Health Canada Santé Canada

News Release
For Immediate Release

Health Canada announces another step to accelerate access to health products for COVID-19

May 27, 2020 Ottawa, Ontario Health Canada

The COVID-19 pandemic has led to a global search for therapies to treat, diagnose, mitigate or prevent the infection. Before new therapies can be made available to Canadians, they must be shown to be safe and effective, and clinical trials are a critical part of that process.

To date, Health Canada has approved 37 clinical trials for potential COVID-19 therapies and vaccines. To accelerate these efforts, the Honourable Patty Hajdu, Minister of Health, has authorized the following change for a more flexible process for clinical trials related to COVID-19, without compromising the safety of participants or the reliability of trials' findings:

- Allow a wider range of health professionals, such as nurse practitioners, to be involved in running clinical trials. Under current regulations, only physicians and dentists can conduct clinical trials for drugs;
- Allow a wider range of investigators, such as physicians, to be involved in running clinical trials for medical devices. Under current regulations, only manufacturers can conduct clinical trials for medical devices;
- Reduce the burden associated with labelling and record-keeping requirements for clinical trials involving drugs that are already marketed for other indications and are being studied to treat COVID-19;
- Enable multiple-stream clinical trials to continue even when one stream has been stopped; and
- Enable more clinical trials by allowing trials where direct interaction with the participant is not feasible, for example when participants who live in remote locations are unable to travel.

Quotes

"We have made progress against COVID-19 by following public health advice, and we need to keep going. We also know that it will take time before a vaccine or treatments are available, and this is why we are making these changes to help the medical community work as quickly and safely as possible."

The Honourable Patty Hajdu
Minister of Health

Quick Facts:

- The changes to the process for clinical trials have been made through an Interim Order signed by the Minister of Health. An Interim Order is one of the fastest mechanisms available to the Government of Canada to help make health products available to address larger-scale public health emergencies.
- As with all drugs and medical devices, Health Canada will assess and monitor the safety of the drugs and medical devices being investigated under this Interim Order, and will take immediate action to protect the health and safety of Canadians, if necessary.
- The Minister of Health recently signed two other interim orders to facilitate access to treatments for COVID-19, specifically:

  - To allow for the importation of drugs, medical devices, and foods for special dietary purposes that are in shortage as a result of the COVID-19 pandemic, and
  - To ensure quicker and more flexible approval of the importation and sale of medical devices that are necessary for Canada's response to COVID-19, including test kits.
- Health Canada and the Canadian Institutes of Health Research, in collaboration with the Canadian Association of Research Ethics Boards, issued a Joint Statement on Clinical Trial Oversight in Canada. The statement announces a new initiative to have monthly engagement sessions where policy makers, regulators, funders and oversight bodies will collaborate and share information on clinical trials.
- Interim Orders remain in effect for 14 days, and can be extended for up to one year by the Governor in Council, after which they may be renewed if required.

Associated Links

Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19
Clinical Trials and Drug Safety
Drugs and vaccines for COVID-19: Conducting a clinical trial
Medical devices for COVID-19: Conducting a clinical trial
Joint Statement on Clinical Trial Oversight in Canada

- 30 -

Contacts

Cole Davidson
Office of the Honourable Patty Hajdu
Minister of Health
613-957-0200

Media Relations
Health Canada
613-957-2983
hc.media.sc@canada.ca

Public Inquiries:
613-957-2991
1-866-225-0709