Refocus PMPRB “Back to the Future”: Part One.

ALL-STAR Line-Up Past and Present Answering Your Questions to Help Shape Future for PMPRB

August 19, 2021

1:00 pm - 2:00 pm

CORD Canadian Organization for Rare Disorders

History of PMPRB

The PMPRB was created by Parliament in 1987 under the *Patent Act* with two roles: (1) regulatory – to ensure prices for patented medicines sold in Canada are not excessive, and (2) reporting – on pharmaceutical trends and R&D spending by pharmaceutical patentees to inform policy making.

1. Amendments to Patent Act 1987

- intellectual property;
- industrial benefits;
- Canada's multilateral relations;
- consumer protection; and
- health care

2. Bill C-22 1987

- extended the "period of patent protection before compulsory licensing could be possible
- established Patented Medicine Prices Review Board.
- The board determines a maximum price for individual drugs through a review process, and negotiates "voluntary compliance agreements" with drug companies to ensure that "manufacturer prices are within justification, and [are] not excessive"
- Reporting on pharmaceutical R&D investment

3. PMPRB Factors for determining non-excessive pricing

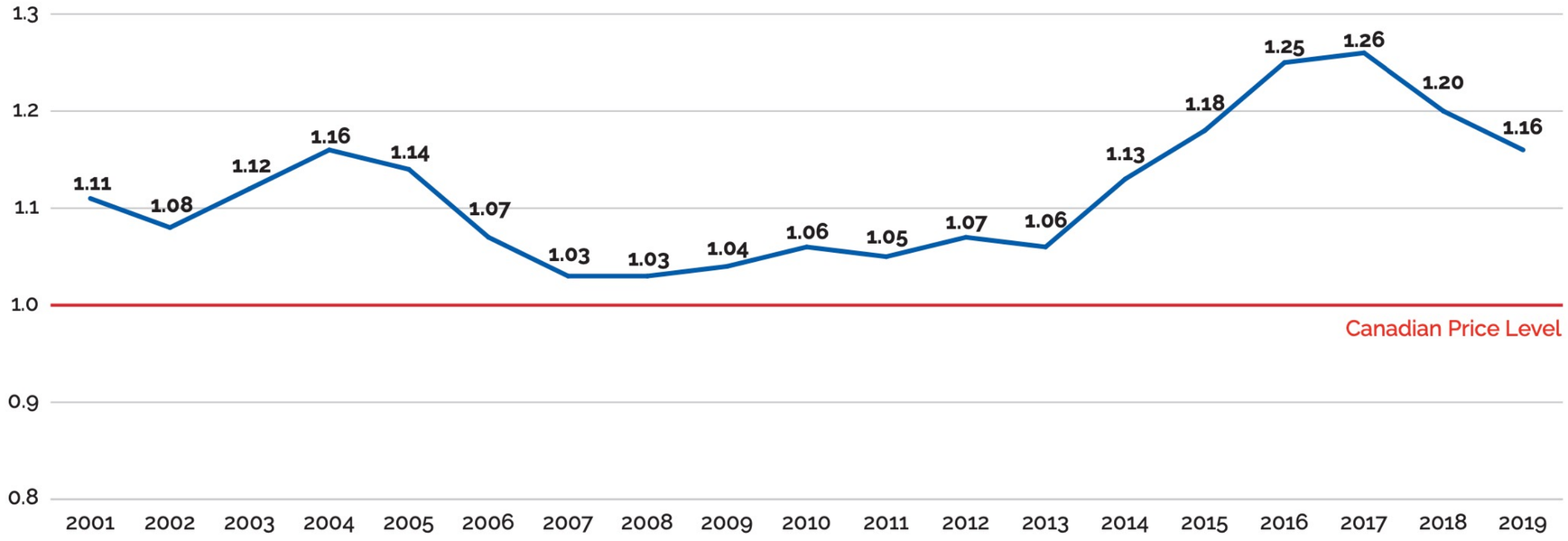
- the prices at which the medicine has been sold in the relevant market;
- the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- changes in the Consumer Price Index; and,
- such other factors as may be specified in any regulations made for the purposes of subsection 85(1) of the Act.

4. PMPRB Role: Report on R&D and protection against excessive drug prices

- 1988 – 2003
  - Compared internationally, Canadian prices on average fell from being 23% above the median price of the seven comparator countries in 1987 to below the median in 1994.
  - Amendments in 1993, combined with the CPI adjustment: Since 1994, with the exception of 2002, prices in Canada have remained below the international median and in line with policy objectives.

