European Health Forum Gastein

Eucomed: Industry's perspective on HTA

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Director General
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Eucomed & the Industry of Medical Technology in Europe

The Industry

- Nearly 3000 manufacturers
- 80% + are SMEs
- Total sales of €55 billion = 30% world market share
- 6.4% of sales in R&D
- 400,000 employees serving 455 million population in EU alone

Improve access to modern, innovative, reliable medical technology

Eucomed

- Since 1979
- Headquarters: Brussels
- Team of 17
- Members (representing +/-70% of the total EU market):
  - → 64 Companies
  - → 26 Associations (also in CEECs)
- Market Segments:
  - → Implants (cardiovascular, orthopedics)
  - → Vascular access (injection devices);
  - → Instruments and other reusable equipment;
  - → Technical aids &
  - → Disposables (incontinence aids, woundcare)

HTA agencies – Industry: *Common interests and challenges*

- **Common goal**: the health and well-being of the patients.

- **Common challenge**: Deliver equal, cost-effective and high quality health services (principle of solidarity).

→ Collaborative approach between stakeholders

Eucomed's HTA vision

Eucomed

- → *considers that HTA can be beneficial to decision-makers,*
- → *values its potential benefits, and*
- → *wishes to be more involved in the growing number of European/national projects and initiatives.*

As for any other science, developments and methodological innovations need to be endorsed by **all** relevant stakeholders to become effective and to achieve wide recognition.

Eucomed's HTA objectives

- **Contribute** to the debate as one of the stakeholders around the table
- Be recognized as an **HTA expert**
- Build greater **awareness** about the **specifics** of the **devices** industry when it comes to HTA, amongst the assessment centers, HTA agencies, HTAi management, administrations and policy-makers

Challenges

- Process **transparency**
- Type of **clinical evidence** that fits best with particular therapy/disease assessment
- Learning curve & **timing** of assessment
- Burden of proof often placed exclusively on the manufacturer; BUT industry sponsored too often perceived as **biased**
- Submission of **confidential data**
- **Possibility to comment** on interim and final draft reports.
- **Appeal** process
- Promotion of an **integrated approach** to HC, leading to better allocation of public health spending

HTA, a value for all : Patients, decision-makers and industry

HTA = bridge between outcomes research and decision-making for the improvement of timely patient access.

To get the most from HTA:

→ **Active involvement of ALL stakeholders.**

→ **Transparent process based on confidence**

→ **Equitably shared burden of proof between stakeholders**

→ **Recognition that different technologies may require different approaches**

Fast and consistent patient access to innovative therapies

Summary and conclusion

- **HTAs have potential benefits**
- Importance of a **holistic approach**
- **Need** for all stakeholders **to cooperate**
- **Eucomed part of the game**

THANK YOU

HAUTE AUTORITÉ DE SANTÉ

Keeping track of rapidly developing technologies

The French experience

Prof. Lise Rochaix

Member of the Board

Haute Autorité de santé (HAS)

Introducing new technologies: what is at stake?

- **Making coverage and pricing decisions in a context of:**
  - incomplete evidence on benefit-risk ratio, clinical effectiveness and cost-effectiveness …
  - pressure from manufacturers and patient-groups to rapidly introduce new technologies into the healthcare system …
  - pressure to reduce healthcare expenditure
- **… While measuring the risks of inappropriate decisions :**
  - Excessively delaying potential benefits to patients
  - Introducing technologies that will turn out to be inefficient, not cost-effective or with a low benefit-risk ratio

The main trade-offs facing decision-makers

- Reducing risk of inappropriate decisions …

  … without unduly delaying access

- Flexibility in urgent situations …

  … without creating a precedent for generalisation

- Rewarding truly innovative technologies,

  … while keeping within the Nation's health care budget

➢ Responsiveness of decision-makers is required:

  ➢ Introduction of innovations under conditions

  ➢ Agreement between stakeholders on these conditions

Background on the French health care system

- General coverage of health products and services for all
- Freedom of choice (patients and professionnals)
- Fee for service payment

A four step procedure to introduce new technologies

- Marketing authorization (drugs) – CE marking (medical devices)
- Assessment of expected and actual clinical benefits (HAS)
- Price negotiation
- Coverage decision

➢ Coverage decision is the most important lever for introduction and generalization of new technologies in France

The key role of HAS in health technology assessment in France

HAUTE AUTORITÉ DE SANTÉ

Medical devices	Drugs	Diagnostic & therapeutic procedures
Clinical studies		
Industry	**Industry**	**Teaching hospitals and health professionals**
Introduction in the market		
Notified bodies for CE Marking **AFSSAPS[1]: -** Competent authority **-** Post-market surveillance	**EMEA[2] – AFSSAPS:** safety/efficacy assessment **European commission - AFSSAPS:** Authorisation	
Assessment of clinical benefit		
	HAS **Assessment and advice on coverage decisions**	
CEPP[3]	**Transparency committee**	**CEAP[4]**
Pricing		
CEPS[5] • fixes price of drugs and devices after negotiation with Industry		**UNCAM[6]** • fixes reimbursement rate for drugs • fixes reimbursement tariffs and rates for procedures after negotiation with Health Professionnals' Unions
Coverage decision		
Ministry of Health • establishes list of reimbursable drugs and medical devices		**UNCAM** • Establishes list of reimbursable procedures

