

Affordable access to essential medicines in the EU

A EU Policymaker's perspective

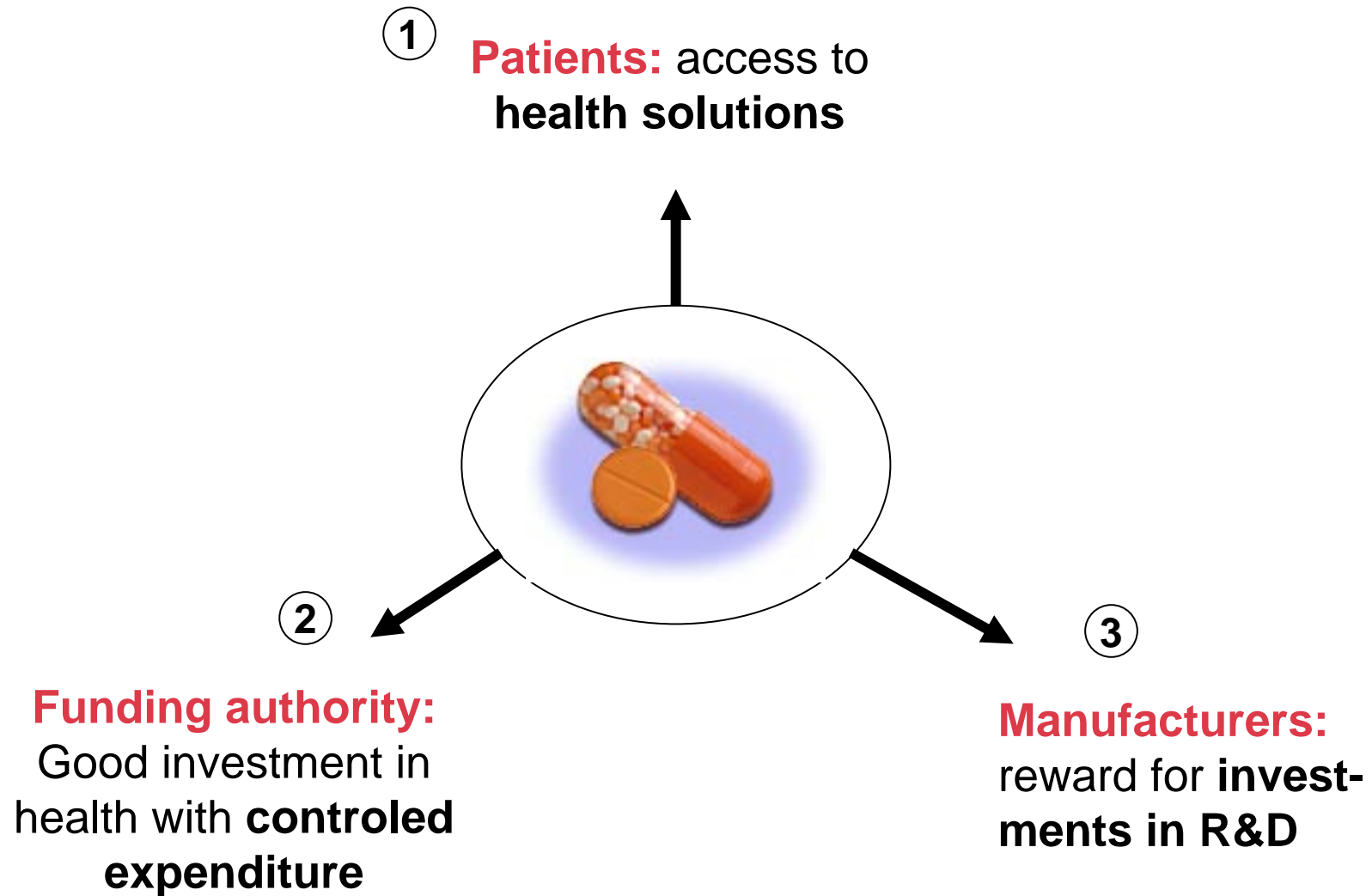
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Competitiveness in Pharmaceutical
Industry and Biotech
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European Commission

