

Ministry of Health

# COVID-19 Vaccine Approval Process and Safety

Version 2.0 – December 30, 2020

## Highlights of changes

- Added information on NACI (page 4)
- Information on post-market surveillance for Moderna (page 5)

This guidance provides basic information only. It is not intended to take the place of medical advice, diagnosis or treatment, legal advice or legal requirements.

- Please check the Ministry of Health (MOH) [COVID-19 website](#) regularly for updates to this document.

The Government of Canada has prepared for months to ensure Canadians will have access to safe and effective vaccines against COVID-19. It has achieved this by carefully reviewing all of the scientific data and evidence for the vaccines, working on distribution plans, and accelerating purchases of the vaccines.

## What you should know:

- **Ontarians can be confident.** Standards of safety, efficacy, and quality have not been compromised to expedite the approval of COVID-19 vaccines.
- **Health Canada oversight of COVID-19 vaccines will NOT stop at approval.** Monitoring of the vaccine's safety and effectiveness will continue now and into the future.
- **How can a vaccine be developed so quickly, when it usually takes years?**

The development of vaccines for COVID-19 is progressing quickly for many reasons, including:

- Reduced time delays in the vaccine approval process
- Quick adaptation of existing research programs such as those focusing on mRNA- and viral-vector-based technology.
- International collaboration among scientists, health professionals, researchers, industry and governments.
- Increased dedicated funding.
- Quick recruitment of participants for clinical trials.
- Rapid set-up of clinical trials to demonstrate effectiveness of the vaccine.

## The expedited process

On September 16, 2020, the Minister of Health signed an Interim Order (IO) introducing temporary regulatory pathway for COVID-19 related drugs and vaccines. The IO Provided greater flexibility and a more agile review process, which allows for the issuance of an expedited authorization of COVID-19 related vaccines without compromising patient safety.

Introduced under the Interim Order, a rolling review allows a drug manufacturer to submit their request for authorization before they have completed all phases of clinical trials. Health Canada begins its review right way using the information submitted by the applicants and accepts new evidence as it becomes available, until the application is deemed complete.

When a submission is received, Health Canada's clinical reviewers thoroughly review the submission by ensuring that the benefits of the vaccine outweigh the potential risks and have assurances that the product is manufactured in a licensed facility that is up to Health Canada standards.

A submission contains data from scientific studies and information about the manufacturing processes, including:

- Pre-clinical studies – toxicology studies and other studies in animals
- Pre-clinical studies – toxicology studies and other studies in animals
- Clinical studies – all phases of clinical trials in humans, including safety and efficacy data
- Manufacturing data – information about how the vaccine is made, and the processes in place to make it consistently

## Vaccine safety

At the federal level, Health Canada and the Public Health Agency of Canada (PHAC) share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry, international regulators and the public.

The National Advisory Committee on Immunization (NACI) is the scientific advisory committee that makes expert and evidence-based recommendations regarding the use of vaccines authorized for use in Canada after reviewing the scientific literature on burden of disease, vaccine characteristics (safety, immunogenicity, efficacy, effectiveness), product monographs & recommendations from other groups such as the World Health Organization.

### Pre-market scientific review

- Demonstrate that the vaccine can protect against disease.
- Determine from the safety and efficacy review, that the benefits outweigh the risks and there are no safety concerns.
- Put in place a plan to minimize any potential risks (e.g. having the manufacturer monitor for adverse events, requiring reporting to Health Canada).

### Post-market surveillance

- **Health care providers** report adverse events to their local public health authority.
- **Provincial and Territorial Public Health Authorities** report to PHAC's surveillance system. Public Health Ontario's program leads the surveillance of adverse events following immunization in Ontario. See their website for details on [COVID-19 Vaccines](#) and [Vaccine Safety](#).
- **Health Canada:**
  - Monitors safety and effectiveness of vaccines authorized for sale in Canada and can require further risk mitigation measures and additional safety information from the vaccine manufacturer.
  - Monitors vaccine-related events in Canada and internationally.
- **Public Health Agency of Canada:**
  - The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is managed by PHAC and is an FPT post-market vaccine safety monitoring system that includes spontaneous, enhanced and active AEFI reporting processes.

- **Manufacturers** monitor the safety and effectiveness of their products.
  - Pfizer-BioNTech is conducting clinical trials and following their participants for at least two years following the administration of the second dose of the vaccine. Should concerns arise, Pfizer-BioNTech is legally obligated to communicate this information to Health Canada.
  - Moderna is planning to follow clinical trial participants for at least 2 years after the second dose of the vaccine is given. It must communicate any safety concerns to Health Canada.