



Pharma-economical situation in Belgium

Prof. Dr. Leo Neels

CEO pharma.be

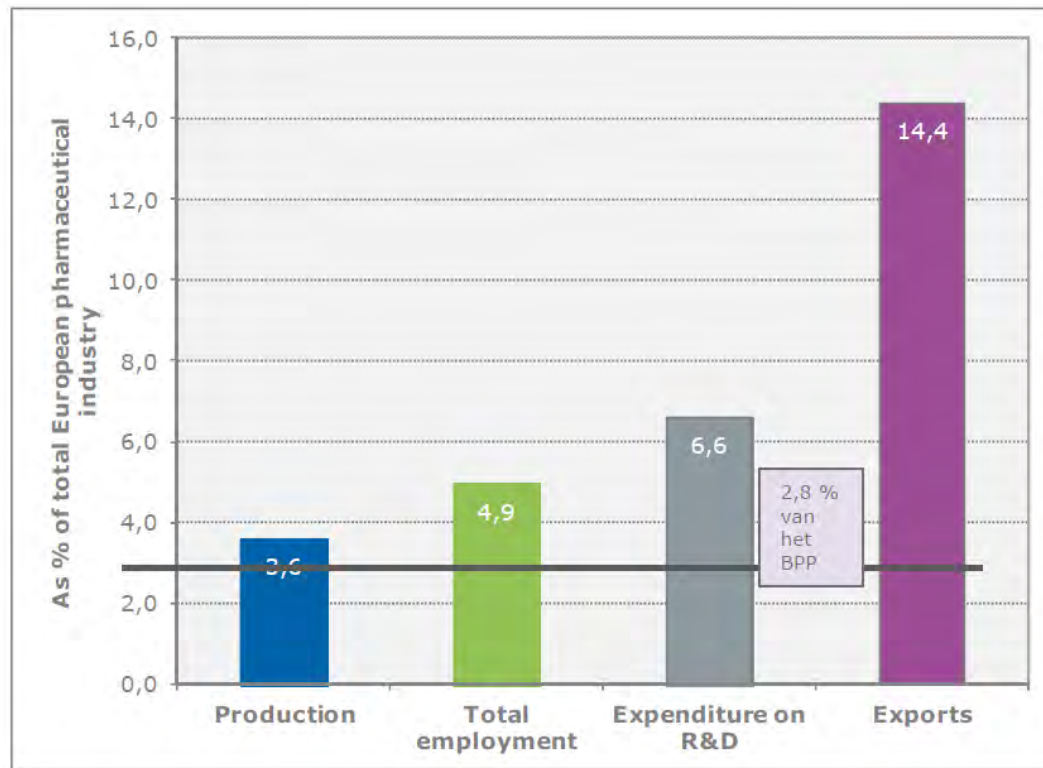


[pharma.be]

