Appendix 1

Reclassification of a Medicine for consideration by the Medicine Classification Committee

This form should be completed in conjunction with the directions in the guidance: How to change the legal classification of a medicine in New Zealand.

Once completed, this application should be sent to committees@moh.govt.nz by the deadline indicated on the Dates and Deadlines page on the Medsafe website.

By submitting this form, you are confirming that all information is true and accurate, and understand that this information and any appendices and/or supporting information that is not considered commercially confidential under the Official Information Act 1982 criteria will be published on the Medsafe website.

Introduction

GSK New Zealand is providing evidence to support the reclassification of *SHINGRIX* vaccine for people 18 years of age and over for pharmacist and authorised vaccinators to be reviewed by the Medicines Classification Committee at its 73rd meeting.

SHINGRIX is now funded by Pharmac for 18+ immunocompromised individuals

The burden of herpes zoster on patients, whānau and the health system is significant, both for acute disease as well as complications such as post-herpetic neuralgia and herpes zoster ophthalmicus. Although herpes zoster in immunocompromised populations represents a small proportion of the total number of cases, immunocompromised patients contribute substantially to the public health burden because of their higher risk for herpes zoster and complications, including persistent post-herpetic neuralgia.[1,2] In immunocompromised patients, the zoster rash tends to be more severe and its duration prolonged. Immunocompromised patients have a higher risk for HZ-associated neurological complications and are more likely to develop disseminated HZ involving various organs or multiple skin dermatomes, which may lead to a fatal outcome.[3]

SHINGRIX is a non-live recombinant, adjuvanted vaccine for the prevention of herpes zoster and post herpetic neuralgia in individuals 50 years and over, and for individuals 18[1,2] years and over at increased risk of herpes zoster[4]. Clinical studies, post marketing surveillance and real-world evidence show that *SHINGRIX* has an acceptable safety, robust immunogenicity and efficacy in various populations at increased risk of herpes zoster, including adults 18 years and older.[4,5] As a recombinant, non-live vaccine, *SHINGRIX* is the only vaccine to address the high unmet need for shingles prevention in

immunocompromised populations.

SHINGRIX became funded in New Zealand for individuals 18 years and over with certain immunocompromising conditions from 1 July 2024.[6] There is support for making *SHINGRIX* more accessible to this high need cohort of patients through pharmacy as highlighted to Pharmac and Te Whatu Ora during public consultation on the funding proposal.[7]

Timely access to immunisation is needed for immunocompromised patients

Immunocompromised patients are more vulnerable to infectious diseases such as herpes zoster, and immunisation at the optimal time with respect to immunosuppression is critical to achieve good health outcomes.[8,9]

In New Zealand, patients who are immunocompromised are usually under the care of a specialist team who refer to primary care for vaccination rather than vaccinating in secondary care. However, the referral process and access to GPs is a significant barrier with long waits for appointments if a patient can register with a practice, and a cost to the patient for a prescription.[10] The consequences of high-risk immunocompromised patients missing out on necessary immunisations could be serious, therefore wider access to immunisation services is needed to ensure immunocompromised individuals get vaccinated when it is optimal and accessible for them. Pharmacy offers longer opening hours, no fee to visit and the convenience of walk-in vaccination services.

Significant sector investment to enable wider access to immunisation

In response to declining immunisation rates, the health sector has introduced many changes with the aim of both enabling vaccinators and making immunisation more accessible to New Zealanders. Te Whatu Ora recently introduced a process for pharmacists to expand their scope of practice to enable wider access to provide paediatric immunisation. Significant investment has been made in resources such as Healthpoint to signpost consumers to vaccination services near them and the Book My Vaccine platform is designed to improve the customer journey. Enabling vaccination through reclassification is an important tenet of improving overall immunisation rates in New Zealand.[11]

Pharmacists are already skilled vaccinators including with immunocompromised patients

New Zealand pharmacists are already vaccinating with *SHINGRIX* following reclassification in November 2022 for individuals 50 years and over (privately funded). Since enabling pharmacists to provide several National Immunisation Programme (NIP)

vaccines from September 2023, approximately 50% of pharmacies (approximately 500 out of 1068 pharmacies in NZ) have ordered *SHINGRIX* to administer the NIP for the 65-year-old cohort.[12] Funding was expanded from July 2024 to include immunocompromised individuals 18 years and over. However pharmacists cannot currently administer to eligible individuals 18 to 49 years without a prescription but can administer *SHINGRIX* to an immuncompromised person over the age of 50 years. Pharmacists are able to administer SHINGRIX for individuals 18 years and over in other countries, including in Australia, US and Canada as detailed within the proposal.

The complexity of access criteria across vaccines (both funding criteria and classification criteria) is creating confusion in the sector about who they can and cannot vaccinate without a prescription.[13] In addition, it is confusing for high-risk patients who want to receive the immunisations they are eligible for but get turned away from pharmacy to obtain a prescription.

