The state as a buyer of pharmaceutical products

Prof. Dr. Peter MIHÁLYI

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Introduction of Prof. Dr. Péter MIHÁLYI

Born in Budapest (1953)

Education: Karl Marx University of Economics (Budapest)

Author of 9 books and many articles.

Work experience:

1983-1993: United Nations Economic Commission for Europe (Geneva, Switzerland)

1994-95: Deputy Government Commissioner for Privatization

1997-98: Deputy Minister of Finance

1998 - to date: University professor

May, 2006 – December, 2007 Head of the Health Reform Committee of the Hungarian Government

January, 2008 – May, 2008: Special adviser to the Minister of Health

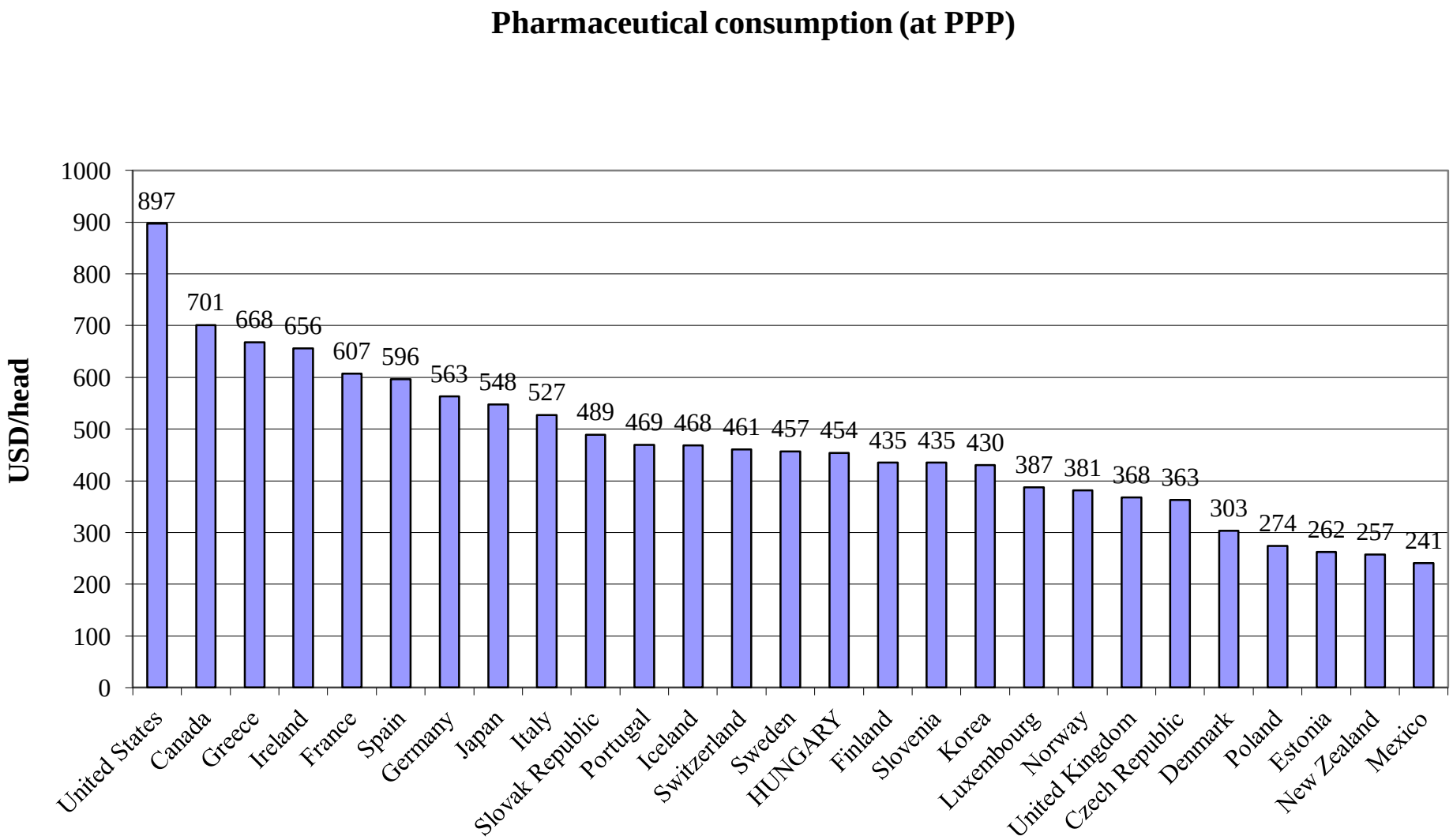
I.

General introduction

Pharmaceuticals (drugs) are major inputs of the health care system

- at least 50% of health improvements are due to new drugs
- major financial-economic interest group within the health industry

- Thousand years of tradition, but industrial manufacturing started in the mid-19th century only.
- Drugs have special impacts in comparison to other health care interventions:
  - Non-invasive
  - Dosing and reversibility
  - Scope for increased labor productivity
  - High price might lead to exclusion
  - Addictivity



Date refer to 2008. Source: OECD

EU / US 'Global' Environment

USA

- Basic patent (20 years)
- Patent Term Restoration – max 5 years, 1984
- Biotech Patent, 1983
- Orphan Drug Act, 1984
- Same levels of Intellectual Property Rights (IPR) across all States
- Bayh-Dole Act + National Institutes for Health
- Economic environment (direct access to a large unified market; competitive market pricing)

EUROPE

- Basic patent (20 years)
- SPC – max 5 years, 1992
- Biotech Patent 2000-yet to be applied in some MS
- Orphan Drug Reg., 2000
- Lower IPRs in some EU MS (+ EU enlargement)
- European Framework Research Program
- Economic environment (no direct market access; price controls; parallel trade)

EU/US 'Healthcare' Environment

USA

- A less regulated health system and no monopsony
- Difference between payer and supplier of health care services
- Scientific and economic system which is flexible and ready for changes and renewals (universities, small enterprises and high-tech laboratories, integration between schools and enterprises, etc)
- Financial and fiscal incentives for scientific and technological innovation (access to credits and capital, incentives, flexibility at work, company aids, etc)

EUROPE

- National health services depending on the restrictive requirements of public budgets (welfare, Maastricht, *etc*)
- No difference between payer/buyer and regulator of health care services
- Rigid economic environment marked by fragmented legislation and policies (lack of a single economic European market)
- Limited incentives to scientific and technological innovation (financial, credit and fiscal incentives)

I. The production side

1. Biology and chemistry

3,000 human diseases, 1,000 remedy, 3,000 NCEs (New chemical entity)

- Target: 400 molecules of the human body
- In 1977, WHO published a list of 186 “essential drugs” – this is still a highly controversial issue.
- In the US, there are 10,000 FDA approved drugs on the market

2. Microeconomics

Experience good is a product or service where product characteristics such as quality or price are difficult to observe in advance, but these characteristics can be ascertained upon consumption. The concept is originally due to Philip Nelson[1], who contrasted an experience good with a *search* good.

- Experience goods pose difficulties for consumers in accurately making consumption choices. In service areas such as healthcare, they reward reputation and create inertia. Experience goods typically have lower price elasticity than search goods, as consumers fear that lower prices may be due to unobservable problems or quality issues.
- Post-experience goods, also called credence goods, are goods for which it is difficult for consumers to ascertain the quality even after they have consumed them (e.g. vitamin supplements).
-

[1] Philip Nelson, "Information and Consumer Behavior", 78(2) *Journal of Political Economy,* 311-329 (1970).

2.1 Regulation is needed

→ Drugs require government authorization (e.g. FDA).

The sad experience: the Contergan-story (1958-61), 12,000 babies were born with serious deformation.

2.2 New area of government/civil society interventions

90% of health research dollars are spent on the health problems of 10% of the world's population

- research on major diseases of the developing world under-funded, not profitable

Example: 13 major pharmaceutical companies, government groups and health charities will work together with the Bill & Melinda Gates Foundation in a push to eliminate or control by 2020 10 tropical diseases that affect more than 1 bn people in poor countries.

2.3 State induced monopoly. Why?

In economics, a monopoly (from Greek monos / μονος (alone or single) + polein / πωλειν (to sell)) exists when a specific individual or an enterprise has sufficient control over a particular product or service to determine significantly the terms on which other individuals shall have access to it.

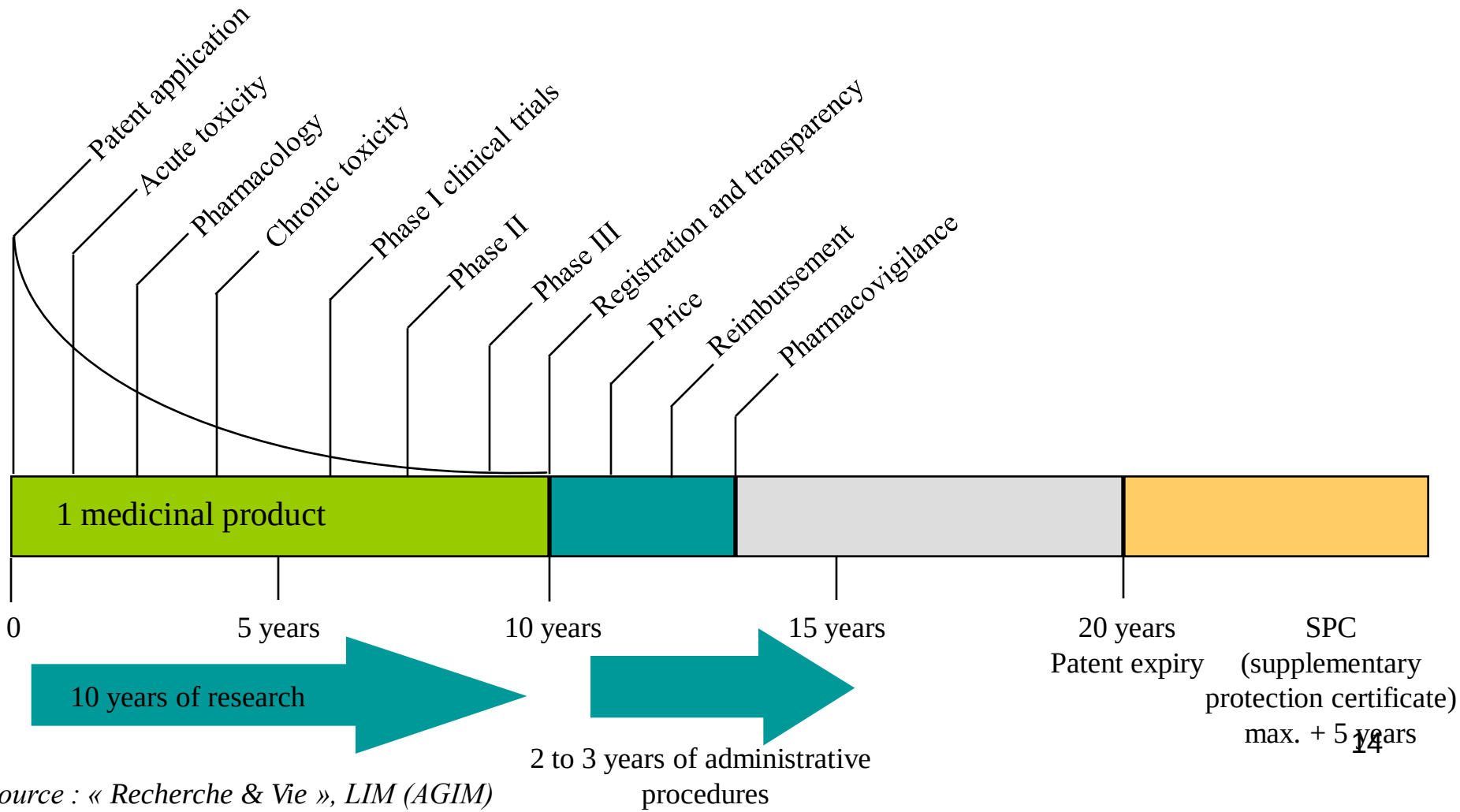
Monopolies are thus characterized by a lack of economic competition to produce the good or service and a lack of viable substitute goods. The verb "monopolise" refers to the process by which a firm gains persistently greater market share than what is expected under perfect competition.

