Media Lines

Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19

Issue Statement: On May 23, 2020, the Minister of Health signed an *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*. This will streamline the investigation of potential therapies and facilitate broader access for Canadians to COVID-19-related investigational drugs and medical devices.

Key Messages:

- To support efforts to develop COVID-19 therapies, the Minister of Health has signed an Interim Order to make the authorization process for clinical trials related to COVID-19 more efficient and flexible, without compromising the safety of participants or the reliability of trials' findings.

- Clinical trials play a critical role in advancing research and evaluation of investigational products, while protecting the safety of Canadians.

- Health Canada's top priority is protecting the health and safety of clinical trial participants. The Department will continue to conduct rigorous reviews of each clinical trial application and protocol under this Interim Order, as it does for all clinical trials.

- Currently, there are no drugs specifically authorized to prevent, treat or cure COVID-19 in Canada.

- The Government of Canada continues to monitor and support emerging science, and is committed to ensuring that our domestic efforts and international contributions are supported by the best available evidence and aligned with global efforts.

Questions and Answers:

Q1. What is the goal of this Interim Order?
The *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19* makes the authorization process for clinical trials for pharmaceutical drugs, biologic drugs (including blood and blood components) and medical devices related to COVID-19 more efficient and flexible, without compromising the safety of participants or the reliability of trials' findings.

There are currently no drugs authorized to prevent, treat or cure COVID-19 in Canada. There is an urgent need to explore effective interventions, and clinical trials play a critical role in the research and evaluation of investigational products. Investigational products could be new products or repurposing marketed products for a COVID-19-related indication.

This Interim Order will:

- Allow a wider range of health professionals, such as nurse practitioners, to be involved in conducting 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 conducting clinical trials for medical devices. Under current regulations, only manufacturers can conduct clinical trials for devices;

- Support innovative trial designs that could shorten the length of time needed to complete a trial;
- Contribute to the global effort to address COVID-19 by being better aligned with other international regulators and organizations, such as the World Health Organization;
- Reduce the labelling and record-keeping requirements for clinical trials involving drugs that are already marketed for other indications and are being studied to prevent, treat or cure 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 (e.g., participants who live in remote locations and that are unable to travel).

The Interim Order also allows Health Canada to stop only part of a multi-treatment clinical trial while allowing other treatments to continue. This would attract trials studying multiple therapies or different populations in the same trial. If new safety concerns arise in one part of the study, but not in the rest of the study, that part could be suspended. The remainder of the trial would be allowed to continue.

Q2. Has Health Canada already authorized any clinical trials for COVID-19?
Health Canada is expediting its regulatory process for any COVID-19-related health products, including the review of submissions and the authorization of clinical trial applications. To date, Health Canada has approved 37 [check for updated numbers before using] clinical trials for potential COVID-19 therapies. A list of all drug clinical trials (including for vaccines) approved for the prevention or treatment of COVID-19 can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html. A list of all medical device clinical trials authorized for the prevention or treatment of COVID-19 is available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-investigational-testing.html

Q3. How will Health Canada ensure the safety of clinical trial participants?
The clinical trials authorized through this Interim Order are subject to strict requirements to protect the health and safety of participants. These include requirements regarding Research Ethics Board approvals and informed consent, labelling, record keeping, incident reporting or serious unexpected adverse drug reaction reporting, as well as amending authorizations to ensure the that safety of clinical trial participants is protected.

Many of these requirements are similar to those in the existing clinical trial schemes in the *Food and Drug Regulations* and *Medical Devices Regulations*. However, where appropriate, some administrative requirements have been removed, such as allowing a broader range of health professionals to conduct clinical trials related to COVID-19. The Interim Order also specifies how to obtain informed consent in cases where the qualified investigator is unable to obtain the consent of a clinical trial participant in person or in writing. This could include remote written informed consent of participant in a clinical trial involving a COVID-19 drug or non-written informed consent obtained by reading the contents of the informed consent form to the trial participant before a witness, and the witness attesting that consent was given.

Q4. To what extent does this Interim Order expand the scope of who is authorized to conduct clinical trials?
This Interim Order expands the scope of health professionals, such as nurse practitioners, to act as qualified investigators in clinical trials for drugs. This is expected to help facilitate large multi-

site clinical trials, as well as trials in remote communities where there may be a limited number of physicians available to conduct them.

The Interim Order also sets out an expanded range of applicants for medical device clinical trial authorizations. Applicants may now include independent clinicians, academic researchers, and contract research organizations, as well as manufacturers and importers.