Has pCODR Improved Access to Oncology Drugs?

Timeliness and provincial acceptance of pan-Canadian Oncology Drug Review recommendations

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Executive summary

Access to new drugs in Canada has been slower than in other countries for decades. Particular concern has been expressed by cancer patients and their advocates and healthcare providers about slow and inequitable access to new oncology drugs, because these can contribute to a significant extension in life. Reports regularly appear in the media about cancer patients pleading with provincial Ministries of Health for financial coverage of new, expensive oncology drugs about which the Ministry has yet to make a decision or which it has declined to fund.

As a response to these concerns, the pan-Canadian Oncology Drug Review (pCODR) was established in late 2010 by the provincial and territorial Ministries of Health, excluding Quebec, to assess the clinical and cost-effectiveness information of new oncology drugs, with the aim of bringing consistency and clarity to the assessment of these drugs (Quebec does not participate in the pCODR as the province completes its own reviews). This report evaluates how successful the pCODR has been in achieving its performance target of 129–149 business days (approximately 185–215 calendar days) to complete reviews, and examines the funding decisions made by the provinces for drugs with pCODR recommendations.

32 submissions to the pCODR relating to 25 oncology drugs were reviewed, of which 26 (81 percent) received a favourable, if conditional, recommendation from the pCODR. However, 50 percent of the submissions took 6–7 months to be reviewed and 50 percent took even more time (total range: 112 to 282 days), which exceeds the 5–8 months to complete reviews claimed by the pCODR. Nevertheless, there is some consistency in the time required for pCODR assessments, which at least allows manufacturers to plan appropriately for negotiations with the provinces. Moreover, the pCODR provides the opportunity for manufacturers to submit their drugs within the six months prior to the anticipated date of the Notice of Compliance (NOC: marketing approval from Health Canada) and there is a clear benefit in terms of reducing the time between NOC receipt and pCODR's final recommendation if the manufacturer takes advantage of this opportunity. The time between NOC and final recommendation was between 55 and 182 days for

pre-NOC submissions to pCODR compared with 194 to 386 days for post-NOC submissions.

The provinces are not bound by recommendations made by the pCODR and, for drugs with pCODR recommendations, the proportion approved for funding by the provinces ranged from less than 10 percent in Prince Edward Island to around 80 percent in Saskatchewan and Ontario. For drugs approved for coverage after pCODR's final recommendation, the time required for provincial approval varied from 5 to 11 months. Therefore, despite a favourable pCODR recommendation, there continues to be wide variation in the number of new oncology drugs approved for coverage by the provinces and, for those that are approved, in the time required for the approval decision.

When compared with a reasonable scenario in which the provinces would be required to approve drugs with a favourable pCODR recommendation within 120 days of the recommendation, none of the provinces came close to achieving this target. A quarter to a third of the drugs were approved for funding in Saskatchewan and Ontario within 120 days of a favourable recommendation and, if one takes into account the drugs approved for funding before the recommendation, British Columbia can be included in this group. In the other provinces, 0–13 percent were approved within the 120 day period.

While a negative recommendation generally means "no" to the provinces, a favourable one seems to mean "maybe, possibly, sometime" to several provinces. Little benefit is achieved by having a review process whose stated aim is to bring "consistency and clarity to the assessment of cancer drugs" if many of the provincial and territorial Ministries of Health that established the pCODR delay implementation of or ignore its favourable recommendations. An organization dedicated to reviewing new oncology drugs, which requires resources from the taxpayer and additional effort from pharmaceutical companies, and which duplicates (at least partially) the work performed by other governmental agencies, adds little benefit to the healthcare system or to the quality and duration of the lives of cancer patients if its activities do not lead to improvements in the timeliness and fairness of access to new oncology drugs.

Introduction

For several years, reports have regularly appeared in the media about cancer patients pleading with a provincial Ministry of Health for insurance coverage of new, expensive oncology drugs that may offer a significant extension of life but which the Ministry had yet to approve for funding or had declined to fund (Armstrong, 2014; Benefits Canada, 2014; Criscione, 2014; MacLeod, 2014; *Oakville Beaver*, 2014; Picard, 2009; Sher, 2012). One of the best-known advocates for improved funding of oncology drugs in Ontario was Kimm Fletcher, who made an unsuccessful direct approach to the provincial health minister to seek coverage for Avastin for her brain cancer—Avastin is not covered for this indication in Ontario, but is funded in three other provinces (Blizzard, 2014). Many patients, including Fletcher, have had to seek donations from families, friends, and neighbours to pay for unfunded drugs (*Huffington Post*, 2013; *Oakville Beaver*, 2014), while others have simply gone without.

Delayed access can be due to slower regulatory approval of new drugs by Health Canada (Rawson, 2013a). A 2012 Fraser Institute analysis of 33 new oncology drugs approved for marketing in Canada between 2003 and 2011 showed that only 24 (73 percent) of the 33 drugs received approval from Health Canada, whereas 30 (91 percent) were approved in the United States (Rawson, 2012). Of the six drugs approved in the United States but not in Canada at the time of the report, three subsequently received approval in Canada, 2.5 to 4 years after being approved in the United States, but the other three have not been approved 5 to 10 years after American approval—the reason for the latter three not being approved in Canada is unknown. The median review time for the drugs that were approved in Canada (the time within which 50 percent were approved) was 356 days, compared with 182 days in the United States for the same 24 drugs.

Once a drug has received marketing approval from Health Canada (i.e., a Notice of Compliance (NOC) has been issued to the manufacturer), it can be prescribed by Canadian physicians and purchased by Canadian patients. However, many new drugs, particularly those for oncology indications, are expensive. Consequently, Canadians can frequently only access them if they are covered within their province's hospital service, by public drug insurance provided by their province, or through a private insurance plan. Under

the current provincial drug coverage approval process, a new oncology drug should first receive a favourable recommendation from the pan-Canadian Oncology Drug Review (pCODR) before it is approved by a public insurance program provided by any province, except Quebec.

