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
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?

Pre-clinical data → Early clinical studies → Late clinical studies → Ongoing data submission

- Initial manufacturing data
- Safety monitoring plan
- Canadian labelling
- Authorization decision
- Establishment of terms and conditions

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/](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

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/