Pharmacists already consult and administer vaccines to higher risk individuals and special groups including Covid 19 and influenza.[13] Pharmacists have also administered the Covid therapeutics programme in New Zealand and are experienced in identifying risk factors, screening for eligibility and counselling on what to expect after a vaccination.

In addition to pharmacists, we seek reclassification of *SHINGRIX* for authorised vaccinators, mostly nurses, who have completed the same vaccinator training and who would provide an additional point of vaccination in clinic for their 18+ patients at increased risk of zoster. By reclassifying *SHINGRIX*, patients 18+ at greatest risk will have more equitable and timely access to immunisation against HZ and post-herpetic neuralgia (PHN).

Part A

1. International Non-proprietary Name of the medicine.

   Recombinant Varicella Zoster vaccine, adjuvanted[4]

2. Proprietary name(s).

   SHINGRIX Recombinant Varicella Zoster Virus glycoprotein E antigen 50 micrograms (AS01B adjuvanted vaccine) powder and suspension for suspension for injection[4]

3. Name and contact details of the company requesting a reclassification.

   [redacted]
   GlaxoSmithKline NZ Limited
   [redacted]
   [redacted]
   [redacted]
   [redacted]d
   [redacted]

4. Dose form(s) and strength(s) for which a change is sought.

   The primary vaccination schedule consists of two doses of 0.5 mL each; an initial dose followed by a second dose 2 to 6 months later.[4]

5. Pack size, storage conditions and other qualifications.

   SHINGRIX is presented as:

   - Powder for 1 dose in a vial (type I glass) with a stopper (butyl rubber)
   - Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber)

   SHINGRIX is available in a pack size of 1 vial of powder plus 1 vial of suspension or in a pack size of 10 vials of powder plus 10 vials of suspension.

   Storage conditions:

   - Store in a refrigerator (2 °C – 8 °C). Do not freeze.
   - Store in the original package in order to protect from light. For storage conditions after reconstitution of the medicinal product, discard any residue. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.[4]

6. Indications for which change is sought.

   Adults 18 years of age or older (at increased risk of herpes zoster)[4]

(Adults 50 years of age or older are already permitted under reclassification)

7. Present classification of the medicine.

Prescription only except when administered for the prevention of herpes zoster (shingles) to a **person 50 years of age or over by a registered pharmacist** who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course).

8. Classification sought.

Prescription only except when administered for the prevention of herpes zoster (shingles) to a **person 18 years or over who has successfully completed the Vaccinator Foundation Course** (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course).

This would enable pharmacist and authorised vaccinators to provide SHINGRIX without a prescription for individuals 18 years and over.

9. Classification status in other countries (especially Australia, UK, USA, Canada).

Canada

The scope of practice for Canadian pharmacists is generally broad. Pharmacists are authorised to prescribe vaccines in 9 out of 13 provinces and can administer SHINGRIX in 11 out of 13 provinces. Zoster vaccine may be administered to individuals from the age of 2 years and 18 years depending on jurisdiction.

INJECTION AUTHORITY AND VACCINE ADMINISTRATION IN PHARMACIES ACROSS CANADA

✓ Authority ✓ Temporary authority under an emergency order V Vaccines D,V Drugs and vaccines L Limited authority X No authority