Pan-Canadian Oncology Drug Review

In an earlier attempt to provide a more consistent approach to the evaluation of new oncology drugs, the assessment of these drugs was transferred, in March 2007, from the Common Drug Review of the Canadian Agency for Drugs and Technologies in Health to an interim cross-jurisdictional review process, known as the Joint Oncology Drug Review (JODR). Under the JODR, new oncology drugs were reviewed by the Ontario Committee to Evaluate Drugs (CED) and the CED-Cancer Care Ontario Subcommittee, using the province's existing review process for cancer drugs (Ontario Ministry of Health and Long-Term Care, 2014). The other provinces, except Quebec, participated in the JODR and had access to the recommendations, but the final funding decision remained the responsibility of each province.

The JODR was replaced by the pCODR in late 2010. The pCODR was established by the provincial and territorial Ministries of Health, which fund and oversee it. Quebec does not participate in the pCODR because it has its own review process. The objectives of the pCODR are to assess the clinical and cost-effectiveness information of new oncology drugs, together with patient perspectives, in an evidence-based review process, and to use the outcome of the review to make recommendations to the provinces and territories to inform their drug funding decisions (Hoch and Sabharwal, 2013). The pCODR review process is designed "to bring consistency and clarity to the assessment of cancer drugs" (pCODR, 2011a) and to include input from clinician groups specializing in the treatment of specific cancers, from pharmaceutical manufacturers, and from patient advocacy groups (pCODR, 2011b).

The pCODR has two procedures to facilitate earlier access to oncology drugs. In the first, the pCODR works with a submitting organization—the manufacturer, pCODR's Provincial Advisory Group (PAG), or clinician-based tumour group—between six and 12 months prior to the actual submission, to assist both the submitter and other stakeholders through the process.[1]

1. The Provincial Advisory Group is a committee whose members come from the provincial Ministries of Health and cancer agencies. A clinician-based tumour group is a group of clinicians affiliated with and recognized by a provincial cancer agency or one of the Ministries of Health working in a specific cancer area.

This presubmission phase includes obtaining input from the PAG, notifying appropriate stakeholder groups of the pending review, determining membership for the Clinical and Economic Guidance Panels, and identifying additional resources and expertise required for the review (pCODR, 2011c). In the second procedure, which can only be used by the manufacturer, a submission may be made before an NOC has been granted by Health Canada if the company's interaction with the regulatory agency indicates that Health Canada is highly likely to approve the NOC within six months of the submission to pCODR being filed. Otherwise, submissions are made after NOC approval and can be submitted by the manufacturer, the PAG, or a clinician-based tumour group.

After receipt of a submission, the pCODR assesses it for completeness and, when the submission has been deemed to be complete, it enters the review process. Drugs receive both a clinical and an economic review; the clinical review consists of a systematic review of the literature regarding the drug performed by the Clinical Guidance Panel and pCODR's Methods Team with input from patient advocacy groups and the PAG, while the economic review summarizes the Economic Guidance Panel's evaluation of the cost-effectiveness evidence in the submission. The results of both reviews are considered, together with adoption feasibility and patient-based values (Hoch and Sabharwal, 2013), by pCODR's Expert Review Committee, which then issues an initial recommendation based on the reviews and patient input. Feedback from the submitter, the PAG, and patient advocacy groups may then be received, after which a final recommendation is issued. A performance target of 129–149 business days (approximately 185–215 calendar days) has been established for the entire process, with a target of 95 business days (about 140 calendar days) for the initial recommendation (pCODR, 2011d), although there is no apparent penalty for failure to meet these targets.

The pCODR may recommend that the drug not be funded, or it may issue a favourable recommendation with or without conditions. Resubmission with new evidence can be made to the pCODR for drugs that receive an unfavourable or conditional recommendation, with the objective of improving the recommendation.

The final pCODR recommendation is made to the participating provincial and territorial Ministries of Health and provincial cancer agencies. However, provinces are not required to follow the recommendation (Hoch and Sabharwal, 2013). The provinces subsequently review the recommendation and perform their own assessment of the drug, which includes the need for the drug in their jurisdiction and its impact on their cancer treatment budget. For each drug reviewed, the pCODR provides, via its website, the rationale for both the initial and final recommendations, the feedback from the submitter, physicians, and patients, and a summary of provincial funding decisions. No information is available on presubmission activities.

Objectives

The objectives of this report are to evaluate how successful the pCODR is in achieving its performance target by examining the reviews completed and published on pCODR's website, and to assess whether the provinces make funding decisions based on pCODR's recommendations—and, if so, how long they take to approve funding. Thus, this analysis measures quantitative aspects of the pCODR review process and adherence to pCODR's recommendations by the provinces.

Results

pCODR review

The pCODR accepted its first submission in mid-2011 and, as of April 30, 2014, had completed reviews of 25 oncology drugs (**table 1**). Five drugs had more than one submission: bendamustine and pazopanib each had three submissions, while brentuximab, crizotinib, and everolimus each had two. Brentuximab and everolimus had submissions for two different indications, bendamustine and pazopanib had submissions for two different indications and a resubmission for one of the indications, and crizotinib had a resubmission. Consequently, 32 submissions were reviewed in this analysis.

15 of the submissions were made before the relevant NOC date (the median time between submission and NOC was 103 days, with a range of 28 days to 180 days prior to the NOC date), and 17 after marketing approval. The 17 post-NOC applications were submitted between six and 2,838 days after marketing approval (median: 84 days post-NOC). The time lag between NOC date and submission to the pCODR was more than a year for five drugs with an NOC date before the pCODR was established, which included bortezomib, the only submission made by a tumour group.[2] One might have expected that there would be more submissions made after NOC approval for drugs submitted soon after the pCODR was established, but there was little difference between submissions made in 2011–2012 and those made in 2013 onwards in terms of the proportion made after NOC approval.

The median time required by the pCODR to review submissions and make its initial recommendation was 141 days, with a range of 112 to 282 days (**table 2**). Adjusting pCODR's 95 business days target for this work to 140 calendar days, only 16 submissions (50.0 percent) met the target, while eight (25.0 percent) took longer than 180 days to complete this stage.

