Health Canada Santé Canada

Canada

Health Canada's COVID-19 vaccine approval process

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February 23, 2021

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Declaration of Interests- Megan Bettle

- None

Objectives

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

Who is involved in bringing vaccines to Canadians?

Health Canada

Authorizes health products for use in Canada, based on evidence of safety, efficacy and quality, and continues to regulate the products after authorization

Public Health Agency

National Advisory Committee on Immunization (NACI) makes recommendations on use of authorized vaccines.

PHAC has a role in vaccine safety surveillance, working with the provinces and territories.

Provinces and Territories

Determine publicly funded vaccination program within their jurisdictions and responsible for vaccine funding, distribution and delivery.

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.

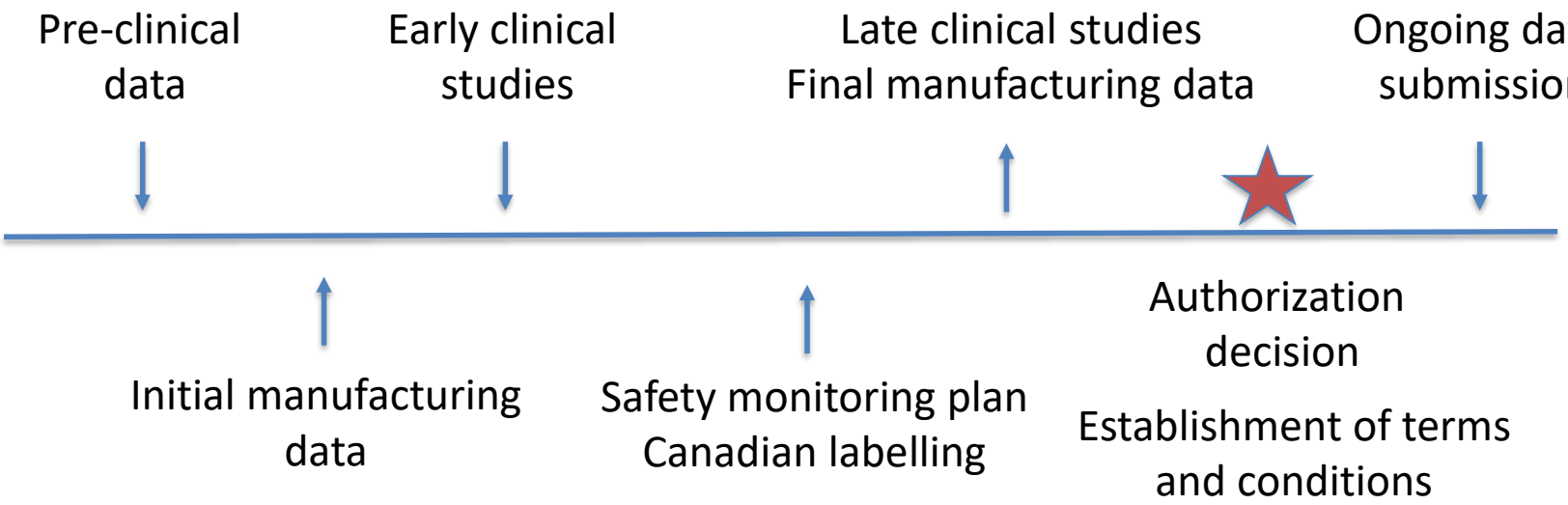
- Developer then provides data to Health Canada

- Health Canada experts review the data to ensure the vaccine:
  - Is safe
  - Works to prevent disease and/or infection
  - Is manufactured consistently and well

How are things being done differently for COVID-19?

- To respond to the COVID-19 pandemic, Health Canada introduced temporary regulatory tools known as Interim Orders, which allow
  - Rolling submissions of data for review as soon it becomes available
  - Flexible administrative requirements
  - Pre-positioning before authorization, in certain circumstances, to support rapid deployment of products after they are authorized
- Although expedited, this process **maintains the same standards for the reviews of the vaccine** (safety, efficacy, quality)
  - Non-clinical and large clinical studies are still required, including randomized and placebo-controlled phase 3 studies in tens of thousands of participants

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?*

Increased Collaboration and Communication

Working internationally

- Major regulators have been working together to:
  - Align scientific approaches, such as agreement on clinical trial endpoints and requirements for authorization
  - Discuss the scientific data under review
  - Share best practices
  - Quickly share information on potential safety issues

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

https://health-infobase.canada.ca/covid-19/vaccine-safety/

- Risk communications regarding any emerging information about products used in COVID-19 patients

Each vaccine review is different

Timelines for completion can be affected by:

- When the manufacturer provides needed data to Health Canada, and if it is sufficient to establish safety, efficacy and quality

- Completion of Canadian-specific review stages, including:
  - Finalization of the product monograph, labels and other information for healthcare professionals
  - Plans for monitoring safety and continuing to study the vaccine in different populations
  - Full information on manufacturing scale-up, processes and supply chain for Canada

- Ability of manufacturers dealing with multiple regulators 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, Health Canada
  - Communicates to the public about the authorization
  - Updates our list of submissions under review to reflect decision issued
  - Posts a summary of the scientific rationale for the decision, and several other detailed documents which describe how the product should be used at https://covid-vaccine.canada.ca/
- 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

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

- Manufacturers are required to continue to submit data to Health Canada
  - From ongoing clinical trials (phase 3 studies will follow participants for up to two years after vaccination)
  - From specified studies or follow up of identified populations, such as children and pregnant women

- Health Canada and the Public Health Agency of Canada work together to assess reports of adverse events after immunization
  - Manufacturers are required to report adverse events to Health Canada, and provide regular safety assessments
  - Provinces and territories and local public health authorities report to PHAC
  - If new safety information is identified, manufacturers can be required to conduct additional studies or analysis, to update their labelling, or to introduce other risk mitigation measures

- Expansion of the conditions of use (such as to children) would require a new submission of safety and efficacy data to Health Canada

Additional Resources

Authorized COVID-19 products

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

Detailed regulatory information for healthcare professionals and others

https://covid-vaccine.canada.ca/

Vaccine safety dashboard

https://health-infobase.canada.ca/covid-19/vaccine-safety/