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NWT	NU
Pharmacist Injection Authority and Prescribing													
Scope of injection authority[1]	D,V	D,V	D,V	D,V	D,V	V[A]	D,V	D,V	D,V	D,V	D,V	X	X
Pharmacists authorized to prescribe vaccines[2]	X[B]	✓[C]	✓[D,E]	✓[F]	X[G]	✓	✓[D,F]	✓[D,H]	✓[D]	✓[D]	✓[D]	X	X
Pharmacist Administration of Vaccines[3,4]													
Influenza	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	X	X
COVID-19	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓[1]	✓	X	X
Respiratory syncytial virus (RSV)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X
Pneumococcal	✓[1]	✓[1]	✓	✓[1]	✓	✓[1]	✓	✓	✓	✓	✓	X	X
Meningococcal	✓[1]	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓	X	X
Haemophilus influenza B	✓[1]	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓	X	X
Hepatitis A	✓[1]	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓	X	X
Hepatitis B	✓[1]	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓	X	X
Measles, mumps, rubella	✓[1]	✓	✓	✓	X	✓[1]	✓	✓	✓	✓	✓	X	X
Diphtheria, tetanus (with/without pertussis)	✓[1]	✓[1]	✓	✓[1]	X	✓[1]	✓	✓	✓	✓	✓	X	X
Varicella zoster (chickenpox)	✓[1]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X
Herpes zoster (shingles)	✓	✓	✓	✓	✓	✓	✓	✓[1]	✓[1]	✓	✓[1]	X	X
Human papillomavirus	✓[1]	✓	✓	✓[1]	✓	✓[1]	✓	✓	✓	✓	✓[1]	X	X
Polio	✓[1]	✓	✓	✓	X	✓[1]	✓	✓	✓	✓	✓	X	X
Pharmacy Student Injection Authority[3,5]													
Influenza	✓	✓	☑	✓	✓	✓	✓	✓	X	✓	X	X	X
COVID-19	✓	✓	☑	X	✓	✓	✓	✓	X	✓	X	X	X
Other drugs/vaccines[6]	✓	✓	X	X	✓	✓	✓	✓	X	✓	X	X	X
Pharmacy Technician Injection Authority[3,5,7]													
Influenza	X	X	☑	X	✓	X	✓	✓	✓	✓	X	X	X
COVID-19	☑	X	☑	X	✓	X	✓	✓	✓	✓	X	X	X
Other drugs/vaccines[6]	X	X	X	X	L[C]	X	✓	✓	✓	✓	X	X	X
Minimum Patient Age													
Minimum patient age	≥2 years intranasal ≥4 years injectable	≥5 years	≥5 years	≥2 years influenza, COVID-19 ≥5 years other injectable, excl. vaccines ≥7 years other vaccines	≥6 months COVID-19 ≥2 years influenza ≥5 years all other injectable	≥2 years influenza or travel-related vaccines ≥6 years all other injectable[I]	≥2 years	≥6 months influenza, COVID-19 ≥2 years all other injectable	≥2 years intranasal influenza ≥5 years influenza, rabies (pre-exposure), traveller's diarrhea, or other drugs ≥12 years COVID-19 ≥18 years other vaccines	≥ 2 years influenza, COVID-19 ≥ 5 years all other injectable	≥5 years		

https://www.pharmacists.ca/advocacy/scope-of-practice/

United States

Pharmacists in all 50 states can administer all vaccines on the recommended CDC adult Immunisation Schedule (which includes SHINGRIX for individuals 19 years and over with immunocompromise). Seventeen states allow pharmacists to prescribe vaccines, and 32

states allow administration via a prescriber-approved protocol or non–patient-specific order.

Australia

Pharmacist vaccinators may administer SHINGRIX to individuals 18 years and over in 6 out of 8 states. In all states, pharmacists can initiate and administer SHINGRIX for appropriate patients pursuant to age criteria.

In 2023, SHINGRIX was included on the National Immunisation Schedule under broad access criteria, including for individuals 18 years and over with immunocompromise, individuals from First Nations 50 years and over and all individuals 65 years and over.

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Shingrix Age restrictions or other conditions specific to the vaccine	50 years and over	18 years and over	5 years and over in line with NT Immunisation Schedule	2 years and over	5 years and over	18 years and over	50 years and over Excludes immunisation with immunoglobulin Excludes travel purposes unless pharmacist/pharmacy is participating in the Victorian Community Pharmacist Statewide Pilot	5 years and over

Pharmacist administered vaccinations - Pharmaceutical Society of Australia (psa.org.au)

10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute.

At least 70 million people have received SHINGRIX in over 40 countries and we estimate between 60,000 and 80,000 New Zealanders have received at least one dose of *SHINGRIX* since launch in 2022.

The timeline of regulatory authorisations and funding changes for SHINGRIX in New Zealand:

- Consent to distribute SHINGRIX for individuals 50 years and over (for the prevention of herpes zoster and post-herpetic neuralgia) in New Zealand was gazetted in January 2020.
- SHINGRIX has been supplied (initially on the private market) in New Zealand since

March 2022.

- Medsafe approval for label expansion for SHINGRIX for individuals 18 years and over at increased risk of herpes zoster (for the prevention of herpes zoster and post-herpetic neuralgia) was approved in June 2022.
- SHINGRIX funded for 65 year olds from August 2022.
- Reclassification gazetted for administration by pharmacist vaccinator for all individuals 50 years and over in November 2022.
- Pharmacists able to access National Immunisation Schedule vaccines from September 2023.
- SHINGRIX funded for 18+ increased risk cohorts July 2024.

We note that the live attenuated zoster vaccine Zostavax, was discontinued in New Zealand in 2022.

11. Local data or special considerations relating to New Zealand (if applicable).

From 1 July 2024, the *SHINGRIX* funding criteria was widened to include adults aged 18 years or older at increased risk of herpes zoster:

- pre- and post-haematopoietic stem cell transplant or cellular therapy;
- pre- or post-solid organ transplant;
- haematological malignancies;
- people living with poorly controlled HIV infection;
- planned or receiving c disease-modifying anti-rheumatic drugs (DMARDs – targeted synthetic, biologic, or conventional synthetic) for polymyalgia rheumatica, systemic lupus erythematosus or rheumatoid arthritis;
- end stage kidney disease (CKD 4 or 5);
- primary immunodeficiency.

