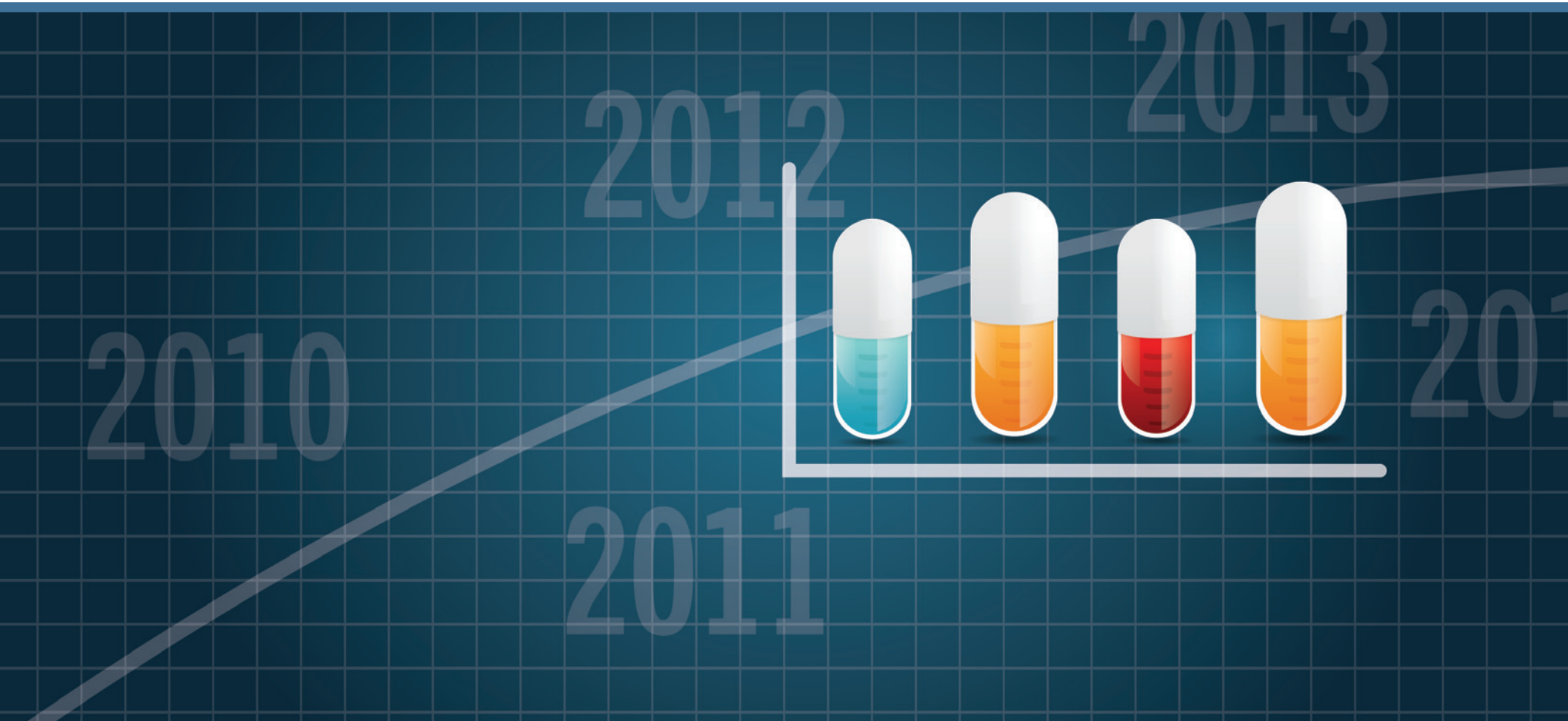
pCODR

PAN-CANADIAN
ONCOLOGY DRUG REVIEW

Performance Measures Report: partial assessment of pCODR's first years



Executive Summary

The pan-Canadian Oncology Drug Review (pCODR) assesses cancer drugs and makes recommendations to the provinces and territories to guide their drug funding decisions. This report, which analyses pCODR activity to December 31, 2013, is an important part of pCODR's commitment to bringing greater transparency and accountability to the cancer drug review process.

The measures against which pCODR is assessed — operations, transparency, stakeholder engagement — are based on its *guiding principles* which can be read in full on the pCODR website at: *www.pcodr.ca*.

Operations

- pCODR has reviewed 35 submissions as of December 31, 2013. This is in line with expectations when the organization was created.
- Over half of the submissions during pCODR's first two years were made before a Notice of Compliance was issued (pre-NOC), an option that allows the review process to begin as early as possible since the pCODR review runs in parallel to Health Canada's review. This improves access.
- pCODR has found that by allowing reviews for pre-NOC submissions have significantly improved access to cancer drug products compared to reviews for post-NOC submissions. This is because pCODR has done some of the work upfront.
- Review timelines met the 150-day average objective; when reviews began pre-NOC, the 150-day average was met while post-NOC reviews required an average of 140 days. (It is important to note that the 150-day average review 'time clock' begins as soon as a manufacturer submits a drug for review and not at NOC approval.)

