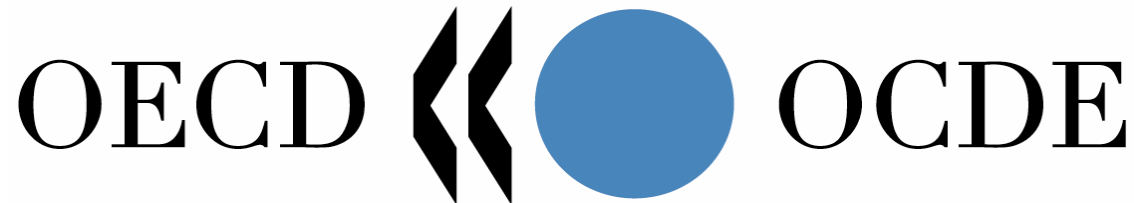


*AARP Health Care '08*  
*April 15-16, Washington, DC*



## **The global impact of pharmaceutical pricing and reimbursement policies**

---

Elizabeth Docteur

Deputy Head, OECD Health Division

# Pharmaceutical policy objectives

- Policies are geared towards health policy objectives
  - promoting public health,
  - containing cost growth to sustainable levels
  - obtaining good value for money in public expenditure, and
  - promoting future innovation in medicine
- ...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 is particularly important for the economy of Ireland and Switzerland
    - Exports relatively most important in: Switzerland, Ireland, France, UK, Sweden, Germany, Denmark, Belgium
    - Industry financed R&D activities are most important to Switzerland and Belgium

# Pharmaceutical policies may also have cross-national and global impacts

- 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
- Sales conditions are affected by globalisation
  - Parallel or cross-border trade in pharmaceuticals is possible within Europe and elsewhere
  - Information on pharmaceutical prices is increasingly available and accessible

# 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
- Many public purchasers **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)
- **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

# Outcomes of price or reimbursement price regulation

- Patent protection gives firms exclusive rights to sell their products, but monopoly position may be weakened by competition in a therapeutic area
- Public payers/regulators often have objectives other than cost-containment (e.g., ensure prompt access to effective medicines, support national industry, encourage future innovation, etc.)  
... and do not always seek to obtain the lowest possible price
- Private payers face strong incentives to negotiate the lowest possible price
  - Outcome depends on relative market power
- 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?

# 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) can affect prices paid in OECD countries through two routes
  - The *direct result* of the pricing methodology (where prices are defined in relation to those paid elsewhere)
  - The *indirect result* of manufacturers' strategic launch strategies intended to maximise profits from global sales
- 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

## 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

## 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 listed prices, even when they are willing to consent to confidential rebates
  - They use strategies to prevent or inhibit parallel trade: supply chain management, product proliferation, litigation, and lobbying against parallel trade

