Canada's Drug Agency
L'Agence des médicaments du Canada

# Feedback on Proposed Improvements to the Drug Reimbursement Review Process

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| **Organization providing feedback:** | Pulmonary Hypertension Association of Canada |
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If your organization is not submitting feedback on this section, please indicate: No relevant feedback to submit.

| Section of consultation | Feedback |
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| **1. Proportionate review processes** | |
| 1.1. Revised procedures for tailored reviews | We welcome the expansion of the tailored review process, so long as the timeframe for providing patient and clinician input is not shortened. It will expedite appropriate reviews, which may free up resources and thus also expedite complex reviews. |
| 1.2. Revised procedures for complex reviews | We appreciate that a more modular approach is likely to speed up the review process, to everyone's benefit. We strongly favour the retention of the ability to submit a societal perspective base case alongside the health care payer perspective base case for the economic evaluation of first drugs in a therapeutic area. |
| 1.3. Simplifying the resubmission processes | We are in favour of waiving certain requirements for resubmissions, as this will expedite the resubmission process and increase efficiency. |
| **2. Review and recommendation reporting** | |
| 2.1. Review report templates | As a patient organization, we applaud the replacement of an Executive Summary with a Key Message section written in language more suitable for a wide audience. Combining patient group and clinician group input by topic moves toward a more inclusive, less tokenistic practice for dealing with patient group input than the previous practice of summarizing patient and clinician input separately. |
| 2.2. Recommendation report template | The inclusion of content from presentations by persons with lived experience at committee meetings is, again, an important step towards a practice more inclusive of patient group information. |
| 2.3. Process for redacting review reports | No relevant feedback to submit. |
| **3. Deliberative process** | |
| 3.1. Presentation by a person with lived experience | We support the inclusion of a presentation by a person with lived experience at committee meetings and encourage close collaboration with patient groups in identifying an appropriate presenter with lived experience. The offer of honoraria, guidance to that person in preparing their presentation, and an emotional debrief afterwards, both helps level the |

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| | playing field for such presenters and recognizes the emotional labour involved in presenting one's lived experience. For in-person meetings, financial and logistical help with accommodation, travel, etc. would be essential. For both virtual and in-person meetings we ask that the presenter with lived experience be allowed to be accompanied by a support person (e.g., patient group representative) and that, where possible, more than one patient representative voice be heard. Including one sole person's voice raises questions about equity and inclusion in both the process of choosing the representative and in who, ultimately, is chosen to speak. We suggest the addition of a transparent nomination process to partially address these issues. |
| 3.2. Deliberative framework | Making the deliberative framework and decision flowchart available is valuable for transparency. We commend the inclusion of factors other than the economic but question how much weight is given to social dimensions vs. economic; the relative weighting should be stated explicitly. We recommend standardization of the weights given to various factors to avoid the potential tokenization of non-economic evidence in the overall decision-making process. |
| 3.3. Drafting recommendations | No relevant feedback to submit. |
| **4. Accelerated access pathways** | |
| 4.1. Rolling submissions | We appreciate that allowing the initiation of a review before all evidence is available and before Health Canada's regulatory decision may expedite the review process, as timely access is a major concern for new pulmonary hypertension treatments. |
| 4.2. Proposed minor expansion of time-limited recommendations to resubmissions | No relevant feedback to submit. |
| **5. Checkpoints with sponsors throughout the drug Reimbursement Review process** | |
| 5.1. New presubmission meeting format and purpose | No relevant feedback to submit |
| 5.2. New evidence presentation meeting | No relevant feedback to submit. |
| 5.3. New in-review meeting | No relevant feedback to submit. |
| 5.4. Reconsideration meeting | No relevant feedback to submit. |
| 5.5. New postsubmission meetings | No relevant feedback to submit. |
| **6. Application requirements for sponsor submissions** | |
| 6.1. Streamlining application requirements | No relevant feedback to submit. |
| 6.2. Indirect treatment comparisons and individual patient data–based comparisons | No relevant feedback to submit. |
| 6.3. Proposed reimbursement conditions | No relevant feedback to submit. |

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| 6.4. Clinical expert suggestions | Allowing sponsors to include a list of suggested clinical experts for the review is a positive step to ensuring rare diseases, for which the population of experts with appropriate clinical knowledge is small, are considered fairly. |
| 6.5. Citing Clinical Study Report data in the sponsor summary of clinical evidence | No relevant feedback to submit. |
| 6.6. Declining to file a Reimbursement Review submission | No relevant feedback to submit. |
| 6.7. New consolidated eligibility inquiry form | No relevant feedback to submit. |