Transparency

- On its website, pCODR has posted an average of nine documents for each of the reviews completed as of December 31, 2013.
- 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 pCODR website.
- Should a participating group feel that the steps in the process have been applied unfairly, they can ask for a procedural review; to date, no procedural reviews have been requested.

Stakeholder Engagement

- pCODR hosted webinars and meetings to help patient groups understand the review process.
- pCODR worked with the Canadian Cancer Action Network to create the *pCODR Guide for Patient Advocacy Groups: How to provide patient and caregiver input for a pCODR drug review*.
- Since pCODR's inception, 34 out of 35 drug reviews have had patient group submissions.
- pCODR received one submission from a provincially recognized clinician-based tumour group and worked with tumour groups on seven other submissions to review data, offer counsel on the process and explain the nature of the information needed by the evaluators.

The pCODR review process results in drug funding recommendations to the provinces; the final decision on whether or not to publicly fund a cancer drug rests with each province. A pCODR recommendation is one of the many factors that would be considered prior to a funding commitment. By December 2013, pCODR had issued 29 final recommendations. Of the 29 recommendations, five resulted in positive recommendations, 18 in conditional recommendations and six in negative recommendations.

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. As of December 31, 2013, pCODR estimates that there are 194 drug-indication pairs that may be submitted for review over the next five years. Of these, 122 are new drug-indication pairings and 72 are new indications for existing drugs.

pCODR also watches for treatment trends such as the use of companion tests. As of December 31, 2013, there were 12 different companion tests linked to 15 individual drugs and 31 drug-indication pairs on the horizon. There may be a need, in the future, for pCODR to provide advice and / or funding recommendations on the combination of companion test + drug-indication pairs.

pCODR 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 efforts have contributed to a more transparent and rigorous review system.

1.0 Introduction

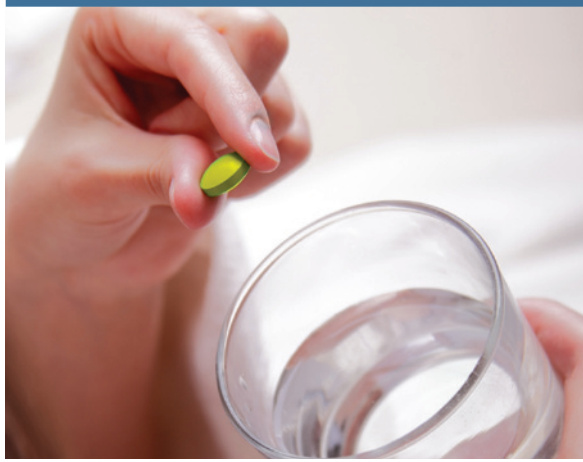
The pan-Canadian Oncology Drug Review (pCODR) assesses cancer drugs and makes recommendations to the provinces and territories to guide their drug funding decisions. Established in 2010 by the provincial and territorial Ministries of Health, pCODR is designed to bring consistency and clarity to the assessment of cancer drugs by looking at clinical evidence, cost-effectiveness and patient perspectives. As of April 1, 2014, the pCODR was transferred to the Canadian Agency for Drugs and Technologies in Health.

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 drug funding 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.

The organization has been operating for more than two years, as it began accepting submissions in July 2011. It is an appropriate time to assess its results and to reflect on its key milestones. This report, which analyses pCODR activity to December 31, 2013, is an important part of pCODR's commitment to bringing greater transparency and accountability to the cancer drug review process.

pCODR'S MANDATE IS TO:

- provide consistency and clarity to the cancer drug review process ensuring that all provinces and cancer agencies benefit from a single, clear approach to new cancer drug evaluation
- leverage best practices and expertise from across Canada to provide provinces and territories with the best possible information to inform their funding decisions
- ensure that scarce health care resources are used to fund only the most effective cancer drugs



2.0 Performance Measures

The measures against which pCODR is assessed are based on its *guiding principles*; those principles (which can be read in full on the pCODR 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, over its first two years pCODR measured and is now reporting on its operations, transparency and stakeholder engagement. The results and their implications are provided on the following pages.

EFFICIENT, EFFECTIVE EVIDENCE-BASED REPRESENTATION

3.0 Results: Operations

The number of reviews, the length of time for those reviews, scope of expertise and providing access to the review process in more than one way, are important markers of pCODR's operational efficiency.

3.1 Volume

pCODR has reviewed 35 submissions as of December 31, 2013. This is in line with expectations when the organization was created. pCODR has also analysed submission data regarding the tumours treated by the drugs and the drugs' routes of administration; please see Appendix A. For more information on priority reviews, please see Appendix B.

