ESMT Competition Analysis

Price Regulation and Incentives to Innovate in the Pharmaceutical Industry

A Simulation Approach

Dr. Hans W. Friederiszick
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This presentation is based on a study by Friederiszick/ Tosini/ de Véricourt/ Wakeman commissioned by Novartis

Pharmaceutical Innovation and Pricing Regulation

- In the context of healthcare cost-containment efforts, pharmaceutical products are increasingly subject **to strict pricing and reimbursement conditions** in many European countries and likely the U.S

- Relatively little attention has been paid to the (potentially adverse) consequences that pricing and reimbursement regulation may have **on pharmaceutical innovation**:
  - Effects on the **number** and **characteristics** of drugs that will be launched in the market in the future?
  - Tension between the **global nature** of pharmaceutical innovation and the **national nature** of pricing regulation?

- In a recent study we evaluated the effect of pricing regulation on innovation in the pharmaceutical industry by performing policy experiments in the context of a **simulation model**

- Friederiszick, H. W., Tosini, N., de Véricourt, F., and Wakeman, S. (2009). *An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in the Pharmaceutical Industry*. ESMT White Paper No. WP–109–03
- Friederiszick, H. W., Tosini, N. (2010). *Balanced future?* Pharmaceutical Marketing Europe, September/ October 2010

Agenda

- Facts on pharmaceutical innovation
- Facts on pricing and reimbursement regulation
- A quantitative theory
- Policy Experiments

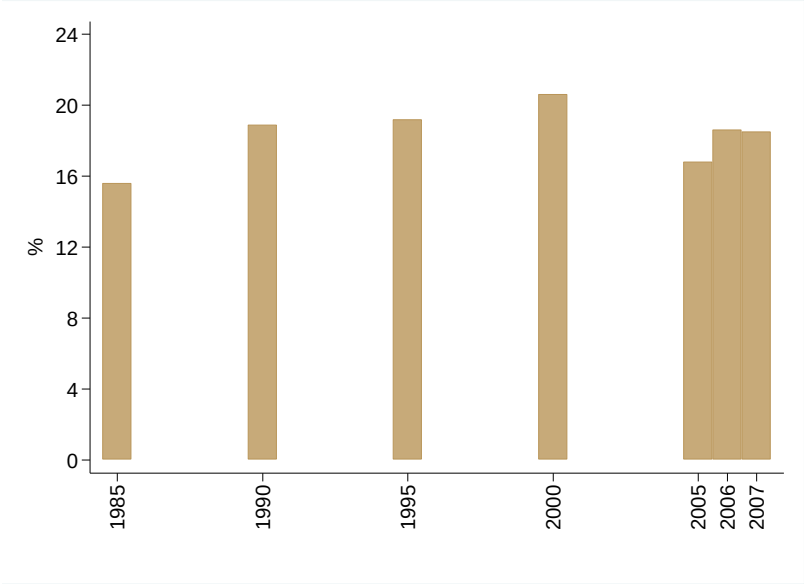
Pharmaceutical R&D expenditures

- Ranking of sectors by R&D expenditures:

ICB Sector	R&D Investment (Millions of Euros)	Sector Share	R&D Investment/Sales Ratio
Pharmaceuticals and biotechnology	71,409	19.20%	16.10%
Technology hardware and equipment	68,154	18.30%	8.50%
Automobiles and parts	63,234	17.00%	4.20%
Electronic and electrical equipment	26,595	7.10%	9.70%
Software and computer services	26,049	7.00%	4.10%
Chemicals	16,428	4.40%	2.80%
Aerospace and defence	15,134	4.10%	4.40%
Leisure goods	13,752	3.70%	6.20%
Industrial engineering	11,052	3.00%	2.60%
Other (27) sectors	61,050	16.40%	2.17%
Total	372,857	100.00%	6.08%

Sources: The 2008 EU Industrial R&D Investment Scoreboard, EC - JRC/DG RTD; efpia (2008 and 2009);

- Pharmaceutical R&D expenditure as a fraction of sales over time:



Relative stable R&D investment/ sales ratio in the past

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Selected pricing and reimbursement regulatory schemes in Europe

Country	External Price Benchmarking	Internal Reference Pricing	Value-Based Pricing	Other Schemes
Czech Republic	X	X		
Denmark		X	X (not mandatory)	
France	X	X		
Germany		X	X	• Market-based pricing of highly innovative, on-patent, drugs
Hungary	X	X	X	
Italy		X		
Netherlands	X	X	X	• Risk sharing (conditional pricing)
Poland		X		• Cost-plus price regulation
Spain	X			• Cost-plus price regulation
UK		X	X	• Pharmaceutical Price Regulation Scheme (PPRS) • Risk sharing (conditional pricing)
…	…	…	…	…

Source: OECD, 2008, *Pharmaceutical pricing policies in a global market*, Paris.