Broader access to vaccination is likely to improve the implementation of the National Immunisation Programme as well as immunisation for at risk patients not covered by funding, by pharmacist and authorised vaccinators. Reclassification for SHINGRIX for the 18+ population was raised during the Pharmac consultation process.[7]

Access challenges to immunisation services could result in high risk individuals missing out

Most immunocompromised individuals are under the care of a specialist in New Zealand, however specialist teams rarely vaccinate. Instead, patients are referred into the primary care system where wait times for appointments and costs for a prescription can be a

barrier to getting vaccinated.

Access to the GP clinic is a barrier with long waits for appointments if a patient can register with a practice and a cost to the patient for a prescription. A study published in the NZJM recently demonstrated that most general practices are selectively enrolling their patients with 79% of respondents in the study having limited or closed enrolments since 2019. This restricted enrolment may lead to access inequity and exacerbate underlying barriers to healthcare access. Access through community pharmacy or via nurses in clinic is an important lever to help alleviate the burden on GP practices and ensure access for those at greatest need for vaccination.[10]

Significant sector investment to improve immunisation coverage in New Zealand

In response to declining immunisation rates, the health sector has introduced many changes with the aim of both enabling vaccinators and making immunisation more accessible to New Zealanders. Recently, Te Whatu Ora introduced a process for pharmacists to expand their scope of practice to enable wider access to paediatric immunisation to communities. Significant investment has been made in resources such as Healthpoint to direct consumers to vaccination services near them and the Book My Vaccine platform, designed to improve the customer journey. Enabling vaccination through reclassification is an important tenet of improving immunisation rates in New Zealand.[11]

Pharmacists are already providing services to immunocompromised patients

Pharmacists are skilled vaccinators who complete the same training as other vaccinators and must meet all the requirements in terms of competency, cold chain standards, equipment and emergency processes than other vaccinators and places that provide vaccinations. In addition, pharmacists can already vaccinate from 3 years and over against influenza and vaccinate a wide range of age groups with other vaccines.[13]

Pharmacists already vaccinate higher risk New Zealanders with a range of comorbidities or immunocompromise including against influenza, Covid-19 and meningococcal disease. Pharmacists can also already vaccinate individuals over the age of 50 years with SHINGRIX, including those who are immunocompromised.

Pharmacists are highly skilled to identify, screen, administer and counsel high-risk individuals and have demonstrated this capability through both vaccination services and the Covid 19 therapeutics programme.

12. Labelling or draft labelling for the proposed new presentation(s).

NA

13. Proposed warning statements (if applicable).

No changes are required to the current warning statement on packaging or datasheet.

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

N/A

Part B- Clinical Context and Implications

1. Indications and dose

– *What is the medicine indicated for, and for which indication(s) is the reclassification application for?*

SHINGRIX is indicated for the prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN) in adults 50 years of age or older and adults 18 years of age or older at increased risk of HZ.[4]

SHINGRIX is already reclassified for pharmacist vaccinators to provide without a prescription from the age of 50 or older. GSK proposes that SHINGRIX is reclassified to expand the age to 18 years and over, and to allow authorised vaccinators to administer without a prescription in addition to pharmacist vaccinators.

What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?

N/A

– *What is the treatment population for the indication (age; gender etc.)?*

Adults 18 years and older (at increased risk of herpes zoster).

– *What is the dose and dose frequency of the medicine for this indication?*

Two doses of SHINGRIX are indicated, administered 2 to 6 months apart.

2. Presentation

– *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*

SHINGRIX is available as one formulation only. SHINGRIX Recombinant Varicella Zoster Virus glycoprotein E antigen 50 micrograms ($AS01_B$ adjuvanted vaccine) powder and suspension for suspension for injection, 0.5 mL.

– *What disposal considerations need to be made for the medicine?*

Disposal would be the same as for other vaccines. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Pharmacies providing a vaccination service are familiar with this practice and have the appropriate processes and equipment for dealing with the safe disposal of vaccines.

– *How practical and easy to use is the proposed presentation?*

The presentation of SHINGRIX will not change as a result of this proposal. Pharmacist vaccinators already reconstitute and administer SHINGRIX. Resources relating to reconstitution and administration are available via the Immunisation Advisory Centre website in addition to GSK resources.