2. The submission was made by the Cancer Care Ontario Hematology Disease Site Group.

Table 1: Submissions of oncology drugs with a final pCODR recommendation, as of April 30, 2014

Generic name	Brand name	Tumour type	Oncology indication	Notice of compliance (NOC) date	Submission date	Difference (days) *
After marketing approval date						
Bortezomib	Velcade	Lymphoma/Myeloma	Multiple myeloma	21 Jan 2005	29 Oct 2012	2,838
Lenalidomide	Revlimid	Lymphoma/Myeloma	Multiple myeloma	17 Jan 2008	5 Apr 2013	1,905
Pazopanib	Votrient	Genitourinary	Metastatic renal cell carcinoma	27 May 2010	14 Jul 2011	413
Pazopanib	Votrient	Genitourinary	Metastatic renal cell carcinoma	27 May 2010	20 Feb 2013	1,000
Lapatanib	Tykerb	Breast	Metastatic breast cancer	30 Sep 2010	14 Dec 2012	806
Sunitinib	Sutent	Gastrointestinal	Pancreatic neuroendocrine tumour	30 Jun 2011	7 Nov 2011	130
Eribulin	Halaven	Breast	Metastatic breast cancer	14 Dec 2011	9 Feb 2012	57
Everolimus	Afinitor	Gastrointestinal	Pancreatic neuroendocrine tumour	2 Feb 2012	27 Feb 2012	25
Crizotinib	Xalkori	Lung	Advanced NSCLC	25 Apr 2012	23 Oct 2012	181
Ruxolitinib	Jakavi	Other	Myelofibrosis	19 Jun 2012	25 Jun 2012	6
Axitinib	Inlyta	Genitourinary	Metastatic renal cell carcinoma	12 Jul 2012	16 Aug 2012	35
Cetuximab	Erbitux	Gastrointestinal	Metastatic colorectal cancer	20 Dec 2012	10 Jun 2013	172
Brentuximab	Adcetris	Lymphoma/Myeloma	Hodgkin's lymphoma	1 Feb 2013	14 Mar 2013	41
Brentuximab	Adcetris	Lymphoma/Myeloma	SALCL	1 Feb 2013	15 Mar 2013	42
Regorafenib	Stirvaga	Gastrointestinal	Metastatic colorectal cancer	11 Mar 2013	22 Mar 2013	11
Pemetrexed	Alimta	Lung	Advanced non-squamous NSCLC	9 May 2013	31 May 2013	22
Arsenic trioxide	Trisenox	Leukemia	Acute promyelocytic leukemia	7 Jun 2013	30 Aug 2013	84
Before marketing approval date						
Ipilimumab	Yervoy	Melanoma	Advanced melanoma	1 Feb 2012	1 Dec 2011	62
Vemurafenib	Zelboraf	Melanoma	Advanced melanoma	15 Feb 2012	6 Dec 2011	71
Crizotinib	Xalkori	Lung	Advanced NSCLC	25 Apr 2012	6 Mar 2012	30
Pazopanib	Votrient	Sarcoma	Soft tissue sarcoma	12 Jul 2012	4 Jun 2012	38
Bendamustine	Treanda	Leukemia	CLL	24 Aug 2012	24 Apr 2012	122
Bendamustine	Treanda	Leukemia	CLL - first line	24 Aug 2012	24 Apr 2012	122
Bendamustine	Treanda	Lymphoma/Myeloma	Non-Hodgkin's lymphoma	24 Aug 2012	24 Apr 2012	122
Everolimus	Afinitor	Breast	Advanced breast cancer	10 Jan 2013	5 Sep 2012	127
Pertuzumab	Perjeta Herceptin	Breast	Metastatic breast cancer	12 Apr 2013	2 Nov 2012	161
Abiraterone	Zytiga	Genitourinary	Metastatic CRPC	28 May 2013	28 Mar 2013	61
Enzalutamide	Xtandi	Genitourinary	Metastatic CRPC	29 May 2013	4 Mar 2013	86
Vismodegib	Erivedge	Other	Advanced basal cell carcinoma	12 Jul 2013	14 Jun 2013	28
Dabrafenib	Tafinlar	Melanoma	Metastatic melanoma	16 Jul 2013	18 Mar 2013	120
Trametinib	Mekinist	Melanoma	Metastatic melanoma	18 Jul 2013	6 May 2013	73
Trastuzumab	Kadcyla	Breast	Metastatic breast cancer	11 Sep 2013	15 Mar 2013	180

Notes: CLL: Chronic lymphocytic leukemia; CRPC: Castration-resistant prostate cancer; NSCLC: Non-small-cell lung cancer; SALCL: Systemic anaplastic large-cell lymphoma.

* For drugs submitted after marketing approval, difference is NOC date to submission date. For drugs submitted before marketing approval, difference is submission date to NOC date.

Source: www.pcodr.ca.

Table 2: Time points in the pCODR review process of the 32 submissions with a final recommendation, as of April 30, 2014

Generic name	Oncology indication	1 Submission date	2 ERC meeting	3 Initial recommendation	Days, 1 to 3	4 ERC reconsideration meeting	5 Final recommendation	Days, 1 to 5
Pazopanib	Metastatic renal cell	14 Jul 2011	20 Oct 2011	3 Nov 2011	112	15 Dec 2011	5 Jan 2012	175
Sunitinib	Pancreatic neuroendocrine	7 Nov 2011	16 Feb 2012	2 Mar 2012	116	19 Apr 2012	3 May 2012	178
Ipilimumab	Advanced melanoma	1 Dec 2011	15 Mar 2012	29 Mar 2012	119	Not required	18 Apr 2012	139
Vemurafenib	Advance melanoma	6 Dec 2011	15 Mar 2012	29 Mar 2012	114	17 May 2012	1 Jun 2012	178
Eribulin	Metastatic breast	9 Feb 2012	17 May 2012	1 Jun 2012	113	19 Jul 2012	2 Aug 2012	175
Everolimus	Pancreatic neuroendocrine	27 Feb 2012	21 Jun 2012	6 Jul 2012	130	16 Aug 2012	30 Aug 2012	185
Crizotinib	Advanced NSCLC	6 Mar 2012	19 Jul 2012	2 Aug 2012	129	20 Sep 2012	4 Oct 2012	192
Bendamustine	CLL	24 Apr 2012	20 Sep 2012	4 Oct 2012	163	15 Nov 2012	29 Nov 2012	219
Bendamustine	Non-Hodgkin's lymphoma	24 Apr 2012	20 Sep 2012	4 Oct 2012	163	15 Nov 2012	29 Nov 2012	219
Bendamustine	CLL - first line	24 Apr 2012	17 Jan 2013	31 Jan 2013	282	Not required	19 Feb 2013	301
Pazopanib	Soft tissue sarcoma	4 Jun 2012	20 Sep 2012	4 Oct 2012	122	15 Nov 2012	29 Nov 2012	178
Ruxolitinib	Myelofibrosis	25 Jun 2012	18 Oct 2012	1 Nov 2012	129	20 Dec 2013	14 Jan 2013	203
Axitinib	Metastatic renal cell	16 Aug 2012	20 Dec 2012	14 Jan 2013	151	21 Feb 2013	7 Mar 2013	203
Everolimus	Advanced breast	5 Sep 2012	21 Feb 2013	7 Mar 2013	183	Not required	25 Mar 2013	201
Crizotinib	Advanced NSCLC	23 Oct 2012	21 Feb 2013	7 Mar 2013	135	18 Apr 2013	2 May 2013	191
Bortezomib	Multiple myeloma	29 Oct 2012	21 Feb 2013	7 Mar 2013	129	Not required	25 Mar 2013	147
Pertuzumab	Metastatic breast	2 Nov 2012	16 May 2013	31 May 2013	210	18 Jul 2013	1 Aug 2013	272
Lapatanib	Metastatic breast	14 Dec 2012	18 Apr 2013	2 May 2013	139	20 Jun 2013	5 Jul 2013	203
Pazopanib	Metastatic renal cell	20 Feb 2013	20 Jun 2013	5 Jul 2013	135	15 Aug 2013	29 Aug 2013	190

