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Reimbursement recommendations for new medicines in Canada: current trends in an uncertain era

Nigel S. B. Rawson, PhD

Affiliated scholar/Senior fellow, Canadian Health Policy Institute, Macdonald-Laurier Institute, Fraser Institute

ABSTRACT

President Trump has introduced his Most-Favored-Nation (MFN) reference-based drug pricing policy, which requires prices of all brand medicines without competitors be set at the lowest price in OECD countries with a GDP per capita of at least 60% of the U.S. GDP per capita to reduce prescription drug costs to Americans and increase prices in other countries, including Canada, to end freeloading on American innovation. This is causing much uncertainty among drug developers and Trump's comparator countries where medicine prices are tightly controlled, although so far Canadian governments seem to be in a state of denial. Canada's Drug Agency (CDA) performs health technology assessments (HTAs) of drugs to try to evaluate their "cost-effectiveness" for all provinces and territories, except Quebec. CDA is one of five gatekeepers that drug developers must work with to get new medicines listed in government drug plans. The objective of this analysis is to assess trends in reimbursement recommendations made by CDA between 2009 and 2025, CDA's use of a specific cost-effectiveness threshold, and the time taken to perform HTAs. The potential impact of Trump's MFN policy on Canada is addressed in the light of these trends and recent CDA policy proposals. CDA's reimbursement recommendations have changed markedly since 2009, with a strong increase in positive recommendations. However, all of these recommendations are conditional on clinical criteria and/or a price condition in recent years. Clinical criteria range widely, but some seem poorly considered and inadequately reflect the complex clinical management of many diseases resulting in clinically inappropriate reimbursement criteria. Price conditions were often non-specific before 2016, but subsequently they have frequently been expressed as a specific percentage reduction to achieve a low cost-effectiveness threshold of $50,000 per quality-adjusted life-year. Between 2016 and 2022, the rate of specific percentage reductions to achieve the cost-effectiveness threshold increased from 12.5% to 93.5%. More than half of CDA recommendations in the last five years included a price reduction of 73% or higher and, in a quarter, the recommended reduction exceeded 90%. Major pharmaceutical companies are committing to investing in research and development and manufacturing in the United States and reducing or closing facilities in less expensive parts of the world. Canadian governments have a choice. They can hope to outlast the Trump administration and continue to under-value and under-invest in pharmaceutical innovation – resulting in fewer medicines being launched in Canada than already occurs and even longer delays to access drugs that are launched here – or face up to higher prices, recognize the benefits innovative medicines can bring to both patients and health care systems, and substantially increase investment in life sciences in Canada.

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INTRODUCTION

In the United States, the Trump administration has introduced a policy known as Most-Favored-Nation (MFN) drug pricing, which requires prices of all brand products without competing generics or biosimilars to be set at "the lowest price in an OECD country with a GDP per capita of at least 60% of the U.S. GDP per capita" (HHS 2025). The policy's aim is to reduce prescription drug costs to Americans and increase prices in European countries, Australia, Israel, Japan and Canada, whose GDPs per capita are comparatively high, to end the freeloading of patients in these countries on Americans (Skinner 2026), while remaining cost-neutral to manufacturers. As a result, major pharmaceutical companies are committing to investing in research and development (R&D) and manufacturing in

the United States and reducing or closing facilities in less expensive parts of the world (Banker 2025). Almost a year after his Executive Order, the President issued a proclamation in which the general duty rate for imported patented pharmaceuticals is set at 100 percent, but for companies that have or are likely soon to have agreements with the Unted States for onshoring pharmaceutical R&D and manufacturing, the rate is 20 percent (Trump 2026)

This is causing much uncertainty among drug developers and Trump's comparator countries where medicine prices are tightly controlled, which includes Canada. Trump's MFN prescription drug policy has amplified the urgency of policy reform in Canada's approach to evaluating the cost-benefit of new medicines and the willingness of government drug plans to cover new medicines to ensure patients can access innovative prescription drugs. Canadian governments presently use two health technology assessment (HTA) agencies to evaluate the cost-effectiveness of new drugs and make recommendations to government drug plans regarding formulary listings and reimbursement prices. Canada's Drug Agency (CDA) performs HTAs of drugs for all provinces and territories, except Quebec, which has its own HTA agency (CDA 2026a). CDA is one of five gatekeepers that drug developers must work with to get new medicines listed in government drug plans.

CDA began as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) in 1989 (Menon 2015), which established the Common Drug Review (CDR) to assess new medicines. CCOHTA became the Canadian Agency for Drugs and Technologies in Health (CADTH) in 2006 (MacPhail and Shea 2017). The first submission was accepted in 2007. Also in 2007, the Joint Oncology Drug Review (JODR) was established outside CADTH, separating HTAs of cancer drugs from other medicines. The decision to establish an independent, cancer-specific national drug review process was based on various factors and influenced by the nature of cancer treatment programs in Canada. JODR later became the pan-Canadian Oncology Drug Review (pCODR).

CDR and pCODR developed their evaluation processes independently with separate expert committees (Rocchi et al. 2008, 2015; Tierney et al. 2008). Some countries like Australia and the United Kingdom use a fixed cost-effectiveness threshold per quality-adjusted life-year (QALY), but for many years, CDR and pCODR were more flexible in their use of cost per QALY, although $50,000 per QALY was commonly thought to be a guideline for non-oncology drugs (Rocchi et al. 2008). A specific threshold was never mentioned in pCODR reimbursement recommendation reports.

In 2014, pCODR was transferred to CADTH to align it with CDR and build on the best practices of both (Rocchi et al. 2015; Binder et al. 2022). The separate expert committees continued. Oncology drug reimbursement recommendation reports continued to follow pCODR's example until 2019 when oncology drug recommendations began to employ the same review template as non-oncology drugs and, like non-oncology recommendations, to regularly use a cost-effectiveness threshold of $50,000 per QALY (Binder et al. 2022). CADTH became CDA in 2024.

