International experiences with medicine price regulations

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outline

1) Health systems and pharmaceutical sector
2) Why use medicine price regulations?
3) Type of policies to control pharmaceutical expenditures
4) Examples of medicine price regulations from OECD countries
5) Lessons learnt
6) Potential options for policy consideration for low and middle income countries

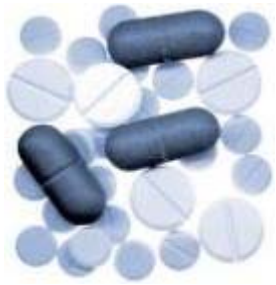
Major recent studies on medicine price regulations

- **2008 OECD Pharmaceutical Pricing Policies in a global market**
  - **Executive summary can be downloaded from**
- http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html#executive_summary
- **2008 PPRI reports Pharmaceutical Pricing and Reimbursement Information**
- **http://ppri.oebig.at/index.aspx?Navigation=r|2-**
- 2007 The Pharmaceutical Price Regulation Scheme - An OFT market study (UK)
- www.**oft**.gov.uk/shared_**oft**/reports/comp_policy/**oft**885.pdf

Controlling pharmaceutical expenditures

Price

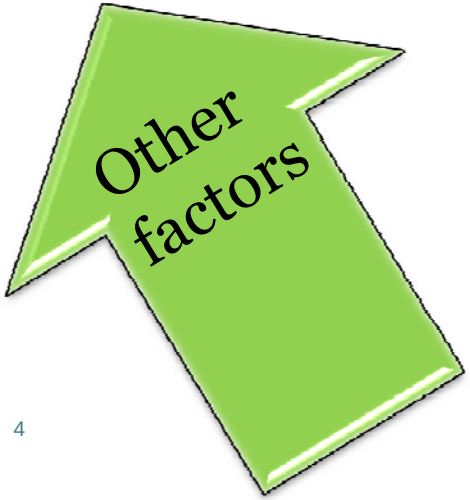
x



Volume

=

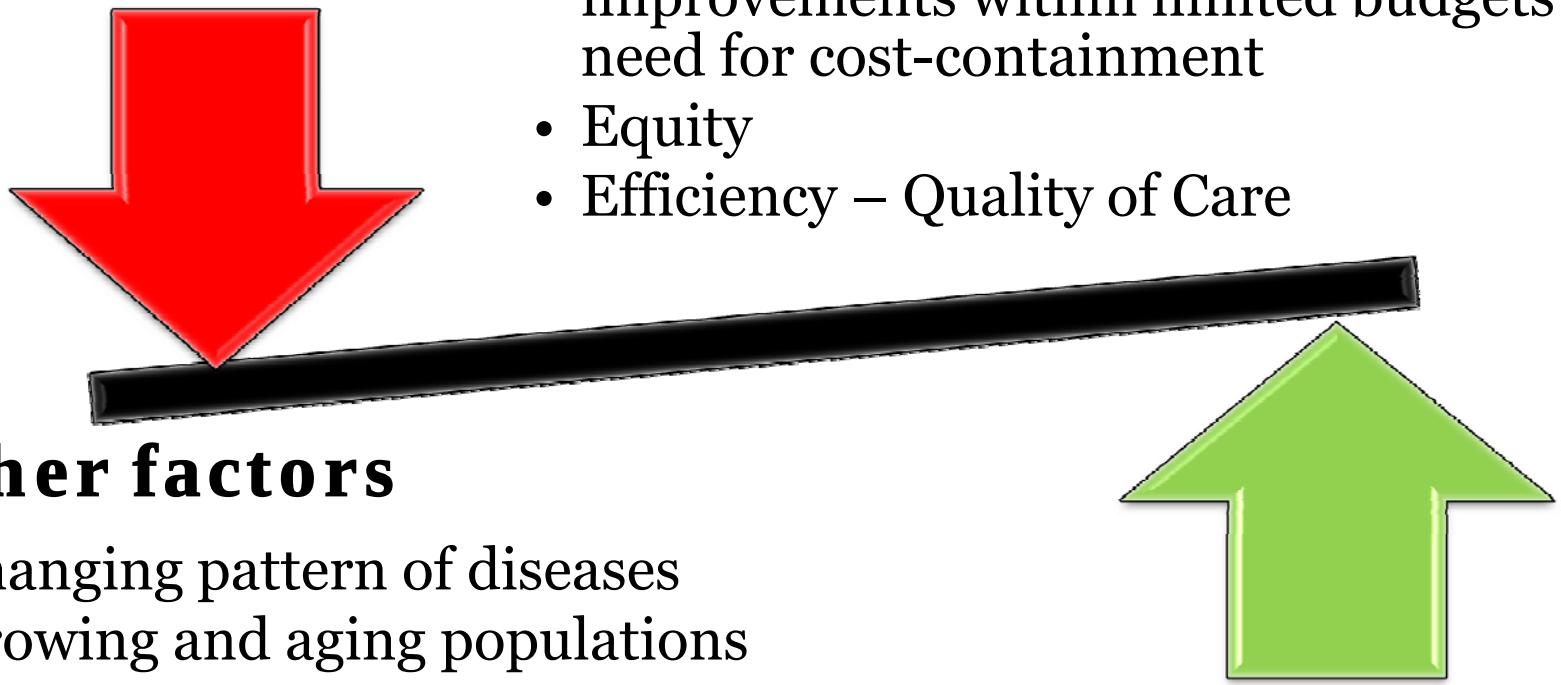
Pharmaceutical Expenditure



Pharmaceutical sector – Pressures on pharmaceutical expenditures

Public health goals

- Ensuring population health improvements within limited budgets – need for cost-containment
- Equity
- Efficiency – Quality of Care



Other factors

- Changing pattern of diseases
- Growing and aging populations
- Increasing demand with growing income and new technologies
- IPRs protection, legal trade issues
- Industrial goals, profitability, revenue collection

WHY MEDICINE PRICE REGULATIONS?

MARKET FAILURES

- **Asymmetry of information: patient vs. Drs, sellers**
- **Imperfect competition**
  - Monopoly position for patented medicines
  - Product proliferation does not automatically induce competition
- **Inalesticity of demand –**
  - medicines not usual commodity people will pay whatever they have to when they get sick - for the poor this can mean catastrophic health expenditures when OOP payment for medicines is high

LIMITED RESOURCES

Pharmaceutical pricing policies globally

- Low and middle income countries:
  - **Free or market based pricing** is **most common**
  - Price regulations are infrequently used, India Pakistan, Egypt, South Africa, China

- High income countries with extensive insurance coverage
  - **Medicine price regulations or**
  - **Price negotiations** are **most common**
  - **Free or market-based pricing** is usually for OTC products and for products that are not reimbursed