Table 2 continues on page 9

Table 2, continued

Generic name	Oncology indication	1 Submission date	2 ERC meeting	3 Initial recommend-ation	Days, 1 to 3	4 ERC reconsid-eration meeting	5 Final recommend-ation	Days, 1 to 5
Enzalutamide	Metastatic CRPC	4 Mar 2013	20 Jun 2013	5 Jul 2013	123	Not required	23 Jul 2013	141
Brentuximab	Hodgkin's lymphoma	14 Mar 2013	20 Jun 2013	5 Jul 2013	113	15 Aug 2013	29 Aug 2013	168
Brentuximab	SALCL	15 Mar 2013	19 Sep 2013	3 Oct 2013	202	21 Nov 2013	5 Dec 2013	265
Trastuzumab	Metastatic breast	15 Mar 2013	17 Oct 2013	31 Oct 2013	230	19 Dec 2013	10 Jan 2014	301
Dabrafenib	Metastatic melanoma	18 Mar 2013	19 Sep 2013	3 Oct 2013	199	21 Nov 2013	5 Dec 2013	262
Regorafenib	Metastatic colorectal	22 Mar 2013	15 Aug 2013	29 Aug 2013	160	31 Oct 2013	15 Nov 2013	238
Abiraterone	Metastatic CRPC	28 Mar 2013	19 Sep 2013	3 Oct 2013	189	Not required	22 Oct 2013	208
Lenalidomide	Multiple myeloma	5 Apr 2013	19 Sep 2013	3 Oct 2013	181	Not required	22 Oct 2013	200
Trametinib	Metastatic melanoma	6 May 2013	9 Sep 2013	3 Oct 2013	150	Not required	22 Oct 2013	169
Pemetrexed	Advanced non-squamous NSCLC	31 May 2013	17 Oct 2013	31 Oct 2013	153	Not required	19 Nov 2013	172
Cetuximab	Metastatic colorectal	10 Jun 2013	17 Oct 2013	31 Oct 2013	143	19 Dec 2013	10 Jan 2014	214
Vismodegib	Advanced basal cell	14 Jun 2013	17 Oct 2013	31 Oct 2013	139	19 Dec 2013	10 Jan 2014	210
Arsenic trioxide	Acute promyelocytic leukemia	30 Aug 2013	16 Jan 2014	30 Jan 2014	153	Not required	18 Feb 2014	172

Notes: CLL: Chronic lymphocytic leukemia; CRPC: Castration-resistant prostate cancer; NSCLC: Non-small-cell lung cancer; SALCL: Systemic anaplastic large-cell lymphoma; ERC: Expert Review Committee.

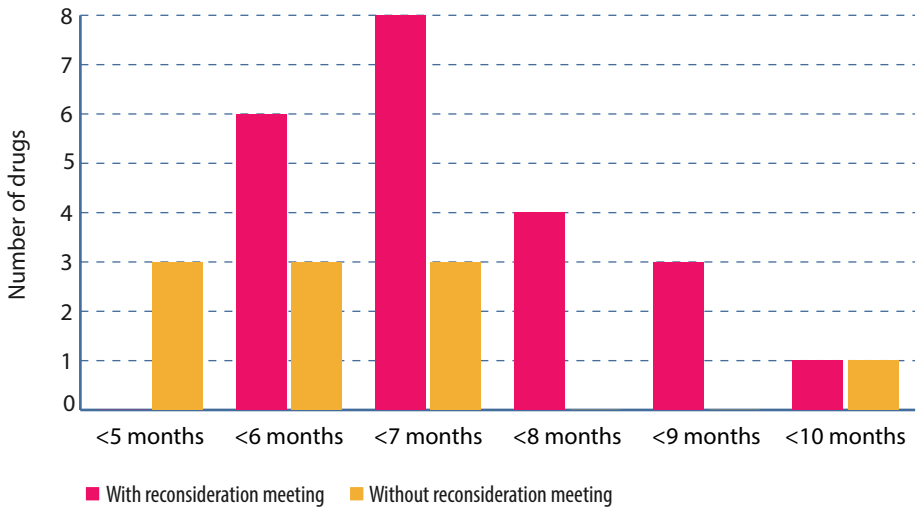
Source: www.pcodr.ca.

Over two-thirds of the submissions required reconsideration by pCODR's Expert Review Committee after feedback was received (table 2). On average, this additional action extended the review time by about a month: the median time from submission to final recommendation for those requiring Expert Review Committee reconsideration was 203 days (range: 168 to 301 days) compared with a median of 172 days (range: 139 to 301 days) for those that did not require reconsideration (**figure 1**). Reconsideration by the Expert Review Committee did not substantially change any of the initial recommendations.

