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Overview of the Hungarian pharmaceutical reimbursement system

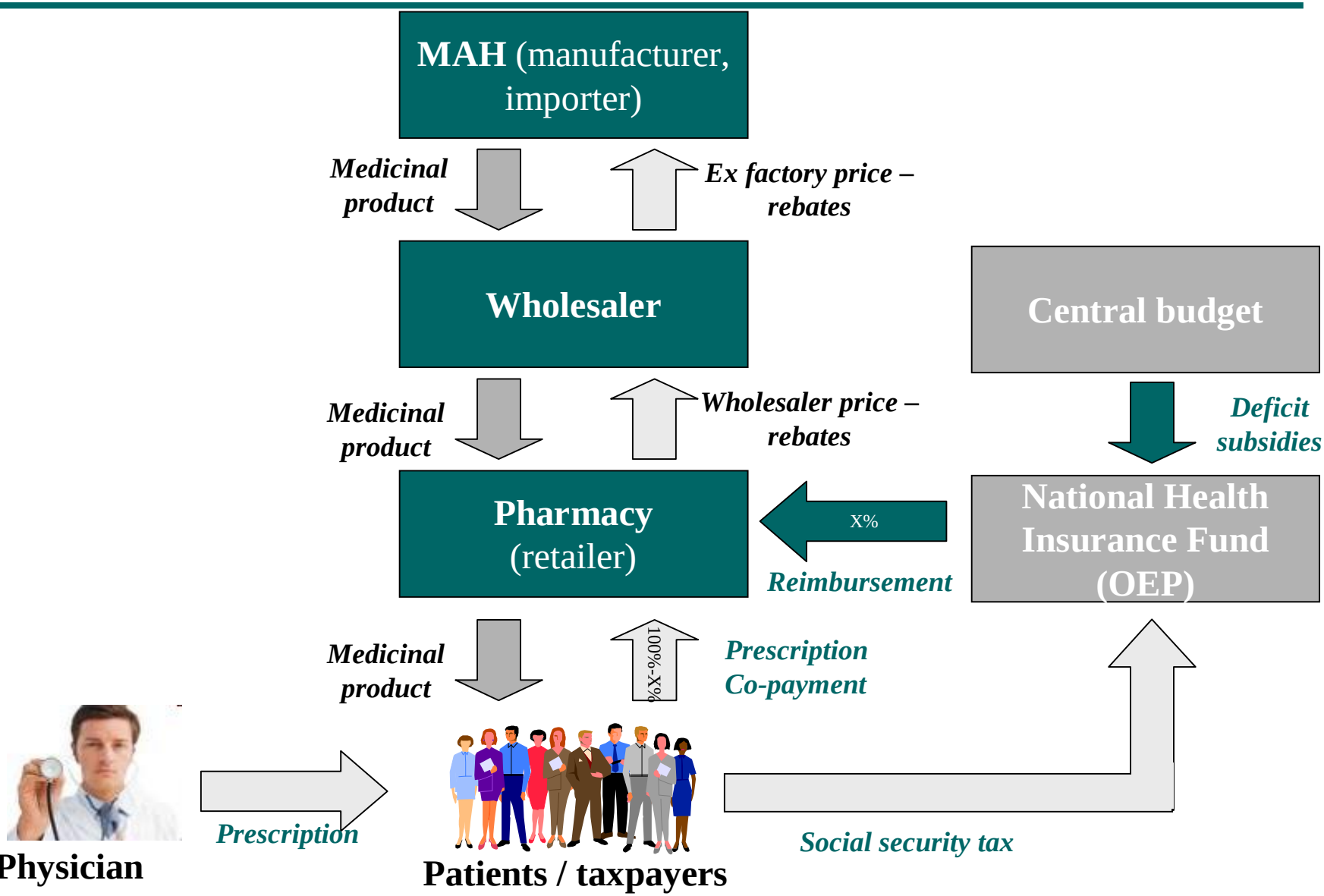
Paris, 12 October 2010

EMAUD
European Market Access University Diploma

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

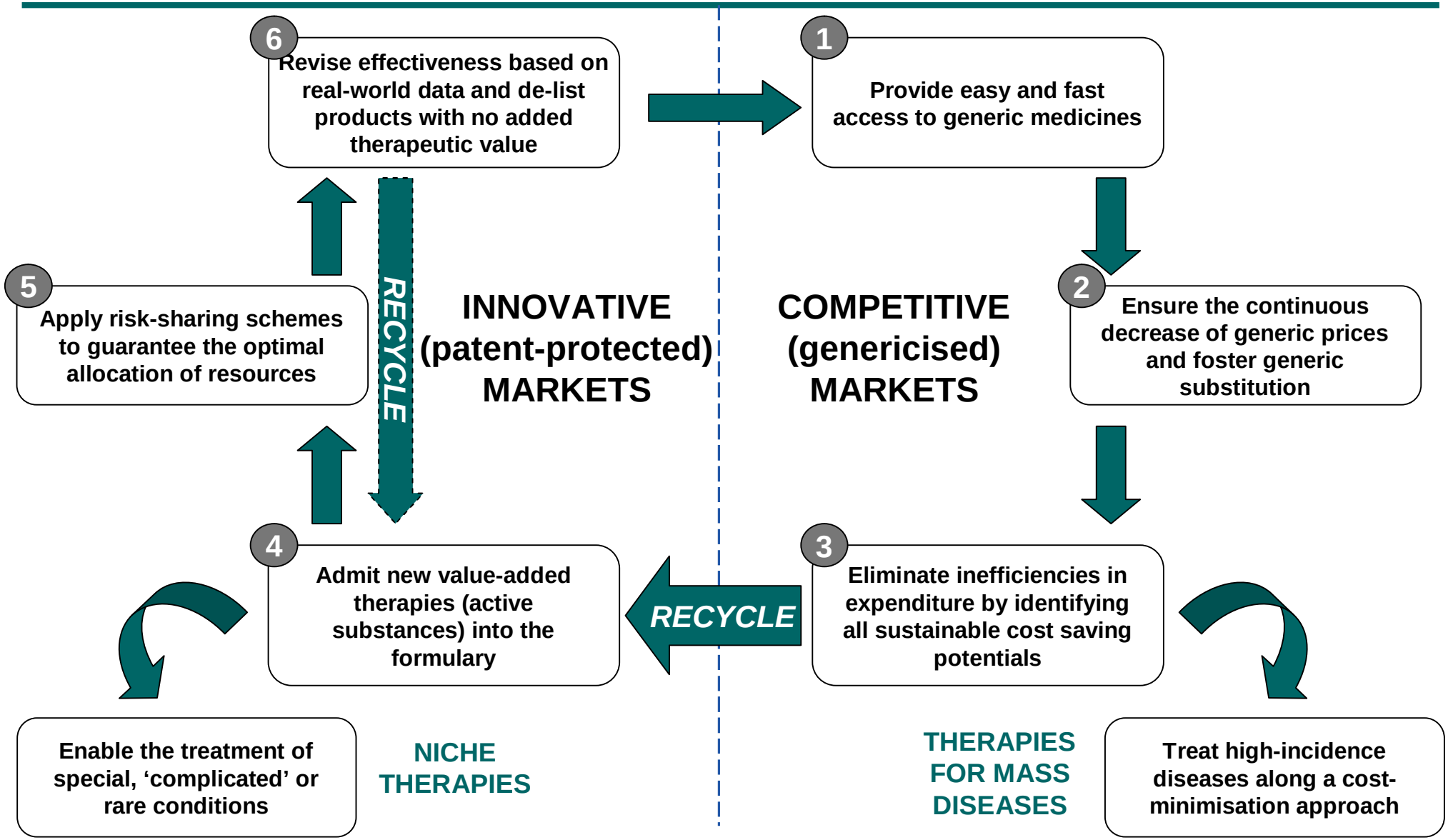


The National Health Insurance Fund Administration (NHIFA) tries to follow an explicit vision in pharma reimbursement

