

## **EU Pharmaceutical Policy**

### **PHARMACEUTICAL MARKET & ECONOMICS**

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EFPIA – Deputy Director General

Parma, 29-30 March 2012

- About EFPIA
- About the Pharmaceutical Industry
- Pharmaceutical Market & Economics
  - Market Access
  - Pricing & reimbursement
  - Financial Crisis & Healthcare Budgets
- EFPIA collaborating with Academics

- About EFPIA

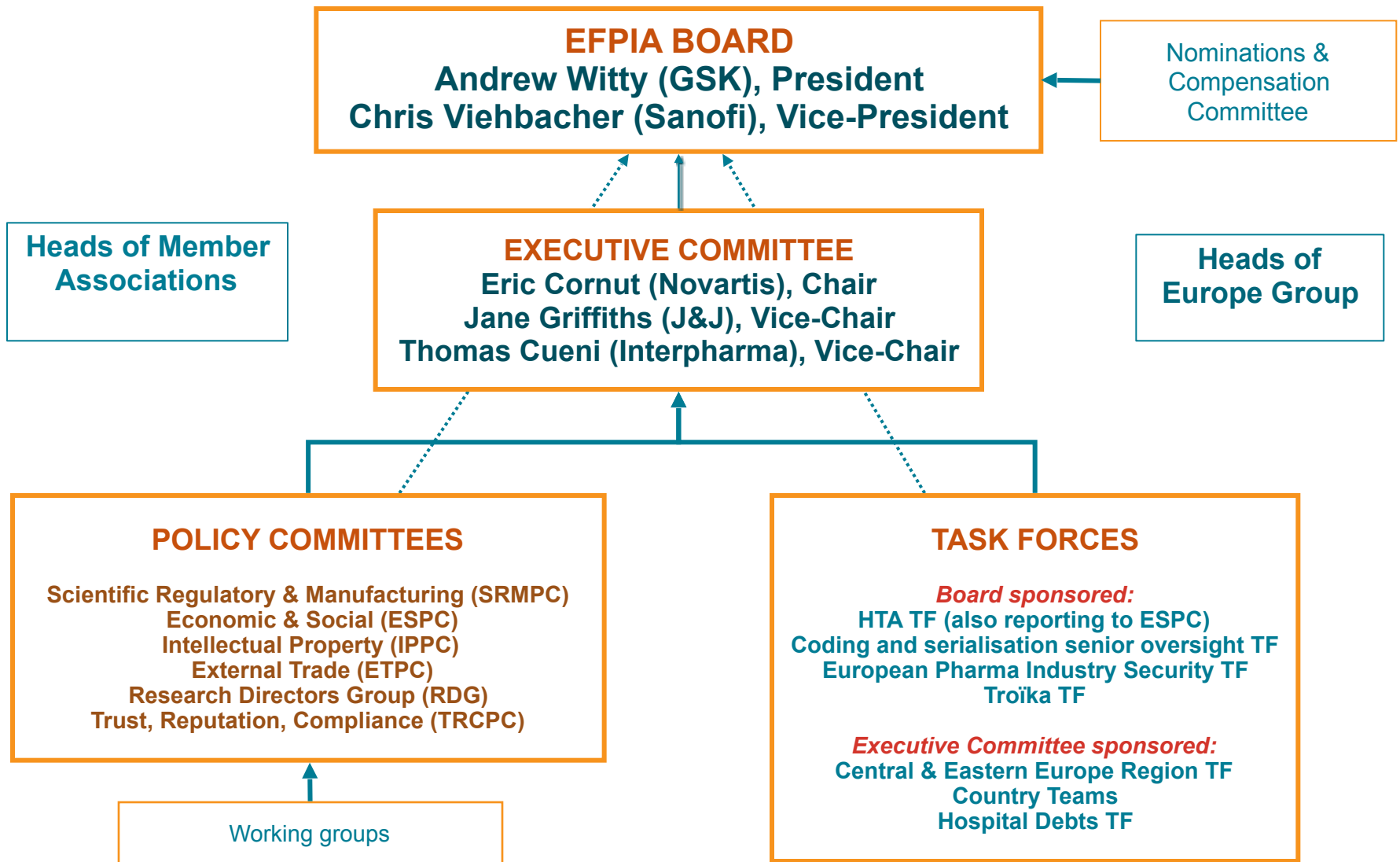
**EUROPEAN FEDERATION OF PHARMACEUTICAL  
INDUSTRIES AND ASSOCIATIONS**

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The aim of the European Federation of Pharmaceutical Industries & Associations, which has no profit-making purpose, is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.

EFPIA pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

EFPIA's represents the pharmaceutical industry operating in Europe. Its direct membership includes **31 national associations and 36 leading companies**. Two specialised groups within EFPIA represent **vaccine manufacturers – EVM**, with 9 member companies) and **emerging / European bio-pharmaceutical companies – EBE** with 65 member companies.



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**KEY DATA – 2011 update**
- Pharmaceutical Market & Economics
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Values in € million, unless otherwise stated	1990	2000	2009	2010 (e)
Production	63,010	123,793	189,012	190,000
Exports	23,180	90,935	249,426	270,000
Imports	16,113	68,841	190,635	200,000
Trade balance	7,067	22,094	58,791	70,000
R&D Expenditure	7,766	17,849	27,440	27,000
Employment (units)	500,879	536,733	640,286	640,000
<i>of which, in R&amp;D</i>	76,126	88,397	116,682	115,000
Market value (ex-factory)	41,147	86,704 x 2.1	149,193	152,500 x 1.8
Market value (at retail prices)	64,626	140,684 x 2.2	217,293	222,000 x 1.6
Pharma spend by statutory HC systems	40,807	76,909 x 1.9	121,228	120,000 x 1.6

## 1999

Regions	Share
North America	40.5%
Europe	26.2%
Japan	15.2%
Latin America	6.1%
ROW	12.0%

## 2005

Regions	Share
North America	47.0%
Europe	30.0%
Japan	10.7%
Latin America	4.2%
ROW	8.2%