Although reviews commonly took 6 to 7 months, the delay between NOC approval and a final pCODR recommendation was reduced if the manufacturer was able to take advantage of the opportunity to submit the drug within the six months before the anticipated NOC date (**figure 2**). For pre-NOC submissions, the time between NOC and final pCODR recommendation varied between 55 and 182 days (median: 111 days), whereas the time between NOC and final recommendation ranged from 194 to 2,985 days (median: 307 days) for post-NOC submissions. If the five submissions—bortezomib, lenalidomide, pazopanib (two submissions), and lapatanib—with an NOC date before the establishment of the pCODR are excluded, the median time for drugs submitted post-NOC decreases to 244 days, which is still more than twice as long as the median for those submitted pre-NOC.

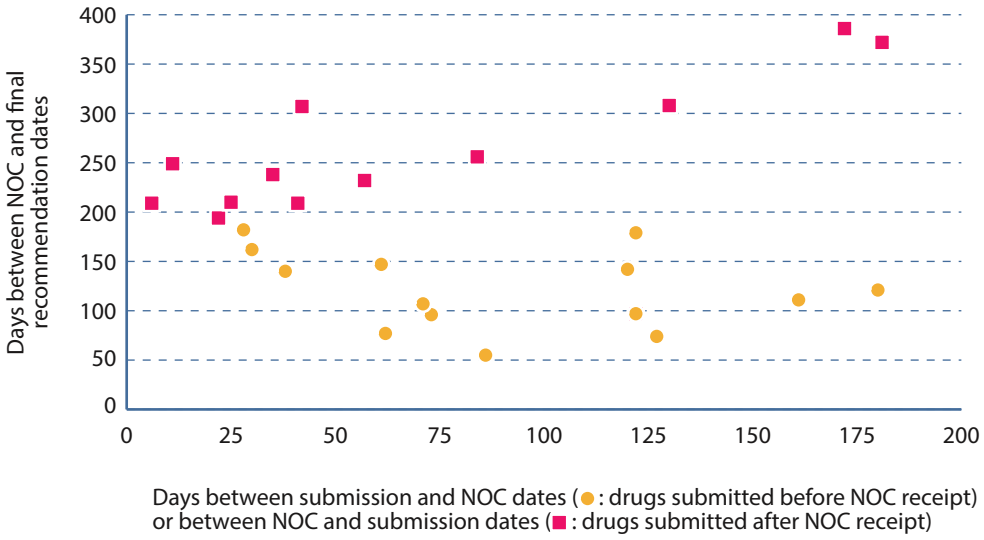
Of the 32 submissions, six (18.8 percent) were not recommended (**table 3**)—in each case, because the Expert Review Committee members were not sufficiently satisfied that the drug had a net clinical benefit, which indicates that the Committee first examines the clinical benefit before it evaluates the drug's cost-effectiveness. Nineteen (73.1 percent) of the other 26 submissions received the most common favourable recommendation of "conditional on the cost-effectiveness being improved to an acceptable level." It is not surprising that the Expert Review Committee often finds the cost-effectiveness analyses in submissions to be unconvincing because, in most cases, they are based on results from pre-marketing clinical trials, which are not representative of the drug's use in the real world. Five of the remaining submissions (19.2 percent) were recommended for a specific type of patient based either on disease status or as an alternative to an existing therapy. Only two (7.7 percent) had no conditions.

Figure 1: Time between submission and final pCODR recommendation, by requirement for Expert Review Committee reconsideration



Source: www.pcodr.ca (see table 2).

Figure 2: Time between NOC and final pCODR recommendation



Source: www.pcodr.ca (see table 1).

Table 3: pCODR final recommendations, as of April 30, 2014

Generic name	Oncology indication	pCODR final recommendation
Pazopanib	Metastatic renal cell	As alternative to sunitinib
Ipilimumab	Advanced melanoma	Conditional on CE improvement
Sunitinib	Pancreatic neuroendocrine	Conditional on CE improvement
Vemurafenib	Advance melanoma	Conditional on CE improvement
Eribulin	Metastatic breast	Conditional on CE improvement
Everolimus	Pancreatic neuroendocrine	Conditional on CE improvement
Bendamustine	CLL	Not recommended
Bendamustine	Non-Hodgkin's lymphoma	Unconditional
Pazopanib	Soft tissue sarcoma	Not recommended
Ruxolitinib	Myelofibrosis	Conditional on CE improvement
Bendamustine	CLL - first line	Conditional on CE improvement
Axitinib	Metastatic renal cell	As alternative to everolimus
Everolimus	Advanced breast	Conditional on CE improvement
Bortezomib	Multiple myeloma	Conditional on clinical status
Crizotinib	Advanced NSCLC	Conditional on CE improvement
Lapatanib	Metastatic breast	Not recommended
Enzalutamide	Metastatic CRPC	Conditional on clinical status
Pertuzumab	Metastatic breast	Conditional on CE improvement
Pazopanib	Metastatic renal cell	Unconditional
Brentuximab	Hodgkin's lymphoma	Conditional on CE improvement
Abiraterone	Metastatic CRPC	Conditional on CE improvement
Lenalidomide	Multiple myeloma	Conditional on CE improvement
Trametinib	Metastatic melanoma	Conditional on CE improvement
Regorafenib	Metastatic colorectal	Not recommended
Pemetrexed	Advanced non-squamous NSCLC	Conditional on CE improvement
Brentuximab	SALCL	Conditional on CE improvement
Dabrafenib	Metastatic melanoma	Conditional on CE improvement
Cetuximab	Metastatic colorectal	Not recommended
Trastuzumab	Metastatic breast	Conditional on CE improvement
Vismodegib	Advanced basal cell	Conditional on CE improvement
Arsenic trioxide	Acute promyelocytic leukemia	Conditional on clinical status

Notes: CLL: Chronic lymphocytic leukemia; CRPC: Castration-resistant prostate cancer; NSCLC: Non-small-cell lung cancer; SALCL: Systemic anaplastic large-cell lymphoma; CE: Cost-effectiveness.

Source: www.pcodr.ca.

Provincial funding approval

Crizotinib was originally submitted in March 2012 and pCODR issued a final recommendation not to fund on October 4 (table 2). The manufacturer rapidly resubmitted the drug on October 23 and a final favourable recommendation was made in May 2013. Only provincial responses to the resubmission are available.