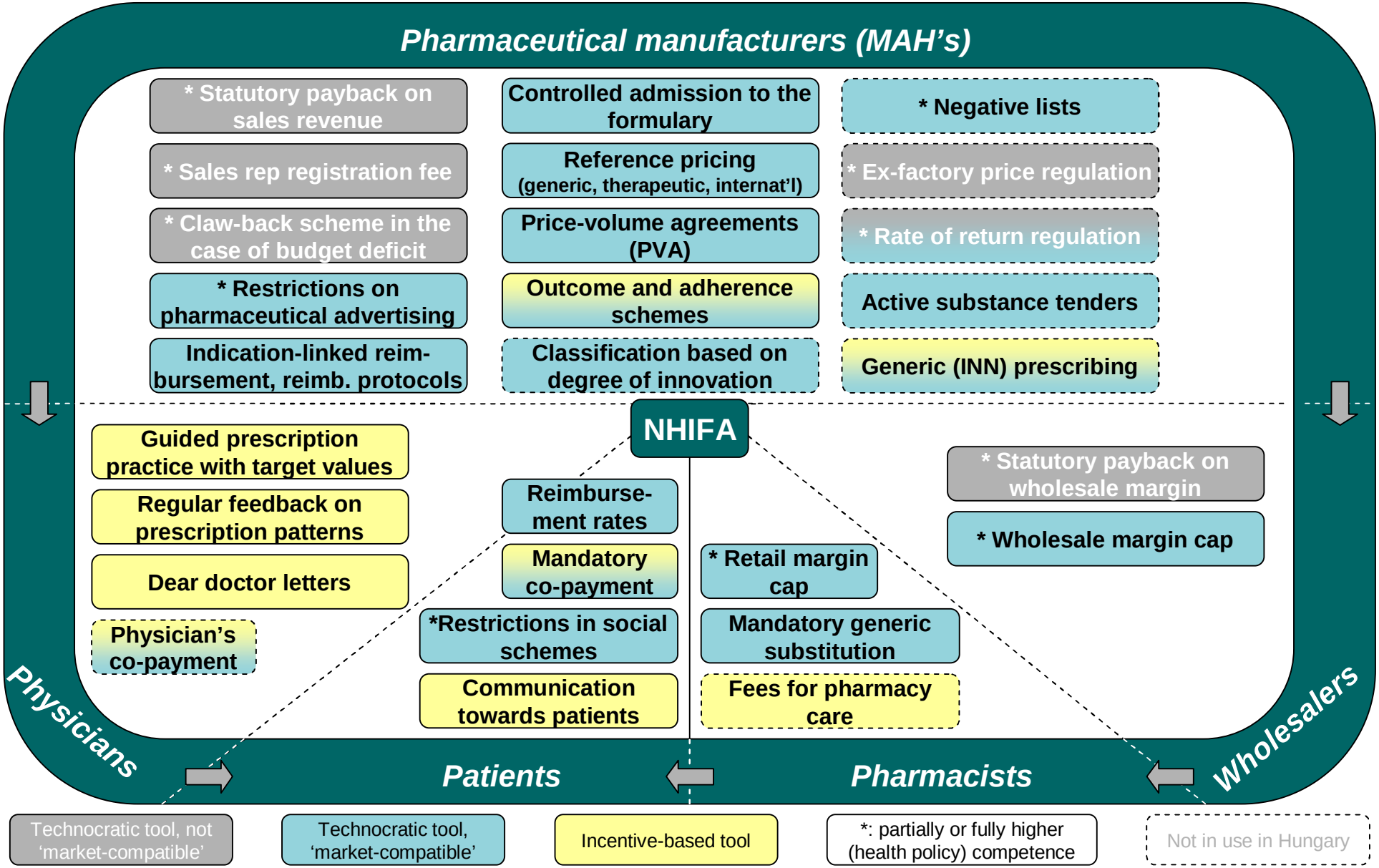
We provide access to new **value-added therapies** by **continuously recycling resources** from off-patent products to innovative products with proven therapeutic effectiveness.

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



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

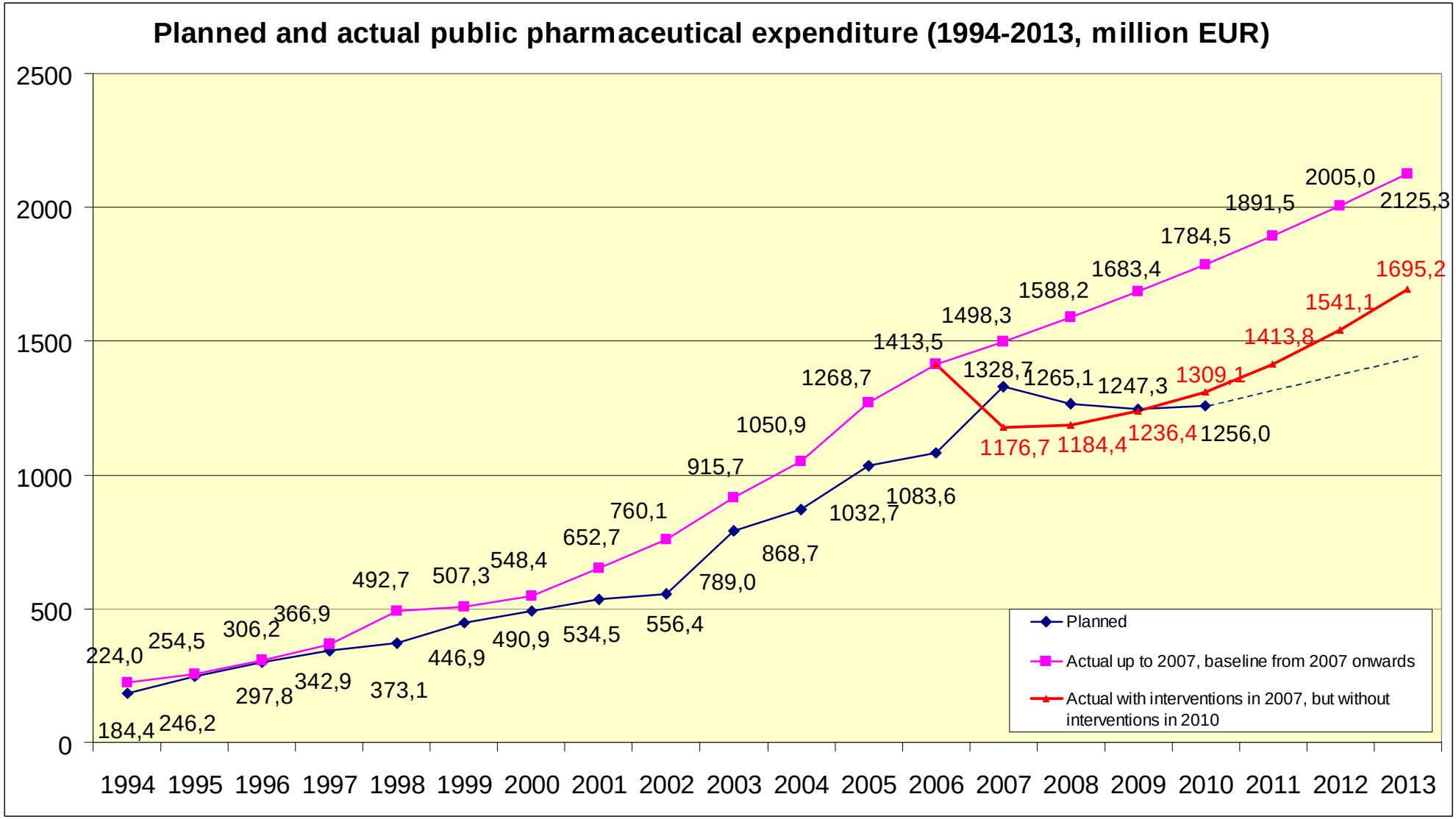


Facts and figures from Hungary (2006—2010)

Total public health expenditure (TPHE)	**6% of GDP (6,2bn €)** **620€/capita/year**
Total public pharmaceutical expenditure	**1,5% à 1,2% of GDP (1,4bn € à 1,0bn €) 140€/capita/year à 100€/capita/year** **25% à 20% of total public health expenditure**
Out-of-pocket pharmaceutical expenditure	**0,37bn € à 0,39bn €** **37€/capita/year à 39€/capita/year** **Average co-payment: ~30 per cent**
Reimbursed pharmaceuticals	**4.700 à 4.400 reimbursed pharmaceuticals** **1.500 à 1.700 generic pharmaceuticals (60% of turnover in DOT)**
Consumption of pharmaceuticals	**30 à 27 units/capita/year** **492 à 481 DOT/capita/year**

N.B.: 1 EUR=275 HUF (as of 11 October 2010)

Trend of public pharmaceutical expenditure in Hungary (1994-2010)



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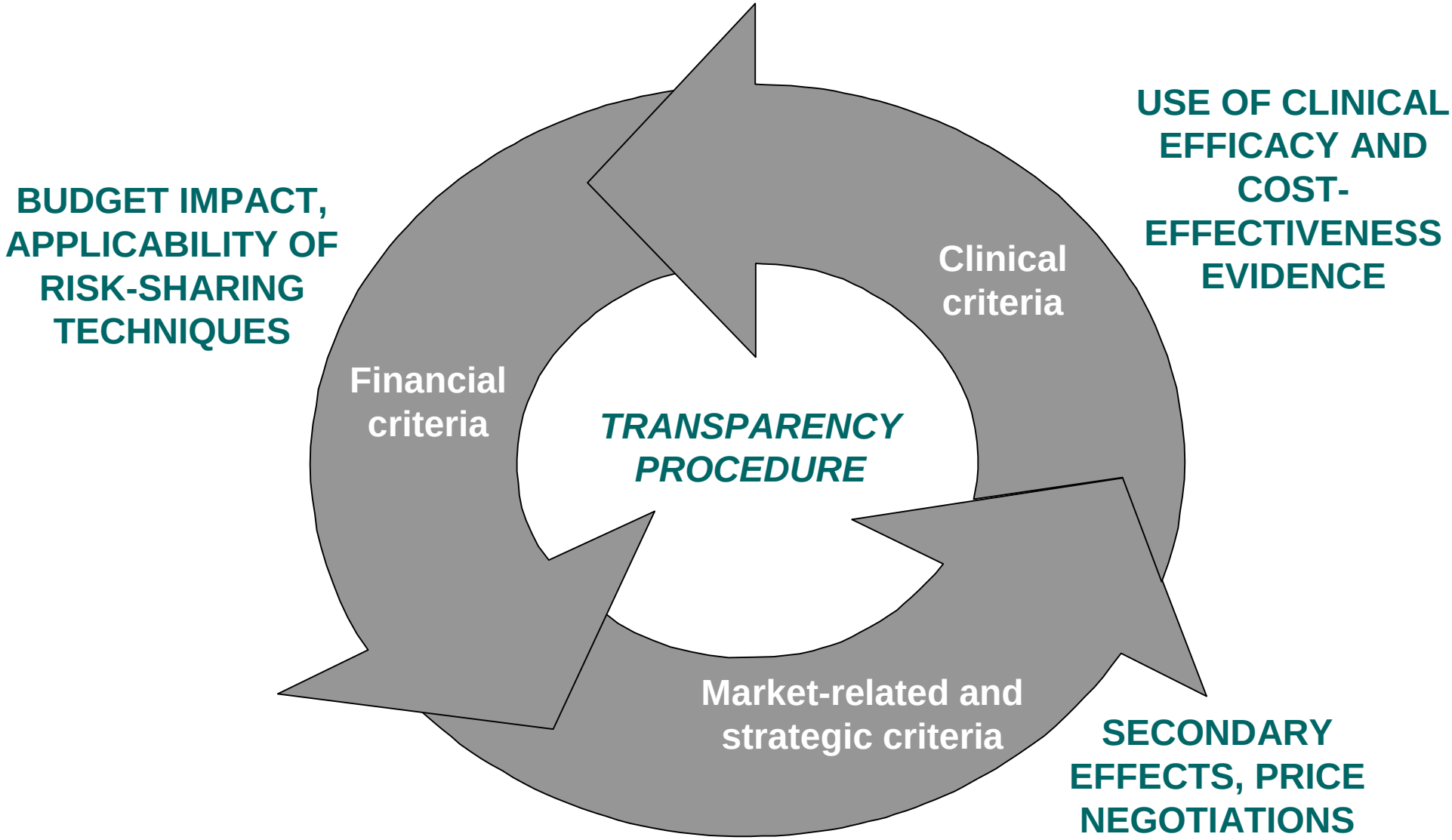
The three main drivers behind reimbursement decisions