## 2010

Regions	Share
USA	42.3%
Europe	29.2%
Japan	10.8%
Latin America	5.3%
ROW	12.4%



## 2001-2005

Regions	CAGR
Europe	8%
Top 5	7%
Other West	8%
Eastern	13%

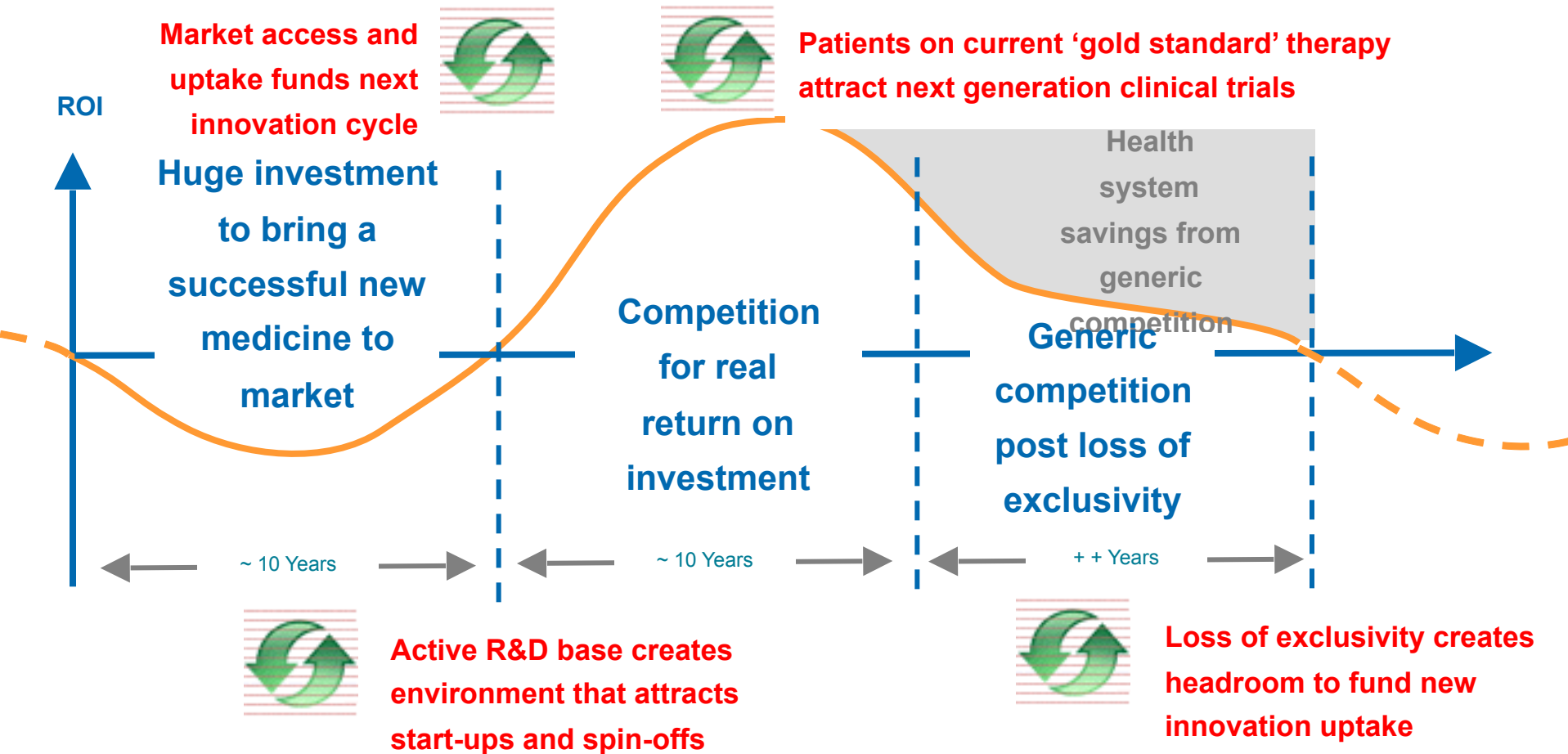
## 2006-2010

Regions	CAGR
Europe	6%
Top 5	5%
Other West	4%
Eastern	11%

## 2011-2015 forecast

Regions	CAGR
Europe	1-4%
Top 5	0 - 3%
Other West	(-1) - 2%
Eastern	6-9%

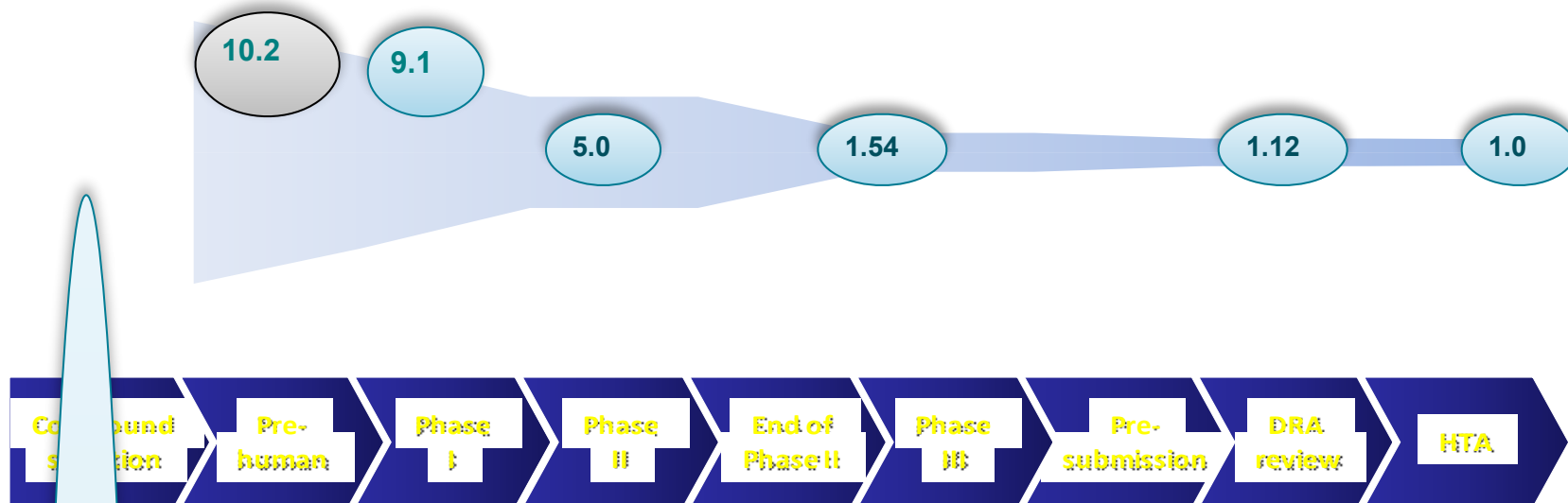
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A (European) framework for financially sustainable healthcare innovation

## Late stage failure

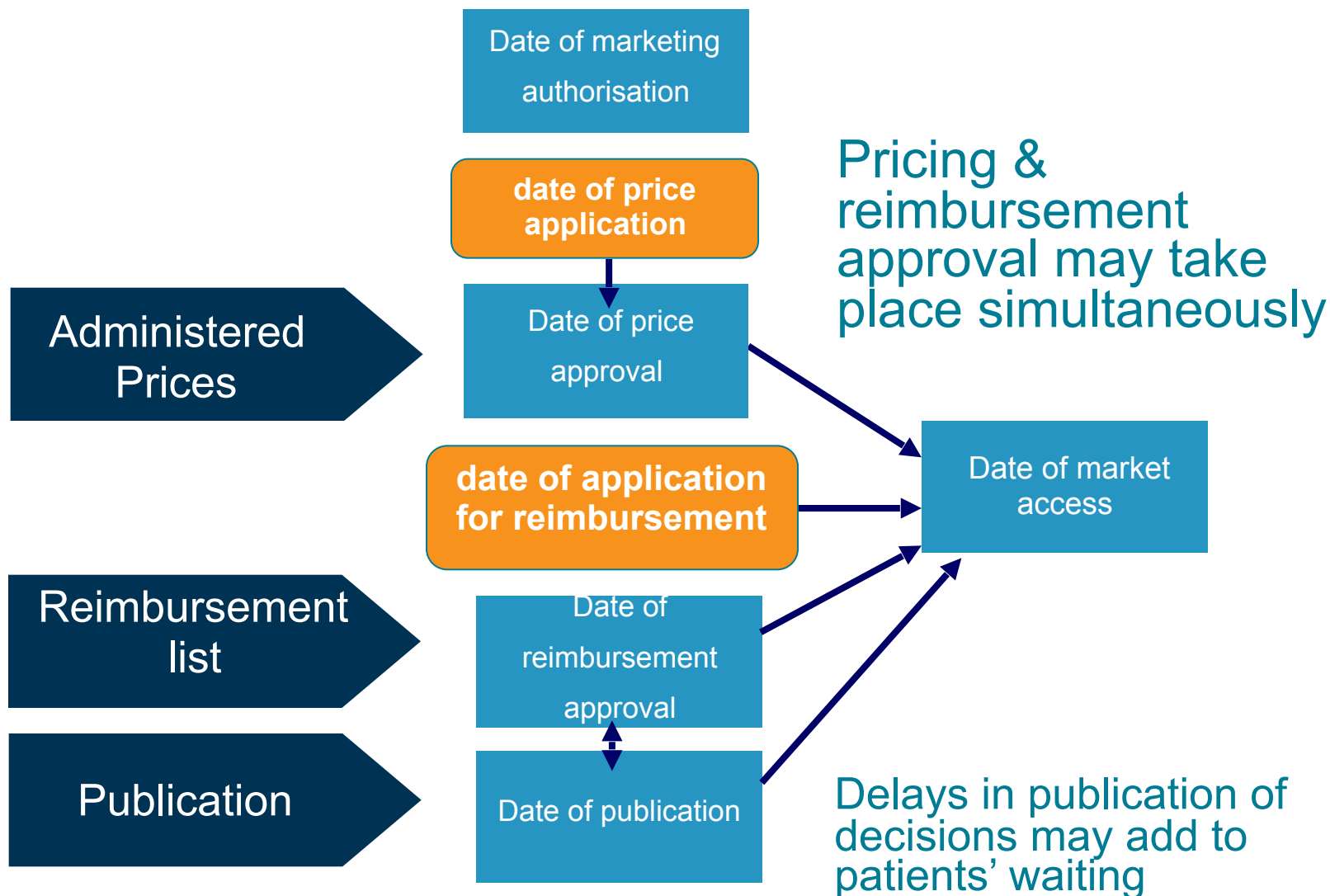
Throughout development and up to market access



