Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada's Patented Medicine Prices Review Board

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June 14, 2011

Canada

Overview

- The PMPRB – 25 Years in the Making
- Overview of the PMPRB Price Regulation Regime
- Observations of the Revised Guidelines
- Emerging Pharmaceutical Realities
- Moving Forward
- Key Messages

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
- **Dual mandate:**
  - **Regulatory:** To ensure that prices at which patentees sell their medicines in Canada are not excessive
  - **Reporting:** To report on pharmaceutical trends of all medicines, and on research and development (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

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

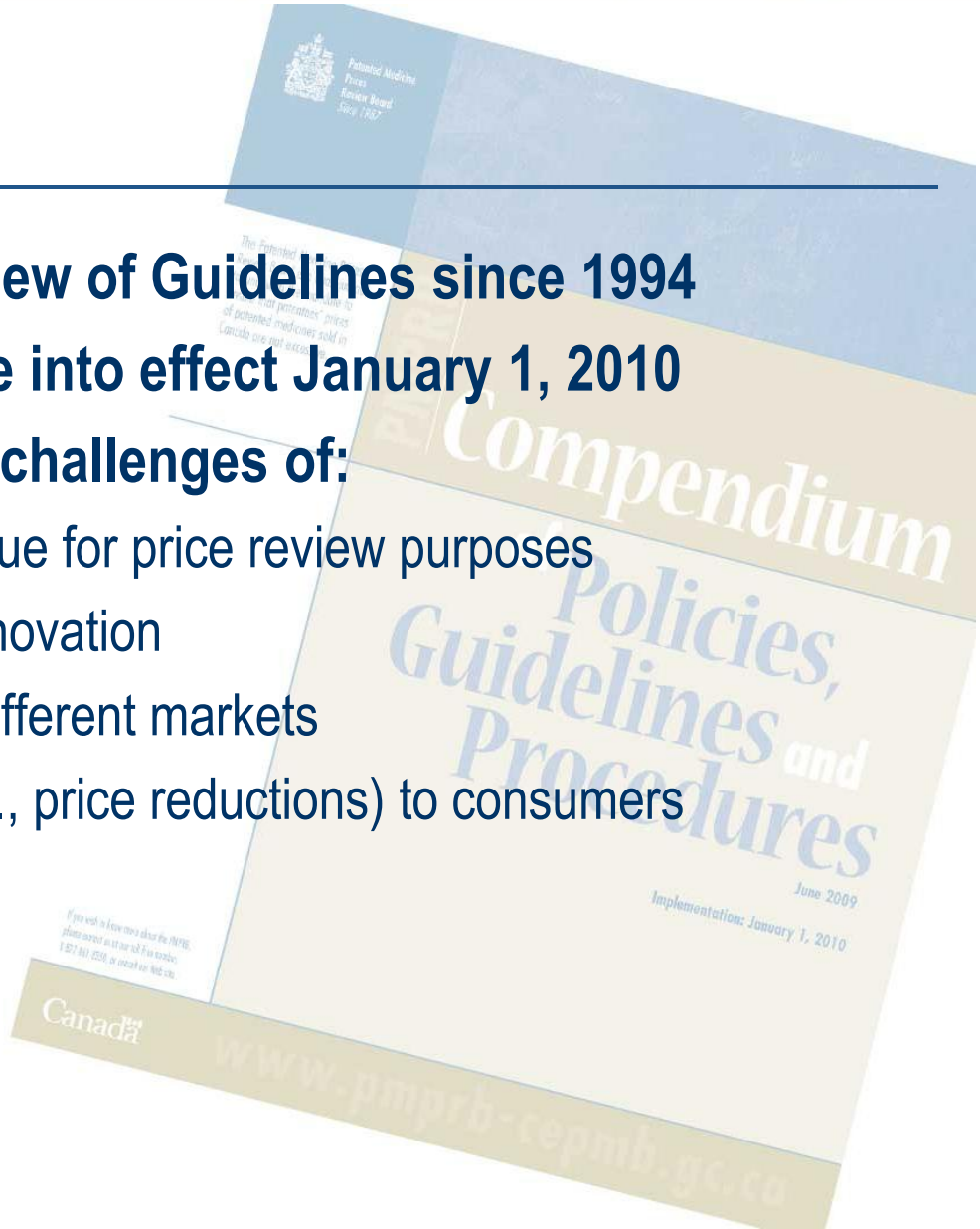
- **Factors to be considered by Board:**
  - Price of medicine sold in Canada
  - Prices of other medicines in same therapeutic class sold in Canada
  - Prices of medicines sold in comparator countries
  - Changes in CPI
- **Reference based**
  - 7 comparator countries: France, Germany, Italy, Sweden, Switzerland, UK and the US
- **Open and transparent price regulation**
  - Hearings are public
  - VCUs publicly disclosed
  - MAPP publically available

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

Guidelines Review

- **First comprehensive review of Guidelines since 1994**
- **Revised Guidelines came into effect January 1, 2010**
- **Key changes to address challenges of:**
  - Assessing therapeutic value for price review purposes
  - Rewarding therapeutic innovation
  - Price variation between different markets
  - Recognizing benefits (e.g., price reductions) to consumers



