

The background of the slide is the European Union flag, featuring a blue field with twelve gold stars arranged in a circle. The stars are slightly offset from their regular positions, giving the impression of a dynamic or fragmented arrangement.

# **MARKET FRAGMENTATION AND ITS IMPACT ON R&D**

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June, 4th 2007 | Madrid

# THE BROAD PICTURE (1)

- Markets for health care services are much more complex than markets in other highly regulated industries, such as public utilities.
- Unlike most publicly regulated goods and services, consumers often do not know, and can not ascertain themselves, the quality of health care service, and may not even be able to observe whether a suggested treatment quality was actually provided or not (Credence goods: Darby and Karni, 1973; Dulleck and Kerschbamer, 2006).
- Depending on market and institutional settings, information problems in the provision of health care services could lead either to undertreatment or to overtreatment (and overcharging).
  
- Traditionally, the provision of health services has been mainly a domestic activity, while the pharmaceutical industry has been highly internationalized.
- However, technological change, trade liberalization and patient mobility are progressively opening up service markets to foreign competition.
- Thus, offshoring and trade of professional health services has been recognized to be a prominent example of a new type of trade (Bhagwati et al., 2004; Mankiw et al. 2006; Markusen, 2005; Amiti and Wei, 2005).
- Medical services such as teleradiology (Levy and Yu, 2006) and arthroscopy (Baldwin 2006) are often cited as paradigm examples of how globalization might threaten highly educated workers both in Europe and the U.S.

# THE BROAD PICTURE (2)

- Increasing consolidation of insurers, providers, and the health industry, including pharmaceutical companies, device manufacturers, and other suppliers of health services, is transforming national health care markets..
- Above all, health care is an innovation based, R&D intensive sector. Technical change is embedded in both goods, such as drugs and medical devices, and health care services, with important consequences in terms of static and dynamic efficiency conditions (see Ahn, 2002).
- Markets for health care services have to provide incentives for both cost-reducing and quality-enhancing technological change. In other terms, the allocation of resources devoted to R&D and the direction of technical change are influenced by the way in which health care is financed.
- The demand for health care is a function of the state of technology, and hence of previous R&D undertakings (Weisbrod, 1991).
- Historically, public coverage and insurance have sustained the development of quality-improving technologies.
- Newhouse (1992) states that almost three-fourths of the increase of health care spending in the last century is attributable to technological change.
- Jones (2002) finds that technological progress may have accounted for as much as half of total spending growth over recent decades throughout the OECD.

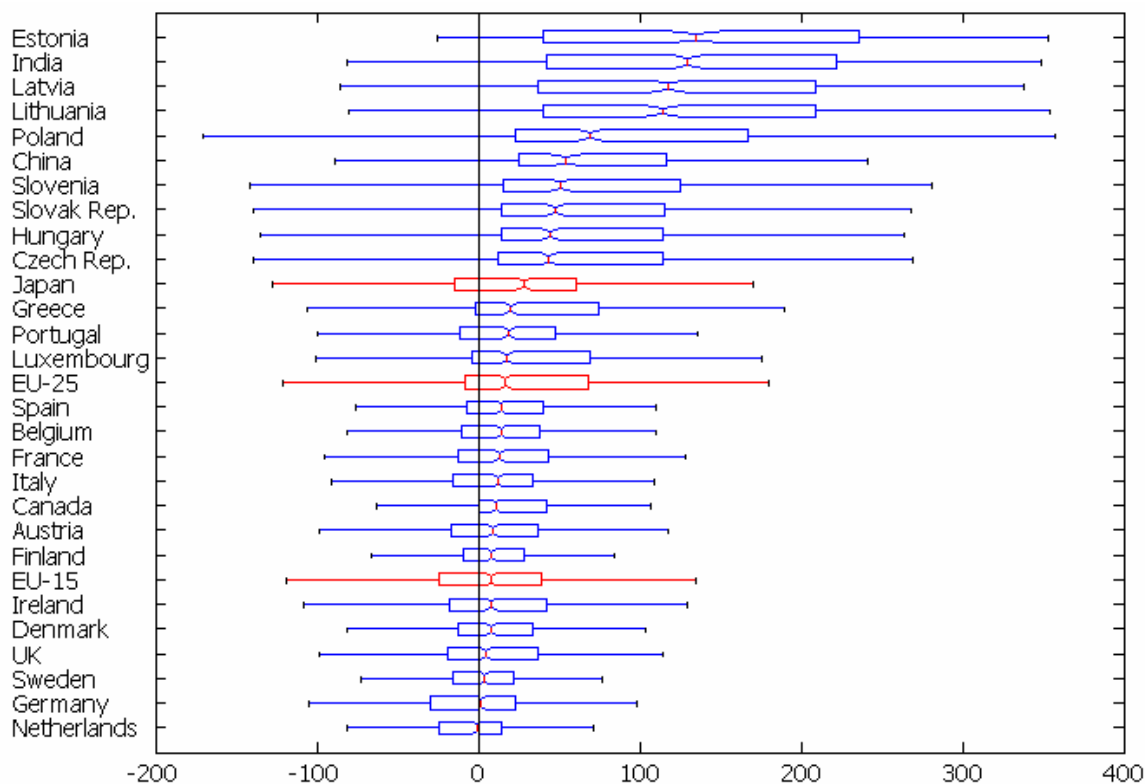
# THE BROAD PICTURE (3)

- Finally, the health care sector is heavily regulated.
- Regulation is not only meant to guarantee and improve access to better health services, but also to control health care expenditure, both on the supply side (tariffs, price controls), and the demand side (co-payment schemes, formularies, contract design) of the market.
- Historically, health policy has been under the responsibility of national state authorities.
- In almost all EU Member States health care is tax funded: healthy young workers pay for the care of sick, usually older citizens. Moreover, European countries have opted for different financial frameworks and regulation schemes to control health care costs, for both pharmaceutical products and hospitals.
- Such a fragmentation of the European institutional and regulatory framework is preventing both the European Union and Member States from taking an active and positive role in balancing and aligning different interests through managed competition (see Abbott, 1995).

# MARKET ACCESS

Differences in launch times between European countries and the US and between countries within European are consistent with price differentials, where the more strongly regulated countries were found to experience longer delay in new drug access (Danzon et al, 2003; Lanjouw, 2005; Kyle, 2006).

## Introduction lag (in months) from launch on the U.S. market of all molecules launched since 1975



Along the positive axis molecules are shown that in the country considered are launched later than in the U.S., along the negative axis those launched earlier than in the U.S.

Source: our computations on IMS Health, Copyright 2005.

To bring new compounds from the bench to the market firms must engage in expensive and risky R&D activities.

As a consequence, the profit of pharmaceutical companies and improvements in social welfare depends, to a large extent, on the success of risky R&D efforts.

The decision to sustain large sunk R&D costs critically depends upon the attrition rates of R&D projects and the expected market return from investment.

Moreover, despite there are theoretical arguments and empirical evidence that a negative relationship is in place between price regulation, dynamic competitions and innovative efforts, most health care payers in both industrialized and less developed countries are understandably concerned about monopoly power and high prices of pharmaceuticals and, in most cases, have implemented explicit price controls and limits to the extent of patent rights.

Whilst the cost of R&D is to a certain extent known, certain and rising, the probability of success and the market benefit  $\pi$  associated to R&D projects are to a large extent uncertain.

For the sake of simplicity, we can assume that each firm knows the stochastic properties of market returns and aim at maximizing the expected present value of net benefits, with a discount rate that is hold constant. In other words, a successful project has an expected discounted payoff of  $\pi$ .

If drug development is discontinued for some reason the expected payoff is  $L$ , the liquidation value of the compound if it does not hit the market. Let  $\alpha$  be the probability of success and  $C$  the sunk cost of R&D. The first-best decision rule is to invest in the project provided that:

$$\alpha\pi - C \geq L$$

which is equivalent to  $\pi \geq R/\alpha$ , where  $R = C + L$  is the total cost of R&D.

- The higher are total R&D expenditures and the probability of failure, the higher has to be the expected market returns in order to decide to undertake a given R&D project.
- Based on this simple relationship it is straightforward to notice that the market value has to be particularly high in the case of complex diseases and radically new therapeutic approaches.
- Moreover, as  $\alpha$  is decreasing and  $R$  is increasing,  $\pi$  has to increase in order to keep the same level of investment in R&D.
- Finally, it is evident that in most cases private incentives may not be sufficient to tackle orphan diseases.