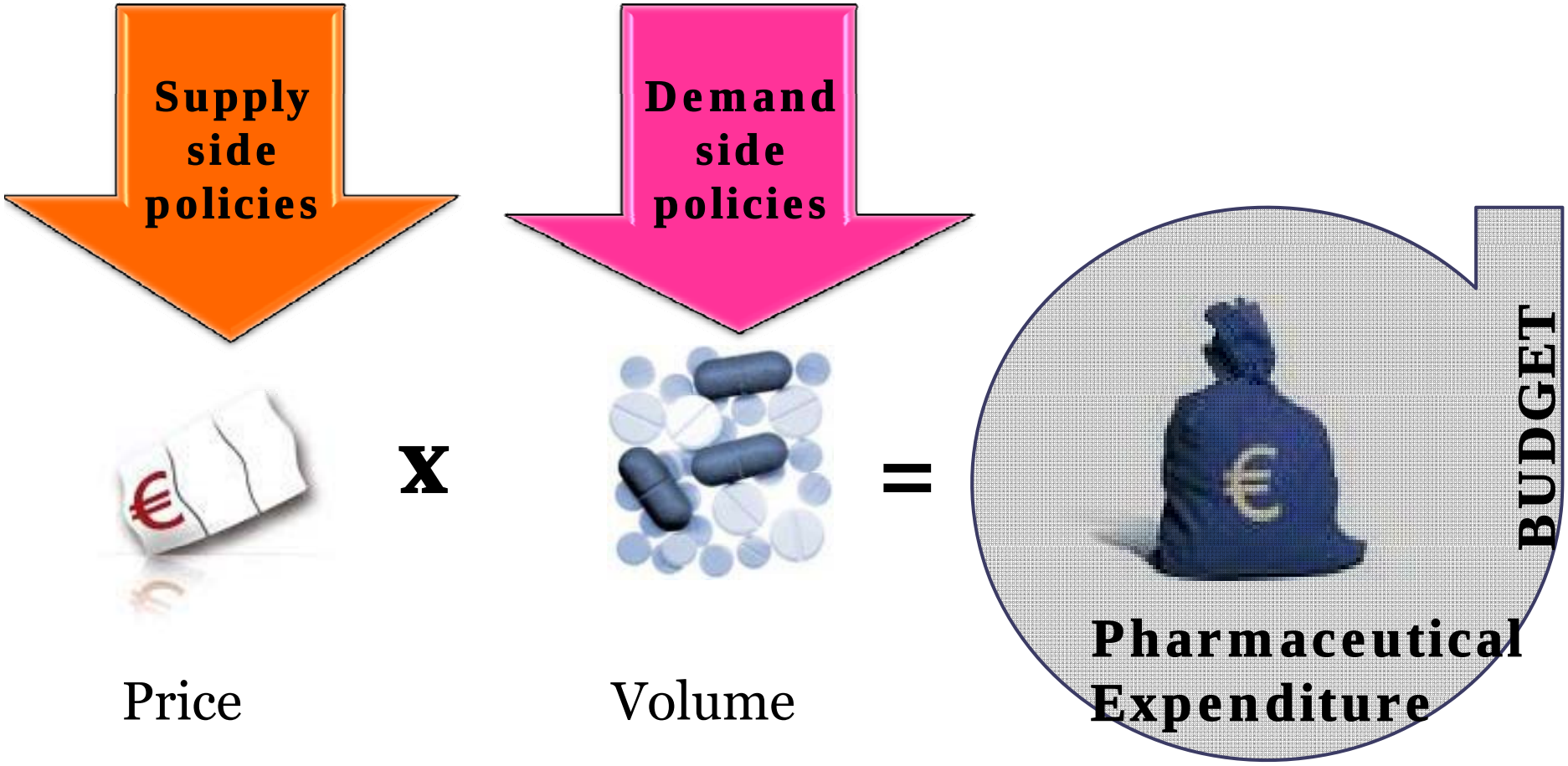
Pharmaceutical price regulatios in OECD countries

- 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**
  - – 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

Cost-containment to control pharmaceutical expenditures



Supply side policy options

1. Free pricing – rely only on competition – price transparency essential
2. Public procurement / Tendering/ competitive purchase methods
3. Direct price controls at ex-manufacturer level at registration or controls for reimbursement prices
4. Distribution controls along supply chain
   - ✓ Fixed mark-ups / margins (%) wholesale/distributor, retail pharmacy, dispensing drs
   - ✓ Regressive mark-ups / margins (motivation to dispense lower cost generics)
   - ✓ Professional fees, fixed, for dispensing
5. Price negotiations (price-volume agreements, pay-backs, discounts)
6. Regulating trade practices:, rebates, bundling, in kind discounted items.

Medicine price controls in EUROPE

- **Price control** (at manufacturer level):
  in all EU-27 excl. DK, DE, MT
- **External price referencing:**
  in 22 EU Member States
- **Price freezes/cuts**:
  - price freezes - observed in DK, HU, IE, NL, UK
  - a common measure (e.g. CY, FI, FR, IT, NL, PT, SK, UK)
- **Price control at distribution level**:
  - wholesale margin in 21 of the 27 EU MS (excl. CY, DK, FI, NL, SE)
  - pharmacy margin in all PPRI countries
- **Margin cuts**:
  - very common, e.g. EL, FR, FI, HU, LT, PL, SK, UK
  - either cuts or changes
- **Statutory discounts**:
  granted to Third Party Payers, e.g. DE, IT (in form of price cuts)

