Media Lines

Clinical Trial Application for the Medicago COVID-19 vaccine

Issue Statement: On June 24, 2020, Health Canada received a clinical trial application for a COVID-19 vaccine from Medicago R&D Inc., a Quebec-based manufacturer of vaccines and other biologic products. Medicago does not currently have any vaccines authorized for sale but is developing influenza and other vaccines. Health Canada authorized Medicago's clinical trial application on July 9, 2020.

Key Messages:

- On July 9, 2020, Health Canada approved a clinical trial application from Medicago R&D Inc. for a COVID-19 vaccine. This is the second clinical trial authorized in Canada for a vaccine specifically designed to prevent COVID-19, and the first from a Canadian company.

- This decision followed careful review of the application, which Health Canada determined met the necessary requirements for safety and quality.

- Health Canada reviewed the submission according to its expedited review process for all clinical trials for COVID-19 products.

- Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

Questions and Answers:

Q1. How does Health Canada evaluate clinical trials?

Health Canada plays an active role in making sure Canadians have access to drugs and vaccines which are safe, effective, and of good quality. As part of this work, we protect the health of Canadians who take part in clinical trials. For example, we:

- review clinical trial applications;
- make sure drug companies do all of the safety tests needed to reduce the risk of side effects;
- inspect sites where clinical trials take place to make sure trial participants are being monitored properly by their doctors and that the trials are conducted properly; and
- keep track of negative side effects that occur in clinical trials and take action when needed.

Clinical trials conducted in Canada are required to adhere to the *Food and Drug Regulations* and internationally accepted standards for Good Clinical Practices.

Before conducting a clinical trial, the sponsor submits a clinical trial application to Health Canada. Our scientists review the application to make sure that:

- the use of the drug in the participants being studied is appropriate;
- any risk associated with use of the drug is minimized as much as possible; and
- the best interests of the people participating in the trial are upheld.

More information on clinical trials and Health Canada's role is available on Canada.ca

Q2. How does Health Canada approve vaccines?

All vaccines in Canada are subject to a strict authorization process.

- Vaccines authorized for use in Canada are carefully assessed for safety, effectiveness and quality before being allowed on the market.
- Clinical trials (studies) are conducted on humans to ensure that the vaccine is safe and effective. Results from these trials must also be submitted, which provide evidence of the safety and efficacy profile of the product.
- Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks.
- Once the manufacturer has acquired sufficient scientific evidence of safety, effectiveness and quality, a submission may be filed with Health Canada for market approval.
- Vaccine manufacturers must supply facility information that outlines the method of manufacture in significant detail.
- Samples of at least three consecutive batches or "lots" of the vaccine are also tested in the laboratories of Health Canada to demonstrate consistency in the manufacturing process.
- The final step in the manufacturing process is quality assurance testing conducted by the manufacturer. The vaccine cannot be considered for use until this testing has been completed.
- Once this testing has been completed, Health Canada undertakes a final safety check to ensure the quality of each vaccine lot. The independent testing performed by Health Canada is performed concurrently with the company's testing so as not to slow down the process. This is an important step in vaccine manufacturing to ensure that the process is producing a consistently safe and high quality vaccine.
- Once Health Canada has determined that the product meets Good Manufacturing Practice standards, the Department provides written approval for sale in the form of a release letter.
- The manufacturer will be required to continue submitting information on the safety and effectiveness of the vaccine and an enhanced post-market surveillance plan is in place to monitor and communicate any potential adverse events following immunization.

Records relating to drug submissions (including applications for clinical trials) are considered confidential third party information and subject to the provisions of the *Access to Information Act*.

Q3. What is Health Canada doing to expedite access to treatments for COVID-19?

Before a health product can be marketed in Canada, Health Canada reviews the product information to confirm that the requirements of the *Food and Drugs Act* and its associated regulations are met. Based on the information provided by the manufacturer, the Department assesses the risks and benefits of the product to ensure Canadians have access to products that are safe, effective and of quality. Health Canada allows products on the market only if studies confirm that the benefits of the product outweigh its risks when used properly.

Health Canada is in active discussions with many manufacturers and researchers about vaccines and treatments for COVID-19, both in Canada and abroad, to provide regulatory and scientific advice for clinical trials to launch in Canada.

Health Canada is working closely with other international regulators and the World Health Organisation to share information about potential COVID-19 treatments. The Department will use all available data to make regulatory decisions about product approvals in Canada. A drug does not need to be tested in Canada for Health Canada to authorize it.

In an effort to facilitate earlier access to a vaccine or therapeutic products for COVID-19, the Department will expedite the review of any COVID-19 related health product submissions or applications once results of studies become available. Doing this will ensure timely access to novel therapies. When expediting these reviews, Health Canada will continue to ensure products are supported by sufficient evidence of safety, effectiveness and quality to benefit Canadians.