



# Pharma-economical situation in Belgium

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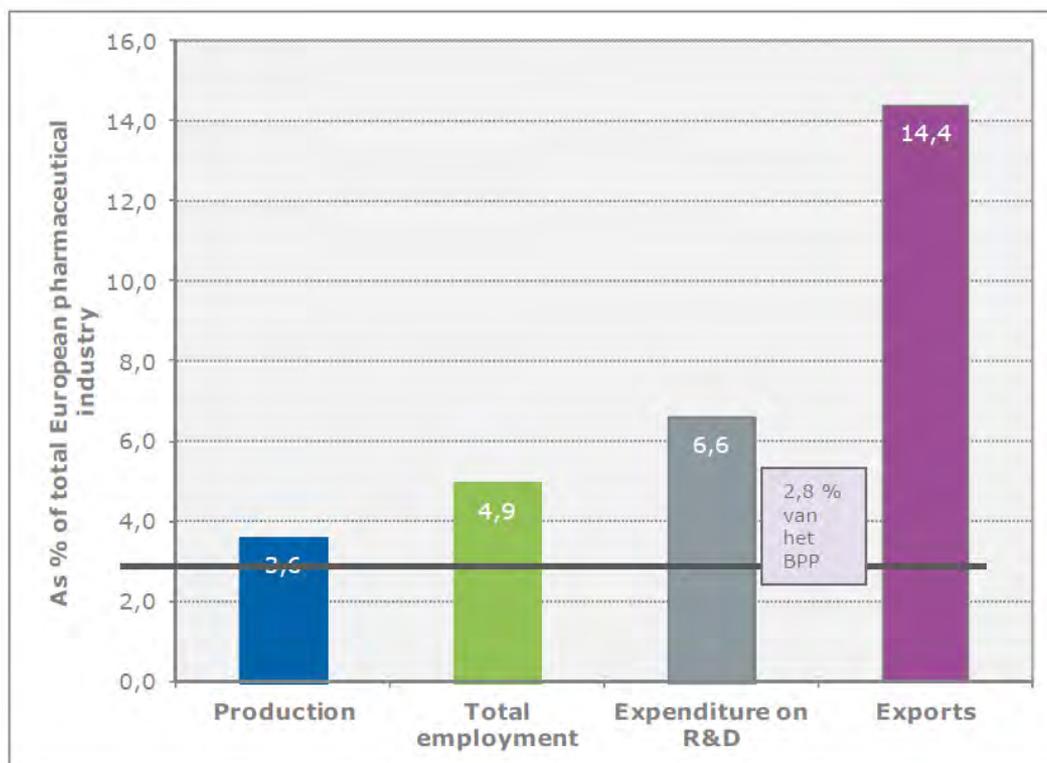


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# Content

- Belgium = pharma country
- Pharma-economy?
- Innovation?
- Legal framework in Belgium for reimbursement of medicines
- Problems of our healthcare system
- Some facts & figures
- Future?

# Belgium: performance pharmaceutical industry



— Aandeel van België in Europese BPP = 2,8%

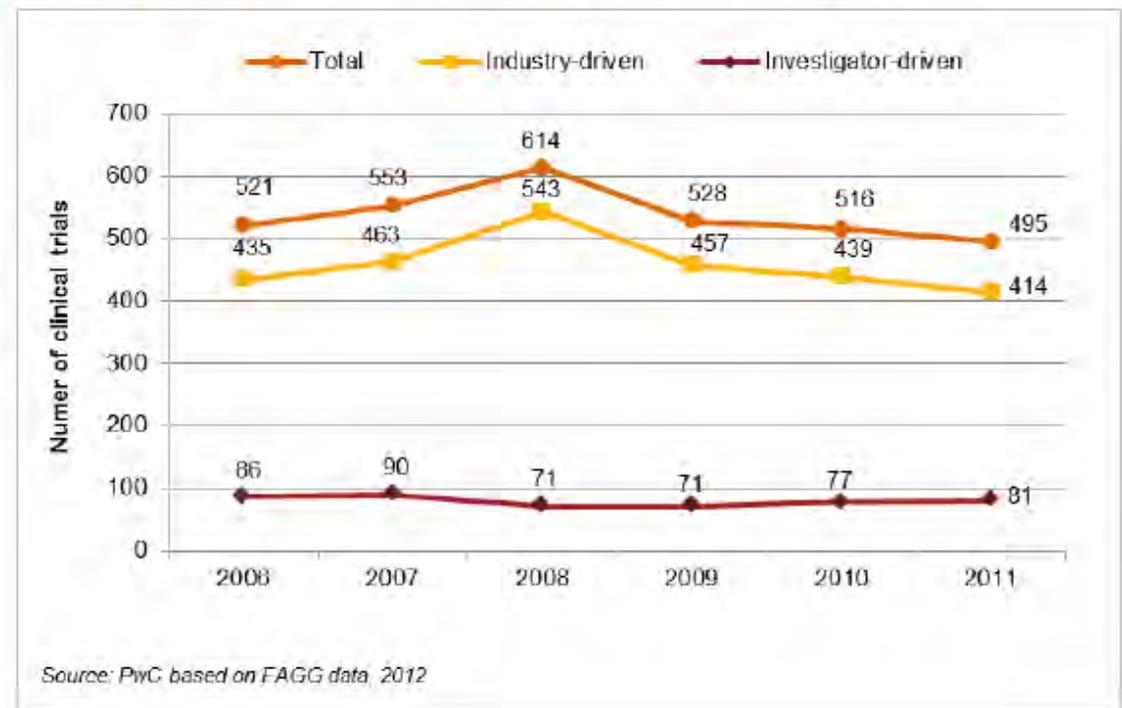
Bron: EFPIA, pharma.be; gegevens 2010 = schattingen

