Pharmaceutical innovation and pricing regulation

A study prepared for Novartis
by ESMT Competition Analysis

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Editorial note:
ESMT Competition Analysis
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E.CA Economics

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

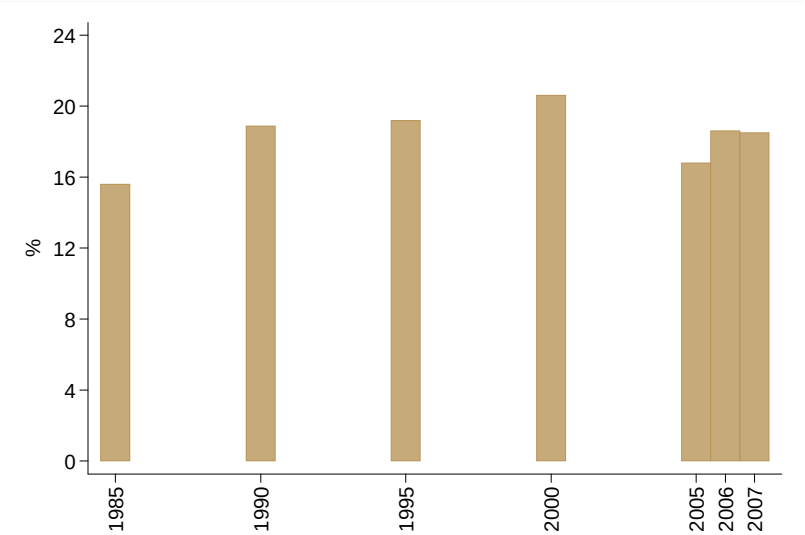
- Facts about pharmaceutical innovation
- Facts about pricing and reimbursement regulation
- A quantitative theory
- Conclusion

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%

- Pharmaceutical R&D expenditures (as a fraction of sales) are relatively constant over time:

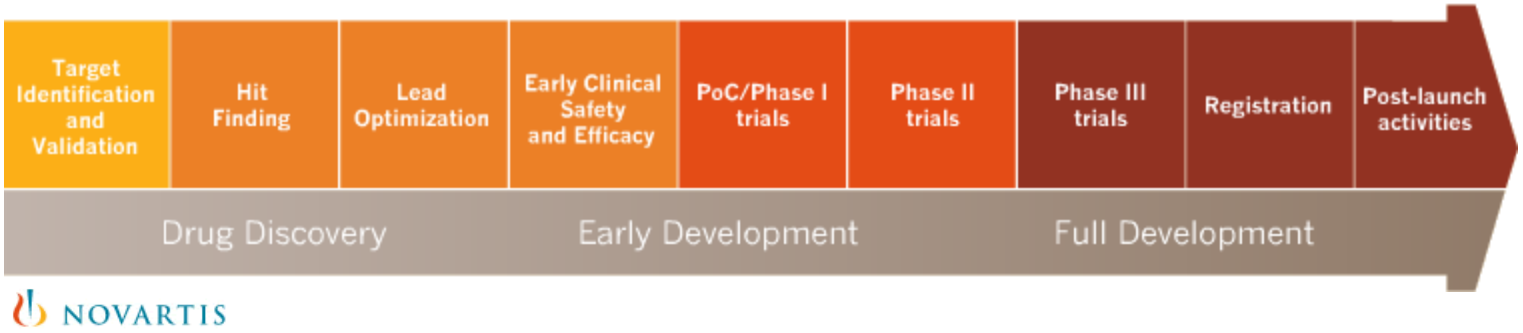


- Novartis had R&D expenditures equal to 20.5% of net sales in 2009 (21.7% in 2008)

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

The pharmaceutical discovery and development process

- Costly, long-lasting, and risky process



- Novartis had 145 projects in development in 2009 (152 in 2008)
- **Portfolio** (cross-section) and **life-cycle** (time-series) points of view on the discovery and development process:
  - According to the portfolio point of view, the emphasis is placed on the whole set of projects that a pharmaceutical firm holds **at a point in time**
  - According to the life-cycle point of view, the emphasis is placed on an individual project, which is followed **over time**

Source: Novartis annual reports 2008 and 2009.

