The PMPRB in Brief

VCUs accepted: 90
Hearings held: 26 Notices of Hearing issued; 11 resolved by way of VCU
Excess revenues offset: $123M in VCUs and Board Orders
Number of staff: From 22 to 76
Budget: From $2.8M to $11.8M
Patented medicines: Average of 70 patents per year and 1,200 patented medicines
Analyses, reports and studies: Over 100 – an regulatory activities, pharmaceutical trends of all medicines, generic, non-patented and patented drugs, R&D, etc.

Previous Board Executives
Professor Harry C. Eastman, Chair and CEO, 1987
Dr. Robert Goyer, Vice-Chair, 1989
Dr. Robert G. Elgie, Chair and CEO, 1995
Mr. Réal Sureau, Vice-Chair, 2001
Dr. Brian G. Benoit, Chair and CEO, 2005
Mary Catherine Lindberg, Vice-Chair, 2008

Current Board
Mary Catherine Lindberg, Chair and CEO, 2011
Dr. Mitchell Levine, Vice-Chair, 2012
Normand Tremblay, Vice-Chair, 2013

Executive Directors
Ray Atkinson, 1987
Wayne Crichley, 1991
Barbara Duellet, 2005
Michelle Boudreau, 2010

1986 The Honourable Harvey Andre, Minister of Consumer and Corporate Affairs, tables Bill C-22, an Act to amend the Patent Act and to create the Patented Medicine Prices Review Board.

Since 1987...

December 7, 1987: The Patented Medicine Prices Review Board is created
- The PMPRB is established to ensure that prices of which patentees sell their patented medicines in Canada are not excessive and to report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patent-holders.

1988: Setting the stage
- Consultation on the Compliance Policy and the Guidelines on Excessive Price is initiated.
- The first issue of the PMPRB Bulletin is published.
- The Patented Medicines Regulations are promulgated.

1989–1991: Ironing out the details
Consultation with stakeholders into key issues continues:
- Calculation of the CPI-Adjusted Price
- Supplementary Guidelines – price review jurisdiction, unit of price review
- Method of determining excessive price
- Therapeutic Class Comparison
- International Price Comparison
- Comparable Dosage Forms
- PMPRB Anatomical Therapeutic Chemical Classification System; Reward for Modest Improvement; Reasonable Responsibility; Breakthrough and Substantial Improvement

1992: Getting down to business
- The review of the Patented Medicines Regulations is initiated.
- The Board issues its first Notice of Hearing in the matter of Genetech Canada Inc. and Genetech Inc., and the medicine Actovin.

1993: Increasing the scope
- The Compliance and Enforcement Policy is implemented.
- The Board holds its first Policy Forum on the Board’s Excessive Price Guidelines.
- Bill C-91, an Act to Amend the Patent Act comes into force on February 15, increasing the PMPRB’s powers and eliminating compulsory licensing for pharmaceuticals, among other things.
- The Chair of the Board approves the first VCU.

1994: Getting it right
- Amendments are made to the Excessive Price Guidelines and the Patented Medicines Regulations.
- The Chair participates in several conferences, and the PMPRB releases studies and discussion papers on cost savings.

1995–1996: Improving the process
- The Board issues its policy on Patent Dedication.
- The Board issues a Notice of Hearing in the matter of ICan Canada Ltd., ICan Pharmaceuticals Inc. and the medicine Vinclozole. In this case, the Federal Court of Appeal held that the Board has jurisdiction to review prices of medicines, even when the review is to a patent is one of the “narrower slimmer threats.”
- Improvements to the price review process are initiated: six-month pricing cycles being examined as well as the simplification of procedures for greater transparency and efficiency of processes.

1997: Making the grade
- The Standing Committee on Industry conducts public hearings on its review of Bill C-91. The Government’s response to the Committee’s Report noted the concerns of Canadians about drug costs and their impact on the health care system. Among other things, the Government acknowledged the need to strengthen the PMPRB and to work with provincial and territorial authorities to examine broadening its mandate to include non-patented drugs. Ministers also agreed to work with the PMPRB to review the mechanisms for regulating the prices of patented drugs and to improve the transparency of the price review process.

1998: Looking to the future
- The PMPRB releases its Road Map for the Next Decade following an in-depth review and pan-Canadian consultation on its role, function and methods.
- The Auditor General tables its report on the PMPRB. Among other things, the AG found that: “...the PMPRB has exerted a constraining influence on the prices of patented medicines sold in Canada...”

1999–2001: Continuous improvement
- The Working Group on Price Review Issues is established to examine the transparency of the price review process, including the international price comparisons and category 3 drug products review.
- The use of U.S. FSS prices is implemented in International Price Comparisons.
- A consultation paper on transparency in the price review process is released.
- The National Prescription Drug Utilization Information System (NPDUS) is established by the federal-provincial-territorial ministers of Health.

2002: Sharing the knowledge
- The Board holds an international symposium on drug prices in Ottawa.
- The NPDUS Steering Committee is established.

- Price increases are being reported, leading to inquiries on the application of the Excessive Price Guidelines and the “in any market in Canada” issue.
- The Board implements a complaint-driven approach for the regulation of patented drug prices for veterinary use.

2005–2010: Overhauling the price review process
- The Board embarks on an in-depth review of the Excessive Price Guidelines and comprehensive consultations with all stakeholders, resulting in the implementation of new Guidelines on January 1, 2010.
- Treasury Board approves the PMPRB’s request for additional funds, namely to complete the Excessive Price Guidelines review and implement, monitor and evaluate changes, hold hearings, as required by statute, update its mission critical database, and meet associated increases in administrative workload.
- The Patented Medicines Regulations are further amended.
- During this period the Board issues an unprecedented number of Notices of Hearing; its decisions are challenged in the Federal Court and jurisdiction is established.
- The Regulatory Affairs and Outreach Branch initiates outreach sessions for patients, further enabling discussions with the regulated industry.

2011–2012: Continuum
- The Supreme Court of Canada hands down its decision in the Cilag Corporation matter (Thalidomide), dismissing the appeal, confirming the Board’s jurisdiction over the price of the medicine, and recognizing that the purpose of the Board’s legislative mandate is the protection of consumers, among other things.
- The complaints process on prices of patented medicines sold in Canada is formalized to assist consumers.
- The PMPRB gains social media @PMPRB_CEPMB.
- The Guidelines are further clarified to assist patentees in their compliance activities.
- The Board’s Rules of Practice and Procedure for Hearings are promulgated.

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