Peer review –
Cost containment
30 June - July 2008
Berlin

European Commission

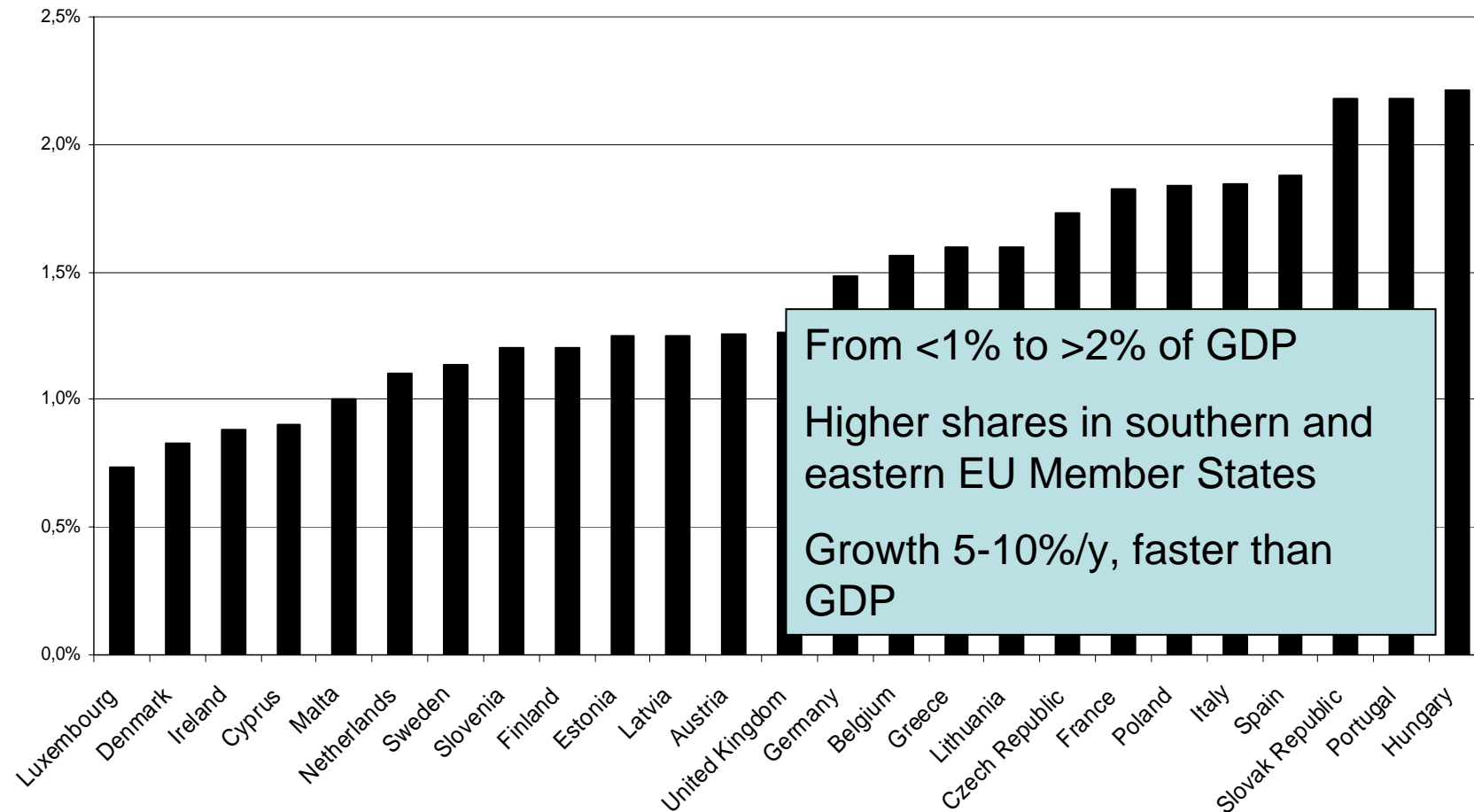


DIFFERENT EXPECTATIONS OF PHARMACEUTICALS



2. PHARMACEUTICAL EXPENDITURE TAKES SIGNIFICANT PART OF WEALTH

(Total* expenditure / GDP)



* Publicly and privately funded

Source: 2004 data OECD except CY,ES,LT,LV,MT,SL 2004 data by Alcimed and Merit Economics European Commission



DRIVING FACTORS

- Patient Side
 - Ageing society
 - Environmental factors
 - Better informed patients
 - More active and demanding patients
 - ...
- Product side
 - Low-volume / high-price products (e.g., specialised medicines, orphan medicines, personalised care, ...)
 - « Emotional factor »
 - ...



COST CONTAINMENT IN EUROPE AND IN U.S.



Europe

- Driven by authorities
- Exchange of long existing experiences
- Experiments with new ideas: risk-sharing, payback, ...
- Mainly controlled pricing



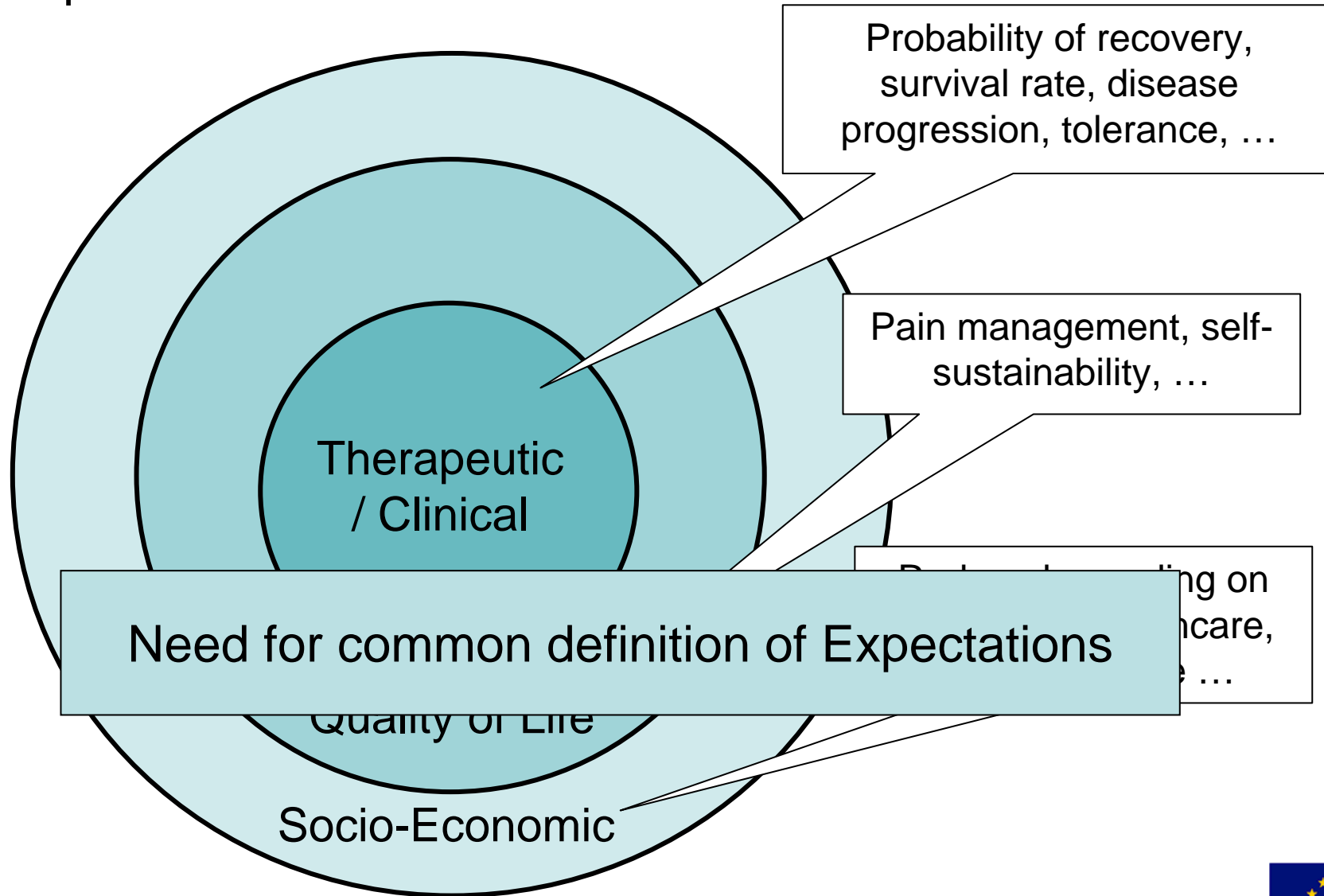
U.S.

