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ORIGINAL RESEARCH

Timeliness of Health Technology Assessments and Price Negotiations for Oncology Drugs in Canada

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Purpose: To evaluate whether time targets for Canadian Agency for Drugs and Technologies in Health (CADTH) reimbursement reviews and pan-Canadian Pharmaceutical Alliance (pCPA) price negotiations are being achieved for oncology drugs.

Materials and Methods: Recommendations, dates of submission and publication, and indications for oncology medicines issued between January 2014 and December 2023 were recorded from CADTH's reimbursement reports webpage. The date any negotiation began and the date it was completed (successfully or not), or when a decision was made not to pursue negotiation was extracted from the pCPA's webpage. The duration of each CADTH review and pCPA negotiation was calculated, together with time between CADTH's recommendation and start of the pCPA negotiation or a decision not to negotiate. Percentages of reviews completed within CADTH's target and of times taken by the pCPA to decide whether to negotiate and by its price negotiations completed within the relevant targets were calculated.

Results: CADTH achieved its 270-days target in 88.2% to 100% of reviews issued between 2015 and 2019 but only in 65.9% to 73.1% of reviews issued in the last three years of the decade. CADTH's "typical timeline" of 180 days was achieved in under 40% of reviews issued in 2015 and not attained in any review in 2021, 2022 or 2023. The pCPA's target of 60 days for deciding whether to negotiate was achieved for all recommendations issued in 2014 but dropped below 40% for the last seven years of the decade; its target of 130 days for negotiations was achieved for over 85% of the recommendations in 2014 but decreased to only 14.3% in 2016 and then gradually increased to 61.5% in 2023.

Conclusion: CADTH's "typical timeline" and the pCPA's targets were not met sufficiently to be meaningful. Their processes take too long for cancer drugs.

Plain language summary: Canadian patients and providers are often frustrated and concerned about the timeliness of the country's health technology assessment (HTA) and price negotiation processes, especially for cancer drugs. HTAs are carried out to evaluate the benefit of a medicine in comparison with its cost to see whether the drug is of sufficient value to add it to the benefit lists of government drug plans. HTAs are performed by the Canadian Agency for Drugs and Technologies in Health (CADTH) for all of Canada, except the province of Quebec, and price negotiations with drug developers are carried out by the pan-Canadian Pharmaceutical Alliance (pCPA) on behalf of all government drug plans. We used data from the websites of CADTH and the pCPA on HTA reviews of cancer drugs issued between January 2014 and December 2023 and price negotiations for these drugs to assess whether CADTH and the pCPA complied with their stated target times for completing their processes. We found that CADTH's reviews and the pCPA's price negotiations failed to meet their targets for cancer drugs in the past 10 years and that the timeliness of their performance has, in most cases, deteriorated. HTA and price negotiation processes for cancer drugs take too long in Canada.

Keywords: oncology drugs, health technology assessment, drug prices, Canada

Introduction

Cancer continues to be a scourge in Canada.[1] Two in five Canadians are expected to be diagnosed with cancer in their lifetime and about one in four will die from the disease.[2] The impact of cancer is felt not only in lives lost.[3–6] The

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economic burden of cancer in Canada has been estimated from a societal perspective to be $26.2 billion, of which almost a third is borne by patients and their families.[7]

In recent years, effective new therapies for cancers have been developed[8–10] that can advance treatment beyond decades-old surgery, radiation and chemotherapy or the "cut, burn and chemo" era.[11] Cancer drugs are given to cure in some cases or to modify the patient's disease or symptoms, which may prolong their lives. However, medicines are only of benefit if they are accessible.[12]

