

Cena innowacyjnego produktu leczniczego z perspektywy globalnego producenta farmaceutycznego

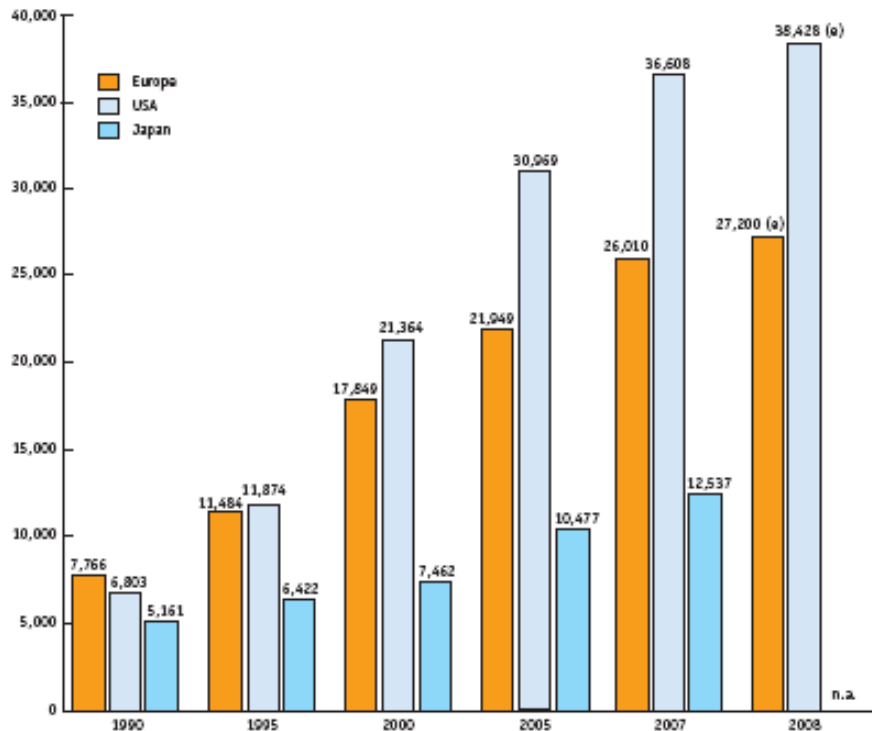


The price of innovative drugs from the perspective of a global pharmaceutical company

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Deterioration of Europe's Competitive Position (1/2)

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN
(MILLION OF NATIONAL CURRENCY UNITS*), 1990-2007



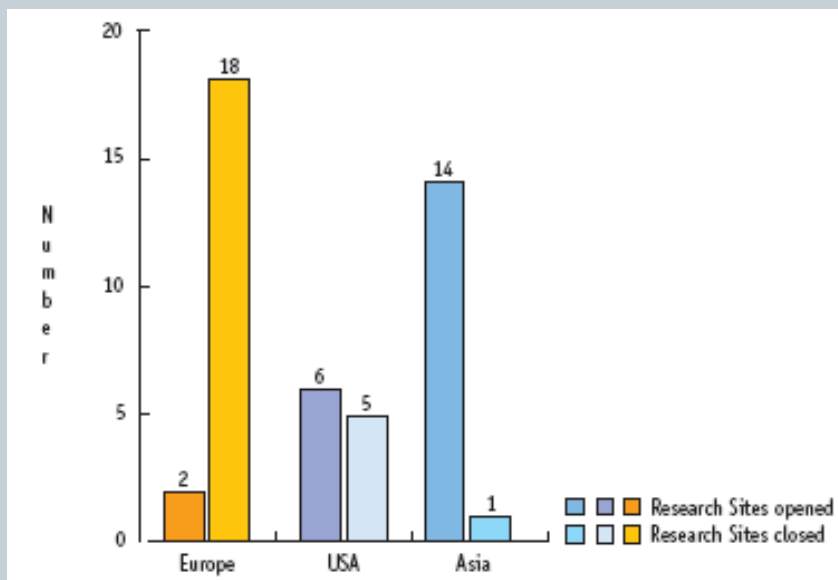
*Note: Europe: € million; USA: \$ million; Japan: ¥ million x 100
(e): estimate

