

Canada falls behind in new drug submissions compared with the United States and Europe

Description

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ABSTRACT

Canada has experienced much uncertainty about the federal government's intention to regulate lower ceiling prices for patented medicines during the past seven years. This study's objective was to examine how many medicines submitted to the US Food and Drug Administration (FDA) and/or the European Medicines Agency (EMA) between 2006 and 2020 were also submitted to Health Canada by the end of October 2022 and to compare trends before and during the proposed federal regulation changes. New medicine submissions to the FDA and/or the EMA between 2006 and 2020 were identified from publicly available data sources. The number submitted to Health Canada by October 31st, 2022 as a percentage of the number submitted to the FDA or the EMA, whichever came first, was calculated for each year of submission to the first agency (FDA or EMA). Over 80% of new medicines submitted to the first agency in each year between 2006 and 2014 were, on average, also submitted to Health Canada, but the percentage decreased to 44% for medicines submitted to the first agency in 2020. Similar trends occurred in oncology therapies and orphan status medicines. Canada's federal government continues with its intention to regulate reduced medicine prices. Adding any tougher price regulations to barriers that must already be overcome to bring medicines to Canadians will further delay or deny patient access. Canada's policy towards new medicines needs to change from obsessive cost-containment to reviving biopharmaceutical research and manufacturing and ensuring patient access.

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REFERENCES

1. Sibbald B. Election 2015: party platforms on health issues. *CMAJ* 2015;187:E487-92.
2. Remarks from the Honourable Jane Philpott, Minister of Health, to the Economic Club of Canada – May 16, 2017. Ottawa: Government of Canada, 2017. https://www.canada.ca/en/health-canada/news/2017/05/economic_club_ofcanada-may162017.html.
3. Patented Medicine Prices Review Board. Mandate and jurisdiction. Ottawa: Government of Canada, 2020. <http://pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction>.
4. Rawson NSB. New Patented Medicine Regulations in Canada: case study of a manufacturer's decision-making about regulatory submission for a rare disorder treatment. Toronto: Canadian Health Policy Institute, 2018. <https://fko.wzo.mybluehost.me/product/new-patented-medicine-regulations-in-canada-case-study-of-a-manufacturer-s-decision-making-2/>.
5. Rawson NSB, Adams J. Use COVID pause to reconsider drug-price regulation. *Financial Post*, 2021 Jan 18. <https://financialpost.com/opinion/opinion-use-covid-pause-to-reconsider-drug-price-regulation>.
6. Rawson N, Vanstone B. Politically-instituted barriers against innovative medicines have a human toll. Toronto: Canadian Health Policy Institute, 2021 Sep 9. <https://fko.wzo.mybluehost.me/opinions/politically-instituted-barriers-against-innovative-medicines-have-a-human-toll/>.
7. Impact of PMPRB pricing changes: final research report. Toronto: Research Etc., 2020 Feb 3. <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>.
8. New drugs at FDA: CDER's new molecular entities and new therapeutic biological products. Silver Spring, MD: US Food and Drug Administration, 2022. <https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products>.
9. Biological approvals by year. Silver Spring, MD: US Food and Drug Administration, 2022. <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year>.
10. Drugs@FDA: FDA-approved drugs. Silver Spring, MD: US Food and Drug Administration, 2022. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.
11. Annual reports and work programs. Amsterdam: European Medicines Agency, 2022. <https://www.ema.europa.eu/en/about-us/annual-reports-work-programmes>.
12. Authorization of medicines. Amsterdam: European Medicines Agency, 2022. <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines>.
13. Human regulatory: marketing authorization. Amsterdam: European Medicines Agency, 2022. <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation>.
14. Medicines for human use under evaluation. Amsterdam: European Medicines Agency, 2022. <https://www.ema.europa.eu/en/medicines/medicines-human-use-under-evaluation>.
15. Drug products: what information can you find here? Ottawa: Government of Canada, 2022. <https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/drug-products.html>.
16. Notice of Compliance search. Ottawa: Government of Canada, 2021. <https://health-products.canada.ca/noc-ac/index-eng.jsp>.
17. Drug and health product submissions under review (SUR): new drug submissions under review. Ottawa: Government of Canada, 2022. <https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review/new-drug-submissions-under-review.html>

