Ministry of Health

COVID-19 Guidance for Individuals Vaccinated outside of Ontario/Canada

V. 4.0 March 24, 2022

Highlights of changes

- Updated information on booster doses for people who have received non-Health Canada approved vaccines (page 4)
- Novavax Nuvaxovid updated to Health Canada authorized vaccine (page 11)
- Updated Scenario 2: COVID-19 vaccines not authorized by Health Canada (page 3)

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

• Please check the Ministry of Health (MOH) <u>COVID-19 website</u> regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

Background

This document is intended to provide health care providers and Public Health Units (PHUs) with approaches for individuals who have received COVID-19 vaccination outside of Ontario or Canada.

This guidance aligns with the Public Health Agency of Canada's (PHAC) <u>COVID-19</u>: <u>Recommendations for those vaccinated with vaccines not authorized by Health</u> <u>Canada for those staying in Canada to live, work or study</u>. This approach is aimed at providing optimal protection on an individual basis and the guidance will be updated as needed based on emerging data that becomes available on international vaccines. The COVID-19 vaccines authorized for use by Health Canada_are listed on the Government of Canada website. A number of vaccines are available in other countries that are not authorized for use in Canada. Some of the vaccines authorized in other countries have been reviewed by the World Health Organization (WHO) and added to their Emergency Use List, some are under review by the WHO and others have not been submitted for review. See the COVID-19 Vaccine Tracker for more information on which vaccines are authorized in different countries. The immunogenicity, vaccine efficacy and effectiveness of COVID-19 vaccines varies. While many of these vaccines appear to be performing well based on available data, others have lower vaccine effectiveness and/or vaccine efficacy.

Limited data for the whole inactivated virus vaccines suggests that this vaccine platform is less efficacious than the mRNA, protein subunit, and viral vector vaccines; hence, there are strong potential benefits of offering one additional mRNA dose to individuals who received a vaccine that uses a whole inactivated virus vaccine platform (regardless whether or not the vaccine is authorized under the WHO Emergency Use List). There is currently limited data available on the efficacy of receiving a Health Canada authorized COVID-19 vaccine after receipt of a non-Health Canada authorized COVID-19 vaccine after receipt of a non-Health Canada authorized COVID-19 vaccine; however, the below guidance is based on immunological principles and expert opinion from PHAC and is similar to the approaches of other jurisdictions (i.e., United Kingdom). Appendix A outlines a list of international COVID-19 vaccine products, their characteristics and the recommendations for additional doses to complete a primary COVID-19 vaccine series; this list is evolving and is not comprehensive.

Individuals Vaccinated outside of Canada/Ontario

- Individuals who have received a partial or complete COVID-19 vaccine series outside of Ontario or Canada should contact their <u>local public health unit</u> to have their COVID-19 immunization record documented in COVax_{ON}.
- Proof of immunization (e.g., an immunization record, proof of vaccination certificate (PVC)¹ is required to verify the COVID-19 vaccine product received out of province.²

¹ See Canadian Immunization Guide to <u>Immunization records.</u>

² The <u>Canadian Immunization Guide</u> outlines that vaccination should only be considered valid if there is written documentation of vaccine administration.

• All vaccine doses administered out of province (regardless of the vaccine product) should be reported, verified and documented into COVax_{ON}.

Scenario 1: COVID-19 vaccines authorized by Health Canada administered outside of Ontario/Canada

- This scenario applies to all vaccine products that are <u>authorized by Health</u> <u>Canada</u>, even if they are authorized under a different trade name in a different country.
- Individuals who have proof of immunization and have received all recommended doses (including booster doses) of a Health Canada authorized COVID-19 vaccine or a combination of Health Canada authorized vaccines with at least the <u>minimum recommended interval</u> between doses outside of Ontario or Canada are considered to be up to date in their COVID-19 vaccination and no additional doses are needed..
- Individuals who received the first dose of a two-dose Health Canada authorized COVID-19 vaccine series outside of Ontario or Canada do not need to restart the vaccine series, but should receive the second dose of a Health Canada authorized COVID-19 vaccine as close to the <u>Ontario recommended interval</u> as possible to complete their primary COVID-19 vaccine series. After completing their primary COVID-19 vaccine series, these individuals should also receive a booster dose of a Health Canada authorized vaccine at the Ontario recommended interval (if eligible based on age).³

Scenario 2: COVID-19 vaccines not authorized by Health Canada

- Individuals who have proof of immunization and have only received one or two doses of a COVID-19 vaccine that is not <u>authorized for use by Health Canada</u>:
 - These individuals should receive one additional dose of an mRNA vaccine to complete their primary COVID-19 vaccine series.⁴ The minimum interval between the preceding dose and the additional dose should be 28 days.
 - After completing their primary COVID-19 vaccine series, these individuals should also receive a booster dose of a Health Canada

³ See the <u>COVID-19 Third Dose Recommendations</u> for more information on intervals and age eligibility.