1. AFSSAPS: French Health Products Safety Agency; 2. EMEA: European Medicines Agency; 3. CEPP: Committee for the assessment of medical devices; 4. CEAP: Committee for the assessment of diagnostic and therapeutic procedures; 5. CEPS: Committee for pricing and reimbursement of healthcare products (reports to the Ministry of Health, Industry and Finances); 6. UNCAM: Association of National Health Insurance funds

1. Temporary authorization for use

- An innovative drug for a severe disease for which there is no effective treatment can be authorised for temporary use in public and private hospitals, even before a market authorization has been granted and with no HAS assessment of clinical benefits.
- Condition: a clinical trial must be under way

  => Example : Protease inhibitors for HIV patients in 1996: introduction nearly one year before other countries
- Price/ coverage status revisions at end of temporary period is made more difficult since technology already in use!

2. Temporary therapeutic protocols

- A drug which already has a market authorization but for which there is evidence for a benefit in a new indication may be reimbursed if used within a temporary therepeutic protocol in hospitals.

  => Example: Herceptin ® as adjuvant therapy for breast cancer

- Introduction without assessment in the new indication but within a well defined protocol of limited duration and with data requirements
- Final decision based on the collected data

3. Conditional coverage

- Coverage for potentially innovative procedures conditionned on prospective data collection
- Strict monitoring of use (within a limited number of institutions) before generalisation

➢ May influence end of product development phase

➢ Mechanism defined jointly by HTA producer (HAS) and payer (NHIF)

4. Post-coverage studies

- May be requested from manufacturers at the time of expected benefit assessment
- Aim: to provide data on use in real-life conditions including organizational and economic impacts, and equity of access
- Request included in the contract signed between firms and CEPS after price negotiation
- 112 requests – 41 drug companies since 1997
- Results analysed at the time of re-assessment of *actual* clinical benefits (coverage decision every 5 years for drugs)

➢ Allows confirmation or modification of decision initally based on the *expected* clinical benefits

5. Fast track procedure

- Innovative drugs may undergo fast-tracking to reduce the interval between market authorization and coverage decision (currently about 300 days on average)

➢ Allows a 3 to 6 months interval reduction

6. Scientific Advice

- Provides manufacturers guidance on the type of data needed for the coverage decision (advice on development plan)
- Increases quality of data submitted for coverage and price decisions

➢ May be determinant for a future technology's market and socially useful in identifying relevant gaps

➢ Some risk-sharing could be implicitly assumed by firms although scientific advice from HAS bears no committment value

THE FRENCH EXPERIENCE - 7

- **In general, these mechanisms were first developed for drugs**
- **They are currently being adapted for medical devices and for new diagnostic and therapeutic procedures**
- **In addition to these measures, there are :**
  - research programs to finance development stages of selected innovations
  - Volume control mechanisms based on contracts either between hospital and regional hospital agencies (ARH) or between health professionals and national health insurance funds.

WHAT CAN BE LEARNT FROM FRENCH EXPERIENCE

Decision makers are pushed to take decisions increasingly early

- Yet unconditional introduction is costly for society (see initial trade-offs)

Response

- Various facilitating and conditional mechanisms set up to deal with uncertainty

Conditions for success:

- Involvement of all stakeholders and agreement on conditions
- Clear definition of responsibilities between agencies involved in the marketing, pricing and coverage decisions
- High quality HTA at all stages of the decision making process

THE POTENTIAL ROLE FOR EUROPEAN INITIATIVES

1. **Contribute towards harmonizing HTA methodologies and assessment tools (EUNetHTA project) and help define high performance instruments for data collection**

2. **Help in the definition of truly innovative technologies**

3. **Encourage use of HTA by decision-makers of all Member States**

4. **Enhance experience sharing among MS to avoid waste of time and resources in assessment process**

Pricing and Reimbursement for new Health Technologies

The Role of HTA

Dr Stefaan Van der Spiegel
Policy Officer
Competitiveness in Pharmaceutical Industry and Biotech
DG Enterprise and Industry
European Commission

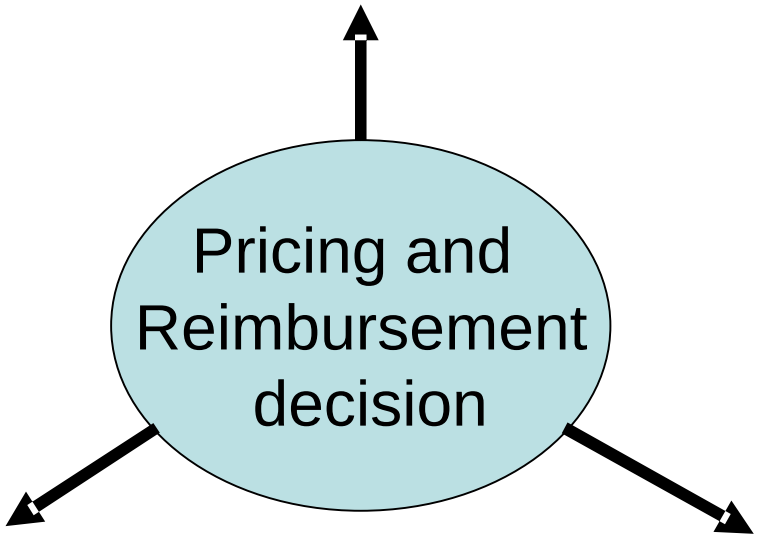
9th European Health Forum
Forum 3 - European HTA
Gastein, 5 October 2006