Average gross wholesale margins EU 2006

Country	Average Margin RX	Fixed or Regressive
Austria	7.3%	Regressive
Belgium	8.5%	Regressive
Czech Republic	4.5%	Fixed
Denmark	6.6%	Regressive
Estonia	7.9%	Regressive
France	7.3%[1]	Regressive
Germany	6.1%	Regressive
Greece	7.8%	Fixed
Hungary	5.3%	Regressive
Ireland	10%, 15%	Fixed
Italy	6.6%	Fixed
UK	12.5%[2]	Fixed
Latvia	6.5%	Regressive

Demand side policy options

- Defining the market: listing systems and formularies
  - Positive lists for reimbursements, essential drug lists
  - Generic prescribing and substitution policies
- Influencing the demand of patients e.g. cost-sharing, co-payment levels can be defined:
  - proportionality to the final price.
  - with a fixed charge per prescription.
  - with an annual deductible amount
- Influencing the prescribing behaviour
  - Guidelines, protocols,
  - Budgets (global at hospital level or individual at GP level
  - Auditing and benchmarking
- STRICTLY Controlling drug promotion, marketing, education, sponsorhsip gifts to doctors. pharmacists

Demand side policy options in EUROPE

- **Generic substitution:**
  - Not allowed in seven countries
  - Allowed in 22 countries: indicative in 14 and mandatory in eight
- **INN prescribing:**
  - Not allowed in five countries
  - Allowed in 23 countries, thereof indicative in 19 and mandatory in four
  - Supported by electronic prescribing system in the NL
- **Monitoring of prescribing behaviour:**
  - Prescription guidelines in 21 countries, thereof indicative in 17 and compulsory in four
  - Sanctions in three countries (BE, DE, LV); rather feedback by payers in 18 countries
  - Prescription monitoring in 13 countries
  - Pharmaceutical budgets in five countries

Methods used to define or limit prices

- **External price referencing** or international reference pricing or international price comparisons,
- reference countries used to set ex-factory prices

- **Internal price referencing** or Reference Price System –
- other products available in the market 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 common reimbursement level is set for a defined group of products (patients pay the difference)

Methods used to define or limit prices (cont.)

- **Cost-plus pricing:** accounting for production cost, R&D, promotions, profit levels etc. to set ex-factory prices India, China, Pakistan
- **Value based pricing**: pharmaco-economic assessment based on considerations of the product's cost-effectiveness (net benefits against costs)
- **Indirect price control** (profit control), UK
- **Regulations of taxes, margins and markups.** Most European countries control:
  - Maximum Wholesale mark ups
  - Maximum Retail mark ups
  - VAT and other taxes
  - Dispensing fees or professional fees for pharmacists, dispensing doctors

More sophisticated approaches are used on a limited or experimental basis

- Some countries or purchasers experiment with approaches such as:
  - Product-specific **price-volume agreements**, especially with products with high risk of overuse or misuse
  - **Risk-sharing agreements** link the price paid to the outcome for products with high uncertainty as to effectiveness of a product in actual experience