PRIORITY REVIEWS

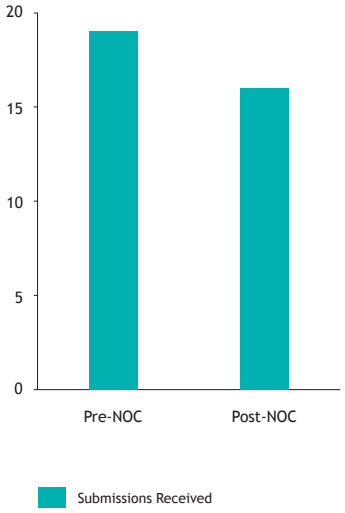
Submissions are reviewed in the order they are received however, at time of filing, a submitter may request that a submission be considered a priority review. This request is assessed against clinically-based criteria, which if met, allows the submission to be reviewed next. Because the review timeline is not condensed, prioritization only impacts on the order of review (if submissions have been queued) and order of placement on the pERC agenda; see Appendix C for the criteria.

Total Submissions = 35 as of December 31, 2013)				
	New Drug	New Indication	Resubmission	Priority Review
Total Submissions	22	11	2	3
July-Dec 2011	3	1	0	0
Jan-Jun 2012	6	2	0	0
July-Dec 2012	2	3	1	0
Jan-June 2013	9	4	1	2
July-December 2013	2	1	0	1

3.2 Access

The pCODR review 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, it allows the review process to begin as early as possible since the pCODR review runs in parallel to Health Canada's review. The option was well-received; over half of the submissions during pCODR's first two years were made pre-NOC.

Pre-NOC vs. Post-NOC



19 (54%) submissions received were pre-NOC

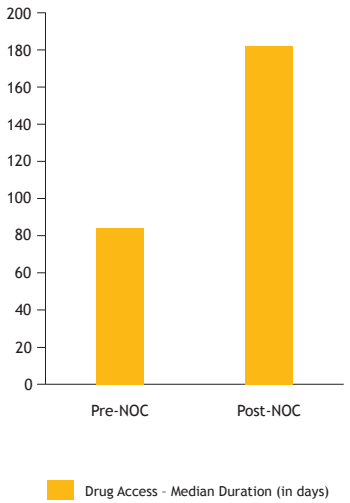
16 (46%) submissions received were post-NOC

i. Timeliness

A pre-NOC review is conducted before a manufacturer has received a Notice of Compliance from Health Canada. Indeed, by doing as much work as possible while Health Canada's review is underway, pCODR has found that significantly fewer overall review days are required for pre-NOC submissions compared to 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 since the review is beginning before all regulatory issues are settled. However, this does not impact patient access since these efforts take place *before* the drug has been approved for sale.

A post-NOC review—conducting the review once a manufacturer has received Notice of Compliance 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.

Time from Receipt of NOC to Notification to Implement



	NOC to Notification to Implement for pre-NOC submission	NOC to Notification to Implement for post-NOC submission
Mean	89 days	289 days
Median	84 days	182 days
Range	49-127 days	143-824 days

NOTIFICATION TO IMPLEMENT refers to a full and final funding recommendation. Once a final recommendation has been made, pCODR provides 10 business days for parties who participated in the review process to make an application for a procedural review if they believe that pCODR did not undertake the review process fully and/or fairly. If there is no procedural review request following the 10 business days, pCODR issues the Notification to Implement, which is the 'green' light for provinces to proceed with making their funding decision.

EARLY CONVERSION:
Feedback on an initial recommendation is assessed to determine if it is eligible to convert 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.

ii. pCODR Review Timelines

When pCODR decided upon an assessment process that included gathering initial input from patient groups and the Provincial Advisory Group, and feedback from patient groups, the Provincial Advisory Group and manufacturers/tumour groups at a second point in the process, there had been concern that this could extend reviews beyond the 150-day average objective. The data shows that this did not happen; when pCODR reviews began pre-NOC, the 150-day average was met while post-NOC reviews required an average of 140 days.

The pre-NOC submission reviews included seven early conversion drug reviews. The post-NOC reviews included two early conversions.

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. Please see Appendix C for more information.

Conclusion

The pCODR process handled the expected volume of submissions in a timely manner and saw significant uptake of its pre-NOC submission option. The organization also identified a pattern concerning the pre-NOC reviews: they require additional time to resolve administrative issues since the manufacturer is still seeking regulatory approval, however this does not affect patient access since, without Health Canada approval, the drug under review cannot be sold in Canada. Nonetheless, pCODR is exploring ways of managing these administrative issues, and thereby, improving its time investment for pre-NOC submissions.

4.0 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 29 final recommendations as of December 31, 2013. There are, on average, nine documents 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 the pCODR Expert Review Committee are listed on the pCODR website. (Please see Appendix D 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 on the pCODR website. One of those steps is a procedural review, should a group feel that the steps have been applied unfairly. To date, no procedural reviews have been requested.

Conclusion

The current pCODR process will remain in place. pCODR will assess the benefits of posting additional information as opportunities arise, based on the information being useful, understandable and helping stakeholders' contribute to the review process.

5.0 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.

