What is Priority Review?

Priority Review is a fast-track status granted to eligible new drug submissions for human use, following review and approval of a request submitted by the sponsor of the drug. Priority Review submissions are introduced into Health Canada’s drug review queue in accordance with an accelerated review target of 180 days.

What is the purpose of Priority Review?

Priority Review status assigns eligible submissions a shortened review target of 180 days, in comparison to 300 days for non-priority. Health Canada believes it is in the best interests of Canadians to review potentially life-saving drugs as early as possible.

Which drug products are eligible for Priority Review status?

Priority Review status may be granted to drug submissions intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating illnesses or conditions where a) there is no existing drug on the Canadian market with the same profile or b) where the new product represents a significant improvement in the benefit/risk profile over existing products.

Are Priority Review submissions reviewed quicker than non-priority submissions?

No. Priority Review submissions are subject to the same quality, safety and efficacy requirements as non-priority submissions and therefore the time required to review the information is the same. However, Priority Review submissions are inserted into Health Canada’s drug submission queue in accordance with a shortened review target and, as such, may be reviewed in advance of non-priority submissions.

How does a sponsor apply for Priority Review status?

Sponsors seeking Priority Review status of a drug submission must first provide a written request together with a completed Clinical Assessment Package to the appropriate Directorate within Health Canada. For additional information on applying for Priority Review, refer to "Guidance for Industry; Priority Review of Drug Submissions."