Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

Canada's Patented Medicine Prices Review Board

Michelle Boudreau, Executive Director

Market Access Summit

November 15-16, 2011

Overview

- Overview of the PMPRB Price Regulation Regime
- Observations of the Revised Guidelines
- Reporting and the National Prescription Drug Utilization Information System (NPDUIS)
- Coming soon at PMPRB
- Emerging Pharmaceutical Realities
- Key Messages
- Annex (Annual Report data & listing of NPDUIS reports)

PMPRB Price Regulation Regime – Overview

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
    - Role confirmed by the Supreme Court of Canada in January 2011 in Celgene matter

PMPRB Price Regulation Regime – Overview

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 R&D spending by pharmaceutical patentees

PMPRB Price Regulation Regime – Overview

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

PMPRB Price Regulation Regime – Overview

- **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 and orders)**

PMPRB Price Regulation Regime – Overview

- **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**
  - Maximum Average Potential Price (MAPP) publicly available
  - VCUs publicly disclosed
  - Hearings are public

Guidelines Review

- **Revised Guidelines came into effect January 1, 2010**
- **Guidelines seek a balance between price regulation and rewarding innovation**
- **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

Main Observations of Revised Guidelines

- **Restructuring of price tests to recognize incremental innovation – 'moderate therapeutic improvement'**
- **DIP methodology – pilot project, final decision in December 2011**
  - Avoid any disincentives for offering "benefits" (e.g. free goods to patients, discounted goods) – new Guidelines allow a rebound in price
- **Challenges with full implementation of any market review recognized - monitoring, with final decision in December 2011**

Moderate Improvement – a few details

- **Moderate Improvement – relative to other drug products sold in Canada, provides moderate improvement in therapeutic effects**
  - Based on:

    Primary Factors – the new drug product provides increased efficacy and reduction in incidence or grade of important adverse reaction

    Secondary Factors – there are 9, including route of administration; patient convenience; compliance improvements leading to improved therapeutic efficacy; caregiver convenience; disability avoidance/savings, to name a few
  - The primary factors will be given the greatest weight, followed by an assessment of any additional improvement as a result of the secondary factors
- **In 2010, 8 medicines received 'moderate improvement**
  - 5 on primary factors: Toctino; Restasis; Afinitor; Ixario; Prevnar 13
  - 3 on secondary factors: Prolia; Invega Sustena; Targin

Guidelines – Monitoring and Evaluation Plan

- **Assess the impact and application of the major changes**
  - Qualitative and quantitative indicators
  - Results of the indicators
- **Monitor emerging issues to identify the need for any future amendments**
  - Summary of major changes, indicators and results are posted on the Web
- **Guidelines are not static but an evolving tool to assist patentees in pricing their patented drugs at a non-excessive price**

Compliance

- New drugs introduced in 2011 to date: 85
- On average, 93-95% overall compliance

2010	New drug products in	Existing drug products	Total
Total	68	1128	1196
Within Guidelines	48	906	954
Under review	11	9	20
Does not trigger	2	133	135
Under investigation	7	78	85
Price Hearings		2	2

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 $26.6 M were collected in 2010 to date
  - Since 1993 – 79 VCUs have been approved; approximately $100M in excess revenues collected through VCUs and Board Orders

Hearings and Jurisprudence – Pricing Issues

Matter	Board Resolution	Judicial Review
Pentacel and Quadracel (March 2010)	▪ Excessive pricing; ordered repayments of excess revenues ▪ *Decision on reconsideration pending*	▪ FC decision issued July 12, 2011 – reconsideration by the Panel ▪ Issue: offset of excess revenues through other drug product
ratio-Salbutamol HFA (My 2011)	▪ Order issued October 17, 2011	JR Application on Decision filed on June 27, 2011 JR Application on Board Order filed on November 7, 2011
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. (June 2011)	▪ Board Order issued requiring ratiopharm to file pricing data on 12 drug products	JR Application filed July 29, 2011
Sandoz Canada Inc.	▪ Decision pending	

Reporting and the NPDUIS

- **Under its reporting mandate, the PMRPB:**
  - Informs all stakeholders on pharmaceutical price trends of all medicines and on R&D spending by patentees
  - Assists decision-makers in making informed decisions
- **National Prescription Drug Utilization and Information System**
  - Established in 2001, in partnership with the Canadian Institute on Health Information (CIHI), at the request of F/P/T Ministers of Health
  - PMPRB-NPDUIS provides critical analyses of price, utilization, and cost trends to support drug plan policy decision-making for participating jurisdiction
  - Steering Committee composed of F/P/T representatives provides PMPRB with advice regarding research needs and priorities
  - Since December 2010, eight publications have been released

NPDUIS – Areas of Research and Analysis

- Provincial reimbursement policies
- Utilization of therapeutic classes of interest
- Patented v. generic drug use and costs
- Utilization v. recommendations for specific medical products
- Methodological study on cost drivers
- Statistical report on drug reimbursement in Canada
- Access to drugs
- New drug pipeline monitor