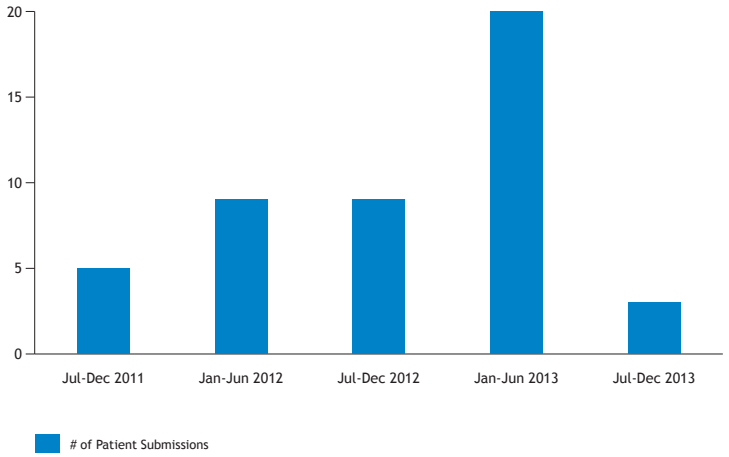
5.1 Patient group support

In addition to webinars and meetings to help patient groups understand the review process, pCODR worked with the Canadian Cancer Action Network to create the *pCODR Guide for Patient Advocacy Groups: How to provide patient and caregiver input for a pCODR drug review*, the first resource of its type in Canada. It is available at www.*ccanceraction.ca* and www.*pcodr.ca*. Collaboration with the Canadian Partnership Against Cancer produced an online tutorial: *How cancer drug funding decisions are made*; the tutorial was created for those with cancer and their families, and is available at www.*cancerview.ca* and www.*pcodr.ca*.

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, 34 out of 35 drug reviews have had patient group submissions.

Submissions from patient groups since inception



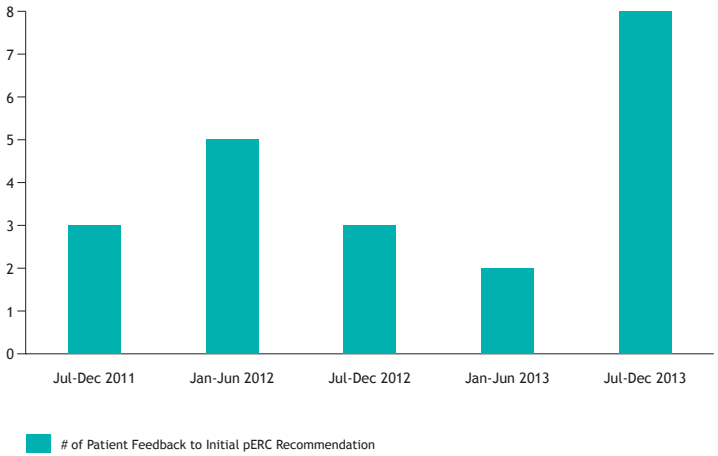
~97% of submissions had patient input (34/35 submissions)

Total Patient Group Submissions = 46* (as of December 2013)

*Note: Certain drug/indication submissions had more than 1 patient group submission

A unique aspect of patient group input to the pCODR process is the ability to comment on an initial recommendation. Seventy per cent of the initial recommendations received patient group feedback.

Patient Group Feedback on Initial Recommendation



Submission cut-off as of December 2013:	
patient feedback to the initial pERC recommendation = 21 (~70%)	manufacturer and PAG feedback to the initial pERC recommendation = 30 (100%)

5.3 Tumour group engagement

Tumour groups are clinical and/or research groups affiliated with a provincial cancer agency or a provincial/territorial Ministry of Health, where cancer specialists, health care professionals and researchers with expertise in tumours related to a specific area of the body, work together. pCODR received one submission from a provincially recognized clinician-based tumour group and worked with tumour groups on seven other submissions to review data, offer counsel on the pCODR process and explain the nature of the information needed by the evaluators. (N.B. The submissions were subsequently made by a drug manufacturer.)

Conclusion

pCODR 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 tumour group involvement.

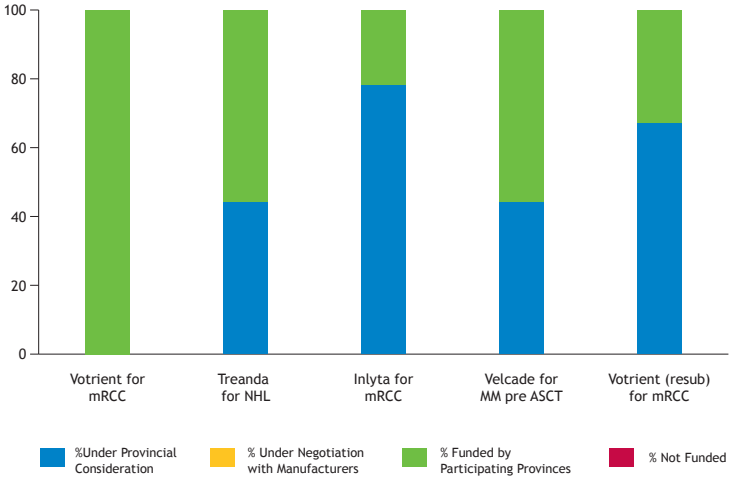
6.0 Provincial Drug Funding Decisions

The pCODR review process results in drug funding recommendations to the provinces; the final decision on whether or not 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 would be considered prior to a funding commitment.