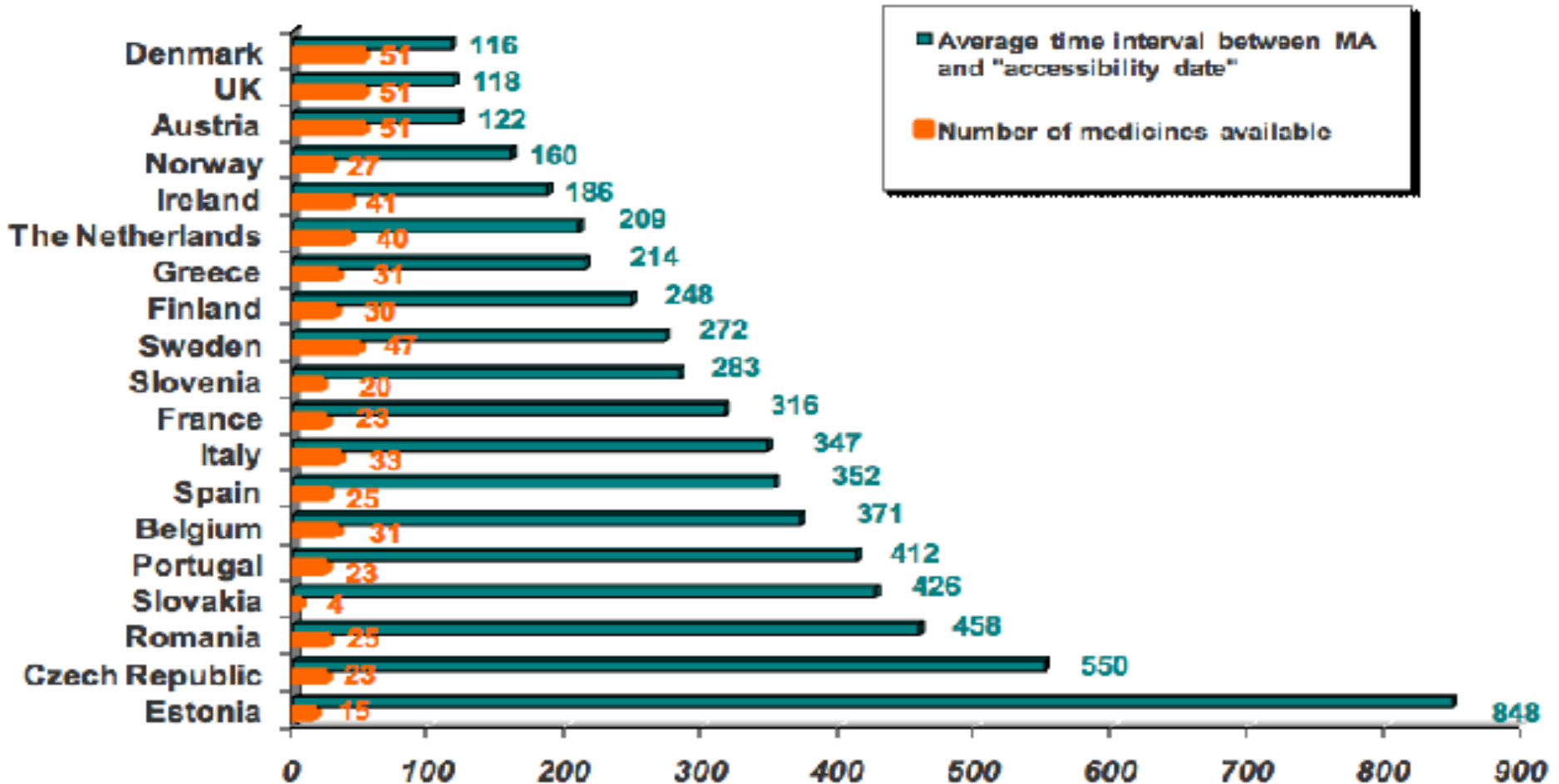
Source: Modified from - 2010 CMR International Pharmaceutical R&D Factbook

Year of MA granted	Total	Of which Orphan medicines
2005	14	3
2006	19	7
2007	31	12
2008	16	4
2009	37	1 + 1 AT
2010	13	5
2011	37	

Year	Active review time	From application to MA date	From CHMP opinion to MA date
<b>2005</b> 14 MA	<b>189 days</b> Min. 181 / Max. 219	<b>497 days</b> Min. 352 / Max. 654	<b>94 days</b> Min. 83 / Max. 143
<b>2006</b> 19 MA	<b>198 days</b> Min. 175 / Max. 224	<b>493 days</b> Min. 294 / Max. 754	<b>73 days</b> Min. 48 / Max. 131
<b>2007</b> 31 MA	<b>197 days</b> Min. 141 / Max. 210	<b>457 days</b> Min. 282 / Max. 660	<b>63 days</b> Min. 35 / Max. 84
<b>2008</b> 16 MA	<b>197 days</b> Min. 177 / Max. 209	<b>460 days</b> Min. 335 / Max. 745	<b>64 days</b> Min. 47 / Max. 78
<b>2009</b> 37 MA	<b>201 days</b> Min. 176 / Max. 210	<b>479 days</b> Min. 129 / Max. 854	<b>74 days</b> Min. 56 / Max. 119
<b>2010</b> 13 MA	<b>202 days</b> Min. 150 / Max. 212	<b>412 days</b> Min. 246 / Max. 483 Not including 1 case: 600 days	<b>75 days</b> Min. 63 / Max 126 Not including 1 case



