Drug policy in Belgium: Pricing & Reimbursement

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Chief Executive of Health Care Department

27th October 2016
Some numbers to start with
DRUG EXPENDITURE (health care insurance)

- Health care insurance budget 2016: €23.812.569.000
- Pharmaceutical budget 2016: €4.389.308.000 ( = 18,43 %)
Some numbers to start with

**DRUG EXPENDITURE (health care insurance)**

- Generics and copies: 10%
- Original medicines admitted to the reference reimbursement system: 19%
- Original medicines: 71%

Source: Pharmanet
Price setting & reimbursement of pharmaceuticals
**Organisation**

**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
- Elderly homes – Nursing homes
Composition of Commission Reimbursement Medicines (CRM)

30 members
- 22 voting members:
  - 7 academics
  - 8 sickness funds
  - 4 physicians association
  - 3 pharmacists association
- 8 non voting members:
  - 4 ministry rep. (Min. Social Affairs, Min. Health, Min. Econ. Affairs, Min. Budget)
  - 1 NIHDI
  - 2 Pharma.be (innovative industry)
  - 1 Febelgen (generic industry)
Reimbursement procedure

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 \(\leq\) max. price set by Economical Affairs)
Reimbursement procedure

Key Features on Pricing & Reimbursement

marketing authorisation

price procedure (90 days)

reimbursement

time to submission

procedure reimbursement

time to reimbursement

key features on pricing & reimbursement

Potential interactions with pharmaceutical company:

Before Day 0
Pre-submission meeting

Day 0
Parallel submission Price & Reimb claim

Day 60
Written Reaction to evaluation report

Day 90
Written / Oral Reaction to Proposal CRM

Day 150
Written request for contract negotiations + face to face negotiations
Evaluation and assessment:
Criteria leading to change of “positive list of reimbursed drugs”

1. **Therapeutic value based on**
   - Efficacy
   - Safety
   - Utility (therapeutic effect in daily practice)
   - Applicability (adequate package, contra-indications,..)
   - Comfort

2. **Price & BoR (price is often level of reimbursement)**

3. **Importance in clinical practice (social and/or therapeutical needs)**

4. **Budget impact**

5. **Cost / Therapeutic value**
   - H2H trials
   - ICER = ΔC / ΔE

This therapeutic value is situated at the level of
• morbidity,
• mortality or
• quality of life
**Price setting procedure**

- **Ex-factory price**:
  - 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, ...

- **Pharmacist fee included in public price;**
  - Fee Pharmacist (fixed amount of 4,16 euro)
  - Economic margin Pharmacist (calculated on ex-factory price)

- **Pharmacist fee excluded from public price:**
  - Fee ‘first delivery’
  - Fee ‘delivery INN prescription’
  - Fee ‘chapter IV’ (canceled in 2017)
Control of drug expenditures
## 1. Restricted reimbursement

### Reimbursement Chapters

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| I       | • Reimbursement when prescribed  
          • For all patients / No other conditions apply |
| II      | • Reimbursement for all common indications (originating from the recommendations of the Reimbursement Committee and based on generally applied recommendations for good practice).  
          • For selection of patients |

**“A posteriori” control**: the prescriber has to keep certain documents in the patient file.

| IV      | • Reimbursement is subject to particular reimbursement conditions.  
          • For selection of patients |

**“A priori” control**: a prior authorization is delivered by advisory physician of sickness fund.
2. Revisions (re-assessment clinical evidence and/or budget)

Principle
- “Individual revision” as part of ministerial decision on reimbursement modalities
- Often real life (local) data is asked (eg observational studies, registries)

Scope
- Confirmation or not of postulated assumptions
- If necessary: modifications to reimbursement modalities or Level or reimbursement after revision

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

Disadvantage
- Instrument has been increasingly overtaken by other mechanisms (future?)
After several years of reimbursement, ex-factory price and reimbursement base of all reimbursed medication (generics and original specialities) with the same active ingredient(s) are lowered:

- 12 years: -17%
- 15 years: -2.41%

Total: -19%

Exceptions

Pharmaceutical companies can ask for a postponement of the measure if their speciality is still protected by a patent or by a supplementary protection certificate.

