DIA Canadian Annual Meeting
October 19-20 | Virtual
#Canada21
Canada’s Approach to COVID-19 Vaccine Strategies
Development and Approval

Overview of COMIRNATY/Pfizer-BioNTech COVID-19 Vaccine

Aline Silahian BPharm
Associate Director, Regulatory Affairs
Pfizer Canada ULC
19 October 2021
Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to DIA, its directors, officers, employees, volunteers, members, chapters, councils, Communities or affiliates, or any organization with which the presenter is employed or affiliated.

These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. DIA and the DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.
Global pandemic required expedited implementation of interim measures and innovative/novel approaches

- Health Canada and Industry mobilized to mitigate impact of COVID-19
  - Interim measures for management of clinical trials
  - Securing supplies of drugs used to manage symptoms of COVID-19
    - Exceptional importation of “designated drugs”
    - Critical Drug Supplies
  - Increased and dedicated manufacturing capabilities

- Deployment of Innovative Regulatory Strategies to Expedite Review of COVID-19 drugs, including vaccines
  - Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
Interim Order & Path to COVID-19 Vaccine Authorization

Allowing expedited regulatory pathway for COVID-19 vaccine development without compromising safety & efficacy

- Implementation of rolling submission concept
- Expedited review timelines
- Regulatory Flexibilities
- Expedited product availability: Importation and pre-positioning
- No cost recovery
- Flexibilities re. GMP requirements
- Authorization with Terms & Conditions
- Conversion to NOC
Rolling Submissions & Real-Time Updates

A First: Unprecedented Regulatory Approach for Canada

- Allows expedited filing & review
  - Submission Plan

- Working in real-time: filing as data becomes available
  - Parallel filings Globally
  - Multiple concurrent clarifaxes/requests
  - Support from all functional experts (Non-clinical, Clinical, CMC, Safety)
  - Open communication and ad hoc meetings with Health Canada

Putting it in perspective - from IO filing to now:

- ✓ 200 sequences and counting…
- ✓ 11 PM updates
- ✓ 28 HC Meetings
- ✓ 3 Health Product Risk Communications
- ✓ Multiple educational materials
- ✓ Numerous ad hoc calls & e-mails
Vaccine available immediately after authorization

Requires multiple parallel & concurrent work

Worldwide Product Allocation

Contractual agreement with Government of Canada

Quality Assurance

Medical Information

Customer Service

Manufacturing & Supply Chain

Translation Service

Trainings & Website

Communications & Media

Points of Use
We are all in this together!

Exemplary Cooperation & Resilience - “No Corners Cut”

- Working in real-time during a Global pandemic requires:
  - Accelerated filing of numerous components as they become available
  - Rapid responses to multiple concurrent requests
  - Flexibility regarding Regulatory requirements and administrative components
  - Open line of communication with Health Canada at all times (including evenings & weekends)
  - International alignment and collaboration
  - Terms and Conditions supports risk-based approach
  - Transparency
Important Lessons Learned

During a Global Pandemic plan for the unexpected!

► Multiple urgent demands on many fronts
  • Numerous concurrent requests with tight response timelines (same-day, 1 or 2 days)
  • Fully dedicated resources required with back-ups to manage high demands & long hours (nights & weekends)
  • Impact on Global resources

► Shipping & storage complexities

► Multiple and expedited translation needs

► Authorization vs Real-world use
  • Implementation not always aligned with clinical trials/authorized label recommendations

► Management of internal and external communications
  • High media attention

► Authorization is not the end
  • High level of activity post-authorization
  • Management of Terms and Conditions
  • Conversion to NOC not just an administrative step
Huge strides taken during the pandemic should serve as a base for continued evolution of our Regulatory Framework

- Build on Regulatory Innovation
- Implementation of Rolling Submissions
- International Cooperation Between Regulators is Key
  - Work-sharing models beyond ACCESS
    - Data & insight sharing
    - Streamlining of Regulatory requirements and Canadian-specific requirements
- Risk-Based Regulatory Decisions
  - Prioritization and fit-for-purpose regulatory strategies
- Expand focus of Advanced Therapeutic Products
- Implement Agile Regulations

Looking into the Future