3. Consumer benefits

– *What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in?*

SHINGRIX was first supplied in Canada and the US from 2017, initially indicated for individuals 50 years and over. Since then, it has been used extensively around the world helping to protect 70 million adults in over 40 countries from herpes zoster.[14]

Supported by data from several studies in immunocompromised patients,[4,15-19] the indication was expanded in the European Union in August 2020 to include adults aged ≥ 18 years at increased risk of HZ, and in the US in July 2021 to include adults aged ≥ 19 years at increased risk of HZ because of immunodeficiency or immunosuppression

caused by known disease or therapy.[9]

A summary of the effectiveness and safety of SHINGRIX based on real world evidence showed high effectiveness against herpes zoster across the studied populations including adults aged ≥ 50 years and patients aged ≥ 18 years with immunodeficiency or immunosuppression.[5] Effectiveness was higher with two doses versus one dose, especially in elderly people and immunocompromised individuals. The safety profile of SHINGRIX was broadly consistent with that established in clinical trials. It does not appear to increase the risk of disease flares in patients with immune-mediated diseases.[5]

- *To what extent is this medicine used for the proposed indication(s) ie, duration of use; frequency of use?*

In New Zealand, Pharmac anticipates that approximately 15,000 immunocompromised patients 18 years and over would be eligible to receive funded SHINGRIX over the first 2 years post-funding and around 2000 individuals per year thereafter. We expect that there would be fewer individuals between the age of 18 to 49 years compared with those 50 years and over within the above estimate.[7]

SHINGRIX is administered as two doses, two to six months apart. There is no indication for a booster dose in either immunocompromised adults 18 years and over or immunocompetent older adults – studies are ongoing to establish the need and appropriate timing for booster vaccinations.[4]

- *What is the evidence that improved access is beneficial for the individual? What are the benefits from a consumer viewpoint?*

Accessibility is an important consideration for vaccine uptake and equity. Community pharmacies are more accessible – there is no enrolment required or appointment fees and broad opening hours (evenings and weekends) make it easier to access for both vaccination and for advice pre- or post-vaccination. This is particularly important for young people who may not be engaged with a general practice, working people and for those that live in areas of high deprivation.

Increasing numbers of New Zealanders are being vaccinated in pharmacy with the percentage of influenza and Covid-19 vaccines administered in pharmacy rising from 2023 to 2024.[12]

Evidence generated in New Zealand showed that access to pertussis vaccination from a community pharmacy improved immunisation uptake in pregnant women but also afforded an alternative, non-traditional healthcare provider point of vaccination to cater to different needs of the community.[20]

There is also a risk if immunocompromised individuals travel to a pharmacy believing they can be vaccinated and told they cannot be, consumers lose confidence in the health system and may also lose the impetus to be vaccinated.

4. Contraindications and precautions

– *What are the contraindications for the medicine and how easy are they to identify and prevent? What are the precautions for this medicine and how easy are these to understand?*

The SHINGRIX datasheet lists the only contraindication to administration is hypersensitivity to the active substances or to any component of the vaccine.

Prior to immunisation, vaccinators are trained to screen patients to ensure vaccination is suitable. This involves:

- Assessment of eligibility and suitability for vaccination (including to check history of shingles, previous shingles vaccination, medical history, reactions to previous vaccinations, Immunisation Handbook recommendations and funding criteria).
- Pharmacist vaccinators have ready access to the Aotearoa Immunisation Register (AIR) to view a patient's vaccination history and to record a patient's vaccination too. Pharmacist vaccinator also utilise pre-vaccination screening checklists and consent forms as part of their practice in their consultation and assessment of patients.

– *Does the medicine have a low therapeutic index?*

N/A

– *What class effects need to be considered and what are the risks?*

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the

administration of the vaccine.

- Vaccination should be postponed in individuals suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.
- As with any vaccine, a protective immune response may not be elicited in all vaccinees.
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.
- Pharmacies that provide a vaccination service must meet all the requirements, including emergency equipment and procedures and vaccinators undergo regular CPR and first aid training as well as other staff members as emergency responders. Vaccinators are not allowed to work alone.
- SHINGRIX is a subunit vaccine, therefore is not associated with risks of live vaccines.

– *What are the risks of the medicine being used in an OTC environment?*

N/A

– *What other drug interactions need to be considered?*

SHINGRIX can be co-administered with other vaccines. Data supports the coadministration of SHINGRIX with unadjuvanted seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23), pneumococcal conjugate vaccine (PCV) or reduced antigen diphtheria- tetanus-acellular pertussis vaccine (dTpa) or coronavirus disease 2019 (COVID-19) messenger ribonucleic acid (mRNA) vaccine.[4,8]

While PPV23 would be rarely administered in pharmacy, we highlight the advice provided in the NZ SHINGRIX datasheet to administer PPV23 at a different injection site. The adverse reactions of fever and shivering were more frequent when PPV23 vaccine was co-administered with SHINGRIX compared to when SHINGRIX was given alone.

– *What food and/or drink interactions need to be considered?*

N/A

- *Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?*

  For SHINGRIX, the data sheet notes that no studies on the effects of SHINGRIX on the ability to drive and use machines have been performed. However, undesirable effects may temporarily influence the ability to drive or use machines.[4]

  In practice, there is a 20 minute observation period following a vaccination in case the vaccinee experiences an immediate adverse event requirement treatment. For the flu, this was changed to 5 minutes, however only if a patient was not driving and was with another adult.