Opmerking: Europa = EU-27 + Zwitserland + Noorwegen

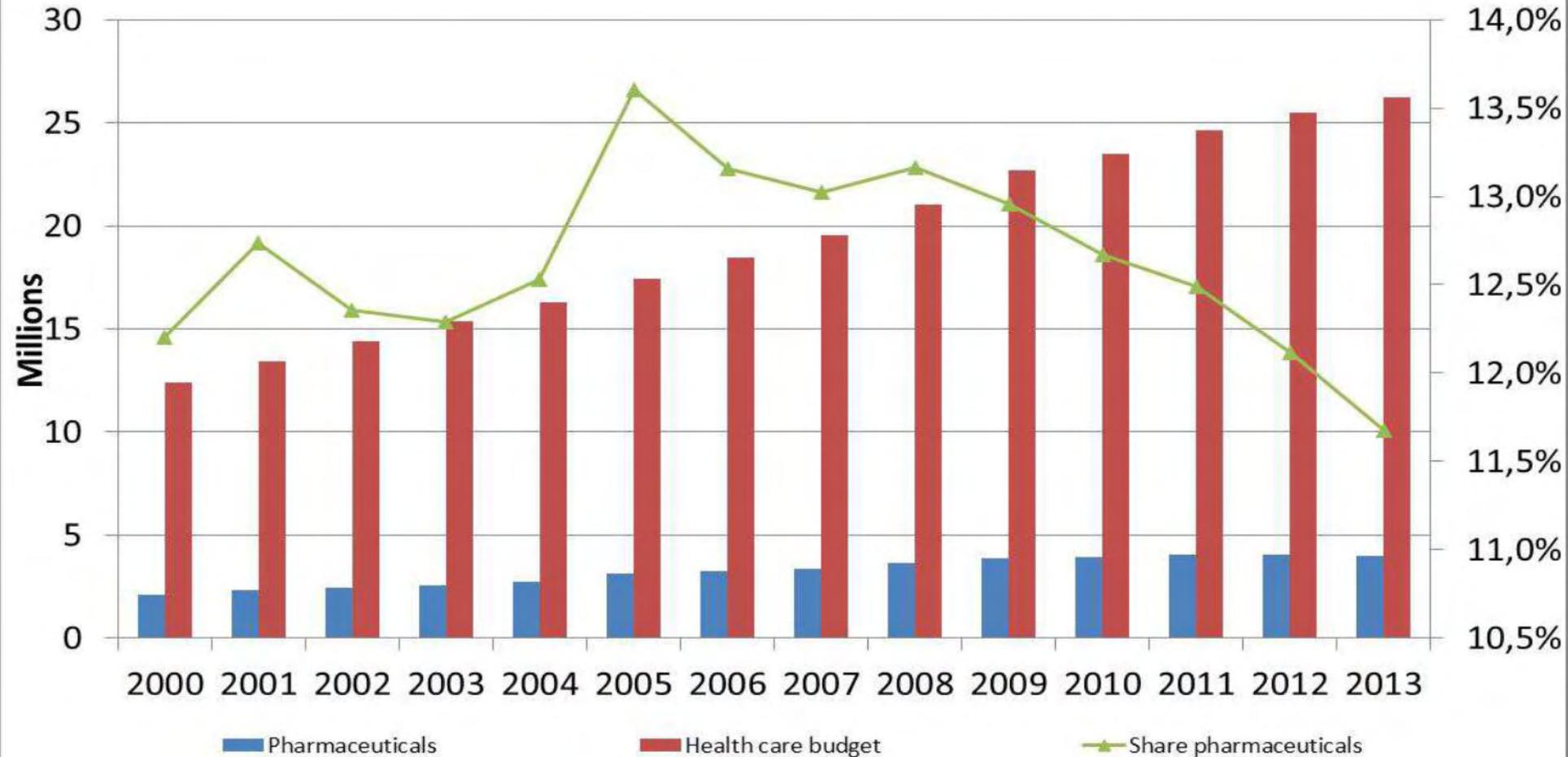
# Clinical trials in Belgium

- Approximately **9%** of all clinical trials conducted in Europe include **Belgian research site** (EudraCT data base)
- In terms of **number of patients** participating in CTs expressed in **per capita** terms, **Belgium emerges as Europe's clear number one**

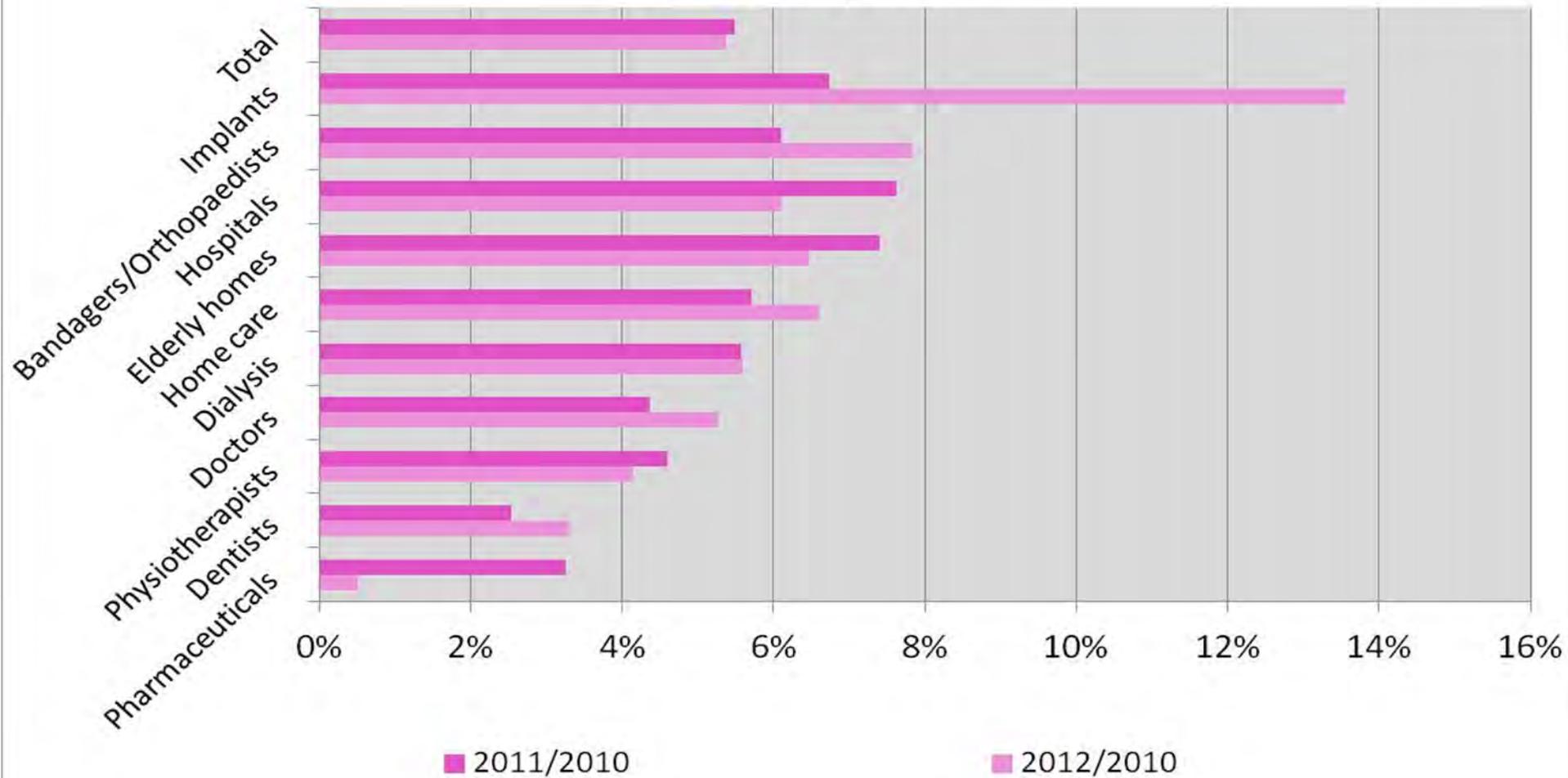
Figure 11<sup>20</sup>: Total number of clinical trials per year in Belgium



# Health care and medicines budget 2013



## Average annual growth in healthcare expenditure 2011-2012/2010



# Affordability



## Staatschuld Meter .be

België

USA

UK

Duitsland

Nederland

**De Staatschuld stijgt met 507 euro per seconde!**

€ 363,146,689,215

### Voorafbetaling Belasting

Spreid zorgeloos uw belastingen. KBC regelt alles.  
Informeer nu!