Total number of medicines within scope: 66





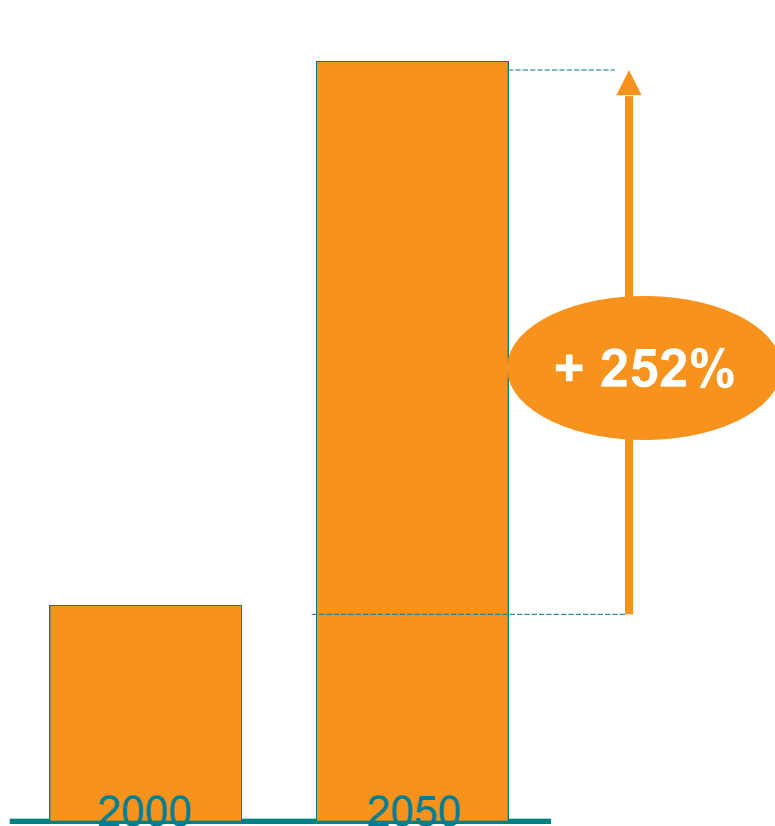


- ❖ **Demographics** and expectations re health outcomes
- ❖ Increasingly **cost-contained healthcare systems** – austerity programmes; healthcare budgets becoming increasingly strained – low economic growth and fiscal consolidation
- ❖ Major losses of revenue owing to patent expirations – “**patent cliff**”
- ❖ **R&D productivity** – industry’s prospects for profitability and growth

Crisis as an opportunity for **structural reform**

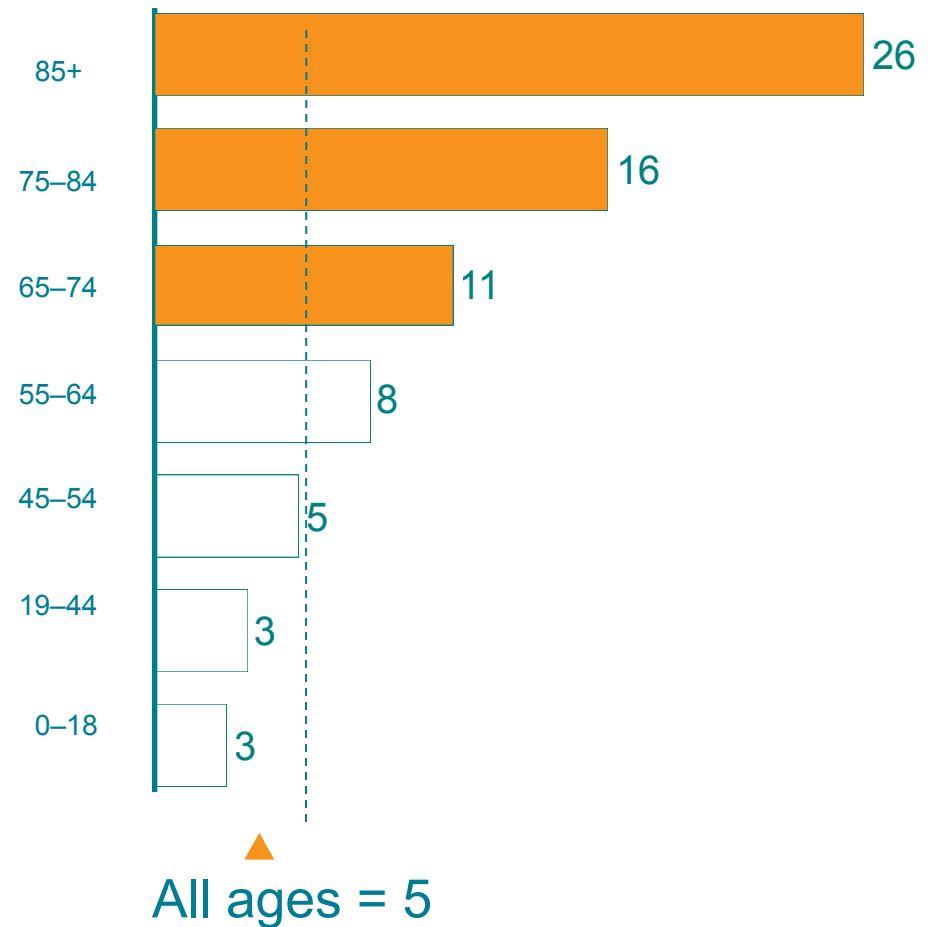
## AGEING POPULATION...

