EU Pharmaceutical Policy

PHARMACEUTICAL MARKET & ECONOMICS

Marie-Claire PICKAERT

EFPIA – Deputy Director General

Parma, 5 April 2013

Programme

- About EFPIA
- About the Pharmaceutical Industry
- Pharmaceutical Market & Economics
  - The Protection of Pharmaceutical Innovation
  - Pricing & Reimbursement
  - Market Access & Competition
  - Cross-border Sales
- EFPIA collaborating with Academics

Programme

- About EFPIA

  EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS

- About the Pharmaceutical Industry Pharmaceutical Market & Economics
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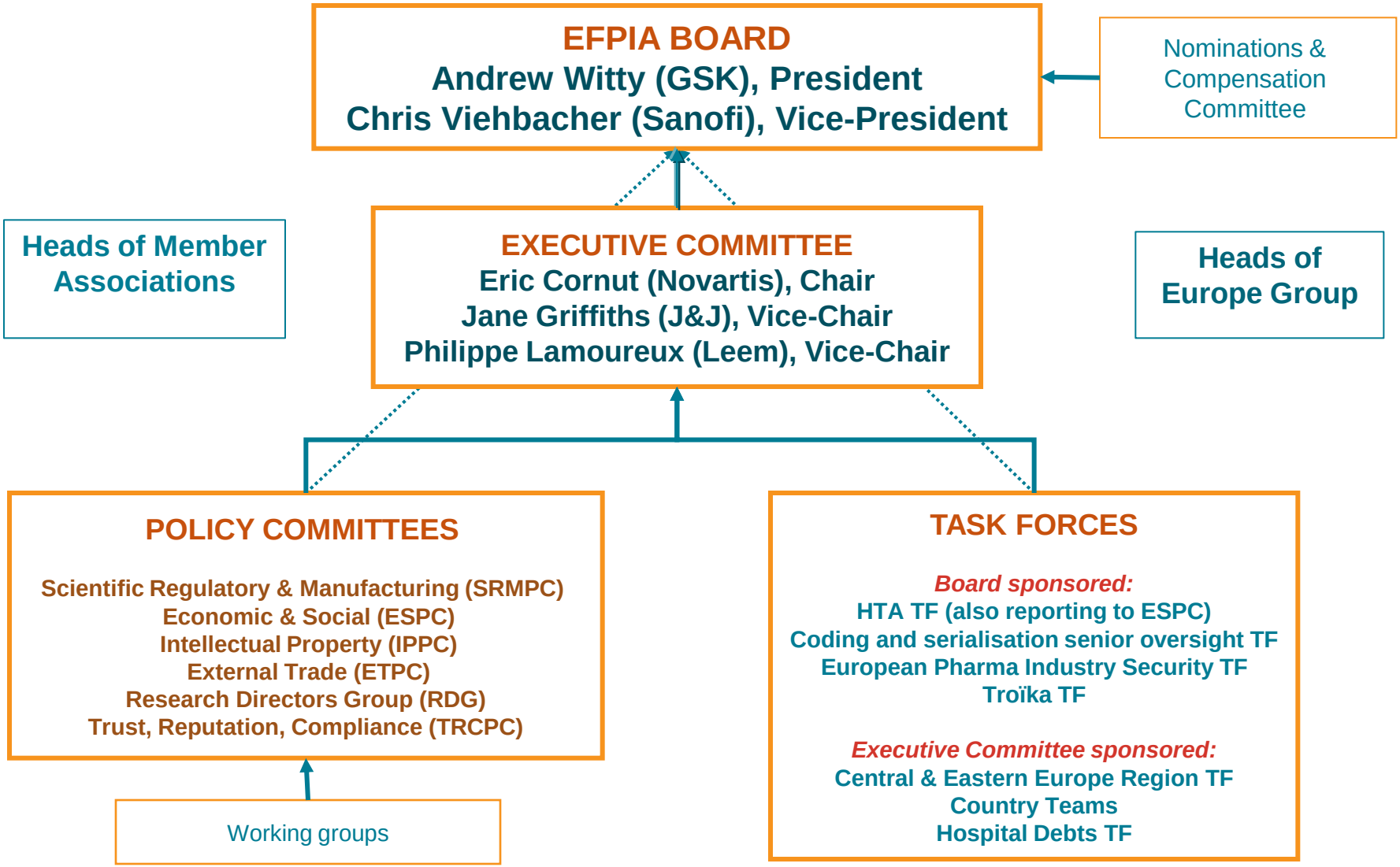
EFPIA – Mandate

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 **33 national associations and 39 leading companies**. Two specialised groups within EFPIA represent **vaccine manufacturers**, **Vaccines Europe** (with 9 member companies); and **emerging / European Bio-pharmaceutical Enterprises** (with 65 member companies).

EFPIA's Structure



General Management
Richard Bergström, Director General
Marie-Claire Pickaert, Deputy Director General
Maria Curatolo, PA to the Director General

Office Management – reporting to Deputy Director General
Sophie Derecque, Human & Financial Resources Manager
Stephane De Molling, IT & RE Manager
Pina Avola, Receptionist
Nathalie Bernardo, Receptionist (temp)
External Chartered Accountants : CEC

Market Access
François Bouvy, Director, Team Leader – ESPC lead
Edith Frénoy, Director – HTA TF lead
Serialisation Project
Andreas Walter, Project Director

Strategy
Richard Torbett, Chief Economist
Vacancy, Data Analyst
External Consultant: IMS Health

Science Policy
Magda Chlebus, Director, Team Leader – RDG Lead
Katharina Angrosch, Manager – Research Partnerships
Anna Szczepańska, Manager – Science Policy
Catherine Lecerf, Assistant Manager – Animal Welfare
Tatiana Kirpitchenok, Assistant Manager

Regulatory
Pär Tellner, Director – Regulatory Affairs & Procedures – SRMPC Lead; ICH Coordinator
Isabelle Clamou, Director
Sylvie Meillerais, Deputy Director
Claudine Backes, Assitant Manager
Sandra Rodrigues, Administrative Assistant

Trade & Intellectual Property
Maria Trallero, Director – ETPC Lead
Louis-Nicolas Fortin, Director – Director
Brendan Barnes, Director – IPPC Lead
Elise Mélon, Assitant Manager
Réka Szanto, Assistant Manager
External Consultant : Steptoe – Baker McKenzie & Andrew Farquharson

Communication & Partnerships
Brendan Barnes, Director – TRCPC lead
Nicholas Elles, Manager – Communication
Camille De Rede, Assistant Manager
Alison Kilian, Assistant Manager
Mélanie Yaminne, Manager – Global Health Initiative
Amélia Kossi, Assistant Manager – Website

Fabienne Muylle, Administrative Assistant

Government Affairs
Gabriella Almberg, Director
Angela Piedra Hernandez, Manager (Maternity Leave)
Raquel Silva Resendes, Manager *(replacement during Maternity Leave)*
Mary Munroe, Assistant Manager

Country Support and Compliance
Marie-Claire Pickaert, Deputy Director General, Team Leader
François Lamérant, Manager Country Support
Vacancy, Compliance Manager

European Vaccines Manufacturers (EVM)
Magdalena Rodriguez de Azero, Executive Director
Angela Bolufer De Gea, Manager
Karam Adel Ali, Assitant Manager
Anne Meynaerts, Administrative Assistant

European Biopharmaceutical Enterprises (EBE)
Titta Rosvall-Puplett, Executive Director
Piers Allin, Director Regulatory Affairs
Audrey Wolf-Claeys, Manager
Rita Detand, Administrative Assistant

Programme

- About EFPIA
- About the Pharmaceutical Industry
  KEY DATA – 2012 update
- About the Pharmaceutical Industry Pharmaceutical Market & Economics
  - The Protection of Pharmaceutical Innovation
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Key Data

The Pharmaceutical industry in Figures, EFPIA (2012)

Values in € million, unless otherwise stated	1990	2000	2010	2011 (e)
Production	63,010	123,793	200,050	205,000
Exports	23,180	90,935	276,357	290,000
Imports	16,113	68,841	204,824	210,000
Trade balance	7,067	22,094	71,533	80,000
R&D Expenditure	7,766	17,849	27,796	27,500
Employment (units)	500,879	536,733	663,503	660,000
of which, in R&D	76,126	88,397	117,191	116,000
Market value (ex-factory)	41,147	86,704 *x 2.1*	153,373 *x 1.8*	157,300
Market value (at retail prices)	64,626	140,684 *x 2.2*	222,453 *x 1.6*	228,100
Pharma spend by statutory HC systems	40,807	76,909 *x 1.9*	120,650 *x 1.6*	122,000

Geographical breakdown of sales

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%

Source: IMS Health

Pharma growth has slowed down

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%

Source: IMS Market Prognosis, October 2011 Note includes EU and non-EU countries.

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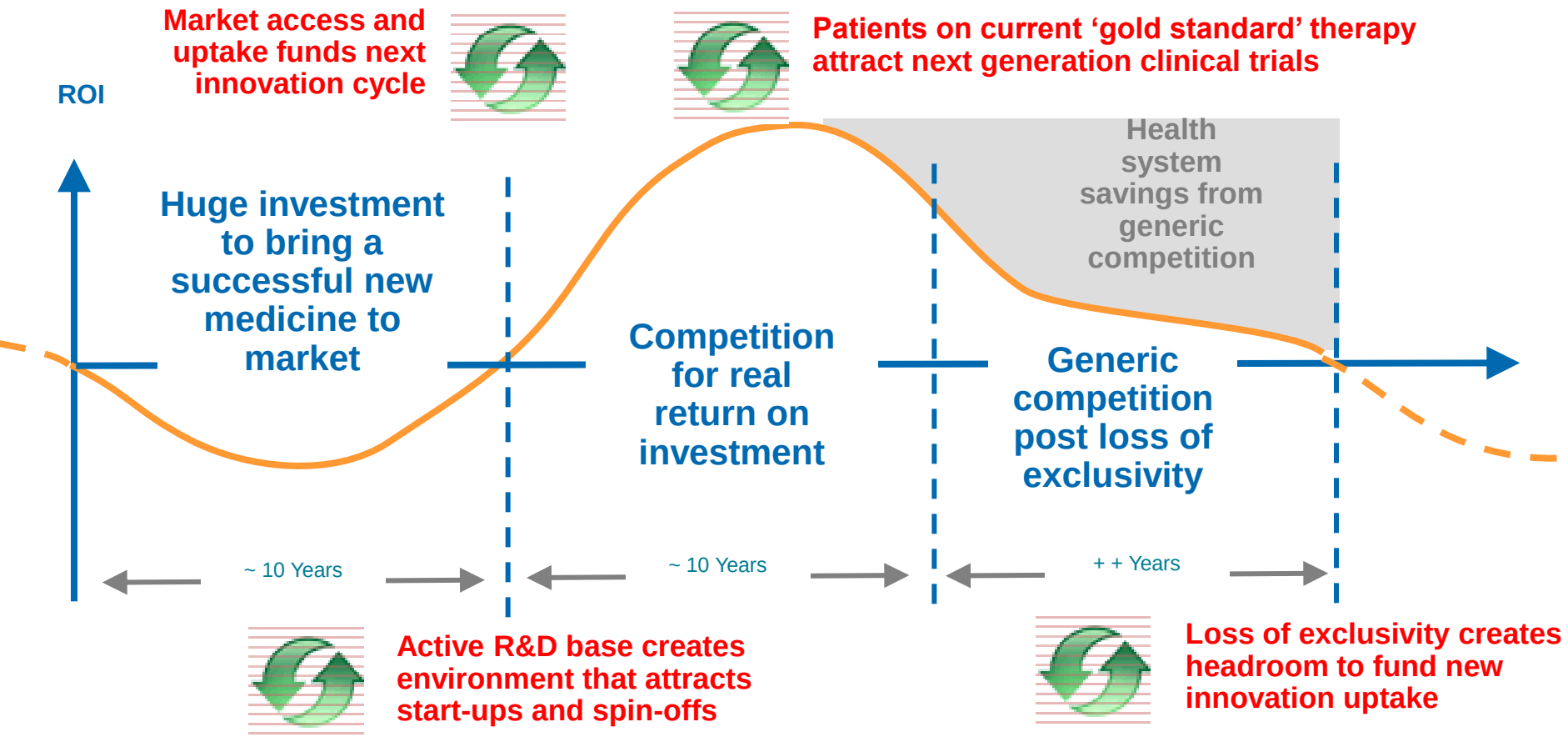
Medicines lifecycle

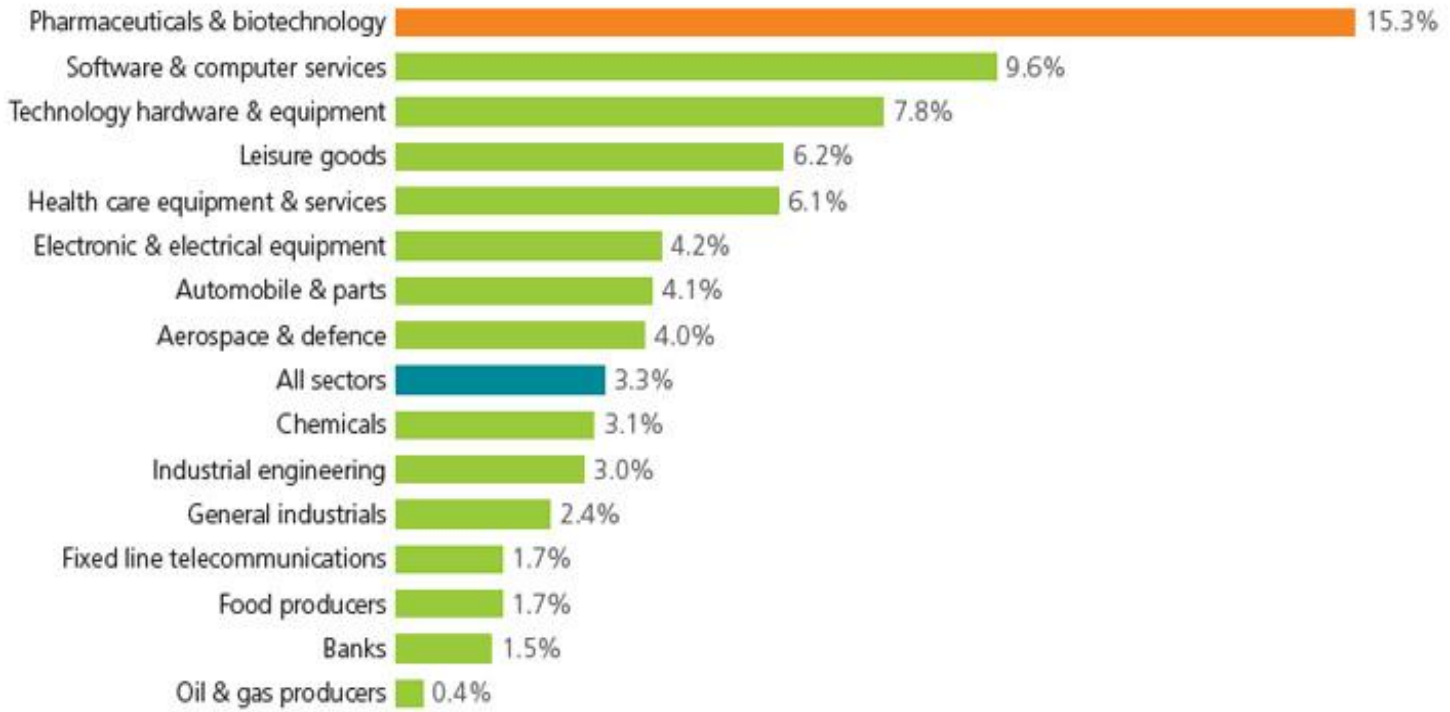


A (European) framework for financially sustainable healthcare innovation

R & D in Pharma Industry

- Innovation is the engine driving economic growth
- Uncertainty is in the nature of most new medicines
- The traditional pharmaceutical business model is not sustainable: ever escalating R&D costs, declining R&D productivity, increasing regulatory and market access hurdles

The EU Industrial Innovation Scoreboard ranked the pharmaceutical industry as the sector with the highest ratio of R&D investment to net sales on a global scale in 2010



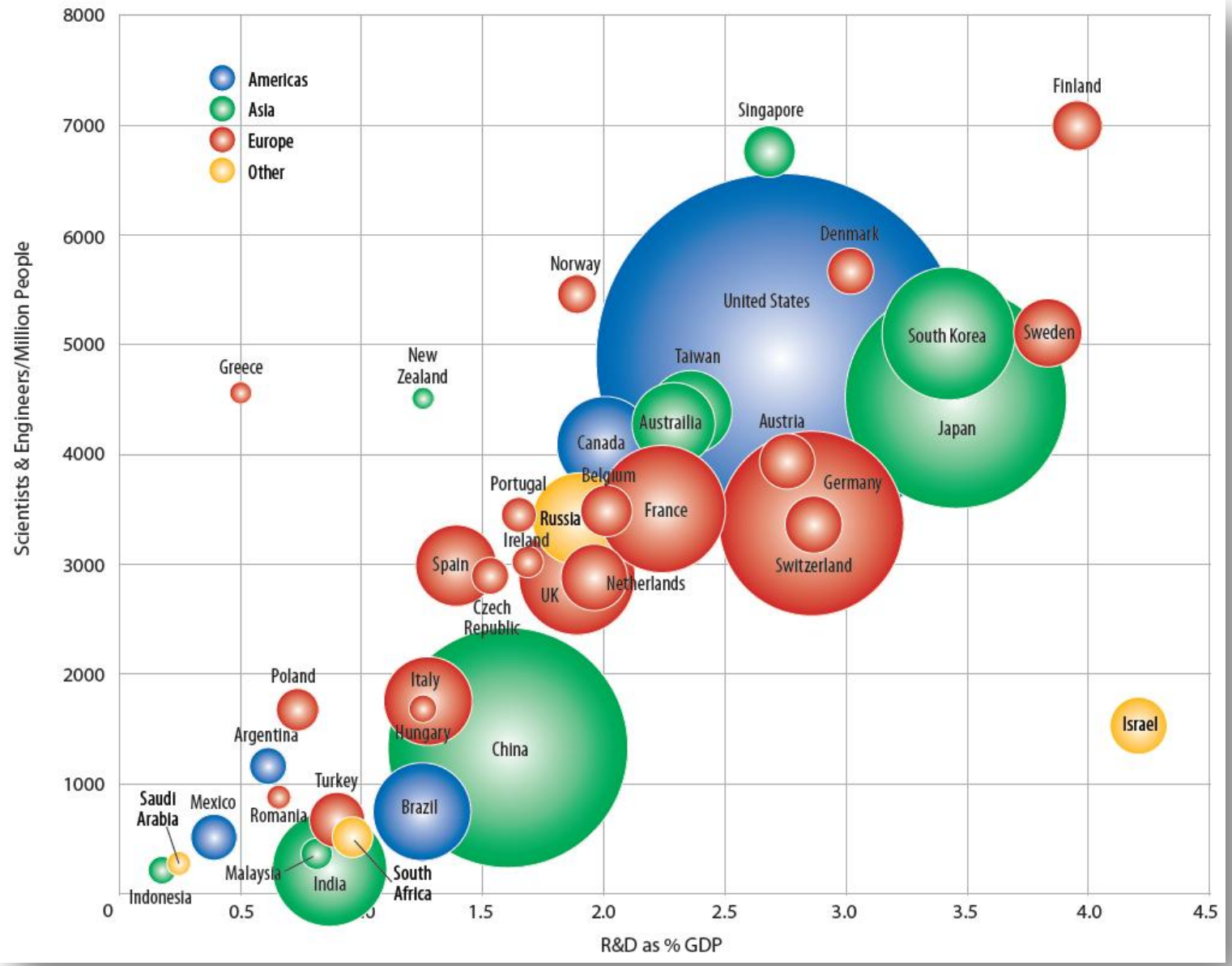
Source: The 2011 EU Industrial R&D Investment Scoreboard, Joint Research Centre, Directorate General Research & Innovation, European Commission.