Agenda

- Pricing and Reimbursement decisions
- Current use of HTA in Pricing and Reimbursement
- The future of HTA

EXPECTATIONS FROM A PRICING AND REIMBURSEMENT DECISION

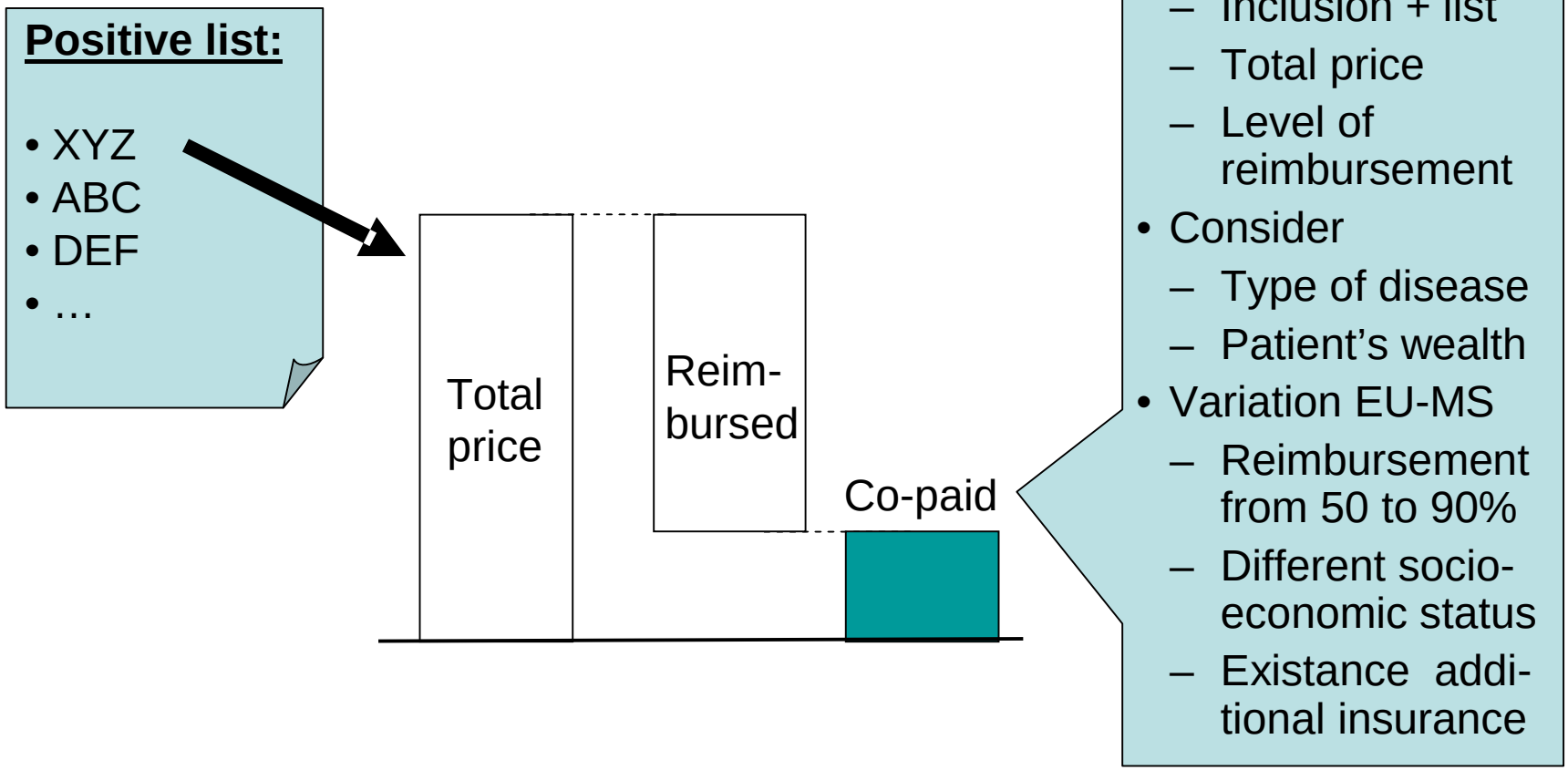
① **Patient: the last necessary step to get access to a new treatment**