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Main aspects of the model

- a **representative, large pharmaceutical firm** which **optimally reacts** to the incentives provided by the pricing and reimbursement regulatory environment
  - forward-looking and takes future pricing regulation into account in making current development decisions
  - evaluates a portfolio of drug candidates, ranks them, and selects the highest-ranking ones
- projects are in **different therapeutic areas**, are at **different development phases**, and have **different degrees of innovativeness**
- development is **dynamic and risky**
  - technical risks (risk of failing clinical trials or not receiving market authorization)
  - competitive risks (external and internal!)
- development budget is linked to (expected) **level of sales**
- **regions are heterogeneous** in their pricing regulation:
  - because of External Price Benchmarking (EPB), whether or not a drug is launched in one region has consequences in another region
  - because of Internal Reference Pricing (IRP), it matters whether a drug is highly innovative or not

Therapeutic areas and number of projects

Therapeutic Area	Phase I	Phase II	Phase III
Analgesia	1	1	0
Anti-Infective	4	2	2
Cancer	10	4	4
Cardiovascular	3	2	2
CNS	5	3	2
Diabetes	1	1	1
Gastro-Intestinal	1	0	0
Genito-Urinary	1	1	0
Hormone Control	0	1	1
Immune System	0	1	0
Inflammation	2	2	1
Metabolism/Endocrinology	0	1	0
Obesity	1	1	1
Ophthalmic	1	1	1
Respiratory	0	3	1
Vaccines	1	1	2
Total	31	25	18

Source: Lehman Brothers' PharmaPipelines, May 2008; Large Pharmaceuticals.

Therapeutic specific net sales and margins

Therapeutic Area	Average Lifetime Net Sales in the US	Median Lifetime Margin in the US
Analgesia	281.3	30.00%
Anti-Infective	332.2	30.00%
Cancer	932.5	40.00%
Cardiovascular	570.3	25.50%
CNS	727.9	36.00%
Diabetes	1149.9	27.50%
Gastro-Intestinal	568.3	21.50%
Genito-Urinary	372.6	22.50%
Hormone Control	479.6	30.00%
Immune System	409.1	37.50%
Inflammation	1325.8	30.00%
Metabolism/Endocrinology	473.1	35.00%
Obesity	663.7	35.00%
Ophthalmic	608.4	35.00%
Respiratory	1121.6	20.50%
Vaccines	1504.7	35.00%

Note: All values are in millions of USD in year 2008.
Source: Lehman Brothers' PharmaPipelines, May 2008; Large Pharmaceuticals.

Calibration
Remaining parameters

Parameter	Value	Source/Target
Phase I development costs	30	DiMasi et al. (2003)
Phase II development costs	36	DiMasi et al. (2003)
Phase III development costs	127	DiMasi et al. (2003)
Costs premium for inno	10%	
Phase I prob tech success	60%	Girotra et al. (2007)
Phase II prob tech success	62.5%	Girotra et al. (2007)
Phase III prob tech success	65%	Girotra et al. (2007)
Discount rate	10%	Lehman Brothers (2008)
Price discount – not inno	75%	
Prob external competitor	2.5%	
Development budget	3,500	Approx. 90% of the value of the portfolio is selected

Note: All values are in millions of USD in year 2008.

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Effect of pricing regulation on the number of drugs developed and launched (…after solving the model and calibrating)

		Policy Scenario			
		Market-Based Pricing	Internal Reference Pricing (IRP)	External Price Benchmarking (EPB)	Pricing Regulation (both IRP and EPB)
Number of potential projects	Highly innovative	46			
	Total	74			
Number of projects developed	Highly innovative	32	30	29	26
	Total	54	49	51	45
Expected number of projects launched	Highly innovative	13.98	12.92	12.68	11.38
	Total	21.94	20.15	20.64	18.61

➔ The expected number of highly innovative drugs launched under IRP and EPB declines by respectively 8% and 9%

➔ Under the combination of IRP and EPB, this decline is equal to 19%

Effect of price regulation on the value of a drug portfolio of a typical pharmaceutical firm

- As a result of Internal Reference Pricing, the value of the selected portfolio moves from USD 24,808m under Market-Based Pricing to USD 21,912m - **a drop of 11.7%.**
- As a result of External Price Benchmarking, the value of the selected portfolio moves from USD 24,808m under Market-Based Pricing to USD 23,389m - **a drop of 5.7%.**
- As a result of Pricing Regulation, the value of the selected portfolio moves from USD 24,808m under Market-Based Pricing to USD 19,904m - **a drop of 19.8%.**

➔ **Under Pricing Regulation (IRP and EPB), not being considered highly innovative in Region A (IRP) spills over to Region B (EPB), and the value drop is greater than the sum of the value drops under IRP and EPB taken separately**

➔ **Because of the reduction in the development budget, the value drop in the selected portfolio is greater than the value drop in the whole portfolio**

Thank you!

Hans W. Friederiszick
Managing Director, ESMT Competition Analysis

hans.friederiszick@esmt.org
+49 (0)30 21231 7010

Nicola Tosini
Manager, ESMT Competition Analysis

nicola.tosini@esmt.org
+49 (0)30 21231 7096

Francis de Véricourt
Professor

francis.devericourt@esmt.org
+49 (0)30 21231 1291

Simon Wakeman
Assistant Professor

simon.wakeman@esmt.org
+49 (0)30 21231 1281

ESMT
European School of Management and Technology

Schlossplatz 1
10178 Berlin

Phone: **+49 (0) 30 21231 7000**
Fax: **+49 (0) 30 21231 7099**

www.esmt.org

The underlying ESMT White Paper is downloadable from
http://www.esmt.org/fm/479/WP-109-03.pdf