The objective of this analysis is to assess trends in CDA reimbursement recommendations made between 2009 (when CADTH was fully established) and 2025, CDA's use of a specific cost-effectiveness threshold of $50,000 per QALY, and the time taken by CDA to perform HTAs. The potential impact of Trump's MFN policy on Canada is addressed in the light of CDA trends and recent CDA policy proposals (CDA 2026b). Throughout this article, "CDA" will refer to the agency regardless of timeframe.

METHODS

Data on recommendations published between January 2009 and December 2025 were downloaded by the author from CDA's reimbursement recommendation reports (CDA 2026c). Only final recommendations were included. Since COVID-19 therapies tend to be dealt with differently, two recommendations for a COVID-19 drug were excluded. Recommendations were placed into one of three categories: (a) reimburse without conditions, (b) reimburse with clinical criteria and/or cost conditions including time-limited reimbursement recommendations (CDA 2023), or (c) do not reimburse.

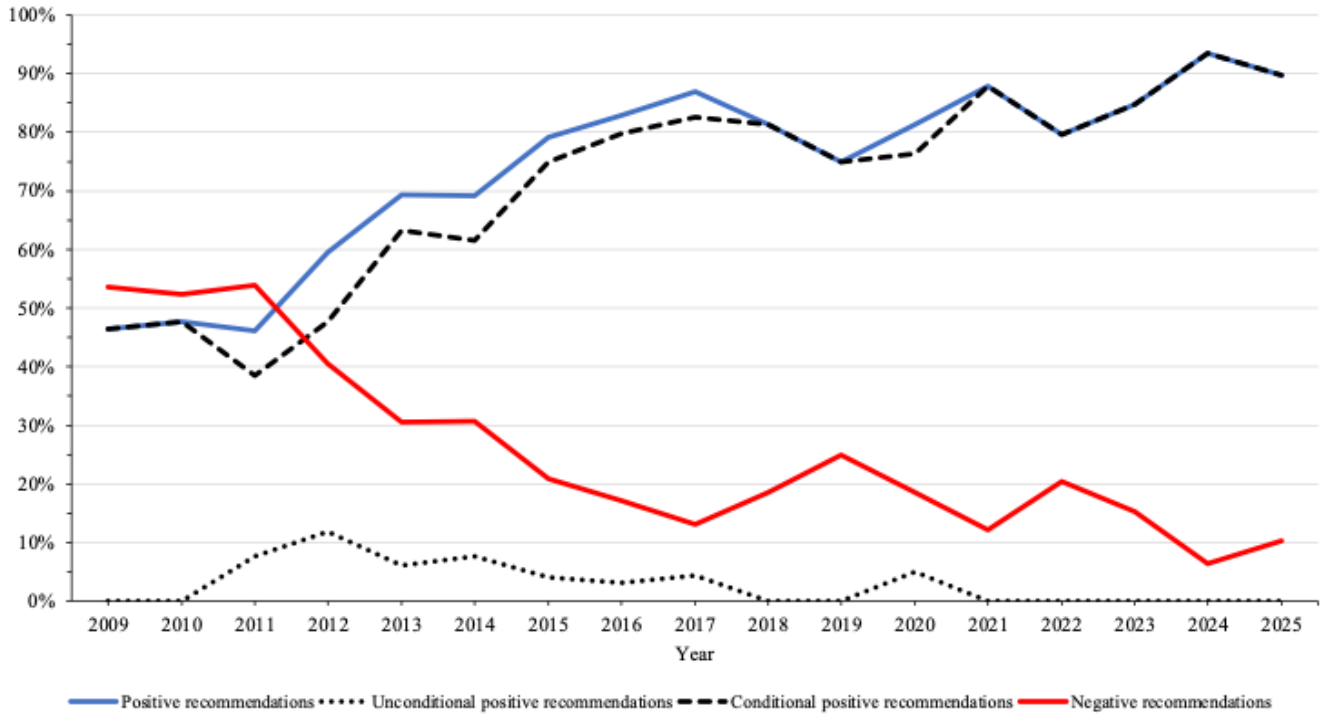
Rates of positive and negative recommendations were calculated for each year between 2009 and 2025. Conditional price recommendations were grouped into those with specific percentage reductions to reach the $50,000 per QALY threshold (using CDA recommendation reports and/or pharmacoeconomic reports) and those with non-specific reductions. Non-specific reduction recommendations included statements such as "the price should be no more than existing medicines in the same class" or "the price should be at a level to provide cost-savings to government drug plans." Trends in price reductions were limited to the period 2016 to 2025 because, before 2016, pCODR recommendations did not include them and few recommendations for non-oncology drugs did.

Calendar days between submission receipt and acceptance, submission acceptance and draft recommendation sent to the sponsor (usually the manufacturer but could be a group of physicians) and government drug plans, and draft and final recommendations were calculated for each recommendation. The length of time taken to produce reimbursement reviews was assessed in the light of CDA's performance standard.

RESULTS

A total of 926 final reimbursement recommendations were published between 2009 and 2025, with the numbers per year ranging from 21 in 2010 to 83 in 2022. The majority of the recommendations (726; 78.4%) were positive; 200 (21.6%) were negative. Overall, the positive recommendation rate for oncology drugs (294; 83.8%) was significantly higher (p=0.002) than the rate for non-oncology drugs (432; 75.1%), but this difference was not consistent across the years.

Figure 1: Percentage of types of CDA reimbursement recommendations by year, 2009-2025.



