

**MEMORANDUM FOR CONSIDERATION BY DIRECTOR OF OPERATIONS
UNDER DELEGATED AUTHORITY**

To: Director of Operations
From: Manager Procurement and Contracts
Date: July 2022

Shingrix (recombinant zoster vaccine) listing and purchase

Recommendations

It is recommended that having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures you exercise your delegated authority and:

resolve to list Varicella zoster vaccine [Shingles vaccine] (Shingrix) inj 50 mcg per 0.5 ml vial plus vial powder and suspension for suspension for injection) in Section I of the Pharmaceutical Schedule from 1 August 2022 at a price of \$0.00 per 1 (ex-manufacturer, excl. GST);

resolve to apply the Xpharm restriction to varicella zoster vaccine [Shingles vaccine] (Shingrix) in Section I of the Pharmaceutical Schedule from 1 August 2022;

resolve to apply the following restrictions to varicella zoster vaccine [Shingles vaccine] in Section I of the Pharmaceutical Schedule from 1 August 2022:

Funded for patients meeting the following criteria:

- 1) Two doses for all people aged 65 years

resolve to list Varicella zoster vaccine [Shingles vaccine] (Shingrix) inj 50 mcg per 0.5 ml vial plus vial in Part II of Section H of the Pharmaceutical Schedule from 1 August 2022 at a price of \$0.00 (ex-manufacturer, excluding GST);

resolve to amend the following restrictions to varicella zoster vaccine [Shingles vaccine] in Part II of Section H of the Pharmaceutical Schedule from 1 August 2022 as follows (addition in bold):

Restricted

Initiation – people aged 65 years (**Zostavax**)

Therapy limited to 1 dose

One dose for all people aged 65 years.

Initiation – people aged 65 years (**Shingrix**)

Therapy limited to 2 doses

Two doses for all people aged 65 years.

resolve to approve the Purchase Order for the following vaccine (Attachment 1):

Vaccine Brand (Antigen)	Supplier	Price per dose	Quantity	Total Cost	Delivery Date
Shingrix (Varicella zoster [shingles])	GSK	s 9(2)(b)	12,000 doses Single dose packs (3 months' supply)	s 9(2)(b)(ii)	July 2022 (stock is currently available in New Zealand)

note that Pharmac staff are assessing a proposal from GSK s 9(2)(b)(ii), s 9(2)(j) s 9(2)(b)(ii), s 9(2)(j) this proposal is due to be ranked on the Options for Investment List on 21 July 2022;

note that Pharmac staff may seek to raise a further Purchase Order for stock, s 9(2)(b) s 9(2)(b)(ii), for a further 3 months' supply, totalling 22,000 doses or s 9(2)(b)(ii), s 9(2)(j) but will assess further information, including feedback from a meeting to discuss the Options for Investment List before putting forward any proposal; and

resolve that no consultation on this proposal is required.

Why proposal should be considered by the Director of Operations under Delegated Authority

The proposal involves a Schedule change that has an estimated Financial Impact (NPV) of less than \$10,000,000 and:

- will not result in the Pharmaceutical budget or its future funding path being exceeded;
- is not inconsistent with previous Board decisions; and
- is not considered contentious by Pharmac staff.

Background and Analysis

Background

Shingles vaccine was first listed in the Pharmaceutical Schedule from [1 April 2018](#).

In August 2020 Merck Sharpe and Dohme (MSD), the incumbent supplier of the currently funded shingles vaccine (Zostavax) advised Pharmac that it would be discontinuing manufacture as it was converting its shingles vaccine manufacturing sites over to manufacture its developmental COVID-19 vaccine. MSD subsequently advised in 2021 that it had stopped development of its COVID-19 vaccine but was still discontinuing its shingles vaccine.

GSK submitted a funding application for Shingrix in April 2022, and this was considered by the Immunisation Advisory Committee at its May 2022 meeting ([record in draft](#)). The Committee considered that Shingrix would be an appropriate alternative to Zostavax in the event of discontinuation or following a commercial process. It also considered that there would be a significant unmet health need if zoster vaccine was no longer available.

The proposed list price for Shingrix is s 9(2)(b)(ii), s 9(2)(i) with a course consisting of two doses given two to six months apart. GSK staff advised that data suggests a compliance of approximately 70% can be expected for the second dose which would mean a cost per patient s 9(2)(b)(ii), s 9(2)(i). This represents s 9(2)(b)(ii), s 9(2)(i) the currently listed Zostavax, which has a net price of s 9(2)(b)(ii), s 9(2)(i), with only one dose required.