By December 2013, pCODR had issued 29 final recommendations. Of the 29 recommendations, five resulted in positive recommendations, 18 in conditional recommendations and six in 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.

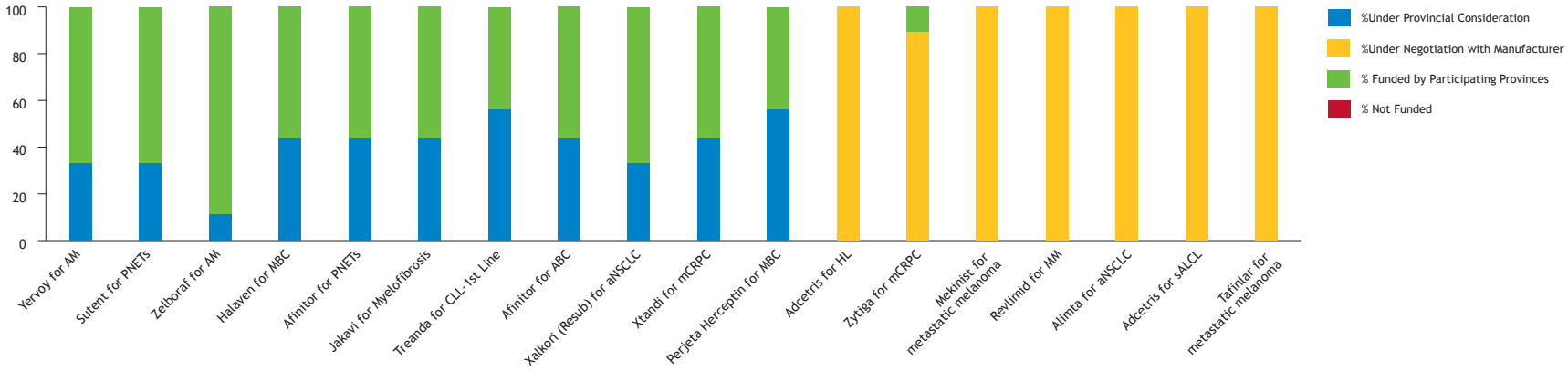
Under Provincial Consideration means that the province is reviewing pCODR's recommendation. This may include the province working with the drug manufacturer to reach an agreement for a drug product that both parties can accept, in particular in cases where the pCODR Expert Review Committee has recommended that the drug be funded only on the condition of cost-effectiveness being improved to an

Provincial Funding Decisions: Positive pCODR Recommendations (as of December 31, 2013)



Drug	Notification to Implement	% Funded	% Under Negotiation with Manufacturers	% Under Provincial Consideration	% Not Funded
Votrient for mRCC	January 20, 2012	100%	—	—	—
Treanda for NHL	December 14, 2012	56%	—	44%	—
Inlyta for mRCC	March 22, 2013	22%	—	78%	—
Velcade for MM pre ASCT	April 11, 2013	56%	—	44%	—
Votrient (Resub) for mRCC	September 16, 2013	33%	—	67%	—

Provincial Funding Decisions: Conditional pCODR Recommendations
(as of December 31, 2013)