2.2 State induced monopoly (cont.)

Intellectual property (IP) is a term referring to a number of distinct types of creations of the mind for which a set of exclusive rights are recognized—and the corresponding fields of law.

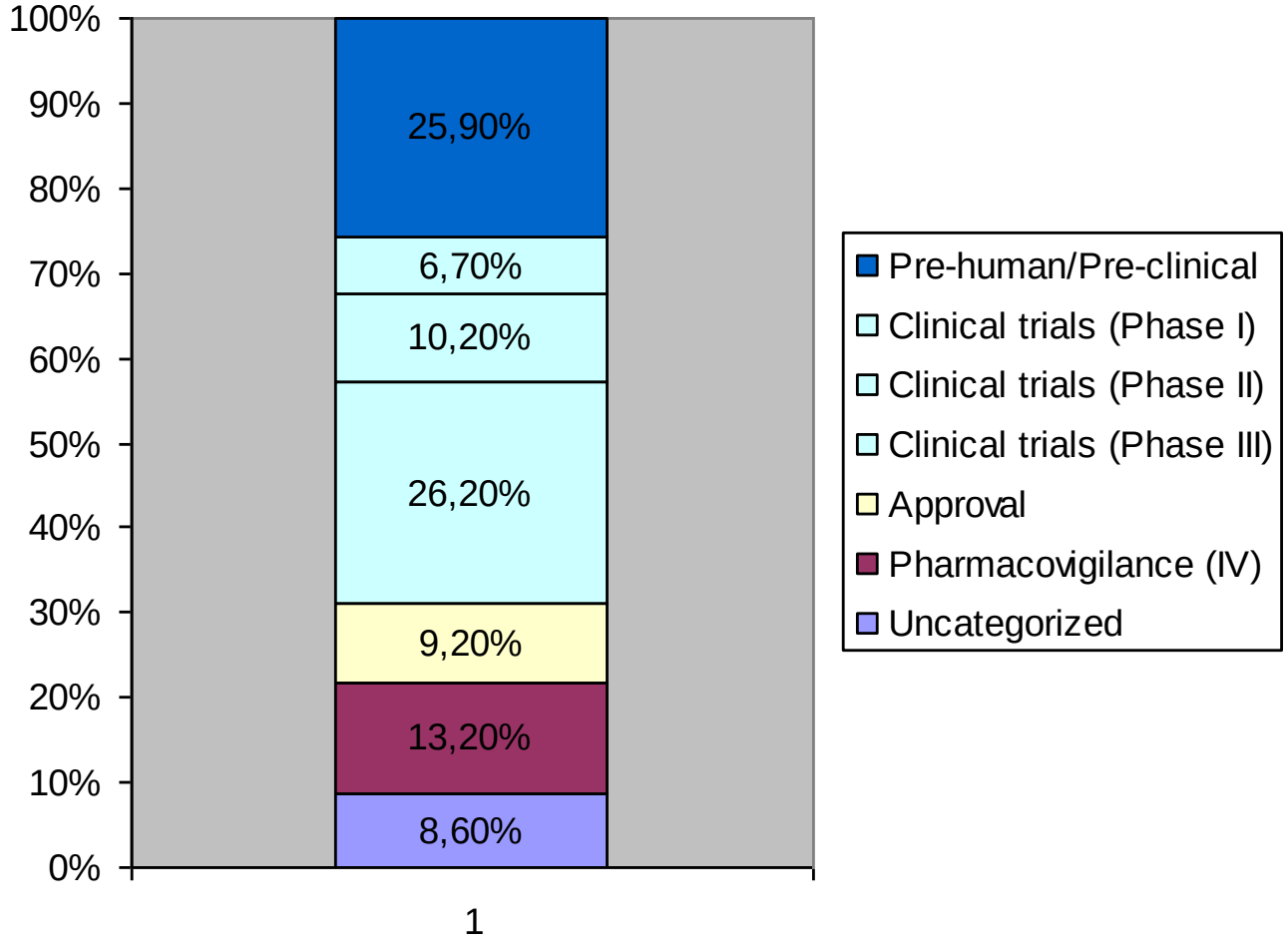
Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works; discoveries and inventions; and words, phrases, symbols, and designs. Common types of intellectual property include copyrights, trademarks, patents, industrial design rights and trade secrets in some jurisdictions.

ROUTE OF A NEW SUBSTANCE FROM DISCOVERY TO PATIENT'S ACCESS



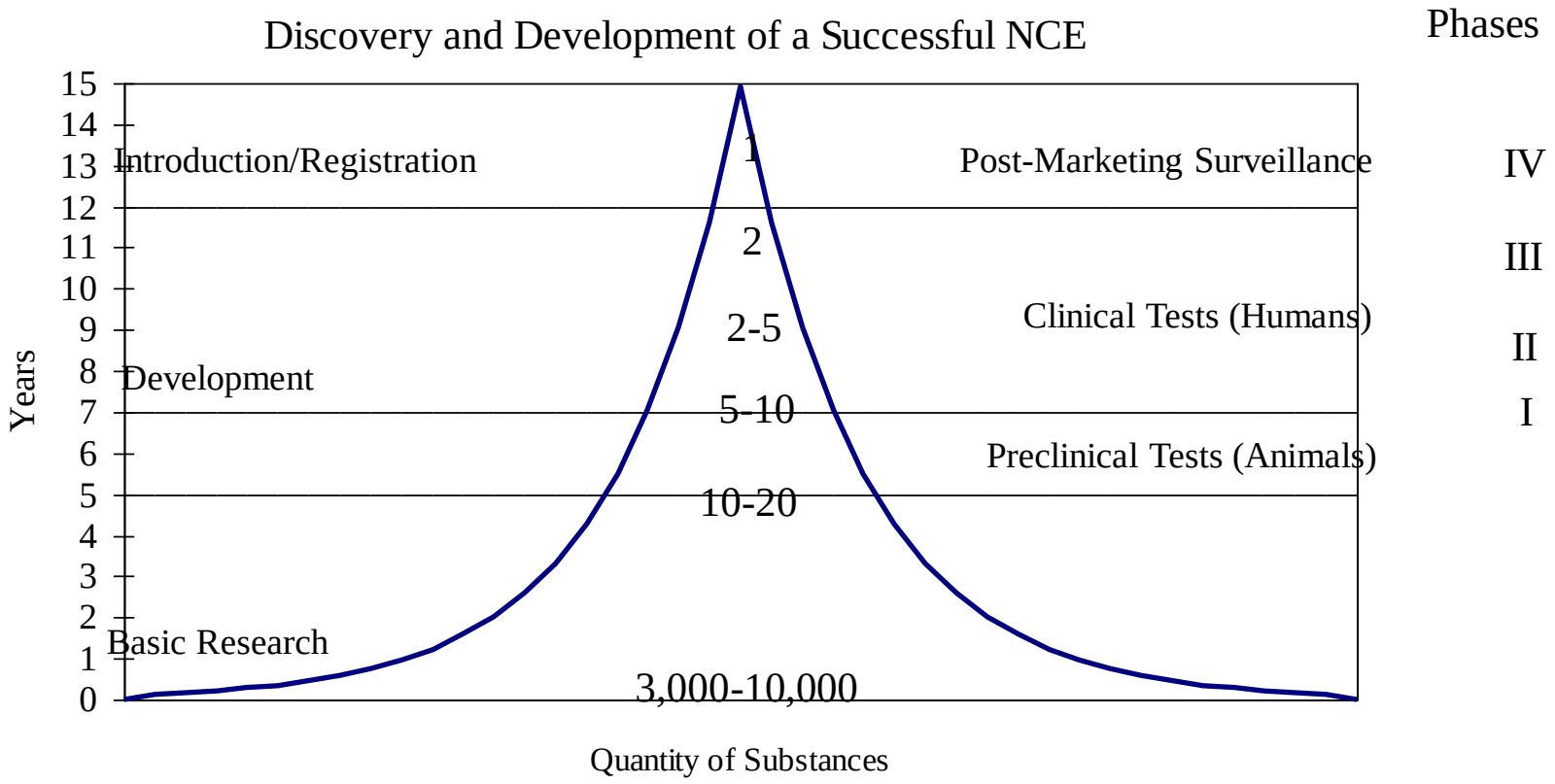
Source : « Recherche & Vie », LIM (AGIM)

