

Submission for Reclassification of the Zoster Vaccine for use in Adults

Executive Summary

This application requests a reclassification for the Zoster vaccination allowing administration to people aged 50 years or over by pharmacists who have successfully completed the Immunisation Advisory Centre (IMAC) or another approved vaccinator's course, and are complying with the immunisation standards and cold chain guidelines of the Ministry of Health.

Shingles (herpes zoster) is a concerning illness, particularly in the elderly. An 80 year old has a 50% lifetime prevalence.¹ Shingles causes pain, depression, insomnia, scarring, time off work and loss of independence.¹ Eye involvement can cause permanent vision loss. Up to 20% of shingles sufferers over 50 years old get post-herpetic neuralgia (PHN), with pain that sometimes lasts years, and which is so difficult to treat that few find their analgesia adequate.¹ Shingles vaccination reduces the incidence and severity of infection, and incidence of PHN.²⁻⁴

Owing to a worldwide shortage, this vaccine has primarily been available in the US (since 2006), with some Canadian use since 2009,⁵ and a short period on the NZ market in 2011-2012. Shingles vaccination is due to again be available in NZ in early 2014.

The local adverse reactions are similar in frequency and severity with that of other vaccinations.³ Other adverse events are less common, with mild systemic reactions in 6% of people vaccinated, and anaphylaxis reported in post-marketing surveillance,⁴ as occurs with other vaccinations.

Internationally, certified pharmacists are increasingly administering vaccinations.^{6-8,9} This includes shingles vaccinations in the US and Canada. The increasing use of pharmacists recognises the accessibility and convenience of pharmacy and the advocacy of pharmacists as health professionals to increase consumer awareness and vaccination opportunities and ultimately increase the uptake. Vaccination rates improve^{10,11} and healthcare consumers and pharmacists support this strategy.^{9,12} Having shingles vaccinations available through pharmacists increases the opportunity for patients to have a discussion with a health professional about this vaccination. As a result, uptake through both medical practices and pharmacy should increase, with resultant reduction in the burden of illness for both people being vaccinated, and the health system in general.

Increasing the number of pharmacists administering vaccinations provides public health benefits for NZ, through greater accessibility, increased advocacy, and better coverage in epidemics or pandemics and offers convenience to the consumer particularly through increased opening hours particularly at the weekend and in the evening.

A comprehensive pharmacy process includes thorough screening, record-keeping, notification to the patient's GP (with consent), and reporting of adverse events to the GP and the Centre for Adverse Reactions Monitoring (CARM). The pharmacy process will meet the

Ministry of Health standards including use of a private area and a 20 minute observation period post vaccination.

To date over 200 pharmacists have successfully completed the MOH approved vaccination course which includes practice using dummy injections. Most vaccination courses have covered the theory behind the use of subcutaneous injections. Clinical assessments for all pharmacists include the administering of two vaccines one of which must be an intramuscular injection. This has been amended in accordance with the MOH recommendations for Pharmacist vaccinators for the 2013 influenza season dated 24 January 2013.

As stated in previous immunisation applications, pharmacists are keen to contribute further to the greater good of public health in NZ.

Part A

We have taken information from IMAC, the Ministry of Health Immunisation Handbook 2011, and CDC in the US as well as the datasheet of the product registered on the NZ market owing to the need to follow latest best practice in this field.

Note: Throughout this application the terms shingles vaccination and zoster vaccination are used interchangeably. This application seeks the reclassification of zoster (shingles) vaccine only. Varicella (chickenpox) vaccine would remain a prescription medicine. See Table 1 for the differences.

Table 1 Vaccinations containing varicella zoster virus

Name	Alternate name	Indication	Brand names	Ingredients
Varicella vaccine	Chickenpox vaccine	Prevention of chickenpox	Varilrix®, Varivax®	At least 1,350 plaque-forming units of VZV (Varivax®)
Zoster vaccine	Shingles vaccine	Prevention of shingles and postherpetic neuralgia (PHN). Reduction of acute and chronic zoster-associated pain	Zostavax®	At least 19,400 plaque-forming units of VZV

VZV = varicella zoster virus

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

Zoster vaccine live (Oka/Merck)

2. Proprietary name(s)

Zostavax®

3. Name of company/organisation/individual requesting reclassification

Pharmacybrands Ltd, the parent company for Life, Unichem, Amcal, Radius and Care Chemist Pharmacies in New Zealand.