Several obstacles to accessing new drugs exist in Canada.[1,13–16] These include government-controlled health technology assessments (HTAs) and price negotiations, government drug plan gatekeepers taking much time to list drugs in their formularies,[17,18] and stringent criteria and out-of-pocket costs that patients must satisfy to gain coverage for medicines even after they are listed.[12] HTAs are performed by the Canadian Agency for Drugs and Technologies in Health (CADTH) for all of Canada, except the province of Quebec.[19] CADTH's roots go back to 1989 when the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) was funded by federal, provincial and territorial governments to focus on medical devices. CCOHTA became CADTH in 2006, with a $2 million budget (Canadian dollars are reported throughout this article), and was expanded to include drugs.[20] CADTH is now a large organization with over 220 staff[21] and a budget of $50 million, with 83% of its revenue coming from federal (81.5%) and provincial (18.5%) governments.[22] Salaries account for $33 million and, because CADTH engages many paid academic contractors, $6 million is spent on professional fees.[22]

Price negotiations with drug developers are carried out by the pan-Canadian Pharmaceutical Alliance (pCPA) on behalf of all federal, provincial and territorial drug plans.[23] The pCPA was created by the premiers of Canada's provinces and territories in August 2010 with the aim of achieving greater value for publicly funded drug programs and patients through the combined negotiating power of participating jurisdictions.[23] In 2015, a new mandate and objectives were developed and a governance structure implemented. Quebec and federal drug plans joined the pCPA in 2015 and 2016, respectively. Following an organizational review in 2019, the pCPA became a standalone incorporated organization in 2022 and issued its inaugural report in 2023,[24] although it provides no information on negotiations performed, staffing or financial statements, which are only available by request (a request remains unanswered after six months). The pCPA has been criticized for its lack of transparency since it was established.[25,26]

In its procedures document for reimbursement reviews, CADTH states that the "typical timeline" for reviews is "≤180 calendar days" (six months), although in the same document, the agency provides target timelines for each individual process that sum to 178 to 192 business days, which is equivalent to 270 calendar days (nine months).[27] The pCPA process begins once a recommendation for a drug is issued by CADTH, with the recommendation and other factors being used to determine whether or not to enter into a price negotiation.[28] Medicines with a positive reimbursement recommendation from CADTH do not automatically enter the negotiation process. The pCPA has a target completion time of up to 40 business days (60 calendar days) from the HTA recommendation date to decide whether or not to engage in price bargaining and, once the pCPA has decided to negotiate, it has a target time of up to 90 business days (130 calendar days) in which to complete the negotiation.[28]

Health professionals want to be able to prescribe what they consider to be optimal therapy for their patients as soon as the drugs are available and patients are concerned that their access is not delayed.[15,29–31] Delays due to processes like HTAs and price negotiations exacerbate these concerns. The objective of this work was to evaluate whether the CADTH and pCPA time standards are achieved for oncology therapies with a reimbursement recommendation issued during the 10-year period, January 2014 to December 2023.

Materials and Methods

For each reimbursement recommendation for an oncology medicine issued during the decade, the CADTH project number, the recommendation, the dates of submission and publication of the recommendation, the drug's indication, whether the submission included data from at least one randomized clinical trial, and whether any percentage price reduction was recommended to achieve a cost-effectiveness threshold of $50,000 per quality-adjusted life-year (QALY) were recorded from CADTH's reimbursement review reports webpage.[32] The pCPA's webpage on brand name drug negotiations was then used to extract information on the status of any negotiation for the drug and indication, including the date the negotiation began and the date it was successfully completed or ended without success, or when a decision

was made not to pursue a negotiation, by March 31, 2024.[33] The CADTH project number was used to ensure the correct pCPA record was identified.

The duration of each CADTH review and each pCPA negotiation was calculated, together with the time between publication of CADTH's recommendation and start of the pCPA negotiation or a decision not to negotiate. All times were calculated in calendar days.

We then calculated percentages of (a) CADTH reviews completed within both the 180-day "typical timeline" and the 270-day target, (b) times taken by the pCPA to decide whether to negotiate within the 60-day target, and (c) pCPA negotiations completed within the 130-day target, both for the 10-year period and by the year in which the recommendations were issued. In addition, for the same metrics, we calculated the number of days representing the 90th percentile period, ie the number of days within which 90% of the reviews or negotiations were completed. If the performance targets are to be meaningful, 90% of the review and negotiation times should be within them.