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

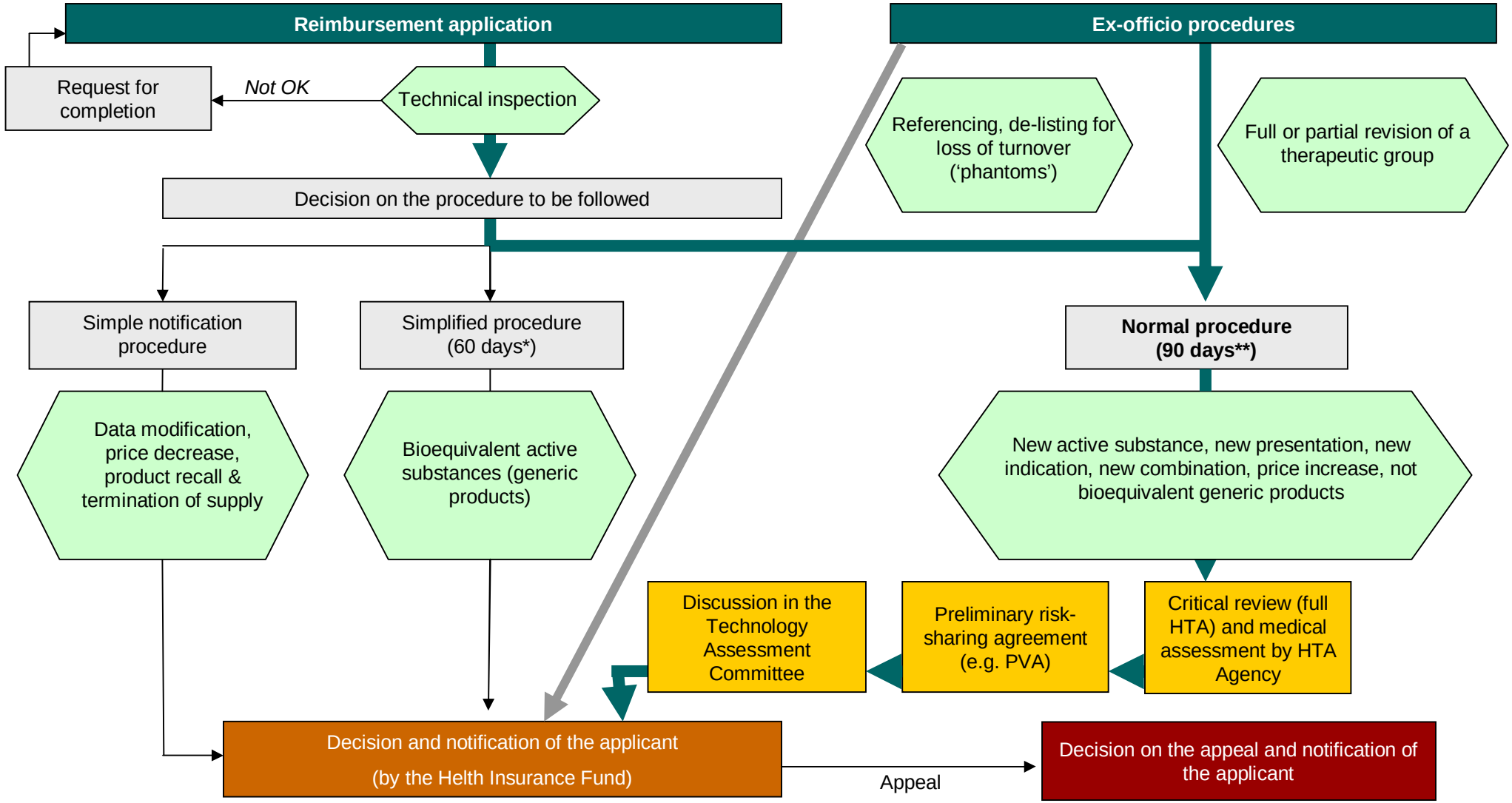
Simplified procedure

- 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



*: 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

Full HTA for new active substances

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% (à 3.7%)
- No explicit QALY-threshold

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

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Reimbursement rates used in Hungary

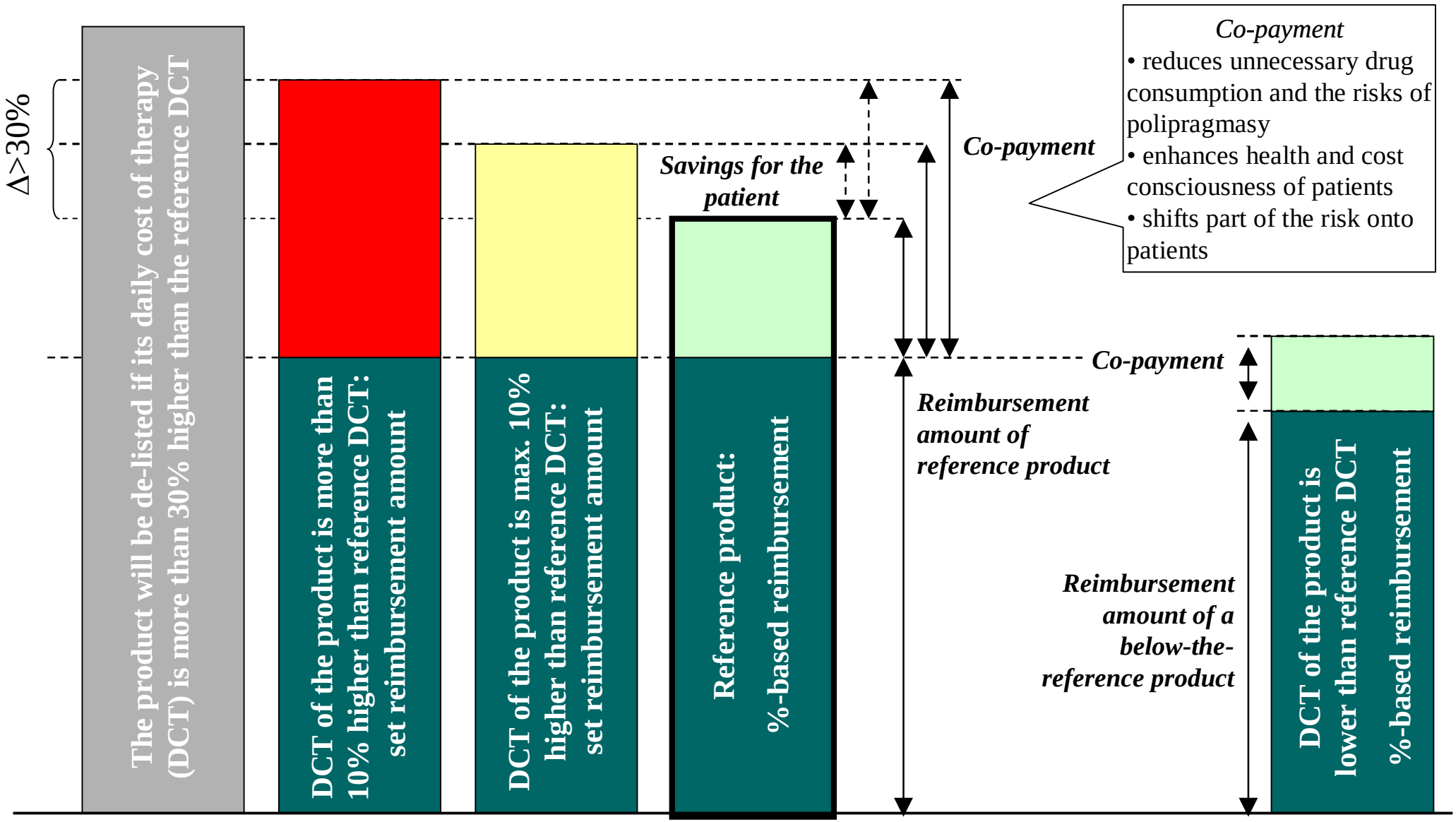
Normative reimbursement (general prescription right for all physicians in all indications listed in the marketing authorisation)

- 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



Reference pricing: goal and key decision variables

GOAL	KEY DECISION VARIABLES
• 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**	**Approach(es) to use** **Timing and frequency of application**