② **Manufacturers: a reward for risky investement in R&D**

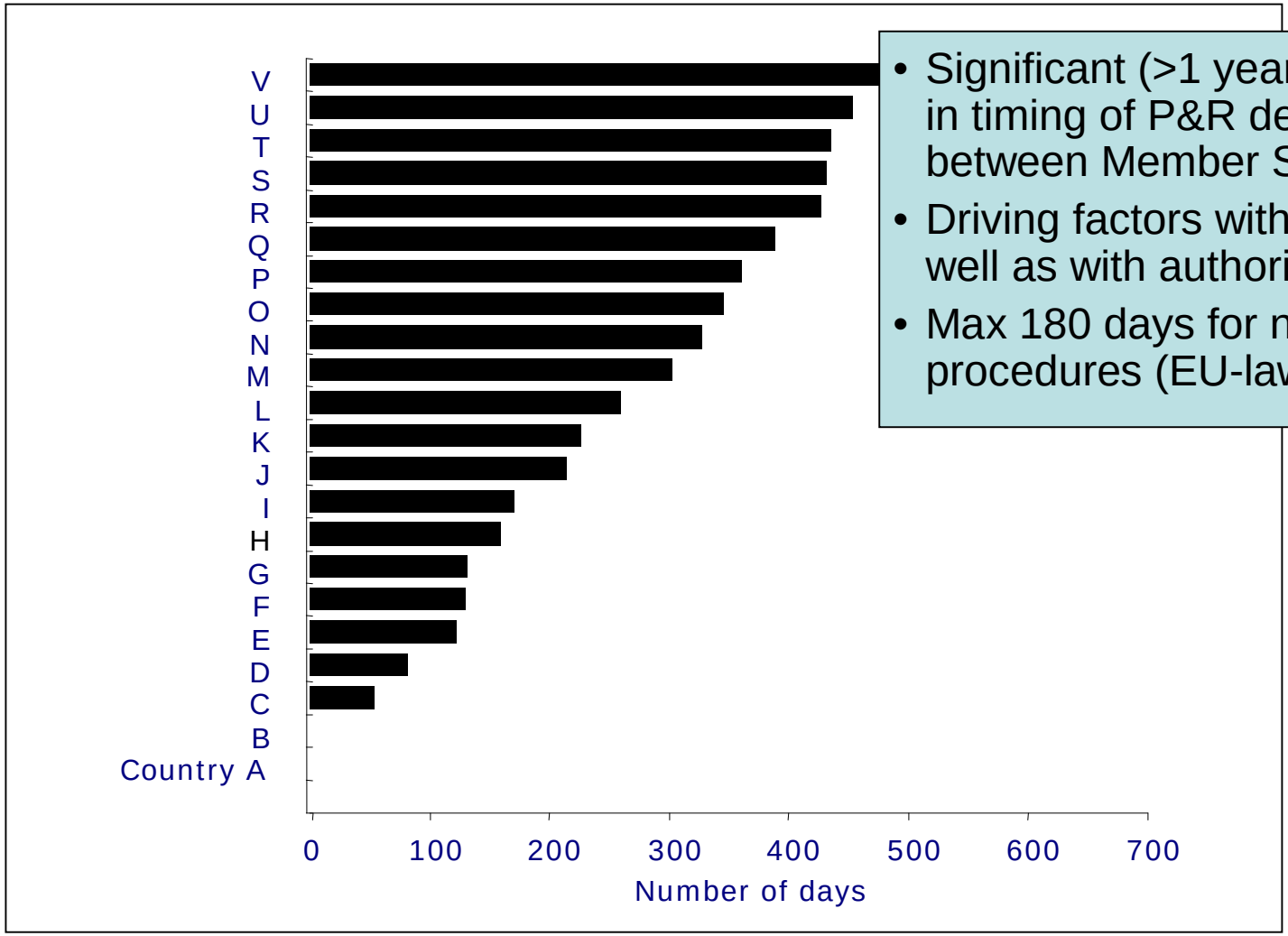
③ **Funding authority: a choice to invest in future health of the population**

1. P&R DECISION DEFINES ECONOMIC ACCESS FOR PATIENT



1. TIMING OF P&R DECISION DEFINES AVAILABILITY

Time between Market Authorisation and P&R decision



- Significant (>1 year) differences in timing of P&R decisions between Member States
- Driving factors with industry as well as with authorities
- Max 180 days for national procedures (EU-law)