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

Dose form: Injection for subcutaneous administration

Strength: 19,400 PFU (plaque forming units) of the Oka/Merck strain of varicella-zoster virus (VZV) when reconstituted.

5. Pack size and other qualifications

Pack sizes are single dose vials for reconstitution

6. Indications for which change is sought

Immunisation for the prevention of herpes zoster (shingles); prevention of postherpetic neuralgia (PHN); and reduction of acute and chronic zoster-associated pain. Zostavax is indicated for immunisation of individuals 50 years of age and older.

7. Present classification of medicine

Prescription medicine

Note: The database of medicine classifications on the Medsafe website, and the Medicines Regulations 1984, updated 29 Nov 2012 lists the following:

Varicella (chickenpox) vaccine: Prescription

Vaccines: except when specified elsewhere in this schedule: Prescription

The Zoster (shingles) vaccine is not separately listed

8. Classification sought

Zoster (shingles) vaccine: Prescription medicine except when administered to a person aged 50 years or over by a pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and is complying with the immunisation standards and cold chain guidelines of the Ministry of Health.

This wording allows the varicella (chickenpox) vaccines (i.e. Varivax and Varilrix) to remain prescription medicines.

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

Internationally, pharmacist-administration of vaccines is becoming common through various mechanisms. In most countries the vaccines remain prescription medicines.

In Canada, shingles vaccine appears to be a prescription medicine currently,¹³ with licensed pharmacist vaccinators administering it on presentation of a prescription.¹⁴ Possibly stock shortages since this medicine was first marketed in Canada (resolved 2012)¹⁵ prevented a

pharmacist-only classification being sought. The Canadian product has required -15°C storage, and therefore in 2012 a news report stated “as few doctors’ offices have the freezers needed onsite, it will probably be available only in pharmacies for the foreseeable future.”¹⁶ Thus, it appears that the vaccination is mainly administered by pharmacist vaccinators (in selected pharmacies with suitable well-controlled freezers), on a doctor’s prescription. Note: the NZ vaccine is a refrigerated vaccine not a frozen vaccine.

In the USA, vaccinations have been available from pharmacies in some states since the 1990s,¹⁷ extended to all states in 2009. Following completion of the American Pharmacists Association Certification Program, pharmacists are able to administer vaccinations¹² through various practices, often by protocol which has some similarities with standing orders or the UK’s patient group directions. Zoster vaccinations are available through pharmacist-supply in the US,¹⁸ and as of June 2012, 51 States allow zoster vaccinations to be administered by pharmacist.¹⁹ In many states pharmacists can do this either by specific protocol or on prescription.

Shingles vaccination has just become available in the UK in 2012, but has suffered from a shortage,²⁰ so PGD availability²¹ appears to be recent and not widespread.

In Australia, vaccines remain prescription medicines and are not administered by pharmacists.

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

Only one zoster (shingles) vaccine is registered in NZ, with consent given 11 Sep 2008. Owing to an international shortage, this vaccine has only been available for a limited period in NZ in 2011-2012. However, this shortage has been resolved, and it is expected on the market in NZ again in early 2014.

Please see Appendix 1 for usage information.

Zostavax was launched in the US in 2006, and in Canada in 2009. Stock shortages resulted in sporadic supply in Canada,¹⁶ and delayed launch in other countries, including NZ. However, these have now been resolved, and the vaccine has more recently been launched in Australia, Europe and many other countries.

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

Labelling would not change for the proposed reclassification. This medicine is not going to be self-administered so consumer labelling is unnecessary.

12. Proposed warning statements if applicable

Current packaging would remain.

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

No other products affected.

