Health Canada Santé Canada

Canada

Vaccine Regulation – Health Canada Updates

Vaccines Task Force Presentation

July 10, 2020

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Current context – COVID trials in Canada

- As of July 9, 2020, 49 trials for treatment or prevention of COVID-19 have been approved in Canada
  - Mix of new and repurposed pharmaceuticals, biologics, convalescent plasma

- 2 trials of vaccines specific to SARS-CoV2 have been authorized to date:

  - CanSino – Phase I/II – May 15, 2020
  - Medicago – Phase I – July 9, 2020

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html

Regulation of COVID-19 clinical trials

Food and Drug Regs (Division 5)	Interim Order (June 12, 2020)	Benefits
Regulations prescribe default authorization if Health Canada does not object to the trial within 30-days.	Not defined in the Interim Order. Performance target to review COVID-19 trials set at 14 days in Guidance.	Prioritizes review of COVID-19 related trials. Provides faster review, allowing trials to begin sooner.
Requires all post-authorization changes be submitted to Health Canada as either an amendment for authorization or as notification.	Non-significant changes would not need to be submitted to HC. However, authorizations holders must keep records of theses changes.	Reduces reporting requirements to lighten administrative burden on sponsors.
Qualified Investigator must be qualified physician or dentist.	Enables broader range of regulated health care professionals (e.g. nurse practitioners, pharmacists, midwives) to conduct drug trials as qualified investigators.	Aligns qualified investigator definition across drugs and medical devices. Supports greater decentralization of trials to multiple/remote sites.
Informed Consent must be written.	Supports alternate means of obtaining informed consent for patients at remote sites or who are too ill to sign consent.	Allows for remote and non-written consent when appropriate to facilitate virtual trials and infection control in the context of COVID-19. Would attract trials where direct interaction with the participant is not feasible.
Authority to suspend or cancel a clinical trial site or the whole trial. No ability to allow arms of the trial to continue.	Allows Health Canada to suspend or cancel a part or the entire trial.	Allows Health Canada to stop only part of a multi-treatment clinical trial, while allowing other treatments that may benefit participants to continue.

Authorization of COVID-19 products

Food and Drug Regs (Division 8)	Proposed Interim Order	Benefits
Detailed reports of the safety and substantial evidence of the clinical effectiveness of the new drug are required at the time of submission	The information may be submitted on a "rolling basis", i.e., it may be submitted as the data become available, based on a submission plan approved by Health Canada in advance	Will allow a review to begin sooner than under the *Food and Drug Regulations*, as the sponsor would not have to wait until every piece of information is available to file their application.
Health Canada can use foreign reviews to inform our review.	A distinct pathway is introduced for drugs that have been approved by a trusted foreign regulatory authority	Health Canada can rely on the foreign review and approval of a COVID-19 drug to expedite the Canadian approval.
Submissions must be initiated by the manufacturer	A new indication can be added by the manufacturer; or a new indication can be added unilaterally by the Minister without an application from the market authorization holder(s)	This can be used to quickly extend indications for generic versions of a drug, and to expedite authorization following a successful clinical trial.
Authority to attach terms and conditions to an Establishment Licence but not to a drug authorization	Authority to add or amend terms and conditions to an authorization or an Establishment Licence	Post- authorization considerations can be better managed by, for example, requiring the manufacturer to conduct further studies or confirmatory trials