* Defined by when medicine gets a pricing and reimbursement decision in a MS

Source: IMS, Marketing Autorisation 30/6/2000 to 30/6/2004

2. CREATING A NEW MEDICINE REQUIRES SIGNIFICANT UPFRONT INVESTMENT

Time (years) 2-3 + 5-7 + 1-2 = 8-12

Success rate

>10,000 molecules

~10 candidate medicines

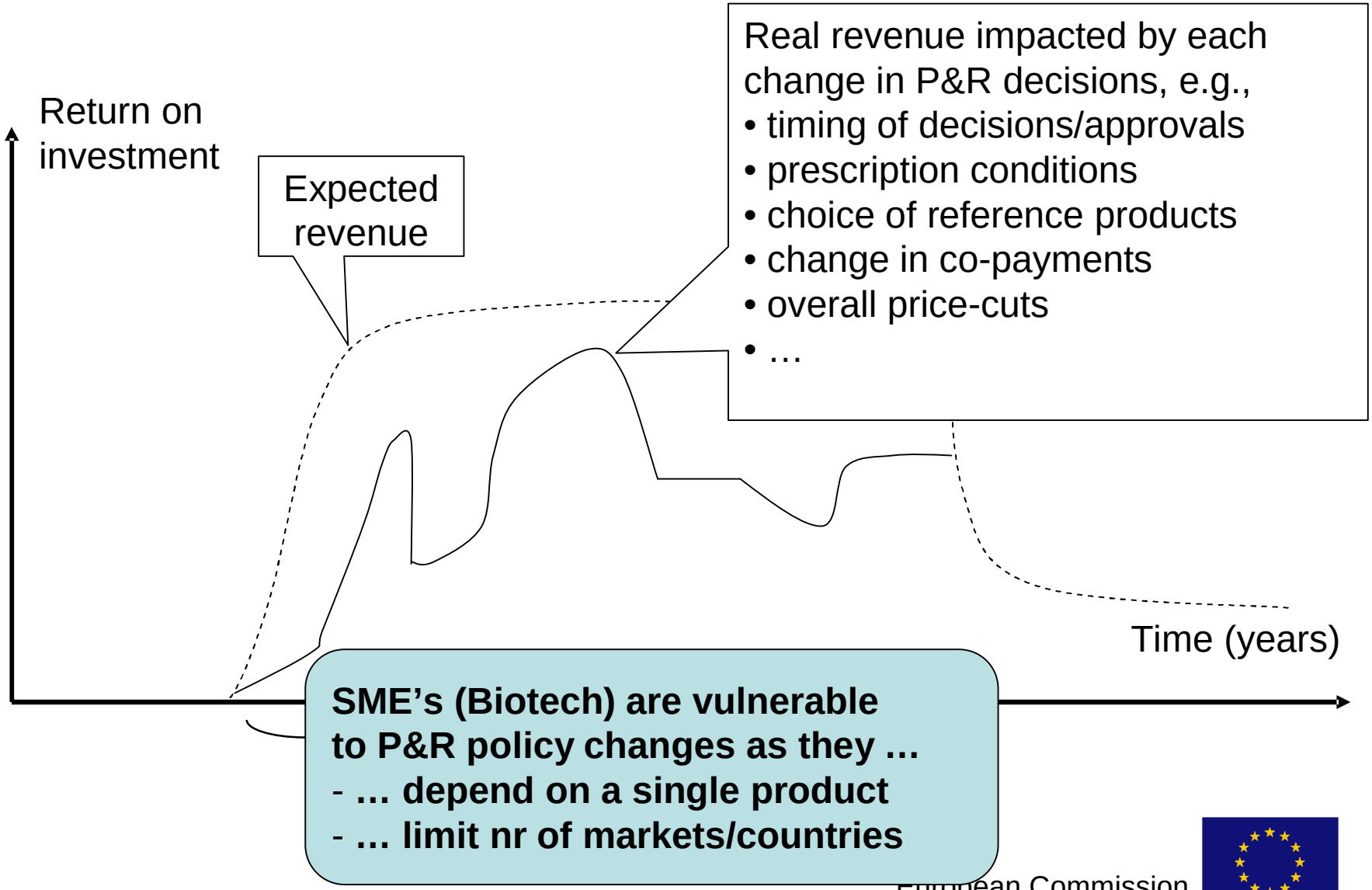
1 new medicine

Investment (Millions €)