5. 1997: working well to keep PPI below CPI

FIGURE 27 Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001 to 2019



Source: PMPRB Annual Report 2019

6. 2012: Mixed achievements

- Prices not excessive compared to international
- BUT Little control over R&D information
- Environmental changes past 3-5 years
  - End of the era of “blockbuster” drugs, and the emergence of lower-cost generics introduced when patents on blockbusters expire*
  - Emergence of (often very costly) drugs/treatments for niche markets*
  - Burgeoning drug costs and assertive drug plan efforts to control those costs;
  - Increased globalization; and
  - Changes in the pharmaceutical industry, which include reduced price transparency as a result of post-purchase rebates (pCPA and private payer negotiation teams)

“Patented medicines are a small fraction (6.5% in 2019) of national health expenditure, even at manufacturer ‘list’ prices. Net of rebates negotiated between manufacturers and public, and private payers, expenditure on patented medicines would be even smaller. Ontario's Auditor General reported that the province’s public drug plan received rebates averaging 36% off list prices.”

Patented Medicines Expenditure in Canada 1990-2019, Canadian Health Policy Institute, June 2021

7. 2017: Scoping paper for New Guidelines to Implement Regulatory Reforms

- a mechanism for estimate of potential non-excessive prices and potential excessive prices; national ceiling price above unreasonable for any consumer in Canada to pay, not an ideal price for each payer based on their individual ability and willingness to pay.
- 1st test: Median of international basket
- 2nd test part 1: priority based on therapeutic value, unmet need, prevalence
- High priority
- QALY: ICER and marginal Cost utility
- Willingness to pay based on life gain, significant QALY
- 2nd test part 2: affordability to payer defined as market size relative to GDP growth
- Patentee: set ceiling pricing with support of pricing on confidential commercial information including
    - Ceiling price based on comparator country prices made public and
    - Ceiling price based on non-transparent discounts and rebates kept confidential
    - Medium and low priority: alternatives available
    - Median of international countries
    - Therapeutic class comparison

8. Re-benching existing medicines on price ceilings

- Change in market size
- Change in market conditions

9. 2019-2021: Guidelines for Implementation of Regulatory Changes

- Draft Guidelines presented December 2019 for consultation
- Revised Comparator countries from seven to new 11 (maximum list price)
- Application of economic factors to set ceiling net prices (negotiated including discounts and rebates) for high, medium, and low priority drugs
- Final Guidelines released October 2020 for implementation January 2021
- Revised Guidelines implementation delayed three times, shifting from July 1, 2020 to January 1, 2022
- Change to Gap and Grandfathered medicines released July 15, 2021 for consultation, deadline extended to August 2021;
    - Change from highest to median international pricing for grandfathered drugs
- February 2021 PMPRB Communications Plan (see Prof. Donald Savoie’s memo on Duty of Neutrality)

10. Relevant legal actions

- 2011: Supreme Court of Canada supports PMPRB jurisdiction over pricing of drugs sold under SAP and from outside Canada
- June 2020: Federal Court of Canada ruled choice of comparator countries and application of economic factors within PMPRB authority BUT reporting of rebates (net prices) beyond scope of authority (Ruling now in appeal)
- December 2020: Quebec Court upholds constitutionality of PMPRB, including replacing comparator countries and introducing economic factors to determine “excessive” drug prices BUT reporting of rebates beyond scope (Ruling now in appeal)
- July 29, 2021: Federal Court of Appeal quashed “excessive price” decision of PMPRB against Alexion (re: Soliris) citing decision was “unreasonable” and, importantly, Board went beyond its permissible statutory mandate:

> *Over and over again, authorities have stressed that the excessive pricing provisions in the Patent Act are directed at controlling patent abuse, not reasonable pricing, price-regulation or consumer protection at large.*
>
> Stratas JA, for the Federal Court of Appeal in *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157 (rev’g 2019 FC 734), at para. 49

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Panelists

- Guillaume Couillard, PMPRB Director 2014-Present
- Wayne Critchley, Global Public Affairs and Executive Director PMPRB 1990-2005
- Neil Palmer, Principal, WN Palmer & Co and PMPRB Compliance & Enforcement 1998-94
- Sheila Frame, President Americas, Amryt Pharma
- Declan Hamill, VP Policy, Regulatory, and Legal Affairs, Innovative Medicines Canada
- Nicolas Rouleau, Nicolas M. Rouleau, Société Professionelle
- Durhane Wong-Rieger, Canadian Organization for Rare Disorders

Moderator

· Bill Dempster, 3Sixty Public Affairs

Refocus PMPRB “Back to the Future”: Part two…

Stand by for another webinar on this fast-moving issue!

Today’s slides available on CORD’s SlideShare page (https://www.slideshare.net/raredisorders)

Today’s webinar will be posted to CORD’s YouTube channel https://www.youtube.com/user/CORDRareDisorders)

Canadian Organization for Rare Disorders