GSK submitted a bundle proposal for shingles and meningococcal B vaccines on 29 June 2022. This proposal includes s 9(2)(b)(ii), s 9(2)(j) for both shingles and meningococcal B vaccines and is being ranked on the Options for Investment List on 21 July 2022. Subject to being ranked in a suitable position on the OFI, staff intend to progress a proposal for one of the bundle options s 9(2)(b)(ii), s 9(2)(j).

Staff estimated that current stocks of Zostavax are likely to be exhausted by mid-August 2022.

Proposal

It is proposed to procure an initial 12,000 doses of Shingrix vaccine to ensure ongoing supply of shingles vaccine at a total cost of s 9(2)(b)(ii), s 9(2)(i). This would be 2-3 month's supply at current usage and assumes most patients would seek only one dose in this time. It does not allow for a safety buffer, although GSK potentially have a further 8,000 doses available in New Zealand if it was required. Pharmac staff propose to continue working to secure a listing agreement for Shingrix s 9(2)(b)(ii), s 9(2)(i), preferably through a bundle proposal, or as a stand-alone agreement if necessary. Any such agreements would be subject to a separate decision.

We note that securing 12,000 doses, which will likely be used as a first dose by 12,000 patients, does imply a commitment for a second dose at a later time (recommended within 2 – 6 months for the first dose). Should we be unable to reach an agreement with GSK, or funding prioritisation does not allow a proposal to be progressed then we would look at strategies and implementation activity to suspend or delist this vaccine.

GSK has advised that it is expecting its next shipment of stock to arrive in New Zealand in October 2022 and is seeking to secure a Purchase Order from Pharmac for this stock totalling 3 months' supply. The cost would be s 9(2)(b)(ii), s 9(2)(j) for 22,000 doses at s 9(2)(b)(ii), s 9(2)(j). We would assess feedback from the 21 July prioritisation meeting before submitting forward any proposal for further stock.

It is proposed that s 9(2)(b)(ii), s 9(2)(j) (see further detail below in the 'Costs and Savings' section).

Agreement (if applicable)

A purchase order for the supply of 12,000 doses of Shingrix is attached as Appendix One.

Health Need

This proposal would ensure continuity of supply of zoster vaccine when the currently listed Zostavax brand is discontinued. The health need remains unchanged from that described in the October 2017 board paper in relation to the listing of Zostavax.

Health Benefit

Summary of the pharmaceutical

Shingrix is an adjuvanted recombinant vaccine containing varicella zoster (VZV) glycoprotein E (gE). It is administered by intramuscular injection. It contains 50 mcg of gE antigen/0.5mL dose and is given as a primary series of two doses administered two to six months apart.

Clinical advice

The Immunisation Advisory Committee considered Shingrix at its May 2022 meeting ([record in draft](#)), where it considered that Shingrix would be an appropriate alternative to Zostavax in the event of discontinuation or following a commercial process. It also considered that there would be a significant unmet health need if zoster vaccine was no longer available.

The Committee also made the following recommendations that Shingrix be listed for:

- people 50 to 64 years of age with a high priority
- people of Māori or Pacific ethnicity 60 years of age or over with a low priority
- people 18 years of age or over who are immunocompromised and awaiting solid organ and stem cell transplant.

It is not proposed to widen access to any of the additional groups recommended by the Committee as part of this proposal. These would be ranked on the Options for Investment List.

Advisor Conflicts of Interest

The following conflict of interest was declared by clinical advisors who contributed to the above advice (actions taken to manage the conflict are recorded in brackets):

§ 9(2)(a), § 9(2)(g)(i) : Has accepted funding from GSK (The Chair deemed that § 9(2)(a) could participate in the discussion but not vote).

Consequences for the health system

Detailed screening prior to vaccination as is currently required for the live attenuated Zostavax vaccine, this would not be required for the recombinant Shingrix vaccine. Shingrix is administered as a two dose primary series vaccine, which means that protocols would need to be implemented to ensure a second dose can be administered (2-6 months after the first dose). The supplier has suggested that administration alongside other vaccines for the requested age group would mitigate the need for additional appointments and healthcare resource.

Suitability

Shingrix has a shelf-life of three years rather than the shorter shelf-life of 18 months for the currently available Zostavax.