18. Rawson NSB. Canadian, European and United States new drug approval times now relatively similar. *Regul Toxicol Pharmacol* 2018;96:121-6.
19. Paul D. Comparison of the drug approval processes in the US, the EU and Canada. *Int J Med Marketing* 2001;1:224-35.
20. Rawson NSB. The timeliness of new drug approvals in Canada. *Int J Health Serv* 1995;25:153-65.
21. Rawson NSB, Kaitin KI, Thomas KE, Perry G. Drug review in Canada: a comparison with Australia, Sweden, the United Kingdom and the United States. *Drug Inform J* 1998;32:1133-41.
22. 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.
23. Rawson NSB. Timeliness of review and approval of new drugs in Canada from 1999 through 2001: is progress being made? *Clin Ther* 2003;25:1203-47.
24. Downing NS, Aminawung JA, Shah ND, Braunstein JB, Krumholz HM, Ross JS. Regulatory review of novel therapeutics – comparison of three regulatory agencies. *N Engl J Med* 2012;366:2284-93.
25. Shajarizadeh A, Hollis A. Delays in the submission of new drugs in Canada. *CMAJ* 2015;187:E47-51.
26. Barua B, Westcott W, Vo VN. Timely access to new pharmaceuticals in Canada, the United States, and the European Union. Vancouver: Fraser Institute, 2021. <https://www.fraserinstitute.org/sites/default/files/timely-access-to-new-pharmaceuticals-in-canada-US-and-EU.pdf>.
27. Bernal JL, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial. *Int J Epidemiol* 2017;46:348-55.
28. Abunassar C, Dowson JP, Fleming M, Loschmann C, Scott V, Burt M. Biopharmaceutical ecosystem index: where does Canada rank on its attractiveness for new medicine launch? Mississauga: PDCI Market Access, 2022. <https://www.pdci.ca/wp-content/uploads/2022/06/PDCI-Biopharmaceutical-Ecosystem-Index-June-2022.pdf>.
29. Jewett C. FDA's drug industry fees fuel concerns over influence. New York Times, 2022 Sep 15. https://www.nytimes.com/2022/09/15/health/fda-drug-industry-fees.html?unlocked_article_code=1hTG4BAxGQMZM3wDxPuK3q3RL42waUJTj9AaPgWP3fOUX7SjFEWIHOE-FtgBQ9iRiXwY2QxlUb68BYq4K1BBATZX1jltC4-zc65sNmMcGPKL0r8PUJP74hVEn-Y4iihuF3SlitNAerSicwvE2y7r36LOJzT_sFAX95Ycc1NDcUvhmt_7YBFO4kqORvsqKhyX1w5y8d-CNqiEbyAm8g7b8GdFbP9wDMWJwrhjqoOFtNjllWBxBR_NL8X6dHEfB8SIDoCuLU3f9g&smid=email_share.
30. Hooper CL, Henderson DL. Expensive prescription drugs are a bargain. Wall Street Journal, 2022 Sep 13. https://www.wsj.com/articles/expensive-medications-are-a-bargain-drug-cost-expense-inflation-reduction-act-brand-name-pharmaceutical-treatments-11663080540?st=no5faitqogcioi5&reflink=article_email_share.
31. Danzon PM, Wang YR, Wang L. The impact of price regulation on the launch delay of new drugs – evidence from twenty-five markets in the 1990s. *Health Econ* 2005;14:269-92.
32. Spicer O, Grootendorst P. The effect of patented drug price on the share of new medicines across OECD countries. *Health Policy* 2022;126:795-801.
33. Voss E. Canada may be losing its status as a top global destination for new medicine launches. Toronto: Life Sciences Ontario, 2020 June 25. <https://lifesciencesontario.ca/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/>.
34. Martell A. Canadian regulator considers changes to new drug pricing plan. Reuters, 2020 Feb 20. https://news.yahoo.com/exclusive-canadian-regulator-considers-changes-184639667.html?fr=sycsrp_catchall

