

April 14, 2017

## Innovative Medicines Canada and BIOTECanada

### Joint Response to Questions posed by the Canadian Association of Provincial Cancer Agencies

#### Overview

This document represents Innovative Medicines Canada and BIOTECanada's joint response to the Canadian Association of Provincial Cancer Agencies' (CAPCA) call for feedback regarding the pan-Canadian Cancer Drug Funding Sustainability Initiative (DFSI).

Innovative Medicines Canada and BIOTECanada are supportive of provincial and territorial (pan-Canadian) efforts aimed at "improving access to high quality, evidence-based cancer drugs for all patients" and "contributing to the sustainability of the cancer drug system for all Canadians."

We remain committed to continuing to work in collaboration with all levels of government and various health system stakeholders to develop solutions that achieve timely access to innovative medicines. We continue to support governments' efforts to do so in a way that meets the long-term needs of Canada's health care systems, while protecting and enhancing our capacity for future innovation.

We appreciate CAPCA's efforts to consult with all stakeholders on this evolving initiative and provide additional information on changes under consideration. However, we believe that further clarity is needed on several priority issues. We respectfully submit that it is reasonable for CAPCA to:

- Clarify the mandate, role, and operations of CAPCA and its new Cancer Drug Implementation Advisory Committee (CDIAC);
- Provide a clear rationale for moving away from an equitable "first-in, first-reviewed" system;
- Elaborate on CDIAC's development and current and/or future use of a prioritization framework;
- Enhance transparency including basic process, reporting, stakeholder engagement and governance issues as identified below; and
- Meaningfully consider how CAPCA can help *improve* access to medicines and decrease overall time that patients must wait to receive new therapies. This could be accomplished, in part, by making the cancer drug review process more efficient and avoiding duplication of review processes.

Our capacity to answer the questions posed by CAPCA in a meaningful way is somewhat limited due to a simple lack of information and transparency with respect to the process. We have previously directed many questions to CAPCA and look forward to receiving your responses on some basic points of information. Access to this information would help us better answer the questions that CAPCA has posed in its online survey.

We note that there are some critical information gaps at present. Additional information and clarity would allow for quality stakeholder input and ensure that future dialogue on DFSI is substantive and meaningful. We look forward to ongoing engagement and dialogue on these issues moving forward.

We would take this opportunity to thank you for the opportunity to provide input. Below are our responses to the specific questions posed by CAPCA in the survey circulated on March 21, 2017.

**1. What do you see as the key problems in the current system that CAPCA is best positioned to address?**

There are many challenges and opportunities related to the current cancer drug funding and review system. We see opportunities to:

- Improve access to new, innovative oncology treatments;
- Reduce the time it takes for patients to access new therapies;
- Reduce any redundancies between review processes;
- Harmonize and ensure cross-provincial equity in accordance with highest standards of access;
- Improve the use of conditional funding and performance-based agreements; and
- Improve our collective capacity for generating and using real-world evidence to enhance the optimal use of medicines.

However, there remains uncertainty with respect to CAPCA's intended scope and what specific cancer drug decision making gaps the Cancer Drug Sustainability Initiative intends to address.

We would note at the outset that there are already many existing review processes and structures in place that address the core functions signaled by CAPCA to date.

We have concerns related to additional review processes within the Canadian reimbursement system and the resulting impact that these will have on timely access for patients. For example, the pan-Canadian Pharmaceutical Alliance (pCPA) is already comprised of jurisdictions who lead on negotiations with manufacturers.

Similarly, the role of pan-Canadian Oncology Drug Review (pCODR) Provincial Advisory Group (PAG – [Terms of Reference](#)) is to ensure:

*"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 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."*

It is unclear how CAPCA and CDIAAC's mandate will impact the clear and well-defined pCODR/PAG role regarding implementation and coordination. We would encourage CAPCA and provincial/territorial jurisdictions to consider how implementation issues might be considered by strengthening existing mechanisms. If pCODR is not meeting the jurisdictions' current needs regarding information to support the implementation of formulary recommendations, then the PAG may be an appropriate venue to manage this and advise on next steps.

pCODR was established to promote uniformity of access for therapies across the country. pCODR performs a comparative cost-effectiveness role and has established mechanisms for jurisdictional input. This process

has been in place and refined over many years through a productive and collaborative dialogue among provincial drug plans, cancer agencies, clinicians, patients and manufacturers.

