*Workshop on Current Pharmaceuticals Challenges*
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OECD OCDE

# Pharmaceutical pricing policy in a global market

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# Pharmaceutical policy objectives

- Policies are geared towards common health policy objectives
  - promoting public health,
  - containing cost growth to sustainable levels, and
  - obtaining good value for money in public expenditure
- Further objective of promoting future innovation in medicine
  - Potential trade-off between static and dynamic efficiency: Getting the best possible price today may impact future health gains
- …and sometimes, also, towards supporting industrial policy objectives, where pharmaceutical industry activity is important to the national economy, or further investment is sought.
  - Of the top 15 pharmaceutical firms, 8 are located in the United States and 7 in Europe (two each in the United Kingdom, Switzerland, Germany, and one in France)
  - But these firms operate globally. Activities are of greatest economic importance in several countries:
    - Pharmaceutical production particularly important for the economy of IRL, CH
    - Exports relatively most important in CH, IRL, FR, UK, SWE, DE, DK, BE
    - Industry financed R&D activities are most important to CH and BE

# Globalisation of the pharmaceutical market is a factor to be accounted for by policy makers, as by firms

- Unlike most other types of health services --- for which health systems or social insurance act as a monopsony purchaser in markets defined by national borders --- the pharmaceutical market is increasingly global
  - New products are launched in an average of 10 countries, with therapeutically important products launched in most developed countries
  - Different versions of products may be released in different countries by a manufacturer, subsidiary or licensee
  - Parallel or cross-border trade in pharmaceuticals is possible within Europe and elsewhere
  - Information on pharmaceutical prices is increasingly available and accessible to other payers, purchasers and regulators

# OECD Pharmaceutical Pricing Policy Project

## (autumn 2005 – winter 2007)

- Hypothesis: pharmaceutical policies have cross-national and global impacts, including effects on
  - the prices and availability of medicines elsewhere
  - investment in R&D for new pharmaceuticals
- These “externalities” may not be well taken into account in national policy making.
- Objectives and rationale of the project
  - Evaluate the national, cross-national and global impact of different types of pharmaceutical pricing policies
  - Evaluate the nature and extent of externalities associated with pharmaceutical pricing policies
  - Provide information needed to assess impact of national pricing policies on national policy objectives, and to take externalities into account in pharmaceutical policy making
- Methods: 6 original case studies, policy analysis, review of research literature
- OECD project team: Elizabeth Docteur, Valérie Paris, Pierre Moïse, Lihan Wei

# Pharmaceutical pricing policy in OECD countries

- Some countries **regulate prices of on-patent drugs** to protect consumers against the risk of manufacturers exploiting their monopoly position, in the face of relatively inelastic demand
  - Approach taken in Canada and Mexico, both with pluralistic coverage schemes

- Public payers in most OECD countries **set or limit the prices of reimbursed medicines** in exchange for subsidy (*de facto* regulation)
  - Manufacturers have the option of not submitting their products for reimbursement, but instead marketing their products directly to consumers (at the cost of losing insurance subsidy)
  - US Medicaid programme approach

- **Free or market-based pricing** is often the rule for OTC products and for products that are not reimbursed, rarely also for products that are reimbursed
  - Free pricing at market entry in DE, DK, US, UK

# Techniques used in OECD countries to define or limit prices or reimbursement prices

- International benchmarking - other payers/purchasers used as a reference
- Internal referencing – other products used as a reference
  - In **therapeutic referencing**, the price for new products is defined in comparison to therapeutic alternatives
  - Under so-called "**reference pricing**," a maximum reimbursement level is set for a defined group of products (patients pay the difference)
- Pharmaco-economic assessment – price based on considerations of the product's cost-effectiveness (net benefits against costs)
- Tendering – seller defines price
- Indirect price control (profit control)

# What determines the outcome of price negotiations?

- Market power of **sellers**
  - Patent protection gives firms exclusive rights, but monopoly position may be weakened by competition in a therapeutic area
  - If there is no competition and drug is important, seller can set high prices: High level of insurance contributes to low price elasticity of demand
- Market power of **payers/purchasers** (public and private) linked to:
  - The number of "covered lives" and willingness/ability to pay
  - The ability to influence the volume and mix of products used
    - Is the insurer obliged to cover all products meeting criteria for reimbursement?
    - Does the insurer have the ability to designate products as preferred or to restrict coverage to particular circumstances?
- **Public payers/regulators** have objectives other than cost-containment (e.g., support national industry, encourage innovation)

  … and do not always seek to obtain the lowest possible price
- In a **competitive insurance market**, private payers face strong incentives to negotiate the lowest possible price
  - Outcome depends on relative market power

