PHARMAC
Pharmaceutical Management Agency

MEMORANDUM FOR BOARD MEETING 27 OCTOBER 2017

To: PHARMAC Directors

From: Chief Executive

Date: October 2017

Proposal to list varicella zoster vaccine (Zostavax)

Recommendations

It is recommended that having regard to the decision-making framework set out in PHARMAC's Operating Policies and Procedures you:

resolve to list varicella zoster vaccine [shingles vaccine] (Zostavax) in Part II of Section H and Section I of the Pharmaceutical Schedule from 1 April 2018 as follows;

Chemical	Presentation	Brand	Pack size	Subsidy
Varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine]	Inj 19,400 PFU prefilled syringe plus vial	Zostavax	10	$0.00
Varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine]	Inj 19,400 PFU prefilled syringe plus vial	Zostavax	1	$0.00

resolve to apply the following restrictions to varicella zoster vaccine [shingles vaccine] in Part II of Section H of the Pharmaceutical Schedule from 1 April 2018;

Restricted
Initiation – people aged 65 years
Therapy limited to 1 dose
One dose for all people aged 65 years.

Initiation – people aged between 66 and 80 years
Therapy limited to 1 dose
One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 March 2020.

resolve to list varicella zoster vaccine [shingles vaccine] (Zostavax) in Section I of the Pharmaceutical Schedule with the Xpharm restriction from 1 April 2018;

resolve to apply the following restrictions to varicella zoster vaccine [shingles vaccine] in Section I of the Pharmaceutical Schedule of the Pharmaceutical Schedule from 1 April 2018;

Funded for patients meeting either of the following criteria:
1) One dose for all people aged 65 years; or
2) One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 March 2020.

resolve to amend the price and subsidy of Fosamax (alendronate sodium tab 70 mg) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2018 as follows:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Alendronate sodium	Tab 70 mg	Fosamax	4	$4.82

resolve to amend the price and subsidy of Fosamax Plus (alendronate sodium with colecalciferol tab 70 mg with colecalciferol 5,600 iu) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2018 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy
Alendronate sodium with colecalciferol	Tab 70 mg alendronate with colecalciferol 5,600 iu	Fosamax Plus	4	$4.82

resolve to approve the 12 September 2017 provisional agreement for Zostavax with Merck Sharp & Dohme (New Zealand) Limited;

resolve to approve the 13 September 2017 amendment to the agreement between PHARMAC and Merck Sharp & Dohme (New Zealand) Limited (MSD) dated 29 July 2009 relating to the listing of Fosamax, Fosamax Plus, Emend, Isentress, Sinemet, Sinemet CR, Timoptol XE and Cosopt on the Pharmaceutical Schedule for a change in the list price and removal of the rebate for Fosamax and Fosamax Plus;

note the above amendment for Fosamax and Fosamax Plus is conditional on approval of the provisional agreement for Zostavax; and

resolve that the consultation on this proposal was appropriate, and no further consultation is required.

SUMMARY OF PROPOSAL				
Market data	**Year ending**	**30 Jun 2018**	**30 Jun 2019**	**30 Jun 2020**
	Number of additional patients	169,913	172,375	77,409
Combined Pharmaceuticals	Subsidy (gross)	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net cost to Schedule	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
	Net distribution costs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
Other DHB costs	Net cost to DHBs	$850,000	$860,000	$390,000
Total	Total cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		

Zoster vaccine				
Market data	**Year ending**	**30 Jun 2018**	**30 Jun 2019**	**30 Jun 2020**
Number of additional patients		169,913	172,375	77,409
Combined Pharmaceuticals	Net cost to Schedule	s9(2)(b)(ii);	s9(2)(b)(ii); s9(2)	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
	Net cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
Other DHB costs	Net cost to DHBs	$850,000	$860,000	$390,000
Total	Total cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		

Alendronate sodium				
Market data	**Year ending**	**30 Jun 2018**	**30 Jun 2019**	**30 Jun 2020**
Number of additional patients		0	0	0
Combined Pharmaceuticals	Subsidy (gross)	$310,000	$220,000	$210,000
	Net cost to Schedule	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
	Net distribution costs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
Hospital Pharmaceuticals	Expenditure (gross)	$1,000	$2,000	$2,000
	Net cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
Total	Total cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		

Alendronate sodium with colecalciferol				
Market data	**Year ending**	**30 Jun 2018**	**30 Jun 2019**	**30 Jun 2020**
Number of additional patients		0	0	0
Combined Pharmaceuticals	Subsidy (gross)	$1,270,000	$850,000	$780,000
	Net cost to Schedule	s9(2)(b)(ii);	s9(2)(b)(ii); s9(2)(j)	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
	Net distribution costs	s9(2)(b)(ii); s9(2)	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii); s9(2)		
Hospital Pharmaceuticals	Expenditure (gross)	$3,000	$7,000	$7,000
	Net cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		
Total	Total cost to DHBs	s9(2)(b)(ii);	s9(2)(b)(ii);	s9(2)(b)(ii);
	Net present value	s9(2)(b)(ii);		

Notes:
1. Subsidy (gross) = forecast of spending on Zostavax at the proposed net price.
2. Net cost to Schedule = forecast of change in total spend on pharms listed on the Schedule compared with status quo.
3. Other DHB costs for Zoster vaccine = admin fee forecast for vaccines not co-delivered with the influenza vaccine
4. All costs are expressed ex manufacturer, excluding GST
5. NPV is calculated over 5 years using an annual discount rate of 8%. Calculations in A1082419

Executive Summary

- Herpes zoster, commonly known as shingles, is caused by the reactivation of the varicella-zoster (chickenpox) virus.
- One in every three people can expect to suffer at least one attack of shingles in their lifetime. Attacks can be painful, prolonged, and debilitating, especially for older people. The impact can be life-changing as some patients do not recover to the point where they are well enough to return to independent living.
- It is estimated that 600,000 individuals would be eligible for funded varicella zoster vaccination, with uptake of around 65% anticipated based on UK precedents and NZ seasonal influenza vaccine uptake.
- Varicella zoster vaccination has been shown to reduce reactivation of the herpes zoster virus (shingles), and prevent the development of post herpetic neuralgia.
- Varicella zoster vaccination has been reviewed by PTAC and by the Immunisation Subcommittee. Funding was recommended for individuals 65 years of age with a medium priority, and for a 2-year catch-up programme for people aged between 66 and 80 years with a low priority.
- The cost-effectiveness is estimated at s9(2) QALYs per $million (s9(2)(b)(ii); per QALY), and s9(2)(b) QALYs per $million for the catch-up programme. This is s9(2)(b)(ii); s9(2)(j) compared to other current investment options, and relative to historical comparators.
- These investments are ranked at number s9(2)(b)(ii); respectively, on our options for investment list. s9(2)(b)(ii); s9(2)(j) s9(2)(b)(ii); s9(2)(j)
- The Ministry of Health is responsible for supporting the implementation of changes to the National Immunisation Schedule. PHARMAC would work closely with the Ministry to ensure alignment to the start of the seasonal influenza vaccine programme.
- Some additional cost offsets are provided by the Fosamax component of this multi-product proposal.
- It is estimated that this proposal would result in an estimated net cost to the Combined Pharmaceutical Budget (CPB) of s9(2)(b)(ii); s9(2)(j) (5 year NPV, 8%) and an estimated net cost to DHBs of s9(2)(b)(ii); s9(2)(j) (5 year NPV, 8%) inclusive of vaccine administration costs.

Why Proposal Not Decided Under Delegated Authority

The proposal outlined in this Board paper has not been dealt with by the Chief Executive under delegated authority because:

- The estimated Financial Impact (NPV) of this proposal is more than s9(2)(b)(ii); s9(2)(j) of the Pharmaceutical Budget. The Financial Impact (NPV) is calculated on the basis of the net present value of the proposed subsidy (ex-manufacturer exclusive of GST) over 5 years at a discount rate of 8% to be paid by the funder for the product(s) and the forecast demand, taking into account any effect of the change/decision on that demand, versus the status quo.

The Proposal

It is proposed to list the varicella zoster virus vaccine (Zostavax) in the Pharmaceutical Schedule from 1 April 2018 for people aged 65 years and with a 2-year catch-up programme for people aged between 66 and 80 years inclusive. Subsidy and delisting protection would apply until 30 June 2021.

The method for distributing Zostavax would be the same as other vaccines (with exception of influenza vaccine). Namely that PHARMAC places order with and purchases the vaccine directly from the supplier, delivery costs to vaccinators in primary care are paid by PHARMAC and the vaccine is delivered free of charge. An Xpharm listing means that pharmacies cannot claim subsidy because PHARMAC has made alternative distribution arrangements.

Zostavax would be listed "Xpharm" with a $0.00 subsidy, but the subsidy applying would be as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Varicella zoster virus (Oka strain) live attenuated vaccine	Inj 19,400 PFU vial with a prefilled diluent syringe	Zostavax	1	$0.00	$152.40
Varicella zoster virus (Oka strain) live attenuated vaccine	Inj 19,400 PFU vial with a prefilled diluent syringe	Zostavax	10	$0.00	$1524.00

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

Patients would be able to get their funded zoster vaccine from their general practitioner. Funded zoster vaccine would not be available through community pharmacies at this point. While allowing for funded zoster vaccine to be administered in community pharmacies is something we continue to work on, and applies to a range of vaccines that could be delivered through pharmacies, we note that wider enabling system changes would be needed first.

A copy of the provisional agreement, conditional on consultation and Board approval, between Merck Sharp & Dohme (New Zealand) Limited and PHARMAC dated 12 September 2017 can be provided to any Board Member, if requested.

The proposal also includes a price reduction and removal of the rebate for Fosamax (alendronate) and Fosamax Plus (alendronate with colecalciferol), effective from 1 January 2018 and is conditional on approval of the agreement for Zostavax.

Fosamax (alendronate) is indicated for the treatment and prevention of osteoporosis. Fosamax Plus (alendronate with colecalciferol) is indicated for the treatment of osteoporosis where vitamin D supplementation is required. Since approval of this proposal would only reduce the price of Fosamax, the Factors for Consideration have not been addressed for Fosamax.

Future Commercial Considerations

s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)
s9(2)(b)(ii); s9(2)(j)

Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the Operating Policies and Procedures. Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The Board is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.

Footnotes

[1] The person receiving the medicine or medical device must be an eligible person, as set out in the Health and Disability Services Eligibility Direction 2011 under Section 32 of the New Zealand Public Health and Disability Services Act 2000.

[2] The current Māori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy.

[3] Government health priorities are currently communicated to PHARMAC by the Minister of Health's Letter of Expectations.

[4] Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

[5] Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this factor should be considered alongside those depicted in the schematic.

Factors for Consideration

Health need

Disease/illness

Herpes zoster, commonly known as shingles, is caused by the reactivation of the varicella-zoster (chickenpox) virus. Anyone who has previously had chickenpox may subsequently develop shingles, and while the incidence tends to be proportionally higher in older patients it does not discriminate between male or female, young or old. Shingles is more common and more severe in patients with poor immunity. After the initial chickenpox infection, the varicella-zoster virus (VZV) may become latent and reside in the dorsal or cranial nerve ganglia. Years later the virus may reactivate and travel through the nerve to the skin surface, causing a painful unilateral vesicular eruption in a restricted dermatomal distribution.

Most cases of herpes zoster are self-limited although the pain can cause considerable suffering, particularly in the elderly. Some patients may continue to experience pain for months to years after the resolution of the rash (post herpetic neuralgia (PHN)), which can be very debilitating with only poorly effective treatments for pain relief available.

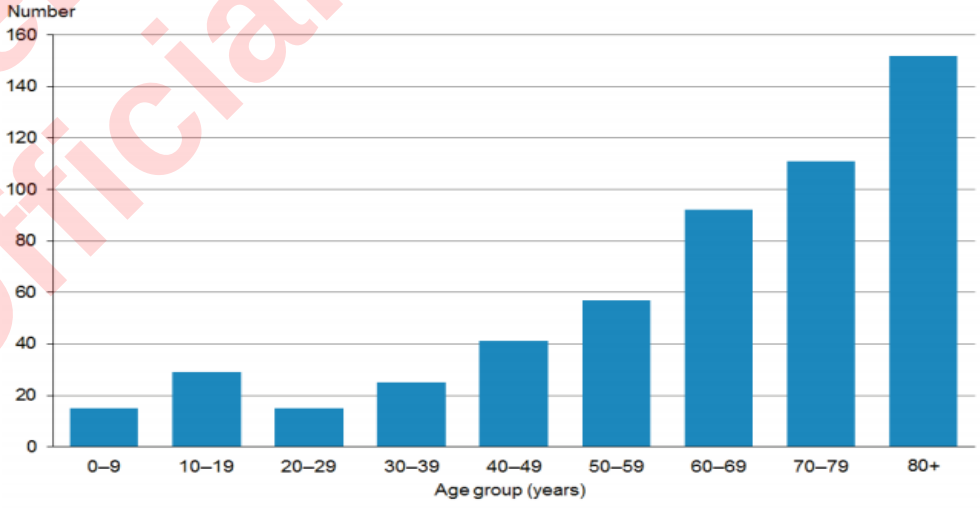
Herpes zoster can also lead to ophthalmic and central nervous system complications, bacterial super-infection may occur and there may be visceral involvement, such as meningoencephalitis, pneumonitis, hepatitis and acute retinal necrosis.

Risk factors for herpes zoster

The most important risk factor for the development of herpes zoster is age, as can be seen in the following graphs. Patients who are immunocompromised or immunosuppressed are also at increased risk. Among patients with zoster, the risk of severe complications, including post-herpetic neuralgia increases with age. The major risk factors identified for post-herpetic neuralgia are older age, greater acute pain and greater rash severity in index shingles.

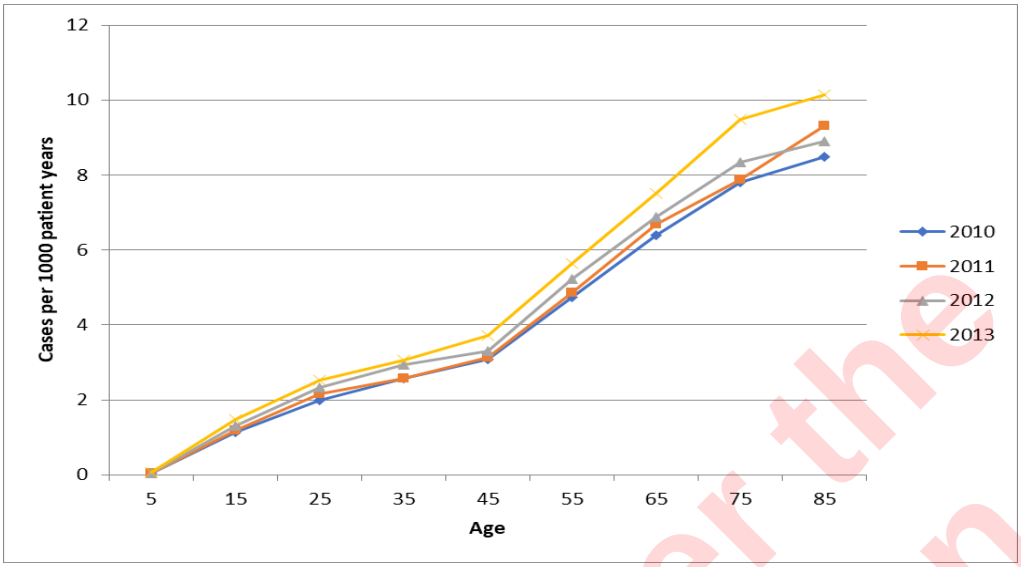
The following graph is from data supplied by the Ministry of Health, detailing the number (not the incidence) of patients hospitalised in New Zealand by age group in 2013. There were 454 hospitalised cases in all, of whom 292 (64%) were over the aged 60 and over.

Herpes zoster hospitalisations by age group, 2015



Source: Ministry of Health

Age-related incidence of herpes zoster



Note: Data generated from Pharmhouse data of aciclovir dispensing

Availability and suitability of existing treatments

There is currently no vaccine funded for the prevention of herpes zoster. Zostavax is the only vaccine for herpes zoster approved by Medsafe in New Zealand.

Early antiviral treatment (within three days of the onset of symptoms) of uncomplicated herpes zoster helps to hasten rash healing and decrease the severity and duration of acute pain. Aciclovir and valaciclovir are funded for the treatment of uncomplicated herpes zoster without restrictions.

Tricyclic antidepressants (amitriptyline, nortriptyline) are considered the mainstay of treatment for post-herpetic neuralgia. Anticonvulsants, mainly gabapentin, are also useful, and the topical application of capsaicin cream has been shown to be effective in a limited number of studies. However, residual pain and suffering can still be appreciable despite best efforts with symptomatic treatments.

Health need of others

The virus that causes shingles, varicella zoster virus, can be spread from a person with active shingles to another person who has never had chickenpox.

Shingles is less contagious than chickenpox and the risk of a person with shingles spreading the virus is low if the rash is covered. Zoster vaccination will therefore have little impact on virus transmission. Impacts on family can however be high in terms of caregiver burden for elderly patients suffering acute shingles and/or refractory post-herpetic neuralgia.

Impact on Māori health areas of focus and health outcomes

There is no difference in the age-standardised incidence of herpes zoster between Māori and non-Māori.

Any other populations experiencing health disparities

None noted.

Government Health Priority

Funding of Zostavax would align with the 2017/2018 Government Health System Priority of "supporting the health of older people."

Health Benefit

Details of vaccine

Varicella zoster virus (Oka strain) live attenuated vaccine (Zostavax) is given as a single dose and presented in a prefilled syringe with a diluent vial. Each 0.65 ml dose of Zostavax contains a minimum of 19,400 plaque forming units (pfu) of live Oka strain of varicella zoster virus when reconstituted. A per all vaccines, Zostavax requires cold-chain management. Booster doses are not recommended.

Zostavax vaccine is a live vaccine and is contraindicated in immunocompromised patients.

Clinical advice

A funding application for Zostavax has been reviewed by PTAC in August 2014 and August 2015 and by the Immunisation Subcommittee of PTAC in February 2015. PTAC recommended funding for individuals 65 years of age with a medium priority, and a 2-year catch-up programme for people aged between 66 and 80 years with a low priority. A full copy of the minutes can be found in Appendix One.

Key points noted were:

- Zostavax vaccination has been shown to reduce reactivation of herpes zoster virus (shingles), and prevent the development of post herpetic neuralgia.
- Zostavax has been shown to reduce the burden of illness due to herpes zoster by 61%, reduce the incidence of post-herpetic neuralgia by 67% and reduce the overall incidence of herpes zoster by 51%.
- There are significant differences in the efficacy of Zostavax in preventing the incidence of herpes zoster, depending on the age of the person when they are vaccinated, with a vaccine efficacy of around 64% for individuals aged 60-69, reducing to 38% in those aged 70 and older, and 18% in people over 80 years. However, zoster vaccination also reduces the severity of disease, and has been shown to reduce the development of post-herpetic neuralgia by 67% in all age groups.
- Zostavax vaccine efficacy wanes over time, and the duration of protection after vaccination against herpes zoster has been shown to be around 5 years.
- Clinical advice considered the cost and benefits of when to vaccinate with Zostavax and recommended vaccination at 65 years was the best option. While Zostavax is registered for use from age 50, it was noted that the major clinical trials did not include patients under the age of 60 years.

- Individuals vaccinated at younger than age 65 years may not be protected by the time they reach the age when the incidence of zoster and its complications are highest. Revaccination with Zostavax as a booster is not recommended and there is no clinical evidence assessing a booster dose. PHARMAC staff note that there is evidence that a second zoster vaccine dose with GSK's Shingrix vaccine is safe and effective, and this will be considered further by PTAC at a later date.
- The Committee also considered that 65 years was a reasonable age for practical reasons, because it could then be provided for the same group of individuals receiving influenza vaccination.
- PTAC considered that it was unlikely that funding of the childhood varicella vaccination (for chickenpox) would have an effect on shingles incidence.

Advisor Conflicts of Interest

The recommendations in this paper rely on PTAC and Subcommittee advice.

[redacted]

Health benefit to others

Since the risk of spreading the herpes zoster virus to others is low, Zostavax is unlikely to reduce transmission of the virus to others.

The development of post-herpetic neuralgia, which is a major consequence of herpes zoster, can be life-changing as some patients do not recover well enough to return to independent living. Prevention of post-herpetic neuralgia is therefore likely to have a health benefits to families and carers by reducing the burden of care on them.

