

Health Canada's COVID-19 vaccine approval process

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Declaration of Interests- Megan Bettle

- None

Objectives

- To provide an overview of Health Canada's regulatory activities to support access to COVID-19 vaccines

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Every attempt has been made to present the most current information however information about COVID-19 vaccines is rapidly evolving and the information presented here may be out of date.

Please check the Health Canada website for the most up to date information.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments.html>

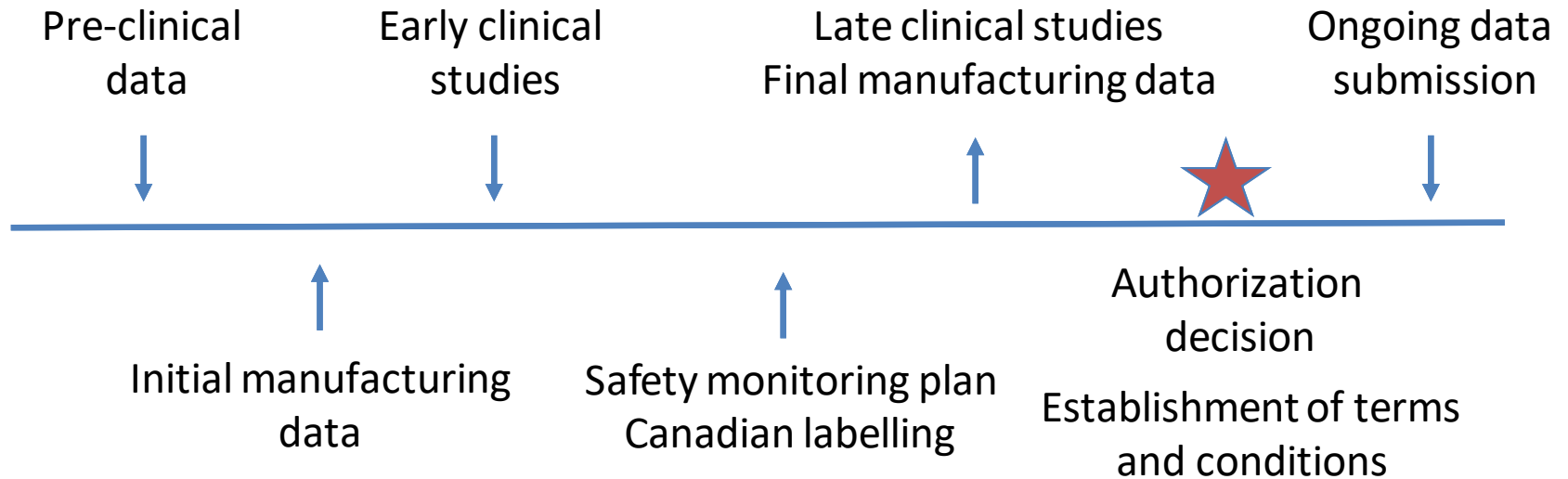
What is the typical vaccine approval process in Canada?

- A vaccine developer generates data from studies that have been done in animals and humans and on the manufacturing process.
- Developer then provides data to HC.
- HC experts review the data to ensure the vaccine:
 - Is safe
 - Works to prevent disease and/or infection
 - Is manufactured correctly

What adaptations have been made to the vaccine approval process to respond to COVID-19?

- To respond to the COVID-19 pandemic, Health Canada introduced temporary regulatory tools known as Interim Orders
 - This flexible process permits for example the filing of study data as soon as available (rolling submission) for Health Canada to advance rapidly the review and approve as soon as possible.
 - Vaccine authorization will be more **responsive and agile** with respect to administrative and application requirements;
 - To ensure **rapid vaccine rollout**, Public Health Agency of Canada (PHAC) is permitted to arrange for the importation of promising COVID-19 drugs for placement (pre-positioning) in Canadian facilities prior to their authorization in Canada if the Government of Canada has entered into a contract for its procurement
- Although expedited, this process **maintains the same standards for the reviews of the vaccine** (safety, efficacy, quality).