Part B

1. A statement of the benefits to both the consumer and to the public expected from the proposed change

The aim of reclassification is to reduce the incidence of shingles and the incidence of postherpetic neuralgia (PHN). This will then reduce the “*considerable morbidity*” associated with shingles, to quote the Ministry of Health’s Immunisation Handbook.¹(p319)

Herpes zoster (shingles)

Shingles is caused by reactivation of the dormant varicella zoster virus (VZV; from an earlier chickenpox infection) in the dorsal root or cranial nerve ganglia.²² More than 90% of adult trigeminal ganglia contain VZV DNA. As most adult New Zealanders have experienced chickenpox,¹ most of the population is at risk from shingles. Shingles is more common in immunocompromised people, and people with diabetes mellitus or cancer.²² Shingles also increases with age as VZV-specific T-cell mediated immunity declines.

In shingles, reactivation of the virus causes infection in a ganglion, causing damage to many neurons and supporting cells.³ Prodromal pain can last three to four days, and itching is common. The virus spreads through the nerve to the skin, resulting in a skin rash that is typically accompanied by pain, and lasts around 2-4 weeks. Scarring may remain afterwards.²³

Shingles is uncommon in people under 40 years, but has a lifetime incidence of around a quarter²³ to a third¹ of people, increasing with age to around half of people over 80 years of age.¹ US data suggests the incidence may be increasing.²² Around 20% of cases occur in people aged 50-59 years, and 45-50% occur in people 60 years and over.³

Pain during shingles is typically moderate to severe, and often rated as worse than labour pain or after surgery.²³ The skin can have burning, stabbing, tingling, aching, or numb sensations. Allodynia often occurs whereby pain is triggered by light touch such as clothing or even a light wind. Shingles can impact physical, psychological, social, and functional health aspects, including causing depression, insomnia, reduced mobility and isolation. Most employed sufferers have to take time off work,²³ on average 27 hours each, with 76% of sufferers believing they were less effective at their work when they were there (presenteeism).²⁴ Some elderly shingles sufferers can have permanent loss of independence.²³ Quality of life scores are similar to those seen in congestive heart failure and depression.²³

Complications are more common with increasing age, with nearly 50% of older persons developing complications.² Complications can include meningitis, encephalitis, limb weakness, dysfunction of bowel or bladder and motor deficits.³ A tenth to a quarter of people

with shingles have eye involvement which can cause long-term pain, vision loss and scarring.¹ Hospitalisation is estimated to occur in 2% of cases.²³ Stroke is more likely after an episode of shingles.²⁵

Post-herpetic neuralgia (PHN)

PHN has differing definitions with recent researchers using pain present 90 days after rash onset (others have used 30 days post rash onset).³ Depending on the definition used, up to 20% of shingles sufferers over 50 years old get PHN, with pain lasting months or years and difficult to treat.²³ Incidence of PHN increases with age,^{3,26} with around 40% of sufferers over 60 years affected.²⁵ Allodynia occurs in over 70% of patients, and can be debilitating.²³ Even with pain relief, PHN pain is typically rated as moderate to severe, often interfering with general activities and enjoyment of life.²³ Simple tasks such as having a bath can be difficult. Many PHN sufferers become medicated for depression, anxiety and insomnia. Pain in PHN is less responsive to analgesia than in shingles, with only 14% of PHN sufferers over 65 years satisfied with their analgesia.²

Zoster vaccination

VZV-immunity declines with age, which was hypothesised to be the reason for the increasing risk of shingles with age.³ Additionally, shingles sufferers infrequently have a recurrence, also suggesting a boost to immunity provides protection. Thus, a vaccine has been developed to boost the immunity.