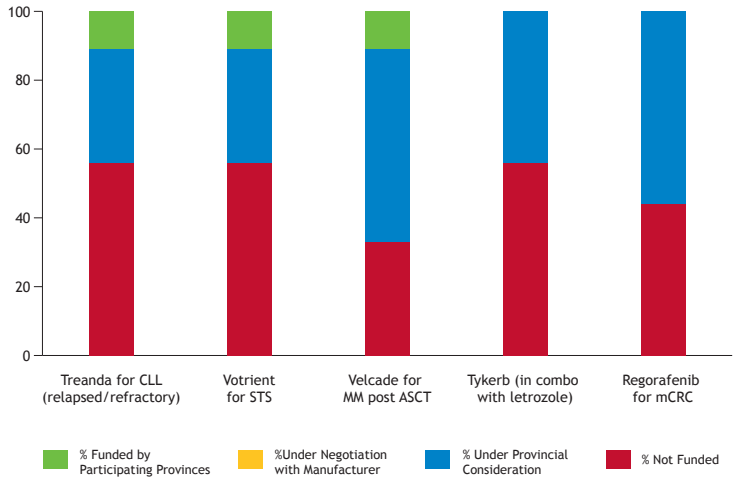


Drug	Notification to Implement	% Funded	% Under Negotiation with Manufacturers	% Under Provincial Consideration	% Not Funded
Yervoy for advanced melanoma	May 2, 2012	67%	--	33%	--
Sutent for PNETs	May 18, 2012	67%	--	33%	--
Zelboraf advanced melanoma	June 18, 2012	89%	--	11%	--
Halaven for MBC	August 20, 2012	56%	--	44%	--
Afinitor for PNETs	September 17, 2012	56%	--	44%	--
Jakavi for Myelofibrosis	January 29, 2013	56%	--	44%	--
Treanda for CLL (1st line)	March 6, 2013	44%	--	56%	--
Afinitor for advanced breast cancer	April 11, 2013	56%	--	44%	--
Xalkori (resub) for aNSCLC	May 17, 2013	67%	--	33%	--
Xtandi for mCRPC	August 8, 2013	56%	--	44%	--
Perjeta Herceptin for MBC	August 19, 2013	44%	--	56%	--
Adcetris for HL	September 16, 2013	--	100%	--	--
Zytiga for mCRPC	November 6, 2013	11%	89%	--	--
Revlimid for multiple myeloma	November 6, 2013	--	100%	--	--
Mekinist for metastatic melanoma	November 6, 2013	--	100%	--	--
Alimta for aNSCLC	December 4, 2013	--	100%	--	--
Adcetris for SALCL	December 20, 2013	--	100%	--	--
Tafinlar for metastatic melanoma	December 20, 2013	--	100%	--	--

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 Manufacturer Negotiation 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 *www.councilofthefederation.ca/en/initiatives/358-pan-canadian-pricing-alliance* or contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.

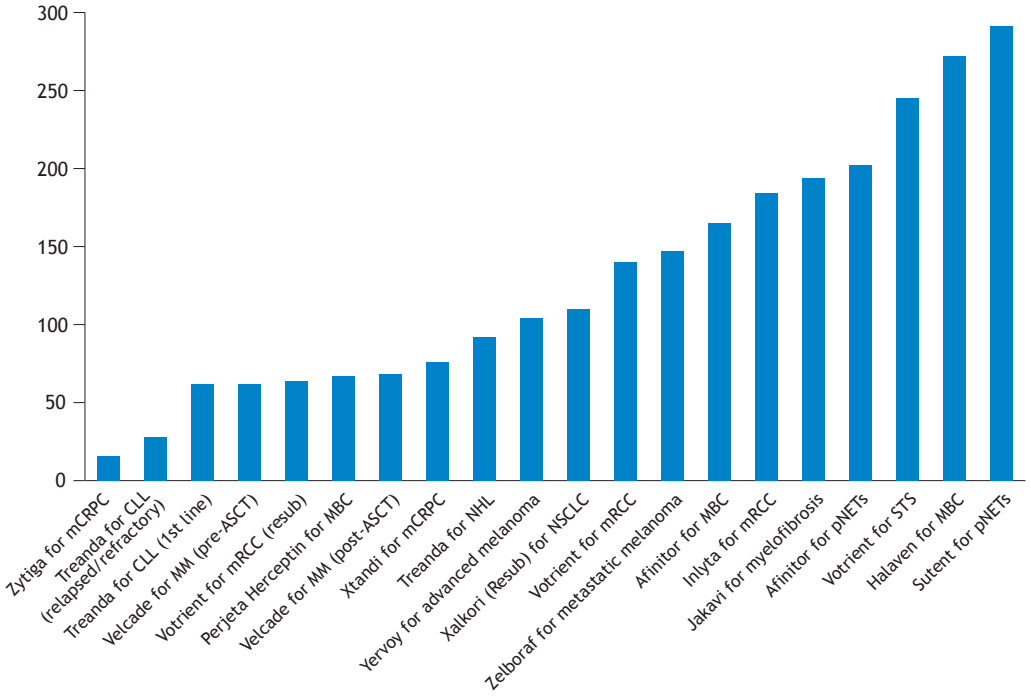
Provincial Funding Decisions: Negative pCODR Recommendations
(as of December 31, 2013)



Drug	Notification to Implement	% Funded	% Under Negotiation with Manufacturers	% Under Provincial Consideration	% Not Funded
Treanda for CLL (relapsed/refractory)	December 14, 2012	11%	—	33%	56%
Votrient for STS	December 14, 2012	11%	—	33%	56%
Velcade for MM (post-ASCT)	April 11, 2013	11%	—	56%	33%
Tykerb (in combo with letrozole) for MBC	July 22, 2013	—	—	44%	56%
Regorafenib for mCRC	December 2, 2013	—	—	56%	44%
Xalkori for advanced NSCLC	**Note:** the manufacturer made a resubmission to pCODR for Xalkori for advanced NSCLC after receiving a negative recommendation, as such, provinces agreed to wait for the final recommendation resulting from the resubmission.				