Allocation of R&D investments by function



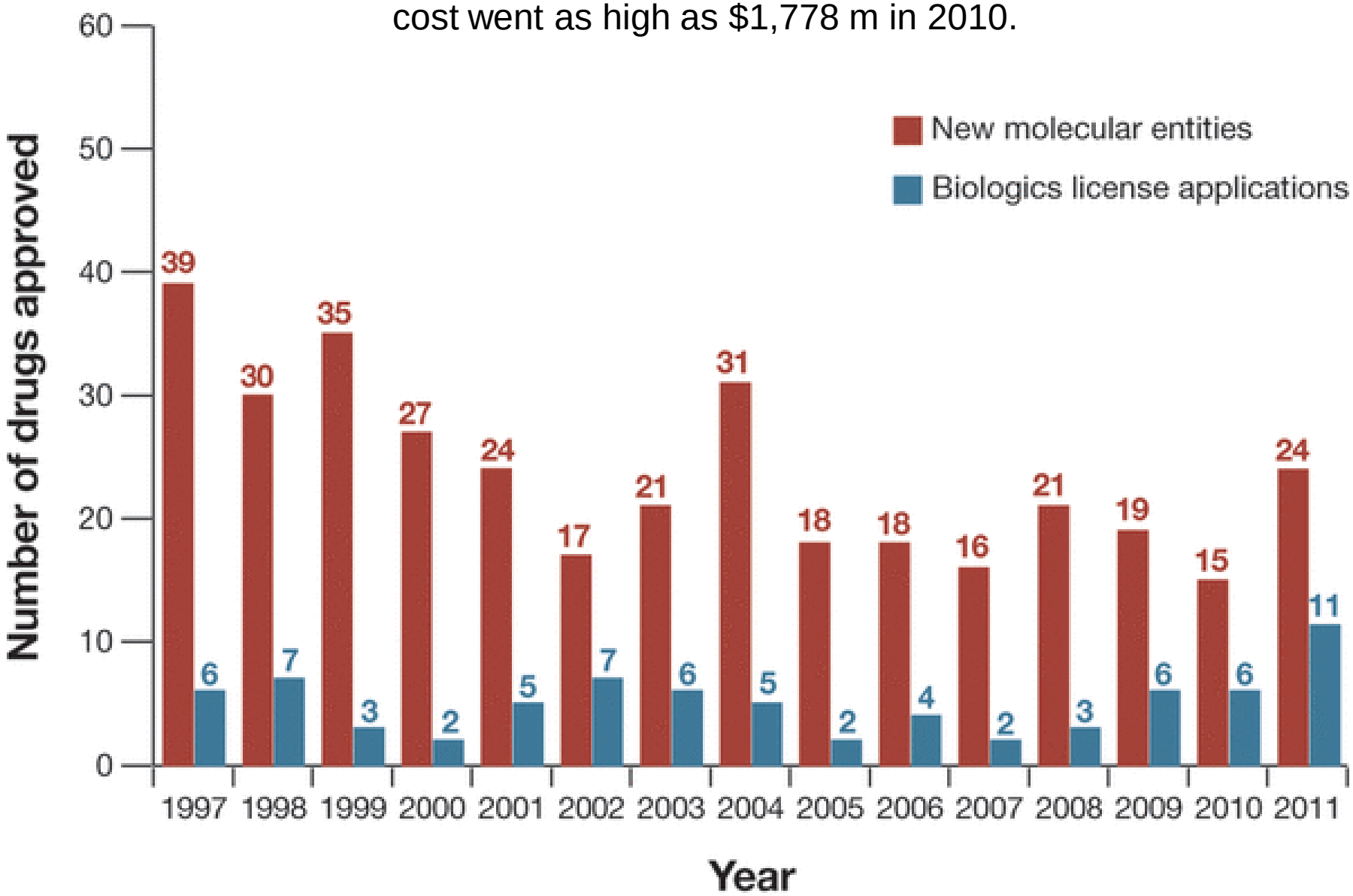
Source: P*h*RMA, Annual Membership Survey 2006 (percentages calculated from 2004 data)

R&D: Scientific Risk



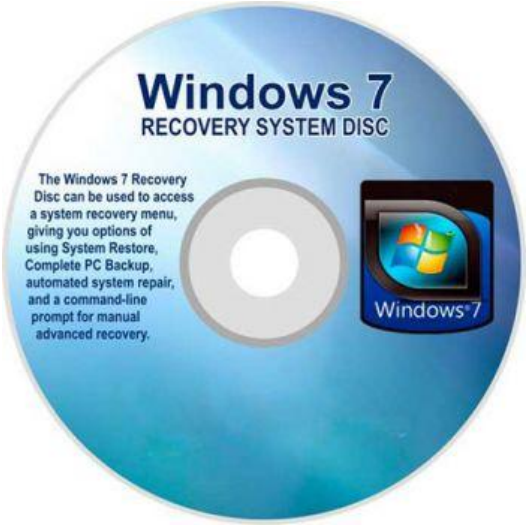
Source: Based on PhRMA analysis, updated for data per Tufts Center for the Study of Drug Development (CSDD) database.

While it cost $842 m to launch a drug in 1999, the cost went as high as $1,778 m in 2010.



Nature Biotechnology 30, 128–131 (2012)

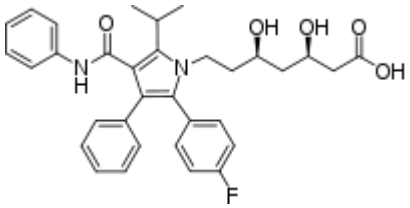
The explanation: The cost of reproduction



The return on a succesful investments

During the 14 ½ years of patent protection*, the block buster anticholesterin drug Lipitor (Pfizer) earned USD 125 bn for the company.

Atorvastatin was first synthesized in 1985, by Bruce Roth while working at Parke-Davis Warner-Lambert Company (now Pfizer).



* Expired in November 2011.

$C_{33}H_{35}FN_2O_5$

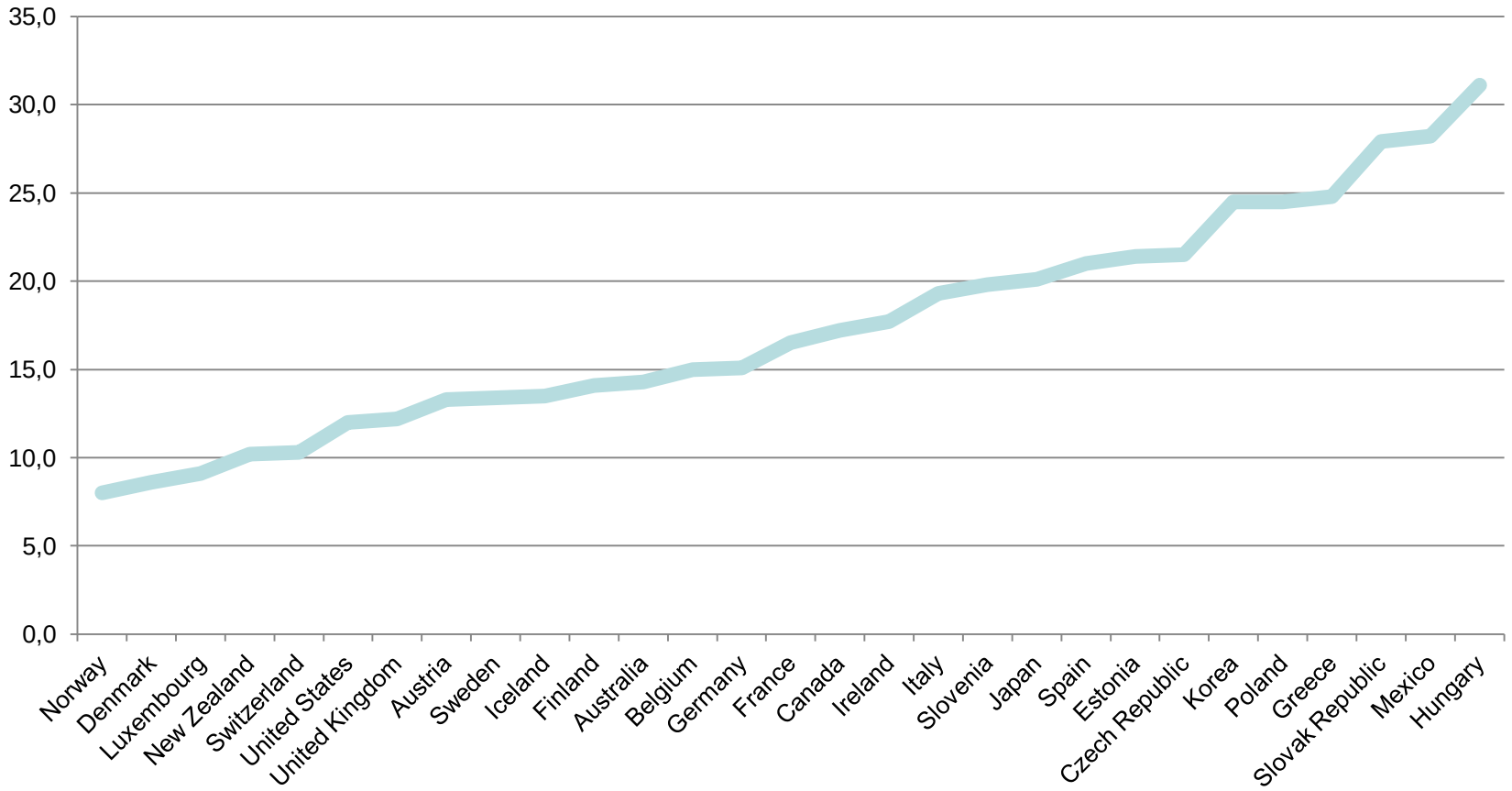
II. The state as a buyer

1) This is part of the „third party payment" mechanism

2) Interesting contradiction: 12 % of U.S. medical costs are spent on drugs. This is not much, and there is no trend growth. U.S. is the only large industrialized country which does not regulate drug prices

Year	Percentage
1960	16,1
1970	12,1
1980	8,8
1990	8,9
2000	11,3
2008	11,9

Total expenditure on pharmaceuticals and other medical non-durables, % total expenditure on health (TEH), 2007



Source: OECD

Who pays for the drugs in the US?