At any given moment, a firm must decide whether to invest in R&D or to wait. If the current value of the project is above the critical threshold  $\pi^*=R/\alpha$ , the firm decides to invest.

The “markup”  $\pi^*-C$  reflects the value of waiting for more information. Due to the trade-off between larger versus later benefits, the optimal choice of  $\pi^*$  is that for which the additional net benefit from making  $\pi^*$  larger just balances the additional cost of discounting. Hence, some firms will undertake the most profitable R&D projects first and continue to undertake additional investment projects so long as the expected rate of return from the next project exceeds the firm’s marginal cost of capital

On the contrary, some firms will prefer to wait to license in compounds in a later stage of development and/or to engage in some form of “me-too” competition.

During the regime of patent protection firms that successfully launched an innovative product benefit from an exclusive market position to charge higher prices

Typically, drug patents provide strong protection against competition because analogous compounds must undergo all clinical trials requested by the competent national authorities from the very beginning.

After patent expiry the price of drugs drastically drops due to the entry of generic drugs and Bertrand competition (Pammolli et al. 2002, Magazzini et al. 2004).

The actual extension of the regime of higher prices is unknown ex-ante and depends on regulatory interventions in single national markets (patent-term extension or reduction), international free-ridership, parallel trade and potential competitors, each of which is trying to develop its own patent.

The success of a competitor might cause  $\pi$  to fall by some random amount. Over time, additional competitors may succeed in entering the market and governmental agencies should restrict the extent of patent rights, so that  $\pi$  continues to fall.

As a result, the expected value of a “sunk” cost investment can be obtained by summing up expected product revenues in the exclusive and competitive regimes.

Moreover, governmental agencies can implement explicit price control. Arguably, production and marketing costs ( $A$ ) as well as the elasticity of the demand ( $\varepsilon$ ) are not directly affected by regulation. Hence, the expected market returns  $\pi$  can be decomposed into two components corresponding to different market regimes:

$$\pi = \lambda(1 - \delta)\overline{M} + (1 - \lambda)(1 - \delta)\underline{M} + \delta M^R - A$$

where  $\lambda$  is the proportion of the final market in which firms are granted market power (for a given period) by patent protection,  $\delta$  is the proportion of the final market subject to price regulation,  $\overline{M} > M^R > \underline{M}$  are the share of market payoffs under different regimes, and  $A$  is the total marketing and production cost.

In the US case  $\delta$  is almost 0 so market competition regimes are split in two: quasi-monopolistic pricing / high profits pre-patent expiry and Bertrand competition / low profits after patent expiry.

On the contrary in Europe  $\delta$  is almost 1. Stronger patent protection regime and looser price regulation in absence of parallel trade and spillovers among markets regimes shall lead to higher expected market returns as the company can sustain higher prices in a larger share of the final market and for a longer time period.

As a consequence, both price and patent regulation contributes to lower incentives to sustain sunk cost investments in R&D which could speed up the passage to the threshold ( $\pi^*$ ). Companies are likely to take into account the effect of regulation in their future investment decisions.

Pharmaceutical firms would either reduce or postpone “sunk” R&D investments. Moreover, in presence of international reference price scheme (such as the European mean price) it can be easily demonstrated that it is rational to delay product launches in countries with a regulated market regime MR characterized by lower prices and/or weaker patent protection after having introduced a new compound in countries that ensure an higher price.

# MARKET GROWTH

## The pharmaceutical market total sales annual growth and its sources: new products, price, volume and mix, 1994-2004

Country	Growth components	1994-2004 <sup>1</sup>	2004
<b>Japan</b>	New products	1.00%	0.61%
	Price	-2.13%	-3.07%
	Volume & mix	5.17%	6.92%
	<i>Total</i>	<i>4.01%</i>	<i>4.46%</i>
<b>France</b>	New products	1.59%	2.22%
	Price	1.78%	2.22%
	Volume & mix	1.00%	1.85%
	<i>Total</i>	<i>4.38%</i>	<i>6.29%</i>
<b>Germany</b>	New products	1.69%	1.99%
	Price	2.28%	1.69%
	Volume & mix	1.96%	-1.90%
	<i>Total</i>	<i>5.96%</i>	<i>1.78%</i>
<b>Italy</b>	New products	1.33%	1.70%
	Price	2.27%	-0.79%
	Volume & mix	2.77%	3.30%
	<i>Total</i>	<i>6.34%</i>	<i>4.22%</i>
<b>UK</b>	New products	0.59%	0.47%
	Price	0.57%	2.06%
	Volume & mix	5.67%	1.85%
	<i>Total</i>	<i>6.83%</i>	<i>4.37%</i>
<b>India</b>	New products	3.27%	3.66%
	Price	2.83%	0.68%
	Volume & mix	0.66%	2.28%
	<i>Total</i>	<i>6.93%</i>	<i>6.62%</i>
<b>Spain</b>	New products	1.76%	1.38%
	Price	2.26%	3.06%
	Volume & mix	4.95%	3.14%
	<i>Total</i>	<i>8.99%</i>	<i>7.58%</i>
<b>United States</b>	New products	2.26%	1.42%
	Price	4.81%	7.13%
	Volume & mix	5.17%	-0.47%
	<i>Total</i>	<i>12.22%</i>	<i>8.07%</i>
<b>China</b>	New products	4.19%	7.95%
	Price	-4.81%	-4.21%
	Volume & mix	13.75%	24.24%
	<i>Total</i>	<i>13.09%</i>	<i>27.98%</i>

1. Compound Annual Growth Rate (CAGR)

Source: our computations on CERM database.

# MARKET CONCENTRATION

**Average market concentration (sales and volumes) and relative prices of the first three products on the market, top 100 ATC4 classes, 1994-2004**

