Overview of the Hungarian pharmaceutical reimbursement system

Paris, 12 October 2010
Agenda

- General overview
- The reimbursement decision process in Hungary
- The main structures of the Hungarian reimbursement system
- Challenges, answers and hot topics
Overview of pharmaceutical provision in Hungary – a classic single-insurer model

MAH (manufacturer, importer)

Medicinal product → Ex factory price – rebates

Wholesaler

Medicinal product → Wholesaler price – rebates

Pharmacy (retailer)

Prescription Co-payment

Patients / taxpayers

Social security tax

Central budget

Deficit subsidies

National Health Insurance Fund (OEP)

Physician

Prescription

X% Reimbursement

Dávid Dankó – Overview of the Hungarian pharmaceutical reimbursement system, Paris – EMAUD, 12 October 2010 (3)
We provide access to new **value-added therapies** by **continuously recycling resources** from off-patent products to innovative products with proven therapeutic effectiveness.

We do this through actively promoting generic competition, **eliminating inefficiencies** in current expenditure and **re-channeling cost savings** in the best interest of patients.
Formulary management is regarded as key to the long-term sustainability of a pharmaceutical reimbursement system.

1. Provide easy and fast access to generic medicines
2. Ensure the continuous decrease of generic prices and foster generic substitution
3. Eliminate inefficiencies in expenditure by identifying all sustainable cost saving potentials
4. Admit new value-added therapies (active substances) into the formulary
5. Apply risk-sharing schemes to guarantee the optimal allocation of resources
6. Revise effectiveness based on real-world data and de-list products with no added therapeutic value

**INNOVATIVE (patent-protected) MARKETS**

- NICHE THERAPIES
- THERAPIES FOR MASS DISEASES
- TREATIES FOR HIGH-INCIDENCE DISEASES

**COMPETITIVE (genericised) MARKETS**

- RECYCLE
- RECYCLE

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The Hungarian reimbursement system is based on a rather wide portfolio of reimbursement methods and tools.

**Pharmaceutical manufacturers (MAH’s)**

- *Statutory payback on sales revenue*
- *Sales rep registration fee*
- *Claw-back scheme in the case of budget deficit*
- *Restrictions on pharmaceutical advertising*
- Indication-linked reimbursement, reimb. protocols
- Controlled admission to the formulary
- Reference pricing (generic, therapeutic, internat’l)
- Price-volume agreements (PVA)
- Outcome and adherence schemes
- Classification based on degree of innovation
- *Negative lists*
- *Ex-factory price regulation*
- *Rate of return regulation*
- Active substance tenders
- Generic (INN) prescribing

**NHIFA**

- Reimbursement rates
- Mandatory co-payment
- *Restrictions in social schemes*
- Communication towards patients
- Fees for pharmacy care
- *Retail margin cap*
- Mandatory generic substitution

**Physicians**

- Guided prescription practice with target values
- Regular feedback on prescription patterns
- Dear doctor letters
- Physician’s co-payment
- *Technocratic tool, not ‘market-compatible’*
- Technocratic tool, ‘market-compatible’
- Incentive-based tool

**Patients**

- *Retail margin cap*
- Mandatory generic substitution

**Pharmacists**

- Fees for pharmacy care

**Wholesalers**

- *Statutory payback on wholesale margin*
- *Wholesale margin cap*

*Technocratic tool, not ‘market-compatible’*
### Facts and figures from Hungary (2006—2010)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
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<tbody>
<tr>
<td>Total public health expenditure (TPHE)</td>
<td>6% of GDP (6,2bn €)</td>
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<tr>
<td></td>
<td>620€/capita/year</td>
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<tr>
<td>Total public pharmaceutical expenditure</td>
<td>1,5% ‡ 1,2% of GDP (1,4bn € ‡ 1,0bn €) 140€/capita/year</td>
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<td>‡ 100€/capita/year</td>
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<td>25% ‡ 20% of total public health expenditure</td>
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<tr>
<td>Out-of-pocket pharmaceutical expenditure</td>
<td>0,37bn € ‡ 0,39bn €</td>
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<td>37€/capita/year ‡ 39€/capita/year</td>
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<tr>
<td></td>
<td>Average co-payment: ~30 per cent</td>
</tr>
<tr>
<td>Reimbursed pharmaceuticals</td>
<td>4.700 ‡ 4.400 reimbursed pharmaceuticals</td>
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<tr>
<td></td>
<td>1.500 ‡ 1.700 generic pharmaceuticals (60% of turnover in DOT)</td>
</tr>
<tr>
<td>Consumption of pharmaceuticals</td>
<td>30 ‡ 27 units/capita/year</td>
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<td>492 ‡ 481 DOT/capita/year</td>
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</tbody>
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N.B.: 1 EUR=275 HUF (as of 11 October 2010)
Trend of public pharmaceutical expenditure in Hungary (1994-2010)