Shingrix is supplied as two vials, one containing a single dose of gE (active ingredient) in a lyophilised form which needs to be reconstituted using the other vial containing a single dose of the Adjuvant System AS01B in suspension.

Costs and Savings

The cost of the proposed purchase order for 12,000 doses of Shingrix is § 9(2)(b)(ii), § 9(2)(j). We would propose § 9(2)(b)(ii), § 9(2)(j).

§ 9(2)(b)(ii), § 9(2)(j)

§ 9(2)(b)(ii), § 9(2)(j)

§ 9(2)(b)(ii), § 9(2)(j)

§ 9(2)(b)(ii), § 9(2)(j)

The § 9(2)(b)(ii), § 9(2)(j) cost for the vaccination of the equivalent number of patients would be § 9(2)(b)(ii), § 9(2)(j). The status quo cost, currently funded out of the CPB, of Zostavax is § 9(2)(b)(ii), § 9(2)(j) one dose required. The Shingrix cost per dose is § 9(2)(b)(ii), § 9(2)(j) 2 doses required. We've assumed a 70% compliance with second dosing in our calculation per advice from GSK.

Comments from Interested Parties

Section 70(a) of the Pae Ora (Healthy Futures) Act 2022 (the Act) requires Pharmac to consult, when it considers appropriate to do so.

Pharmac staff do not, however, consider it appropriate to consult on the recommendations contained in this paper as there are no proposed material changes to the eligibility criteria for shingles vaccine. The purpose of this proposal is to secure continuity of supply for a currently funded indication.

Legal advisors' view

Legal advice has not been sought on this proposal because Pharmac staff do not consider it to be contentious or to raise any issues of legal concern.

Implementation

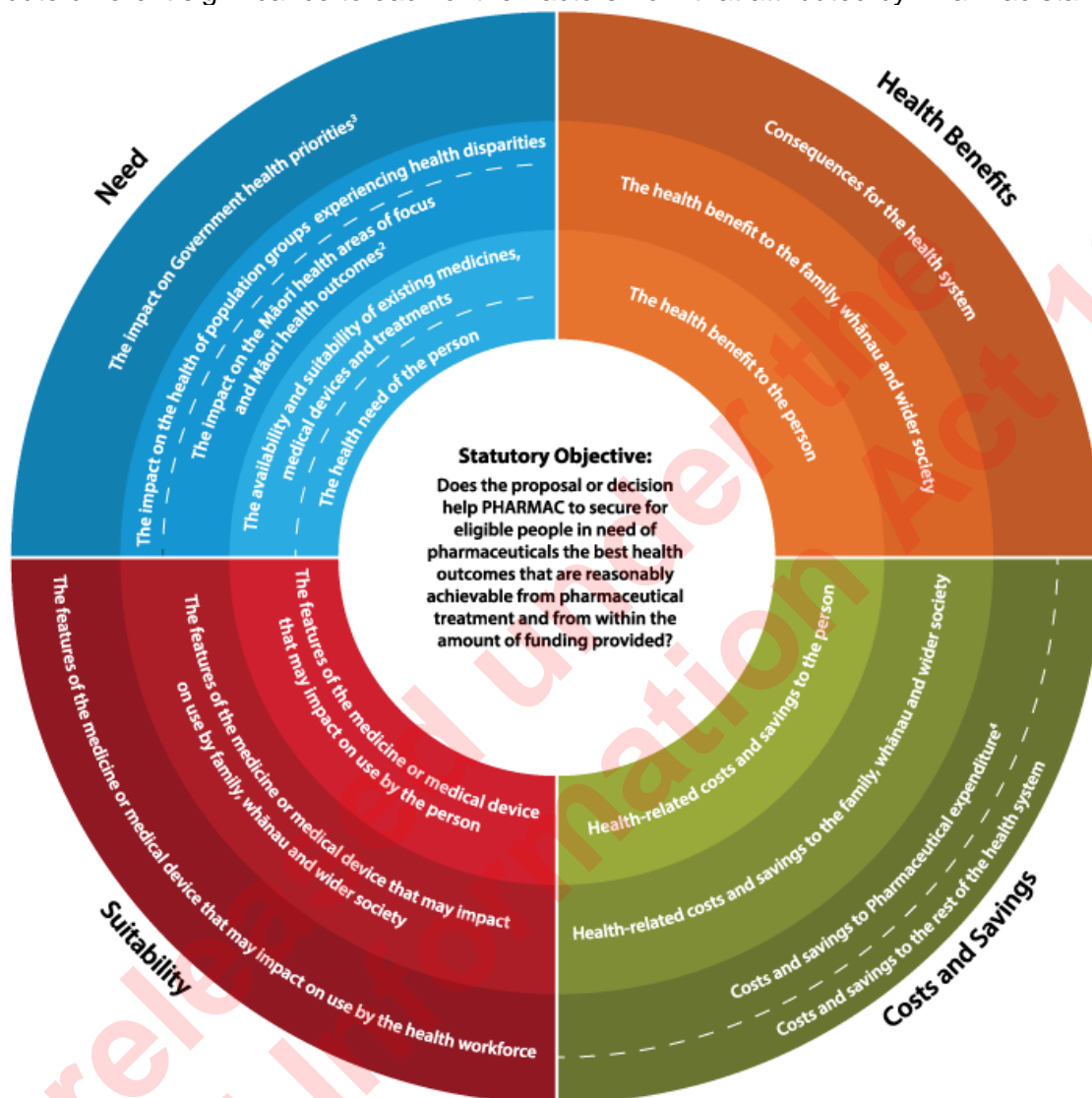
Section 70(b) requires Pharmac to take measures to inform the public, groups and individuals of Pharmac's decisions concerning the Pharmaceutical Schedule. Accordingly, if the Director of Operations adopts the recommendations contained in this paper Pharmac staff will notify all suppliers, and implement the listing of these products via the usual Schedule processes.

