Pricing & Reimbursement of medicines in Belgium

ADRIAENS Catherine
VAN DE VIJVER Inneke

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- Some **numbers** to start with

- **Price setting & Reimbursement** of medicines:
  - Key features on organisation, legislation and procedure

- **Control** of health insurance **expenditures**:
  - Pay back system & contracts with individual companies

- **Access** to innovative & orphan drugs
Some numbers to start with

Financing of the Belgian Health Care System

Health Care Budget

Expenditure on Medicines
Financing of the Belgian Health Care System

Out goes Up and In comes Down

SOCIAL CONTRIBUTIONS
employers and employees

TAXES

National Office for Social Security
(RSZ – ONSS)

Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (RIZIV)

National Institute for Health and Disability Insurance (NIHDI)

Institut national d'assurance maladie-invalidité (INAMI)

Health Insurance Funds

cost of medical act or good

CO or OUT OF POCKET PAYEMENT by patient

“compulsory health insurance”
Financing of the Belgian Health Care System

Some numbers to start with

SOCIAL CONTRIBUTIONS employers and employees

TAXES

COOPAMI
Medicines budget 2014 fixed at 4,112 billion € = +3.2%
Price setting & Reimbursement of Medicines

Key features on organisation, legislation and procedure
Organisation

FEDERAL GOVERNMENT

Marketing Authorization
Minister of Public Health
(FAMHP)

Price Setting
Minister of Economy
(Pricing Service)

Reimbursement
Minister of Social Affairs
(NIHDl)

FLEMISH COMMUNITY - FRENCH COMMUNITY

Health Promotion
Preventive Measures
Elderly homes – Nursing homes
Organisation of the NIHD

General Management Committee

Chief Executive Officer and Deputy Chief Executive Officer

- Health Care Department
- Department for Medical Evaluation and Inspection
- Benefits Department
- Department for Administrative Inspection
- General Support Departments
- Fund Medical Accidents

**Direction Pharmaceutical Policy**

- Organizes and controls on conceptual, technical, legal, budgetary and administrative terms the consultative bodies and their working groups (including Commission Reimbursement Medicines)
- Conducts scientific and statistical research and interprets information from databases
- Supports operation of the sector and solves its problems
- Supports decision taking process on reimbursement criteria of pharmaceutical products (medicines, radioisotopes, medical nutrition, ...)
- Organizes negotiations between different actors involved in compulsory health insurance
Composition of 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. (Min. Social Affairs, Min. Health, Min. Econ. Affairs, Min. Budget)
  - 1 NIHDI
  - 2 Pharma.be (innovative industry)
  - 1 Febelgen (generic industry)

3 important missions:
- Issues on reimbursement proposals (not decisions) => 2/3 majority
- Advice on request of Minister on politics concerning reimbursement
- Formulate proposals to the Insurance Committee on interpretation rules of reimbursement conditions
Marketing Authorisation

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

Price setting 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
Price setting procedure

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

### Key Features on Pricing & Reimbursement

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

#### NON-REIMBURSED
- With prescription
  - Original pharmaceutical product
  - Generic, copy, hybrid, biblio

- OTC

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*Innovative (non-reimb) drugs containing a new active ingredient and having a new therapeutic indication => notification*
Key Features on Pricing & Reimbursement

Price setting procedure

- Ex-factory price
  - 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’

- 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, ...
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 $\Delta C / \Delta E$

Key Features on Pricing & Reimbursement
Reimbursement procedure

**Evaluation and assessment:**

*Criteria leading to change of “positive list of reimbursed medicines”*

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

   - This therapeutic value is situated at the level of
     - morbidity,
     - mortality or
     - quality of life

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
Types of claims

CLASS 1: innovative drugs - added therapeutic value
- 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)
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
  - and
  - 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
Reimbursement procedure

Key Features on Pricing & Reimbursement

Marketing authorisation → Price procedure (90 days) → Reimbursement

Time to submission → Procedure → 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
Control of health insurance expenditures

- Pay back (claw back) system
- Contracting (Art 81 agreements)
- Revision (re-assessment clinical evidence and/or budget)

- Reimbursement dependent on social status
- Maximum Billing or Maximum Invoice
- Differential reimbursement (different categories: A, B, C, Cx ..)
- Restricted reimbursement (different chapters: I, II, IV...)
- Lump sum reimbursement at hospital
- Reference Reimbursement System
- INN prescription
- Price reduction measure “Old medicines”
- Price freeze of reimbursed medicines
Pay back (claw back) system

**Principle**
- Pay back share of revenue by manufacturers, if a prespecified 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 + 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’
Provision fund (abolished end 2008)