Pharmaceutical companies can ask non-application of the measure if:

- their speciality has already a price 65% lower than the price of the first speciality when it was admitted to reimbursement
- the active ingredient of their speciality represents in total an annual revenue lower than 1.5 million euros
4. Reference Reimbursement System

• **General**

  1. 4 times a year (January – April – July – October)

  2. Opening of a reference cluster:

     1. When a reimbursed generic with the same active ingredient(s) is available on the market 2 months before the opening of the cluster.

        ➢ A new reimbursement level is determined
        ➢ A new max. price is determined
4. Reference Reimbursement System

- Decrease reimbursement level original specialities

<table>
<thead>
<tr>
<th></th>
<th>Before March 1st 2016</th>
<th>Since March 1st 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening cluster</td>
<td>Cat. A: - 41%</td>
<td>Cat. A: - 51,52%</td>
</tr>
<tr>
<td></td>
<td>Other: - 32,5 %</td>
<td>Other: - 43,64 %</td>
</tr>
<tr>
<td>2 years after opening cluster</td>
<td>- 6 %</td>
<td></td>
</tr>
<tr>
<td>4 years after opening cluster</td>
<td>Cat. A: - 7 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other: - 5,5 %</td>
<td></td>
</tr>
<tr>
<td>6 years after opening cluster</td>
<td>- 6 %</td>
<td></td>
</tr>
</tbody>
</table>

Ex-factory level

+ measure ‘OLD’ when not yet applied
4. Reference Reimbursement System

- **Measure ‘OLD’ when unchanged**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Decrease in price and reimbursement base</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 12 years reimbursed</td>
<td>- 19 %</td>
</tr>
<tr>
<td>12 – 15 years reimbursed</td>
<td>- 2.41 %</td>
</tr>
<tr>
<td>&gt; 15 years reimbursed</td>
<td>- 0 %</td>
</tr>
</tbody>
</table>

Ex-factory level
**4. Reference Reimbursement System**

- **Reimbursement level original specialities since April 1st 2016**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Cat. A</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 12 years reimbursed</td>
<td>-60,72%</td>
<td>-54,35%</td>
</tr>
<tr>
<td>12 – 15 years reimbursed</td>
<td>-52,68%</td>
<td>-45%</td>
</tr>
<tr>
<td>&gt; 15 years reimbursed</td>
<td>-51,52%</td>
<td>-43,64%</td>
</tr>
</tbody>
</table>

Ex-factory level
4. Reference Reimbursement System

- **Generics – price at admission**

<table>
<thead>
<tr>
<th>Before March 1st 2016</th>
<th>Since March 1st 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price original medicine, lowered by:</td>
<td>Price original medicine, lowered by:</td>
</tr>
<tr>
<td>- Cat. A: - 41 %</td>
<td>- Cat. A: - 51,52 %</td>
</tr>
<tr>
<td>- Other: -32,5 %</td>
<td>- Other: - 43,64 %</td>
</tr>
</tbody>
</table>

+ ‘OLD’

<table>
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Ex-factory level

No changes at cluster opening
## 4. Reference Reimbursement System

- **Reaction firm on opening cluster - options**

<table>
<thead>
<tr>
<th>Option</th>
<th>Before March 1st 2016</th>
<th>Since March 1st 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>1°</td>
<td>$P_{public} = BR + \text{security margin (max. 25% BR / max. € 10,80)}$</td>
<td>$P_{public} = BR + \text{security margin (max. 25% BR / max. € 5,00)}$</td>
</tr>
<tr>
<td>2°</td>
<td>Intermediary between option 1° and 3°</td>
<td>Intermediary between option 1° and 3°</td>
</tr>
<tr>
<td>3°</td>
<td>$P_{public} = BR$</td>
<td>$P_{public} = BR$</td>
</tr>
<tr>
<td>4°</td>
<td>Removal by law</td>
<td>Removal by law</td>
</tr>
<tr>
<td>No reaction firm</td>
<td>Removal by law</td>
<td>$P_{public} = BR$</td>
</tr>
</tbody>
</table>
4. Reference Reimbursement System

**Exceptions**
- By law:
  - Injectable form original medicine, in case of non-injectable generics
  - Example: Amoxicilline

- On demand of the firm:
  - Original medicine with a administration form with a significantly higher therapeutic value
  - Original medicine with a significantly higher safety and/or efficacy

**Reduction reimbursement level**

<table>
<thead>
<tr>
<th></th>
<th>Cat. A</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-27.82%</td>
<td>-23.37%</td>
</tr>
</tbody>
</table>

