Ministry of Health

Transition to Publicly Funded Shingrix® Vaccine for Ontario's Shingles (Herpes Zoster) Immunization Program: Information for Health Care Providers

This questions and answers sheet for health care professionals provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment. For more information about Shingrix® vaccine, please refer to the product monograph authorized by Health Canada.

Starting mid-October 2020, the Ontario publicly funded shingles (Herpes Zoster) immunization program will begin to transition to Shingrix® vaccine instead of Zostavax®II vaccine.

Q1. What is herpes zoster?

A1. The varicella zoster virus (VZV) causes two distinct clinical syndromes: varicella (chickenpox), and herpes zoster (shingles). Herpes zoster (HZ) infection arises from the reactivation of latent varicella zoster virus from a previous chickenpox infection.

Q2. Who is at risk for herpes zoster?

A2. Herpes zoster (HZ) can develop at any time following a varicella (chickenpox) infection and can occur in individuals of any age. However, HZ occurs most frequently among seniors and immunocompromised persons. Age is the most important risk factor for development of HZ and two-thirds of the cases occur in individuals over 50 years of age. In addition, the severity of illness associated with herpes zoster and its complications also increases with age. Post-herpetic neuralgia (PHN) is the most frequent complication of acute HZ and is characterized by prolonged and often debilitating neurogenic pain that persists for more than 90 days from the onset of rash.

Q3. What is the incidence/prevalence of herpes zoster in Canada?

A3. In recent studies, the lifetime risk of HZ has been estimated to be as high as 30% in the general population. In Canada, each year there are an estimated 130,000 new cases of HZ, and 17,000 cases of PHN which result in 2,000 hospitalizations.

Q4. What is new with the Ontario publicly funded shingles (herpes zoster) program?

A4. Starting mid-October 2020, the Ontario publicly funded shingles immunization program, available for seniors ages 65 to 70 years, will begin to transition from offering the Zostavax®II (Merck Canada Inc.) vaccine to the Shingrix® (GSK) vaccine.

Shingrix® is a recombinant, adjuvanted subunit vaccine that was authorized for use in Canada in October 2017 as a two-dose series for individuals 50 years of age and older for the prevention of herpes zoster (HZ).

The vaccine is supplied as a vial of lyophilized recombinant varicella zoster virus surface glycoprotein E (VZV gE) which is reconstituted at the time of use with the accompanying vial of adjuvant suspension. Shingrix® is administered intramuscularly as a two-dose schedule 2 to 6 months apart.

Q5. Why is Ontario changing to the Shingrix® vaccine product used in the publicly funded shingles program?

A5. Current evidence and expert recommendations from the National Advisory Committee on Immunization (NACI) indicate that Shingrix® is more effective for preventing HZ infection and related complications.

Q6. What are the eligibility criteria for the Shingrix® vaccine?

A6. Since September 2016, Ontario has offered seniors 65 to 70 years the opportunity to receive a one-time publicly funded dose of HZ (Zostavax® II) vaccine through the publicly funded immunization program.

Starting mid-October, Ontario seniors age 65 to 70 years (i.e., from the 65th birthday to the day prior to the 71st birthday) are eligible for the 2-dose publicly funded Shingrix® series, provided they have not received the Zostavax® II vaccine through the Ontario publicly funded shingles immunization program. The series needs to be completed before the 71st birthday. Seniors outside the eligibility criteria can speak with their primary care providers about purchasing the vaccine privately.

PLEASE NOTE: As a result of COVID-19, individuals born in 1949 or 1950 (i.e., 70-year olds turning 71 in 2020 or 2021 calendar year) who have missed the opportunity to receive the publicly funded Zostavax® II are eligible to receive Shingrix® and complete the 2-dose series by December 31, 2021.

Q7. How will the eligible cohort access publicly funded Shingrix®?

A7. Individuals aged 65 to 70 will be able to receive the Shingrix® vaccine through their primary health care provider. Primary health care providers are encouraged to identify and offer the Shingrix® vaccine to their eligible patients.

