CAPA
Canadian Arthritis Patient Alliance

www.arthritispatient.ca
contact@arthritispatient.ca
@CAPA_Arthritis

August 9, 2020

Re: Proposed Alignment of CADTH Drug Reimbursement Review Processes

To Whom It May Concern,

On behalf of the Canadian Arthritis Patient Alliance (CAPA), I am writing to you to provide our feedback on the Proposed Alignment of CADTH Drug Reimbursement Review Processes. We have reviewed the proposed alignment document from the perspective of people who live with arthritis, a chronic health condition that affects close to six million people in Canada. Many people with arthritis need medicines to participate in activities of daily living, make contributions at work and retain quality of life.

The Canadian Arthritis Patient Alliance is a grass-roots, patient driven, independent, national organization with members across Canada and supporters in Canada and beyond. We believe the first expert on arthritis is the individual who lives with the condition. We provide a strong voice and concerted effort to promote the well-being of people living with arthritis and we assist our members to become advocates not only for themselves but for all people with arthritis. The organization is a small virtual

Our responses and input to the consultation questions are attached to this letter. Given our perspective, we have primarily focused on questions related to Patient Engagement along with some others where we feel we are engaged and qualified to provide input. While our provided feedback is selective with respect to CADTH's drug reimbursement review processes, we also wish to note the importance of these processes being improved overall within a larger healthcare system context, not just within CADTH's own silo. Compared to the United States and major European Union markets, Canadians face delays in accessing important medications due to our inefficient and siloed approval processes. This study by Salek *et al* found that the average overall timelines for public reimbursement after Notice of Compliance were long, with most of this time taken up by Health Technology Assessment and the pan-Canadian Pharmaceutical Alliance processes, at 236 and 273 days, respectively. A new drug agency was proposed in the 2019 federal budget and it is critical from a patient perspective that we see a clear re-alignment of processes to provide patients with access to medicines in a timely manner. Given that we recently submitted our input on the Patented Medicines Review Pricing Board revisions, we are pleased that CADTH is asking for input on its processes at what seems to be an opportune time. We encourage CADTH to examine these processes within this broader ecosystem when taking in to

account this feedback, and to remember that Canadian patients count on its processes to access critical medications that often mean huge improvements to their lives.

We are grateful for being able to provide this input on behalf of people living with arthritis and look forward to seeing how this input is considered.

Sincerely

Dawn Richards, PhD
Individual who lives with Rheumatoid Arthritis
Volunteer Vice President

Input to Proposed Alignment of CADTH Drug Reimbursement Review Processes

Communications for Drug Reimbursement Reviews

Does your organization agree with the proposal to streamline communications for CADTH's drug reimbursement reviews?

- Like other patient organizations that are submitting to this process, we encourage CADTH to consider the ICER 2020-23 Value Assessment Framework (January 31, 2020) best practice in terms of doing HTA (p 5-6 and 13-14) including:
    - *Page 5 – ICER has "a commitment to explore how 'real-world' observational evidence can contribute to a more comprehensive and accurate view of the risks, benefits, and costs associated with any intervention. This commitment extends not only from using available published sources, but includes the possibility of working with life science companies, patient groups, or data aggregator companies to develop and analyze new sources of real-world evidence in* a way that will meet the evidentiary standards relevant to the questions being addressed." In numerous submissions to CADTH, we have mentioned that Canada has large real world cohorts in rheumatology (for example, the Canadian Early Rheumatoid Arthritis Cohort) that would be beneficial to share insights in to how medications impact 'real world' patients in addition to those whose experiences are captured in randomized controlled trials.
    - *Page 6- "Even when trials do capture the clinical outcomes that matter most to patients, there are other aspects of the treatment regimen that have a significant impact on the overall value of the treatment" (e.g., impact of care options on*

return to work, on family and caregivers, on overall public health). The ICER value framework identifies these "potential other benefits or disadvantages" as important elements of any overall judgment on long-term value for money, and all ICER reports have separate sections in which evidence and information pertaining to these elements are presented."

- In terms of process for this consultation, we encourage CADTH to follow ICER's process of seeking input from all of the groups listed in the ICER Value Assessment Framework (including "patient advocacy organizations, clinical societies, drug manufacturers, and payers, as well as several individual commenters" - p. i) and following the process of making the input, and CADTH's summary response to each one, public.
- We agree with CADTH's proposed process of streamlining its communications and find that the proposed process seems straightforward to accessing those communications.

Do you or your organization have any suggestions for improving CADTH's drug reimbursement reviews communications?

- Ensure that patients and patient groups have an opportunity to sign up for any communications they want from CADTH.
- Include communications about news, new drug submissions, seminars, or other topics as available.
- Communications should be in plain language to make them as accessible as possible to the patient community (and the public).
- Consider sending the call for patient input on a new drug review and input on drug review recommendations (as well as other input submission opportunities) on a Monday rather than on a Friday. Even if unintended, communications issued on a Friday provides an impression that there is a two-day loss in the timeline allocated for the process to occur due to the weekend.

CADTH Reports and Recommendations

Does your organization have any suggestions for improving the clarity and consistency of CADTH clinical and pharmacoeconomic reports?

- See our input above.

Does your organization have any suggestions for improving the clarity and consistency of CADTH recommendations?

- Given that the pCODR and CDR review processes are different, there should be consistency and alignment between them.

How could the final recommendation document be improved? Is there content that should be added, removed, or presented in a different way?