# Pharmaceutical industry's traditional strategy

- The objective is to maximise profit over a product's life cycle, by
  - Launching as quickly as possible in profitable markets
  - Pricing at the level that will maximize profits, assessed according to market conditions and regulatory constraints
  - Trying to extend the period of market exclusivity
  - Engaging in promotional activities to grow the market and gain market share

- Firms have traditionally sought to maximise their rents by segmenting markets and **differentiating their sales prices according to purchasers' ability and willingness to pay**, within and across countries, to the extent possible

# How do national pricing policies affect the prices and availability of medicines in other countries?

- The very widespread use of **international benchmarking** (external price referencing)
  - 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
- The practice of making **confidential rebate or discount agreements** may result in higher prices in other countries not entering such agreements
  - Countries using external referencing will benchmark to artificially high "list" prices
  - Artificially high prices will result in lost opportunities to achieve lower prices through parallel trade
- Expected impact = convergence of list prices at higher levels; delays or foregone launch in countries with markets that don't support sales in the price range; efficiency losses

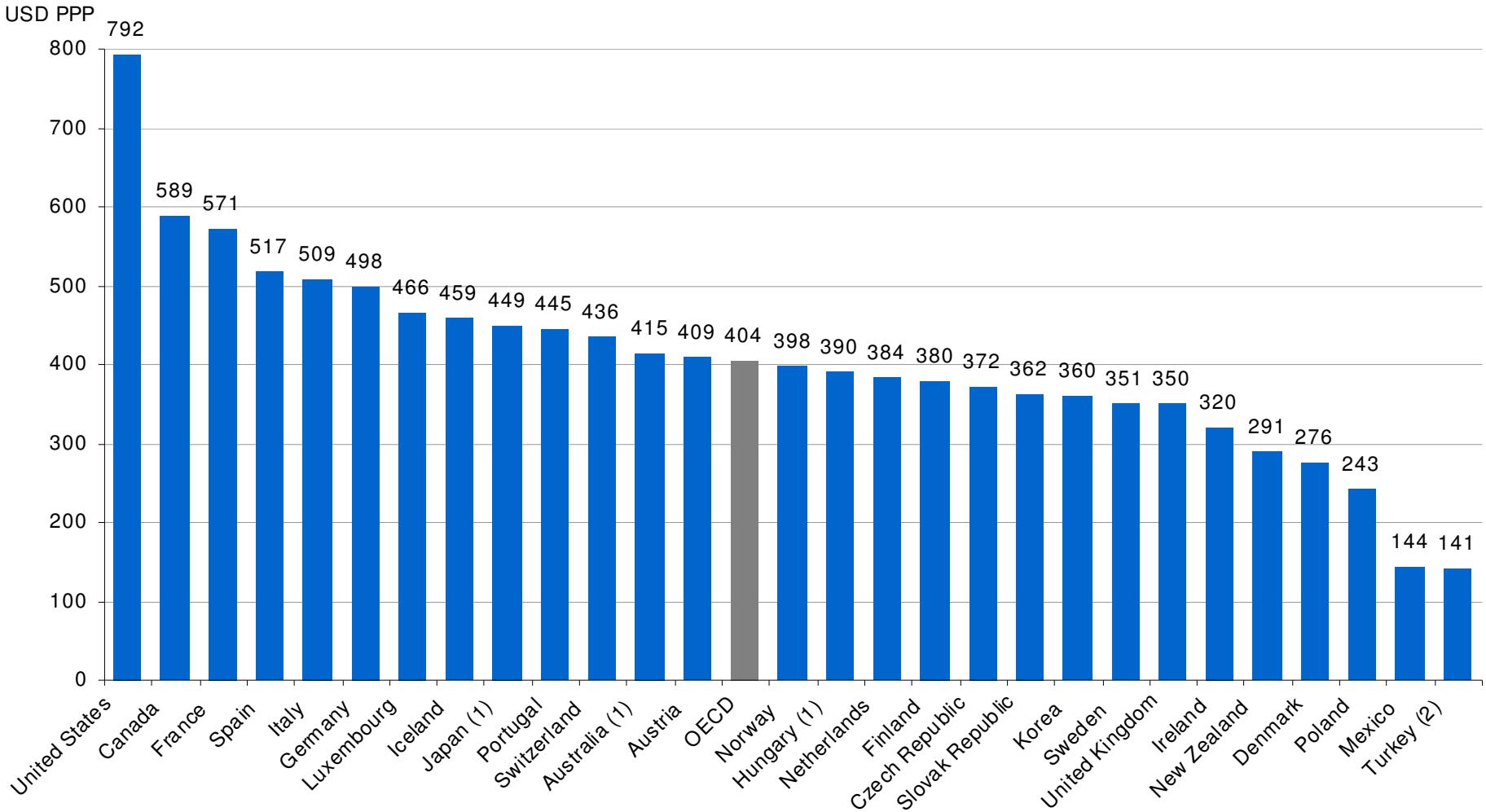
# Manufacturers have adapted to the increasingly global market