Planned and actual public pharmaceutical expenditure (1994-2013, million EUR)

N.B.: 1 EUR=275 HUF (as of 11 October 2010)
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The three main drivers behind reimbursement decisions

- Clinical criteria
- Market-related and strategic criteria
- Financial criteria

**TRANSPARENCY PROCEDURE**

**USE OF CLINICAL EFFICACY AND COST-EFFECTIVENESS EVIDENCE**

**SECONDARY EFFECTS, PRICE NEGOTIATIONS**

**BUDGET IMPACT, APPLICABILITY OF RISK-SHARING TECHNIQUES**
Reimbursement procedures

**Normal procedure**
- New active substance, new presentation, new indication, new combination, not bioequivalent generic products, price increase
- Detailed health technology assessment
- A fee of 1.500.000 HUF (approx. 5500 EUR) is payable

**Simplified procedure**
- Reimbursement of bioequivalent generics
- No HTA, the sick fund has all decision rights
- A fee of 300.000 HUF (approx. 1100 EUR) is payable

**Simple notification procedure**
- Data modification, price decrease, product recall
- The sick fund accepts the notification automatically (without any right of consideration)
- No fee is payable
Reimbursement procedures including health technology assessment

**Reimbursement application**
- Request for completion
- Technical inspection
  - Not OK
- Decision on the procedure to be followed
- Simple notification procedure
- Simplified procedure (60 days*)
  - Data modification, price decrease, product recall & termination of supply
  - Bioequivalent active substances (generic products)
- Decision and notification of the applicant (by the Health Insurance Fund)

**Ex-officio procedures**
- Referencing, de-listing for loss of turnover (‘phantoms’)
- Full or partial revision of a therapeutic group
- Normal procedure (90 days**)
  - New active substance, new presentation, new indication, new combination, price increase, not bioequivalent generic products
  - Critical review (full HTA) and medical assessment by HTA Agency
  - Preliminary risk-sharing agreement (e.g. PVA)
  - Decision on the procedure to be followed

- Appeal

*: in practice decisions are normally taken within 30 days
** if the medicinal product belongs to an ATC5-group which is as of now unreimbursed, a decree modification is needed which can take more time

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### Institutional setting

- Independent HTA agency (Technology Assessment Bureau: ESKI TÉI) carries out critical review
- Sick fund carries out budget impact analysis, outcome analysis and international comparisons
- Professional chambers provide incidence / prevalence information

### Methodology

- Detailed description of need required
- Payer perspective required, but can be complemented with societal perspective
- CMA, CEA or CUA preferred, CBA dispreferred
- All models should be adapted using Hungarian data
- Discount rate: 5% (± 3.7%)
- No explicit QALY-threshold

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The HTA landscape is complemented by 3-4 not-for-profit research centres and 2-3 major for-profit companies providing expert services.
Reimbursement rates used in Hungary

Normative reimbursement (general prescription right for all physicians in all indications listed in the marketing authorisation)

- Normative 25%
- Normative 55%
- Normative 80%

Indication-linked reimbursement (prescription rights restricted to certain medical professions and/or reimbursement is granted only in a subset of authorised indications)

- Indication-linked 50% (Eü. 50%)
- Indication-linked 70% (Eü. 70%)
- Indication-linked 90% (Eü. 90%)
- Indication-linked 100% (Eü. 100%)
The basic model for generic referencing

Δ > 30%

- The product will be de-listed if its daily cost of therapy (DCT) is more than 30% higher than the reference DCT.

