esmt european school of management and technology

Pharmaceutical innovation and pricing regulation

A study prepared for Novartis by ESMT

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Workshop at the EC - DG Enterprise
Brussels, 12 May 2010

Agenda

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

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 adverse consequences** that pricing and reimbursement regulation may have on pharmaceutical innovation, by
  - **Reducing the value** of pharmaceutical projects
  - **Curtailing the resources** available to carry them out
- Pharmaceutical discovery and development is a **long-lasting process** and the consequences of the pricing and reimbursement regulation that is introduced today **affects 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 **regional (national) nature of pricing regulation**
- We set out to evaluate the effect of pricing regulation on innovation in the pharmaceutical industry by
  - **Qualitatively** exploring how a pharmaceutical firm is likely to strategically respond
  - Performing policy experiments in the context of a **quantitative** theory

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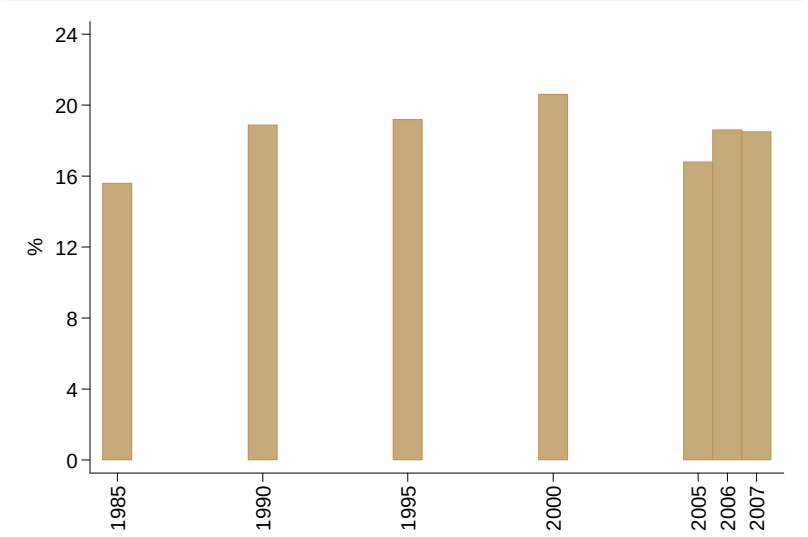
Pharmaceutical R&D expenditures

- 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:

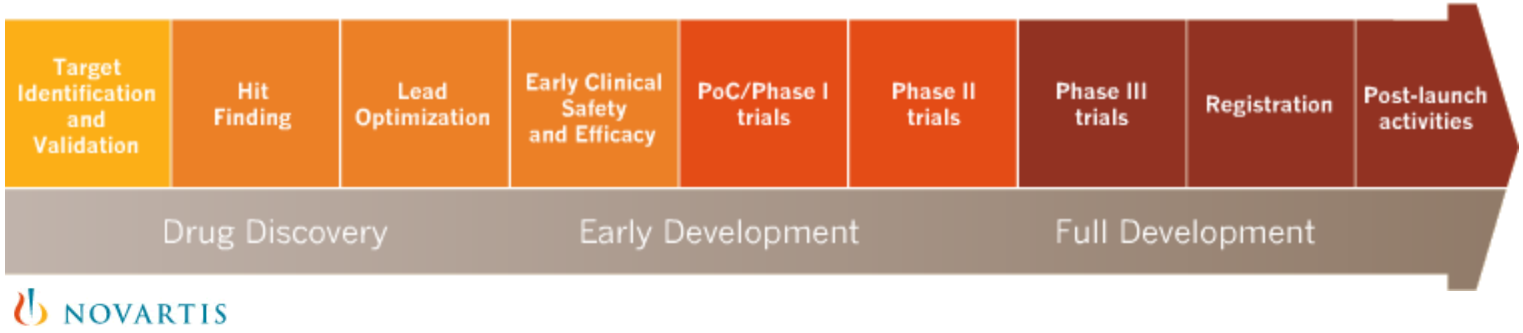


- Novartis had R&D expenditures equal to 20.5% of net sales in 2009 (21.7% in 2008)

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.