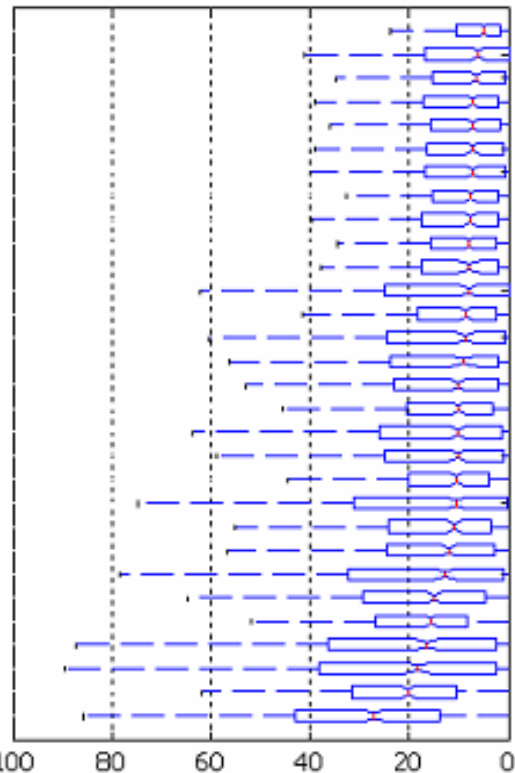
	<b>C<sub>1</sub>(S)</b>	<b>C<sub>1</sub>(Q)</b>	<b>P<sub>1</sub></b>	<b>C<sub>2</sub>(S)</b>	<b>C<sub>2</sub>(Q)</b>	<b>P<sub>2</sub></b>	<b>C<sub>3</sub>(S)</b>	<b>C<sub>3</sub>(Q)</b>	<b>P<sub>3</sub></b>
<b>EU-25</b>	41.72	34.70	1.20	64.61	56.95	1.13	77.31	71.47	1.08
<b>EU-15</b>	41.18	34.17	1.21	63.83	56.05	1.14	76.53	70.49	1.09
<b>Japan</b>	39.77	34.61	1.15	62.74	54.75	1.15	78.25	69.36	1.13
<b>United States</b>	49.72	34.63	1.44	74.96	59.48	1.26	85.56	70.74	1.21
<b>India</b>	21.98	21.80	1.01	37.06	38.10	0.97	47.21	47.96	0.98
<b>Germany</b>	29.97	22.94	1.31	47.42	38.49	1.23	58.87	50.95	1.16
<b>China</b>	36.15	19.20	1.88	56.78	32.31	1.76	67.62	39.95	1.69
<b>Italy</b>	36.68	33.49	1.10	57.57	54.07	1.06	71.49	67.14	1.06
<b>France</b>	39.01	31.21	1.25	64.88	54.45	1.19	78.18	71.16	1.10
<b>Spain</b>	40.36	32.62	1.24	62.37	52.72	1.18	75.94	67.92	1.12
<b>Canada</b>	42.03	32.68	1.29	65.71	54.51	1.21	79.35	69.12	1.15
<b>Latvia</b>	45.07	35.23	1.28	68.63	63.24	1.09	82.96	79.67	1.04
<b>Czech Rep.</b>	46.26	40.80	1.13	72.70	66.68	1.09	86.77	83.83	1.04
<b>Portugal</b>	46.73	39.65	1.18	70.41	61.34	1.15	84.32	79.63	1.06
<b>Belgium</b>	48.33	42.24	1.14	76.64	70.27	1.09	92.24	86.65	1.06
<b>Austria</b>	48.43	41.12	1.18	74.19	66.51	1.12	87.70	82.03	1.07
<b>Netherlands</b>	48.56	37.60	1.29	72.35	58.42	1.24	86.24	76.38	1.13
<b>Luxemburg</b>	49.54	39.93	1.24	76.49	68.20	1.12	89.91	83.20	1.08
<b>Slovak Rep.</b>	50.02	42.52	1.18	76.77	72.70	1.06	90.69	90.27	1.00
<b>Poland</b>	50.16	39.71	1.26	76.55	68.63	1.12	89.29	85.30	1.05
<b>Ireland</b>	51.19	43.77	1.17	77.50	72.42	1.07	91.76	87.10	1.05
<b>Lithuania</b>	51.53	44.06	1.17	77.37	72.95	1.06	90.67	88.95	1.02
<b>Finland</b>	52.30	45.58	1.15	78.95	73.26	1.08	92.65	89.54	1.03
<b>Greece</b>	52.73	43.08	1.22	78.00	69.76	1.12	88.90	83.08	1.07
<b>Denmark</b>	53.50	45.22	1.18	80.34	75.33	1.07	93.07	91.05	1.02
<b>Sweden</b>	53.68	44.70	1.20	79.70	75.51	1.06	91.60	89.95	1.02
<b>Estonia</b>	54.71	45.13	1.21	80.74	75.51	1.07	93.32	91.67	1.02
<b>Hungary</b>	54.85	52.29	1.05	84.04	82.19	1.02	96.11	95.72	1.00
<b>United Kingdom</b>	55.69	48.34	1.15	79.61	75.16	1.06	90.20	87.75	1.03
<b>Slovenia</b>	61.25	54.13	1.13	88.25	84.98	1.04	97.89	97.47	1.00

*Source: our computations on IMS Health, Copyright 2005.*

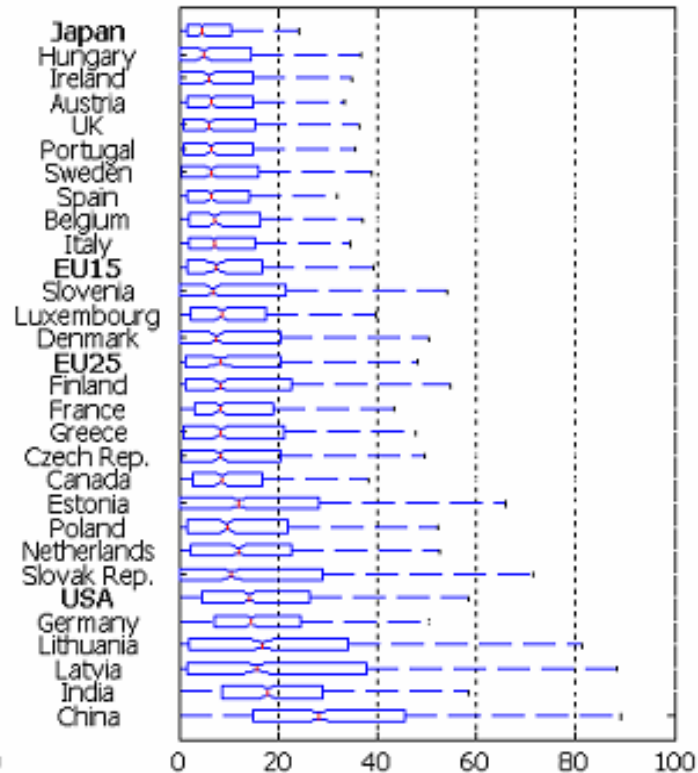
# MARKET TURNOVER

Product mobility statistics over all ATC4 therapeutic markets\*

**Turnover (sales)**



**Turnover (quantities)**



\* The product mobility index is computed as in Hymer, Pashigian (1962).

Source: our computations on IMS Health, Copyright 2005.

# MARKET CONTESTABILITY

## The persistence of the leading product in top 100 ATC4 markets

Country	Leadership change (%)										Average Persistence
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	
<b>Japan</b>	7.22	4.12	6.65	4.85	4.29	10.58	7.52	8.00	6.77	6.03	15.15
<b>Portugal</b>	6.42	6.36	7.62	9.26	7.74	4.95	5.86	9.88	8.72	9.06	13.18
<b>Spain</b>	6.50	9.97	7.20	10.37	7.33	9.74	7.95	6.98	8.55	8.53	12.03
<b>Italy</b>	7.40	9.72	8.14	9.14	7.79	7.01	9.84	7.51	9.66	7.41	11.96
<b>Sweden</b>	4.99	10.69	9.62	7.93	10.56	8.62	7.43	10.70	9.30	8.66	11.30
<b>UK</b>	10.46	8.92	8.00	8.71	10.16	8.38	9.11	9.50	8.16	7.24	11.28
<b>Ireland</b>	11.39	10.00	11.39	9.17	9.01	6.61	8.16	10.91	11.82	7.42	10.43
<b>Belgium</b>	8.36	7.24	7.56	9.58	9.78	11.36	9.86	10.31	11.52	11.08	10.35
<b>Finland</b>	7.76	9.67	9.85	9.79	10.88	9.50	7.19	11.24	11.31	12.06	10.08
<b>Austria</b>	7.32	9.38	10.09	11.31	8.92	10.54	13.84	9.53	11.78	9.82	9.75
<b>EU-15</b>	10.70	10.94	9.84	10.71	10.15	9.34	10.23	10.25	10.81	10.16	9.70
<b>EU-25</b>	10.95	11.14	10.05	10.97	10.43	9.52	10.30	10.36	10.89	10.40	9.52
<b>France</b>	9.30	10.57	9.82	12.01	10.42	10.28	10.00	11.00	12.76	11.28	9.31
<b>Luxembourg</b>	12.30	10.71	13.44	11.08	11.05	9.89	8.11	10.33	10.11	10.63	9.29
<b>Hungary</b>	14.46	14.98	13.67	12.67	10.67	9.86	5.26	9.73	7.07	10.93	9.15
<b>Netherlands</b>	9.61	10.59	11.54	10.18	14.24	10.85	11.08	10.39	9.04	12.28	9.11
<b>Denmark</b>	12.33	13.38	11.18	12.54	13.61	9.81	8.97	10.03	13.03	9.90	8.71
<b>Greece</b>	7.63	10.38	11.72	14.97	9.54	12.53	11.66	11.65	14.83	12.63	8.51
<b>Germany</b>	16.49	14.16	12.66	11.94	12.14	10.02	12.96	13.12	12.12	12.94	7.78
<b>Slovenia</b>	16.17	14.99	13.91	14.08	15.67	11.94	12.81	8.72	9.89	14.67	7.53
<b>Poland</b>	17.47	12.66	15.22	14.95	17.45	12.76	11.26	13.54	13.25	16.02	6.92
<b>Canada</b>	13.88	17.32	16.57	15.13	15.78	18.54	15.07	12.70	10.21	10.79	6.85
<b>Estonia</b>	0.00	0.00	0.00	66.67	11.59	11.55	16.52	19.46	16.77	13.69	6.40
<b>Czech Rep-</b>	18.37	18.55	15.27	15.74	18.58	15.82	13.56	11.65	16.58	13.42	6.35
<b>USA</b>	17.20	17.12	17.35	19.67	18.59	15.65	15.85	17.48	16.40	14.87	5.88
<b>China</b>	0.00	0.00	0.00	0.00	88.39	23.55	19.22	16.96	16.15	18.40	5.47
<b>Slovak</b>	22.22	21.35	18.86	26.32	21.28	14.74	13.76	13.31	14.66	18.70	5.40
<b>India</b>	0.00	0.00	86.01	21.88	17.42	19.03	19.28	16.04	17.04	15.54	4.71
<b>Lithuania</b>	0.00	73.10	28.03	25.23	22.09	19.51	28.19	16.57	17.83	19.29	4.00
<b>Latvia</b>	83.16	25.08	23.49	24.14	18.36	24.65	20.17	24.23	15.45	18.85	3.60

Source: our computations on IMS Health, Copyright 2005.