[KBC.be/VAB](http://KBC.be/VAB)

### Courtage Forex avec FxPro

Optez cTrader ECN pour trader. Démarrez avec des spreads de 0 pips

### Sieraden-Juwelen, Aankoop

Inkoop van Gouden Juwelen, Diamant en Munten. Nergens Betere Prijzen !

[www.edelmetaalrichard.be/sinds-1956](http://www.edelmetaalrichard.be/sinds-1956)

Info ▶

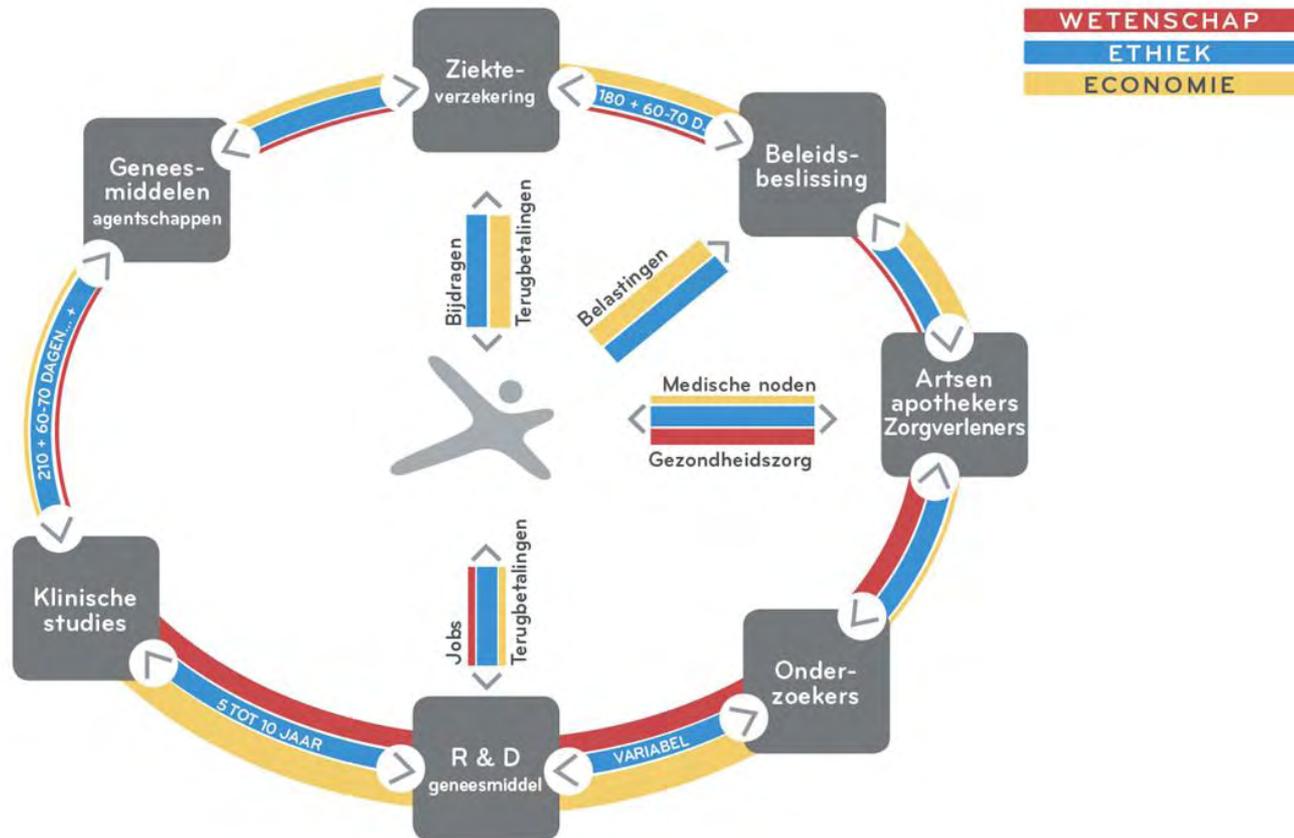
€ 33.660 schuld per inwoner

€ 67.319 schuld per werkzame inwoner

