Linking Drug Pricing with Pharmaceutical Patents in Canada

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International Seminar on Pharmaceutical Pricing &
Regulatory Framework for Affordable Medicines
New Delhi, India
April 12, 2008

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Overview of Presentation

- I: Highlights of Canadian Approach to the Regulation of Pharmaceutical Prices
- II: Policy Context in the 1980s
- III: Effectiveness Canada's Price Regulation
- IV: Key Features of Patented Medicine Prices Review Board's (PMPRB) Price Regulation
- V: Some Lessons & Possibilities for India from Canada's Experience

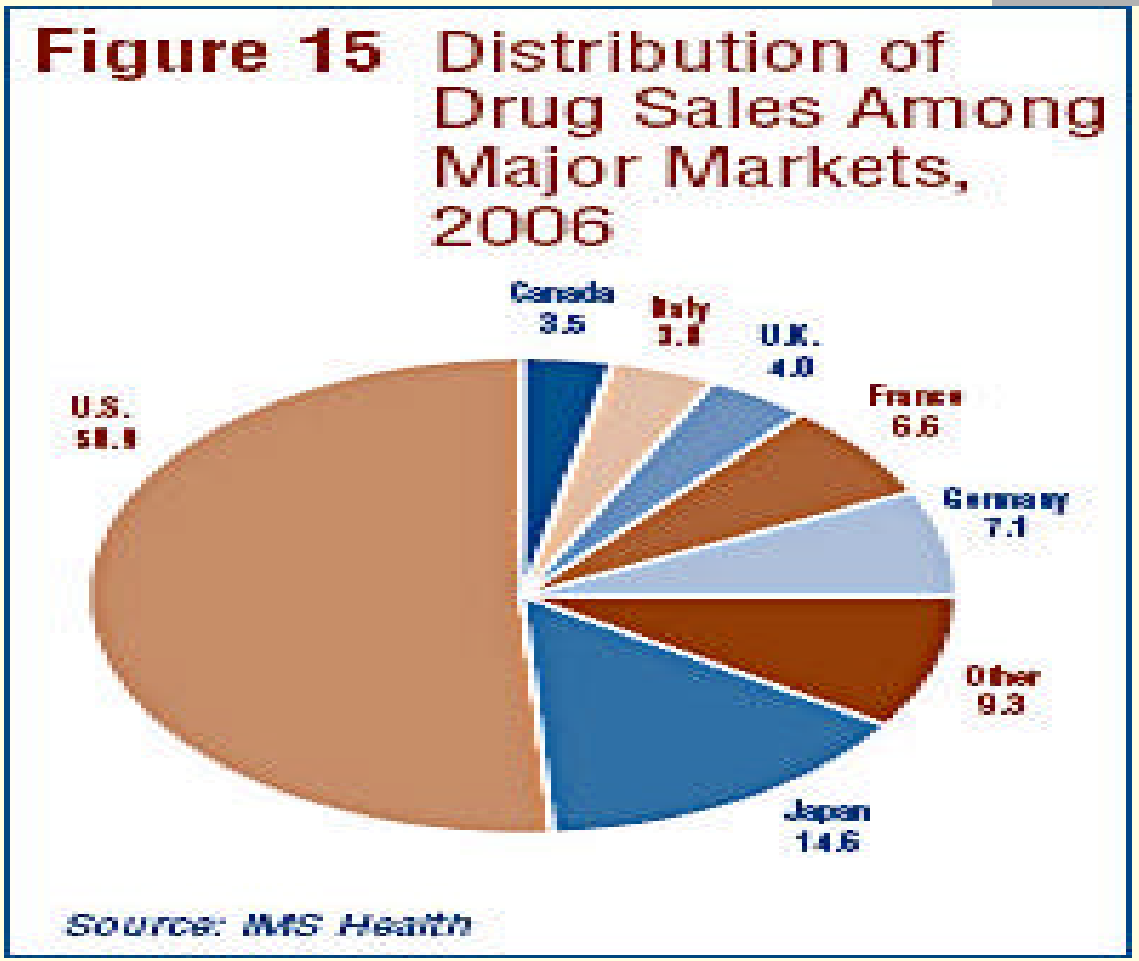
I: Highlights of Canadian Approach

- Federal drug price regulation only of patented medicines
- The regulator (PMPRB) reviews factory gate prices to ensure they are "not excessive" (a price ceiling). Prices are set by buyers & sellers. Reviews are after the fact.
- PMPRB could, but has not, used cost plus methods
- Transparent pricing guidelines based on inflation for existing drugs, and prices of similar drugs in Canada or 7 other countries for the introductory price of new drugs.
- High levels of compliance, significant reduction in prices, low administrative cost to Government and industry.
- Regulator reports on all drug prices and pharmaceutical R&D in Canada, (which doubled due to a side deal).

II Canada's 1987 Policy Context

- From 1929 through the 1960's the Patent Act sought to increase competition for drugs by allowing compulsory licenses virtually as a matter of right in return for a 4% royalty on sales
- Compulsory licensing lead to a generic pharma industry which did little R&D and marketing but delivered 7% of Canadian drugs provincial health plans
