ATTACHMENT 1

Minutes

MINISTRY OF HEALTH
MANATŪ HAUORA

2017 National Immunisation Schedule Review Meeting

Date:	24 November 2017
Time:	9:00am – 4:30pm
Location:	Ministry of Health, 133 Molesworth Street, Room GC-1 & GC-2
Chair:	s 9(2)(g)(ii) Ministry of Health
Attendees:	ESR: s 9(2)(g)(ii) IMAC: s 9(2)(g)(ii) Immunisation Handbook Medical Writer: s 9(2)(g)(ii) MOH: s 9(2)(g)(ii) PHARMAC: s 9(2)(g)(ii) Expert Advisors: s 9(2)(g)(ii) (See Appendix 3 for attendee titles and positions)
Apologies:	MOH: s 9(2)(g)(ii) PHARMAC: s 9(2)(g)(ii) Expert advisors s 9(2)(g)(ii)

Overview

On 24 November 2017, the Ministry of Health (the Ministry) convened a meeting with a technical group of experts to review the current National Immunisation Schedule (the Schedule). The meeting objective was to consider the antigens on the Schedule and agree on the ideal timing for the primary immunisation series and subsequent vaccine boosters in order to provide optimal protection against vaccine preventable diseases across the lifespan.

The Ministry commissioned the Immunisation Advisory Centre (IMAC) to undertake a literature review of the Childhood Immunisation Schedules to provide evidence to support the discussion and subsequent recommendations.

s 9(2)(b)(ii)

2020-21-055; Appendix 1
A1446580; 2017 National Immunisation Schedule Review meeting minutes

s 9(2)(b)(ii) [redacted]

For each of the antigens listed below, the evidence from the review, disease surveillance and specific questions formed the basis of discussion. The antigens discussed at the meeting were:

- Out of scope
- Tetanus
- Out of scope
- Out of scope
- Out of scope
- Out of scope
- Out of scope

A number of follow up actions were identified at this meeting including the Ministry's development of:

- an impact assessment on possible Schedule changes for the sector
- possible 2020 Schedule changes for PHARMAC consideration. (Refer Appendix 1).

Discussion Points and Recommendations

Pertussis – overview

Out of scope [redacted]

Tetanus/diphtheria – Overview

The table below outlines the World Health Organization (WHO) recommendations to ensure lifelong protection from tetanus/diphtheria, and the current New Zealand Immunisation Schedule.

WHO recommendations	Current NZ Immunisation Schedule
Six doses in total of tetanus vaccine (Three primary doses and three booster doses)	Five doses of tetanus vaccine for children, (Three primary doses and two booster doses)
The first three primary vaccines are recommended to be given in the first year of life, from as early as age 6 weeks, with at least a four week interval between each dose.	Three primary vaccine doses are given in the first year of life at ages 6 weeks, 3 months and 5 months (DTaP).

The remaining three boosters are recommended to be given in: - Second year of life (12-23 months) - at 4-7 years - at 9-15 years of age* Ideally, there should be at least four years between booster doses.[1]	Booster doses are given to children at - age 4 years (DTaP) and - age 11 years (Tdap). Booster doses are not provided in second year of life as cases of tetanus are rare in children, particularly in vaccinated children.
*the sixth (third booster dose) dose is recommended for young adults to provide additional assurance of long-term protection.	Boosters are also offered to adults at 45 and 65 years of age (Td) – note only the vaccine is funded not the administration.
	Pregnant women are also offered a Tdap vaccine, between 28 and 38 weeks' gestation.

Despite only five doses being delivered in childhood, the incidence of tetanus and diphtheria in New Zealand remains low.

It was noted that the tetanus vaccine positively alters the immune response to conjugate vaccines, which means it would need to be given with or before the pneumococcal conjugate (PCV), meningococcal C (MenC) and *Haemophilus influenzae* type B (Hib) vaccines.

Maternal antibodies enhance baby's response to tetanus toxoid (TT) but may decrease response to diphtheria. In addition, the TT conjugate vaccine may enhance TT response but clinical relevance of this unclear.

Questions for discussion	The WHO recommend a tetanus/diphtheria dose for children in their second year of life. For children with co-morbidities, does New Zealand need another dose in addition to the booster dose which is currently prior to pre-school entry?

Recommendations

As there is not currently a high incidence of tetanus and diphtheria cases in New Zealand, the current Schedule continues to be appropriate to provide protection (ie, three primary doses in the first year of life, followed by boosters at ages 4 and 11 years). Any changes to New Zealand's scheduling for tetanus and diphtheria will be driven by the need to change the pertussis component in the vaccine, (eg, the introduction of another DTaP booster in the second year of life).