Yearly R&D expenditure

2011

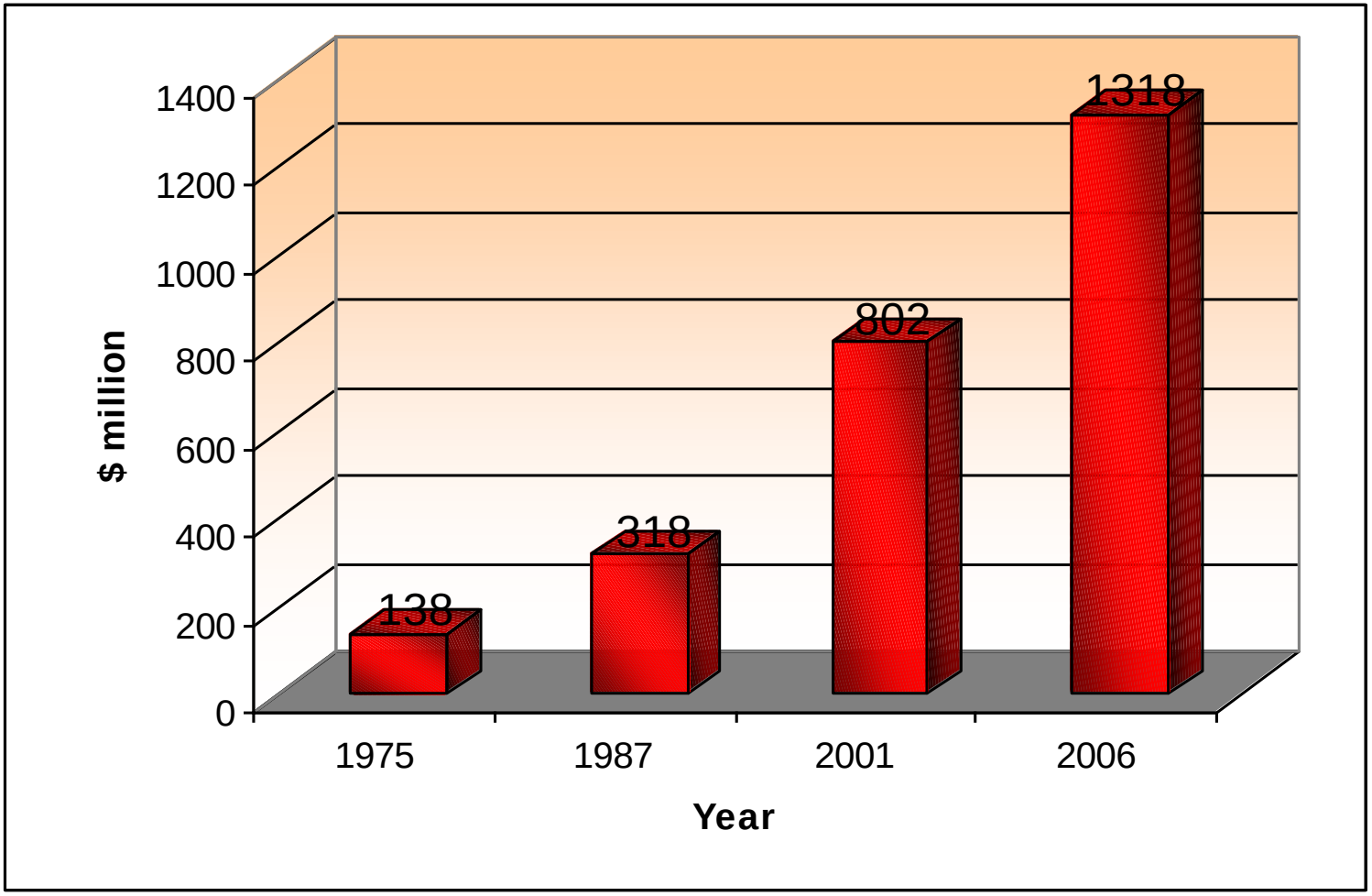
The size of circle reflects the relative amount of annual R&D spending by the country noted.

Source: Battelle, R&D Magazine, International Monetary Fund, World Bank, CIA World Factbook, OECD (2012 Global R&D funding forecast, December 2011)



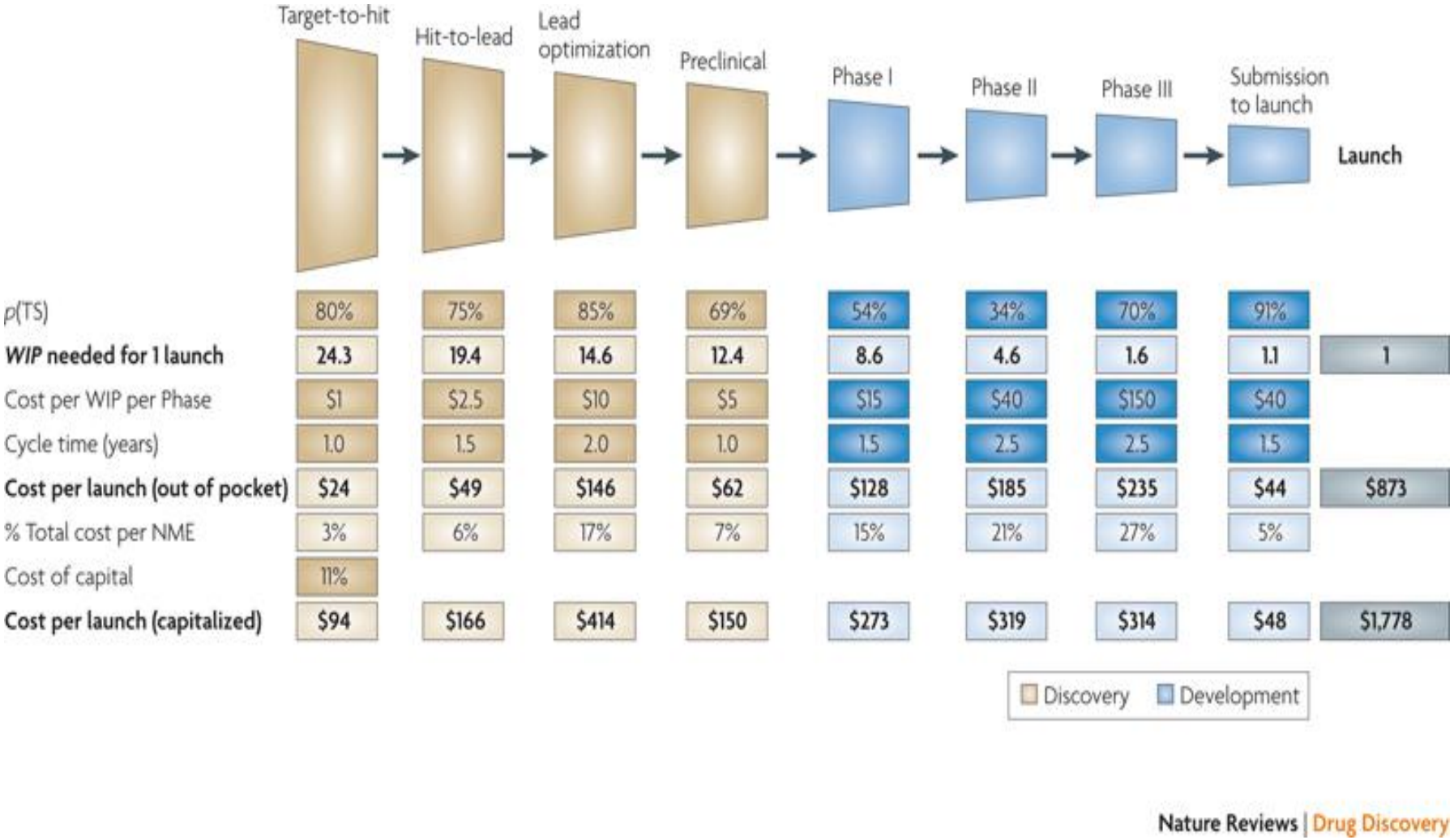
Estimated full cost of bringing a new chemical / biological entity to market

($ million – year 2005 $)



Source: J.A. Di Masi and H.G. Grabowski, 'The Cost of Biopharmaceutical R&D: Is biotech Different? Managerial and Decision Economics 28 (2007): 469-479

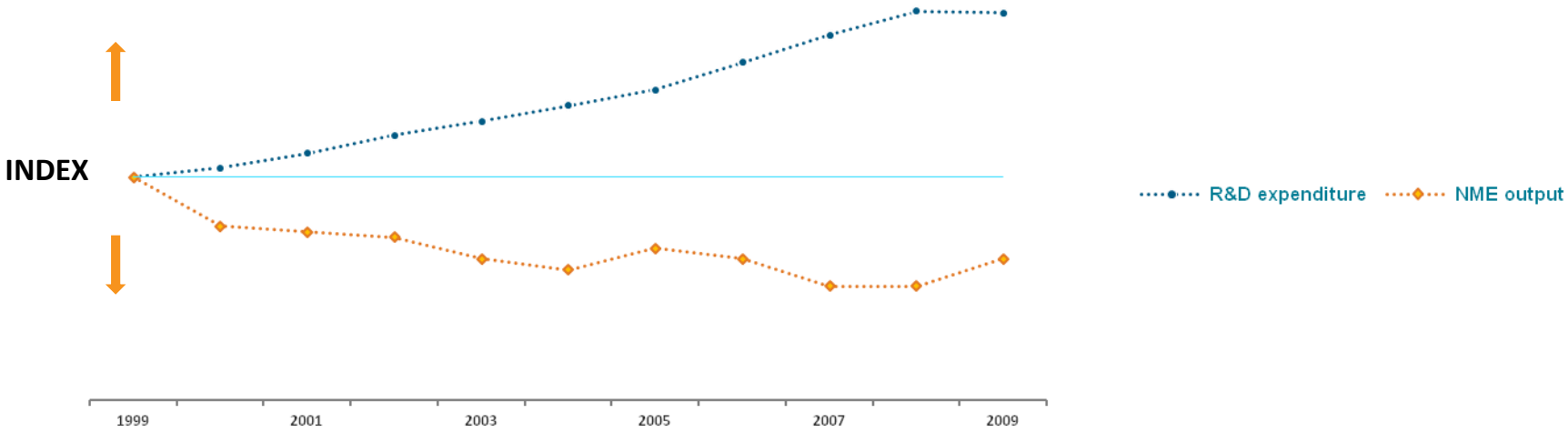
R&D Model Yielding Costs



Nature Reviews | Drug Discovery

Falling NMEs, rising costs

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

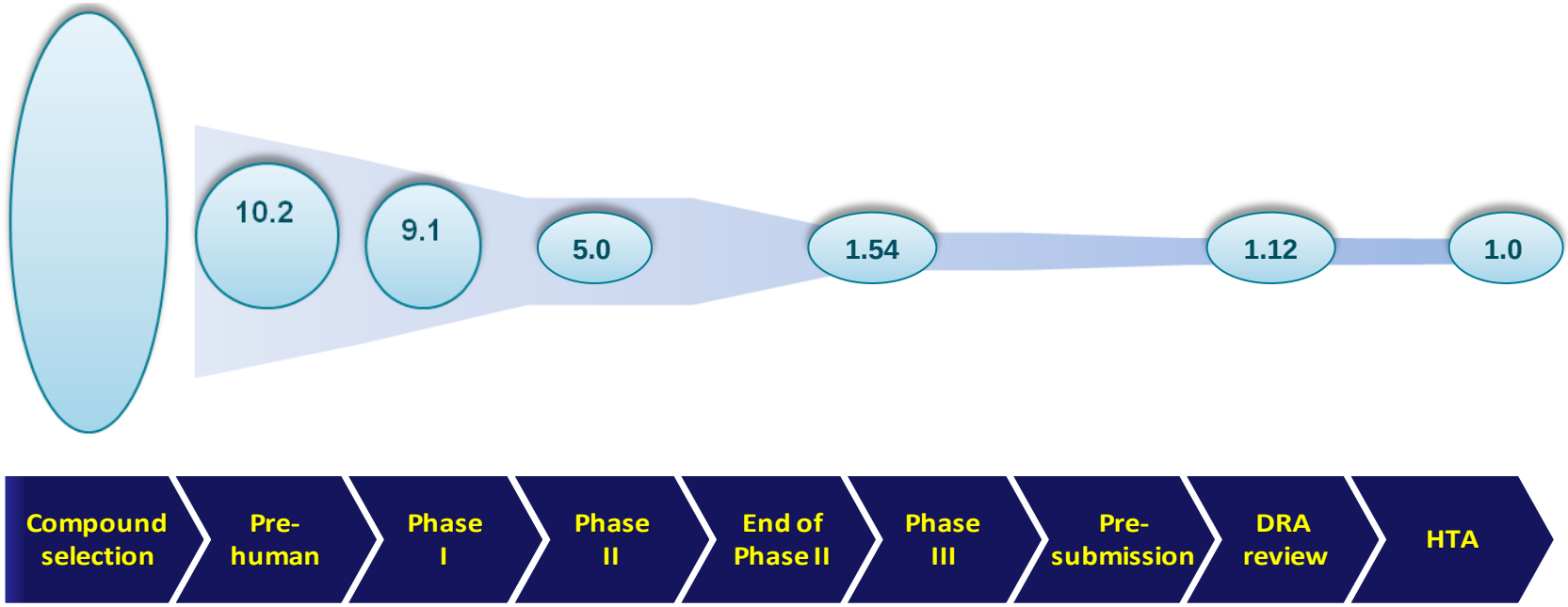


Source: Modified from - 2010 CMR International Pharmaceutical R&D Factbook.