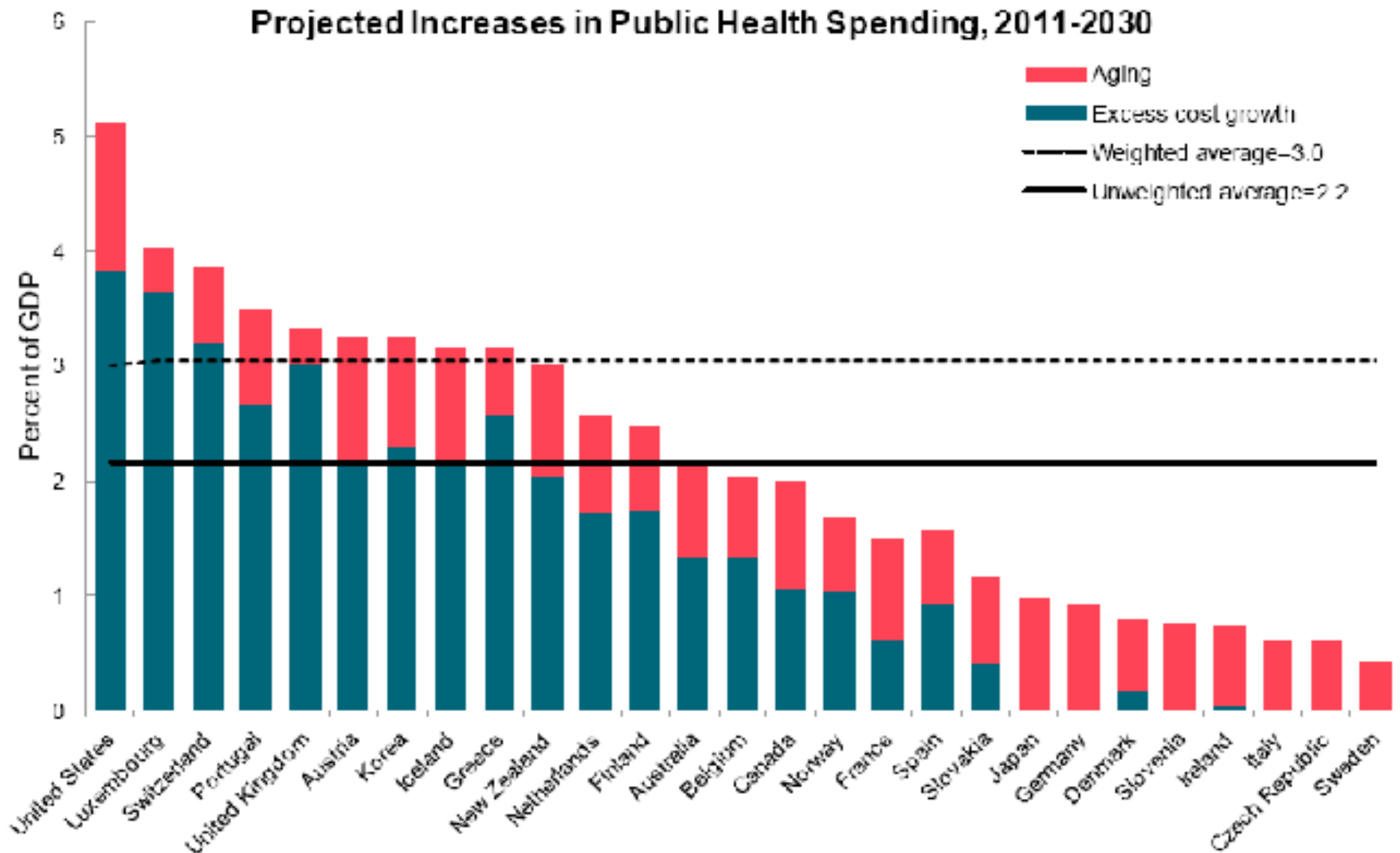
Billion people over 65



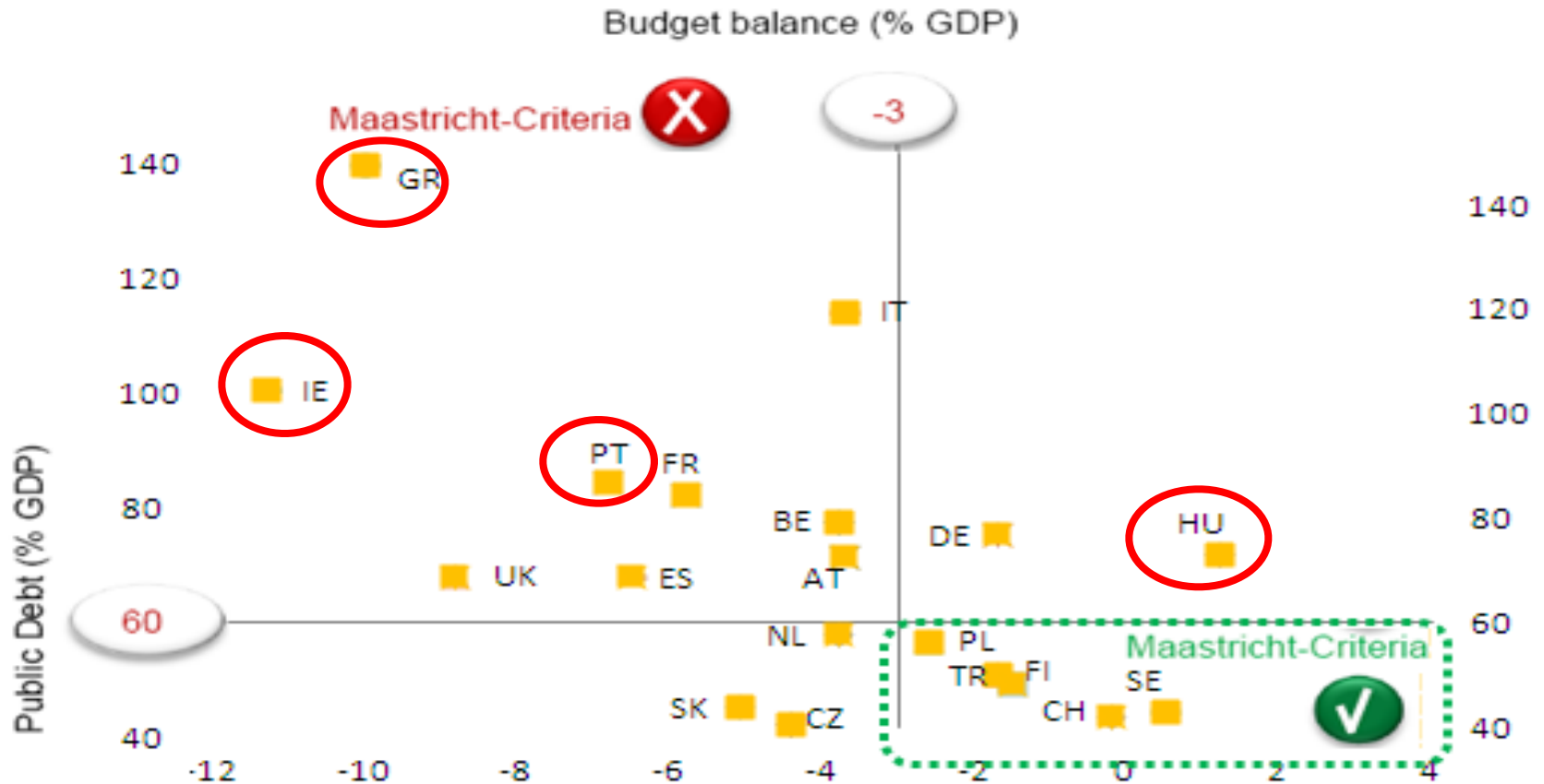
## annual healthcare spend per capita

US – 2004 (000 USD)