We also examined whether having data from a randomized clinical trial in the submission to CADTH was associated with a shorter review time and whether the length of the pCPA negotiation was impacted by a 70% or greater CADTH-recommended price reduction to achieve the cost-effectiveness threshold of $50,000 per QALY.

Results

Two hundred and forty-eight recommendations for oncology medicines were issued by CADTH between January 2014 and December 2023 (Table S1). The number of individual drugs was 117 of which 62 (53.0%) had only one CADTH recommendation; 30 (25.6%) had two, 12 (10.3%) had three, three (2.6%) had four, and seven (6.0%) had five. The remaining two medicines (nivolumab and pembrolizumab) had 15 and 22 recommendations, respectively. Most recommendations (200; 80.6%) were to reimburse the medicines with or without clinical criteria or conditions.

More than half of the drugs (64.9%) were indicated for leukemias, lung cancer, lymphomas, breast cancer, hepatocellular, renal cell and urothelial carcinomas, and multiple myeloma. Overall, 82.7% of CADTH review times were within the 270-day target, but only 9.3% were within the 180-day "typical timeline". Over 70% of the review times for all cancer types were within the 270-day target (Table 1), whereas review times within the 180-day timeline varied from 0.0% for drugs for

Table 1 Percentage Achieving Target Times for CADTH Reviews and pCPA Processes and 90th Percentile Times by Cancer Type

Cancer Type	No. of CADTH Recommendations	CADTH			pCPA			
		Review Times ≤180 days	Review Times ≤270 days	90th Percentile of Review Times (days)	Decision Times ≤60 days	90th Percentile of Decision Times (days)	Negotiations ≤130 days	90th Percentile of Negotiation Times (Days)
All types	248	9.3%	82.7%	303	37.8%	198	42.1%	313
Breast	22	4.5%	81.8%	283	31.8%	183	47.4%	226
Colorectal	10	10.0%	90.0%	246	70.0%	198	40.0%	554
Gastrointestinal/ esophageal/pancreatic	14	0.0%	85.7%	267	35.7%	192	46.2%	296
Hepatocellular/renal cell/urothelial	19	15.8%	94.7%	247	26.3%	174	40.0%	245
Leukemias	40	10.0%	87.5%	277	43.6%	158	35.5%	258
Lung cancer	39	5.1%	74.4%	330	28.9%	211	48.4%	275
Lymphoma	24	8.3%	70.8%	312	25.0%	239	50.0%	357
Melanoma	13	23.1%	92.3%	253	58.3%	125	41.7%	271
Multiple myeloma	17	5.9%	94.1%	234	29.4%	383	0.0%	420
Ovarian/cervical/ endometrial	12	8.3%	83.3%	312	63.6%	97	44.4%	297
Prostate	11	0.0%	81.8%	452	22.2%	199	50.0%	285
Thyroid	6	16.7%	83.3%	288	33.3%	185	40.0%	139
Other	21	19.0%	71.4%	306	50.0%	144	53.3%	371

Abbreviations: CADTH, Canadian Agency for Drugs and Technologies in Health; pCPA, pan-Canadian Pharmaceutical Alliance.

gastrointestinal, esophageal, pancreatic and prostate cancers to 23.1% for drugs for melanomas. Overall, 37.8% of the times between CADTH recommendation and the pCPA deciding whether to pursue a price negotiation were within the 60-day target, but the rate varied from 22.2% for prostate cancer drugs to 70.0% for colorectal cancer drugs (Table 1). The pCPA negotiation times were within the 130-day target for 42.1% of the recommendations; the rate for most cancer drugs was between 35.5% and 53.3%, but for multiple myeloma drugs, it was 0.0%.