Up to 800 million Euro

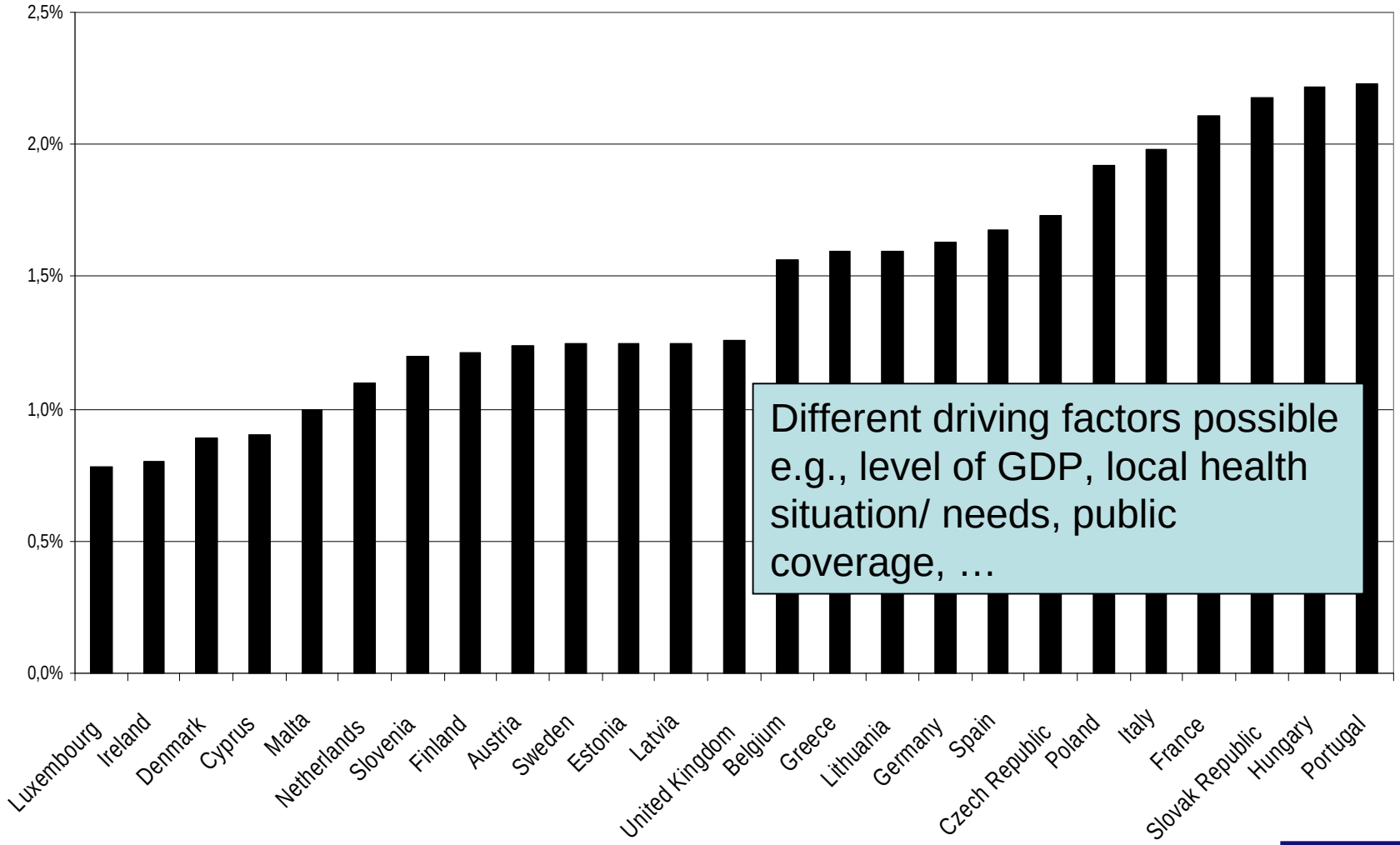
2. RETURN ON THIS INVESTMENT DEPENDS ENTIRELY ON P&R DECISIONS

THEORETICAL EXAMPLE



3. PHARMACEUTICAL EXPENDITURE TAKES SIGNIFICANT PART OF WEALTH

(Total* expenditure / GDP)