<table>
<thead>
<tr>
<th>Δ ≥ 10%</th>
<th>Δ &lt; 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>- DCT of the product is more than 10% higher than reference DCT: set reimbursement amount</td>
<td>- DCT of the product is max. 10% higher than reference DCT: set reimbursement amount</td>
</tr>
<tr>
<td>- Reference product: % based reimbursement</td>
<td>- Reference product: % based reimbursement</td>
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<tr>
<td>- Savings for the patient</td>
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</tbody>
</table>

Co-payment:
- reduces unnecessary drug consumption and the risks of polipragmasy
- enhances health and cost consciousness of patients
- shifts part of the risk onto patients

Reimbursement amount of reference product

Reimbursement amount of a below-the-reference product

Co-payment

Savings for the patient

- reduces unnecessary drug consumption and the risks of polipragmasy
- enhances health and cost consciousness of patients
- shifts part of the risk onto patients
Reference pricing: goal and key decision variables

**GOAL**

- Support *generic competition* through providing the same reimbursement amount to biologically equivalent / interchangeable products
- Set constraints to the proliferation of ‘*me-too*’ products
- Eliminate unjustifiable *international price differences*

**KEY DECISION VARIABLES**

- Approach(es) to use
- Timing and frequency of application
**Reference pricing: timing and frequency of application**

**ADMISSION TO THE FORMULARY**

- **International price comparison for original products**: the price of the product may not be higher than in any of 13 selected countries of the EU/EFTA region (N.B. regulation should be modified to cover all EU member states with higher per capita GDP)

- **Generic threshold for newly competitive markets**: the first generic must be at least 30% cheaper than the original product, whereas each of the subsequent two products has to be 10% cheaper than the previous one

- **Generic threshold for established markets**: new products are accepted at, or below, the daily cost of therapy of the reference product

**MANAGEMENT OF THE FORMULARY**

- **Generic reference pricing**: widely used with 203 reference groups (ATC5)

- **Therapeutic reference pricing**: 47 ‘jumbo groups’ (ATC4)

- **International reference pricing**: under implementation (much contested)

- Continuous acceptance of **price reduction proposals** from manufacturers

- **Monthly update** of reimbursement list

- **Quarterly bidding**, referencing and de-listing
Impact of generic referencing: risperidone

20070101, original, retail price: 155€  ➡️  20080901, generic, retail price: 42€

Market share in total reimbursement value

Original product
Impact of generic referencing: atorvastatin

20070101, original, retail price: 28,5€  ➔  20080901, generic, retail price: 21,2€

Market share in total reimbursement value

Original product
### Types of price-volume agreements (PVA) used in Hungary

<table>
<thead>
<tr>
<th>Types of Price-Volume Agreements (PVA)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Simple payback</strong></td>
<td>In view of strategic pricing considerations, the marketing authorisation holder is not willing to reduce list price but agrees to a payback on every unit sold.</td>
</tr>
<tr>
<td><strong>Financial risk-sharing</strong></td>
<td>The marketing authorisation holder accepts to pay back a pre-determined amount if the number of units sold with reimbursement exceeds the volume cap.</td>
</tr>
<tr>
<td><strong>Therapeutic risk-sharing</strong></td>
<td>The marketing authorisation holder accepts to pay back a pre-determined amount if the product’s real life therapeutic effectiveness or patient adherence (persistence) falls behind a set value.</td>
</tr>
</tbody>
</table>

#### Simple payback (NOT RISK-SHARING)

- **Payer’s risk**: real patient number exceeds the patient number on which the dossier was based.

#### Financial risk-sharing

- **Volume cap with or without advance payment**
- **Individual / Shared by products / Shared by MAH’s**

#### Therapeutic risk-sharing

- **Criteria for real life therapeutic effectiveness (outcome)**
- **Criteria for patient adherence / persistence**
PVA payback clearly reflects the increasing use of such agreements

Source: NHIFA (*: forecast)
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What is changing about pharmaceuticals?