What does a rolling submission look like?



Several months to receive complete data from manufacturer

Authorization based on integrated evidence of safety, quality and efficacy

- *Are we confident that the product is safe and effective?*
- *Are any known risks mitigated to the extent possible?*
- *Are potential risks going to be adequately characterized?*
- *Does the product labelling accurately reflect what we know?*

Health Canada expertise for reviewing vaccine submissions

- Multidisciplinary team of reviewers at HC
- Toxicologists review the lab data and animal data
- Physicians, infectious disease specialists, microbiologists, immunologists and other experts review the clinical data
- Biostatisticians review the statistics and epidemiology
- Specialists review the complicated manufacturing process

Increased Collaboration and Communication

Increased international collaboration

- Exchanges of information with key international partners to detect and discuss any emerging safety signals and proposals for risk management
- Co-chairing ICMRA COVID-19 RWE Working Group and associated technical working groups on vaccine vigilance and observational studies
- Leveraging global safety information for rapid signal identification and risk mitigation

Increased communication to Canadians and healthcare professionals

- Additional transparency for Canadians, in collaboration with PHAC, to provide information on both vaccine coverage and adverse reactions
- More frequent and prioritized risk communications regarding any emerging information about products used in COVID-19 patients

Factors influencing the regulatory timelines

While manufacturers have provided high level filing plans, there are a number of uncertainties:

1. Uncertainties with respect to when required components will be provided to Health Canada
 - Clinical trials may take longer than expected to recruit participants or may take longer to accumulate enough data for an early analysis
 - Clinical trials may be paused or stopped for safety reasons
 - Full information on manufacturing scale-up, processes and supply chain will need to be established and provided for review
2. Regulatory review may identify problems that need further assessment and information from manufacturer
3. Evidence bar may not be met
4. Developers dealing with multiple regulators will be challenged to respond to our questions on time

Transparency

- When a vaccine submission is received, it is added to our online list of submissions under review
- When a decision is made to approve a new vaccine, within 24 hours, Health Canada will
 - Issue a Tweet with information on the product name and the company
 - Update our list of submissions under review to reflect decision issued
 - Post a summary of the scientific rationale for the decision
 - Update a number of our product information databases to reflect the new approval
- A few weeks later, more detailed information will be made available to Canadians, including
 - A detailed description of the data used to make the authorization decision
 - Clinical study information, including summaries and the detailed study reports which were contained in the drug submission
 - Only Canada and Europe release this evidence contained in the drug submissions, allowing external experts to analyze the data independently

Ensuring long-term safety of authorized COVID-19 vaccine(s)

- Data available at the time of authorization will only include information on short- to medium-term side effects. Surveillance will continue to monitor the long-term safety of the vaccine.
- Post-market activities is required for manufacturers to follow the long-term safety of the vaccine (enhanced surveillance, int'l collaboration)
- In addition, international regulatory bodies are collaborating to capture global safety information.
- If any side effects are reported to be unexpected or serious:
 - A thorough investigation will take place
 - Information will be rapidly communicated to Canadians

On December 9, Health Canada approved the Pfizer-BioNTech COVID-19 vaccine:

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**

Our independent scientific review process found:

- **Strong evidence that the vaccine is safe and works for people 16 years and over, including seniors**
 - Only minor side effects were observed, similar to ones you might get from any shots
 - It is not recommended for children or pregnant women until further data becomes available
- **It is highly effective across age, sex, race and ethnicity**
 - 95% of people that got the vaccine in clinical trials were protected
 - 2 doses are required, 21 days apart, for highest level of immunity

For more details on our assessment, visit: <https://covid-vaccine.canada.ca>

Current Status: Vaccines Under Review

UNDER REVIEW	
Vaccine	Date received
AstraZeneca	2020-10-01
Moderna	2020-10-12
Janssen	2020-10-30

Additional Resources

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization.html>

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/regulatory-response-health-product-access.html>