The number of oncology drug recommendations by year varied from 10 in 2014 to 41 in 2022. Between 2014 and 2018, 91 recommendations (36.7%) were issued compared with 157 (63.3%) between 2019 and 2023. By year, CADTH review times achieving the 270-day target was 88.2% to 100% between 2015 and 2019, but the rate then decreased to 65.9% in 2022; in 2023, it increased to 73.1% (Figure 1). The deterioration in the rate was due to more CADTH reviews taking longer from 2018 onwards, as demonstrated by the increase in the 90th percentile of the review times. The 180-day "typical timeline" was met in only 39.1% of the reviews issued in 2015 and not achieved in any review issued in 2021, 2022 or 2023.

The time taken by the pCPA to decide whether to negotiate the price with the manufacturer was within the 60-day target for all oncology drugs with CADTH recommendations in 2014, but the rate sharply decreased to 27.3% in 2018 and remained below 36% until the end of the decade (Figure 2). The pCPA took over 196 days (6.5 months) in 2018 and 2020 to 2023 to decide whether to negotiate for 90% of the drugs.

Almost 86% of pCPA negotiations for oncology medicines with reimbursement recommendations in 2014 were within the 130-day target. The rate fell to 14.3% for drugs with recommendations in 2016 but then increased so that, by 2023, it was 61.5% (Figure 3). This change is reflected in the shorter 90th percentile of negotiation times in 2019 to 2023. Nevertheless, almost 30% of the negotiations for oncology medicines with CADTH recommendations in 2023 took longer than the 130-day target.

Fifty-seven (23.0%) submissions to CADTH did not include data from a randomized clinical trial and had significantly (p=0.021) longer review times (median: 224 days; inter-quartile range: 203–283 days) than the 151 submissions with data from a randomized trial (median: 213 days; inter-quartile range: 195–237 days). Submissions without randomized trial data were much more likely to receive a negative recommendation from CADTH (36.8% versus 14.1%; p=0.0003).

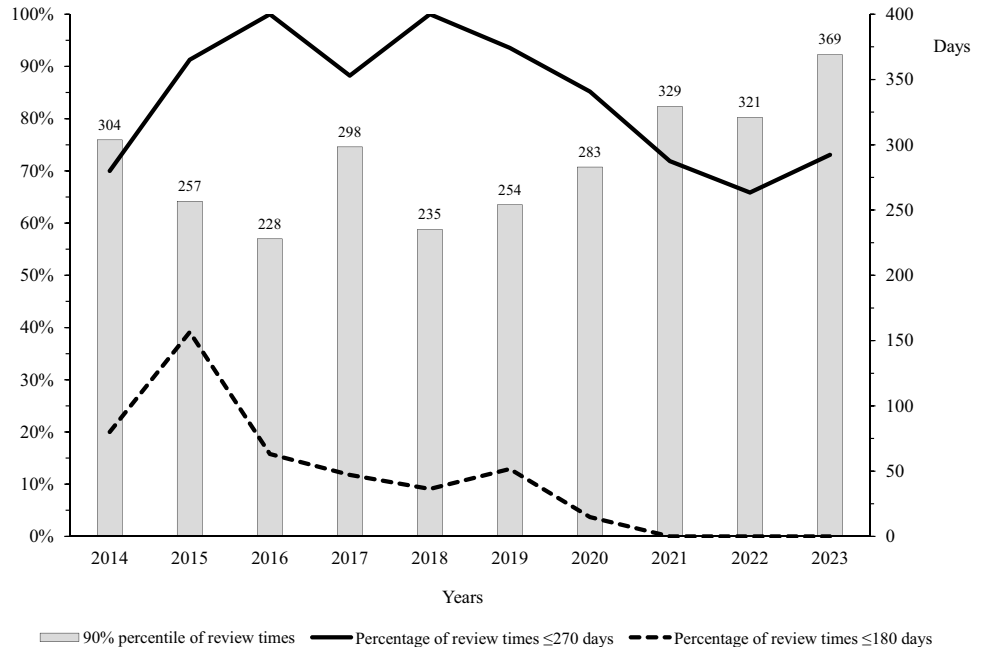

Figure 1 Reimbursement review times by year: percentage within 180 and 270-day targets and 90th percentile of review times.