- Manufacturers have developed strategies to maximize profits in an increasingly global market
  - They launch first in countries where they can set prices freely or can negotiate relatively high prices
  - They delay or refrain from launch in relatively lower-priced countries (affecting timely availability of new medicines), to avoid cross-pollination of low prices
  - They strive to maintain high list prices, even when they are willing to consent to confidential rebates
  - They use strategies to prevent or inhibit parallel and cross-border trade: supply chain management, product proliferation, litigation, and lobbying

# Evidence of price convergence

- There is, in fact, some evidence of price convergence among OECD countries
  - An analysis of evidence from three studies with longitudinal data suggests that there has been some convergence in ex-manufacturer pharmaceutical prices within Europe (incl. Switzerland) and Canada since the early 1990s, but not for the United States
  - For other types of tradable goods, price convergence has been observed in the 1990s (except for markets with high trade barriers) and price divergence since then.

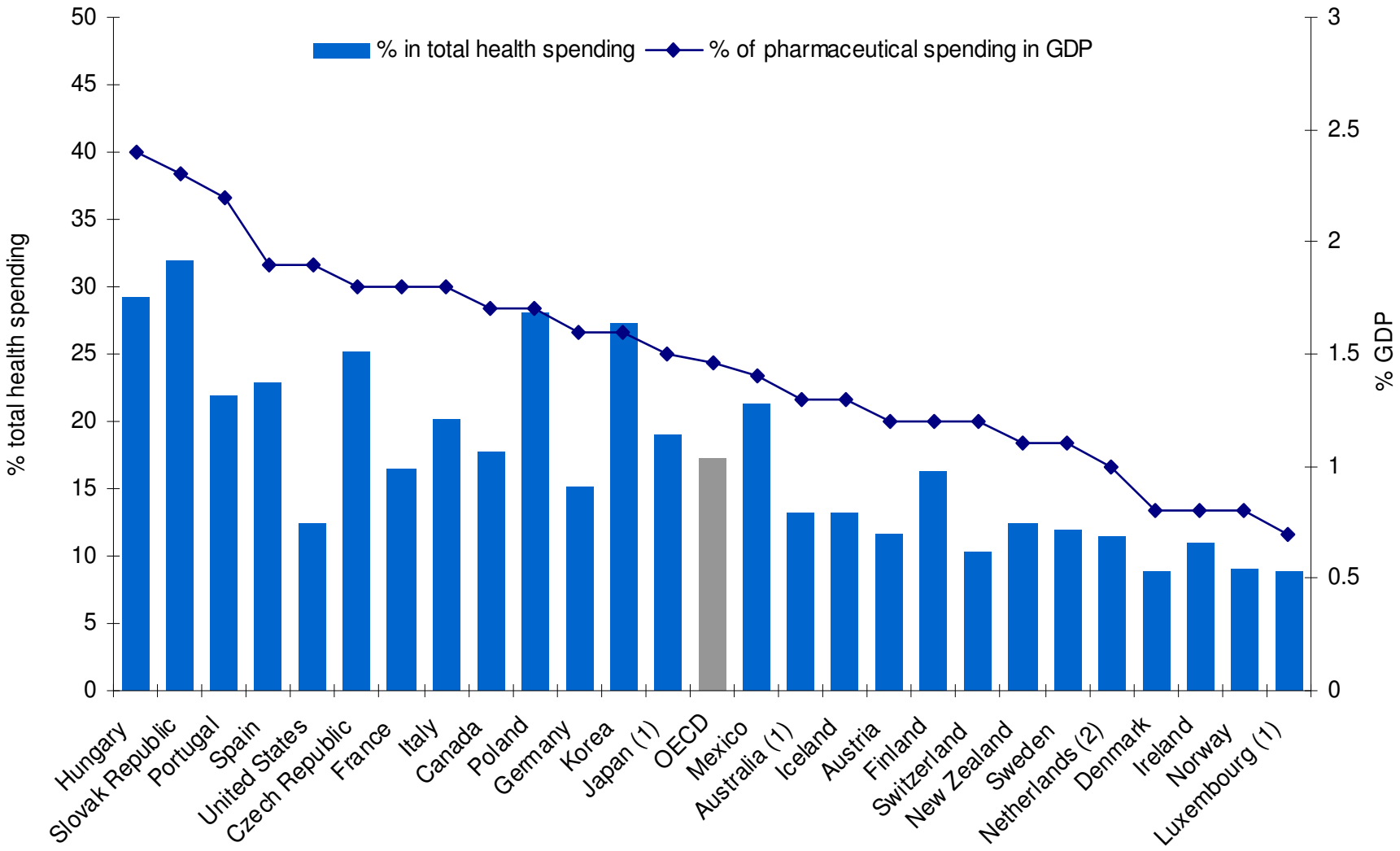
# Per capita spending on pharmaceuticals: More than half of OECD countries within ± 20% of the OECD average in 2005



