Pricing & Reimbursement of medicines in Belgium

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Some numbers to start with
Budget for pharmaceuticals:
4 billion €

- 2.7 billion € (Public pharmacies)
- 1.3 billion € (Hospital pharmacies)
Pharmaceuticals delivered by public pharmacies and hospital pharmacies

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

Source: Pharmanet
net NIDHI expenditures in public pharmacy for reimbursed medicines

Millions €

Z
V
S
R Respiratoire
P
N neuro
M
L Onco
J
H
G
D
C Cardio
B
A Gastro
net NIDHI expenditures in hospital pharmacies for reimbursed medicines

Milliards d'euros

2004 2005 2006 2007 2008 2009 2010

- Z
- X(forfait)
- V
- S
- R (Respiratory)
- P
- N (neuro)
- M (Musculo sq)
- L (onco)
- J
- H
- G
- D
- C(cardio)
- B (blood)
- A (Gastro)
Reimbursement of medicines

key features, legislation, procedure
Key features

FEDERAL GOVERNMENT

Marketing Authorization
  Minister of Public Health

Price Setting
  Minister of Economy

Reimbursement
  law 14.07.1994
  Royal Decree 21.12.2001
  Minister of Social Affairs

FLEMISH COMMUNITY - FRENCH COMMUNITY

Health Promotion

Preventive Measures
Key features

Marketing Authorisation

- Mainly regulated at European level
- European authorisations / national autorisations

Price setting and reimbursement

Regulated at national level

- strict deadlines (90 days + 90 days)
- Transparency : evaluation based on objective and verifiable criteria

Principles adopted by the gouvemment in Octobre 2000
Legal basis established in law of 14th July 1994
Execution regulated by the royal decree of 21 decembre 2001
Key Features

Reimbursement of medicines

+ Evidence Based Medicine
+ pharmaco-economics

Decisions on reimbursement:
• Are made by Minister of Social Affairs and are based on proposition of “Commission of Reimbursement of Medicines” (CRM)
  → reimbursement conditions and
  → reimbursement level (reimbursement level ≤ price set by Economical Affairs)

Time limits are very strict! If not respected → latest proposition of pharmaceutical company is accepted.
Key Features

**positive list** – nomenclature

**unrestricted** reimbursement versus **restricted** reimbursement
  (chapter I versus chapters II and IV)

reimbursement **ambulatory** versus **hospital** use

**differential reimbursement**
  (self-employed persons versus salaried persons: modified 01 01 2008)
  (active versus OMNIO group)
  (category A B C Cs Cx D)

**Maximum Billing** or **Maximum Invoice**

**Reference Reimbursement System**

**Revision**

**Contracting**
Commission Reimbursement Medicines

30 members
- 22 voting members:
  - 7 academics
  - 8 insurers
  - 4 physicians association
  - 3 pharmacists association

- 8 non voting members:
  - 4 ministry rep.
  - 1 INAMI/RIZIV
  - 2 Pharma.be 1 Febelgen
**Procedure**

- Marketing authorisation
- Reimbursement
- Procedure reimbursement
- Evaluation
- Day 90
- Claim
- Day 0
- Decision
- Day 180
- Proposal
- Day 150

**Time to Submission**

**Time to Reimbursement**
Evaluation and assessment: Marketing Authorization vs 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 $\Delta C/\Delta E$
1. THERAPEUTIC VALUE
= efficacy + safety + efficiency + applicability + comfort
Determined by:
MORBIDITY - MORTALITY – QUALITY OF LIFE
   class 1  Added value
   class 2  comparable value
   class 3  generics and copies

2. PRICE & LEVEL OF REIMBURSEMENT

3. IMPORTANCE IN THE CLINICAL PRACTICE (social and/or therapeutical needs)

4. BUDGET IMPACT

5. COST/THERAPEUTIC VALUE
Price & Reimbursement level

1. Public Price → often = Level of reimbursement
   
   **BUT EXCEPTIONS:** Original medicines in reference reimbursement system, cat. F

2. **Maximum price** is fixed by Economical Affairs (= before setting level of reimbursement)

3. **Level of reimbursement:** decision by minister of social affairs
   → = used to calculate how much the NIDHI reimburses and how much is left for the patient to pay
   → most cases = price used in practice).
Price & Reimbursement level

Public price =
ex-factory price
+ margin wholesale
+ economical margin pharmacist
+ pharmacist fee
+ taxes
How to control the expenditures of the health insurance?
Control of the expenditures

- Different statuts: Active, Omnio..
- Different categories: A, B, C, Cx ..
- Different chapters: I, II, IV...
- Lump sum reimbursement at hospital
- Contracting
- Revision
- Reference reimbursement system
- ...