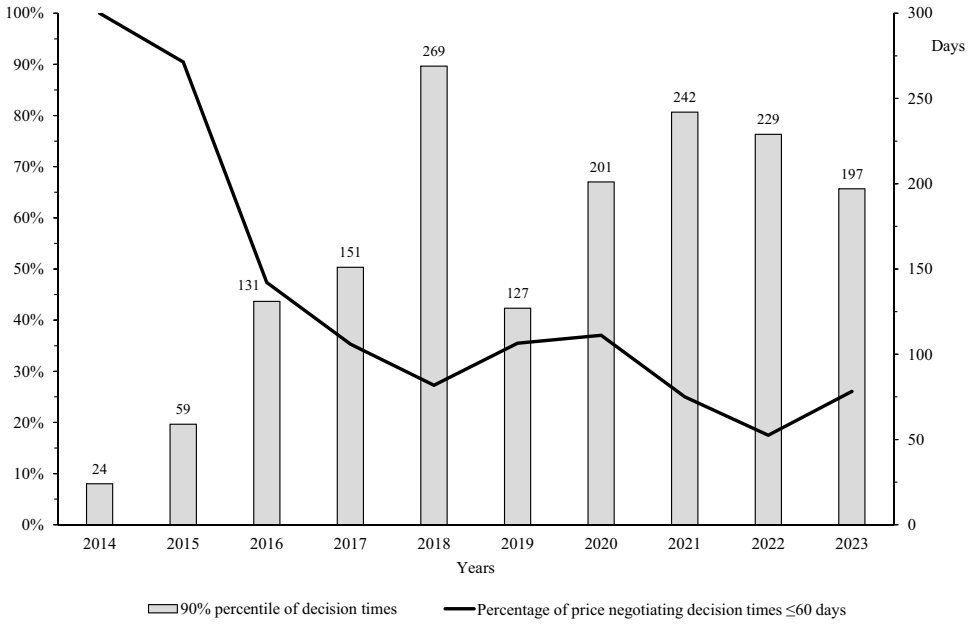

Figure 2 Price negotiation decision times by year: percentage within 60-day target and 90th percentile of decision times.

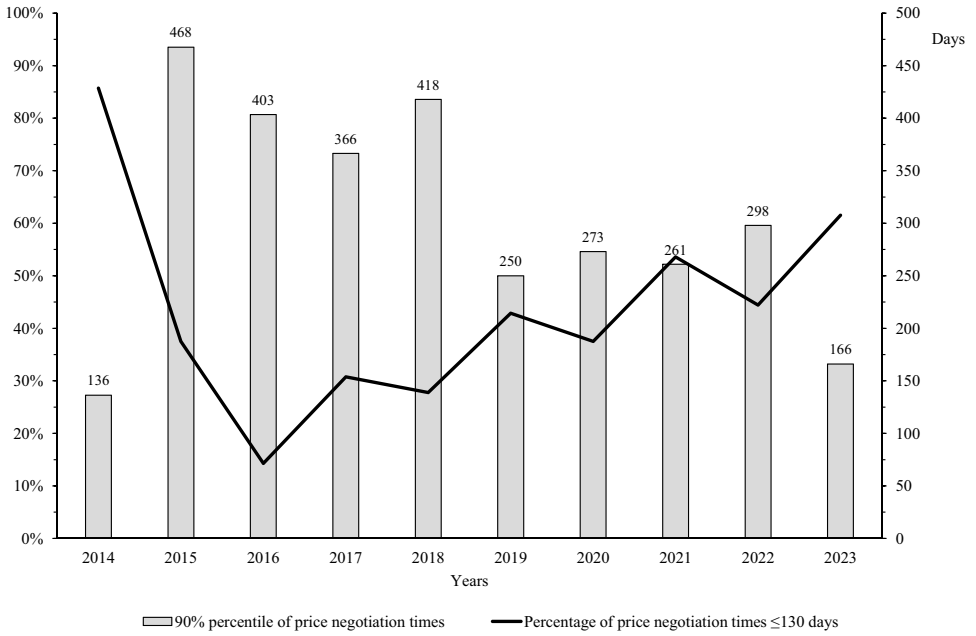

Figure 3 Price negotiation times by year: percentage within 130-day target and 90th percentile of price negotiation times.