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%

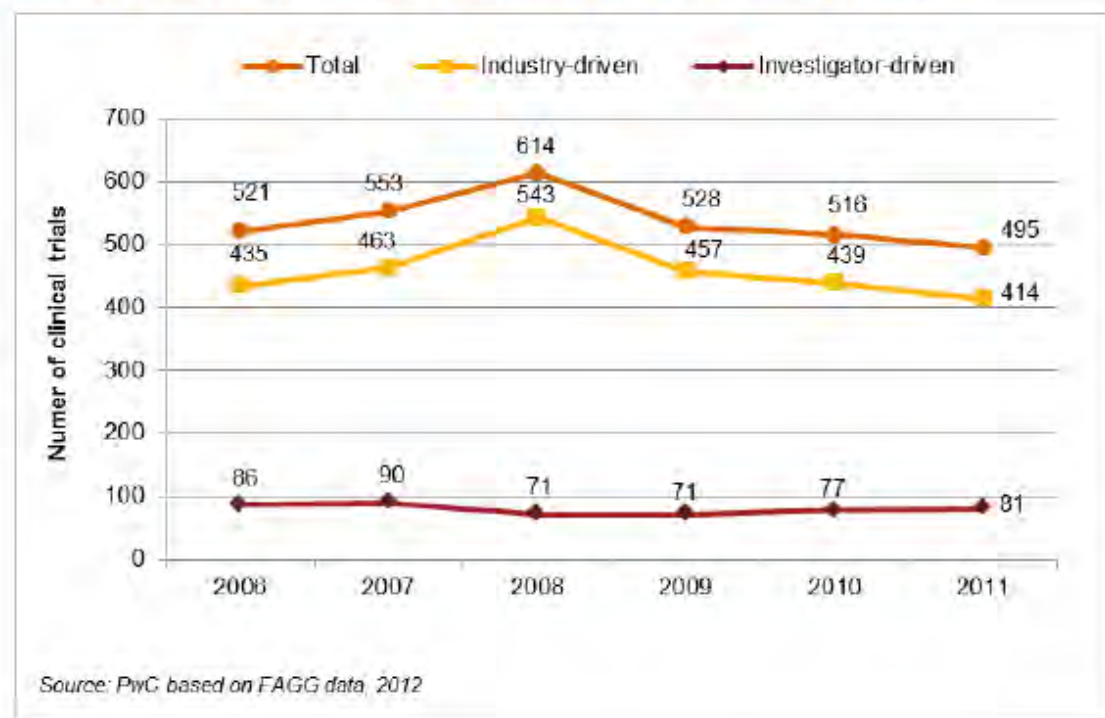
Bron: EFPIA, pharma.be; gegevens 2010 = schattingen

