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pCPA Brand Process FAQs



Version 1.0

RECORD OF UPDATES TO pCPA BRAND PROCESS FAQS

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1.0	Original Version	May 2018

INQUIRIES

All inquiries related to the pCPA Brand Process FAQs should be submitted in writing.

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FAQs

1. How is a Lead(s) selected?

A Lead(s) is identified based on a combination of factors including:

- Expertise in a given therapeutic area
- Ease of access to required resources
- Jurisdictional negotiation capacity

2. When and how is Lead identification communicated to the Manufacturer?

The Lead(s) is first communicated to the Manufacturer via the Engagement Letter. The Engagement Letter is sent out by the pCPAO once the Drug is considered by the Jurisdictions and common pan-Canadian objectives are established for the Drug.

3. Which agencies are included when referring to HTA?

HTA includes CADTH and INESSS. With pCPA representing all of Canada, including Québec, recommendations from both CADTH and INESSS are included in consideration by the pCPA.

4. Does pCPAO meet with Manufacturers to discuss specific Drugs prior to HTA Review?

The pCPAO will typically not accept meetings from Manufacturers to discuss specific Drugs prior to HTA Review. The pCPAO may, however, accept a meeting with a Manufacturer in circumstances where a Manufacturer is unfamiliar with the pCPA negotiation process, in order to address the Manufacturer's process-related inquiries.

5. Can a Proposal for a Drug with an HTA recommendation be considered by the pCPA prior to the pCPA issuing an Engagement Letter?

Unsolicited Proposals will not result in expedited timelines and there is no commitment from Jurisdictions to respond to Unsolicited Proposals. If a Manufacturer wishes to submit an Unsolicited Proposal, the Proposal should be sent to the pCPAO to be shared with all Jurisdictions, and not directly to individual Jurisdictions.

Manufacturers may decide to submit an Unsolicited Proposal to:

- Address issue(s) raised by HTA requiring further attention; and/or
- Demonstrate readiness to offer significant value.

6. What can impact negotiation timelines?

Some factors include:

- Proposal requirements are not met.
- Complexity of the proposal with more complex proposals usually requiring greater time for understanding and review by Lead(s) and Jurisdiction(s).
- Disagreement with HTA recommendations/concerns and attempts to resolve through pCPA negotiations, which the pCPA process is not meant to address.
- Introduction of new clinical aspects at the time of the negotiations that have not been reviewed by HTA and which the pCPA process is not meant to address.
- BIA issues such as:
 - BIA is not updated to match the HTA recommendation prior to commencing negotiations.
 - BIA assumptions are not explained.
 - Discrepancies between the BIA provided by the Manufacturer and the BIA prepared by the pCPA.
 - No BIA formulae provided, etc.
- Continued significant differences in expected value between the Manufacturer and the pCPA.
- Ambiguity on more detailed implementation issues (i.e. specific clinical criteria).
- Meetings between the parties where no new information is presented.
- Changes in the therapeutic space.
- Requests to amend LOI template provisions.

7. Can negotiations with individual Jurisdictions begin after a Close Letter is sent to the Manufacturer?

Decisions to send a Close Letter are made on a collective pan-Canadian basis. Any interest in pursuing negotiations with one or more jurisdictions should be raised through the pCPAO to those jurisdictions.

8. What are the options for a Manufacturer when they receive a Close Letter?

A Manufacturer can request a meeting with the pCPAO to discuss possible next steps specific to their Drug.

If the decision to send a Close Letter was based on a negative/no therapeutic value HTA recommendation, the Manufacturer should contact CADTH/INESSS.

9. Can a decision to close negotiations without LOI be reconsidered?

If a Manufacturer wishes to provide a new Proposal after receiving a Close Letter, this may be submitted through the pCPAO (not individual Jurisdictions), and will be at the discretion of the pCPA for reconsideration. It should be noted that changes in therapeutic/funding environment may impact the objectives previously sought through negotiations.