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Classification of national pricing and reimbursement regulatory schemes

- Market-based pricing and bilateral bargaining
  - Health insurer is a “price taker”. Maximum increment that a firm can charge for an innovative new product is the marginal difference in purchaser’s willingness to pay for the new product relative to the existing treatment or competitive alternatives. It is further constrained by its bargaining position relative to the health insurer that pays for the product.
- Internal reference pricing
  - The price of or the amount reimbursed for a drug in a country is based on the price of chemically, pharmaceutically or therapeutically similar drugs in the same country, unless the drug is considered highly innovative.
- External price benchmarking
  - The price of a drug in a country is based on the price of the same drug in other countries.
  - The basket of benchmark countries is selected on the basis of economic and/or geographic proximity. In particular, European countries tend to benchmark each other.
- Schemes based on a pharmaco-economic assessment (value-based pricing)
  - The price of a drug in a country is based on a cost-effectiveness or cost-benefit analysis in which the cost of a drug is traded against its health benefits (quantity and quality of life).
  - Pharmaco-economic assessment goes hand in hand with tailored drugs.

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

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.

General comments

- All forms of pricing regulation—compared to a counterfactual of market-based pricing—are likely to **reduce the value of projects** and the resources available for R&D activities.
- All three major forms of pricing regulation involve **some form of benchmarking or referencing** to the prices of other products.
- If the prices of the referenced products are inefficient or the conditions under which they were set do not exist in the new environment then the referenced prices will **create, perpetuate, or enhance any distortions**.
- Furthermore, whenever a pricing regulatory scheme **requires a judgment**, whether a drug is highly innovative or not, the risk is incurred that a drug that is highly innovative from the point of view of the patients is **not perceived as equally highly innovative by the pricing regulator**.

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Main aspects of the model

- The point of view that we take is that of a representative pharmaceutical firm which, when taking development decisions, optimally reacts to the incentives provided by the pricing and reimbursement regulatory environment.
- In particular, a pharmaceutical firm is forward-looking and takes future pricing regulation into account in making current development decisions.
- The pharmaceutical firm 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 (cases studies by De Reyck et al., London Business School 2005, and Girotra et al., Wharton 2004).
- The evaluation of a project takes into account future development and launch decisions contingent on the realization of uncertain events.

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.

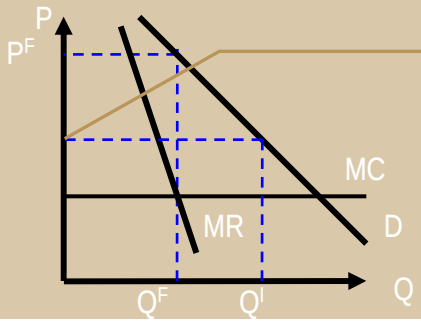
Regional dimension and competition

- Regions are heterogeneous in their pricing regulation:
  - Because of Internal Reference Pricing (IRP), it matters whether a drug is highly innovative or not.
  - Because of External Price Benchmarking (EPB), whether or not a drug is launched in one region has consequences in another region.
- In addition to the risk of failing clinical trials or not receiving marketing authorization, highly innovative projects face the risk of losing their high degree of innovativeness by the time they are launched in the market, because of:
  - External (exogenous) competition
  - Internal (endogenous) competition

Pricing regulation around the world
Regions and pricing regulation

Region A

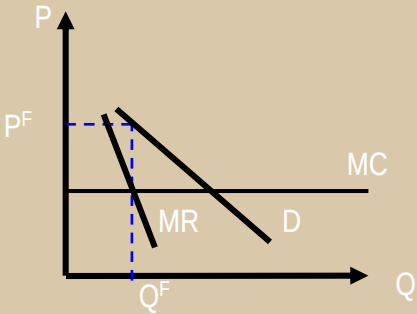
Internal
Reference Pricing (IRP)