Pharmaceutical R&D outcomes

- Addressing an **unmet medical need** may take the shape of discovering and developing
  - **First-in-class drugs**, which utilize a novel mechanism of action
  - **Best-in-class drugs**, which—while utilizing the same mechanism of action as an existing drug—are particularly safer, more effective, and more convenient
- **Rise in tailored drugs**, which focus (aided by diagnostic tools) on particular patients to achieve particularly significant therapeutic advantages

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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.

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Preliminary remarks

- 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**

External price benchmarking

- Depending on how the basket of benchmark countries is selected, external price benchmarking may have to various degrees the following effects:
  - A change, potentially even an increase, in the average price of a drug as a consequence of inducing price equalization across countries
  - Strategic differentiation of products across countries in order to limit price comparisons
  - A focus on indications that are more prevalent in high willingness-to-pay countries
  - A delayed launch of the product in the countries with low willingness-to-pay or the focusing of R&D efforts of products that address the specific needs of high willingness-to-pay countries
- In rare cases, external price benchmarking—in the context of a bargaining game between a national health insurer of a country that is referenced by other countries and a pharmaceutical firm—might lead to more favourable reimbursement conditions

Internal reference pricing

- Effect depends on difference between doctor/patient judgment of marginal value and the regulator's definition of "innovativeness"
  - If marginal value and "innovativeness" coincide, then internal reference pricing ≈ market-based pricing
  - Appropriateness of the price of the referenced drugs
- If the regulator simultaneously increases amount paid for "innovative" products, then overall effect on investment is ambiguous
- Under internal reference pricing, pharmaceutical firms direct their investment towards indications where there is a lower probability that a drug will end up being "later in class"
  - Under the extreme form of internal reference pricing, drugs that lose their patent protection are kept in the reference basket ("jumbo group") and thus later-in-class drugs face a reduction in their effective patent life
- This may lead to abandoning otherwise worthwhile projects in the later phases of clinical trials—including projects that may become best in class drugs

Schemes based on a pharmaco-economic assessment (value-based pricing)

- In theory, value-based pricing replicates market-based pricing
- Differences arise because of the way in which value-based pricing is implemented
  - Time delay in conducting the pharmaco-economic assessment may increase uncertainty
  - Additional evidence required for the pharmaco-economic assessment may increase costs
- Value-based pricing may encourage development of different types of products
  - To the extent that they can be measured, value-based pricing balances overall welfare considerations
  - Market-based pricing emphasizes value to the payers with higher willingness-to-pay

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Introduction
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

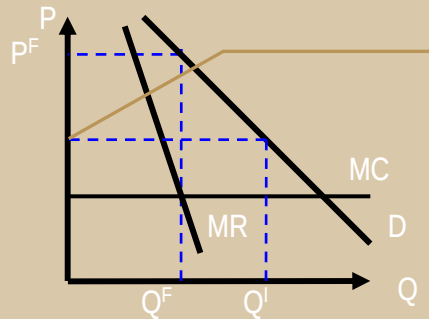
Introduction
Main aspects of the model (continued)

- 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

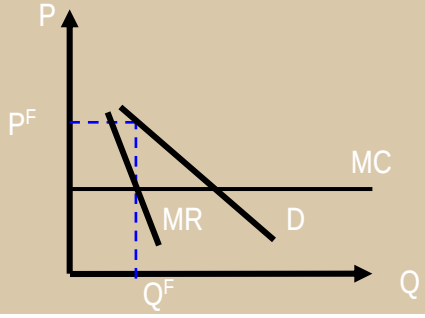
Internal
Reference Pricing (IRP)