Productivity of R&D Investment

Late stage failure

Throughout development and up to market access

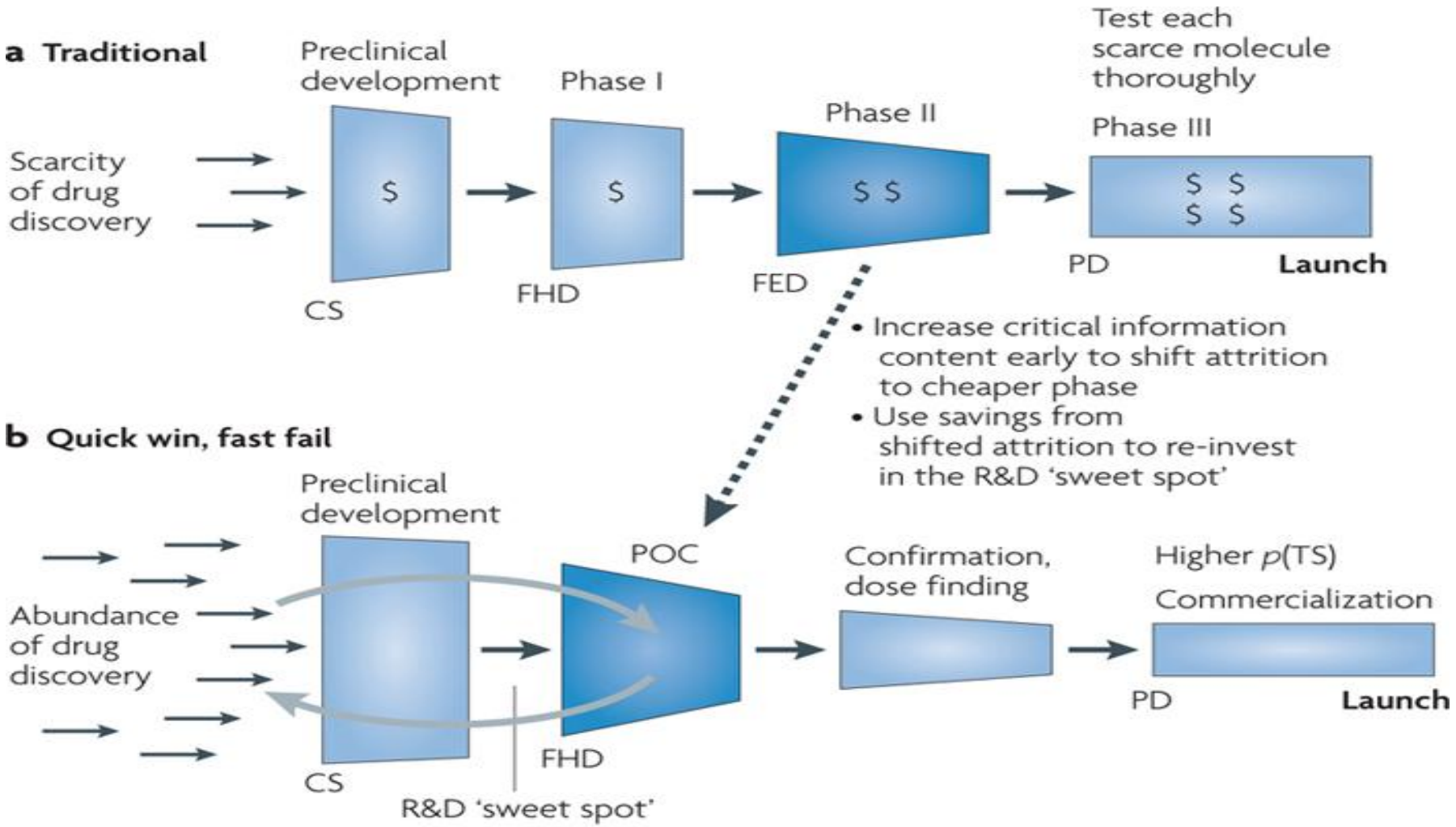


Source: Modified from - 2010 CMR International Pharmaceutical R&D Factbook

Centrally approved medicines

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	

Drug Development Paradigm



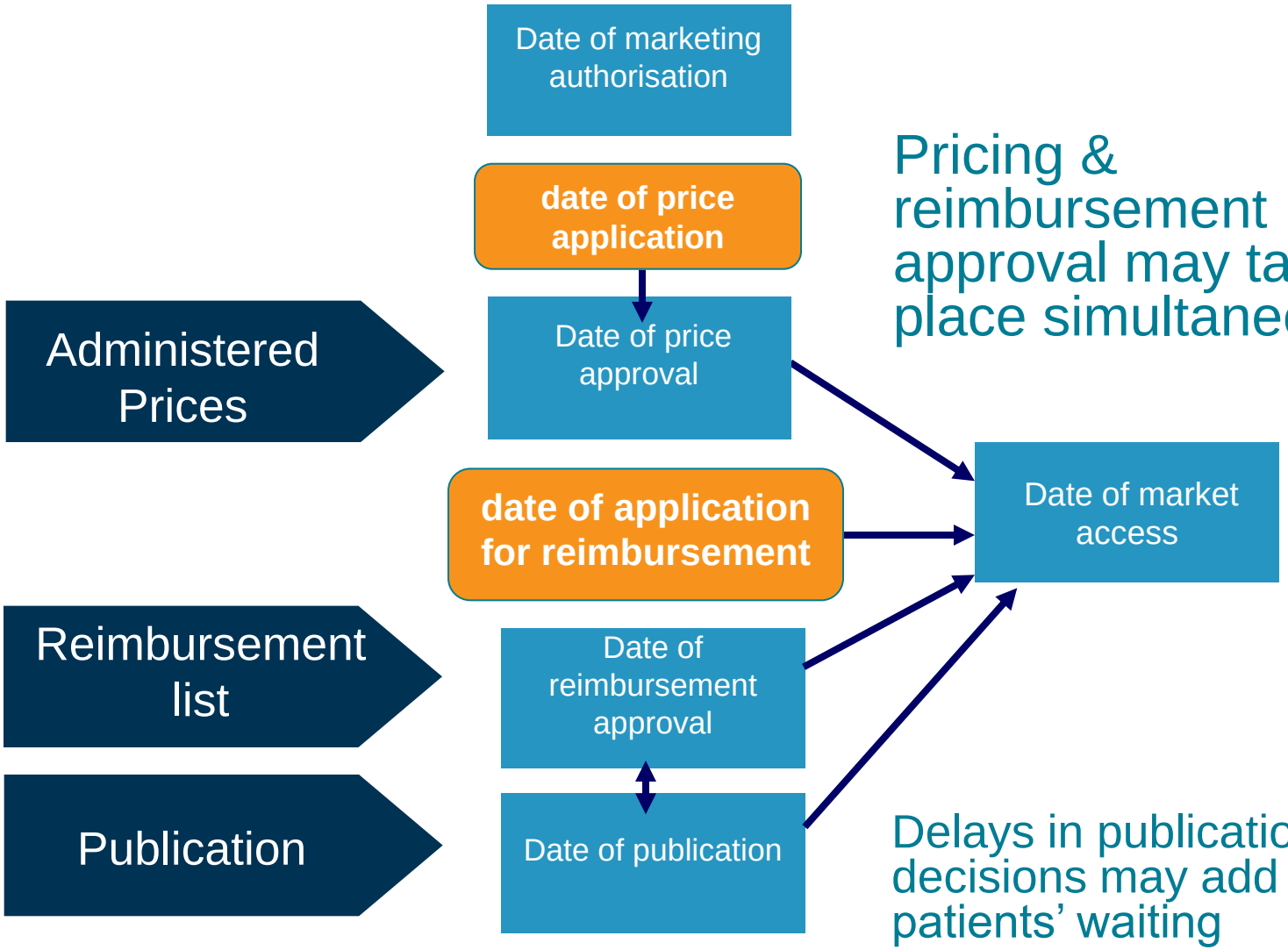
Nature Reviews | Drug Discovery

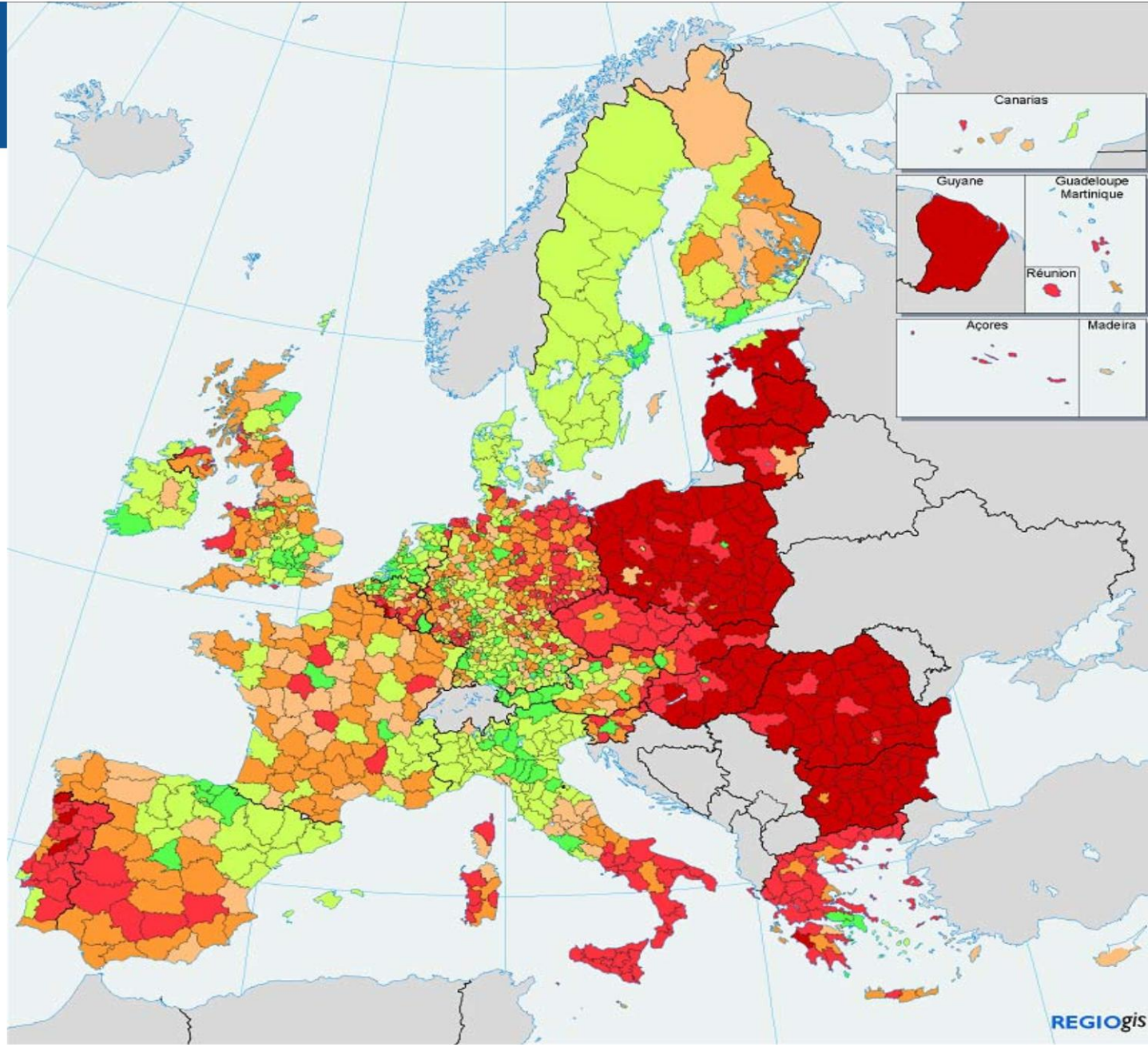
Marketing Authorisation Process

new approvals (medicines including new active substance)

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

Pricing & Reimbursement



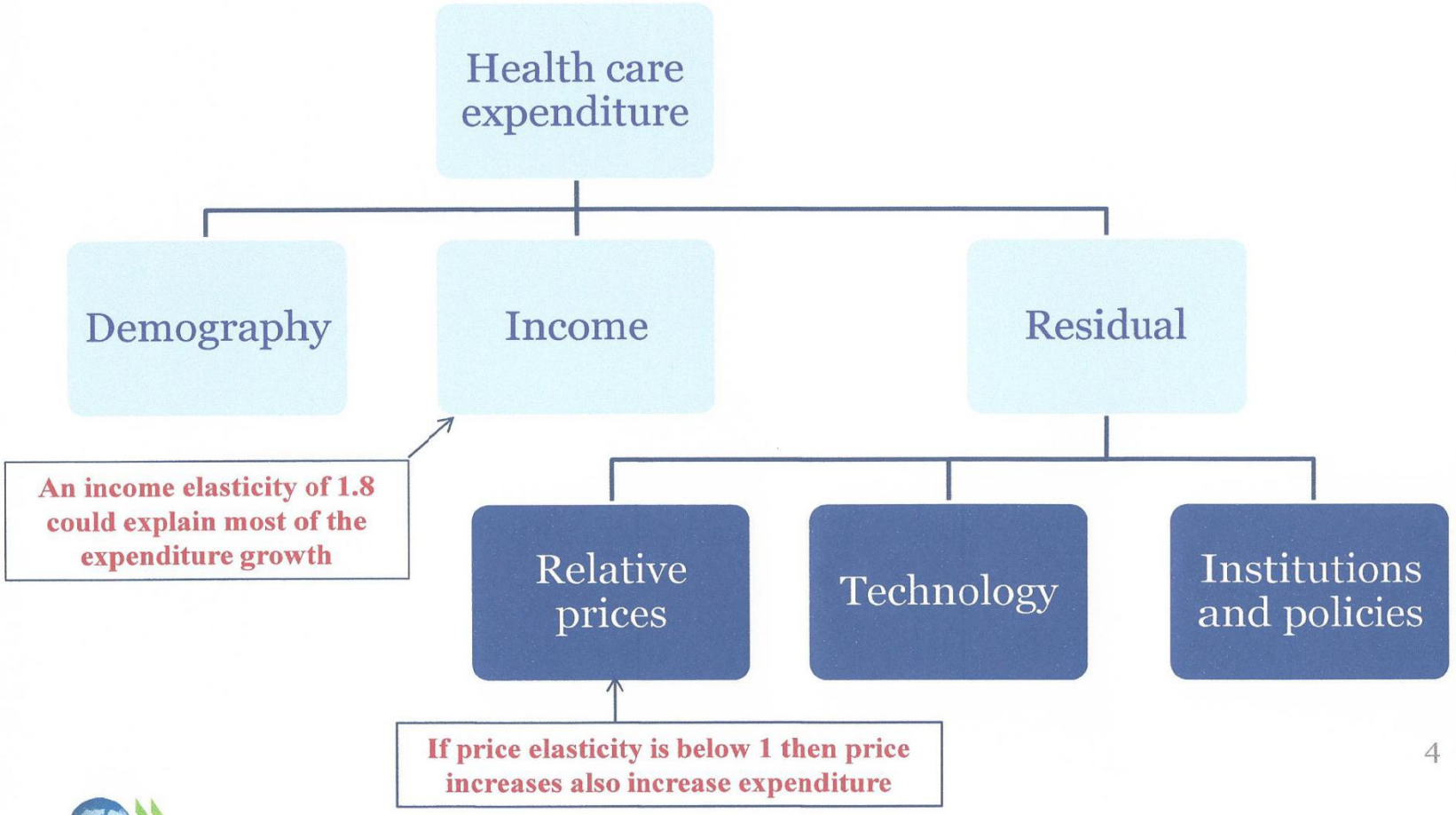

Canarias
Guyane
Guadeloupe
Martinique
Réunion
Açores
Madeira
GDP/head (PPS) of NUTS3 regions, 2007
Index, EU-27 = 100
< 50
50 - 75
75 - 90
90 - 100
100 - 125
>= 125
REGIOgis

Steady growth of public Health + LTC spending

Public Health and LTC expenditure as a % of GDP, OECD countries

Source: OECD Health database (2011).

WHAT DRIVES HEALTH EXPENDITURES?



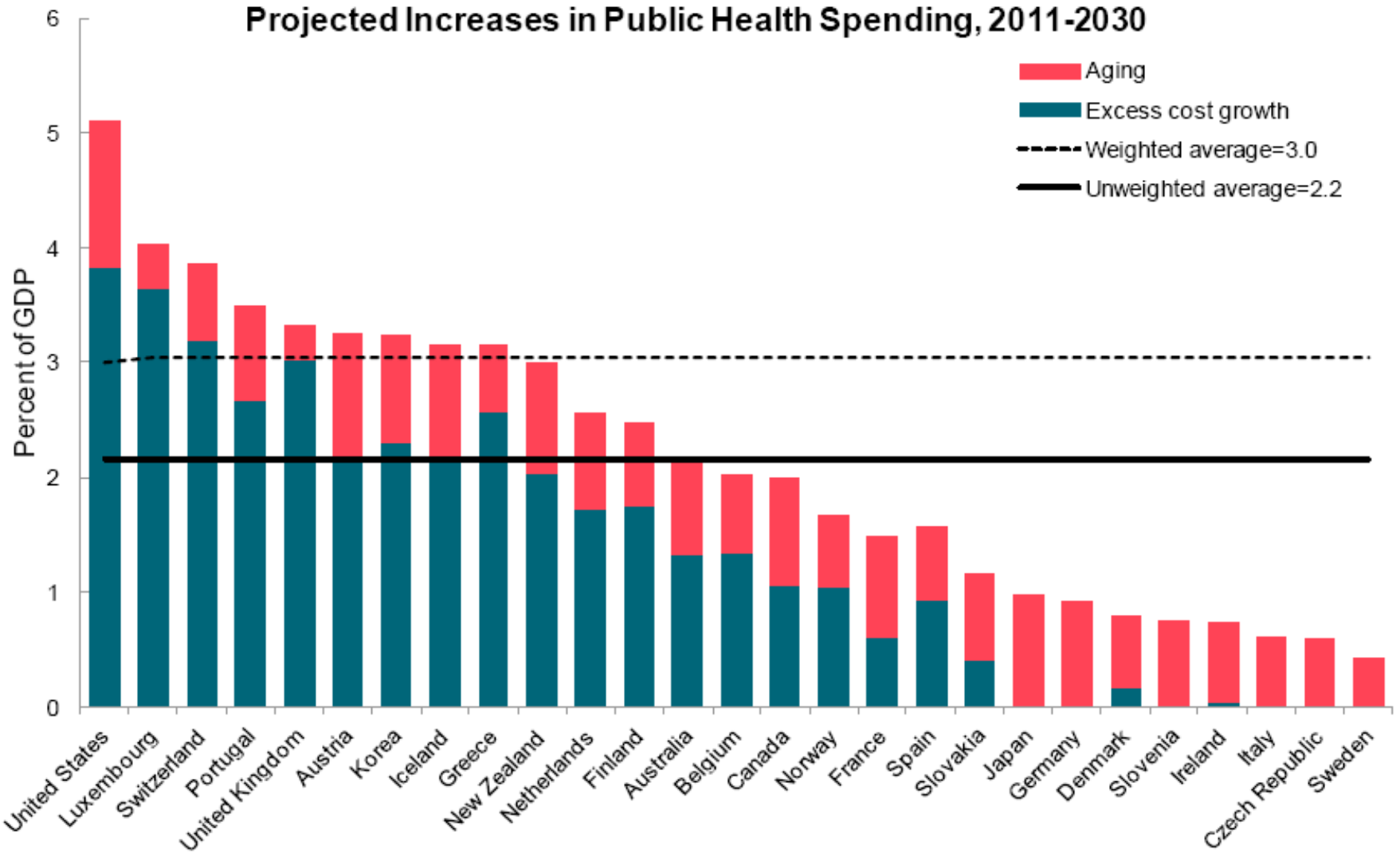
OECD

3) Residual: Estimation of the expenditure residual (1995-2009) assuming an income elasticity of 0.8

