The Conference Board of Canada

Access and Time to Patient

Prescription Drugs in Canada

Data briefing | January 4, 2024

Contents

Key findings

- The time between regulatory approval for new drugs and their listing on public provincial formularies averaged 736 days (25 months) in 2022. This is double the average time reported in comparable Organisation for Economic Development (OECD) countries.
- After initial listing, it took 90 days to be available to half of public drug plan beneficiaries in Canada, for a total time of 825 days from regulatory approval to patient.
- Overall time to patient in 2022 varied considerably by province, driven mainly by delays surrounding completion of the individual provincial product listing agreements (e.g., 44 days in Quebec and 662 days in Prince Edward Island after pan-Canadian Pharmaceutical Alliance [pCPA] negotiation).
- Governments and manufacturers should collaborate to streamline drug review and listings with an emphasis on accelerating Canadian Agency for Drugs and Technologies in Health (CADTH) to pCPA engagement and pCPA conclusion to provincial listing within a 30-day target.

Delays in patient access to pharmaceuticals in Canada

Delays in patient access to drugs that have been deemed effective are not only detrimental to the lives of Canadians but negatively impact Canada's capacity for economic growth.

The biotechnology sector and innovative pharmaceuticals are increasingly important components of the Canadian economy and the health of Canadians.[1] Despite their importance, on average, Canadians wait two years for access to new medicines through public drug plans following drug approval from Health Canada.[2] This is double the average time reported in several other high-income OECD countries.[3] According to the Canadian Organization for Rare Disorders, approval in Canada can take up to six years longer than in the United States or Europe for rare disorder drugs, while one in 12 Canadians lives with a rare disorder.[4] Canadians who could otherwise work or contribute to the economy are unable to do so while they await new medicines that can significantly impact their quality of life.[5]

This data briefing examines the time it takes for drugs to become publicly available to patients, with breakdowns by year, province, and therapeutic area (e.g., oncology). To do this, we used IQVIA's Market Access Metrics Database, which tracks all new products through the Canadian access journey. (See Appendix A.)

The regulatory pathway of medicines in Canada

Canada has a long approval and listing process for innovative medicines, also known as new active substances (NAS).[6] The timing of drugs in various stages of the process is important to explore to be able to understand where exactly the delays exist, how listing times evolve over years as policies are implemented, and to identify opportunities for improvement to ensure patients have timely access to new therapies.

1 Canadian Institute for Health Information, "Trends in Public Drug Program Spending in Canada."
2 Hoskyn, *Explaining Public Reimbursement Delays for New Medicines for Canadian Patients*.
3 Ibid.
4 Canadian Organization for Rare Disorders, "Key Facts."
5 Van Mulligen and others, *Tomorrow Can't Wait*.
6 Health Canada, *Access to Therapeutic Products*.

Overall, several complex steps are involved before a NAS (a drug that has not been marketed in Canada) becomes approved and readily available to patients. First, the Therapeutic Products Branch of Health Canada tests the NAS through multiple phases to ensure that it is safe and effective.[7] Health Canada offers priority regulatory processes but, unlike other countries—such as England and Wales, France, Germany, Italy, and Australia—does not have a formalized early access program that allows patients to use the drugs before the review process is completed.[8]

Health Canada aims to provide regulatory approval within 300 days, or 180 days for priority review files. The organization is currently finalizing regulatory amendments, scheduled to be published in 2024, to implement some of the efficiencies used to approve novel medications and vaccines during the COVID-19 pandemic.[9,10]

The next step involves issuing a Notice of Compliance (NOC) for a NAS that has been approved by Health Canada. At this point, companies can market their product, and it can be listed in private insurance plans. If the pharmaceutical company plans for the drug to be covered in public insurance plans, several other critical steps in the process follow.

Phase 1: CADTH submission. After the NAS receives a NOC, pharmaceutical companies must file an application with the Canadian Agency for Drugs and Technologies in Health (CADTH) if they want their NAS to be covered in public insurance plans. CADTH is a government-funded health technology assessment agency[11] for public insurance coverage assessment. In Quebec, the health technology assessment is conducted by the Institut national d'excellence en santé et en services sociaux (INESSS).[12]

Phase 2: CADTH process. This stage involves the review of the NAS application by CADTH or INESSS. These agencies complete a clinical and cost-effectiveness assessment and recommend whether the drug should be reimbursed by public provincial/territorial plans.