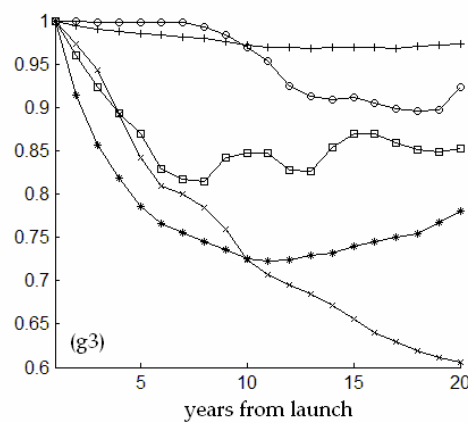
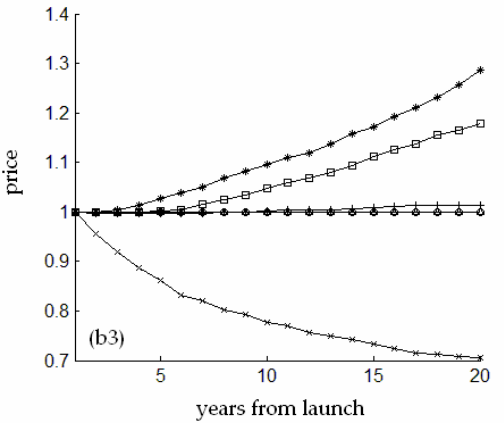
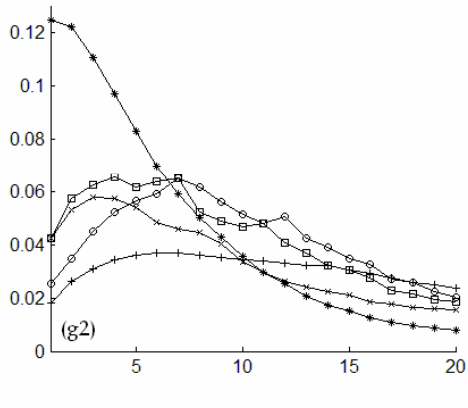
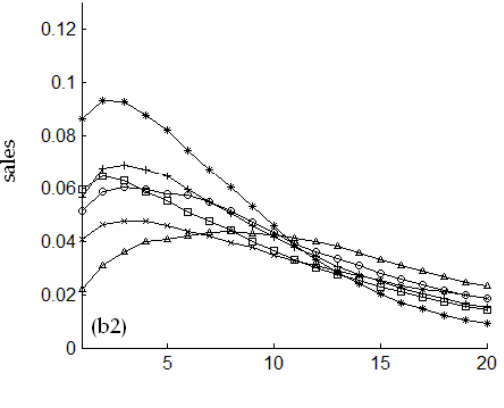
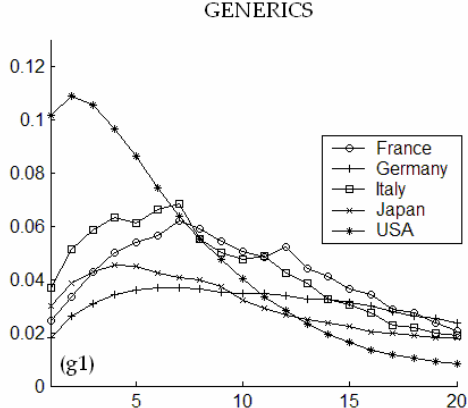
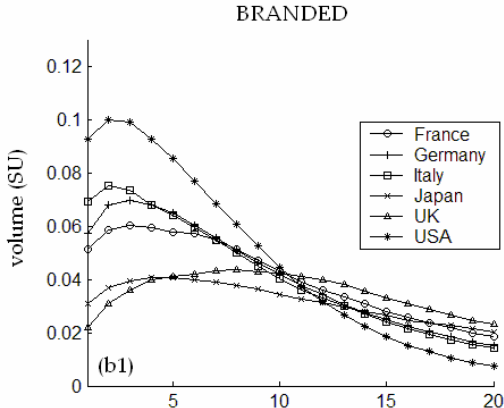
# MARKET OPENESS

**Total market share of local non-multinational companies (non-MNCs) present only in domestic market**

<b>Country</b>	<b>Market Share</b>
Sweden	0.3%
Ireland	0.6%
Belgium	0.9%
UK	1.0%
Denmark	1.1%
Finland	1.2%
Austria	1.6%
Netherlands	2.6%
France	3.1%
USA	3.5%
EU-25	3.7%
EU-15	3.7%
Germany	4.3%
Spain	5.0%
Italy	6.5%
Greece	9.8%
Portugal	11.1%
Japan	17.1%
India	43.7%
China	69.5%

*Source: our computations on IMS Health, Copyright 2005.*

# MARKET LIFECYCLES



years from launch

years from launch

# MARKET PREMIUMS

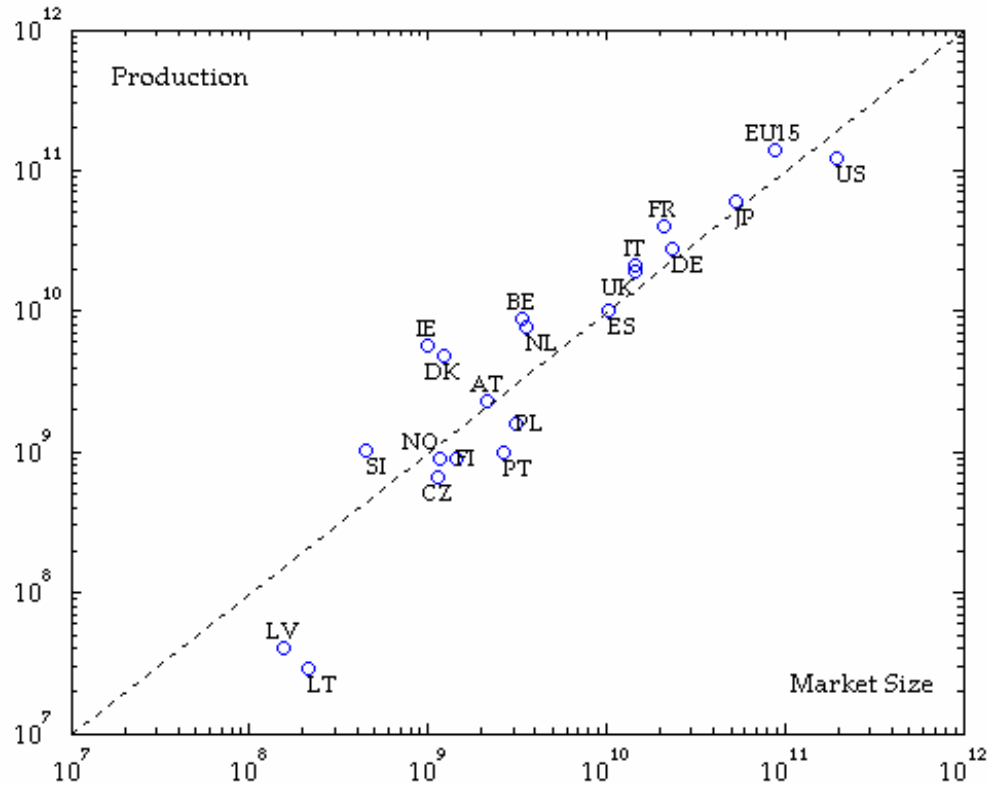
**The ratio between drug price at launch and the mean price of branded drugs in the market. Average for all ATC4 markets, 1994-2004**

	Branded	Generics
Austria	1.220	0.836
Belgium	1.181	0.659
Finland	1.253	0.855
France	1.339	0.769
Germany	1.061	0.735
Italy	1.248	0.827
Japan	1.039	0.820
Portugal	1.162	0.777
Spain	1.550	0.703
Sweden	1.437	0.793
UK	1.410	0.873
USA	1.434	0.603
EU15 <sup>1</sup>	1.282	0.776

*1. Weighted average of available countries. Source: our computations on IMS Health, Copyright 2005.*

# ... AND FINALLY MARKET SIZE

Pharmaceutical market size versus total production, 2003, double logarithmic scale (€values)



(1) The EU-15 refers to 2001.

