Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada's Patented Medicine Prices Review Board

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Webinar

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Canada

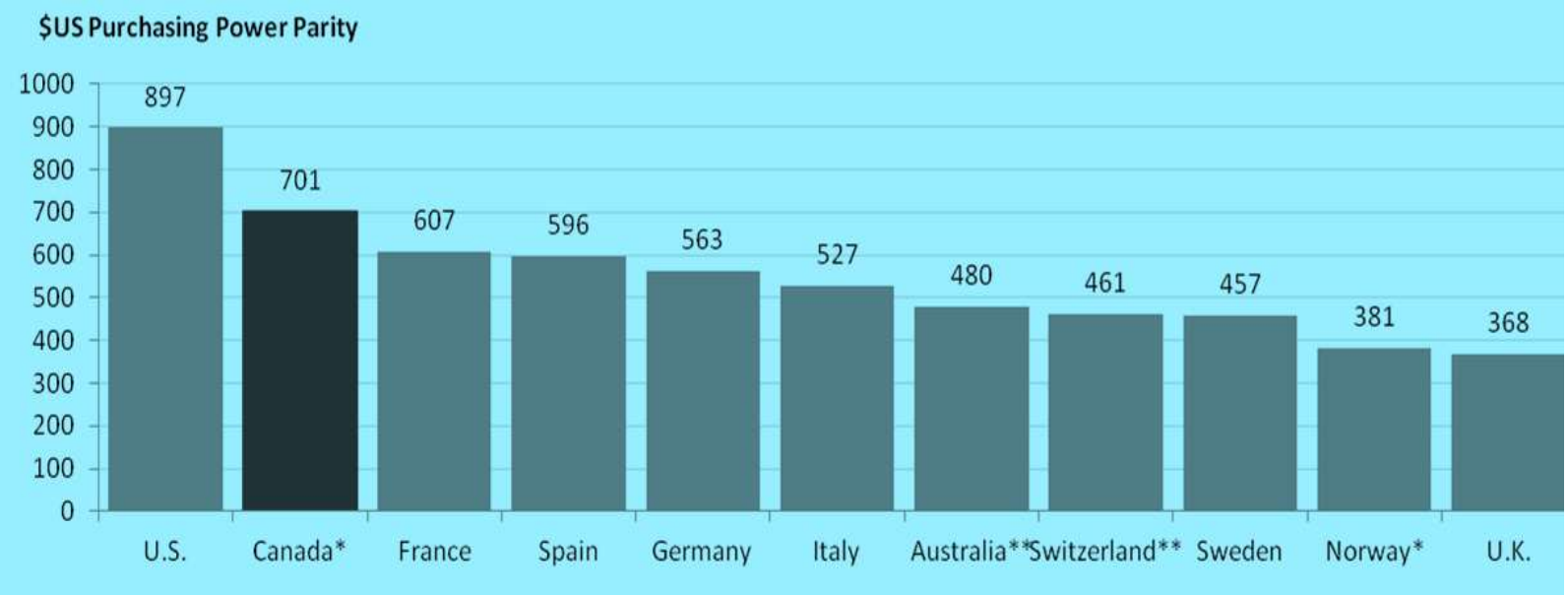
Overview

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

Pharma Market in Canada

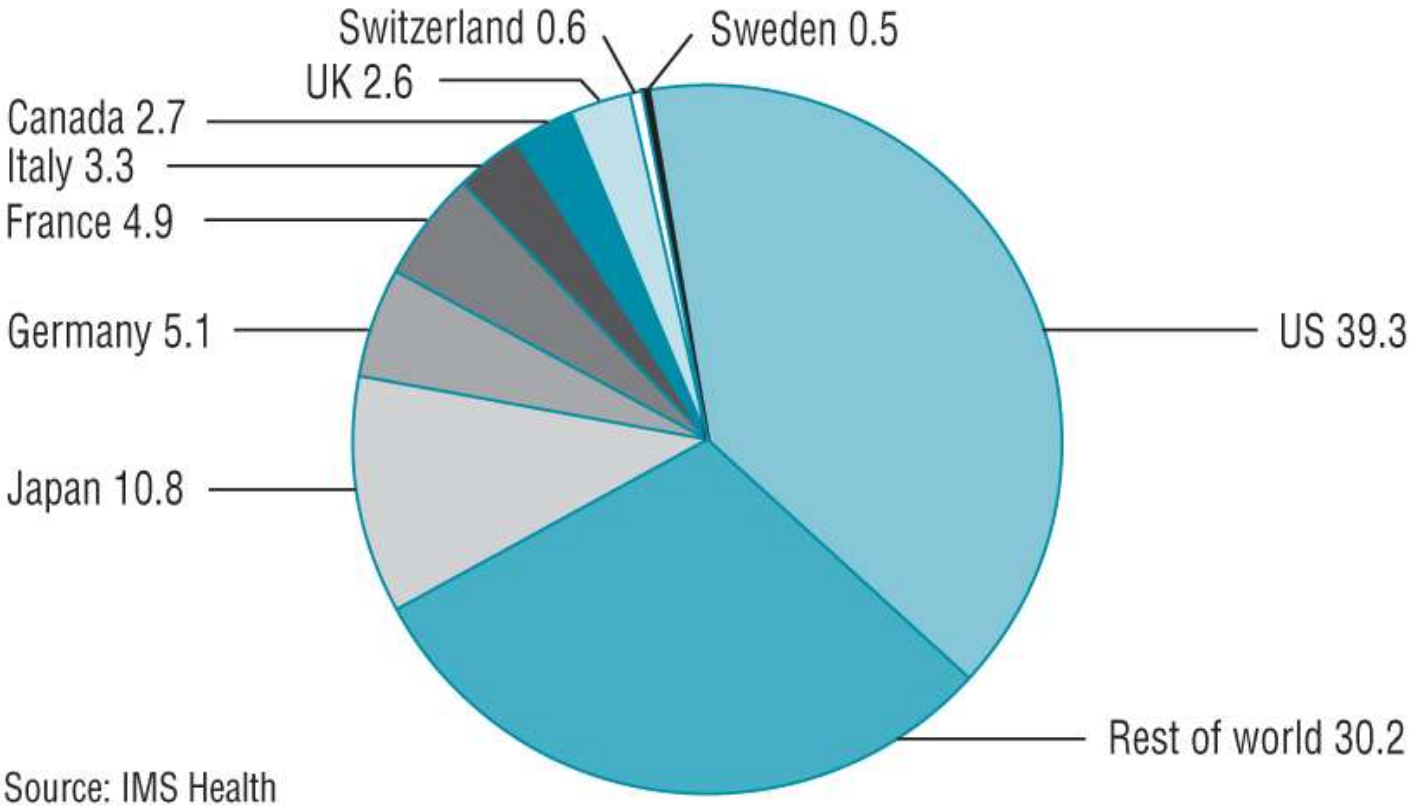
International Comparison

Total Pharmaceutical Expenditure Per Capita



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

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



Source: IMS Health

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

Canadian Context: Responsibilities

Federal Government

- Establishes national principles of healthcare (e.g., *Canada Health Act*)
- Transfers payments to provinces and territories
- Direct health care services for certain populations (e.g., First Nations)

Provincial Governments

- Deliver and fund physician and hospital services
- Administer provincial health insurance plans

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 (CADTH)

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 research and development (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 of Canada
    - 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

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

Price Regulatory Framework

Patent Act

- Sets out factors to be considered by Board:
  1) Price of medicine sold in Canada
  2) Prices of other medicines in the same therapeutic class sold in Canada
  3) Prices of medicines sold in comparator countries
  4) Changes in CPI

Patented Medicines Regulations

- Require patentees to file price and sales information for each class of customer in each province/territory
- Identify 7 comparator countries:
  France, Germany, Italy, Sweden, Switzerland, United Kingdom, United States

Guidelines

- Provide transparency and predictability for patentees in price review process
- Not binding on Board or patentee in a hearing

