

Ministry of Health

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

V. 2.0 September 14, 2021

Highlights of changes

- Updated scenario 2 (page 3) to align with the Public Health Agency of Canada's (PHAC) COVID-19: Recommendations for those vaccinated with vaccines not authorized by Health Canada for those staying in Canada to live, work or study.
- New Appendix A: Characteristics of COVID-19 Vaccine Platforms and Recommendations for Additional Doses for Individuals Vaccinated Outside of Ontario/Canada

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 is being updated to align with PHAC's <u>COVID-19</u>: <u>Recommendations</u> for those vaccinated with vaccines not authorized by <u>Health Canada for those</u> staying in <u>Canada to live</u>, work or study, published on August 17, 2021. This approach is aimed at providing optimal protection on an individual basis and the



guidance will be updated as needed based on new data that will become available on international vaccines.

In Canada, as of September 13, 2021, the following four COVID-19 vaccines are authorized for use by Health Canada: Pfizer-BioNTech (mRNA), Moderna (mRNA), AstraZeneca/COVISHIELD (viral vector) and Janssen/Johnson & Johnson (viral vector). 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 <a href="Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Emergency_Eme

This guidance aims to balance optimal protection against COVID-19, limiting reactogenicity by minimizing the number of additional doses provided and providing a straightforward approach that is easy to implement. Limited data for the whole inactivated virus vaccine platform suggests that this platform is less efficacious than the mRNA 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 World Health Organization Emergency Use List). There is currently limited data available on the safety or efficacy of receiving a 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 vaccines, their characteristics and the recommendations for additional doses, this list is evolving and non-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} prior to
receiving any additional doses and for their <u>vaccination receipts</u>..



- Proof of immunization (e.g., an immunization record, proof of vaccination certificate (PVC)¹ is required to verify the COVID-19 vaccine product received.²
- All vaccine doses administered out of province (regardless of the vaccine product) should be reported, verified and documented by public health units into COVax_{on}.³

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

- This scenario applies to all vaccine products that are authorized by Health Canada, even if they are authorized under a different trade name in a different country (e.g. Comirnaty, Spikevax).
- Individuals who have proof of immunization and have received all
 recommended doses of a Health Canada authorized COVID-19 vaccine or a
 combination of Health Canada authorized vaccines with at least the minimum
 recommended interval between doses⁴ outside of Ontario or Canada are
 considered to have a complete vaccine series 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 as close to the interval recommended by Ontario as possible.⁵

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 administration.

³ COVax_{oN} is the provincial data base where COVID-19 immunization records are stored and provides the information that is used for <u>vaccination receipts</u>.

⁴ See NACI's immunization schedule, by COVID-19 vaccine: Table 3 for the minimum intervals.

⁵ NACI recommends that the vaccine series be completed with the same COVID-19 vaccine product if readily available. See <u>NACI's recommendations on interchangeability</u>.



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

- Individuals who have proof of immunization and have received a complete
 one or two-dose series of a COVID-19 vaccine that is not <u>authorized for use</u>
 by <u>Health Canada</u> will be offered one additional dose of an mRNA vaccine.⁶
 - The minimum interval between the preceding dose and the additional dose should be 28 days.
 - If the individual has already received three doses of a non-Health Canada authorized COVID-19 vaccine at the appropriate interval, no additional doses should be offered at this time.
- Individuals who have proof of immunization and have received an
 incomplete series of a non-Health Canada authorized vaccine, should
 receive one additional dose of an mRNA vaccine.⁶
 - The minimum interval between the preceding dose and the additional dose should be 28 days.

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.
 - o Per <u>NACI recommendations</u>, if the previous date of immunization was 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.

⁶ 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.



Individuals leaving Canada before Completion of COVID-19 Vaccine Series

 If an individual needs to leave Ontario or Canada before completion of their COVID-19 vaccination series, they should bring proof of immunization from their first dose and follow public health guidance from the jurisdiction they are entering. If the individual is going to another province they should contact the health authority in the jurisdiction they arrive in to complete their COVID-19 vaccine series.