Given that implementation and coordination are already addressed within the system, it appears that CDIAAC's central role will be the prioritization cancer drug reviews and reimbursement decision-making. We have many questions about CDIAAC's role in facilitating or limiting patients' access to therapy. In particular, we are unclear on how CAPCA defines core concepts such as 'prioritization' and 'affordability'. For some stakeholders, this has created the perception of an emerging "black-box" regarding important healthcare decisions. For example, CAPCA has stated that CDIAAC review will take 3-4 months, but will not extend the overall drug review and decision-making timeframe. In our view, it would only be possible for this to happen if other portions of the process were compressed. If this is indeed the case, transparency around those timeline goals would be appreciated and valuable for planning purposes.

In Canada, there is already a large lag between regulatory approval and listing/patient access. Canada lags in total time to public reimbursement compared to many OECD countries. Following Health Canada Notice of Compliance (NOC), Canadians wait another two years on average before a public drug plan funding decision on a new medicine. CAPCA processes should not in any way contribute to lengthening this.

**2. Including the work already underway, what are the most important changes or improvements to the current system that could be led by CAPCA?**

With CAPCA's work focused on "improving access to high quality, evidence based cancer drugs for all patients", we believe that CAPCA could work together with oncology stakeholders to develop creative solutions aimed at improving the speed and breadth of access to innovative treatments in oncology.

It is recommended CAPCA conduct a review on how the provinces and territories could optimize their processes to get the best drugs to cancer patients in a timelier manner. Ideas to explore include:

- Optimize pre-NOC processes with the goal of enhancing review efficiency and reducing overall time-to-listing;
- Adaptive pathways based on real-world evidence where conditional funding for new cancer therapies is provided soon after approval by Health Canada and during the HTA process;
- Framework for conditional funding and life-cycle evidence building programs; and
- Cancer drug funding aligned with performance objectives and equity of access for both oral and IV therapeutics and support drugs.

**3. Are there other jurisdictions that CAPCA should look to for examples of (1) innovative approaches to prioritization; or (2) the successful collection and use of real world evidence after a drug is in use in the population?**

Before engaging in prioritization, CAPCA should take a step back to explore and better articulate the rationale for prioritization. Health Canada already has a transparent and criteria-based priority review process that helps to address cases of unmet need or significant advancement of treatment options.

Any move away from the principles of fairness embodied in the "first-in, first-reviewed" approach at the reimbursement level requires elaboration of scope.

- i. Regarding prioritization, we are not aware of any proven international best practices that would easily translate to Canada. CAPCA should engage in more detailed study and analysis of existing and potential prioritization models to serve as a baseline for future discussions with all stakeholders. This is especially important for patients who would be most impacted by prioritization. In particular, the ethical dimensions of prioritization need to be subject to considerable study and open social dialogue before a framework is implemented. Any departure from an efficient “first-in, first-reviewed system” will require ethical, logistical and impact analyses.

For example, provisions that would bundle or group the review of similar products entail potential ethical implications. These issues require further study.

Priority setting in health care is complex and multifaceted. Processes must be designed to ensure adequate public input, and allow for the reflection of public values. This includes identifying and agreeing on the principles that will be incorporated into the evaluation of the costs/benefits of interventions and evaluating the effect of the prioritization decisions on policy, practice and outcomes (e.g. review process and evaluation of performance).

We are interested in working together with CAPCA and other health system stakeholders to explore the issue of ethical prioritization further.

- ii. Real-World Evidence (RWE) is a clear opportunity for collaboration.

We note there are elements of the systems in the United Kingdom, Sweden, Italy, Germany, the U.S. private insurer market, and some other countries that may have potential learnings for Canada in developing RWE and outcomes based payment models. Many of the HTA bodies, payers and regulators in these countries are actively trying to better understand how best to use RWE, and where its use is appropriate.

There are many technical, logistical, and data-access issues that require further consideration. The following is a non-exhaustive list of options to explore further:

- Accelerate the adoption of Health Information Technology (HIT) in Canada and closer collaboration with Health Infoway;
- Leverage technology to collect health outcomes data and improve information systems and interlinkage of the existing information systems;
- Promote risk sharing agreements based on outcomes based payment models;
- Fund a drug for a limited period while efficacy and safety data are collected;
- Develop clear guidelines in validating and assessing the RWE data via expert consultations;
- Consider including robust prospective methodology for collecting data in addition to using retrospective data; and
- Enhance transparency regarding the impact on timelines, what will be required by industry, and what opportunities industry should expect to engage with CAPCA for product specific inquiries related to RWE, local data generation, and other issues.