Average annual growth rate (in %)

	Health spending	Age effect	Income effect	Residual	*Memo item:* Residual with unitary income elasticity
Selected countries:					
Australia	4.1	0.4	1.7	1.8	1.4
Canada	2.6	0.6	1.3	0.8	0.5
France	1.6	0.5	0.9	0.3	0.0
Germany	1.7	0.6	0.8	0.2	0.0
Italy	3.1	0.6	0.4	2.1	2.0
Japan	2.7	1.2	0.4	0.7	0.5
Korea	11.0	1.1	3.1	6.5	5.7
Portugal	4.6	0.6	1.2	2.4	2.0
Sweden	3.2	0.2	1.6	1.4	1.0
United States	3.6	0.3	1.1	2.3	2.0
Brazil	4.8	0.6	1.2	2.9	2.6
China	11.2	0.6	7.3	3.0	1.3
India	6.6	0.3	4.2	2.0	1.0
OECD total average	4.3	0.5	1.7	2.0	1.5
BRIICS average	6.2	0.5	3.2	2.5	1.7
Total average	4.6	0.5	2.0	2.0	1.5

Demographic pressures on budgets

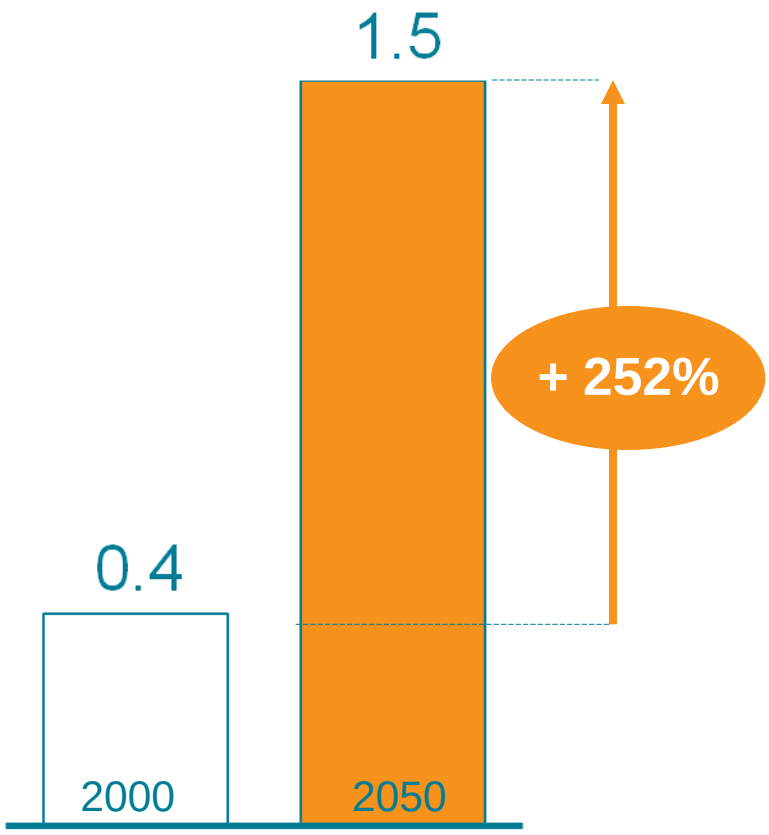


Source: Global Trends in Public Health Spending and the Outlook , International Monetary Fund (IMF), 2011.

Healthcare demand

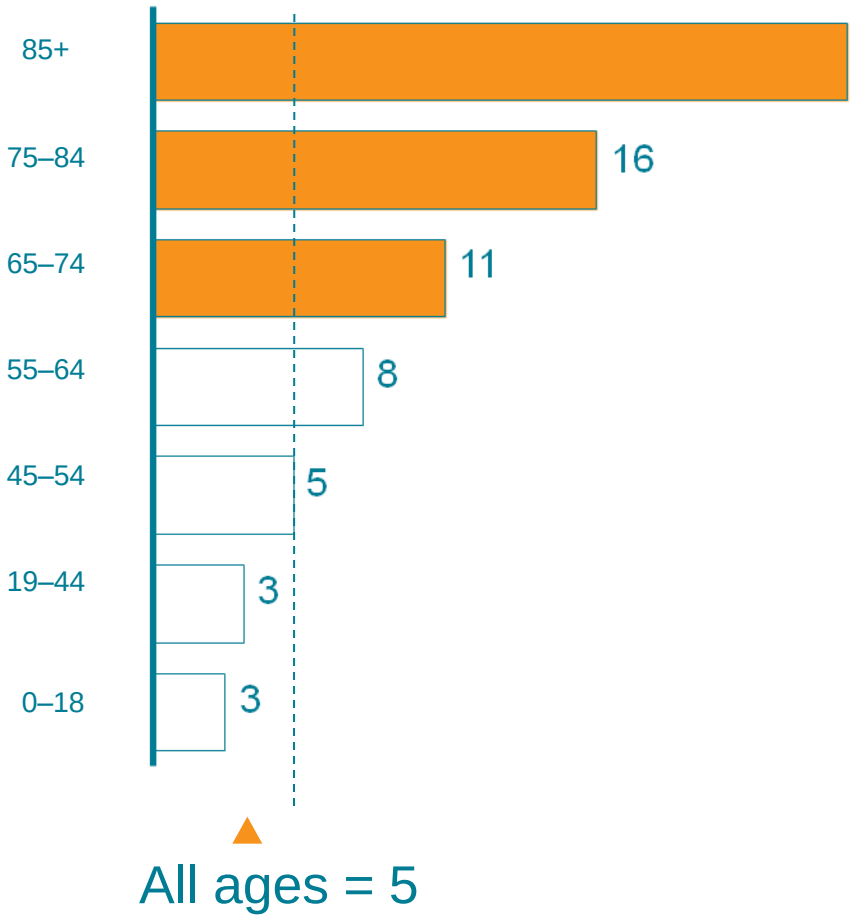
AGEING POPULATION…

Billion people over 65



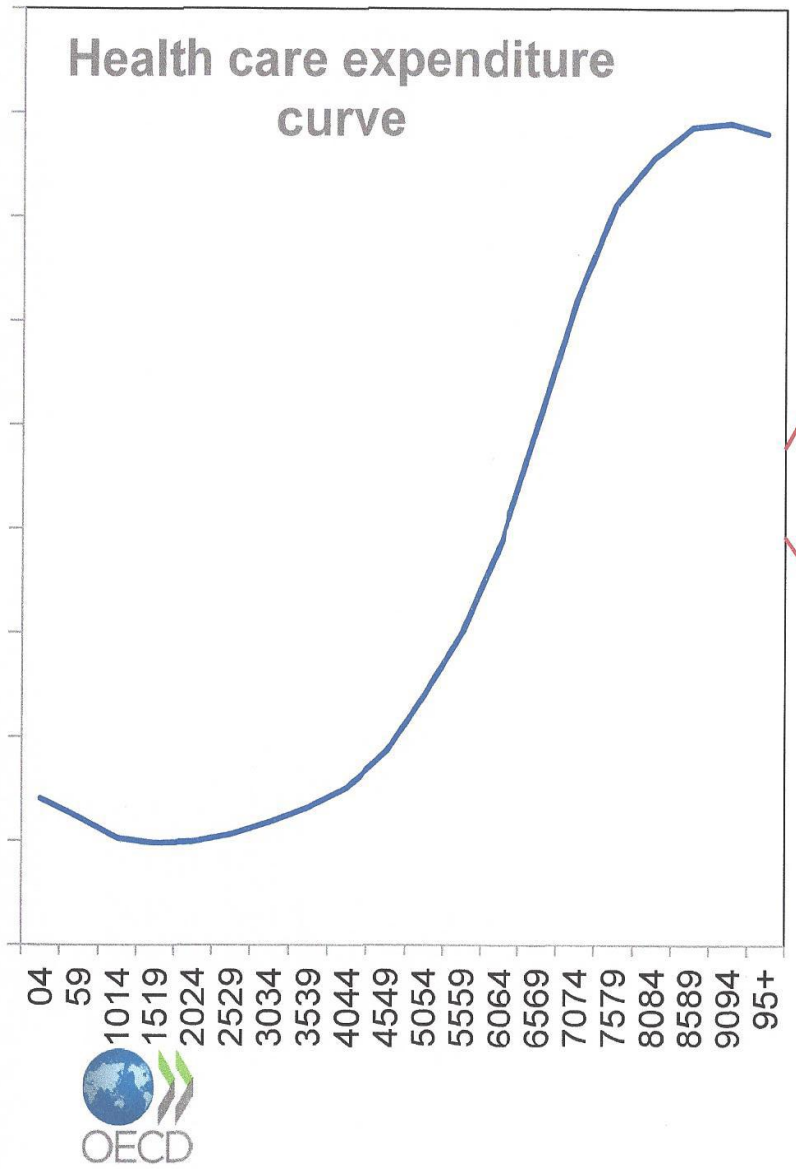
annual healthcare spend per capita

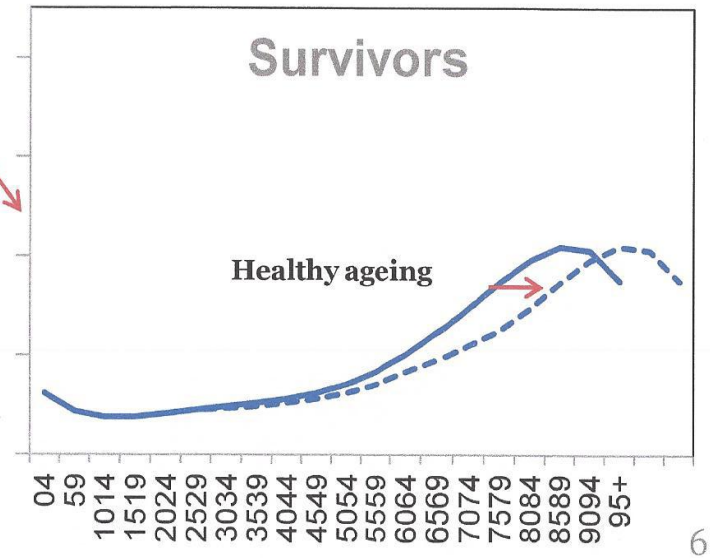
US – 2004 (000 USD)



Source: UN population database, US Centers for Medicare and Medical Services.

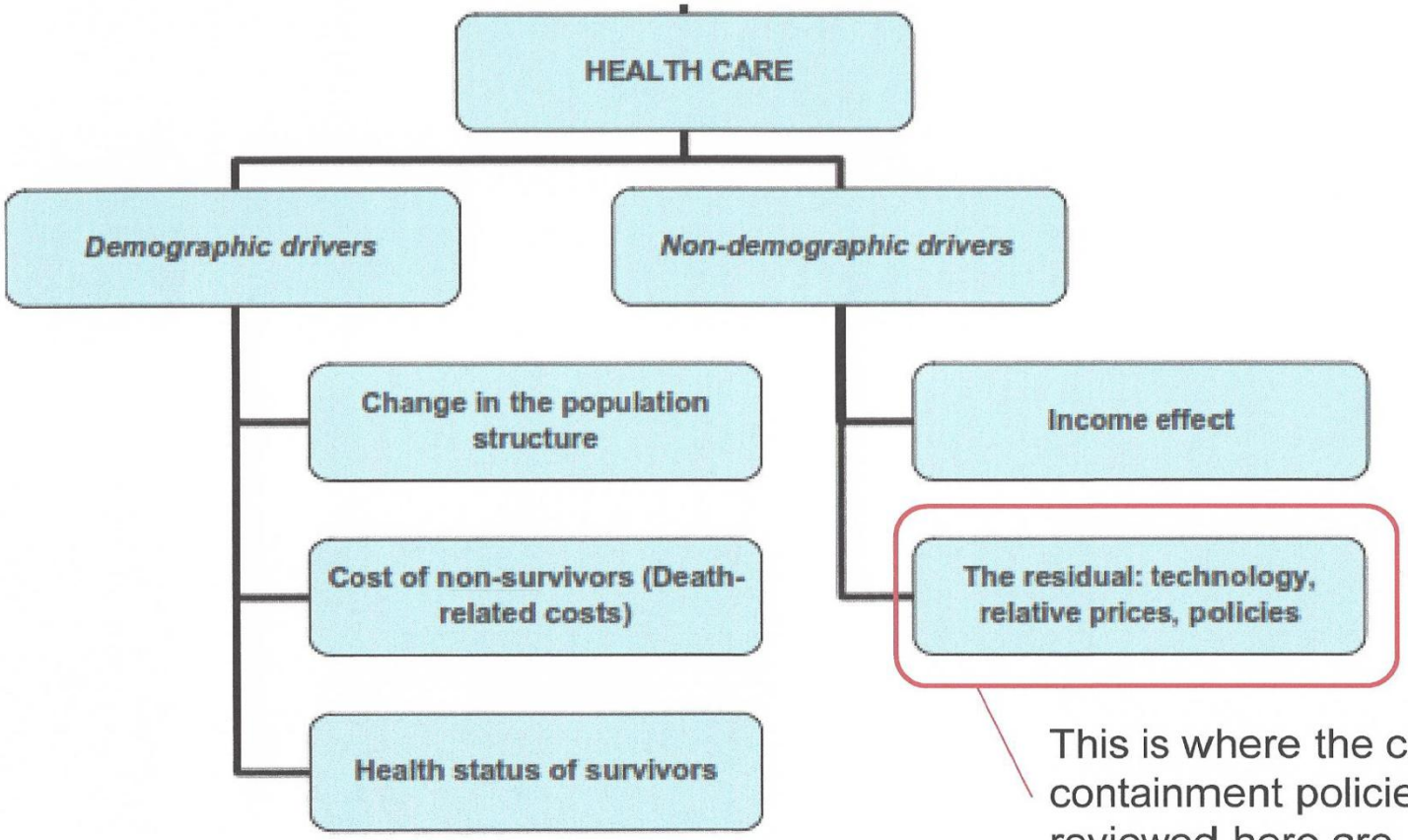
Why health care expenditure curves display such a profile?





OECD

Background: expenditure drivers



Source: Oliveira Martins et al. (2006)

A stylised economic framework

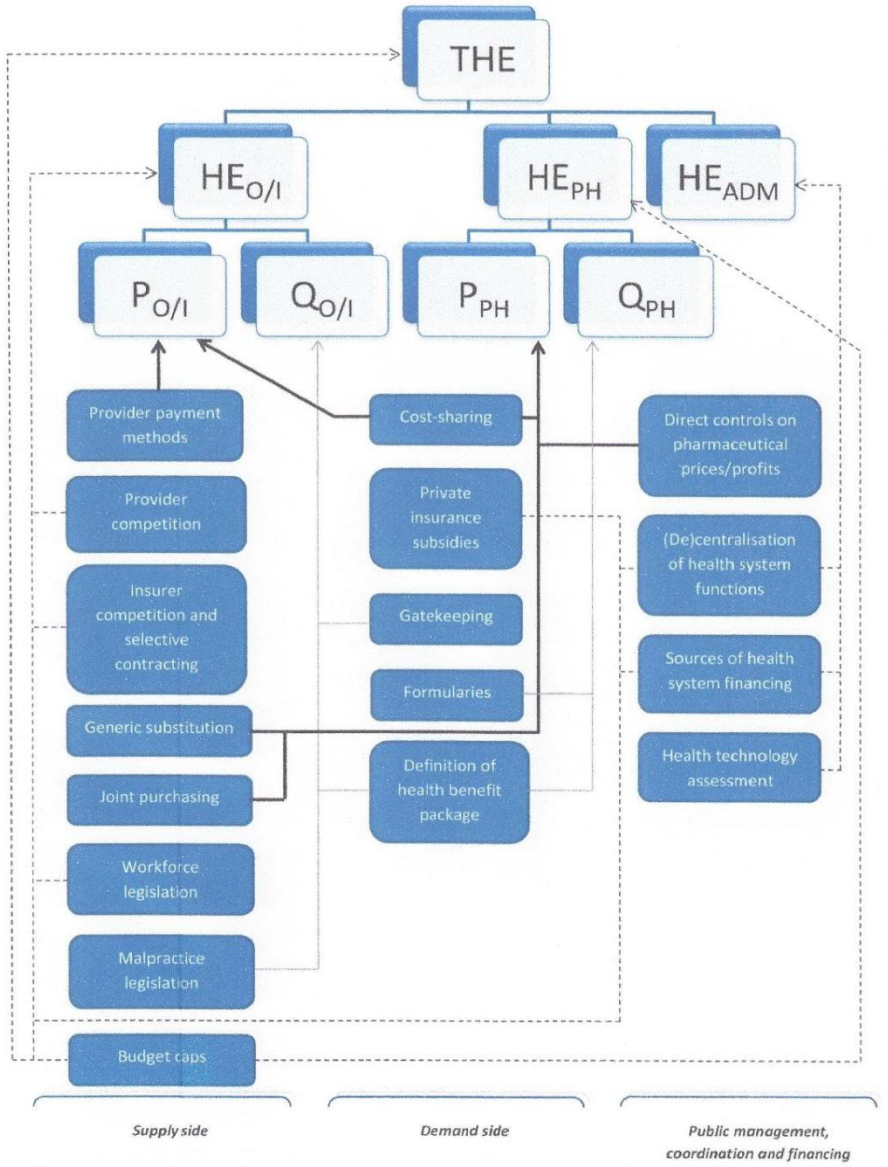
THE: total health expenditure

Health expenditure (HE) components:

