Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

Canada's Patented Medicine Prices Review Board

25 Years of Experience

Michelle Boudreau

Executive Director

Pharma Pricing and Market Access Outlook

London, United Kingdom

March 21, 2012

Outline

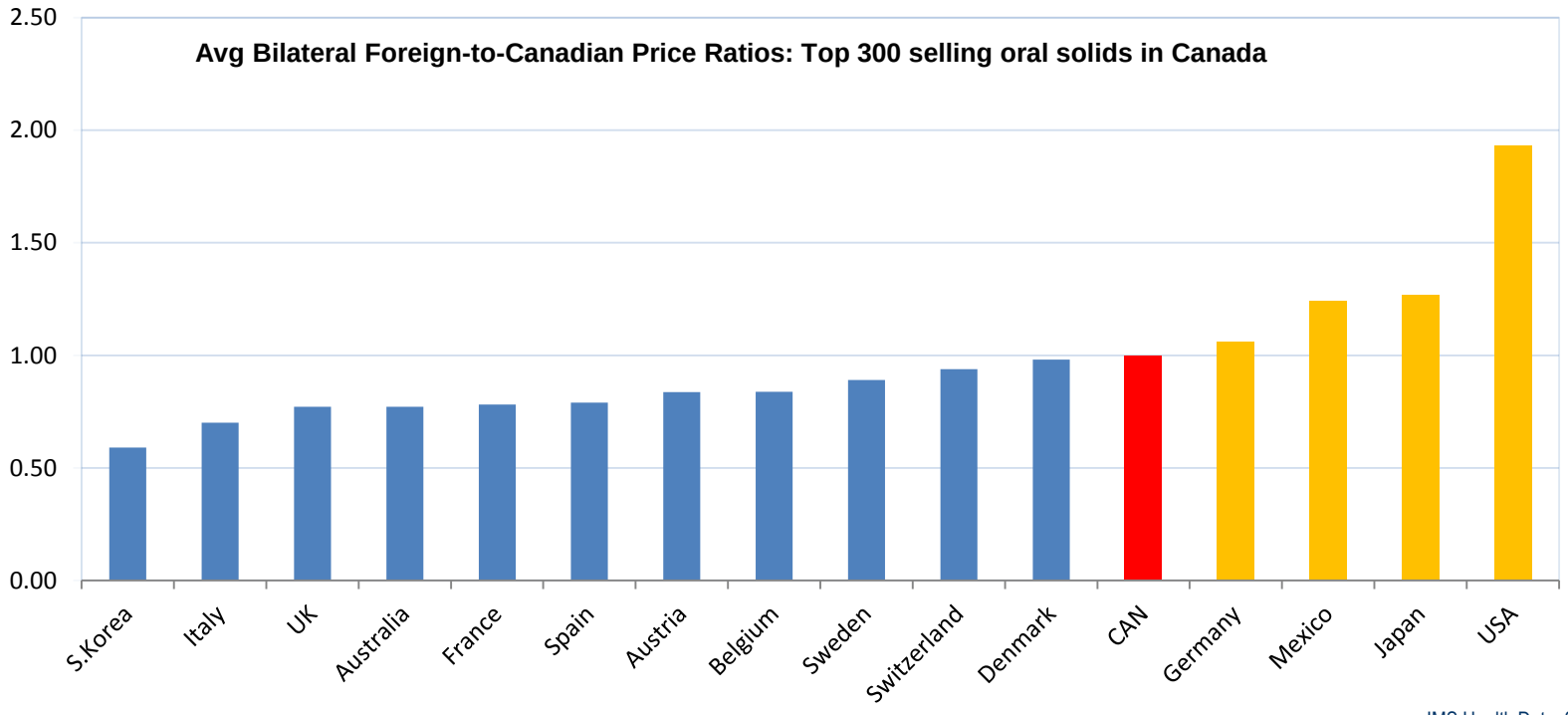
- Overview of the PMPRB
- Canada Compared to the World
- Decisions of Interest
- Strengths and Challenges of the Canadian Price Regulatory System
- Common Challenges
- Regulator and Regulatee Relationship
- Looking Forward