## Evidence of price convergence

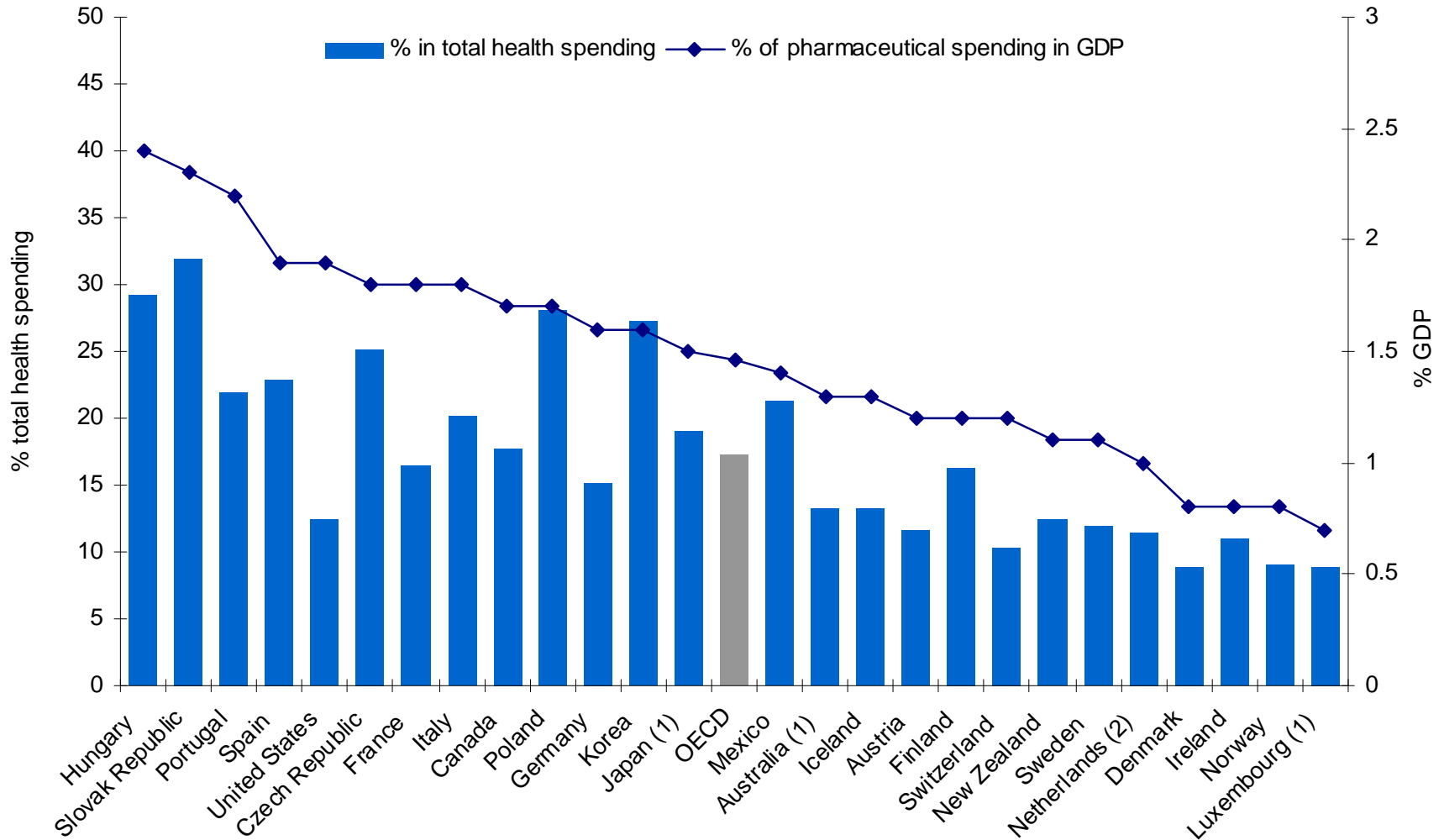
- There is, in fact, some evidence of price convergence among OECD countries
  - An analysis of evidence from three studies with longitudinal data suggests that there has been some convergence in ex-manufacturer pharmaceutical prices within Europe (incl. Switzerland) and Canada since the early 1990s, 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.



## Policy implications

- As pharmaceutical firms have done, OECD policy makers need to take account of the external impact of their policies to avoid impairing affordable access to pharmaceuticals in the global pharmaceutical market place
- 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?