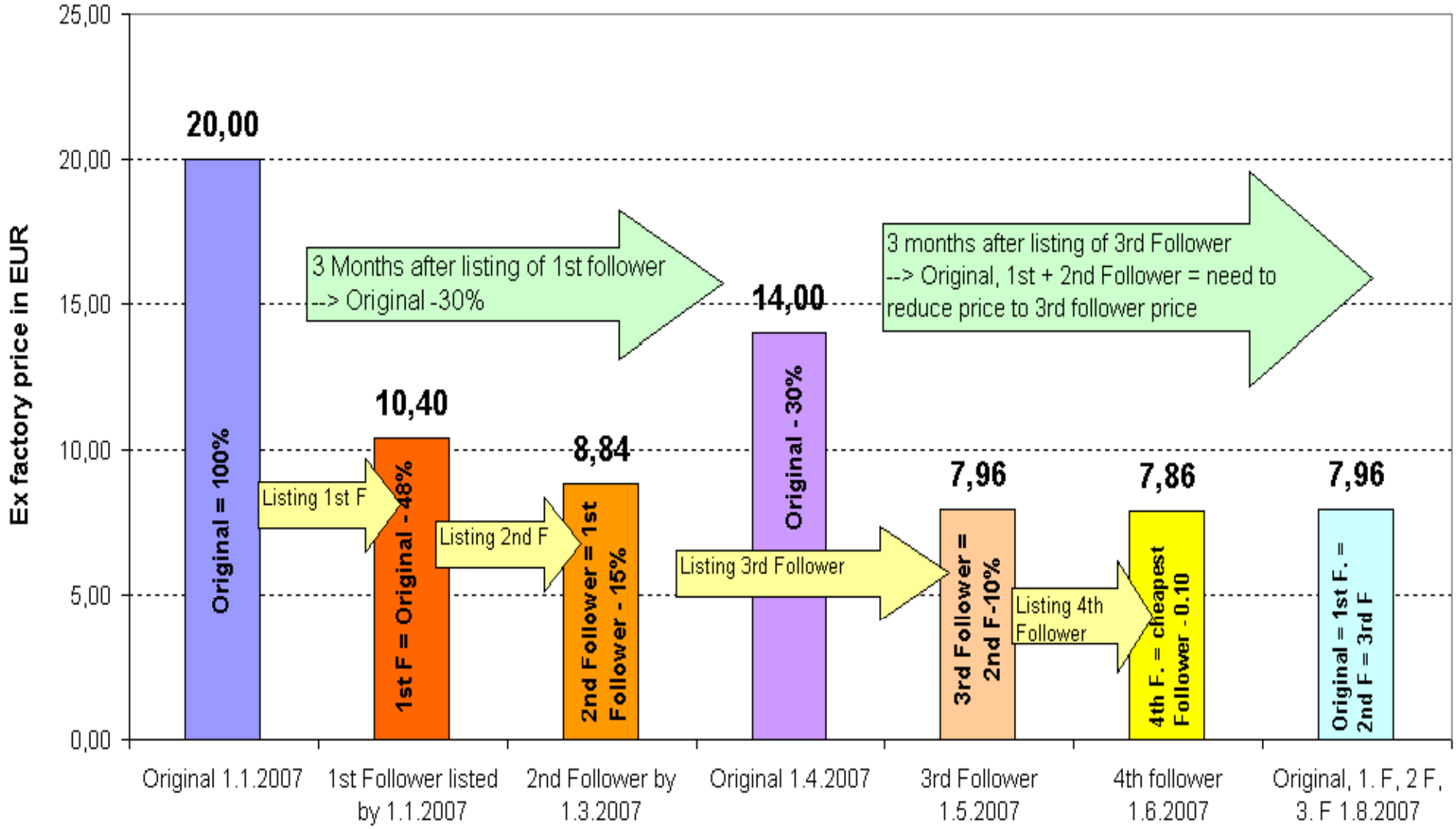
Who makes the decisions?

Market Authorization		Pricing		Reimbursement	
Decision	Advising	Decision	Advising	Decision	Advising
NDRA	MA committee	MOH,	Pricing Committee	MOH	Evaluation board
NDRA		MOF		Social Insurance	Reimbursment ent Committee
NDRA		Mo Social Affairs		NDTC	NDR
NDRA		Mo Developme nt	Social Insurance	Pharm Pricing board	NDRA
NDRA		Mo Economics		Social Insurance	Med Cont Committee Soc Ins.

Case study Austria regressive pricing for off-patent/generic drugs

- Economic efficiency criteria for inclusion in reimbursement
- First generic product at least 48% below the price of the newly off-patent original brand.
- Second and each subsequent generic “follower” reduce it's price by at least 15% compared to the first follower,
- The price of the **original brand** has to be reduced by at least 30% within three months of the inclusion of the first generic to ensure the economic efficiency of the original brand.