Oxman, *et al.* enrolled 38,546 adults 60 years old or over for an average of 3 years in a randomised, double-blind, placebo-controlled trial of the vaccine.² The vaccine reduced the incidence of shingles by 51%, and of PHN by 66%, and the burden of illness by 61%. The vaccine was more effective in preventing shingles in the 60-69 age group (64%) than in those 70 years and over (38%), but the PHN prevention rate was similar in both age groups. On further analysis, the vaccine reduced the incidence in people 70-79 years old by 41% and in 80 years plus by 18%.³ For those who did get shingles, the duration of illness reduced from 24 days to 21 days, and the severity of illness was significantly lower, particularly in older persons. A retrospective cohort study also showed reduced incidence of zoster infection, and a reduction in complications, including ophthalmic complications.³

Despite the vaccination being less effective in the 70 year plus age group in preventing shingles,² because of the increased burden of illness in this group, and the high reduction in PHN,² it remains a worthwhile option. In fact, a cost per quality-adjusted life year (QALY) gained modelling in the Netherlands found that the shingles vaccination was most cost-effective for 70 year olds.²⁷

A 2011 Herpes Zoster review from the US reported that "*follow-up studies indicate that the vaccine is effective for at least 6 years.*"²² There is no current recommendation for a booster dose.

Shingles vaccinations will reduce opportunity for transmission of the virus from shingles lesions (through the overall reduction in shingles). Such transmission can cause chickenpox

infection. US research followed 290 people with shingles and identified 84 secondary varicella (chickenpox) cases infected from the shingles sufferers.²⁸ This fact is poorly understood in the community, and thus prevention of transmission may not be practiced.

US Recommendations

In the US, this vaccination is recommended for all people 60 years and over, based on stock shortages and risk of shingles and PHN (see *further information*, below).²⁶

UK Recommendations

The UK has added this vaccination to their funded vaccines for people 70 years and over from September 2013.²⁰ The high minimum age reflects funding limits, and private availability remains for the lower age groups.

NZ Recommendations

The Ministry of Health's Immunisation Handbook does not make a specific recommendation about the vaccine's use in NZ given it was not marketed at the time of the handbook printing (2011), but reports the following:¹

Zostavax is a higher titre formulation of the varicella vaccine and has been

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Immunisation Handbook 2011

tested as a vaccine to protect against herpes zoster.⁶ By mimicking the immune response seen following a dose of shingles and boosting cell-mediated immunity in older adults, zoster may be prevented by the high-titre vaccine.

In a large clinical trial of 38,586 adults aged 60 years and older, with either a history of chickenpox or of having lived in the US for more than 30 years, the participants received the high-dose zoster vaccine or a placebo. The results showed that the zoster vaccine reduced the burden of illness of zoster by 61 percent in all age groups, by 65.5 percent in the age group 60–69 years and by 55.4 percent in those aged 70 years and older. There was also a 66.5 percent reduction in post-herpetic neuralgia in all age groups. Over five years of follow-up the incidence of zoster and post-herpetic neuralgia was reduced. In the individuals who received the zoster vaccine but developed zoster, the illness was less severe. Zostavax is approved for use in New Zealand, though it was not marketed (available) at the time of writing.

Place of pharmacist-supply

We anticipate that most vaccinations through pharmacy will be incremental gains, e.g. people who never get around to booking in with their doctor, may not have a doctor, or who may be unaware of the availability of the shingles vaccination. Most community pharmacies are open at least six days a week, and many are open extended hours. An appointment will often not be necessary. In Australia, time and inconvenience were cited by a quarter of adults under 65 years with chronic medical conditions who did not get an influenza vaccination.²⁹ Pharmacies will be able to provide the information leaflet (being finalised) to inform patients about shingles, PHN and the availability of the vaccination.

In the US, a small study in three pharmacies found a month-long pharmacy campaign approximately trebled the number of people accessing shingles vaccination.³⁰ A further study in the US used ophthalmologists to recommend and administer zoster vaccinations owing to their concerns about the disease.³¹ They found one barrier to uptake of the vaccination was that the patient's primary care doctor had not recommended it to the patient. A similar finding (of non-recommendation by a primary care doctor as a barrier) occurred in pharmacies where pharmacist-advocacy increased the uptake of vaccination.³² For many older people there may be more pressing concerns within a doctor's consultation than suggesting a shingles vaccination. Thus, it is likely that pharmacist-vaccinations in NZ would increase the opportunity for health professionals to have conversations with people identified to be at risk of shingles.