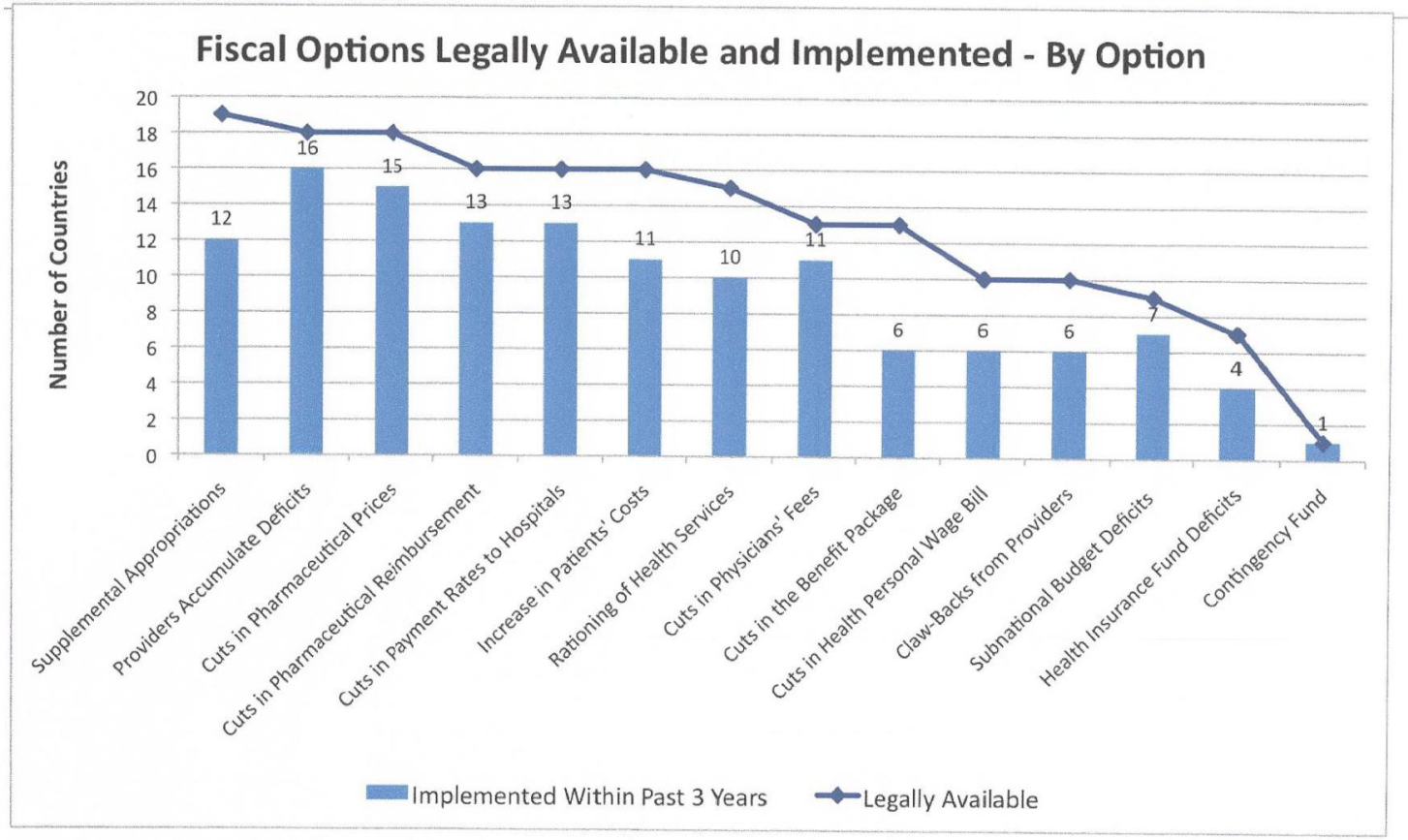
- O/I: outpatient & inpatient care
- PH: pharmaceutical sector
- ADM: public administration

Policies may influence HE primarily via:

- Service prices (P): black lines
- Service quantities (Q): light grey lines
- P & Q (indirectly): dotted lines



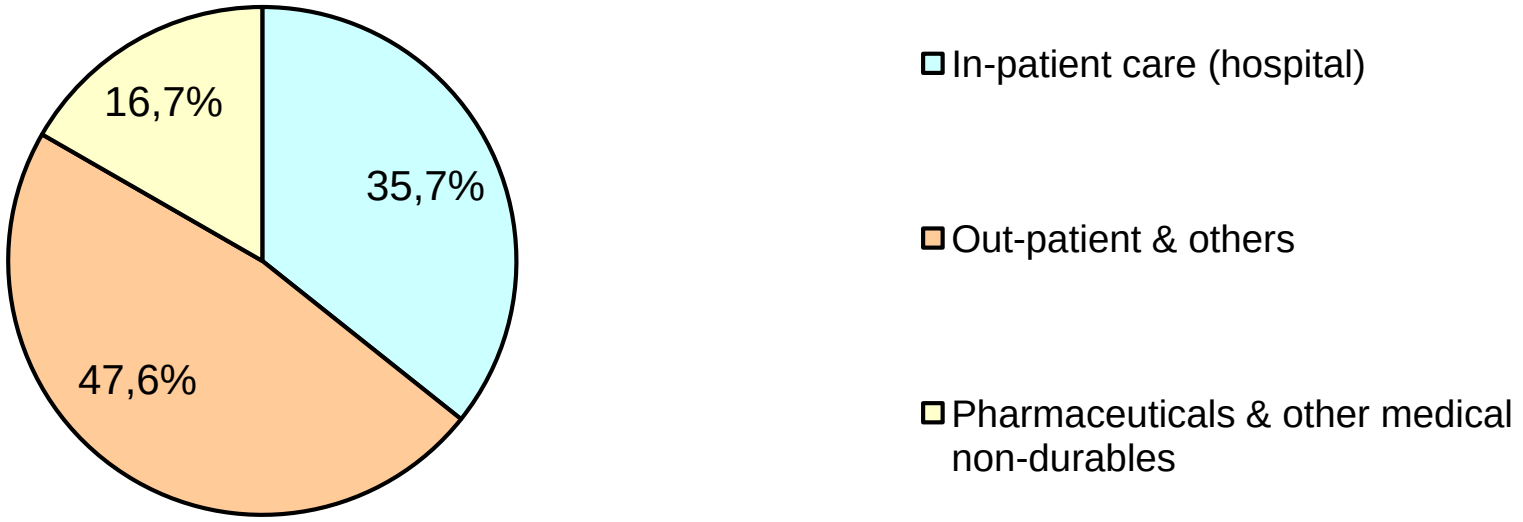
7.1. Budget tools available if health spending exceeds targets – by option



Source: OECD Health Committee Survey on Health Systems Characteristics 2012

Health Expenditure Breakdown

Europe – 2009



Source: OECD Health Data 2011 - EFPIA calculations (non-weighted average for 24 EU & EFTA countries)

Transparency Directive

89/105/EEC

- **The Directive clarifies procedural obligations incumbent upon Member States, without affecting national social security policies, except as far as it is necessary to achieve the transparency of national procedures and the effectiveness of the internal market legislation.**

  - Removing distortions to intra-Community trade – reducing the effects of disparities in national measures
  - Ensuring that national measures comply with minimum procedural requirements enabling the parties concerned to verify that these measures do not constitute quantitative restrictions to imports or exports or measures having equivalent effect

Transparency Directive – Underlying Principles

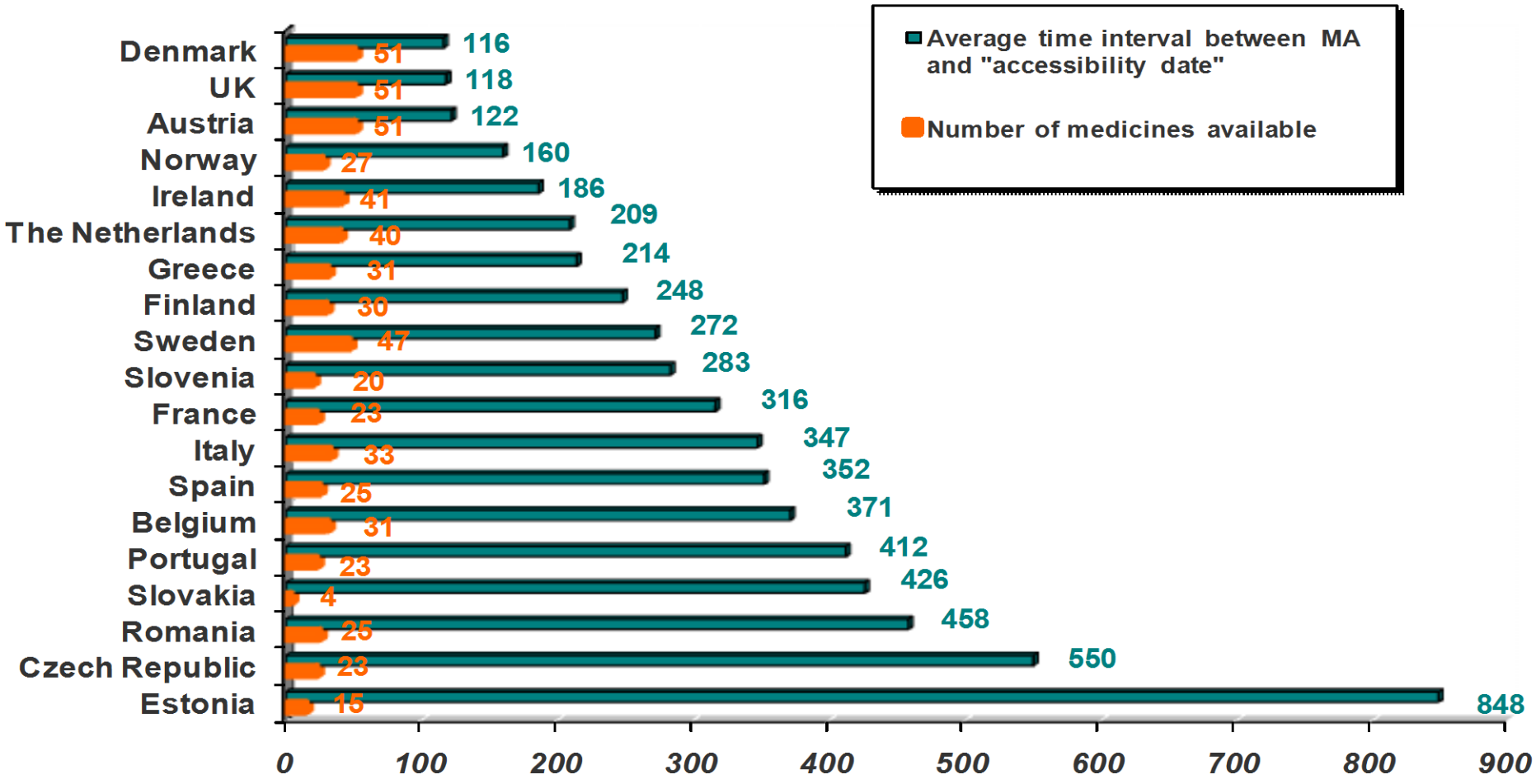
- **Minimum interference in the organisation by Member States of their domestic social security policies**
  - Not approximation of national pricing and reimbursement measures
  - No restrain on the ability of Member States to freely determine the prices of medicines and the conditions of their public funding on the basis of criteria they chose
  - Subsidiarity and proportionality principles applying – the Directive does not go beyond what is necessary to ensure the functioning of the internal market, which cannot be sufficiently achieved by Member States acting individually and can, therefore, be better achieved by the EU.

Transparency Directive – Key elements

- **Transparency** in pricing and reimbursement **procedures**:
  - Objective and verifiable criteria: predictability of rules
  - Time-limits: obligation to make pricing and reimbursement decisions within 90/180 days
  - Motivation of decisions: obligation to provide reasoned decisions to the applicant based on objective and verifiable criteria
  - Judicial appeal: obligation to provide effective legal remedies for applicants

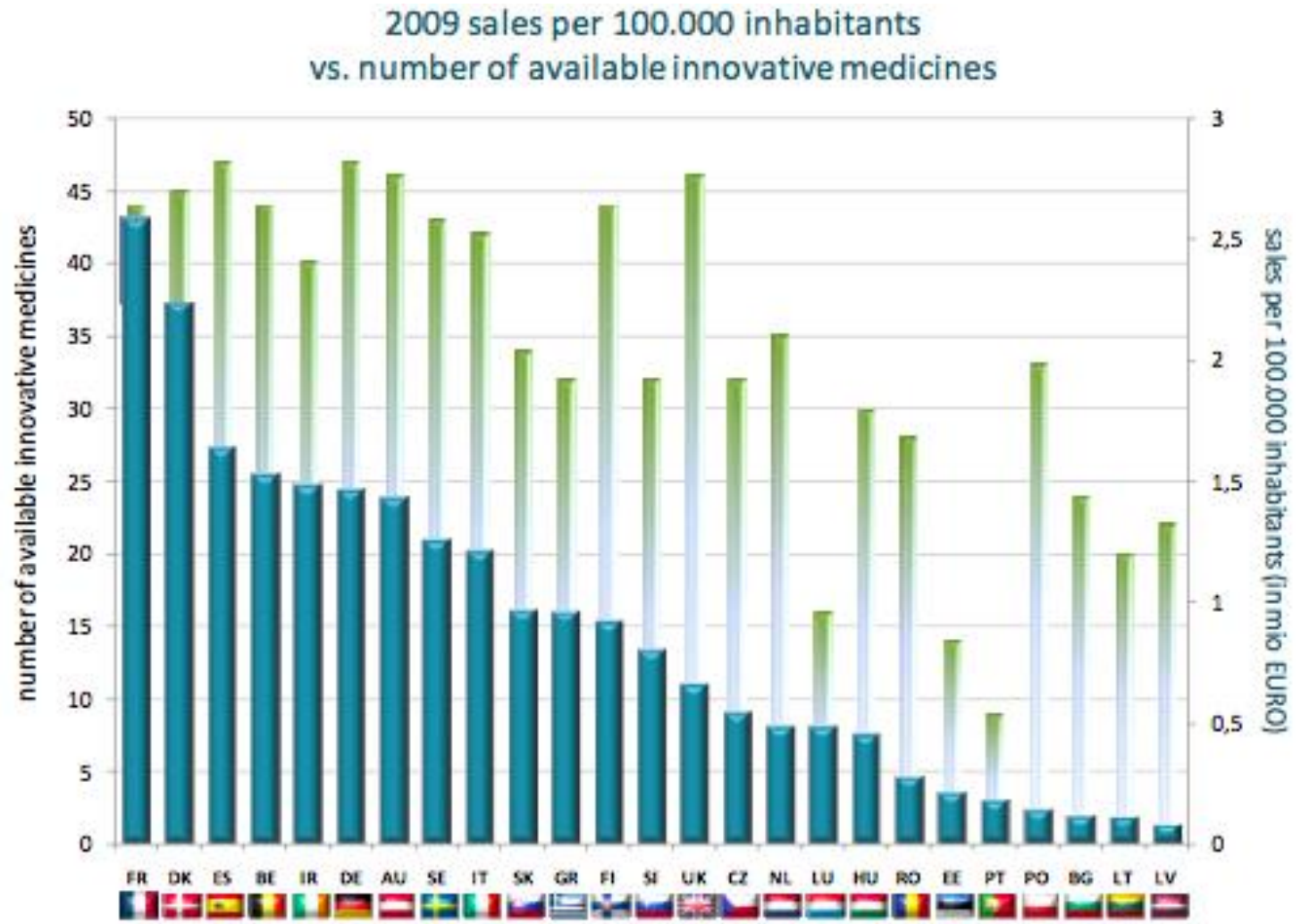
Patients W.A.I.T. Indicator 2010

Total number of medicines within scope: 66



Availability of / Access to Innovation

In September 2010, the Belgian Presidency of the EU published an analysis of 47 innovative medicines marketed in EU Member States from 2005 - 2009. The findings showed no consistent correlation between availability (green columns) and uptake of innovative medicines (blue columns) from market to market. GDP appeared to be a more significant factor. For example, the amount per capita spent on innovative medicines during this period was more than ten times higher in France and Denmark than in Portugal, Poland, Bulgaria, Lithuania and Latvia.