- In 2008, the pharmaceutical industry invested an estimated EUR 27 billion in Europe
- However, between 1990 and 2008, R&D investment grew by 5.6 times in US compared to 3.5 times in Europe
- In Poland, no significant investments for the last 10 years

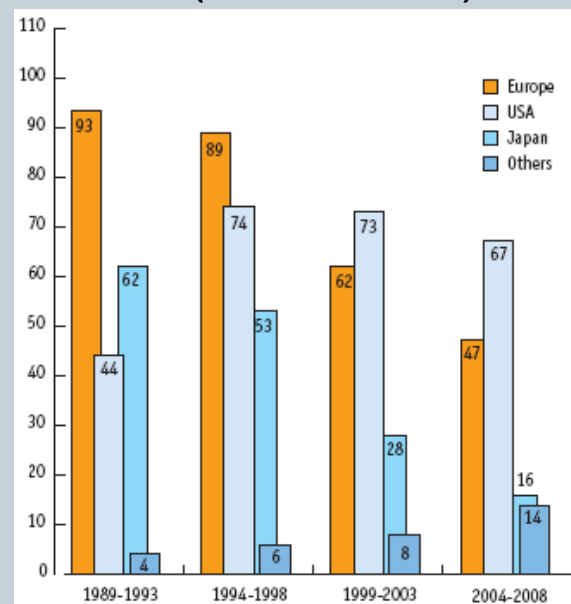
Lack of attractiveness for R&D investment in Europe

Deterioration of Europe's Competitive Position (2/2)

Changes in Research Sites (2001-06)



New Chemical or Biological Entities (1989-2008)



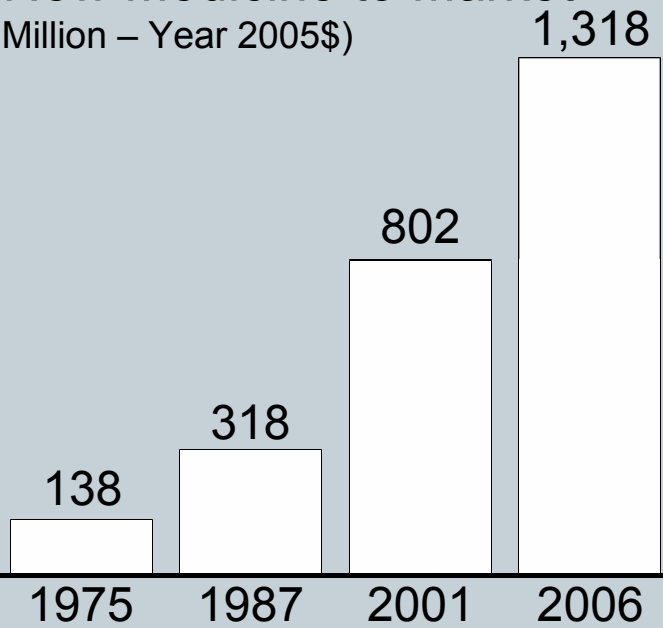
- Rapid growth of research environment in emerging economies like China or India
- Declining number of new chemical / biological entities in Europe (-50% in ~15 years)