CDA reimbursement recommendations

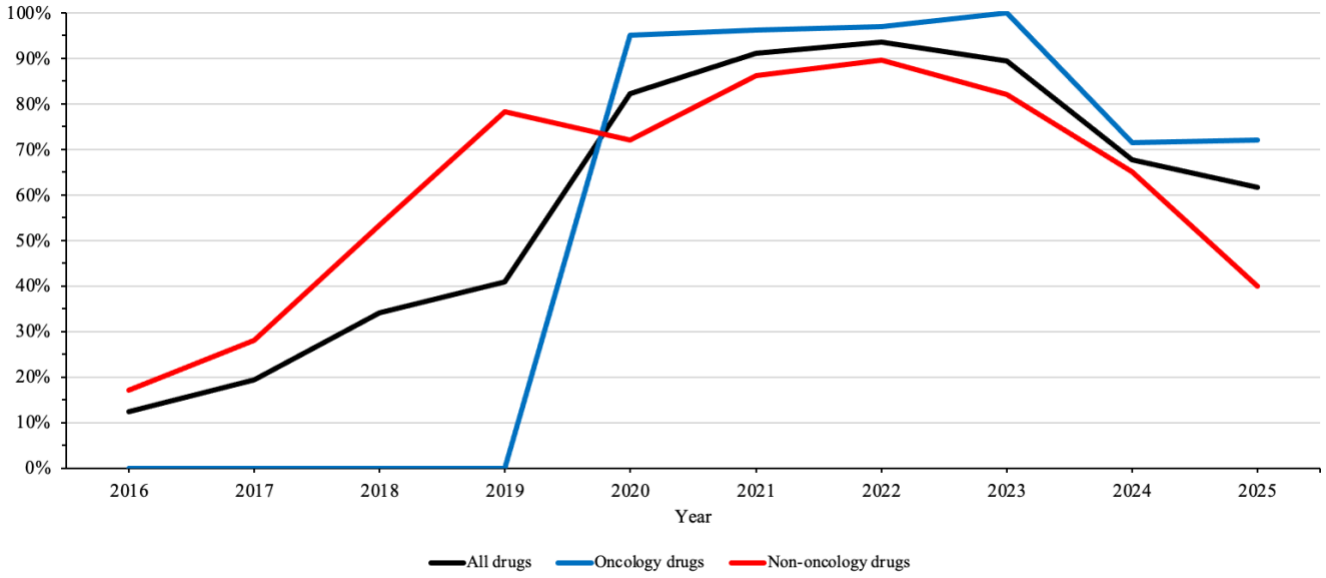
Only 23 (3.2%) of the positive recommendations were unconditional; the rest (703; 96.8%) were conditional on clinical criteria and/or cost reductions. The rate of positive recommendations increased from under 50% in 2009 to 2011 to almost 90% in 2025 (Figure 1). Most positive recommendations were conditional until 2020 and all have been conditional since then.

CDA reimbursement recommendation conditions

Between 2016 and 2025, 649 reimbursement recommendations were issued; 548 were positive and 101 were negative. Seven (1.3%) of the positive recommendations were unconditional and 541 (98.7%) were conditional; 24 (4.4%) of the conditional recommendations had clinical criteria only, 41 (7.6%) had a price reduction condition only, and 476 (88.0%) had clinical criteria and a price reduction condition. Each year during the 10-year period, more than 90% of the recommendations had a price condition, while the rate of recommendations with clinical criteria varied during the first five years but was over 90% in each of the last five years. Recommended clinical criteria ranged between statements that the drug should be prescribed by a physician with knowledge and experience with the disease being treated to complex requirements for extensive physical and/or genetic tests or the patient's condition to be assessed via a disease-specific questionnaire with results that must satisfy defined criteria for the drug to be funded. Price conditions could be a specific percentage reduction to achieve a cost-effectiveness threshold of $50,000 per QALY or non-specific statements such as "the price should be reduced to achieve an acceptable cost-effectiveness level" (a phrase commonly used by pCODR), "the price should be no higher than existing comparable medicines," or "a price reduction is required."

The rate of reimbursement reviews with a specific percentage price reduction increased from 12.5% in 2016 to 93.5% in 2022 followed by a decrease to 61.8% in 2025 (Figure 2). Trends were different between oncology and non-oncology drugs. As previously mentioned, no recommendations for oncology drugs using pCODR's format included a specific price reduction, but when oncology drug recommendations began to use CDA's template in 2019, the rate of specific price reductions increased in 2020 to over 90% and rose to 100% in 2023. Nearly half of the recommendations in 2024 and 2025 were for drugs with numerous previously-approved uses (particularly oncology drugs such as Keytruda, Opdivo and Imfinzi) for which developers were seeking recommendations for new or extended indications, or for other drugs with conditions for which several medicines already exist. Nearly two-thirds of recommendations for these drugs were to price similar to existing medicines or simply to reduce the price. When these non-specific recommendations were excluded, the rates of reimbursement reviews of innovative medicines with a percentage price reduction in 2024 and 2025 were over 80%. The median recommended percentage price reduction for oncology drugs varied between 70% and 81% between 2020 and 2024 and was slightly lower in 2025. Considerable variation occurred in the median recommended percentage price reduction for non-oncology drugs between 2016 and 2020 (Table 1), but subsequently it was similar to that for oncology drugs, rising from 68.5% to 77.0%.

