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#Canada21
Canada’s Approach to COVID-19 Vaccine Strategies Development and Approval

Health Canada’s COVID-19 Pandemic Vaccine Experience

Celia Lourenco, PhD
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Health Products for COVID-19

EXPEDITED REGULATORY REVIEW

- 7 Interim Orders (temporary regulations) to manage shortages and expedite review, importation and sale of COVID-19 medical devices, treatment and drugs

AUTHORIZING

- 5 Vaccines
- 7 treatments
- 650 medical devices
- 4,500 new hand sanitizer products and 270 new disinfectants
Implemented Interim Orders (IO) to facilitate clinical trials and to support access to COVID-19 vaccines

Clinical Trials:
- Over 50 pre-CTA consultation meetings
- Decreased review target to 14 days
- Authorized 18 clinical trials for vaccines

Interim Order flexibilities included:
- Use of terms and conditions
- Broadened criteria for qualified investigators
- Decentralized trials, remote informed consent
For market authorization of vaccines, **IO flexibilities** include:

- Rolling submissions – data filed as it becomes available
- Flexible data requirements
- The use of terms and conditions on an authorization to require ongoing evidence submission
- Prepositioning

• These flexibilities have been **introduced** under the *Food and Drug Regulations* (FDR) to continue to support access to safe, effective, and high quality COVID-19 drugs and vaccines following IO expiry

• Vaccines authorized under the IO are now transitioning to authorization under the FDR for continuity
Expediting Reviews: Outreach, Readiness and Collaboration

Outreach and Engagement

- Provided regulatory and scientific advice to vaccine sponsors for clinical trials & submissions
- Developed a dedicated website for the health product industry to provide regulatory guidance and updates
- Developed COVID-19 Vaccines and Treatments web portal for transparency
- Responded to media, provided press briefings and communicated with Canadians on regulatory activities

Operational Readiness

- Created COVID-19 Regulatory Response Team as a focal point for COVID-19 regulatory activities
- Adapted existing review framework including SOPs and templates
- Formed dedicated review teams focusing on vaccine submissions and post-market surveillance
- Collaborated with PHAC including to enhance mechanisms to share information from regulatory and public health surveillance activities, to identify and assess safety signals

International Collaboration

- Worked with international partners both pre and post authorization on a coordinated and aligned approach, including joint statements and guidance
- Leveraged international partnerships at multi-national fora and bilaterally to share information and to raise collective level of awareness of evidence-based approaches
- Conducted parallel reviews and information sharing to maximize the use of global expertise
What does a Rolling Submission Look Like?

Submission plan & Pre-clinical data

Early clinical studies

Late clinical studies

Final manufacturing data

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, effective, and of acceptable quality?
- 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?

Multiple review teams, average of ~2000 hours spent per vaccine over the course of several weeks/months
Supporting Vaccine Confidence: Transparency

• When a vaccine submission is received, it is added to the online list of submissions under review.

• When a decision is made to approve a new vaccine, HPFB publishes a number of key documents, including:
  • The Canadian Product Monograph (prescribing information)
  • The Regulatory Decision Summary – overview of review decision
  • Any necessary communications to healthcare professionals

• A few weeks later, more detailed information is 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 that were contained in the drug submission

https://covid-vaccine.canada.ca/
Post-market Activities in Place for COVID-19 Vaccines

Standard requirements on manufacturers

- Risk management plans
- Adverse event reporting – all serious domestic adverse events, all serious, unexpected foreign reports

Enhanced surveillance and communication by HPFB

- Ongoing assessment of any reported adverse events
- Manufacturers required to provide monthly safety analyses
- Close collaboration with PHAC and PTs to assess and take action on any emerging safety signals (e.g., communicating information on risks, revising conditions of use or population to be vaccinated, other risk mitigation measures)
- Frequent exchange of information bilaterally and multilaterally with international partners to detect and discuss any emerging safety concerns and risk mitigation measures.
- Additional transparency for Canadians, in collaboration with PHAC, to provide regular updates and risk communications on adverse events and emerging safety information
What worked well

- Interim Orders and their flexibility
- Dedicated teams
- Sponsor engagement and responsiveness
- Engagement with PHAC and PSPC
- Transparency and risk communications
- International engagement
- Safe and effective vaccines

Considerations for next time

- Availability of emergency pathways
- Rigour around rolling reviews
- Foreign Decisions pathway not utilized
- Worksharing with international partners
- Labelling and Risk Management Plans
- Health Canada vs public health communications
- Transition to FDR
- Biomanufacturing in Canada
Where do we go from here?

- Apply lessons learned to regulatory innovation agenda
- Agile Phase 1
  - Terms and Conditions
  - Rolling Reviews
  - Mandatory Risk Management Plans
  - Renewal of Division 4