Explanatory note: Order Respecting Certain Time Limits under the Food and Drug Regulations (COVID-19)

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Proposal

The *Order Respecting Certain Time Limits under the Food and Drug Regulations (COVID-19),* made by the Minister of Health on August 13, 2020, extends the default period for review of applications and amendments made under Division 5 of the *Food and Drug Regulations* (FDR) from 30 days to 45 days.

The Order is made pursuant to subsection 7(2) of the *Time Limits and Other Periods Act (COVID-19).* The extension provided by the Order will apply to all applications received by November 16, 2020.

Objective

The objective of this Ministerial Order is to ensure that Health Canada is able to review all applications for new clinical trials or amendments to ongoing trials within the default period, by extending the default review period for clinical trial submissions and amendments to 45 days, from 30 days.

Background

COVID-19 is the infectious respiratory disease caused by the most recently discovered coronavirus, SARS-CoV-2. The World Health Organization (WHO) declared a global pandemic related to COVID-19 on March 11, 2020. Globally, a combined effort is being put forward to find effective vaccines and treatments against the disease. In order to provide expedited access to drugs, including vaccines, for human use in clinical trials related to COVID-19, Health Canada has been prioritizing the review of these clinical trial applications.

The sale and importation of most types of drugs for human use for the purposes of clinical trials are regulated through Division 5 of the FDR. Division 5 of the FDR includes a 30-day default review period for applications to sell or import a drug for the purposes of clinical trials in Canada. Under the regulations, if the Minister of Health has reasonable grounds to believe that a clinical trial may not meet safety requirements or the trial is not expected to meet its objectives, the Department has 30 days

after receipt of the complete application to send the applicant a notice indicating that they may not sell or import the drug. If no notice is given, the clinical trial is considered to be authorized and can proceed. The default period of 30 days also applies to the review of applications for amendments for clinical trials previously authorized.

Implications

Given the current focus on clinical trials related to COVID-19 and the rapid influx into Health Canada of applications for those trials, it has become difficult for the Department to review all clinical trial applications and amendments submitted under Division 5 within the 30-day period. Allowing clinical trial applications and amendments to be authorized by default could expose clinical trial participants to undue risk since Health Canada would not have had the opportunity to complete the assessment of the newly proposed or amended trial with respect to the health and safety of participants.

To address the influx of clinical trial applications related to COVID-19 and to mitigate the risk of defaulting approvals, this Ministerial Order, is extending the default period for review of applications and amendments made under Division 5 of the FDR from 30 days to 45 days. This will not impact clinical trial applications for the prevention, mitigation or treatment of COVID-19, which will continue to be expedited. These extensions will come into effect on the date the Order is made. Any applications or amendments for clinical trials that were submitted up to 30 days before the date that the Ministerial Order comes into force will be subject to the 45-day default review period. This extension will be in effect until November 16, 2020, and will revert back to 30 days for any applications received following that date.

Consultation

Consultations have not been held in the development of this Ministerial Order. It is a temporary measure that does not require the sponsor to take any specific action.

Several measures are being taken to minimize the impact on stakeholders, including increasing capacity for clinical trial reviews by taking on additional staff and continuing to issue No Objection Letters to applicants as quickly as reasonably possible.

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