Overview of the PMPRB

- **Established in 1987 as consumer protection pillar via amendments to *Patent Act***
- **The PMPRB is an independent quasi-judicial body with a dual mandate:**
  - ***Regulatory*: To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive**
  - ***Reporting*: To report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees**
- **Jurisdiction**
  - Regulate prices patentees charge (i.e., factory-gate price) for patented drug products sold in Canada, to wholesalers, hospitals or pharmacies, for human and veterinary use

Canada Compared to the World

- **Canadian prices comparatively higher than a number of OECD countries**

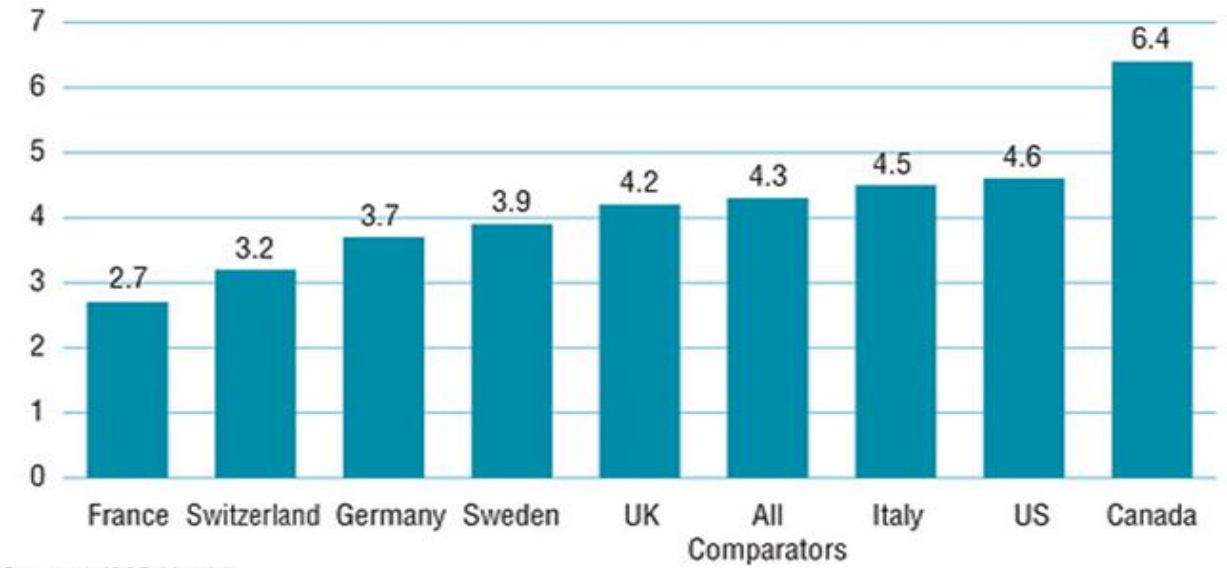


IMS Health Data, 2010

Canada Compared to the World (cont'd)