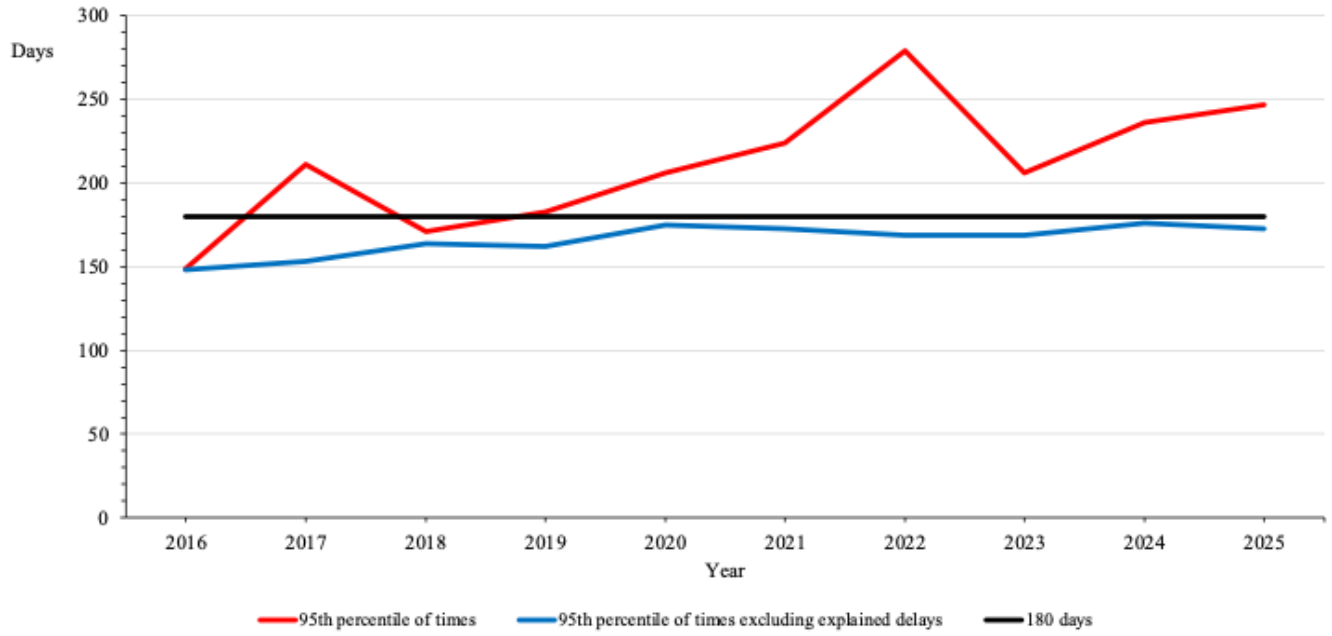
Figure 2: Percentage of CDA recommendations with specific price reductions to achieve $50,000 per QALY by year, 2016-2025.



Timeliness of CDA reimbursement recommendations

For many years, CDA has said that the typical timeline for its HTA reviews is 180 days, which, due to a lack of clarity on CDA's part, has been taken to mean the days between submission and final recommendation. However, as its 2025 procedure manual shows (CDA 2025), the 180-day performance target relates to days between submission acceptance and the draft recommendation being sent to the sponsor and participating government drug plans. Other time taken by CDA to accept submissions and activities following the draft recommendation are not counted. CDA claims it always achieves its target; between 2021 and 2025, the target was almost met but not entirely according to CDA website data. External factors, such as delayed regulatory approval from Health Canada or waiting for data or other information from sponsors, led to the performance standard not being achieved in 51 reviews (7.9%), but these are regarded by CDA as "not applicable." Five reviews (0.8%) took longer than the performance standard but were not explained in the CDA data. For a performance standard to be meaningful, it should be achieved at least 95% of the time. Figure 3 shows that this is the case for CDA's performance standard when reviews with delays outside the agency's control are excluded, i.e. the blue line in the figure is below the 180-day target.

Figure 3: 95th percentile of time between submission acceptance and draft recommendation exceeding 180 days, 2016-2025.



Patients and healthcare professionals are more focused on the overall time between submission to CDA and its final recommendation because long HTA reviews add to delays in potential coverage by government drug plans. Before any work on a submission takes place, CDA consistently takes a median of 14 to 15 days to decide whether the submission in acceptable (Figure 4; interquartile ranges to evaluate variation are in Table 1). The median time from submission acceptance to draft recommendation has increased substantially in the past decade, while the median time from draft to final recommendation has decreased.

Figure 4 hides a difference between oncology and non-oncology drugs. While the median of time between submission acceptance and release of the draft recommendation for oncology drugs was generally around 150 days with a modest increase during the COVID-19 pandemic, the median for non-oncology drugs was just over 80 days until 2020 but subsequently rose to the same duration as oncology drugs (Figure 5; interquartile ranges to evaluate variation are in Table 2). A strong difference can be seen in the median days for oncology and non-oncology drugs between draft and final recommendation in 2016 to 2020, but after the pandemic, they were similar.

In recent years, sponsors have the opportunity to request reconsideration of the recommendation following the draft recommendation. Requests can be made only on the grounds that the recommendation is not supported by the evidence submitted or identified in the review report; it cannot be made solely because the sponsor disagrees with the recommendation (CDA 2025). CDA states that reconsiderations result in a significant extension of the overall review timelines (typically two to three months). Of the 361 reimbursement recommendations in the last five years, sponsors requested reconsideration for 80 (22.2%).

As might be expected, reconsideration requests were submitted for more negative recommendations (41 of 47; 87.2%) than positive ones (39 of 314; 12.4%) and the time between draft and final recommendations for reconsidered reviews was significantly longer (median: 126 days; interquartile range: 117-154 days) than for those without reconsideration (median: 37 days; interquartile range: 36-43 days) ($p<0.0001$). The time from submission acceptance to final recommendation for 90% of reconsidered recommendations was over 11 months. Drugs for rare diseases formed 41.0% of the 39 reconsidered positive recommendations compared with 14.6% of reconsidered negative recommendations. CDA data do not disclose whether reconsideration of a negative draft recommendation resulted in a positive final recommendation, but it seems reconsiderations rarely, if ever, change CDA's recommendation.

Figure 4: Median days taken for stages of CDA's review process by year, 2016-2025.

