

## Fewer new drug approvals in Canada: early indication of unintended consequences from new PMPRB regs?

### Description

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*Canadian Health Policy*, March 2020. ISSN 2562-9492

### Abstract

In July 2020 the Canadian federal government plans to introduce sweeping changes to the price review guidelines of the Patented Medicine Prices Review Board, the agency whose role is to set ceiling prices for patented medicines sold in Canada. The changes were first proposed by the government in 2016, with new regulations released in 2018 followed by the publication of guidelines in 2019. This has led to much concern among the pharmaceutical industry, patients, health care providers, researchers and many others. The objective of this analysis is to investigate whether the development and introduction of the new regulations and guidelines are associated with changes in the pattern of new drugs being approved in Canada between 2013 and 2019. Although reasonable consistency existed across the years and between jurisdictions in the median review times and inter-quartile ranges, the percentage of new drugs approved in Canada before or within a year after approval in the United States decreased substantially from an average between 2013 and 2016 of 55.4% to 15.6% in 2019. The decrease was even greater for new cancer medications and was substantial for new drugs for rare disorders, although small numbers make the pattern less obvious. In contrast, the percentage of new drugs approved in Canada before or within a year after approval in Europe remained stable. The results suggest that the pharmaceutical industry has taken note of the impending changes and begun to view Canada as a less attractive market when compared with the United States.

### References

1. George CF. Atlantic crossing and drug lag. *BMJ* 1980;281:507-8.
2. Rawson NSB. The timeliness of new drug approvals in Canada. *Int J Health Serv* 1995;25:153-65.
3. Rawson NSB. Time required for approval of new drugs in Canada, Australia, Sweden, the United Kingdom and the United States in 1996-1998. *CMAJ* 2000;162:501-4.
4. Rawson NSB. Human resources for the approval of new drugs in Canada, Australia, Sweden, the United Kingdom and the United States. *Can J Clin Pharmacol* 2002;9:73-8.
5. Rawson NSB. Timeliness of review and approval of new drugs in Canada from 1999 through 2001:

is progress being made? Clin Ther 2003;25:1230-47.

6. Rawson NSB. Canadian, European and United States new drug approval times now relatively similar. Regul Toxicol Pharmacol 2018;96:121-6.

7. Ascending the peak of pharmaceutical innovation. Biopharmaceutical competitiveness and investment (BCI) survey, 4th edition. Washington, DC: Pugatch Consilium, 2017. [http://www.pugatch-consilium.com/reports/BCI\\_2017\\_Report.pdf](http://www.pugatch-consilium.com/reports/BCI_2017_Report.pdf).

8. Rawson NSB, Lawrence D. New patented medicine regulations in Canada: updated case study of a manufacturer's decision-making about a regulatory submission for a rare disorder treatment. Can Health Policy. Toronto: Canadian Health Policy Institute, January 2020. <https://fko.wzo.mybluehost.me/products/new-patented-medicine-regulations-in-canada—updated-case-study—en-fr-.html>.

9. Impact of PMPRB pricing changes: final research report. Toronto: Life Sciences Ontario, February 2, 2020. <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>.

10. Drug products. Ottawa: Government of Canada, 2019. <https://www.canada.ca/en/health-canada/services/drugs-health-products/reportspublications/drug-products.html>.

11. Notice of Compliance (NOC) database. Ottawa: Health Canada, 2017. <https://www.canada.ca/en/health-canada/services/drugs-healthproducts/drug-products/notice-compliance/database.html>.

12. Summary Basis of Decision (SBD). Ottawa: Health Canada, 2018. <https://www.canada.ca/en/health-canada/services/drugs-healthproducts/drug-products/summary-basis-decision.html>.

13. New drugs at FDA: CDER's new molecular entities and new therapeutic biological products. Silver Spring, MD: US Food and Drug Administration, 2020. <https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-andnew-therapeutic-biological-products>.

14. Drugs@FDA. Silver Spring, MD: US Food and Drug Administration, 2020. <https://www.accessdata.fda.gov/scripts/cder/daf/>.

15. Medicines. Amsterdam: European Medicines Agency, 2020. <https://www.ema.europa.eu/en/medicines>.

16. Downing NS, Aminawung JA, Shah ND, Braunstein JB, Krumholz HM, Ross JS. Regulatory review of novel therapeutics – comparison of three regulatory agencies. NEJM 2012;366:2284-93.

17. Shajarizadeh A, Hollis A. Delays in the submission of new drugs in Canada. CMAJ 2015;187:E47-51.

18. Authorization of medicines. Amsterdam: European Medicines Agency, 2020. <https://www.ema.europa.eu/en/about-us/what-wedo/authorisation-medicines>.

19. Rawson NSB. Canadian, European and United States new drug approval times now relatively similar. *Regul Toxicol Pharmacol* 2018;96:121-6.

20. Rawson NSB, Lawrence D. New patented medicine regulations in Canada: updated case study of a manufacturer's decision-making about a regulatory submission for a rare disorder treatment. *Can Health Policy*. Toronto: Canadian Health Policy Institute, January 2020. <https://fko.wzo.mybluehost.me/products/new-patented-medicine-regulations-in-canada—updated-case-study—en-fr-.html>.

21. Impact of PMPRB pricing changes: final research report. Toronto: Life Sciences Ontario, February 2, 2020. <https://lifesciencesontario.ca/wpcontent/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>.

22. Cooke A. 'Heartbreaking' death of cystic fibrosis patient shines light of drug access issues. Halifax: CBC, February 21, 2020. <https://www.cbc.ca/news/canada/nova-scotia/chantelle-lindsay-cystic-fibrosis-death-canada-drug-access-1.5471605>.