There are various DTaP[2] vaccine options which may be considered depending on the schedules required for the other antigen components in these vaccines, for example change from the hexavalent DTaP/IPV/HepB-Hib at 5 months to DTaP-IPV or DTaP and then use a hexavalent vaccine as a booster in the second year of life.

Group discussion concluded not to consider funding Tdap as well as ADT as there is no evidence it reduces disease, and evidence shows there is no gain in a universal pertussis dose at 45 years.

[1] World Health Organization, 2017. *Programmes, Immunization, Vaccines and Biologicals – Tetanus.* Website: www.who.int/immunization/diseases/tetanus/en/

[2] D-Diptheria, T-tetanus, IPV- Inactivated polio vaccine, aP – acelluar pertussis, HepB- Hepatitis B, Hib – haemophilus *influenza type b)*

Other considerations

- Would introducing a sixth dose of tetanus/diphtheria in children negate the need for any adult boosters?
    - It was commented that although WHO recommend six doses, there may not be any evidence behind six rather than five doses. WHO notes the exact schedule in each country will be flexible so available health care services in each country can be maximised.
    - If a sixth dose is introduced, could we consider funding six doses of tetanus/diphtheria across the lifespan? (ie, as long as there are six documented doses, a person would be considered fully immunised. The sixth dose could be added when adults aged 65 years receive their zoster and influenza vaccine if not previously completed, and can consider eliminating the 45 year tetanus dose).

Meningococcal - Overview

Out of scope

[redacted]

[3] See NZ Pharmaceutical Schedule for list of high risk individuals

Considerations

- Consider risk of horizontal transmission from individuals overseas.
- Level of risk is before a baby begins their infant vaccine schedule.

Proposed Summary of Options for the National Immunisation Schedule

There are a number of recommended changes to the Schedule timings for both the primary immunisation series and vaccine boosters across the lifespan. The discussion also focused on the possible introduction of new vaccines onto the Schedule.

There was general consensus that New Zealand's highest priority should be to target high antenatal pertussis immunisation coverage and second priority should be broadening access to pertussis vaccination from 16 weeks gestation.

The recommended changes for consideration are outlined below, and are further shown as a graphic version of the Schedule in Appendix 1.

Stage of life vaccinations	Summarised changes
Pregnancy	The Schedule for pregnant women would remain the same for influenza. Consider offering pertussis vaccination during the second trimester (ie. from 16 weeks' gestation) to extend protection for pre-term infants, and an increased focus on increasing immunisation coverage for pregnant women.
Primary course	All infant immunisations would continue to start at 6 weeks, until further evidence on the impact of maternal blunting on the infant's immune system for pertussis immunisation is available. Out of scope • Consider the various DTaP vaccine options depending on the schedules required for the other antigen components in these vaccines, if more cost effective. Out of scope
2nd year of life	Out of scope
Out of scope	

	Out of scope
4-year	• DTaP or Tdap (Tdap is less reactogenetic) Out of scope
School-based immunisations	Out of scope • Tdap (if not given at age 4 years)
45 years	• Consider funding Tdap as well as ADT • Remove ADT dose at age 45 as there is no evidence for this. The recommendation is for 6 does across the lifespan for tetanus. Tdap is to be given at age 65 for anyone who has not completed six tetanus does.
65 years	Out of scope • Tdap at aged 65 years (only if have not had 6 doses already in their lifetime of ADT or Tdap) Out of scope

Appendix 1: Possible National Immunisation Schedule based on discussion

- Based on the day's discussion and recommendations made for each specific antigen, the group reviewed the current Schedule, and made possible changes incorporating their antigen recommendation discussed at this meeting.
- This table is a visual summary of the recommended changes to the Schedule as described above. For comparison, a copy of the Schedule as it currently stands is in Appendix 2.
- *Hexavalent vaccine (hexa), consisting of DTaP-IPV-HepB-Hib

Antigen	DTaP/Tdap, containing vaccines	PCV	RV (oral)	MenB	Men ACW-Y (conjugate)	MMR or MMRV	Varicella	HPV		Zoster
Pregnancy	Tdap (from 16wks)									
Primary										
6 weeks	DTaP-IPV-HepB/Hib	PCV	RV (oral)	MenB						
3 months	DTaP-IPV-HepB/Hib		RV (oral)	MenB (check gap)						
5 months	DTaP, DTaP-IPV-HepB/Hib or DTap-IPV	PCV								
Boosters										
12 months		PCV		MenB		MMR				
15 months	DTaP-IPV-HepB/Hib (replaces Hib, provides pertussis booster)				Men ACW-Y (conjugate)	MMRV or MMR +	Varicella			
4 years	DTaP or Tdap									
School-based										
9-12 years	Tdap						Varicella (catch-up)	HPV (dose 1)	HPV (dose 2) 6m+	
Adolescent - 14 years)					Men ACW-Y (conjugate)					
>65 years	Tdap									Zoster