- Driven by insurers
- Medicare Part D triggered gov't budgets and interest for cost-containment
- Implementing the basics
- Mainly free price competition

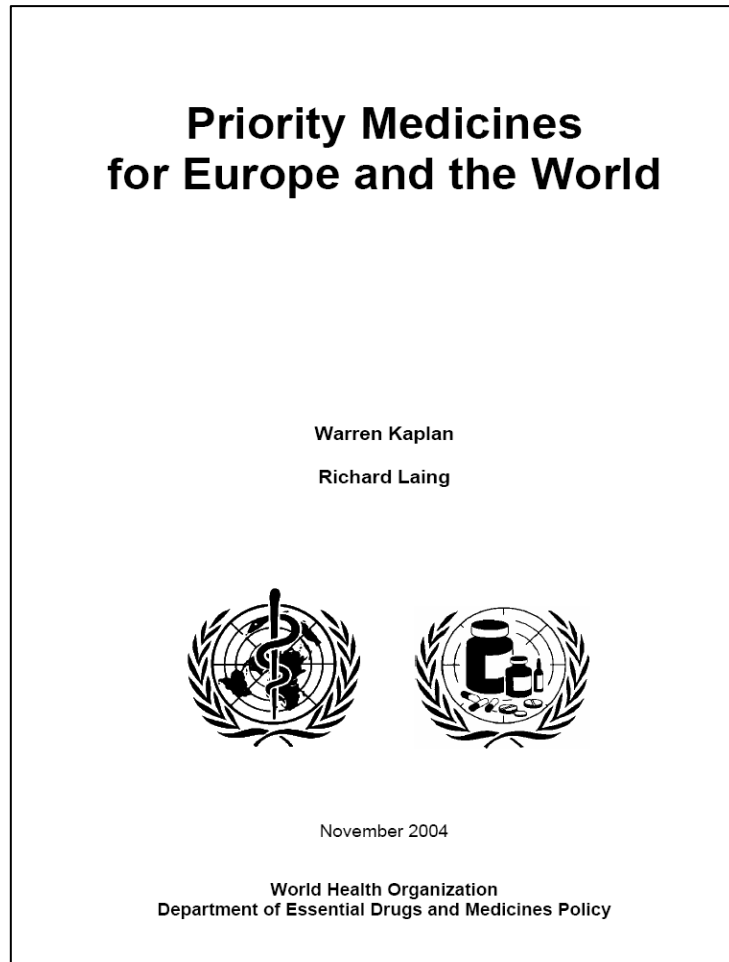


DIFFERENT VIEWS AND COMMON GROUND IN EU

Expected value of innovation...