35. Rawson NSB. Leading causes of mortality and prescription drug coverage in Canada and New Zealand. *Front Public Health* 2020;8:544835.
36. Developing a truly Canadian approach to improving the lives of Canadians with rare diseases. Toronto: Canadian Organization for Rare Disorders, 2022 July 8.
http://www.raredisorders.ca/content/uploads/CORD-letter-to-Premiers_08July2022.pdf.
37. Cross P. An entrepreneurial Canada? Understanding Canada's chronic lack of innovation and how we can fix it. Ottawa: Macdonald-Laurier Institute, 2020.
https://macdonaldlaurier.ca/files/pdf/20200901_Innovation_Creative_Destruction_Cross_PAPER_FV
38. Rawson N, Adams J, Koester O. Innovative medicines or fewer cheaper drugs: which way will the Trudeau government go? Ottawa: Macdonald-Laurier Institute, 2021.
https://macdonaldlaurier.ca/files/pdf/Dec2021_Innovative_medicines_Rawson_Adams_Koester_CO
39. Tasker JP. COVID-19 vaccine maker Providence says it's leaving Canada after calls for more federal support go unanswered. CBC News, 2021 Apr 30.
<https://www.cbc.ca/news/politics/providence-therapeutics-pulling-out-canada-1.6009068>.
40. Picard A. Canadian philanthropist gives \$250-million for pandemic research centre – in Australia. Globe and Mail, 2022 Aug 30. <https://www.theglobeandmail.com/canada/article-canadian-philanthropist-gives-250-million-for-pandemic-research-centre/>.
41. Nurturing growth: measuring the return from pharmaceutical innovation 2021. London: Deloitte, 2022. <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/Measuring-the-return-of-pharmaceutical-innovation-2021-Deloitte.pdf>.
42. Health Canada. Statement from Minister of Health on the coming-into-force of the Regulations Amending the Patented Medicines Regulations. Ottawa: Government of Canada, 2022 Apr 14.
<https://www.canada.ca/en/health-canada/news/2022/04/statement-from-minister-of-health-on-the-coming-into-force-of-the-regulations-amending-the-patented-medicines-regulations.html>.
43. PMPRB draft guidelines 2022. Ottawa: Patented Medicine Prices Review Board, 2022.
<https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html>.
44. Rawson N, Adams J. PMPRB continues plan to drive down drug prices as patients suffer. Ottawa: Macdonald-Laurier Institute, 2022 Nov 23. <https://macdonaldlaurier.ca/pmprb-continues-plan-to-drive-down-drug-prices-as-patients-suffer-nigel-lawson-and-john-adams-for-inside-policy/>.
45. *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*. 2021 FCA 157.
<https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do>.
46. Owens RC. Defending our rights: eliminating dysfunction in Canada's intellectual property regime. Ottawa: Macdonald-Laurier Institute, 2017. https://macdonaldlaurier.ca/mli-files/pdf/MLI_IPPaper3_06-17_webready.pdf.
47. Rawson NSB, Adams J. Do reimbursement recommendation processes used by government drug plans in Canada adhere to good governance principles? *Clinicoecon Outcomes Res* 2017;9:721-30.
48. Rawson N. Pan-Canadian Pharmaceutical Alliance lacks transparency and accountability. Ottawa: Macdonald-Laurier Institute, 2019. <https://macdonaldlaurier.ca/pan-canadian-pharmaceutical-alliance-lacks-transparency-accountability-nigel-lawson-inside-policy/>.
49. Wells P. Trudeau and Big Pharma: not a love story. Maclean's, 2021 Feb 22.
<https://www.macleans.ca/politics/ottawa/trudeau-and-big-pharma-not-a-love-story/>.
50. Rawson NSB, Adams J. More than a dose of collaboration: what Ottawa should do if it wants

drugs and vaccines to be made in Canada and benefit patients. Ottawa: Macdonald-Laurier Institute, 2021.

https://macdonaldlaurier.ca/mli-files/pdf/20210525_More_than_a_dose_of_collaboration_Rawson_Adams_PAPER_FWeb.pdf?mc_

51. Cooke A. 'Heartbreaking' death of cystic fibrosis patient shines light on drug access issues. CBC, 2020 Feb 21. <https://www.cbc.ca/news/canada/nova-scotia/chantelle-lindsay-cystic-fibrosis-death-canada-drug-access-1.5471605>.
52. Bussi re M. Fighting the bureaucracy for one's life. Ottawa Life Magazine, 2020 Mar 19. <https://www.ottawalife.com/article/fighting-the-bureaucracy-for-ones-life?c=1>.
53. O'Brien A. Ontario family forced to fight for life-saving drug highlights need for national rare disease strategy. CTV News, 2022 Apr 20. <https://toronto.ctvnews.ca/ontario-family-forced-to-fight-for-life-saving-drug-highlights-need-for-national-rare-disease-strategy-1.5869037>.
54. Stewart D. Cancer sucks, but so does Canada's response to it. Ottawa Citizen, 2022 June 20. <https://ottawacitizen.com/opinion/stewart-cancer-sucks-but-so-does-canadas-response-to-it>.
55. Rawson NSB, Abunassar C, Lawrence D. Effect of amended Patented Medicine Regulations on industry decisions to launch new drugs in Canada. Toronto: Canadian Health Policy Institute, 2022. <https://fko.wzo.mybluehost.me/product/effect-of-amended-patented-medicine-regulations-on-industry-decisions-to-launch-new-drugs-in-canada/>.
56. Rail P. Canada's health-care system is 'collapsing around us,' warns CMA president. CTV News, 2022 June 15. <https://www.ctvnews.ca/health/canada-s-health-care-system-is-collapsing-around-us-warns-cma-president-1.5948416>.
57. Fleming S. The outsized effect of 'modest' price controls on pharmaceutical innovation. Boston, MA: STAT, 2022 Aug 4. <https://www.statnews.com/2022/08/04/outsized-effect-modest-price-controls-pharma-innovation/>.