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

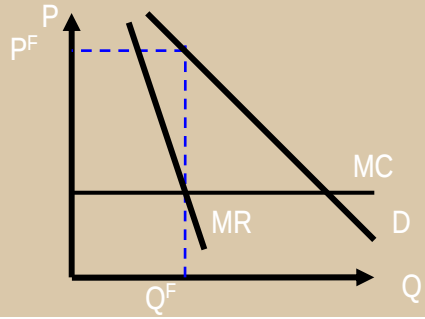
Region C

Market-Based Pricing,
Low Willingness to Pay



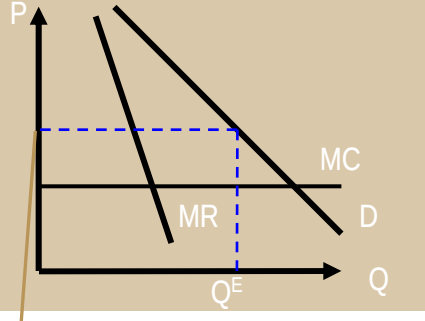
Region D

Market-Based Pricing,
High Willingness to Pay



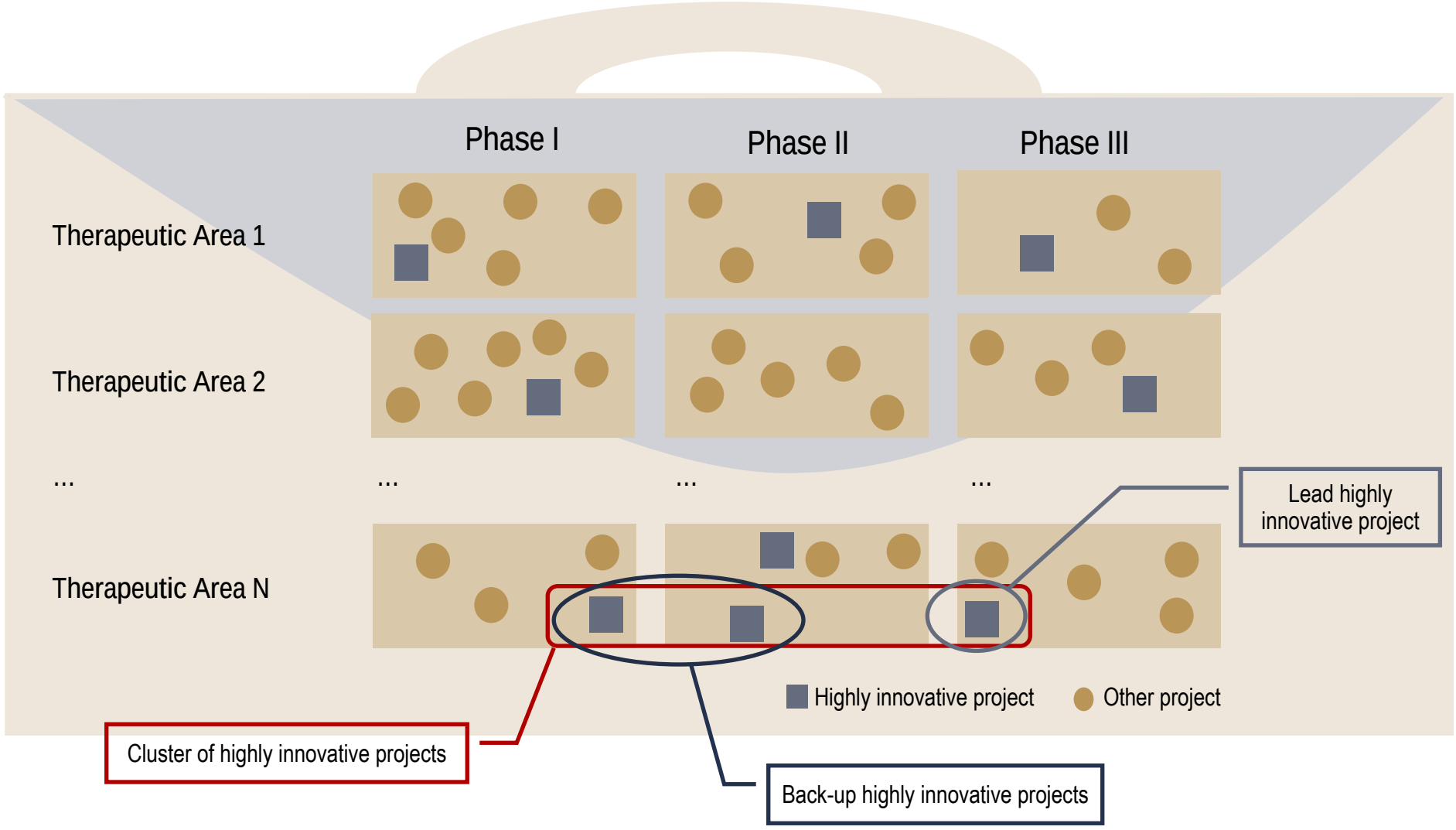
Region B

External
Price Benchmarking (EPB)