- In 1960, 70s and 80s continuing pressures on health care costs, partly from increasing pharma budgets
- International pressures on Canada to comply with international norms of patent protection and reverse policy on compulsory licensing & royalities
- International debate (e.g. USA, EU) about the regulation of drug prices
- Canada seeking a modern economy marked by R&D intense industries, pharma seen as potentially key industry, IP protection viewed as important for pharmaceuticals and other sectors
- Pro-free market government with preference for limited regulation, and low industry compliance cost, limited use of formal regulatory hearings
- Canada one of 8 countries generating over 80% of global pharmaceutical revenues and thereby covering global R&D costs

Drug Sales in Major International Markets



The 1987 Deal: Policy & Legislative Framework

- Canada signalling its willingness to pay its “fair share” of international costs for developing new patented drugs, but not an “excessive” amount,
- Easy access to compulsory licences was suspended, re-establishing patent holders monopoly (later abolished)
- Regulation to limit the risk of price increases & high monopoly prices
  - Under Patent Act PMPRB reviews for “excessive” prices,
  - If prices “excessive” taking into account Canadian inflation and prices in 7 industrial countries*, a generic licence could be issued
  - In 1994 modified to roll-backs or fines & double penalties
- Negotiated “side deal” on R&D
  - patentees to undertake Canadian R&D from less than 5% of Canadian drug sales in 1984 to 8% in 1991 and 10% by 1994.
- PMPRB public reports: all drug prices & patentees’ R&D