Reference pricing: timing and frequency of application

ADMISSION TO THE FORMULARY

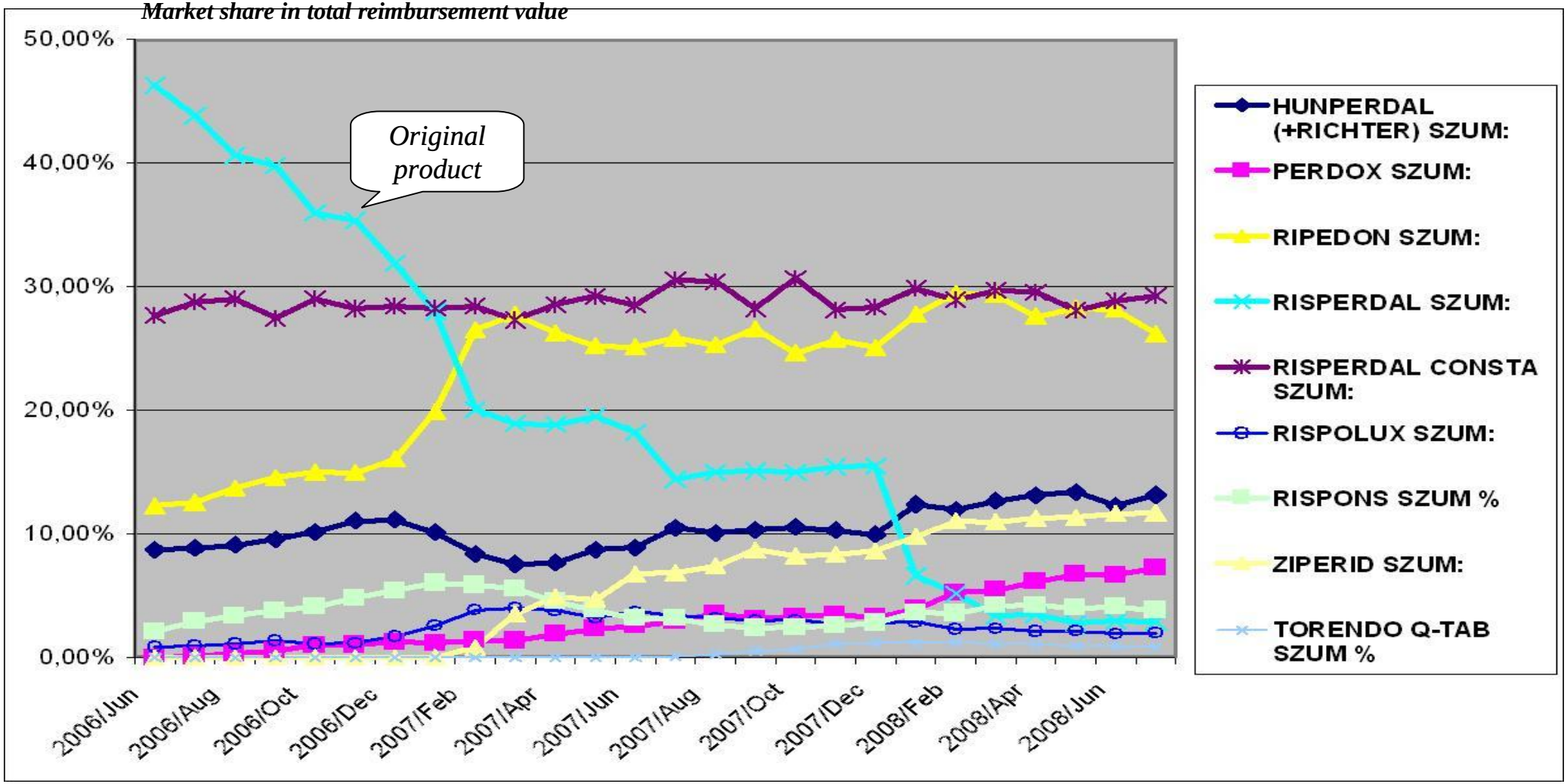
- **International price comparison for original products:** the price of the product may not be higher than in any of 13 selected countries of the EU/EFTA region (N.B. *regulation should be modified to cover all EU member states with higher per capita GDP*)
- **Generic threshold for newly competitive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

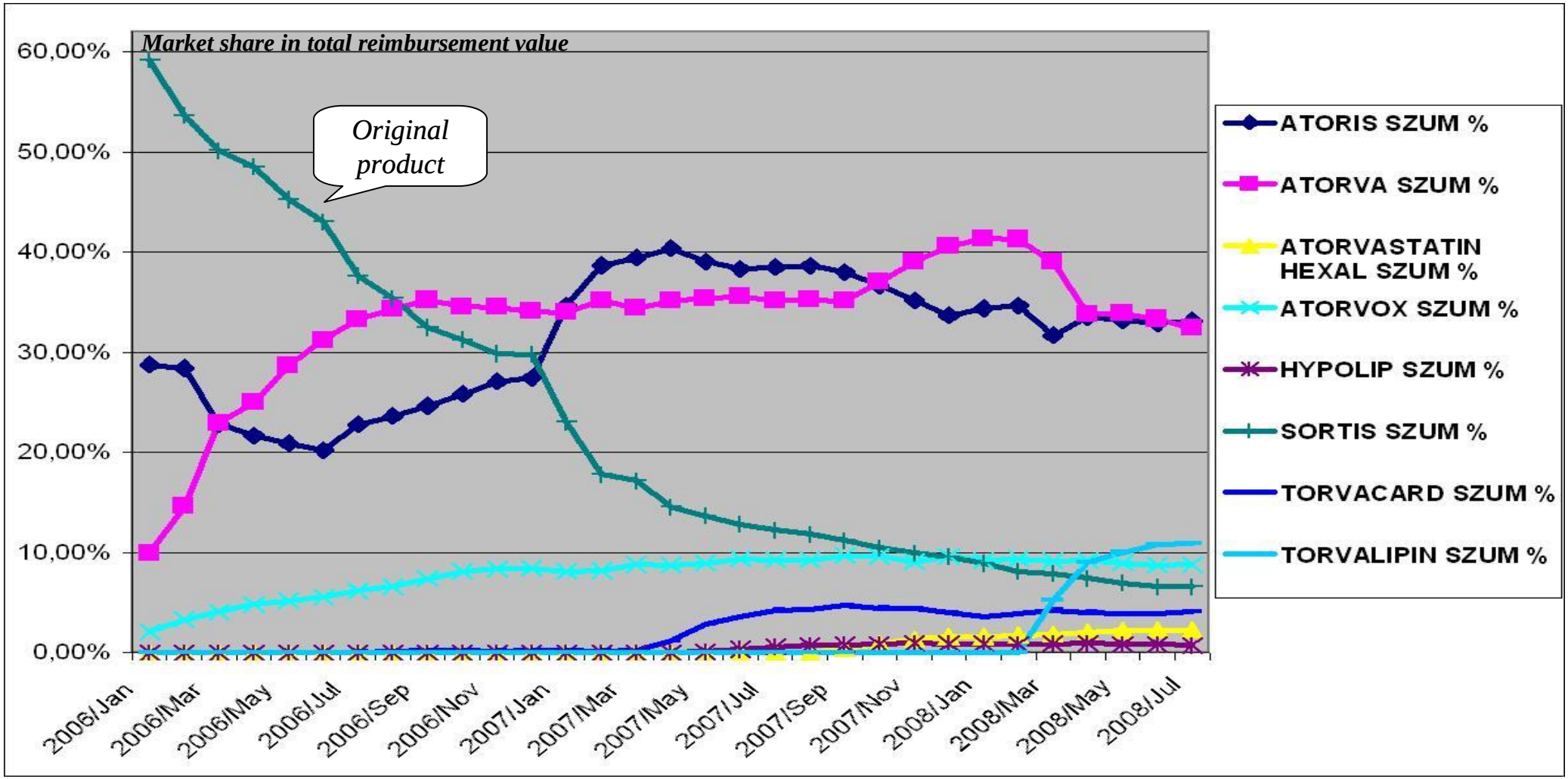
20070101, original, retail price: 155€ → **20080901, generic, retail price: 42€**



Impact of generic referencing: atorvastatin

20070101, original, retail price: 28,5€

20080901, generic, retail price: 21,2€



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

Simple payback
(NOT RISK-SHARING)

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

Financial risk-sharing

The marketing authorisation holder accepts to pay back a pre-determined amount if the number of units sold with reimbursement exceeds the volume cap

Payer's risk: real patient number exceeds the patient number on which the dossier was based