- Provision Fund: fixed amount of 100 million euro
- Funded by manufacturers and supplemented if provisory fund was used in case of budget overshoot
- Abolished end 2008 and budget repayd to manufacturers in Feb 2009

➢ Reason of abolishment: accountant difficulties of pharmaceutical industry when planning possible supplementary payments to supplement fund

➢ Consequence: subsidiary tax
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

Source: Carone et al. Economic Papers 461 | September 2012. Cost-containment policies in public pharmaceutical spending in the EU
Control of health insurance expenditures

Contracting (Art. 81 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 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

Scope

- **Risk sharing** in case of **uncertainties**
  - Clinical uncertainty
  - Budgetary uncertainty

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

**Disadvantages:** time consuming, what when contract has finished?
Control of health insurance expenditures

Contracting (Art. 81 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
Contracting (Art. 81 agreements)

Composition of the Permanent Working Groep “art 18”

- 1 representative Min Social Affairs
- 1 representative Min Budget
- 1 representative Min Economy
- 3 representatives sick funds
- 1 representative Pharma.be
- (vice-)President of CRM or academic member CRM
- 2 representatives company with “decision taking power”
Contracting (Art. 81 agreements)

Types of compensation models

- Budget cap
- Price-Volume
- Fixed amount per unit
- Pay for performance scheme
- Reduction price other drugs (cross deal)
- ...

And combinations
Control of health insurance expenditures

Contracting (Art. 81 agreements)

Uncertainty related to ‘type of compensation model’

- Coverage with Evidence Development
- Pay for Performance Deconnection with added value-development

- No need for MEA “Normal” reimbursement = chapter IV + revision
- Financial agreement Budget Cap Deconnection without added value-development

Source: pharma.be
Control of health insurance expenditures

Contracting (Art. 81 agreements)

Risk Sharing Principle
Contracting (Art. 81 agreements)

Strengths

- Clear Framework
  - Legal certainties: NIHDI & applicant
  - Timelines
  - Template of MEA
  - Intensive negotiation with headroom for creative and flexible solution seeking

- Transparent Decision Process
  - Procedures
  - MEAs are not confidential

- Financial Safeguards
  - List price = financial guarantees for the Pharma company
  - Budget management and control
Downsides

- Relevant New Evidence in short Time Frame? Value of Information?
  - Obtain which information? Satisfies this our questions?
  - Period of 3 years, only observational studies are realistic
  - Epidemiological data on national level is limited
  - How evaluate value of study before end of MEA?

- What After the MEA? Are problems solved? Did we obtain more information on the main questions?

- Reduces the transparency in effective prices of pharmaceuticals, as payback is changing the effective prices but not the listed prices, thereby reducing the effectiveness of external reference pricing

- May discourage introducing new pharmaceuticals, if budget overshooting is an issue and the expected turnover on the new pharmaceuticals has to be paid back
Principle
- “Individual revision” as part of ministerial decision on reimbursement modalities
  - All class 1 products + orphan drugs
  - Class 2 or 3 products for which the Minister decided to have a revision (mostly budgetary uncertainty)
  - Modifications for which the Minister decided to have a revision

  - 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
Access to innovative medicines and orphan drugs
Rationale
- **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.
  - To provide an additional safety net to cover "regular" medical care insurance

Principle
- 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
  - College is composed of doctors (or their representatives) of each Belgian medical care insurance and INAMI’s physicians
  - College of Medical Directors take into account
    - Advice given by eg Commission Reimbursement Medicines during “regular” reimbursement processes
    - Interest of individual patient
    - Collective ethical interests (to ensure the existence of the compulsory health insurance based on solidarity)
Conditions

- Rare disease or indication, or
- Rare disease and need of continuous treatment and complex care, or
- In need of medical devices and/or care which are considered as innovative medical techniques

AND

- Expensive treatment
- Threatening the vital functions of the patient
- Treatment is no longer experimental/value is well established
- No alternative treatment is available

Examples

- Non-reimbursed medications, medical devices, ...
- Non-registered indications
- Unavailable products (in Belgium, EU)
- Pharmaceuticals withdrawn from reimbursement by manufacturer and made available at very high prices
Special Solidarity Fund

**Term**
- Average time between request and advice College is 8,7 days

**Financing of SSF**
- Partial budget of total health insurance incomes
- Yearly decision of General Council

**More information**
A potential way to consider for high innovative compounds or applications with lack of alternatives.
Access to innovative medicines and orphan drugs

Early Temporary Authorization / Early Temporary Reimbursement (ETA/ETR)