Consequences for the health system

Since Zostavax can be administered at the same time as the influenza vaccine and is proposed to be funded for individuals aged 65 and over, funded zoster vaccine may improve the uptake of influenza vaccine in this age group, which is currently at 67%.

Suitability

After reconstitution with the accompanying pre-filled syringe of diluent, 1 dose (0.65mL) of Zostavax contains a minimum of 19,400 PFU of the Oka/Merck strain of varicella zoster virus.

Zostavax is administered as a subcutaneous injection and may be administered at the same time as the inactivated influenza vaccine.

We foresee no issues with the acceptability of the product for either patients, or the health system.

Costs and Savings

Health related costs and savings to the person.

There would be no cost for Zostavax to patients who meet the funding criteria for subsidised zoster vaccine, although patients would incur the cost of a visit to their general practice.

Since Zostavax would be available to individuals that are already eligible for funded influenza vaccine, they could receive both vaccines in one visit and would therefore not have any additional general practice visit fees.

Those patients who are 65 years or older, who choose to obtain their influenza vaccine through a community pharmacy, would incur separate costs through a visit to their general practice to obtain the zoster vaccine. When PHARMAC decided to expand the funding of the influenza vaccine via community pharmacy for patients who are pregnant or over 65, we estimated that up to 2% of patients were likely to access treatment via this channel per year.

Zostavax is currently available on the private market, so there would be cost savings to patients who would have otherwise purchased the vaccine.

Health related costs and savings to the family, whānau and wider community.

None noted.

Cost and savings to Pharmaceutical expenditure

The net cost of Zostavax would be s9(2)(b) during the 2-year catch-up programme (2018-2019), and s9(2)(b) in later years. Assuming a 65% uptake rate (which is based on uptake of the influenza vaccine), PHARMAC staff estimate the cost of the vaccine to the Combined Pharmaceutical Budget to be s9(2)(b)(ii); s9(2)(j) (5 year NPV, 8%). Inclusion of the cost offsets due to the price reduction and rebate removal for Fosamax and Fosamax Plus, would reduce the estimated cost to the Combined Pharmaceutical Budget to approximately s9(2)(b)(ii); s9(2)(j) (5 year NPV, 8%).

PHARMAC staff note that the estimated uptake rate of Zostavax is uncertain, and consider there could have been fiscal risk if the vaccine uptake was higher than estimated. This has been managed by a s9(2)(b)(ii); s9(2)(j)

s9(2)(b)(ii); s9(2)(j)

PHARMAC staff note s9(2)(b)(ii); s9(2)(j). Expenditure for forecasted uptake is estimated at s9(2)(b)(ii); from 1 April 2018 – 30 June 2018.

Expected uptake of Zostavax

While there are 600,000 individuals aged between 65 and 80 years in New Zealand that would be eligible for funded zoster vaccine, adjusting for individuals that have already purchased the vaccine on the private market and an uptake rate of 65%, gives an estimate of around 400,000 people that would access the vaccine during the 2-year catch-up programme. After the catch-up programme is complete from 1 April 2020, the vaccine would only be funded for people at the age of 65, and therefore we estimate that 35,000 people would access the vaccine each year.

Since individuals that would be eligible for funded zoster vaccine and funded influenza vaccine at the same age, PHARMAC anticipates that most people would receive both vaccines in one visit. Therefore, we anticipate that zoster vaccine uptake would be highest during the initial months of the influenza vaccine programme, and heavily weighted to the first three months of listing from 1 April – June 2017. 80% of influenza vaccine uptake occurs within this period each year. Therefore, the s9(2)(b)(ii); s9(2)(j) for this period is the same as for the following 12 months of the catch-up programme.

Distribution costs

Vaccines are distributed differently to most other pharmaceuticals (excepting the influenza vaccine) and distribution costs to vaccinators in primary care are paid by PHARMAC. Given the large number of vaccines that would need to be distributed in a short timeframe, there may need to be extra deliveries to vaccinators to help manage fridge capacity at both the vaccinator and wholesaler level; this could incur additional distribution costs to PHARMAC.

PHARMAC staff would work with our contracted vaccine distributors and the Ministry of Health Immunisation team responsible for implementation to manage a delivery schedule to distributors and vaccinators to manage any additional costs that may be incurred.

Vaccine delivery

In order for funded vaccines to be delivered via community pharmacy, pharmacists must be able to make a claim to be reimbursed for the product costs (and the service fee). This is the case for the influenza vaccine (which is also purchased and claimed by general practice). Since all other funded vaccines (other than the influenza vaccine) are currently delivered to general practices free of charge, two distinct mechanisms of delivery and claiming for vaccines would be required if funded vaccines were to be administered via pharmacies as well as general practice, which is not possible or desirable. For funded vaccines (other than the influenza vaccine) to be delivered in pharmacies, it would be preferable to have a consistent approach whereby general practice and pharmacy (or any other approved vaccinator) orders and claims reimbursement for vaccines. Wider system changes, including claiming software changes (which are managed by the Ministry of Health) would be needed for this to occur.

Costs and savings to the rest of the health system

PHARMAC anticipates that approximately 70% of individuals would receive the zoster vaccine at the same time as the influenza vaccine, and therefore no additional vaccine administration fees would apply in these circumstances.

For approximately 25% of individuals that would not have zoster vaccine at the same time as other vaccinations, a $20 vaccine administration fee would be charged by primary care to DHBs via the Ministry of Health. This has been factored into the other DHB costs in the budget impact analysis.

In the long run, every vaccination is estimated, on average, to save the rest of the health system $33 (lifetime NPV at 3.5% discount rate). This is comprised of $20 of administration cost and $53 of future savings in avoiding treatment of herpes zoster and post-herpetic neuralgia.

A case of herpes zoster is calculated to cost approximately $80, while a hospitalisation due to herpes zoster is estimated to cost $3,901 on average.

Cost-Effectiveness

The cost-effectiveness estimates set out in this paper consider only health benefits to the person vaccinated. Including any health benefits to carers (as noted in the Health Benefits section above) would improve our cost-effectiveness estimates.

The cost-effectiveness of funding zoster vaccine for the ongoing cohort of 65-year olds is estimated at s9(2) QALYs per $million (s9(2)(b)(ii); s9(2)(i) per QALY), with a likely range of s9(2)(b)(ii); s9(2) QALYs per $million. This estimate is most sensitive to assumptions made about vaccine waning.

The cost-effectiveness of funding the catch-up cohort of patients 66 to 80 years old is s9(2) QALYs per $million, with a likely range of s9(2)(b)(ii); s9(2)(i) QALYs per $million. This estimate is most

sensitive to assumptions made about vaccine waning and assumptions about age-related uptake. If more patients in the older part of the cohort receive the vaccine, the vaccine becomes less cost-effective.

Cost-effectiveness varies by age of person vaccinated. Although the vaccine is more effective in younger people, the actual risk of shingles increases with age. Regardless of age, these cost-effectiveness estimates s9(2)(b)(ii); s9(2)(j) s9(2)(b)(ii); s9(2)(j)

The proposal was last ranked by PHARMAC staff in September 2017. Funding zoster vaccine for 65 year olds was ranked s9(2)(b)(ii); on the list of Options for Investment, while the proposal for funding the 2-year catch-up programme for individuals aged 66-80 was ranked s9(2)(b)(ii);

All assumptions made as part of the model are outlined in TAR 250, which is available on request.

Comments from Interested Parties

Section 49(a) of the New Zealand Public Health and Disability Act 2000 (the Act) requires PHARMAC to consult, when it considers appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of PHARMAC, may be affected by decisions on those matters.

Accordingly, a consultation letter was circulated on 15 September 2017. Of note, the consultation was sent to all professional health organisations such as medical, nursing and pharmacy bodies as well as vaccinator groups aged care associations.

The consultation letter and all responses received by 4 October 2017 are attached as Appendix Three.

Forty-seven responses were received in relation to the proposal to fund Zostavax and feedback was overwhelmingly supportive; responders included members of the public, clinicians, pharmacists, nurses, and other groups/individuals.

Summaries of what PHARMAC staff believe are the significant matters raised in these responses are provided below. For a detailed summary table of each response, please refer to Appendix Two.

Theme	**Comment**
Most respondents were supportive of the proposal to fund Zostavax for 65 year olds with a 2-year catch-up programme for individuals aged 66-80.	Noted.

A number of respondents requested that Zostavax be funded for individuals aged younger than or older than 65 – 80 years old.	PTAC considered the cost and benefits of when to vaccinate with Zostavax on several occasions and recommended vaccination at 65 years was the best approach. There is a significant difference in the efficacy of Zostavax depending on the age of the person when they are vaccinated, with vaccine efficacy dropping to 18% in people over 80 years. Zostavax efficacy also wanes over time, with protective efficacy estimated to be less than 5 years. Individuals vaccinated when younger than age 65 years may not remain protected once they reach older ages (when the incidence of herpes zoster and its complications becomes highest).
A small number of respondents noted that influenza vaccine season is a busy time for general practice and were concerned about the resources required to administer influenza vaccine during the same appointment as the zoster vaccine.	We understand that funding zoster vaccine may lead to a busier period for general practice, and we have discussed this, and health sector support that might be required, with the Ministry of Health team responsible for immunisation implementation. We consider that the net overall health impact of the proposal would be a positive one since vaccine uptake would reduce the incidence of shingles and more serious complications in older individuals (and thus those impacts on health services).
Some respondents suggested that PHARMAC should instead fund GSK's zoster vaccine, Shringrix.	PHARMAC staff note that Shingrix is not registered in New Zealand for sale, although it was registered in the USA in September 2017. We understand that GSK plans to submit to Medsafe for approval in mid-2018, with potential to supply in New Zealand from 2020. We note that, while the provisional agreement with MSD would be until 30 June 2021, the proposal would not preclude PHARMAC from listing Shingrix in the Pharmaceutical Schedule prior to that date. PHARMAC plans to include zoster vaccine in the next RFP, following consideration by PTAC, for implementation in 2021.
Some respondents requested that funded zoster vaccine be available via community pharmacies since pharmacies currently offer Zostavax on the private market.	While allowing for funded zoster vaccine to be administered in community pharmacies is something we continue to work on and applies to a range of vaccines that could be delivered through pharmacies, we note that wider system changes would be needed first.

Legal Advice

Where necessary, management will obtain legal advice on issues such as whether any proposal is consistent with PHARMAC's legislative and public law obligations, including those which may have specific relevance to the particular proposal eg human rights implications of a proposal. If the Board considers that further legal advice is required on any issue, this should be communicated to management in advance of the Board meeting. Management will then obtain the required advice.

Legal Advisors' View

Confidential and Privileged Legal Advice from PHARMAC's General Counsel

Implementation

Implementation of any changes to the National Immunisation Schedule is the responsibility of the Ministry of Health's Immunisation team. The Ministry would support these changes with communications for both health professionals and members of the public through its regular channels including: the monthly Immunisation Update fax; DHB teleconferences, and working though health agencies and professional bodies to ensure that providers are aware of the changes.

While the Ministry of Health is leading the implementation of this proposal, PHARMAC's communication team is providing support where requested or needed.

Section 49(b) of the Act requires PHARMAC to take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the pharmaceutical schedule. Accordingly, if the Board adopts the recommendations contained in this paper PHARMAC staff will take the following measures to inform the public, groups and individuals of that decision:

- Notify health professionals including physicians through the Pharmaceutical Schedule Update and email networks, including wholesalers responsible for vaccine distribution.
- Notify health professionals including clinicians and pharmacists through appropriate information channels, including the Pharmaceutical Schedule Update, and other newsletter and email networks.
- Contact relevant key stakeholders, including the Ministry of Health and the Minister's office informing them of the decision.
- Continue to work closely with the Ministry of Health to support implementation of the zoster vaccine programme.

PHARMAC has regular meetings with the Ministry of Health's Immunisation team and have provided updates regarding the possibility of funding zoster vaccine to coincide with the start date of the influenza programme in this financial year since February 2017. To help support effective implementation of this proposal, PHARMAC provided a confidential update to the Ministry of Health's Implementation team on 9 August 2017, followed by a written update on

17 August 2017 notifying them that PHARMAC was in direct negotiations with a supplier regarding a possible listing of Zostavax and the expected timeframes for listing.

PHARMAC staff note that the Ministry of Health provided a consultation response that supports the proposal to fund the zoster vaccine, but raised the following concerns:

- that the timeframe is tight for implementation in 1 April 2018 and requests longer lead times for future vaccine introductions.

  PHARMAC staff note that the Immunisation team has been updated regarding the possible funding and listing dates for the zoster vaccine at minimum on a monthly basis since early 2017, and it would not have been feasible to provide any earlier information regarding possible funding decisions to support implementation – the CPB budget uplift was confirmed in May 2017. In this case a longer lead time for the implementation would require PHARMAC to divert the budget resources to other investments because there is no facility to 'carry over' the available funds and a requirement that we use the available funds to secure the 'best health outcomes'.

- requests that PHARMAC prioritise changes that are needed to enable funded zoster vaccine to be delivered in pharmacies.

  As noted earlier in this paper, in order for funded vaccines to be delivered via community pharmacy, pharmacists must be able to make a claim to be reimbursed. Since the zoster vaccine would be delivered to general practices free of charge, two distinct mechanisms of delivery and claiming for vaccines would be required, which is not currently possible or desirable. For funded vaccines (other than the influenza vaccine) to be delivered in pharmacies it would be preferable to have a consistent approach whereby general practice orders and claim's reimbursement for vaccines. Wider system changes, including claiming software changes (which are managed by the Ministry of Health) would be needed for this to occur.

- notes that it has no allocated resources to support any public messaging regarding the funding of the zoster vaccine.

  PHARMAC is working closely with the Ministry of Health, and verbal communication from the Ministry has subsequently confirmed that implementation planning for the proposed April 2018 listing is underway. PHARMAC will continue to work closely with the Ministry to manage and support this process, including a process to manage additional vaccine deliveries.

- fridge capacity storage capacity at the vaccinator level may need to be managed due to timing with the influenza vaccine.

  As noted earlier in this paper, there may need to be extra deliveries to vaccinators to help manage fridge capacity at both the vaccinator and wholesaler level. PHARMAC staff would work with our contracted vaccine distributors and the Ministry of Health Immunisation team responsible for implementation to manage a delivery schedule to distributors and vaccinators to manage costs and capacity issues.

Appendices

Appendix One: PTAC minutes.

Appendix Two: Summary table of consultation responses.

Appendix Three: Consultation letter and all responses received by 4 October 2017.

Zoster virus vaccine was considered by PTAC at their August 2014 and August 2015 meetings. The Immunisation Subcommittee considered it at their February 2015 meeting. The relevant minute sections are included below:

PTAC August 2014

Application

1.1. The Committee reviewed an application from Merck Sharp and Dohme (New Zealand) Ltd for the listing of zoster vaccine on the Pharmaceutical Schedule.

Recommendation

1.2. The Committee **recommended** zoster vaccine be listed on the Pharmaceutical Schedule with a medium priority.

1.3. The Decision Criteria particularly relevant to this recommendation are: *i) The health needs of all eligible people within New Zealand; iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; iv) The clinical benefits and risks of pharmaceuticals; v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services; and vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

1.4. The Committee considered that the clinical evidence provided for zoster vaccinated was generally of high quality, although it was noted that evidence for the durability of the vaccine was weak.

1.5. The Committee noted that the herpes zoster vaccine in this application is a lyophilized preparation of a live attenuated varicella vaccine zoster virus at a dose 14 times greater than that of the varicella (chickenpox vaccine). The Committee noted that the major studies had used a dosage of 0.5 ml compared with the commercial dose of 0.65 ml offered in the application, but noted that the number of plaque forming units per dose is similar between the two with a minimum dosage of 19,400 in the current vaccine versus a dose range between 18,700 and 60,000 in the trials.

1.6. The Committee noted that herpes zoster is a common illness in New Zealand. The Committee noted that there was no specific surveillance data available for New Zealand but considered that the data collected in the BEACH study in Australia could be generalised to estimate incidence in New Zealand, giving an incidence of ~13,200 cases of herpes zoster per year for those over 60 year of age (incidence 15.2/1000 for that age group). The Committee noted that apart from the acute illness morbidity, the major consequence of herpes zoster is the development of post herpetic neuralgia (PHN) which occurs in between 5% and 50% of cases and can be very debilitating with only poorly effective treatments for pain relief available.

1.7. The Committee noted the Oxman trial (NEJM 2005;352:2271) was a major clinical trial with 38546 participants aged 60 years and older with a mean duration

of herpes zoster surveillance of 3.13 years. The primary endpoint in this trial was a burden of illness due to herpes zoster and the secondary endpoint was calculated as the incidence of PHN defined as pain associated with herpes zoster that was rated 3 or more on a scale of 0 to 10, persisting or appearing more than 90 days after the onset of rash. The Committee noted that the use of the zoster vaccine reduced the burden of illness due to herpes zoster by 61%, reduced the incidence of PHN by 67% and reduced the overall incidence of herpes zoster by 51%. There was a marked difference between the 64% efficacy for herpes zoster in the 60-69 year age group compared to the 38% efficacy seen in those aged 70 years and older.

1.8. The Committee noted that Schmader et al (Clin Infect Dis.2012;54:922-8) confirmed the efficacy of herpes zoster vaccine with an efficacy of 70% in the 50-59 year age group (95% confidence interval 54.1-80.6%). The study enrolled 22,439 individuals with a mean follow up of 1.3 years.

1.9. The Committee noted the retrospective study of individuals enrolled in the Kaiser Permanente Southern California Health Plan conducted by Tseng et al (JAMA 2011;305:160-6). The study matched 75,761 community dwelling vaccinated adults over the age of 60 years 1:3 with 277,283 unvaccinated individuals. Vaccination was associated with a reduced risk of herpes zoster with a vaccine efficacy of 55% consistent across all age strata over a 1.56 year follow-up period.

1.10. The Committee noted that, while the efficacy of the vaccine had been clearly demonstrated in the Oxman and Tseng studies, there was uncertainty about the duration of activity extrapolated by the clinical trial data (Schmader et al CID 2012;55:1320). The statistical methodology was considered complex in the extension studies of the Oxman trial and its' add-ons, but there appeared to be some durable activity out to 10 years with a trend towards decreasing vaccine efficacy over time. The Committee considered that cost utility analysis (CUA) modelling would need to be developed with different levels of long-term efficacy within sensitivity analyses.

1.11. The Committee noted that further data on the durability of vaccine may arise from case-control studies with longer follow-ups than had been reported for the Kaiser Permanente Southern California Health Plan discussed above.

1.12. The Committee noted that shingles and PHN have high levels of morbidity particularly for the elderly and can be life-changing, as some patients do not recover well enough to return to independent living and require rest home care. The Committee noted that acute treatment of zoster is difficult as many patients present late and it is difficult to treat PHN in the elderly as it is difficult to achieve satisfactory pain relief.

The Committee considered that, at current pricing, vaccination against herpes zoster represents a considerable cost to the pharmaceutical budget. The Committee requested PHARMAC prepare CUAs covering a range of assumptions including age-related disease burden scenarios that incorporated remaining life expectancy for specific demographic groups (hence varying need and benefit over time), for PTAC to review. The Committee requested that assumptions include a waning of vaccine efficacy over time as per currently available data, and that sensitivity analysis include a possible booster at 10 years (although members did recognise that the 10-year booster scenario has no current evidence base).

Immunisation Subcommittee February 2015

1.1 The Subcommittee noted that in May 2014 PHARMAC received an application for funding zoster vaccination, which was reviewed by PTAC at its August 2014 meeting. The Subcommittee noted that PTAC recommended funding zoster vaccination with a medium priority.

1.2 The Subcommittee noted that PTAC requested PHARMAC prepare CUAs covering a range of assumptions including age-related disease burden scenarios that incorporated remaining life expectancy for specific demographic groups for PTAC to review. The Subcommittee also noted that PTAC requested that assumptions include a waning of vaccine efficacy over time as per currently available data, and that sensitivity analysis include a possible booster at 10 years (although members did recognise that the 10-year boosted scenario has no current evidence base).

1.3 The Subcommittee noted the number and age of patients who were dispensed 35 x 800 mg aciclovir tabs and considered this to be a good indication of the incidence of herpes zoster in New Zealand. The Subcommittee also noted the number and age of patients being treated with capsaicin cream 0.075% without any diabetic products being concomitantly prescribed.