* USA, UK, France, Germany, Italy, Sweden, Switzerland

Patented Medicines as % of Total

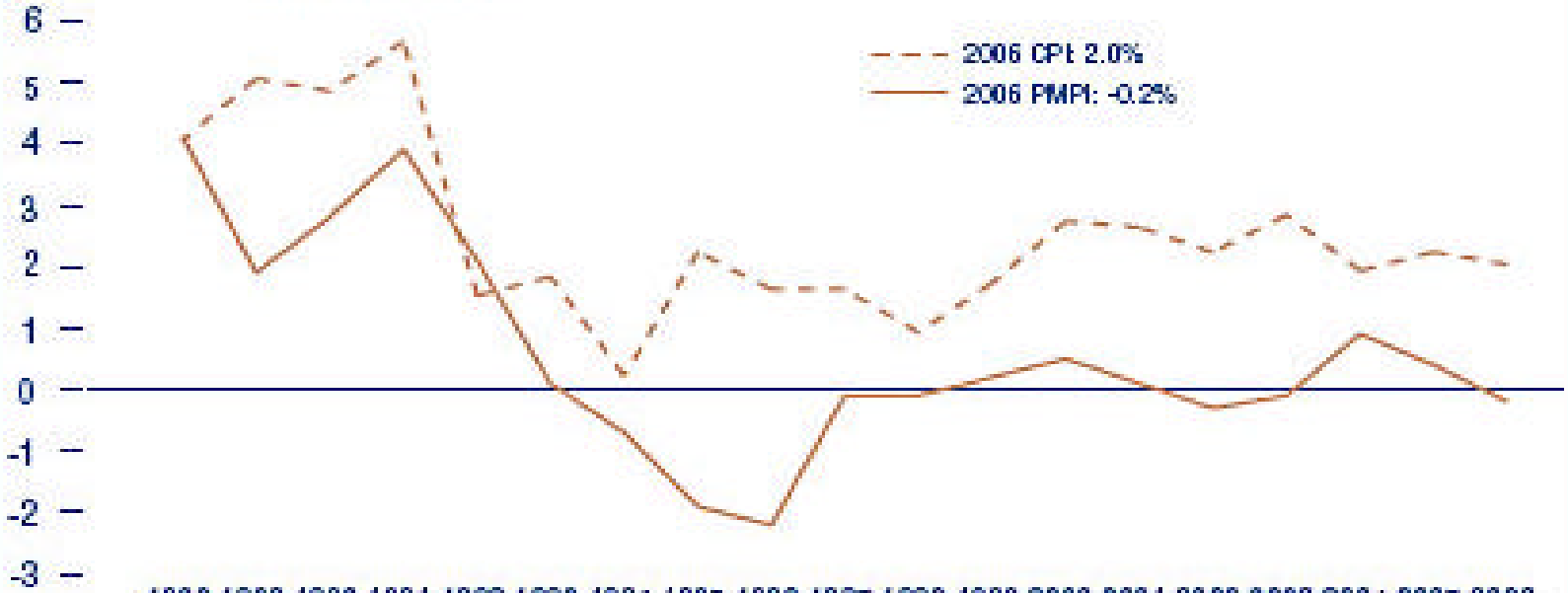
Table 8 Sales of Patented Drugs, 1990-2006

Year	Patented Sales ($Billions)	Change (%)	Patented Drugs as Percentage of Total Drug Sales
2006	12.0	3.7	68.1
2005	11.6	4.9	71.4
2004	11.0	8.6	68.6
2003	10.1	14.3	66.9
2002	8.9	17.5	67.4
2001	7.6	18.9	65.0
2000	6.3	16.7	63.0
1999	5.4	27.0	61.0
1998	4.3	18.9	55.1
1997	3.7	22.6	52.3
1996	3.0	12.8	45.0
1995	2.6	10.8	43.9
1994	2.4	-2.1	40.7
1993	2.4	9.4	44.4
1992	2.2	14.0	43.8
1991	2.0	13.1	43.2
1990	1.7	-	43.2