*NB – Possible widening of criteria to include children requires further discussion

Appendix 2: Current National Immunisation Schedule

Antigen(s)	DTaP-IPV-HepB/Hib	PCV10	RV1	MMR	Hib	VV	DTaP-IPV	Tdap	HPV9	Td	Influenza
Brand	Infanrix-hexa	Synflorix	Rotarix	Priorix	Hiberix	Varilrix	Infanrix-IPV	Boostrix	Gardasil 9	ADT Booster	Influvac
Pregnancy								Tdap			Influenza
6 weeks	DTaP-IPV-HepB/Hib	PCV10	RV1								
3 months	DTaP-IPV-HepB/Hib	PCV10	RV1								
5 months	DTaP-IPV-HepB/Hib	PCV10									
15 months		PCV10		MMR	Hib	VV					
4 years				MMR			DTaP-IPV				
11 years								Tdap			
11/12 years									HPV9 (2 doses)		
45 years										Td	
65 years										Td	Influenza (annually)

Key: = diphtheria; T = tetanus; aP = acellular pertussis; IPV = inactivated polio vaccine; HepB = hepatitis B; Hib = *Haemophilus influenzae* type b; PCV10 = 10-valent pneumococcal conjugate vaccine; RV1 = rotavirus vaccine (monovalent); MMR = measles, mumps and rubella; VV = varicella vaccine; d = adult diphtheria; ap = adult acellular pertussis; HPV9 = human papillomavirus (9 serotypes).

Appendix 3 - Expert Advisor attendees and positions:

Name	Position	From
s 9(2)(g)(ii)		ESR
s 9(2)(g)(ii)		IMAC
s 9(2)(g)(ii)		Immunisation Handbook
Ministry of Health attendees		
s 9(2)(g)(ii)		Ministry of Health
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s 9(2)(g)(ii)		Ministry of Health
s 9(2)(g)(ii)		Ministry of Health
s 9(2)(g)(ii)		Ministry of Health
PHARMAC attendees		
s 9(2)(g)(ii)		PHARMAC
s 9(2)(g)(ii)		PHARMAC
Expert Advisors		
s 9(2)(g)(ii)		Canterbury District Health Board
s 9(2)(g)(ii)		IMAC
s 9(2)(g)(ii)		University of Auckland/Starship

s 9(2)(g)(ii)	[redacted]	University of Otago
s 9(2)(g)(ii)	[redacted]	Starship Children's Heatlh
s 9(2)(g)(ii)	[redacted]	Auckland Regional Public Health Service (ARPHS) and IMAC
s 9(2)(g)(ii)	[redacted]	Massey University
s 9(2)(g)(ii)	[redacted]	Ora Toa Health Services
s 9(2)(g)(ii)	[redacted]	Starship Children's Health

IMMUNISATION SUBCOMMITTEE MEMORANDUM

To: Immunisation Subcommittee

From: Therapeutic Group Manager

Date: February 2019

Vaccine RFP 2019: Possible RFP brand or dose schedule changes

CONFIDENTIAL: The information in this paper is commercially sensitive, and must not be shared outside the Subcommittee.

PHARMAC issued an RFP for various vaccines in November 2018 for the supply of vaccines from July 2020. The RFP closed on 18 January 2018 and the bids are currently under evaluation As part of the evaluation process, PHARMAC seeks advice from the Immunisation Subcommittee about possible changes that could occur as a result of the RFP.

Withheld under section 9(2)(b)(ii) and 9(2)(j)

Withheld under section 9(2)(b)(ii) and 9(2)(j)

Withheld under section 9(2)(b)(ii) and 9(2)(j)

Withheld under section 9(2)(b)(ii) and 9(2)(j)

Each possible vaccine change is considered below with questions for the Subcommittee For some vaccines, we seek advice about the clinical need for ongoing access to some vaccines. Updated clinical advice from the Subcommittee will help inform any decision to accept the price increase or manage the cost implications in other ways This could include considering delisting a vaccine, change the vaccine to a different product or providing clinical justification to confirm that there is an ongoing clinical need for a particular vaccine.

