



Value for money and valued innovation: A trade-off or mutually compatible goals?

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Economic context: Can we leave it to the market?

- Pharmaceuticals considered a “merit good” that would be under-consumed in the absence of market interventions
- This has led to important public subsidies of pharmaceuticals
 - through insurance coverage and/or public provision in all OECD countries
 - even in the US and Canada , which provide a tax exemption for employer-provided private insurance benefits
 - Public financing accounts for 60% of expenditures for medicines used outside the hospital setting and a higher share of hospital medicines
- The combined impact of patent protection and insurance subsidies = tendency to inflate prices and consumption of medicines, increasing expenditure/sales revenue
- Policy makers seek to offset these inflationary pressures and ensure affordable access to needed medicines through market regulation

The pharmaceutical policy-maker's dilemma

- We want to promote **valued innovation**.
 - How to ensure development of valued products in the future?
 - Why so many “me-too” drugs and products with no therapeutic advantage relative to existing treatments? Encouraged by pricing policy?
 - Is it the case that price regulation by definition has a negative impact on future innovation?

- We are under pressure to get **good value from public expenditure**
 - In many countries, medicine costs are increasing faster than other components of health care.
 - In many countries, the standard of ensuring affordable access to needed medicines is not being met.
 - Challenge is to maximize benefits from spending on medicine without increasing cost pressure

N.B. The presentation focuses on policies to meet policy objectives within the existing market and policy framework.