# MARKET SIZE AND COMPETITIVENESS

- The size of the U.S. market is not the only source of the U.S. leadership.
- The benefits of internal market size decrease with the extent of the international integration of pharmaceutical markets.
- As a matter of fact, trade openness has increased over time, and as the world pharmaceutical market becomes more integrated, the benefits of large countries tend to vanish in favor of smaller countries.
- On the one hand, this effect can explain the positive growth performances of small northern EU countries in this sector.
- On the other hand, as globalization reduces the advantages of sizeable internal markets, there are less incentives to administrative and regulatory integration and the EU pharmaceutical markets tend to be more fragmented.
- Centrifugal forces have to be counterbalanced by a relaunch of the process of European pharmaceutical market integration.

# THE ROLE OF INSTITUTIONS (1)

Number of R&D projects addressing diseases without therapy (DNET), by nationality and institution type of originator and developer (1980-2004)

	projects originated								projects developed							
	Total		PRO		DBF		EC		Total		PRO		DBF		EC	
	n	%	n	%	N	%	n	%	n	%	N	%	n	%	n	%
USA	860	53.9%	177	70.5%	524	70.2%	159	26.5%	771	48.3%	104	68.0%	481	67.4%	186	25.5%
	100.0%		20.6%		60.9%		18.5%		100.0%		13.5%		62.4%		24.1%	
EU-25	334	20.9%	25	10.0%	115	15.4%	194	32.4%	356	22.3%	13	8.5%	121	16.9%	222	30.5%
	100.0%		7.5%		34.4%		58.1%		100.0%		3.7%		34.0%		62.4%	
Japan	138	8.6%	15	6.0%	2	0.3%	121	20.2%	169	10.6%	12	7.8%	2	0.3%	155	21.3%
	100.0%		10.9%		1.4%		87.7%		100.0%		7.1%		1.2%		91.7%	
Other	264	16.5%	34	13.5%	105	14.1%	125	20.9%	300	18.8%	24	15.7%	110	15.4%	166	22.8%
	100.0%		12.9%		39.8%		47.3%		100.0%		8.0%		36.7%		55.3%	
Total	1,596	100.0%	251	100.0%	746	100.0%	599	100.0%	1,596	100.0%	153	100.0%	714	100.0%	729	100.0%
	100.0%		15.7%		46.7%		37.5%		100.0%		9.6%		44.7%		45.7%	

Reading key:

number of projects	as % of total by column
as % of total by row	

# THE ROLE OF INSTITUTIONS (2)

**Number of R&D projects on Africa's diseases (AD), by nationality and institution type of originator and developer (1980-2004)**

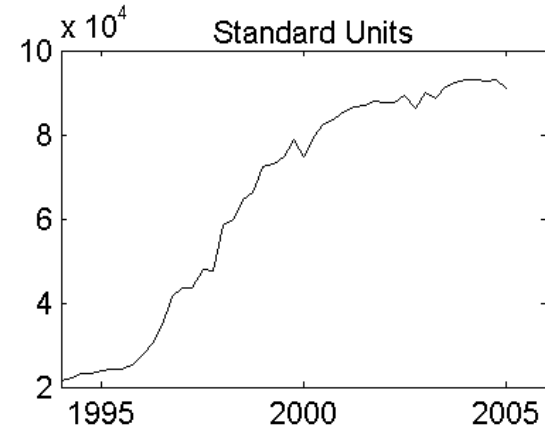
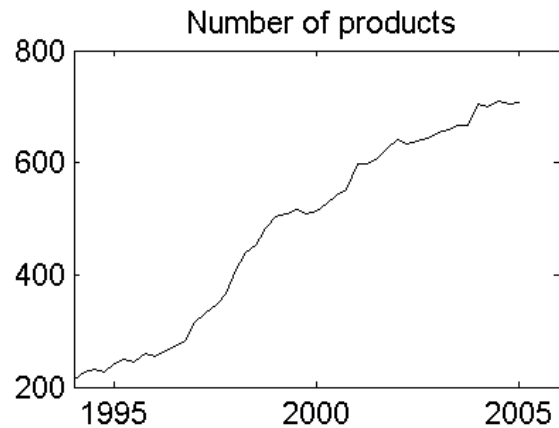
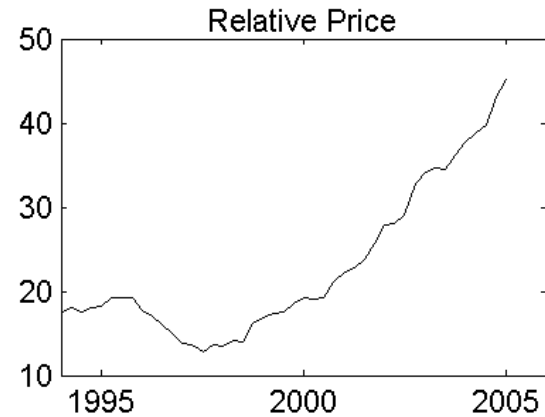
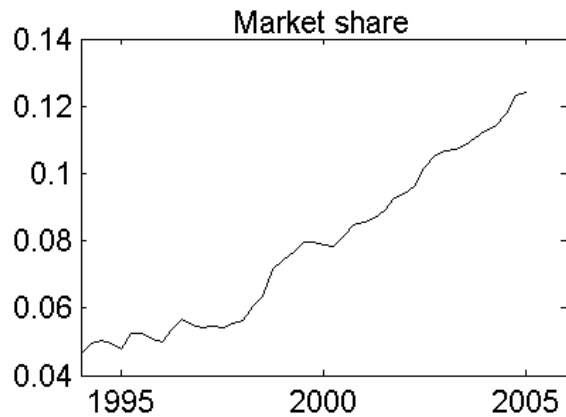
	projects originated								projects developed							
	Total		PRO		DBF		EC		Total		PRO		DBF		EC	
	n	%	n	%	N	%	n	%	n	%	N	%	n	%	n	%
<b>USA</b>	822	56.8%	239	61.8%	369	74.7%	214	37.9%	762	52.7%	184	57.0%	356	71.1%	222	35.7%
	100.0%		29.1%		44.9%		26.0%		100.0%		24.1%		46.7%		29.1%	
<b>EU-25</b>	338	23.4%	65	16.8%	73	14.8%	200	35.4%	383	26.5%	64	19.8%	85	17.0%	234	37.6%
	100.0%		19.2%		21.6%		59.2%		100.0%		16.7%		22.2%		61.1%	
<b>Japan</b>	86	5.9%	17	4.4%	-	-	69	12.2%	85	5.9%	17	5.3%	-	-	68	10.9%
	100.0%		19.8%		-	-	80.2%		100.0%		20.0%		-	-	80.0%	
<b>Other</b>	200	13.8%	66	17.1%	52	10.5%	82	14.5%	216	14.9%	58	18.0%	60	12.0%	98	15.8%
	100.0%		33.0%		26.0%		41.0%		100.0%		26.9%		27.8%		45.4%	
<b>Total</b>	1446	100.0%	387	100.0%	494	100.0%	565	100.0%	1446	100.0%	323	100.0%	501	100.0%	622	100.0%
	100.0%		26.8%		34.2%		39.1%		100.0%		22.3%		34.6%		43.0%	

Reading key:

number of projects	as % of total by column
as % of total by row	

## ... AND INSTITUTIONAL CHANGE

The biopharmaceutical products are gaining momentum: US market share, relative price, number of products on the market and number of standard units sold.