Since late 2020, CADTH reviews of oncology medicines have regularly included a recommendation for a specific percentage price reduction to achieve a $50,000 per QALY threshold.[34] Eighty-eight reviews in this analysis had this type of recommendation. The median negotiation time for the 55 reviews (62.5%) with a recommendation for a price reduction of 70% or more was 145 days (inter-quartile range: 100–213 days), whereas the median for the 33 reviews (37.5%) with a lower price reduction recommendation was 78 days (inter-quartile range: 11–133 days) (p=0.0009).

Discussion

Performance time standards are established to provide a target for an organization and its staff to aim towards and a benchmark with which external stakeholders can evaluate the organization's efficiency. However, if a target is just something an organization repeatedly states but rarely achieves, it is meaningless. Drug regulatory agencies in several countries, including Canada,[35] have performance standards that they generally accomplish each year. There is no reason why agencies like CADTH and the pCPA should not have clearly specified performance targets that they achieve 90% or more of the time, especially for life-saving medications like oncology drugs. If their targets were truly what CADTH and the pCPA claim, 90% of CADTH's reimbursement reviews would be completed within 270 days, 90% of the pCPA's decisions whether to pursue a price negotiation would be completed within 60 days, and 90% of the pCPA's price negotiations would be completed within 130 days.

However, our analysis demonstrates that these targets were not met for oncology medicines in the past decade and, furthermore, that CADTH's and the pCPA's performance has deteriorated, despite a modest rebound in the timeliness of pCPA negotiations. Overall, in the decade, 90% of CADTH reviews were completed within 10 months (close to the nine-month target but not the six months commonly cited), 90% of the pCPA's decisions about whether to pursue a price negotiation were made within six to seven months (not two months), and 90% of the pCPA's price negotiations were completed within 10 months (not four months). These are the agencies' de facto performance standards.

Neither CADTH nor the pCPA provide the level of accountability to external stakeholders – manufacturers that pay for the reviews (CADTH's review fees range from $49,810 to $174,180[36]) and patients needing access to the medicines – that they should be able to expect. Accountability is a fundamental principle of good governance.[37]

Transparency is another key governance principle[37] and again neither agency does well. CADTH and the pCPA have not explained why they are failing to achieve their stated targets. In fact, CADTH and others[18,38] perpetuate the myth that the "typical timeline" for its reimbursement reviews is ≤180 calendar days, when no review – whether for an oncology medicine or any other medicine[39] – was completed within this time in 2021, 2022 or 2023.

Accountability and transparency require processes to report, explain and answer for the consequences of decisions so that all stakeholders can see how and why the decisions were taken.[37] Every stakeholder should also have an opportunity to improve their wellbeing by participating throughout the process and having a voice in decision-making. Patients and providers are often frustrated and concerned about the lack of transparency in CADTH's and the pCPA's processes.[29–31,40,41] CADTH and the pCPA are both non-profit corporations, not government departments. As such, they do the work for governments, but the traditional accountability tools and requirements of freedom of information requests, independent ombudsperson appeals, and parliamentary auditor-general performance reviews do not apply to them.

Could other factors have influenced HTAs and price negotiations over the decade? The most obvious is the COVID-19 pandemic. Although this may have slowed CADTH recommendations, the deterioration in pCPA activities began well before the pandemic was declared. The numbers of oncology medicines reviewed by CADTH and negotiated by the pCPA in the second half of the decade was 72% higher than the numbers in the first half. This increase could have led to a slow-down in performance due to increased workload. Nevertheless, CADTH should have been able to manage because its financial resources just over the years between 2020 (the earliest year available) and 2023 increased by about 40%.[22] The lack of transparency in pCPA finances makes a similar comparison impossible.

