BELGIUM

National Institute for Health and Disability Insurance (NIHDI)

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PPRI Pharmaceutical Pricing and Reimbursement Information

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11,7 mio inhabitants
pharmaceutical expenditure: approx.. 5 billion €

PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES

new pharmaceutical

MARKETING AUTHORISATION

Minister of Public Health or EMA

Task: decision on marketing authorization and registration

Criteria: quality-safety-efficacy

Advisory board (Federal Agency FAMHP):

Medicines Committee

PRICING

Minister of Economic Affairs

Ex-factory level

Task: maximum price setting

Criteria: statutory pricing (external & internal price referencing)

Advisory boards (Federal Agency for Economic Affairs):

Price Committee for Pharmaceuticals (reimbursable) | *General Committee for Price Setting (non-reimbursable)*

Wholesaler level

Maximum percentage wholesale mark up scheme
(set by Minister of Economic Affairs)

Pharmacy level

Fixed pharmacy mark up scheme
(set by Minister of Economic Affairs + Minister of Social Affairs)

Distribution via wholesaler & public pharmacy ← Pharmaceutical company → *Direct supply to hospital +/- wholesaler*

REIMBURSEMENT

Minister of Social Affairs

Task: decision on reimbursement & reimbursement level

Criteria: therapeutic value, price, medical practice related to therapeutic & social needs, budget impact, pharmaco-economics

Advisory boards (NIHDI):

Committee on Reimbursement Medicines (CRM) and Taskforce on Negotiations (art 81/111)
Technical Board for radioisotopes

Positive Reimbursement list (pharmaceuticals)
(in- & out-patient sector)

Fixed reimbursement level

Chapter I – 3852 specialties
Reimbursement if prescribed within authorized indications (SPC)
No additional restrictions on reimbursement

Chapter II – 168 specialties
Reimbursement for all common indications (based on generally applied recommendations for good practice)
Reimbursement does not depend of a prior authorization delivered by the sickness fund
Prescribing HP must respect the recommendations and keep certain documents in the patient file ("a posteriori" control)

Chapter III – 286 specialties
Solutions for perfusion / parenteral nutrition
Reimbursement if prescribed within authorized indications (SPC)
No additional restrictions on reimbursement

Chapter IV – 3027 specialties (sometimes through Managed Entry Agreements
Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the sickness fund ("a priori" control)

Chapter V – 1 specialty
Reimbursement imposed by the Minister of Social Affairs

Chapter VIII – 133 specialties
Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the sickness fund ("a priori" control) - after execution of an associated predictive test and linked to CIVARS (and PITTER register)

No fixed reimb. level

Chapter IVbis
Pharmaceuticals not authorized in Belgium – imported by pharmacist
Reimbursement is subject to particular reimbursement conditions and depends of a prior authorization delivered by the sickness fund ("a priori" control)

Fixed reimb. level

Positive Reimbursement list (radioisotopes) – 590 products
(in-patient sector)

Co-payment (pharmaceuticals)

Out patient (RB = Reimbursement Base):

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.)			
$RB_{ex\ fact}$ < 14.38 EUR	0 % $RB_{ex\ fact}$	26,52 % $RB_{ex\ fact}$	44,20 % $RB_{ex\ fact}$	88,39 % $RB_{ex\ fact}$	106,07 % $RB_{ex\ fact}$	141,43 % $RB_{ex\ fact}$
$RB_{ex\ fact}$ ≥ 14.38 EUR	0 EUR + 0% $RB_{ex\ fact}$	1,50 EUR + 16% $RB_{ex\ fact}$	2,50 EUR + 27% $RB_{ex\ fact}$	5,00 EUR + 54% $RB_{ex\ fact}$	6,00 EUR + 65% $RB_{ex\ fact}$	8,00 EUR + 86% $RB_{ex\ fact}$
Max. (EUR)	No co-payment	8 (< 60 units) 9,9 (> 60 units)	12,1 (< 60 units) 15 (> 60 units)	9,9 (P.A.) 15 (R.A.)	No max	No max

In patient:

Ambulatory:

Category	A/Fa	B/Fb		C	Cs	Cx
		Preferentially assured (P.A.)	Regularly assured (R.A.)			
	0 % RB	15 % RB	25 % RB	50 % RB	60 % RB	80 % RB

Hospitalized:

flat-rate amount of EUR 0.62 per day of stay

Reference Pricing System (RPS) in a nutshell

- Monthly
- When first generic/biosimilar is reimbursed and available on the Belgian market

Active ingredient > 12 years reimbursed :

Decrease rate	Cat. A	51,52 %
	Other	44,75 %

Active ingredient < 12 years reimbursed :

Sales (EUR)		< 3mio	3 mio <30 mio	30 mio < 60mio	≥ 60 mio
Decrease rate	Cat. A	61,22 %	63,64 %	66,06 %	68,49 %
	Other	55,80 %	58,56 %	61,32 %	64,09 %

National governmental disease program

- Art 56 "children cancer medication": aim of the agreement is to provide equal and structural funding for cancer medication and supportive medication for children and young adults. Since 01 January 2024, the agreement foresees the reimbursement of approximately 50 identified 'off-label' cancer drugs.

Reimbursement process (HTA)