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)

Observations of Revised Guidelines (cont'd)

Guideline Changes	Rationale for Change	Observations
DIP Methodology	▪ Avoid creating disincentives for offering benefits	▪ Board adopted Working Group report and recommendations as a pilot project ▪ Patentees have successfully invoked DIP methodology in context of several ongoing investigations
Any Market	▪ Ensuring that no sub-national market is paying excessive prices	▪ Monitoring only ▪ Not fully implemented

Investigation Criteria

- **Board Staff commences an investigation into the price of a patented medicine when any of the following criteria are met:**
  - **New Drug Products**
    - 5% above the maximum average potential price (MAPP); or
    - Cumulative excess revenues are $50,000 or more; or
    - Complaint filed
  - **Existing Drug Products**
    - Cumulative excess revenues are $50,000 or more over the life of the patent; or
    - Complaint filed
- **Patentee given opportunity to make further written submissions to Board Staff to substantiate the price**

Investigation Outcomes

- **Price within the Guidelines**
  - Investigation closed
- **Price outside the Guidelines**
  - Patentee given an opportunity to submit a Voluntary Compliance Undertaking (VCU); or
  - Board Staff refers the matter to the Chairperson with a recommendation to issue a Notice of Hearing for public hearing
- **Disposition of investigations / hearings**
  - In addition to price reductions, excessive revenues totalling $24.6 million were collected in 2010 to date
  - Since 1993 – 74 VCUs have been approved; approximately $110M in excess revenues collected through VCUs and Board Orders

Hearings and Jurisprudence – Pricing Issues

Matter	Board Resolution	Judicial Review
Nicoderm (April 2010)	▪ Price not excessive	
Pentacel and Quadracel (March 2010)	▪ Excessive pricing; ordered repayments of excess revenues	▪ FC decision expected by end of June 2011 ▪ Issue: offset of excess revenues through other drug product
Penlac (January 2011)	▪ Excessive pricing; ordered repayment of excess revenues - $9.4M	

Hearings and Jurisprudence – Pricing Issues

Matter	Board Resolution	Judicial Review
ratio-Salbutamol HFA (May 2011)	▪ Price excessive; exclusion of all benefits for lack of proof; ordered Board Staff to file, by end of June, amount of excess revenues for repayment; commentary on Pfizer decision	
Copaxone Redetermination	▪ Decision pending	

Hearings and Jurisprudence – Jurisdiction

Matter	Board Resolution	Judicial Review
Celgene Corporation and Thalomid	▪ Board confirms jurisdiction: sales from US to Canada under Health Canada's Special Access Programme	▪ Supreme Court of Canada found in favour of the PMPRB, confirmed consumer protection role of the Board and determined reasonableness as standard of review
ratiopharm Inc.	▪ Decision to be issued by end of June 2011	
Sandoz Canada Inc.	▪ Decision pending	

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
- 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

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

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
- 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
- Ongoing monitoring and evaluation of Guidelines

Key Messages

- **PMPRB's role and mandate within broader health policy agenda**
- **Courts have confirmed several important elements of the current framework, including consumer protection mandate**
- **Numerous stakeholders**
- **Guidelines promote compliance and provide fairness, transparency and predictability**
- **Revised Guidelines are still very new and Board continues to monitor implementation/impact**
- **Outreach, communications and engagement with affected parties**

Thank you.

Merci.