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

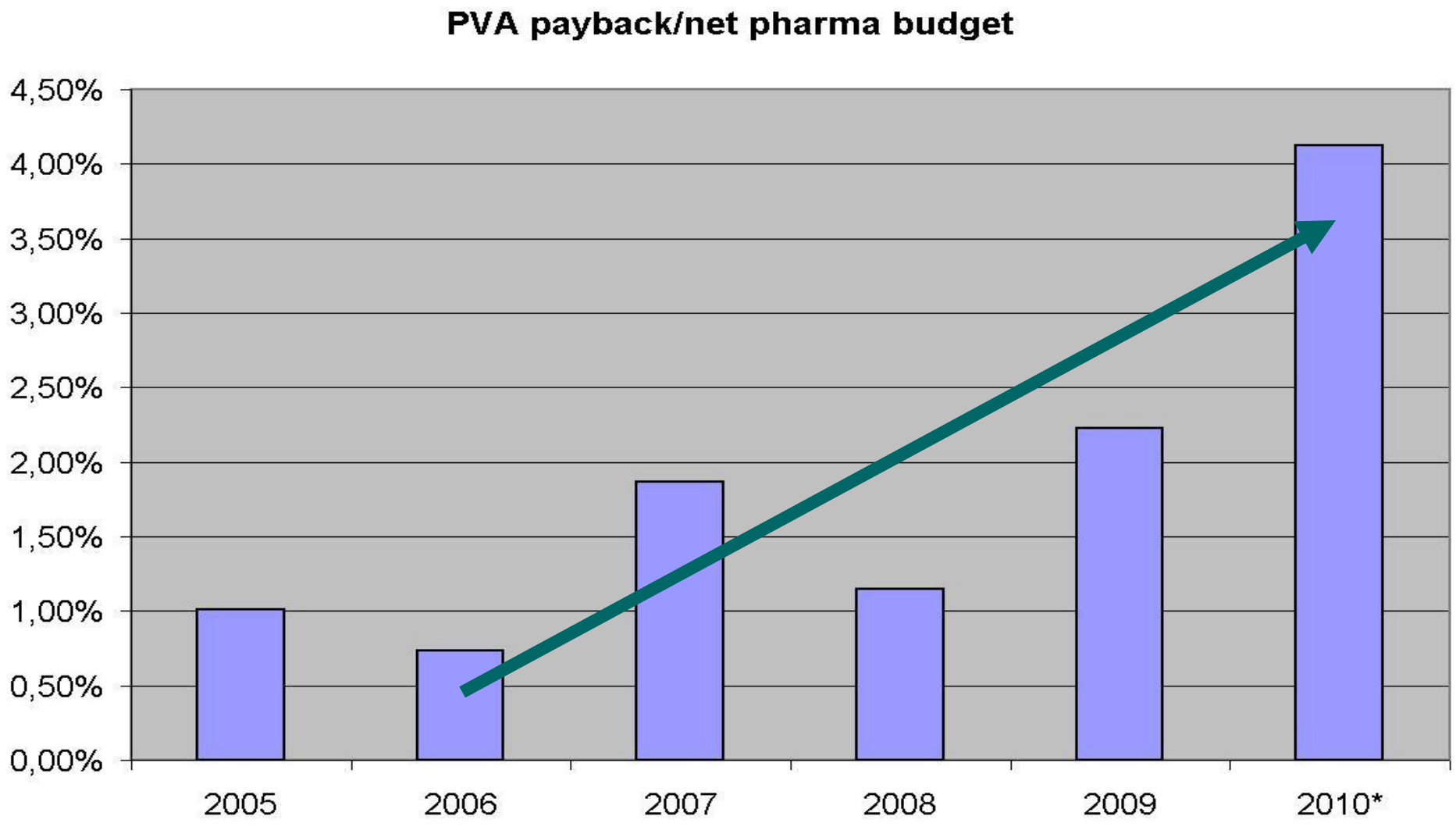
Therapeutic risk-sharing

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

Payer's risk: real life therapeutic effectiveness is lower than presented in the dossier

- 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?

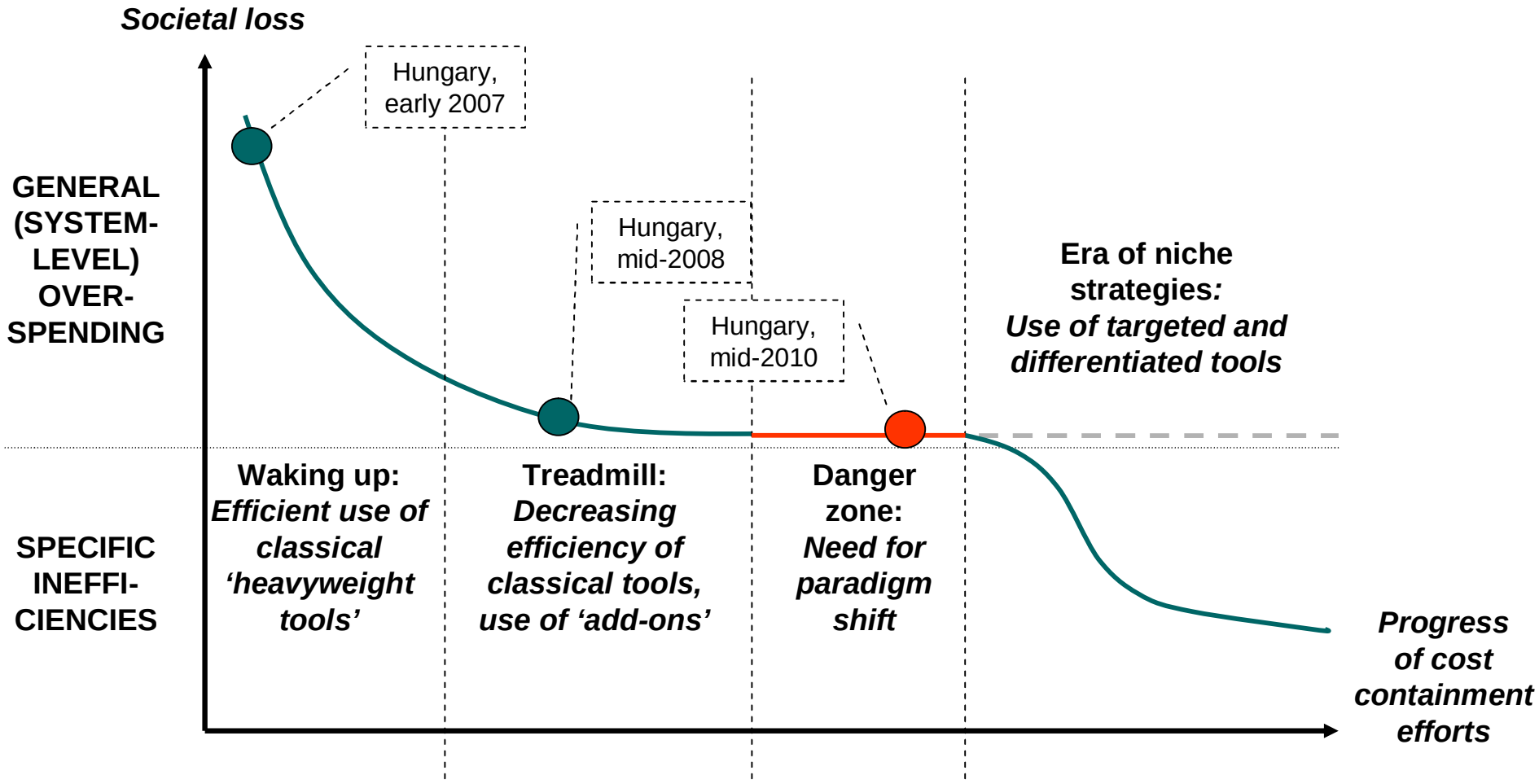
CHALLENGES WHICH ARE ALREADY HERE

- 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

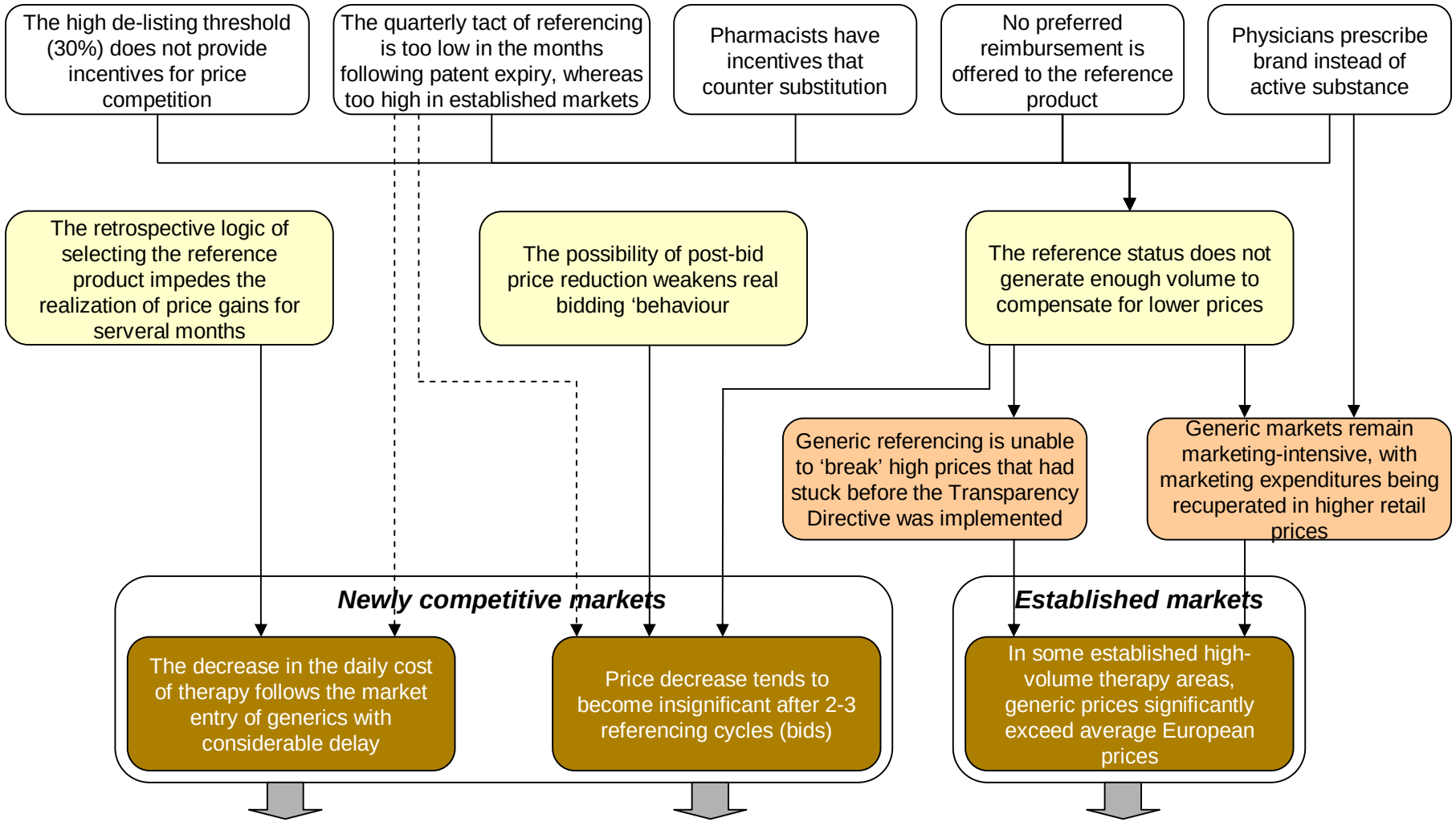
- Arrival of **personalized medicine** (with its associated costs)
- Patient need for **comprehensive health services** instead of simple product supply
- **Restricted or unavailable evidence** upon admission to the reimbursement formulary
- Poor **patient adherence** to treatment