PMPRB – Coming soon

- **Analysis briefs**
- **NPDUIS annual report**
  - High-level report that provides an overview of drug utilization, cost drivers and market segmentation in public drug programs
  - Focus on NPDUIS participating jurisdictions
  - Produced on annual basis
  - Expected release: Spring 2012
- **User friendly "field searchable" information regarding new**
- **Updated Guidelines – June 2012**

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
- **Top sellers are shifting towards high cost drugs (mainly "biologics")**
- **Therapeutic direction towards personalized medicines and rare diseases**
- **Subsequent Entry Biologics**
- **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**
- **CETA proposals include focus on pharmaceutical intellectual property**

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

Key Messages

- PMPRB's role and mandate within broader health policy agenda
- Guidelines promote compliance and provide fairness, transparency and predictability – need to remain actual
- Emphasis on outreach, communications and renewed engagement with all stakeholders and international organizations
- *PMPRB remains committed to openness, transparency and predictability*

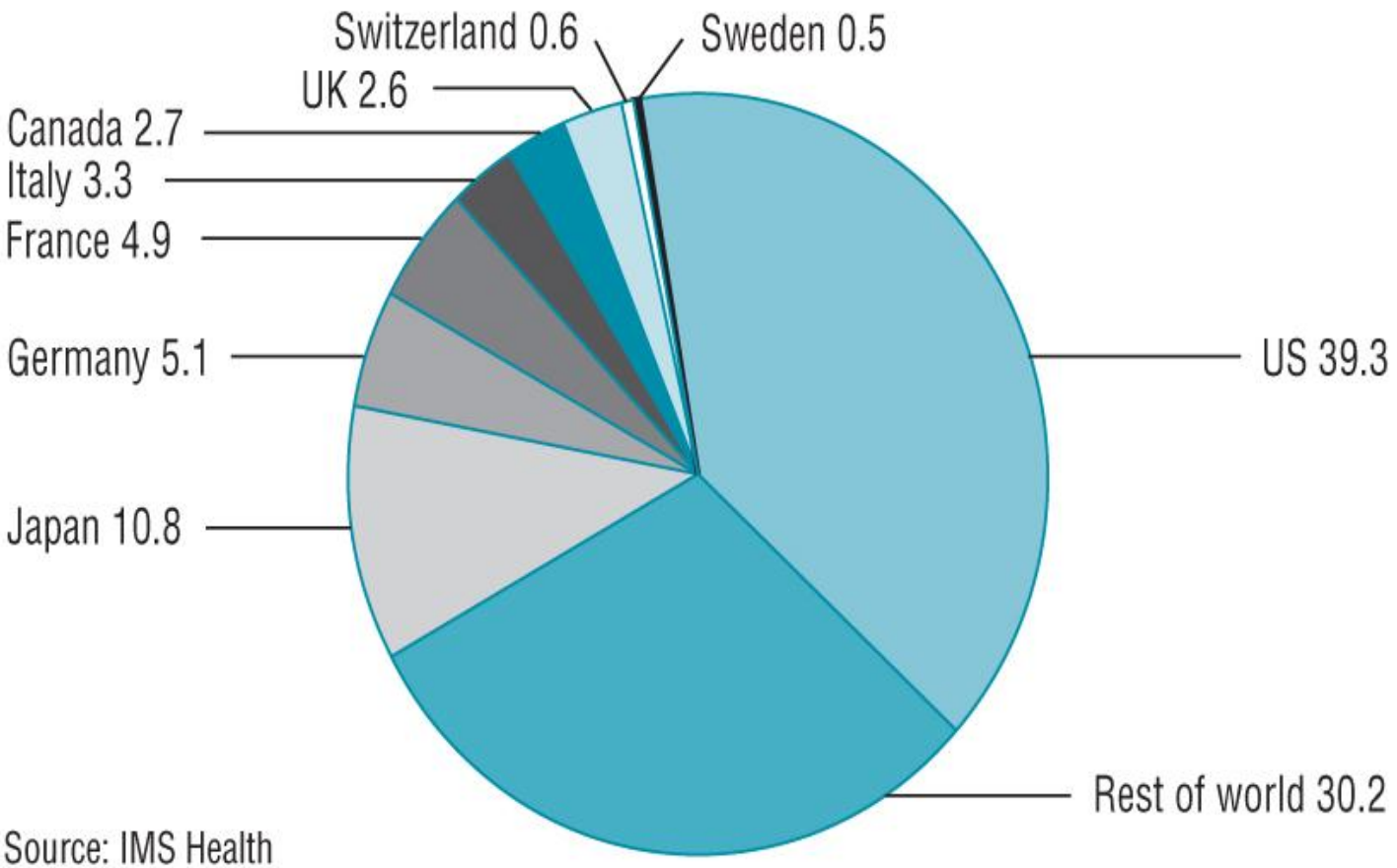
Annex

Table 7 Sales of Patented Drug Products, 2000–2010

Year	Patented drug products		Sales of drug product share of all drug sales (%)
	Sales ($billions)	Change (%)	
2010	12.9	-3.4	58.0
2009	13.3	3.3	65.5
2008	12.9	5.0	64.7
2007	12.3	3.3	63.2
2006	11.9	3.6	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