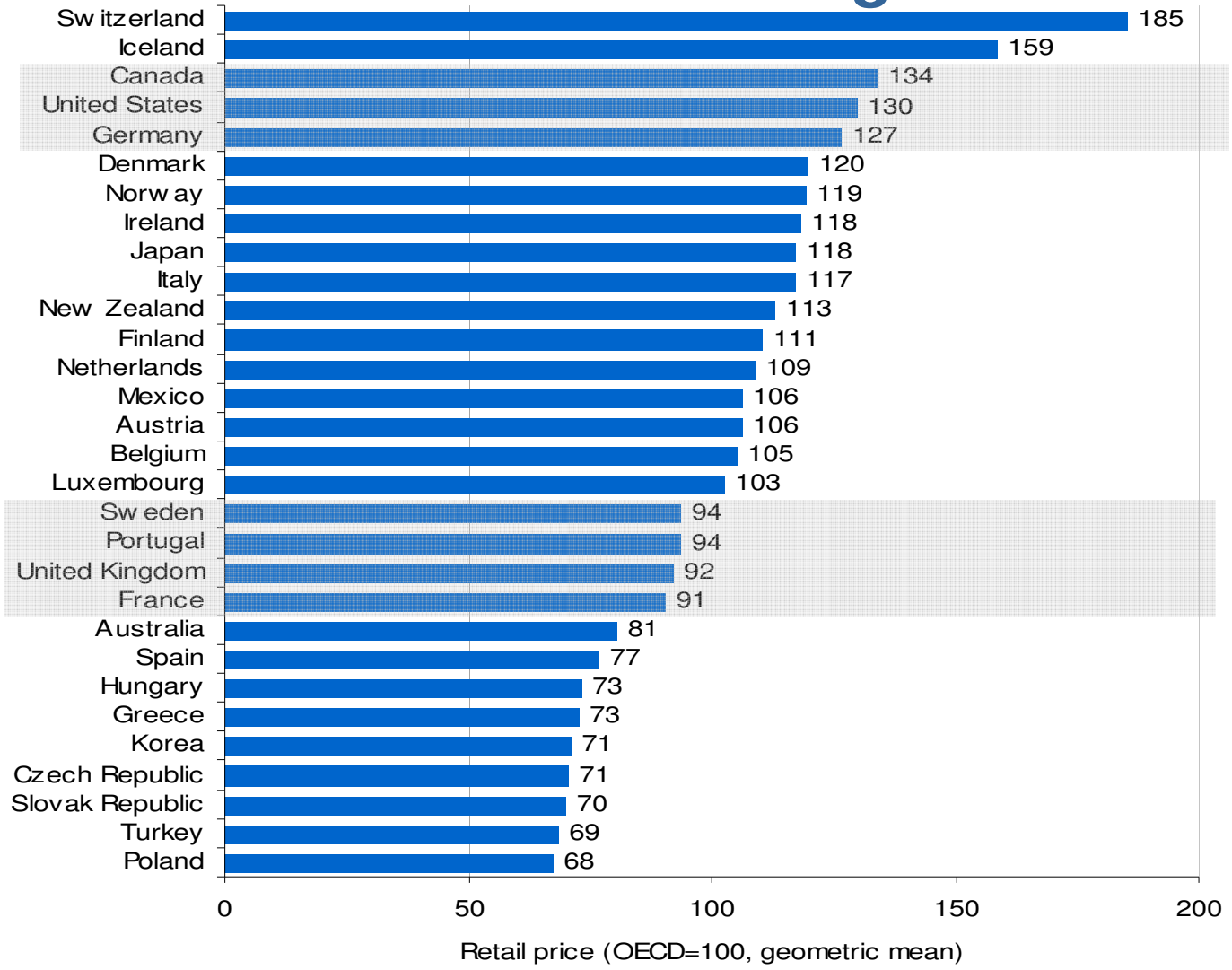

(1) 2004; (2) 2003; (3) 2005 pharmaceutical sales per capita

Source OECD HEALTH DATA 2007, July 07

# Importance of pharmaceutical expenditure in total health expenditure and GDP, 2005



# Retail pharmaceutical prices vary between -30% to + 85% of the OECD average

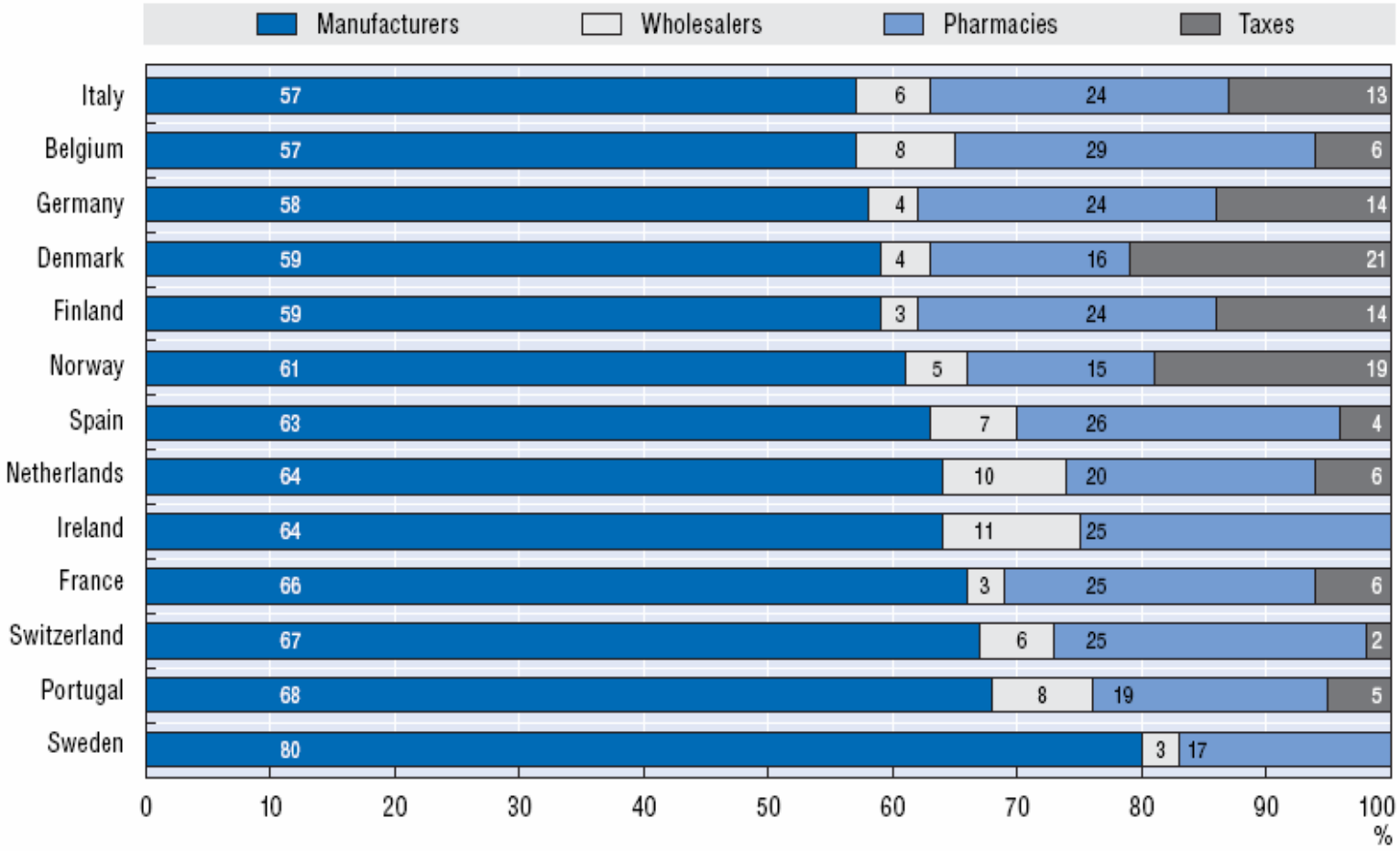





Note: Prices were converted to a common currency using the 2005 average exchange rate

Source: Eurostat-OECD Purchasing Power Parity Programme, 2007, Pharmaceutical Pricing Project Final Report, forthcoming