19
Patients:
Active or preferential status

OMNIO status

➔ Preferential reimbursement = higher degree of reimbursement

➔ Status determined by financial and economical capacity of families
# Categories of reimbursement

<table>
<thead>
<tr>
<th>Category</th>
<th>Preferential reimbursement</th>
<th>Normal reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category A (and Fa)</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 (and Fb)</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 (and Fb) big pack</strong> (≥ 60 units)</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 (diarrhea)</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>
## Different reimbursement chapters

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| I       | Reimbursement when prescribed  
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).  
"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. |
### UNRESTRICTED REIMBURSEMENT

**chapter I**

Reimbursed:

- all (registered) indications
- for all patients
- prescriptions by all prescribers

### RESTRICTED REIMBURSEMENT

**chapter II and IV**

Reimbursed:

- selection of (registered) indications
- for selection of patients
- prescriptions by selection of prescribers
Restricted reimbursement

General structure of chapter IV (content)

- **Indication**: which is reimbursed: with or without conditions for diagnosis

- **History of treatment**: E.g. first treatment, second treatment, intolerance, resistance…

- **Doctor**: is specific specialisation required? Linked to certain type of hospital?

- **Patient**: age, sexe, weight…

- **Medical history of patient**: co-morbidity, unsuccessful treatment, first or second line treatment, medical contraindication

- **Dosage**: or number of packages reimbursed

- **Duration**: of treatment: acute or chronic, stopping rules

- **Prolongation**: when, duration…
Medicines for hospitalised patients

Most medicines in hospital: **Lump sum system**

= fixed amount per patient, independent of actual consumption

→ Fixed amount is calculated based on patients and consumption during past years

→ Fixed amount is calculated to cover 75% of costs

→ Health insurance pays lump sum amount + 25% of real consumption

But exceptions:

- Important medicines (therapeutical and social needs, innovative medicines)

- If cost of medicine could lead to ↘ administration
Contracting

**Principle:**
By negotiations with pharmaceutical company a contract can be concluded between NIDHI and company

→ Temporary reimbursement based on conditions set out in contract

**Scope:** risk sharing in case of uncertainties

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

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

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
Contracts in Belgium
Risk sharing
Procedure

Talks CONTRACTS if no proposition from the CRM
Contracts in Belgium

Risk sharing

Procedure

The CRM can propose a CONTRACT procedure
Contracts in Belgium
Risk sharing

![Bar chart showing turnover and budget allocations]
Revision

Principle:

When the CRM proposes to reimburse a medicine: possibility to propose a revision:

→ goal: evaluate reimbursement after 1 – 3 years
→ If necessary: modifications in reimbursement
Measures for extra protection
Maximum Bill or Maximum Invoice

= ‘safety net’ principle

→ Maximum amount a person or family has to contribute for reimbursed medical care during one year.

→ Maximum amount is determined by several factors, as salary and social situation
Special Solidarity Fund

Additional financial protection for individual patients

The fund can reimburse some medical costs (partially) which are not reimbursed by “classical reimbursement system”.

Conditions:

• Rare disease or indication
• Expensive treatment
• Treatment is no longer experimental/value is well established
• No alternative treatment is available
Reimbursement of medicines

Generic policy, reference reimbursement system …
Types of claims

CLASS 1: added therapeutic value

CLASS 2: comparable value (subclasses 2A, 2B and 2C)

CLASS 3: generics, hybrids… (registration type)
subclass 3A – if some cumulative conditions are fulfilled
subclass 3C

copies, if some cumulative conditions are fulfilled (subclass 3B)

Cumulative conditions:

1) The reference product as mentioned on the marketing authorization is reimbursed,
2) Dose, galenic form and package size are equal to the reference product,
3) The applicant proposes the same conditions for reimbursement as those of the reference product,
Standard procedure

Marketing authorization

Reimbursement procedure
- Claim Day 0
- Evaluation Day 90
- Proposal Day 150
- Decision Day 180

Commission of Reimbursement

Min ECONOMIC AFF.

Price procedure

External expert for class 1 and orphan drugs
Class 3C procedure

Reimbursement procedure

Marketing authorization

Claim Day 0

Evaluation & proposal Day 60

Decision Day 90

CRM

Min ECONOMIC AFF.

Price procedure

REIMBURSEMENT
Administrative procedure

MARKETING AUTHORIZATION

REIMBURSEMENT

procedure reimbursement
claim proposal decision
day 0 day 30 day 60

secr. CRM Min SOCIAL AFF.

Min ECONOM. AFF.

Price procedure:
notification

39
Pricing

Margins/fees included in public price:

Pharmacist

- Fee Pharmacist (fixed amount of 4,16 euro)
- Economic margin Pharmacist (calculated on ex factory price)

Margin Wholesale

Fees (pharmacist) excluded from public price:

- Fee ‘first delivery’
- Fee ‘delivery INN prescription’
- Fee ‘chapter IV’
- **Class 1:**

  Reimbursement according to the demonstrated therapeutic added value taking into account the galenic form, the dose and the pack size.

