



Patented
Medicine Prices
Review Board

Conseil d'examen
du prix des médicaments
brevetés

Pharmaceuticals Management in Canada

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Canada

Since **1987**
Depuis



The PMPRB

- Created through amendments to the *Patent Act* in 1987 as a quasi-judicial tribunal, independent of government
- Protects consumer interests
- Two-fold mandate:
 - ♦ Regulatory: To protect consumers and contribute to Canadian health care by ensuring manufacturers' prices for patented medicines are not excessive
 - ♦ Reporting: To contribute to informed decisions and policy making by reporting on pharmaceutical trends and on R&D spending by pharmaceutical patentees



Context

- **The PMPRB does:**
 - ♦ Ensure manufacturers' prices of patented drugs are not excessive through compliance with Excessive Price Guidelines
 - ♦ Publish objective annual reports that include:
 - Analysis of Canadian and international pharmaceutical sales trends, and Canadian R&D expenditures by patentees
 - ♦ Partner with Canadian Institute for Health Information (CIHI) in the National Prescription Drug Utilization Information System (NPDUIS)
 - ♦ Monitor & report on prices of non-patented prescription drugs in the context of National Pharmaceuticals Strategy (NPS)



Context (2)

- **The PMPRB does not:**
 - ♦ Set prices of patented drugs
 - prices are the result of customer/payer negotiations on actual/reimbursement prices; and
 - Market competition
 - ♦ Have a role in formulary listing and reimbursement decisions
 - ♦ Analyze relative cost-effectiveness or value as part of the price review
 - ♦ Regulate prices of non-patented drugs



Pharmaceutical Sales in 2004

- **Global sales across major markets** (in CDN \$)
 - ♦ Over \$452 billion
 - ♦ Canadian share: 2.9%
- **Canadian sales**
 - ♦ all drugs: \$15.9 billion
 - ♦ **patented: \$10.9 billion – over 68% of market sales**
 - ♦ non-patented: \$3 billion
 - ♦ generics: \$2 billion



PMPRB'S Regulatory Jurisdiction

- All patented drugs sold in Canada are subject to PMPRB regulation:
 - ♦ whether for human or veterinary use;
 - ♦ whether prescription or non-prescription; and
 - ♦ whether already approved for market (Notice of Compliance) or not (investigational new drugs or compassionate drugs through Health Canada's Special Access Program)



Concept of Excessive Price

- Set limits, i.e., establish the maximum non-excessive price
 - ♦ Introductory maximum non-excessive price tests
 - ♦ Price increases then limited by CPI
 - ♦ Prices can never (at introduction or later) be the highest internationally (i.e. when compared to 7 comparator countries: France; Germany; Italy; Sweden; Switzerland; United Kingdom; and United States)



Price Review Process

- Board Staff reviews scientific and pricing data as filed by patentees under the *Patented Medicines Regulations*
 - ♦ New Active Substances (NASs) – referred to Human Drug Advisory Panel (HDAP) for drug categorization, comparators and dosage regimens
 - ♦ Board Staff reviews prices of all patented medicines to determine whether they are within the Board's Excessive Price Guidelines
- If a price appears to be outside the Guidelines, Board Staff initiates an investigation



Resolution of Investigation

- Closure – price within Guidelines
- Voluntary Compliance Undertaking
 - ♦ Recommendation to the Chairperson to accept the proposed VCU from the patentee
- Issuance of a Notice of Hearing
 - ♦ Recommendation by Board Staff to the Chairperson to hold a public hearing
 - ♦ Board Chairperson decides whether or not a Hearing would be in the public interest



Enforcement Activities

- Voluntary Compliance Undertakings
 - ♦ 8 VCUs approved in 2005; Total of 35 VCUs to date
 - Price reductions
 - Excess revenues offset – \$2.8M in 2005; over \$24M in total
- Hearings
 - ♦ Hoechst Marion Roussel Canada Inc. and the medicine **Nicoderm**
 - ♦ Notices of Hearings issued in 2006
 - Shire BioChem Inc. and the medicine **Adderall XR**
 - Janssen-Ortho Inc. and the medicine **Risperdal Consta**
 - 3M Canada Company and the medicine **Airomir**
 - Teva Neuroscience G.P.-S.E.N.C. and the medicine **Copaxone**