Case study Austria - regressive pricing for



The patented medicine price review board (PMPRB) of Canada

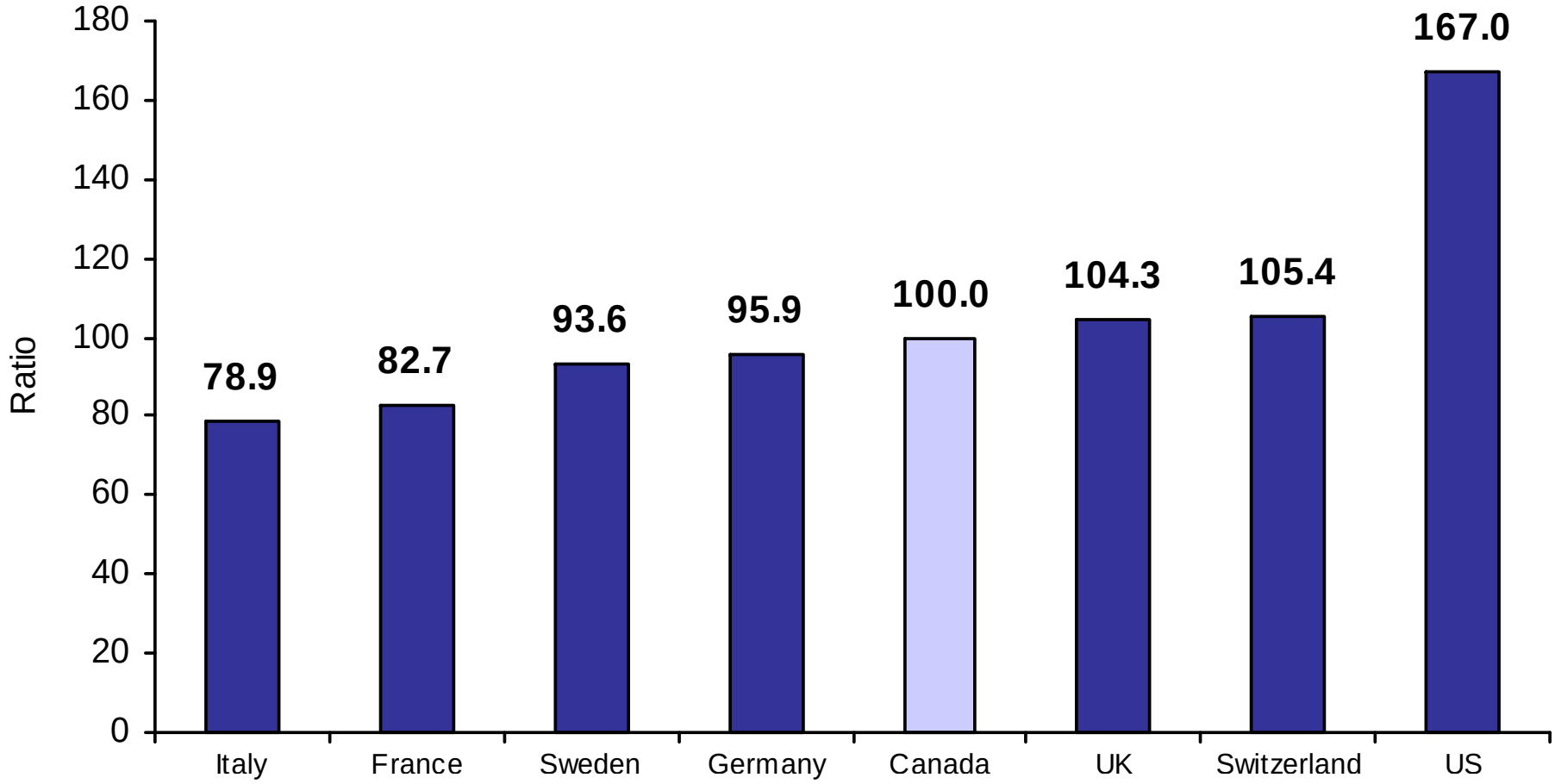
- Two-fold mandate:
  - **Regulatory** – To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive
  - **Reporting** – To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees
- Arms-length from federal gov't policy-making
- Reports to Parliament through Minister of Health
- Minister of Industry and of provincial/territorial health ministries are statutory parties under the *Patent Act*

Price Review Process by PMPRB of Canada

Application of price tests

- Reasonable Relationship
  - Association between strength of the medicine and price
- Therapeutic Class Comparison
  - Price of the drug compared to that of clinically equivalent drugs sold in same therapeutic class at non-excessive price
- International Price Comparison
  - Price of the drug compared to that of the same dosage form and strength of the drug sold in countries listed in the *Patented Medicines Regulations*
- Highest International Price Comparison
  - Canadian price cannot be the highest in the world (i.e. 7 comparator countries)