The average length of time between provinces receiving a funding recommendation (regardless of whether it was positive, negative or conditional) and making a positive funding decision is detailed here:

Average Funding Time (in Days)



Note: as of December 31, 2013
Days = Business Days from pCODR's Notification to Implement to Provincial Listing Date

Drug Product	Average Funding Time (in Days)
Zytiga for mCRPC	16
Treanda for CLL (relapsed/refractory)	28
Treanda for CLL (1st line)	62
Velcade for MM (pre-ASCT)	62
Votrient for mRCC (resub)	64
Perjeta Herceptin for MBC	67
Velcade for MM (post-ASCT)	68
Xtandi for mCRPC	76
Treanda for NHL	92
Yervoy for AM	104
Xalkori (Resub) for NSCLC	110
Votrient for mRCC	140
Zelboraf for MM	147
Afinitor for MBC	165
Inlyta for mRCC	184
Jakavi for myelofibrosis	194
Afinitor for pNETs	202
Votrient for STS	245
Halaven for MBC	272
Sutent for pNETs	291

7.0 Looking Ahead

pCODR is continually assessing how the drug review process can be improved. Knowing what new cancer drugs are on the horizon will allow for better planning. As of December 31, 2013, pCODR estimates that there are 194 drug-indication pairs that may be submitted for review over the next five years. Of these, 122 are new drug-indication pairings and 72 are new indications for existing drugs. Most of the drug-indication pairs would treat genitourinary tumours, lymphoma and myeloma, and gastrointestinal and breast cancers.

Note: These numbers include drugs that are in both phase 2 and phase 3 trials. Phase 3 trials are estimated to complete in and around 2016-2020. These numbers are estimates only and may be subject to regulatory delays or the company 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.

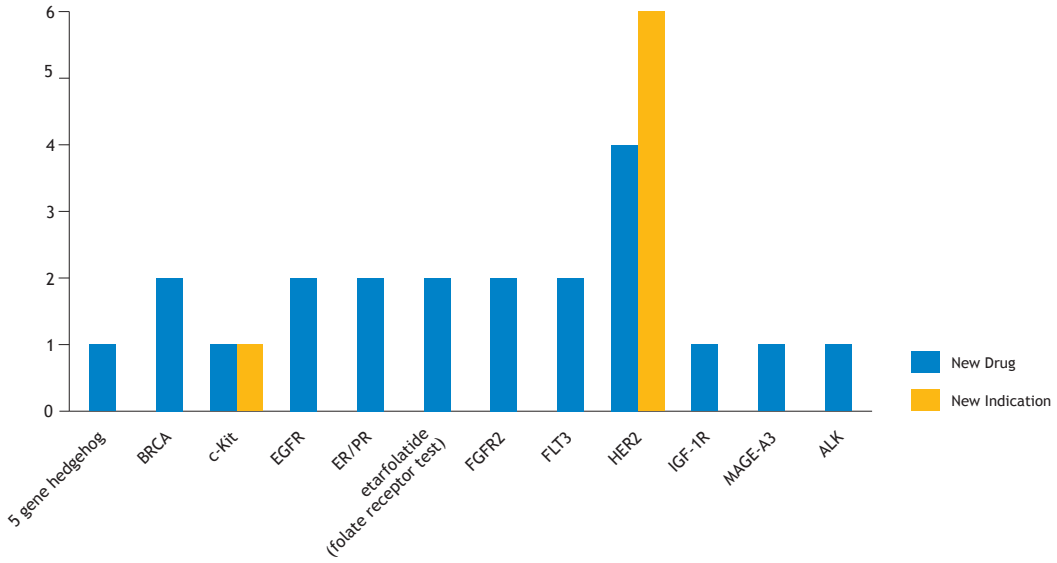
pCODR also watches for treatment trends such as the use of companion tests. According to the U.S. Food and Drug Administration, "Companion diagnostic tests define the subset of patients who are most likely to benefit from a therapy or who should not receive the therapy because of ineffectiveness or predicted 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, 2013, there were 12 different companion tests linked to 15 individual drugs and 31 drug-indication pairs. There may be a need, in the future, for pCODR to provide advice and / or funding recommendations on the combination of companion test + drug-indication pairs.

COMPANION TESTS

- 12 different tests
- 15 distinct drugs (new and existing)
- 31 drug-indication pairs

Companion Tests

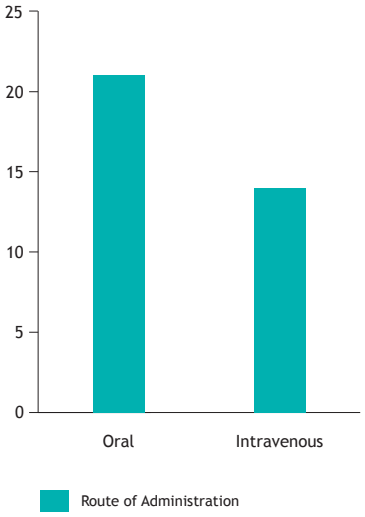


pCODR will continue to assess its performance and report back to its stakeholders each year. Created to bring consistency and clarity to the assessment of cancer drugs, pCODR's efforts have contributed to a more transparent and rigorous review system.

