



The Canadian Vaccine Catalogue

Working Group Meeting - COVID Terminology

December 3, 2020

Attendees

- Anil Patel, Canada Health Infoway
- Arielle Goldman Smith, Shared Health Manitoba
- Cameron Bell, CANImmunize
- Christine Patterson, Shared Health Manitoba
- Dennis Sharkey, BCCDC
- Enerosa Cepe, Shared Health Manitoba
- Helen Xing, BCCDC
- Igor Sirkovich, Ministry of Health Ontario
- Joy Pulickal, PHAC
- Linda Parisien, Canada Health Infoway
- Lori Kane, Ministry of Health Ontario
- Marc L'Arrivee, Shared Health Manitoba
- Maruchi Wotogbe, UNICEF
- May Canning, BCCDC
- Robert Pless, Health Canada
- Ruth Deane, Shared Health Manitoba
- Sherri Boucher, Health Canada
- Tara Mahwinney, PHAC
- Taylor Rubens-Augustson, CANImmunize
- Tracy Alderson, Shared Health Manitoba
- Tong Lin, Shared Health Manitoba

Agenda

Objective: to determine how and when COVID-19 vaccine trade name concepts can be created and implemented in the Canadian Vaccine Catalogue

- Summary of last CVC meeting
- Additional codes in January 2021 release
- Publicly available product information
- Questions/Discussion

Summary of Last Meeting

CVC Working Group Meetings and Communications

- CVC Working Group communications and meeting information will be moved to the Public Health Surveillance Community on InfoCentral to leverage knowledge and expertise from several stakeholder groups.

Creating COVID-19 vaccine concepts and configuring them in provincial repositories

- Product monographs are typically needed to create trade name concepts, however it is unlikely these will be available in time to have codes created before COVID-19 products become available.
- P/Ts will require 3-4 weeks at the very least to configure these codes in their systems.

Summary of Last Meeting cont'd...

Data flow for Lot Numbers and Expiry Dates








- Ad hoc reports of newly released lots of COVID-19 vaccine are being set up so that this will flow automatically and the formalization of this is in progress.

GTINs and Barcode Scanning

- PHAC to follow-up with Vaccine Safety Working Group about asking manufacturers to upload their data into ECCNet and the possibility to publish this to the CVC.

Publicly available information from Health Canada

List of authorized drugs and expanded indications for COVID-19

Authorization holder 	Brand name, proper name or common name 	DIN, medicinal ingredient(s), strength, dosage form, route of administration 	Therapeutic area 	Control number 	Date of authorization or expanded indication 	Authorization or expanded indication 
Eli Lilly Canada Inc	Bamlanivimab Bamlanivimab solution for injection	DIN 02508176 - 700 mg/20 mL bamlanivimab, solution, intravenous administration	Immune sera and immunoglobulins, for human use	244947	2020-11-20	Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Authorized with terms and conditions.

Source:

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

Publicly available information from Health Canada

Applications received related to the COVID-19 pandemic

Applicant ↑↓	Medicinal ingredient(s) ↑↓	Therapeutic area ↑↓	Date application was received ↑↓	Outcome of application ↑↓	Date of decision/outcome ↑↓
AstraZeneca Canada Inc.	Adenovirus vaccine vector (ChAdOx1)	Vaccines, for human use	2020-10-01	Pending	n/a
Eli Lilly Canada Inc.	Bamlanivimab (LY-CoV555)	Immune sera and immunoglobulins, for human use	2020-10-12	Authorized (with terms and conditions)	2020-11-20
Gilead Sciences Canada Inc.	Remdesivir	Antivirals for systemic use, for human use	2020-06-19	Authorized (with conditions)	2020-07-27
Janssen Inc	JNJ-78436735/Ad26.COV2.S	Vaccines, for human use	2020-11-30	Pending	n/a
Moderna Therapeutics Inc.	mRNA-1273 vaccine	Vaccines, for human use	2020-10-12	Pending	n/a
Pfizer Canada ULC/BioNTech SE	mRNA vaccine BNT162b2	Vaccines, for human use	2020-10-09	Pending	n/a

Source:

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

Updated: Proposed Generic COVID-19 Concepts

Existing generic concepts

- 28531000087107 | Vaccine product against disease caused by Severe acute respiratory syndrome coronavirus 2 (medicinal product)|

Additional generic concepts, in scope for the January 2021 release:

- 1119305005 |Vaccine product containing only Severe acute respiratory syndrome coronavirus 2 antigen (medicinal product)|
- 1119349007 |Vaccine product containing only Severe acute respiratory syndrome coronavirus 2 messenger ribonucleic acid (medicinal product)|
- 1119350007 |Administration of vaccine product containing only Severe acute respiratory syndrome coronavirus 2 messenger ribonucleic acid (procedure)|
- 840534001 |Administration of vaccine product containing only Severe acute respiratory syndrome coronavirus 2 antigen (procedure)| (This concept already exists but with a different FSN)

Challenges

- Although much of the information needed to create trade name concepts is publicly available on Health Canada's website for COVID-19-related drugs authorized under an interim order, this information is usually only made available shortly before the vaccine comes to market.
- Individual codes will be for the Pfizer and Moderna vaccines will be essential before they are on the market.
- In the absence of a product monograph, what could be used as a reference to support the RFCs?