Europe has lost its leading position in pharmaceutical R&D

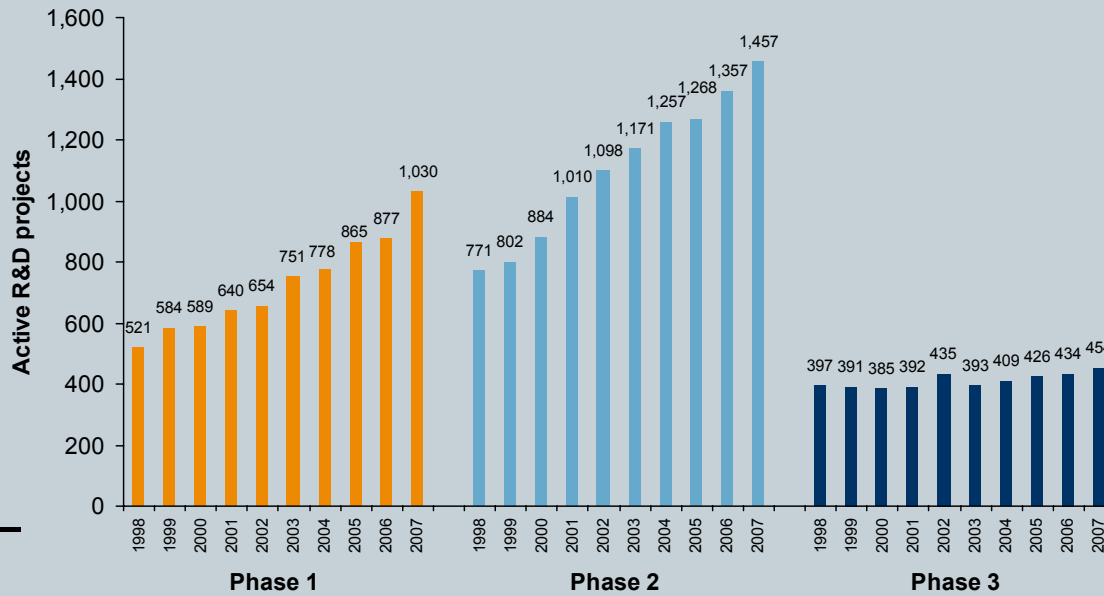
It is increasingly difficult to bring a new medicine to market



Estimated Full Cost of Bringing a New Medicine to Market (\$ Million – Year 2005\$)



Trends in Total Number of Global R&D Projects by Stage of Development



Total number of R&D projects increased; however, growing failure rate phase II / III
 Trend towards tailored therapeutics/biologics associated with higher development risk

Personalized medicines more difficult (and costly) to develop

The Definition of Innovation



Unmet Need

Innovation advances medical care in conditions lacking sufficient treatment options

Improvement

Innovation incrementally improves upon available treatment options, which may also address unmet needs

Comparative

Innovation improves patient outcomes relative to existing treatments

Value

Innovation perceived as valuable enough to be paid for, used, prescribed, and/or recommended

Perspective

What is innovative depends on the perspective of the individual or entity



**Improving
Patient
Health
Outcomes**

Variation in Valuation and Pricing Approaches Across Europe

(1/2)



- **OECD Report on Pharmaceutical Pricing 2008**

“In the interest of encouraging valuable innovation, efforts to link the level of expenditure for a given pharmaceutical product to **the value of the benefits offered by the new product** are attractive in that they can be used by manufacturers to assess willingness to pay for future innovations and should thus provide incentives for investment in R&D leading to valued innovation.”