Opmerking: Europa = EU-27 + Zwitserland + Noorwegen

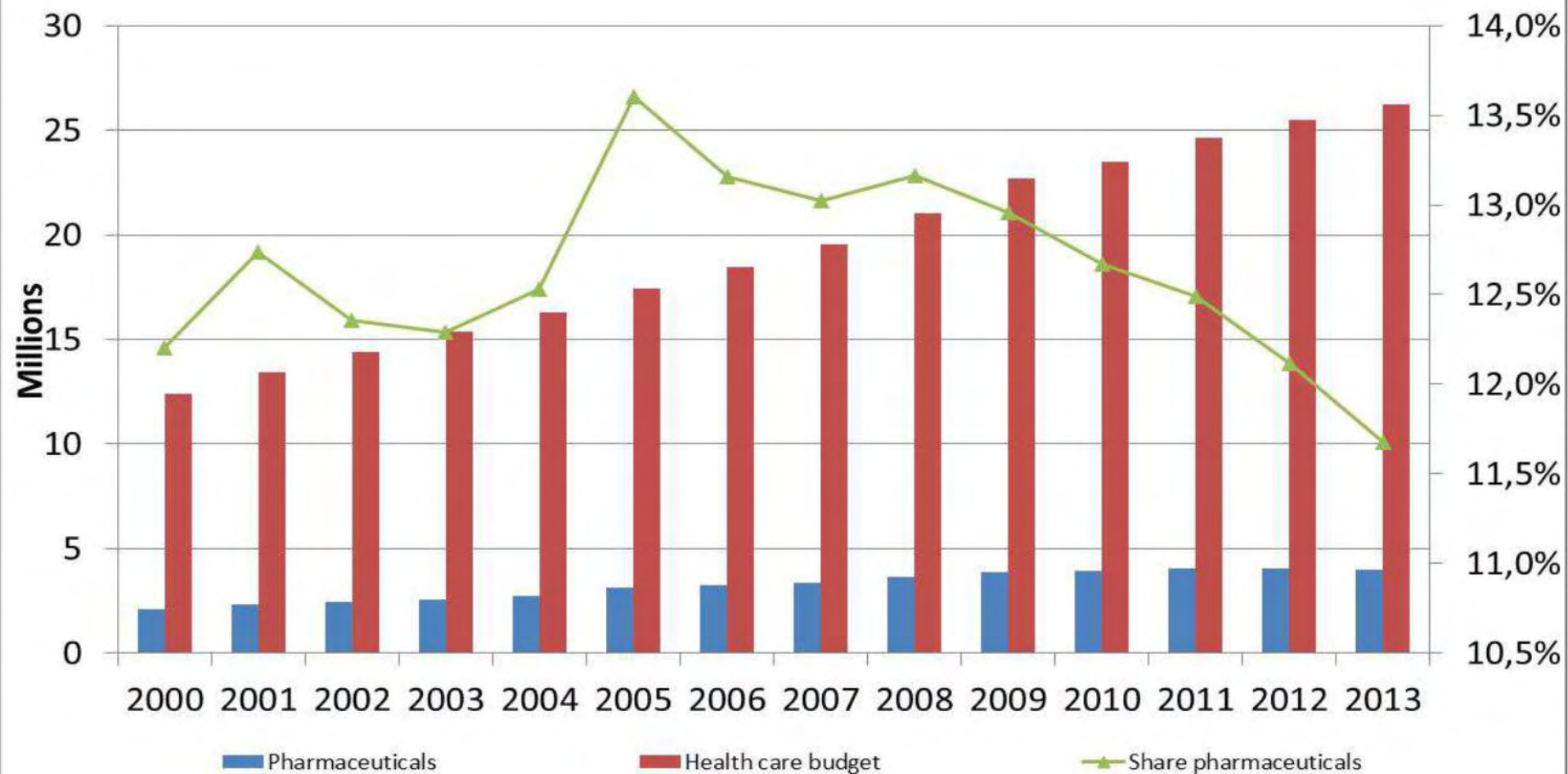
Clinical trials in Belgium

- 