QUESTIONS TO SUBCOMMITTEE

Note to Subcommittee members: These questions have been identified by PHARMAC staff as being particularly relevant to the possible changes resulting from the Vaccine RFP. Please feel free to provide additional information as appropriate

Adult Diphtheria and Tetanus Vaccine

1. Does the Subcommittee consider that Boostrix would be suitable for giving a tetanus booster at the 45 and 65 year old visits?
2 Does the Subcommittee consider that a tetanus and diphtheria vaccination visit for 45 and 65 year olds is still required?
3. Does the Subcommittee consider that Boostrix would be suitable for vaccination of previously unimmunised or partially immunised patients?
4. Does the Subcommittee consider that Boostrix would be suitable for re-vaccination following immunosuppression?
5 Does the Subcommittee consider that Boostrix would be suitable for boosting of patients with tetanus prone wounds?

6. Does the Subcommittee consider that Boostrix would be suitable for use in testing for primary immunodeficiency diseases?

7 Does the Subcommittee consider that there are any patient groups currently receiving ADT Booster for whom the additional pertussis component of Boostrix would not be suitable?

8. Does the Subcommittee consider that there would be any unmet need if ADT Booster was delisted from the Pharmaceutical Schedule?

9. Does the Subcommittee have any further comments about tetanus and diphtheria vaccinations?

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PURPOSE OF THIS PAPER

The purpose of this paper is to seek advice from the Subcommittee regarding possible changes to vaccine listings that could occur as a result of the 2018/19 Vaccines RFP, and to inform the evaluation of the RFP

DISCUSSION

Minutes from previous Immunisation Subcommittee meetings in 2018 are provided in Appendix 1 (May 2018) and Appendix 2 (September 2018)

Collated Subcommittee minutes regarding a particular vaccine are provided in later Appendices as needed

Minutes from the Ministry of Health National Immunisation Schedule review meeting held in November 2017 are provided in Appendix 3

Adult Diphtheria and Tetanus Vaccine

Background

Adult diphtheria and tetanus vaccine (ADT Booster) is currently included in the National Immunisation Schedule at 45 and 65 year old visits It is also used ad hoc for tetanus boosters It is listed in the Pharmaceutical Schedule with the following criteria:

Any of the following:

1. For vaccination of patients aged 45 and 65 years old; or
2. For vaccination of previously unimmunised or partially immunised patients; or
3. For revaccination following immunosuppression; or
4 For boosting of patients with tetanus prone wounds; or
5. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician

Diphtheria and tetanus antigens are also administered as part of a hexa-valent vaccine (Infanrix-hexa) at ages 6 weeks, 3 and 5 months, and in a Tdap (Boostrix) dose at age 11 years. The Subcommittee considered ADT Booster vaccine at its May 2016 meeting (Excerpt from the minute provided in Appendix 4)

RFP proposals

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii)

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii) seek the Subcommittee's advice about possible alternative vaccines that may be used instead for the currently funded patient populations.

Tdap vaccine (Boostrix) contains the diphtheria and tetanus components but also includes a pertussis component Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii)