**CHALLENGES WHICH ARE ALREADY HERE**

- Rapidly growing market share of expensive biopharmaceuticals
- Expensive targeted therapies (‘end of the blockbuster era’) with indication fragmentation
- Expensive generic products
- Restricted evidence upon admission to the reimbursement formulary
- Poor patient adherence to treatment

**MID-TERM AND LONG-TERM CHALLENGES**

- Arrival of personalized medicine (with its associated costs)
- Patient need for comprehensive health services instead of simple product supply
- Restricted or unavailable evidence upon admission to the reimbursement formulary
- Poor patient adherence to treatment
In Hungary, we are experiencing a clear need for paradigm shift.

![Diagram showing the progress of cost containment efforts in Hungary.]

- **Societal loss**
  - **GENERAL (SYSTEM-LEVEL) OVERSPENDING**
    - **Hungary, early 2007**
  - **SPECIFIC INEFFICIENCIES**
    - **Waking up:** Efficient use of classical ‘heavyweight tools’
    - **Treadmill:** Decreasing efficiency of classical tools, use of ‘add-ons’
    - **Danger zone:** Need for paradigm shift
  - **Era of niche strategies:** Use of targeted and differentiated tools

- Undifferentiated ‘heavyweight’ cost containment tools lose their momentum as soon as general (system-level) overspending has been eliminated.

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Limitations of generic referencing: experience from Hungary

The high de-listing threshold (30%) does not provide incentives for price competition.

The quarterly tact of referencing is too low in the months following patent expiry, whereas too high in established markets.

Pharmacists have incentives that counter substitution.

No preferred reimbursement is offered to the reference product.

Physicians prescribe brand instead of active substance.

The retrospective logic of selecting the reference product impedes the realization of price gains for several months.

The possibility of post-bid price reduction weakens real bidding ‘behaviour.

The reference status does not generate enough volume to compensate for lower prices.

Generic referencing is unable to ‘break’ high prices that had stuck before the Transparency Directive was implemented.

Generic markets remain marketing-intensive, with marketing expenditures being recuperated in higher retail prices.

Physicians prescribe brand instead of active substance.

Newly competitive markets
- The decrease in the daily cost of therapy follows the market entry of generics with considerable delay.

Established markets
- In some established high-volume therapy areas, generic prices significantly exceed average European prices.

A Active substance-based (generic) referencing fails to generate a perfectly competitive generic market and is insufficient to minimize deadweight loss.
Differentiated referencing leverages savings and enables a quicker recycling of resources to innovative therapies

First generic  Second generic  Third generic  Fourth generic  Fifth generic  Sixth generic  Seventh generic  Eighth generic  Ninth generic

The end of the frontloaded phase may be linked to exact milestones (e.g. Herfindahl-index).

FRONTLOADED REFERENCING until the market becomes highly competitive

- As soon as the first generic appears, referencing enters into force
- Referencing is repeated monthly until the market becomes highly competitive (~6-8 brands or approx. 6 months)
- Prospective supply guarantee taken by generic entrants (instead of retrospective choice of reference product)
- Symbolic threshold for de-listing to allow for adaptation
- Possibility for post-bid price reduction

LINKING MORE ATTRACTIVE BENEFITS to the reference status as soon as the market has become highly competitive

- Semi-annual or annual referencing to provide suppliers with incentives to ‘build their markets’
- Regular international referencing
- Retrospective choice of the reference product
- Preferred reimbursement for the reference product (+5%)
- Low (10%) threshold for de-listing
- Possibility for post-bid price reduction (or no possibility, but then it’s really tough…)

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There are at least three reasons why the reimbursement of biosimilars should be taken seriously:

1. **Substantial reserves in the prices of biological products**
   - A significant decrease in prices can be achieved

2. **Limited growth in production capacity for biological products**
   - Companies manufacturing biosimilar products are currently unable to supply all markets immediately on patent expiry

3. **Need to manage biological product prices transparently**
   - As a negative externality, less effective reimbursement schemes for biological products might jeopardise the effectiveness of existing (effective) reimbursement schemes
   - In lack of price transparency, biogeneric companies will tend to supply high-price markets first
The special characteristics of biosimilars should be taken into consideration but should not be mystified.

Clinical / pharmacological characteristics

• Immunogenicity concerns
• No clinical evidence on the interchangeability of biosimilars

Health economics considerations

• Considerable savings potential in the use of biosimilars
• Need to encourage price competition

Referencing is not a viable method of cost containment, therefore a new reimbursement logic is needed.