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# Shared Responsibility



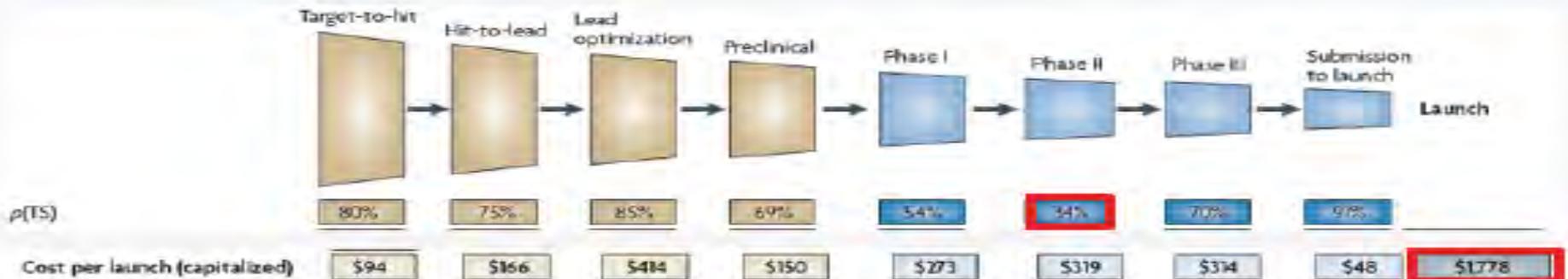
# R&D-based industry



Source: 2012 World pharma yearbook

# “Sunk funds...”

## Chicken and egg problem: payor engagement



Timing of Payor Engagement  
- % of Respondents by Product Responsibility -  
(n=166)



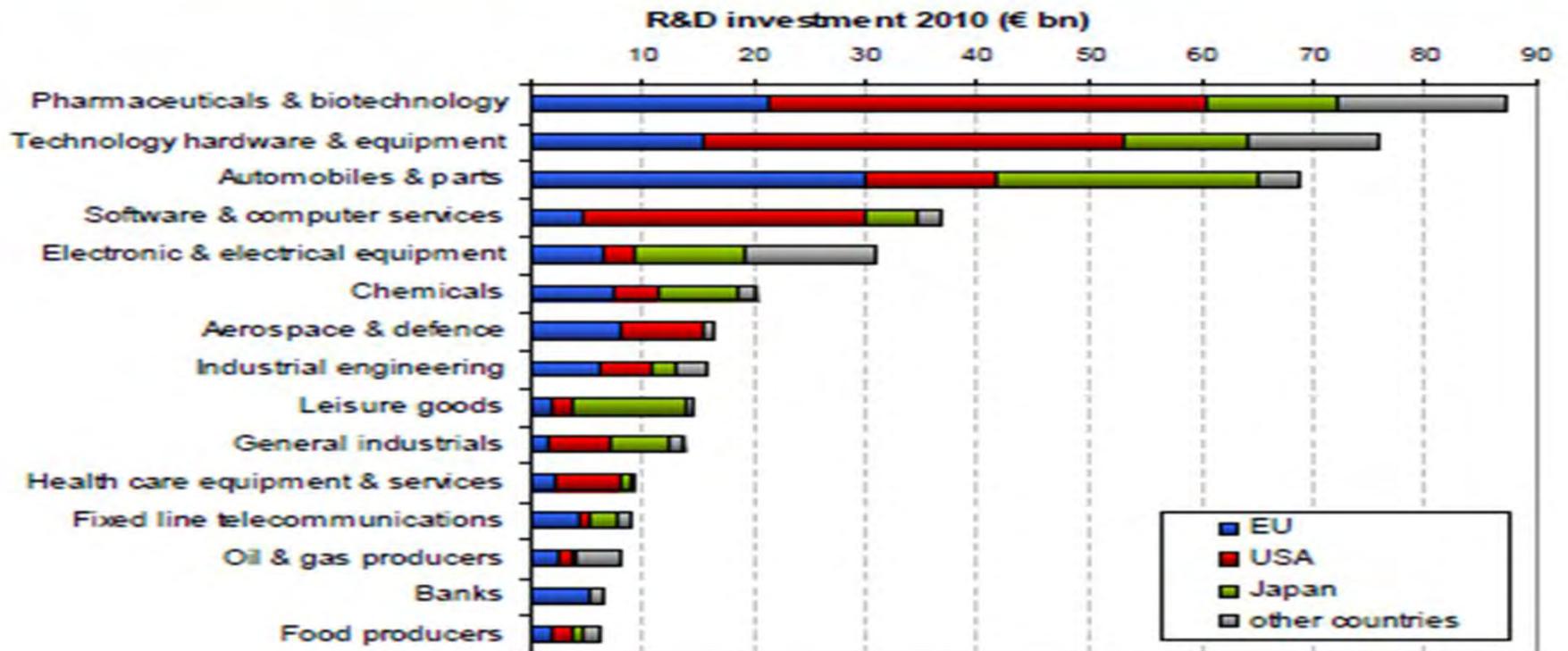
**Efficiency would dramatically improve when patients would be involved before Phase II**