US physician support of pharmacist-vaccinations

The American College of Physicians and American Society of Internal Medicine stated in 2002:
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"ACP-ASIM supports the use of the pharmacist as immunization information source, host of immunization sites and immunizer, as appropriate and allowed by state law. ACP-ASIM will work with pharmacy organizations to increase immunization awareness."

No concerns about pharmacist-immunisation were outlined by these doctor groups who noted:

- The potential benefit of non-physician immunisation
- Pharmacists increase access to immunisation through extended opening hours and locations
- Benefits expected include decreased antibiotic resistance and increased adult immunisation

In the US, pharmacist-administered vaccinations also have the support of the Centers of Disease Control and Prevention (CDC).⁷

Working with the GP

Pharmacist-led shingles vaccination will be complementary to general practice, offering another option of administration and promoting the need for vaccination. With patient consent the patient's GP is notified of the vaccination. As is usual in pharmacy, the pharmacist will refer patients onto their GP where appropriate, and as identified through the robust history taking/consent process.

Pharmacist administration of shingles vaccinations in USA and Canada

All US States but one allow pharmacists to administer zoster vaccinations, usually by protocol or on a prescription.¹⁹ In Canada this medicine requires a prescription, but is typically administered in pharmacy.¹⁶

Other international research and experience of pharmacist-administered vaccinations

In the US, pharmacists have administered vaccinations to adults since the 1990s, expanding to all states in 2009.¹⁷ Pharmacists administer influenza vaccinations through a practice which has some similarities with standing orders or the UK's patient group directions. This has led to 18% of influenza vaccinations in adults being given in the US through pharmacy, versus 40% through doctors and 17% at workplaces.¹⁷ In Walgreens alone (a large community pharmacy chain), more than 4.5 million seasonal influenza vaccinations were pharmacist-administered in the 2009/2010 season, including 1.7 million in medically underserved areas.⁶

In June 2012, CDC in the US wrote to pharmacists to thank them for their "*tremendous efforts this past year to raise immunization rates in the United States.*" CDC noted that "*Pharmacists and community vaccinators are uniquely positioned to promote and provide vaccines to people in a wide range of communities.*"⁷ Furthermore, special authority was given to pharmacists in New York to administer influenza vaccinations in children to help manage a severe influenza epidemic in 2012-2013,³⁴ and provide tetanus injections following Hurricane Sandy, given the risk to people involved in clean-ups.³⁵

Advocacy by health professionals is an important motivator for people to become vaccinated.^{1,36} Pharmacist advocacy, even without vaccination administration, also significantly increases influenza vaccination rate in at-risk populations.³⁷⁻⁴⁰ We anticipate that pharmacist encouragement of shingles immunisation will assist in uptake by elderly people, as well as raise awareness of the importance of immunisation in general. The implementation of the new Community Pharmacy Services Agreement namely around the registration of Long Term Condition patients encourages pharmacists to have a more holistic approach to patient centric care and presents further opportunities around immunisation discussions.

US studies have shown increased uptake of influenza vaccination and pneumococcal vaccination in states with community pharmacist-vaccination versus states without.^{10,11,41} Pharmacist input in hospitals has also improved rates of vaccination.^{42,43,44} Vaccinations by pharmacists have been well received by patients, e.g. in Portugal 99.5% of consumers were satisfied with their pharmacist immunisation provider, and 98% with the privacy available, and satisfaction with pharmacist-provided vaccinations was also high in Aberdeen.⁹ In NZ in

2012 Professor Sarah Hook (School of Pharmacy, Dunedin) found that 42% of surveyed consumers who had a flu vaccine in pharmacy in the 2012 season had never had a flu vaccine prior to this (personal communication). This indicates the success that pharmacy has had in not only raising awareness but increasing the numbers of those consumers vaccinated.

NZ government strategy

Administration of shingles vaccinations by approved pharmacists both provides public health benefits and potential benefits to the taxpayer given the potential debilitation of shingles and associated complications. A reduction in shingles and complications will reduce demands on health resources, and may reduce the number of people who need extra care (e.g. moving temporarily or permanently into a rest home) as a result of their illness. It is also clearly in line with the government strategy of better, sooner, more convenient healthcare.

