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Title: Time to potential for listing of new drugs on public and private formularies in Canada: a cross-sectional study
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Reviewer 1: Dr. Maria Mathews
Institution: Schulich School of Medicine and Dentistry
General comments (author response in bold)

This paper examined the time to completion for two intervals in the drug review process in Canada. Overall this is a straightforward paper. Data sources and analyses are clearly described. Limitations of the available data and analysis are described. Relevant comparisons with the literature are made. Potential applications are described.

I have two relatively minor suggestions:

1. The change in submission timing is presented within the final objective. More information about the change in submission policy would be helpful: why it was introduced and what was the expected impact of the new policy?
At the end of the Introduction, I now say that according to a CADTH official these changes were made to eliminate delays between regulatory approval and CADTH funding recommendations.

2. A table (or flow chart) listing times by recommendation and therapeutic value as well as other relevant variable to describe the type of drug, or manufacturer would be useful).
A new Table 2 summarizes the various times reported on.

Reviewer 2: Dr. Fiona Clement
Institution: University of Calgary
General comments (author response in bold)

This paper explores the time from NOC to positive listing decision by pCPA from 2011-2020. This is an interesting database to have assembled by pulling the various pieces of data together from the disparate data holdings. But, to be a useful, thought provoking contribution, I think the author needs to engage more critically with these issues and help the reader to do the same. I offer some suggestions in the spirit of improving the manuscript.

1. The paper would benefit from more clarity about the issue it is trying to address. The rationale talks about the difference between when a person with private insurance may have access to a drug compared to when a person with public insurance may be able to access and how this might be a larger issue with Pharmacare. But then the research objectives are to assess the effect of the early submission to CADTH as a tool to reduce time to access (public listing). Within the paper, both objectives can't be done justice and that results in a very superficial, confusing presentation of these data. The paper would benefit from more clearly articulating the arguments for its objectives and then mapping the analysis and interpretation to that purpose.
The primary purpose of the paper is to look at the important time periods between when a drug is approved by Health Canada and when it is eligible to be listed on public formularies. If there is a pharmacare program then only drugs that are

listed on the national formulary will be eligible for coverage. Therefore, it is important to determine the various time intervals. One of those intervals is the time between drugs are approved by Health Canada and when a submission is made to CADTH. CADTH now accepts submissions before Health Canada issues a NOC in order to accelerate the process of listing drugs on public formularies. If companies are not taking full advantage of early submissions then that is important information since a change in company policy would lead to earlier availability of publicly funded drugs. I am unclear about why Dr. Clement thinks that there are multiple objectives. In the Introduction I now explain the reason for the change in CADTH policy about the timing of submissions and that I am examining the key time periods between Health Canada approval and eligibility for public formulary listing.

2. The process for evaluation is complex and hard to follow in the introduction. This would be very effectively communicated through a figure. The author should consider developing a visual to help the reader follow the complex timelines and process.
Figure 1 already outlines the process that drugs go through before they are listed on public formularies. The new Table 2 summarizes the various time intervals for each of the key periods considered in the paper.

3. The methodological decisions made throughout are not clearly communicated. For example, why were only positive list decisions from pCPA included in the analysis? Why wasn't the CADTH recommendation analysed as a variable? These decisions need to be explained and a rationale given in the methods.
The paper now considers all the pCPA decisions. The CADTH recommendation was not analyzed as a separate variable because, as explained in the paper, even products receiving a negative CADTH decision were still considered by the pCPA.

4. A reader must be very familiar with the different organizations and their roles to be able to follow this manuscript. The author should include more context about the agencies. This could be achieved with a Box, for example, that provides a mandate overview of each organization. Further, there is a lot of jargon in the manuscript about NOC, NDS without clarity for your reader about what these milestones mean. It makes the figures every hard to follow if your knowledge about these processes is limited.
The Introduction describes the role of each of the organizations – Health Canada, CADTH, pCPA. I do not believe that a box is necessary but can provide one if the editors think that it is important. There is now a brief explanation that a NDS initiates the approval process and that Health Canada's approval is a NOC.

5. The interpretation section is very hard to follow. The author needs to consider what the main findings of the paper are and then discuss them through a critical lens. The findings of this paper could lead to a very rich, thoughtful discussion on what could be done now to address the issues identified.
I am not clear why Dr. Clement found the Interpretation section hard to follow. The beginning of the Interpretation section clearly presents the main finding that there is at least a 1 year difference between when drugs can be listed on private formularies and when they become eligible for listing on public formularies.
In addition to the changes made in response to the comments from the editors and reviewers I also became aware that one of the submissions to CADTH came from public drug plans and not from the manufacturer of the drug and this is now mentioned in the Methods and the analysis was redone without the data for this

submission. Finally, the manuscript has been edited to ensure its length is in line with CMAJ Open's requirements.