- *Are there any special populations where exposure to the medicine needs to be restricted?*

  Given that SHINGRIX is typically given to individuals aged 50 years and over, a special population that needs to be considered are individuals 18+ at increased risk of herpes zoster who may be pregnant, planning to get pregnant, or those who are breast feeding. Although studies are ongoing, at this point, there is no data in the use of SHINGRIX in pregnant or females who are breast-feeding, or the impact it may have on fertility. We propose further education (listed in risk mitigation section) on this precaution given that there are likely to be women of child bearing age being vaccinated if SHINGRIX is reclassified.

The NZ Immunisation Handbook states "*there is limited data on the use of rZV in human pregnancy however, since it is a non-live vaccine, there are no theoretical safety concerns should it be inadvertently administered during pregnancy."*[8]

5. Undesirable effects

- *What are the known undesirable effects and the frequencies of these? Do these vary for special populations?*

  More than 17,000 adults aged 50 through 96 years of age received at least one dose of SHINGRIX in 17 clinical studies.[4] The incidence of solicited local and general symptoms was higher in subjects who received SHINGRIX than in subjects who received control (placebo or other vaccines). SHINGRIX was generally well tolerated.

  Additionally, in clinical studies, 1,587 subjects ≥ 18 years of age who are

immunodeficient or immunosuppressed due to disease or therapy were vaccinated with at least 1 dose of SHINGRIX. The reported adverse reactions were consistent with those reported clinical trial adverse reactions of adults 50 years of age and older.[4,5]

Overall, there was a higher incidence of some adverse reactions in younger age groups. However, the overall frequency and severity of these events did not indicate a clinically meaningful different reactogenicity profile in the younger age strata. In immunocompromised adult studies, there was a higher incidence of pain at the injection site, fatigue, myalgia, headache, shivering and fever in subjects aged 18 to 49 years compared with those aged 50 years and older. In older adult studies, there was a higher incidence of pain and swelling at the injection site, fatigue, myalgia, headache, shivering, fever and gastrointestinal symptoms in subjects aged 50 to 69 years compared with those aged 70 years and older.[4]

Table 1: (from SHINGRIX NZ Datasheet)[4]: Percentage of Subjects with Solicited Local and General Adverse Reactions within 7 Days of Vaccination in Adults Aged ≥18 Years following Autologous Hematopoietic Stem Cell Transplant, Renal Transplant, or with Hematologic Malignancies, or with Solid Malignant Tumours (Total Vaccinated Cohort)

	ZOSTER-002 Autologous Hematopoietic Stem Cell Transplant		ZOSTER-041 Renal Transplant[b]		ZOSTER-039 Hematologic Malignancies[c]		ZOSTER-028 Solid Malignant Tumours[d]	
	SHINGRIX (%)	Placebo[e] (%)	SHINGRIX (%)	Placebo[e] (%)	SHINGRIX (%)	Placebo[e] (%)	SHINGRIX (%)	Placebo[e] (%)
Local Adverse Reactions	**n = 901**	**n = 892**	**n = 131**	**n = 132**	**n = 278**	**n = 274**	**n = 112**	**n = 110**
Pain	84	9	87	8	80	16	80	6
Redness	33	1	25	2	41	2	36	0
Swelling	19	1	12	1	23	1	16	1
General Adverse Reactions	**n = 901**	**n = 894**	**n = 131**	**n = 132**	**n = 278**	**n = 274**	**n = 112**	**n = 110**
Myalgia	54	26	50	24	44	18	54	28
Fatigue	56	38	47	40	58	37	70	62
Headache	34	19	34	26	41	23	38	36
Shivering	26	13	22	12	25	7	35	23
Fever[f]	20	6	16	4	25	8	18	5
Gastrointestinal[g]	26	21	18	18	27	11	46	45

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).
[a] 7 days included day of vaccination and the subsequent 6 days.
[b] Renal transplant recipients on chronic immunosuppressive treatment.
[c] Subjects with hematologic malignancies during a cancer therapy course or after the full cancer therapy course.
[d] Subjects with solid tumours undergoing chemotherapy.
[e] Placebo was a sucrose/saline solution.
[f] Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route.
[g] GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

– *What are the risks and consequences of known undesirable effects?*

In 18+ immunocompromised clinical study participants, local and general adverse events were generally mild to moderate and resolved in 1 to 3 days. Adverse events were graded on a scale from 1 to 3, with grade 3 being described as severe: significant at rest and preventing normal everyday activities. For individuals aged 18-49, 16.7% of solicited local adverse event and 21.6% of solicited general adverse events were classified as grade 3.[21]

Guillain-Barré syndrome (GBS) is a rare event following SHINGRIX vaccination. In a post-marketing observational study in individuals aged 65 years or older, an increased

risk of Guillain-Barré syndrome (estimated 3 excess cases per million doses administered) was observed during the 42 days following vaccination with SHINGRIX.[4] The association between SHINGRIX vaccination continues to be assessed as post-marketing safety accrues. GSK notes that the risk of GBS has not been age stratified therefore the risk in individuals under 50 years has not been reported.