Source: Paul Steven M. Paul, Daniel S. Mytelka, Christopher T. Dunwiddie, Charles C. Persinger, Bernard H. Munos, Stacy R. Lindborg and Aaron L. Schacht (2010), *How to improve R&D productivity: the pharmaceutical industry's grand challenge*, *Nature Reviews Drug Discovery* 9, pp. 203-214

Source: Booz 2012

# Sector investment in R&D

Figure 5. R&D ranking of industrial sectors and share of main world regions for the world's top 1400 companies



Ranked by total worldwide R&D investment of the sector.  
 Source: The 2011 EU Industrial R&D Investment Scoreboard  
 European Commission, JRC/DG RTD.

# Investment / Approved Medicine

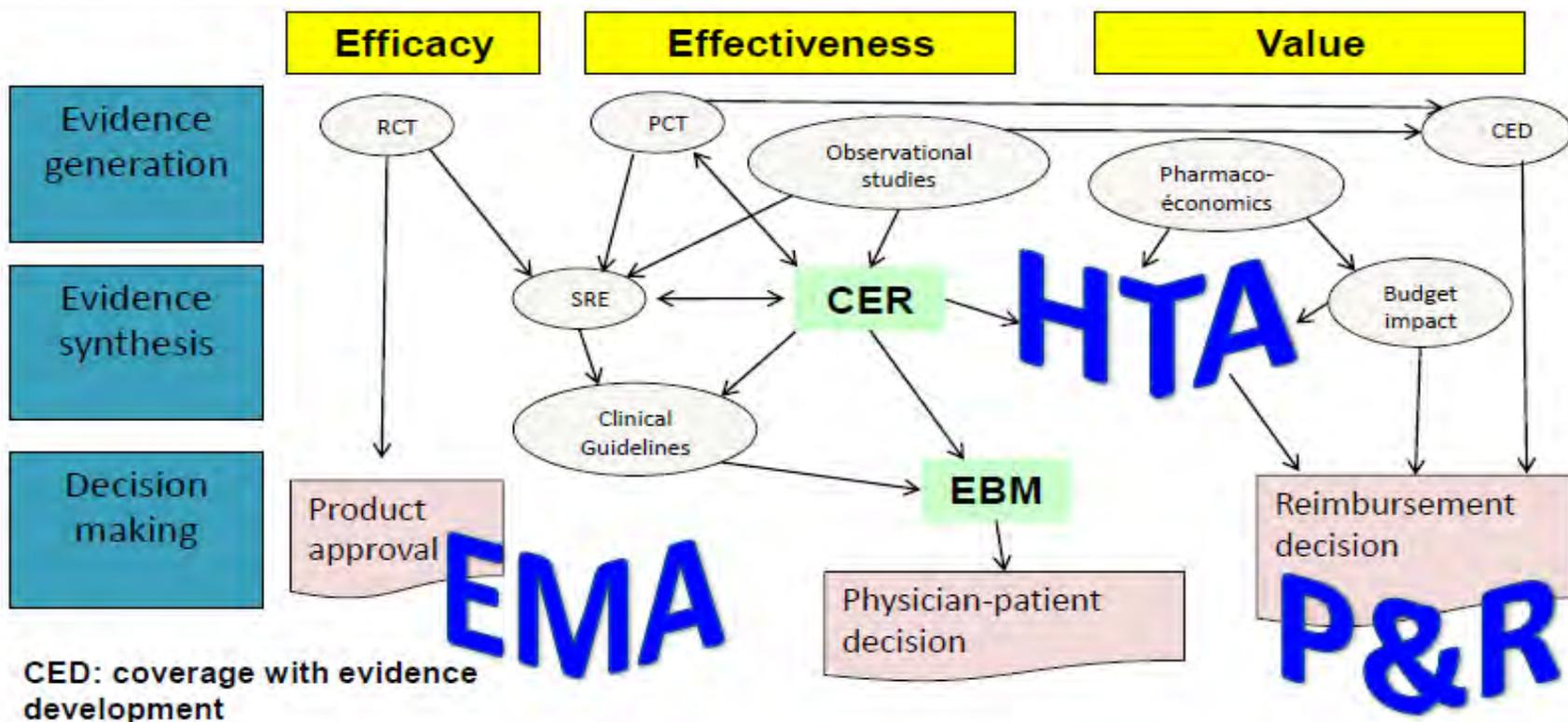
|                             | Number of approved products | Total R&D spending, 1997-2011 (US\$ bill.) | Cost per product (US\$ bill.) |
|-----------------------------|-----------------------------|--|-------------------------------|
| AstraZeneca                 | 5                           | 58.96                                      | 11.79                         |
| GlaxoSmithKline             | 10                          | 81.71                                      | 8.17                          |
| Sanofi                      | 8                           | 63.27                                      | 7.91                          |
| Roche                       | 11                          | 85.84                                      | 7.80                          |
| Pfizer                      | 14                          | 108.18                                     | 7.73                          |
| Johnson & Johnson           | 15                          | 88.29                                      | 5.89                          |
| Eli Lilly                   | 11                          | 50.35                                      | 4.58                          |
| Abbott Laboratories         | 8                           | 35.97                                      | 4.50                          |
| MSD (Merck & Co. in the US) | 16                          | 67.36                                      | 4.21                          |
| Bristol-Myers Squibb        | 11                          | 45.68                                      | 4.15                          |
| Novartis                    | 21                          | 83.65                                      | 3.98                          |
| Amgen                       | 9                           | 33.23                                      | 3.69                          |