- Canada's drug review and funding system is unique internationally. While there are various international models that Canada may be able to learn from, this will necessarily involve borrowing elements from other systems rather than the wholesale adoption of any one model.

#### 4. What can CAPCA do to ensure that stakeholders better understand the role of CDIAAC?

There would be a significant benefit for oncology stakeholders to have additional clarity on CDIAAC. There remain many questions on this committee that would benefit from additional discussion and elaboration. We recommend CAPCA publish and consult on each of the following as related to CDIAAC:

- Terms of Reference including governance;
- A clear process overview including any assessment methodology;
- The recommendations or decision-making framework being considered;
- A framework for engaging with stakeholders including patients; and
- Any prioritization framework or principles that are currently being used to prioritize files; and
- Ongoing assessment of process performance including reporting metrics developed in consultation with stakeholders.

In addition to these basic process and reporting elements, we would recommend that there be regular scheduled meetings between CAPCA, industry, clinicians and patient stakeholders to provide context on operations, discuss progress, and address any issues that may arise. For example, CADTH offers regular meetings with the industry associations and umbrella patient advocacy groups to discuss topics of mutual interest.

#### 5. How can CAPCA address any concerns that CDIAAC will duplicate efforts or increase system inefficiency?

Based on the information currently available on CDIAAC, we believe that CDIAAC duplicates efforts already being conducted by pCODR/PAG and under the jurisdictions in pCPA.

As identified above, CAPCA should clarify the role of CDIAAC and engage in further study of the prioritization issue.

CAPCA could also consider how to consolidate functions and improve overall process efficiency within the cancer drug review system.

CAPCA has identified that the CDIAAC's review will take 3-4 months. It is not currently clear how and when this could be added to the existing drug review process in Canada without adding time to the overall process.

#### 6. What key steps does CAPCA need to take to optimize the potential of RWE?

As identified in #3 above, we have provided CAPCA with a scoping document that we hope can form the basis for productive collaboration on RWE going forward.

Given the complexity of the RWE topic and need for a multi-disciplinary and multi-stakeholder approach, we recommend that joint industry-CAPCA technical and policy working group(s) be established to explore the

RWE issue in depth. It is critical to have a better understanding of the options within RWE and which is most appropriate.

Technical and policy working group(s) could explore such critical issues as:

- Guiding principles for health system engagement between private and public stakeholders in establishing and optimizing the application of RWE to inform decision-making;
- Collection and application of relevant and meaningful data to generate RWE to assess clinical benefit and cost-effectiveness;
- Data management policies and processes including governance in regards to storage, access and ownership issues, sharing including inter and intra-provincial, and patient confidentiality;
- Data systems, infrastructure and interoperability;
- Role of various stakeholders (e.g. cancer agencies; industry; Health Canada; HTA agencies; patients; clinicians; health economists, epidemiologists and vendors);
- Costs, roles and responsibilities, and resource requirements;
- Early engagement with technology and data-infrastructure experts;
- Potential roles for domestically produced versus international RWE efforts; and
- The role of RWE within the funding process and its role in decision making.

**7. What could be done by CAPCA to identify and engage the right experts to help collect, analyze and use RWE?**

The issue of *who* leads and develops RWE is a key question that requires further discussion. There are also legal and practical issues of research questions, data ownership, methods of analysis, quality assurance, and approach to managing any data gaps. Given that different health system partners have different expertise and practical roles at various stages of the RWE pathway, this effort will necessarily reflect a collaborative exercise. As highlighted above in response to question #6 above, we feel these issues must be addressed through more detailed work, cooperation and technical dialogue.

Better coordination of the generation, synthesis, and assessment of evidence by the various established decision-making bodies in Canada (regulatory, HTA and payers) is important to ensure meaningful and positive impact on patients through robust evidence-based policy changes.

**8. Please describe any data sources that could be evaluated as potential contributors of RWE data. If possible, please provide the name and contact information for a person most familiar with the data source.**

As per #6 above, this issue must be addressed through more detailed work, cooperation and technical dialogue. This can be coordinated through our associations and we will ensure that the right expertise is brought to the table.