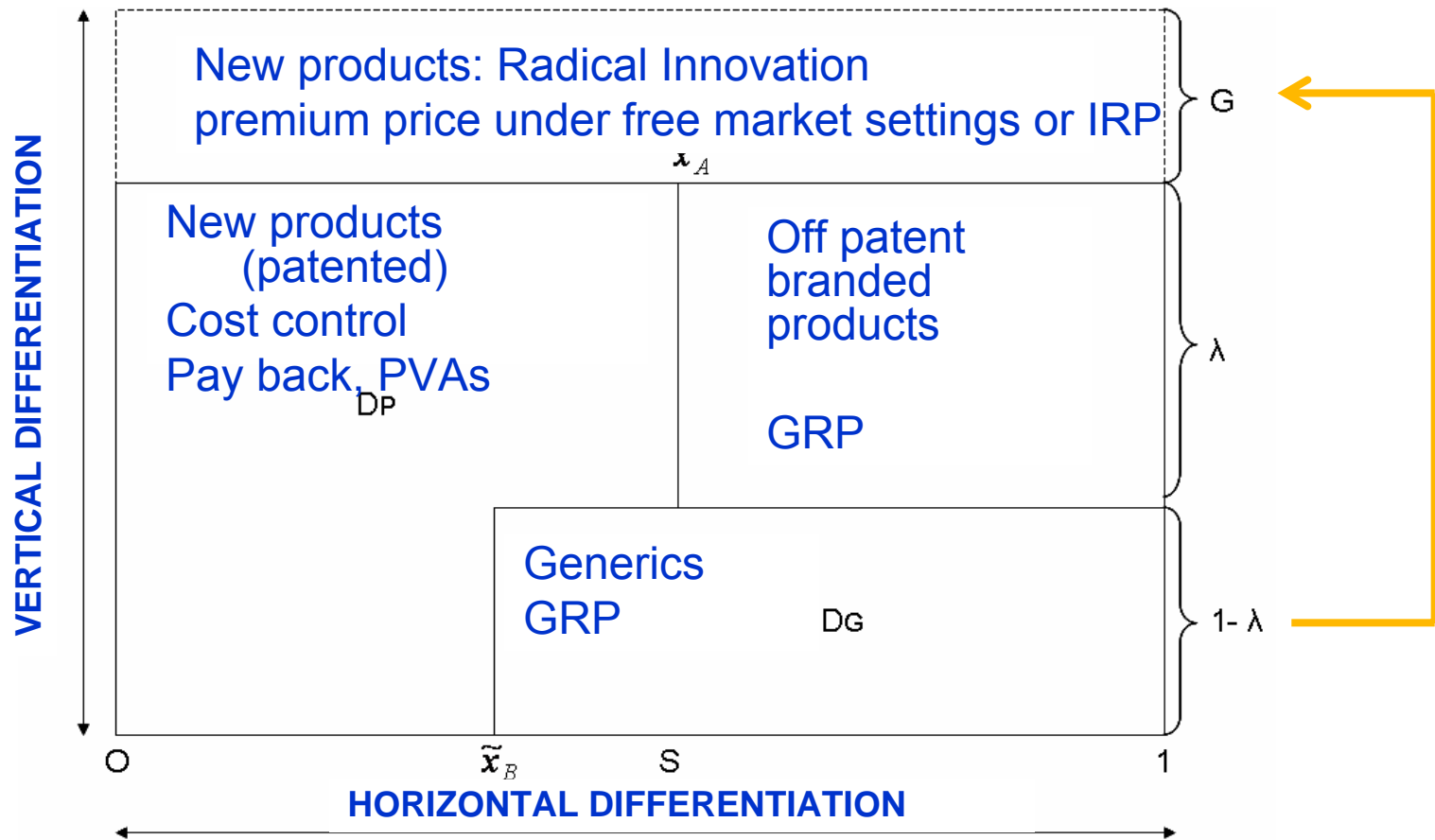


The increasing number of new biologicals, price and sales trends in a regime of production and regulatory constraints, raise serious concerns as far as future access, diffusion and sustainability of (bio)pharmaceutical innovation.

First of all, a common definition of biopharmaceutical is strongly needed.

Need for a common definition of biopharmaceuticals. Second, to ensure dynamic competition, it is extremely important to favour off-patent competition (biogenerics, or biological follow-ons), within the jurisdiction of the FDA, EMEA and other national authorities, by establish standards for approving biogenerics using an expedited pathway, similar to the review process for generic versions of conventional drugs

# INNOVATION IN PRICE REGULATION



# LONG TERM PROJECTION OF AGE-RELATED PUBLIC EXPENDITURES

## The work of ECOFIN-AWG

*In 1999, the European Policy Committee established the Working Group on Ageing Population (AWG) with the precise aim at evaluating the economic and political consequences of the ageing population at the European level.*

*The first reply arrived in 2001. The study involved all Member States and tried to characterize the dynamics of public expenditure on pensions, health care, long-term care, education, unemployment transfers and, where possible, contributions to pensions/social security systems in the following 50 years.*

*In 2003, the ECOFIN Council gave the Economic Policy Committee a mandate to produce a set of age-related public expenditure projections for all twenty-five Member States.*

*The second issue of the age-related expenditure projections in 2006 has been preceded by a profound re-examination of the assumptions and a second methodologies previously adopted. This resulted in a report prepared by AWG and issued in 2005.*

## THE TWO MAIN ASSUMPTION CONCERN:

A common scenario for population projection for the period 2004 to 2050, to be used in all projections exercise and for all Member States. The population projection used are those prepared by Eurostat (EUROPOP2004), in which:

- fertility rates are derived from an analysis of postponement of childbearing and recuperation of fertility rates at a later age for the EU15.
- life expectancy at birth is differentiated among countries.
- net migration trends are extrapolated using time series analysis.

In order to make reliable projections on GDP, several macroeconomic hypotheses have to be made, covering the labour force (participation, unemployment rates), labour productivity and the real interest rate:

- overall participation rates (for the age group 15-64) in the EU25 are projected to increase by about 6% over the period 2003-2050.
- for what concerns unemployment rates, they are assumed to converge to their structural level, or NAIRU, by 2008, and then remaining constant.
- for labour productivity growth, the approach followed by AWG is the production function approach, which draws on the assumptions concerning Total Factor Productivity (TFP) and investment,<sup>1</sup> as well as the assumptions on labour input projections.

The table below reports the EPC projections results of Health and Long Term Care Expenditure both in 2001 and 2006. The projection scenarios included in the table are:

for health expenditure, respectively

- the *central demographic assumption* with costs growing in line with GDP per capita;
- the *death-related cost* scenario, in which base year age-related expenditure profiles are held constant over the projection period but split into spending on decedents and survivors, and costs grow as much as GDP per capita;

for long term care, respectively

- the *central demographic assumption* with costs growing in line with GDP per capita;
- the *AWG reference* scenario, which assumes that half of the projected gains in life expectancy up to 2050 would be spent in good health.

As in the previous release of the projections exercise, ECOFIN performs sensitivity analysis, providing results computed on the basis of alternative demographic and macroeconomic assumptions.

# ACUTE AND LONG TERM HEALTH CARE PUBLIC SPENDING AS % OF GDP

(2001 vs 2006 EPC Projections)

GDP %	2001 release			2006 release			peak change
	2000	2050 ECOFIN	2050 change ECOFIN	2004	2050 ECOFIN	2050 change ECOFIN	
Austria	5.8	8.6	2.8	5.9	8.1	2.2	2.2
Belgium	6.1	8.2	2.1	7.1	9.1	2.1	2.1
Denmark	8.0	10.7	2.7	8.0	9.8	1.8	1.8
Finland	6.2	9.0	2.8	7.3	10.2	2.9	2.9
France*	6.9	8.6	1.7	7.7	9.1	1.4	1.4
Germany				7.0	9.0	2.0	2.0
Greece*				5.1	6.5	1.4	1.4
Ireland	6.6	6.6		5.9	8.0	2.1	2.1
Italy	5.5	7.4	1.9	7.3	9.0	1.8	1.8
Luxembourg				6.0	7.5	1.4	1.4
Netherlands	7.2	10.4	3.2	6.6	8.2	1.6	1.6
Portugal*				6.7	6.9	0.2	0.2
Spain				6.6	8.8	2.2	2.2
Sweden	8.8	11.8	3.0	10.5	13.0	2.4	2.4
United Kingdom	6.3	8.1	1.8	8.0	10.6	2.6	2.6
*projections do not include long-term care spending					<i>Average</i>	1.9	1.9

ECOFIN scenario: demographic driver (refined through the “death related costs” methodology).

