Waiting for new medicines in Canada, Europe, and the United States 2018-2023

Description

TITLE
Waiting for new medicines in Canada, Europe, and the United States 2018-2023

CURRENT CONTRIBUTORS
Brett Skinner, PhD, Canadian Health Policy Institute (CHPI)

ATTRIBUTION
This paper is corporately authored and edited based on proprietary template models and methods that are intended to facilitate regular updates. The design and content are a cumulative reflection of the diverse contributions collectively attributable to the CHPI affiliated researchers who may have variously participated in updating each edition. Data sources, methods and editorial presentation may evolve from previous editions.

DISCLAIMER
This study uses data from IQVIA Inc. The analysis, conclusions and opinions expressed in this paper do not necessarily reflect the views of the data supplier.

CITATION
Canadian Health Policy Institute (CHPI) (2024). Waiting for new medicines in Canada, Europe, and the United States 2018-2023. *Canadian Health Policy*, APR 2024. ISSN 2562-9492 https://doi.org/10.54194/QQVC3893, canadianhealthpolicy.com

SPONSORSHIP
Open access to this article was sponsored by CHPI's Canadian Access to Innovative Medicines (CA2IM) research program.

REVISED

This paper was revised on 14 APR 2024 to include additional data omitted from the original version published on 11 APR 2024. The revisions appear on pages 10 and 11.

[DOWNLOAD THE FULL PDF TO ACCESS TABLES AND CHARTS]

Highlights

- Canada is a low priority market for new drug launches:
  - During 2018-2022 Health Canada (HC) received 208 new drug applications (NDA) for new active substances (NAS), compared to 335 received by the European Medicines Agency

(EMA) and 386 received by the US Food and Drug Administration (FDA).
    - Pharmaceutical companies waited an average of 327 days after submitting a new drug application to the EMA or the FDA to file an application for the same drug to Health Canada.
- Regulatory approval added significantly to the overall wait for access to new medicines:
    - During 2018-2022 Health Canada reported 166 marketing authorizations (MA) for NAS, while the FDA accrued 241 MA and the EMA accrued 214 MA that were comparable to the HC cohort.
    - On average, the time consumed from the NDA submission to the issuance of a marketing authorization, was 379 days in Canada, 442 days in the EU, and 321 days in the US.
- The process leading to public drug insurance coverage in Canada delayed access to new medicines:
    - CADTH's health technology assessment (HTA), PCPA's centralized reimbursement negotiations, and the provincial and federal public drug plans' formulary listing process collectively added 770 days to the overall wait time for access to new medicines.
- Overall, the total number of new drugs accessible in public drug plans was lower in Canada, and wait times were longer:
    - Of the 166 NAS authorized for marketing in Canada during 2018-2022, only 30 (18%) on average were listed on provincial and federal public drug formularies as of 31 DEC 2023. Counting NAS matching, accruing, or uniquely corresponding to the Canadian study cohort there were 214 comparable public drug formulary listings in the EU and 241 in the US.
    - The average total wait time from the first global new drug application to formulary listing in a public drug plan was 1476 days in Canada, 647 days in the EU, and 530 days in the US.
- Patent term restoration should be extended to compensate for all time lost due to government regulations and processes. Canada's PTR currently compensates for a maximum two years lost patent time attributable to Health Canada's approval process. PTR does not compensate for subsequent delays caused by HTA, and federal-provincial formulary processes.
- The availability and wait for new drugs could be improved through regulatory harmonization under which, Health Canada would automatically and immediately recognize new drug approvals occurring first in either the EMA or the FDA. Over the five years from 2018-2022, regulatory harmonization could have potentially made an additional 171 new drugs available to Canadians and shortened average wait times by up to 58 days.
- Germany's system for pharmaceutical pricing and reimbursement, uses structured negotiation instead of regulation and is designed to allow immediate interim insurance coverage following marketing authorization, with permanent insurance coverage pending the outcome of negotiations. Expediting formulary listings using a similar approach in Canada would have shortened average wait times by 770 days.
- Research has shown that price regulation is a significant factor in company decisions about prioritizing markets for new drug launches. The federal government should end its price control regime.