IMS Health, 2010

Source: Innovation and Solidarity in Pharmaceuticals, EU Belgian Presidency Ministerial Conference, 09/2010

Austerity


Προς Άγιο Αντώνιο/Άγιο Δημήτριο
To Aghios Antonios/Aghios Dimitrios
Προς Αιγάλεω / Αεροδρόμιο
To Egaleo / Airport

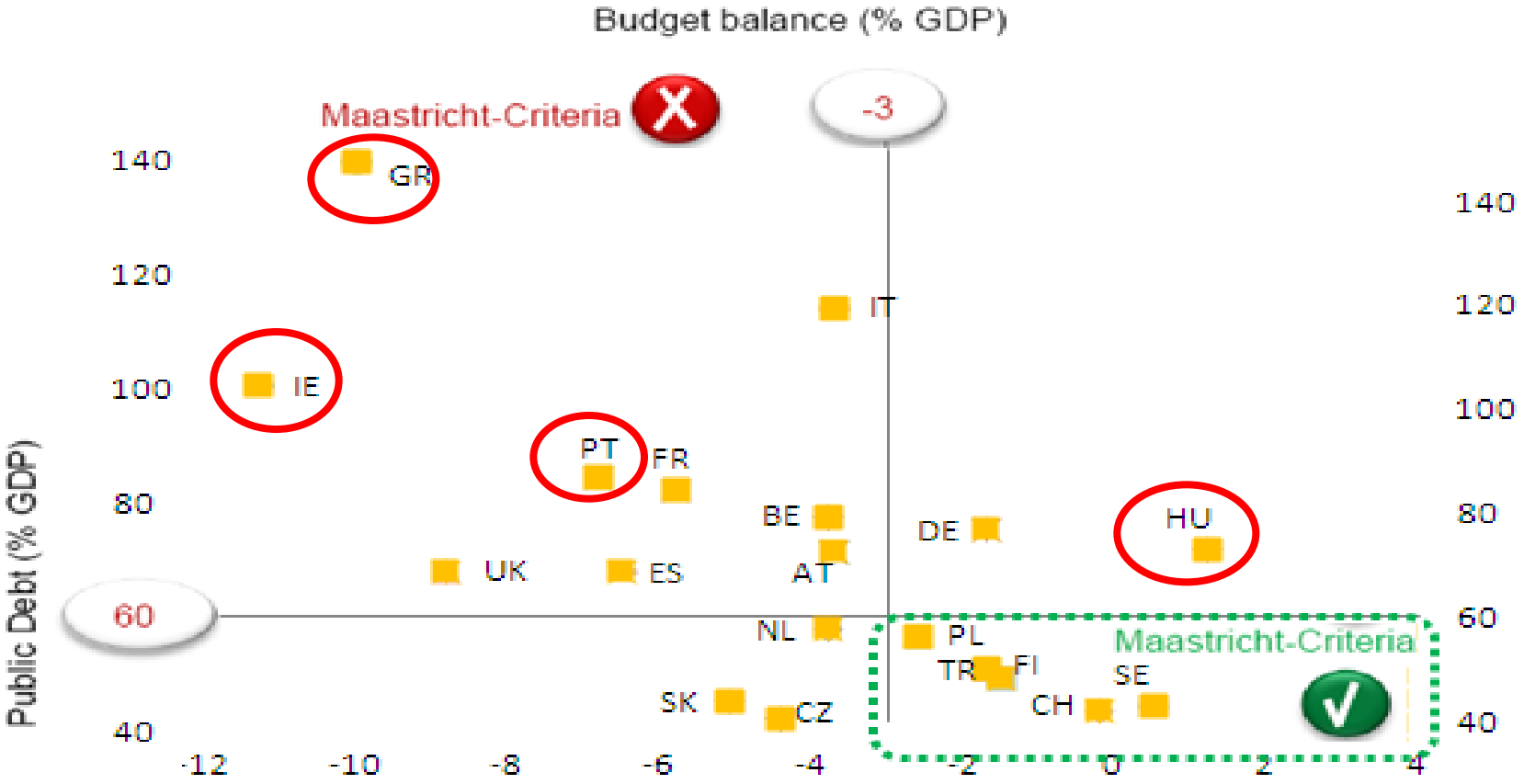
Challenges

- **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**

Budgettary Orthodoxy

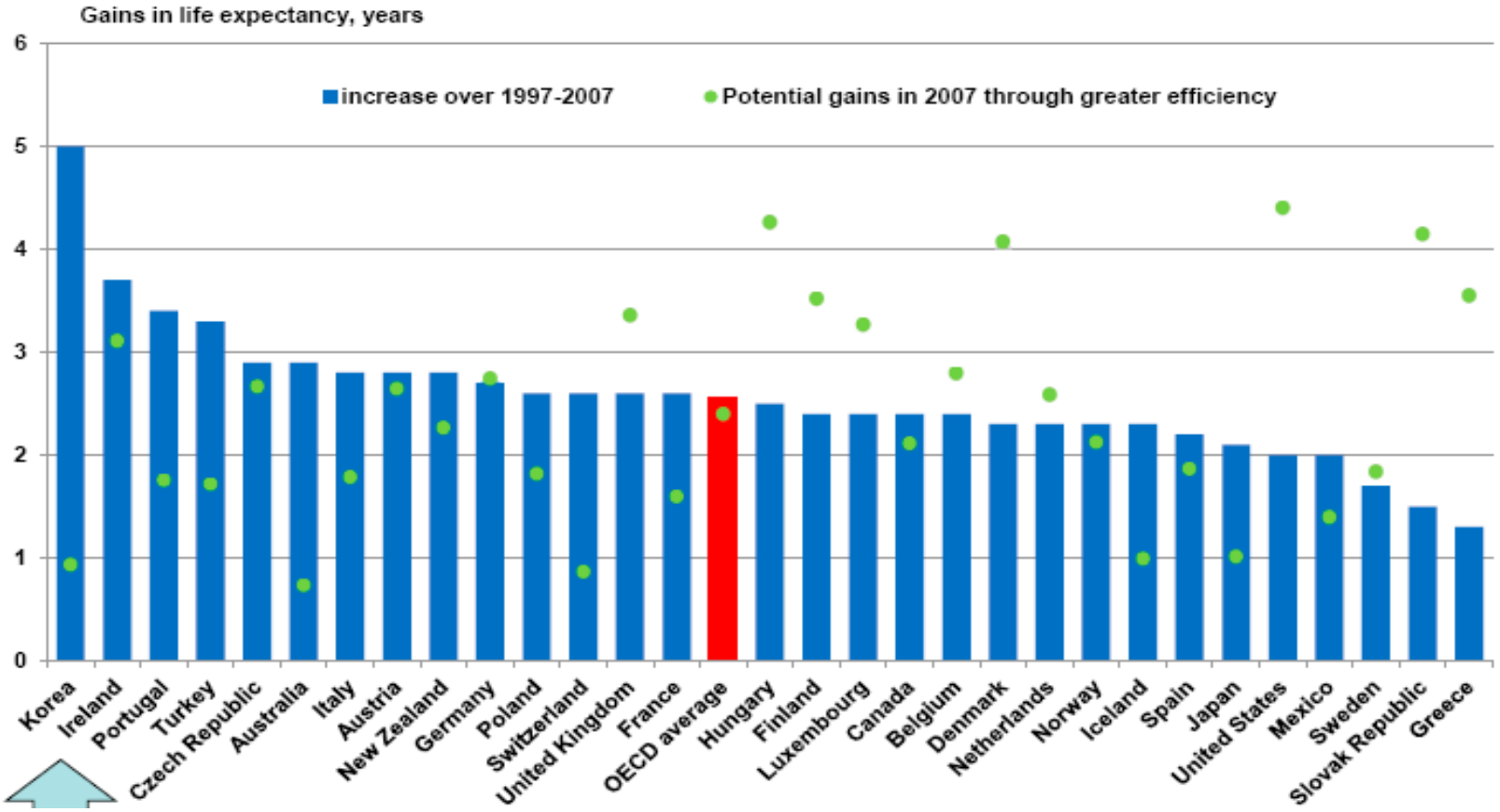
Continuous Violation of Maastricht Criteria in Europe (2011,Q4/11)



Source: OECD Economic Outlook 90 database, 2011, Source: Region Europe Pharma, Global Insight 2011, Deutsche Bank 2011.

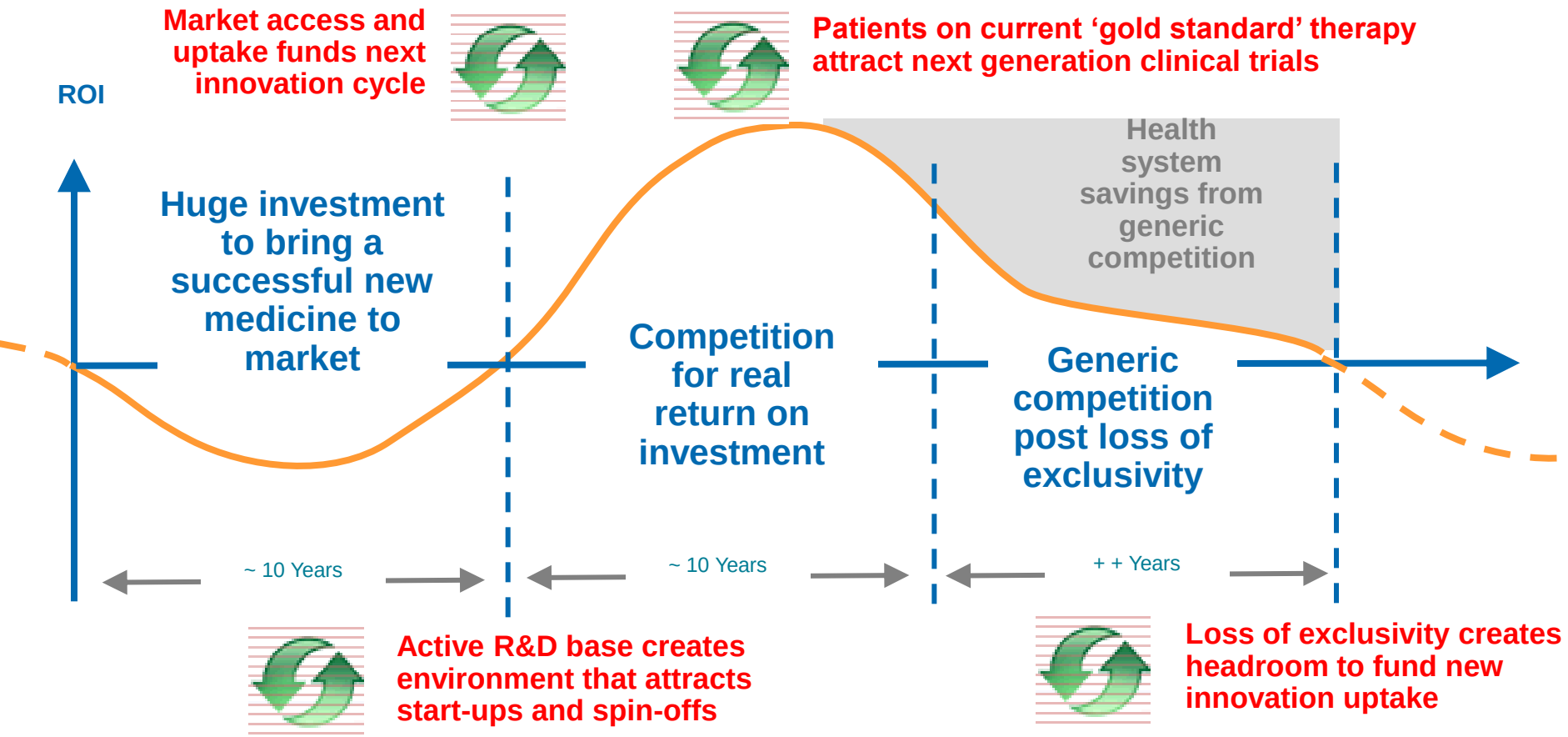
Efficiency in healthcare (1/2)

Exploiting efficiency gains would allow to improve health outcomes further…



Source: OECD Health Data 2009; OECD calculations.

Medicines lifecycle



A (European) framework for financially sustainable healthcare innovation

Generic Competition

Definition

"Generic" means a medicine based on an active substance that is out-of-patent and which is marketed under a different name from that of the original branded medicine – *copy medicine*

- A generic medicine is produced by a manufacturer, who is not the inventor of the (original) medicine.
- Generics shall comply with the same quality, efficacy and security requirements as those applicable to the original.
- In principle, generics come to market when intellectual property protection rights are exhausted.
- The "originator" can also produce copy versions of their own medicines – *these are usually qualified as "defensive generics"*

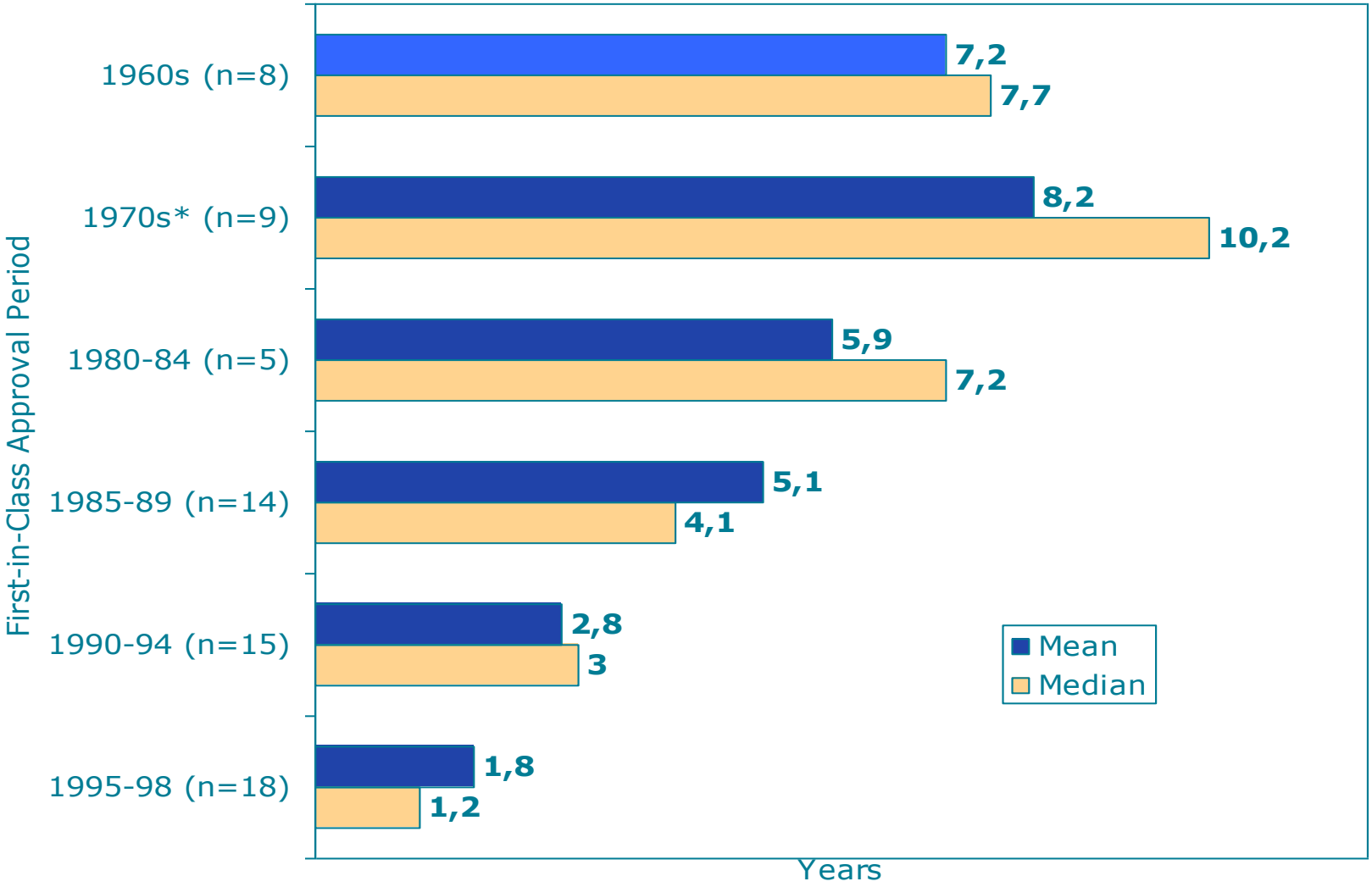
Regulatory Definitions

- **Generic:** a generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised, called the “reference medicine” (as per Art. 10(1) of Directive 2001/83/EC)

- **Hybrid:** in cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided (as per Art. 10(3) of Directive 2001/83/EC)

- **Bio-similar:** a similar biological or 'bio-similar' medicine is a biological medicine that is similar to another biological medicine that has already been authorised for use (as per Art. 10(4) of Directive 2001/83/EC)