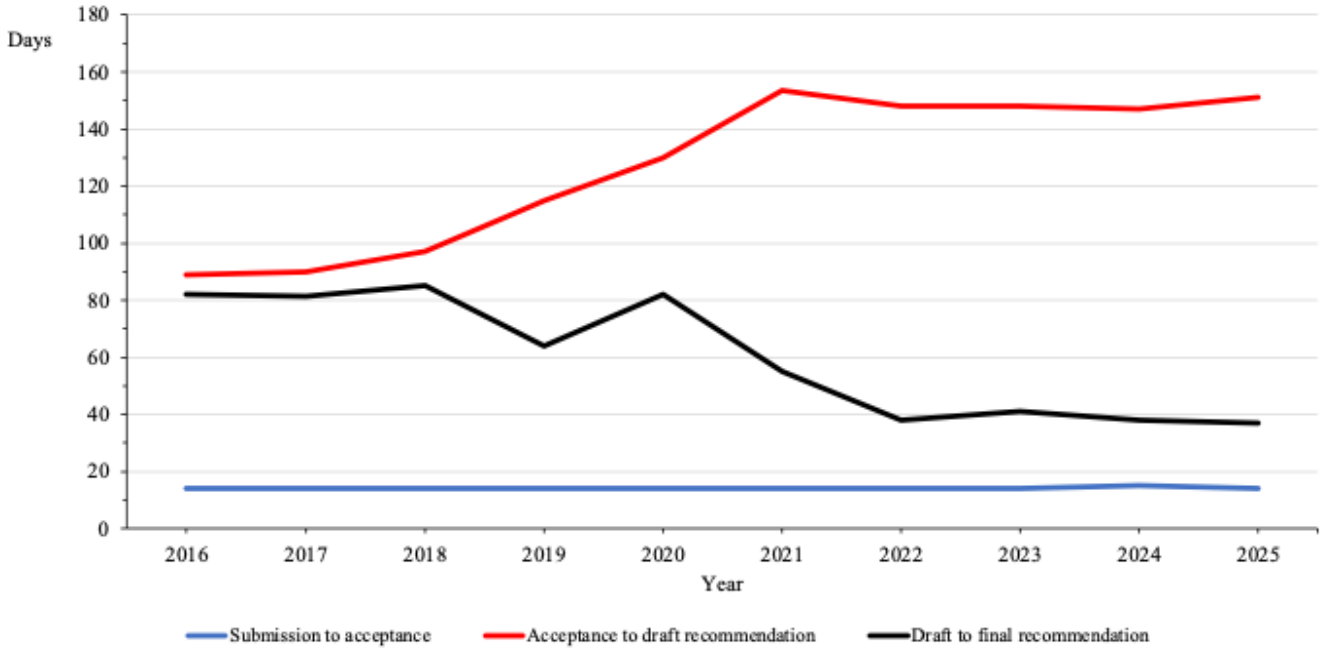
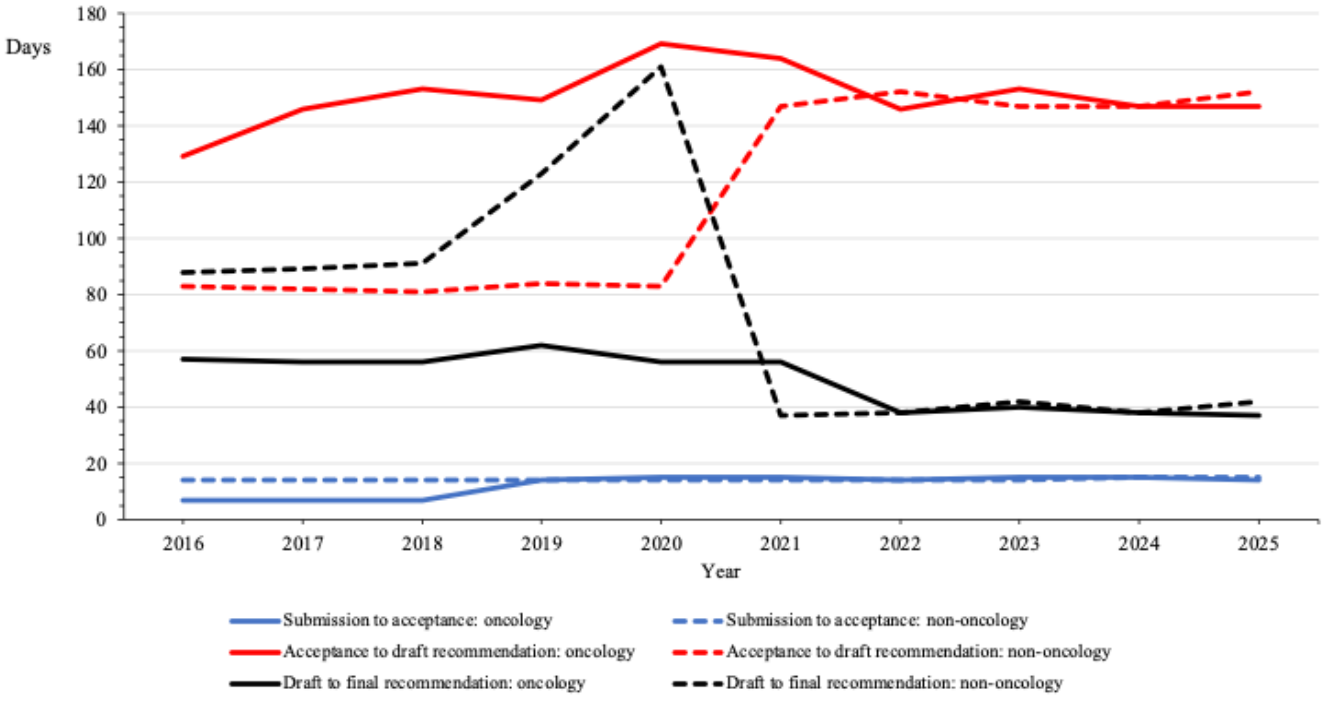


Figure 5: Median days taken for stages of CDA's review process by drug type by year, 2016-2025.