1.4 The Subcommittee did not identify any literature on the severity of recurrent episodes compared with the initial presentation therefore had no evidence that subsequent cases differed in severity

1.5 The Subcommittee noted that it is reasonable to use the number of patients treated with 800mg aciclovir 5 times daily as a base for the incidence rate in New Zealand and it compared well to other estimates of incidence, eg. the Australia BEACH estimate of 15.2 per 1000 for those aged over 60 years (Stein et al. Vaccine 2009;27:520-529). The Subcommittee also noted that these patients dispensed acyclovir with only partially represent all patients with symptomatic shingles presenting for medical care in general practice, being approximately only 80% of all presenting patients in the Wallis et al Dunedin study (J Prim Health Care 2014;6(2):108-113).

1.6 The Subcommittee noted that it is unclear why the incidence of zoster is increasing but this has been noted overseas and hence the incidence may continue to rise.

1.7 The Subcommittee noted that the zoster vaccination provided good protection for at least 5 years but ongoing immunity is not clear. The Subcommittee noted there was no evidence or information on the need for booster vaccinations. .

1.8 The Subcommittee noted that zoster vaccine efficacy does vary by age with vaccine efficacy for herpes zoster, at approximately 64% in the 60-69 year age group, 41% in the 70-79 year age group and 18% in the over 80 year age group (Oxman et al. N Eng J Med 2005;352:2271.).

1.9 The Subcommittee noted that implementation costs could be reduced if zoster vaccination was given concurrently with the influenza vaccine funded for all aged 65 years and over although the Subcommittee also noted that it may not be easy to incorporate the zoster vaccination into the annual influenza vaccination due to

the primary care workload in the pre-flu season

1.10 The Subcommittee noted that the incidence of secondary cases of herpes zoster is uncertain but reported as 2-5%. The Subcommittee also noted that a prior attack of herpes zoster will usually confer substantial protection against subsequent attacks for some years and the safety of the zoster vaccine has been demonstrated in such situations.

1.11 The Subcommittee noted that the van Hoek paper highly influenced the UK funding the zoster vaccination at age 70. The Subcommittee also noted that the US and Australia recommend zoster vaccination be given at age 60.

1.12 The Subcommittee **recommended** funding zoster vaccination for patients at 65 year of age with a catch-up.

The Subcommittee noted that further analysis and research should be undertaken to ensure that Maori and Pacific Island patients receive equal benefits from funded Zoster vaccination at age 65 considering their age of death is lower than the rest of the population.

PTAC August 2015

Application

1.13. The Committee reviewed a PHARMAC generated paper on the cost-utility analysis (CUA) of zoster vaccination.

Recommendation

1.14. The Committee **recommended** zoster vaccination be listed on the Pharmaceutical schedule for vaccination of people aged 65 and older with a catch-up programme with a medium priority.

1.15. The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (ii) The particular health needs of Māori and Pacific peoples (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

1.16. The Committee noted that it had reviewed zoster vaccination previously at its August 2014 meeting and had recommended zoster vaccine be listed on the Pharmaceutical Schedule with a medium priority. The Committee had requested PHARMAC prepare CUAs for PTAC to review covering a range of assumptions, including age-related disease burden scenarios that incorporated remaining life expectancy for specific demographic groups (hence varying need and benefit over time). The Committee requested that assumptions include a waning of vaccine efficacy over time as per current available data, and that sensitivity analysis include a possible booster at 10 years (although members did recognise that the 10-year booster scenario has no current evidence base).

1.17. The Committee noted a significant increase year on year in the dispensing of

aciclovir 35 x 800 mg tabs in New Zealand over a five year period, particularly in those aged 50 years or age or older. The Committee noted that capsaicin cream 0.075% is fully funded by endorsement for post-herpetic neuralgia or diabetic peripheral neuropathy. The Committee noted that in 2013 and 2014, approximately 2,300 patients were dispensed capsaicin cream 0.075% without a dispensing for a diabetic product such as test strips and this data was used to determine local rates of post-herpetic neuralgia.

1.18. The Committee noted a published review of 130 studies conducted in 26 countries (Kawai et al. 'Systematic review of incidence and complications of herpes zoster: towards a global perspective' BMJ Open 2014;4:e004833). The authors reported similar age-specific rates of herpes zoster in North America, Europe and Asia-Pacific which are similar to the rates seen in New Zealand. The Authors quoted rates of 4 per 1000 population at age 50 years through to 11 per 1000 population at age 80 and again these figures are similar to those in New Zealand. The Committee noted that Kawai et al. state that 30-50% of patients who have herpes zoster develop post-herpetic neuralgia, Members noted this is higher than estimated for the New Zealand population (based on capsaicin cream claims data) but the difference may be accounted for by patients who are being dispensed capsaicin cream 0.075% having a more severe case of post-herpetic neuralgia.

1.19. The Committee noted that there appeared to be international evidence of an increase in incidence of herpes zoster of ~0.25/1000 over the past few years and that there was a 0.2% to 1% per year recurrence rate. The Committee noted that there was no evidence as to whether recurrent episodes were worse than or the same as the initial episode. The Committee noted from a study by Heymann et al. Infection 2008;36:226-30) that diabetes mellitus was associated with an increased risk of herpes zoster (OR = 1.53; 95% CI 1.44-1.62).

1.20. The Committee noted that there was a significant difference in the efficacy of herpes zoster vaccination dependent of the age of vaccination with efficacy of ~64% in 60-69 year olds dropping to 38% in those 70 plus. The Committee noted the Immunisation Subcommittee had not recommended a booster dose as the Subcommittee had considered that there was no evidence or information on the need for a booster vaccination at this stage. The Committee noted there have been no controlled clinical trials using booster vaccinations and considered there was no need to model a booster dose until the evidence becomes available.

1.21. The Committee considered that if the zoster vaccine was not given at the same time as the influenza vaccine there would be additional costs to the health sector due to the $20 payment for vaccination. The Committee noted that in the UK, 75% of patients received the zoster vaccine at the same time as the influenza vaccine, and 25% received the zoster vaccine outside of the influenza season. The Committee noted that there was no evidence of any effect on either vaccine if they were given concurrently.

1.22. The Committee considered that there is no evidence of a change in efficacy of the vaccine if the person has previously had one or more episodes of shingles.

1.23. The Committee considered that determination of the age of vaccination is

largely a financial decision taking into account budget impact and the cost utility analysis. The Committee noted that while Zostavax is registered for use from age 50, the major clinical trials did not include patients under the age of 60 years. The Committee considered 65 was a reasonable age as that coincided with influenza vaccination however it is important to note that that efficacy decreases markedly with age. The Committee noted a recently published long term follow up of the Shingles Prevention Study by Morrison et al. ('Long-term persistence of zoster vaccine efficacy, CID 2015:60 (15 March) DOI:10.1093/cid/ciu918). The study followed 6867 Shingles Prevention Study vaccine recipients and followed them for up to 11 years. Morrison et al. reported that statistically significant vaccine efficacy for herpes zoster burden of illness persisted into year 10 post vaccination; whereas statistically significant vaccine efficacy for incidence of herpes zoster persisted only through year 8. The Committee considered PHARMAC should use this information to update the cost utility model.

1.24. The Committee considered that zoster vaccination at 65 years with a catch-up was the best option. The Committee recognised that while the vaccine may be more efficacious in younger age groups, there would be a significant cost associated with these age groups due to the larger numbers of people that could be vaccinated. The cost of vaccination outweighs the benefits in these age groups. As the efficacy of vaccination wanes in older age groups, the benefit of vaccination may not be achieved although the cost to the Combined Pharmaceutical Budget would be less. The Committee **recommended** PHARMAC reconfirm its cost utility model to ensure that 65 years is the most cost efficient age of vaccination.

The Committee **recommended** the catch-up programme should allow for all people over the age of 65 years the opportunity to receive one dose of zoster vaccine but that the time period for the catch-up programme should be limited to two years.

Appendix Three: Summary of zoster vaccine consultation responses and PHARMAC response

Stakeholder group	Theme	PHARMAC Staff Comment
Clinicians / DHBs		
section 9(2)(ba)(ii) section 9(2)(ba)(ii) Emma Henderson CCDHB/HVDHB Infection Services Team Dr Kevin Snee CEO HBDHB Jillian Boniface Vaccine Preventable Disease Team SDHB Prof Felicity Goodyear-Smith Auckland University Tina Tyacke Compass Health Wairarapa Dr Margaret Chavasse Dr Aine McCoy Dr Lyn White Dr Vanessa Fardon Kitchener Rd Medical Centre Dr Julian Foster, The Terrace Medical Centre Dr Clive Cameron Dr Sally Talbot Dr Andrew Rawstron Derek Sherwood Nelson Marlborough DHB	Fully supportive	Noted.
Sue Stevens Outreach Immunisation Nurse, BOP DHB Dr Alex Moreland	Supportive. Requests that zoster vaccine be funded for individuals from age 50. Supportive. Requests that zoster vaccine be funded for individuals from age 60	PTAC considered the cost and benefits of when to vaccinate with Zostavax on several occasions and recommended vaccination at 65 years was the best option. Zostavax efficacy wanes over time, with protective efficacy estimated to be less than 5 years. Individuals vaccinated at younger than age 65 years may not be protected when the incidence of herpes zoster and its complications are highest.

Stakeholder group	Theme	PHARMAC Staff Comment
Dr Rick Franklin Auckland Sexual Health Service Dr Ron Baker Three Kings Accident and Medical Clinic	Questions whether PHARMAC should wait to fund GSK's Shingrix zoster vaccine, which provides better protection than Zostavax.	PHARMAC staff note that Shingrix has received FDA approval in September 2017. GSK plan to submit to Medsafe for approval in mid-2018, with potential to supply from 2020. We note that while the provisional agreement with MSD would be until 30 June 2021, the contract does not preclude PHARMAC from listing Shingrix in the Pharmaceutical Schedule prior to that if we choose. PHARMAC plan to include zoster vaccine in the next RFP for implementation in 2020 if Shingrix is considered by PTAC in time.
Dr Janet Vaughan, Turuki Health Care	Supportive. Suggests fully funding the zoster vaccine for community service card holders and part funding for non-community service card holders.	Noted.
Medical Organisations		
Dr Kate Baddock NZMA Dr Jo Scott-Jones, Pinnacle Health	Supportive. Requests that zoster vaccine be funded for individuals from age 50.	See above.
Sian Gilhooley Comprehensive Care PHO	Supportive. Requests that zoster vaccine be funded for individuals from age 50. Questions whether PHARMAC should wait to fund GSK's Shringrix zoster vaccine, which provides better protection than Zostavax.	See above. See above.
Alison Van Wyk Green Cross Health	Supportive. Requested that funded zoster vaccine be available through community pharmacies.	While allowing for funded zoster vaccine to be administered in community pharmacies is something we continue to work on and applies to a range of vaccines that could be delivered through pharmacies, we note that wider system changes would be needed to enable this to occur.
Consumer Groups		
section 9(2)(a) Grey Power NZ section 9(2)(a) Zone 7 Grey Power	Fully supportive.	Noted.

Stakeholder group	Theme	PHARMAC Staff Comment
Consumers		
section 9(2)(a) section 9(2)(a) section 9(2)(a) section section 9(2)(a) section 9(2)(a) section 9(2)(a) section 9(2)(a) section 9(2)(a) section 9(2)(a)	Fully supportive.	Noted.
Section 9(2)(a)	Questions whether PHARMAC should instead fund GSK's Shingrix zoster vaccine, which provides better protection than Zostavax.vaccine.	See above.
Section 9(2)(a)	Questions whether PHARMAC should instead fund GSK's Shringrix zoster vaccine, which provides better protection than Zostavax vaccine. Notes that the Zostavax proposal includes reduced prices for other products from the same supplier, questioning whether this is an anti-competitive arrangement.	See above. Zostavax is currently the only vaccine registered for prevention of herpes zoster in New Zealand. PHARMAC notes that competition in the market is taken into consideration in all PHARMAC transactions.
Section 9(2)(a)	Questions the safety of vaccines.	Noted.
Industry		
Noel Wright, ProPharma Palmerston North	Supportive. Supportive. Requests that zoster vaccine be funded for individuals between the ages of 50-60.	See above.
Dr Kate McLellan, GSK	Noted that the catch up programme with Zostavax is unlikely to be cost effective due to the limited and rapidly declining efficacy in the 65 to 80 year old group. Requested PHARMAC review the Zostavax data and reconsider the value of the catch up programme.	PTAC considered the cost and benefits of when to vaccinate with Zostavax on several occasions and recommended vaccination at 65 years was the best option. PHARMAC considers that the catch-up programme will provide benefits to those patients despite the waning of Zostavax.
Lance Gravatt, TeArai BioFarma	Supportive. Concerned at the inconsistency of accepting a bundled vaccine proposal for	PHARMAC staff note that the agreement for Zostavax is not part of an RFP process.

Stakeholder group	Theme	PHARMAC Staff Comment
	Zoster when the RFP for national vaccine supply specifically excluded bundled proposals. Suggests consulting on the approach to accept bundled proposals including vaccines and apply it to all vaccines, not just Zoster.	
Ministry of Health		
Rayoni Keith Immunisation Service Commissioning MOH	Supportive. Notes that using cost effectiveness as a factor in determining the funded age groups is a reasonable approach based on current evidence. Also notes that Australia and the US recommend zoster vaccine from age 60 years.	Noted.
	Recommends that the question of the most appropriate age for vaccination be revisited should the cost:benefit for younger age groups change due to a decrease in vaccine costs and/or change in zoster epidemiology.	Noted.
	Notes that the Ministry has no allocated resources to support any public messaging regarding the funding of zoster vaccine.	PHARMAC staff note that the Ministry of Health is responsible for implementation. The supplier is also likely to do some public messaging.
	Agrees that co-delivery of the zoster vaccine with the influenza vaccine would be the most efficient model of service delivery and has the potential to increase coverage for both vaccines. Noted that there will be an additional administration cost to the health sector of $20 for the zoster vaccine if it is not given at the same time as the influenza vaccine.	Noted. PHARMAC staff estimate that zoster vaccine will be co-delivered with influenza vaccine in 75% of individuals. The additional administration costs of the 25% of administrations that would not be co-delivered have been factored into the additional costs to DHBs in the BIA for this proposal.
	Suggests that access to zoster vaccine through pharmacies should be enabled as a to maximise the co-delivery model.	See above.
	Availability through pharmacies and co-administration with influenza vaccine would help reduce the workload for general practices during one of their busiest times of the year.	

Stakeholder group	Theme	PHARMAC Staff Comment
	Noted the proposed introduction date is 1 April 2018, which is Easter Sunday. Suggested a start date of 3 April 2018 would enable a smoother transition for updating of IT and practice management systems. Noted that the proposed implementation in April 2018 is a tight timeframe for the work required for implementation. Requests that PHARMAC confirms all changes and criteria as soon as possible.	Changes to the Pharmaceutical Schedule occur on the 1st of the month. PHARMAC have communicated this with the Ministry of Health on a number of occasion. PHARMAC notes that they meet regularly with the Ministry of Health Immunisation Team and have provided updates regarding the possibility and progress for funding zoster vaccine to align with the 2018 influenza vaccine programme since February 2017. PHARMAC will keep the Ministry of Health updated if any changes are proposed.
Mandy Benson Operations Support MOH	No technical or resource impacts are anticipated as a result of the proposal.	Noted.

PHARMAC
Pharmaceutical Management Agency

CONSULTATION

Proposal to fund zoster vaccine

15 September 2017

What we're proposing

PHARMAC is seeking feedback on a proposal to fund the zoster vaccine (Zostavax) for the prevention of shingles (herpes zoster) from 1 April 2018 through a provisional agreement with Merck Sharpe & Dohme Limited.

We are proposing to list the zoster vaccine in Section B and in Part II of Section H of the Pharmaceutical Schedule for people aged 65 years and with a 2-year catch up programme for people aged between 66 and 80 years inclusive.

Consultation closes at **5 pm on Wednesday, 4 October 2017** and can be emailed to vaccines@pharmac.govt.nz .

What would the effect be?

From 1 April 2018 people aged 65 years would be able to get one funded zoster vaccine from their general practitioner.

There would also be a catch-up programme where, from 1 April 2018 until 31 March 2020, people aged between 66 and 80 years old would be eligible to receive a funded zoster vaccine.

People who meet the funding criteria could receive their zoster vaccine at the same time as their annual influenza vaccine.

Patients would be able to get their funded zoster vaccine from their general practitioner. Funded zoster vaccine would not be available through community pharmacies at this point, but this may be considered in the future.

Who we think will be interested

Doctors in general practice, infectious disease specialists, geriatricians, public health services, nurses, vaccinators, DHBs, people 65 years and over, consumer groups focused on the elderly such as Grey Power and Age Concern, rest homes and retirement villages, organisations with an interest in immunisation.

About the zoster vaccine

Herpes zoster, commonly known as shingles, is caused by the reactivation of the varicella-zoster (chickenpox) virus. Anyone who has previously had chickenpox may subsequently develop shingles, and the incidence tends to be proportionally higher in older patients. Shingles is more common and more severe in patients with poor immunity.

Zostavax is indicated for the prevention of herpes zoster (shingles), for prevention of post herpetic neuralgia and for reduction of acute and chronic zoster-associated pain in people aged 50 years and older. Each 0.65 ml dose of Zostavax contains a minimum of 19,400 plaque forming units (pfu) of live Oka/Merck strain of varicella-zoster virus when reconstituted.

Zostavax vaccine is contraindicated in immunocompromised patients and healthcare professionals should assess the patient's immunological status before vaccination (see the September 2017 Prescriber Update issued by Medsafe: http://www.medsafe.govt.nz/profs/PUArticles/PDF/PrescriberUpdate_September2017.pdf).

Zostavax can be administered concurrently with influenza vaccine.

Why we're proposing this

A funding application for Zostavax has been reviewed by the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Immunisation Subcommittee of PTAC. Funding was recommended for individuals 65 years of age, and for a 2-year catch-up programme for people aged between 66 and 80 years.

One in every three people can expect to suffer at least one attack of shingles in their lifetime. Attacks can be very painful, prolonged and debilitating, especially for older people. Shingles and post-herpetic neuralgia have high levels of morbidity, and can be life changing as some patients do not recover to the point where they are well enough to return to independent living.

Zostavax vaccination has been shown to reduce reactivation of herpes zoster virus (shingles), and prevent the development of post herpetic neuralgia.

Clinical advice carefully considered the cost and benefits of when to vaccinate with Zostavax and recommended vaccination at 65 years was the best option.

There is a significant difference in the efficacy of Zostavax depending on the age of the person when they are vaccinated, with a vaccine efficacy of around 64% for individuals aged 60-69, dropping to 38% in those aged 70 and older, and 18% in people over 80 years.

More information, including links to the PTAC and Immunisation Subcommittee minutes, can be found via PHARMAC's Application Tracker.

Details about our proposal

PHARMAC has entered into a provisional agreement with Merck Sharp & Dohme (New Zealand) Limited to list Zostavax.

Zostavax would be listed in Section I (National Immunisation Schedule) and Part II of Section H of the Pharmaceutical Schedule from 1 April 2018 at the following price and subsidy (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Subsidy	Manufacturer's price (ex GST)
Varicella zoster virus (Oka strain) live attenuated vaccine	Inj 19,400 PFU vial with a prefilled diluent syringe	Zostavax	1	$0.00	$152.40
Varicella zoster virus (Oka strain) live attenuated vaccine	Inj 19,400 PFU vial with a prefilled diluent syringe	Zostavax	10	$0.00	$1524.00

A confidential rebate would apply to Zostavax, reducing the net price to the Funder. Subsidy and delisting protection would apply until 30 June 2021.

Vaccines are distributed differently to most other pharmaceuticals. The method for ordering Zostavax would be the same as other vaccines. Zostavax would be listed "Xpharm" with a $0.00 subsidy. An Xpharm listing means that pharmacies cannot claim subsidy because PHARMAC has made alternative distribution arrangements.

Zostavax would be listed in Section I and Part II of Section H of the Pharmaceutical Schedule with the following eligibility criteria:

Section I

Funded for patients meeting either of the following criteria:
1) One dose for all people aged 65 years; or
2) One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 March 2020.

Section H

Restricted
Initiation – people aged 65 years
Therapy limited to 1 dose
One dose for all people aged 65 years.