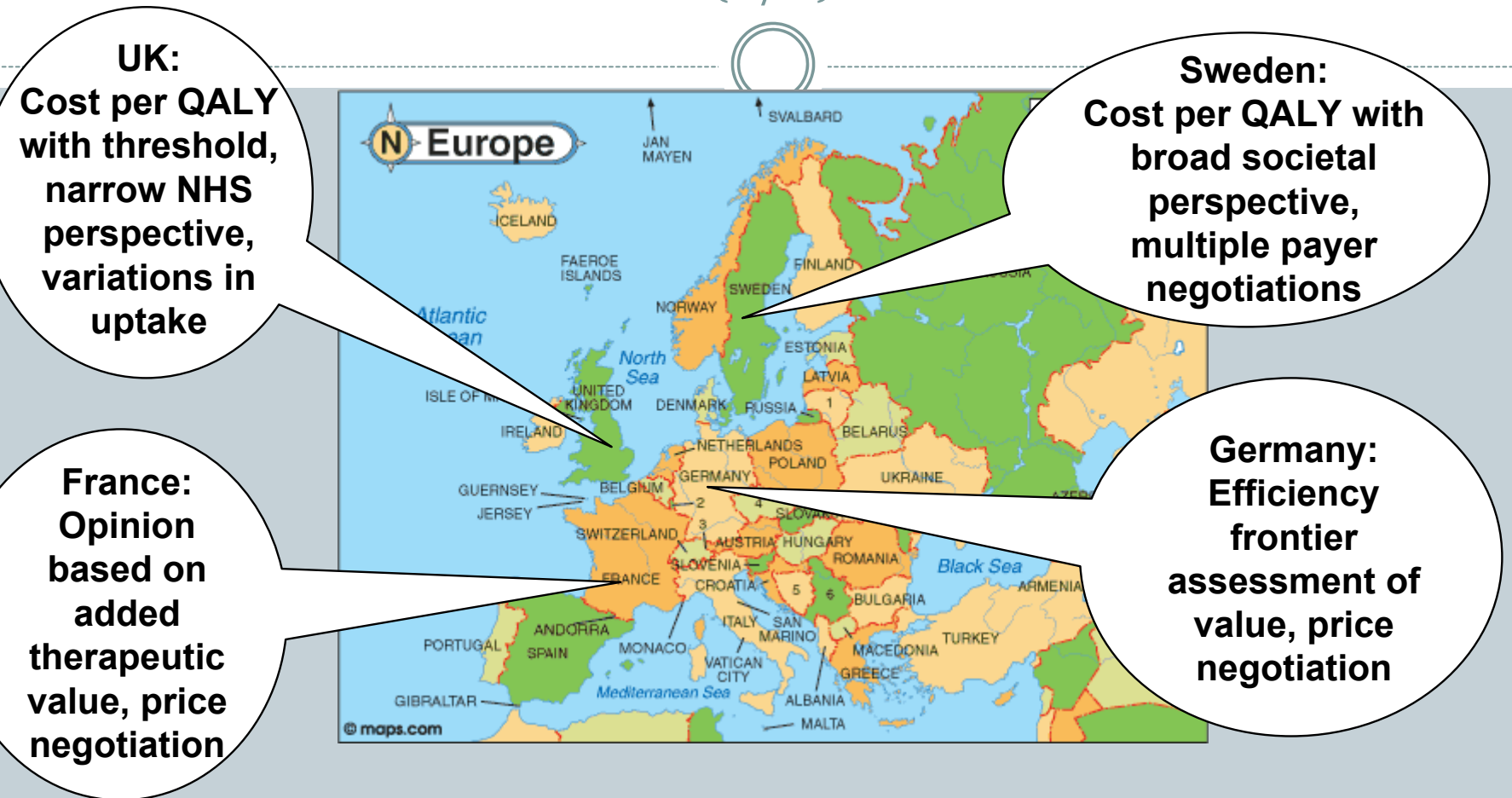
- **European markets may be “price takers” or “price makers”**

UK: A “price taker”: Price is set by manufacturer at launch and assessment of value made by NICE.

France: A “price maker”: Price is negotiated following assessment of value by the Transparency Commission