DISCUSSION

CDA is one of five gatekeepers that drug developers must work with to get new medicines listed in Canadian governments' drug plans – the others are Health Canada, the pCPA, government drug plans, and the Patented Medicine Prices Review Board (Rawson and Adams 2024, 2025). CDA is a large non-profit corporation with over 250 staff and a budget of almost $70 million in 2024–25, with 87% of its revenue coming from federal, provincial and territorial governments (KPMG 2025). CDA performs work for governments but is not a government agency, which means regular parliamentary scrutiny, freedom-of-information requests, independent ombudsperson appeals and auditor-general performance reviews are unavailable to examine its independence, transparency or accountability (Rawson and Adams 2017). CDA's responsibility is to the governments that own and fund the agency, rather than patients.

Patient groups have frequently expressed concern about how much emphasis CDA places on the input from them and their clinicians when making recommendations. Unlike the transparency of some HTA agencies in other countries, CDA committees hold closed-door meetings and, consequently, members' perspectives and official votes are not known. This means that, despite numerous and extensive reports being produced by CDA about HTA reviews, the public, patients and health care providers know little about the decision process and what evidence was given the most weight. Patients are often frustrated and concerned when their expert clinicians support access to an innovative medicine in submissions to CDA, but CDA recommends not reimbursing the drug or restricting access, based on advice from its own anonymous clinicians or staff.

In addition to patients' concerns about CDA giving inadequate emphasis on their needs, the agency has long been known to take a considerable amount of time to produce its reimbursement recommendations (Rawson 2023; Rawson and Adams 2025; Rawson and Katsof 2024; Rawson and Stewart 2024; Sehdev et al. 2024). CDA's performance standard only applies to the part of its review process between acceptance of a submission and releasing the draft recommendation to participating government drug plans and the sponsor. The median time between these two points has been relatively consistent at around 150 days for oncology drugs, with a modest increase at the time of the COVID-19 pandemic. Until the pandemic, the median time was much shorter for non-oncology drugs at just over 80 days, but subsequently it dramatically increased to a duration consistent with oncology drugs and has continued at that level. This raises the question: why have reviews of non-oncology drugs not returned to their pre-pandemic timeframe?

Not only has the time taken for different stages of HTAs changed, but CDA's reimbursement recommendations have transformed markedly over the past 15 years. Before the creation of the pCPA, some drugs were not recommended by CDA based more on the drug's list price than its value to patients, although the cost-effectiveness threshold was not explicit (CCOHTA 2004; CADTH 2010). The pCPA's establishment has allowed CDA to reduce negative recommendations and pass pricing issues to the pCPA for negotiation with the drug developer (Rawson 2025a). As a result, the rate of positive recommendations increased from just under 47% in 2009 to 90% in 2025. Nevertheless, all positive CDA recommendations have been conditional on clinical criteria and/or a price condition during the past five years.

Clinical criteria to obtain access to drugs range from requiring prescribers to have experience with the disease being treated to extensive physical and/or genetic tests or an assessment of the patient's condition via a disease-specific questionnaire with results that must satisfy defined criteria. More detailed criteria are frequently based on highly selective conditions used to enrol patients in clinical trials submitted as evidence of efficacy and safety in drug developers' applications to Health Canada and CDA. Access to clinical tests or measures for these criteria may not be available in everyday medical practice in Canada, or the tests are only available in specialized centres requiring patients to travel long distances and pay for accommodation that they may not be able to afford. Furthermore, some clinical criteria seem poorly thought out and do not adequately reflect the complex clinical management of many diseases resulting in clinically inappropriate reimbursement criteria, which have been criticized by both patients and physicians (Begovic 2022; Darke 2024; Zinman et al. 2024). In other cases, the criteria may not account for values meaningful to patients and their quality of life (Darke and Orsulak 2025; Meyer et al. 2026).

The failure to acknowledge patients' value of their quality of life is further demonstrated in HTAs for five medicines (Soliris, Ultomiris, Empaveli, Piasky and Fabhalta) for paroxysmal nocturnal hemoglobinuria, a rare, genetic disease that causes stem cells in the bone marrow to mature into abnormal red blood cells that lack the protein protecting them from the body's immune system, which destroys them and leaves the sufferer at risk of life-threatening illnesses. Each PNH drug has an improved mode of administration from intravenous (IV) infusion to subcutaneous administration to taking orally that has enhanced patients' quality of life. CDA's recommendation for IV infusion Soliris was do not reimburse, partly because its cost was considered to be "exceptionally high" (CADTH 2010), although the manufacturer later successfully negotiated a price with the pCPA for Soliris, which is now funded on an exceptional basis by all provincial government drug plans. The other drugs have received recommendations to reimburse with conditions, but no

price premium was recommended to acknowledge the progressive advantages in administration. Nevertheless, Ultomiris and Empaveli have exceptional status coverage in most provinces and the price for Piasky has been successfully negotiated with the pCPA. However, the pCPA negotiation for oral Fabhalta concluded without agreement – perhaps because the benefit to patients' quality of life of being taken orally and not requiring attendance at a health care facility (Bienz et al. 2026) at additional cost to the health care system is not recognized by a price premium in Canada. In contrast to patients in several other countries, Canadians with PNH are unlikely to be able to access Fabhalta through government drug plans for the foreseeable future.