# Share of pharmaceutical expenditure in total health spending and in GDP, 2005

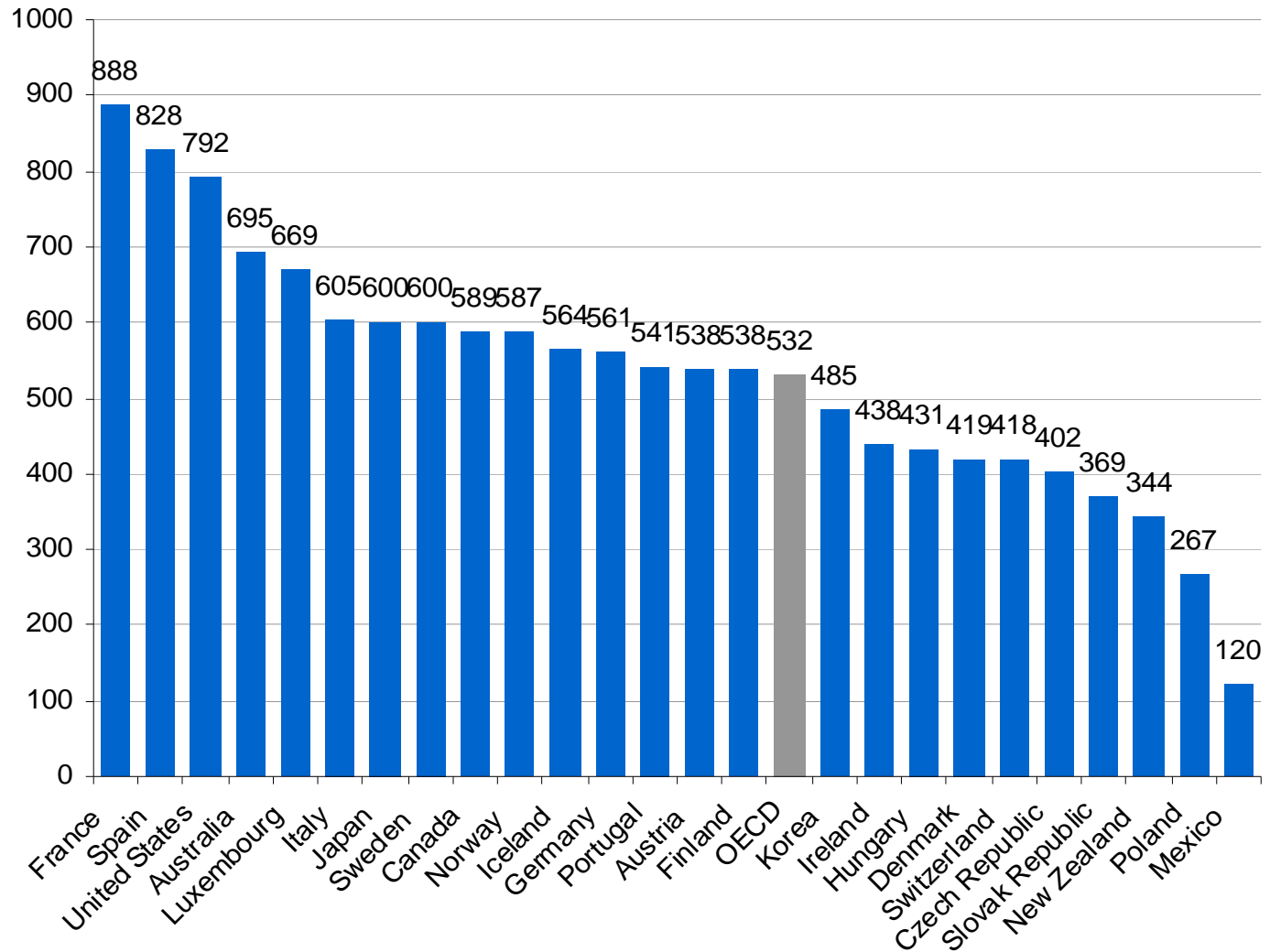


(1) 2004; (2) 2002

Source: OECD Health Data 2007, July 07

# Per capita pharmaceutical consumption, 2005

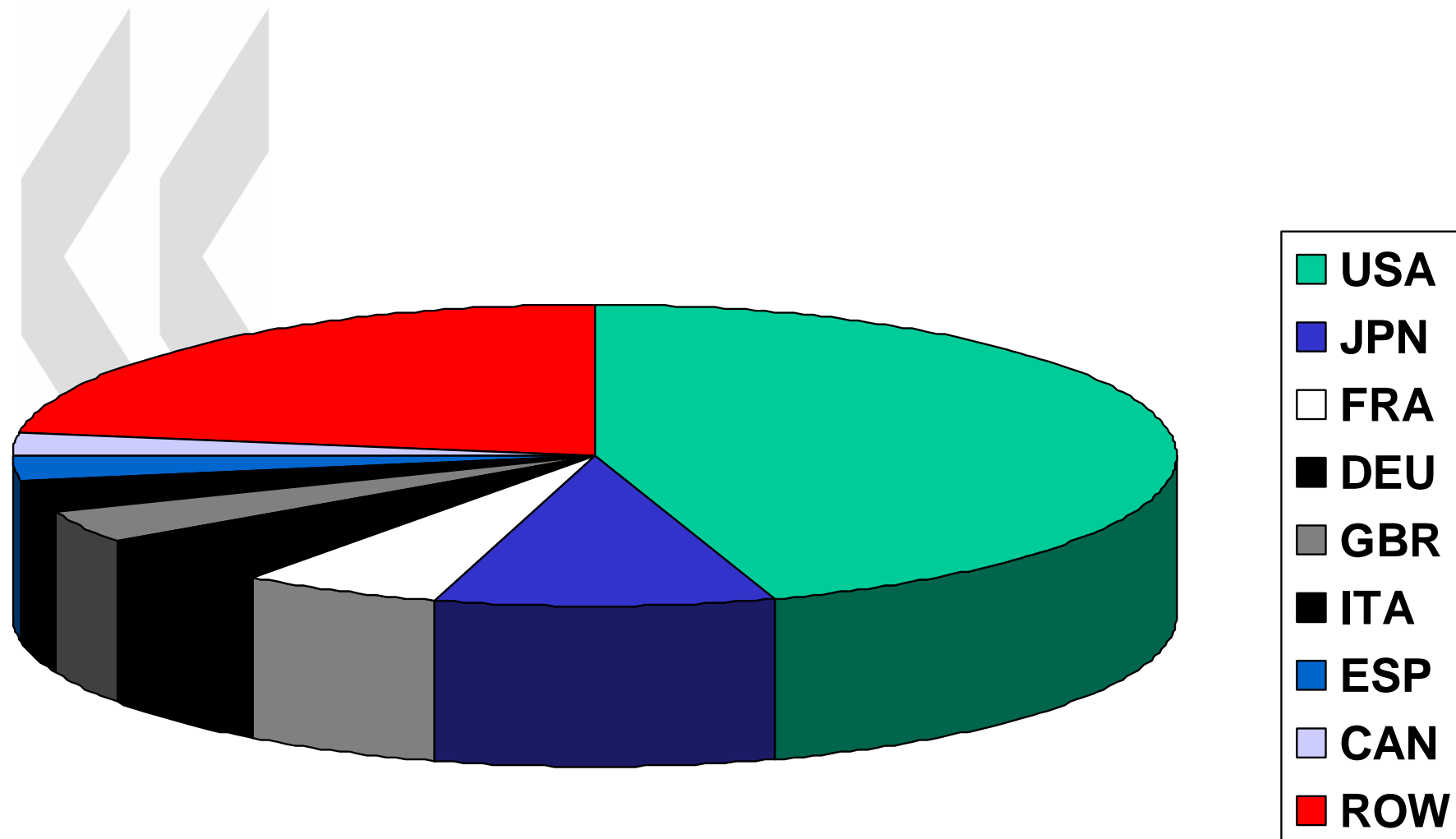
pharma PPP (USA=100)