- Measure ‘OLD’ not simultanuously

Ex-factory level
4. Reference Reimbursement System

• **Exceptions**

  • Every trimester, check if conditions for exception status are still fulfilled
    • Yes: check next trimester
    • No: Cluster will fully open

  • Decrease in reimbursement level:

<table>
<thead>
<tr>
<th></th>
<th>Cat. A</th>
<th>Other</th>
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<tbody>
<tr>
<td>&lt; 12 years reimbursed</td>
<td>-45.59%</td>
<td>-40.42%</td>
</tr>
<tr>
<td>12 – 15 years reimbursed</td>
<td>-34.45%</td>
<td>-28.22%</td>
</tr>
<tr>
<td>&gt; 15 years reimbursed</td>
<td>-32.83%</td>
<td>-26.45%</td>
</tr>
</tbody>
</table>

Ex-factory level
4. Reference Reimbursement System

• **Regularisation January 1st 2017 of generics without a reimbursed original medicines**
  
  • Decrease in price and reimbursement level to ‘patent cliff’ level
4. Reference Reimbursement System

- **Safety Margin**
  - The permitted limit for the supplement charged to the patient on top of the patient copayment.
  - A safety margin can only be applied for reference medicines.

  **Before March 1st 2016**: The safety margin cannot exceed 25% of the public reimbursement base, with a maximum of €10,80.

  **Since March 1st 2016**: The maximum amount is lowered from €10,80 to €5,00.
Most drugs in hospital: **Lump sum system**

= fixed amount per patient, independent of actual consumption

But exceptions:
- Important drugs (therapeutical and social needs, innovative drugs)
- If cost of medicine could lead to ↓ administration
6. Managed Entry Contracting

Rationale

- **New generation pharmaceutical specialties** (orphan drugs, biotechnological or personalized based drugs, ..) that *often meet Unmet Medical Need* are associated with exuberant price tags
- Growing need for systems that can **limit their budgetary impact while ensuring early access for patients**

Principle

- By **negotiations** with pharmaceutical company a **contract** can be concluded between NIDHI and a pharmaceutical company
- Agreements try to link the price 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

**Advantages:** early access, risk sharing for both parties

**Disadvantages:** time consuming, what when contract has finished?
Objective

- **Tackle the uncertainty** to allow access, generate data to reduce uncertainty and to control the budget impact

→ Key sources of uncertainty:

- Eligible patient population
- Clinical evidence / Outcomes
- Cost-effectiveness
- Budget impact
- Price / Cost

6. Managed Entry Contracting

Risk Sharing Principle
6. Managed Entry Contracting

**Timelines**

Clock stop, **120 days** during which

- Taskforce **negotiations** and **proposal text** convention
- Ministers of Social Affairs and Budget give **consent** (or not)
- Agreement is **signed** between NIHDI and applicant

**Execution term**

**Temporary** enlisting (1 – 3 years max. + 1 year prolongation) during which gathering of new and/or additional clinical **evidence or information** on the balance price/cost versus added (therapeutic) value

OUTCOME ASSESSMENT
6. Managed Entry Contracting

The plan

Claim added value → CRM: evaluation → CRM: motion → Added value

Outcomes:
- Yes: Outcome determines framework for Taskforce
- No: No motion (no framework)

Reimbursement:
- No reimbursement
- ‘Normal’ reimbursement
- Start MEA-procedure + framework
- MEA procedure if company introduces demand to minister
- MEA not possible
- No need for MEA

MEA procedure possible if accepted by minister
6. Managed Entry Contracting

Total number of MEA procedures (Since April 2010)

133 demands for MEA procedure

7 not approved by minister: no MEA procedure started after demand company

85 MEAs concluded (74 valid, 11 expired)

31 no MEA

10 procedures pending

Status 12.02.2016 (period 2010 – feb 2016)
6. Managed Entry Contracting

End of MEA

MEA: max 3 years + 1 year to cover new reimbursement procedure
first MEAs in 2010 → February 2016: 11 MEAs expired

8 → “normal” reimbursement
2 → no reimbursement after new CRM procedure
1 → no reimbursement (no new CRM procedure)

Status after expiry date convention

- 72.7%: definitive admission after new CRM procedure
- 18.2%: no reimbursement after new CRM procedure
- 9.1%: no reimbursement (no new CRM procedure)
6. Managed Entry Contracting

Biggest hurdle to overcome in negotiations

Conflicting interests ↔ Common ground

In practice: Defending “Trenches & Bunkers”