Sources: PMPRB, IMS Health

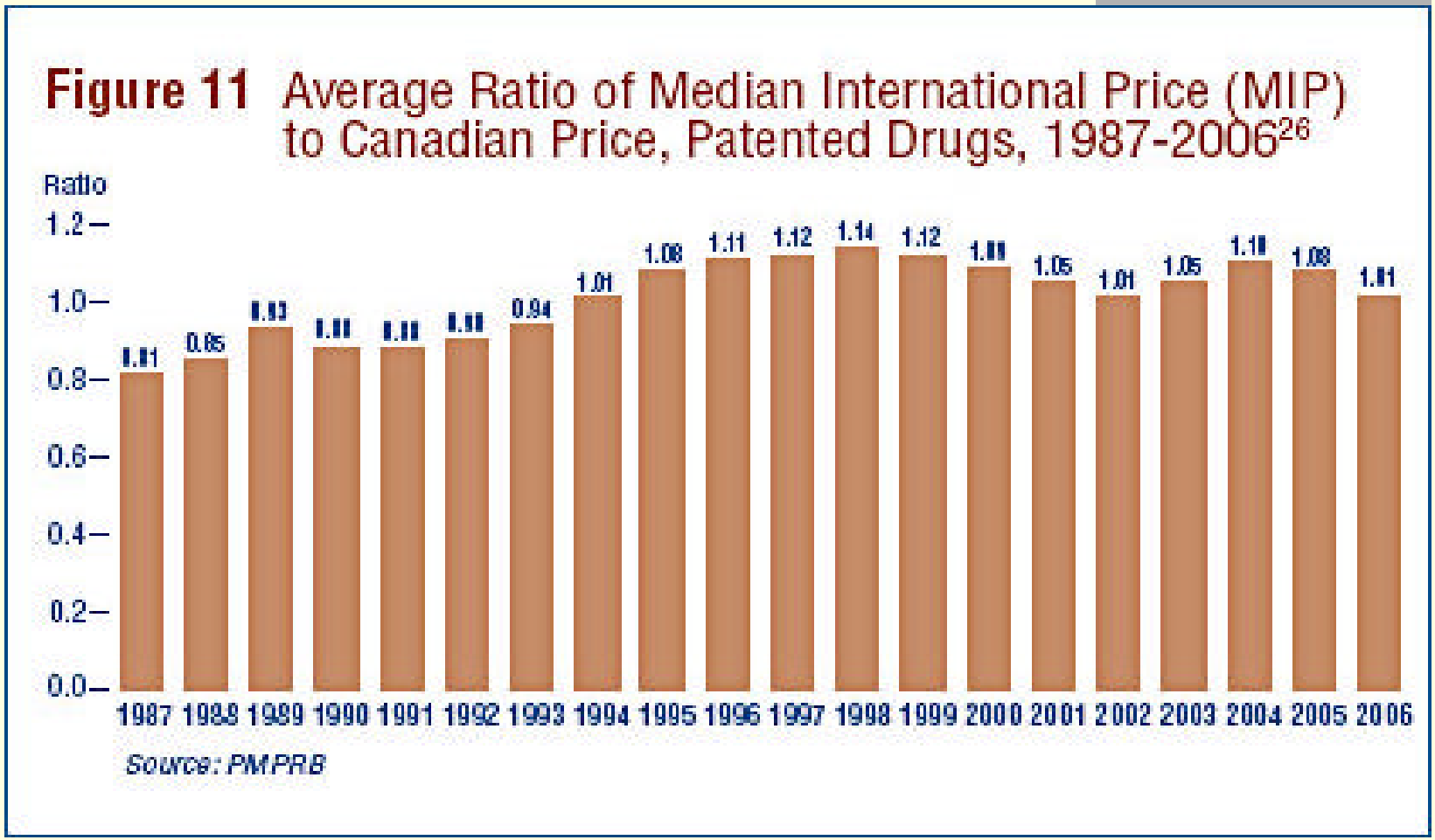
III Effective Price Regulation: Prices Relative to Inflation

Figure 6 Annual Rate of Change, Patented Medicine Price Index (PMPI) and Consumer Price Index (CPI), 1988-2006