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**

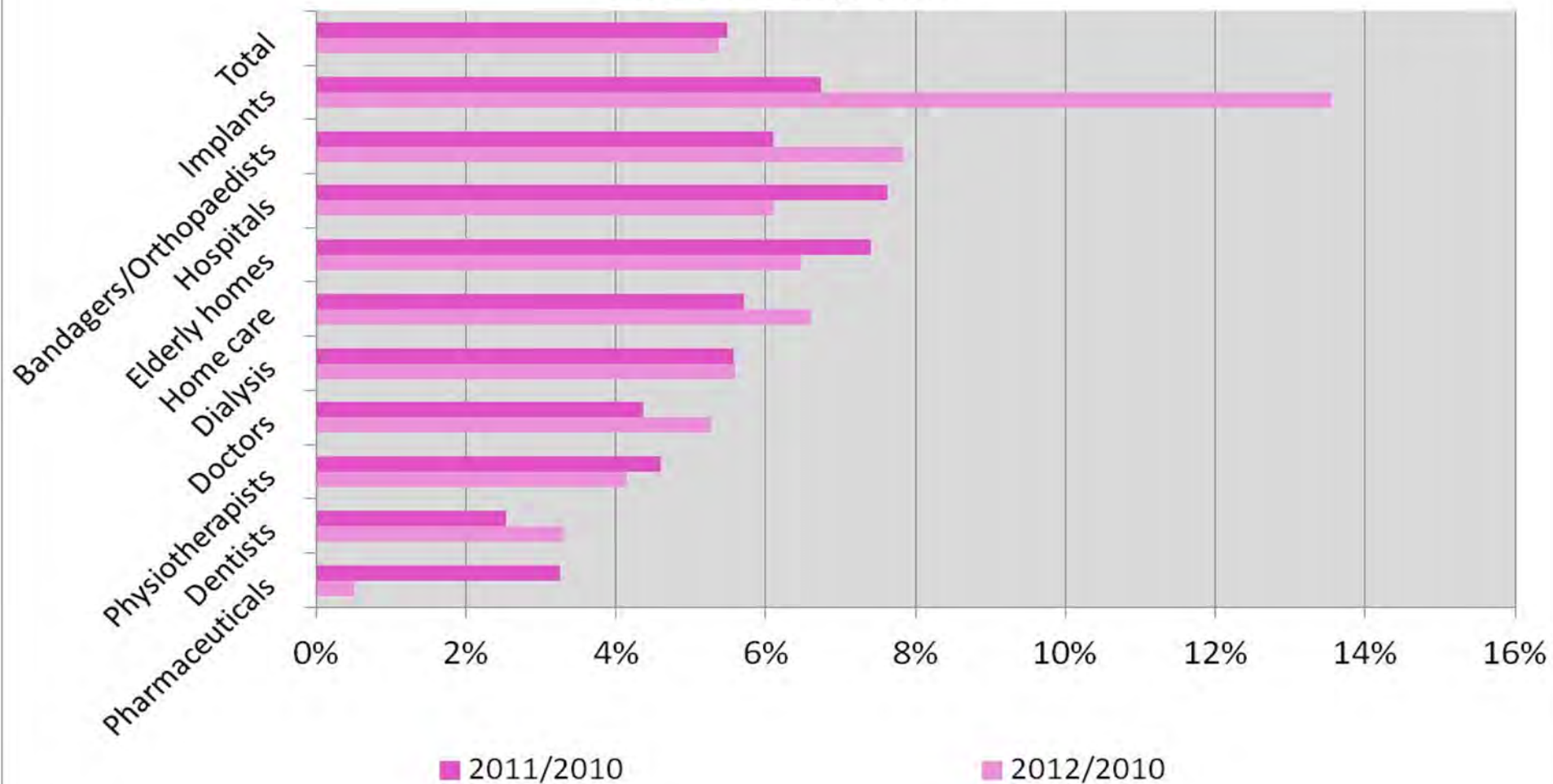
Figure 11²⁰: Total number of clinical trials per year in Belgium



Health care and medicines budget 2013



Average annual growth in healthcare expenditure 2011-2012/2010



Affordability



Staatsschuld Meter .be

België

USA

UK

Duitsland

Nederland

De Staatsschuld stijgt met 507 euro per seconde!

€ 363,146,689,215

Voorafbetaling Belasting

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

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

Info

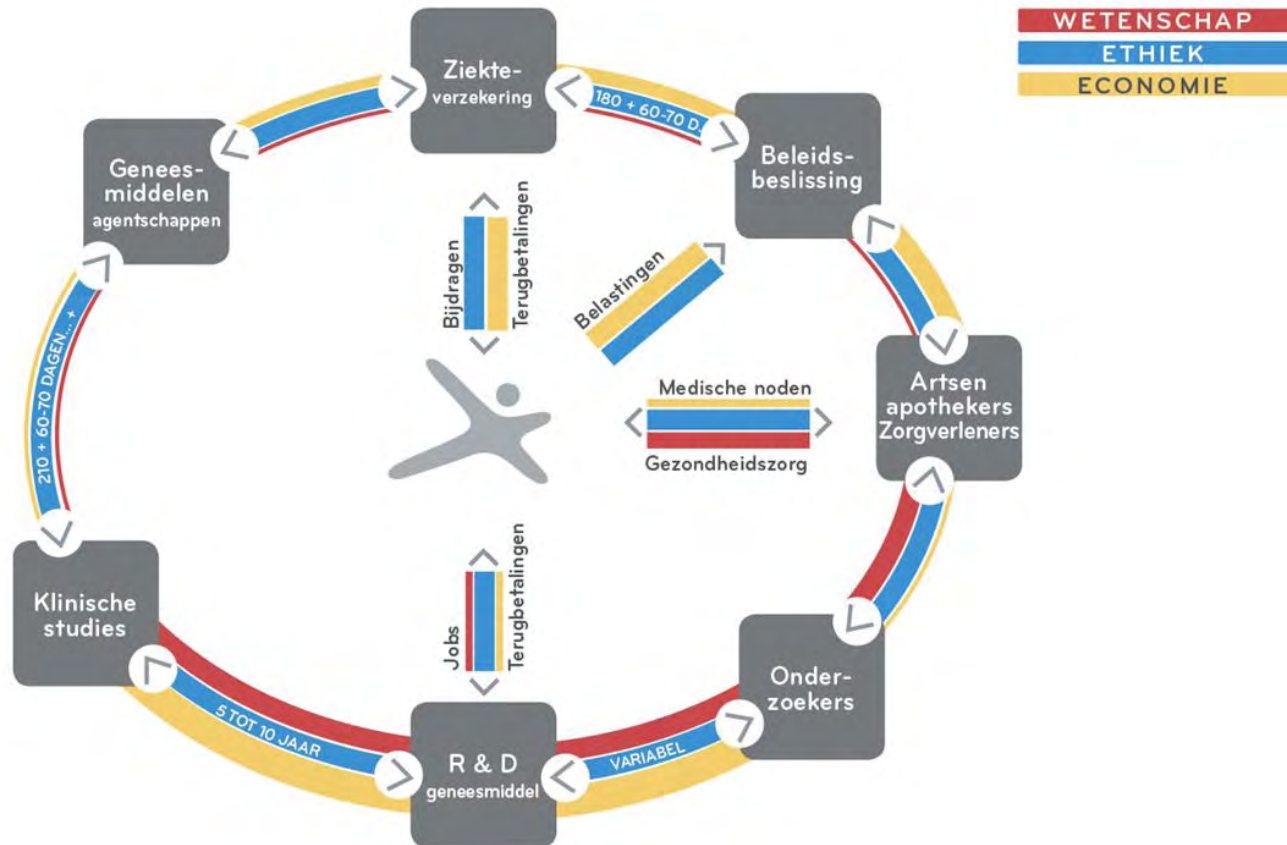
€ 33.660 schuld per inwoner

€ 67.319 schuld per werkzame inwoner

pharma.be

19/04/2013

Shared Responsibility



R&D-based industry

R&D worldwide and US



Source: 2012 World pharma yearbook

“Sunk funds...”

Chicken and egg problem: payor engagement



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

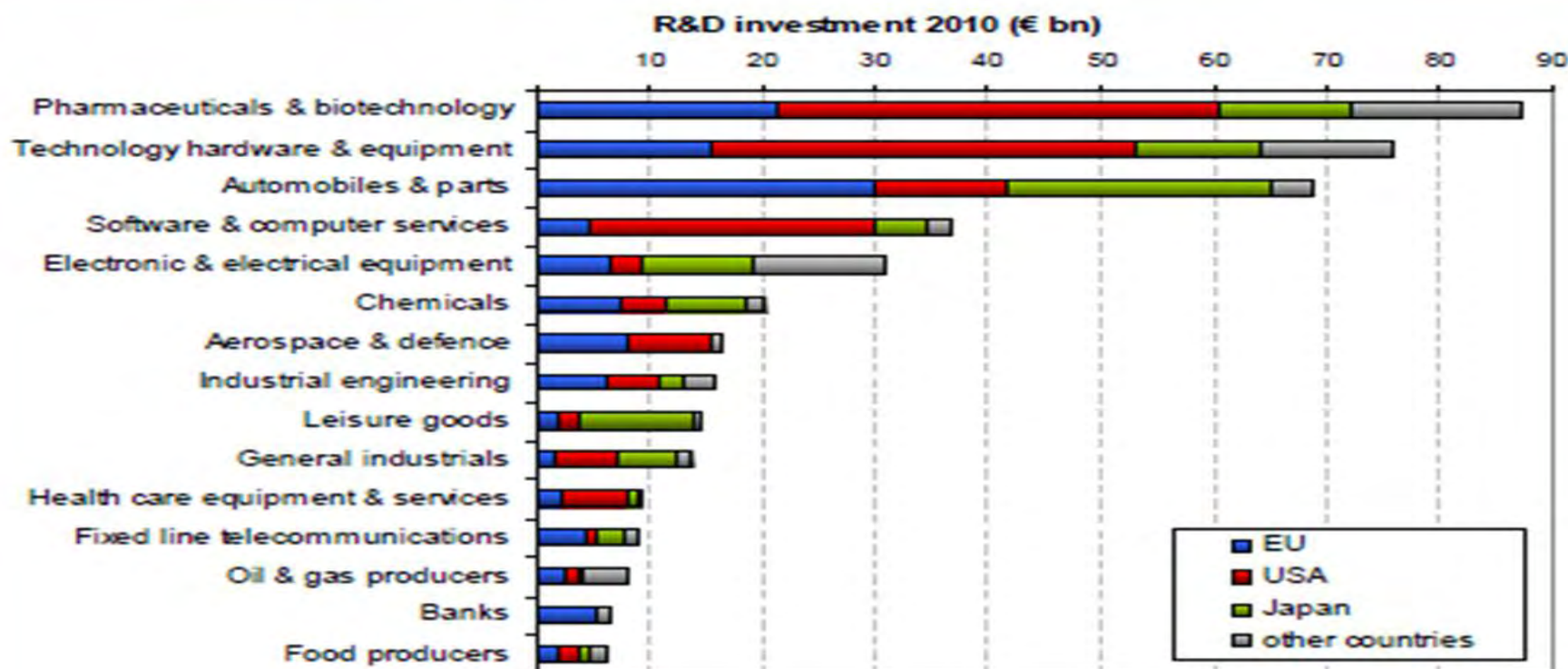


Source: Paul Steven M. Paul, Daniel S. Mytelka, Christopher T. Dunwiddie, Charles C. Persinger, Bernard H. Munos, Stacy R. Lindborg and Aaron L. Schacht (2010), *How to improve R&D productivity: the pharmaceutical industry's grand challenge*, Nature Reviews Drug Discovery 9, pp. 203-214

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

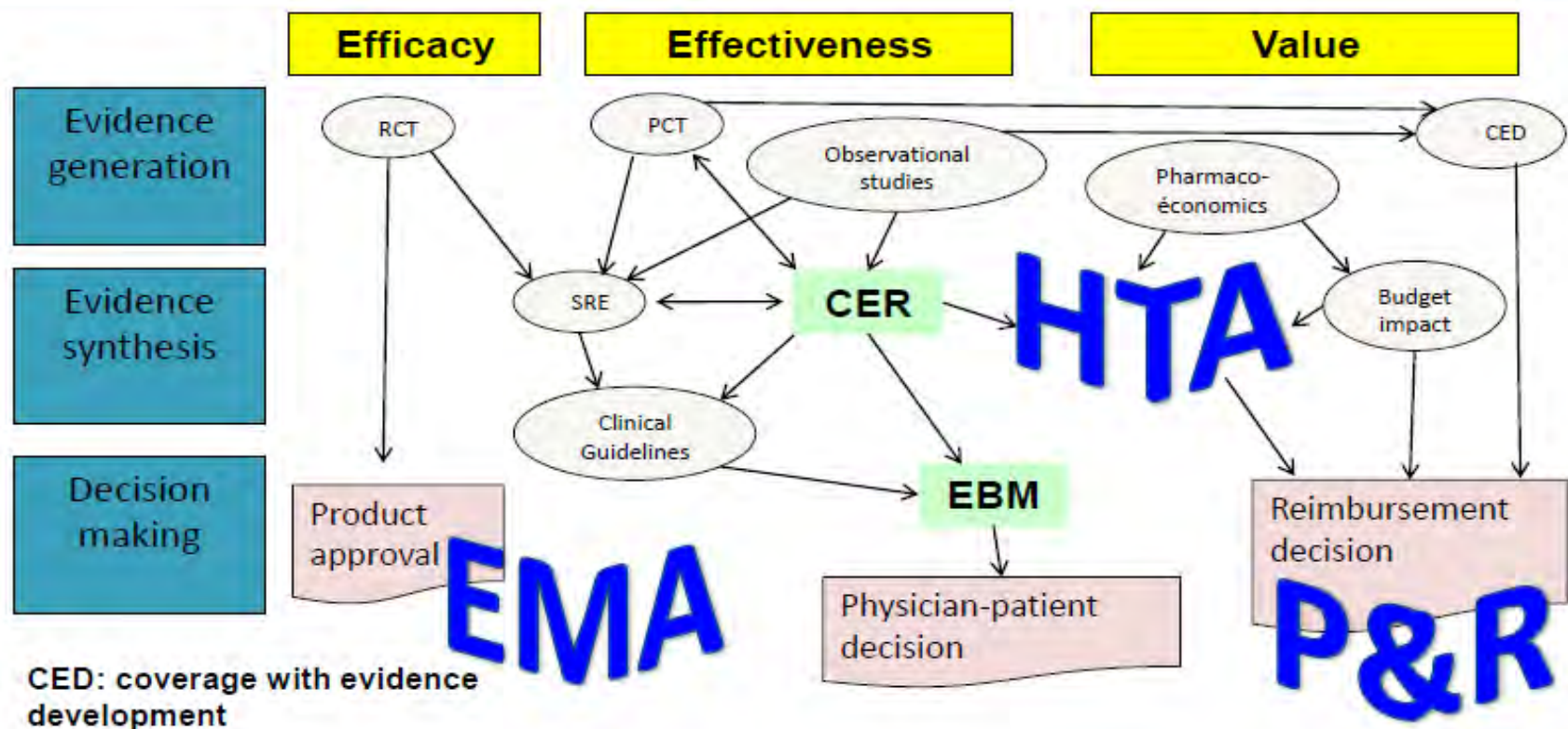
	Number of approved products	Total R&D spending, 1997- 2011 (US\$ bill.)	Cost per product (US\$ bill.)
AstraZeneca	5	58.96	11.79
GlaxoSmithKline	10	81.71	8.17
Sanofi	8	63.27	7.91
Roche	11	85.84	7.80
Pfizer	14	108.18	7.73
Johnson & Johnson	15	88.29	5.89
Eli Lilly	11	50.35	4.58
Abbott Laboratories	8	35.97	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

6

Bruno Flamion – HTA 5-year perspective

the Belgian pharmaceutical conference

pharma.be

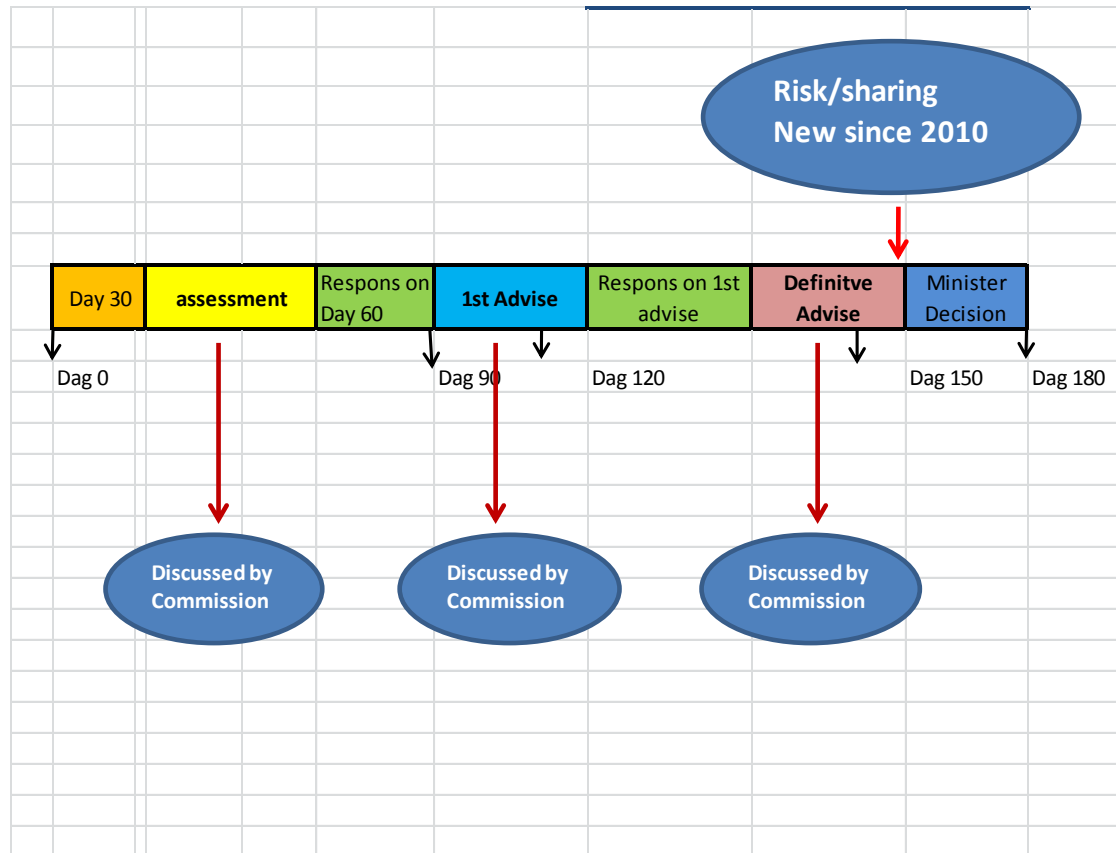
19/04/2013

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 21st December 2001



Reimbursement Procedure: RD 21st December 2001 art.1 – 21°

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

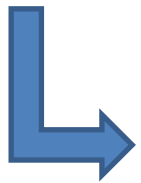
Activity

Efficacy – (relative efficacy)

Safety

Applicability

User friendliness

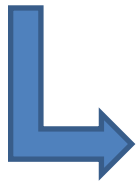


QoL – morbidity – mortality

(Mandatory to obtain a premium price)

Reimbursement Procedure: RD 21st 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

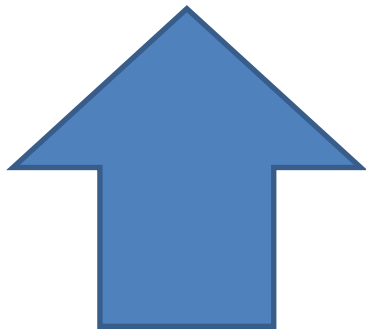
Reimbursement Procedure: RD 21st December 2001 – art.81

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

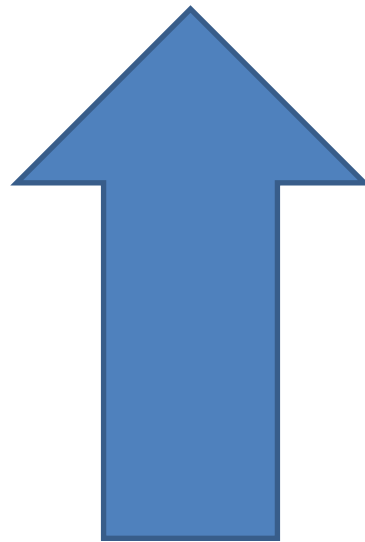
“ An agreement between a payer and a manufacturer where the price level and / or revenue received is related to the future performance of the product in either research or real-world environment.”

Towards a common definition of innovation

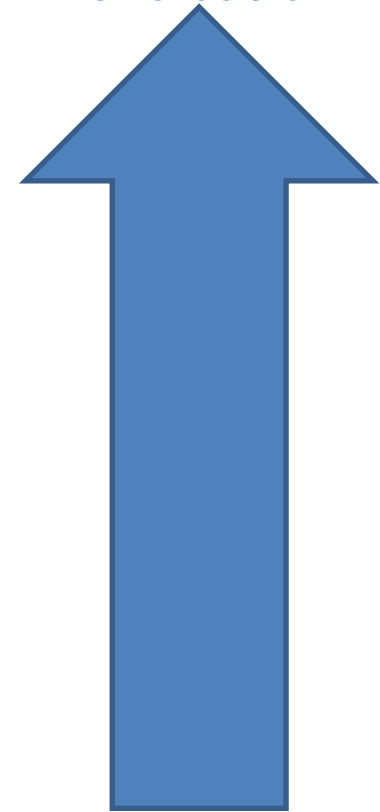
'truly innovative' = added therapeutic value
= relative efficacy and/or effectiveness.



'valuable innovation' = truly
+ filling an unmet need



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



Reimbursement Procedure: RD 21st December 2001

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

How to deal with uncertainties ?

Thank you!