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

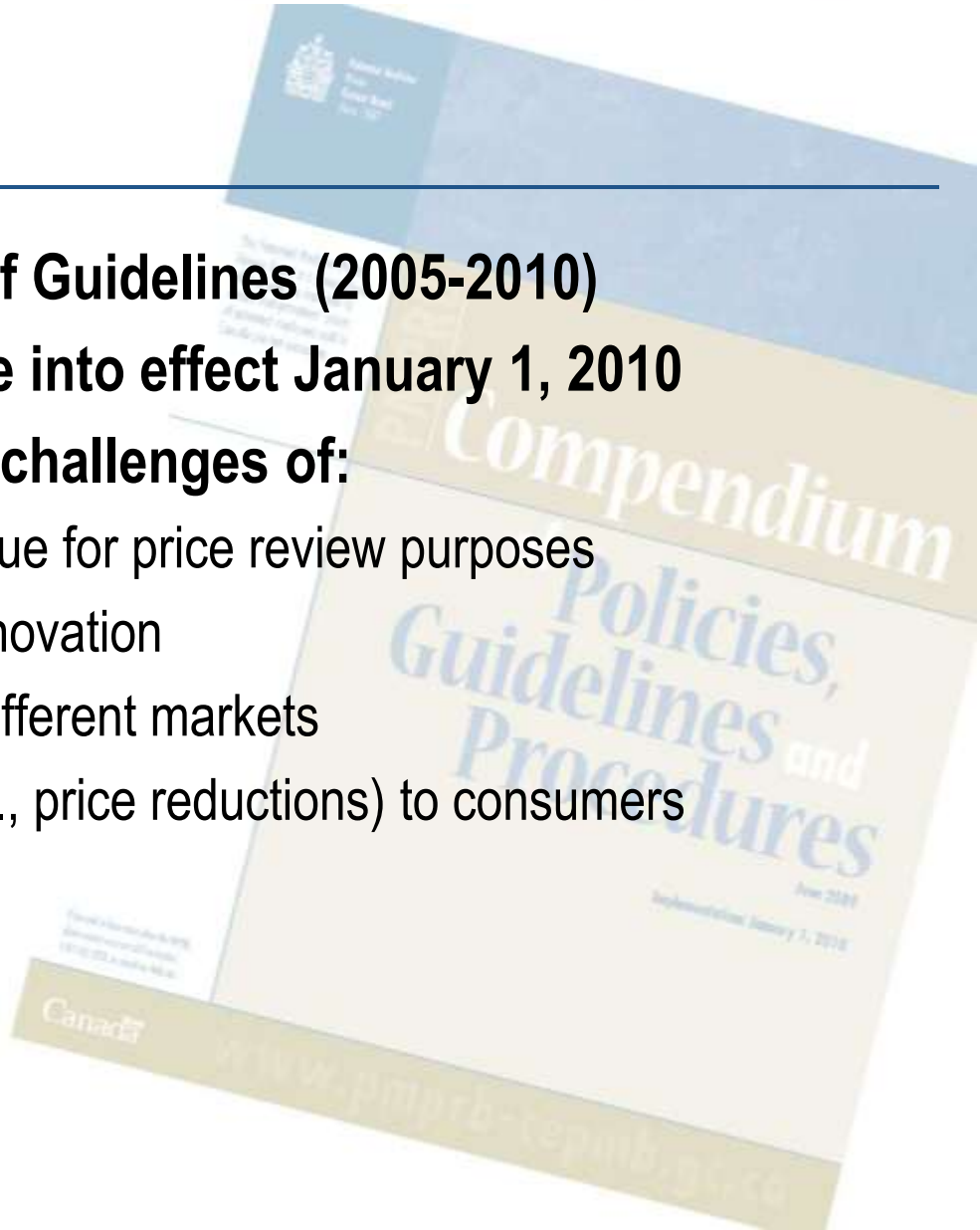
- **Factors to be considered by Board:**
  - Price of medicine sold in Canada
  - Prices of other medicines in same therapeutic class sold in Canada
  - Prices of medicines sold in comparator countries
  - Changes in CPI
- **Reference based**
  - 7 comparator countries: France, Germany, Italy, Sweden,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

- **Comprehensive review of Guidelines (2005-2010)**
- **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 Human Drug Advisory Panel (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 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

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* (Notice of Compliance)*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

Thank you.

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