Source: *Forbes*

# What is a Health Economic Evaluation?

The comparative analysis of alternative courses of action in terms of BOTH their costs and health consequences

# Building evidence for clinical use of medicines (3)



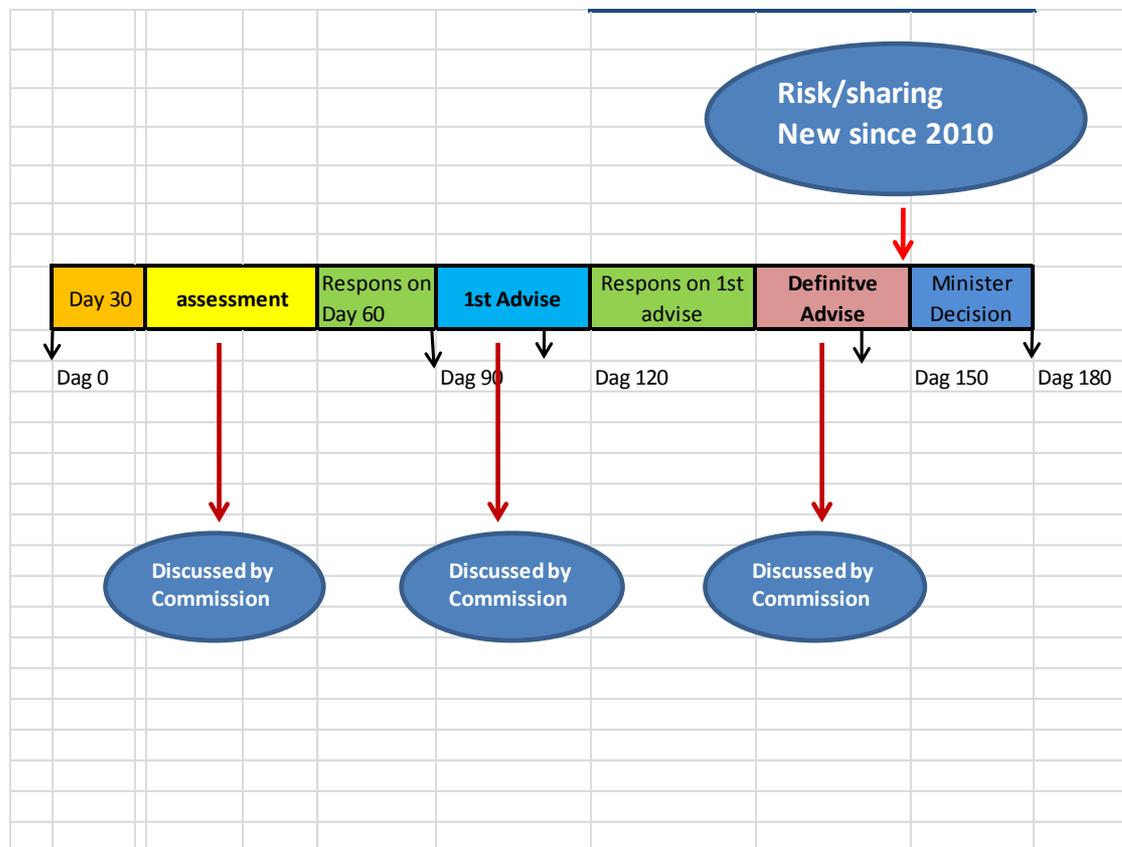
Adapted from: Luce et al., Milbank Quarterly 2010