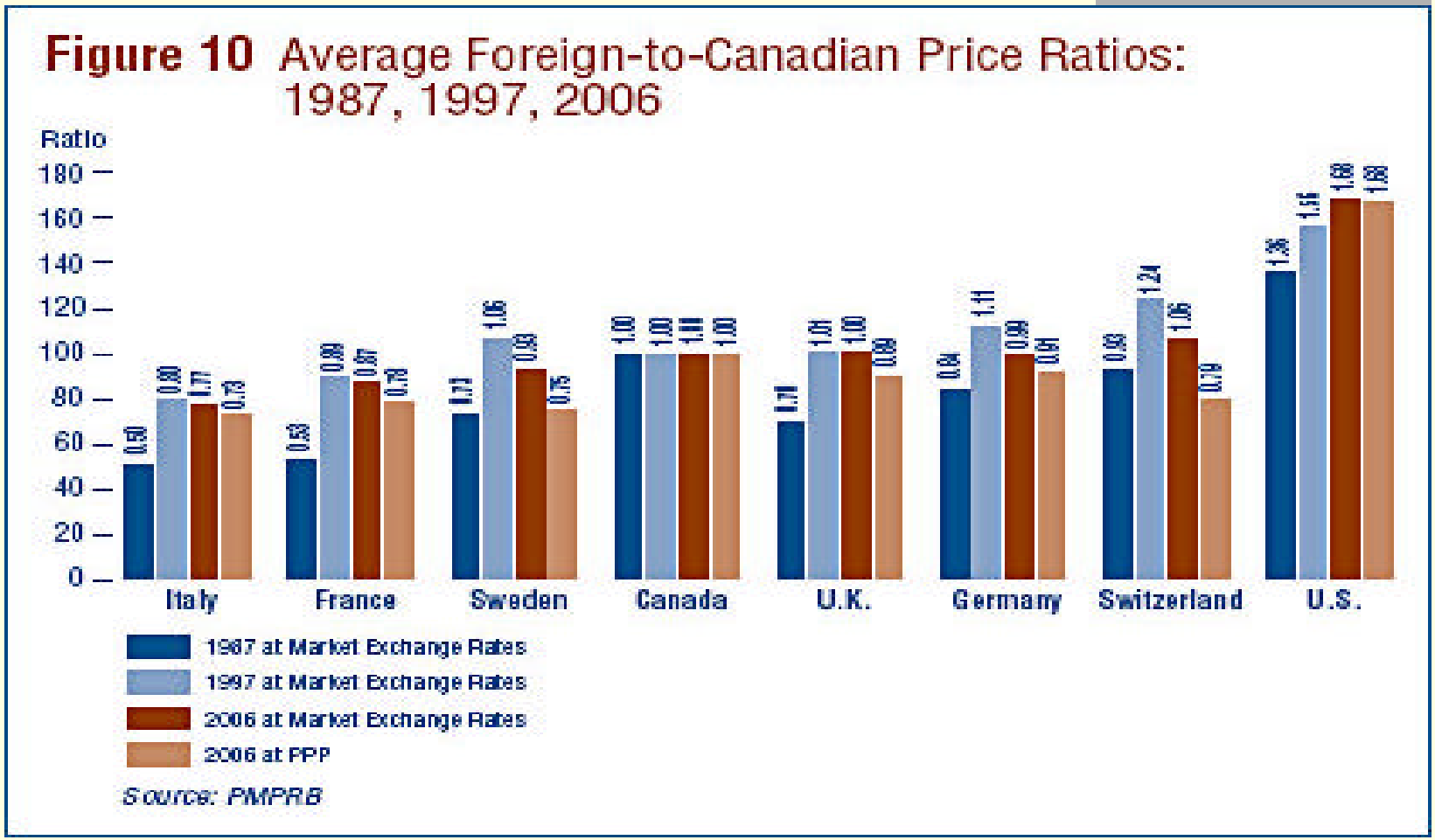


Sources: PMPRB and Statistics Canada

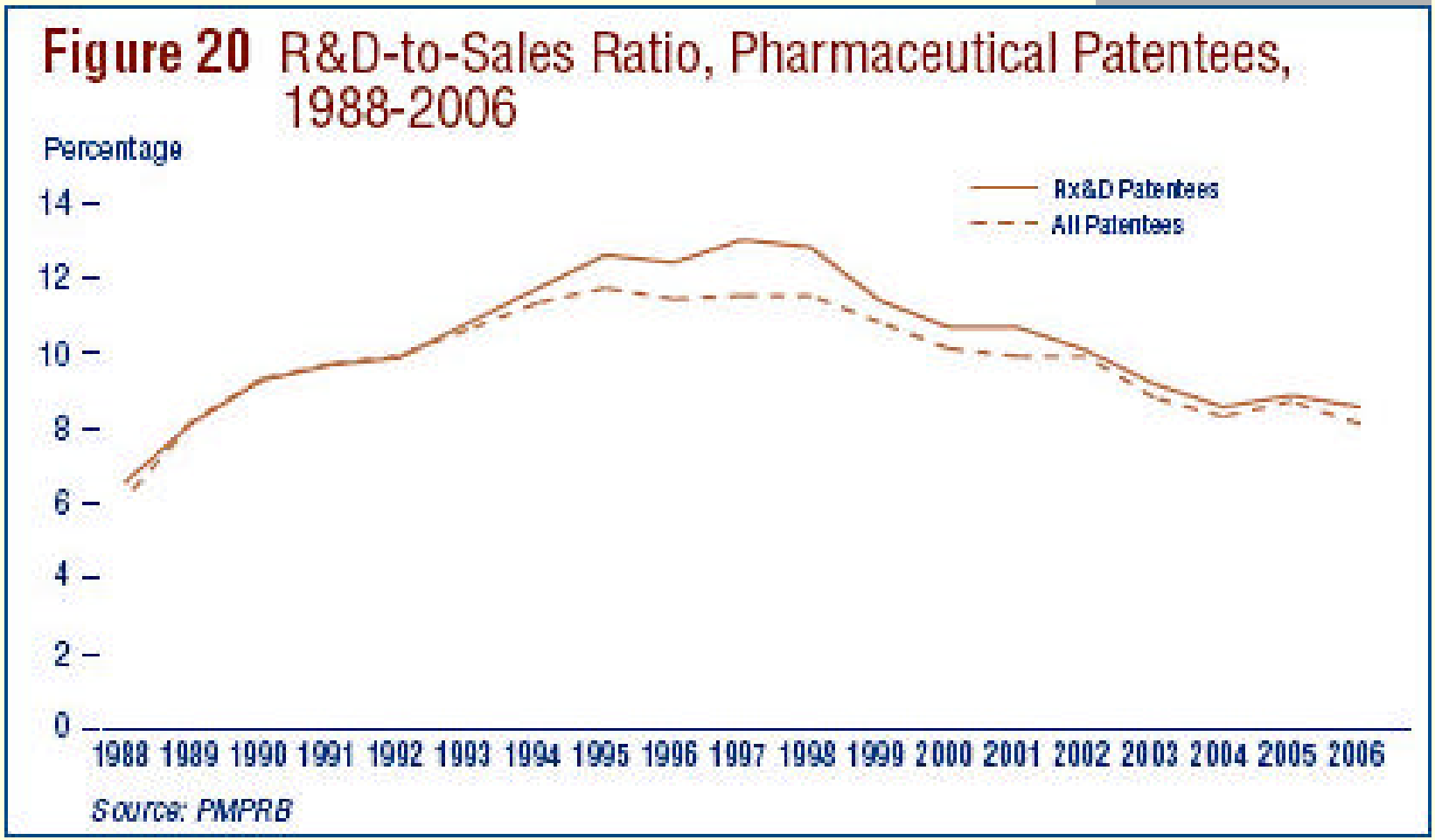
Canada: median of international pricing



Canada: middle of international pricing of patented pharmaceuticals



R&D to Sales Ratio in Canada



IV: Key PMPRB Policies and Enforcement Strategies

- Defining the concept of “Excessive Price” for patented drugs
- Compliance & Enforcement Strategy
- Price Review Process

Concept of Excessive Price

- **PMPRB set limits establishing the maximum non-excessive price**
  - Once a drug is sold in the market at a non-excessive price, price increases must be less than increases in CPI
  - Different tests for maximum introductory price of new drug:
    - Line extensions of existing medicines
    - Breakthrough or significant therapeutic benefit
    - No or modest therapeutic improvement
  - Prices can never (at introduction or later) be the highest internationally (i.e. when compared to 7 comparator countries: Germany; France; Italy; Sweden; Switzerland; United Kingdom; and United States)