$$P^I = \lambda * P^F$$

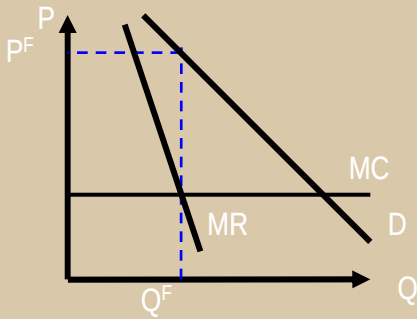
Region C

Market-Based Pricing,
Low Willingness to Pay



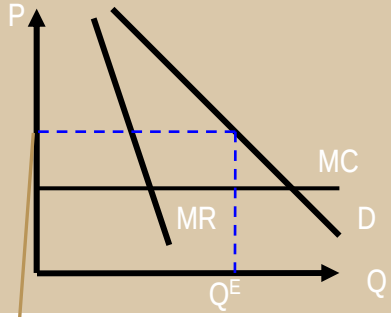
Region D

Market-Based Pricing,
High Willingness to Pay



Region B

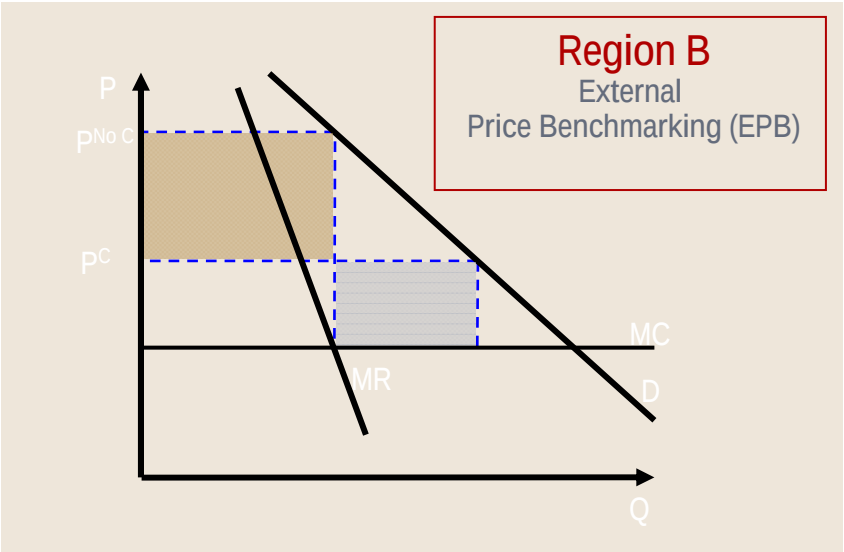
External
Price Benchmarking (EPB)

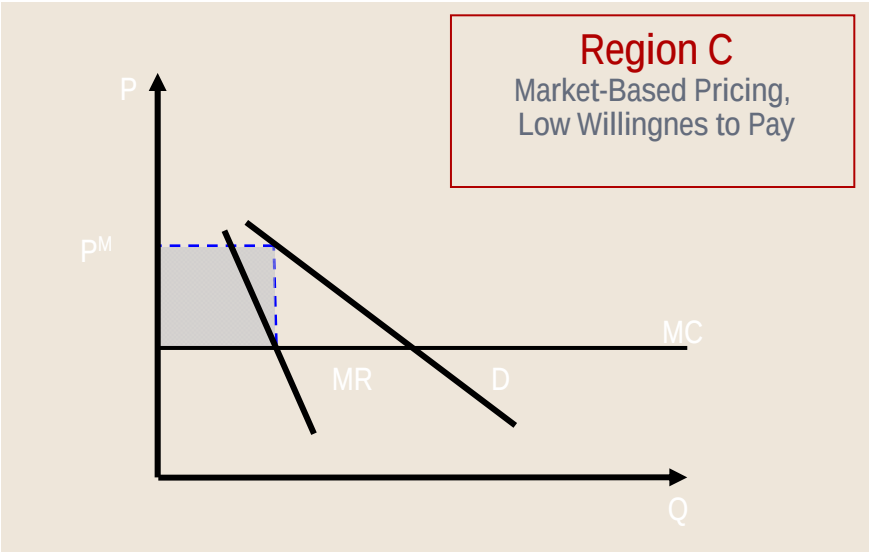


$$P^E = \sum_{j \in \{A,C,D\}} w_j * P_j$$

Drug development
A project's market launch

- Global net sales of a drug are the sum of net sales of the drug in the regions in which it is launched.
- Launch in Region C?
  - Trade-off between gaining net sales in Region C and losing net sales in Region B (EPB)





Effect of price regulation on the value of a drug portfolio of a typical pharmaceutical firm (…after solving the model and calibrating)

- 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.

Effect of pricing regulation on the number of drugs developed and launched

		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%.

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Pharmaceutical innovation and pricing regulation

- Pricing and reimbursement regulation affects pharmaceutical innovation, by
  - Reducing the value of pharmaceutical projects.
  - Curtailing the resources available to carry them out.
- The benefits of more affordable or cost-effective drugs must be traded against the costs of less pharmaceutical innovation:
  - Fewer projects are developed in general.
  - Fewer projects are developed in particular in low-margin, low-sales therapeutic areas, at early development stages, and with limited potential of being considered highly innovative at the time of market launch.
- Through external price benchmarking, not being considered highly innovative in one region spills over to other regions.
- The initial development portfolio, which was taken as given in our study, may also be affected.

Thank you!

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