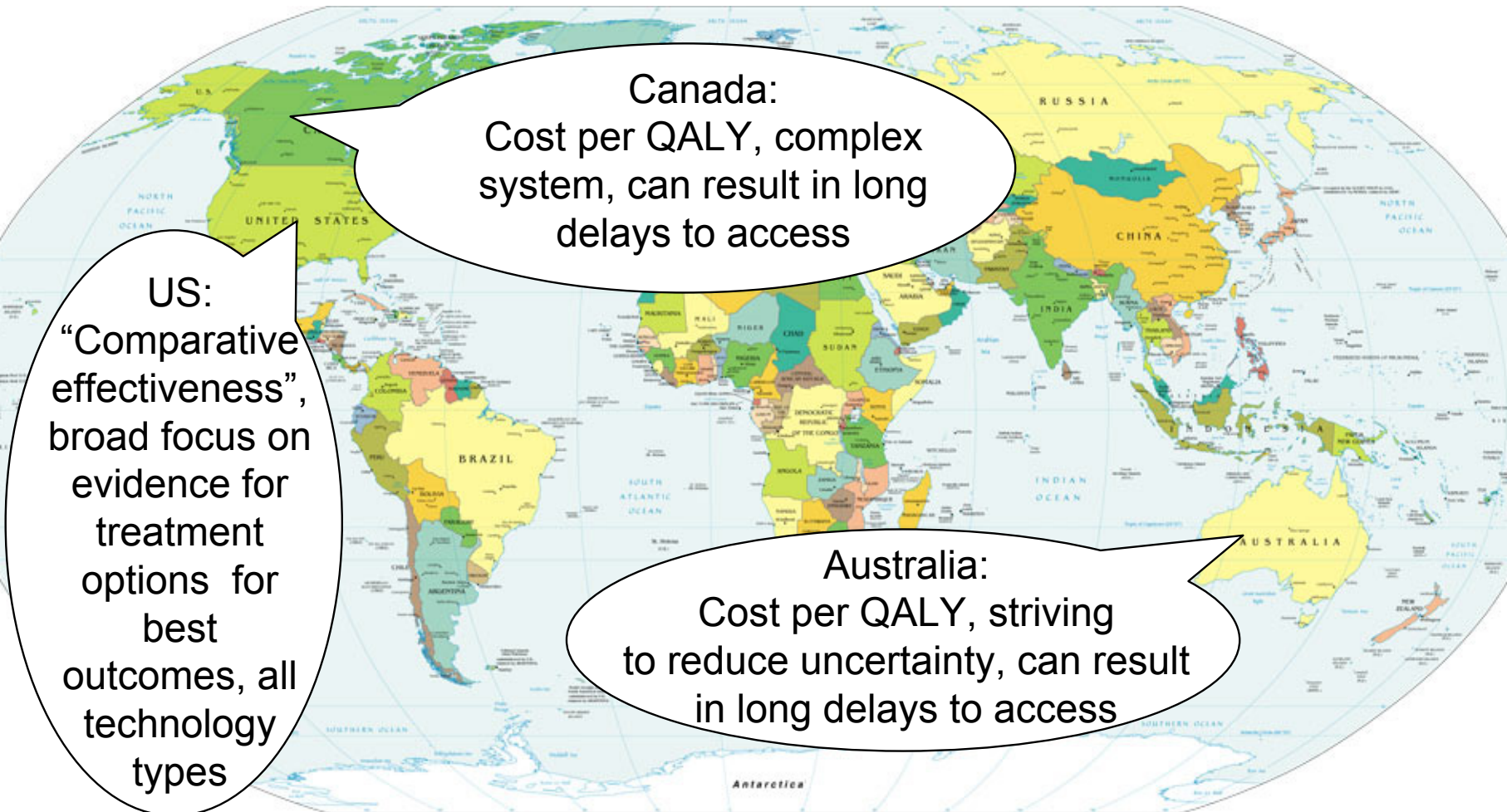
Variation in Valuation and Pricing Approaches Across Europe

(2/2)



- All start with scientific assessment of relative effectiveness.
- However, pros and cons with perspective, methodological weaknesses, extent of evidence to work with

Approaches Outside of Europe



US:
“Comparative effectiveness”, broad focus on evidence for treatment options for best outcomes, all technology types

Canada:
Cost per QALY, complex system, can result in long delays to access

Australia:
Cost per QALY, striving to reduce uncertainty, can result in long delays to access

Lessons:

- HTA can become very complex and resource intensive, uncertainty is always present
- Often results in delays in patient access
- A pragmatic, solution focus is preferable. Ideally don't just focus on pharmaceuticals

Managing uncertainty: Is “risk sharing” the answer?



- Few examples of true “risk sharing”
- Many examples of price-volume agreements (form of profit share, but also used to target use where most appropriate)
- Increasing number of “Patient Access Schemes” but many are discounts or rebates, sometimes linked to specific aspects of use
- Possible short term solution when agreement on value assessment can’t be reached
- Longer term, prefer other options:
 - Early engagement between companies and payers regarding evidence needs
 - “Coverage with Evidence Development” when agreed gaps in evidence supporting the value proposition
 - Room for creative partnerships if truly support both party’s needs and deliver patient access

Outlook into the Future



- Continue to start with scientific assessment of relative effectiveness
- Ensure a comprehensive assessment of value, including how the innovation benefits patients and the health system
- Consider wider perspectives when appropriate (e.g Alzheimer's Disease)
- Consider how the innovation might reduce variability in patient outcomes