Initiation – people aged between 66 and 80 years
Therapy limited to 1 dose
One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 March 2020.

The Ministry of Health is responsible for supporting the implementation of changes to the National Immunisation Schedule and PHARMAC would work closely with the Ministry to ensure Zostavax would be available at a similar time to the start of the seasonal influenza vaccine programme.

Other changes associated with this proposal

As part of this proposal, from 1 January 2018, there would also be a price reduction for alendronate sodium 70 mg tablets (Fosamax) and alendronate sodium with colecalciferol 70 mg with colecalciferol 5,600 iu (Fosamax Plus) as follows (prices are ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy[#]	Proposed price and subsidy
Alendronate sodium	Tab 70 mg	Fosamax	4	$12.90	$4.82
Alendronate sodium with colecalciferol	Tab 70 mg alendronate with colecalciferol 5,600 iu	Fosamax Plus	4	$12.90	$4.82

[#] A confidential rebate applies.

The price reduction for Fosamax and Fosamax Plus is conditional on the proposed listing of Zostavax on the Pharmaceutical Schedule.

To provide feedback

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by Wednesday, 4 October 2017 to:

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

Email: vaccines@pharmac.govt.nz
Fax: 04 460 4995

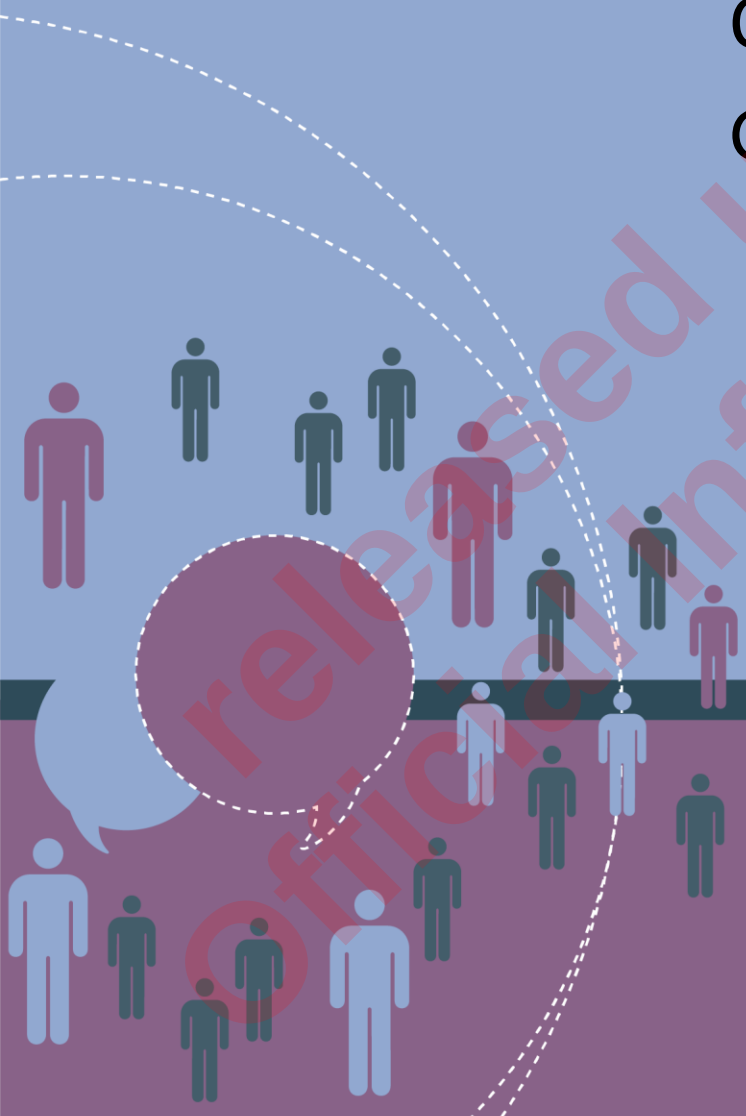
All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

PHARMAC Board Meeting

Clinician / Clinical Group Feedback



To: Vaccines[vaccines@Pharmac.govt.nz]
From: section 9(2)(ba)(i)
Sent: Mon 18/09/2017 7:34:45 p.m
Importance: Normal
Subject: Feedback on funding zoster vaccine
MAIL_RECEIVED: Mon 18/09/2017 7:37:45 p.m

;;
We would welcome this with open arms!

A lot of patients that really want to have this can't afford it (over 65 yrs) so having it funded alongside the flu shot would be great - thanks

Regards

section 9(2)(ba)(i)

section 9(2)(ba)(i)

section 9(2)(ba)(i)

section 9(2)(ba)(i)

section 9(2)(ba)(i) section 9(2)(ba)(i)

NB: Please note new email address

CompassHealth
Working together, towards healthy and flourishing communities

4th October 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

Dear Doctor Ancelet

Re: Proposal to fund zoster vaccine

I would just like to write in support of your proposal to fund the zoster vaccine to people aged 65 years of age from 1st April 2018, and a catch of for those aged between 66 and 86 years of age.

In my role as the Immunisation Facilitator for the Wairarapa, I work with a lot of aged care groups, so am very aware of the impact that Shingles has on their lives.

I regularly deliver talks about vaccines for our older population within the Wairarapa, and the zoster vaccine is always a key topic that is raised. A lot of concern is always expressed by community members regarding the cost of the vaccine, as it was something that was out of reach for a lot of our community. Therefore, having this as a funded vaccine, would be very well received.

I have also spoken with both doctors and registered nurses from each of our seven medical centres, whom are all also strongly in favour of this proposal.

Thank you.

Kind regards,

Tina Tyacke
District Immunisation Facilitator
Compass Health Wairarapa

To: Vaccines[vaccines@Pharmac.govt.nz]
Cc: Craig Murray[section 9(2)(a) Ajay Makal[section 9(2)(a) Andre George[section 9(2)(a)]; Jenni Waddell[section 9(2)(a)]
From: Sian Gilhooley
Sent: Mon 2/10/2017 3:20:08 a.m
Importance: Normal
Subject: Zosavax Feedback
MAIL_RECEIVED: Mon 2/10/2017 3:20:40 a.m

…
,,,
Afternoon Dr Ancelet

Thank you for the opportunity to feedback. Please see the collective responses from the clinical directorate at Comprehensive Care PHO.

Great idea to add to Immunisation schedule – wholly endorse the plan.

Will help with equity gap of those who, have not been able to afford it.

The positive clinical and social benefits on Zoster-associated pain and discomfort, related disability and morbidity are very encouraging.

Our only concern is the proposed age for funded vaccine of 65years.

The clinical evidence, is strongly supportive of Immunisation earlier, around 50 years for optimum efficacy.

We would advocate for earlier Immunisation for greater benefit on the following grounds:

- before reduced T-cell mediated immunity

- Before patients have increased likelihood of being on immunosuppressive therapy and therefore CI for vaccination

- To mitigate significant impact on working life

- Reduce incidence of recurrent episodes / flares

- prior to increase contact with varicella disease through grandchildren

Question; would it be more beneficial waiting for the licensure of Shingrix® (the GSK recombinant zoster vaccine)? This would increase the eligibility pool of potential vaccinees by mitigating some of the risks and CI for older patients.

Kind Regards

Sian Gilhooley

BSc Nursing, PGDip Pub Health

From: Aine McCoy <section 9(2)(a)>
Sent: Tuesday, 26 September 2017 9:47 a.m.
To: Vaccines
Subject: re Zostvax proposal

Dear Sir or Madam,
I support the proposal to list this vaccine on the Pharmaceutical Schedule for those aged 65 years and over. As a GP, I have seen first hand the misery that herpes zoster causes, not only in the acute phase but the post herpetic neuralgia that frequently follows, causing pain for many years afterwards.
Yours faithfully
Aine McCoy MB BCh BAO DRCOG FRNZCGP
section 9(2)(a)

From: Alex Moreland <section 9(2)(a)>
Sent: Monday, 25 September 2017 11:44 a.m.
To: Vaccines
Subject: Zoster Vaccine

I endorse the proposal to offer the Zoster Vaccine to the 65+ age group as a funded Vaccine. ?start from age 60yrs.

Dr A Moreland

Sent from my iPad

To: Vaccines[vaccines@Pharmac.govt.nz]
From: Dr. Bart Nuysink
Sent: Mon 25/09/2017 1:39:02 a.m
Importance: Normal
Subject: shingles vaccination 80+
MAIL_RECEIVED: Mon 25/09/2017 1:39:28 a.m

…
;;;
Hi

I applaud this move.

It may be helpful to make clearer what vaccination fee would be.

I note the cut off at 80yr with the justification of decreased efficacy. But shingles in a 90year old can subject them to severe neuralgia. It is my impression that the neuralgia increases with age. This could well be immune related. Could a different vaccination schedule eg repeat vaccination at 2yearly intervals address the risk of neuralgia for these vulnerable individuals?

I appreciate your considerations regarding future programmes for the 80+ group.

Dr Bart Nuysink | Chief Medical Officer

The Selwyn Foundation

Medical Centre | Selwyn Village

21 Shaftesbury Avenue, Point Chevalier, Auckland 1022

Phone: section 9(2) | Mob: section 9(2) | Fax: 09 845 0735

www.selwyncare.org.nz

From: Clive Cameron <section 9(2)(a)>
Sent: Tuesday, 3 October 2017 2:15 p.m.
To: Vaccines
Subject: varicella-zoster vaccine

Kia Ora Emma,
I think making the vaccine available free to those over 65 and the 2 year catch up program is a very good plan. Zoster causes a lot of morbidity in the older age-group. I think there would be a good take- up of the vaccine if free, judging from the interest expressed by patients.
Thank you.
Clive Cameron

From: Derek Sherwood [redacted]
Sent: Sunday, 17 September 2017 5:33 p.m.
To: Vaccines
Subject: Herpes Zoster Vaccination Proposal Consultation

Thank you for the opportunity to submit with regard to this consultation.
Firstly can I comment that in your introduction section on who might be interested in this proposal you have not mentioned Ophthalmology/Ophthalmologists which is at odds with the pathophysiology of Herpes Zoster which involves the eye in 15% of cases and in 50% of these cases there are ocular sequelae including keratitis, uveitis and secondary glaucoma. Many who do not have sight threatening sequelae have Post Herpetic Neuralgia.
Patients with ocular sequelae often require life long treatment and may suffer significant visual loss.

Clearly with the potentially devastating effects on vision and eye health as well as the debilitating effects of Post Herpetic Neuralgia, funding vaccination would be strongly supported by Ophthalmologists.

You may wish to approach one of the University Ophthalmology centres in NZ to get a more comprehensive review of the evidence based with regard to the impact of Ophthalmic Zoster in NZ but as a general ophthalmologist working here for 28 years I am very aware of the burden on eye health services that these patients represent and the significant distress and disability incurred by patients.

Nga mihi nui

Derek Sherwood

To: Vaccines[vaccines@Pharmac.govt.nz]
From: fayez khalil
Sent: Sun 24/09/2017 10:12:04 p.m
Importance: Normal
MAIL_RECEIVED: Sun 24/09/2017 10:12:28 p.m

…
;;;
Thanks
I think it would be good idea ,especially for the immnuno-compromosed patients
Regards Fayez

From: Felicity Goodyear-Smith [redacted]
Sent: Monday, 25 September 2017 7:06 p.m.
To: Vaccines
Subject: request for feedback

I support the proposal of providing the Zoster vaccine given at the same time as influenza vaccine for people aged 65 years with a 2-year catch up programme for people aged between 66 and 80 years inclusive.

Felicity Goodyear-Smith

Professor Felicity Goodyear-Smith, Academic Head & Goodfellow Chair
MBChB, MD, FRNZCGP (Distinguished), FFFLM (RCP)
Department of General Practice & Primary Health Care, University of Auckland, PB 92 019 Auckland 1142 New Zealand
Tel [redacted]; Mob [redacted]; [redacted] Email [redacted]
Website https://unidirectory.auckland.ac.nz/profile/fgoo003

Deliveries: [redacted] Building 730 School of Population Health,Tamaki Campus, University of Auckland, 261 Morrin Rd, Glen Innes, Auckland

To: Vaccines[vaccines@Pharmac.govt.nz]
From: Rob & Janet Vos/Vaughan
Sent: Mon 25/09/2017 12:12:49 a.m
Importance: Normal
Subject: Funding of zoster vaccine
MAIL_RECEIVED: Mon 25/09/2017 12:13:15 a.m

;
I am comfortable with the idea of funding the zoster vaccination for those 65-80.
Can I suggest an alternative?

Fully fund all those with a community services card and part fund those without.....$40-50 would be acceptable for most people on a higher income as a one off vaccination.
I do not promote zostervax. Usually it is patients whose friend has had either the disease itself or the vaccination that come in enquiring about vaccination. Most do not pursue it once they are aware it costs $200 but say they could afford a lower charge.

With the money saved by part charging for non-community services card holders, fund pneumovax for a wider range of patients such as those with COPD.

Nga mini

Dr Janet Vaughan
Turuki Health Care
Mangere
Auckland
section 9(2)(a)

To: David Oldershaw [redacted]
Cc: Vaccines[vaccines@Pharmac.govt.nz]
From: Jo Scott-Jones
Sent: Mon 18/09/2017 2:20:03 a.m
Importance: Normal
Subject: RE: PHARMAC: Consultation on proposal to fund zoster vaccine
MAIL_RECEIVED: Mon 18/09/2017 2:20:33 a.m

.....
,,,,,,,,
Dear David,

Thanks for the opportunity to comment.

Herpes zoster is a significant illness that affects 1:3 people over the age of 50 and it is welcome to see free access to vaccine available on the schedule.

I understand there may be a cost implication to providing the vaccine to people aged 50 and above, and the determination to introduce the vaccine at 65 years and above is potentially a decision based on wider issues that simply the clinical efficacy.

Just as we aim to immunise children as soon as possible to reduce the time they are most vulnerable to infections, we should be aiming to protect adults over the age of 50 from shingles as opposed to waiting, leaving them in this scenario with increased risk for 15 years.

Not only does this not make sense from a vulnerability point of view, there is mixed evidence about the effectiveness of the vaccine as people get older. (http://www.immune.org.nz/sites/default/files/vaccines/datasheets/Zostavax%20August%202017.pdf)

Whilst we support the introduction of a free shingles vaccine, we think it should be available from age 50 onwards, not from age 65 onwards.

Yours sincerely,

Dr Jo Scott-Jones (Medical Director)

From: David Oldershaw
Sent: Monday, 18 September 2017 11:03 a.m.
To: Jo Scott-Jones
Subject: FW: PHARMAC: Consultation on proposal to fund zoster vaccine

Jo, FYI

From: Fiona Thomso [redacted]
Sent: Monday, 18 September 2017 10:19 a.m.
Subject: PHARMAC: Consultation on proposal to fund zoster vaccine

Email forwarded to GPNZ Exec, Nursing Exec and NZHCN CEO Group

To: Vaccines[vaccines@Pharmac.govt.nz]
From: Julian
Sent: Wed 27/09/2017 7:12:21 p.m
Importance: Normal
Subject: Zostavax funding for over 65's
MAIL_RECEIVED: Wed 27/09/2017 7:12:52 p.m

;
Dear Sir/Madam,

I strongly support this.

Yours faithfully,

Dr. Julian Foster

The Terrace Medical Centre,

PO Box 10184,

Wellington

To: Vaccines[vaccines@Pharmac.govt.nz]
From: Lyn White
Sent: Tue 26/09/2017 4:18:03 a.m
Importance: Normal
Subject: Zostavac vaccine
MAIL_RECEIVED: Tue 26/09/2017 4:18:13 a.m

;
I endorse this action.
Zoster is a painful and debilitating condition not just restricted to the acute phase.
Zoster vaccination is un-affordable to may elderly people.
Lynette White section 9(2)(a)

To: Vaccines[vaccines@Pharmac.govt.nz]
From: Margaret Chavasse
Sent: Thur 21/09/2017 1:01:51 a.m
Importance: Normal
MAIL_RECEIVED: Thur 21/09/2017 1:15:34 a.m

;;
Dear Lyndsay
Re the Zostavax - I was initially unsupportive of its use due to its poor efficacy in the over 60s. But due to a recent spate of older people with shingles with severe sequelae, I have decied that anything that can reduce its incidence and morbidity is worthwhile.
Regards
Dr Margaret Chavasse

From: Nikki Turner [redacted]
Sent: Monday, 18 September 2017 12:09 p.m.
To: [redacted] Vaccines
Subject: RE: Variola vaccine

Hi [redacted]
While I absolutely agree with your concern about ageism in vaccine decision there is a genuine problem with this vaccine working quite poorly on older age groups - for those over 80 yrs it is probably only around 18% effective so I can see why the decision

I do think the big question is that the world divides people very crudely by age group not by immune responsiveness and the difference between a sprightly healthly more mature person is very different from someone with multiple comorbidies. I would like to see us get more sophisticated and move away from a blunt age measure for older folks but the alternative measures are still difficult to pin down for decisions such as ages to vaccinate….

I agree with funding studies to look at the differences in immune responses in elderly – I think they would be considerable. I suspect it is not particularly in the interests of Pharma companies to fund though…..and not sure where else we would get funding as they are not cheap studies to run

We are getting to national records – have it with the kids and using it has significantly closed our equity gaps ….sadly our NIR is only 12 years old though and will take a while till it gets to my age group !

Best wishes
Nikki

From: [redacted]
Sent: Sunday, 17 September 2017 6:26 AM
To: vaccines@pharmac.govt.nz; Nikki Turner
Subject: Fwd: Variola vaccine

Sent from my Samsung Galaxy smartphone.

-------- Original message --------
From [redacted]
Date: 17/09/17 6:21 AM (GMT+12:00)
To: vaccines@pharmac.co.nz
Subject: Variola vaccine

As an 86 year old I suppose I need to contest the decision to limit the catch up age to 80.
I have no personal interest in this as I had mine a few years ago tho it cost me $50.
I can see the logic behind your decision but I wonder about the robustness of the data in those over 80.

We are not that numerous but are divisible into two groups the halt blind and the lame and those who seem to have relatively good health. I would like to suggest that you fund a small study of healthy 80 plus year olds to see if the current limit is defensible.
The is of course the wisdom of setting one age thereafter at 65. I seems like a good idea but it doesn't take account of human nature. The people who are least likely to get the vaccine are the most dispossessed who may have no personal relationship with a gp or are moving or lack motivation born of despair.
I think a more humane way of doing this would be to keep a national record of those who get the vaccine and instituting a programme to catch those who haven't. As you know the current government plan for a single medical record makes this possible.
Yours with one foot in the grave.
section 9(2)(a)
section 9(2)(a)

PS shingles might reduce the amount of dirt that has to be shoveled Ion too of the casket.

Sent from my Samsung Galaxy smartphone.

From: Rick Franklin (ADHB) <section 9(2)(a)>
Sent: Monday, 25 September 2017 10:55 a.m.
To: Vaccines
Subject: FW: Re Zostervax aprroval for funding (and Shingerix)

Hi Pharmac
would it not be wise to just fund Shingerix , once it is registered?
See this from Paul Sax on HIV/ID blogs NEJM September 2017

Inactivated Zoster Vaccine Soon to Be Approved — Should Patients Wait for It?

For the last year or so, conversations with patients about getting the zoster vaccine have gone something like this:
Patient: So should I get the shingles vaccine? I saw an ad for it on TV.
Me: Well, yes … and no.
Patient (confused — he/she has never heard me say anything but an enthusiastic "Yes!" to vaccines): What does that mean?
Me: There's a better shingles vaccine coming soon, likely within a year. So I'd wait.
Now it looks like that wait is almost over.
This past week, an FDA advisory panel voted unanimously that the investigational inactivated zoster vaccine is safe and effective for adults older than 50. The materials the panel reviewed are here.
FDA approval should follow soon — potentially next month — along with the critical review and recommendations from the Advisory Committee on Immunization Practices (ACIP).
The expert advisory panel based their decision on two pivotal randomized trials, ZOE-50 and ZOE-70, which compared the vaccine (administered as two doses) to placebo in people aged 50 and older or 70 and older, respectively. The studies enrolled nearly 30,000 subjects.
Vaccine efficacy was 97% in the first study, 89% in the second. The incidence of post-herpetic neuralgia was also reduced.
Importantly, adverse events were more common in vaccine recipients, but most were of mild severity. There was no significant difference in the incidence of severe side effects, deaths, or autoimmune processes.
Though these studies were not a direct comparison with the currently available live-attenuated zoster vaccine (Zostavax), remember that the efficacy of that vaccine is only around 50%.
Plus, it has been around long enough that we now know its efficacy wanes substantially over time.
That Zostavax is a live-virus vaccine creates additional difficulties. There is understandable concern — and confusion — about giving it to people with defects in cell-mediated immunity, for whom it's contraindicated, and their household contacts, for whom it isn't.
Finally, there are the practical difficulties of storing it before administration. Even clinics that do lots of immunizations — ours, for example — don't have the required stand-alone freezer for storage of this vaccine. Many patients currently need to go to a pharmacy to get it, which adds an additional required step.
So this inactivated zoster vaccine won't be just a "me-too" approval, but a real advance in prevention of what can be a truly debilitating condition. With the caveat that we lack safety data in very large patient populations — that should come after licensing — I'm not surprised the advisory panel voted the way they did.