Population growth, an ageing population and developments in health are increasing demand for health services in a constrained fiscal environment. These require better use of the existing health workforce, including extending existing roles,⁴⁵ and preventive care – keeping elderly people out of hospital and in their own homes where appropriate. Having shingles vaccinations available through pharmacy will provide such benefits. Furthermore, increasing the pool of vaccinators helps to meet the population needs now and in the future.

Community pharmacies are easily accessible and used by most of the population, healthy and unwell, and particularly the elderly. Availability of shingles vaccination through trained pharmacists provides the community with another health professional group actively involved in immunisation and advocating for its use. US experience indicates pharmacists can provide advocacy and accessibility that increase vaccinations. Increased advocacy plus convenience/accessibility provide a strong reason to reclassify this medicine, to reduce the debilitation associated with shingles.

2. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated

Pharmacists able to provide shingles vaccinations will have successfully completed a Ministry of Health approved vaccinator's course and clinical assessment and have met the requirements in standards set by the Ministry of Health. Establishing appropriate persons to vaccinate will be straight-forward for these trained pharmacists. The pre-vaccination checklist and consent form attached (Appendix 2) will be used by the pharmacist, recording each consultation. While created by Pharmacybrands, these materials will be available to any pharmacist vaccinator. Those fulfilling referral criteria would be referred to the GP, those answering no to all questions will be vaccinated if they consent. The details of their vaccination will be forwarded to their GP if the consumer consents.

3. Relevant comparative data for like compounds

Two vaccinations have become available through the pharmacist: Dukoral[®], an oral vaccination for prevention of cholera and ETEC travellers' diarrhoea, and influenza vaccination. For the latter vaccination, the pharmacist needs to have undergone appropriate training first, and the vaccination should only be provided to adults 18 years and older. At

time of writing, a decision is awaited on the reclassification of the Tetanus-diphtheria-acellular pertussis booster vaccination, and the meningococcal vaccination.

4. Local data or special considerations relating to New Zealand

As recently highlighted by the Minister of Health, the Right Honourable Tony Ryall, NZ has an ageing population, and increasing pressure on health resources.⁴⁶ For this reason, NZ has had increasing focus on preventing illness. Reducing the prevalence and severity of shingles and PHN will prevent morbidity in elderly people, reduce use of health resource, and be consistent with government policy.

There is high awareness of herpes zoster in NZ. In a 22-country study, 100% of New Zealanders over 50 years old surveyed were aware of shingles (in contrast to many other countries).⁴⁷ Across respondents from all countries, there was little understanding of the cause of shingles, and the complications of shingles. Furthermore, many respondents erroneously considered they were unlikely to get shingles. The survey noted broad public health efforts were required to increase awareness of shingles and optimise benefit from the vaccination and early use of antivirals in an acute episode. Pharmacy would help to raise the awareness of both.

Shingles vaccine is not funded in NZ.

5. Interactions with other medicines

Zoster vaccination is a live vaccine, and therefore must not be used in people with immunodeficiency, such as with immunosuppressant medication.⁴ These will be screened for and referral would occur.

The shingles vaccine should not be mixed with any other vaccinations. Pharmacists would not be mixing vaccinations.

The shingles vaccine can be given at the same time as the influenza vaccine (different syringes), but according to the datasheet should be separated in timing from the 23-valent pneumococcal polysaccharide vaccine.⁴ The CDC states that while Merck found the average titer against VZV was lower where the vaccines were co-administered, the clinical relevance is unknown, and other research suggests this is not a problem (see Appendix 3).²⁶ To avoid providing barriers to vaccine uptake, CDC has not changed its recommendation. Given an update of the Immunisation Handbook is currently in progress, we are referring pharmacists to the datasheet and Immunisation Handbook should there be other vaccinations recently given.

Use with antiviral drugs, e.g. aciclovir, for 24 hours before or 10 days after the vaccination could affect the vaccine's performance.³ This is screened for, and mentioned in the patient information.

