

Health Canada approves new COVID-19 vaccine and will monitor its efficacy going forward

Last Friday (March 5) Health Canada authorized the COVID-19 vaccine manufactured by Janssen Inc.

Health Canada received an application from Janssen Inc. for authorization of its COVID-19 vaccine on November 30, 2020. After a thorough, independent review of the evidence, the Department has determined that the vaccine meets Canada's stringent safety, efficacy and quality requirements.

The Janssen vaccine is the first single-dose COVID-19 vaccine to be authorized in Canada, and can be stored and transported at refrigerated temperatures (from 2° to 8°C) for at least three months, facilitating distribution across the country. The vaccine is authorized for use in people over 18 years of age, and is a viral vector-based COVID-19 vaccine.

The vaccine was authorized with terms and conditions under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. This process allowed Health Canada to assess information submitted by the manufacturer as it became available during the product development process, while maintaining Canada's high standards.

The terms and conditions of the Janssen vaccine authorization require the manufacturer to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine to ensure the benefits of the vaccine continue to be demonstrated through market use.

The Department is committed to openness and transparency. As such, Health Canada is publishing a number of documents related to this decision, including a high-level summary of the evidence that we reviewed to support the authorization of the vaccine. More detailed information will be made available in the coming weeks, including a detailed scientific summary and the full clinical trial data package.

Health Canada will continue to monitor the safety of the Janssen COVID-19 vaccine once it is in use, in collaboration with the Public Health Agency of Canada, the provinces and territories and the manufacturer. The Department will monitor for any adverse events that may develop after immunization, and will take appropriate action, if required, to protect the health and safety of Canadians.