Post-marketing data

Adverse reactions reported are listed according to the following frequency:

Very common: ≥1/10

Common: ≥1/100 to <1/10

Uncommon: ≥1/1,000 to <1/100

Rare: ≥1/10,000 to <1/1,000

Very rare: <1/10,000

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Rare	Hypersensitivity reactions including rash, urticaria, angioedema

- *Are there any significant safety concerns for the medicine under review?*

  No

- *Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?*

  No

- *Are there any withdrawal effects following cessation of use of the medicine?*

  N/A

- *Is there a potential for overdose of the medicine?*

  There is potential for any vaccine to be administered more frequently than indicated. However, with the introduction of the AIR, a vaccinator is required to establish an individual's vaccination history/status prior to administration of any vaccine, minimising the possibility of unnecessary additional doses.

- *What are the consequences of overdose of the medicine?*

  Insufficient data are available.[4]

- *Are there any reports of overdose of the medicine?*

N/A

6. Medication errors and abuse/misuse potential

- *Would reclassification affect the risk of unnecessary use?*

  No, pharmacists are able to apply both the funding criteria and Immunisation Handbook to identify appropriate patients for SHINGRIX vaccination and use the Aotearoa Immunisation Register to assess the patients vaccination history. The risk to a patient if it was administered unnecessarily is likely to be very low given it is a non-live vaccine. We note that the live attenuated zoster vaccine Zostavax, was discontinued in New Zealand in 2022 which was contraindicated in immunocompromised individuals.

- *Is the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?*

  Two vials are provided for powder and suspension. A syringe and two needles are required to reconstitute the powder and administer the vaccine (needles are not provided). This is common for vaccines provided in New Zealand and often, needles supplied in the pack are not used as they are not the appropriate size for intramuscular injection for New Zealand vaccinees.

- *What are the reported medication errors post-market?*

  Administration errors are recorded when reported to IMAC, GSK and or CARM in New Zealand. However, we do not expect there to be changes in the type of errors reported as a result of expanding the population to 18+.

- *What are the reported cases of abuse/misuse/accidental overdose?*

  N/A

- *How would reclassification affect import considerations?*

  The vaccine still holds the prescription-only classification until point of administration. As such, there are no changes in requirements around import or distribution.

- *What is the addiction potential of the medicine?*

  N/A

7. Communal harm and / or benefit

- *What are the possibilities of community harm resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased*

immunisation rates)?

N/A

- *What are the possibilities of community benefit resulting from wider use of the medicine in question (eg, greater herd immunity because of improved access to a communicable disease vaccine)?*

  Access of SHINGRIX through community pharmacy will very likely increase the uptake of vaccination ensuring those with highest need can be protected, and sharing vaccination services across providers will decrease the burden on general practice.

8. Integrated benefit-risk statement

- *A summary of the reclassification benefits*
  - Availability of SHINGRIX through community pharmacy will allow consumers to access it from a larger pool of vaccinators. It will also spread the workload more evenly amongst authorised and pharmacist vaccinators to relieve pressures across primary care sectors ensuring patients can be protected.
  - Pharmacists have been providing influenza vaccines since 2013 and the Covid-19 experience has shown that New Zealanders find community pharmacies to be a trusted provider for vaccinations. Since SHINGRIX can be administered with other adult vaccines, the availability of both from the same provider will be important for vaccine uptake.
  - Patients 18+ at increased risk need to receive vaccination at certain times around their treatment cycle when a strong immune response is most likely. Delays with access to primary care may result in either no vaccination or it could be given at a suboptimal time.
  - Authorised vaccinators have traditionally been the primary provider of scheduled and funded vaccines. Reclassification will allow consumers to receive this vaccine from authorised and pharmacist vaccinators without obtaining a prescription first which will streamline the process and reduce confusion around the pathway to receive vaccination.

- *A summary of the reclassification risk of harm*

  The potential of harm arising from the proposed reclassifications is minimal however we propose that the risk to individuals at risk of herpes zoster remaining unprotected or not accessing timely vaccination is an important consideration.

- *A summary of the need for the medicine at the classification proposed*

  Community pharmacies have proven to be an accepted and commonly used provider

for consumers to receive their vaccination and is necessary for equitable and accessible uptake. Reclassification as proposed will also allow consumers to receive vaccinations from authorised vaccinators without obtaining a prescription first, from the provider they feel most comfortable with.