Solution: Need for mandate
7. Influencing prescription and dispensing behavior

**Low cost prescriptions**
- Minimum percentages or quotas for some drugs
- Defined by specialty

**International Non-proprietary Name (INN) prescription**
- All packages of available drugs with same active ingredient, same dosage, same package size and same administration form → 1 “INN-group”
- If Prescription by active Ingredient → Pharmacist **MUST** deliver one of the “cheapest drugs” from the group

**Prescription of antibiotics of antimycotics**
- For acute treatment: Pharmacist **MUST** deliver one of the “cheapest drugs” from the group
- Also applicable if prescription of specific brand !
- Exception: therapeutical objection
8. Pay back (claw back) system

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
  - 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 + max. of budget overshoot is set at 100 million €
    - **“Marketing tax”**: 0.13% on total revenu (not officially installed yet)
    - **“Orphan tax”**: percentage per ‘revenu slice’
Access to innovative drugs and orphan drugs
1. Special Solidarity Fund

- **Additional financial protection** for individual patients
  - To help a patient in a very serious medical condition to get essential medical services that are not reimbursed and particularly expensive.
  - Limited annual budget: is funded by a levy on the resources of the compulsory health insurance
  - **Request is done by individual patient** – no influence of pharmaceutical company
  - College of Medical Directors decides to grant allowances and determines its amount
2. Early Temporary Authorization / Early Temporary Reimbursement

A potential way to consider for high innovative compounds or applications with lack of alternatives.
2. Early Temporary Authorization / Early Temporary Reimbursement
Pact for the Future with the pharmaceutical industry
Pillars

1. Greater patient access to innovative therapies
2. Growth and Innovation
3. Ethical framework
4. Budgetary sustainability and predictability
### Growth in %

(average 0.5% / year over 3 years)

<table>
<thead>
<tr>
<th>Year</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.3% (60)</td>
<td>0.1% (36)</td>
<td>0.1% (30)</td>
</tr>
</tbody>
</table>

### Measures and Budgetary Benefit for Patient and Government

**Patent cliff “R”**
- **Patient:** 11
- **Government:** 59.3

**Max safety margin 5:**
- **Patient:** 3.2
- **Government:** 0.9

**Croissance taxe sur le chiffre d’affaires**
- **Patient:** 0
- **Government:** 1.1

**EBM on ATC 5 level**
- **Patient:** 6.4
- **Government:** 32

**Δ definition application R**
- **Patient:** 0.6
- **Government:** 3.1

**Biosimilars and biologicals**
- **Patient:** 4
- **Government:** 20

**Ceiling price, e.g. β blockers**
- **Patient:** 0.7
- **Government:** 3.5

**Volume antibiotics**
- **Patient:** 0.5
- **Government:** 2.5

**1% more ‘cheapest’**
- **Patient:** 5
- **Government:** 1.1

**Increase in sales levy**
- **Patient:** 0
- **Government:** 1.1

### Reduction of the Sales Levy for the Companies

<table>
<thead>
<tr>
<th>Year</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>/</td>
<td>1% (-35)</td>
</tr>
</tbody>
</table>

### Positive Measures and Budgetary Cost

**Strengthen administrations and implementation of pact (-1,1)**

**Total, Net Structural Savings (Cumulative)**

<table>
<thead>
<tr>
<th>Category</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the patient</td>
<td>14.2</td>
<td>28.2</td>
<td>34.4</td>
</tr>
<tr>
<td>For the government</td>
<td>60.3</td>
<td>6.4</td>
<td>126</td>
</tr>
</tbody>
</table>
International cooperation
1. Collaboration Initiative: Coalition of the willing

- Letter of intent signed by 4 ministers
  - Belgium – Netherlands – Luxembourg – Austria
  - Mandate to deliver proposals for cooperation on HTA, Horizon Scanning and Pricing and Reimbursement topics
  - To perform pilots on these topics

- Expensive medicines
  - High cost per patient
  - High budget impact

- Voluntary
  - Consensus based cooperation
  - Reimbursement decisions are national competence
2. Platform for Coordinated Access to Orphan Medicinal Products (Moca)

- Mechanism for European countries that seeks collaborative ways to identify and assess the added value of orphan medicinal products

- Voluntary, dialogue-based approach, intended to create a fluid set of interactions between key stakeholders and across all aspects of an OMP

- 1 Pilot concluded (Sobi)