Determinants of pharmaceutical innovation

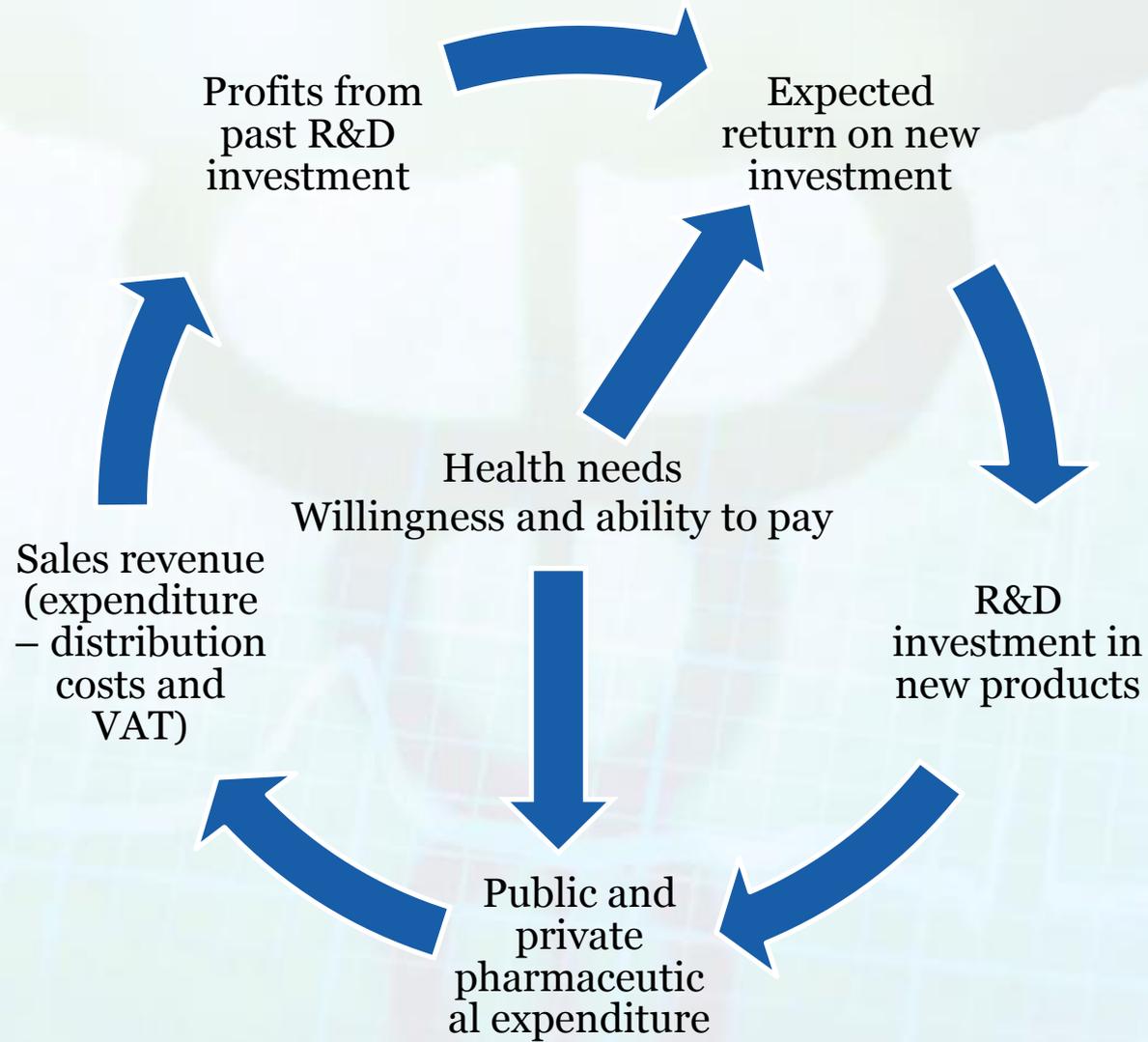