Decide what you want to pay for,
and PARTNER to assess and reward that

Polish reimbursement challenges 1



Poland – member of EU from May 1, 2004

No full implementation of the Directive 89/105

Key implications:

- no individual decisions
- absence of decision verification and justification
- no appeal process

Polish reimbursement challenges 2

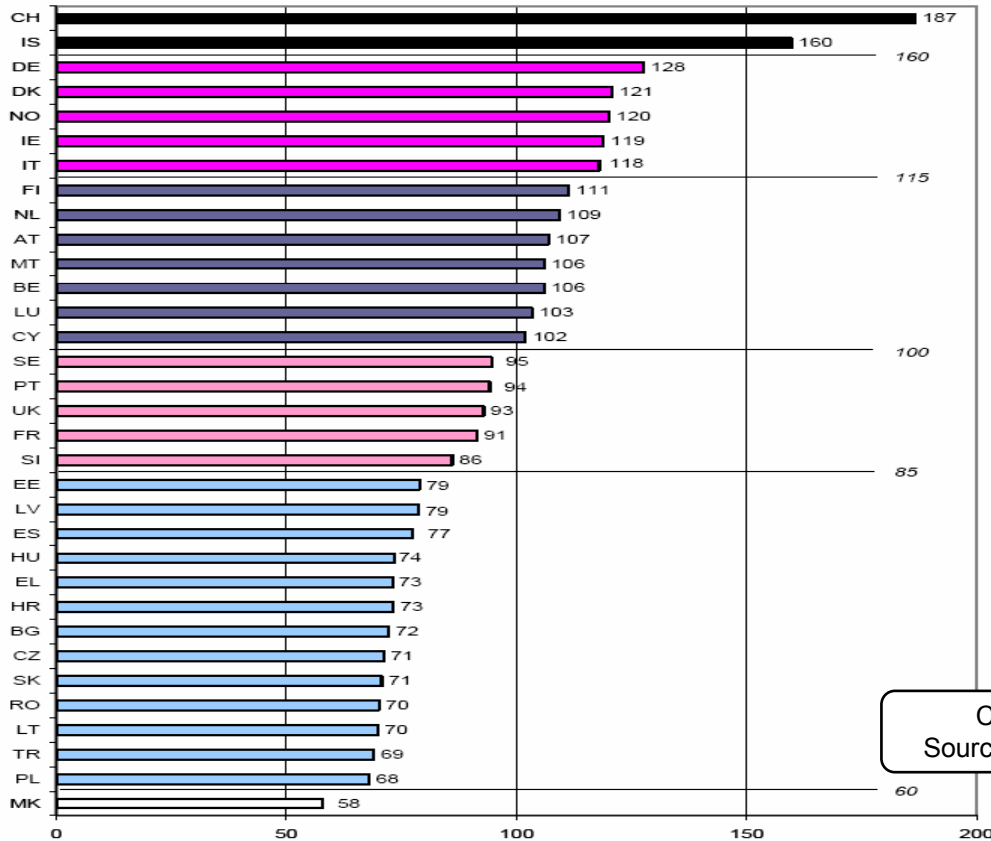


- Outcome of the last 5 years:
 - - continuous promises by the Government of full implementation of Transparency Directive
 - - lack of any Draft Project on reimbursement system by the MoH
 - - Draft of Reimbursement Act prepared in 2008 by local industry organization INFARMA and presented to the MoH
 - - no dialogue with the industry with this respect

Polish pricing challenges



Chart 1: Price level indices for pharmaceutical products, EU25=100



Comparative price levels in 33 European countries in 2005;
Source: Eurostat-OECD Purchasing Power Parity (PPP) Programme

Poland - The lowest pricing level in EU

Summary of the innovative company position



Full implementation of the Transparency Directive

Rather comprehensive Act on Reimbursement regulating the whole complex system

Pricing as a part of a broader value assessment, not a „stand alone” value of the drug policy