6. Contraindications and precautions

The Zostavax datasheet (Appendix 4) lists the following contraindications:⁴

- Hypersensitivity to any component of the vaccine including neomycin and gelatin
- Primary and acquired immunodeficiency states due to conditions such as acute and chronic leukaemias, lymphoma, other conditions affecting the bone marrow or lymphatic system, HIV/AIDS, cellular immune deficiencies and radiation
- Immunosuppressive therapy (including high dose corticosteroids but not topical or inhaled steroids or low-dose systemic corticosteroids)
- Active untreated tuberculosis
- Pregnancy

Contraindications will be covered in the vaccination checklist (Appendix 2), and pharmacists will have received the comprehensive training and completed vaccinator requirements including first aid training to level 3. Pharmacies offering the vaccinations will have a private area for consultation available and will have the necessary emergency equipment available. The pharmacist-administered vaccination would be advised to the patient's GP with consent as previously discussed. Patients will wait within line of sight in the pharmacy for 20 minutes after being vaccinated. They will also be given details of a process to be followed should they become unwell post vaccination (Appendix 2).

A fever above 38.5°C should result in a deferral of the vaccine⁴ – this is included in the screening.

Zostavax does not protect all recipients – this is discussed in the consent process and information sheets (Appendix 2, and information to be supplied).

Although not seen in clinical trials, it is theoretically possible that transmission may occur from a varicella-like rash that the vaccination rarely causes.⁴ Therefore this is covered in the consent process.

7. Possible resistance

Not applicable.

8. Adverse events - nature, frequency etc.

The seminal text "Vaccines" reports that while local reactions are more common than placebo (48% versus 16%), the severity and frequency is in line with other vaccinations.³ One in one thousand got one or more vesicles at the injection site. Mild systemic effects occur in around 6% of patients but there was no greater incidence of fever.

The datasheet reports the following as very common (10% or more) and common (1% to <10%):⁴

- Very common: erythema, pain, swelling, pruritis

- Common: Headache, haematoma, warmth, induration, pain in extremity

Anaphylaxis can also very rarely occur, although no incidence of this effect is available.

After immunisation the healthcare consumer will be given an information sheet for managing adverse events (Appendix 2).

9. Potential for abuse or misuse.

There is no potential for abuse.

Misuse is unlikely. It would be highly unlikely that someone would get two shingles vaccines. A vaccination is usually reasonably memorable, so this seems highly unlikely. Pharmacists will notify doctors of administration of the vaccination (with consent of the healthcare consumer) which minimises this risk. Additionally, pharmacies will provide the consumer with a vaccination wallet card that identifies the vaccine given and the date administered.

10. Further information

Cold Chain

Appropriate storage and handling of the vaccination is important for viability of the vaccination, currently 2-8°C. Pharmacy currently manages the supply of cold chain products and has efficient cold chain Standard Operating Procedures to manage this. Vaccinator assessment includes the cold chain and potential resulting issues. During assessment, cold chain SOP's are reviewed together with contingency plans in the event of a cold chain failure. Fridges are currently monitored within pharmacy and are also subject to the pharmacy Medsafe audit process. Pharmacists will be familiar with this also from supplying influenza vaccinations as well as from the multitude of current pharmaceuticals that are cold chain managed. It is also important to note that all pharmacies that offer vaccination are currently undergoing cold chain accreditation either through the local DHB Immunization co-ordinators or IMAC.

Compliance with standards

Pharmacists will comply with immunisation standards of the Ministry of Health, as described in Appendix 3 of the Immunisation Handbook 2011 (attached to this application as Appendix 5).

Vaccinator training

Vaccinator training through the Immunisation Advisory Centre is comprehensive and involves a choice of a two-day course or a flexible learning course requiring 12 hours self-guided study workbook and manual followed by a four hour face-to-face clinical tutorial.⁴⁸ To become authorised the person must do the training, achieve a pass mark of 80% on an open book test, and be clinically assessed on a minimum of two vaccinations relevant to their clinical area. Updates for trained vaccinators can be either four hours face-to-face or conducted on-line every 2 years.