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

Drug development
Project portfolio

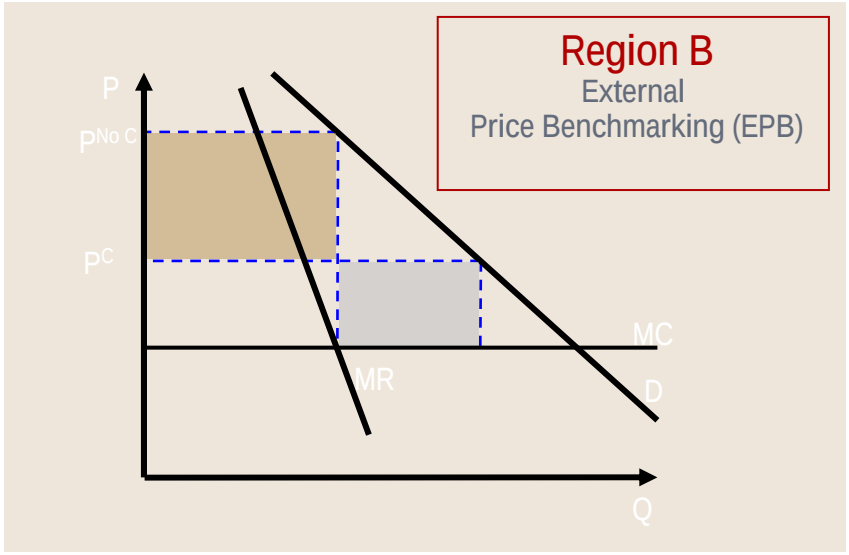


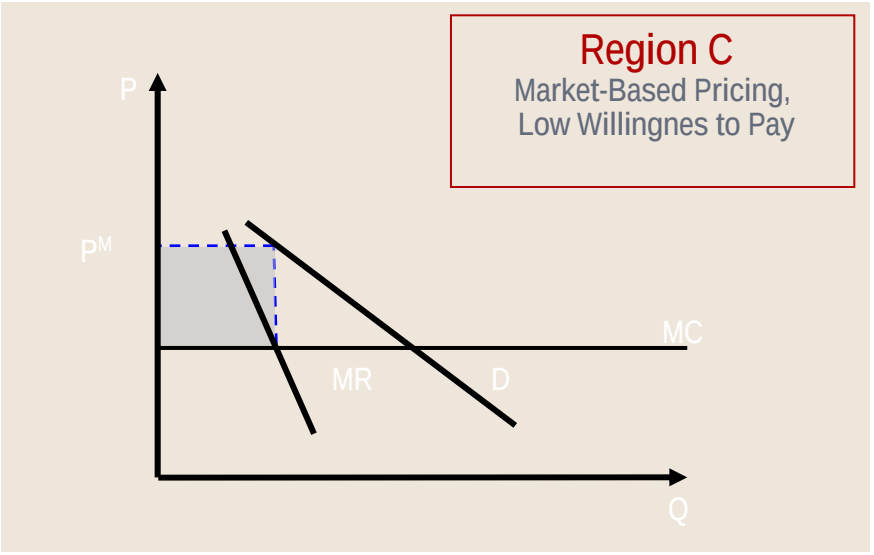
Drug development
A project's life cycle

- The evaluation of a project takes into account future development and launch decisions contingent on the realization of uncertain events
- There are four decision periods: three development phases (Phases I, II, and III) and market launch
- At each development phase, a go/no-go decision is taken
  - If a go decision is taken, current development costs are incurred and—depending on technical success—the project advances to the next development phase or (if the project is in Phase III) market launch
  - Between consecutive periods, a project may lose its high degree of innovativeness because in the meanwhile other highly innovative projects are launched in the market by the same (internal competition) or other pharmaceutical firms (external competition)
- At market launch—once all uncertainty about technical success and degree of innovativeness is resolved—a decision is taken of whether or not to launch in Region C

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)





Drug development
Ranking and selection of projects

- Optimal development and launch decisions yield an Expected Net Present Value (ENPV) for every project in the portfolio
- Because of internal competition, optimal development decisions (and the resulting ENPV) for earlier-phase highly-innovative projects in a cluster depend on optimal development decisions for later-phase highly-innovative projects in the cluster
- The Expected Profitability Index (EPI) is constructed as the ratio of the ENPV to initial development costs
- Ranking of (clusters of) projects by their EPI
- Selection of the highest-ranking (clusters of) projects until the cumulative sum of initial development costs reaches the development budget limit