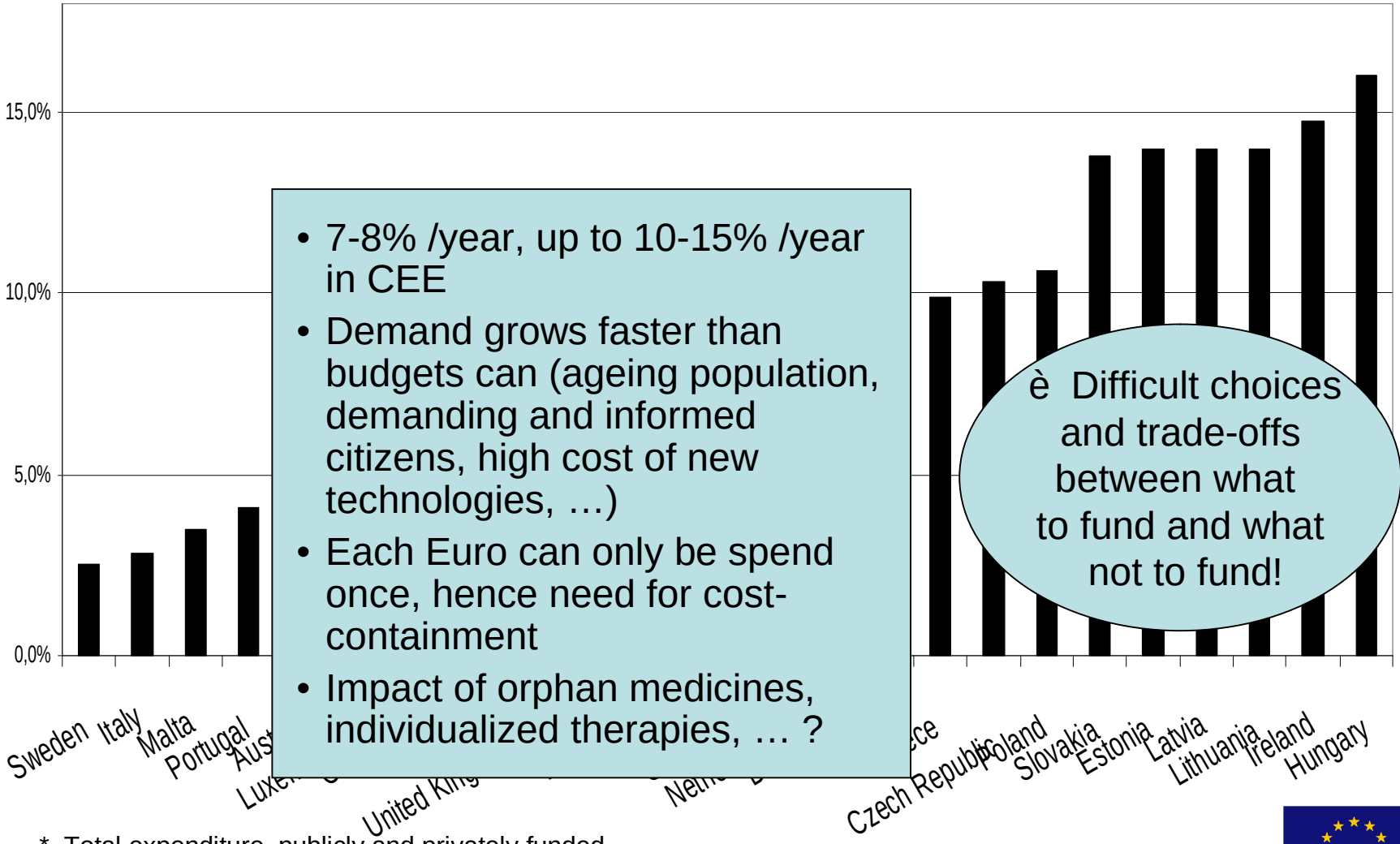


* Publicly and privately funded

Source: 2002 data OECD except CY,ES,LT,LV,MT,SL 2004 data by Alcimed and Member States

3. HIGH GROWTH RATES OF EXPENDITURE IN MS

% annual growth* 00-03



- 7-8% /year, up to 10-15% /year in CEE
- Demand grows faster than budgets can (ageing population, demanding and informed citizens, high cost of new technologies, …)
- Each Euro can only be spend once, hence need for cost-containment
- Impact of orphan medicines, individualized therapies, … ?

è Difficult choices and trade-offs between what to fund and what not to fund!

* Total expenditure, publicly and privately funded

Source: OECD except CY,ES,LT,LV,MT,SL data by Alcimed and Member States

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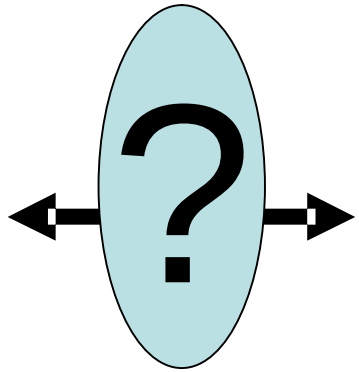
- Current use of HTA in Pricing and Reimbursement
- The future of HTA



HTA helps to identify and choose how much of the limited resources to allocate to which medicines

HTA is used to support:
- **… pricing decisions**
- **… reimbursement decisions**
- **… clinical guidance**

MOST MEMBER STATES ACTIVELY WORK WITH HEALTH TECHNOLOGY ASSESSMENTS

National use of HTA (2004)*

	Price decision	Reimbur-sement	Clinical guidance
AT	X	(X)	
BE	X	X	
CR	X		
DK		X	X
FI	X	X	X
FR	X		X
HU		X	X
IC		X	X
IR			
IT	X	X	X
LV		X	X
LT		X	X
LU		X	
MT		X	X
NL		X	
NO		X	X
PL			
PT		X	
SL		X	
ES	X	X	X
SE	X	X	X
UK			X

* Source: 2004 questionnaire to Transparency Committee Members

Dedicated national institutes

- U.K. NICE
- France HAS
- Germany IQWiG
- Belgium Kenniscentrum
- …

Cross-border initiatives

- MEDEV
- Baltic Guidelines
- Pharmaceutical Forum
- EUnetHTA
- …

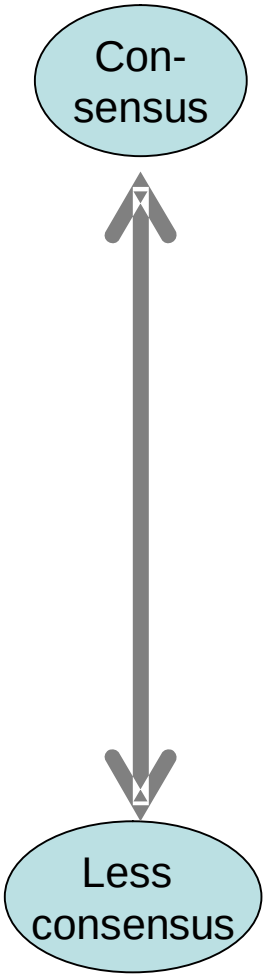
HTA IS STILL STRUGLING WITH TWO BIG ISSUES