Q8. What if seniors previously received the publicly funded Zostavax®II vaccine, will they be eligible to receive the publicly funded Shingrix® vaccine?

A8: Seniors aged 65 to 70 years who received the publicly funded Zostavax® II are not eligible for the publicly funded Shingrix® vaccine series. Seniors interested in privately purchasing Shingrix® should speak to their health care provider.

Q9. What if seniors previously paid for Zostavax® II vaccine, will they be eligible to receive the publicly funded Shingrix® vaccine?

A9. Seniors aged 65 to 70 years who previously paid for Zostavax® II vaccine are eligible to receive the publicly funded Shingrix® vaccine. Primary care

providers should discuss the risks and benefits of re-immunization with Shingrix® vaccine according to NACI recommendations and expert opinion.

Q10. What are the similarities and differences between Shingrix® and Zostavax® II?

A10. Shingrix® has been shown to be safe and effective for the prevention of HZ and its most common complication, post-herpetic neuralgia (PHN). Based on clinical studies, the incidence of HZ and PHN, as well as the duration and severity of HZ were significantly reduced in Shingrix® vaccine recipients. Overall vaccine efficacy was above 90% for HZ incidence and 88-91% for the prevention of PHN and slower waning immunity.

Table 1: Similarities and differences highlighted between Zostavax® II and Shingrix®

	Zostavax®II	Shingrix®
Manufacturer	Merck Canada Inc.	Glaxo Smith Kline (GSK)
Publicly funded age eligibility	Seniors age 65 to 70 years	Seniors age 65 to 70 years
Number of doses	**1**	2
Interval between doses indicated in product monograph	**N/A**	2 to 6 months*
Route of administration	Subcutaneous (SC) Injection	Intramuscular (IM) Injection
Formulation	Live, attenuated vaccine	Non-live recombinant subunit vaccine, AS01B adjuvanted
Contraindications (for complete information see product monograph)	• Immunocompromised individuals • Known anaphylactic hypersensitivity to previous dose of vaccine, or any component of the vaccine	• Known anaphylactic hypersensitivity to previous dose of vaccine, or any component of the vaccine
Co-administration with other vaccines as indacted in product monograph	As indicated in product monograph	As indicated in product monograph**

* According to NACI's 2018 Updated recommendations on the use of herpes zoster vaccines an alternative dosing schedule of 0, 12-months may be considered for Shingrix® to improve coverage of the second dose (e.g., through simultaneous administration with another vaccine such as annual influenza vaccination) based on evidence of an acceptable safety profile and robust immune response.

** More information can be found in the Canadian Immunization Guide for co-administration of other vaccines with Shingrix vaccine.

Q11. Are booster doses of Shingrix® recommended?

A11. The need for a booster dose following the primary two-dose vaccine series has not been established. Available studies have demonstrated a longer duration of protection against HZ from Shingrix® with immunogenicity being demonstrated up to nine years post-immunization. Minimal waning in vaccine efficacy was seen after four years following vaccination with Shingrix® remaining at 90 percent or more protection for all four years.

Q12. What if an individual does not have a previous history of chickenpox - should they still be offered the vaccine?

A12. Yes, Shingrix® vaccine should be administered to individuals eligible for the vaccine regardless of whether or not the person has a history of varicella infection. Nearly all Canadians eligible for shingles immunization will have had prior varicella exposure, even if a diagnosis of varicella cannot be recalled.

Please note: At this time there is insufficient evidence to assess the risk related to herpes zoster ophthalmicus recurrence following Shingrix® vaccination.

Q13. Can Shingrix® be given simultaneously with the other vaccines?

A13. Shingrix® may be administered concomitantly with, or at any time before or after, other inactivated vaccines or live vaccines using different injection sites and separate needles and syringes.

Shingrix® may be given at the same time as unadjuvanted seasonal influenza vaccine. Studies of co-administration with adjuvanted seasonal influenza vaccine (Fluad®) have not been conducted. Review the product monograph for further information on concomitant administration of Shingrix® and the annual influenza vaccine.