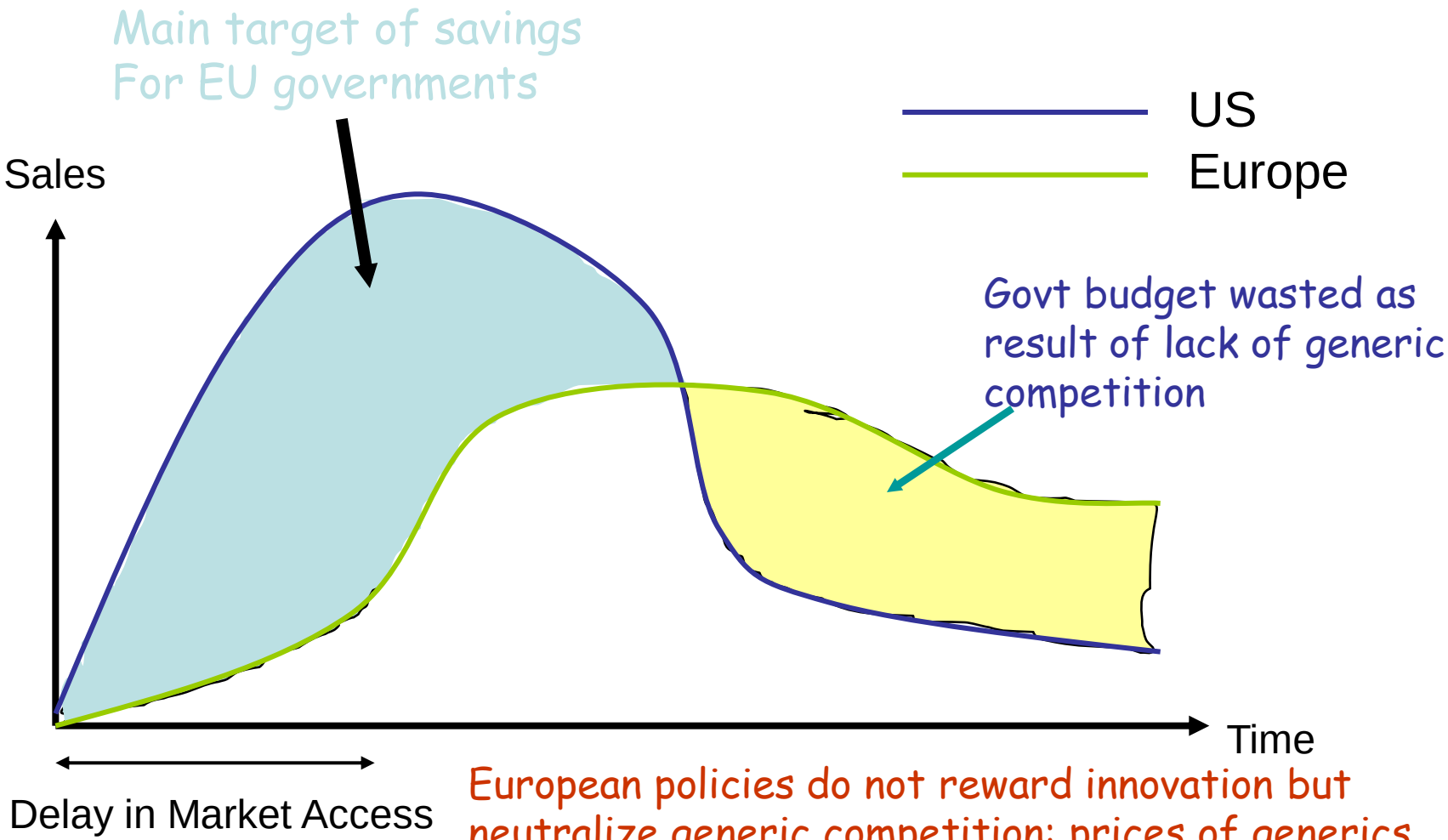
- 55% out-of-pocket
- 25% private insurance
- 17% Medicaid
- 3% Other (VA, Workman's Comp, IHS, etc..)

Generics in the US

- Increased market share among prescription drugs
  -1983 = 15%
  -1993 = 40%
  -2000 = 42%
- -2006 = 55%
- -2010 = 78%

Average cost 1/3 of comparable name-brand drug

Product life cycle in US and Europe



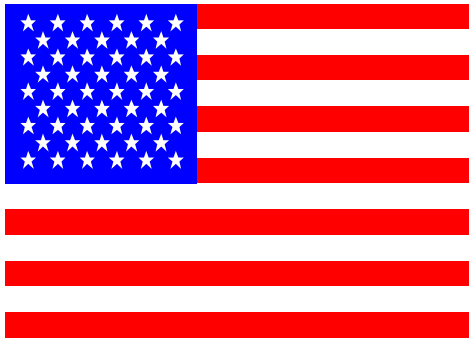
European policies do not reward innovation but neutralize generic competition: prices of generics are much lower in the US than in Europe.

Methods to control drug prices

- Evidence based medicine
- Cost-cutting techniques
- Volume control
- Cost-transfer
- Lists
- Protocols
- Generic substitution