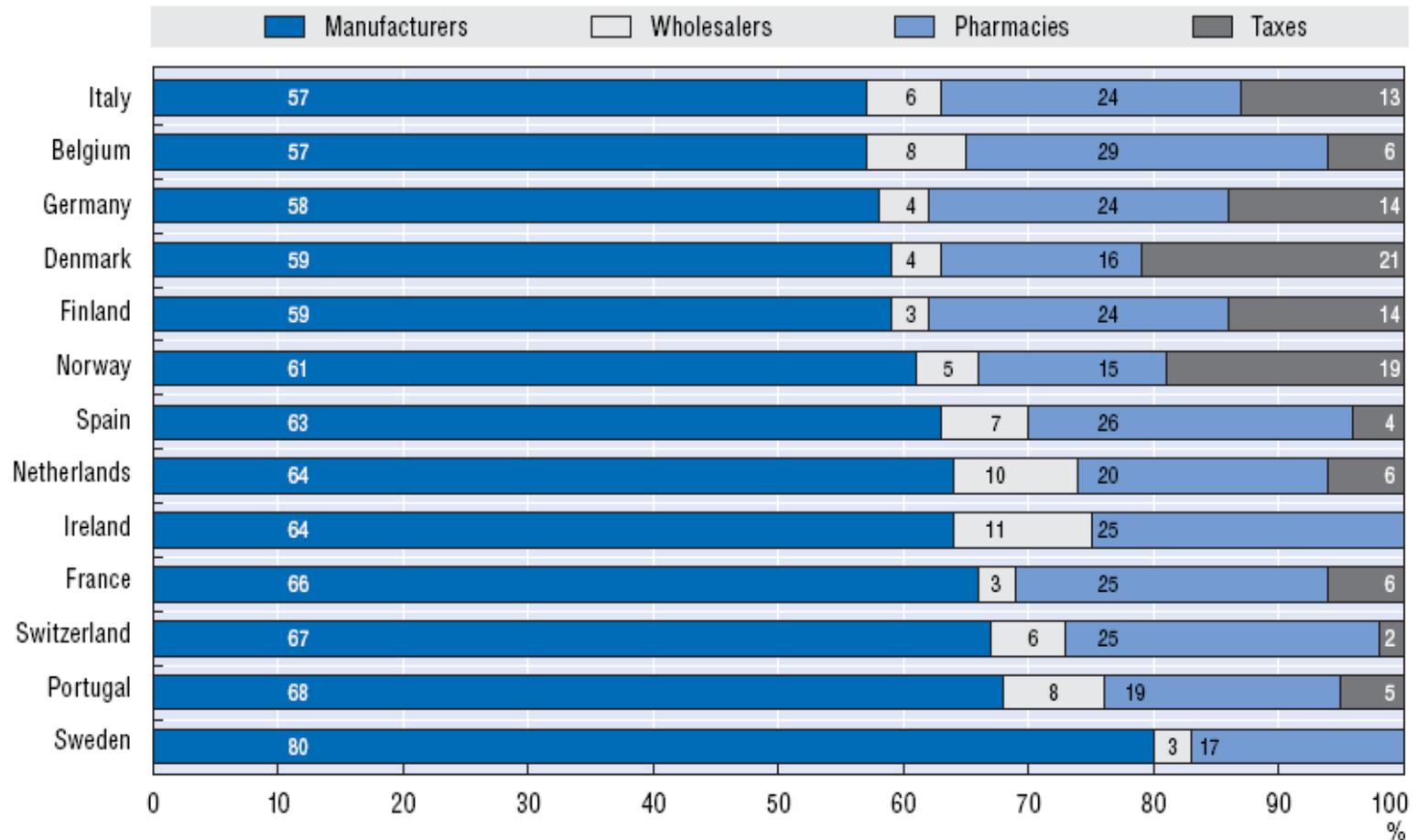


