Evaluation of the PMPRB regulatory performance on price review for new patented drugs in Canada, 2008-2021

Description

Evaluation of the PMPRB regulatory performance on price review for new patented drugs in Canada, 2008-2021

Nigel SB Rawson, PhD* and Brett J Skinner, PhD**

ABSTRACT

The Patented Medicine Prices Review Board (PMPRB) is the federal tribunal with a mandate to prevent “excessive” pricing of patented drugs. In 2015, the PMPRB initiated a strategic planning process, which proposed legislative changes that would strengthen its powers and broaden its mandate. In August 2019, the Government of Canada announced the implementation of the regulatory amendments. The pharmaceutical industry launched legal challenges in the Quebec and Federal Courts, which resulted in rulings that invalidated major provisions of the regulations, and the federal Health Minister withdrew the provisions in April 2022. During the 2015-2022 period, the PMPRB was engaged in public consultations, as well as media communications and policy advocacy to build support for the regulatory changes. This analysis assesses the regulatory performance of the PMPRB regarding the price review process for new patented drugs in Canada over the 14 years from 2008 to 2021 to determine whether there was any impact associated with the post-2015 period of consultation and advocacy by observing differences before (2008–2014) and after (2015-2021). We compared the number of new patented drugs and their distribution by price review status. We also examined the PMPRB budget and staffing levels over the same period. The Board does not publish the dates when new drugs were reported and assessed. Alternative data were obtained from the list of New Patented Medicines Reported to the PMPRB. We collapsed the six categories that the PMPRB publishes for the price review status of new patented drugs into three groups: compliant with the price guidelines, subject to investigation, or under review. We observed a post-2015 decline in the percentage of new patented drugs that were compliant with the price guidelines, and a corresponding increase in the percentage that were subject to investigation or under review. The number of new patented drugs reported to the PMPRB was virtually the same in the seven years before and after the release of the Board’s strategic plan in 2015. We also observed a post-2015 increase in the PMPRB budget and staffing. We speculate that the PMPRB: (1) redirected its resources away from its price review responsibilities to activities that supported the consultation process and its policy advocacy goals; and (2) surreptitiously changed its interpretation and application of the threshold for triggering an investigation.

Acknowledgements: n/a

Author(s) affiliations: * Affiliated scholar, Canadian Health Policy Institute (CHPI); ** Founder and CEO, CHPI, Editor, CHPJ.

Correspondence: Rawson – eastlakerg@gmail.com; Skinner – brett.skinner@canadianhealthpolicy.com

.

Cite: Rawson, Nigel SB; and Skinner, Brett J (2023). Evaluation of the PMPRB regulatory performance on price review for new patented drugs in Canada, 2008-2021. *Canadian Health Policy*, MAY 2023. https://doi.org/10.54194/LLAJ7141. canadianhealthpolicy.com.

Disclosure: Dr Skinner is chair of CHPI's Canadian Access to Innovative Medicines (CA2IM) research program, sponsored in part by sales of corporate subscriptions to pharmaceutical companies.

Journal: ISSN 2562-9492 | DOI https://doi.org/10.54194/XYCP5241

Key Words: Canada, pharmaceutical, innovation, health, patented drugs, regulation

Open access sponsor: CHPI's CA2IM Research Program.

Publisher: Canadian Health Policy Institute Inc. www.chpi.ca

Status: Peer reviewed.

Submitted: 28 APR 2023. Published: 10 MAY 2023.