Health Canada Santé Canada

February 6, 2009

NOTICE

Our file number: 09-101263-867

Administrative Corrections to Health Canada`s Priority Review Documents

Administrative changes were made to the French and English versions of the following Health Canada documents:

- *Policy: Priority Review of Drug Submissions/ Politique: Évaluation prioritaire des présentations de drogues*
- *Guidance for Industry: Priority Review of Drug Submissions/ Ligne directrice à l'intention de l' industrie: Évaluation prioritaire des présentations de drogues*

On December 20, 2007, administrative changes were made to the English and French versions of Priority Review Policy and Guidance documents to ensure consistent messaging for both official languages. However, in the process of making these administrative changes, errors were inadvertently introduced in the documents. Health Canada has therefore made the subsequent corrections to ensure consistent application of terminology.

Questions or concerns related to the policy and guidance documents should be directed to:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
Holland Cross, Tower B,
Address Locator 3102C3
1600 Scott Street
Ottawa, Ontario
K1A 0K9

Tel: (613) 948-4623
Fax: (613) 941-1812
E-mail: Policy_Bureau_Enquiries@hc-sc.gc.ca

Canada

Health Canada Santé Canada

Policy

Health Canada

Date Adopted: 1996/12/13
Revised Date: 2005/11/30
Effective Date: 2006/03/01
Administrative Changes Date: 2008/12/18

Document Change Log		
Change Date	**Location (section, paragraph)**	**Nature of and/or Reason for Change**
1996/12/13		Date of Original Adoption
2002/11/06	Throughout document	Clarification of eligibility criteria and the application process
2006/03/01	Section 3.6	Reflecting necessary changes resulting from finalization of the guidance document *Reconsideration of Final Decisions Issued for Human Drug Submissions*
2007/12/20	Throughout document	Consistent application of terminology
2008/12/18	Throughout document	Consistent application of terminology

Priority Review of Drug Submissions

1. PURPOSE

This policy statement supercedes the previous policy, ***Priority Review of Drug Submissions*** effective November 1, 2002. The purpose of this policy statement is to:

a) Provide for the priority review of drug submissions for new therapies, preventatives and diagnostic agents for serious, life-threatening or severely debilitating diseases or conditions.

b) Provide details of the procedures relating to the determination of Priority Review status of drug submissions.

c) Provide a mechanism for Health Canada to manage the flow of drug submissions and prioritize incoming workload.

2. BACKGROUND

On December 13, 1996, the former Therapeutic Products Programme issued a policy statement entitled ***Priority Review of Drug Submissions***. The policy provided for the "fast-tracking" of eligible New Drug Submissions (NDS) and Supplemental New Drug Submissions (S/NDS) intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating disease or conditions.

A reassessment of this policy was prompted in December 1999 by concerns communicated through industry and the HIV/AIDS community. These groups questioned the criteria used to assign priority review status to submissions and expressed a desire for increased transparency of the drug review process. In particular, concerns related to an increase in the current submission backlog within Health Canada, confusion with respect to eligibility criteria for Priority Review status and a desire to ensure that relevant breakthrough therapies would be captured within the scope of Priority Review.

Assigning shorter review time-frames to a selected group of submissions impacts on Health Canada's ability to meet performance targets for other submission types. In providing additional clarification for both eligibility criteria and the process by which Priority requests are assessed, Health Canada aims to increase the consistency of the Priority Review process while continuing to satisfy the intent of the policy in providing a prioritized review of critical new drugs and breakthrough therapies under the identified scope.

3. SCOPE

This policy applies to a New Drug Submission (NDS) or Supplemental New Drug Submission (S/NDS) for a serious, life-threatening or severely debilitating disease[1] 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.

---

1 Guidance on serious, life-threatening and severely debilitating is outlined in "*Guidance for Industry; Priority Review of Drug Submissions.*"

4. PROCEDURE

a) Sponsors are encouraged to deliver a brief presentation to the appropriate directorate within Health Canada, prior to submitting a request for Priority Review status.

b) 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) in a format similar to that outlined in "*Guidance for Industry: Priority Review of Drug Submissions*". Incomplete packages and requests received subsequent to, or concurrent with, the arrival of the submission will not be accepted.

c) 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.

d) 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.

e) 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 not be eligible for Priority Review status.

f) In the event that an initial Request for Priority Review is rejected, sponsors may file a Request for Reconsideration of the decision in accordance with the procedure outlined in the Health Canada's *Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions*.

g) Alternately, sponsors may file a second Priority Review request and CAP, for additional consideration for the same indication, following a period of 60 days from the date of the original request. New information in support of the Priority Review status of the submission must be evident, i.e. results of ongoing clinical trials. Re-analysis of data to address reasons for the rejection of the original

request falls within the scope of the Reconsideration procedure and may not be used as the basis for a second request. A sponsor re-filing a request must adhere to the procedures outlined in Section 4 b) through f).

In the event that the second Request for Priority Review status is rejected, sponsors may file a Request for Reconsideration of the second decision. As per section 5.1 of Health Canada's *Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions*, the rejection of either a first or second Rejection of Priority Review Request under the *Priority Review Policy* is eligible for Reconsideration. However, sponsors may only file a Request for Reconsideration of the first rejection *or* file a second Request for Priority Review status - they may not file both.

5. BASIS FOR APPROVAL

A drug submission which has been granted Priority Review status shall contain all the information and material required for purposes of Division 8, Part C of the *Food and Drug Regulations*.

6. MANAGEMENT OF SUBMISSIONS AND CHARGES

Priority Review requests and submissions reviewed under this policy will be subject to the Therapeutic Product Directorate's *Guidance for Industry: Management of Drug Submissions* and any applicable fee regulations.

Submissions granted Priority Review status will be subject to the following reduced target time frames:

- 25 calendar days for submission screening, and
- 180 calendar days for submission review.

7. DISCONTINUANCE OF PRIORITY REVIEW STATUS

Priority Review status will be re-evaluated upon issuance of a Notice of Noncompliance (NON) or Notice of Deficiency (NOD). Sponsors will receive formal notification of Health Canada's decision to continue or reject Priority Review status based on whether the conditions precedent for Priority Review status still apply.

If there is more than one submission for drugs for the treatment, prevention or diagnosis of the same disease or condition and a Notice of Compliance is issued in relation to one of the submissions, the Priority Review status of the remaining submission(s) will continue until such time as a NON or NOD is issued and Priority Review status is re-evaluated.

8. ALLOCATION OF RESOURCES

The policy on Priority Review will be utilized to establish review priorities but will not preclude staff from working on other projects. Priority Review requests and submissions will be subject to established Performance Standards.

Submissions receiving Priority Review status may result in re-allocation of Health Canada resources to address the identified needs. As a result, Health Canada has the expectation that sponsors requesting Priority Review status market the product in a timely fashion, i.e. within 60 days.

9. EFFECTIVE DATE

This revised policy statement is effective as of March 1, 2006 and replaces the previous Policy dated November 1, 2002.

10. RELATED RESOURCES

For more information, please consult the *Priority Review of Drug Submission* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/priorit/priordr-eng.php) guidance document.