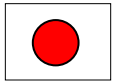
Innovation – market penetration

Geographical breakdown (by main markets) of sales of new medicines launched



57% USA

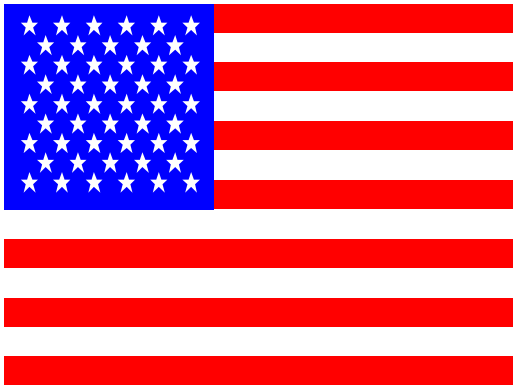
25% EUR



5% JPN

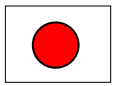
13% ROW

1995 - 2000



66% USA

24% EUR



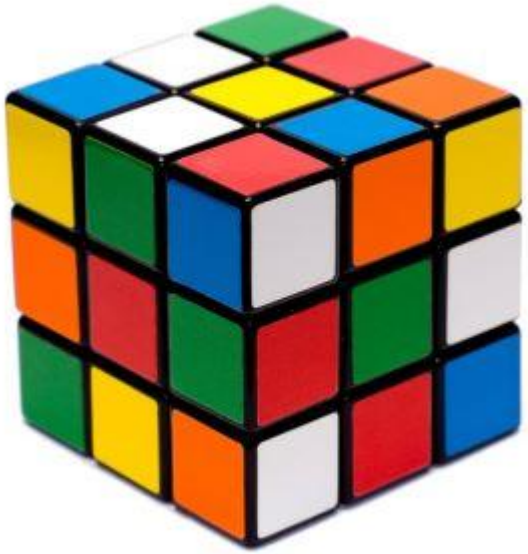
4% JPN

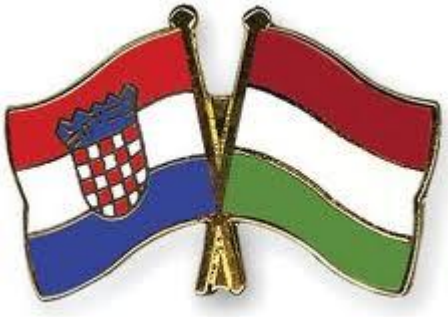
6% ROW

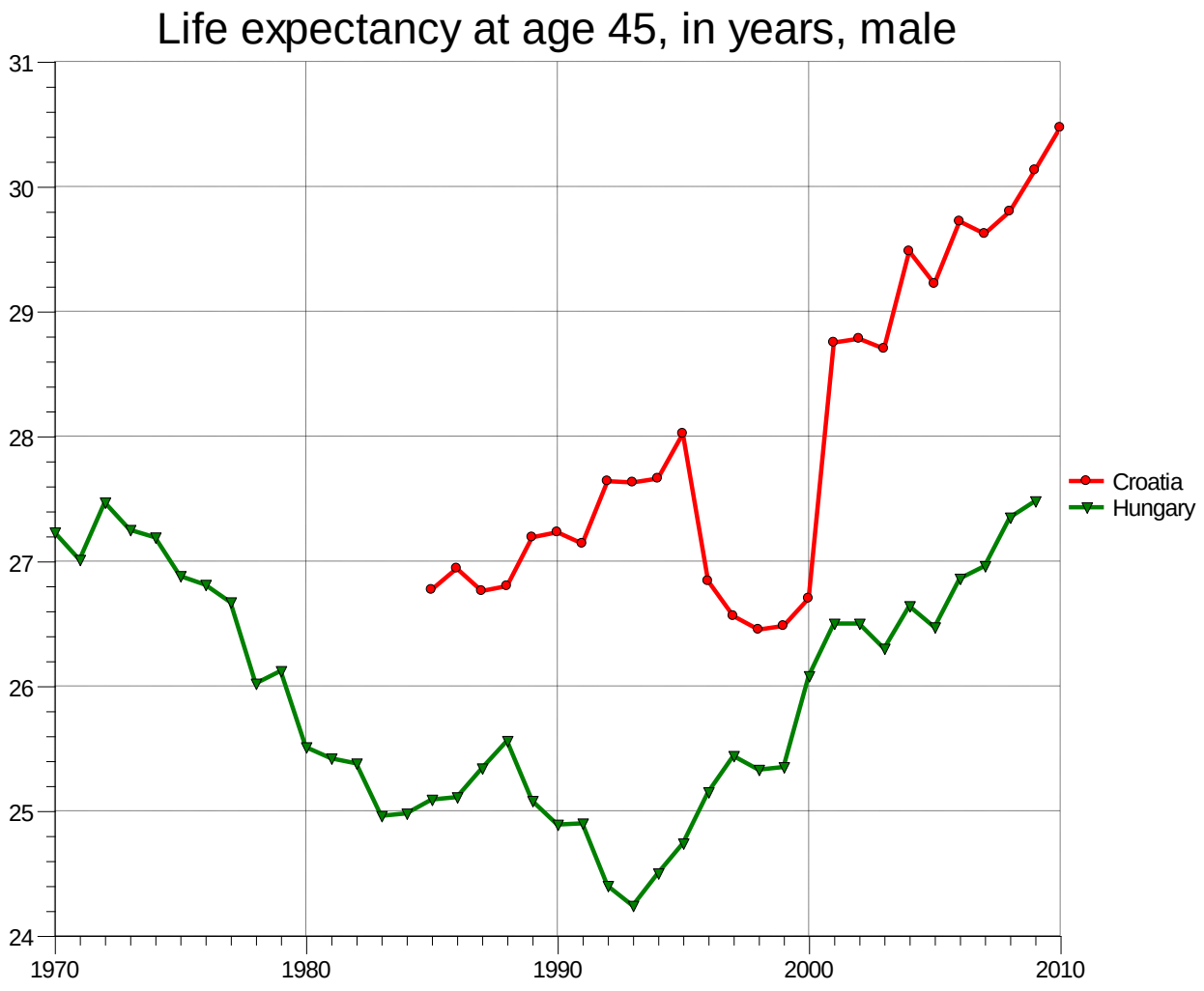
2001 - 2005

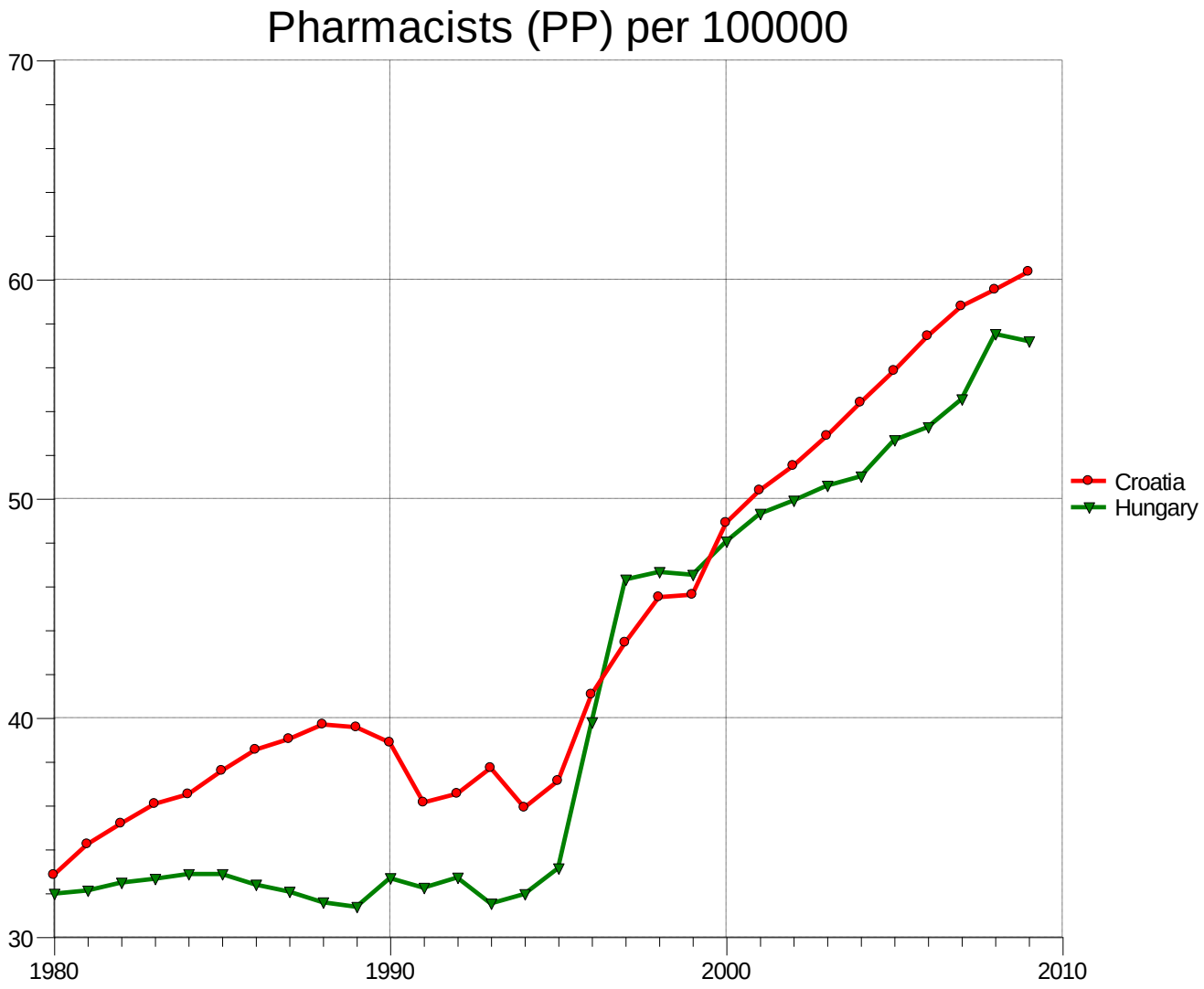
Source: IMS Health MIDAS MAT December 2005

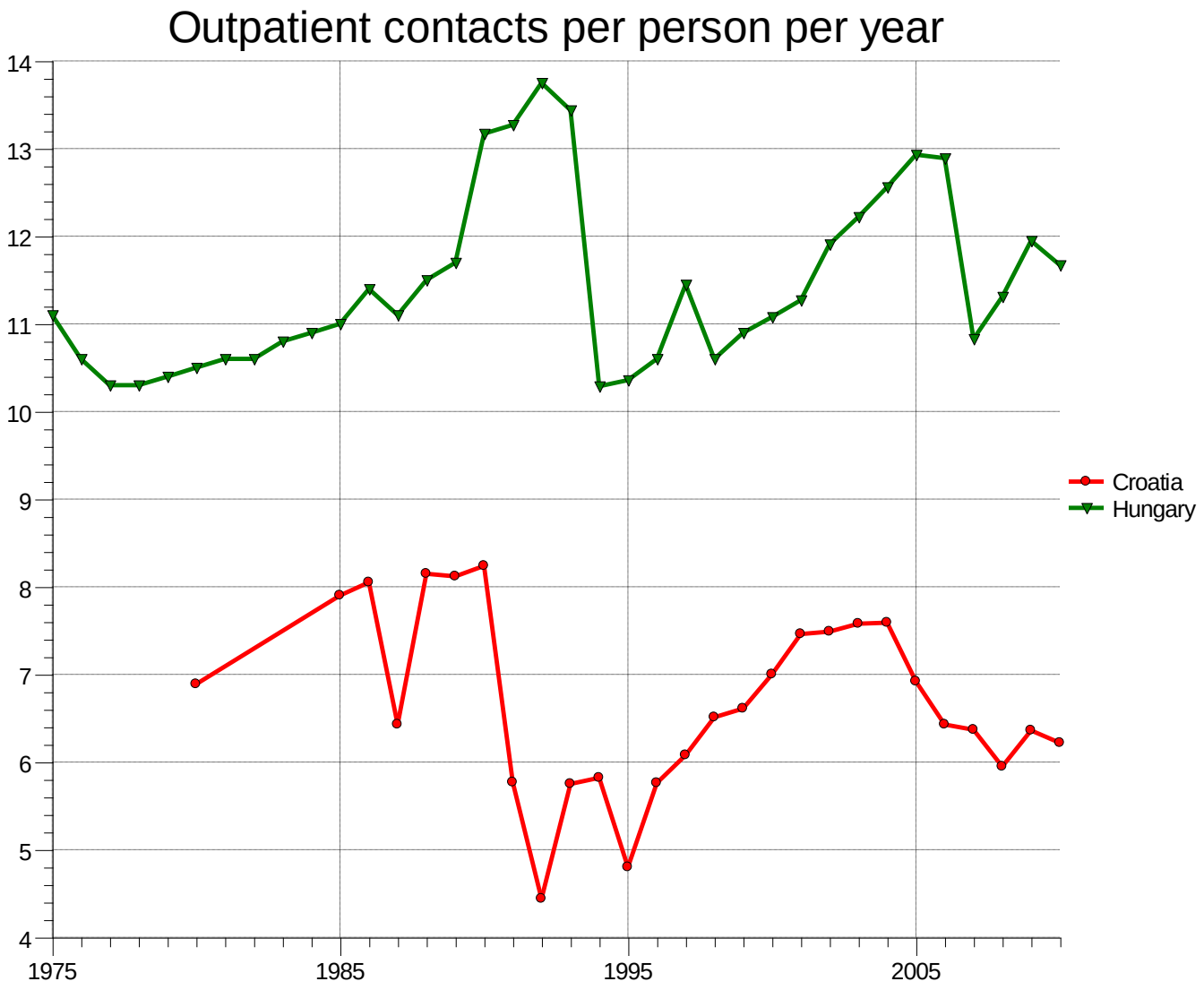
III. Hungary



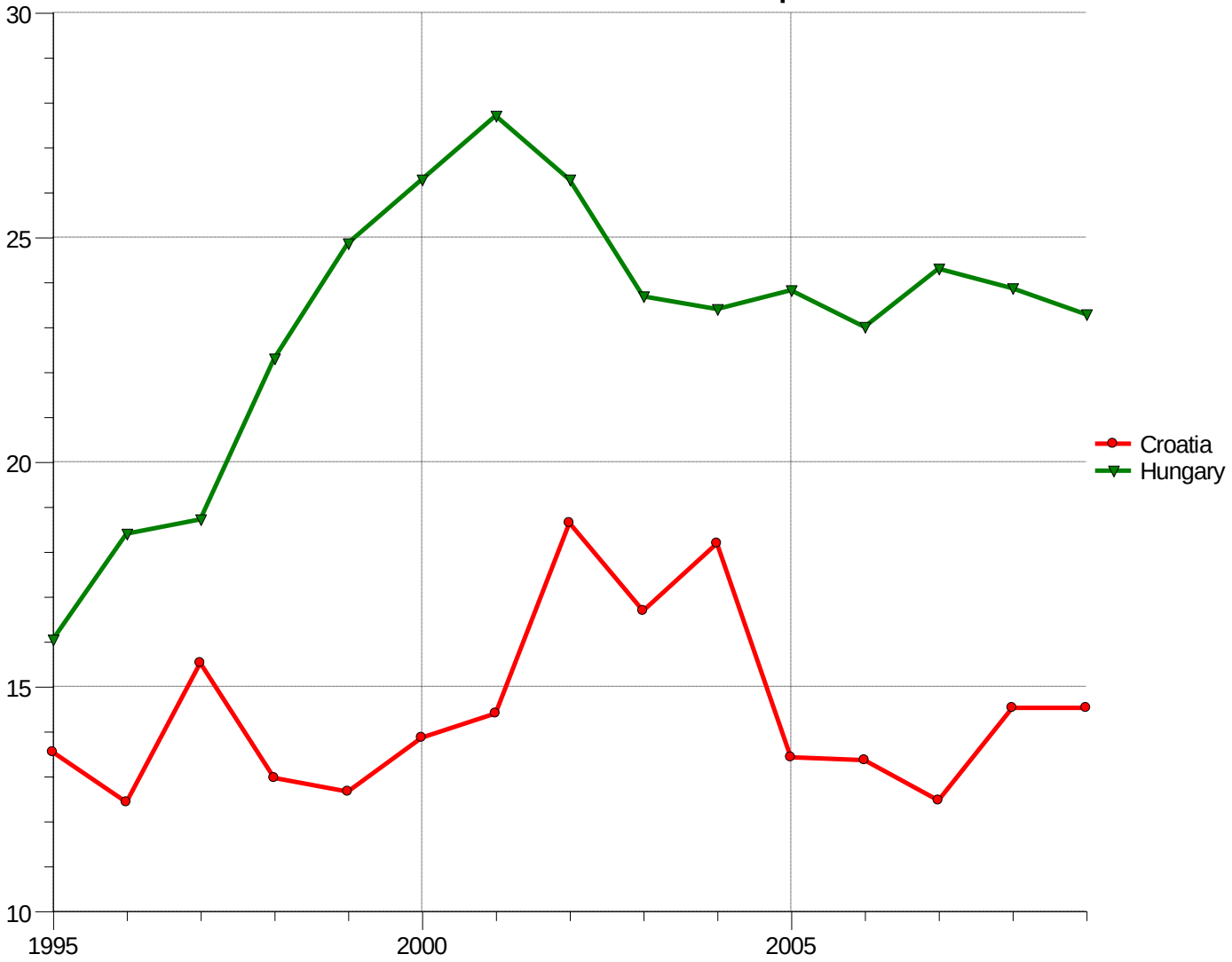



Life expectancy at age 45, in years, male
31
30
29
28
27
26
25
24
1970
1980
1990
2000
2010
Croatia
Hungary

