Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada's Patented Medicine Prices Review Board

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Canada

Overview

- Pharmaceutical Regulation in Canada
- The PMPRB – 25 Years in the Making
- Pharma Market in Canada
- Overview of the PMPRB Price Regulation Regime
- Early Observations of Revised Guidelines
- Emerging Pharmaceutical Realities in Canada
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Pharmaceutical Regulation in Canada

PMPRB

Jurisdiction covers patented drug products sold in Canada, whether through market approval or under special authority
(i.e., market approval not required)

Over Life of Patent

Health Canada
Review For Safety, Efficacy & Quality

Market Approval

Health Canada
Post-Market Surveillance

Private Drug Plan Reimbursement

Public Drug Plan Reimbursement

Common Drug Review

Individual Federal/Provincial Public Drug Plan Listing

Any and all patents:
"merest slender thread",
worked or not

The PMPRB – 25 Years in the Making

Establishment of the PMPRB

- **1987 amendments to *Patent Act***
  - Strengthened patent protection of medicines
    - Incentive to invest in more pharmaceutical R&D in Canada
  - Established the PMPRB as the consumer protection pillar
    - Ensure prices of patented medicines are not excessive
    - Reporting role to contribute to informed policy decision making in health care

The PMPRB – 25 Years in the Making (cont'd)

The PMPRB Regime:

- **Quasi-judicial body**
  - Remedial orders carry the force of the Federal Court
    - Price reductions, repayment of excess revenues, double damages
- **Has dual mandate:**
  - **Regulatory:** Ensure prices charged by patentees for patented drug products sold in Canada are not excessive
  - **Reporting:** Report on pharmaceutical trends and on R&D spending by pharmaceutical patentees

The PMPRB – 25 Years in the Making (cont'd)

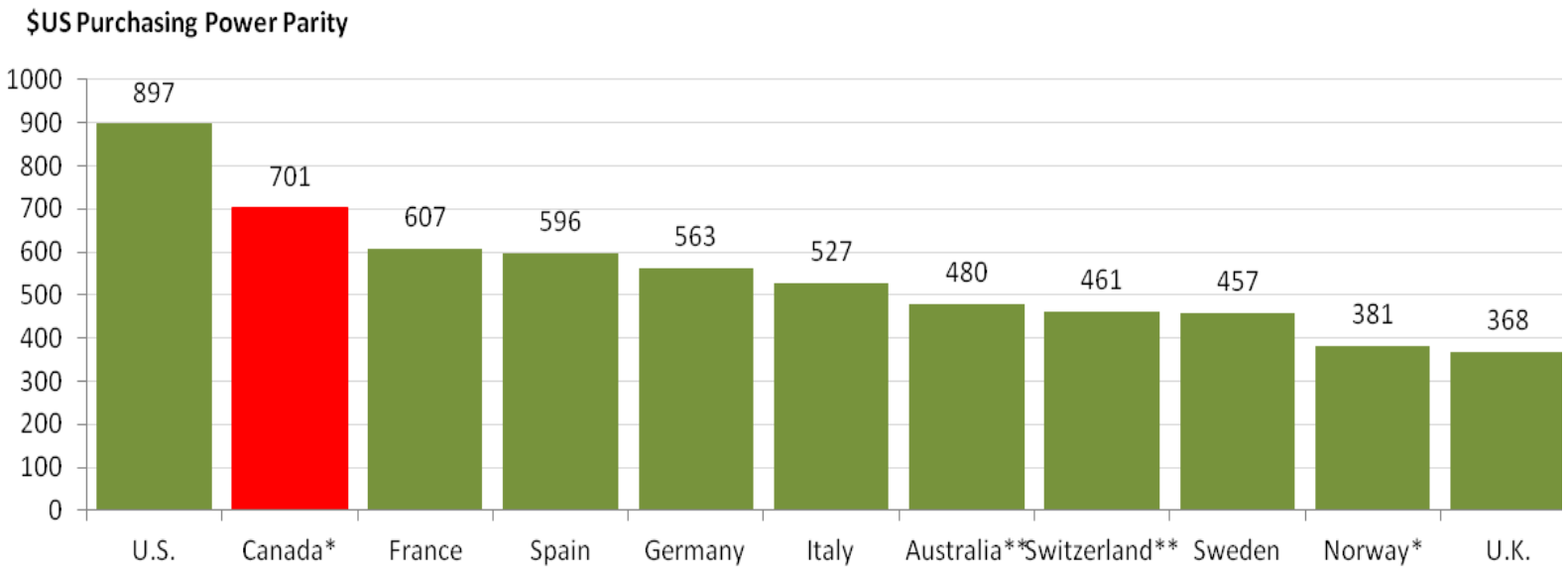
Amendments:

- **1993 amendments to *Patent Act***
  - Eliminated compulsory licensing
  - Expanded PMPRB's remedial powers
- **2008 amendments to *Patented Medicines Regulations***
  - Prices of veterinary drugs, and over-the-counter drugs for human use, are reviewed on a complaints-based approach