Figure 1.9. Components of retail pharmaceutical prices, selected OECD countries, 2004



Source: VFA (2006), *The Pharmaceutical Industry in Germany*, Verband Forschender Arzneimittelhersteller e.V. (German Association of Research-Based Pharmaceutical Companies) Berlin: the original source of these data is the European Federation of Pharmaceutical Industry Associations (EFPIA).

Determinants of profits of the research-based pharmaceutical industry in OECD markets

- **Ex-manufacturer prices of original products**
 - Freedom to set profit-maximizing level upon market entry (e.g., UK, US, Germany)
 - Low pressure to reduce original product price after market entry
 - to compete for market share
 - upon patent expiry (e.g., Quebec)

- **Per-capita volume of consumption** of original products
 - Patient and physician preferences favouring use of medicines (e.g., France)
 - Fast diffusion of new products into medical practice (e.g., France, Japan, Australia, Spain)
 - Comprehensive coverage of all/most products approved for marketing with no/limited formulary management (e.g., Switzerland)
 - Low cost-sharing for covered medicines
 - Consumer advertising permitted (e.g., US)

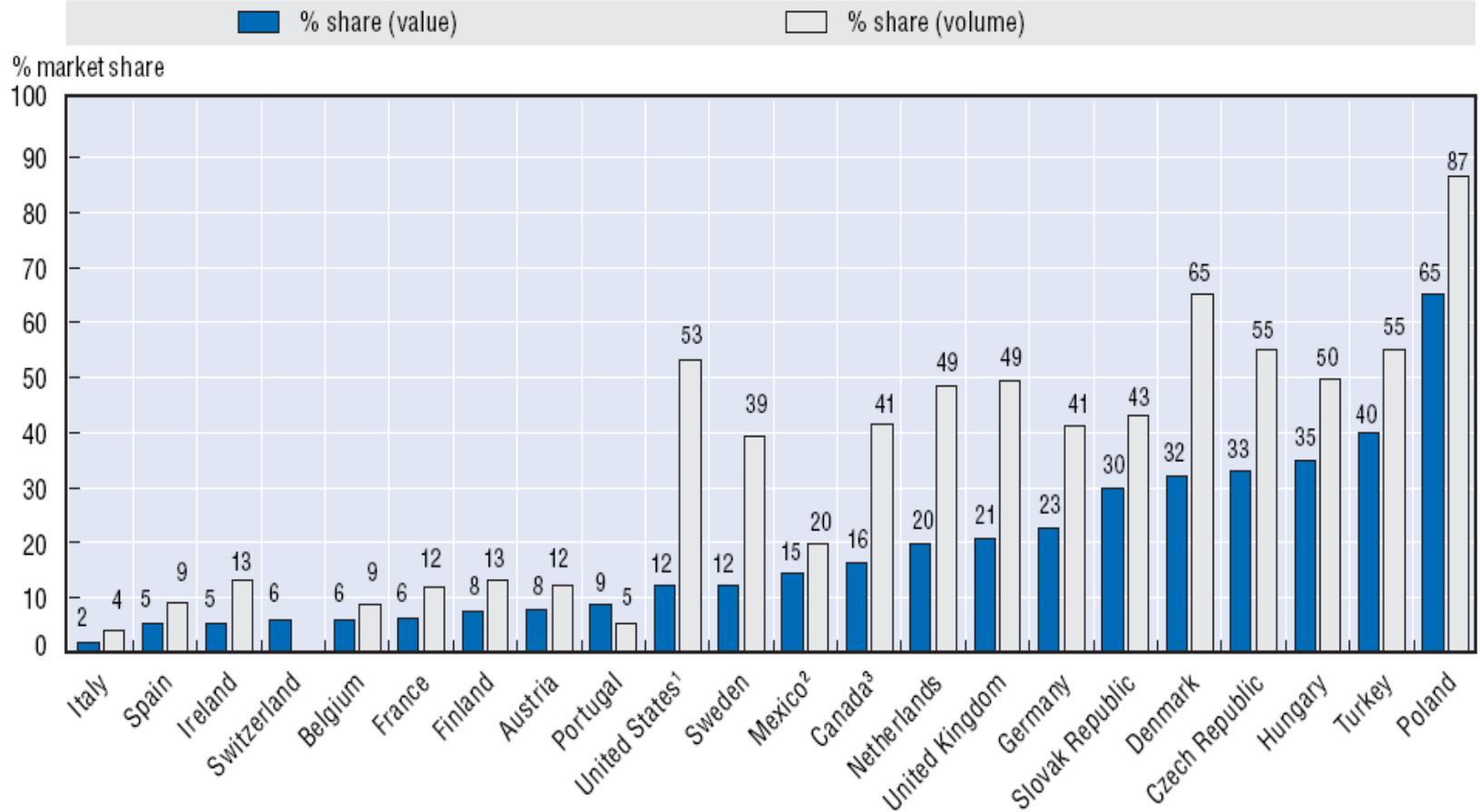
Determinants of profits in the research-based pharmaceutical industry (cont'd)

- Effective lifespan of original products
 - Early launch in market, relative to first world launch (e.g., US, Germany, UK)
 - Automatic coverage/reimbursement (e.g., Germany) or prompt coverage decision-making
 - Early adoption of new products into medical practice (e.g., US)
 - Receptiveness to patent extension/"ever-greening" efforts
 - Slow and limited market penetration of generic alternatives to off-patent originals (e.g., Italy, Spain)

- Costs of doing business
 - No claw-backs or mandatory rebates
 - No profit controls
 - Limited manufacturer liability for product safety

Depending on which factors are considered, different markets look more or less profitable. Some criteria run counter to health policy objectives; others not.

Figure 2.5. **Market share of generics in terms of value and volume, 2004**



1. Overview of North American Generic Market, presentation by R. Milanese, President, RSM Pharmaceutical Services Inc., to the SFBC Anapharm Workshop, Malta, 19 June 2005, www.anapharm.com/sfbc/upload/sfbc/Generateur/RobertMilanese_Overview.pdf, accessed 7 September 2005.
2. 2002, ANAFAM (Asociación Nacional de Fabricantes de Medicamentos), www.anafam.org.mx/quienes/historia.html, accessed 7 September 2007 (in Spanish).
3. CGPA (2007).

Source: EGA – European Generics Manufacturers Association (2007); except Switzerland EFPIA (2006).

Broad policy aims

What can policy makers do to increase efficiency of pharmaceutical expenditure while supporting and incentivizing valued innovation?