# What to do with innovative technologies?

*“We need to stimulate and make available innovative technologies that offer a therapeutic benefit at an acceptable cost (i.e. are cost-effective), and fill unmet medical needs”*

- OECD 2003
- Report of the Belgian EU Presidency, adopted by the EU Council of Ministers of Health in Dec 2010

# Reimbursement Procedure: Royal Decree 21<sup>st</sup> December 2001



# Reimbursement Procedure: RD 21<sup>st</sup> December 2001 art.1 – 21<sup>o</sup>

- Criteria assessed by the Reimbursement Commission to determine therapeutic benefit:

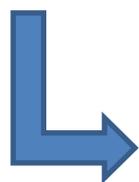
Activity

Efficacy – (relative efficacy)

Safety

Applicability

User friendliness

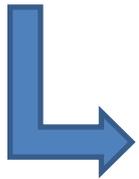


**QoL – morbidity – mortality**

(Mandatory to obtain a premium price)

# Reimbursement Procedure: RD 21<sup>st</sup> December 2001

- Decision Criteria used by the Reimbursement Commission :  
art.4



Therapeutic Value

Price

Medical, Therapeutical, Social needs

Budget Impact

Relation between "Cost & Therapeutic value" =

**Health Economic evaluation**

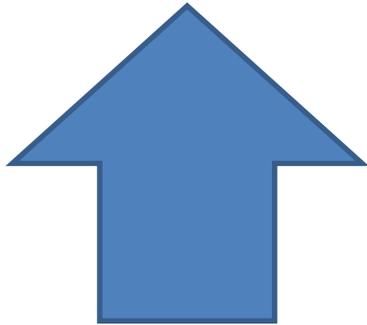
# Reimbursement Procedure: RD 21<sup>st</sup> December 2001 – art.81

True risk-sharing has been defined by Garrison & Towse as:

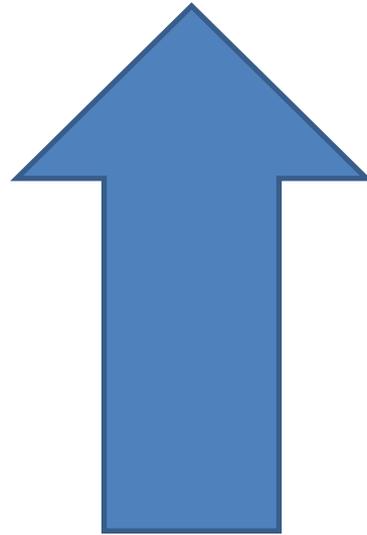
“ An agreement between a payer and a manufacturer where the price level and / or revenue received is related to the future performance of the product in either research or real-world environment.”

# Towards a common definition of innovation

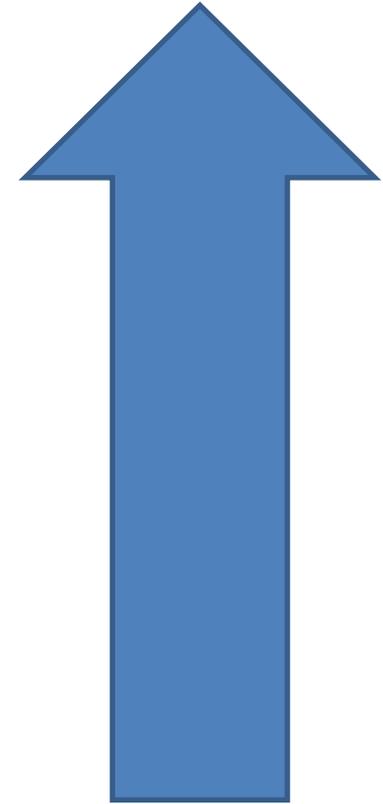
**'truly innovative'** = **added therapeutic value**  
= relative efficacy and/or effectiveness.



**'valuable innovation'** = truly  
+ filling an unmet need



**'value for money'** = valuable  
and cost-effective and  
affordable



# Reimbursement Procedure: RD 21<sup>st</sup> December 2001

- Risk sharing agreements : art.81  
Negociation between Authorities &  
Pharmaceutical Company

How to deal with uncertainties ?

Thank you!



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