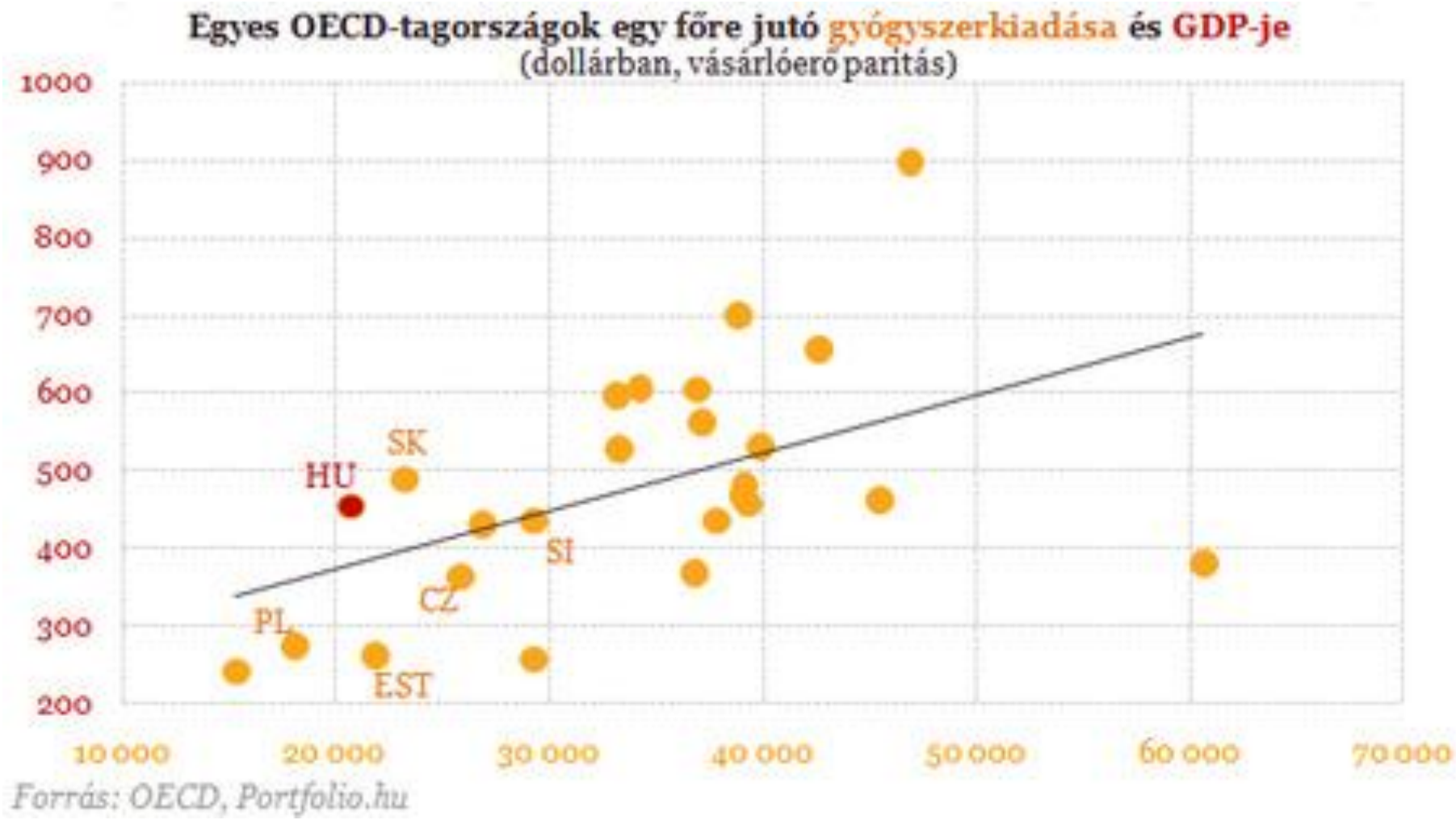

Pharmacists (PP) per 100000
70
60
50
40
30
1980
1990
2000
2010
Croatia
Hungary


Outpatient contacts per person per year
14
13
12
11
10
9
8
7
6
5
4
1975
1985
1995
2005
Croatia
Hungary

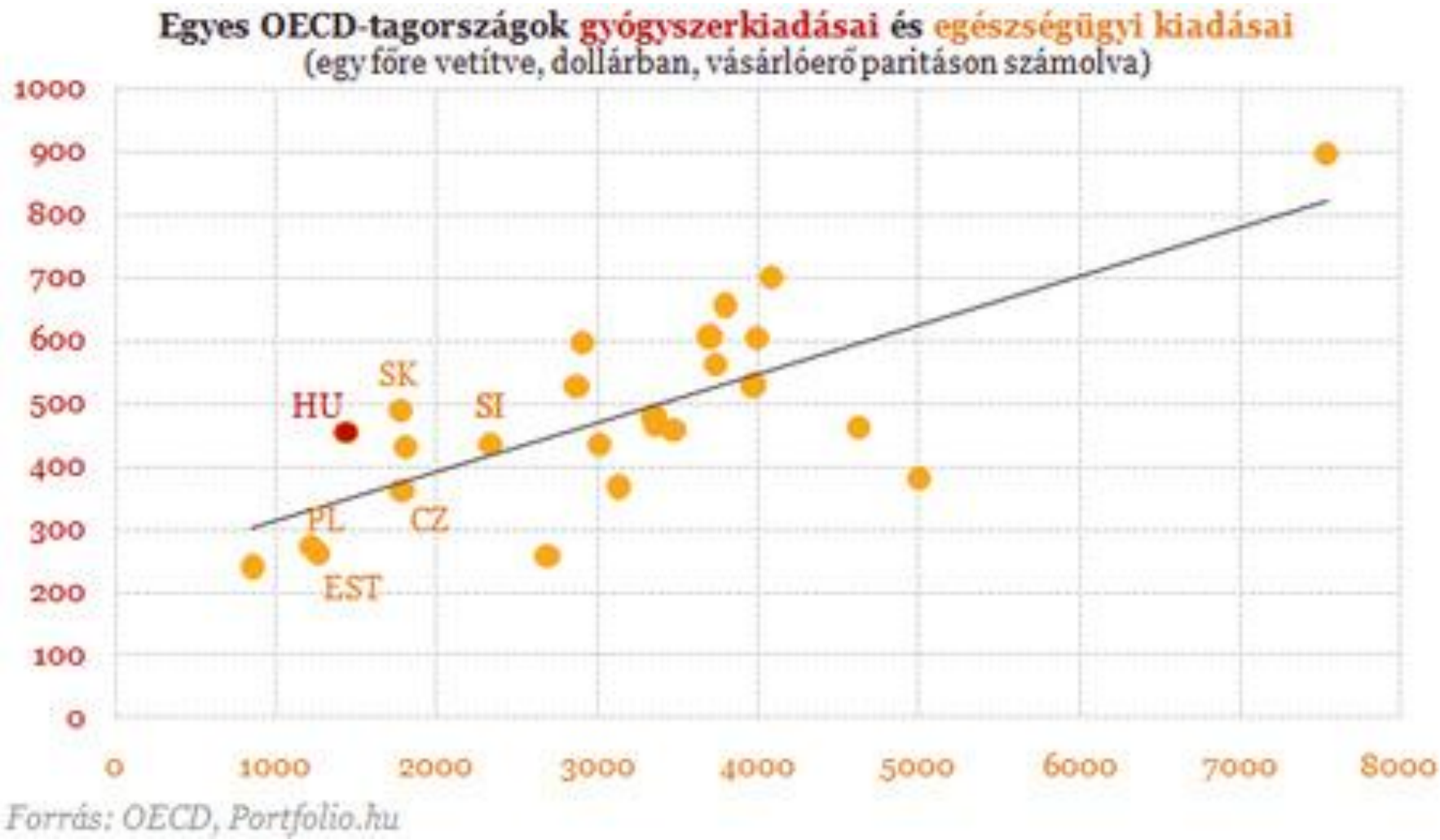
Private households' out-of-pocket payment on health as % of total health expenditure



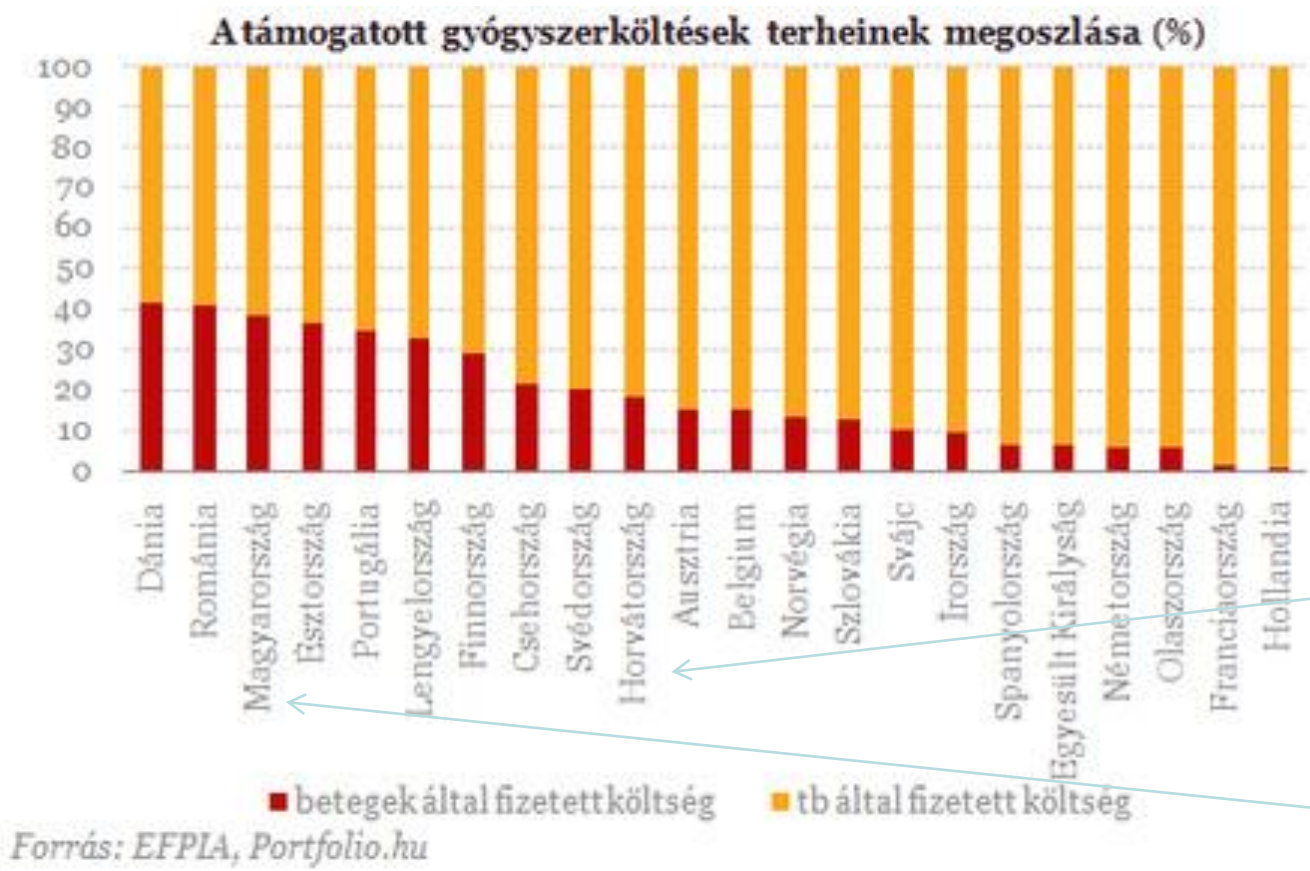
Pharmaceutical expenditures vs. GDP in international $ at PPP in 2008