COVaxon Documentation

- PHUs are responsible for documenting immunization information for individuals who have received a partial or complete COVID-19 vaccine series 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 one/both doses outside of Ontario and therefore this information would not be recorded in COVax_{ON}. The historical OOP dose(s) must be recorded in COVax_{ON}.
 - For a client that had Dose 1 OOP: The client must contact their PHU to enter the dose 1 (i.e., historical dose) prior to booking their appointment for dose 2.
 - For a client that had both doses or only Dose 2 OOP: The client should contact their PHU to enter those historical doses prior to booking an appointment for dose 3 (if needed).
 - **B. Non-Ontario Stock (NOS):** A client may have received one/both doses from non-Ontario vaccine stock (i.e., Federal Stock used for correctional facilities, military groups, 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. If the client received their first dose via NOS, the historical entry of dose 1 needs to be made prior to booking their second dose appointment.



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 vaccines that are not listed below.

mRNA vaccines

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



Whole inactivated virus vaccines

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Ontario Guidance
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	COVID-19 vaccine BIBP	WHO EUL	21-28 days	2 or 3 doses	3 doses (complete)	No further doses
Biological Products	/BBIBP-CorV / Covilo				2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Sinopharm/Wuhan Institute of Biological Products	COVID-19 vaccine WIBP, Inactivated SARS-CoV-2 Vaccine (Vero	China	21 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
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	Ontario Guidance
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
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	Туре	Interval	Schedule	Scenario	Ontario Guidance
AstraZeneca/ Oxford	AstraZeneca COVID-19	WHO EUL	Recombinant ChAdOx1-S	weeks	2 doses	2 doses (complete)	No further doses
University	Vaccine / Vaxzevria / ChAdOx1-S / AZD1222		adenoviral vector	(valid dose if 28 days or more)		1 dose (incomplete)	Administer 1 dose of an mRNA vaccine ⁷
Serum Institute of India (SII)	COVISHIELD/ ChAdOx1- S.nCoV-19	WHO EUL	Recombinant ChAdOx1-S adenoviral	4-12 weeks (valid dose	2 doses	2 doses (complete)	No further doses
			vector	if 28 days or more)		1 dose (incomplete)	Administer 1 dose of an mRNA vaccine ⁷
Janssen (Johnson & Johnson)	COVID-19 Janssen / JNJ- 78436735 / Ad26.COV2.S	WHO EUL	Recombinant adenoviral vector (Ad26)	Not applicable	1 dose	1 dose (complete)	No further doses

⁷ NACI preferentially recommends an mRNA vaccine following AstraZeneca/COVISHIELD, but individuals may receive a second dose of AstraZeneca/COVISHIELD in Ontario.



Non-replicating, recombinant viral vector-based vaccines continued

Vaccine Manufacturer	Vaccine	Authorization	Туре	Interval	Schedule	Scenario	Ontario Guidance
Gamaleya National Centre of Epidemiology and Microbiology	Sputnik V/ Gam- COVID-Vac	Russia and 69 other countries	Recombinant adenoviral vector (Ad26 (prime), Ad5 (-boost) expressing full length spike glycoprotein	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	Recombinant adenoviral vector (Ad26 (prime), Ad5 (-boost) expressing full length spike glycoprotein	Not applicable	1 dose	1 dose (complete)	Administer 1 dose of an mRNA vaccine
CanSino Biologics	Ad5-nCoV / Convidecia	China and 7 other countries	Recombinant adenoviral vector (Ad5)	Not applicable	1 dose	1 dose (complete)	Administer 1 dose of an mRNA vaccine



Protein subunit vaccines

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Ontario Guidance
Novavax	NVX-CoV2373 / CoVovax	Pending authorization in Canada	21 days	2 dose	2 dose (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Anhui Zhifei Longcom	RBD-Dimer / ZF2001 / ZIFIVAX	China Uzbekistan	30 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
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



Protein subunit vaccines continued.

Vaccine Manufacturer	Vaccine	Authorization	Interval	Schedule	Scenario	Ontario Guidance
Center for Genetic Engineering and Biotechnology	Abdala / CIGB-66	Cuba	14 days	3 doses	3 doses (complete)	No further doses
(CIGB), The Havana					2 doses (incomplete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine
Medigen	MVC-COV1901	Taiwan	28 days	2 doses	2 doses (complete) or 1 dose (incomplete)	Administer 1 dose of an mRNA vaccine