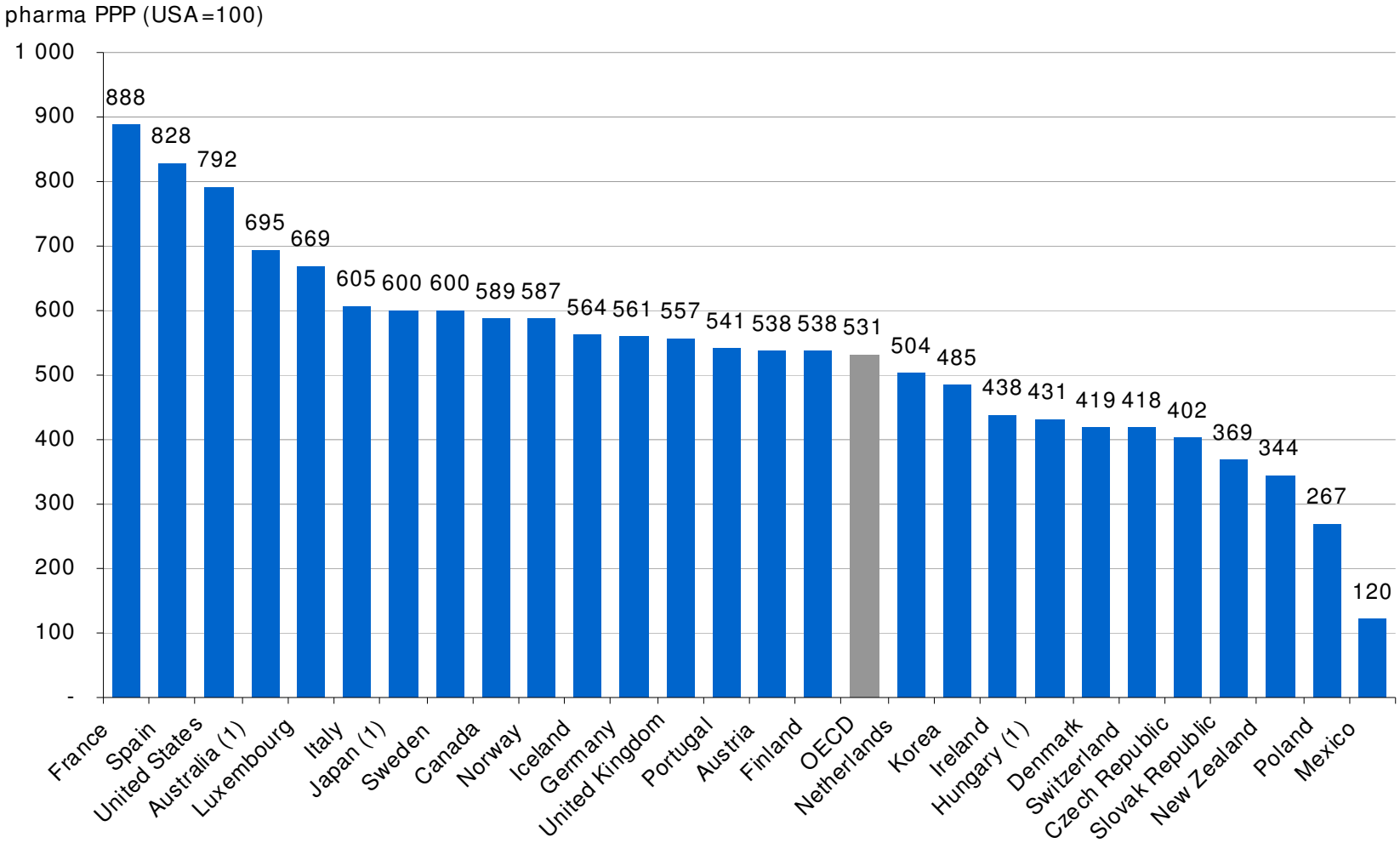
Figure 1.9. **Components of retail pharmaceutical prices, selected OECD countries, 2004**




*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).

# Limited cross-national variation is also seen in pharmaceutical consumption levels, but the range is somewhat larger than it is for expenditures

