



# Priority Review of Drug Submissions (Therapeutic Products)

## 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."

## For further information

Write:

Therapeutic Products Directorate  
Holland Cross, Tower B  
1600 Scott Street, 2nd Floor  
Address Locator 3102D1  
Ottawa, Ontario  
K1A 1B6  
Tel: (613) 941-5057

or visit our Web site:

[http://www.hc-sc.gc.ca/dhp-mps/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/index_e.html)