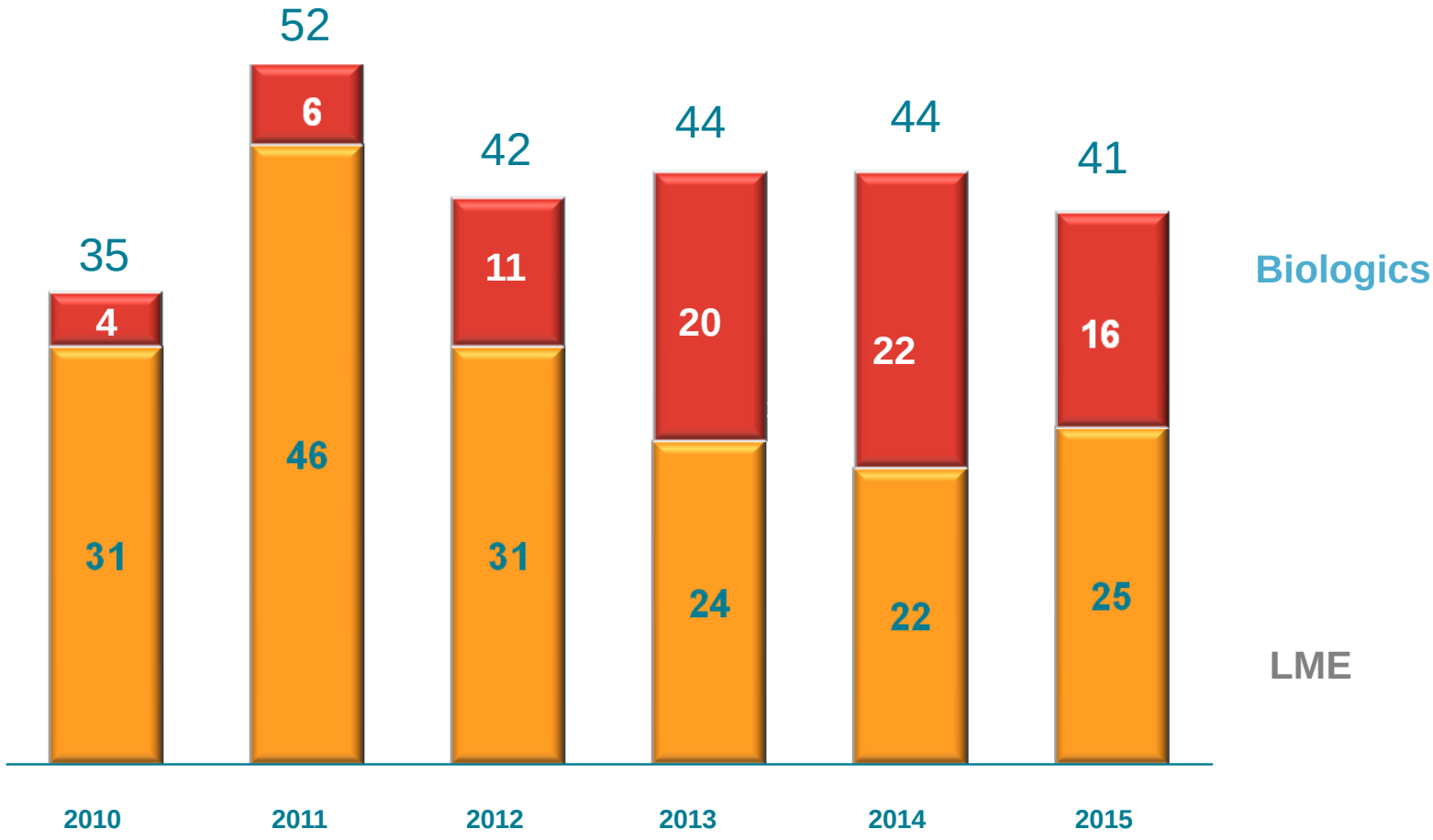
Innovator Competition



“Patent Cliff”

Worldwide sales of expiring[1] patents, USD billion

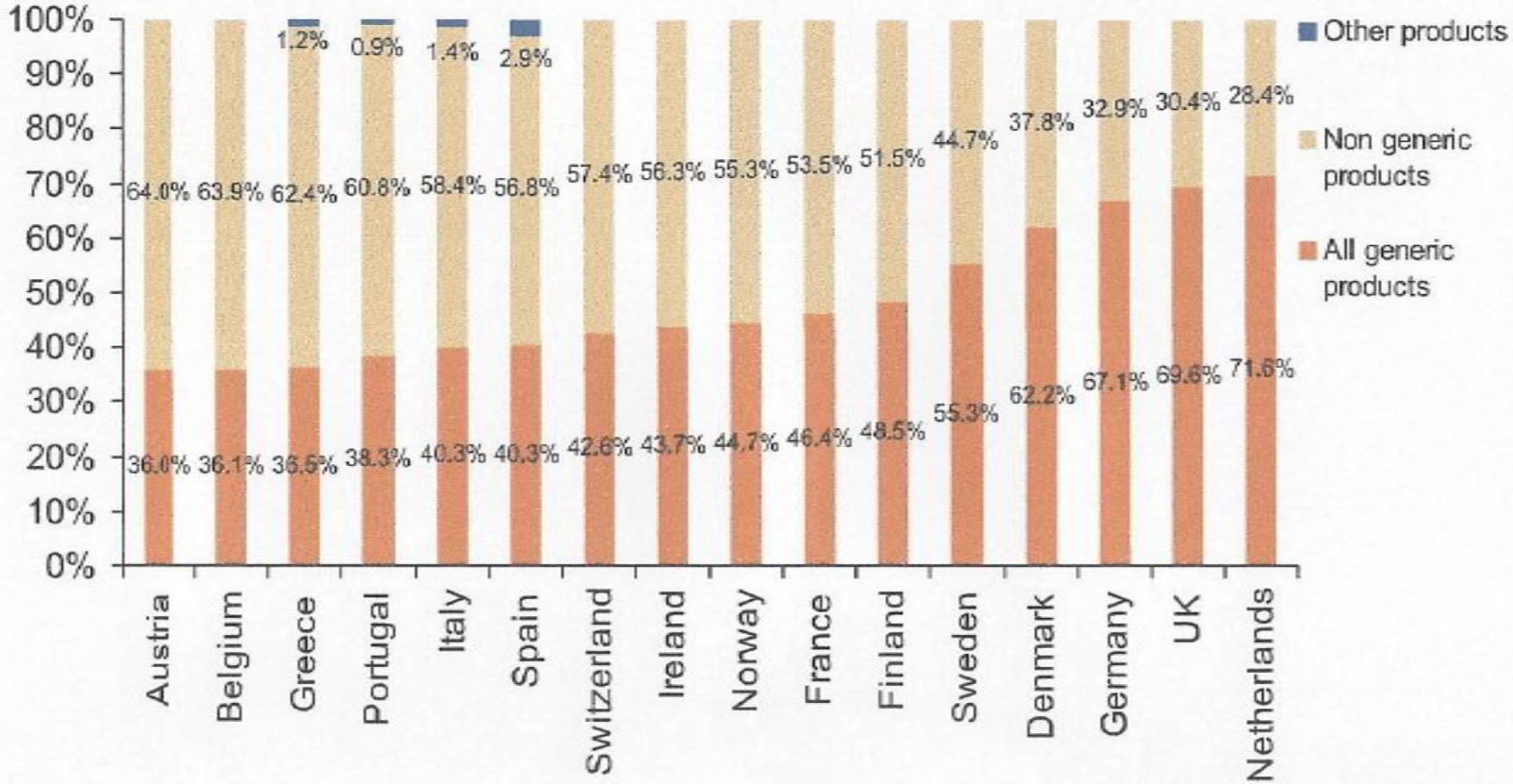
Calculations based on US patent expiry



Source: Sandoz 2008, NI/EA

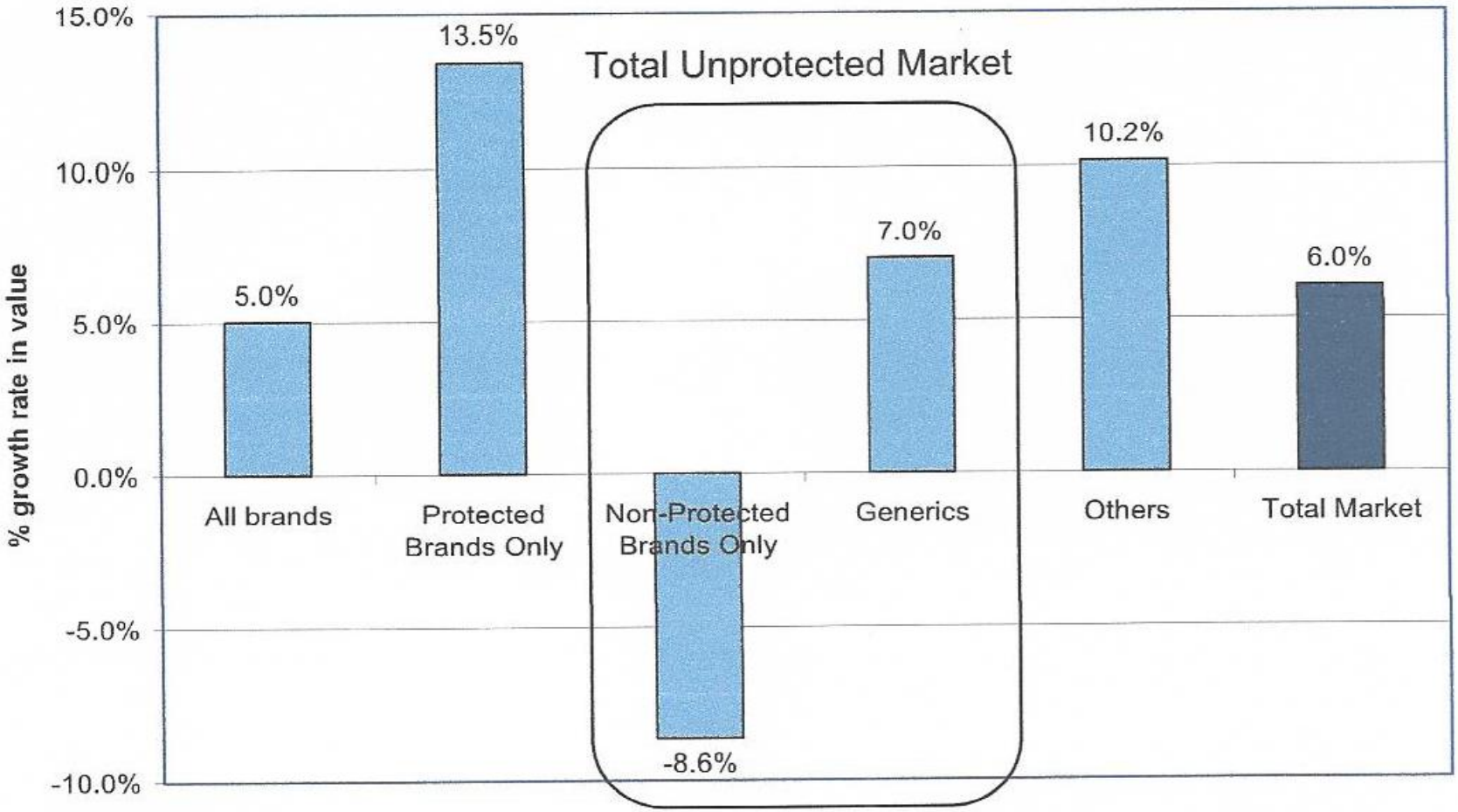
Share of Generics in Markets

Figure 2: Generic penetration by volume share of the unprotected market (Standard Units)[7]



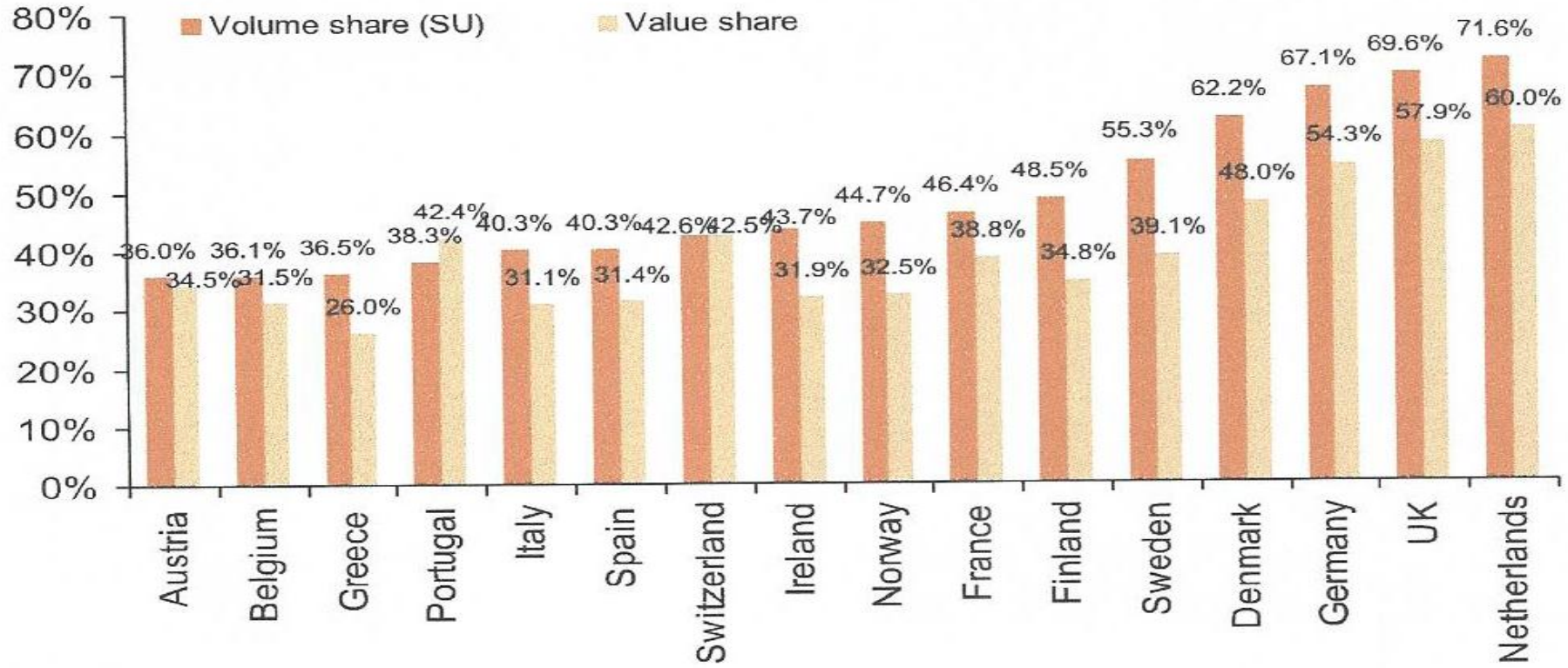
Practical Definitions

Figure 1: The growing importance of the European off-patent market in 2007[5]



More Volume at Lower Prices

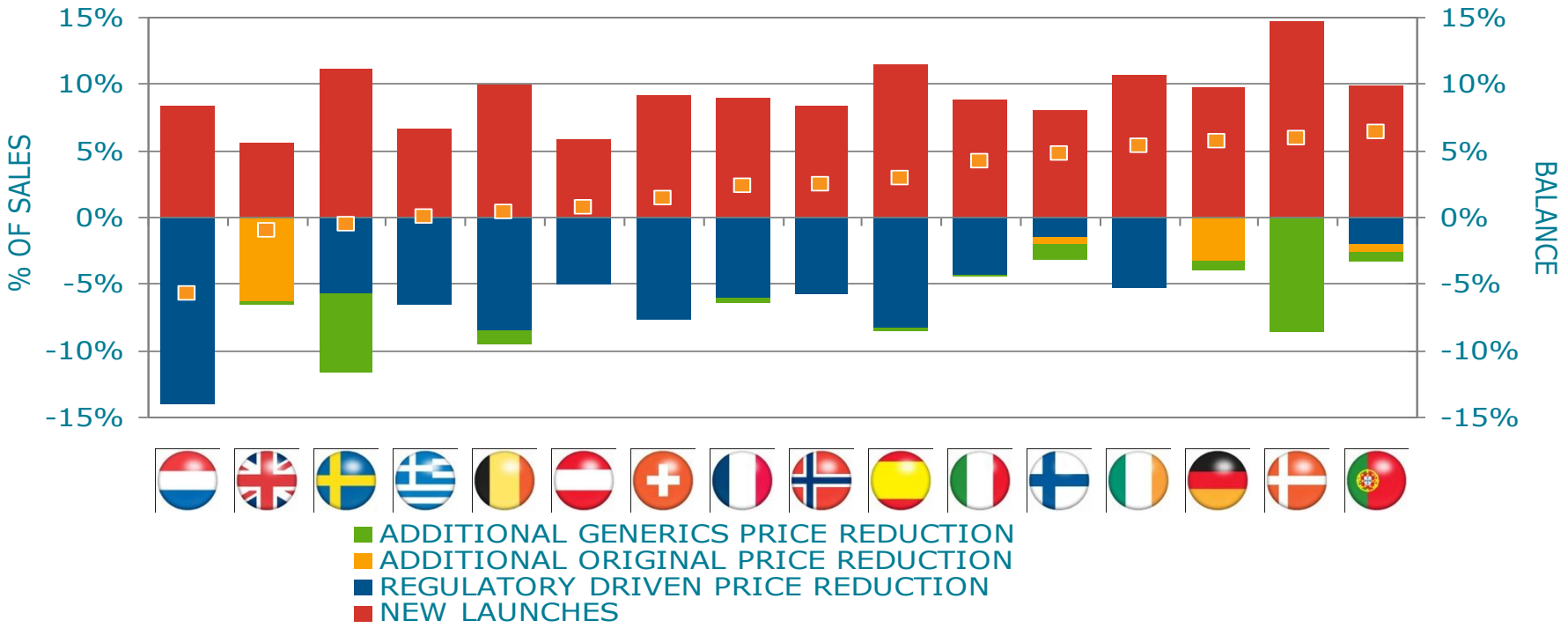
Figure 3: Generic penetration by volume (Standard Units) and value