- **Class 2:**

  Reimbursement basis cannot exceed these of the reference drug fixed by the Commission.
Pricing

- Class 3C

If first generic (or if cluster not yet open):

```
Generic

Ex-factory price

Margins/Fee (calculation in function of ex factory price)

Tax

Original “reference”

min 32.5%

If cat A: - 41%
```
Pricing

- Class 3C

Not first generic (and cluster open):

From 1th July 2014:

Price setting not based on reference product, but on prices of other specialities in cluster.
Pricing

- **Class 3C**

**Strength**

- guaranteed 32.5% lower prices (41% for class A products)
- price control – regulated by Law – no assessment
- high speed

**Weakness**

- stationary (not dynamic)
- no competition (but do we need that?)
- lack of incentives for pharmaceutical industry to offer lower prices
Reference reimbursement system

- **Linear price-cut 32.5%** on ex-factory level (or 41% if cat A) if **generic available** (2 months prior)

- **ATC5 level** (molecule) + salts, enantiomers, ethers,... of the concerned molecule

- executed **4 x per year**

→ **Opening reference cluster**
Reference reimbursement system

- Reference price
- Original "reference"

Supplement

- Min 32.5%
- Or
- Min 41% if cat A
Reference reimbursement system

Example

<table>
<thead>
<tr>
<th>ACCURETIC (PharmaPartner)</th>
<th>PHARMAPARTNER</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-21 2154-813 2154-813</td>
<td></td>
</tr>
<tr>
<td>28 filmomhulde tabletten, 20 mg / 12,5 mg</td>
<td>28 comprimés pelliculés, 20 mg / 12,5 mg</td>
</tr>
<tr>
<td>R</td>
<td>12,35</td>
</tr>
<tr>
<td>B-21 * 0776-971</td>
<td></td>
</tr>
<tr>
<td>1 filmomhulde tablet, 20 mg / 12,5 mg</td>
<td>1 comprimé pelliculé, 20 mg / 12,5 mg</td>
</tr>
<tr>
<td>R</td>
<td>0,2854</td>
</tr>
<tr>
<td>B-21 ** 0776-971</td>
<td></td>
</tr>
<tr>
<td>1 filmomhulde tablet, 20 mg / 12,5 mg</td>
<td>1 comprimé pelliculé, 20 mg / 12,5 mg</td>
</tr>
<tr>
<td>R</td>
<td>0,2343</td>
</tr>
</tbody>
</table>
Reference reimbursement system
Reference reimbursement system

- Financial protection patients ("security margin")
  supplement patient limited to 25% of the level of reimbursement, max 10,80 euro

- Scope reference reimbursement system:
  → “hybrid” generics included
  → salts, ethers, enantiomers,... included
Reference reimbursement system

Exemption → reimbursement base lowered by half (16.25%; or 20.5% for cat A)

- 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
- for the salts, enantiomers, ethers, ... of molecules eligible for entering the reference reimbursement system with a proven substantial added value concerning effectiveness and safety
Reference reimbursement system

Strength

- automatic (regulated by Law – exceptions possible)
- guaranteed budget impact (32.5 %) for concerned molecule
- incentive physicians (target % - profiles - accreditation)
- reference (originator) usually follows (adjusts price)

Weakness

- legal issues (patent protection)
- financial protection patients (maximum invoice)
- lack (?) of incentives for patients: financial responsibility (co-payment) is limited
- lack (?) of incentives for pharmaceutical industry
- lack (?) of incentives for pharmacist: no substitution allowed
- quid biosimilars
Application of measure « old product »

- Molecule > 12 years reimbursable: min 17%
- Molecule > 15 years reimbursable: min 2,41 % (total – 19%)
- 2 x per year
- Relevant for original and generics
- Exceptions

More information:
- Or
International Non-proprietary Name (INN) prescription

All packages of available medicines with same active substance, same dosage, same package size and same administration form
⇒ 1 “INN- group”

If Prescription by Active Ingredient ⇒ Pharmacist MUST deliver one of the “cheapest medicines” from the group

Cheapest medicines: Calculation:
- Index = cost per unit
- Medicine within group with lowest index + medicines with index that is < cheapest index + 5% (“margin of 5 %)”)
- At least 3 specialities available
International Non-proprietary Name (INN) prescription

“Dark green”: < cheapest index + 5%

“Light green”: extension $\rightarrow$ at least 3 specialities

No color: not one of cheapest medicines
Prescription of antibiotics of antimycotics

If Prescription of antibiotic or antimycotic for **acute treatment**: Pharmacist MUST deliver one of the “cheapest medicines” from the group

Also applicable if prescription of specific brand!
**Exception**: therapeutic objection

More information:
http://www.inami.fgov.be//drug/nl/drugs/general-information/prescription/index.htm

Or
http://www.inami.fgov.be//drug/fr/drugs/general-information/prescription/index.htm
Questions
???