Solution: combination of bidding and conditional reimbursement.
A viable reimbursement scheme for biosimilar products combines bidding with conditional reimbursement

1. **BIOTECH BID**
   - Submission of price bids twice a year (in one-round bids)

2. **CONDITIONAL REIMBURSEMENT**
   - **New patients** can only be treated with:
     1. the lowest DCT product
     2. products with a DCT maximum 5% higher than the lowest DCT
   - **Patients already on therapy** can stay on the current therapy

- No switch ‡ no safety (immunogenecity) concerns for patients already on treatment
- Conditional reimbursement terms apply for the 6-month period following the bid
- Bidders have to provide full supply guarantee and always keep a total of 200,000 DOT in inventory
- Incentives for price competition (6-month preferred status for ‘good’ bids, 6-month freeze for expensive products)
- New products which are at least 10% cheaper will automatically receive the preferred status
The logic underlying performance-pay (performance-based risk-sharing agreements)

Real-life therapeutic effectiveness
Value creation for society

Level 1: CONVENTIONAL REIMBURSEMENT SCHEMES
- ‘Cash & Carry’ logic
  - Product sale
  - No adherence / persistence guarantee
  - No effectiveness guarantee

Level 2: ADHERENCE SCHEMES
- ‘Best Effort’ logic
  - Sale of service package
  - Explicit adherence / persistence guarantee
  - No effectiveness guarantee

Level 3: OUTCOME SCHEMES
- ‘Success Fee’ logic
  - Sale of service package
  - Implicit adherence / persistence guarantee
  - Explicit effectiveness guarantee

Real-world therapeutic effectiveness information tends to significantly differ from clinical efficacy data.

Focusing on outcomes should, at least theoretically, result in higher quality of medical care.

Development of patient and payer requirements

Real-world therapeutic effectiveness information tends to significantly differ from clinical efficacy data.

Focusing on outcomes should, at least theoretically, result in higher quality of medical care.
In Hungary, all risk-sharing schemes are incorporated into price-volume agreements between the MAH and the National Health Insurance Fund.
Payer requirements towards outcome schemes

- The scheme should be implementable in an already existing legal framework (‡ price-volume agreements)
- Measurement should be exact, simple and preferably based on data which is already available
- Measurement costs should be proportional to potential benefits
- End-points of real-life therapeutic effectiveness should be based on consensus
- Monitoring real-life therapeutic effectiveness should contribute to the development of health provision (‡ avoid l’art pour l’art schemes)
- The scheme should not entail any indirect budgetary risks
The relevance of adherence schemes

Time to discontinuation of 6 chronic therapy classes (allowing for 60-day treatment gap)

- Oral antidiabetics
- ARBs
- Statins
- Bisphosphonates
- Prostaglandins
- OAB medications

Source: Yeaw et al. (2009), J Manag Care Pharm
Adherence schemes offer a potential win-win situation

<table>
<thead>
<tr>
<th>Payers</th>
<th>Physicians and pharmacists</th>
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<tbody>
<tr>
<td>• Higher utilisation of pharmaceutical spending</td>
<td>• Higher therapeutic effectiveness of medicines prescribed and dispensed</td>
</tr>
<tr>
<td>• Lower risks of polipragmasy, complications and over-consumption of health services</td>
<td>• Closer contact and communication with patients</td>
</tr>
<tr>
<td>• Lower exposure to ‘expansive’ patient acquisition strategies</td>
<td>• Tools and platforms to educate patients and design communication messages</td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>• More valuable contribution to health and society</td>
<td>• Better and more information</td>
</tr>
<tr>
<td>• Chance to move from expansive patient acquisition strategies toward patient retention</td>
<td>• Real therapeutic effect of medicines taken</td>
</tr>
<tr>
<td>• Increased turnover and reduced promotion costs in an ethical way, through patient retention</td>
<td>• Improved understanding of ‘drivers of health’</td>
</tr>
<tr>
<td></td>
<td>• Better health</td>
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<table>
<thead>
<tr>
<th>Pharmaceutical companies</th>
<th>Patients</th>
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There is an always growing emphasis on soft tools: the example of NHIFA*’s online physician feedback system

* NHIFA: Hungarian National Health Insurance Fund Administration