- *Precedent – how are other medicines in the same class classified?*

  SHINGRIX is the only herpes zoster vaccine available in New Zealand. Many other adult vaccines are administered through community pharmacy by pharmacist vaccinators. Current vaccines available through pharmacy without a prescription:[13]

  - Influenza from 3 years+
  - Diphtheria, tetanus and pertussis from 13 years+ (maternal) and from 18 years+ (non-maternal)
  - Covid-19 from 3 years+
  - HPV9
  - MMR from 3 years+
  - Meningococcal B from 16 years+
  - Meningococcal ACYW from 16 years+
  - Varicella zoster from 50 years+
  - Cholera (as a pharmacist only medicine)

9. Risk mitigating strategies.

- *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required eg, healthcare professional education; integration of care; consumer information to be provided etc?*

Potential Risks	***Mitigation Plan***
Healthcare professionals are not familiar with the reconstitution and administration of SHINGRIX	**Availability of the Data sheet and package insert** The data sheet describes reconstitution steps for those who are not currently familiar with preparing SHINGRIX (around 50% pharmacies in New Zealand have ordered funded stock for administration to patients – as of July 2024). Reconstitution of SHINGRIX is similar to the preparation of other vaccines. All necessary information on reconstitution, administration and precautions will be available for reference and use for all prescribers and administrators. In addition, the Immunisation Advisory Centre has produced a video on reconstituting and administering SHINGRIX, available to all HCPs.

	Provision of educational resources and materials In addition, GSK will undertake to provide relevant educational materials and resources to healthcare providers on how to correctly reconstitute and administer SHINGRIX.
Adverse events or injection site reaction management	**Data sheet** Similar to other vaccines, the SHINGRIX datasheet sets out the requirements to guide safe and appropriate vaccination, frequency of adverse effects and management of adverse events including the website for reporting adverse events. **Education materials and resources** The Immunisation Advisory Centre provides educational materials and resources to equip healthcare providers to respond to and manage adverse events. The Pharmacy Guild, The Pharmaceutical Society as well as banner groups in New Zealand provide resources for pharmacists to help support safe and appropriate vaccination and to meet all immunisation standards in terms of emergency equipment, procedures and collateral. GSK and Te Whatu Ora provides materials to help consumers understand what to expect after vaccination, and how to report adverse events. Pharmacists are more accessible than many other healthcare professionals, making it easier to call or revisit (including evenings and weekends) if a patient was concerned about an adverse reaction.
Appropriate screening to avoid vaccination of pregnant or breastfeeding individuals.	SHINGRIX is typically given to patients who are 50 and over, however there is a risk that individuals who are pregnant, planning for pregnancy, or breast feeding may come in for vaccination under the new eligibility criteria. The data sheet outlines that there is currently a lack of data

	in the use of SHINGRIX in these special groups, and therefore vaccination should be restricted in this group. Ensure that screening includes questions to elicit whether individuals 18+ are planning a pregnancy, are pregnant or breastfeeding. GSK will work with IMAC to update training materials and GSK will work with stakeholders to add appropriate questions to screening tools.
Identification of eligible patients at increased risk of shingles 18+	Pharmacists are trained identify and confirm through patient history, clinical records, dispensing data and/or through communications with physicians whether a person should be vaccinated with SHINGRIX. Pharmacists are required to maintain their competency in understanding who should be receiving any vaccine and the administration of various vaccines, by both self-learning and regular updates as part of their scope of practice as a vaccinator. National resources already exist to support the vaccination of individuals 18+ with immunocompromise. **Health New Zealand Immunisation Handbook** Pharmacists will be guided by local clinical recommendations such as the Immunisation Handbook – where reference to chapter 4 (special groups) and chapter 24 (Zoster recommendations), outlining the criteria for identifying IC patients and recommendation of vaccination. These guidelines will enable pharmacists to make informed decisions about vaccinating eligible patients independently. **Education campaigns** Pharmacies are captured by the support of regional immunization coordinators and professional development programs offered by bodies such as IMAC. Through these initiatives, they will be regularly updated and educated about the latest criteria and eligibility. This ongoing education will reinforces their ability to safely and effectively vaccinate these individuals without requiring a prescription.

Unnecessary vaccinations	The AIR is a national register for vaccines and is a centralised platform to view individuals' vaccination status, mitigating the risk of inadvertently administering an additional dose of the same vaccine when not scheduled. With the introduction of the AIR, pharmacist vaccinators are required to have access and establish an individual's vaccination history/status prior to the administration of any vaccine, minimising the possibility of additional doses.

- *What post-market surveillance activities would be carried out?*

  Post marketing surveillance activities would not change as a result of this proposal.

- *Is the proposed reclassification supported by professional bodies?*

  Yes. Supported by the Pharmacy Guild New Zealand (See support letter attached).

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