ECOFIN: rate of growth of per capita expenditure aligned to GDP per capita.

## MATTERS OF CONCERN

The two series of projections are hardly comparable since changes in the definitions of coverage have been occurred in the meanwhile

The difference in the final projection values in 2050 is on average equal to 18.7% of the value in 2050 reported in EPC (2001), with a strong variations within countries (from 17.5% for the Netherlands to 36.6% in the case of UK) (*see figure below*).

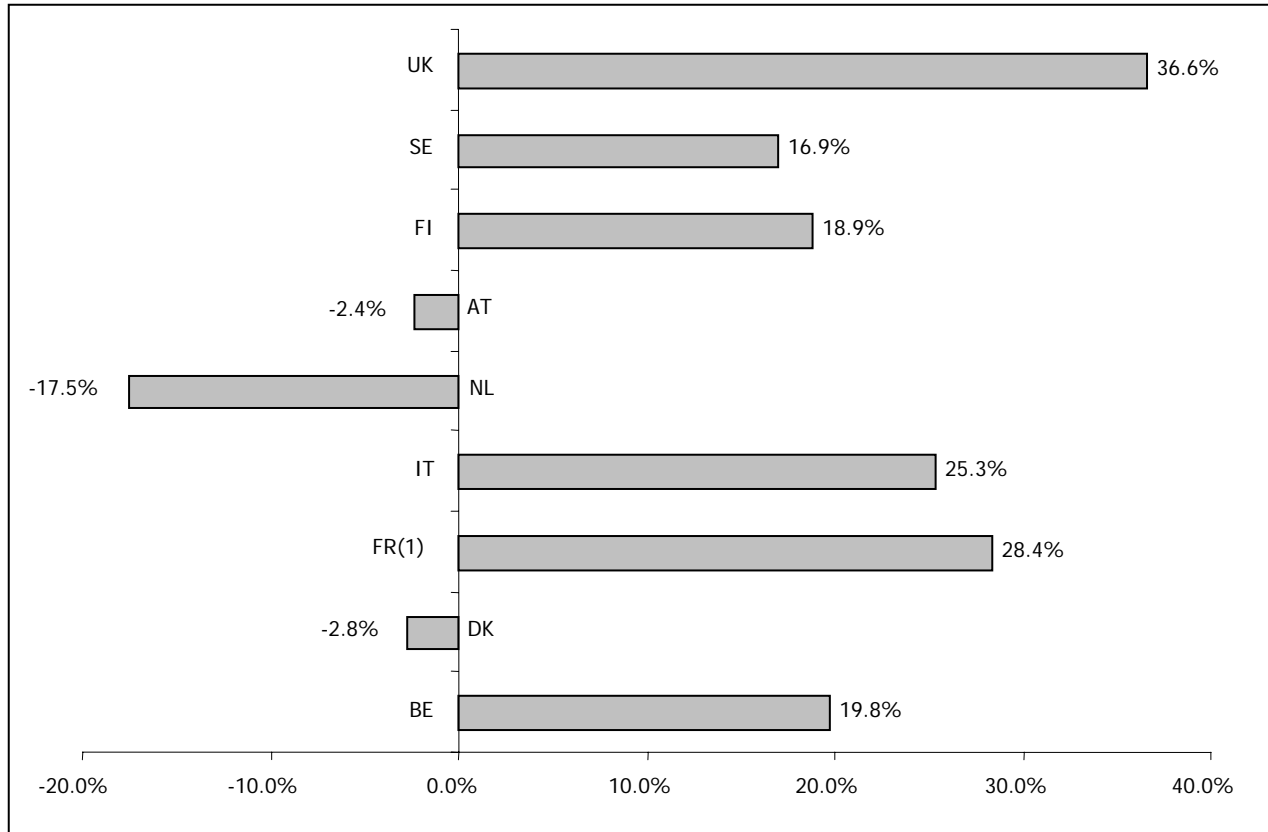
There is he need for increasing the degree of comparability among projections produced by different authorities. In particular, it would be desirable a clear comparison between results, assumptions and variables definitions, highlighting the major differences and the motivations behind them. (OECD vs. ECOFIN).

Projection exercises should provide information about the degree of uncertainty of the results.

# ACUTE AND LONG TERM CARE EXPENDITURE PROJECTIONS

## The problem of uncertainty

Differences between projected values in 2050 provided by ECOFIN2001 and ECOFIN2006 as % of 2050 projected value in ECOFIN2001



(1) ECOFIN projections do not include long term care - Source: *EPC (2001) and EPC (2006)*.

**IN ORDER TO EXTEND THE LONG TERM PROJECTION  
OF AGE-RELATED PUBLIC EXPENDITURES  
WE PROPOSE TREE INVESTIGATIONS FIELD**

1

IMPROVE THE  
PROJECTION METHODOLOGY

2

A CO-INTEGRATION  
APPROACH

3

STUDY THE IMPACT OF INSTITUTIONAL VARIABLES  
ON HEALTH CARE EXPENDITURE

# HEALTH CARE SPENDING

## A co-integration approach

### **ECOFIN 2006 and OECD 2006 reports:**

Homogeneous income elasticity of health care demand across countries and fixed equal to one, arbitrarily.

No welfare implication.

### **Fill the gap!**

Country-specific estimated income elasticity of health care demand through cointegration analysis.

Welfare implication: how much has the size of government to be reduced in order to stabilize the public health spending, saying at 2004 level?

## RISING QUESTIONS FROM GERMANY

**Table: Growth in real health care expenditure and GDP, by Decade (% per year)**

	Growth in real total health care, per capita	Growth in real GDP, per capita	Total health care share of GDP at the end of the period
1970-1980	7.49%	2.68%	8.7%
1980-1990	1.79%	2.01%	8.5%
1990-2000	2.46%	0.44%	8.6%
2000-2004	1.00%	0.47%	10.6% (8.1%) <sup>†</sup>
<i>Estimated long run income elasticity of health care demand = 1.98</i>			
2004-2050	3.39%	1.71%	15.34% (11.7%) <sup>†</sup>

Size of government in health sector = 76%

Size of government in 2050 stabilizing public expenditure at 8.1% = 52.8%

<sup>†</sup> In parenthesis public health expenditure as share of GDP.

## ... A POSSIBLE ANSWER FROM SWEDEN

**Table: Growth in real health care expenditure and GDP, by Decade (% per year)**

	Growth in real total health care, per capita	Growth in real GDP, per capita	Total health care share of GDP at the end of the period
1970-1980	4.94%	1.58%	9%
1980-1990	1.05%	1.88%	8.3%
1990-2000	1.59%	1.54%	8.4%
2000-2004	3.29%	1.46%	9.1% (7.7%) <sup>†</sup>

*Estimated long run income elasticity of health care demand = 1.03*

2004-2050	1.72%	1.67%	9.2% (7.8%) <sup>†</sup>
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Size of government in health sector = 84.6%