Phase 3: Begin pCPA negotiation. Once a CADTH recommendation has been made, the provincial/territorial drug plans must then negotiate with the manufacturer through pCPA. pCPA negotiates drug prices and improves access to cost-effective treatments for publicly funded drug programs in Canada.[13]

7 Ibid.
8 Cowling and others, "Early Access for Innovative Oncology Medicines."
9 Health Canada, "Service Standards for Drug Submission Evaluations."
10 Health Canada, "Regulatory Innovation for Health Products: Agile Licensing for Drugs."
11 Canadian Agency for Drugs and Technologies in Health, "About CADTH."
12 Institut national d'excellence en santé et en services sociaux, "About the Institut."
13 Pan-Canadian Pharmaceutical Alliance, "The Negotiation Process."

Phase 4: pCPA negotiation. During this phase, provincial/territorial drug plans negotiate with the manufacturer through pCPA, using LOE (Letter of Engagement) and LOI (Letter of Intent). The LOI is signed with the manufacturer to identify pricing and coverage terms. These LOIs form the basis of formal Product Listing Agreements with provinces, territories, and some federal plans. Once this process is completed, a NAS can be listed on public drug plans.

The negotiation phase takes several months for pharmaceutical companies due to the complexity of negotiations, the need for data analysis, legal and regulatory considerations, administrative processes, stakeholder input, a high volume of negotiations, and strategic factors influencing discussions.

Phase 5. Initial listing. This is the time it takes for a NAS to become listed in the first provincial/territorial public plan, with formalized pricing and coverage agreements, after the pCPA negotiation is completed.

Phase 6. Subsequent listings. The final phase is of greater importance as this is when more provinces and territories begin to list the drug in their public plans. For the purposes of our analysis, we assess how long it takes to move from being listed in one public plan to 50 per cent of public beneficiaries (each province/territory may have multiple public drug plans).

Analyzing drug listing times in Canada

Time spent in different phases in the Canadian drug-listing process

In 2022, it took approximately 25 months from receiving a notice of compliance for a NAS to the first initial listing on a public plan (736 days), and then an additional three months for it to be listed on additional provincial and territorial plans and cover 50 per cent of public beneficiaries (90 days). (See Chart 1.)

The time in each phase varied across the years. The time from notice of compliance to CADTH submission (Phase 1) ranged from -61 days in 2020 to 116 days in 2021. The negative values indicate that some products were engaged by CADTH before their Health Canada approval as part of the Health Canada–Health Technology Assessment (HTA) aligned review process that was implemented in 2012.[14]

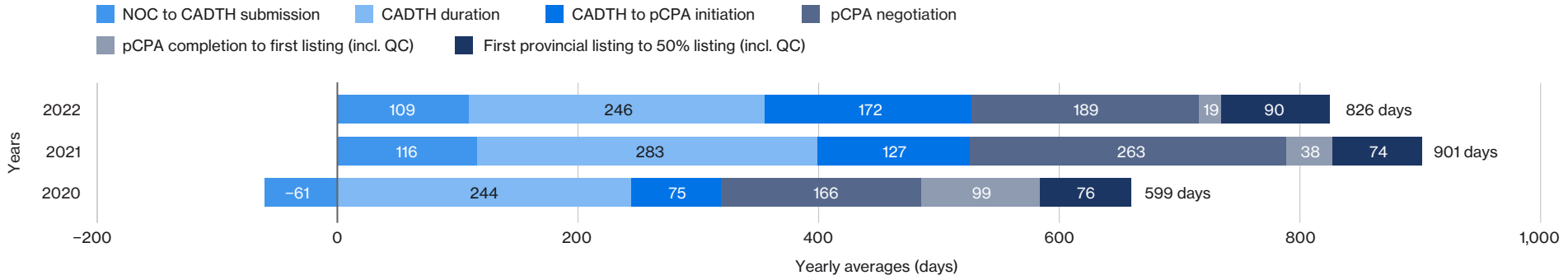
The average time spent for products waiting to be engaged by pCPA after CADTH recommendation was 172 days in 2022, almost three times as long as the *pCPA Brand Process Guidelines* target of approximately 60 calendar days or 40 business days.[15]

Furthermore, the average time spent in pCPA negotiations in 2022 was 189 days. This is greater than the recommended time frame of 120 calendar days, or 90 business days, from initiation to completion as mentioned in the *pCPA Brand Process Guidelines*.[16] Following pCPA negotiation completion, it took on average 19 days days for the drug to be listed in the first public provincial/territorial drug plan.