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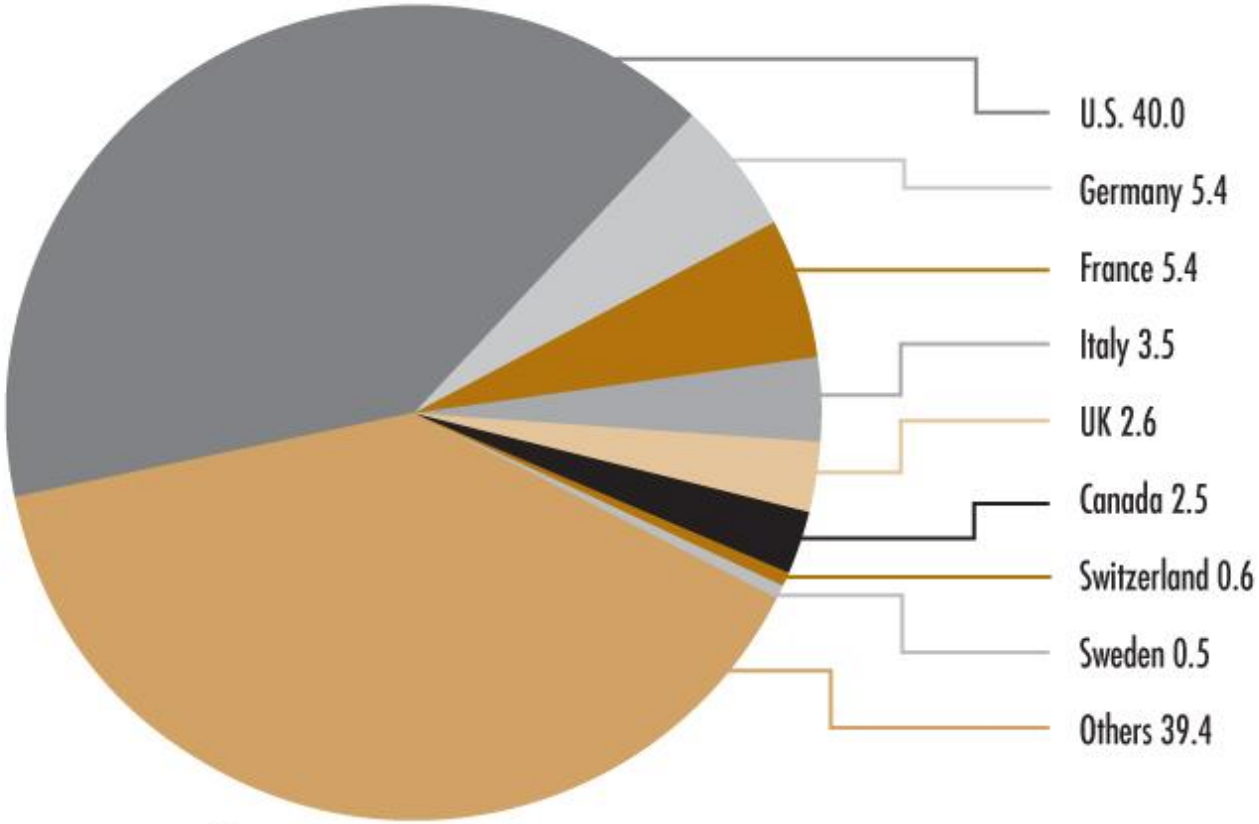
Annex

FIGURE 15 Distribution of Global Drug Sales Among Major National Markets, 2009

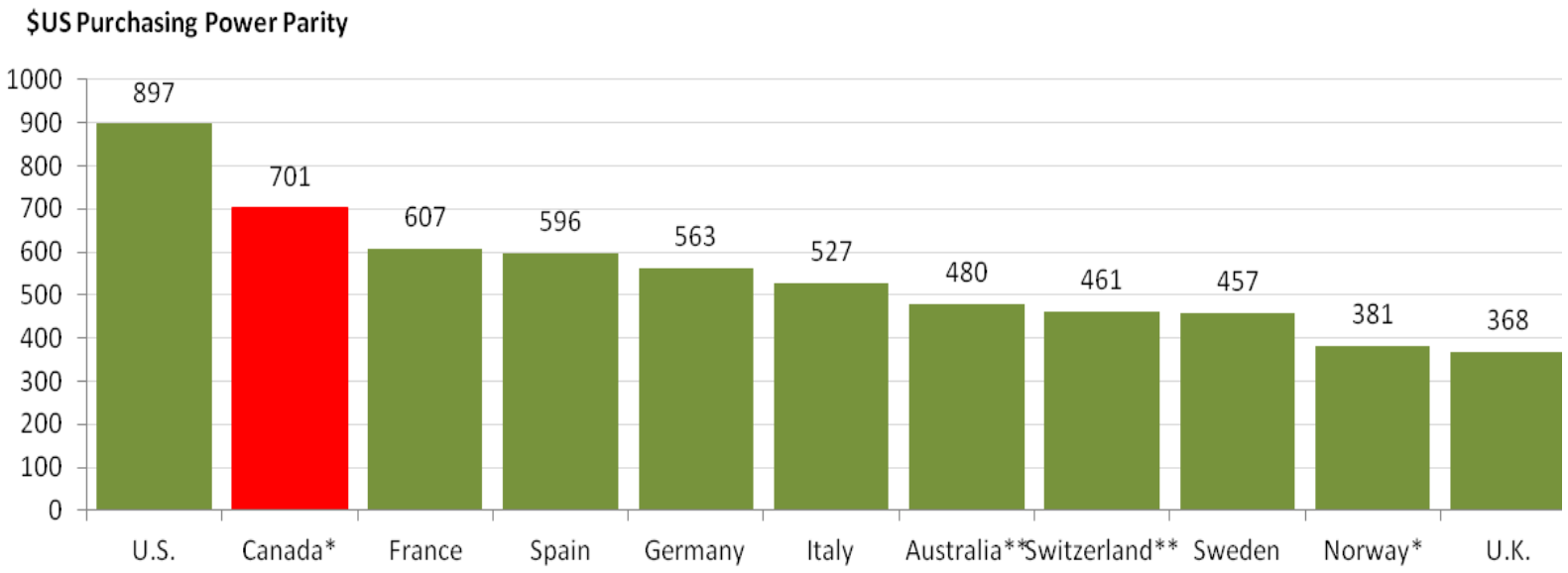


Source: IMS Health

Pharma Market in Canada

International Comparison

Total Pharmaceutical Expenditure Per Capita



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

Pharma Market in Canada
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