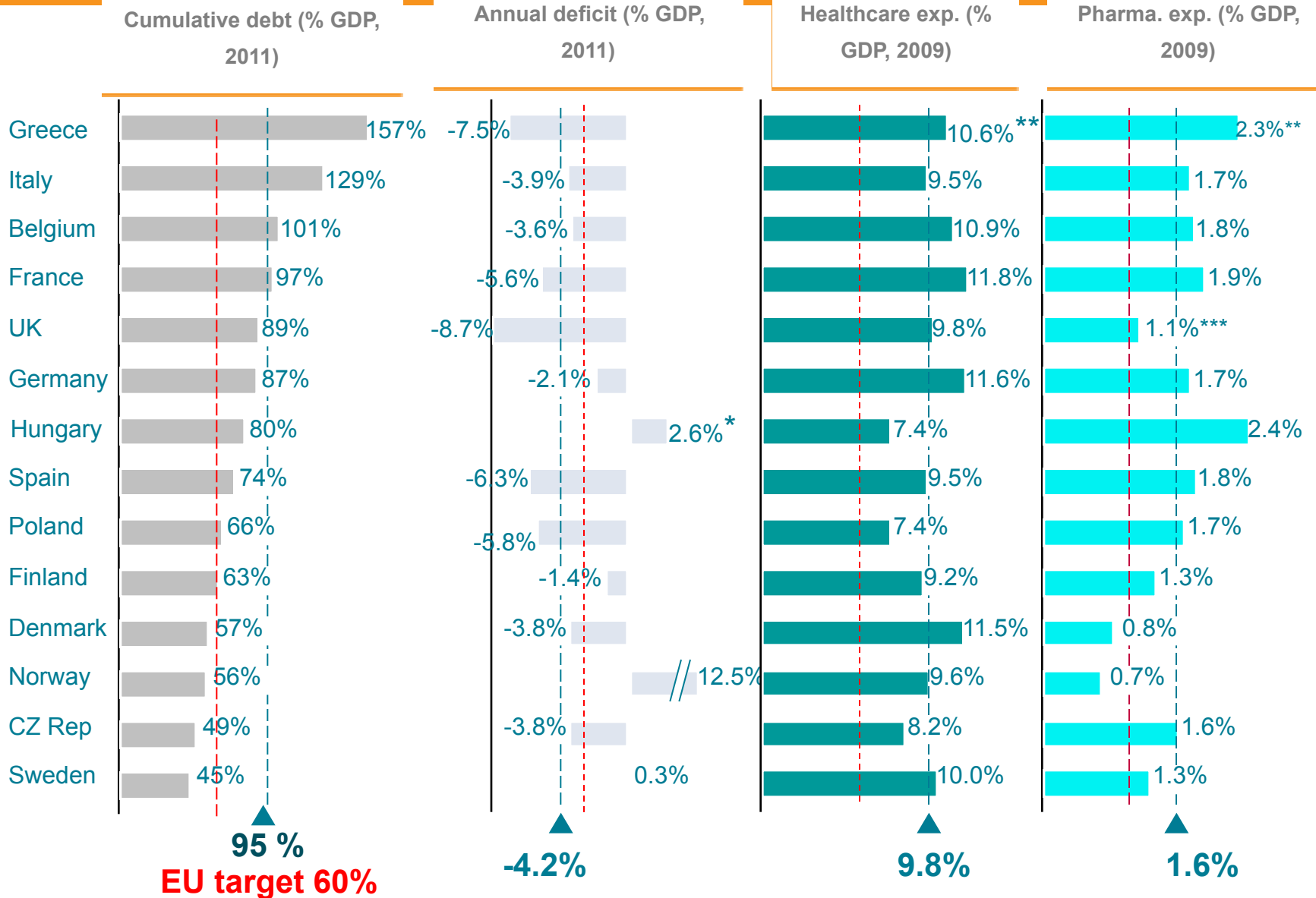




## Continuous Violation of Maastricht Criteria in Europe (2011, Q4/11)

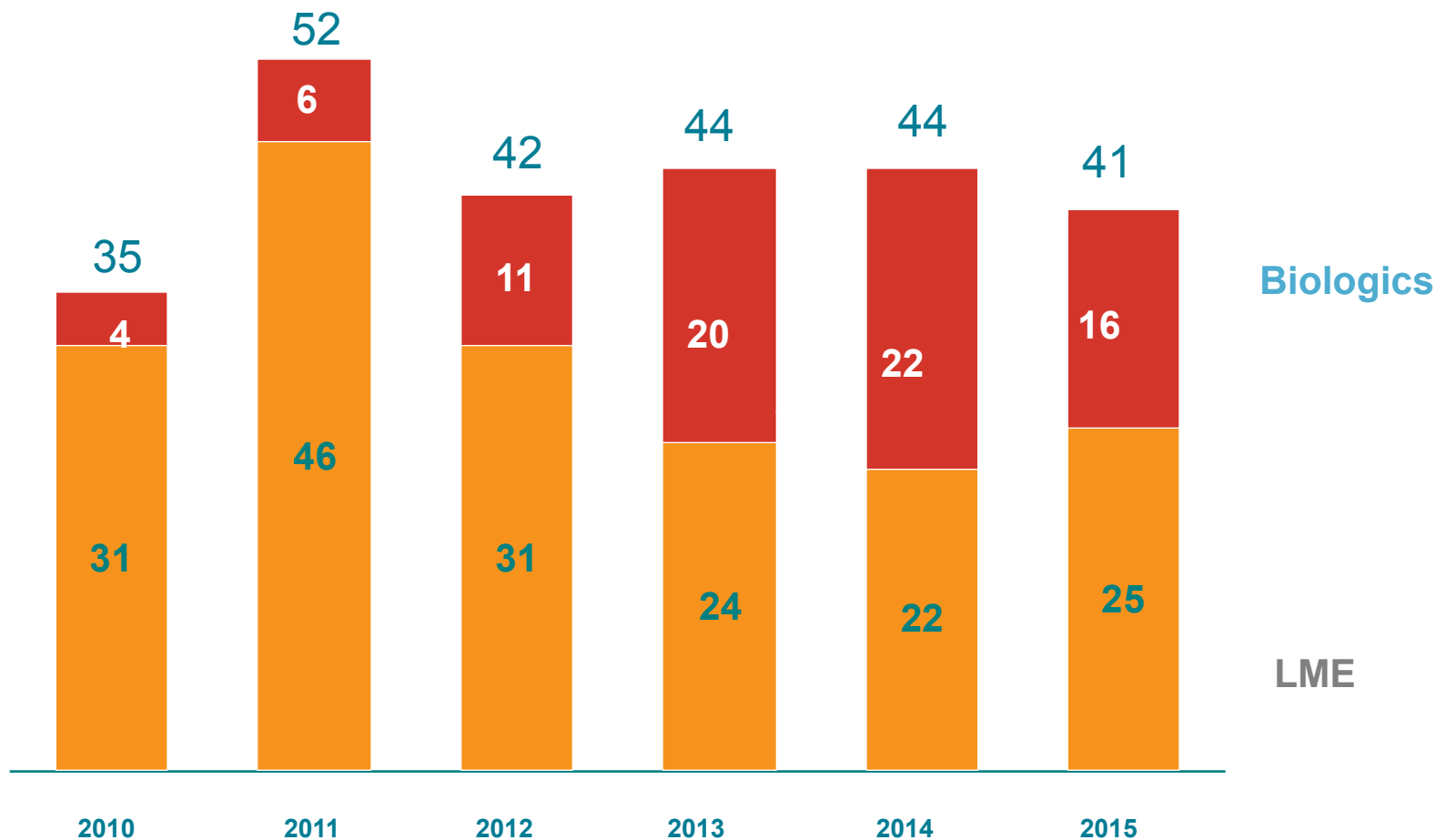


# Public Debts and Deficits Crisis

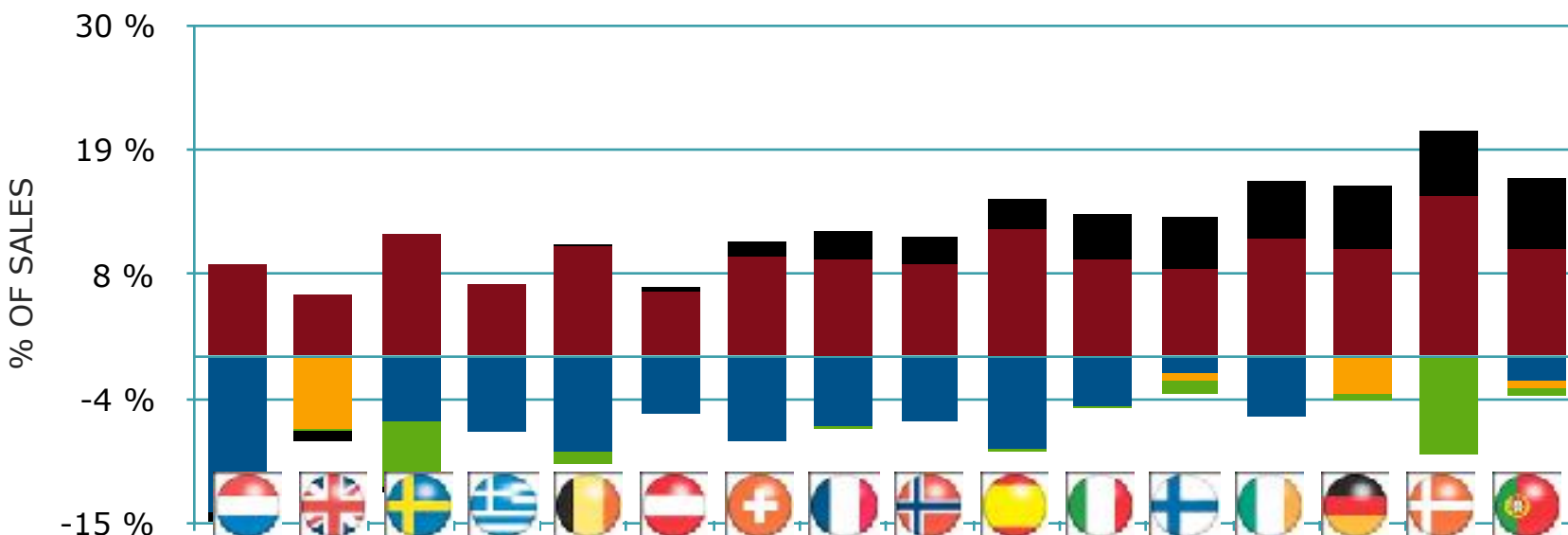


## Worldwide sales of expiring<sup>1</sup> patents, USD billion

Calculations based on US patent expiry