Introductory Price Review

- **Category 1 Drug Products (Line Extensions)**
  - Reasonable Relationship Test (RR) – compares price of new drug to prices of existing drugs with comparable dosage forms
- **Category 2 Drug Products (Break-through or significant therapeutic improvement) Higher of:**
  - Therapeutic Class Comparison (TCC) test – up to highest price of therapeutic comparators; or
  - International Price Comparison (IPC) test – up to median of prices of the new drug in the seven comparator countries
- **Category 3 Drug products (No or modest improvement)**
  - Therapeutic Class Comparison (TCC) test
- **For all drugs: Canadian price can't be the highest of 7 comparator countries**

PMPRB's Compliance and Enforcement Strategy

- Presumes that companies want to comply with law and regulations and not charge excessive prices
- PMPRB created clear transparent guidelines for a maximum non-excessive price ("Bright Line" tests)
- PMPRB staff monitor and take action if prices in excess of guidelines.
- Firms can voluntarily bring excessive prices into compliance, and return excess earnings, or
- PMPRB can call a hearing and exercise its authority
- Low compliance cost for companies and PMPRB
- Generally high levels of compliance, no regulatory hearing on first 5 years, more recently
- Results: effective regulation, low cost low public visibility

PMPRB's Price Review Process

- Scientific review (establishes category: line extension, modest or significant improvement)
- Therapeutic Class Comparison (establish comparators - 4th level of ATC system)
- Introductory price review for new drugs
- Price review for existing drugs
- Investigations and their resolution

V: Lessons from the Canadian Policy

- Industry support for price regulation policy & regulatory system helped compliance
  - Finding an acceptable balance between consumers and industry is key to achieving creating a stable environment and industry compliance
  - Particularly critical in early days, unless well resourced and aggressive enforcement is the preferred.
- Public visibility and reporting on pricing were strong incentives for industry compliance
- Potential for negotiations with domestic and international industry, & industry “facilitation” of enforcement of policy & “benefits” agreement
- Expect common vision from MNE industry that they will defend:
  - Strategic importance of IP,
  - Protecting high prices in industrial markets that generate the bulk of their revenue,
  - Wary of international demonstration effects
  - Willing to trade R&D and reasonable limits on prices to protect IP and key industrial markets

Lessons from the PMPRB

- Ex post price reviews facilitate speedy decisions and introduction of new medicines by business
- Use of external references (inflation, prices in similar countries) in PMPRB price guidelines create transparency and adaptability over a wide range of changing economic & business conditions
- PMPRB's "bright line" guidelines for non-excessive prices led to high levels of compliance and low regulatory costs for both government and industry.

Can Canadian Experience Be Adapted to India?

- For **drugs that are not patented** and are subject to actual or potential competition, is it acceptable to have no, limited or different price regulation?

- In general, would it be acceptable for the price of **existing patented drugs** to increase in relation to the rate of inflation, perhaps up to inflation?
- For **new patented drugs providing no or little added therapeutic benefit over existing medicines**, would it be acceptable to allow them to charge a price up to the highest price of the existing medicines addressing the same health issue, or another norm related to this group of drugs?
- For **new "break-through" patented drugs** is there a group of comparator countries that could provide an acceptable norm for the introductory price? Would the resulting prices attract early supply of these medicine to India, and sustain a viable Indian R&D intensive pharmaceutical sector? Should one policy goal dominate the other?

- Do conditions exist that would allow India to **negotiate a "benefits agreement**" with the national or international pharmaceutical industry, perhaps similar to the Canadian undertaking to increase R&D in return for strengthened IP? If yes, what is it? If not, does it matter?

Resources

- Patented Medicines Prices Review Board
  - http://www.pmprb-cepmb.gc.ca/
- Roy Atkinson
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Thanks to

- Department for International Development (DFID) UK
- DFID Human Resource Centre