In Hungary, we are experiencing a clear need for paradigm shift

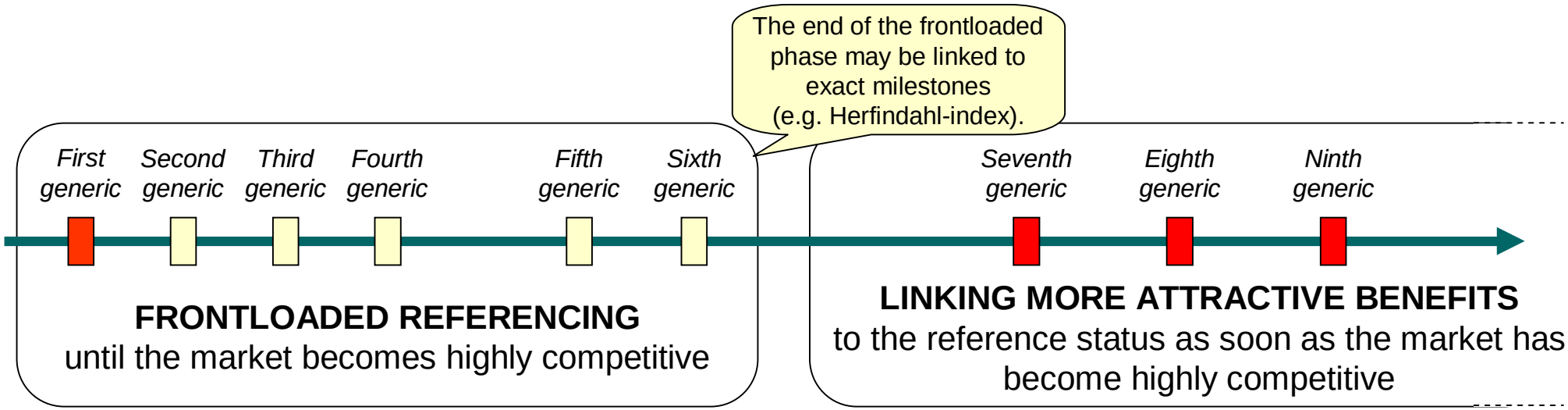


Undifferentiated 'heavyweight' cost containment tools lose their momentum as soon as general (system-level) overspending has been eliminated.

Limitations of generic referencing: experience from Hungary



Differentiated referencing leverages savings and enables a quicker recycling of resources to innovative therapies



- 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

- 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…*)

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**

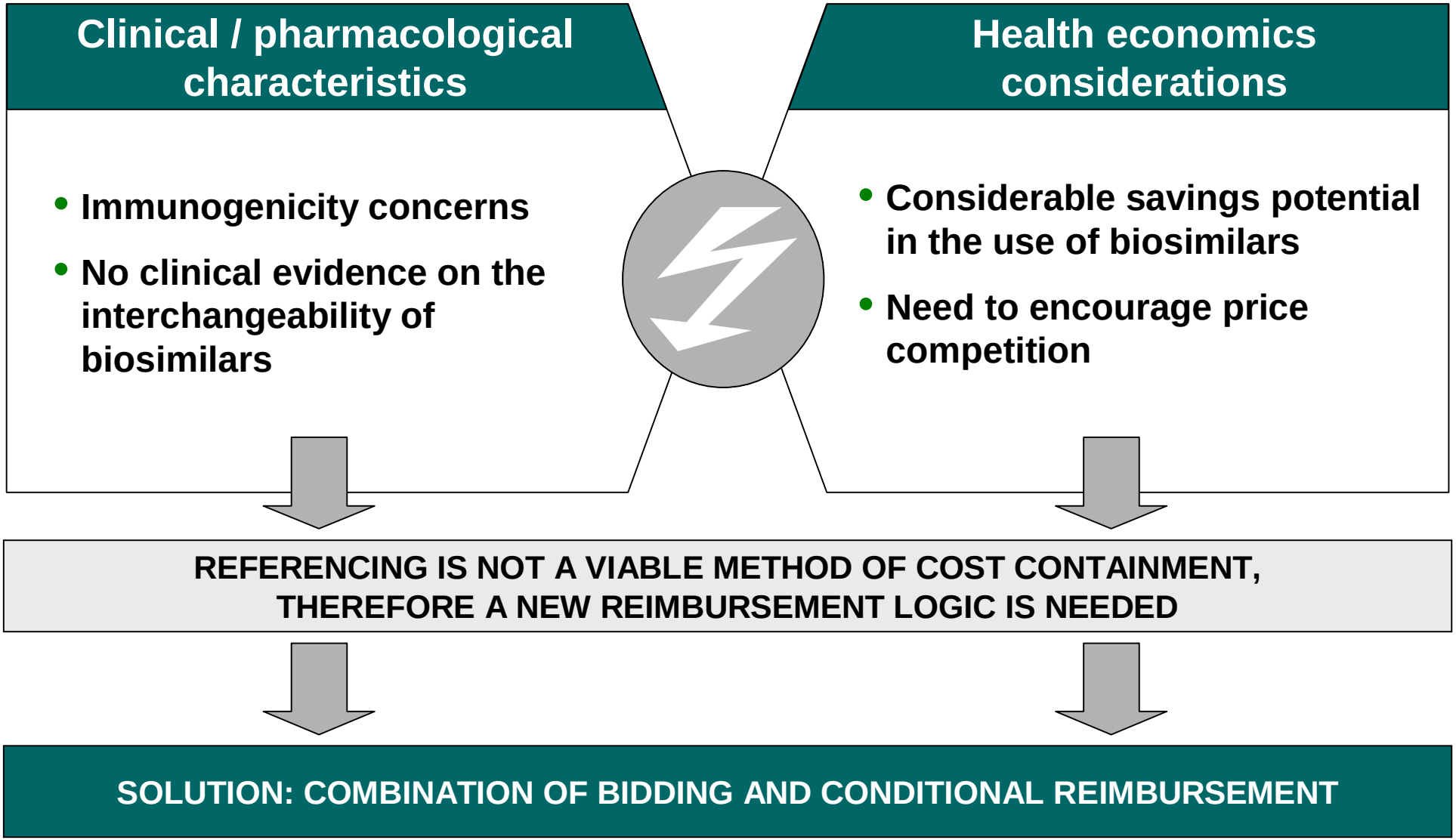
→ Companies manufacturing biosimilar products are currently unable to supply all markets immediately on patent expiry

3 **Need to manage biological product prices transparently**

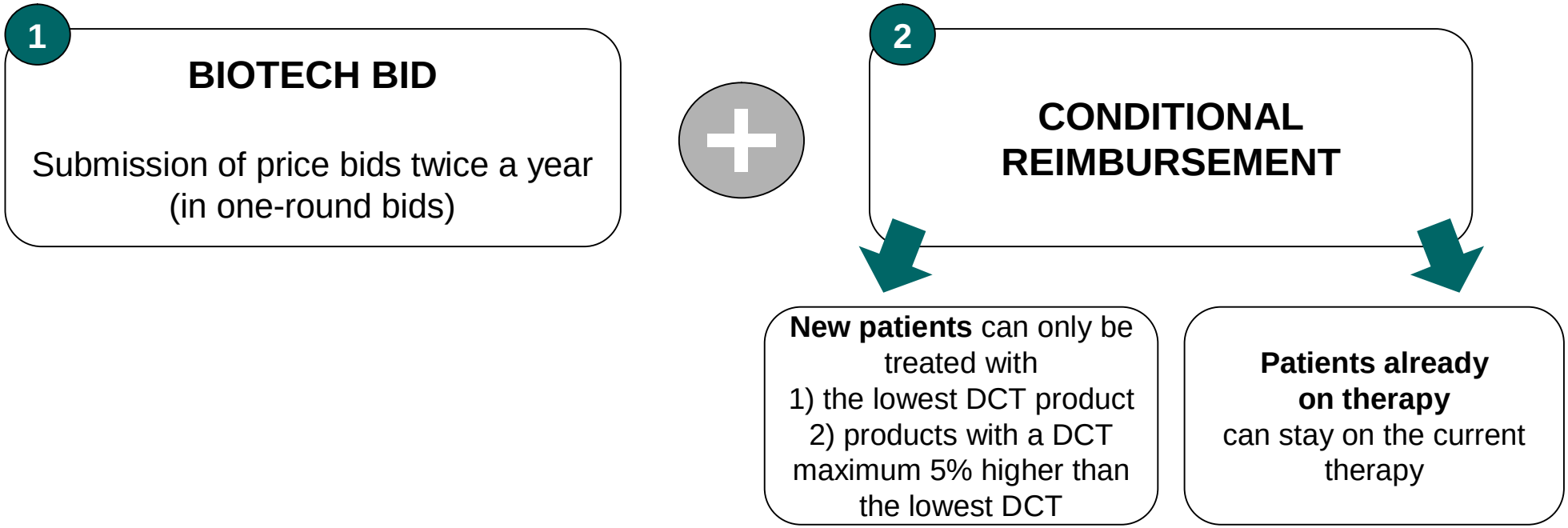
→ As a negative externality, less effective reimbursement schemes for biological products might jeopardise the effectiveness of existing (effective) reimbursement schemes