Transparency

- Compendium of Guidelines, Policies and Procedures
 - ◆ Developed by the Board in consultation with stakeholders
 - ◆ Lays out approach to price review
- Patentees' Guide to Reporting
 - ◆ Guidance on reporting under the *Patented Medicines Regulations*



Transparency (2)

- Quarterly NEWSletter
 - ◆ Updates on policies and practices
 - ◆ Updates on Consultations/Notice & Comments – e.g. Proposed regulatory amendments; Guidelines
- Web site
 - ◆ Status of drug reviews
 - ◆ Summary reports on price review of new drugs
 - ◆ Compendium of Guidelines, Policies and Practices
 - ◆ Filing Requirements
 - ◆ Publications

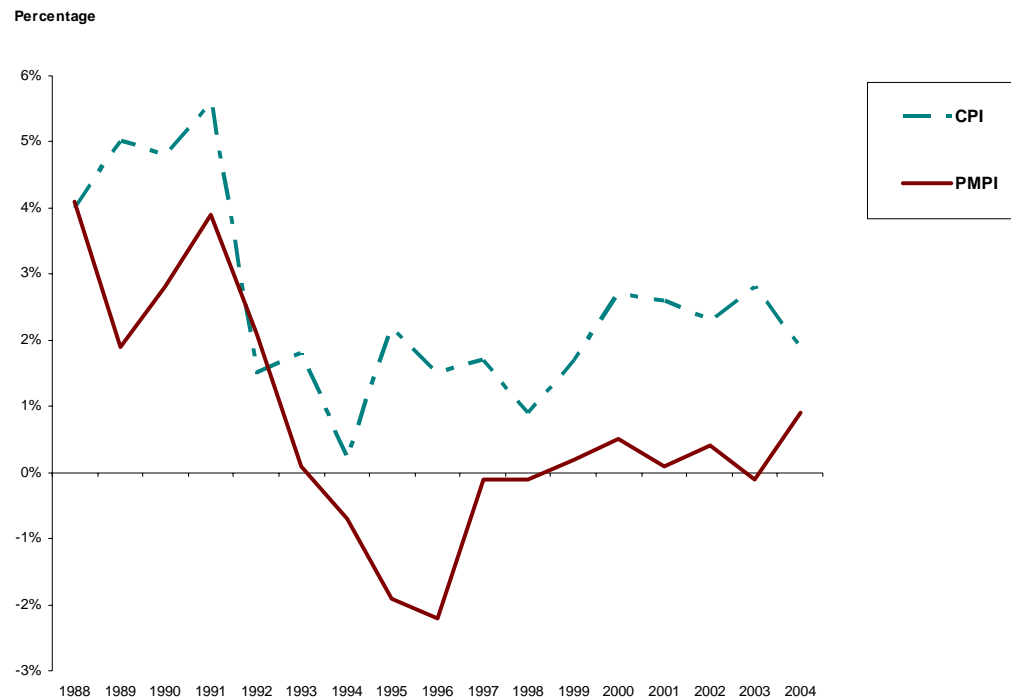


PMPRB reports annually on

- Its overall activities
- Pharmaceutical trends for all medicines
 - ♦ Prices of patented medicines remained relatively stable during last decade
 - Patented Medicine Price Index for 2004 was 0.9%
 - Prices in Canada remained below the international median in seven comparator countries
- R&D expenditures by pharmaceutical patentees
 - ♦ R&D-to-sales ratio was 8.3% in 2004
 - ♦ Ratio for all patentees decreasing since 1998