Dr Rick Franklin
Sexual Health Physician
Auckland Sexual Health Service
Building 7,Greenlane Clinical Centre
Private Bag 92189
Auckland
New Zealand
mobile section 9(2)(a)

From: Ron Baker <section 9(2)(a)>
Sent: Tuesday, 26 September 2017 4:48 p.m.
To: Vaccines
Subject: Zostavax vaccine
Attachments: Shingles HZsu vaccine 2015.docx; Shingles new GSK vaccine NEJM study.docx; Shingles--Zostavax Efficacy Limited and Fades Soon.docx

Why fund zostavax?? It only provides maybe 50-70% reduction in the incidence of shingles for maybe 5-7 years. GSK has developed a far more effective vaccine with something like 97% reduction in the incidence of shingles in a 3-4 year study, about the same length as the studies that got Zostavax approved. The GSK vaccine will likely become available in about a year. I'm telling my patients to wait for it, in case there is a conflict between the vaccines (analogous to the ability of pneumovax to limit the effectiveness of prevenar 13 if the former is given shortly before the latter, such that a whole year should be waited between these vaccines, though some say only 6/12).

Look into the GSK vaccine first. I will attach some summaries I have kept from 2014-15. I have asked GSK when they expect it to be available and within a year from now seems likely. At that point it should take over the market from Zostavax. No wonder Merck is promoting Zostavax so much now. They need to may hay while they can.

Ron Baker
Three Kings Accident and Medical Clinic
Auckland

From: Vanessa & [redacted] <[redacted]>
Sent: Wednesday, 27 September 2017 10:44 p.m.
To: Vaccines
Subject: reply re zoster vaccine

I fully support the funding of the zoster vaccine . We see a lot of shingles and post herpetic neuralgia .
A younger age may be beneficial but it would also seem sensible to combine it with the flu vaccine , uptake will almost certainly be higher in this scenario.
Yours Sincerely
Dr Vanessa Fardon
Kitchener Rd Medical Centre
Milford
Auckland

GSK candidate vaccine for the prevention of shingles demonstrates overall efficacy of 97.2% which does not diminish in the age groups studied

28 April 2015

Shingles is a significant public health burden, more than 90% of adults aged 50 years and over are at risk

Issued: London, UK - LSE Announcement

GlaxoSmithKline plc (LSE/NYSE: GSK) today presented detailed data from a randomised phase III study of its investigational vaccine candidate for the prevention of shingles, HZ/su, showing vaccine efficacy was maintained across age groups, from 50 years to 70 years and over. The data was presented at the 25th Scientific Congress of the European Society of Clinical Microbiology and Infectious diseases (ECCMID) in Copenhagen and published online simultaneously in the New England Journal of Medicine.

Analysis of the primary endpoint showed that a two-dose schedule of HZ/su reduced the risk of herpes zoster by 97.2% (95% confidence interval [CI] 93.7-99.0) in adults aged 50 years and older compared to placebo. Vaccine efficacy was maintained across the various age groups included in the study, ranging between 96.6% in people aged 50-59 years, 97.4% in those aged 60-69 years, 97.6% in people aged 60 years and above, and 98% in those 70 years or older. There was no significant difference in vaccine efficacy among the age groups.

The proportions of subjects with serious adverse events, potential immune-mediated diseases, or deaths were similar in vaccine and placebo groups. The most commonly reported local adverse reaction was pain with the others being redness and swelling at the injection site. These were graded severe in 9.5% of HZ/su recipients compared to 0.4% of placebo recipients. The more frequently reported systemic adverse reactions were muscle pain, fatigue and headache, of which 11.4% were graded severe in the HZ/su group compared to. 2.4% in the placebo group. These reactions mostly occurred within 7 days of vaccination with most lasting 1-3 days.

The HZ/su candidate vaccine is non-live and combines gE, a protein found on the virus that causes shingles, with an adjuvant system, AS01B,1 which is intended to enhance the immunological response to gE.

Additional trials to evaluate the ability of HZ/su to prevent shingles are ongoing in people aged 70 and older and in adults with compromised immune systems. These studies will provide additional information with respects to the safety of HZ/su and its ability to stimulate immune responses in specific populations. These studies will also address the degree to which HZ/su can prevent complications of shingles, such as chronic neuropathic pain, also known as post-herpetic neuralgia (PHN).2

Dr Moncef Slaoui, Chairman Global Vaccines at GSK, said: “We are extremely encouraged that the results may point out a health benefit in the prevention of shingles. This disease can be painful and potentially debilitating for some people and older people are particularly at risk. We look forward to continuing the development of our Zoster programme”

Notes to editors

About the ZOE-50 trial

The ZOE-50 Zoster efficacy in adults aged 50 years and over study is a randomised, observer-blind, placebo-controlled (saline solution) multicentre, multinational (North America, Europe, Latin America, Asia-Pacific) phase III trial involving 16,160 adults aged 50 years and older. The study started in August 2010 and reported headline efficacy data in December 2014. Doses were given intramuscularly on a 2-dose schedule at 0 and 2 months. The primary endpoint of this study is the overall vaccine efficacy (VE) of the candidate vaccine HZ/su across all age cohorts compared to placebo in reducing the risk of developing shingles. The study includes subjects in the age ranges 50-59, 60-69, 70-79, and ³80 years.

About the phase III HZ/su study programme

Involving more than 37,000 subjects globally, the phase III programme for candidate vaccine HZ/su will evaluate its efficacy, safety and immunogenicity. In addition to older adults, HZ/su is being evaluated in immunocompromised patient populations, including solid and haematological cancer patients, haematopoietic stem cell and renal transplant recipients and HIV-infected people.

Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults

Himal Lal, M.D., Anthony L. Cunningham, M.B., B.S., M.D., Olivier Godeaux, M.D., Roman Chlibek, M.D., Ph.D., Javier Diez-Domingo, M.D., Ph.D., Shinn-Jang Hwang, M.D., Myron J. Levin, M.D., Janet E. McElhaney, M.D., Airi Poder, M.D., Joan Puig-Barberà, M.D., M.P.H., Ph.D., Timo Vesikari, M.D., Ph.D., Daisuke Watanabe, M.D., Ph.D., Lily Weckx, M.D., Ph.D., Toufik Zahaf, Ph.D., and Thomas C. Heineman, M.D., Ph.D. for the ZOE-50 Study Group
N Engl J Med 2015; 372:2087-2096May 28, 2015DOI: 10.1056/NEJMoa1501184

BACKGROUND

In previous phase 1–2 clinical trials involving older adults, a subunit vaccine containing varicella–zoster virus glycoprotein E and the AS01B adjuvant system (called HZ/su) had a clinically acceptable safety profile and elicited a robust immune response.

METHODS

We conducted a randomized, placebo-controlled, phase 3 study in 18 countries to evaluate the efficacy and safety of HZ/su in older adults (≥50 years of age), stratified according to age group (50 to 59, 60 to 69, and ≥70 years). Participants received two intramuscular doses of the vaccine or placebo 2 months apart. The primary objective was to assess the efficacy of the vaccine, as compared with placebo, in reducing the risk of herpes zoster in older adults.

RESULTS

A total of 15,411 participants who could be evaluated received either the vaccine (7698 participants) or placebo (7713 participants). During a mean follow-up of 3.2 years, herpes zoster was confirmed in 6 participants in the vaccine group and in 210 participants in the placebo group (incidence rate, 0.3 vs. 9.1 per 1000 person-years) in the modified vaccinated cohort. Overall vaccine efficacy against herpes zoster was 97.2% (95% confidence interval [CI], 93.7 to 99.0; P<0.001). Vaccine efficacy was between 96.6% and 97.9% for all age groups. Solicited reports of injection-site and systemic reactions within 7 days after vaccination were more frequent in the vaccine group. There were solicited or unsolicited reports of grade 3 symptoms in 17.0% of vaccine recipients and 3.2% of placebo recipients. The proportions of participants who had serious adverse events or potential immune-mediated diseases or who died were similar in the two groups.

CONCLUSIONS

The HZ/su vaccine significantly reduced the risk of herpes zoster in adults who were 50 years of age or older. Vaccine efficacy in adults who were 70 years of age or older was similar to that in the other two age groups. (Funded by GlaxoSmithKline Biologicals; ZOE-50 ClinicalTrials.gov number, NCT01165177.)

Zostavax Efficacy Limited and Fades Soon

One randomized, placebo-controlled trial has evaluated short-term efficacy of herpes zoster vaccine administered to adults aged 50 through 59 years. This study of 22,439 adults in this age group showed a vaccine efficacy of 69.8% (95% confidence interval [CI] = 54.1%–80.6%) for the prevention of herpes zoster over a mean follow up period of 1.3 years.[8] Efficacy for prevention of PHN and long-term vaccine efficacy in this age group were not studied.

Two studies have evaluated the short-term efficacy of the zoster vaccine in adults aged ≥60 years. The shingles prevention study (SPS),[9] a randomized controlled trial, followed 38,546 subjects for up to 4.9 years after vaccination (median = 3.1 years) and found a vaccine efficacy of 51.3% (CI = 44.2%–57.6%) for prevention of herpes zoster and 66.5% (CI = 47.5%–79.2%) for prevention of PHN. The short-term persistence substudy (STPS)[10] followed a subset of 14,270 SPS subjects primarily 4 to 7 years after vaccination and found a vaccine efficacy of 39.6% (CI = 18.2%–55.5%) for prevention of herpes zoster and 60.1% (CI = -9.8%–86.7%) for prevention of PHN. The point estimates for vaccine efficacy for prevention of herpes zoster by year after vaccination from the combined SPS and STPS studies decreased from 62.0% (CI = 49.6%–71.6%) in the first year after vaccination to 43.1% (CI = 5.1%–66.5%) in year 5. The 95% CIs around the point estimates for years 6 (30.6%) and 7 (52.8%) included zero; therefore vaccine protection could not be demonstrated after year 5. Vaccine efficacy for prevention of PHN decreased from 83.4% (CI = 56.7%–95.0%) in year 1 to 69.8 (CI = 27.3%–89.1%) in year 2. Estimates for years 3 through 7 after vaccination were not statistically significantly different from zero, although point estimates were generally higher compared with estimates of vaccine efficacy against herpes zoster.

The long-term persistence study[11] continued to follow 6,687 vaccinated subjects from STPS primarily from year 7 through year 10 after vaccination. By the end of the STPS, subjects in the placebo group had been vaccinated; therefore, no concurrent control group was available for comparison. Instead, a statistical model estimated herpes zoster and PHN incidence in a comparable unvaccinated group using historical SPS control subjects. The model estimated a vaccine effectiveness of 21.1% (CI = 10.9%–30.4%) for prevention of herpes zoster and 35.4% (CI = 8.8%–55.8%) for prevention of PHN over years 7 to 10 combined. Methodologic challenges in reliance on herpes zoster incidence in historical controls for calculation of vaccine effectiveness against herpes zoster include the fact that several studies[3,12–14] have shown increases in herpes zoster incidence over time. The lack of a concurrent control group seriously diminishes the strength of evidence for duration of vaccine protection from years 7 through 10. In addition, although some vaccine protection is demonstrated during the combined years 7–10 using this methodology, there is a high degree of uncertainty about trends in vaccine effectiveness over this time frame. For these reasons, effectiveness of herpes zoster vaccine administered to persons aged ≥60 years for preventing herpes zoster beyond 5 years remains uncertain.

Because the protection offered by the herpes zoster vaccine wanes within the first 5 years after vaccination, and duration of protection beyond 5 years is uncertain, it is unknown to what extent persons vaccinated before age 60 years will be protected as they age and their risk for herpes zoster and its complications increases.

ACIP Review

At the October 2013 meeting, ACIP reviewed results from an updated cost-effectiveness analysis comparing health outcomes, health care resource utilization, costs, and quality-adjusted life years (QALYs) related to herpes zoster, PHN, and non-pain complications among unvaccinated persons and persons vaccinated at either age 50, 60, or 70 years.[15] The model assumed waning of vaccine protection against herpes zoster to zero over 10 years for all ages, based on SPS, STPS, and long-term persistence study data. Projecting outcomes from ages 50 to 99 years, vaccination at age 60 years would prevent the most shingles cases (26,147 cases per 1 million persons) followed by vaccination at age 70 years and then age 50 years (preventing 21,269 and 19,795 cases, respectively). However, vaccination at age 70 years would prevent the most cases of PHN (6,439 cases per 1 million persons), followed by age 60 years and then age 50 years (preventing 2,698 and 941 PHN cases, respectively). From a societal perspective, vaccinating at age 70, 60, and 50 years would cost $37,000, $86,000, and $287,000 per QALY saved, respectively. The high cost per QALY saved with vaccination at age 50 years results from limited impact on prevention of PHN and other complications from ages 50 through 59 years and no remaining vaccine protection after age 60 when risk for PHN and other complications increases sharply. Results were robust in sensitivity analyses in which various more optimistic and pessimistic assumptions were made regarding waning of vaccine protection.

Because the protection offered by the herpes zoster vaccine wanes within the first 5 years after vaccination, and duration of protection beyond 5 years is uncertain, it is unknown to what extent persons vaccinated before age 60 years will be protected as they age and their risk for herpes zoster and its complications increases. Because duration of protection offered by the vaccine is uncertain, the need for revaccination is not clear. Assuming waning of vaccination protection according to currently available studies, the cost-effectiveness model projects a substantially greater reduction of disease burden, health care utilization, and costs with vaccination of older adults who have higher incidence of herpes zoster and related complications. Considering that the burden of herpes zoster and its complications increases with age and that the duration of vaccine protection in persons aged ≥60 years is uncertain, ACIP maintained its current recommendation that herpes zoster vaccine be routinely

recommended for adults aged ≥60 years.

With FDA approval, Zostavax is available in the United States and indicated for use among adults aged ≥50 years. Vaccination providers considering the use of Zostavax among certain persons aged 50 through 59 years despite the absence of an ACIP recommendation should discuss the risks and benefits of vaccination with their patients. Although the vaccine has short-term efficacy, there have been no long-term studies of vaccine protection in this age group. In adults vaccinated at age ≥60 years, vaccine efficacy wanes within the first 5 years after vaccination, and protection beyond 5 years is uncertain; therefore, adults receiving the vaccine before age 60 years might not be protected when their risks for herpes zoster and its complications are highest. CDC is actively monitoring postmarketing data on duration of vaccine protection in adults vaccinated at age ≥60 years. As additional data become available, ACIP will reevaluate the optimal age for vaccination and the need for revaccination to maintain protection against herpes zoster and its complications.

Corporate Services

HAWKE'S BAY
District Health Board
Whakawāteatia

29 September 2017

PHARMAC
PO Box 10254
WELLINGON

Email: vaccines@pharmac.govt.nz

Dear Sir/Madam

Proposal to Fund Zoster Vaccine

Thank you for the opportunity to provide feedback on the proposed amendment to the Pharmaceutical Schedule to list the zoster vaccine in Section B and in Part II of Section H of the Pharmaceutical Schedule to enable from 1 April 2018 people aged 65 years to get one funded zoster vaccine from their general practitioner, and with a 2-year catch up programme for people aged between 66 and 80 years inclusive.

Hawke's Bay District Health Board (HBDHB) supports this vaccine being placed on the Schedule and being made available via general practice, and strongly supports your intention to extend this to pharmacist vaccinators also. Pharmacist vaccinators would increase accessibility of this product to those who are not enrolled with a general practice or those unlikely to be able to access general practice services during working hours. Hawke's Bay has a significant aging population. The ability for our contracted pharmacist vaccinators to administer this funded vaccine to aged residential care facility residents in a coordinated approach would be welcomed.

We ask PHARMAC to reconsider the time frame of the catch up programme; a longer time frame would be welcomed to enable public awareness of this vaccine and provide general practice teams more time to recall all those who have not received the vaccination.

We are mindful there is a possibility that an administration fee may be charged, which could pose an access barrier for some in our community.

This submission has been compiled with guidance from the HBDHB Immunisation Coordinator, Hospital Pharmacy Manager (acting), Clinical Pharmacist Facilitator, Health Hawke's Bay PHO Clinical Advisory Pharmacist, and Strategic Services team members.

Yours sincerely

Dr Kevin Snee
CHIEF EXECUTIVE OFFICER

CHIEF EXECUTIVE'S OFFICE
Hawke's Bay District Health Board
Telephone section 9(2)(a) Fax 06 878 1648 Email: section 9(2)(a) www.hawkesbay.health.nz
Corporate Office, Cnr Omahu Road & McLeod Street, Private Bag 9014, Hastings, New Zealand

29 September 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

Dear Lindsay,

We thank you for the opportunity to provide feedback on the 'Proposal to fund the zoster vaccine' (17 Sept 2017).

The CCDHB/HVDHB Infection Service supports the initiative of funding Zostavax for the prevention of herpes zoster and the development of post herpetic neuralgia. We agree that listing the vaccine for those aged 65 years with the catch up programme should deliver optimal health outcomes within economic considerations. We agree with the clinical evidence that vaccinating at 50 years may not provide an adequate duration of immunity due to the waning efficacy of the vaccination over time.

Yours sincerely,

Dr Michelle Balm
Infectious Diseases Physician,
CCDHB

Dr Matthew Kelly
Infectious Diseases Physician,
HVDHB

On behalf of the Infection Services team at CCDHB/HVDHB

Prof. Tim Blackmore, Infectious Diseases Physician, CCDHB
Dr James Taylor, Infectious Diseases Physician, CCDHB
Dr Nigel Raymond, Infectious Diseases Physician, CCDHB
Dr Juliet Elvy, Clinical Microbiologist, WSCL
Dr Maxim Bloomfield, Senior Registrar, Infectious Diseases, CCDHB
Dr Olivia Bupha-Intr, Senior Registrar, Infectious Diseases, CCDHB
Chris Little, Anti-infective Pharmacist, CCDHB
Emma Henderson, Anti-infective Pharmacist, HVDHB

The Immunisation Advisory Centre (IMAC) Feedback – Re: Pharmac proposal to fund the zoster vaccine (Zostavax)

IMAC staff were asked to submit collective feedback on the above.

In summary, the following was collated and we would like to recommend Pharmac and the Ministry of Health considers these points:

IMAC supports the funding of the zoster vaccine for a national programme

- Request for consideration that Zostavax can be perceived as an 'older' vaccine and should we be waiting for the new subunit vaccine which appears much more immunogenic and possibly will give longer duration
- There is concern that the catch up programme in particular will be complex and create logistical difficulties for Primary Care, when General Practice is already under pressure to deliver a lot of new vaccines
- General Practice will need extra resources to support delivering the two year catch up
- We strongly recommend that General Practice be able to claim two separate Immunisation Benefit Subsidies if zoster vaccine and the influenza vaccine are given at the same time, as additional time is required for informed consent, preparation and delivery
- There are concerns regarding when the best time to give the vaccine is. This is based upon the individual and varies from case by case. Recognising that the vaccine immunity wanes within about seven years, but if given to very elderly the immune response is less vigorous, so there is a balance regarding when the best age to deliver this vaccine is.
- Not every 65 year-old is the same immunologically and we recommend a differential approach. Healthy elderly where the benefits are likely greater if the vaccine is given at a later age, versus those with significant comorbidities where the gains would be greater at a slightly younger age.