Average Foreign to Canadian Price Ratios, Patented Drugs, 2002



Source: PMPRB

Pros and cons of current policies

- **External price referencing – not the best future option**
  - Does not take into account cross-country differences in the value of a product
  - Readily gameable by the pharmaceutical industry (launch in high price country
  - Contributed to convergence of list prices, leading to list price inflation i.e. HIGHER PRICES
  - Provides manufacturers with incentives to delay launch in lower-priced markets where there is risk of spill-over

- **Internal price referencing** can promote value-for-money provided that:
  - Existing alternatives are priced at a level which reflects their value to society
  - Information about the relative « added value » of the new product over existing alternatives is available

Pros and cons of current policies (cont'd)

- The use of **pharmaco-economic assessment**
  - define prices that more reflective of the "value" or "added value" of products to patients or society
  - Could result in different prices and expenditures for products across countries, given cross-country variation in health care needs and preferences, health care costs, etc…
  - Is technically challenging and costly
  - Has proven to be technically and politically feasible in the few countries that employ this tool formally
  - UK: NICE, SMC

Scottish Medicines Consortium (SMC) HTA evaluation

- The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland.
- **ADVICE: following a full submission tocilizumab, (RoActemraÒ) is accepted for restricted use within NHS Scotland.**
- **Licensed indication under review: in combination with methotrexate, for the treatment of** moderate to severe active rheumatoid arthritis in adult patients who have either responded inadequately …….
- Addition of tocilizumab to disease-modifying anti-rheumatic drugs resulted in an increased response rate for reduction of disease activity.
- **Restriction: It is restricted for use in combination therapy within NHS Scotland. The** manufacturer did not present an economic case for monotherapy. Toculizumab should be used in accordance with the British Society of Rheumatology guidelines for prescribing TNF-blockers in adults.

How do manufacturers respond to pricing policies?

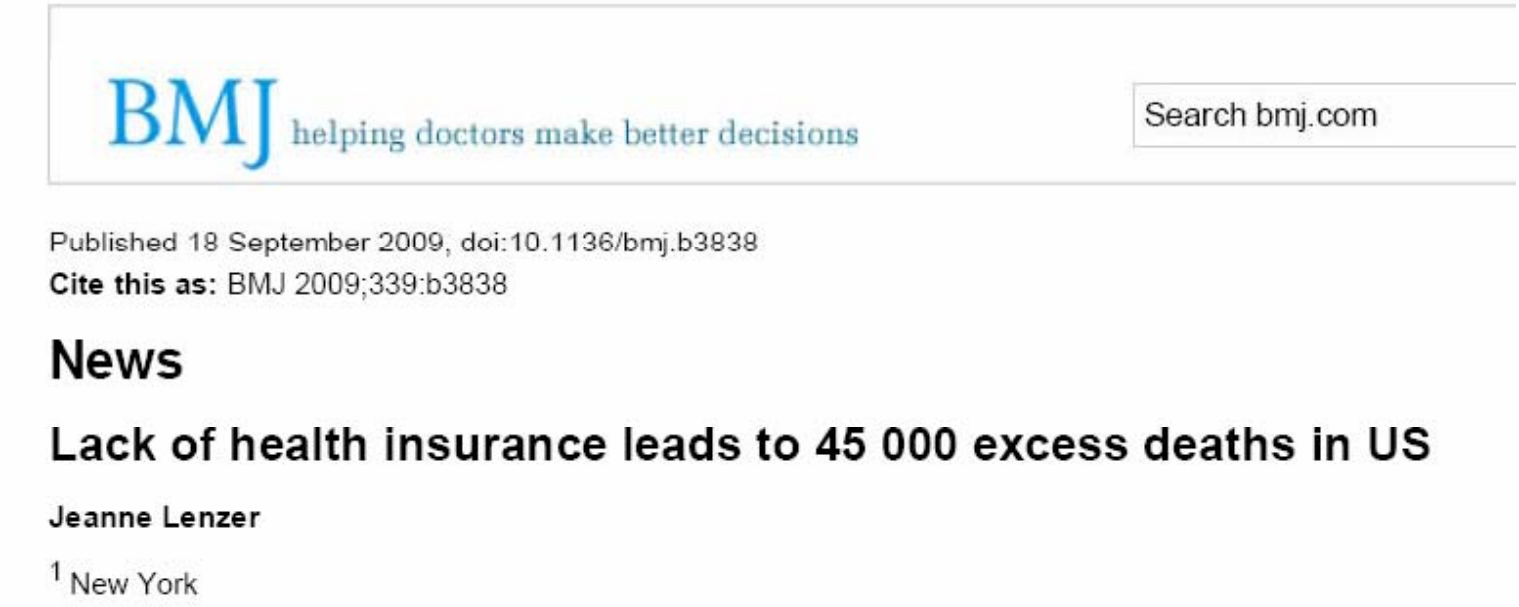
- **In response to external price referencing,** companies
  - launch their products first in countries where they can set prices freely or can negotiate relatively high prices (often in the country where they have their headquarters),
  - delay or refrain from launching in relatively lower-price countries
  - maintain artificially high list prices, even when they are willing to consent to confidential rebates.
- **They also use strategies to inhibit parallel trade,** such as supply-chain management, litigation, lobbying and product proliferation (*e.g., release of products with different formulations, strengths and package* sizes).
  - The latter technique also serves to limit opportunities for international price referencing.