Chart 1

Canadians wait two years on average to have access to pharmaceuticals following health approval

(overall time to listing, yearly average in days, 2020–22)



Note: NAS only. Excludes CADTH resubmissions, non-sponsored submissions, and requests for advice. Excludes products with pCPA negotiations subsequent to the first negotiation.
Negative values indicate that some products were engaged by CADTH before Health Canada approval.
Data source: IQVIA Market Access Metrics Database, January 1, 2012, to March 31, 2023, data period. Analysis: The Conference Board of Canada.

14 Salek and others, "Factors Influencing Delays in Patient Access to New Medicines in Canada."

15 pan-Canadian Pharmaceutical Alliance, *pCPA Brand Process Guidelines*.

16 Ibid.

There was a delay of approximately 3.5 months for NAS to reach 50 per cent of public beneficiaries (provincial and territorial drug plans; Phase 6) following completion of pCPA negotiations. Detailed listing metrics for each province are available in Appendix C.

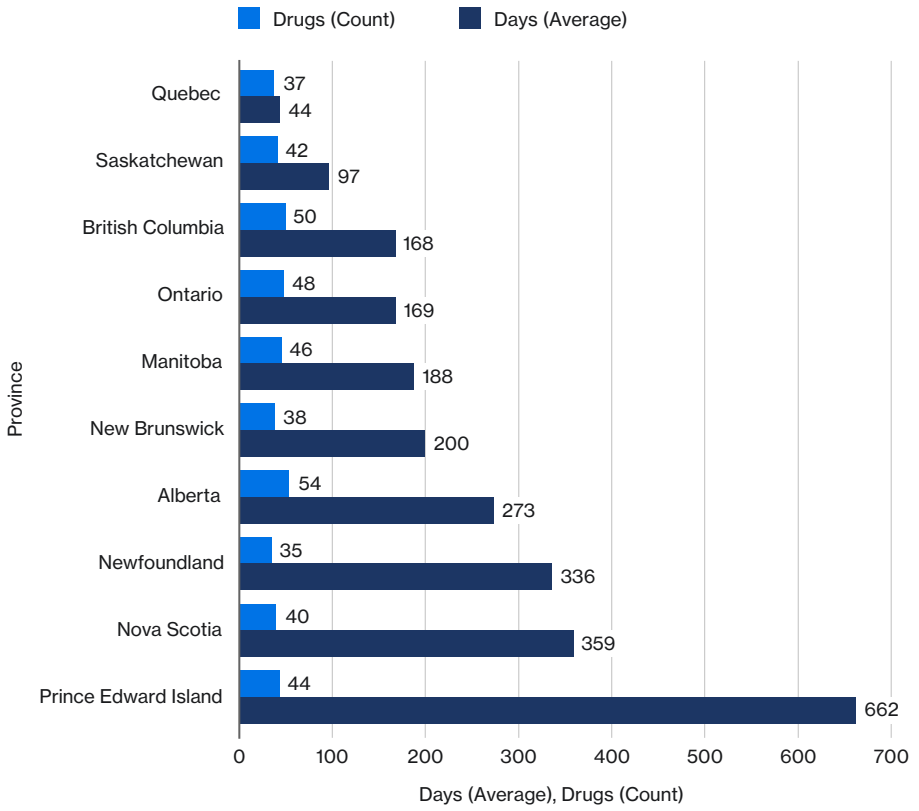
Provincial variations in drug listings after pCPA negotiation

The average time to patient in 2022 once Phase 4 (pCPA negotiation) was completed varied significantly across the provinces. (See Chart 2.) The listing time was the longest in Prince Edward Island (662 days) and the shortest in Quebec (44 days). It appeared that the eastern provinces took longer to list relative to other provinces. The other provinces of Ontario, British Columbia, and Alberta took 169, 168, and 273 days, respectively. The number of drugs being listed does not appear to have an impact on listing times across provinces. For example, while both Prince Edward Island and Manitoba had 44 and 46 drugs listed, respectively, the time to patient in Prince Edward Island was more than three times longer.

When segmenting the data by province, the long time to patient in Prince Edward Island was largely driven by drugs that were listed in 2020, which had an average time to patient of 1,241 days. Compared with 2021, time to patient decreased in 2022 in six of the provinces—British Columbia, Manitoba, Newfoundland and Labrador, Saskatchewan, Prince Edward Island, and Quebec—while it increased in all other provinces. Overall, there is a decreasing trend in time to patient in Quebec, with an increasing trend in time to patient for most other provinces over the years 2020–22. (See Chart 3.)

