



KEY MESSAGES ON COVID-19 VACCINE APPROVAL

- As of Dec 23, 2020, Health Canada has **approved two vaccines** for use in Canada, the Pfizer-BioNTech vaccine and the Moderna vaccine
- Health Canada understands **the urgency and the impact** vaccines will have on the lives of Canadians, and has been working diligently and **as quickly as possible** to review and distribute approved vaccines

Regulatory Approval

- Canadians can be **confident** in Health Canada's approval:
 - Vaccines are **only** approved if the evidence shows they are **safe and effective**
 - Regulatory processes were adapted to do an independent review as quickly as possible but at no time did we compromise on our **meticulous, in-depth review**
 - Health Canada's top experts, scientists and medical professionals **carefully review** all of the scientific data and evidence for vaccine safety, effectiveness and quality
 - Health Canada's oversight of COVID-19 vaccines does **NOT stop at approval**. We will continue to monitor the safety and effectiveness of the vaccines now and into the future
 - **Canadians who want to know more, can.** [Detailed information](#) on the vaccines and the evidence behind the decisions are easy to access and openly available
- **Two other vaccines** are currently under the **same careful review** and we anticipate more in the future
- Having a variety of approved vaccines will improve our flexibility and contingency in implementing our COVID-19 immunization plan

Approved Vaccines to date

- The **Pfizer-BioNTech vaccine** is approved for people **16 years and over**; it requires 2 doses, 21 days apart
- The **Moderna vaccine** is approved for people **18 years and over**; it requires 2 doses, one month apart





- Evidence for both vaccines found them to be **highly effective** against COVID-19 based on clinical trials with tens of thousands of participants
 - Protection against the disease was observed one or two weeks after the second vaccine dose
 - **Minor side effects** were observed, similar to ones you might get from any injection
 - Neither are recommended for children or pregnant women until more research is conducted

Vaccine Distribution

- The first doses of the Pfizer-BioNTech vaccine are already being distributed to provinces and used in priority populations, and a first shipment of the Moderna vaccine is expected in December
- Until there is sufficient population immunity, Canadians need to continue their efforts in minimizing the spread of COVID-19 through the wearing of masks, staying home when sick, and practicing social distancing.
- **Vaccines save lives and livelihoods**, and mass vaccination will **help Canada's recovery**



COVID-19 vaccines approved for use in Canada



YOUR HEALTH AND SAFETY... OUR PRIORITY.

The Government has prepared for months to ensure Canadians will have access to safe and effective vaccines



Safety and efficacy



Manufacturing and availability



Transport and storage



Managing misinformation



Building trust and confidence

On the scientific review and approval...

Working with global manufacturers to provide **early regulatory guidance and advice**

Emergency regulatory pathways were set up to expedite the review and approval process, such as allowing for early data submission and the ability to put conditions on approvals

Collaboration with international regulators to align on the need for **high evidence standards**

On distribution plans...

Working with provinces and territories, and First Nations, Inuit and Métis leaders, to determine plans to **distribute and prioritize access to vaccines**, once approved

On accelerated purchasing...

Making **advance agreements to purchase millions of doses** of the most promising vaccine candidates

Health Canada has now approved two COVID-19 vaccines: Pfizer-BioNTech and Moderna

Health Canada **only approves a vaccine** if it is supported by very robust scientific data and evidence showing that the **benefits of the vaccine clearly outweigh any potential risks**

To date, **2 vaccines** have been approved following our independent scientific review.



- For people 16 years and over
- 2 doses required, 21 days apart
- Storage & transport: ultra-frozen at -80 °C

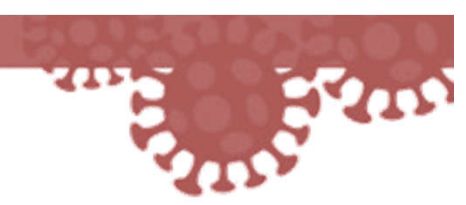
moderna

- For people 18 years and over
- 2 doses required, one month apart
- Storage & transport: frozen at -20 °C

Our reviews found:

- ▶ **Strong evidence that the vaccines are safe**
 - Only minor side effects were observed, similar to ones you might get from any injections
 - Safety and efficacy not yet established in children or pregnant women
- ▶ **Evidence that they are both highly effective across age, sex, race and ethnicity**

For more details on approved vaccines, visit the [Health Canada website](#)



Oversight of COVID-19 vaccines will not stop once approved

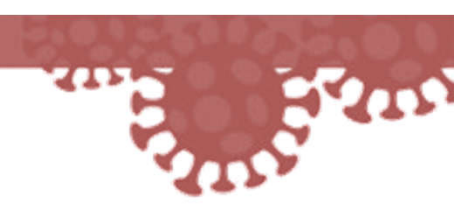
Health Canada, in collaboration with the Public Health Agency of Canada and international regulators, will continue to monitor any potential safety or effectiveness issues and act promptly if required

Once a vaccine is on the market...

- **A well-established safety system** supports collection of data from provincial public health, manufacturers and other sources
- **Procedures are in place** for rapid assessment of any potential risks and immediate action when necessary
- **Emerging information** will be communicated promptly to Canadians if needed, such as new information on risks, or changes to who can be vaccinated

As more data becomes available...

- Health Canada will assess **new clinical data**, such as:
 - Evidence to support use in broader populations, e.g. children
 - Long-term safety and effectiveness, including final data from ongoing clinical trials



Canadians will have easy access to the information they need to feel confident about approved vaccines

Status updates are provided on vaccines approved and under review on Health Canada's website

In the weeks following approval, Health Canada will also publish technical information about each authorized vaccine, including a summary of:

- the scientific rationale for the decisions
- the data supporting the vaccine's approval
- the clinical trial results assessed

Any new information that affects the assessment of the vaccine will be shared rapidly

For further information, please visit:
[*the Health Canada website*](#)