Some examples of these differential approaches:

- The general population are likely to benefit from age 70 as their immune response declines within around 7 years. Recent NZ data has just shown that the peak age of incidence in General Practice presentations is in the 80 – 90 year age group. Vaccinating at 65 years is too early and not likely to be effective at this peak age.
- Those with significant comorbidities could be advantaged by starting earlier e.g. from 65 years. The literature does identify some groups that are at higher risk of zoster, including cellular immune deficiencies, HIV infection, malignancies, organ transplants, immune-mediated disease of systemic lupus erythematosus and rheumatoid arthritis, chronic obstructive pulmonary disease, chronic kidney disease, type 1 diabetes and cardiac disease. We are happy to provide references regarding these conditions.
- Immunocompromised individuals cannot receive a live vaccine. There is a group that would benefit from being given the vaccine prior to becoming immunocompromised e.g.those starting on rheumatology immunosuppressive drugs or about to start chemotherapy.

IMAC is pleased that Pharmac is considering extending funding to include vaccinations for more vaccine preventable diseases. We are committed to working in partnership to support the delivery of a zoster vaccination programme.

NZMA
New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

27 September 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

By email: vaccines@pharmac.govt.nz

Proposal to fund zoster vaccine

Dear Lindsay

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. We note that PHARMAC is proposing to fund the zoster vaccine for the prevention of shingles for people aged 65 years, and with a 2-year catch up programme for people aged between 66 and 80 years inclusive. We note that this proposal is consistent with recommendations by PTAC and the Immunisation Subcommittee of PTAC. The NZMA is strongly supportive of this proposal.

We hope that our feedback is helpful.

Yours sincerely

K. Baddock

Dr Kate Baddock
NZMA Chair

NZMA
New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

4 October 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

By email: vaccines@pharmac.govt.nz

Proposal to fund zoster vaccine: supplementary submission

Dear Lindsay

Further to our submission of 26 September 2017, we wish to make a supplementary submission on the proposal to fund zoster vaccine. While PHARMAC is proposing to fund the zoster vaccine for the prevention of shingles for people aged 65 years, we note that PTAC's assessment in 2015 acknowledged that the vaccine may be more effective in younger groups. Accordingly, we ask PHARMAC to consider lowering the age threshold for this vaccine.

We hope that our feedback is helpful.

Yours sincerely

K. Baddock

Dr Kate Baddock
NZMA Chair

NEW ZEALAND NURSES ORGANISATION
TŌPŪTANGA TAPUHI
KAITIAKI O AOTEAROA

2017-09/007
TD102
29 September, 2017

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

By email: vaccines@pharmac.govt.nz

Tenā koe

Re Proposal to fund zoster vaccine for the prevention of shingles (herpes zoster) for over 65 year olds

The New Zealand Nurses Organisation warmly welcomes the proposal to fund the zoster vaccine. We have consulted with nurse members in relevant colleges and sections, including the College of Primary Health Care Nurses, Infection Prevention and Control Nurses College and the Gerontology Nurses Section who enthusiastically support the proposal which will prevent suffering to a large group of New Zealanders who are at increased risk from this infectious disease. Nurses are particularly pleased that PHARMAC has factored in a 'catch up' phase to for those up to the age of 80 years.

We note, however, that co-payments remain a barrier to equitable access to funded vaccines and draw your attention to the fact that few aged care facilities currently offer the funded 'flu vaccine to their residents. Retirement villages generally either provide them for free or at least organize them, though many residents prefer to go to their own GPs. We urge PHARMAC to facilitate ways of ensuring that all those aged 65 years enjoy the same access to funded vaccines.

Nāku noa, nā

Marilyn Head

Marilyn Head BA, Dip Tchg, M Sc, PGCert PH
Senior Policy Analyst
section 9(2)(a)
section 9(2)(a)

National Office
Level 3
Crowe Horwath House
57 Willis Street
Wellington 6011
PO Box 2128
Wellington 6140
T 0800 28 38 48
www.nzno.org.nz

Southern District Health Board
Piki Te Ora

Public Health South

Dunedin: Private Bag 1921, Dunedin 9054
Ph: 03 476 9800 Fax: 03 476 9858

Invercargill: PO Box 1601, Invercargill 9840
Ph: 03 211 8500 Fax: 03 214 9070

Queenstown: PO Box 2180, Wakatipu, Queenstown 9349
Ph: 03 450 9156 Fax: 03 450 9169

SUBMISSION TO PHARMAC ON PROPOSAL TO FUND ZOSTER VACCINE

To: **Dr Lindsay Ancelet**
Therapeutic Group Manager
PHARMAC
P O Box 10254
WELLINGTON 6143

Details of Submitter: **The Southern District Health Board**

Address for Service: **Southern District Health Board**
PO Box 1601
INVERCARGILL 9840

Contact Person: **Jillian Boniface**
section 9(2)(a)
section 9(2)(a)

Our Reference: **17Sept08**

Date: **2 October 2017**

Introduction

Southern District Health Board (SDHB) presents this submission through its public health service, Public Health South (PHS). This Service is the principal source of expert advice within Southern DHB regarding matters concerning Public Health. Southern DHB has responsibility under the New Zealand Public Health and Disability Act 2000 to improve, promote and protect the health of people and communities. Additionally there is a responsibility to promote the reduction of adverse social and environmental effects on the health of people and communities. With 4,250 staff, we are located in the lower South Island (South of the Waitaki River) and deliver health services to a population of 306,500.

Public health services are offered to populations rather than individuals and are considered a "public good". They fall into two broad categories – health protection and health promotion. They aim to create or advocate for healthy social, physical and cultural environments.

General Comments

This submission is in response to the Pharmac discussion document: 'Proposal to fund Zoster Vaccine'. Southern DHB is responding to this discussion document through the Vaccine Preventable Disease (VPD) Team as part of the Public and Population Health Services. Vaccination programmes are delivered predominantly through the 89 General Practices (members of the WellSouth Primary Health Network) with professional oversight provided by the Medical Officers of Health and VPD Team.

Southern DHB understands and supports the rationale of funding the zoster vaccine for those aged 65 – 80 years. We understand the vaccine efficacy for those aged over 80 years provides minimal protection.

Assumptions:

- For those who are offered the **one** funded vaccine at 65 years, we assume there will be guidance of the value or otherwise regarding any further booster dose.
- The consultation document refers several times to the zoster vaccine being administered concurrently with the Flu vaccine. We assume the immunisation administration fee can be claimed when given separately/out of season to the Flu vaccine.

Recommendation

We recommend that from 1 April 2018 funding for the zoster vaccine (Zostavax) for people aged 65 years and over is implemented, and this includes a two year catch up for people aged between 66 and 80 years.

Jillian Boniface
District Programme Leader, Vaccine Preventable Disease Team

From: Sue Stevens <section 9(2)(a)>
Sent: Wednesday, 20 September 2017 1:37 p.m.
To: Vaccines
Subject: Proposal to Fund Zostervax submission

Good afternoon Lindsay,

Here are my comments and submission:

I am enthusiastic about the proposal to fund Zostervax to the elderly population from 65 years through to 80 years of age.

I have always been led to believe (and from what I've read) that Shingles is prevalent from the 50th year onwards and the burden of residual pain and neuralgia would be for longer.

When Zostervax was promoted in NZ a few years ago, it was targetted at those in their 50's.

I would like to see the vaccine available for 50years of age.

Kind regards – sue
(also Outreach Immunisation Nurse)

Sue

Sue Stevens R/N

Support Net
Kupenga Hao Ite Ora
Needs Assessor/Service Coordinator
510 Cameron Road
Tauranga 3112

section 9(2)(a)
section 9(2)(a)
F: section 9(2)(a)
E: section 9(2)(a)

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From: andrew and section 9(2)(a) rawstron <section 9(2)(a)>
Sent: Friday, 6 October 2017 9:49 p.m.
To: Vaccines
Subject: Give shinlges vaccine at a 65 year old recall not at flu season and fund the giving of this with the tetanus vaccine

Dear Pharmac,
This is some feedback on you proposal to provide funding for Shingles vaccination.

I think it is good to fund and provide the shingles vaccine in a funded vaccination programme.

I disagree that it should be given at the same time as the flu vaccination.

I have concern about General practice capacity to provide 2 vaccines at once in the flu vaccine season. The flu vaccine season is a pressured time to give many vaccines in one month. Giving two vaccines slows this down and there is no extra funding to provide this. The giving of vaccines is underfunded and does not met the cost of providing the service.

Also with recent decision to let pharmacies provide the flu vaccines there is less incentive to provide recall services for this vaccine because the patient may go elsewhere. Maybe you now need a separate recall contract to provide this service.

I think it would be more appropriate to fund a vaccination programme at the 65th birthday and fund the giving of tetanus and shingles at the same time to allow the funded tetanus vaccine to be given to lift the rates of the population of 65+ year olds to be covered for this disease. The flu vaccination should be given separately.

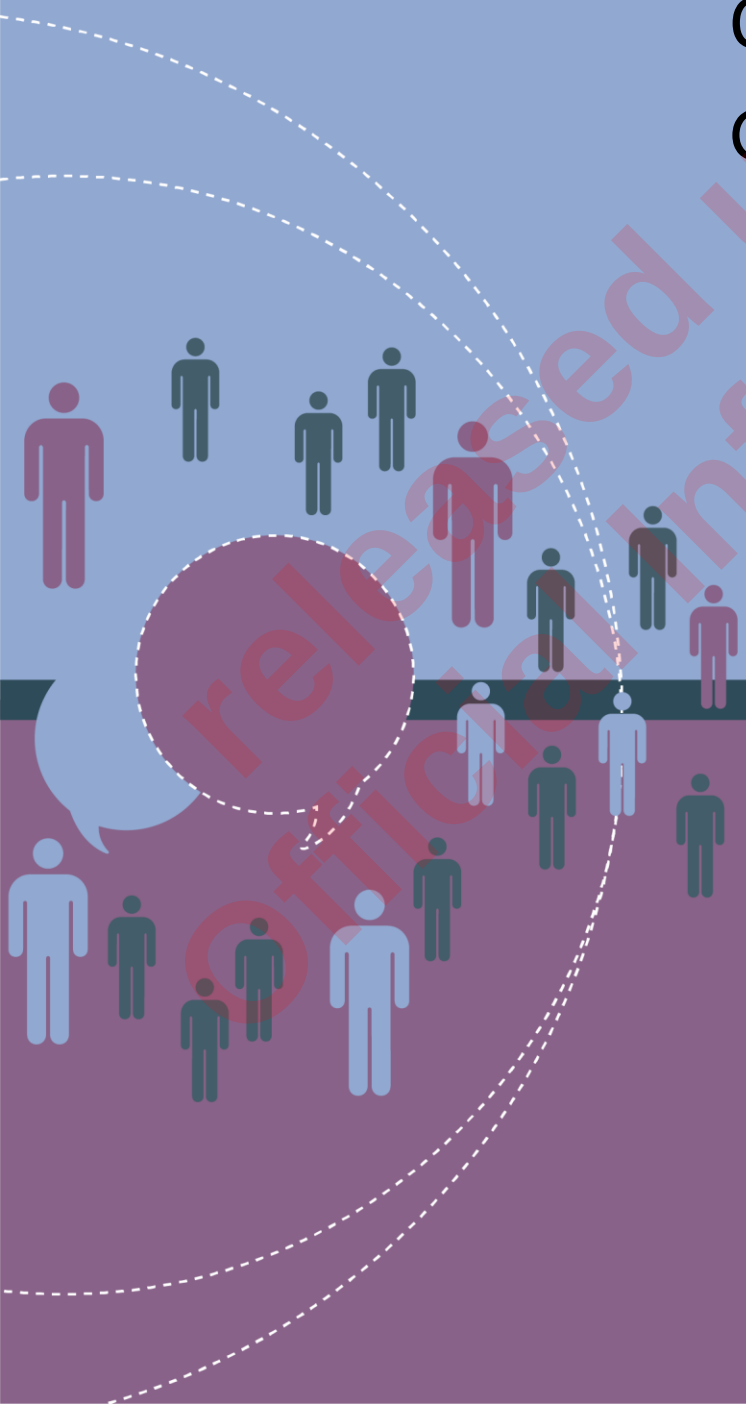
I would recommend the shingles be given at the same time as tetanus vaccination and that these 2 vaccines be funded to be given together at the same time rather at time pressured flu session.

yours sincerely

Dr Andrew Rawstron
GP
Leeston Medical Centre
MB.ChB., DCH, DipsOBS, FRNZCGP, MBA.

PHARMAC Board Meeting

Consumer / Consumer Group Feedback



From: section 9(2)(a) <section 9(2)(a)>
Sent: Friday, 15 September 2017 10:52 a.m.
To: Vaccines
Subject: RE Consultation on proposal to fund zoster vaccine

I'm writing in support of the proposal to fund the zoster vaccine (Zostavax) for the prevention of shingles, and also the price reduction for Fosamax and Fosamax Plus.

section 9(2)(a)

From: section 9(2)(a) <section 9(2)(a)>
Sent: Tuesday, 19 September 2017 1:14 p.m.
To: Vaccines
Subject: Shingles vaccine for over 65's

Is there no provision for people over 80? If not, why not?

section 9(2)(a)

To: Vaccines[vaccines@Pharmac.govt.nz]
From: section 9(2)(a)
Sent: Wed 20/09/2017 11:45:27 p.m
Importance: Normal
Subject: Shingles Vaccination: Zostavax proposal
MAIL_RECEIVED: Wed 20/09/2017 11:45:45 p.m

While I applaud the effort to ensure over 60 year olds are vaccinated against shingles, I have a few questions.
Why choose a vaccine that:
A. Uses live vaccine
B. Is only about 50 percent effective
When Shinglerix is meant to be 90 percent effective and does not use live vaccine.
Surely it is worth considering the effectiveness of the vaccine before funding it?
I had the Zostavax vaccine in 2014 and got a bad dose of disseminated shingles in 2017. It seems a myth that if you get shingles post Zostavax shingles vaccine, it will be a milder dose.

Best regards
section 9(2)(a)
Sent from my iPad

From: section 9(2)(a) <section 9(2)(a)>
Sent: Friday, 15 September 2017 3:09 p.m.
To: Vaccines
Subject: Zostavax

I support the scheme to introduce Zostavax vaccine to the population over 65. I am 77 and understand this would not apply to me until next year.

section 9(2)(a)
section 9(2)(a)
section 9(2)(a)

To: Vaccines[vaccines@Pharmac.govt.nz]
From: section 9(2)(a)
Sent: Fri 15/09/2017 7:59:47 a.m
Importance: Normal
Subject: Shingles Vaccine Eye Damage
MAIL_RECEIVED: Fri 15/09/2017 8:00:15 a.m

ATTENTION

https://www.longolegal.com/shingles-vaccine-zostavax-eye-damage/

Given the known problems and poor efficacy of this vaccine Zostavax and having studied the clinical trials and Product Monograph, placebo used, adverse outcomes etc....as well as this attachment and other assorted 2017 updates on the legal action against Merck, in 2017, a vaccine company with an atrocious history of unsafe vaccines and corruption, for which they are also in Court over still, I find it astounding, that Pharmac is contemplating the use of this vaccine at all and prepared to trust such manufacturer that has such a poor record. What are you thinking?!

As an authority that is meant to regulate, assure and protect, along with Medsafe, your credibility is fast facing, in my opinion.
You must have more money than sense, or tax payers money..

Do the words Precautionary Principle come to mind, or the common sense to just say NO to this one and save some money and suffering, by those NZ consumers, who may develop Necrotizing retinitis or other ophthalmic pathologies, after receiving this vaccine, or any of the other adverse effects.

Will you tell them, sorry it's 'just a coincidence,' a ' rare occurrence,' 'temporally linked only,' ...sorry no ACC, but thanks for being an unpaid lab rat and giving us more proof of something we knew already. More importantly, will these consumers be afforded full disclosure of these adverse events, many of whom will be on a myriad of drugs which might be contraindicated with this vaccine, or any if its contents, who might be immune compromised and not know it. What screening will you suggest for health professionals to protect their patients to establish if it us safe to administer Zostavax to them.

Will you tell them about the 'exclusion criteria' that was used in the clinical trials, which probably excluded people like them, yet, they are now considered to be at risk and needing this vaccine, even though it was never tested on people like them in those pre licensing clinical trials?

It seems to me that your organisation has some thinking to do about this.
Can you honestly say that the benefits outweigh the risks? Surely more evaluation is required. Cost benefit analysis?

Maybe consider how the Varilrix vaccine is contributing to this problem of Shingles. This is not rocket science if you understand Immunology right?

P.S IMAC need to update their information on this, regarding adverse effects...

Yours Sincerely,
section 9(2)(a)

From: section 9(2)(a) <section 9(2)(a)>
Sent: Sunday, 1 October 2017 3:32 p.m.
To: Vaccines
Subject: ZOSTAFAX

I whole heartedly support the availability of the Zoster vaccine for persons over the age of 65.
Shingles is such a debilitating disease and those in the older age groups need to be protected.
section 9(2)(a)

From: section 9(2)(a) <section 9(2)(a)>
Sent: Wednesday, 27 September 2017 11:03 a.m.
To: Vaccines
Subject: Vaccine feedback

To Management:- Pharmac.

Thank you for the opportunity to contribute to your proposal to subsidize the Herpes zoster Vaccine.
In my view as a 71 yr old who, as a child, contracted chicken pox and had 'cold sores' in the winter, there is a possibility could contract 'shingles' in my 'senior years' I believe? In good health at present but if the vaccine has a preventive measure for citizens in the future, there could be less of a burden on New Zealand's health budget and Health personnel, rather than complex treatment, ongoing health issues of those that contract the virus.
With thanks,
section 9(2)(a)

Glenburn Retirement Village
79 Margan Avenue
New Lynn
Auckland 0600

2nd October 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

Ref: Proposal to fund zoster vaccine

I am writing on behalf of the 65 residents of the Glenburn Retirement Village and the Retirement Village Residents Committee.

We commend your proposal to fund the zoster vaccine and support your efforts to introduce the vaccine from 1 April 2018.

However, we are concerned that the cut off age for eligible recipients would be 80 years. The average age of residents in this village is 84. Therefore, we estimate that only 10% of our residents would qualify for vaccination under your proposal, at this time.

While we appreciate that the effectiveness of the vaccine is, according to your proposal, only 18% at that age, we expect that this would improve as the vaccine becomes more effective over time.

We note that you think retirement villages will be interested, but with the age restriction on eligibility, it is our opinion that most villages will be in a similar situation to ourselves, and will not be eligible. Many villages do not allow entry now before age 75, therefore their average age will be similar if not higher, than ours.

While we applaud your initiative, we believe your eligibity criteria should be revisited to give 80+ year olds a better deal in their old age.

Thank you for your consideration.

section 9(2)(a)

section 9(2)(a)

GREY POWER NZ INC. SHINGLES VACCINE SUBMISSION

To Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
Po Box 10254
Wellington 6143

Email: vaccines@pharmac.govt.nz

1. Introduction

1.1 This submission is made on behalf of the **Grey Power New Zealand Federation Inc.**

1.2 The contact is Jo Millar – phone 03 455 4234

Email: section 9(2)(a)

1.3 The Grey Power New Zealand Federation (Inc) is a non-sectarian and non-party political, advocacy organisation that aims to advance, promote and protect the welfare and well-being of people 50 years old plus.

1.4 The Grey Power New Zealand Federation (Inc) is made up of some 75 individual Associations with an overall membership of approximately 68,000.

2. General Comments

2.1 Grey Power supports and has lobbied for subsidised or free Zoster vaccine for older people because we understand that shingles;

a) is becoming more prevalent in New Zealand,
b) may affect 40 per cent of people between the ages of 45-85, more women than men[1] and for those over the age of 85 years the odds of contracting the infection move to 50 percent along with the likelihood of a more severe attack, [2]

[1] https://www.sciencedaily.com/releases/2011/02/110201122536.htm
[2] Fuatai. T; shingles risk on the rise, NZ Herald; Feb 16, 2014

c) can progress to post-herpetic neuralgia (PHN) which may cause severe pain, depression, fatigue and social isolation for months or even years after the shingles rash has disappeared,[3]
d) vaccine side effects are usually quite minor,[4]
e) vaccine can be administered at the same time as the influenza vaccine, therefore it will be more convenient for many older people.