**9. Based on best practices and your previous experience, how should CAPCA be engaging with stakeholders going forward?**

As suggested for RWE above, CAPCA could establish technical and policy working groups with industry for each of its focus areas (Prioritization; Implementation; and RWE) and hold regular scheduled liaison



meetings. If CAPCA is willing to engage in a working group model, we would be happy to propose names of industry representatives for participation and draft terms of reference.

**10. Is there a stakeholder engagement design, or approach best practice, that CAPCA should be considering?**

As per #9 above, we believe a working group model would be most productive. We would also suggest CAPCA align with the collaborative approach pursued when establishing and refining iJODR/pCODR.

The interim Joint Oncology Drug Review (iJODR) program, established in March 2007, drew upon the expertise of provincial drug plans, cancer agencies, practicing oncology clinicians, tumour-specific oncologists, patients, and innovative pharmaceutical companies. As an interim process, it evolved over time and involved extensive consultations with all affected stakeholders. The result of those discussions was the creation of the pCODR in 2010. Following an 18-month period of organizational evolution, development and extensive consultations, the pCODR review process was launched in mid-2011.

While some challenges remain, pCODR has distinguished itself as a process committed to continuous improvement and excellence, primarily through dialogue with affected stakeholders and its partners. It is because of this that pCODR has developed a credible international reputation as a thoughtful and well-considered review process with broad support from affected stakeholders.

The process includes multiple opportunities for input from interested parties (i.e., pre-submission comments, clarification opportunities during the review, feedback on the initial recommendation and an option to request a procedural review). The result is that stakeholders can recognize their input in the resulting decisions through the provision of detailed recommendations. pCODR addresses and responds to all the key considerations identified during the review process. As a good starting point for further transparency enhancements, CAPCA should also review pCODR's approach to reporting and publicly posting information including topics/products under review and provincial listing statistics.

We encourage CAPCA to engage those provincial officials with experience on pCODR to advise on how best to leverage that engagement approach.

**11. Which other organizations need to be involved in these conversations?**

It will be of the utmost importance for CAPCA to ensure robust stakeholder engagement and full transparency in these efforts.

We encourage CAPCA to ensure consultation proceedings and related information/materials be made available to all/any interested parties, including patients, clinicians, manufacturers, government and academia (e.g. bioethicists). Consultation and document distribution should not be limited to those who were included in the original CAPCA webinar.

We greatly appreciated the face-to-face meetings that CAPCA facilitated in Vancouver and Toronto, and encourage CAPCA to look at ways to expand the reach of these in person opportunities using technology (e.g. teleconference/dial-in capability live broadcasting or proceedings).

We understand that clinicians have been consulted separately, and note that it would be helpful for patients and all stakeholders to also benefit from these insights.

We also believe it is reasonable for all material, slides and documents provided to be posted to CAPCA website along with the governance and process items discussed above.

## **12. Do you have any other questions?**

To date, we have submitted several questions to CAPCA including the priority questions listed below. We would welcome CAPCA's efforts to provide clarity on these points:

- What is the definition of 'prioritization' being used by CAPCA? What is the scope and how will CAPCA prioritize reviews if not based on "first-in, first-reviewed"?
- What are the key drivers and principles behind 'prioritization'? It was perceived from the presentations during the Vancouver and Toronto roundtables that CDIAAC is conducting some sort of prioritization and some clarity will be helpful as we are preparing a response to this question. It was also perceived that 'affordability' concerns may be the primary driver.
- Is CAPCA considering prioritization before the HTA reviews (i.e., pCODR), between pCODR and pCPA, at pCPA level or at multiple levels through the process?
- How will CAPCA mitigate against the risk that CDIAAC leads to delays in access?
- What will be the potential impact on other drug reviews (non-Oncology)? How will CAPCA and its partners address prioritization outside of oncology?
- Does CAPCA have a definition of 'sustainability'? Does it include the complete value proposition of effective cancer drugs or is it focused primarily on addressing the drug budgets?
- How will CAPCA measure the value of a drug (including health system / hospital impact) and balance this value against its cost?
- Can CAPCA share examples of what it considers a successful CDIAAC recommendation already implemented?

Thank you for your attention to these important issues. We look forward to your responses and further productive dialogue. Kindly direct any questions or further information to Chander Sehgal ([csehgal@imc-mnc.ca](mailto:csehgal@imc-mnc.ca))