Appendix

Appendix A: Submissions by Route of Administration and Tumour Type

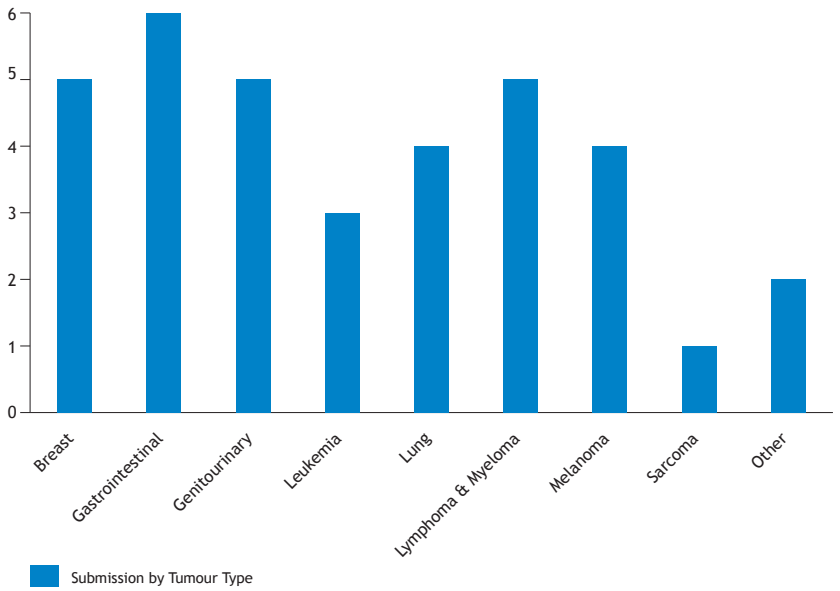
Submissions by Route of Administration



21 (60%) for oral dosage format | **14 (40%) for intravenous format**

Note: Submissions received as of December 2013

Submissions by Tumour Type



Top submissions were for breast, gastrointestinal, genitourinary and lymphoma & myeloma as of December 31, 2013

Appendix B: Priority Review

Submissions to the 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 or not it meets priority review criteria. Request for priority review must be initiated by a manufacturer/tumour group. The request is assessed by a three-person panel consisting of the 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/treatment is currently marketed in Canada

Appendix C: pCODR Timelines

Below is a snapshot of pCODR's drug review timelines as of December 31, 2013. The pCODR 150-day average review 'time clock' begins as soon as a manufacturer submits a drug for review (and not at NOC approval). Both pre-NOC and post-NOC submissions met the 150 day-average targeted timelines.

pCODR pre-NOC Submission Review Timelines (July 2011 to December 2013)

	Initial Recommendation	Final Recommendation	Notification to Implement
Mean	116 days	139 days	150 days
Median	113 days	135 days	146 days
Range	75-189 days	90-201 days	100-212 days

Note: 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 for pre-NOC submission is beyond the 150-day objective.

pCODR post-NOC Submission Review Timelines (July 2011 to December 2013)

	Initial Recommendation	Final Recommendation	Notification to Implement
Mean	93 days	129 days	140 days
Median	89 days	127 days	138 days
Range	76-138 days	96-181 days	107-192 days

Note: For post-NOC submissions, there were also a few 'outlier' submissions from manufacturers that had delays beyond pCODR's control. This is why the *range* of days for post-NOC submission is also beyond the 150-day objective.

NOTIFICATION TO IMPLEMENT refers to a full and final funding recommendation. Once a final recommendation has been made, pCODR provides 10 business days for parties who participated in the review process to make an application for a procedural review if they believe that pCODR did not undertake the review process fully and / or fairly. If there is no procedural review request following the 10 business days, pCODR issues the Notification to Implement, which is the 'green' light for provinces to proceed with making their funding decision.

Appendix D: Committee Roles

Members of pCODR's committees, panels and advisory groups are drawn from every participating province, to ensure geographic representation.

The pCODR Expert Review Committee (pERC)

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

The pan-Canadian Oncology Drug Review 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. The pan-Canadian Oncology Drug Review 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 that are submitted to pCODR's Expert Review Committee (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 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/territories and cancer agencies for evidence-based recommendations that guide drug funding decisions. Issues brought forward by the PAG may include considerations related to the implementation of recommendations, advice around consultation and information exchange, and information about emerging trends in the development and use of cancer drugs. Membership consists of appointed representatives from each of the participating provincial/territorial Ministries of Health and provincial cancer agencies. In addition to these voting members, the pCODR Executive Director stands as an Ex-officio Member.

Need more information?

Please visit ***www.pcodr.ca*** and take a look at our frequently asked questions. If your question is not answered here, contact us at ***info@pcodr.ca*** or call us at **(416) 673-8381.**

pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW