Pricing & Reimbursement of medicines in Belgium

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7th June 2017
Overview

- Drug Pricing and Reimbursement system
- Global (fixed) budget mechanisms for pharmaceuticals in Belgium
- Process and Factors associated with fixed budget mechanism
- The most recent reforms about drug pricing system and fixed budget mechanism
- Rebate (clawback) system for pharmaceuticals
Key Features

**FEDERAL GOVERNMENT**

Marketing Authorization
- Minister of Public Health
  - FAMHP

Price Setting
- Minister of Economy
  - Pricing Service

Reimbursement
- Minister of Social Affairs
  - NIHDI

**FLEMISH COMMUNITY - FRENCH COMMUNITY**

Health Promotion
Preventive Measures
Homes nursing/elderly
Key Features - legislation

**Marketing Authorisation**
- Mainly regulated at European level
- European authorisations / national authorisations

**Pricing and Reimbursement**
- Regulated at national level

  - Strict deadlines (90 days + 90 days)
  - Transparency:
    - Evaluation based on objective and verifiable criteria
    - Evidence Based Medicine + pharmaco-economics

**Pricing**
  - Book V Section 2 of the Code of Economic Law: the law of 3 April 2013 “Setting the prices of drugs and similar products”
  - Execution regulated by the royal decree of 10th April 2014

**Reimbursement**
  - Principles adopted by the government in October 2000
  - Legal basis established in law of 14th July 1994
  - Execution regulated by the royal decree of 21st December 2001
Procedure

- Price application / procedure depends on “status”
- A maximum price is set by Economical Affairs

**REIMBURSED**

- With prescription
  - Original pharmaceutical product
  - Generic, copy, hybrid, biblio

**NON-REIMBURSED**

- With prescription
  - Original pharmaceutical product
  - Generic, copy, hybrid, biblio

**OTC**

- Radiopharmaceuticals
- Raw materials (compounding)

Innovative (non-reimb) drugs containing a new active ingredient and having a new therapeutic indication => notification
**Price setting decision** is based on

- Therapeutic value
- Price of comparators (similar MOA, similar indication,...)
- EU prices of the product

Ex-factory price = ± 50% of public price

Based on comparators & EU prices

‘Price structure ex-factory price’:  
  ✓ purchase price  
  ✓ import & distribution costs  
  ✓ R&D Belgium  
  ✓ medical information (dispatch, storage)  
  ✓ salaries, general costs, ...
Reimbursement procedure

Since 2002 ‘Evidence Based Medicine’ and ‘pharmaco-economics’ established in the legislation (RD of December 21, 2001)

Reimbursement application

- The company introduces a claim for reimbursement (or change of modalities) at the CRM

OR

- A change of reimbursement modalities is introduced by the CRM or Minister

- Mostly applications for officially registered indications, off-label reimbursement is possible on request of CRM or Minister

Decision on reimbursement

- Made by Minister of Social Affairs and based on proposition of “Commission of Reimbursement of Medicines” (CRM)
  - reimbursement conditions
  - reimbursement level + level of co-payment
    - (reimbursement level ≤ max. price set by Economical Affairs)

Time limits are very strict! If not respected → latest proposition of pharmaceutical company is accepted
Marketing authorisation / pos advice CHMP

Price procedure (90 days)
- Claim day 0
- Evaluation day 90
- Proposal day 150
- Decision day 180

Assessment

Appraisal

Decision

Convention negotiations (120 d)

Time to submission

Reimbursement procedure

Time to reimbursement

Potential interactions with pharmaceutical company:

Before Day 0
- Pre-submission meeting (in case of questions)

Day 60
- Written / Oral Reaction to evaluation report

Day 120
- Written / Oral Reaction to Proposal CRM

Art. 81 or Art 81.bis
- Written request for contract negotiations + face to face negotiations

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Evaluation and assessment

Marketing Authorization versus Reimbursement

**Marketing Authorization (MA)**

1. European Centralised or MRP/DCP (or national procedure)

2. Evaluation based on
   - Pharmaceutical quality
   - Safety
   - Efficacy

3. Benefit/risk balance of the drug **on its own**

**Reimbursement decision**

1. Per member state

2. Evaluation goes **beyond** MA elements:
   - Effectiveness
   - Convenience
   - Others

3. **Relative therapeutic value** as compared to alternatives

4. **Relative economic value** as compared to alternatives $\Delta C/\Delta E$
Criteria for evaluation and assessment