- Promote appropriate use of effective medicines
- Deter overuse and misuse of medicines
- Subsidize purchase of medicines where use is cost-effective from social perspective
- Employ reimbursement pricing policies that take into account therapeutic value (for breakthrough products) and/or relative value-added (for new entrants in a therapeutic class) of patented medicines
- Ensure that information on costs and benefits relevant to alternatives is available to decision-makers (pricing and coverage authorities, physicians, pharmacists, patients)

Broad policy aims (cont'd)

- **Align incentives** of physicians, pharmacists and patients to favour cost-effective alternatives
- Promote fast and deep market penetration of generic alternatives to off-patent originals
- Promote fast and deep price erosion for bio-equivalent products once original is off-patent
- Ensure an **efficient distribution system**

Pricing policy assessment: International benchmarking

Overview

- **International benchmarking** (external price referencing) is the most commonly used approach (22/30 OECD countries) to cap prices (or reimbursement levels) of innovative medicines.
- Germany, UK and France are the three most commonly referenced by OECD countries. Germany and the UK do not restrict manufacturer price at market launch.

Pricing policy assessment: International benchmarking (cont'd)

Assessment

- Does not support aim of cost-effective expenditure.
 - Whether use of a medicine is cost-effective at a given price depends on health needs, income, preferences and health care costs, which vary across countries.
 - Confidential rebates result in effective price below price publicly known.

- Does not provide market signals for valued innovation.
 - Use may be cost-effective at a higher price than elsewhere, in which case the policy has a negative impact on rewards to valued innovation.
 - Promotes minor product differentiation (with no therapeutic advantages) across markets

- Adds to problem of affordable access in global market.
 - Has reduced the ability to price to market and contributed to convergence of list prices, likely resulting in list price inflation
 - Provides manufacturers with incentives to delay launch in lower-priced markets where there is risk of spill-over

Pricing policy assessment: So-called reference pricing

Overview

- Many OECD countries set a maximum reimbursement amount for defined groups of products, with patients to pay out of pocket any amount above maximum
- Products in reference groups account for as little as 5% or as much as 44% of total value of sales
- Most groups are bioequivalent products (off-patent original, generic alternatives and parallel imports)
- A few countries have broader clusters (therapeutic equivalents)

Pricing policy assessment: So-called reference pricing (cont'd)

Assessment

- Cost-effectiveness
 - Can promote cost-effective expenditure for products with alternatives, particularly if maximum reimbursement amount is regularly adjusted to promote price erosion
 - No impact on cost-effectiveness of spending across clusters

- Innovation
 - Can reward **valued incremental innovation** by allowing sellers to obtain a price premium where buyers know about added benefits and consider them worth added cost. Creates **strong incentives for innovation sufficient to avoid inclusion in an existing cluster.**
 - Disincentivizes **incremental innovation** to the extent that those making purchasing decisions do not have the information on relative cost-effectiveness or incentives to provide it to patients (in the case of prescribing physicians)

SOMETHING TO THINK ABOUT...

**THE PRACTICE
IS YOURS.**

**THE PATIENTS
ARE YOURS.**

**THE PRESCRIPTIONS
ARE YOURS.**

MAKE THE PRESCRIBING DECISION YOURS, TOO

SPECIFY "D.A.W."

Pricing policy assessment: Value-based pricing

Overview

- A number of countries (e.g., Canada, France, Japan, Switzerland) allow a price premium for new products with added benefits. Fewer explicitly consider **whether benefits are worth the added cost**.
- Several insurers (e.g., Canadian public payers) and health systems (e.g., England, Sweden) make coverage or provision contingent on determination that use of the product would be cost-effective (from payer or social perspective) at the proposed price.
 - This requires a comparison of the cost/QALY against an explicit or implicit threshold (which may vary according to characteristics of drug or target condition).
- Pharmaco-economic assessment may be used as a tool for formal assessment or decision-makers may rely on information from industry.

Pricing policy assessment: Value-based pricing

Assessment

- Because of cross-country differences in income, health needs and costs, per-capita expenditures and unit prices for individual medicines could vary widely if more countries used value-based pricing to define reimbursement levels.
- Can help ensure costs do not exceed benefits, although may result in some countries paying higher prices for certain medicines.
- Promotes valued innovation and provides a disincentive for innovation that does not offer demonstrable added value, relative to existing therapies.