Lessons learned

- Experience from OECD countries show that there is a potential for to:
  - Improve the use of generic alternatives through better implementation of generic policies for cost-containment strategies
  - Improve demand side controls through promotion of rational use of medicines
  - Improve price competitions for generic products and use pharmaco-economic evaluation (value-based pricing) for patented product
  - Achieve more efficient distribution systems for prescription and OTC drugs
  - Use more sophisticated reimbursement pricing strategies

Lack of Access to effective medicines exist even in OECD countries

- Gaps in coverage: in some countries, some people are uninsured or under-insured,
- And in case of catastrophic expenditures they may not able to afford to buy medicines
- Gap in availability: Fully subsidized medicines are not always available in public sector facilities



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News

Lack of health insurance leads to 45 000 excess deaths in US

Jeanne Lenzer

[1] New York

Which way to go?

Potential roadmap

1

- Increase price transparency
- Introduce regulations for price disclosure to patients; labelling, itemised billing from GPs, clinics
- Continue Price Monitoring and dissemination of info

2

- Increase efficiency (both supply and demand side
- Evaluate and improve price negotiations, procurement, distribution system
- Enforce generic policies, strict control of MOH formulary, promotion of generic substitution
- Deal with predatory and unethical marketing practices (regulation, enforcement)
- Deal with irrational demand: implement CPGs linked with CE and Expenditure data - link to Quality of Care assessment
- Implement incentives to reward rational prescribing

3

- Identify appropriate health financing mechanism
- Design appropriate pharmaceutical financing system
- Identify Positive negative lists, provider payment mechanism,

4

- Implement Pricing reimbursement mechanism – start with easiest to implement
- Consider price cuts, price freezes, regulating margins i.e. regressive mark up controls
- Professional fee increases

5

- Patented branded new prescription medicines introduce - HTA, CEA before admitting it to MOH formulary
- See NICE, PMPRB, PSB as examples

6

- Consider internal reference pricing when therapeutic equivalents exist and set reference price for therapeutic category (lots of me-toos)
- Leave generics to competitions for old medicines with plenty generic alternatives or use regressive pricing
- Resist introducing external reference pricing , unless you have good quality price info from comparable markets,

7

- MONITOR – EVUALUATE- & REDESIGN SYSTEMS / REGULATIONS AS NEEDED (can be a long journey and may never be a perfect systems for everyone)

Summary and conclusions

- Pharmaceutical policies in can vary widely
- Pricing schemes have different objectives, apply different approaches and achieve different outcomes
- There is no “magic bullet” solution!
- It is important to develop a coherent pharmaceutical policy framework with policies, **including but not limited to pricing policies, working consistently to achieve desired objectives**
- Policies need to be monitored evaluated and redesigned as needed per country specific circumstances

Thank you for your attention!