Questions addressed by reimbursement procedure:

- Clinical data (RCT)
- Epidemiological data
- Real Life data
- Health economics data ('willingness to pay')
- Budget impact data ('ability to pay')

**Efficacy**
(werkzaamheid/efficacité)
controlled setting
= Can it work?

**Effectiveness**
(doeltreffendheid/utilité)
daily practice
= Does it work?

**Efficiency**
(doelmatigheid/efficience)
cost-effective
= Is it worthwile?

Drummond MF. Et al.,
« Methods for the Economic Evaluation of Health Care Programmes”, Ch.8
Types of claims

CLASS 1: innovative drugs - added therapeutic value – ‘first in class drugs’
- Reimbursement basis according to the demonstrated therapeutic added value taking into account the galenic form, the dose and the pack size

ORPHANS: orphan status designated by EMA
- Reimbursement basis according to the demonstrated therapeutic added value taking into account the galenic form, the dose and the pack size
- Similar to class 1 procedure, except no pharmaco-economic assessment

CLASS 2: ‘me too’ drugs - comparable value (subclasses 2A, 2B and 2C)
- Reimbursement basis cannot exceed these of the reference drug fixed by the Commission

CLASS 3: generics, hybrids, copies… (registration type) (subclasses 3A, 3B and 3C)
First generic: fixed price reduction compared to reference product
- Other generics already on the market: price setting not based on reference product, but on prices of other specialities in cluster

BIOSIMILARS: biosimilar registration
- Reimbursement basis cannot exceed these of the reference drug fixed by the Commission
- Similar to class 1 or 2 procedure (depending if applicant provides pharmaco-economic data)
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Health care budget RIZIV-INAMI 2016

- Physicians: 33%
- Pharmaceuticals: 17%
- Hospitalizations + one day: 23%
- Other health care: 25%

Health care budget 2016 fixed at **23.8 billion euro**

Budget pharmaceuticals 2016 fixed at **4.1 billion euro (17%)**
Fixed budget mechanisms to control health insurance expenditures

- Restricted reimbursement (different chapters: I, II, IV...)
- Differential reimbursement (different categories: A, B, C, Cx ..)
- Revision (re-assessment clinical evidence and/or budget)
- Managed Entry Agreements
- Reference Reimbursement System – Patent Cliff

And also...
- Price reduction measure “Old medicines”
- Pay back (claw back) system
- Reimbursement dependent on social status
- Maximum Billing or Maximum Invoice
- Lump sum reimbursement at hospital
- INN prescription
- Price freeze of reimbursed medicines
## Restricted reimbursement

### Positive list (September 2016: 7,292 packages listed)

Listed in different chapters:

**UNRESTRICTED REIMBURSEMENT**  
chapter I

- Reimbursed:
  - all indications
  - for all patients
  - prescriptions by all prescribers

**RESTRICTED REIMBURSEMENT**  
chapter II and IV

- Reimbursed:
  - selection of indications
  - for selection of patients
  - prescriptions by selection of prescribers

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## Restricted reimbursement

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No restriction for reimbursement.</td>
</tr>
</tbody>
</table>
| II      | Reimbursement for all common indications (originating from the recommendations of the Reimbursement Committee and based on generally applied recommendations for good practice).  
**“A posteriori” control:** the prescriber has to keep certain documents in the patient file. |
| IV      | Reimbursement is subject to particular reimbursement conditions.  
**“A priori” control:** a prior authorization is delivered by the medical officer of the health insurance. |
# Reimbursement categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Preferential reimbursement</th>
<th>Normal reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category A</strong></td>
<td>100% reimbursed</td>
<td>100% reimbursed</td>
</tr>
<tr>
<td>→ Absolutely essential medicines (needed to survive)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>→ e.g. oncology</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Category B</strong></td>
<td>maximum € 7,80</td>
<td>maximum € 11,80</td>
</tr>
<tr>
<td>→ Important medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>→ E.g. some antibiotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Category B (big pack (≥ 60 units))</strong></td>
<td>maximum € 9,70</td>
<td>maximum € 14,70</td>
</tr>
<tr>
<td><strong>Category C</strong></td>
<td>maximum € 9,70</td>
<td>maximum € 14,70</td>
</tr>
<tr>
<td>→ Symptomatic treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>→ E.g. loperamide (diarrea)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Category Cs</strong></td>
<td>without maximum patient contribution</td>
<td>without maximum patient contribution</td>
</tr>
<tr>
<td>→ e.g. anti allergic medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Category Cx</strong></td>
<td>without maximum patient contribution</td>
<td>without maximum patient contribution</td>
</tr>
<tr>
<td>→ Contraceptives</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Revisions (re-assessment clinical evidence and/or budget)

**Principle**
- “Individual revision” as part of ministerial decision to modify the list of reimbursed medicines (inscription or modification)
- Confirmation or not of postulated assumptions
- Possible outcome of revision: modification of reimbursement modalities or level of reimbursement, or even delisting
- Often real life (local) data is asked (eg observational studies, registries)

**Scope**
- Class 1 products and orphan drugs: *mandatory*
- Class 2, Class 3 products and application for modifications: *optional*

**Term**
- 18 months to 3 year after first inscription on list or after modification of conditions

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Managed Entry Agreements

Rationale
- **New generation pharmaceutical specialties** (orphan drugs, biotechnological or personalized based medicines, ..) are associated with exuberant price tags
- Growing need for systems that can **limit their budgetary impact**

Principle
- By **negotiations** with pharmaceutical company a **contract** can be concluded between NIDHI and a pharmaceutical company
- Agreements try to link the cost of a medicinal product to its **specific added value**, and no longer to the willingness-to-pay
- **Temporary reimbursement** based on conditions set out in contract (T)

Scope
- **Access** to promising therapies for patients
- **Risk sharing** in case of uncertainties
  - Clinical uncertainty
  - Budgetary uncertainty
Managed Entry Agreements

Procedure
- Possible upon request of Commission of Reimbursement of Medicines or when CRM cannot formulate proposition
- Permanent working party
- Max. 120 days negotiation

Contract
- Facial price
- Terms of compensation for budgetary risks
- Terms of scientific reporting and/or evaluation
- Notification of turnover
- Reimbursement conditions (T)

Term
- 1 to 3 years, followed (or not) by a normal procedure
Reference Reimbursement System – Patent cliff

- **Linear price-cut** on ex-factory level if **generic available** (2 months prior)
- **ATC5 level** (molecule)
- **executed 4 x per year**

**Exceptions**
- for the intravenous form of a original pharmaceutical (except if the reimbursed intravenous alternative (generic or copy) is/becomes also available)
- for pharmaceutical forms with a proven substantial therapeutic added value

- **Additional decrease** at the moment of opening the cluster **if mesure 'old medicines' has not yet been applied**:
  - min 54,35%
  - min 60,72% - category A
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Group revisions

Re-evaluations of products that are already reimbursed

⇒ Evidence Based Medicine-guidelines are used to evaluate the current situation

⇒ **Group revision** = a revision for all products that are reimbursed for the same or a similar indication, based on the ATC-code.

  introduced by the CRM or Minister of Social Affairs

⇒ **“Change of reimbursement modalities”:**
  to change the current reimbursement criteria to make them more in line with Evidence Based Medicine-guidelines.

  introduced by the CRM or Minister of Social Affairs
Recent reforms on pricing and fixed budget mechanisms

e.g. ANTIBIOTICS

⇒ Group revision:

⇒ Reimbursement category was changed from B to C
   = higher patient contribution

Aim:

more conscious use of antibiotics:
   - Reduce overuse of antibiotics in Belgium
   - Stop growing resistance to antibiotics

Indirect consequence:

savings
Recent reforms on pricing and fixed budget mechanisms

The Collaboration Initiative

Participating countries

**B**
- Ministry Public Health and Social Affairs
- KCE
- RIZIV - INAMI

**NL**
- Ministry VWS
- Zorginstituut Nederland

**LUX**
- Ministries Public Health and Social Affairs
- respective administrations

**A**
- Federal Ministry of Health and Womens’ Affairs
- Austrian Institute of Public Health
- Main Association of Austrian Social Security Institutions

April 2015: NL + B
September 2015: + L
June 2016: + A

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International interest…
It is not about…..

Belgium, Netherlands team up to take on pharma over prices

Until now pricing was almost exclusively negotiated between one country and company.

By RINET O’DONNELL | 2/4/15, 1:56 PM CET | Updated 2/4/15, 12:04 PM CET

The Dutch and Belgian health ministers are teaming up to negotiate prices with drug firms, in a bid to gain new leverage and economies of scale as they face a crop of pricey new drugs.

The announcement late on Monday — by Edith Schippers of the Netherlands and Maggie De Block of Belgium — was made at the informal meeting of European ministers in Riga.
The Collaboration Initiative

A proof of concept for the ‘coalition of the willing’ to collaborate on

Health Technology Assessment

Horizon Scanning

Information Sharing on pharmaceutical markets, prices and disease specific cross border registries

Pricing and Reimbursement including joint negotiation
Price and Reimbursement
*Including Joint negotiation(s) for Managed Entry Agreements*

Possible outcomes of the pilot(s):

- common assessment report
- commonly negotiated agreement/contract/financial arrangement
- common BE-NL-LUX-A registry

NOT joint procurement
The Collaboration Initiative

Where are we now?

Objective is to examine and test in practice true collaboration

Feasibility and added value (lessons learned) of the collaboration in the different areas will be documented (terms of reference and communication), evaluated and shared with stakeholders and other interested Member States

Therefore need to be able to work in ‘serene’ environment (discretion equals NOT intransparency), based on mutual understanding and trust

Commitment to play an active role on EU level (EUNetHTA JA3, MoCA, Senior Party, EU presidency, etc..)
Where are we now?

Expansion is welcome, but:

It’s not a ‘set menu’
  Step-wise approach in participation
  Different mandate/contribution for information scanning vs. Joint negotiations needed

Reimbursement systems need to align

Political will is essential

Voluntary participation
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Pay back (claw back) system

Principle
- Pay back share of revenue by manufacturers, if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded
- Most often based on an annually approved global target-budget
- Exemptions (e.g. orphans, reimb in cat Cx, blood derivates, MEAs)

Scope
- Share financial risk of budget overshooting between all stakeholders (manufacturers/wholesalers or pharmacists and payers)
- Rest on assumption that industry, wholesalers and pharmacists steer the volume and can be held responsible for volume increases

Trends in Belgium
- Classic pay back system installed since 2006
- Lower pay back percentages since 2010 as no budget overshoot in 2009
- Due to budgetary instable situation, additional taxes installed

Source: Carone et al. Economic Papers 461 | September 2012. Cost-containment policies in public pharmaceutical spending in the EU
Current types of pay back in Belgium

- **Contribution** per package
  - ca. 1500€ per available package
  - Exception if revenu by particular package < 61 973.38€

- **Taxes**
  - Yearly defined in Program Law
  - Often paid in two terms (advance + final payment)
  - Different types
    - “Classic tax”: 6.73% on total revenu*
    - “Crisis tax”: 1% on total revenu (will be abolished if budgetary situation improves)*
    - “Subsidiary tax”: percentage on total revenu fixed if budget overshoot is expected [0 to 3.5%]*
    - “Marketing tax”: 0.13% on total revenu (not officially installed yet)
    - “Orphan tax”: percentage per ‘revenu slice’: 0-3-5%
Advantages

- Powerful tool for public authorities to prevent budget overshooting
- Increases predictability of the level of public pharmaceutical expenditures
- Alternative to price reductions of pharmaceutical products and therefore often preferred by the industry
- Payback does not aggravate the problem of parallel trade, as listed prices are unchanged (in contrast to price reductions)
- Technically relatively easy to implement, provided that there is a well-functioning IT-system registering all sales of reimbursed medicines
- May be conducive to government and industry working towards ensuring reduction of unnecessary consumption

Source: Carone et al. Economic Papers 461 | September 2012. Cost-containment policies in public pharmaceutical spending in the EU
**Downsides**

- If the budget is set too high with respect to actual health care needs
  => over-consumption of pharmaceuticals can be incentivised

- If the budget is set too low with respect to actual health care needs
  => industry is penalised by payback for serving actual health care needs

- May lower incentives for structural reforms, as it in theory guarantees that all excess consumption as defined by the target budget is paid back

➢ Pay back system should be aligned with existing or additional incentives for rational use of medicines aimed at the distributors of medicines and physicians

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*Source: Carone et al. Economic Papers 461 | September 2012. Cost-containment policies in public pharmaceutical spending in the EU*