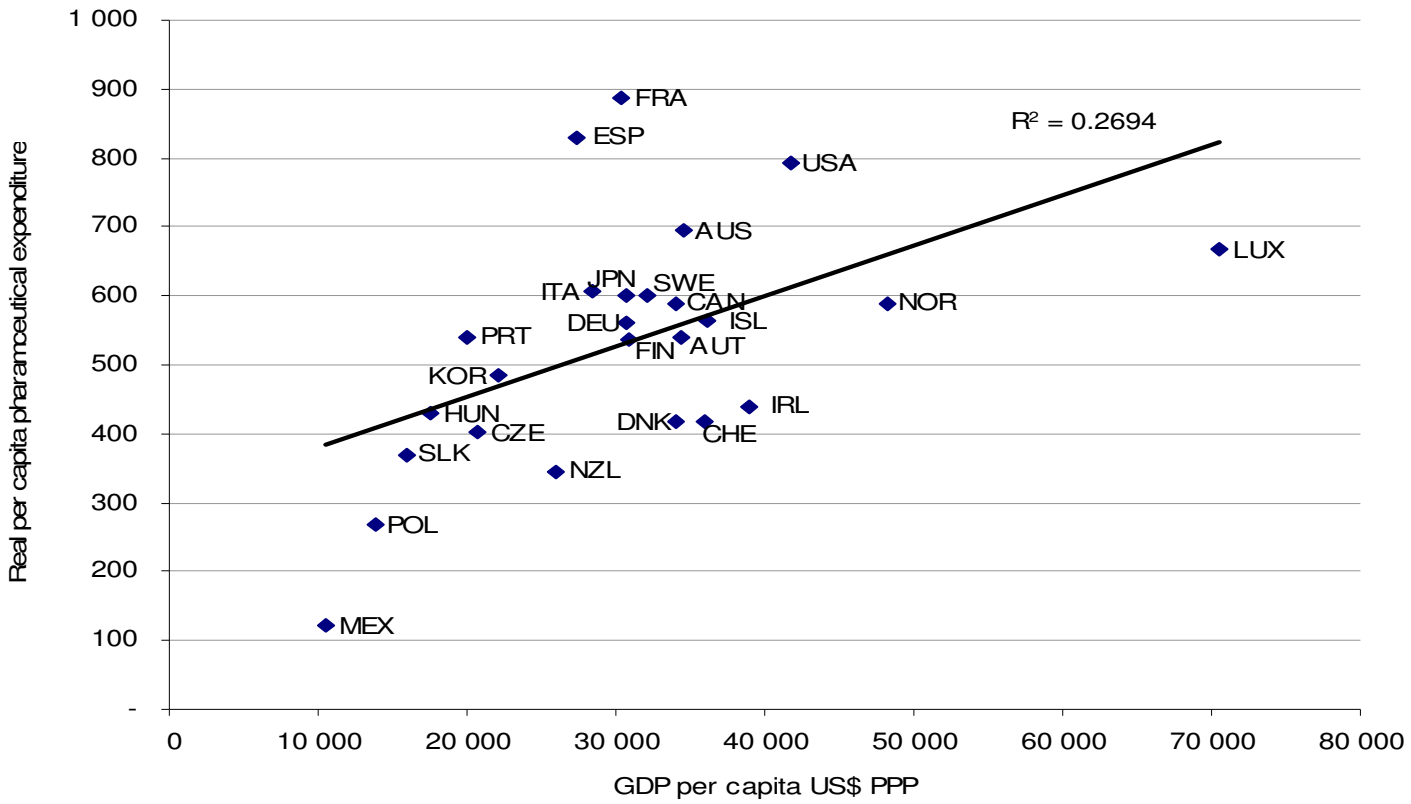
Real pharmaceutical expenditure per capita, 2005




Source: Eurostat-OECD Purchasing Power Parity Programme, 2007; OECD Health Data 2007, July 07;

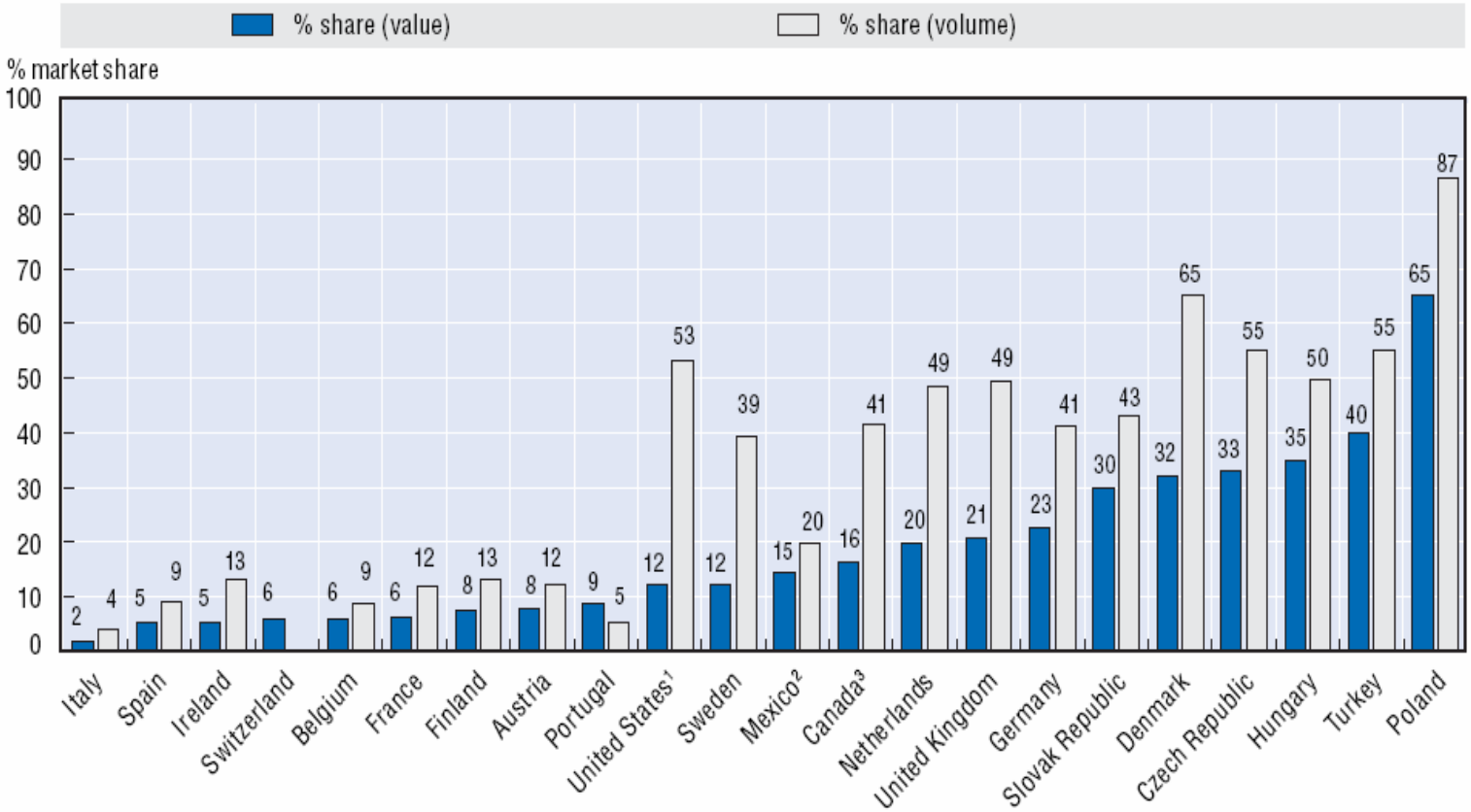
Pharmaceutical Pricing Project Final Report, forthcoming