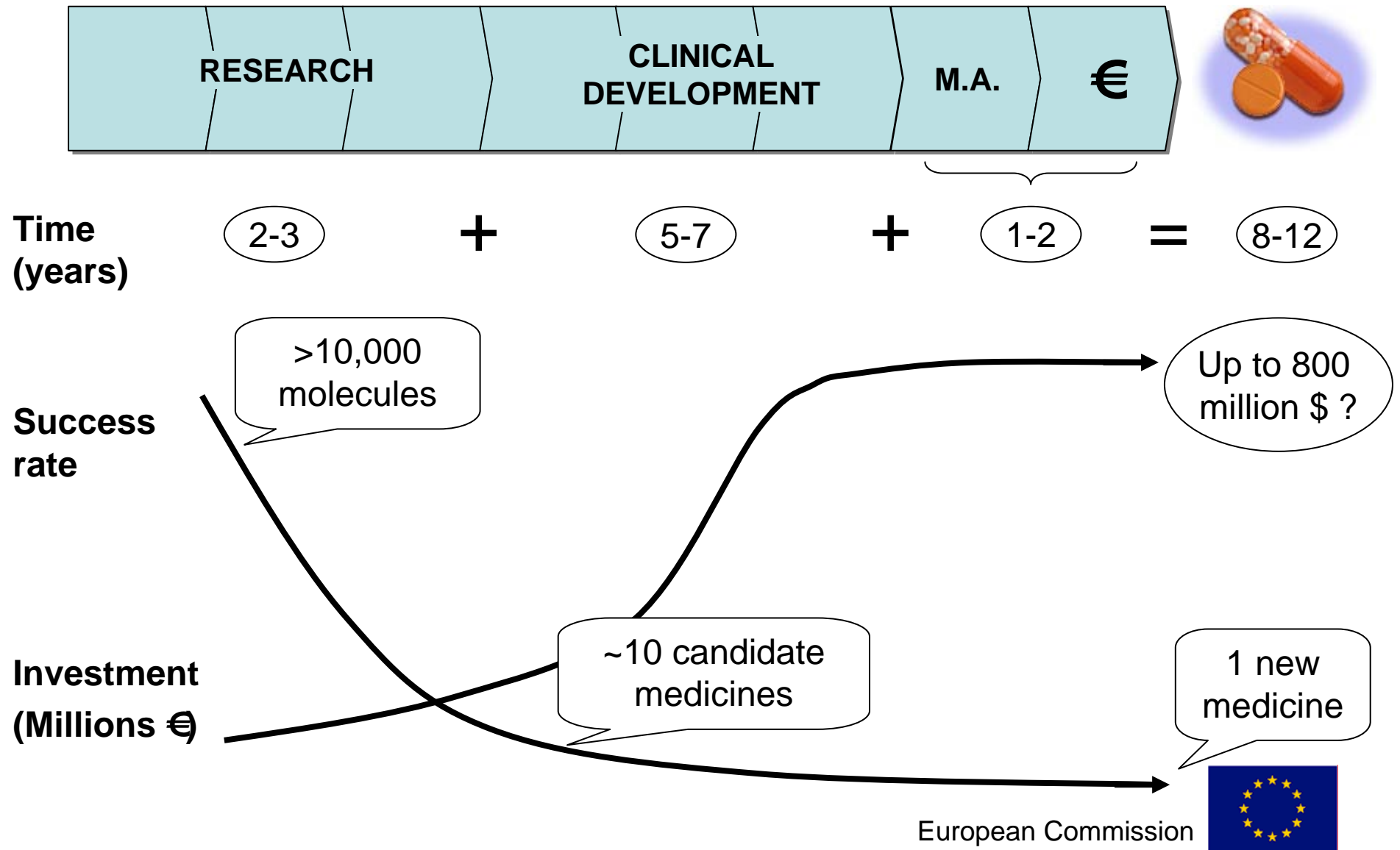
EXPECTED HEALTH NEEDS



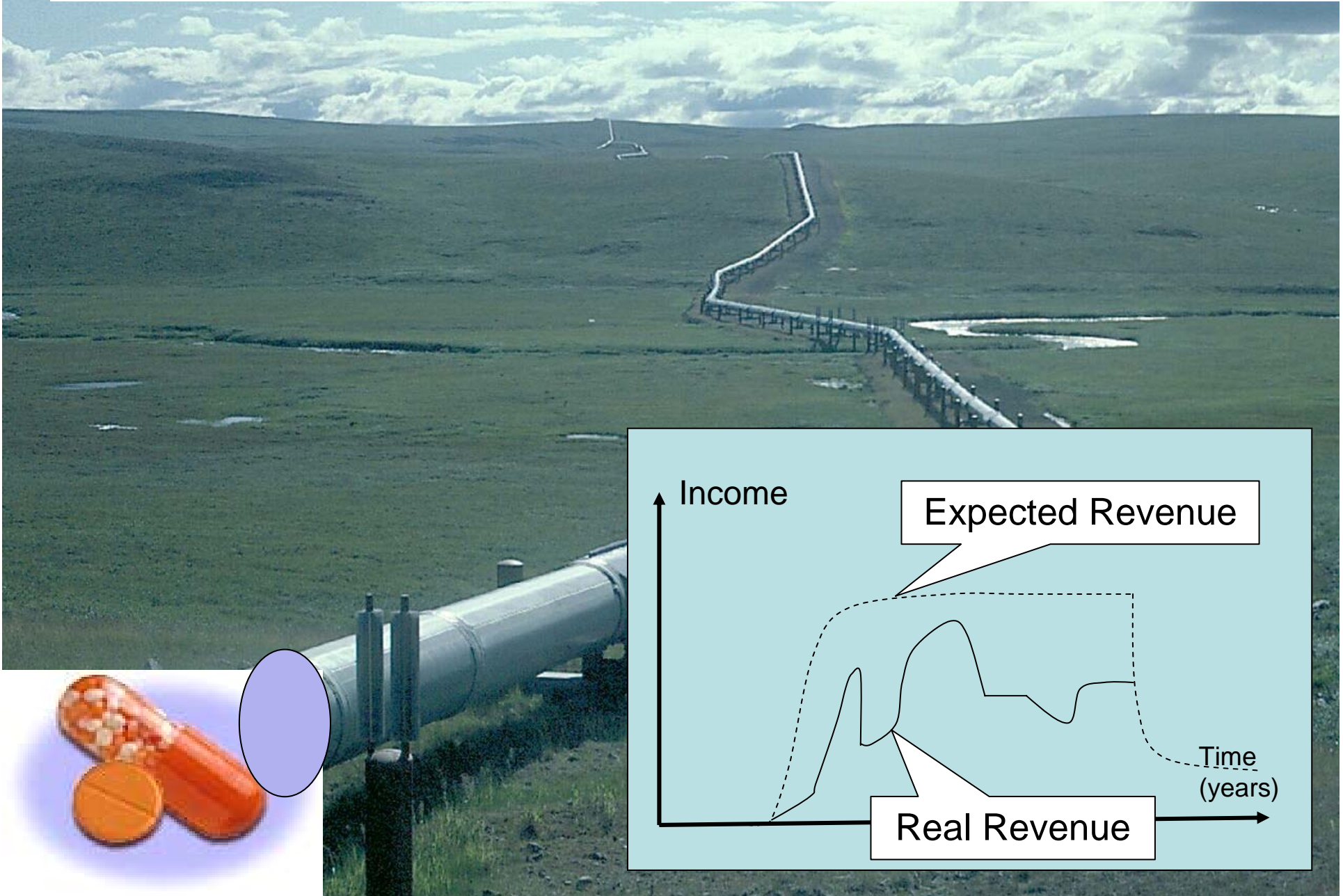
- Aging population: Alzheimer, osteoporosis, ...
- Major treats: pandemic influenza, antibacterial resistance, ...
- High-burden diseases: Cardio-vascular, Diabetes, Cancer, ...
- Neglected areas: HIV/AIDS, TBC, Malaria, Orphan areas, heat-stable oxytocin, ...
- Need for new reward mechanisms where markets fail: e.g. orphan status, special funds, paediatric initiative, ...