Year-over-Year Changes in the PMPI and CPI, 1988-2004



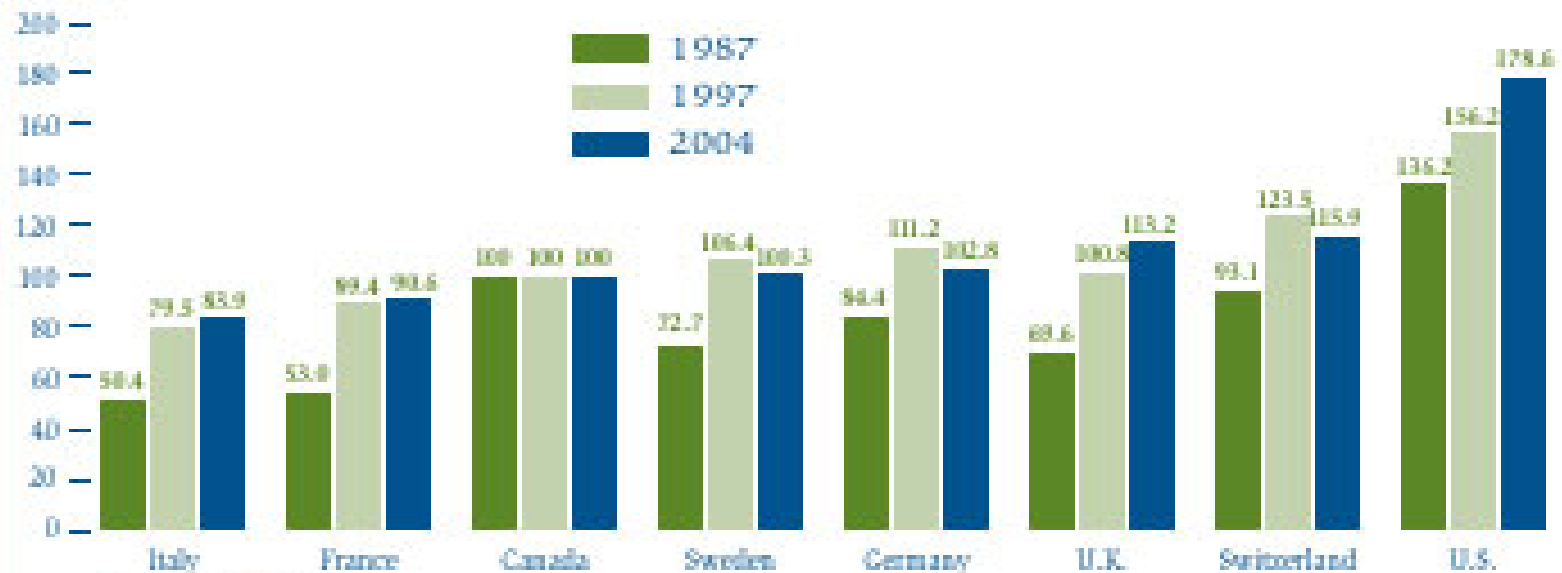
Source: PMPRB and Statistics Canada



Figure 9

Average Foreign to Canadian Price Ratios, Patented Drug Products,
1987, 1997 and 2004

Ratio



Source: PMPRB



R&D

- In 1987, Rx&D committed to doubling its R&D spending to 10% of sales by 1996
- In 1997, the industry reached 12.9%
- In 2004, the industry was at an all time low of 8.3%
- In 2000, Canada's R&D investment was 10.1% of sales compared to 19% in 7 comparator countries (which includes the US with high rates of R&D)



NPDUIS

- In 2002, under Section 90 of the *Patent Act*, the Minister of Health directed the PMPRB to provide timely analysis of price, utilization and cost trends to support sound pharmaceutical policies and the effective management of Canada's public drug benefits programs
- Collaborative effort between the PMPRB and the Canadian Institute for Health Information (CIHI)



Federal/Provincial/Territorial National Pharmaceuticals Strategy

- Key priority in First Ministers 10-Year *Plan to Strengthen Health Care* (September 2004) –
implementation confirmed in May 2, 2006 Budget
- 9 elements, encompassing access, affordability, safety and effectiveness; appropriate utilization; and prices/costs
- PMPRB participating as observer on Task Force
- October 23, 2005: F/P/T Ministers of Health gave the PMPRB the responsibility to report on non-patented drug prices
 - ♦ First quarterly report : Canadian to foreign price comparisons (spring 2006)



Pharmaceuticals Management in Canada

▪ Federal Government

- ♦ *Food and Drugs Act* (Assessment of new medicines by Health Canada)
- ♦ *Patent Act* (PMPRB) and *Patented Medicines Regulations*
 - Non-excessive prices for patented medicines; annual report to Parliament on the price trends of medicines and R&D expenditure
- ♦ *Patented Medicines (NOC) Regulations* (Health Canada, Industry Canada)
 - Market exclusivity; data protection

▪ Federal/Provincial/Territorial Governments

- ♦ Common Drug Review (CDR)
- ♦ Canadian Optimal Medication Prescribing and Utilization Service (COMPUS)
- ♦ National Prescription Drug Utilization Information System (NPDUIS)



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