Q14. Are there any side effects from the Shingrix®?

A14. Shingrix®, like all medicines, can cause side effects, although not everyone gets them. The most common side effects of receiving the Shingrix® vaccine are mild and include injection site pain, swelling or redness.

Other side effects that have been reported include headache, stomach and digestive complaints (e.g., nausea, vomiting, diarrhea and/or stomach pain), muscle pain, tiredness, chills and fever. Most of these side effects experienced were mild to moderate and on average did not last longer than three days.

Patient education on the short-term reactogenicity of the Shingrix® vaccine is recommended prior to vaccine administration to promote adherence to the second dose. Please see the product monograph for a complete list of reported side effects / adverse reactions.

Q15. Who should not receive Shingrix®?

A15. Shingrix® should not be given to individuals who have had an anaphylactic hypersensitivity reaction to past doses of the vaccine, or allergies to any component of the Shingrix® vaccine. Further information on who should not receive the Shingrix® vaccine can be found in the product monograph.

Q16. Can the vaccine be given to individuals when they are ill?

A16. Those with a severe acute illness with or without fever should usually wait until the symptoms subside before being immunized.

During the COVID-19 pandemic, individuals with symptoms of acute respiratory infection, including minor symptoms such as sore throat or runny nose, should defer immunization until they have recovered, as they can pose an unnecessary risk to others and health care providers if they have COVID-19. Further information on general advice on administering vaccine during COVID-19 precaution can be found in the **Guidance for Immunization Service During COVID-19**.

Q17. How do I order Shingrix®?

A17. Health care providers can begin ordering the Shingrix® vaccine as of October 19, 2020 through their vaccine supply source (i.e., local public health unit or the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)). Information on public health units can be found using the locator tool.

Q18. How should Shingrix® be stored?

A18. In order to ensure optimal protection, Shingrix® must be maintained at a temperature between +2˚C and +8˚C and this temperature must always be monitored to ensure cold chain is maintained. For additional information on provincial vaccine storage and handling requirements please refer to the Vaccine Storage and Handling Guidelines available at: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/reference/vaccine%20_storage_handling_guidelines_en.pdf

See also the Storage and Stability section of the product monograph.

Q19. How should I document administration of Shingrix® to the eligible cohort?

A19. As with all vaccines administered in Ontario, health care providers are expected to document administration of the vaccine in both the patient's medical record and personal immunization record (i.e., the "Yellow Card").

Q20. What information should be provided to individuals related to potential adverse events following immunization (AEFIs) with the Shingrix® vaccine?

A20. As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine, particularly any of the following:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40˚C or 104˚F)
- Convulsions (seizures)
- Other serious reactions

Health care providers (e.g., physicians, nurses and pharmacists) are required by law (i.e., *Health Protection and Promotion Act*, s. 38) to report AEFIs. Reports should be made using the Ontario AEFI Reporting Form (available at:

www.publichealthontario.ca/vaccinesafety) and sent to the local public health unit.

A list of public health units is available at: www.health.gov.on.ca/en/common/system/services/phu/locations.aspx .

Q21. Where can I get more information?

A21. For more information on Ontario's publicly funded immunization program including Shingrix®, please visit: www.health.gov.on.ca/en/public/programs/immunization. You may also contact your local public health unit.

The Shingrix® product monograph can be found at: https://pdf.hres.ca/dpd_pm/00056533.PDF

Updated Recommendations on the Use of Herpes Zoster Vaccines (Aug 2018), An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): www.canada.ca/en/services/health/publications/healthy-living/updated-recommendations-use-herpes-zoster-vaccines.html

Warrington R, Samail S. Summary of the NACI Update on Herpes Zoster Vaccines. Can. Commun Dis Rep. 2018;44(9): 220-225. http://doi.org/10.14745/ccdr.v44i09a06

Canadian Immunization Guide: www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php#