Pharmaceutical expenditures vs. total health expenditures in int.$ at PPP in 2008



The burden sharing of (subsidized) prescription drugs in out-patient care (%)

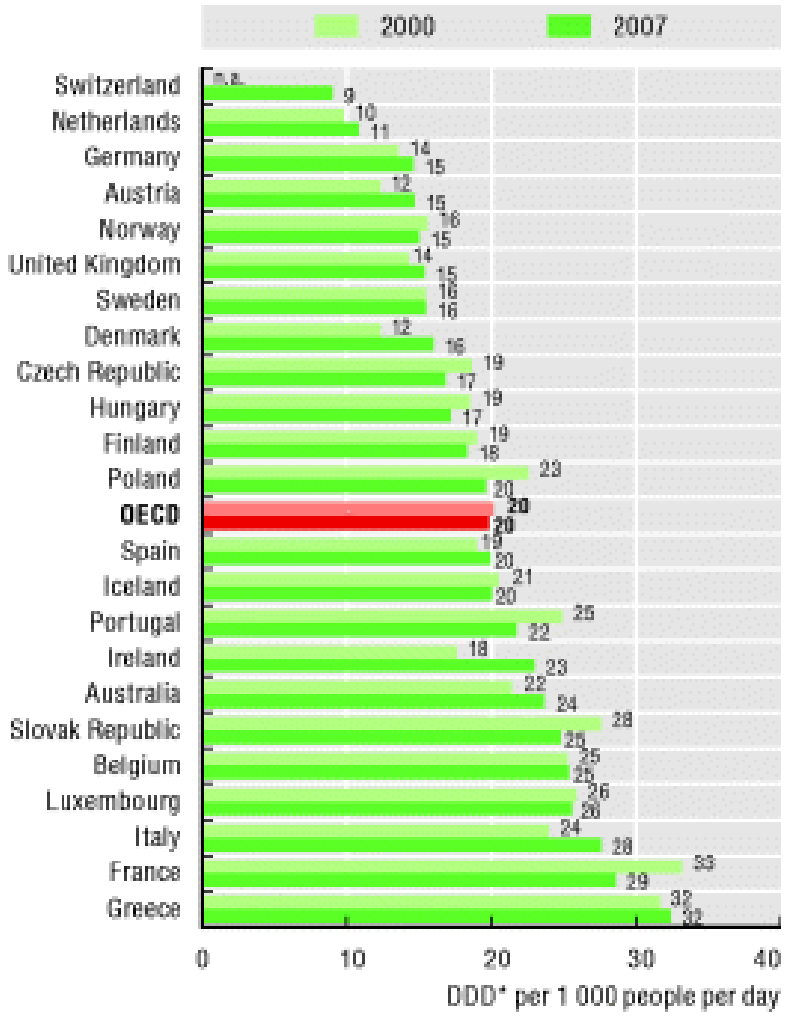


Costs paid by the patient and by the social security (or state)

Croatia

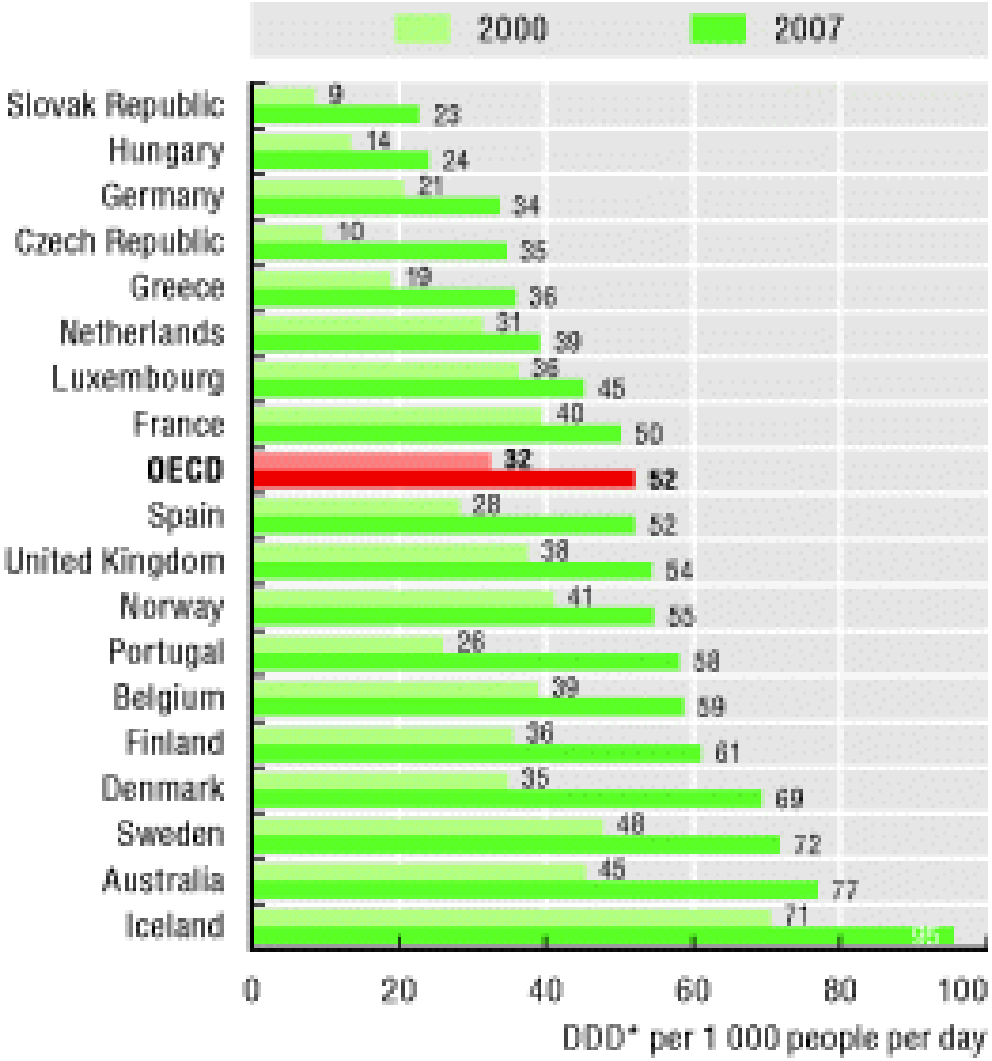
Hungary

Structure of drug consumption



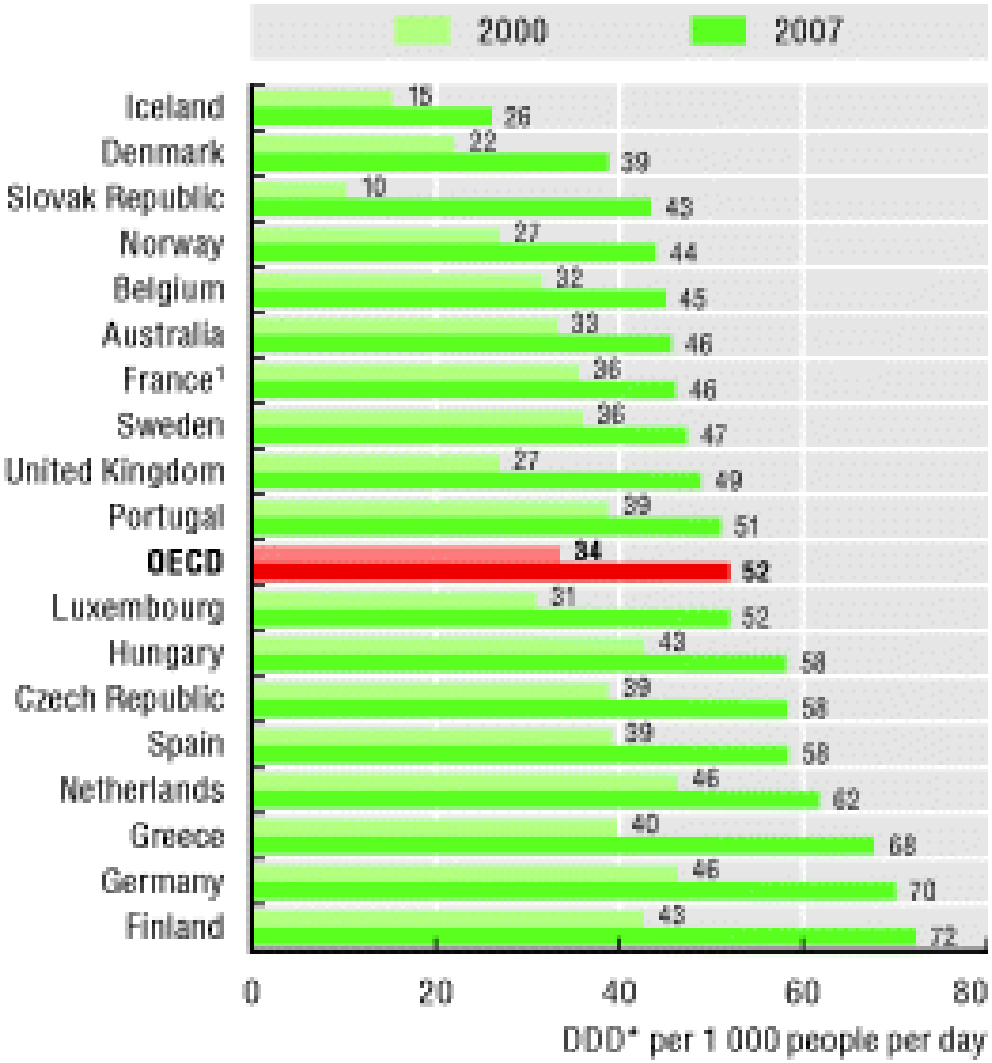
Antibiotics consumption, DDD per 1 000 people per day, 2000 and 2007 (or nearest year)

Structure of drug consumption (cont.)