The provincial funding approval situation as of April 30, 2104 is shown in **table 4**. Some drugs are reported by the pCODR as receiving provincial coverage (especially in British Columbia) before its recommendation was issued—these are indicated in bold type in table 4, with the value representing the number of days that provincial coverage occurred before the pCODR recommendation. Of the 26 submissions receiving a favourable recommendation, the numbers approved for coverage by the provinces reported by the pCODR were 16 (61.5 percent) in British Columbia, 16 (61.5 percent) in Alberta, 21 (80.8 percent) in Saskatchewan, 12 (46.2 percent) in Manitoba, 20 (76.9 percent) in Ontario, 13 (50.0 percent) in New Brunswick, 9 (34.6 percent) in Nova Scotia, 2 (7.7 percent) in Prince Edward Island, and 13 (50.0 percent) in Newfoundland and Labrador (**figure 3**). Although neither submission received a favourable pCODR recommendation, British Columbia also approved bendamustine for chronic lymphocytic leukemia and Saskatchewan approved pazopanib for soft tissue sarcoma.

The median times to approve drugs after the final recommendation were 197 days in British Columbia, 183 days in Alberta, 154 days in Saskatchewan, 249 days in Manitoba, 150 days in Ontario, 339 days in New Brunswick, 218 days in Nova Scotia, 309 days in Prince Edward Island, and 366 days in Newfoundland and Labrador. Not only did considerable variation exist between provinces in the proportion of drugs approved for coverage, but when they were approved, some provinces took much longer than others.

Some of the drugs that received a final recommendation in the later part of the study period are reported as being "under provincial consideration". According to the pCODR, this means that the province is reviewing its recommendation, which may include "the province working with the drug manufacturer to reach an agreement for a drug that both parties can accept, in particular in cases where the Expert Review Committee recommended that the drug be funded only on the condition of cost-effectiveness being improved to an acceptable level." These negotiations may occur before or after pan-Canadian Pricing Alliance (pCPA) negotiations. The pCPA is an initiative established in 2010 by the provincial and territorial Ministries of Health to negotiate prices with pharmaceutical companies. Other drugs are reported as being "under negotiation with manufacturer," which most likely means within the pCPA. Negotiations through the pCPA are not publicly reported (Rawson, 2014) but may add to delays in access.

Table 4: Days between pCODR final recommendation and funding approval, by province, as of April 30, 2014

Generic name	Oncology indication	Days between pCODR final recommendation and provincial funding approval*								
		BC	AB	SK	MB	ON	NB	NS	PE	NL
Pazopanib	Metastatic renal cell	**126**	55	56	559	307	208	180	382	32
Ipilimumab	Advanced melanoma	197	184	139	74	148	654	258	UC	258
Sunitinib	Pancreatic neuroendocrine	**337**	326	274	713	504	554	577	UC	662
Vemurafenib	Advance melanoma	122	140	95	115	91	467	276	UC	567
Eribulin	Metastatic breast	517	455	425	355	362	UC	UC	UC	395
Everolimus	Pancreatic neuroendocrine	**456**	207	155	UC	435	476	UC	UC	553
Bendamustine	CLL	64	NF	NF	UC	NF	NF	NF	UC	NF
Bendamustine	Non-Hodgkin's lymphoma	28	116	125	UC	173	429	223	UC	398
Pazopanib	Soft tissue sarcoma	NF	NF	382	UC	NF	UC	NF	NF	NF
Ruxolitinib	Myelofibrosis	291	290	315	457	249	339	UC	UC	366
Bendamustine	CLL - first line	UC	149	43	UC	91	347	141	UC	317
Axitinib	Metastatic renal cell	359	363	284	405	285	UC	UC	UC	UC
Everolimus	Advanced breast	251	269	266	UC	228	269	UC	UC	346
Bortezomib	Multiple myeloma	**1,059**	115	221	UC	95	313	160	UC	372
Crizotinib	Advanced NSCLC	303	182	154	168	152	190	213	UC	334
Lapatanib	Metastatic breast	NF	NF	NF	UC	NF	UC	UC	NF	NF
Enzalutamide	Metastatic CRPC	131	149	125	267	79	149	UC	UC	196
Pertuzumab	Metastatic breast	92	140	116	225	116	UC	UC	UC	UC
Pazopanib	Metastatic renal cell	**728**	187	**304**	230	110	165	UC	235	UC
Brentuximab	Hodgkin's lymphoma	UC	UC	159	UC	174	UC	UC	UC	UC
Abiraterone	Metastatic CRPC	40	UC	418	176	114	UC	UC	UC	UC
Lenalidomide	Multiple myeloma	UN	UN	UN	UN	UN	UN	UN	UN	UN
Trametinib	Metastatic melanoma	UN	UN	UN	UN	UN	UN	UN	UN	UN
Regorafenib	Metastatic colorectal	NF	NF	NF	UC	UC	UC	UC	UC	NF
Pemetrexed	Advanced non-squamous NSCLC	UC	UC	104	UC	UC	UC	NK	UC	UC
Brentuximab	SALCL	UC	UC	61	UC	76	UC	UC	UC	UC
Dabrafenib	Metastatic melanoma	UN	UN	UN	UN	UN	UN	UN	UN	UN
Cetuximab	Metastatic colorectal	UC	NF	NF	UC	NF	UC	UC	UC	NF
Trastuzumab	Metastatic breast	UC	UC	97	UC	UC	UC	UC	UC	UC
Vismodegib	Advanced basal cell	UC	UC	UC	UC	96	UC	UC	UC	UC
Arsenic trioxide	Acute promyelocytic leukemia	UC	UC	UC	UC	UC	UC	UC	UC	NF