Sources: PMPRB and IMS Health

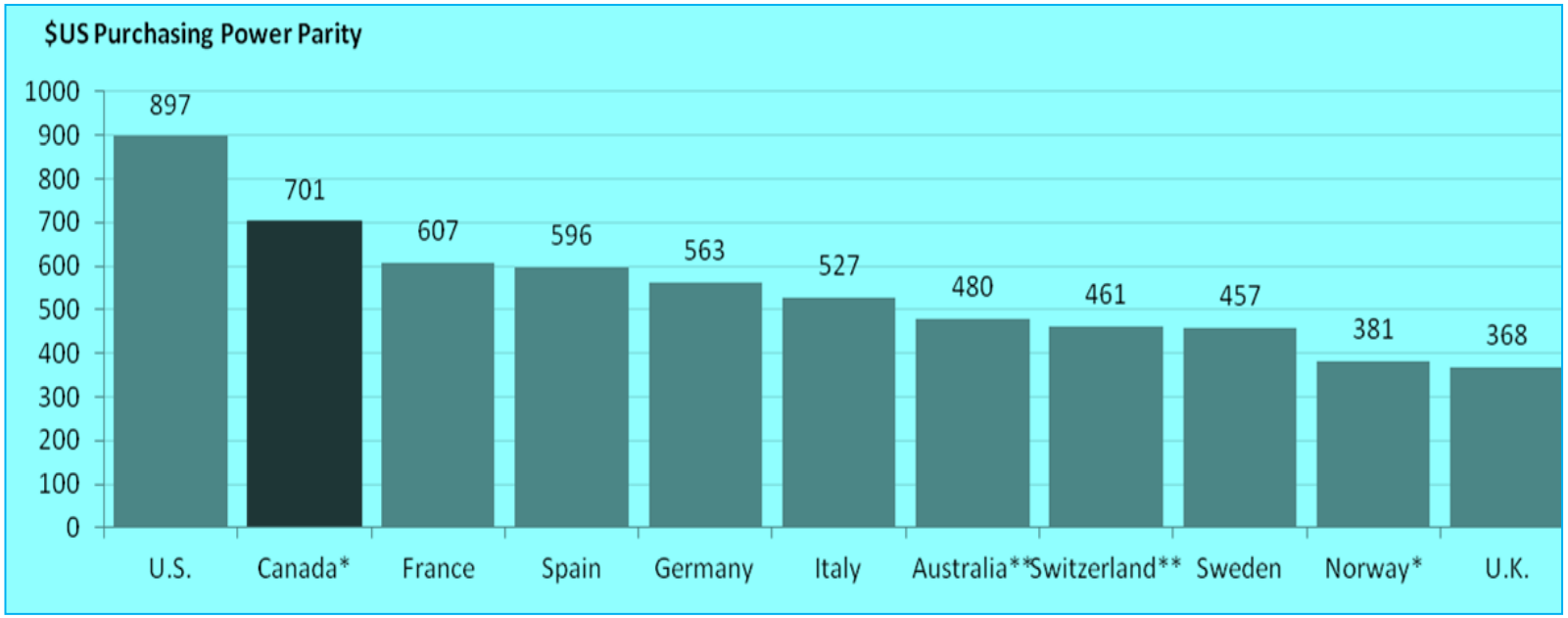
Figure 13 Distribution of Drug Sales Among Major National Markets, 2010



Source: IMS Health

Pharma Market in Canada – International Comparison

Total Pharmaceutical Expenditure Per Capita



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

Recent NPDUIS Publications

- Baby-Boomer Effect on Prescription Expenditures and Claims, December 2010
- Use of the World Health Organization Defined Daily Dose in Canadian Drug Utilization and Cost Analyses, December 2010
- Generic Drugs in Canada: Market Structure — Trends and Impacts, December 2010
- Generic Drugs in Canada: Price Trends and International Price Comparisons, 2007, December 2010
- The Impact of Generic Entry on the Utilization of the Ingredient, September 2011
- Public Drug Plan Dispensing Fees: A Cost-Driver Analysis, 2001/02 to 2007/08, September 2011
- Generic Drugs in Canada: International Price Comparisons and Potential Cost Savings, September 2011
- New Drug Pipeline Monitor, July 2011

Thank you.

Merci.

michelle.boudreau@pmprb-cepmb.gc.ca