Calibration

Parameters to which a value must be assigned

- Therapeutic areas and number of projects by therapeutic area and development phase
- For every development phase, development costs and probability of technical success: C_k , π_k
- Development cost premium for highly innovative projects: φ
- Probability of external competition's success: ρ
- Discount rate: r
- For every region and every therapeutic area, demand intercept and slope: a_j^i , b_j^i
- Average/marginal manufacturing/marketing cost: c
- Price discount for not highly innovative drugs in Region A (IRP): λ
- Development budget constraint: B

To calibrate the parameters, we use only information that is available in marketing-research publications or in published academic research

Calibration

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.

Calibration
Other empirical statistics

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
Demand parameters

- From Net Sales and Margin in the US we recover the demand parameters for Region D
- Assume that under market-based pricing:

$$\text{Net Sales}_j^A = \text{Net Sales}_j^B = \frac{1}{2}\text{Net Sales}_j^D,\ \text{Net Sales}_j^C = \frac{1}{20}\text{Net Sales}_j^D$$

$$\text{Margin}_j^A = \text{Margin}_j^B = \text{Margin}_j^D,\ \text{Margin}_j^C = 5\%$$

Calibration
Remaining parameters

Parameter	Value	Source/Target
C_1	30	DiMasi et al. (2003)
C_2	36	DiMasi et al. (2003)
C_3	127	DiMasi et al. (2003)
φ	10%	
π_1	60%	Girotra et al. (2007)
π_2	62.5%	Girotra et al. (2007)
π_3	65%	Girotra et al. (2007)
r	10%	Lehman Brothers (2008)
λ	75%	
ρ	2.5%	
B	3,500	Approx. 90% of the value of the portfolio is selected

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

Policy experiments
Description

- The solution of the quantitative model yields several statistics (expected value of projects, number of projects selected, expected number of projects launched,…)
- To evaluate the effect of pricing regulation on innovation, we compare the statistics coming from alternative versions of the model (policy scenarios)
- In particular, starting from Market-Based Pricing, we add:
  - Internal Reference Pricing (IRP) to Region A
  - External Price Benchmarking (EPB) to Region B
  - IRP to Region A and EPB to Region B—the Pricing Regulation policy scenario
- In all experiments, it is assumed that the development budget is reduced by the same proportion by which the value of the whole portfolio is reduced

Policy experiments

Percentage change in the ENPV of a project under Internal Reference Pricing

Therapeutic Area	Empirical Net Sales	Empirical Margin	Phase I		Phase II		Phase III	
			Highly Innovative	Other	Highly Innovative	Other	Highly Innovative	Other
Analgesia	281	30%	-	-	-3%	-47%	-1%	-29%
Anti-Infective	332	30%	-22%	-100%	-2%	-37%	-1%	-26%
Cancer	932	40%	-1%	-14%	-1%	-12%	0%	-11%
Cardiovascular	570	26%	-3%	-32%	-1%	-23%	-1%	-20%
CNS	728	36%	-2%	-19%	-1%	-16%	0%	-14%
Diabetes	1,150	28%	-2%	-22%	-1%	-19%	0%	-18%
Gastro-Intestinal	568	22%	-2%	-29%	-1%	-21%	0%	-18%
Genito-Urinary	373	23%	-7%	-63%	-2%	-28%	-1%	-21%
Hormone Control	480	30%	-4%	-42%	-1%	-27%	-1%	-22%
Immune System	409	38%	-3%	-36%	-1%	-19%	0%	-15%
Inflammation	1,326	30%	-2%	-22%	-1%	-20%	0%	-19%
Metabolism/Endocr.	473	35%	-3%	-31%	-1%	-20%	0%	-16%
...	...	...	...	...	...	...	...	...

Note: “Highly Innovative” refers to lead highly innovative projects, “Other” to not highly innovative projects.