⁴ Per the <u>Public Health Agency of Canada</u>, for individuals that have received a complete course/series of a non-Health Canada authorized vaccine, the mRNA vaccine is expected to optimize protection.



authorized vaccine at the Ontario recommended interval (if eligible based on age).⁵

- Individuals who have proof of immunization and have received one dose of a COVID-19 vaccine that is <u>not authorized for use by Health Canada</u> and one dose of a Health Canada authorized vaccine (in either order):
 - These individuals need no additional doses to complete their primary COVID-19 vaccine series.
 - These individuals should receive a booster dose of a Health Canada authorized vaccine at the Ontario recommended interval (if eligible based on age).⁶
- Individuals who have proof of immunization and have received **three doses** of any COVID-19 vaccine (**in any order/combination** of Health Canada authorized and non-Health Canada authorized vaccines):
 - These individuals need no additional doses to complete their primary COVID-19 vaccine series.
 - These individuals should receive a booster dose of a Health Canada authorized vaccine at the Ontario recommended interval (if eligible based on age).⁶

Scenario 3: Unknown COVID-19 Vaccine Product

- If the individual indicates that they have received a previous dose(s) of a COVID-19 vaccine, but have no proof of immunization, consider whether further investigation can be done to obtain proof of immunization (e.g., contacting clinic location/health care provider or immunizer, etc.).
- If the COVID-19 vaccine product used for a previous dose(s) remains unknown, or if written proof of immunization is provided for a vaccine whose generic or trade name is not recognized (see Appendix A), a new vaccine series should be started with a Health Canada authorized COVID-19 vaccine.
 - Per <u>NACI recommendations</u>, if the previous date of immunization is known, it would be prudent to wait for a period of at least 28 days after the administration of any other COVID-19 vaccine dose(s) before initiating a new Health Canada authorized COVID-19 vaccine series.

⁵ See the <u>COVID-19 Third Dose Recommendations</u> for more information on intervals and age eligibility.

Individuals leaving Canada before Receiving all Recommended Doses of COVID-19 Vaccines

• If an individual needs to leave Ontario or Canada before receiving all recommended doses of COVID-19 vaccine (including booster doses), they should bring proof of immunization from all doses received and follow public health guidance from the jurisdiction they are entering. If the individual is going to another province or territory in Canada they should contact the health authority in the jurisdiction they have arrived in to complete their primary COVID-19 vaccine series.

COVaxon Documentation

- PHUs are responsible for documenting immunization information for individuals who have received COVID-19 vaccine doses outside of Ontario into COVax_{ON}. The information stated on the client's immunization record or proof of immunization will need to be entered. See the COVax_{ON} job aid and functionality change communications for more information.
- Functionality has been developed within COVax_{on} under 'historical dose administration' with two options for recording:

A. Out of Province (OOP): A client may have received COVID-19 vaccine doses outside of Ontario and therefore this information would not have been recorded in COVax_{ON}. The historical OOP dose(s) must be recorded in COVax_{ON} by the PHU or other AO users that have been approved by the PHU. These historical OOP dose(s) do not need to be recorded in COVax_{ON} before clients are able to receive a dose in Ontario, however, entry of these historical doses in COVax_{ON} is necessary to generate an enhanced vaccine certificate. Clients are required to have proof of vaccination of their OOP dose(s) for historical entry.

• For a client that had OOP dose(s): The client must provide proof of vaccination to their PHU prior to receiving their next dose.

B. Non-Ontario Stock (NOS): A client may have received COVID-19 vaccine dose(s) from non-Ontario vaccine stock (i.e., Federal Stock used for correctional facilities, <u>military groups</u>, embassies, etc.). The historical NOS dose(s) can be recorded in COVax_{ON}. The location that conducted the vaccination will provide a list of data to be entered in COVax_{ON} by the PHU/approved group.

Appendix A: Characteristics of COVID-19 Vaccine Platforms and Recommendations for Additional Doses for Individuals Vaccinated Outside of Ontario/Canada

*This is an evolving and non-comprehensive list, the <u>WHO's list of vaccines for emergency use</u> and the <u>CDC's list</u> can be referenced if needed on a case by case basis for other non-Health Canada authorized vaccines that are not listed below. The guidance below is what is required for individuals to complete their primary COVID-19 vaccine series. See the <u>COVID-19 Third Dose Recommendations</u> Guidance for information on booster doses to stay up to date with recommended COVID-19 vaccinations.

mRNA vaccines

Vaccine Manufacturer	Vaccine	Authoriz ation	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Pfizer- BioNTech	Pfizer-BioNTech COVID-19 Vaccine/Comirnaty/BNT162B2 / Tozinameran/Pfizer- BioNTech Comirnaty podiatric	WHO EUL	21 days (valid dose if 19 days or more)	2 doses	2 doses (complete)	No further doses
	BioNTech Comirnaty pediatric COVID-19 Vaccine				1 dose (incomplete)	Administer 1 dose of mRNA vaccine
Moderna	Moderna COVID-19 vaccine /Spikevax / mRNA-1273 / TAK-	WHO EUL	28 days (valid	2 doses	2 doses (complete)	No further doses
	919 / elasomeran		dose if 21 days or more)		1 dose (incomplete)	Administer 1 dose of mRNA vaccine