- **Growth in drug sales outpacing comparator countries**

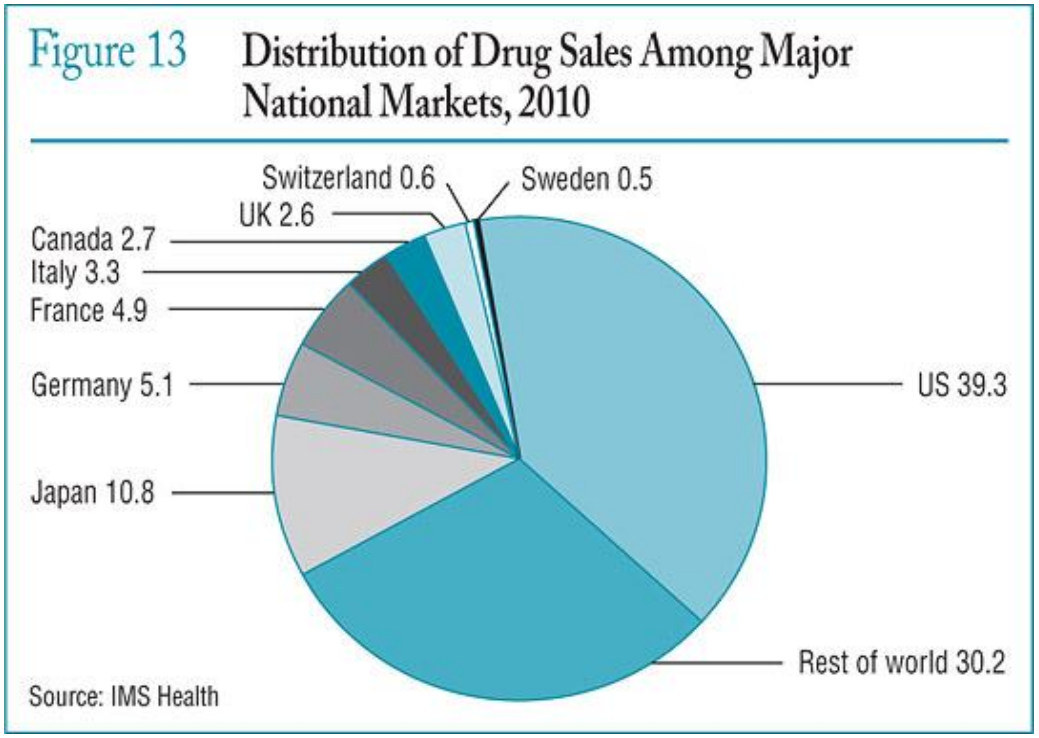
Figure 15 Average Rate of Growth, Drug Sales, at Constant 2010 Market Exchange Rates by Country, 2005–2010



Source: IMS Health

Canada Compared to the World (cont'd)

- In 2005 and 2010, Canadian drug sales accounted for 2.4% and 2.7%, respectively, of the global market



- Small, but a growing market

Canada Compared to the World (cont'd)

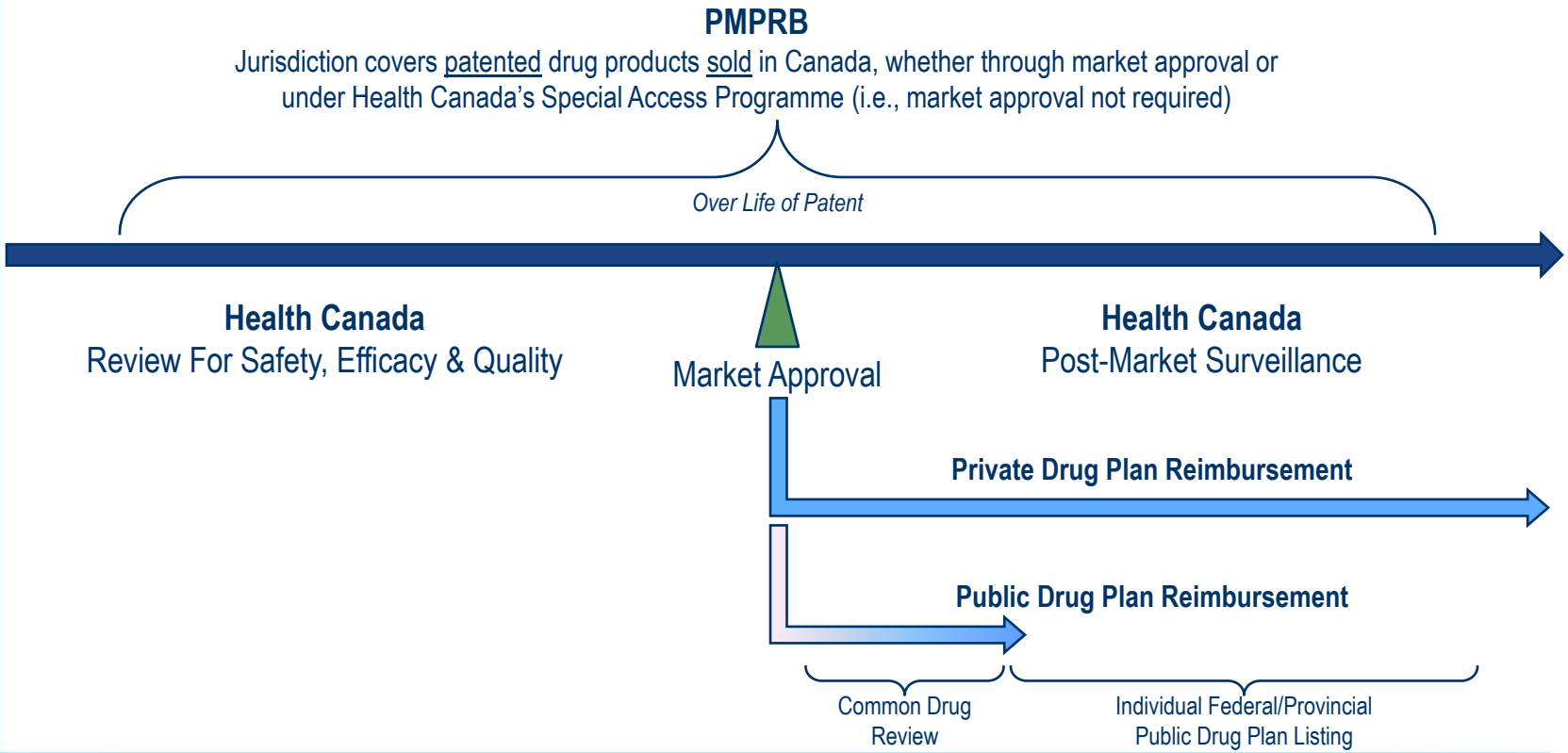
- **Reference pricing at introduction and for existing drugs based on 7 comparator countries – France, Germany, Italy, Sweden, Switzerland, UK, and USA**
  - Policy changes in these countries impact prices in Canada
- **Recently, Germany cited most often as pivotal introductory price**
  - Cost containment measures in Germany likely to lead to lower introductory prices in Canada
  - Between 2008 to 2010, prices in Germany were the pivotal introductory price 25%, 58%, 60% of the times, respectively, by way of the Highest International Price Comparison test