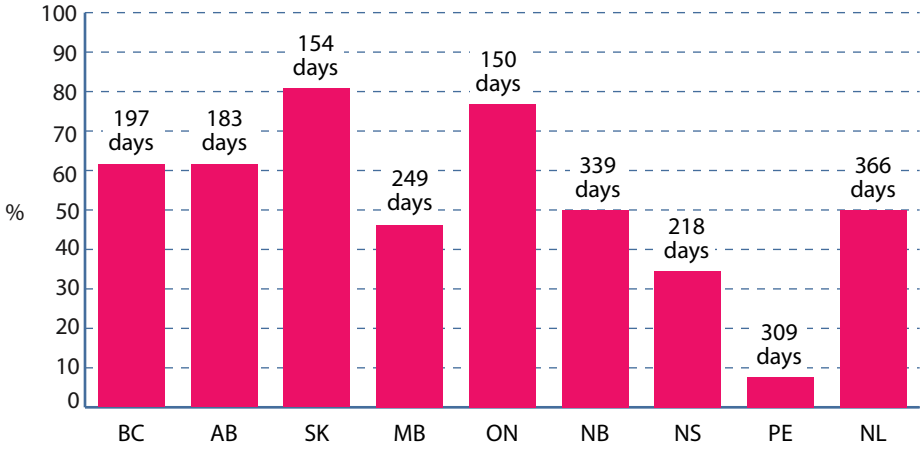
Notes: NF: Not funded; NK: Funded, date not known; UC: Under provincial consideration; UN: Under negotiation with manufacturer.

BC: British Columbia; AB: Alberta; SK: Saskatchewan; MB: Manitoba; ON: Ontario; NB: New Brunswick; NS: Nova Scotia; PE: Prince Edward Island; NL: Newfoundland and Labrador.

* When provincial approval occurs before the pCODR final recommendation, days in bold indicate provincial approval to pCODR final recommendation.

Source: www.pcodr.ca.

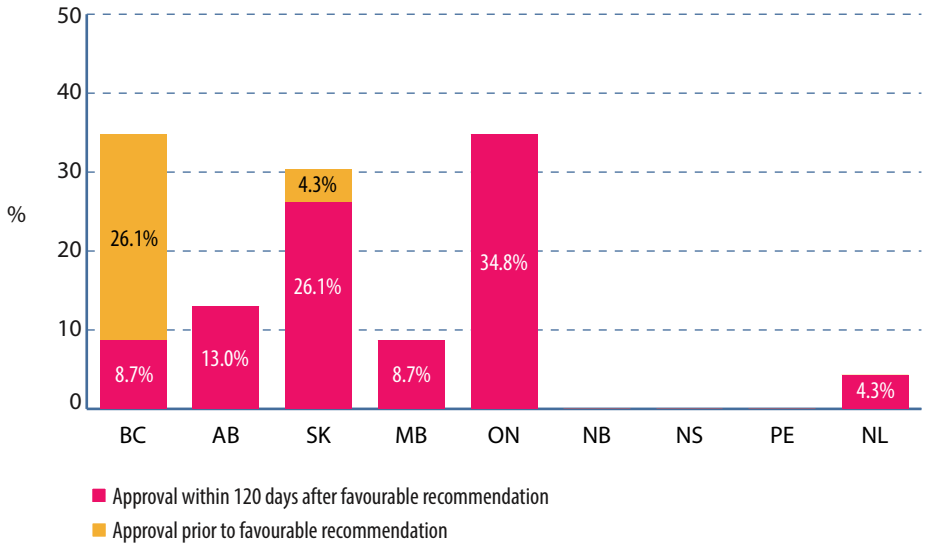
Figure 3: Provincial approval rates for drugs receiving a favourable final recommendation, and median time required to approve the drugs after the recommendation



Source: www.pcodr.ca (see table 4).

If the provinces were required to accept drugs with a favourable pCODR recommendation, it would not be unreasonable to expect them to approve them within a period of 120 days. This would allow the provinces time to review the business impact model and negotiate pricing with the manufacturer. Twenty-three submissions received a favourable recommendation up to the end of December 2013 (120 days prior to April 30, 2014). When the actual funding approval situation for these 23 submissions was compared with this target (**figure 4**), Saskatchewan and Ontario approved 26 percent and 35 percent within 120 days of a favourable pCODR recommendation. However, when funding approvals made before the pCODR recommendation are included, the proportion approved for coverage was 34.8 percent in British Columbia, 13.0 percent in Alberta, 30.4 percent in Saskatchewan, 8.7 percent in Manitoba, 34.8 percent in Ontario, 4.3 percent in Newfoundland and Labrador, and 0.0 percent in New Brunswick, Nova Scotia, and Prince Edward Island.

Figure 4: Provincial approval rates for drugs receiving a favourable final recommendation, and median time required to approve the drugs after the recommendation



Source: www.pcodr.ca (see table 4).

Discussion

The pCODR claims that its review process "takes between 5–8 months to complete" (pCODR, 2011e). This analysis indicates that the median time taken to review submissions is 172 days (almost 6 months) for the submissions that do not require reconsideration by pCODR's Expert Review Committee and 203 days (approximately 7 months) for those that do. However, reviews for both types of submissions have taken up to 301 days (10 months). Nevertheless, the pCODR review times are relatively consistent when compared with the huge variation that one sees in the time taken by Health Canada to review and approve new drugs (Rawson, 2013a), which at least allows manufacturers to plan appropriately for negotiations with the provinces. Being able to strategically anticipate resource requirements in the areas of provincial liaison, marketing, and sales allows manufacturers to train staff on new drugs and develop cross-functional teams at the appropriate time, rather than having staff working on a drug prematurely or tardily, both of which waste assets.

The pCODR also provides manufacturers with two opportunities to facilitate earlier drug access. No data are available on whether presubmission activities reduce delays, but the opportunity to submit their drugs up to six months before the anticipated NOC date has a clear benefit in terms of reducing the time between NOC and pCODR's final recommendation. The time between NOC and final recommendation was between 55 days and six months for pre-NOC submissions, compared with 194 to 386 days (omitting the five submissions with an NOC date before the establishment of the pCODR) for post-NOC submissions.

Of the submissions with a final recommendation issued before April 30, 2014, the pCODR favourably recommended 81 percent. Close to 75 percent of the submissions with a favourable recommendation were conditional on an improvement in the cost-effectiveness of the drug. However, it is not apparent who is going to evaluate the drug's real-world cost-effectiveness, or whether it will be done at all. The provinces generally do not have the resources to complete such assessments. If the responsibility falls to the manufacturer, the information may only made be publicly available if much improved cost-effectiveness is achieved. Such conditional recommendations may simply be an attempt to get manufacturers to reduce their prices. Some submissions

were not recommended due to concerns about the drug's net clinical benefit, which indicates partial duplication between pCODR's reviews and Health Canada's pre-marketing reviews. When provinces subsequently perform similar reviews, there is the potential for even greater wasteful replication.