# Per capita income explains only one quarter of the variability observed in per capita volumes of consumption across OECD countries




Note: Data from Japan, Hungary and Australia are from 2004.
*Source*: Pharmaceutical Pricing Project Final Report, forthcoming

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).

# Policy implications

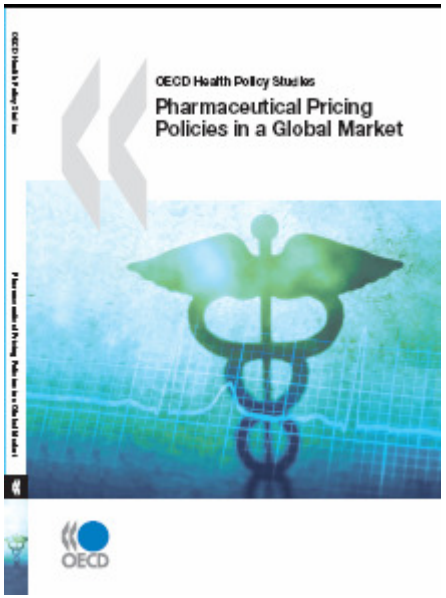
- As pharmaceutical firms have done, OECD policy makers should
  - take account of the external impact of their policies to avoid impairing affordable access to pharmaceuticals in the global pharmaceutical market place
  - Be aware of how the pricing policies of other countries stands to affect the price and availability of medicines domestically
- What is the desirable policy response to globalisation of the pharmaceutical markets and list price convergence pressures?
  - Should we promote more transparency in pharmaceutical prices, or recommend that lower-income countries seek to enter confidential agreements to increase timely and affordable access?
  - If income-based price differentials are desirable to promote access in lower-income countries, how to reconcile transparency with threat of parallel trade?

# Opportunities for increasing value in pharmaceutical expenditure: pricing of on-patent products

- Use pharmaco-economic assessment to inform price and payment decisions
  - Helps to align expenditures with value considerations
  - Signals to industry as to which innovations are most valued
  - To avoid allocative inefficiencies, use HTA comprehensively, not just in pharmaceutical sector

- Explore use of price-volume and risk-sharing agreements
  - Potential to address affordability problems for lower-income countries
  - Moves focus off of unit prices and on to value for money
  - Cost is reduced transparency

# For more information




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

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

| | |
|---|---|
| Canada | Sweden |
| Germany (forthcoming) | Switzerland |
| Mexico | Slovakia |

# OECD High-Level Symposium on Pharmaceutical Pricing Policy

- 27-28 October at OECD headquarters in Paris
  - Participation by 30 OECD member states plus 5 accession candidates, WHO, World Bank, social partners
- First day: senior level officials with responsibility for pharmaceutical policy discuss key issues
  - Affordable access to medicines
  - Ensuring value for money and valued innovation
  - Taking into account cross-national impacts of policy making
- Second day: Ministerial roundtable
  - What additional information is needed to ensure a solid framework for policy making in the global market?
  - What are the opportunities for improved outcomes through international collaboration or coordinated activities?
  - What is the way forward?