→ 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

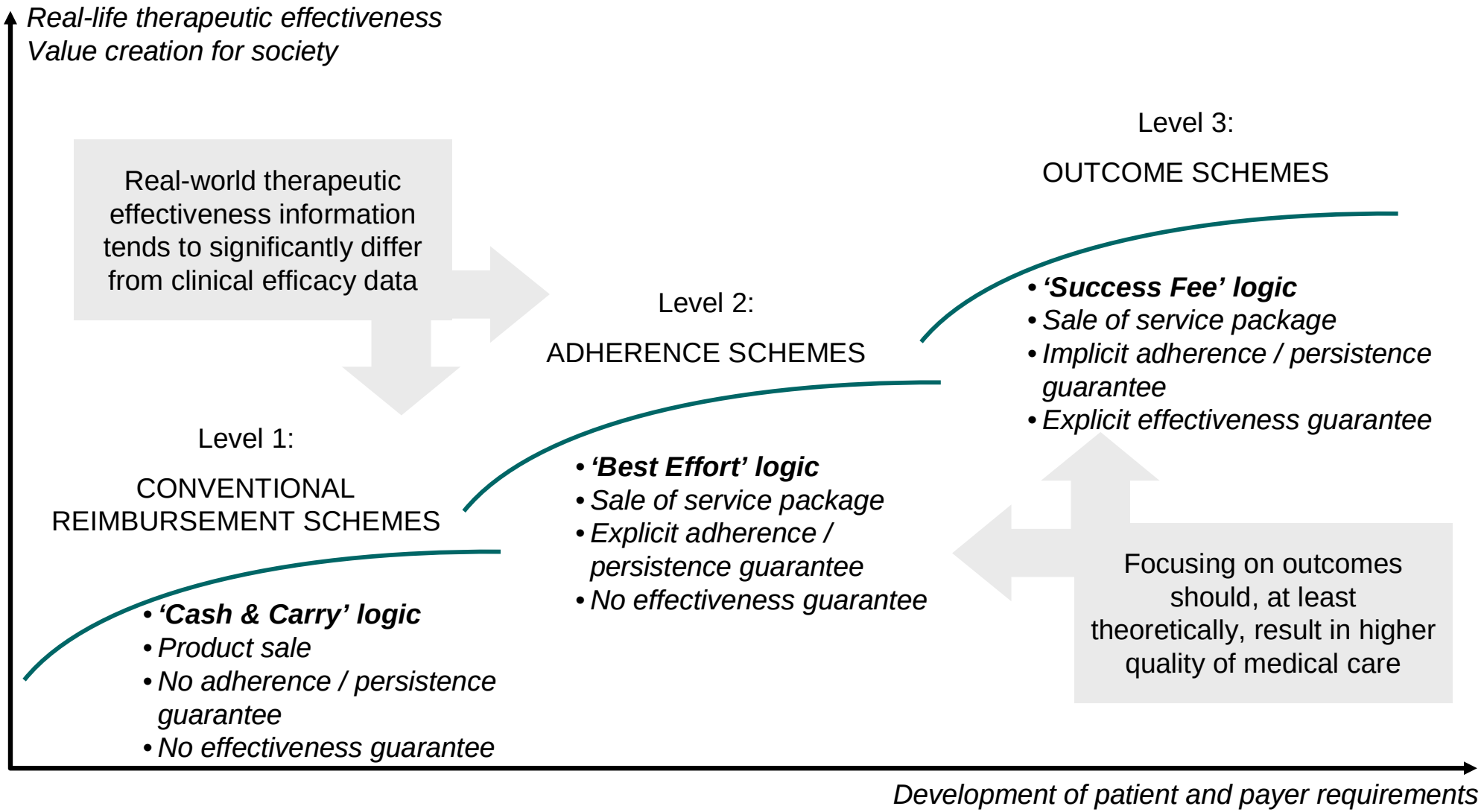


A viable reimbursement scheme for biosimilar products combines bidding with conditional reimbursement

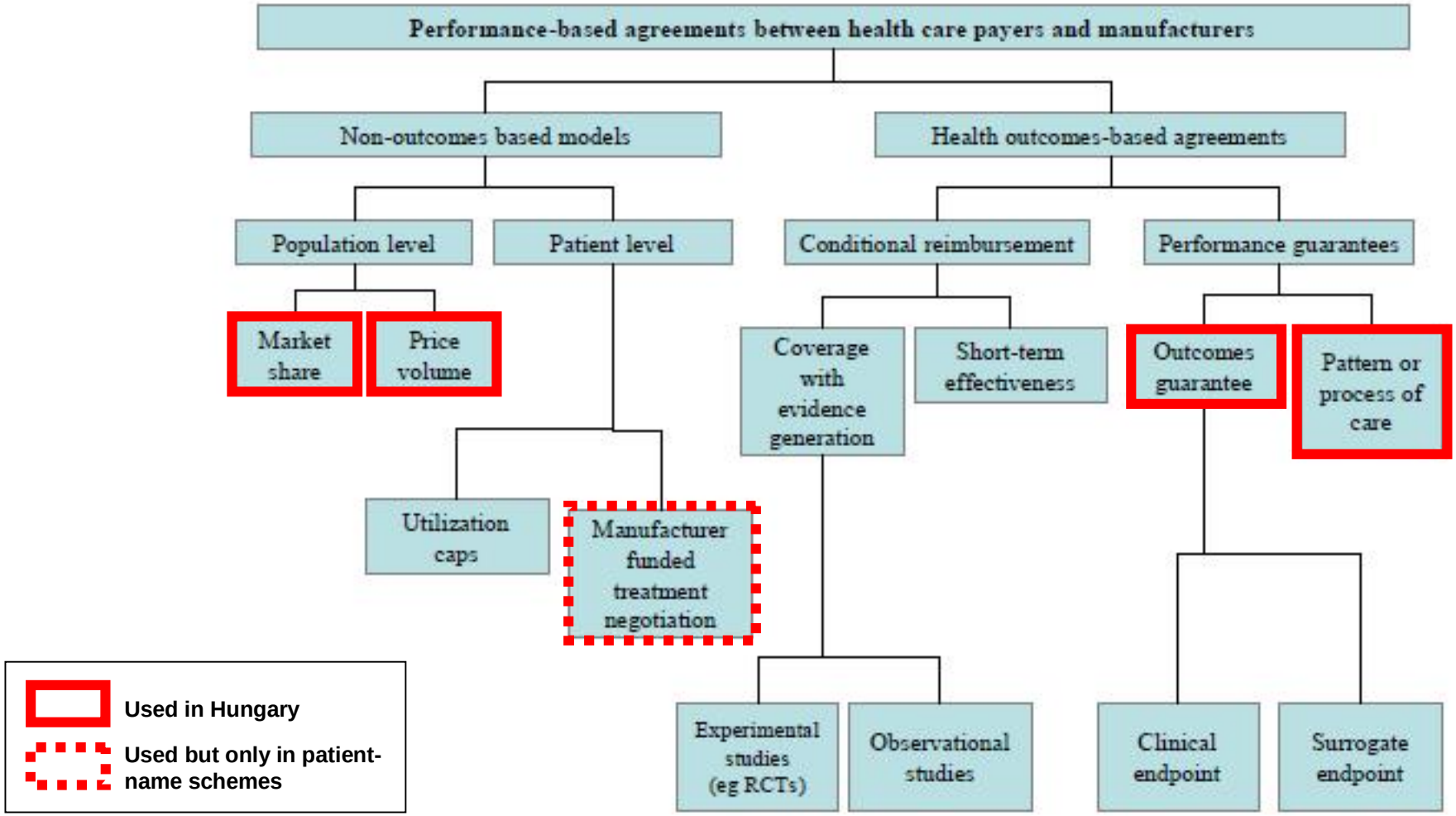


- **No switch à no safety (immunogenecity) concerns for patients already on treatment**
- **Conditional reimbursement terms apply for the 6-month period following the bid**
- **Bidders have to provide full supply guarantee and always keep a total of 200.000 DOT in inventory**
- **Incentives for price 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)



General overview of risk-sharing schemes



In Hungary, all risk-sharing schemes are incorporated into price-volume agreements between the MAH and the National Health Insurance Fund.