Health New Zealand is responsible for implementation for vaccines. It has advised that it is supportive of the proposal to list Shingrix to maintain continuity of supply of shingles vaccine.

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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 Decision Maker 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.

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 Te Whatu Ora 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.

APPENDIX ONE: PURCHASE ORDER

(next page)

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Purchase Order for Vaccines

To: GlaxoSmithKline NZ Ltd

Private Bag 106600
Downtown
Auckland

Attention: Michelle Spargo

Purchase

Purchase Order Number 2031
Date 21 July 2022
Vaccine **Shingrix**
50 micrograms powder and 50 micrograms adjuvant suspension for suspension for injection Recombinant Varicella Zoster Virus glycoprotein E Vaccine
Quantity (doses) 12,000 doses
Value of Order s 9(2)(b)(ii), s 9(2)(j)

Delivery

Delivery Date per discussion with Pharmac staff on 20 July 2022 – delivery as soon as reasonably available preferred.
Delivery Address HealthCare Logistics
58 Richard Pearse Drive, Airport Oaks
Mangere
Auckland 2022
New Zealand
Contacts Cristine Della Barca – Commercial Relationships Manager
email: s 9(2)(a)
Phone : DDI s 9(2)(a) ; Reception s 9(2)(a) ; Mob s 9(2)(a)
Fax +64 9 918 5101

Invoice & Terms of Trade

Invoice Address PHARMAC
PO Box 10-254
Wellington 6143
New Zealand
Contacts Graham Durston - Finance Manager, email: accounts@pharmac.govt.nz
Sophie Geden – Contract Manager, email: sophie.geden@pharmac.govt.nz
Phone +64 4 460 4990
Terms of Trade GSK standard terms of trade apply except where modified by mutual agreement in writing.

Authorisation



Lisa Williams – Director of Operations, PHARMAC

**MINUTE OF THE DIRECTOR OF OPERATIONS DECISION UNDER
DELEGATED AUTHORITY**

July 2022

The Director of Operations, exercising the authority delegated by the Chief Executive under the Financial Delegations Policy has made the following decision to:

resolve to list Varicella zoster vaccine [Shingles vaccine] (Shingrix) inj 50 mcg per 0.5 ml vial plus vial powder and suspension for suspension for injection) in Section I of the Pharmaceutical Schedule from 1 August 2022 at a price of \$0.00 per 1 (ex-manufacturer, excl. GST);

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note that Pharmac staff are assessing a proposal from GSK that would provide a discount on the list price for future purchases of stock, this proposal is due to be ranked on the Options for Investment List on 21 July 2022;

note that Pharmac staff may seek to raise a further Purchase Order for stock, (at s 9(2) s 9(2)(b)(ii)), for a further 3 months' supply, totalling 22,000 doses or s 9(2)(b)(ii), s 9(2)(i) but will assess further information, including feedback from a meeting to discuss the Options for Investment List before putting forward any proposal; and

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