1. How to define what is valuable innovation?

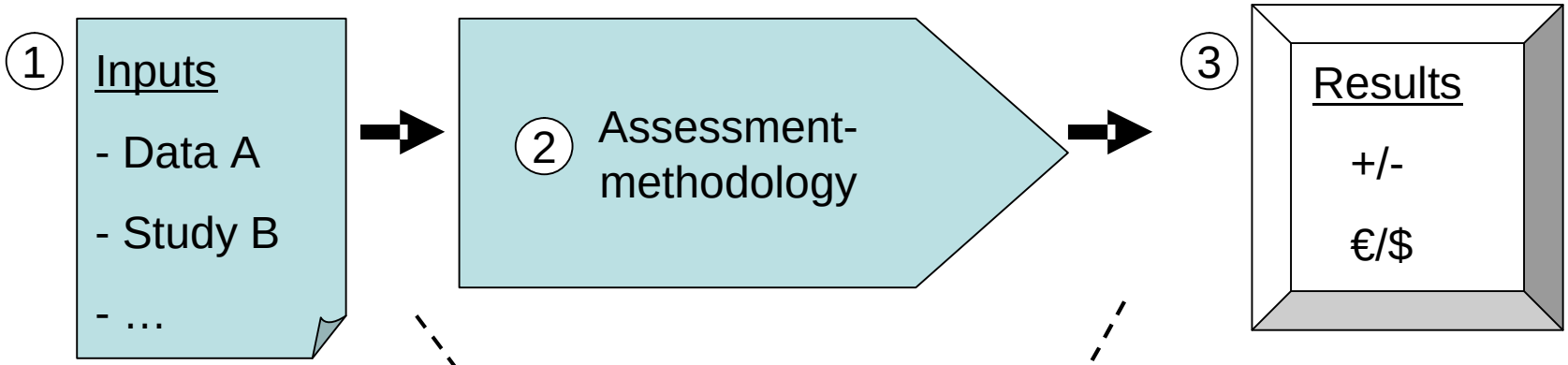
2. How to come to a robust methodology?

1. WHAT IS VALUABLE INNOVATION ?

Targeted improvement	**Examples of potential value**
• Medical outcome	• Morbidity, mortality • Side effects, interactions with other drugs • Probability of recovery, speed of recovery • Pandemias, resistance • …
• Quality of life	• Pain-management • Self-management at home • Social possibilities • …
• Cost effectiveness	• Cost of medication • Overall treatment costs • Non-healthcare spending • Cost of sick-leave, missed productivity • …



2. METHODOLOGICAL PROBLEMS



- Incomplete data-sets at moment of decision
- No standard of data
- Few sources available
- …

- Treatment comparator
- Type of benefits to consider
- Costs to include
- Time horizon
- …

- Variation in outcome assessment
- Link to reimbursement status and level
- …

2. STAKEHOLDERS GET ANXIOUS FOR ROBUST HEALTH TECHNOLOGY ASSESSMENTS

Recent Scrip-headlines

- UK to hear nine appeals against guidance on glioma prescribing (25/8)
- German agency defends procedures in stem cell row (4/8)
- NICE rejects Velcade for multiple myeloma and urges more research (2/8)
- Local health body challenges NICE Herceptin assessment (2/8)
- Eisai refers NICE's refusal to disclose costing models to ombudsman (19/7)
- UK Parkinson's patients still awaiting treatment recommendations (7/7)

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THE FUTURE OF HTA

What can not be expected

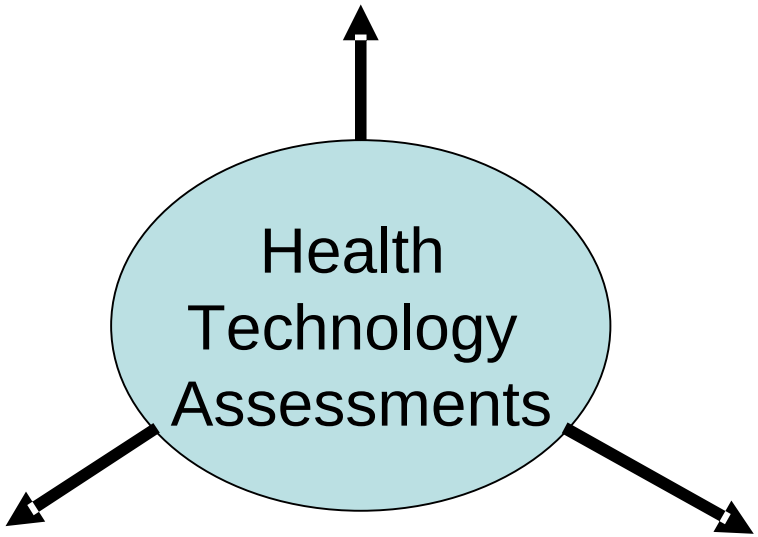
- Full reward for whatever comes out of the pipeline
- Similar end-decisions by all national authorities regarding prices and reimbursement levels

What could be expected

- A fair premium for valuable innovations, along possibilities of each country
- Clearer view on the value expected from innovation
- More robust HTA-methodologies, including clearer definition of the data-sources needed
- More common understanding and approaches shared between countries
- Managed expectations from all stakeholders

… HTA HAS A LOT TO OFFER

① **Patients: access to the most valuable innovative treatments**



② **Manufacturers: clarity on what innovation is expected and rewarded**

③ **Funding authority: most effective allocation of scarce resources**