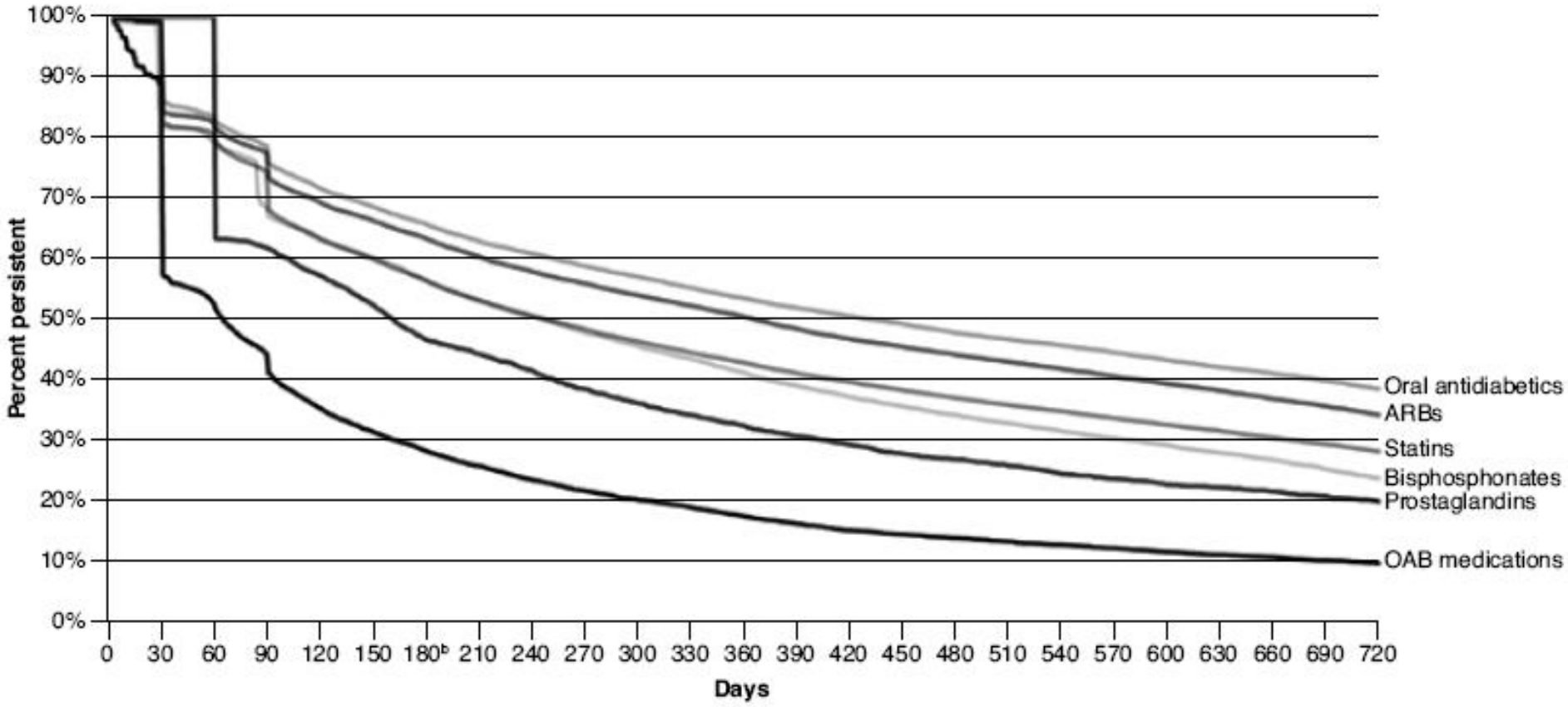
Source: Adapted from Espín (2008) based on ISPOR

Payer requirements towards outcome schemes

- The scheme should be implementable in an **already existing legal framework** (**à** 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** (**à** avoid *l'art pour l'art* schemes)
- The scheme should not entail any indirect **budgetary risks**

The relevance of adherence schemes

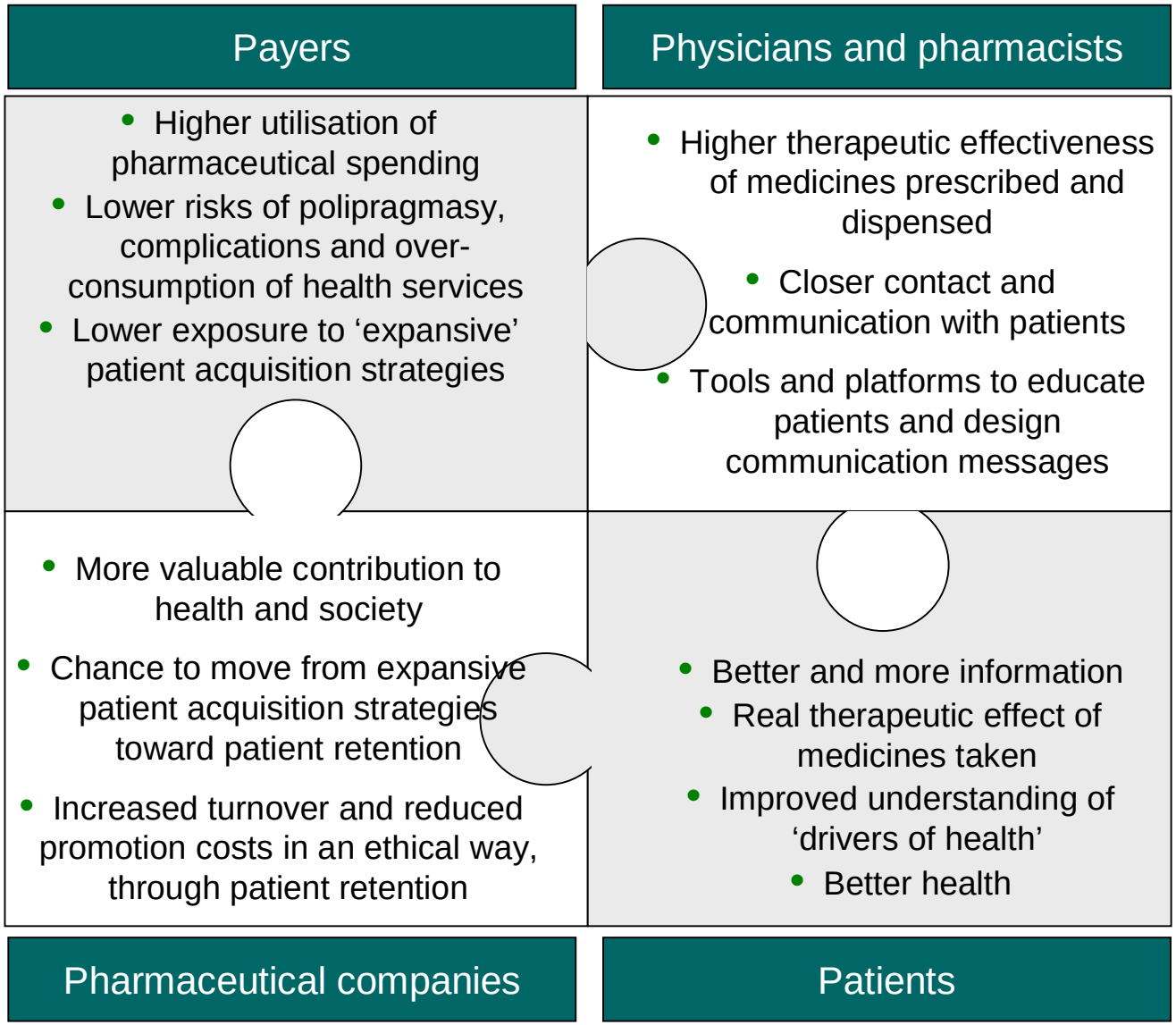
Time to discontinuation of 6 chronic therapy classes (allowing for 60-day treatment gap)



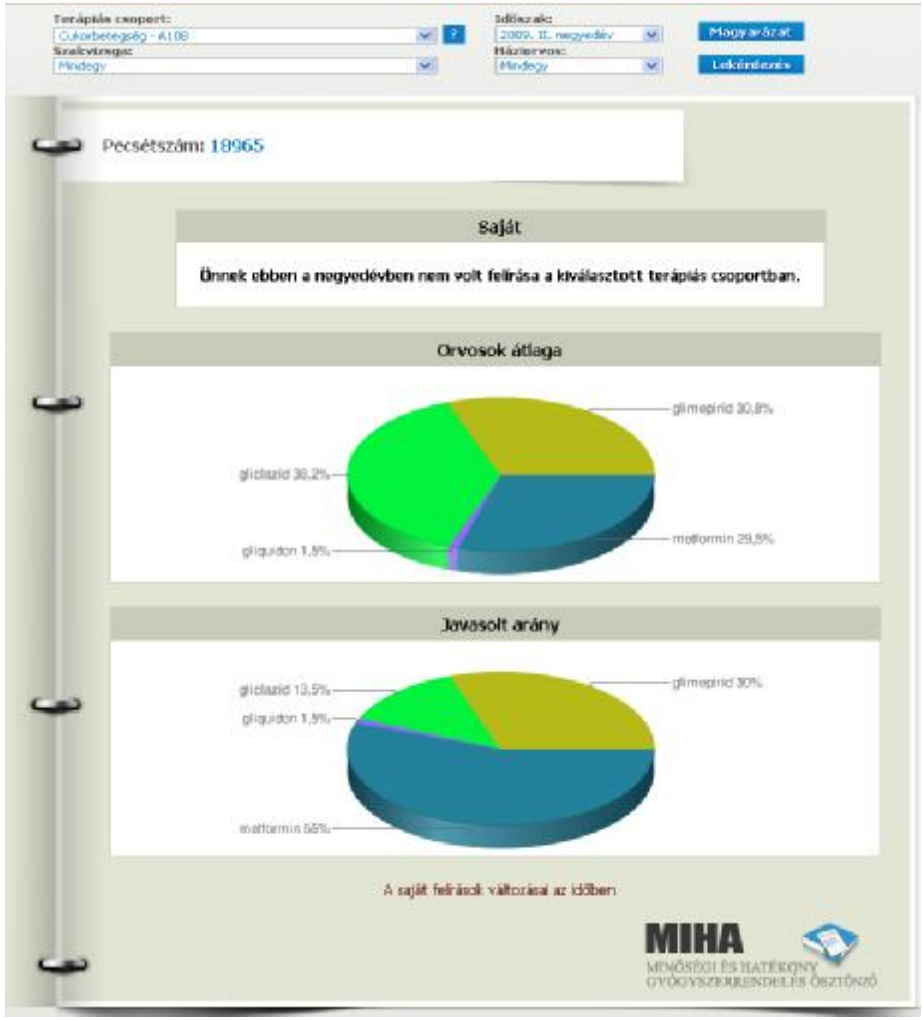
[a]*Discontinuation was defined as the end of days supplied for an index medication class pharmacy claim immediately preceding a 60-day gap in therapy. A minimum of 12 months (maximum 24 months) continuous eligibility following the index date (day 0) was required. Beginning at day 390, the denominator for the calculation consisted of all remaining eligible patients with continuous enrollment through the end of the 30-day interval. Patients with continuous enrollment ending between day 360 and day*

Source: Yeaw et al. (2009), J Manag Care Pharm

Adherence schemes offer a potential win-win situation



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*