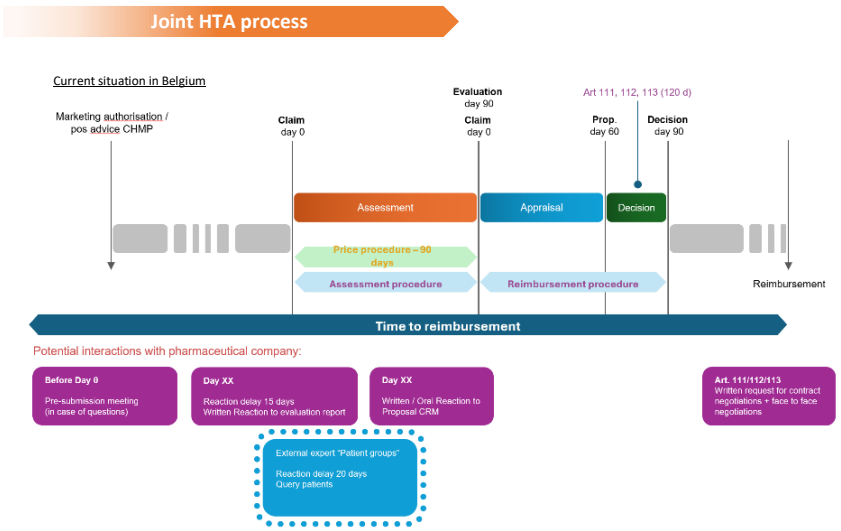
- Reform Chapter IV: administrative simplification of reimbursement conditions
- **From 09.2025**: patient will no longer have to submit a paper certificate to the health insurance fund to be reimbursed (= faster reimbursement)

OTHER CHANGES

- The royal decree restricting the prescription of GLP-1 analogues to prevent shortages has been extended until november 2025
- **Since 01.2025**:
  - Essential drugs, when not available in Belgium, can be imported from other countries and will be reimbursed. Patient cost stays the same, additional costs will be funded by companies
  - Change in law regarding MEA for new pharmaceutical specialities/indications: automatic expiry of agreement after patent expiry and extinction agreement after expiry of agreement
- **From 01.2026**: EARLY and FAST procedures: to improve EARLY access for patients with unmet medical need before market authorisation and to accelerate access (FAST) after market authorisation (ongoing)
- **From 01.2027**: determining indicative post-contract price (iPCP): at the latest one year before the end of the period of protection of the main active substance
- Transparency regarding MEA in line with Roadmap: publication of public parts of MEA on website NIHDI + other transparency envisaged in nearby future

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

As of January 2025 EU member states will carry out HTAs jointly. The Belgian Health Care system (NIHDI) will lead the consortium that has been tasked by the EC with the implementation of this joint work.
The NIHDI will play a managing role, to ensure efficient collaboration between the 34 HTA agencies, representing 19 EU member states



Implications
- Incorporation of European reports in national Belgian reports
- Reviewing draft European reports
- Participation to European consultations (non-existent on national level)

Changes required
- Internal staff training
- Consultation rounds with stakeholders
- Adaptation of the legislation and of the internal house rules for the reimbursement committee

Obstacles and challenges
- Spending staff hours to various European procedures that will run in parallel
- Adaptation of information exchange moments within The Beneluxa Initiative