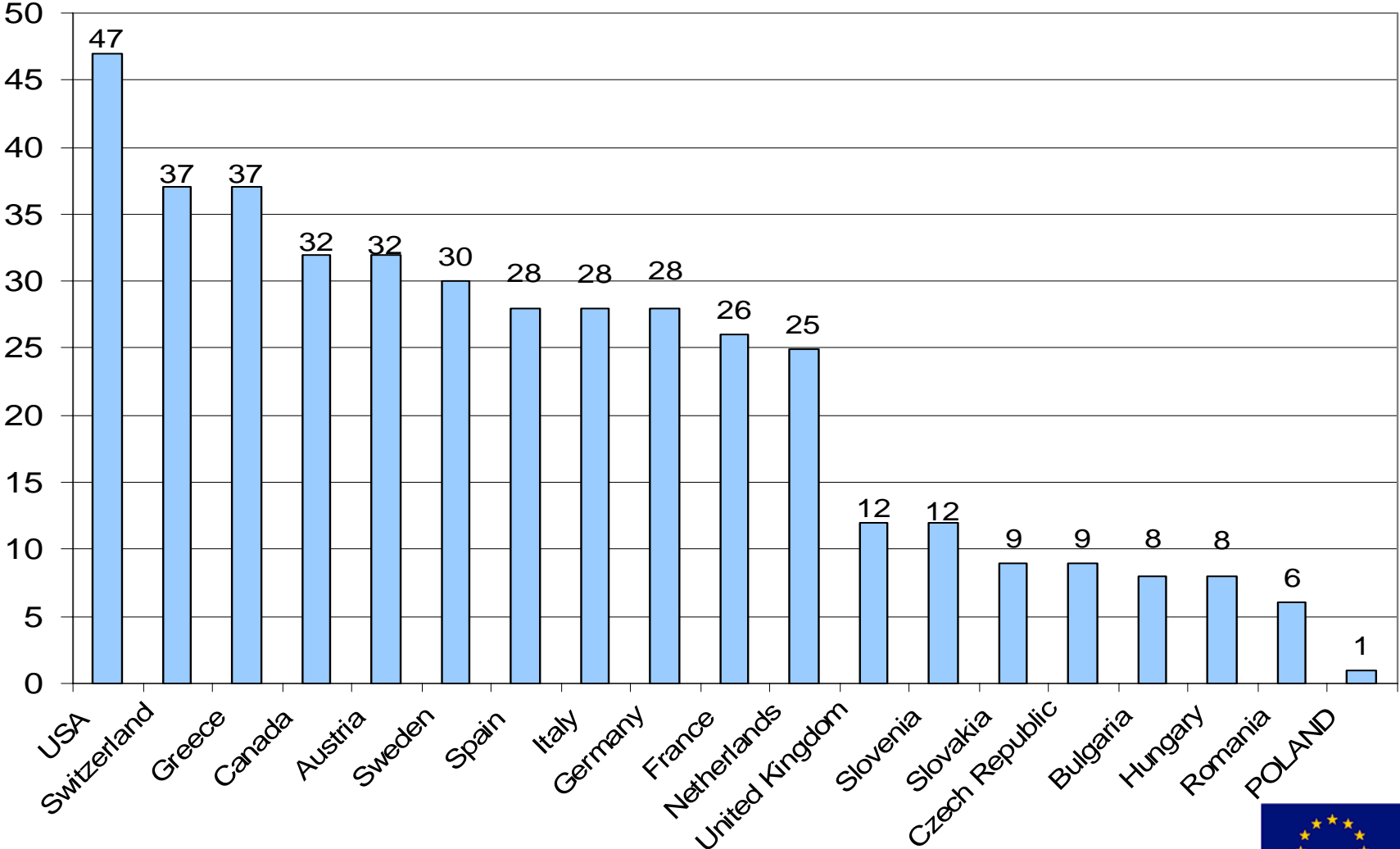
3. THE LONG PROCESS OF R&D IN PHARMA...



COMPANIES' NEED FOR CONSISTENCY OF REWARD



1. USE OF IMMUNOMODULATING MS-THERAPIES (%, 2004)



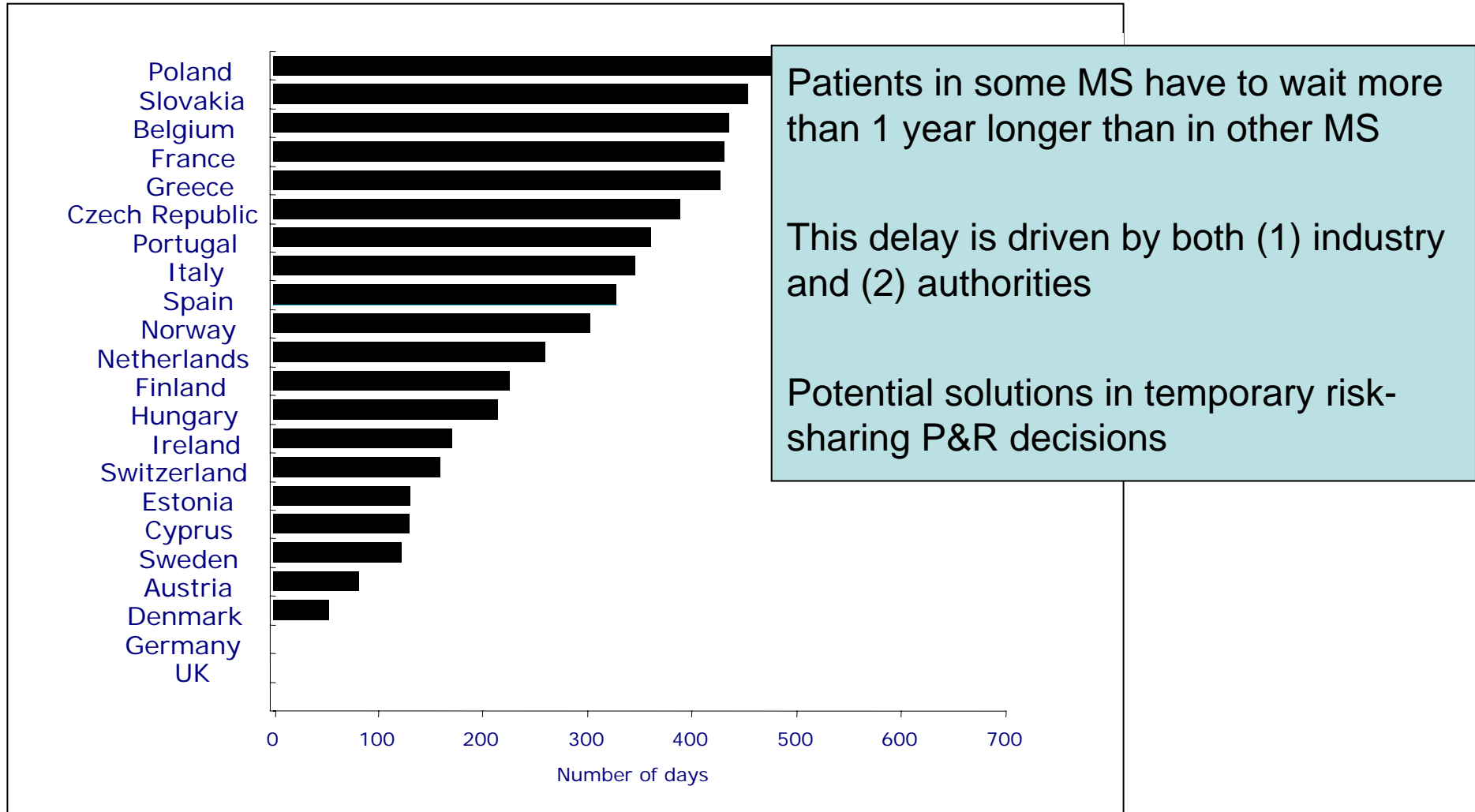
Source: European Multiple Sclerosis Platform

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TIMING OF ACCESS

Average Time Delay between MA and Effective Market Access*



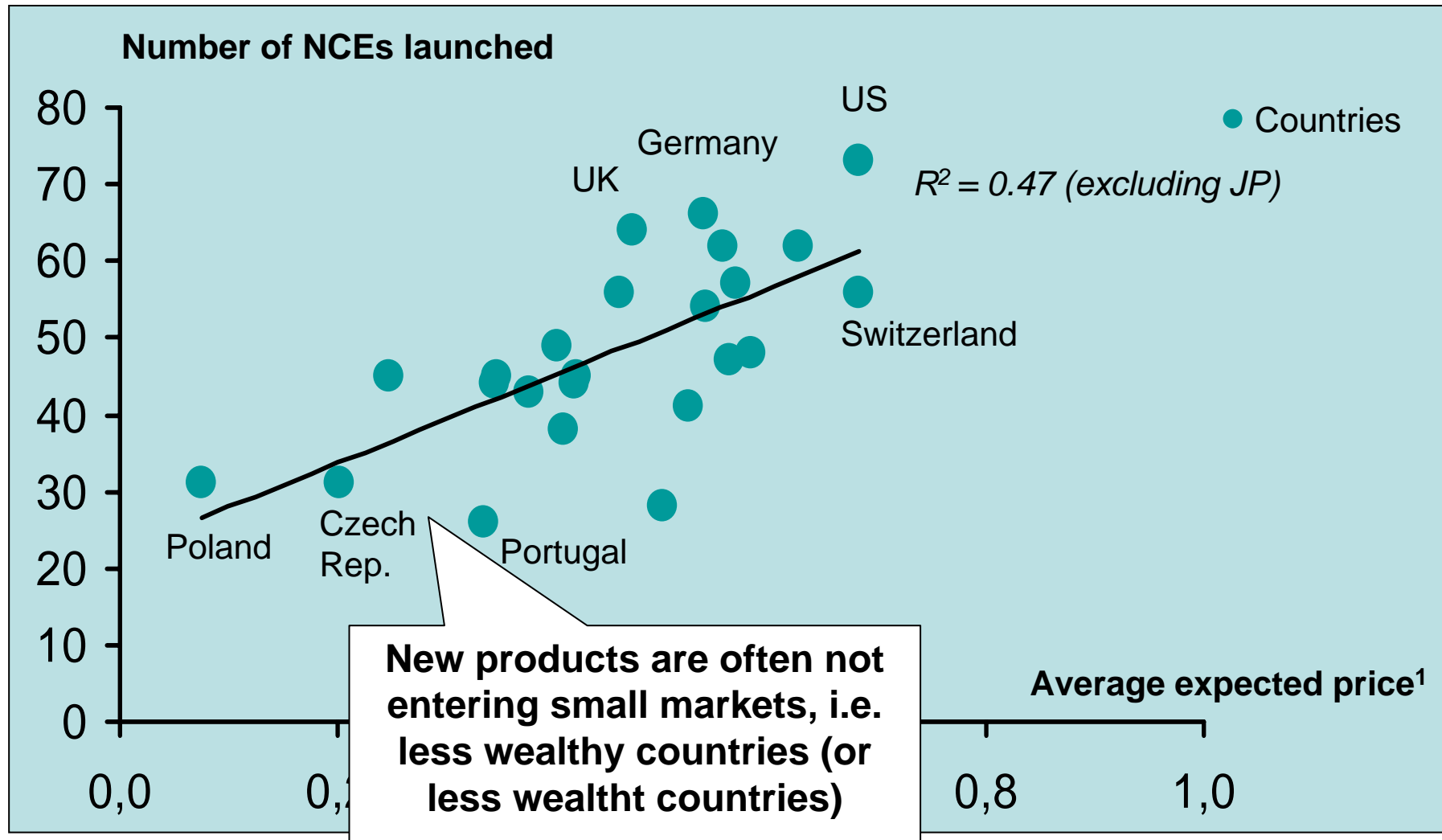
* Defined by when medicine gets a pricing and reimbursement decision in a MS

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

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EQUAL AVAILABILITY



1 Per standard unit

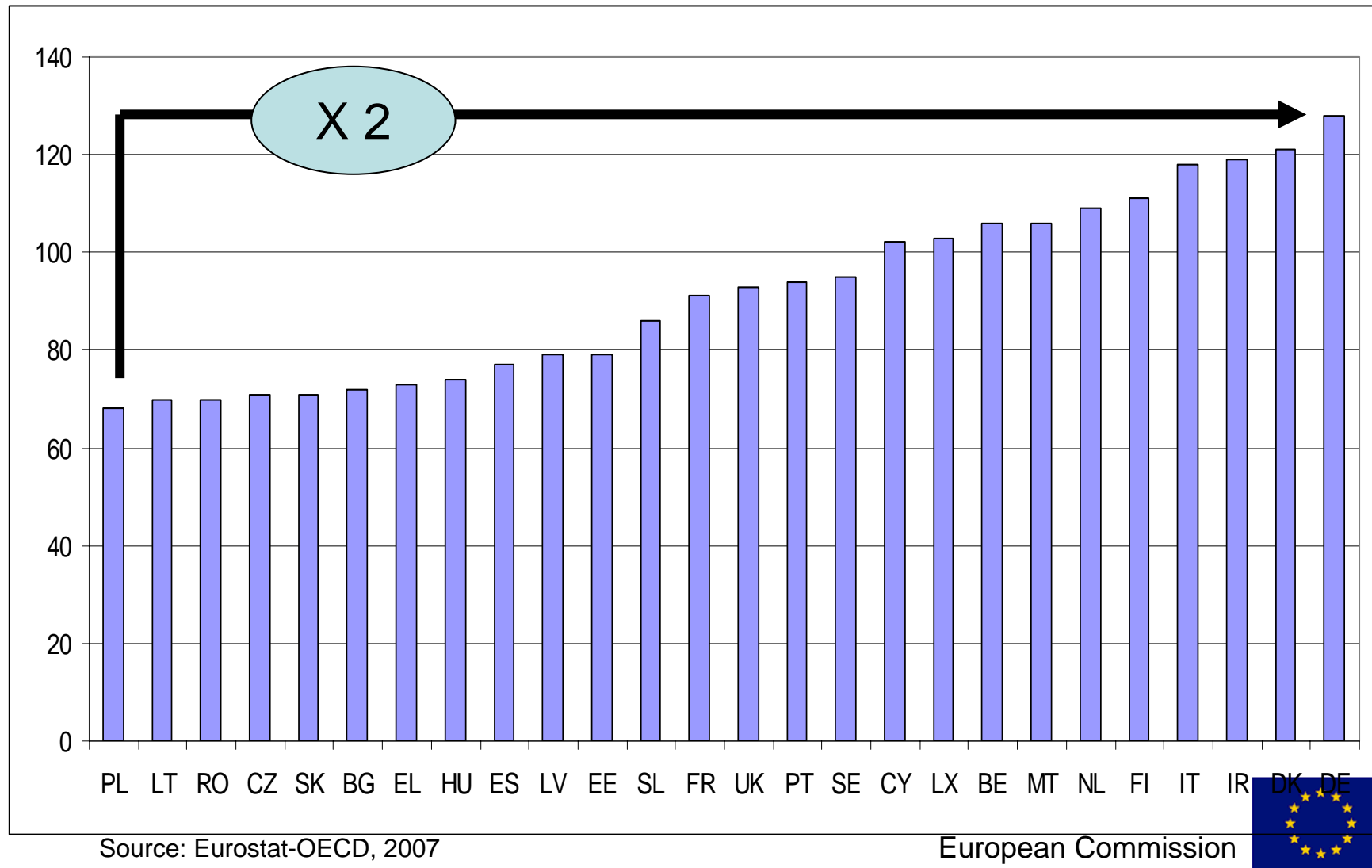
2 Based on 85 new chemical entities (NCEs) launched in the UK or US outpatient market between 1994 and 1998

Source: "The impact of price regulation on the launch delay of new drugs – a study of 25 major markets in the 1990s", Danzon, Wang, Wang (2003)

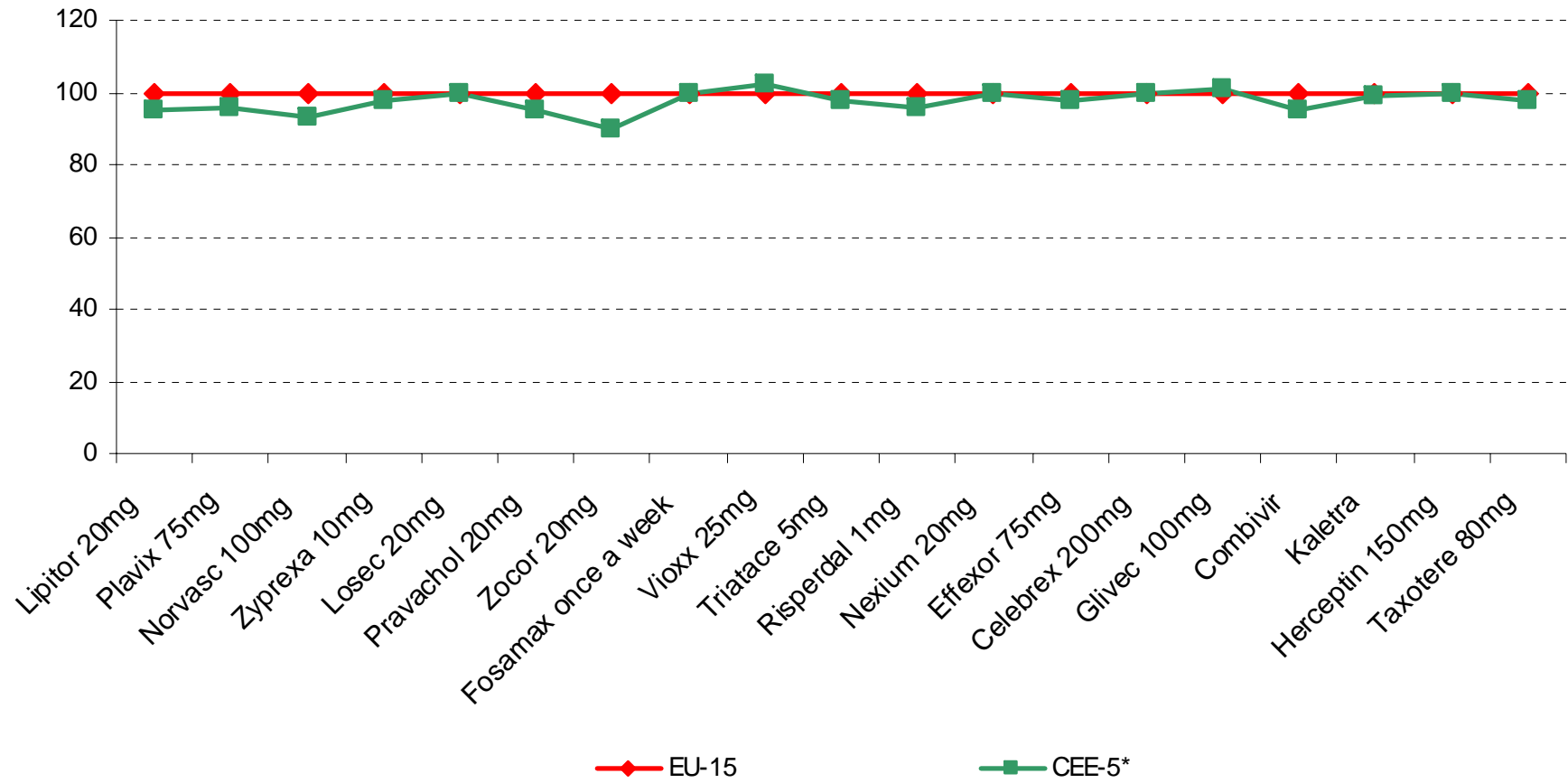


CONVERGENCE OF EU-PRICES

Eurostat- OECD survey of 181 products, retail prices-levels in EU MS



COMPARISON AT EX-FACTORY PRICE LEVEL 2003



(Average of HU, PL, CZ, SL, SK)

Source: Cambridge report basing on
IMS MIDAS data, Average EU-15 price = 100

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CROSS-BORDER REFERENCE PRICING... OR NOT...

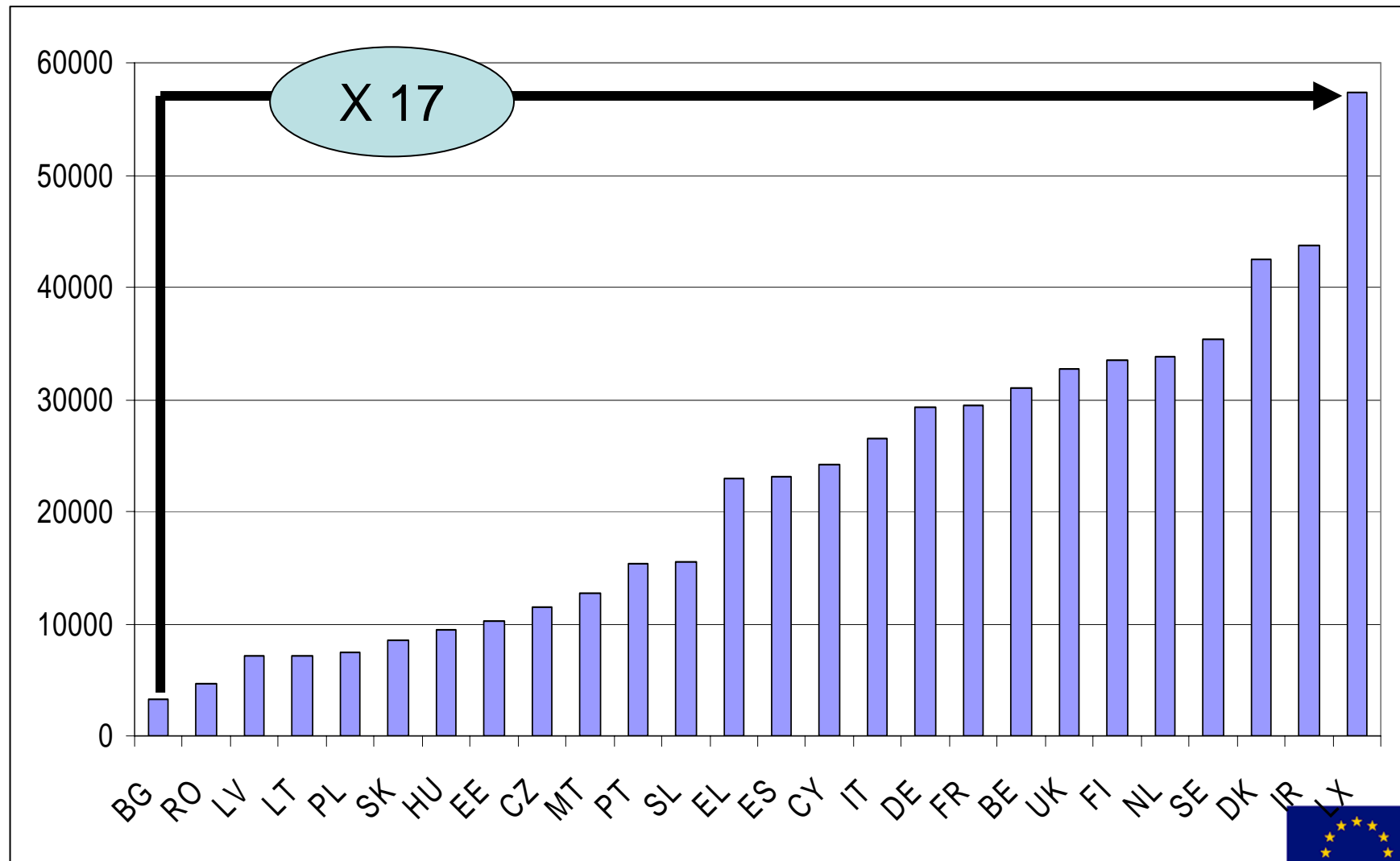
	AT	BE	CY	EL	ES	FI	FR	HU	IE	LT	LV	NL	NO	PL	PT	RO	SK	SI
CRITERIA	Average	Average and	Average	Average	Minimum	Others	Others	Minimum	Average	Average (95%)	Others	Average	Average (three lowest)	Other	Minimum	Minimum	Average (not exceed 10 % three lowest)	Average
COMPARE	But what about...																	
COUNTRIES REFERENCE	Ex-factory	Ex-factory	Ex-factory	Pharmacy purchases	Ex-factory	Ex-factory	Ex-factory	Wholesale										
	LT	LV	NL	NO	PL	PT	RO	SK	SI									
AT				X			X	X										
BE			X	X														
BG																		
CY																		
CZ																		
DE	X						X	X	X									
DK							X	X										
EE	X																	
EL																		
ES														X			X	
FI													X					
FR							X							X			X	X
HU	X															X	X	
IE									X									
IT														X	X	X	X	X
LT																X		
LU																		
LV	X																	
MT																		
NL													X					
NO																		
PL	X															X	X	
PT																		
RO																		
SE													X					
SK	X															X		
SI																		
UK												X	X	X		X		
EU*		X									X			X				

- Discounts
- Rebates
- Conditional P&R
- Prescription guidelines
- Price-Volume agreements
- Payback
- PPRS
- Clawback
- ...



AFFORDABILITY OF MEDICINES IN EU

GDP/capita in EU MS (IMF, 2005-2006)



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GUIDING PRINCIPLES

WG Pricing – Pharmaceutical Forum

- ① Control of expenditure
 - 1. Potential of free pricing
 - 2. Align demand side
 - 3. Leverage generics
- ② Reward for R&D investment
 - 4. Set expectations
 - 5. Recognise innovation
 - 6. Be consistent
- ③ Access to health solutions
 - 7. Ensure timely access
 - 8. Ensure availability in all markets
 - 9. Ensure affordability for all EU citizens



More info:

Annex A of the 2nd Progress Report:

http://ec.europa.eu/enterprise/phabiocom/docs/pf_20070626_progr_report.pdf

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