Conclusion:
Grey Power thanks PHARMAC for this opportunity to comment and support the free Zostavax vaccine for older people. We believe that although the efficacy rate decreases with age, because the vaccine side effects are minor, its provision with no charge to older people, coincides with our main objective 'to advance, support and protect the welfare and well-being of older persons in New Zealand.'[5]

Written on behalf of Grey Power by section 9(2)(a) – Co – Coordinator Grey Power Advocacy Standing Committee

[3] https://www.health.harvard.edu/pain/shingles-vaccination-pros-and-cons
[4] http://www.nytimes.com/2007/10/03/health/03iht-snbrody.1.7730476.html
[5] Grey Power constitution p.6 2017

To: Vaccines[vaccines@Pharmac.govt.nz]
From: section 9(2)(a)
Sent: Tue 3/10/2017 6:48:19 p.m
Importance: Normal
Subject: zoxter vaccine
MAIL_RECEIVED: Tue 3/10/2017 6:48:54 p.m

;
Good morning

Grey Power Zone 7 comprising 7 Associations from Oamaru; Dunedin; Balclutha; Alexandra ;Gore; Invercargill and Queenstown commend and thank Pharmac for their consideration of the introduction of a vaccine for Shingles for people over the age of 65.

section 9(2)(a)

Zone 7 Representative

Grey Power

From: section 9(2)(a)
Sent: Sunday, 24 September 2017 1:50 p.m.
To: Vaccines
Subject: Fund for zoster

I am in total support of this proposal to fund zoster vaccine having had mild dose of shingles and seeing how sick some friends have been
Owing to the current cost we in the age group 65+ find the cost of this too costly especially with all the other high costs of doctors' fees and
Repeat prescriptions any vaccine for shingles intends to be put to the back and hope for the best, that you do not have to suffer in silence

section 9(2)(a)
Orewa

From: section 9(2)(a) <section 9(2)(a)>
Sent: Wednesday, 4 October 2017 11:33 a.m.
To: Vaccines
Subject: Injections

I am 68yrs and I would like to have the injection as I would not like too have shingles.
Thank you section 9(2)(a)

Sent from my iPad

To: Vaccines[vaccines@Pharmac.govt.nz]; Nikki Turner[n.turner@auckland.ac.nz]
From: section 9(2)(a)
Sent: Sat 16/09/2017 6:25:42 p.m
Importance: Normal
Subject: Fwd: Variola vaccine
MAIL_RECEIVED: Sat 16/09/2017 6:26:03 p.m

;;

Sent from my Samsung Galaxy smartphone.

-------- Original message --------
From: section 9(2)(a)
Date: 17/09/17 6:21 AM (GMT+12:00)
To: vaccines@pharmac.co.nz
Subject: Variola vaccine

As an 86 year old I suppose I need to contest the decision to limit the catch up age to 80.
I have no personal interest in this as I had mine a few years ago tho it cost me $50.
I can see the logic behind your decision but I wonder about the robustness of the data in those over 80.
We are not that numerous but are divisible into two groups the halt blind and the lame and those who seem to have relatively good health. I would like to suggest that you fund a small study of healthy 80 plus year olds to see if the current limit is defensible.
The is of course the wisdom of setting one age thereafter at 65. I seems like a good idea but it doesn't take account of human nature. The people who are least likely to get the vaccine are the most dispossessed who may have no personal relationship with a gp or are moving or lack motivation born of despair.
I think a more humane way of doing this would be to keep a national record of those who get the vaccine and instituting a programme to catch those who haven't. As you know the current government plan for a single medical record makes this possible.
Yours with one foot in the grave.
section 9(2)(a)
section 9(2)(a)

PS shingles might reduce the amount of dirt that has to be shoveled Ion too of the casket.

Sent from my Samsung Galaxy smartphone.

From: section 9(2)(a) <section 9(2)(a)>
Sent: Friday, 15 September 2017 11:58 a.m.
To: Vaccines
Subject: Proposal to fund zoster vaccine Submission

Good morning

I strongly support the proposal to fund the zoster vaccine.

I currently have both my parents I would like to have vaccinated but the price of at least $200 each is cost prohibitive, especially on a pension. Even for me to pay for them would mean financial issues.

I feel this would be an excellent use of public funds with our aging population as it is such a debilitating illness, exacerbated by the age you can develop it and causing increased vulnerability. A programme would also eventually have a finite end as those children receiving varicella vaccine now (so will not carry the virus into their senior years) will not require zoster vaccination.

Although still more vulnerable to complications, Seniors are increasingly staying productive in their advancing years. If not in paid employment still, often they volunteer or care for grandchildren, for example. If struck down by this illness, therefore, their absence can still cause far-reaching consequences for workplaces, family and their community so the benefits of funding the vaccine and, therefore, increasing vaccine uptake has wider benefits than just on the individual's health.

Regards - section 9(2)(a) New Plymouth

From: section 9(2)(a) <section 9(2)(a)>
Sent: Monday, 18 September 2017 4:40 p.m.
To: Vaccines

What a wonderful idea unfortu natl;y I suffer from blood disorder myleodisplasia and have been told thjat I cant have the shingle vaccine Best folk to check thanks

From: section 9(2)(a)
Sent: Tuesday, 3 October 2017 6:25 p.m.
To: Vaccines
Subject: Shingles Vaccine - Zostavax

Hi,

Reference the above and Pharmac's review whether to fund Zostavax.

"PHARMAC is seeking feedback on a proposal to fund the zoster vaccine (Zostavax) for the prevention of shingles (herpes zoster) from 1 April 2018 through a provisional agreement with Merck Sharpe & Dohme Limited."

I note that at 13 Sept 17 a U.S. Food and Drug Administration advisory panel on voted 11-0 that the safety and efficacy of GlaxoSmithKline's Shingrix shingles vaccine warrants approval for its use in adults aged 50 and over. Listed below is the applicable link.

http://www.businessinsider.com/r-update-1-fda-panel-unanimously-votes-to-recommend-gsk-shingles-vaccine-2017-9?IR=T

It appears that the GSK vaccine is significantly more effective than the Zostavax vaccine. The Pharmac web site does not make reference to the GSK vaccine as a possible alternative. I assume the GSK product has been considered and the potential benefits evaluated?
Assume the Merck proposed deal does not lock out the GSK product for an extended period?

It also appears that part of the proposal for the Zostavax vaccine results in reduced purchase prices for other Merck products. This would appear to be possibly an anticompetitive approach by the supplier, ie the value vs price of the vaccine is not standing on its own merits.

I stumbled across the Pharmac website when researching my wife's recent bout of Shingles and 20 year old daughter's subsequent chickenpox. (Id recommend that there is more advertising on the availability of the chickenpox vaccine , we would certainly have paid for the vaccine if we had been more aware and possible effects of chickenpox on adults).

Regards

section 9(2)(a)

To: Vaccines[vaccines@Pharmac.govt.nz]
From: section 9(2)(a)
Sent: Mon 18/09/2017 6:24:33 a.m
Importance: Normal
Subject: Shingles vaccine
MAIL_RECEIVED: Mon 18/09/2017 6:24:44 a.m

;;
Dear Sir/Madam
As a shingles sufferer I urge you to provide this vaccine. I had it on one of my legs 3 years ago and still suffer from it.
Please please make this vaccine free of charges excepting the usual prescription charge.
Yours sincerely
section 9(2)(a)

To: Vaccines[vaccines@Pharmac.govt.nz]
From: section 9(2)(a)
Sent: Wed 4/10/2017 9:59:28 a.m
Importance: Normal
Subject: Zostavax
MAIL_RECEIVED: Wed 4/10/2017 9:59:56 a.m

;;
Dear Staff,

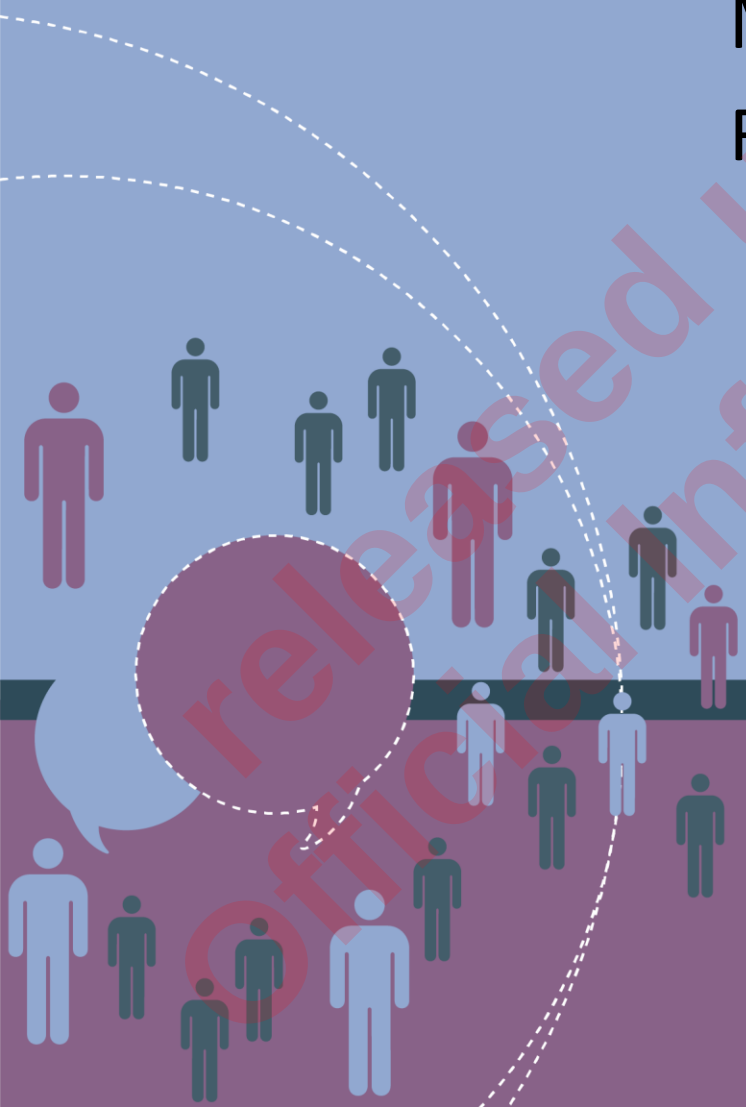
I fully support the funding of this vaccine for older kiwis

section 9(2)(a)
GP
Wellington

PS can you also inform me when Bexsero (Meningococcal B)will be licensed in NZ as it is in UK, USA, Australia?

PHARMAC Board Meeting

Ministry of Health Feedback



MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

2 October 2017

Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

Dear Lindsay

Re: Feedback on proposal to fund zoster vaccine consultation

The Ministry of Health (the Ministry) welcomes the opportunity to provide feedback on PHARMAC's consultation document *Proposal to fund zoster vaccine*.

The Ministry's position

The Ministry supports PHARMAC's proposal to fund the zoster vaccine (Zostavax) for the prevention of shingles (herpes zoster) in those aged 65 years and over. Given the high incidence of zoster and potential for long-lasting complications, we believe that the vaccine would be a valuable addition to the National Immunisation Schedule and would have benefits for those most at risk of shingles.

The Ministry's feedback relates to the details of the proposal, in particular, availability through pharmacies and timing of the vaccine introduction.

Age at vaccination

The Ministry notes that the determination of the age of vaccination was largely a financial decision taking into account budget impact and the cost-utility analysis, and declining efficacy of the vaccine with age.(PTAC meeting minutes; 13-14 August 2015) We understand that the Pharmacology and Therapeutics Advisory Committee (PTAC) concluded that the cost of vaccination would outweigh the benefits in younger age groups because, while the vaccine is more efficacious in younger age groups, the cost would be too high due to the larger numbers of people that could be vaccinated.

Whilst the Ministry accepts that this approach is reasonable based on current evidence and to coincide with the age for funded influenza immunisation for elderly people, it should be noted that other countries such as Australia and the US recommend zoster vaccine from age 60 years. The Ministry therefore recommends that the question of the most appropriate age for vaccination be revisited should the cost:benefit for younger

age groups change due to a decrease in vaccine costs and/or change in zoster epidemiology.

The Ministry supports a time-limited catch-up programme via general practice to allow for all people over the age of 65 years the opportunity to receive one dose of zoster vaccine, up to age 80 years. However, the Ministry currently has no allocated resources to support any public messaging regarding this and we welcome the opportunity to discuss this further with PHARMAC.

Co-delivery of the influenza and zoster vaccines

The Ministry is in agreement with PHARMAC that co-delivery of the zoster vaccine with the influenza vaccine for those aged 65 years and over would be the most efficient model of service delivery and has the potential to increase coverage for both vaccines. In the UK, it has been estimated that 75 percent of patients receive the zoster vaccine at the same time as the influenza vaccine, and 25 percent receive the zoster vaccine outside of the influenza season.

However, the Ministry feels that access to zoster vaccine through pharmacies needs to be enabled as a priority in order to maximise the co-delivery model. The Ministry is committed to supporting expanded access to vaccines to benefit communities, including provision of funded influenza vaccine through pharmacies for those aged 65 years and older. The zoster vaccine was reclassified in 2013 to be a prescription medicine 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 a vaccinator training course approved by the Ministry and who is complying with the immunisation standards of the Ministry.

As noted by PTAC, there will be an additional administration cost to the health sector of $20 for the zoster vaccine if it is not given at the same time as the influenza vaccine. (PTAC meeting minutes; 13-14 August 2015). Furthermore, there is a risk that older people presenting to pharmacies for the influenza vaccine will not return to their general practice to receive the zoster vaccine, leaving them vulnerable to shingles.

Introduction of zoster vaccine at the start of the influenza vaccine season has the potential to support co-delivery and ensure good uptake. However, if the two vaccines cannot be co-delivered, there is the potential for the workload for general practices to be increased at one of their busiest times of the year, especially when they also need to focus on providing influenza vaccine to individuals aged under 65 years with certain medical conditions. Availability of zoster vaccine through pharmacies would help manage this workload.

Timing of vaccine introduction

We note that the proposed date of zoster vaccine introduction is 1 April 2018. This is Easter Sunday. An introduction date of Tuesday 3rd April would enable a smoother transition for updating of IT and practice management systems.

The Ministry would also like noted that the lead time to April 2018 is tight for the work that is required to support the implementation. In order for smooth implementation of the zoster vaccine, the Ministry asks PHARMAC to confirm all changes and criteria as soon

as possible. Any delays to PHARMAC's decision making will place pressure on the ability of the Ministry to complete all the tasks required for successful implementation of the vaccine by 1 April 2018.

Conclusion

The Ministry supports PHARMAC's proposal to fund the zoster vaccine for the prevention of shingles in those aged 65 years and over. We note that an introduction date of 3 April 2018 may be more appropriate. We request that longer lead times are allowed for in future vaccine introductions.

The Ministry requests that PHARMAC prioritises the changes that are needed to enable funded zoster vaccine to be delivered in pharmacies to support co-delivery with influenza vaccine for those aged 65 years and over.

Yours sincerely

Rayoni Keith
Manager, Immunisation
Service Commissioning
Ministry of Health

MINISTRY OF HEALTH
MANATŪ HAUORA

29 September 2017

179 St Hill Street
Private Bag 3015
Whanganui Mail Centre
Whanganui 4540
New Zealand
T +64 6 349 1990

Therapeutic Group Manager
PHARMAC
PO BOX 10 254
Wellington

Re: Proposal to fund zoster vaccine

Thank you for providing the Ministry of Health with the opportunity to respond to this consultation.

Based on the information contained in the consultation document of 15 September 2017, the Ministry of Health advise that no technical or resource impacts are anticipated as a result of your proposal.

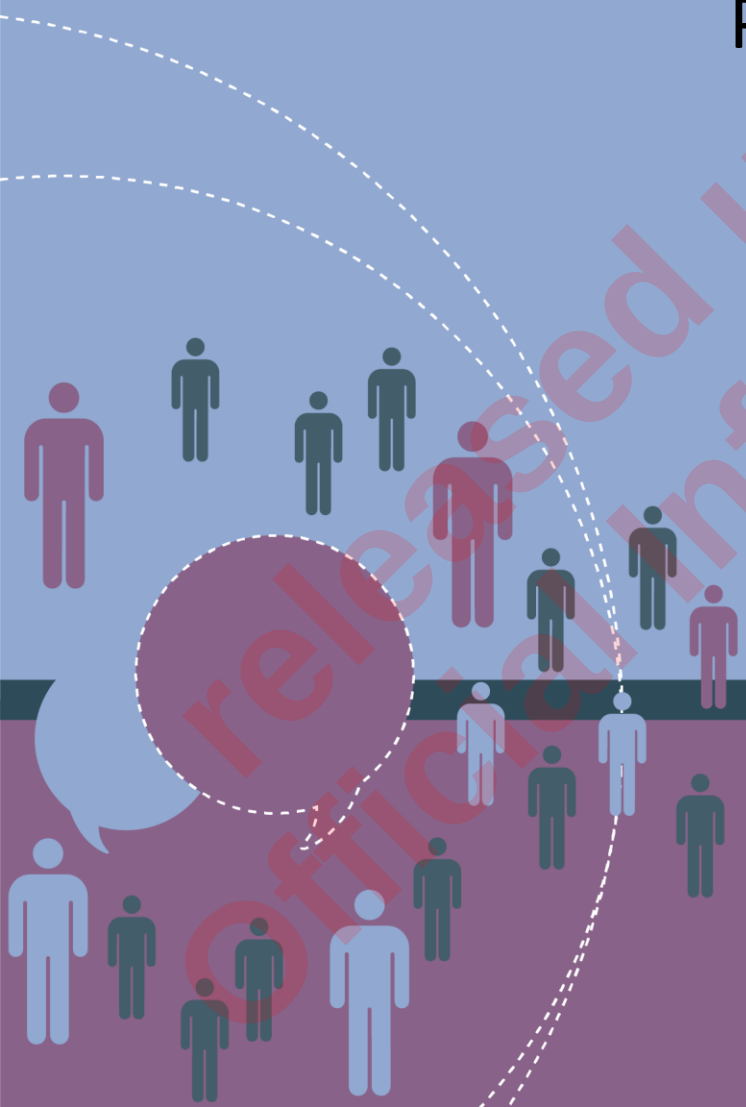
If you would like to discuss the content of this letter, please do not hesitate to contact me by email [redacted] section 9(2)(a)

Yours sincerely

Mandy Benson
Operations Analyst
Operational Support
Ministry of Health

PHARMAC Board Meeting

Pharmacy Feedback



3rd October 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

Re: **PROPOSAL TO FUND ZOSTER VACCINE**

Dear Lindsay,

Thank you for the opportunity to comment on the above-mentioned proposal. We are fully supportive of the funding of Zoster Vaccine for those 65 years of age and older. We have taken the opportunity to provide the following feedback:

1. The proposed age group of people who are eligible to receive a funded vaccine to protect against Shingles aligns with those people 65 years of age and over, who are eligible to receive a funded Influenza vaccine. As Zoster vaccine can be administered at the same time as the Inactivated Influenza Vaccine we suggest that it is important to align the proposed funding date of Zoster from April 2018 to commence at the same time as the 2018 funded Influenza vaccine. This would ensure that the eligible cohort of people would not be required to make two separate trips to access both vaccines. The proposal states that people would be able to receive their vaccines at the same time but the funding dates do not align for both. Influenza Vaccine is typically available and distributed towards the end of February beginning of March each year.

2. We are disappointed that the funding of Zoster vaccine does not extend to Community Pharmacists. Community Pharmacists who are vaccinators have been providing funded Influenza vaccine nationally to those 65 years and older since 2017. This has seen Pharmacists administering Influenza vaccines to those eligible people who are in rest home and retirement villages and this aligns with those who would be eligible for a Zoster vaccine. It is not a good use of healthcare professionals time to administer one vaccine and then refer the person to another healthcare professional for a separate vaccine, when they are trained, willing and able to support the programme by administering both vaccines. This defeats the purpose of convenient access and fostering increased uptake of the Zoster vaccine. Pharmacists have been administering Zoster vaccine to their communities since 2014 after a successful reclassification process. They are well versed with the administration of Zoster vaccine.

   The more barriers placed in the way of access can lead to reduced uptake and those most vulnerable not receiving the vaccine. As you have not been specific as to why

Pharmacists have been excluded from the funding of Zoster vaccine, we would welcome further clarification from you on this matter so that we could provide a response to address the concerns you may have that could support you in reconsidering your position on the funding of Zoster vaccine through Pharmacists.

You have outlined the impact of Shingles on our population and so we are sure you would welcome the ability to have the Zoster vaccine available through the touch points that this cohort of people would see on a frequent basis, namely Community Pharmacists.

