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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Canada	**Agency Name:** Health Canada	
Name of FRP: Priority Review of Drug Submissions		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 12/13/1996		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☒	☐

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	Before the marketing authorisation submission
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	The Priority Review for Drug Submissions policy applies to a New Drug Submission (NDS) or Supplemental New Drug Submission (S/NDS) for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides: - effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or - a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada. *Definitions - Clinical Benefit: outcomes that have an overall positive impact on the treatment of a disease - Significant Increase/decrease: statistically significant and clinically relevant increase (or decrease) identified through well controlled clinical trials.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Health Canada will publish a Notice of Intent in Canada Gazette every fall specifying the fee amounts that will take effect the following April 1st. Health Canada's web site will be updated accordingly. Note that the fee payable is based on the filing date of the

	submission or application. That is, the date Health Canada deems the submission or application to be administratively complete with all elements completed to Health Canada's standards. The filing date and the date Health Canada receives the submission or application will be the same if the submission or application is accepted for preliminary examination as is, with no adjustments required. However, the filing date will lag behind the date of receipt in the event that Health Canada finds the submission or application to be administratively incomplete and must ask the sponsor for additional information.
Total target (agency) time for assessment (calendar days)	Priority Review status allows for the insertion of eligible drug submissions into Health Canada's submission workload on the basis of a shortened review target of **180 calendar days**. As such, qualifying submissions may undergo review in advance of non-eligible submissions in accordance with approaching target dates. *Submission workload consists of all submission types, differentiated across biological, pharmaceutical and medical device product lines. Specific therapeutic expertise within the Biologics and Genetic Therapies Directorate (BGTD) and the Therapeutic Products Directorate (TPD) is directed towards the review of corresponding submission types where required. As such, the review of a priority submission will commence before the review of other pending submissions of the same therapeutic area, which have a target completion date after that of a priority submission. The review of submissions with a target review date preceding the target review date of the priority submission, will not be disrupted. Once priority review status has been granted, there is a stated expectation that the submission will: 1. be filed within 60 calendar days; 2. contain the information and material for the purposes of Division 8, Part C of the Food and Drug Regulations; and 3. be subject to the *Guidances for Industry Management of Drug Submissions*.
Total target (company) time for responses to agency questions (If stated)	The clinical evaluator may, on occasion, request additional supporting information to support and clarify the information provided in the Priority Review request. The sponsor is required to submit, **within two (2) business days of a request,** any supplementary information needed to assist in the assessment. In the event that supplementary information is not received within the above period, the

	decision to accept or reject a request for Priority Review status will be based on the information provided in the original request, subject to the interpretation of Health Canada evaluators. Health Canada will notify the sponsor of the decision to accept or reject Priority Review status within 30 calendar days of receipt of the request. If the request is accepted, the sponsor will submit the full drug submission to Health Canada within 60 calendar days of, but not prior to, the date of issuance of the acceptance letter. Submissions received in advance of the acceptance letter will undergo screening and, if found acceptable, shall enter the review queue as a non-priority submission. The review of a Priority request related to the submission shall cease immediately upon receipt of the submission.

Select one of the following (* see definitions at end of document)

Is this a verification review (a recognition pathway)?*	Is this an abridged* review (selected dossier portions)? (a reliance pathway)?*	Is this a full* review of all parts of the dossier?
☐	☐	☒

If this is a reliance or recognition pathway, what are the accepted reference agencies?	Health Canada makes their own independent decisions. However, it is possible (and recommended) to submit the major Q & As issued during the foreign review, along with the Foreign Agency Reviewers Reports. If the submission includes foreign review report, it is recommended to include a completed Foreign Review Attestation Template. The extent to which Health Canada will use foreign reviews varies. The Canadian regulatory decision can be based on a critical assessment of the foreign reviews, on the Canadian review only or on a mixture of both.
How many reference agency decisions are required?	Not Applicable.
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this process is not through a Regional Regulatory Initiative.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how	Health Canada makes their own independent decisions. However, it is possible (and recommended) to submit the major Q & As issued during the foreign review, along with

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long?	the Foreign Agency Reviewers Reports. If the submission includes foreign review report, it is recommended to include a completed Foreign Review Attestation Template. The extent to which Health Canada will use foreign reviews varies. The Canadian regulatory decision can be based on a critical assessment of the foreign reviews, on the Canadian review only or on a mixture of both. The provision of foreign review reports in an NDS is not mandatory, but highly recommended. Indeed, they are usually requested at screening if not included within the original submission. In addition, within the Screening Acceptance letter, Health Canada usually requests the sponsor to share the Questions from foreign regulatory agency reviews and the sponsor's answers, during the review of the NDS. When the Canadian agency has questions that have already been addressed in a response to questions from a foreign agency, it likely reduces the number of questions to be raised to the sponsor, accordingly.
How are queries to the companies sent?	As they arise
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- as needed
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- On December 13, 1996, the former Therapeutic Products Programme issued a policy statement entitled Priority Review of Drug Submissions. The policy, replacing Information Letter, number 804, provided for the "fast-tracking" of eligible New Drug Submissions (NDS) and Supplemental New Drug Submissions (SNDS) intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases or conditions. - Sponsors seeking Priority Review status are encouraged to deliver a brief presentation to Directorate review staff, prior to submitting a written request for Priority Review status. The sponsor may, at this time, discuss details of the submission, as well as the potential eligibility of the submission for Priority Review status. Sponsors should submit a pre-submission meeting information package to the Submission Management Division/Unit of the appropriate

	Directorate in advance of the meeting. For further information, sponsors are advised to contact the Submission Management Division/Unit of the appropriate review Directorate. The sponsor is required to submit, **in advance of the filing of the drug submission,** a written request for Priority Review status to the Director of the appropriate Bureau within Health Canada and a completed Clinical Assessment Package (CAP).
Date of this update	5 APRIL 2020
References	1. Guidance for Industry - Priority Review of Drug Submissions. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/priority-review/drug-submissions.html Accessed on 5 April 2020. 2. FAQ – The Drug Regulatory and Approval Process in Canada. https://spharm-inc.com/frequently-asked-questions-on-the-drug-regulatory-approval-process-in-canada/ Accessed on 5 April 2020. 3. Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees/fees-review-drug-submissions-applications-2019/document.html#s2.4 Accessed on 5 April 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.