Size of government in 2050 stabilizing public expenditure at 7.7% = 83.6%

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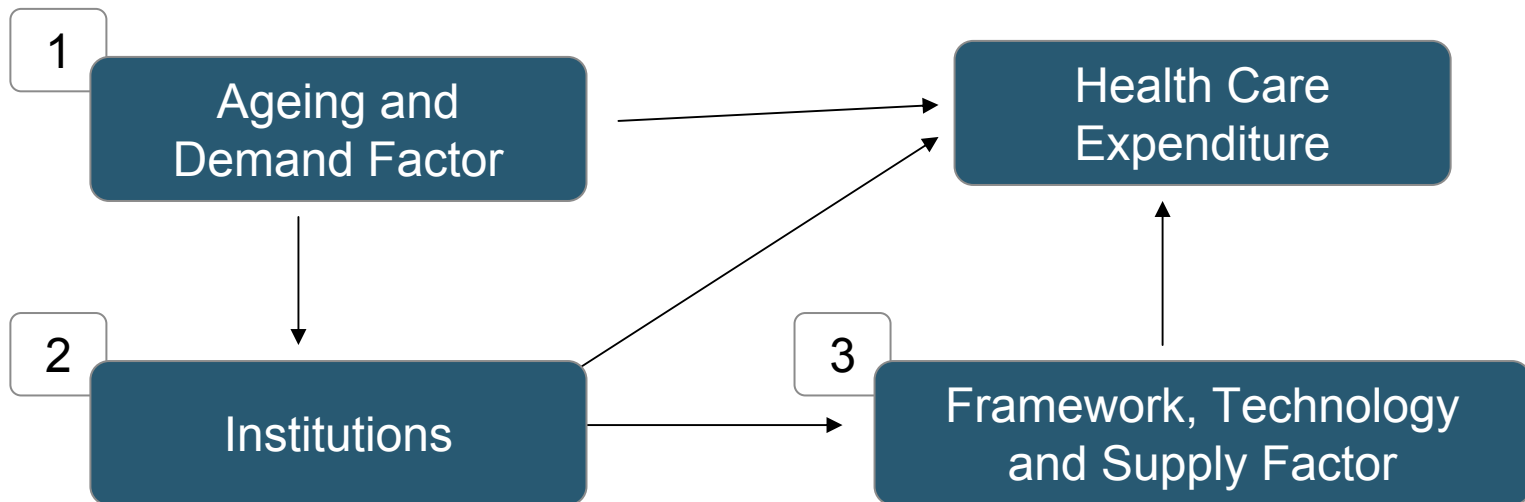
<sup>†</sup> In parenthesis public health expenditure as share of GDP.

## Further Analyses

1. Enlarge the analysis to all EU15 countries
2. Disentangle the mechanisms at work behind the income elasticity of health care demand: what characterize the virtuous countries?
3. Sensitivity and/or new cointegration analysis taking into account the following factors: population aging, technological progress (Newhouse, JEP 1992), and life expectancy effect (Jones and Hall, QJE 2007).

## THE MODEL

The first step of the analysis we measure the relationship between ageing and the development in health care expenditure **(1)** on a macro-level including economic and variables regarding the organization of the health care system at country-level **(3)** according to the proposed model (further analysis deserves the point **(2)**):



*The panel is formed by 15 european countries (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and United Kingdom) for a period of 24 years (1980-1995).*

# VARIABLES

## Dependent variable:

**THCEPC** *Total Health care expenditure per capita US international \$ PPP*

**PUHCEPC** *Public Health care expenditure per capita US international \$ PPP*

**PHETPE** *Share of Public Health care expenditure to General Government total outlays*

## Independent variables (Ageing, Economic and Demand Factor):

(1) **GDP** *GDP per capita US international \$ PPP (there is a well known positive relationship between GDP and HE)*

(1) **POP05** *Proportion of the population aged 0-5*

(1) **POP65** *Proportion of the population aged 65-74 (ageing of population could increase HE)*

(1) **POP75** *Proportion of the population aged 75+ (ageing of population could increase HE)*

(1) **ALCOCN** *Alcohol consumption (litres of pure alcohol per capita per year)*

(1) **TOBCON** *Tobacco consumption (cigarettes per capita per year)*

(1) **FLFPR** *Female labour force participation rate (%ratio to active population aged 15-65)*

(1) **UNEMP** *Unemployment rate (% ratio to labour force)*

(1) **LE65F** *Life expectancy at age 65 for females*

(1) **LE65M** *Life expectancy at age 65 for males*

## VARIABLES CONTD.

### Independent variables (Framework, Technology and Supply Factor) FTS

(3) **COPAY** *Dummy variable for countries with significant co-payment for Hospital inpatient, zero otherwise.* Co-payment could restrain HE

(3) **PHUES** *Public health expenditure as share of total HE.* Indicates whether an higher share of Public health expenditure affect total Health care expenditure per capita

(3) **SALARYGP** *Dummy variable for countries with salaried General Practitioners zero otherwise*

(3) **CAPGP** *Dummy variable for countries with capitation payment GPs, zero otherwise*

The reference level is countries remunerating their GP by **Fee For Services**.

(3) **GLOBALHO** *Dummy variable for countries with global budget reimbursement of hospitals, zero otherwise*

(3) **CASEHO** *Dummy variable for countries with case-based reimbursement of hospitals, zero otherwise.* Indicate whether countries remunerate their hospitals mainly by global budget (**GLOBALHO**) or by case-based remuneration (**CASEHO**). The reference level is countries remunerating their hospitals per diem, FFS and countries with mixed systems.

## VARIABLES CONTD.

### Independent variables (Framework, Technology and Supply Factor) FTS

- (3) **PHYSH** *Physicians per 100 hospital beds*
- (3) **TOMSCA** *Tomographic scanners per 1,000,000 inhabitants*
- (3) **BEDS** *Acute care beds per 1,000 inhabitants*
- (3) **DIALY** *Patients undergoing dialysis per 100,000 inhabitants*

## THE ANALYSIS

In **FIXED EFFECTS Model** we analyze the effect of independent Variable on the level of Health Expenditure

**Model Fixed Effects** : *Age variables + time trend +country effect+ demand factor*  
*+ framework, technology and supply sector variables*

## RESULTS EU 15

Variable	Coeff	Std Error	T-Stat	Signif
*****				
1. POP05	-0.010015092	0.013016394	-0.76942	0.44226516
2. POP65	0.015945877	0.014585548	1.09327	0.27517830
3. POP75P	0.009895450	0.012195107	0.81143	0.41778091
4. LRGDP	0.844358555	0.050493427	16.72215	0.00000000
5. LE65F	-0.014147257	0.013437760	-1.05280	0.29330364
6. LE65M	0.013537944	0.016300720	0.83051	0.40692786
7. FLPR	0.005214859	0.001820666	2.86426	0.00448297
8. UNEMP	0.004543503	0.002136068	2.12704	0.03425489
9. ALCCON	-0.014068330	0.005020292	-2.80229	0.00541341
10. TOBCON	0.000007974	0.000026413	0.30189	0.76295274
11. PHUES	0.001986303	0.001273788	1.55937	0.11999274
12. COPAY	-0.008633187	0.009092051	-0.94953	0.34313565
13. GLOBALHO	0.021981850	0.010917541	2.01344	0.04498531
14. CASEHO	-0.056572725	0.026372173	-2.14517	0.03276421
15. SALARYGP	-0.002072461	0.026810006	-0.07730	0.93843643
16. CAPGP	0.015005470	0.022973223	0.65317	0.51415924
17. PHYSH	0.001227593	0.000662080	1.85415	0.06472636
18. BEDS	0.008359491	0.018310672	0.45654	0.64834359
19. DIALY	0.000460628	0.000820320	0.56152	0.57487204
20. TOMSCA	0.005818686	0.001920991	3.02900	0.00267298

# DISCUSSION

## Regressions on level of HE

**GDP** *per capita* shows a high association up to 84%

**POP05** exhibits a negative correlation with HE

**POP65-74** there is the presence of a spurious correlation over time between age profile 65-74 and health expenditure

**POP75** exhibits a negative correlation with HE

**FLRP** is significant but the coefficient assume a small value

**PUHES** has a positive coefficient so the higher the share of public health expenditure the higher the level of HE

**FTS variables: SALARYGP** is negatively correlated

**CAPGP** is positively correlated (capitation payment GPs increase HE)

**COPAY** has a slight negative coefficient (this could mean that co-payment retains HE)

**CASEHO** is negatively correlated

**GLOBALHO** is positively correlated (global budget reimbursement of hospitals could increase HE)

**BEDS, DIALY, TOMSCA** are positively correlated with HE.

# Implications for Policies



1. The positive sign of PUHES could suggest that public sector is ineffective to control the growth of HE
2. The reforms of Health sector could consider effective measure to control HE (see COPAY, CASEHO)
3. Technology has a positive influence
4. There is a need to develop in the european country a private pillar (insurance)

# Further Analyses

1. More attention will be deserved to Institutional Variables (part 2 of the model) : i.e. Proportional representation Vs Majority representation in order to better capture the heterogeneity between countries
2. Detecting more appropriate Framework, Technology and Supply Factor variables
3. Regressions on growth rate of Health Expenditure (Total, Public, Share). Fig's below suggests that there could be a *catching up* effect i.e. the lower is the level of HE at the starting period the higher is the growth rate of HE
4. Enlarge the panel to the new EU members and to USA and Japan
5. Use regression results for forecasts