Whole inactivated virus vaccines

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID- 19 vaccine series
Sinovac	Sinovac- CoronaVac/ Ad5- nCoV	WHO EUL	14-28 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Sinopharm/Beijing Institute of Biological Products	COVID-19 vaccine BIBP / BBIBP-CorV / Covilo / CDIBP / LIBP / CCIBP	WHO EUL	21-28 days	2 or 3 doses	3 doses (complete) 2 doses (complete) or 1 dose (incomplete)	No further doses Administer 1 dose of an mRNA vaccine
Sinopharm/Wuhan Institute of Biological Products	COVID-19 vaccine WIBP, Inactivated SARS-CoV-2 Vaccine (Vero cell)	China	21 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID- 19 vaccine series
Bharat Biotech	Covaxin /BBV152	India and 8 other countries	28 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Whole inactivated virus vaccines (continued)

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Minhai Biotechnology Co.	SARS-CoV-2 Vaccine (Vero Cells)	China	14 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Chumakov Center	KoviVac	Russia	14 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Kazakhstan RIBSP	QazCovid-in / QazVac	Kazakhstan	21 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Shifa Pharmed Industrial Group	COVIran- Barekat	Iran	28 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Non-replicating, recombinant viral vector-based vaccines

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
AstraZeneca/ Oxford	AstraZeneca COVID-19	WHO EUL	4-12 weeks	2 doses	2 doses (complete)	No further doses
University	Vaccine / Vaxzevria / ChAdOx1-S / AZD1222		(valid dose if 28 days or more)		1 dose (incomplete)	Administer 1 dose of an mRNA vaccine ⁶

⁶ NACI preferentially recommends an mRNA vaccine following AstraZeneca, but individuals may receive a second dose of AstraZeneca in Ontario.

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Serum Institute of India (SII)	COVISHIELD/ ChAdOx1- S.nCoV-19	WHO EUL	weeks (valid dose	2 doses	2 doses (complete)	No further doses
	if 28 days or more)		1 dose (incomplete)	Administer 1 dose of an mRNA vaccine		
Janssen (Johnson & Johnson)	COVID-19 Janssen / JNJ- 78436735 / Ad26.COV2.S	WHO EUL	Not applicable	1 dose	1 dose (complete)	No further doses

Non-replicating, recombinant viral vector-based vaccines (continued)

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Gamaleya National Centre of Epidemiology and Microbiology	Sputnik V/ Gam-COVID- Vac	Russia and 69 other countries	21 days	2 doses	2 doses (complete)	Administer 1 dose of an mRNA vaccine
Gamaleya National Centre of Epidemiology and Microbiology	Sputnik Light	Russia and 11 other countries	Not applicable	1 dose	1 dose (complete)	Administer 1 dose of an mRNA vaccine
CanSino Biologics	Ad5-nCoV / Convidecia	China and 7 other countries	Not applicable	1 dose	1 dose (complete)	Administer 1 dose of an mRNA vaccine

Protein subunit vaccines

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Novavax Nuvaxovid	NVX-CoV2373 / CoVovax		21 days	2 dose	2 dose (complete)	No further doses
		WHO EUL			1 dose (incomplete)	Administer 1 dose of mRNA vaccine or Novavax Nuvaxovid vaccine ⁷
Anhui Zhifei	RBD-Dimer /	China	30 days	2 or 3	3 doses (complete)	No further doses
Longcom	ZF2001 / Uzbekistan doses ZIFIVAX Image: state s		uoses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine	
Vektor State Research Center of Virology and Biotechnology	Epi VacCorona	Russia Turkmenistan	21 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

⁷ Although <u>NACI preferentially recommends</u> a complete series with mRNA vaccines be offered, NACI notes that Novavax Nuvaxovid may be offered as a homologous or heterologous (mixed) primary series.



Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Instituto Finlay de Vacunas Cuba: Soberana Plus	Soberana 02 / Soberana Plus / FINLAY-FR-1A	Cuba	28 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Protein subunit vaccines (continued)

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID- 19 vaccine series
Center for Genetic Engineering and	Abdala / CIGB-66	Cuba	14 days	3 doses	3 doses (complete)	No further doses
Biotechnology (CIGB), The Havana					2 doses (incomplete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Ontario 😵

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID- 19 vaccine series
Medigen	MVC-COV1901	Taiwan	28 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Vaxine/ CinnaGen Co.	Spikogen / Vaxine/CinnaGen Co. COVAX-19	Iran	21 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine

Plant based virus-like particle vaccines

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Guidance to complete primary COVID-19 vaccine series
Medicago Inc.	Medicago Covifenz	Canada	21 days	2 doses	2 doses (complete)	No further doses
	COVID-19 vaccine / COVIFENZ				1 dose (incomplete)	Administer 1 dose of an mRNA vaccine or Medicago vaccine ⁸

⁸ Although <u>NACI preferentially recommends</u> a complete series with mRNA vaccines be offered, NACI notes that Medicago COVID-19 vaccine may be offered as a homologous or heterologous (mixed) primary series.