Source: IMS Health MIDAS January 2008

Headroom for innovation

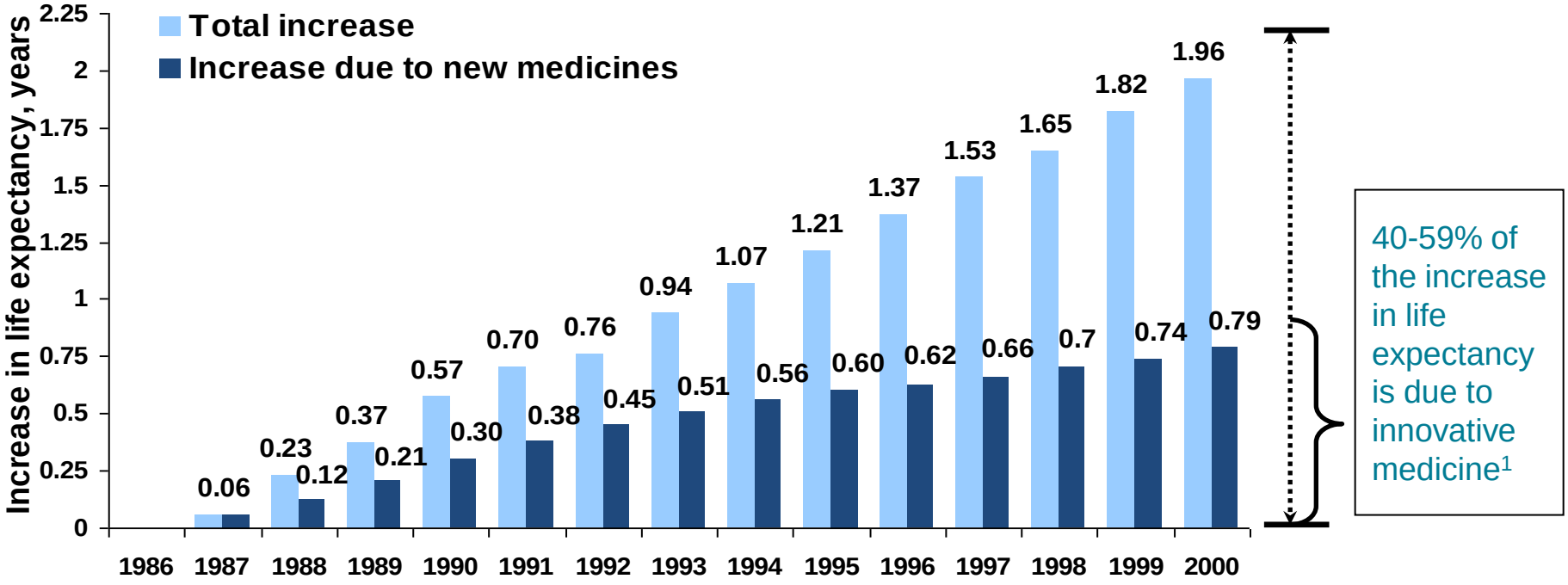
Expected “freed-up financial value” from patent expirations versus “cost of innovation” – cumulative share of total market sales of 5 years (% of 2009 sales for patent expirations and % of sales in the given year for launches)



Source: IMS Health MIDAS database MAT Sept 2009

Innovative Medicines & Life Expectancy

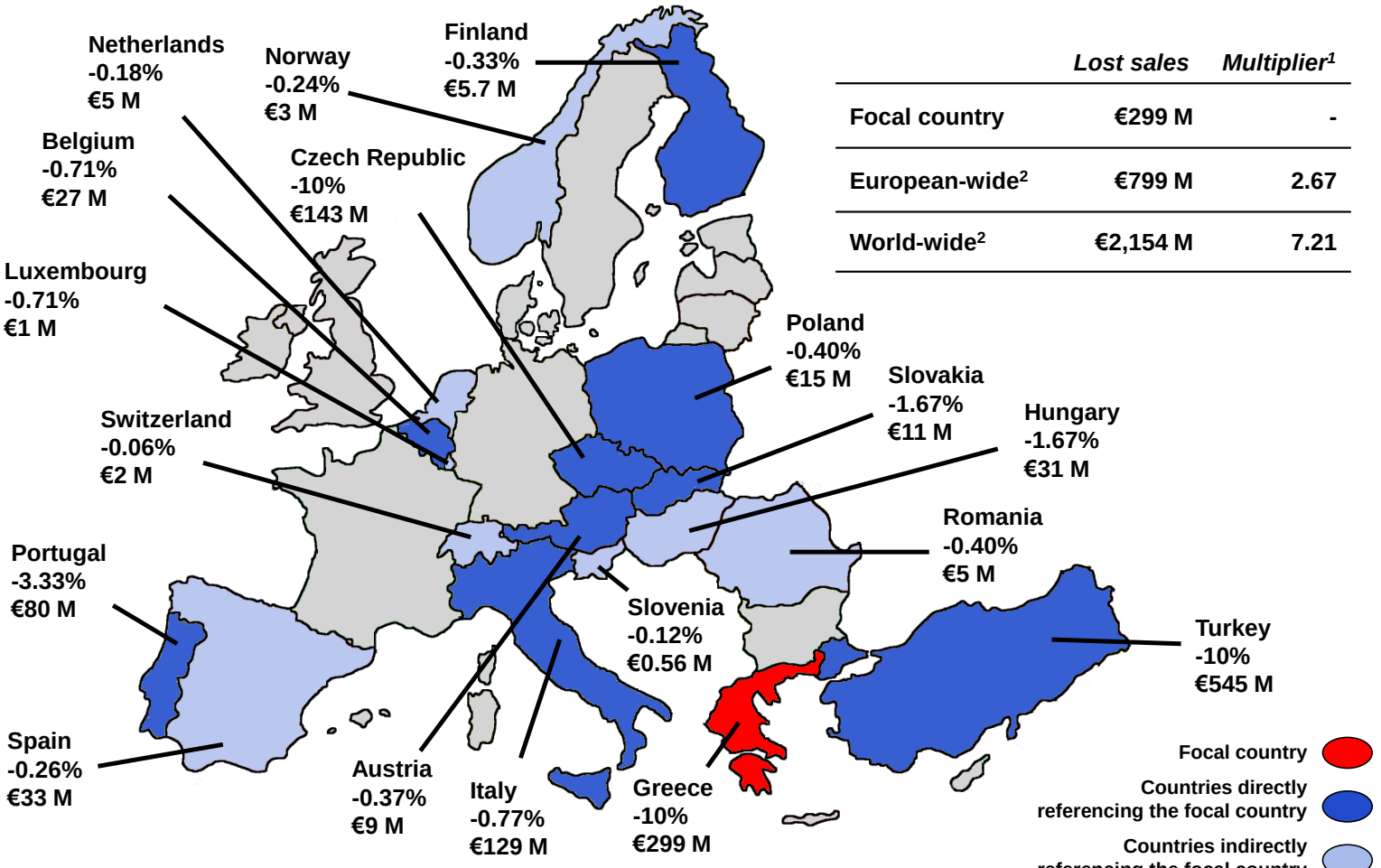
40-59% of the total increase in life expectancy across 52 countries is attributable to innovative medicine launches. Life expectancy is continuing to increase as a result of progress in the treatment and prevention of cardiovascular disease and cancer[1]



Global-level data

[1]Lichtenberg (2005)

International Price Referencing



	Lost sales	*Multiplier*[1]
Focal country	€299 M	-
European-wide[2]	€799 M	2.67
World-wide[2]	€2,154 M	7.21

1 *Ratio between wider and focal country lost sales*
2 *Including focal country*

Source: CRA – September 2012

International Reference Pricing (IRP) is used in some form in most European countries

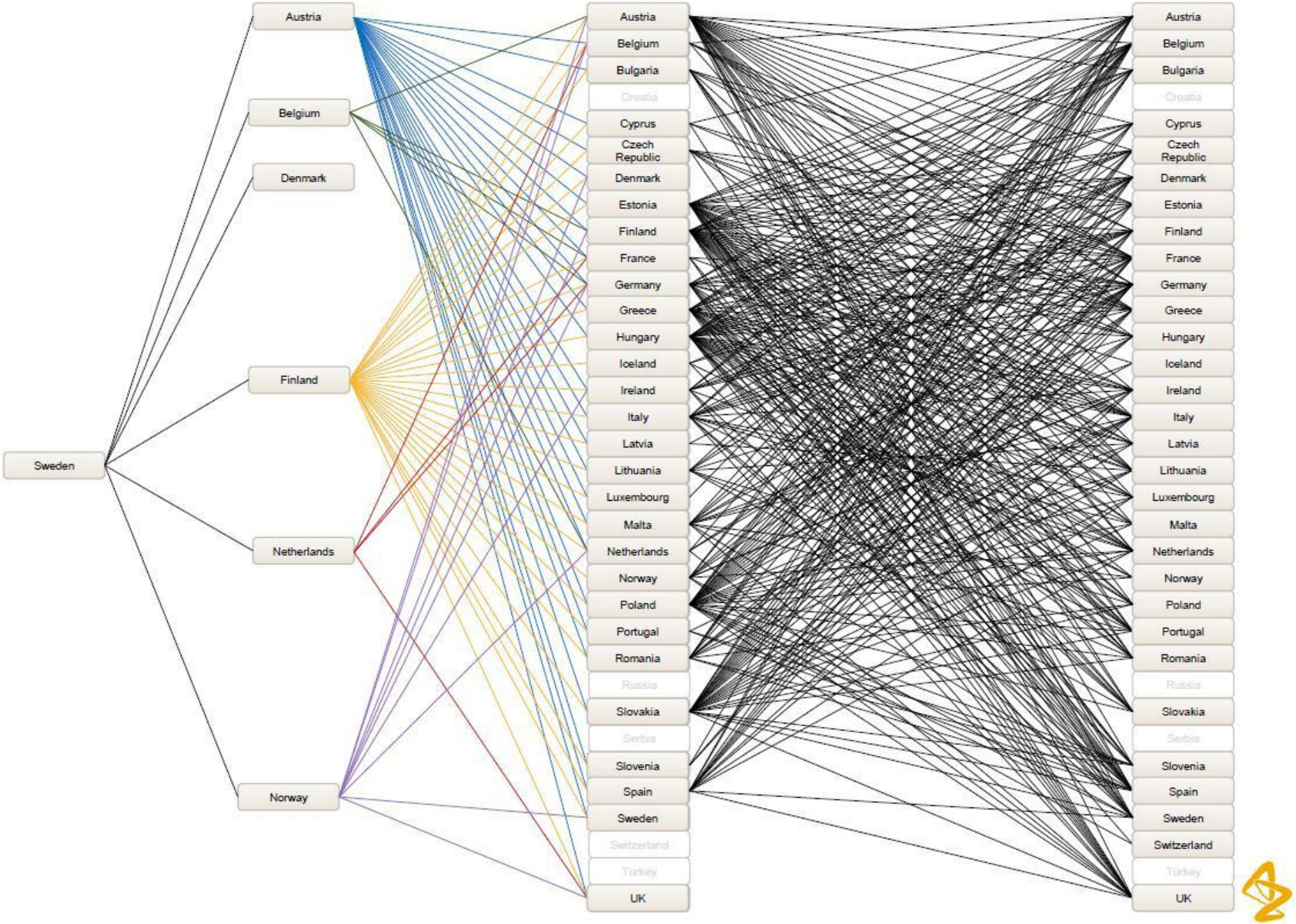
IRP Matrix

COUNTRY	IRP used?	Formal/ Informal	Calculation used	Price referenced	Drugs	Frequency of re-referencing (months)	No. of Reference Countries
Austria	Y	F	AVERAGE	MNF	Reimbursed	-	25
Belgium	Y	I	AVERAGE	MNF	All	18	26
Bulgaria	Y	F	LOWEST	MNF	POM	6	15
Cyprus	Y	F	AVG. OF LOWEST 4	TRD	Imported medicines	24	4
Czech Republic	Y	F	AVERAGE	MNF	All	12	8
Denmark	N	-	-	-	-	-	
Estonia	Y	F	Not defined	MNF	Reimbursed	3	3
Finland	Y	I	AVERAGE	TRD	Reimbursed	60	26
France	Y	I/F	AVERAGE	MNF	Innovative medicines	60	4
Germany	Y	I	Not defined	MNF	Innovative medicines	-	15
Greece	Y	F	AVG. OF LOWEST 3	MNF	All	6	22
Hungary	Y	F	LOWEST	TRD	Reimbursed	-	26
Ireland	Y	F	AVERAGE	MNF	Innovative medicines	24	9
Italy	Y	I/F	AVERAGE	MNF	Reimbursed	24	25
Latvia	Y	F	THIRD LOWEST	MNF	Reimbursed	6	25
Lithuania	Y	F	AVERAGE	MNF	Reimbursed	12	8
Luxembourg	Y	I	AVERAGE	MNF	All	18	
Malta	Y	F	AVERAGE	MNF	All	-	12
Netherlands	Y	F	AVERAGE	TRD	POM	12	4
Norway	Y	F	AVG. OF LOWEST 3	TRD	POM	12	9
Poland	Y	I	LOWEST	MNF	Reimbursed	-	26
Portugal	Y	F	AVERAGE	MNF	POM	12	4
Romania	Y	F	LOWEST	MNF	Reimbursed	12	12
Slovakia	Y	F	AVG. OF LOWEST 6	MNF	Reimbursed	6	25
Slovenia	Y	F	95% OF AVG OF 3	MNF	Reimbursed	24	3
Spain	Y	I	LOWEST	MNF	Innovative medicines	-	26
Sweden	N	-	-	-	-	-	
UK	N	-	-	-	-	-	

Referencing market

SOURCE: IMS HEALTH Pharmaquery Sept 2012

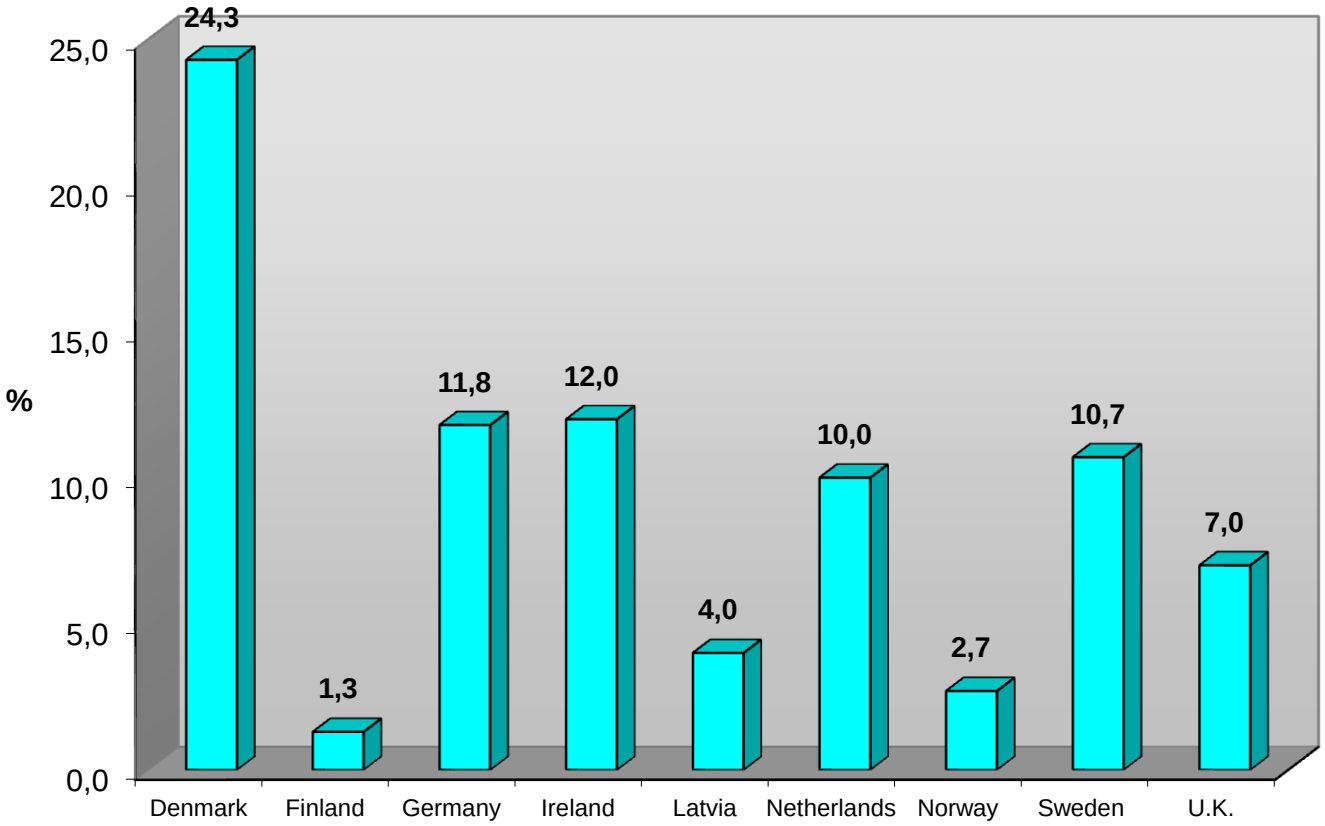
efpia



Source: Adapted From Kanavos P, Vandoros S Et Al. Differences In Costs Of And Access To Pharmaceutical Products In The Eu. Policy Department A: Economic And Scientific Policy. 2010-12. Available at: http://www.Europarl.Europa.Eu/Activities/Committees/Studies.Do?Language=En

Share of Parallel Imports in Pharmacy Market Sales

(%) – 2010



Note: Parallel trade was estimated to amount to € 5,100 million (value at ex-factory prices) in 2010.
Source: EFPIA Member Associations

Programme

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  - Market Access & Competition
  - Cross-border Sales
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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.

Procedure & Evaluation

- **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)

PRIZE

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 *(net)* + basic package (including group insurance)
  - Where appropriate, other allocations could be agreed, such as contribution for accomodation in Brussels

- **Award Ceremony**

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For more information

- Website
  www.efpia.eu

- By phone
  + 32.2.626 25 55 (Général)

- By e-mail
  firstname.familyname@efpia.eu
  marieclaire.pickaert@efpia.eu