# The impact of pharmaceutical pricing on innovation

- Pharmaceutical pricing policies affect profitability of the industry and returns on prior investment in R&D
- They stand to affect future investment by providing signals as to willingness to pay for prospective new products
- Other policies, including policies affecting volume of products purchased, patterns of consumption, and period of exclusivity on the market, can have equal or greater impact (particularly in small countries with little power to obtain price concessions)
  - e.g., IPR policies, marketing authorisation, policies affecting prescribing and dispensing
- The marginal impact of any one country's policies will be proportional to market size --- a function of population, income, and appetite for pharmaceutical consumption --- and thus minor, with the exception of the United States
  - Exception is markets with large spill-over effects --- those (early launch) countries (Germany, UK) that are frequently referenced by others in external benchmarking

# Global pharmaceutical sales, 2006



# Incentives established by different types of pricing policies/practices

- Policies limiting prices to prices of therapeutic comparators provide disincentives for investment in developing products representing incremental innovation
- Reimbursement policies using reference pricing may also do this, unless patients and their doctors will pay more for incremental innovation that they value
- The use of therapeutic referencing and reference pricing provide incentives to invest in differentiation of products at whatever level is necessary to avoid inclusion in an existing group
- The practice of external benchmarking provides incentives for product proliferation (differentiation without clinical benefit)
- Pharmaco-economic assessment can be used to reward and incent innovation with greatest relative value (to patients, payers, society)

## Summary table: Incentives and disincentives for innovation

Pricing or reimbursement policy	Incentive	Disincentive
Pharmaco-economic assessment	Valued innovation	
Therapeutic referencing	Innovation that offers demonstrably more value than existing therapies	Incremental innovation that offers little or no improvement over existing therapies
Reference pricing		
External referencing/ international benchmarking	Product differentiation that lacks therapeutic benefit	

## Some conclusions from the OECD project

- In a global market, pharmaceutical pricing policies and practices have cross-national and global implications. These externalities should be acknowledged by policy makers.
- Pharmaceutical policies can affect price, volume of consumption, mix of consumption, timing of uptake and diffusion of new products, length of market exclusivity, etc.... Judging the impact of policies requires a comprehensive assessment. Price is only part of the equation.
- Although very commonly used and technically easy, relative to alternative approaches, external referencing/international benchmarking does not provide an ideal foundation for pricing policy
  - Arbitrary, gameable
  - Results in convergence of list prices that may impair affordable access in lower-income countries

## Conclusions (cont'd)

- Pharmacoeconomic assessment, though technically challenging, holds promise for improving performance in meeting policy goals
  - Value for money in pharmaceutical coverage, reimbursement decisions
  - Providing incentives for investment in innovation considered most valuable
- Income-related differences in expenditures for a given product would be expected where pharmacoeconomic assessment was used.
  - Costs and benefits associated with a product's use will vary by income and other factors (e.g., population health needs, health care costs).