Charts showing time to patient for oncology versus non-oncology drugs by province are presented in Appendix C.

Chart 2
There has been significant variation in the time to patient after pCPA negotiation across provinces
(cross provincial listings, average approval in days and number of drugs reimbursed, 2022)

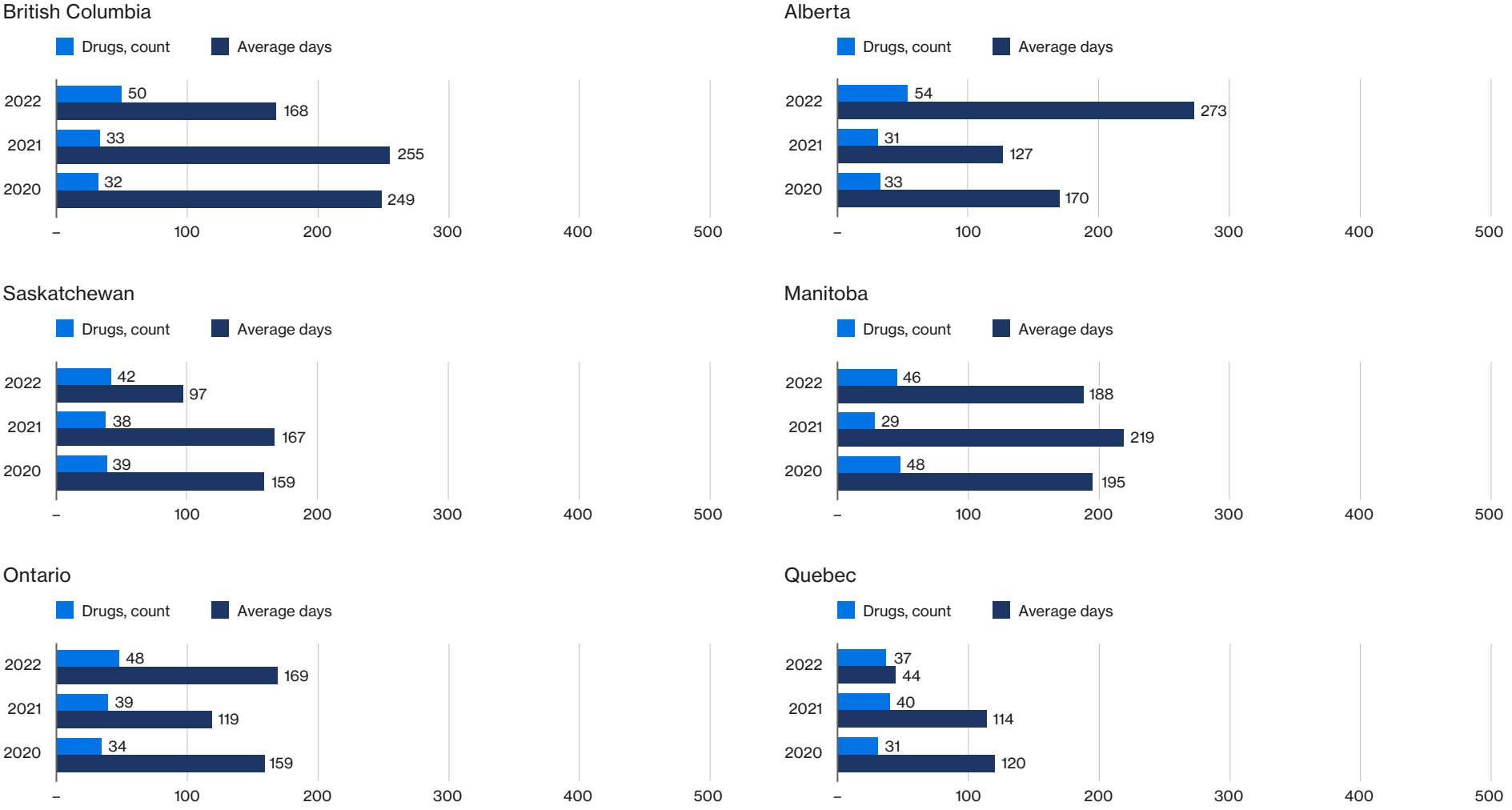


Data source: IQVIA Market Access Metrics Database, January 1, 2012, to March 31, 2023, data period.
Analysis: The Conference Board of Canada.