Policy experiments

Percentage change in the ENPV of a project under External Price Benchmarking

Therapeutic Area	Empirical Net Sales	Empirical Margin	Phase I		Phase II		Phase III	
			Highly Innovative	Other	Highly Innovative	Other	Highly Innovative	Other
Analgesia	281	30%	-	-	-7%	-6%	-4%	-4%
Anti-Infective	332	30%	-37%	-15%	-5%	-5%	-3%	-3%
Cancer	932	40%	-3%	-3%	-3%	-3%	-3%	-3%
Cardiovascular	570	26%	-4%	-4%	-3%	-3%	-2%	-2%
CNS	728	36%	-4%	-4%	-3%	-3%	-3%	-3%
Diabetes	1,150	28%	-3%	-3%	-2%	-2%	-2%	-2%
Gastro-Intestinal	568	22%	-4%	-4%	-3%	-3%	-2%	-2%
Genito-Urinary	373	23%	-11%	-8%	-4%	-4%	-3%	-3%
Hormone Control	480	30%	-6%	-5%	-4%	-3%	-3%	-3%
Immune System	409	38%	-10%	-7%	-4%	-4%	-3%	-3%
Inflammation	1,326	30%	-3%	-3%	-2%	-2%	-2%	-2%
Metabolism/Endocr.	473	35%	-7%	-6%	-4%	-4%	-3%	-3%
...	...	...	...	...	...	...	...	...

Note: “Highly Innovative” refers to lead highly innovative projects, “Other” to not highly innovative projects.

Policy experiments

Percentage change in the ENPV of a project under Pricing Regulation

Therapeutic Area	Empirical Net Sales	Empirical Margin	Phase I		Phase II		Phase III	
			Highly Innovative	Other	Highly Innovative	Other	Highly Innovative	Other
Analgesia	281	30%	-	-	-11%	-65%	-5%	-40%
Anti-Infective	332	30%	-65%	-100%	-8%	-51%	-4%	-36%
Cancer	932	40%	-5%	-21%	-4%	-18%	-3%	-16%
Cardiovascular	570	26%	-8%	-44%	-4%	-32%	-3%	-28%
CNS	728	36%	-6%	-28%	-4%	-23%	-3%	-20%
Diabetes	1,150	28%	-5%	-30%	-4%	-27%	-3%	-25%
Gastro-Intestinal	568	22%	-7%	-41%	-4%	-30%	-3%	-26%
Genito-Urinary	373	23%	-20%	-90%	-6%	-40%	-3%	-30%
Hormone Control	480	30%	-11%	-58%	-5%	-38%	-4%	-31%
Immune System	409	38%	-14%	-53%	-6%	-28%	-4%	-22%
Inflammation	1,326	30%	-5%	-30%	-4%	-27%	-3%	-26%
Metabolism/Endocr.	473	35%	-10%	-45%	-5%	-29%	-4%	-24%
...	...	...	...	...	...	...	...	...

Note: “Highly Innovative” refers to lead highly innovative projects, “Other” to not highly innovative projects.

Policy experiments
Evaluation of lead and back-up highly innovative projects under Internal Reference Pricing

Therapeutic Area	ENPV (in Phase I)				Percentage Change in ENPV (in Phase I)			
	Lead	Back-Up (Lead in PII)	Back-Up (Lead in PIII)	Back-Up (Lead in PIII and Another Back-Up in PII)	Lead	Back-Up (Lead in PII)	Back-Up (Lead in PIII)	Back-Up (Lead in PIII and Another Back-Up in PII)
Analgesia	0.0	0.0	0.0	0.0	-	-	-	-
Anti-Infective	4.1	3.5	0.7	0.0	-22%	-67%	-94%	-100%
Cancer	172.7	168.6	163.8	161.3	-1%	-6%	-9%	-11%
Cardiovascular	70.5	66.4	61.4	58.9	-3%	-15%	-22%	-26%
CNS	115.1	111.4	106.7	104.3	-2%	-9%	-13%	-16%
Diabetes	232.0	217.4	206.2	200.1	-2%	-10%	-15%	-18%
Gastro-Intestinal	70.1	66.8	62.4	60.2	-2%	-13%	-20%	-24%
Genito-Urinary	15.5	15.0	12.3	11.1	-7%	-32%	-46%	-53%
Hormone Control	45.1	41.9	37.5	35.3	-4%	-20%	-29%	-34%
Immune System	26.0	26.7	24.6	23.8	-3%	-17%	-26%	-30%
Inflammation	280.9	262.4	248.9	241.3	-2%	-10%	-15%	-17%
Metabolism/Endocr.	43.8	42.9	39.9	38.6	-3%	-15%	-22%	-26%
...	...	...	...	...	...	...	...	...

