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EXECUTIVE SUMMARY

In April 2014, the pan-Canadian Oncology Drug Review (pCODR) was transferred to CADTH to consolidate policy direction across Canada’s drug review programs and to strengthen the pCODR governance structure, helping ensure its long-term viability and sustainability. pCODR assesses cancer drugs and makes reimbursement recommendations to the provinces and territories to guide their drug funding decisions.

Phase I of the transfer, which was primarily administrative, is close to completion. Phase II is also under way. It explores better alignment of the pCODR and CADTH Common Drug Review (CDR) evaluation criteria while taking advantage of the best practices of both processes. CDR is a pan-Canadian process that assesses drugs (non-cancer) and makes reimbursement recommendations to Canada’s federal, provincial, and territorial publicly funded drug plans, with the exception of Quebec, to guide their drug funding decisions.

One of CADTH’s core corporate values is the pursuit of excellence. Specifically, CADTH is committed to ensuring that the needs and expectations of its customers are met in an efficient, credible, affordable, and timely manner. As part of this commitment, CADTH is pleased to publish this second pCODR performance report, which analyses pCODR activity from its 2011 launch to December 31, 2014. It is an important part of CADTH’s commitment to bringing greater transparency and accountability to the cancer drug review process.

The measures against which pCODR is assessed are based on CADTH’s core values. Those values incorporate pCODR’s guiding principles, which can be read in full on the CADTH website.

Operations

- pCODR has reviewed 50 submissions as of December 31, 2014.
- Significantly fewer overall review days (90) are required for submissions made before a Notice of Compliance is issued (pre-NOC), compared with post-NOC submissions (182 days), from the time of receipt of NOC to time of Notification to Implement. This improves timeliness of reviews.
- 60% of pCODR submissions were made for pre-NOC submissions, an option that allows the review process to begin as early as possible because the pCODR review runs parallel to Health Canada’s review. This improves access.
- pCODR is working with stakeholders to ensure timely reviews. The process has taken a median of 150 business days for both pre-NOC submissions (150 days) and post-NOC submissions (141 days). It is important to note that the 150 business day review “time clock” begins as soon as a manufacturer submits a drug for review, and not at NOC approval.

Transparency

- pCODR continues to post an average of nine documents for each of the reviews on its website.
- Interested parties can follow the progress of a review using pCODR’s online process tracking tool.
- Members of the Clinical Guidance and Economic Guidance Review Panels and the pCODR Expert Review Committee are listed on the CADTH website. pCODR has a roster of approximately 60 active clinical and economic review panel members.
• Should a participating group feel that the steps in the process have been applied unfairly, it can ask for a procedural review; as of December 31, 2014, no procedural reviews have been requested.

Stakeholder Engagement
• pCODR continues to host webinars and meetings to help patient groups understand the review process.
• As of December 31, 2014, of 47 drug reviews, 45 have had patient group submissions.
• pCODR had received two submissions from a provincially recognized clinician-based tumour group as of December 31, 2014 and worked with tumour groups to review data, offer counsel on the process, and explain the nature of the information needed by the evaluators.
• pCODR is collaborating with the Canadian Cancer Action Network (CCAN) to implement a Patient Engagement Collaboration Project, funded by CCAN.

pCODR currently tracks drug funding recommendations to the provinces; the final decision on whether to publicly fund a cancer drug rests with each province. A pCODR recommendation is one of the many factors that are considered prior to a funding commitment. By December 31, 2014, pCODR had issued 39 final recommendations. Of the 39 recommendations, seven were positive recommendations, 24 were conditional recommendations, and eight were negative recommendations.

Looking Ahead
pCODR is continually assessing how the drug review process can be improved. Knowing what new cancer drugs are on the horizon allows for better planning across the system. As of December 31, 2014, pCODR estimates that there are 225 drug-indication pairs that may be submitted for review over the next five years. Of these, 139 are new drug-indication pairings and 86 are new indications for existing drugs.

pCODR continues to watch for treatment trends, such as the use of companion diagnostics. As of December 31, 2014, there were 14 different companion diagnostics linked to 34 individual cancer drugs and 44 cancer drug-indication pairs on the horizon.

As was announced in May 2014, CADTH will be implementing an application fee for manufacturers filing with the pCODR program. The application fee was mandated by the Conference of Deputy Ministers of Health and will supplement existing provincial and territorial funding. The fees will be used to offset some of the costs of a drug review and help to finance an increase in the number of cancer drugs that CADTH reviews on an annual basis. Application fee performance metrics, which will track compliance in accordance with the Guidelines for Manufacturers on Application Fees for pCODR, will be reported on the CADTH website annually. It is anticipated that the first performance metrics for the application fees will be posted in the spring of 2016.

Created to bring consistency and clarity to the assessment of cancer drugs, pCODR’s continued operations have contributed to a more transparent and rigorous review system.
1. INTRODUCTION

The pan-Canadian Oncology Drug Review (pCODR), a CADTH program, assesses cancer drugs and makes reimbursement recommendations to the provinces and territories to guide their drug funding decisions. pCODR is designed to bring consistency and clarity to the assessment of cancer drugs by looking at clinical evidence, cost-effectiveness, and patient perspectives.

The pCODR review process is comprehensive, and benefits from the input of patient groups, drug manufacturers, clinicians, and government. It’s a collaborative approach, which means that reimbursement recommendations reflect the thinking of Canada’s most respected oncologists, economists, and administrators, who have had the benefit of hearing from patient groups as well.

This second report, which analyses pCODR activity to December 31, 2014, is an important part of CADTH’s commitment to continue bringing greater transparency and accountability to the cancer drug review process.

2. PERFORMANCE MEASURES

The measures against which pCODR is assessed are based on CADTH’s core values. These values incorporate pCODR’s guiding principles. Those principles (which can be read in full on the CADTH website) include:

- Efficient and Effective: A review process that is cost-efficient, effective, and streamlined (i.e., reduced duplication) to support timely decision-making
- Evidence-based: A review process with capacity for rigorous and consistent evidence-based clinical and pharmacoeconomic reviews to support evidence-based decision-making
- Representation: A review process that is multidisciplinary, cross-jurisdictional, and collaborative in nature, and includes appropriate input from key stakeholders and links to other key national initiatives.

With these principles in mind, the pCODR program is publishing its second performance report on operations, transparency, and stakeholder engagement. The results and their implications are provided on the following pages.

3. RESULTS: OPERATIONS

The number of reviews, the length of time for those reviews, scope of expertise, and access provided to the review process through multiple channels are important markers of pCODR’s operational efficiency.
3.1 Volume

pCODR has reviewed 50 submissions since launch (July 2011 to December 31, 2014). Of the 50 submissions, six submissions were granted priority review (see Appendix A for priority review criteria and pCODR’s experiences to date). pCODR has also analyzed submission data regarding the tumours treated by the drugs and the drugs’ routes of administration (see Appendix B).

Table 1: Summary of Submissions Received Since Launch of pCODR

<table>
<thead>
<tr>
<th>Total Submissions = 50 (as of December 31, 2014)</th>
<th>New Drug</th>
<th>New Indication</th>
<th>Resubmission</th>
<th>Priority Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Submissions</td>
<td>31</td>
<td>16</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>July-Dec 2011</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Jan-June 2012</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>July-Dec 2012</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Jan-June 2013</td>
<td>9</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>July-December 2013</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Jan June 2014</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>July-December 2014</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

pCODR = pan-Canadian Oncology Drug Review.

3.2 Access

The pCODR process offers manufacturers and tumour groups the option to submit drugs for review before Notice of Compliance (NOC) approval is received from Health Canada. Unique in Canada when it was introduced, this mechanism allows for the review process to begin as early as possible, as the pCODR review runs parallel to Health Canada’s review. The option has been well received; 60% of pCODR’s submissions have been made pre-NOC.

**Priority Reviews**

Submissions are reviewed in the order they are received; however, at time of filing, a submitter may request that a submission be considered a priority review. This request is assessed against clinically based criteria which, if met, allow the submission to be reviewed next. Because the review timeline is not condensed, prioritization only affects the order of review (if submissions have been queued) and order of placement on the pERC agenda; see Appendix A for the criteria.
3.2.1 Timeliness
A pre-NOC review is conducted before a manufacturer has received an NOC from Health Canada. Indeed, by doing as much work as possible while Health Canada’s review is under way, pCODR has found that significantly fewer overall review days are required for pre-NOC submissions compared with post-NOC submissions. This finding supports pCODR continuing with this approach to improve patient access to cancer drug products. pCODR has noted that pre-NOC submissions may require additional clarification with manufacturers, as the review is beginning before all regulatory issues are settled. However, this does not affect patient access because these efforts take place before the drug has been approved for sale.

A post-NOC review — conducting the review once a manufacturer has received an NOC from Health Canada — differs from a pre-NOC review because all of pCODR’s work takes place post-NOC. Indeed, in some cases, manufacturers choose not to submit for review as soon as NOC is received. This, of course, extends the time from NOC to pCODR’s Notification to Implement.
3.2.2 pCODR Review Timelines

pCODR has observed that key factors for timely review are good planning (e.g., having an accurate anticipated submission filing date in pre-submission information is important), and accurate information provided by the submitter. pCODR has found that approximately one-third of submissions have deficient information, which significantly affects pCODR review timelines. Some of the reasons included insufficient economic information, and/or incomplete NOC requirements and/or other submission requirements. pCODR continues to work with stakeholders to ensure timely reviews.

Having an accurate anticipated submission filing date is important. It is used to notify patient groups of a pending drug submission and the target deadline date for providing input in order to maximize the time that patient groups have to prepare their input into the review process. It is also important for planning and for identifying resources for the review (e.g., managing the review process, assessing the current submission volumes, and planning for the proposed new submission).

pCODR currently requests that a submitter provide at least six to 12 months’ notification of a submission in advance of the anticipated filing date. Figure 3 shows a snapshot of submitters’ compliance rate on the pre-submission notification period. About 80% of submitters have provided at least four months’ notification in advance of the anticipated filing date for pre-NOC

NOC = Notice of Compliance.
and post-NOC submissions, and about 63% of submitters have provided at least six months’ notification in advance of the anticipated filing date for pre-NOC submissions. Of submitters, 53% have provided at least six months’ notification in advance of the anticipated filing date for post-NOC submissions.

**Figure 3: Snapshot of Submitters’ Compliance Rate Regarding Pre-Submission Notification Period**

![Bar chart showing compliance rates for pre-NOC and post-NOC submissions across different notification periods.]

NOC = Notice of Compliance.

Figure 4 shows pCODR’s drug review timelines as of December 31, 2014. The pre-NOC submission reviews included 10 early conversion drug reviews. The post-NOC reviews included three early conversions.

---

**Early conversion**

*Feedback on an initial recommendation is assessed to determine if it is eligible to be converted to a Final Recommendation without reconsideration. If it is, the Final Recommendation will be posted on the pCODR website. This step allows for more timely recommendations in a limited set of instances.*

---

**Figure 4: pCODR’s Drug Review Timelines as of December 31, 2014**

**Pre-NOC Submissions**

<table>
<thead>
<tr>
<th></th>
<th>Initial Recommendation</th>
<th>Final Recommendation</th>
<th>Notification to Implement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>118 days</td>
<td>145 days</td>
<td>158 days</td>
</tr>
<tr>
<td>Median</td>
<td>113 days</td>
<td>139 days</td>
<td>150 days</td>
</tr>
<tr>
<td>Range</td>
<td>75-189 days</td>
<td>89-222 days</td>
<td>100-233 days</td>
</tr>
</tbody>
</table>
Figure 4: pCODR’s Drug Review Timelines as of December 31, 2014 (cont’d)

Post-NOC Submissions

<table>
<thead>
<tr>
<th></th>
<th>Initial Recommendation</th>
<th>Final Recommendation</th>
<th>Notification to Implement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>94 days</td>
<td>131 days</td>
<td>142 days</td>
</tr>
<tr>
<td>Median</td>
<td>92 days</td>
<td>130 days</td>
<td>141 days</td>
</tr>
<tr>
<td>Range</td>
<td>76-138 days</td>
<td>112-181 days</td>
<td>123-192 days</td>
</tr>
</tbody>
</table>

NOC = Notice of Compliance; pCODR = pan-Canadian Oncology Drug Review.

Note: The pCODR 150-day average review “time clock” begins as soon as a manufacturer submits a drug for review (and not at NOC approval). When a manufacturer submits pre-NOC, there can be a range of factors outside of pCODR’s control that extend the days required for a review, such as regulatory questions or manufacturer issues related to securing Health Canada approval. This is why the range of days (pre- and post-NOC) is beyond the 150-day objective. The same is true for post-NOC; there were a few “outlier” submissions from manufacturers that had delays beyond pCODR’s control.

3.3 Conclusion

The pCODR process has been successfully handling the expected volume of submissions and has seen significant uptake of its pre-NOC submission option. The program also identified a pattern with pre-NOC reviews. Generally, they require additional time to resolve administrative issues, as the manufacturer is still seeking regulatory approval; however, this does not affect patient access because without Health Canada approval, the drug under review cannot be sold in Canada. pCODR is managing these administrative issues and improving its time investment for pre-NOC submissions because they can yield faster access. In June 2014, pCODR removed the following submission requirements: a letter confirming ability to supply; the drug notification form; and the patent expiry information.

4. RESULTS: TRANSPARENCY

Transparency is a core pCODR value. It is demonstrated through the amount and type of information that is publicly posted, and the nature of the review process itself.

4.1 Posted Information

Since its inception, pCODR has committed to posting publicly both the initial and final funding recommendations, as well as the clinical and economic reviews that are considered in formulating a recommendation. pCODR has met this objective for each of the reviews that completed the process and has issued 39 final recommendations as of December 31, 2014. There are, on average, nine documents (e.g., initial and final clinical and economic reports, initial and final recommendations, feedback from eligible participants, conflict of interest declarations) posted per review. Interested parties can follow the progress of a review using pCODR’s online process tracking tool. In addition, the members of the Clinical Guidance and Economic Guidance Review Panels and of the pCODR Expert Review Committee (pERC) are listed on the [CADTH website](https://cadth.ca). (Please see Appendix C for an explanation of each committee’s role.)
4.2 Procedural Fairness
A number of groups — provincial government representatives, patient groups, manufacturers, clinicians, and academics — were involved in developing the current pCODR process to ensure its effectiveness and fairness. pCODR has also held a number of webinars and information sessions since 2011 to explain how the process works. The steps are also summarized in a short video. One of those steps is a procedural review, should a group feel that the steps have been applied unfairly. No procedural reviews have been requested as of December 31, 2014.

4.3 Conclusion
The current pCODR process is working well. pCODR will assess the benefits of posting additional information as opportunities arise, based on the information being useful, understandable, and helpful to stakeholders in terms of contributing to the review process.

5. RESULTS: STAKEHOLDER ENGAGEMENT
Activities to support patient group submissions, the number of submissions received, and engaging tumour groups provide data to assess pCODR’s level of stakeholder engagement.

5.1 Patient Group Support
In addition to webinars and meetings to help patient groups understand the review process, pCODR is collaborating with the Canadian Cancer Action Network (CCAN) to implement a Patient Engagement Collaboration Project funded by CCAN. The initiative’s many elements include:
- Hiring our first dedicated Patient HTA Navigator to help patient advocacy groups navigate the pCODR process (as part of a six-month pilot project)
- Presenting an abstract on patient involvement in health technology assessment (HTA) processes and participating on an international panel of speakers where there was significant interest in Canada’s work in the area of patient engagement in HTA
- Offering two webinars
- Conducting a survey of pCODR reviewers; currently under way are a series of key informant interviews and an online survey with those patient advocacy groups that completed a submission to pCODR between September and December 2014.
We are also creating two narrated, interactive slide presentations to help illustrate some of the key components of the Guide for Patient Advocacy Groups: How to Provide Patient and Caregiver Input for a pCODR Drug Review.

5.2 Patient Group Input
Patient group submissions allow reviewers to understand patients’ perspectives about the experience of living with cancer and undergoing treatment for it. Since inception, 45 out of 47 drug reviews have had patient group submissions.

Figure 6: Submissions From Patient Groups Since Inception

A unique aspect of patient group input to the pCODR process is the ability to comment on an initial recommendation. Of the initial recommendations, approximately 70% received patient group feedback.

Figure 7: Patient Group Feedback on Initial Recommendation


5.3 Tumour Group Engagement
Tumour groups are clinical and/or research groups affiliated with a provincial cancer agency or a provincial or territorial Ministry of Health, where cancer specialists, health care professionals, and researchers with expertise in tumours related to a specific area work together. pCODR received two submissions from a provincially recognized clinician-based tumour group as of December 31, 2014 and worked with tumour groups to review data, offer
counsel on the pCODR process, and explain the nature of the information needed by the evaluators. (NB: the submissions were subsequently made by a drug manufacturer.)

5.4 Conclusion
The pCODR program will continue supporting patient group involvement and building the capacity of stakeholder groups to participate meaningfully in the review process. This includes exploring ways of increasing patient and clinician involvement.

6. PROVINCIAL DRUG FUNDING DECISIONS

The pCODR review process results in reimbursement recommendations to the provinces; the final decision on whether to publicly fund a cancer drug rests with each province. There are many factors that go into a province’s (or cancer agency’s) decision to fund an oncology drug. These include, but are not limited to, available budget, regional health system priorities, and local political priorities. A pCODR recommendation is one of the many factors that are considered prior to a funding commitment.

By December 2014, pCODR had issued 39 final recommendations. Of the 39 recommendations, seven were positive recommendations, 24 were conditional recommendations, and eight were negative recommendations. Given that pCODR was created to assist the provinces with their decision-making, there is value in examining how the provinces use pCODR’s funding recommendations.

pCODR is exploring provincial funding concordance in more detail through a commissioned research project. However, based on general observations, there is a suggestion of high concordance rate with pCODR’s funding recommendations.

Figure 8: Provincial Funding Decisions as of December 31, 2014

a. Provincial Funding Decisions: Positive Recommendations
b. Provincial Funding Decisions: Conditional Recommendations

As of December 31, 2014

- Green: % Funded by Participating Provinces
- Yellow: % Under Negotiation with Manufacturer
- Blue: % Under Provincial Consideration
- Red: % Not Funded

c. Provincial Funding Decisions: Negative Recommendations

As of December 31, 2014

- Green: % Funded by Participating Provinces
- Yellow: % Under Negotiation with Manufacturer
- Blue: % Under Provincial Consideration
- Red: % Not Funded

Note: “Under Provincial Consideration” means that the province is reviewing pCODR’s recommendation. This may include the province working with the drug manufacturer to reach an agreement for a drug product that both parties can accept, in particular in cases where the pCODR Expert Review Committee has recommended that the drug be funded only on the condition of cost-effectiveness being improved to an acceptable level. This may occur before or after the pan-Canadian negotiations. Please contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.

“Under Negotiation with Manufacturer” means that the Pan-Canadian Pricing Alliance is conducting a joint pan-Canadian negotiation for this drug. For more information on the Pan-Canadian Pricing Alliance, please see http://www.pmpournecisterritoires.ca/en/initiatives/358-pan-canadian-pricing-allicance or contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.

As of December 31, 2014, pCODR had issued 37 notifications to implement for cancer drug products. Of these, 31 included both positive and conditional funding recommendations. Figure 9 shows the number of positive funding decisions made by the provinces.
pCODR = pan-Canadian Oncology Drug Review.

The average length of time between provinces receiving a reimbursement recommendation (regardless of whether it was positive, negative or conditional) and making a positive funding decision is detailed in Figure 10.

**Figure 10: Average Time Between Notification to Implement and Provincial Funding Decision**

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Average Funding Time (in Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abraxane for NPC</td>
<td>16</td>
</tr>
<tr>
<td>Trisenox for APL</td>
<td>68</td>
</tr>
<tr>
<td>Velcade for MM (post-ASCT)</td>
<td>68</td>
</tr>
<tr>
<td>Giotrif for aHCLC</td>
<td>85</td>
</tr>
<tr>
<td>Zytiaga for mRPC</td>
<td>86</td>
</tr>
<tr>
<td>Stivarga for GIST</td>
<td>95</td>
</tr>
<tr>
<td>Alimta for aHCLC</td>
<td>101</td>
</tr>
<tr>
<td>Xandi for mRPC</td>
<td>107</td>
</tr>
<tr>
<td>Velcade for MM (pre-ASCT)</td>
<td>107</td>
</tr>
<tr>
<td>Perjeta Herceptin for MBC</td>
<td>109</td>
</tr>
<tr>
<td>Entyve for RCC</td>
<td>119</td>
</tr>
<tr>
<td>Adcetris for SALLCL</td>
<td>123</td>
</tr>
<tr>
<td>Treanda for NHL &amp; HCL</td>
<td>138</td>
</tr>
<tr>
<td>Treanda for CLL (1st line)</td>
<td>136</td>
</tr>
<tr>
<td>Treanda for CLL</td>
<td>136</td>
</tr>
<tr>
<td>(relapsed/refractory)</td>
<td></td>
</tr>
<tr>
<td>Votrient for mRCC (resub)</td>
<td>138</td>
</tr>
<tr>
<td>Votrient for mRCC</td>
<td>140</td>
</tr>
<tr>
<td>Kedralla for mBBC</td>
<td>143</td>
</tr>
<tr>
<td>Xalkori (Resub) for NSCLC</td>
<td>143</td>
</tr>
<tr>
<td>Zelboraf for MM</td>
<td>147</td>
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<tr>
<td>Tarfor for AM</td>
<td>166</td>
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<tr>
<td>Vynvoir for AM</td>
<td>187</td>
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<tr>
<td>Adcetris for HL</td>
<td>190</td>
</tr>
<tr>
<td>Mekinst for AM</td>
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</tr>
<tr>
<td>Affinitor for mBBC</td>
<td>216</td>
</tr>
<tr>
<td>Revlimid for MM</td>
<td>234</td>
</tr>
<tr>
<td>Jakavi for myelofibrosis</td>
<td>240</td>
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<tr>
<td>Votrient for sBC</td>
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<tr>
<td>Inlyta for mRCC</td>
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<tr>
<td>Halaven for mBBC</td>
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<tr>
<td>Affinitor for PhETs</td>
<td>302</td>
</tr>
<tr>
<td>Sutent for PhETs</td>
<td>336</td>
</tr>
</tbody>
</table>
7. **LOOKING AHEAD**

CADTH and the pCODR program are continually assessing how the drug review process can be improved. Knowing what new cancer drugs are on the horizon would allow for better planning. As of December 31, 2014, pCODR estimates that there are 225 drug-indication pairs that may be submitted for review over the next five years. Of these, 139 are new drug-indication pairings and 86 are new indications for existing drugs. Most of the drug-indication pairs would treat leukemia, lymphoma and myeloma, lung, and gastrointestinal cancers.

**Figure 11: Estimated Upcoming Drug-Indication Pairs**

![Drug-Indication Pairs](image)

Note: These numbers include drugs that are in both phase 2 and phase 3 trials. Phase 3 trials are estimated to be complete in and around 2016 to 2020. These numbers are estimates only and may be subject to regulatory delays, or the manufacturer may decide not to pursue licensing and marketing in Canada. “Drug-indication pairs” means a particular drug prescribed for a particular indication. In certain cases, a drug manufacturer may provide a submission with more than one drug-indication pair for a particular drug product.

pCODR also watches for treatment trends, such as the use of companion diagnostics. According to the US Food and Drug Administration, “Companion diagnostic tests define the subset of patients who are most likely to benefit from a therapy or who should not receive the therapy because of ineffectiveness or predicted adverse effects.” Such tests are being used more frequently to determine the applicability of certain cancer drugs for the treatment of tumours. As of December 31, 2014, there were 14 different companion diagnostics linked to 34 individual drugs and 44 drug-indication pairs. In the future, there may be a need for CADTH to provide advice and/or reimbursement recommendations on the combination of companion diagnostics plus drug-indication pairs.

The pCODR program will continue to assess its performance and report back to its stakeholders each year. Created to bring consistency and clarity to the assessment of cancer drugs, pCODR’s continued efforts have contributed to a more transparent and rigorous review system.
APPENDIX A: PRIORITY REVIEW

Submissions to the pan-Canadian Oncology Drug Review (pCODR) process are reviewed in the order they are received (i.e., first come, first served). However, at time of filing, a submitter may request that their submission be assessed to determine whether it meets priority review criteria. Request for priority review must be initiated by a manufacturer or tumour group. The request is assessed by a three-person panel consisting of the pCODR Expert Review Committee (pERC) Chair, the pERC Vice-Chair, and one additional pERC member, according to the following clinically based criteria:

- A new oncology drug, or an oncology drug with a new indication and employed for the active treatment of cancer, where use offers potential substantial improvements on significant outcomes, such as (but not limited to):
  - Improved overall survival in the adjuvant setting; or
  - Elimination or substantial reduction of treatment side effects associated with standard of care; or
  - Measurable and substantial improvements in quality of life over other available therapies in Canada

OR

- A new oncology drug, or an oncology drug with a new indication and employed for the active treatment of cancer, where no other comparable drug or treatment is currently marketed in Canada.

What is pCODR’s Experience With Priority Requests?
To date, pCODR has assessed 10 requests for priority review. Priority status has been granted for six of the 10 requests.

Submissions that were granted priority review:
- There were no other viable treatment options available in Canada, and the drug or indication demonstrated some certainty in the magnitude of benefit in the outcomes of interest.
- There was certainty in the magnitude of benefit in the outcomes of interest, and the magnitude of benefit was substantial compared with currently available treatments.

Submissions that were not granted priority review:
- The pivotal studies provided by the submitter required further in-depth analyses (i.e., a full review) to reduce uncertainty in the results (e.g., subgroup analyses, non-validated surrogate outcomes).
- The magnitude of improvement in outcomes of interest was not considered to be sufficient to warrant priority status over other submissions, given other relevant available treatments.
APPENDIX B: SUBMISSIONS BY ROUTE OF ADMINISTRATION AND TUMOUR TYPE

Figure B1: Submissions by Route of Administration

Route of Administration

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>28</td>
</tr>
<tr>
<td>Intravenous</td>
<td>23</td>
</tr>
</tbody>
</table>

Note: Submissions received as of December 2014.

Figure B2: Submissions by Tumour Type

Note: Submissions received as of December 2014.
APPENDIX C: COMMITTEE ROLES

Members of the pan-Canadian Oncology Drug Review’s (pCODR’s) committees, panels, and advisory groups are drawn from every participating province, to ensure geographic representation.

The pCODR Expert Review Committee
The role of the pan-Canadian Oncology Drug Review Expert Review Committee (pERC) is to assess the clinical evidence and cost-effectiveness of cancer drugs, enabling pCODR to make recommendations to the provinces and territories to guide their drug funding decisions. Recommendations for drug products that may be considered for funding are provided to the provincial or territorial Ministries of Health and provincial cancer agencies, along with the reasons why the recommendations have been made. The recommendations and the reasoning behind them are also available to the public.

Guidance Panels
pCODR relies on the medical expertise of its Clinical Guidance Panels to ensure that the review of each cancer drug draws from the most important, relevant, and current clinical information. pCODR relies on the expertise of its Economic Guidance Panels to assess the economic evidence provided when a drug is submitted to pCODR.

For each pCODR review, the panels generate an Economic Guidance Report and a Clinical Guidance Report, which are submitted to pERC. The documents are used as part of pERC’s deliberative process to make funding recommendations.

Patient Advocacy Group Input
Patient input is important to the pCODR drug review process, as it describes patients’ experiences of living with cancer and undergoing treatment for it. In particular, patient input means that those reviewing the drug can begin to appreciate the impact (both good and bad) that the drug under review may have on those taking it, as well as on those caring for patients living with cancer.

Provincial Advisory Group
A Provincial Advisory Group (PAG) is in place to provide advice to the pCODR Steering Committee about operational issues, as well as to inform strategic and policy direction. Input from the PAG ensures that the pCODR drug review process and the resulting recommendations meet the needs of participating provinces and territories and cancer agencies regarding evidence-based recommendations that guide drug funding decisions. Issues brought forward by the PAG may include considerations related to the implementation of recommendations, advice about consultation and information exchange, and information on emerging trends in the development and use of cancer drugs. Membership consists of appointed representatives from each of the participating provincial and territorial Ministries of Health and provincial cancer agencies; it is chaired by a Steering Committee Member. In addition to these voting members, the pCODR Executive Director stands as an Ex-officio Member.