The absence of data from a randomized clinical trial in submissions to CADTH increases the chance that the review will take longer because reviewers are more likely to be concerned about the efficacy of the medicine.[42] The same data that were submitted to CADTH would probably have been in the submission to Health Canada for regulatory review of efficacy, safety and quality, because it is unlikely that a multinational biopharmaceutical company would perform a separate trial specifically for a moderate-sized country like Canada. Consequently, when assessing a drug's benefit, CADTH is most likely duplicating work already done by Health Canada. When CADTH reviewers doubt the efficacy of a drug, they are delaying patient access to second-guess Health Canada's assessors.

Drug prices have increased rapidly over the past decade, but this should not impact the duration of CADTH reviews. Higher prices may have led to recommendations from CADTH for steeper price reductions which, in turn, may have

resulted in longer price negotiations. However, this appears to have had only limited impact because the percentage of price negotiations being completed within the pCPA's target increased within the last few years.

Recommendations

Our analysis quantified the failure of CADTH and the pCPA to meet their performance time targets. Qualitative research into the CADTH and pCPA processes are recommended to identify reasons for this under-performance. An in-depth audit of a number of oncology medicines as they move through the agencies' processes should be performed.

Meanwhile, CADTH and the pCPA should implement measures to achieve their performance standards and there should be financial consequences if they fail to do so.

Delays between positive CADTH recommendations for oncology drugs and the start of pCPA negotiations have increased dramatically over the past decade, which is time wasted between processes that slows access to new medicines for no valid reason. The pCPA should be required to automatically undertake a price negotiation with the manufacturer of an oncology drug that receives a positive CADTH reimbursement recommendation and to start the negotiation within a much shorter period than 40 business days.

More radically, we recommend that Canada should – as some countries do – make new oncology drugs available to Canadians who need them while reimbursement reviews and other assessments are pursued. This would not only allow earlier access to new oncology drugs but also provide regulatory and HTA agencies with valid real-world data on their effectiveness and safety.[43] Patients and their health care providers are more appropriate to decide on benefits and risks than a HTA organization trying to predict the benefits of drugs in everyday clinical practice from premarketing trials.

Conclusions

CADTH and the pCPA have been aligning their processes for over 10 years,[44] but this has yet to accelerate Canadians' access to medicines through government drug plans.[45] Canadians with cancer not only have to wait for CADTH and the pCPA to perform their work but then have to wait even longer before drugs are listed on government drug plan formularies and accessible.[12,17] Overall, Canada takes an average of two years to initiate public funding for medications that have been approved by Health Canada – a delay in public funding that is twice as long as in peer Organization for Economic Cooperation and Development countries.[46] The results of our analysis demonstrate that, instead of CADTH and the pCPA completing their processes in a year, they are taking over two years for many oncology medicines, which can include months between a positive reimbursement recommendation being issued and a decision being made to pursue a price negotiation.

Many calls have been made for Canada to reduce delays in patient access to new oncology medicines via government drug plans.[3–5,11,12,15,29–31,47] Canada's governments have established HTA and price negotiation organizations and allowed them to develop procedures without accountable performance targets. Even when a drug has passed through these processes, government drug plans do not automatically list the medicine, leading to further delays.[12,17] Delays in bringing effective new cancer medicines to Canadians may lead to thousands of lives being lost,[3–5] which is unacceptable.

Abbreviations

CADTH, Canadian Agency for Drugs and Technologies in Health; CCOHTA, Canadian Coordinating Office for Health Technology Assessment; HTA, Health technology assessment; pCPA, pan-Canadian Pharmaceutical Alliance; QALY, Quality-adjusted life-year.

Data Sharing Statement

Data were extracted from publicly available sources.[32,33]

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