In apparent response to criticisms of the length of time CDA takes to complete its HTAs, the agency is proposing to "streamline" its review process. CDA plans to have a 180-day target for the time between submission acceptance and final recommendation "to provide a predictable process and support timelier patient access to new drugs" (CDA 2026b), which will be accomplished by eliminating the draft recommendation in each HTA and going straight to a final recommendation with an undefined embargo period for the sponsor. In CDA's present system, no performance standard exists for actions after draft recommendations are sent to sponsors and government drug plans; this stage can be protracted when sponsors request reconsideration, which is currently an informal process. CDA's procedure manual indicates that reconsiderations add two to three months (CDA 2025), although at least half of the reconsiderations in 2021 to 2025 exceeded four months, while 10% took longer than 5.5 months. CDA is proposing to formalize the reconsideration process as a new project with a performance standard of 150 days. The sponsor's reason for reconsideration and review reports on the reconsideration will be published and input from patient and clinician groups considered by CDA and its expert committee and included in the reports. Reconsiderations will not allow the submission of new data from the sponsor. Sponsors must submit new data via the resubmission process.

CDA plans to extend the period before each HTA when patient and clinician groups can submit their views on the health issue, current treatment and the new drug to allow more time for these groups to collect and submit input. These stakeholders presently have an opportunity to provide feedback on draft recommendations (it is not shared with the review committee) and will continue to have an opportunity after the final recommendation in the proposed change, but feedback will not be shared with the review committee unless the sponsor requests reconsideration. CDA reports and documents commonly feature the phrase "stakeholder engagement." Real engagement of patients and their doctors would mean that their concerns are implemented in CDA recommendations, even if they conflict with government priorities. If engagement amounts to "busy work" for patients and clinicians, it is just tokenism

The planned CDA changes beg the question: what is different? CDA is stopping reviews at what is now the draft recommendation stage with an embargo period for sponsors. This will allow CDA to achieve its 180-day target between submission acceptance and final recommendation and counter complaints that the agency takes longer than its performance standard. The current reconsideration opportunity for sponsors, which extends review times beyond 180 days, will be transferred to a formal process with a separate performance standard of 150 days and, unlike at present, reasons for reconsideration will be published. However, the end result will be little different from the current situation because the time between submission acceptance and final recommendation for 90% of the drugs with reconsiderations during the past five years was over 11 months – the same as the sum of the proposed 180-day review and 150-day reconsideration standards. Sponsors with drugs receiving a positive recommendation who want reconsideration of clinical criteria or price condition may be deterred from requesting reconsideration by the additional time required for the process before the drug can move to the next gatekeeper (the pCPA), while sponsors with drugs receiving a negative recommendation and wanting it reconsidered will find that the process continues to take 11 months or more and, based on evidence from the past five years, CDA's recommendation is extremely unlikely to change.

CDA's proposed changes do not include reducing the number of reimbursement recommendations with conditions or addressing the deficiencies of the use of QALYs. QALYs use an arbitrary, linear scale between zero representing death and one representing perfect health as a measure of an individual's quality and quantity of health. In reality, health is a complex, multi-dimensional and non-linear physical, psychological and social state (Pettitt et al. 2016; Prieto and Sacristán 2003; Sawhney et al. 2023). QALYs are inconsistent with the real world and patient impact and they fail to consider the potential benefit of a therapy on other health care or societal costs (Binder et al. 2022; Radu et al. 2026; Rawson and Adams 2025; Stewart et al. 2024).

The changes also do not raise the cost-effectiveness threshold above $50,000 per QALY. A $50,000 threshold does not work well for modern medicines, given increases in longevity and population health. CDA's HTA reports frequently include recommendations for price reductions of 70% to over 90% to achieve $50,000 per QALY (Rawson 2021; Balijepalli et al. 2024). The reality is CDA's use of a $50,000 per QALY threshold first proposed in 1990 (Grosse 2008) has never been adjusted for inflation, economic growth, severity or rarity of disease or the significant increase in research, production and regulatory costs of innovative medicines in the last four decades. It is not fit for its purpose.

Many Canadians would place a much higher value on healthy life. The failure to increase the threshold is concerning because, out of 23 countries with an identifiable cost-effectiveness threshold for medicines (mostly European but also Australia, Canada, Japan and South Korea), Canada's threshold ranks fifteenth lowest, with only Bulgaria, Australia, the United Kingdom, Greece, Portugal, Slovenia, Norway and Croatia ranking lower (ABPI 2026). Canadian governments and academics have long complained that medicine prices in Canada are among the highest in the world and worked to control them, despite Canada's medication spending being proportionately lower and growing more slowly than most other health care sectors (Jeffcott 2026) and Canada being one of only six of 23 industrialized countries where the cost per QALY threshold is substantially lower than their GDP per capita, a key measure of ability to pay (ABPI 2026).

The global market for pharmaceuticals is entering an era of uncertainty with President Trump's Executive Order and proclamation (HHS 2025; Trump 2026) to lower prices of medicines in the United States by establishing the MFN pricing policy and returning the development and production of medicines to the United States by lower tariff rates for pharmaceutical companies willing to make the change. Executive orders can be overturned, but Trump is trying to get Congress to pass a law to ensure his policies continue past his presidency. Canadian governments have a choice; they can hope to outlast Trump's administration and continue to under-value and under-invest in pharmaceutical innovation, resulting in fewer medicines being launched in Canada than already occurs and even longer delays to access the drugs that are launched here, or face up to higher prices, recognize the benefits innovative medicines can bring to patients and the health care system and substantially increase investment in life sciences in Canada.

Some may believe the threat to access to medicines in Canada is not real, but they should look to Europe where early evidence indicates a decrease in the number of launches of innovative medicines and an increase in the number of withdrawals of branded drugs from the market (Fick et al. 2026; Gurung 2026). Launches of drugs are being delayed and others are being withdrawn due to President Trump's policy. For example, the developer of Brinsupri, the first and only treatment for non-cystic fibrosis bronchiectasis (a serious chronic lung disease), is delaying the drug's launch in Europe and Japan until further clarity on the MFN policy becomes available (Bruce 2026). In Denmark, the manufacturer of Repatha used to treat high cholesterol has withdrawn the drug to avoid being penalized in the United States (Kleja 2026; Skeem et al. 2026) and more drugs are likely to be withdrawn in small wealthy countries like Denmark and Switzerland (Plüss and Turuban 2026) as a result of the MFN policy. Any other country in the MFN comparison group that negotiates low drug prices is at risk of delayed or denied access to new medicines or withdrawals of already marketed drugs.

Canada's governments are adept at using its gatekeepers to extract price concessions through extensive and overlapping reviews, slow price negotiations and other processes to control medicine prices (Rawson and Adams 2025), but they are less able or willing to improve the speed, methodological flaws, predictability and administrative coherence of their processes. This situation already creates uncertainty for drug developers, which has led to them placing a low priority on launching new medicines in Canada or not introducing them here at all (Rawson 2023; Skinner 2025) as well as reducing manufacturing and R&D in Canada. Even when developers decide to launch a medicine here, the process through CDA and the other gatekeepers takes too long. Furthermore, successful passage through CDA and the pCPA does not guarantee that federal, provincial and territorial drug plans' reimbursement processes will result in the drug being added to their benefit lists without restrictive access conditions (often based on criteria used in premarketing experimental trials), which limit patient access (Rawson 2025b). Trump's MFN policy will only make the position worse.

LIMITATIONS

The analyses in this article depend on the quality and detail of the CDA reimbursement recommendation reports whose structure and contents have varied over time as CDA has evolved.

CONCLUSIONS

Trends in CDA reimbursement recommendations show that they take too long and, in recent years, are always conditional on clinical criteria and/or significant price reductions using a low cost-effectiveness threshold. CDA is proposing some modifications to its process, but these are unlikely to lead to real change. Effective change would reduce reviews to three months in total (this is possible; submission acceptance to draft recommendation took less than 99 days for 90% of non-oncology reviews issued between 2016 and 2019) and would ensure that feedback from patients and expert clinicians is heavily weighted in HTAs. It would also use clinical criteria that can be achieved in everyday medical practice instead of criteria developed by experimental researchers for premarketing clinical trials that may not be meaningful to patients. In addition, much higher and flexible cost-effectiveness thresholds would be used for innovative treatments for diseases that are rapidly fatal and/or severely debilitating.

Canadians are already concerned about delays and denials of access to innovative medicines. They cannot afford to wait and see how actions in the United States play out. We already know that current processes mean patients die or become devastatingly debilitated while waiting for access to medicines (Faubert 2026). Global drug pricing pressures are not going away. The federal government

recently announced the creation of the Pharmaceutical and Life Sciences Sector Task Force (Government of Canada 2026) to explore innovative, made-in-Canada solutions to enhance competitiveness and long-term growth to support reliable and sustainable access to pharmaceutical products in Canada. However, this will have little effect unless governments are prepared to change their policies to recognize the value of innovative medicines and fundamentally restructure CDA, the pCPA and their own processes for listing drugs in their formularies with the aim of getting new medicines to patients as quickly as possible without unnecessary barriers (Bourbara 2026). Canadians need their governments to do more than nibble around the edges by taking fundamental action to minimize the delays and complexities of the current system to ensure patients receive the best and most appropriate medicines for their health problems as rapidly as possible.

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APPENDIX

Table 1: Median and interquartile range of recommended percentage price reductions by drug type, 2016-2025.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Oncology drugs:										
Median	-	-	-	-	75.0	73.5	70.0	75.0	81.0	68.5
Interquartile range					62.5-83.5	46.5-92.3	39.5-89.3	54.0-83.0	68.5-87.3	32.5-86.3
Non-oncology drugs:										
Median	52.0	80.0	42.5	78.0	68.5	71.0	70.0	74.0	77.5	77.0
Interquartile range	32.0-74.3	55.0-90.0	20.5-78.0	70.3-99.5	54.3-90.0	40.0-85.0	42.3-92.8	54.5-93.5	54.3-96.6	61.0-90.0

Table 2: Median and interquartile range (IQR) of durations in days of three components of CDA reviews by drug type, 2016-2025.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Submission to acceptance										
All drugs:										
Median	14	14	14	14	15	14	14	14	15	14
IQR	14-14	13-14	7-15	14-15	14-15	14-19	14-15	14-15	14-15	14-15
Oncology drugs:										
Median	7	7	7	14	15	15	14	15	15	14
IQR	7-11	7-14	7-7	14-15	14-17	14-22	14-15	14-17	14-16	14-15
Non-oncology drugs:										
Median	14	14	14	14	14	14	14	14	15	15
IQR	14-15	14-15	14-17	14-15	14-15	14-15	14-15	14-15	14-15	14-17
Acceptance to draft recommendation										
All drugs:										
Median	89	90	97	115	130	154	148	148	147	151
IQR	78-121	81-138	79-145	84-150	82-170	144-168	141-165	144-160	144-161	144-167
Oncology drugs:										
Median	129	146	153	149	169	164	146	153	147	148
IQR	123-144	136-164	137-161	137-157	157-175	147-171	140-159	144-165	144-166	142-166
Non-oncology drugs:										
Median	83	82	81	84	83	147	152	147	147	152
IQR	77-89	78-87	77-92	79-88	77-91	143-160	144-170	145-154	144-160	146-173
Draft to final recommendation										
All drugs:										
Median	82	82	85	64	82	55	38	41	38	37
IQR	63-95	63-91	63-96	61-108	59-181	36-69	37-117	37-115	37-44	36-44
Oncology drugs:										
Median	57	56	56	62	56	56	38	40	38	37
IQR	55-63	20-63	20-63	55-63	20-63	52-60	36-115	37-45	37-44	36-40
Non-oncology drugs:										
Median	88	89	91	123	161	37	38	42	38	42
IQR	82-105	82-132	85-125	84-170	92-218	35-96	37-112	37-121	36-77	36-119