Decisions of Interest

Matter	Issue	Court Proceedings
ratio-Salbutamol HFA, Teva Canada (formerly ratiopharm Inc.)	▪ Jurisdictional issue: Whether the Board has the authority to regulate prices of 'patented generics'	Issue before the Federal Court of Canada
Celgene Corporation, and the patented medicine Thalomid	▪ Jurisdictional issue: Does the Board have the authority to regulate the prices of patented drugs sold to Canadians pursuant to Health Canada's Special Access Programme (SAP)	▪ Supreme Court of Canada confirmed: -the Board's authority to regulate prices of patented drugs available under SAP - the purpose of the legislation to protect consumers from excessive pricing of patented medicines sold in Canada

Strengths and Challenges of the Canadian Price Regulatory System

1) Pharmaceutical Regulation in Canada is a shared responsibility



Strengths and Challenges of the Canadian Price Regulatory System (cont'd)

2) High level of compliance

- On average, 93-95% overall compliance

2010	New drug products	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**

Strengths and Challenges of the Canadian Price Regulatory System (cont'd)

3) **New levels of therapeutic improvements and associated price tests better recognize and reward innovation**
   - Scientific review process establishes 4 levels of therapeutic improvement
   - Reference domestic and foreign ex-factory market prices to reward innovation

4) **PMPRB establishes the price ceiling, not the selling price of patented drug products**
   - Patentees have flexibility to set price up to price ceiling
   - No jurisdiction over:
     - Non-patented drug products
     - Prices beyond the factory-gate prices

Strengths and Challenges of the Canadian Price Regulatory System (cont'd)

5) Current Guidelines

- Ongoing consultations and dialogue with key stakeholders (e.g., P/Ts, private payers, patentees) to ensure currency and effectiveness