Pharmacists have had access to the ImmuniseNow web portal since the end of 2016 and it has proven to be a reliable repository for documenting the administration of Influenza vaccine by person. The Zoster vaccine could be added to this recording system thereby reducing fragmentation of care. Pharmacists feedback on the use of this system has been very positive. Pharmacists have also accessed their Flu vaccine from the same Logistics Provider as other vaccinators and we anticipate this would be the same in accessing Zoster vaccine. There would be no need to set up any separate mechanism for access to the vaccine by Community Pharmacists.

Community Pharmacists have shown over the years their ability to support and contribute to national health programmes and feedback from Pharmacists indicates that they are very supportive of being part of this programme to protect our most vulnerable.

We hope you will look favorably on the above feedback as we believe that Community Pharmacists who are vaccinators could make a significant contribution to the awareness and uptake of the Zoster vaccine.

I look forward to hearing from you.

Yours Sincerely,

ALISON VAN WYK
Executive- Professional Services
Green Cross Health
section 9(2)(a)

PHARMACY GUILD OF NEW ZEALAND

3 October 2017

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Sent via e-mail to: vaccines@pharmac.govt.nz

Dear Lindsay

RE: Proposal to fund zoster vaccine

Thank you for the opportunity to provide feedback on the above consultation.

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing the majority of community pharmacy owners. We provide leadership on all issues affecting the sector and advocate for the business and professional interests of community pharmacy.

Our feedback on this consultation focuses on Guild members' concerns around general economic, funding and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, issues of safety, efficacy or individual patient utility.

We support the decision to fund the zoster vaccine to people aged 65 years from 1 April 2018. This would increase access to the vaccine to those who are most at risk of developing shingles.

Although PHARMAC have suggested funded zoster vaccine may be available through community pharmacy in the future, we are disappointed people will not be able to access the funded zoster vaccine through their community pharmacy from 1 April 2018.

Since 2012, pharmacists who have successfully completed an approved vaccinator training course have been providing vaccines, including the zoster vaccine, to many New Zealanders who can afford to pay. Today there are over 600 pharmacists who can provide vaccines across approximately 300 pharmacies. We believe allowing pharmacists to provide the funded zoster vaccine will make use of the additional skills of vaccinating pharmacists, and support an integrative care model.

Since April 2017 vaccinating pharmacists have been able to provide funded influenza vaccine to people aged 65 and over. Like the influenza vaccine, we feel eligible people should be able to choose whether they receive their funded zoster vaccine from their community pharmacy or their general practice, as this will increase access and help address health inequalities, and help reduce burdens in other areas of the health system.

Like general practitioners, pharmacists would also be able to offer the funded zoster vaccine at the same time an eligible patient received their annual influenza vaccine.

Allowing funded zoster vaccine available through community pharmacy makes sense as pharmacies are often the part of the health system that people have the most regular contact with and the easiest access to. Additionally, some pharmacies offer an offsite vaccination service. To help improve access and uptake of zoster vaccines among the elderly several pharmacies will be able to provide an offsite vaccination service at local rest homes and retirement villages.

We would like to see supply and funding mechanisms put in place that would allow people to access funded zoster vaccine from either their community pharmacy or their general practitioner.

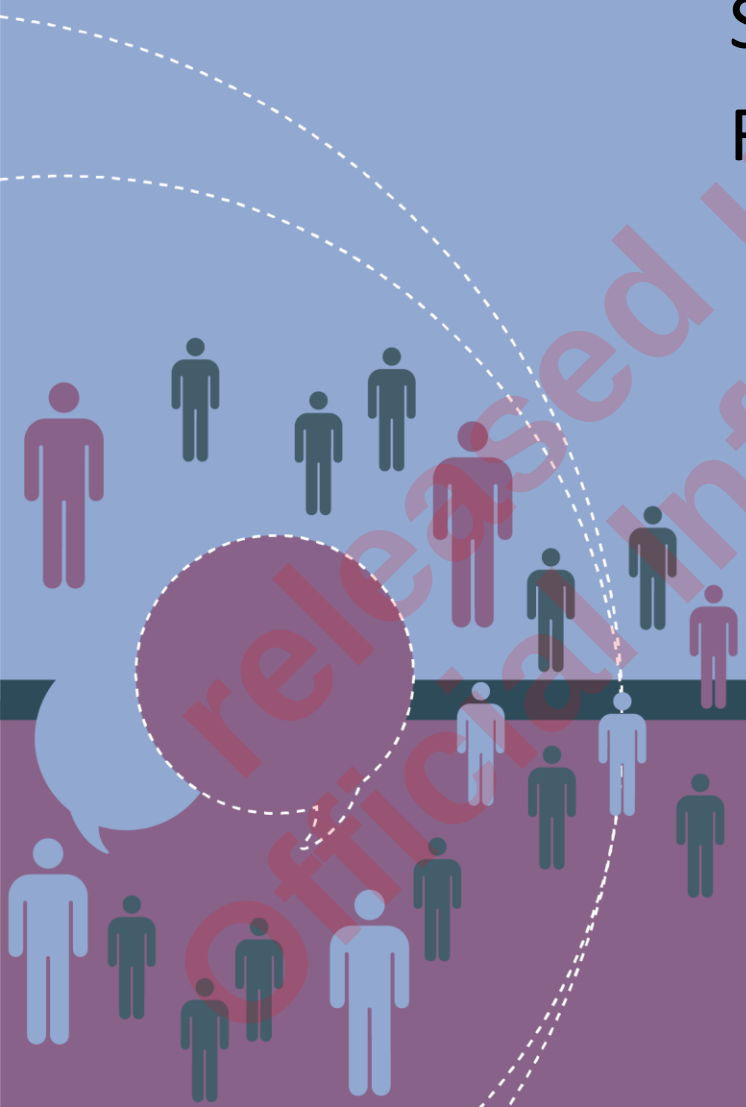
Thank you for considering our response to your consultation document. If you have any questions about our feedback, please contact Guild Pharmacist, Sarah Bannerman, at section 9(2)(a) or section 9(2)(a).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

PHARMAC Board Meeting

Supplier / Supply Chain Feedback



Pharmaceuticals
Level 11, Zurich House
21 Queen Street, Auckland
New Zealand 1010

Tel +64 9 367 2900
Fax +64 9 367 2910
www.gsk.com | www.gsk.co.nz

Dr Lindsay Ancelet
Therapeutic Group Manager
PHARMAC
PO Box 10254
Wellington 6143

03 October 2017

Feedback from GlaxoSmithKline (GSK) NZ Ltd on PHARMAC's proposal to fund zoster vaccine

GSK welcomes PHARMAC's proposal to recognise the significant clinical and health economic burden of herpes zoster and its complications by funding a zoster immunisation programme for those aged 65 to 80 years. However, GSK believes it is important that careful consideration is given to the likely effectiveness of the programme to ensure best utilisation of the healthcare budget for New Zealanders.

GSK believes that PHARMAC should reconsider the size of the cohort in the 2-year catch-up programme and the potential budget impact by taking into account the following:

1. The efficacy of the vaccine in the target populations. GSK notes that while the burden of disease is higher in older age groups, Zostavax® (Zoster Vaccine Live [Oka/Merck], Merck Sharp & Dohme New Zealand Ltd) becomes less effective with increasing age (41%; 95% CI 28 to 52% in individuals 70-79 years of age) and therefore the catch-up cohort is unlikely to receive the same benefit as the 65-year-old cohort.[i,ii,iii]

2. The duration of protection, which would impact the cost-effectiveness of the programme with Zostavax efficacy estimated to wane rapidly over time to 21% as early as 4.7 years after vaccination.[iv]

GSK notes that in 2016 PTAC recommended that zoster vaccination be funded for people aged 65 years with a medium priority and a 2-year catch-up programme for people aged between 65 and 80 years with a low priority. PTAC members noted the significant budget impact of a broad catch-

up programme and that it would unlikely be affordable due to the poorer cost effectiveness in this age group and high cost of the vaccine. The committee also highlighted that vaccine efficacy with Zostavax decreases markedly with age and that the evidence for durability for the vaccine was weak.[v] There have been no significant changes in the environment since this low priority recommendation was made.

While some countries consider that Zostavax offers public health benefits (e.g. UK, Australia, France and Italy),[vi,vii] others consider that the clinical profile is not sufficient. GSK would like to highlight the position published in the German STIKO (Standing Committee on Vaccination) Annual Update, dated 24 August 2017 and question whether PTAC and the PTAC Immunisation Sub-Committee are also aware of this recommendation.[viii] STIKO has published a non-recommendation for routine vaccination with Zostavax based on the data detailed above, and also because immunocompromised people who are at significantly increased risk of HZ often cannot be vaccinated since Zostavax is a live vaccine. In England it was found that the immunocompromised population accounted for 17.7% of the hospital admissions due to zoster.[ix] Based off both the PTAC and STIKO reviews of Zostavax, it is unclear why the funding of this catch-up programme has been prioritised over other important medical interventions being considered by PHARMAC.

GSK would also like to highlight that in the United States, the Advisory Committee on Immunization Practices (ACIP) are considering issuing guidance to 'revaccinate' people previously vaccinated with Zostavax with the adjuvanted herpes zoster subunit vaccine, due to waning of Zostavax efficacy.[x] With this in mind, PHARMAC should consider that vaccinating a 65-year-old with Zostavax will potentially leave them unprotected in their 70s, when a high incidence of the disease occurs.

In summary, investing in a catch-up programme with Zostavax is unlikely to be cost-effective due to the limited and rapidly declining vaccine efficacy in this age group, which has led to PTAC giving it a low priority assessment and STIKO advising against its use for routine immunisation. In addition, ACIP are also considering revaccination for those people previously vaccinated with Zostavax, due to waning of efficacy. GSK request that PHARMAC review the Zostavax data and reconsider the value in implementing such a catch-up programme in New Zealand.

Yours sincerely

Louise Talbot
Medical Affairs Manager, Vaccines

References :

[i] Oxman MN, *et al. N Engl J Med* 2005;352:2271–84
[ii] Zostavax datasheet NZ. Available at: http://www.medsafe.govt.nz/profs/Datasheet/z/zostavaxinj.pdf Accessed: 25th September 2017
[iii] Merck & Co. *Zostavax* Prescribing information: FDA; [updated March 2017; accessed 2017 June]. Available from: https://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi2.pdf
[iv] Morrison VA, *et al. Clin Infect Dis* 2015;60:900–9
[v] PHARMAC. PTAC meeting held on 11 & 12 February 2016 minutes. Available at: https://www.pharmac.govt.nz/assets/ptac-minutes-2016-02-update-2.pdf Accessed: 25th September 2017
[vi] Ansaldi F *et al*. *Adv Ther.* 2016;33:1094–1104
[vii] WHO vaccine-preventable diseases: monitoring system. 2017 global summary. Available at: http://apps.who.int/immunization_monitoring/globalsummary/schedules?sc%5Br%5D%5B%5D=EURO&sc%5Bc%5D%5B%5D=AFG&sc%5Bd%5D=&sc%5Bv%5D%5B%5D=ZOSTER&sc%5BOK%5D=OK
[viii] STIKO Epidemiologisches Bulletin Available at; https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2017/Ausgaben/34_17.pdf?__blob=publicationFile Accessed: 25th September 2017
[ix] Hobbelen PH *et al*. *J Infect*. 2016;73(3):241-53
[x] CDC ACIP Meetings. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2017-06/zoster-05-dooling.pdf Accessed: 3rd October 2017

From: Lance Gravatt <[redacted]>
Sent: Friday, 15 September 2017 2:01 p.m.
To: Vaccines
Subject: Feedback regarding Zoster Vaccine proposal

We are supportive of funding for vaccine preventable diseases and so welcome the proposed funding of Zoster Vaccine.

However, we note that the current proposal appears to be a bundled agreement wherein the listing of Zoster Vaccine is directly linked to price reductions on Fosamax and Fosamax Plus. Our concern arises with respect to the current bundled proposal and the RFP for national vaccine supply issued by PHARMAC on 15th February 2016 which specifically excluded proposals that involved products other than vaccines.

We are not opposed to bundled agreements, but if PHARMAC are looking to change their approach to proposals for funding vaccines to include bundles with products other than vaccines perhaps this change in process should be consulted on separately and applied to all vaccines not just Zoster Vaccine.

Kind Regards,

Lance

Lance Gravatt BSc, MSc Hons(1st), PhD, Dip Tchng
Non-Executive Chairman

Ph: 0800 TE ARAI (832 724) calling from NZ
Ph: 1800 TE ARAI (832 724) calling from Australia
Mob: [redacted]
Email: [redacted]
Post: P.O. Box 46205, Herne Bay,
Auckland, New Zealand 1147
www.tearaibiofarma.com

From: Noel Wright <section 9(2)(a)>
Sent: Friday, 22 September 2017 9:25 a.m.
To: Vaccines
Cc: Anthony Aitken
Subject: Proposal to fund zoster vaccine

To whom it may concern.

1 – Absolutely fantastic news to see this treatment funded for over 65 year old, but in reality between the age of 50 to 60 would have far greater effect and I believe would reduce incidents of Hospitalisation. That would be cost restrictive presently but to see a progressive change to funding at an earlier age would be have on going benefits and associated cost savings.

2 – As part of the proposal from 1 January 2018, there would also be a price reduction for alendronate sodium 70 mg tablets (Fosamax) and alendronate sodium with colecalciferol 70 mg with colecalciferol 5,600 iu (Fosamx Plus)

The concern and potential major issue is the continuation of supply pending this major price reduction.

If this were related to a Tender rather than a Proposal then there would be guaranteed price support to the supply chain effective from the 22nd of the month preceding the change in the Pharmaceutical Schedule.

As this proposed change relates to the cessation of the confidential rebate is it possible to include a similar clause to the Tender process to ensure the supplier provides price support for stock on hand in the supply chain (wholesaler) a COB 21st December 2017, which will enable the price to be available to DHB Hospitals, Community Pharmacy and others effective from 22nd December 2017.

Without this support the potential for the supply chain to be compromised is high. Taking into account that the new reimbursement commences 1 January 2018 and volumes a relatively high there could be significant losses incurred by all involved in the supply chain.

We hope his is taken into account.

Kind Regards

Noel Wright
Manager: ProPharma Palmerston North
Ph: section 9(2)(a) **Cell:** section 9(2)(a) **Fax:** 06 952 0035
Email: section 9(2)(a) **Web:** www.propharma.co.nz
Enthusiastic Supporters of Community Pharmacy
Find us on facebook.com/ProPharma-and-PWR

To: Vaccines[vaccines@Pharmac.govt.nz]
From: Sarah Whittall
Sent: Fri 15/09/2017 12:01:02 a.m
Importance: Normal
Subject: FW: PHARMAC - Consultation on proposal to fund Zoster Vaccine
MAIL_RECEIVED: Fri 15/09/2017 12:01:03 a.m

;;;;;;;;;;
;;;;;;;;;;
Please see below

Sarah Whittall | Team Assistant, Operations

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
section 9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

[SEEMail]

From: Noel Wright [mailto: section 9(2)(a)]
Sent: Friday, September 15, 2017 12:00 PM
To: Sarah Whittall
Subject: RE: PHARMAC - Consultation on proposal to fund Zoster Vaccine

Sarah

Congratulations to PHARMAC on this much needed move.

Can you please clarify the price reduction for Fosamax and Fosamax Plus will apply to both Section B and H – it is not stated

Have a great day

Kind Regards

Noel Wright
Manager: ProPharma Palmerston North
Ph: 06 952 0039 **Cell:** section 9(2)(a) **Fax:** 06 952 0035
Email: section 9(2)(a) **Web:** www.propharma.co.nz

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Find us on facebook.com/ProPharma-and-PWR

From: Sarah Whittall [mailto:sarah.whittall@pharmac.govt.nz]

MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING OCTOBER 2017

The meeting was held at Level 9, 40 Mercer Street, Wellington, starting at 9:48am with the following attendees:

Present

Stuart McLauchlan	Chair
Jens Mueller	Board Member
Jan White	Board Member
Nicole Anderson	Board Member
Ross Lawrenson	Board Member
David Lui	Observer, CAC Chair
Mark Weatherall, Observer	PTAC Chair

In attendance

Steffan Crausaz	Chief Executive
Sarah Fitt	Director of Operations
Jude Urlich	Director of Engagement & Implementation
Michael Johnson	Director of Strategic Initiatives
John Wyeth	Medical Director
Mark Woodard	Director of Corporate Services/CFO
Lizzy Cohen	Board Secretary

Angela Mansell, Rebecca Elliott, Alexis Poppelbaum, Andrew Park, Lindsay Ancelet, Andrew Oliver, Andrew Davies and Graham Beever (PHARMAC staff) attended for relevant items.

1. Directors' Only Discussion

2. Apologies

3. Minutes of Previous Meeting

resolved to adopt the minutes of the meeting on 29 September 2017 as being a true and correct record, and

noted the minutes of the PHARMAC Audit and Forecast Committee meeting on 29 September 2017.

Jan White and Nicole Anderson **(carried)**

4. Interests Register

Out of scope

5. Matters Arising

noted the Matters Arising.

6. Chairman's Report

6.1 Verbal Report

noted the Chairman's verbal report.

6.2 Correspondence

noted the correspondence received this month.

7. Chief Executives Report

noted the Chief Executive's Report.

8. Key Issues

8.1

Out of scope

8.2 Out of Scope

9. Out of Scope

9.1 Out of Scope

9.2 Out of Scope

9.3 Proposal to list varicella zoster vaccine (Zostavax)

resolved to list varicella zoster vaccine [shingles vaccine] (Zostavax) in Part II of Section H and Section I of the Pharmaceutical Schedule from 1 April 2018 as follows;

Chemical	Presentation	Brand	Pack size	Subsidy
Varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine]	Inj 19,400 PFU prefilled syringe plus vial	Zostavax	10	$0.00
Varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine]	Inj 19,400 PFU prefilled syringe plus vial	Zostavax	1	$0.00

resolved to apply the following restrictions to varicella zoster vaccine [shingles vaccine] in Part II of Section H of the Pharmaceutical Schedule from 1 April 2018;

Restricted
Initiation – people aged 65 years
Therapy limited to 1 dose
One dose for all people aged 65 years.

Initiation – people aged between 66 and 80 years
Therapy limited to 1 dose
One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 March 2020.

resolved to list varicella zoster vaccine [shingles vaccine] (Zostavax) in Section I of the Pharmaceutical Schedule with the Xpharm restriction from 1 April 2018,

resolved to apply the following restrictions to varicella zoster vaccine [shingles vaccine] in Section I of the Pharmaceutical Schedule of the Pharmaceutical Schedule from 1 April 2018;

Funded for patients meeting either of the following criteria:
1) One dose for all people aged 65 years; or
2) One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 March 2020.

resolved to amend the price and subsidy of Fosamax (alendronate sodium tab 70 mg) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2018 as follows:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Alendronate sodium	Tab 70 mg	Fosamax	4	$4.82

resolved to amend the price and subsidy of Fosamax Plus (alendronate sodium with colecalciferol tab 70 mg with colecalciferol 5,600 iu) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2018 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy
Alendronate sodium with colecalciferol	Tab 70 mg alendronate with colecalciferol 5,600 iu	Fosamax Plus	4	$4.82

resolved to approve the 12 September 2017 provisional agreement for Zostavax with Merck Sharp & Dohme (New Zealand) Limited;

resolved to approve the 13 September 2017 amendment to the agreement between PHARMAC and Merck Sharp & Dohme (New Zealand) Limited (MSD) dated 29 July 2009 relating to the listing of Fosamax, Fosamax Plus, Emend, Isentress, Sinemet, Sinemet CR, Timoptol XE and Cosopt on the Pharmaceutical Schedule for a change in the list price and removal of the rebate for Fosamax and Fosamax Plus;

noted the above amendment for Fosamax and Fosamax Plus is conditional on approval of the provisional agreement for Zostavax; and

resolve that the consultation on this proposal was appropriate, and no further consultation is required.

Nicole Anderson and Jan White **(carried)**

9.4 Out of scope

10.

10.1

11.

11.1

11.2

11.3

11.4

11.5

11.6

12. Out of scope

13.

14.

Date of Next Meeting

The date for the next Board meeting is set for Friday 1 December (November meeting) in Wellington, commencing with the Directors only from 9.00am, and attendees and relevant staff from 9.30am.

The meeting closed at 10.49am

Chairman Date