Chart 3

Overall time to patient slightly increased across provinces over time

(within provincial listing time, average in days and number of drugs reimbursed, 2020–22)

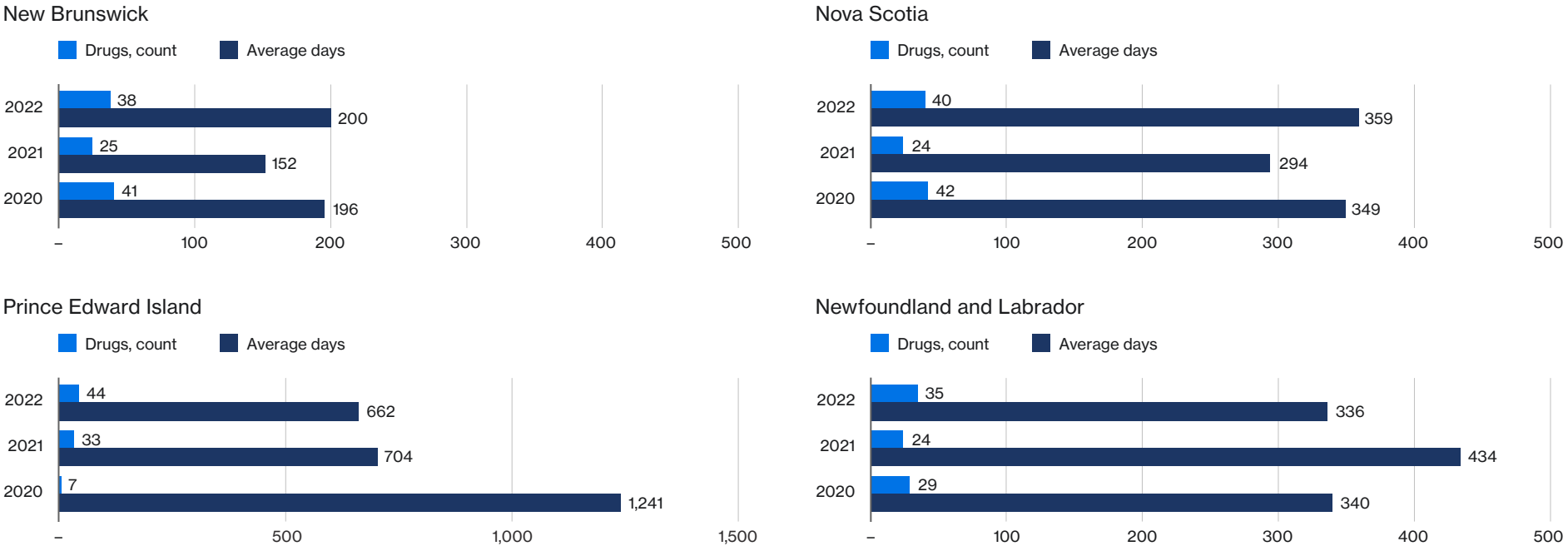


Data source: IQVIA Market Access Metrics Database, January 1, 2012, to March 31, 2023, data period. Analysis: The Conference Board of Canada.

Chart 3 (cont'd)

Overall time to patient slightly increased across provinces over time

(within provincial listing time, average in days and number of drugs reimbursed, 2020–22)