- CADTH should consider having the final recommendation written in plain language (e.g. as a one-page summary). Though we understand that CADTH's reports are technical, it would be helpful for the recommendation document to be as accessible as possible to a wide patient audience. This approach would also make it easier for patient organizations to communicate the findings to their own patient communities and helps contribute to transparency to the public.

Patient Engagement

As a patient group, is it useful to have the opportunity to review CADTH's summary of patient group input?

- This process is useful and it provides patient groups the opportunity to clarify any points they made during their submission and to ensure that information was captured accurately in the synthesis.
- It should be noted, though, that up until we asked about a year ago, it was not clear to us what the purpose of the summary was until we asked.

Do you or your organization have any suggested improvements for CADTH's patient engagement processes?

- We would like to see patients fully included in all CDEC and pERC processes, beyond the written patient input submission process. We recommend inclusion of the patient group representative who wrote the submission in CDEC and pERC meetings by telephone or videocall in the same way that clinicians are engaged (i.e., an opportunity to join at least a portion of the CDEC and pERC meetings for the patient group representative who wrote the submission). Alternatively, at the very least, ensuring that a person who lives with the condition described in the submission is present at the meeting is important. This practice is used efficiently by NICE in the UK and lessons learned from their experiences could be adopted in Canada.
- It remains unclear why pERC has patient representatives while CDEC has public representatives. We believe it is important for a patient to be part of the Committees to represent a patient perspective. We feel it would be best to include a person who lives with the condition that is subject of the submission at the meeting.
- As part of CADTH's engagement and alignment with other government bodies (i.e., INESSS, BC Pharmacare) it would be very useful to streamline the patient submission processes and forms to be completed across these HTA bodies, or to come to agreement about one form being used by all agencies. As a very small organization run by volunteers and without paid staff, having the Ontario public reimbursement process use the CADTH submissions has been extremely helpful for us. This represents an opportunity to create efficiencies for organizations such as ours so we can focus on other efforts that are important to our community.

- We recommend that there be a very clear standard set of guidelines and instructions for conflict of interest: what it means, what needs to be declared, and how this information needs to be declared. This should be the same standard for clinician and patient groups (i.e., clinicians who are involved in a review should have to declare conflict of interest in the same manner that patients do; this includes funding for clinical trials, consultancy agreements, speaker's fees, etc.).
- CADTH should consider working with patient groups to develop diverse funding sources for their work and also to consider providing funding specifically for the preparation of submissions. Well written and thoughtful submissions take a substantive amount of time and resources. Given that CADTH is encouraging these submissions, it would be very helpful for it to provide resources to enable this work. Additionally, this is one way of helping remove potential conflicts of interest associated with specific submissions.
- Ensure that the current patient input submission template is useful to Committees. It is unclear to us how useful the description of life with our illness is to the Committee members. We are inclined to think, given our own life experiences, that the quantitative data that is part of the review is more heavily weighted than the qualitative data the submissions like ours provide. Perhaps there is an opportunity for a workshop or project to be undertaken so that patient groups can better understand what type of data the Committee members are expecting from patient groups and for members of the patient community and Committee members to develop such a template. Research from Dr. Katherine Boothe is useful to seeing how much perceptions related to HTA and patient input has changed/not changed since its introduction by CADTH ("Getting to the Table": Changing Ideas about Public and Patient Involvement in Canadian Drug Assessment. J Health Polit Policy Law (2019) 44 (4): 631–663. https://doi.org/10.1215/03616878-7530825).

Review Procedures

Do you or your organization have any suggestions for improving CADTH's processes for reviewing clinical evidence?

- We support a more transparent review process. For example, NICE and Australia allow people to attend the deliberations. While not the entirely the same, the FDA has created the Patient Focused Drug Development series that is open to anyone to attend (often in person as well as virtually).

Do you or your organization have any suggestions for improving CADTH's processes for reviewing economic evidence?

- See answer to question one above

Are there aspects of the deliberative processes of CDEC and pERC meetings that you would like to understand in greater detail?

- As mentioned previously, we recommend inclusion of the patient group representative who wrote the submission in CDEC and pERC meetings by telephone/video in the same way that clinicians are engaged currently.

Reconsideration Process

Do you or your organization support CADTH's proposal to reduce the number of reviews that undergo reconsideration following issuance of the initial recommendation?

- In ensuring that patient perspectives are adequately addressed, we recommend that patient representatives be provided the opportunity to seek clarification on decisions made by CDEC, including a more comprehensive understanding of the reasons for the decision. After a negative reimbursement recommendation, there is no opportunity to seek feedback from CADTH including any outstanding questions raised by patient groups. The formal written patient submission process does not lend itself well to constructive and meaningful dialogue particularly where patients may be significantly limited in accessing medicine needed to treat their condition.

Do you or your organization support CADTH's proposal to introduce greater flexibility to the reconsideration process (i.e., requests for major revisions, minor revisions, or editorial revisions)?

- Patient groups should have the opportunity to engage in and request a reconsideration under appropriate circumstances.
- Notwithstanding the feedback provided to patient groups, we should have the opportunity to seek clarifications on the decisions made by CDEC and have these questions addressed by the subject matter experts, advisory committee members and others involved in making the decision.

Do you or your organization have any suggested improvements for the reconsideration process?

- See the answer to question above
- We would also recommend that there be performance metrics developed for the timelines for this process.