Conclusion

The continuing inequality in access to new oncology drugs across the provinces is of concern. In British Columbia, Alberta, Saskatchewan, and Ontario, where 60–80 percent or more of the drugs were approved for coverage, access for 50 percent of the drugs approved after a favourable pCODR recommendation was delayed by a further 5 to 7 months and some drugs took 15 to 17 months. The proportion of oncology drugs approved in Manitoba and the Atlantic provinces was lower, ranging from less than 10 percent in Prince Edward Island to around 50 percent in Manitoba, New Brunswick, and Newfoundland and Labrador, and 50 percent of the drugs that were listed in these provinces took 7 to 12 months to be approved, with some taking almost two years.

When compared with a reasonable scenario in which the provinces would be required to approve drugs with a favourable pCODR recommendation with 120 days of the recommendation, none of the provinces came close to achieving this target. A quarter to a third of the drugs were approved for funding in Saskatchewan and Ontario within 120 days of a favourable recommendation and, if one takes into account the drugs approved for funding before the recommendation, British Columbia can be included in this group. In the other provinces, 0–13 percent were approved within the 120 day period.

Concern has been expressed by Canadian patients and healthcare providers for many years about the inability to access to new oncology drugs under provincial insurance plans in a timely manner and, once they are approved for coverage, about the inequality of access across the country (Chafe et al, 2011; Chan et al, 2012; Drummond et al, 2009; LeLorier et al, 2008; Picard, 2009; Turner & Associates, 2008). The introduction of the pCODR has so far done little to alleviate these concerns. Instead, the pCODR appears to have simply added a further bureaucratic layer to the process of getting a new oncology drug approved for coverage. Lack of access to new oncology drugs is not a trivial matter—it can impact thousands of Canadian patients. For example, it has been conservatively estimated that the potential number of Canadian patients negatively impacted by federal regulatory and provincial reimbursement approval delays for just five new oncology drugs was more than 5,000 (Rawson, 2013b).

This analysis is limited by the accuracy of the publicly available information on drugs approved for funding by the provinces and, in particular, by the reliability of the dates of their approval. Errors were identified in the dates on the pCODR website on which some provinces were reported to have approved funding. Past experience has indicated that recordkeeping of such dates by provinces is not always of the highest quality (Rawson, 2013b). Moreover, it is common for funding to be announced well ahead of the actual date on which it becomes accessible and it is not apparent whether the pCODR website records the date on which funding was officially announced or approved, or the date on which patients could actually obtain the drug coverage. On the other hand, some patients may have been able to access the drug earlier if compassionate approval was given on a case-by-case basis. A comprehensive, national, publicly-accessible database of new oncology drugs approved for funding in each province (including the dates on which funding began) would not only be of assistance in work of this kind but would also be of significant value to cancer patients.[3]

A further limitation of this analysis is that it represents a snapshot of an evolving environment. New pCODR recommendations appear regularly and the provincial funding situation also changes frequently. This analysis also did not attempt to assess the appropriateness of pCODR's recommendations.

In April 2014, the pCODR was moved under the umbrella of the Canadian Agency for Drugs and Technologies in Health (CADTH, 2014), thus returning the assessment of new oncology drugs to the organization from which it was separated in 2007. The Agency currently performs clinical and economic reviews of non-oncology drugs via its Common Drug Review process for the provincial and territorial Ministries of Health (CADTH, 2014). Until April 2015, the pCODR will continue its work as previously under CADTH's governance. After that time, the objective will be to explore better alignment of the pCODR and Common Drug Review evaluation criteria and to identify best practices from both review processes. The Common Drug Review has a favourable recommendation rate of only 50 percent compared with pCODR's 81 percent (like the pCODR, CADTH recommendations do not have to be followed by the provinces). It will be important to monitor whether pCODR's higher rate of favourable recommendations will be maintained.

Cancer has a strong political dimension, so that decisions about which drugs to fund can be politically and emotionally charged. In addition, oncology drugs have also become more complex in recent years, requiring highly specialized expertise to be involved in any review process. According to its Executive Director, "pCODR is able to support an infrastructure in which clinical experts throughout Canada come together in disease site teams to

3. There are two websites with information regarding oncology drugs approved for coverage, but they are not always complete and do not contain dates on which funding began.

review the evidence in their area. Not only does this leverage the expertise in the country, but it also creates buy-in among clinicians and patients knowing that the right expertise has been actively involved. The pooling of expertise is especially important in health economics" (Hoch and Sabharwal, 2013).

The end result is intended "to bring consistency and clarity to the assessment of cancer drugs" in Canada (pCODR, 2011a) with, presumably, the objective of delivering evidence-based recommendations that lead to evidence-based decision making by the provincial and territorial Ministries of Health which established the pCODR. If provinces make funding decisions about new oncology drugs that are consistent with pCODR's recommendations, this should provide confidence for patients, physicians, and manufacturers that clinically and economically valid decisions are being made, and should improve fairness in patient access to new drugs.

However, there continues to be wide variation in provincial approval for funding of new oncology drugs, despite their receiving favourable pCODR recommendations, and also, for those approved, in the time required for the decision. Little benefit is achieved in having a review process that engages physicians, health economists, and patients to bring consistency and clarity to the assessment of cancer drugs—at, presumably, considerable cost (the pCODR does not publicly report its annual budget)—if many of the provincial and territorial Ministries of Health that established the review organization defer or ignore its favourable recommendations. In practice, a negative recommendation generally means "no" to the provinces, but a favourable one seems to mean "maybe, possibly, sometime" to several provinces. An organization dedicated to reviewing new oncology drugs, which requires resources from the taxpayer and additional effort from pharmaceutical companies, and which duplicates (at least partially) the work performed by other governmental agencies, adds little benefit to the healthcare system or to the quality and duration of the lives of cancer patients if its activities do not lead to improvements in the timeliness and fairness of access to new oncology drugs. The provinces should make a commitment to accept at least a high percentage (e.g., 80 percent, since two provinces eventually reached this level) of the drugs receiving a favourable pCODR recommendation, and to do so within a reasonable time period, such as 120 days.

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