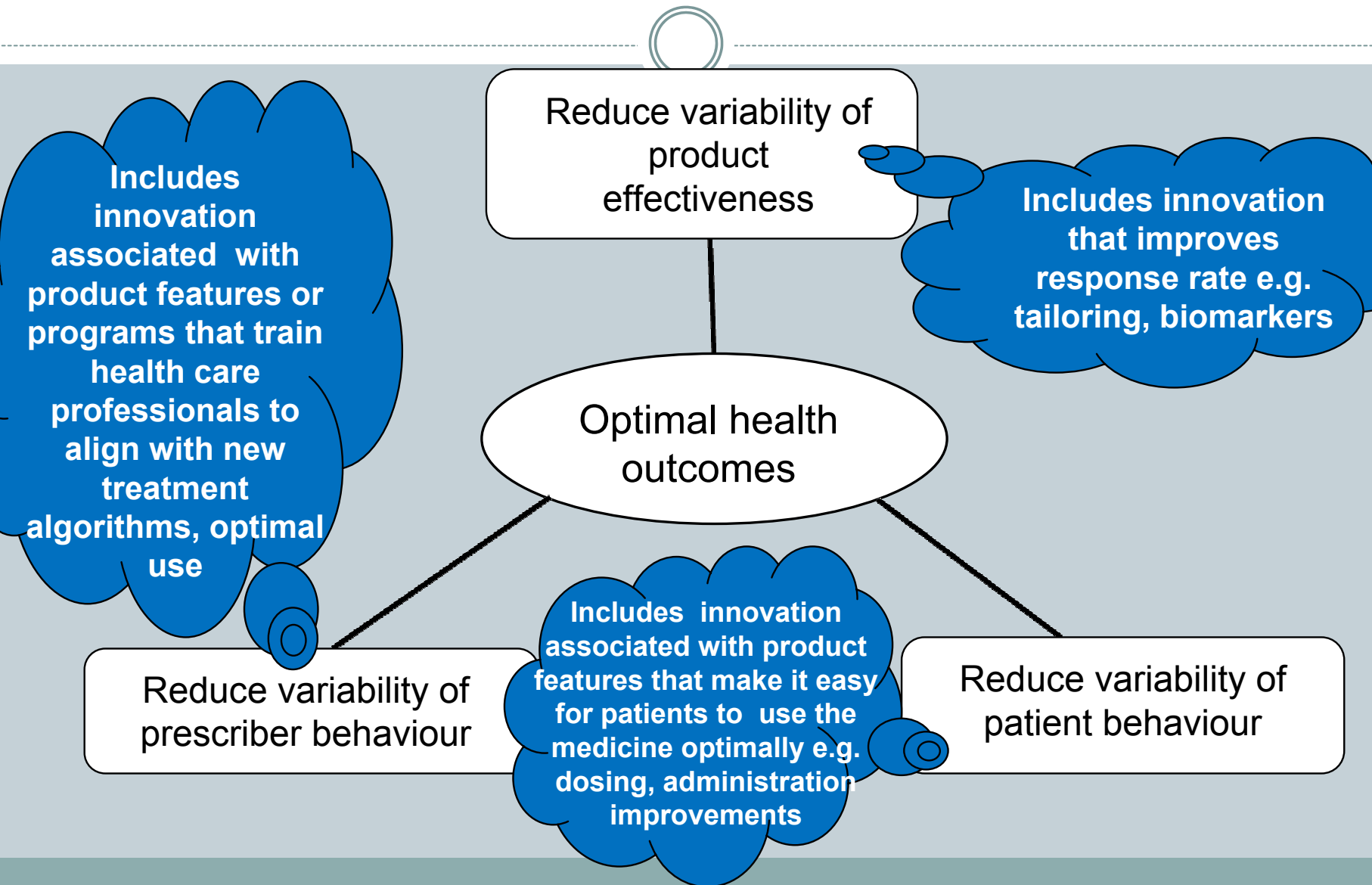
Full involvement of HTA agency in a decision making process

Improved patients' access to innovative treatment



Backup

Assessment of Innovation



Assessment of Impact on the Health System: Balanced Score Card



Burden of disease

Budget impact

Improved
patient
outcomes

National health
strategy for this
disease or
condition

Opportunities for quality
improvement within the
NHS: e.g. decreased
tertiary referrals,
increased role for
paramedical staff,
shorter hospital stays



Potential Hierarchy of Managed Access Schemes