Policy experiments
Value of the whole portfolio

- As a result of Internal Reference Pricing, the value of the whole portfolio moves from USD 27,177 m under Market-Based Pricing to USD 24,869m—a drop of 8.5%
- As a result of External Price Benchmarking, the value of the whole portfolio moves from USD 27,177 m under Market-Based Pricing to USD 26,437m—a drop of 2.7%
- As a result of Pricing Regulation, the value of the whole portfolio moves from USD 27,177m under Market-Based Pricing to USD 23,517m—a drop of 13.5%

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

Policy experiments
Ranking and selection

		Policy Scenario			
		Market-Based Pricing	Internal Reference Pricing	External Price Benchmarking	Pricing Regulation
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

Policy experiments
Value of the selected portfolio

- 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%

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

Policy experiments
Summary of results

- Internal Reference Pricing reduces the expected value of all projects—including highly innovative projects
- Internal Reference Pricing reduces in particular the value of projects in low-margin, low-sales therapeutic areas, at early development stages, and with little 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
- Because of the ensuing reduction in the development budget, the value drop under pricing regulation in the selected portfolio is greater than in the whole portfolio
- Overall, under pricing regulation fewer projects are developed and launched in the market

Agenda

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

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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http://www.esmt.org/fm/479/WP-109-03.pdf

Annex with alternative calibrations

Alternative calibrations

Calibration with alternative lambda and with alternative regional weights

- Alternative lambda: The price discount for not highly innovative drugs in Region A (IRP) is higher than in the benchmark calibration and in particular is equal to 50%:[1] $\lambda = 0.50$
- Alternative regional weights: The weight of Region D (Market-Based Pricing) is equal to 50% of the weight of Region A (IRP)—the reverse of the benchmark calibration. This entails that the regional distribution of weights is as follows:

$$\begin{cases} \text{Net Sales}_j^A = 1 \\ \text{Net Sales}_j^B = 0.5 \\ \text{Net Sales}_j^C = 0.05 \\ \text{Net Sales}_j^D = 0.5 \end{cases}$$

[1] As in the benchmark calibration, we assume that the price-cost margin never falls below 5%. This implies that when the margin under Market-Based Pricing is lower than 55%, the effective price discount is lower than 50%.

Alternative calibrations
Summary of results

			Benchmark Results	Results with Alt. Lambda	Results with Alt. Regional Weights
Internal Reference Pricing	Drop in the value of selected portfolio		-11.7%	-18.7%	-31.1%
	Drop in the expected number of projects launched	Highly innovative	-7.6%	-18.6%	-9.3%
		Total	-8.2%	-15.2%	-23.0%
External Price Benchmarking	Drop in the value of selected portfolio		-5.7%	-5.7%	-5.7%
	Drop in the expected number of projects launched	Highly innovative	-9.3%	-9.3%	-9.3%
		Total	-5.9%	-5.9%	-5.9%
Pricing Regulation	Drop in the value of selected portfolio		-19.8%	-24.1%	-38.6%
	Drop in the expected number of projects launched	Highly innovative	-18.6%	-9.3%	-7.6%
		Total	-15.2%	-15.5%	-27.8%

Alternative calibrations
Summary of results (continued)

- Increasing the price discount for not highly innovative drugs or increasing the weight of Region A (IRP) at the expense of Region D increases the drop in the value of the selected portfolio and in the expected number of total projects launched under the IRP and the Pricing Regulation policy scenarios
- The EPB scenario is obviously independent of the price discount or the relative weights of Region A and Region D
- Increasing the price discount for not highly innovative drugs, increasing the weight of Region A, or moving from the IRP scenario to the Pricing Regulation scenario have two conflicting effects on the number of highly innovative projects:
  - A ranking effect, pushing highly innovative projects towards the top of the list
  - A budget effect, reducing development resources
- In the benchmark calibration, the budget effect prevails over the ranking effect and more highly innovative projects are dropped under the Pricing Regulation than under the IRP scenario
- In the alternative calibrations, the ranking effect prevails over the budget effect and more highly innovative projects are dropped under the IRP than under the Pricing Regulation scenario