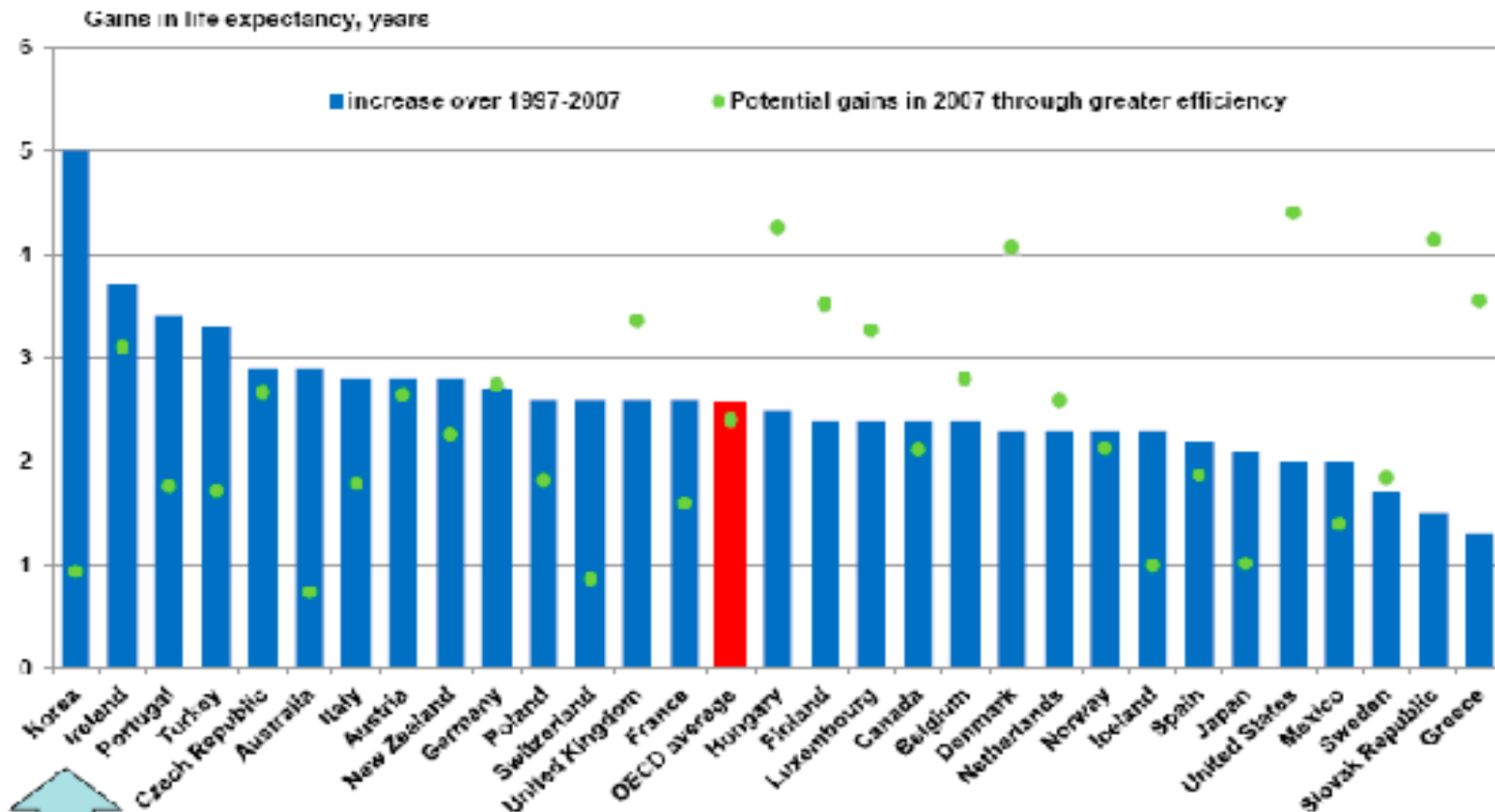
Expected “freed-up financial value” from patent expirations versus “cost of innovation” – cumulative share of total market sales of 5 years (% of 2009 sales for patent expirations and % of sales in the given year for launches)