WONS provides a two day vaccinator training course, an open book test, and clinical assessment (two vaccinations) with one-on-one mentoring before the clinical assessment for new vaccinators. Alternatively a one-day influenza only course and clinical assessment is offered.⁴⁹

Use in people who have previously had shingles

Recurrence of shingles is uncommon,²² therefore we will be screening for previous shingles and advising them that recurrence is uncommon. This will also be included in the information sheet (to be supplied). They may still choose to be vaccinated, as some protection is likely, but will be fully informed. The Advisory Committee for Immunization Practices (ACIP) in the US recommends the zoster vaccine for adults 60 years and over regardless of prior history of shingles.

Reconstitution and SC Injection

Pharmacy students receive training and hands-on experience in handling vials, syringes and needles, drawing up liquids and reconstituting powder for injection in their aseptic preparation training. This includes rigorous practical examinations. We have included clear information on the check list and consent form to ensure the reconstitution is not more than 30 minutes before administration, the correct volume is drawn up and the needle is changed for administration.

A subcutaneous injection into the deltoid region is straight-forward with the main points being to use a 45° angle and the correct length of needle. Most pharmacists have not administered subcutaneous injections previously although many pharmacists have been trained in the delivery of insulin subcutaneously. However, when the flu pandemic struck influenza vaccine was not available in single doses but multidose vials that nurses had not used since the 1970's. MOH approval was received by IMAC to use a training video uploaded on line that was used to train nurses in this technique and we envisage the same would apply for pharmacists who have completed the theory in the course. This will be circulated through Pharmacybrands to vaccinator pharmacists. We will also ask the Pharmacy Guild, the Pharmaceutical Society, and Pharmacy Today to please ensure pharmacists are aware that this is a subcutaneous injection and further online training is required prior to administration. Additionally, a clear reminder on administration is on the checklist/consent form to reduce errors. These measures provide strong protection against incorrect administration. CDC reports that where the injection is inadvertently given by intramuscular injection, it does not need to be repeated as a subcutaneous injection.²⁶

Pharmacist insurance

ALL pharmacists once they pass assessment are requirement to inform the Pharmacy Defence Association to ensure that they have insurance coverage to provide vaccinations and have to advise the date of completion of their vaccination course.

Information for patients

To ensure consumers are well informed prior to being vaccinated, an information sheet has been developed. This is being finalised and will be supplied prior to the MCC meeting after input from relevant bodies.

How long does protection last post-vaccination?

As is common with many vaccines, the exact duration of protection is unknown. Wilson reports it is at least six years.²² A booster is not currently indicated, although CDC reports that ongoing studies will assess the need, if any, for booster doses.²⁶

Need to check for previous chickenpox

As in the US,²⁶ there is no need to check the NZ population 50 years and over for previous history of chicken pox, given the extremely high infection rate in childhood.¹

Recommendations around age for administration

In the US the ACIP has recommended zoster vaccination for people 60 years and over (reflecting the licensed indication).²⁶ The licensed indication changed in 2011 to 50 years and over. ACIP did not change their recommendation because the risk of shingles and having PHN in someone under 60 is “*much lower*” than for people 60 years and over, when there were shortages of the vaccine. However, CDC noted that “*health care providers can still offer herpes zoster vaccine to patients 50 through 59 years. Health care providers may want to first consider whether the patient would have poor tolerance to herpes zoster or postherpetic neuralgia symptoms.*” Furthermore, Levin, in the text “*Vaccines*” favours offering the vaccine to people 50-59 years given nearly 20% of shingles cases and 11% of all PHN occur in this age group.³ Gilden had a similar view in 2011.²⁵

In NZ, the licensed indication is for 50 years and over.⁴ International shortages have been resolved, and therefore it would be unnecessary to limit the use in pharmacy to those 60 and over. To ensure consumers are appropriately informed, the information sheet for patients will include that the risk of shingles and PHN increases with age, and is low under 60 years of age (to be supplied).