Pharma Market in Canada

International Comparison

Total Pharmaceutical Expenditure Per Capita



Source: OECD Health Data 2010
** Estimate*
*** 2007 value*

Pharma Market in Canada (cont'd)

Proportion of Market Regulated by PMPRB

TABLE 9 Sales of Patented Drug Products, 1990—2009

Year	Patented Drug Products		Sales of Patented Drug Products as Share of All Drug Sales (%)
	Sales ($Billions)	Change (%)	
2009	13.3	2.8	62.4
2008	13.0	4.9	64.7
2007	12.4	3.3	65.4
2006	12.0	3.7	67.8
2005	11.5	4.7	70.6
2004	11.0	8.6	72.2
2003	10.2	14.3	72.7
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 and IMS Health

Overview of the PMPRB Price Regulation Regime

- **Jurisdiction:**
  - Drug products patented and sold in Canada
  - Instruments:
    - *Patent Act* (s. 79–103)
    - *Patented Medicines Regulations*
    - Compendium of Policies, Guidelines and Procedures
- **Price approval not required before sale**
- **PMPRB establishes a price ceiling, but DOES NOT set selling price of drug product**
- **Regular price reviews to monitor compliance with Guidelines combined with enforcement mechanisms (investigations, Voluntary Compliance Undertakings, hearings, orders)**

Overview of the PMPRB Price Regulation Regime

- **Factors to be considered by Board:**
  - Price of medicine sold in Canada
  - Prices of other medicines in same therapeutic class sold in Canada
  - Prices of medicines sold in comparator countries
  - Changes in CPI
- **Reference based**
  - 7 comparator countries: FR, DE, IT, SE, CH, UK, US
- **Open and transparent price regulation**
  - Hearings are public
  - VCUs publicly disclosed
  - MAPP publically available
  - * **BUT,** pricing data filed is confidential (s. 87)

Overview of the PMPRB Price Regulation Regime (cont'd)

- **Policies, Guidelines and Procedures**
  - Promote compliance
  - Provide fairness, transparency, openness and predictability
- **Advisory assistance offered pre and post market authorization**
- **Comprehensive revisions over past five years with new Guidelines implemented in January 2010**
- **Guidelines seek a balanced approach between price regulation and an aim to reward innovation**
  - E.g., introduction of 4 levels of therapeutic improvement based on primary and secondary factors

Early Observations of Revised Guidelines (cont'd)

Guideline Changes	Rationale for Change	Observations
Overall Implementation		▪ Ongoing monitoring, evaluation, and resolution of issues ▪ Proactive outreach and education
Overall Restructuring of Price Tests	▪ Price premium to reflect therapeutic value	▪ Board Staff proactive in publishing clarification via NEWSletter ▪ Board Staff continue to monitor issues
New Levels of Therapeutic Improvement	▪ Recognizing incremental therapeutic innovation	▪ Successfully applied by HDAP members ▪ To date, 11 moderate improvements (4 based on secondary factors)

Early Observations of Revised Guidelines (cont'd)

Guideline Changes	Rationale for Change	Observations
DIP Methodology	▪ Avoid creating disincentives for offering benefits	▪ Evidence requirements are being clarified to ensure they are feasible and can be easily applied
Any Market	▪ Ensuring that no sub-national market is paying excessive prices	▪ Monitoring only ▪ Not fully implemented

Emerging Pharmaceutical Realities in Canada

- Patent cliff and competition with generic prices
  - $7.4B (33%) of brand products in Canada will lose patent protection through 2014*
  - Continued downward pressure on generic drug prices
- Therapeutic direction towards personalized medicines and rare diseases
  - E.g., possibility of companion diagnostics being included in price of drug
- New frontiers: Subsequent Entry Biologics and nanotechnology

* Source: IMS Brogan, Canadian Drug Stores and Hospital Purchases, MAT May 2010; MIDAS, MAT December 2009.

Emerging Pharmaceutical Realities in Canada (cont'd)

- Increased focus by payers to stretch budget dollars
- Changing distribution channels and pricing models to maximize profits and enhance market penetrations
- Impact of lower international prices (mandated price reductions), and appreciating Canadian dollar

Emerging Pharmaceutical Realities in Canada (cont'd)

Canadian-European Union Comprehensive Trade Agreement (CETA)

- In May 2009, Canada launched trade negotiations with the European Union (EU)
- CETA proposals include focus on pharmaceutical intellectual property:
  - Ability for brand pharmaceutical companies to appeal court decisions under *Patented Medicines* (NOC) *Regulations*
  - Patent term restoration
  - Data protection
- If proposals implemented, longer period of PMPRB regulation over affected patented drugs

Moving Forward

- Engagement with all stakeholders
- Ongoing monitoring and evaluation of Guidelines
- Engaging with international organizations to assist in identifying broad policy concerns and issues being addressed by international counterparts
- Improving transparency of the PMPRB price review process by publishing summaries of all new medicine price reviews

Thank you.

Merci.

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PMPRB Website:

http://www.pmprb-cepmb.gc.ca