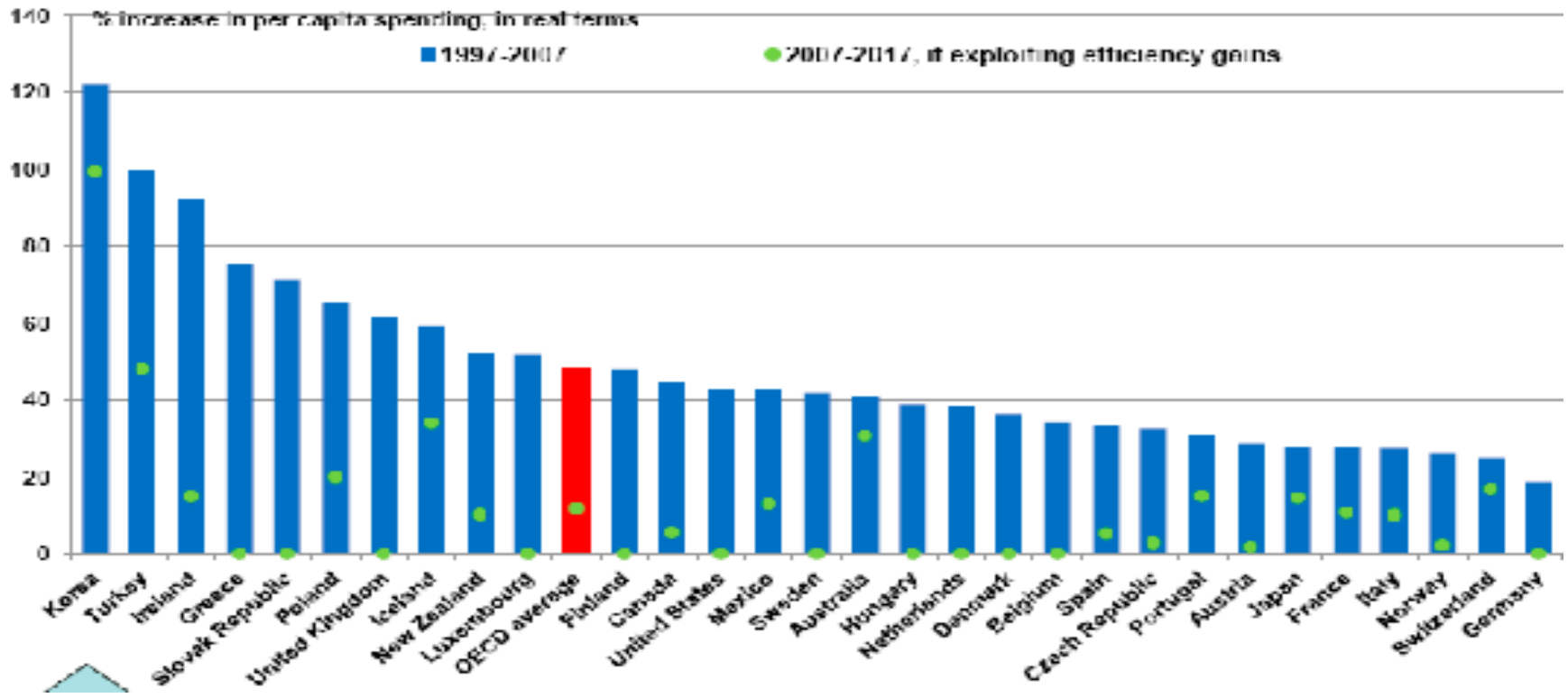
- ABSOLUTE TOTAL
- NEW LAUNCHES (MAXIMUM)
- NEW LAUNCHES (MINIMUM)
- ADDITIONAL GENERICS PRICE REDUCTION
- ADDITIONAL ORIGINAL PRICE REDUCTION
- REGULATORY DRIVEN PRICE REDUCTION



Exploiting efficiency gains would allow to improve health outcomes further...



...and help to contain future health care spending



## Challenges

1. Escalating price and cost pressure
2. Rising R&D costs
3. Declining R&D-productivity
4. Difficult market access and reimbursement

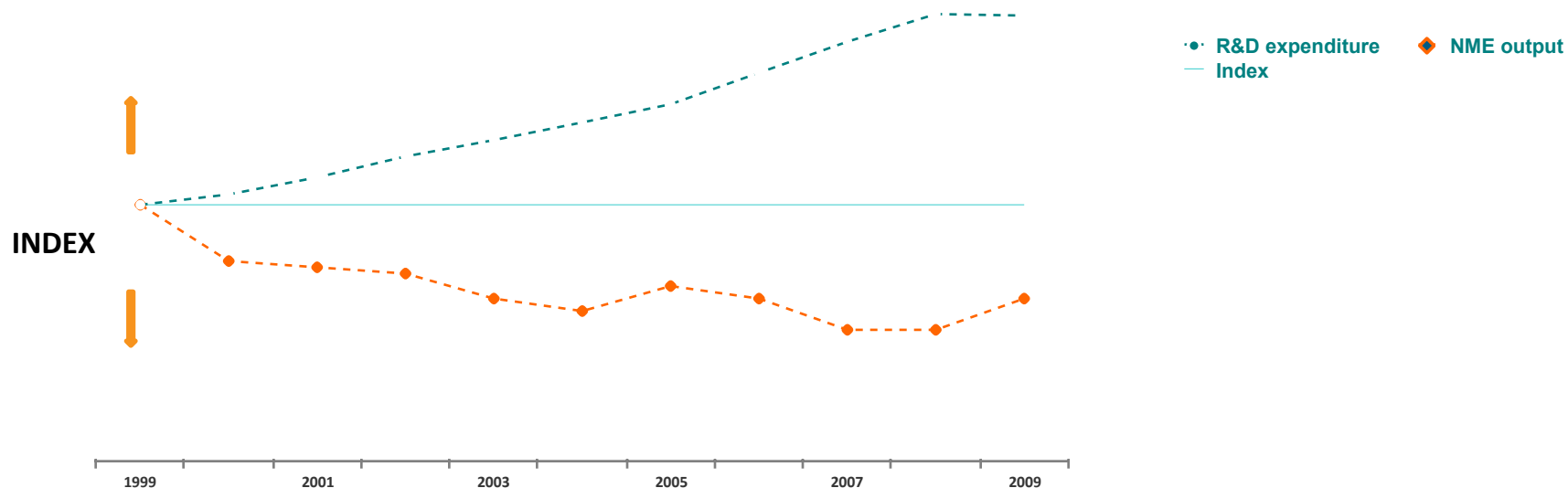
## Opportunities

1. Demand for innovative healthcare is growing
2. Increased importance of emerging markets
3. Consolidation (M&A, strategic alliances, partnerships)
4. Personalised medicines

„Nearly a quarter of the world’s leading pharmaceutical companies consider that **diversifying** away from selling medicines while expanding sales in **emerging markets** are the **most promising ways to sustain growth**”

## Falling NMEs, rising costs

Despite increasing R&D expenditure, the number of innovative medicines is dropping



Source: Modified from - 2010 CMR International Pharmaceutical R&D Factbook.

## Multiple exciting areas of research,

e.g.



Delivery technologies  
(e.g., needle-free, nano)



Drug device combinations



Genomic sequencing



Molecular and cellular diagnostics



Protein engineering



RNAi, Aptamers



Therapeutic vaccines



Evidence-based  
medicine

Personalised medicine

Remote patient  
monitoring/shift of  
location of care

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The EFPIA AWARD will be given to a student of the European College of Parma Foundation for a DASE Thesis covering an area of particular interest to the pharmaceutical industry.

This new Award will be open to students who have followed the Seminar on « EU Pharmaceutical Policy », and who will submit their Thesis for evaluation within 6 months following the Academic year.

- **Subject of the Thesis** – an area of particular interest to the pharmaceutical industry, chosen by the student – EN / FR
- **Guidance & support** – the Thesis will be written under the supervision of (a) Professor(s) of the College – within admissible boundaries, EFPIA will offer access to information, including organisation of contacts, where appropriate
- **Academic evaluation** – the Thesis will be evaluated under the general rules applicable at the College, without intervention of EFPIA - a mark of 15/20 or higher
- **Selection of winning Thesis** – EFPIA evaluation process, involving the EFPIA Award Jury

### **Evaluation criteria:**

- Comprehensiveness
- Coherence of argumentation
- Understanding of fundamental issues
- Introduction of new dimensions (innovative solutions)



## The Prize for the winning Thesis includes:

- **Distribution of the Thesis** – communication of the Thesis to all EFPIA members and posting on the EFPIA website
- **A remunerated stage** – a 12-month employment contract with EFPIA (which could partly be at one of EFPIA's member associations or companies)
  - Including a net monthly remuneration of € 1.500 + basic package (including group insurance)
  - Where appropriate, other allocations could be agreed, such as contribution for accommodation in Brussels
- **Award Ceremony**



## MEDICINES FOR MANKIND

Today's Research, Tomorrow's cures

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