

BELGIUM

High-cost medicines

- Specific funding / reimbursement schemes for high-cost / innovative medicines:

During the reimbursement procedure “contract” negotiations can take place.

Scope:

- class 1 (added value) and orphan drugs
- new indication (with a therapeutic/social need)

- if the Reimbursement Committee formulates a negative advice regarding the inclusion on the (positive) reimbursement list
- a “contract” is concluded between the NIHDI and the pharmaceutical company
- a “contract” has a duration of 1 to 3 years (1 possible review with a maximum duration of 3 years)
- a “contract” defines the compensatory mechanism(s), such as
 - reimbursement of a % of the sales
 - reimbursement of (part of) the difference between the real and the estimated cost
 - price reduction of another/other medicines
 - reimbursement of the difference between the price and the granted reimbursement level

- Pricing of innovative medicines:

Innovative medicines are priced according to the ordinary pricing rules.

- Are innovative medicines bound to specific settings (e.g. hospital setting)?

Innovative medicines (like other medicines) can be bound to specific settings

- if special requirements/expertise are needed for e.g. safety reasons
- if a hospital setting is desirable
- for budgetary reasons

Key challenges of innovative medicines and approaches for solutions

Coordinated access to orphan medical products

Based on set up of **programs** between companies and groups of competent authorities

Added value through a **coordinated approach**

- in defining and identifying **Unmet Need** and assessing the value of the solution
- in assessing cost and deciding on reimbursement
- in taking care of patients