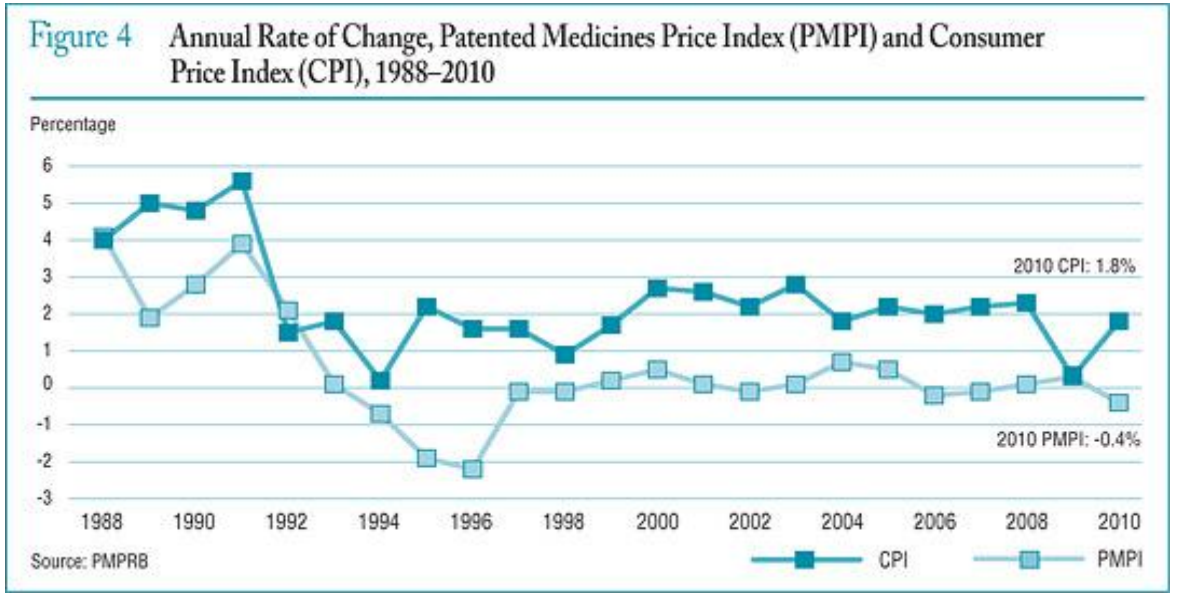
6) Canada: A federation of 13 Provinces and Territories

- P/Ts privately and independently negotiate product listing agreements for public plans
  - Some provinces have stronger negotiation powers
    - Inconsistent access to certain drug products across the country
    - Tradeoffs between transparency and confidentiality
- Reimbursement of drug products via private, P/T, or federal plans
  - Most Canadians insured by 3rd party payers

Strengths and Challenges of the Canadian Price Regulatory System (cont'd)

7) Price ceiling set at introduction

- Subsequently, growth of Average Transaction Price (ATP) limited to changes in CPI



- No price test subsequent to introduction
  - No mechanism to re-bench based on new science

Common Challenges

- **Similar challenges to other jurisdictions regarding transparency of drug pricing**
- **Next wave of new drugs (e.g., biologics) expected to be costly**
- **Defining therapeutic value and innovation and how to assess vis-à-vis sustainable pricing policies for payers?**
- **Networking with foreign regulators**
  - Information sharing
  - Learning from shared experiences
  - Dealing with global pricing strategies

Regulator and Regulatee Relationship

- **PMPRB Regulatory Framework not as daunting as it may appear:**
  - Regular meetings and open dialogue with patentees (e.g., advisory assistance on pricing)
- **Success stories:**
  - Co-operative dialogue with Rx&D, Industry Canada, and Canadian Institute for Health Research (CIHR) on R&D spending and definition
  - Engaging with Canadian Generic Pharmaceutical Association (CGPA) to discuss regulatory options for generics
  - Annual outreach sessions
  - Board members' engagement with stakeholders on Guidelines and other issues

Looking Forward

- **Canadian-EU Comprehensive Trade Agreement (CETA)**
  - If proposal implemented, longer period of PMPRB regulation over patented drugs; but could also cause a re-evaluation of the balance between intellectual/industrial policies and health care/drug costs
- **Ongoing engagement and outreach with stakeholders**
- **Board adopted two priorities:**
  - alternate dispute resolution (ADR) to further enhance compliance
  - reducing regulatory burden
- **Continued engagement with international organizations**

Thank you.

Merci.

michelle.boudreau@pmprb-cepmb.gc.ca

PMPRB Website: www.pmprb-cepmb.gc.ca

Follow us on twitter @PMPRB_CEPMB