A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04470427

Recruitment Status ⓘ : Active, not recruiting

First Posted ⓘ : July 14, 2020

Last Update Posted ⓘ : October 28, 2020

Sponsor:

ModernaTX, Inc.

Collaborators:

Biomedical Advanced Research and Development Authority
National Institute of Allergy and Infectious Diseases (NIAID)

Information provided by (Responsible Party):

ModernaTX, Inc.

Arms and Interventions


Go to

Arm ⓘ	Intervention/treatment ⓘ
Experimental: mRNA-1273 Participants will receive 1 intramuscular (IM) injection of 100 microgram (ug) mRNA-1273 on Day 1 and on Day 29.	Biological: mRNA-1273 Sterile liquid for injection
Placebo Comparator: Placebo Participants will receive 1 IM injection of mRNA-1273-matching placebo on Day 1 and on Day 29.	Biological: Placebo 0.9% sodium chloride (normal saline) injection

Source:

<https://clinicaltrials.gov/ct2/show/NCT04470427?term=vaccine&cond=covid-19&draw=5>

Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04368728

[Recruitment Status](#) ⓘ : Recruiting
[First Posted](#) ⓘ : April 30, 2020
[Last Update Posted](#) ⓘ : November 23, 2020
See [Contacts and Locations](#)

Sponsor:
BioNTech SE

Collaborator:
Pfizer

Information provided by (Responsible Party):
BioNTech SE

Source:

<https://clinicaltrials.gov/ct2/show/study/NCT04368728?term=vaccine&cond=covid-19&draw=3>

COVID-19: the green book, chapter 14a (Provisional guidance subject to MHRA approval of vaccine supply)

Presentation

Each pack of the Pfizer BioNTech vaccine contains 195 vials with 5 doses per vial (975 doses per pack). It is supplied with 0.9% sodium chloride diluent for injection plastic ampoules.

The AstraZeneca vaccine is supplied in packs of 10 vials. Each vial contains 8 or 10 doses of vaccine, and is a colourless to slightly yellow, clear to slightly opaque liquid.

Dosing and schedule

Pfizer BioNTech COVID-19 vaccine*

The dose of Pfizer BioNTech COVID-19 vaccine is 30µg contained in 0.3ml of the diluted vaccine.

Source: COVID-19: the green book, chapter 14a (Provisional guidance subject to MHRA approval of vaccine supply)
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/939119/Greenbook_chapter_14a_provisional_guidance_subject_to_MHRA_approval_of_vaccine_supply_.pdf

PRESS RELEASES

AMA announces vaccine-specific CPT codes for coronavirus immunizations



NOV 10, 2020

For quick reference, the new Category I CPT codes and long descriptors for the vaccine products are:

91300 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use → Pfizer

91301 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use → Moderna

Source: [AMA media release](#), "AMA announces vaccine-specific CPT codes for coronavirus immunizations"

<https://www.ama-assn.org/press-center/press-releases/ama-announces-vaccine-specific-cpt-codes-coronavirus-immunizations>

Trade Name Information

	Pfizer	Moderna
Trade Name¹	?	?
Strength²	30 micrograms per 0.3 milliliter	100 micrograms per 0.5 milliliter
Dose Form³	Intramuscular injection	Sterile liquid for injection
Manufacturer/MAH⁴	Pfizer Canada ULC/BioNTech SE	Moderna Therapeutics Inc.

¹Health Canada is not requiring a trade name in order for products to be authorized; this information is not available elsewhere

²**Source:** [AMA media release](#); U.S. National Library of Medicine Clinical Trials; U.K. Green Book (for Pfizer vaccine)

³**Source:** [AMA media release](#); U.S. National Library of Medicine Clinical Trials; U.K. Green Book (for Pfizer vaccine)

⁴**Source:** [Health Canada](#), "Drug and vaccine authorizations for COVID-19: List of applications received"

Questions/Discussion/Updates

- Do we have enough information to create trade name concepts for the Pfizer and Moderna vaccines?
- Is it possible to create temporary trade name concepts and update them when we have more information?
 - Creating new concepts vs. changing them once more information is available?