Pricing policy assessment: Purchasing agreements

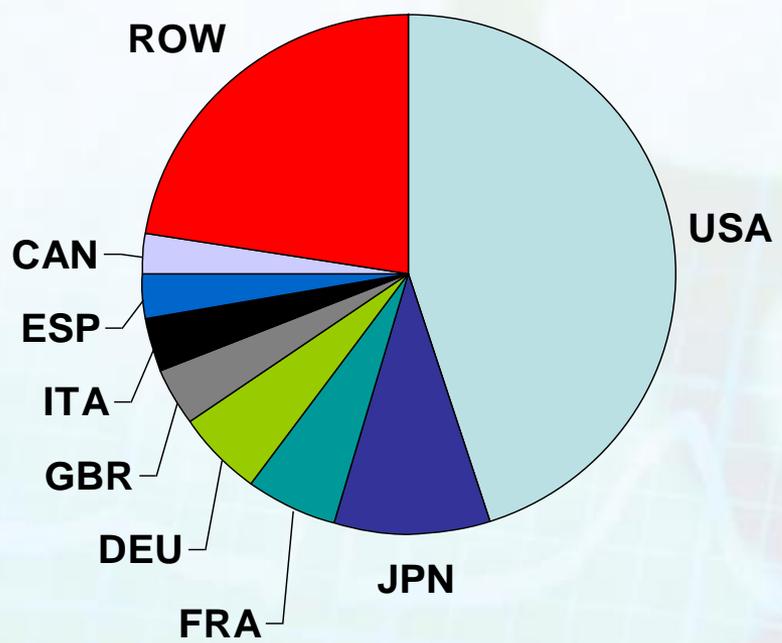
- Examples of arrangements between pharmaceutical sellers and buyers
 - **Price-volume agreements** have potential to address affordability problems for lower-income countries
 - **Risk-sharing agreements** could facilitate affordable access to medicines in the face of uncertainty
 - **Framework agreements** between state and industry make expectations explicit

- Move focus off of unit prices and on to value for money

- Cost is **reduced transparency**

Individual and collective impact of policies on future innovation

Share of global pharmaceutical sales

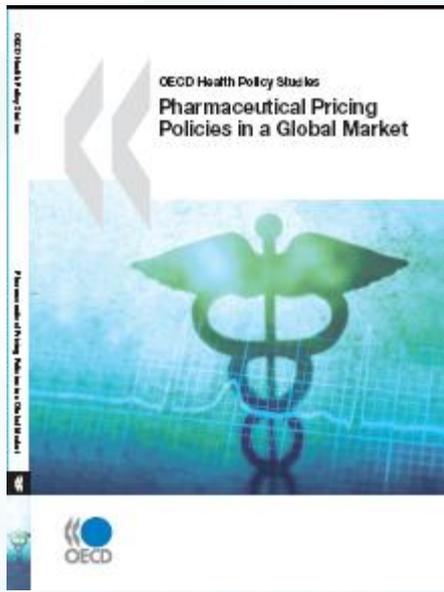


- A few big markets with a lot of influence in global market; their policies will have an important effect
- But some smaller markets are influential because of spill-over effects (e.g., early launch, reference countries)
- Some coordination (e.g., agreement on certain priorities) could promote a consistent message to industry

Some conclusions

- It is possible to employ policies that promote both value for money and valued innovation.
- Need to strive for a coherent pharmaceutical policy framework with policies, **including but not limited to pricing policies**, working consistently to achieve desired objectives.
- Most countries have room to improve in one or more areas, in terms of the cost-effectiveness of pharmaceutical expenditure and/or the incentives and support for valued innovation their policies provide.

For more information



Pharmaceutical Pricing Policies in a Global Market (OECD, 2008)

Case study reports available for download:
www.oecd.org/health/pharmaceutical

Canada
Germany
Mexico

Sweden
Switzerland
Slovakia