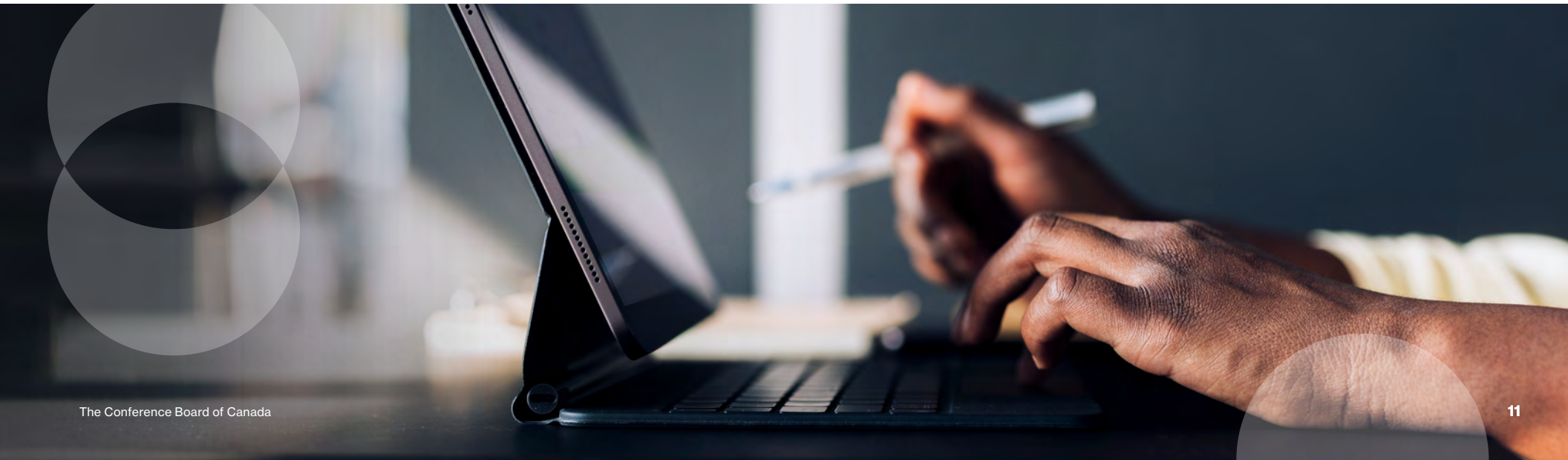
Data source: IQVIA Market Access Metrics Database, January 1, 2012, to March 31, 2023, data period. Analysis: The Conference Board of Canada.

Analyzing Canada's drug approval timelines: Opportunities for improvement

Several significant trends emerge from this analysis. Notably, the data highlight the sequential and lengthy drug review processes in Canada, spanning from the issuance of NOC for a NAS to its initial and subsequent listings on public plans. In 2022, this process took an average of 25 months to achieve the first listing, with an additional three months needed to reach 50 per cent of public plan beneficiaries. These findings align with reports indicating that Canadians continue to wait an average of two years for pharmaceutical access after being approved by Health Canada.[17,18]

Analysis across the years 2020–22 highlighted significant variation in time to patient across provinces and years. The large variations highlight that there is opportunity for companies, regulatory bodies, and public payers to collaborate in streamlining processes for expeditious drug approval and listing, with a particular emphasis on accelerating CADTH to pCPA (Phase 2) engagement and pCPA conclusion to provincial listing (phases 3, 4, and 5) processes. Future research should focus on identifying the factors contributing to time variations, such as pinpointing areas for improvement in the Health Canada–HTA aligned review process, identifying delays in pCPA engagement and negotiations, and exploring best practices among time from pCPA conclusion to provincial listing.

17 Dobrescu, "Canadian Public Insurance Plans and Delays in Patient Access to Innovative Medicines."
18 Hoskyn, *"Explaining Public Reimbursement Delays for New Medicines for Canadian Patients."*



Appendix A

Methodology

This study uses IQVIA's Market Access Metrics Database, which tracks all new products and their indications through the Canadian access journey. The database collects information from NOC to HTA reviews, pCPA negotiations, and provisional listings. The data are sourced from Health Canada, CADTH, INESSS, pCPA, and provincial drug listings. The dataset consists of data from the January 1, 2012, to March 31, 2023, data period.

Findings in this publication are based in part on this data, delivered under licence to Innovative Medicines Canada by IQVIA Solutions Canada Inc. (IQVIA) on May 15, 2023.

Time differences were recorded in days for each drug and then grouped by year. Where applicable, counts and averages are presented and compared between the time it takes from:

a) NOC to CADTH submission
b) CADTH duration
c) CADTH to pCPA initiation
d) pCPA LOI to LOE
e) pCPA completion to first listing
f) first provincial listing to 50 per cent listing

Appendix B

Acronyms and initialisms

Table 1

Acronym or initialism	Title
CADTH	Canadian Agency for Drugs and Technologies in Health
DRDs	Drug for Rare Diseases
EMA	European Medicines Agency
FDA	Food and Drug Administration
HTA	Health Technology Assessment
IMC	Innovative Medicines Canada
INESSS	Institut national d'excellence en santé et en services sociaux
LOE	Letter of Engagement
LOI	Letter of Intent
NAS	New active substances
NOC	Notice of Compliance
OECD	Organisation for Economic Co-operation and Development
pCPA	Pan-Canadian Pharmaceutical Alliance

Appendix C

Access the data

Download the data supplement for more, including:

- Charts included in this briefing
- Charts on timelines for oncology vs. non-oncology drugs
- List of products that completed pCPA negotiation between January 1, 2022, and March 31, 2023, across provinces

Download charts and list of products

Appendix D

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