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Helping Canadians get faster access to the prescription drugs they need to live healthier lives

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News release

Government of Canada consults on new approach to fast-track the review of treatments for serious, rare and debilitating diseases

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The Government of Canada is committed to helping all Canadians access affordable treatment options they need to help them improve and maintain their health. For many Canadians, managing the symptoms of rare or debilitating diseases can be overwhelming. When the availability of treatments for these diseases is limited, or highly expensive, it is even more challenging.

Health Canada has launched consultations on a new approach for faster reviews of new and promising drugs for patients suffering from serious, life-threatening, or severely debilitating diseases. The Department published revised [guidance](#) for industry that identifies new criteria for triggering an accelerated review. Interested Canadians, industry and healthcare providers have until July 21 to provide feedback on the draft guidance.

The draft guidance proposes to take into consideration the needs of Canadian patients and the health care system when deciding whether to fast-track a particular review. For example, the current priority review process allows only

the first drug in a certain class or the first drug for a specific condition to be prioritized.

The proposed guidance aims to broaden the eligibility criteria for accelerated review, allowing more drugs to go through a fast-track review to get them to the patients who need them sooner, while still ensuring safety.

Quotes

"Canadians with rare diseases already face enough challenges, without having to worry about lengthy approvals and regulatory delays. By streamlining the review process, we will ensure they get can access to treatments they need as quickly as possible."

*The Honourable Ginette Petitpas Taylor
Minister of Health*

Quick facts

- The proposed guidance is an important element of Health Canada's Regulatory Review of Drugs and Devices initiative. Additional measures to accelerate access to treatments for Canadians include:
 - Using more information about drugs in real-world settings [link] to contribute to our understanding and facilitate the approval of drugs for rare diseases;
 - Conducting more work with international regulators to better understand innovative treatment options even sooner;
 - Modernizing the Special Access Program that provide access to drugs in extreme situations to better meet the needs of physicians and patients; and

- Working with provinces and territories through the Canadian Agency for Drugs and Technologies in Health and the Institut national d'excellence en santé et en services sociaux to align reviews and share information to streamline processes.
- In the past five years, approximately 30% of the drugs Health Canada authorized were to treat rare diseases.
- Budget 2019 spells out new measures the Government of Canada has proposed to support Canadians with rare diseases in getting the medications they need by announcing a national strategy for high-cost drugs for rare diseases to help Canadians get better access to the effective treatments they need. Working with provinces, territories, and other partners, the Government will co-develop a plan to ensure that patients with rare diseases have better and more consistent coverage for their treatments, which are often life-saving. Budget 2019 proposes to invest up to \$1 billion over two years, starting in 2022-23, with up to \$500 million per year ongoing, to help Canadians with rare diseases access the drugs they need.

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