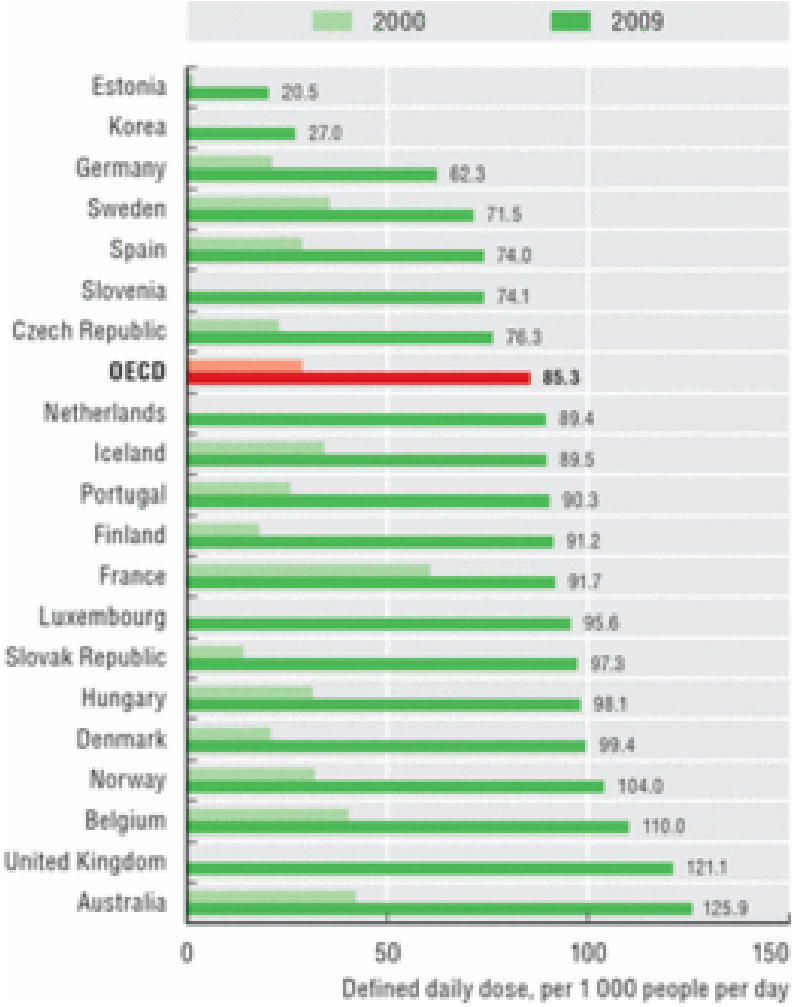
Antidepressants consumption, DDD per 1 000 people per day, 2000 and 2007 (or nearest year)

Structure of drug consumption (cont.)

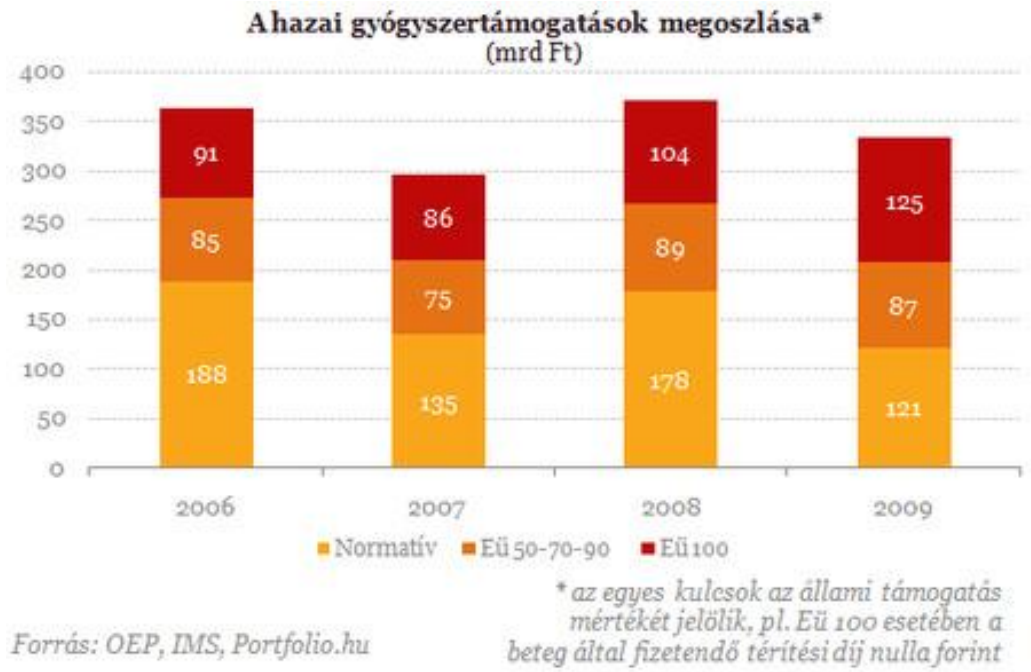


Antidiabetics consumption, DDD per 1 000 people per day, 2000 and 2007 (or nearest year)

Structure of drug consumption (cont.)



Anticholesterols consumption, 2000 and 2009 (or neare st year)

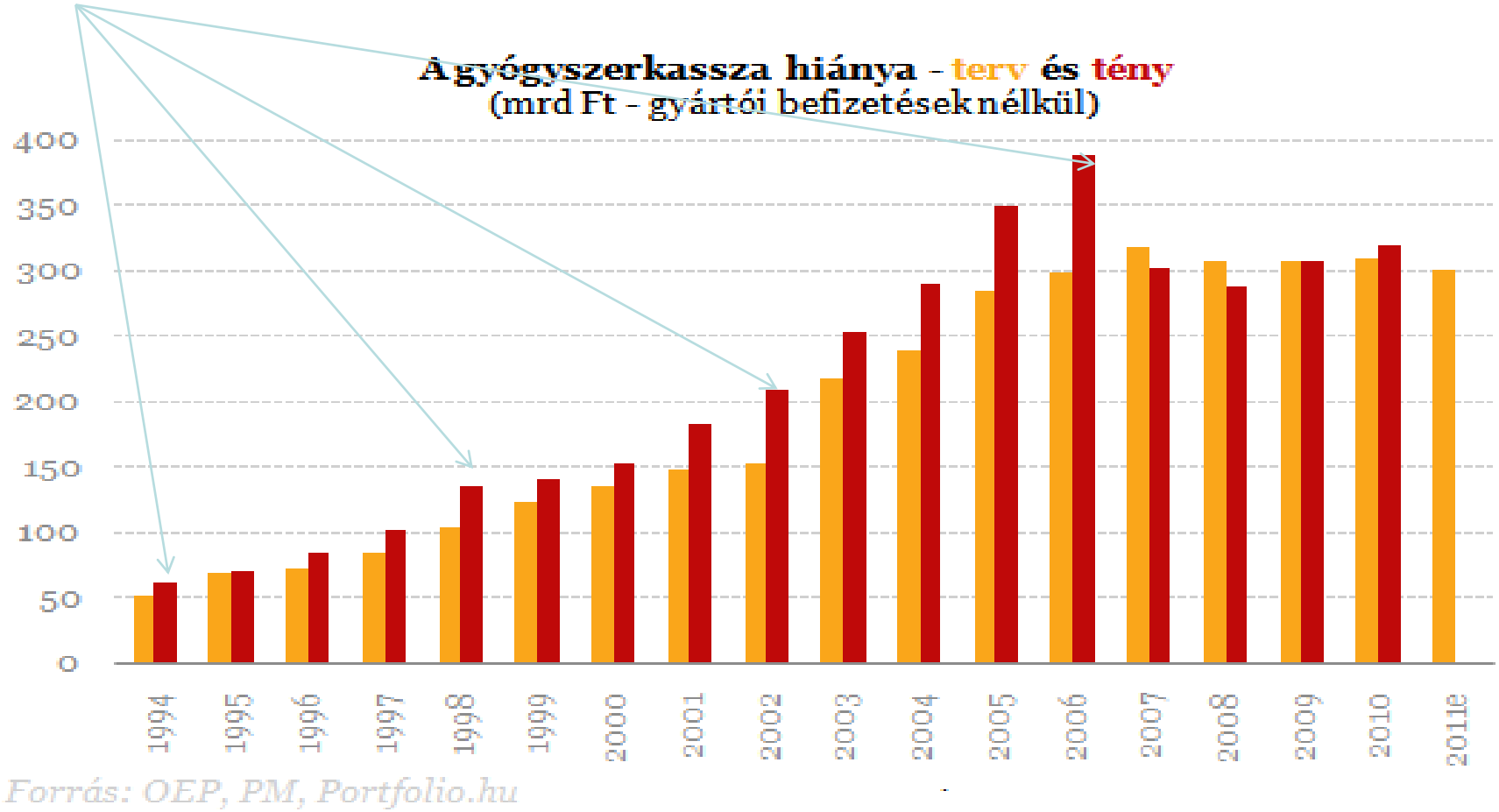


The structure of subsidies in out-patient care in HUF and in percentage

It is estimated that an average Hungarian regularly consumes 7 different type of chemical compounds.

The election cycles in Hungary

The deficit of the state pharmaceutical budget line in Hungary – planned vs. factual, in HUF bn



New period started after 2006, but further cuts are needed…

Measures applied after the 2006 Act:

- Producers + importers were required to offer price cuts in contracts with the Health Insurance Fund (HIF).
- If sales surpass the figure determined by the Fund's budget - producers have to share the costs of this overrun.
- Open bidding through the internet.
- A HUF 5mn license fee is required for sales people.
- New measures to support generics, including a downloadable software to help doctors in selecting the least costly therapy.
- Prescriptions are verified in each and every Hungarian pharmacy via on-line connection to a central data base.
- Patient pay a minimum HUF 300/box, even if the drug is 100% subsidized.
- Physicians, GPs in particular, are counter-incentivised against the prescription of expensive medicaments.

Liberalization of retail trade

1) The existing protective rules which prevent the opening of new retail outlets were abolished.
2) Non-prescription drugs are allowed to be sold outside of pharmacies. The list of 280 OTC medicines included pain killers, anti-fungal creams, medical disinfectants, anti-inflammation drugs, antihistamines, antacids, vitamins, some salves, eye drops and nasal sprays.

From October 2011

1) Blind bidding. On the first occasion bidders were invited in 165 chemical components (2011 different drugs!!!). Prices fell in 154 cases.
2) Assuming that the average male patient needs 7 types of drugs, the monthly cost fell from HUF 9808 to 4165.
3) Threat to punish the „irregular" patients.

From January - April 2012

1. Alternative prices are provided with the invoice in all pharmacies.
2. Anti-cholesterols cannot be prescribed by name.

New plans for the 2nd half of 2012 and 2013

Alternatives considered:

1) Increase of the HUF 300 box-price for 100% subsidized drugs
2) % point decrease in the lower subsidy categories (75%, 50%, 25%). The 25% category might be abolished.
3) VAT rise for OTC products.
4) Spanish model for generics. The prices of 10 year old original drugs without generic substitution will be cut by 38% (or 32% or 25%).


Thank You!