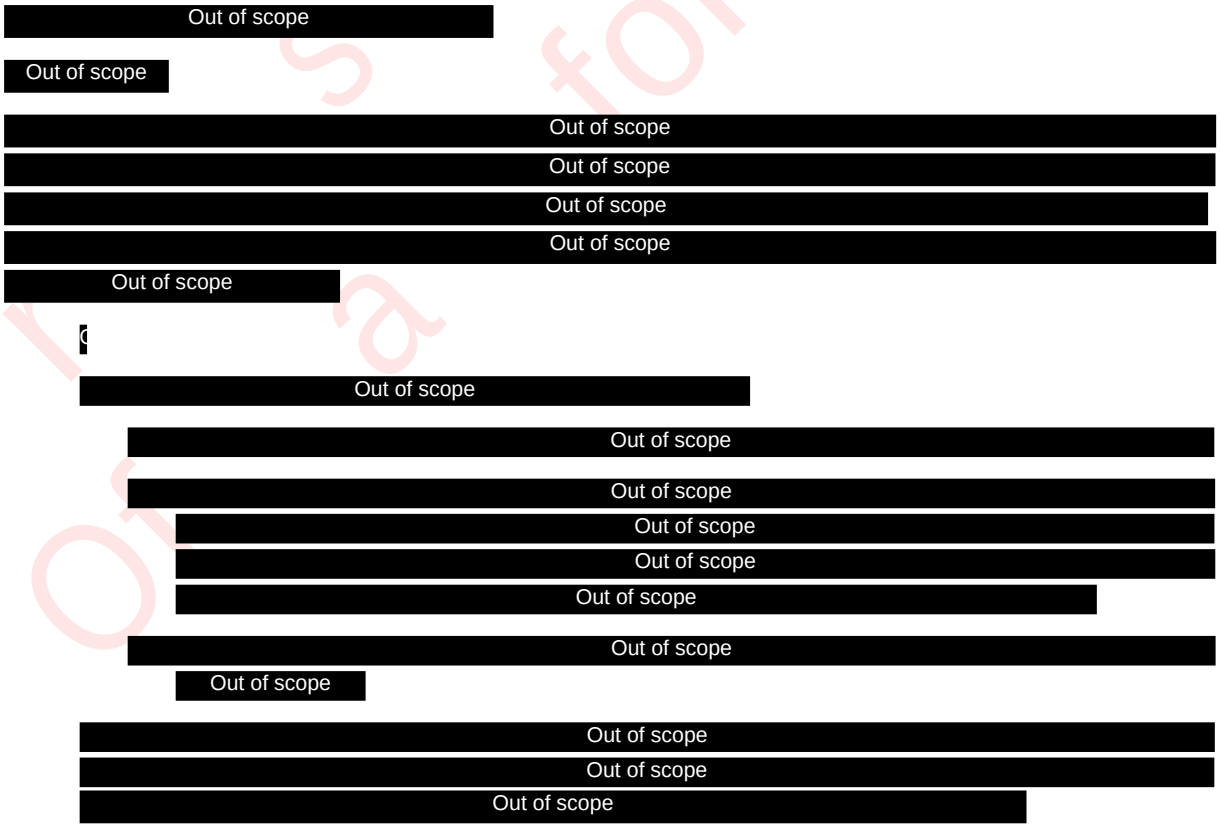
Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii)

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii)

We seek the Subcommittee's advice on whether Tdap (Boostrix) would be a suitable replacement for Td (ADT Booster) for all the currently funded eligibility criteria.

Questions to the Subcommittee

1. Does the Subcommittee consider that Boostrix would be suitable for giving a tetanus booster at the 45 and 65 year old visits?
2. Does the Subcommittee consider that a tetanus and diphtheria vaccination visit for 45 and 65 year olds is still required?
3 Does the Subcommittee consider that Boostrix would be suitable for vaccination of previously unimmunised or partially immunised patients?
4 Does the Subcommittee consider that Boostrix would be suitable for re-vaccination following immunosuppression?
5. Does the Subcommittee consider that Boostrix would be suitable for boosting of patients with tetanus prone wounds?
6. Does the Subcommittee consider that Boostrix would be suitable for use in testing for primary immunodeficiency diseases?
7 Does the Subcommittee consider that there are any patient groups currently receiving ADT Booster for whom the additional pertussis component of Boostrix would not be suitable?
8 Does the Subcommittee consider that there would be any unmet need if ADT Booster was delisted from the Pharmaceutical Schedule?
9. Does the Subcommittee have any further comments about tetanus and diphtheria vaccinations?



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APPENDICES

Appendix 1: May 2018 Immunisation Subcommittee minutes

Appendix 2: September 2018 Immunisation Subcommittee minutes

Appendix 3: Ministry of Health National Immunisation Schedule Review Meeting November 2017

Appendix 4: May 2018 Immunisation Subcommittee minutes relating to ADT Booster

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THE FACTORS FOR CONSIDERATION

Factors are presented here in the order they appear in the paper, without implying any ranking or relative importance.

NEED

- The health need of the person
- The availability and suitability of existing medicines, medical devices and treatments
- The health need of family, whānau, and wider society
- The impact on the Māori health areas of focus and Māori health outcomes
- The impact on the health outcomes of population groups experiencing health disparities
- The impact on Government health priorities

HEALTH BENEFITS

- The health benefit to the person
- The health benefit to family, whānau and wider society
- Consequences for the health system

SUITABILITY

- The features of the medicine or medical device that impact on use by the person
- The features of the medicine or medical device that impact on use by family, whānau and wider society
- The features of the medicine or medical device that impact on use by the health workforce

COSTS AND SAVINGS

- Health-related costs and savings to the person
- Health-related costs and savings to the family, whānau and wider society
- Costs and savings to pharmaceutical expenditure
- Costs and savings to the rest of the health system

PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR BOARD MEETING 28 JUNE 2019

To: PHARMAC Board of Directors

From: Chief Executive

Date: June 2019

Proposal for the supply of various vaccines with proposed changes to the funded brand or eligibility criteria and to decline bids for various other vaccines

Recommendations

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

note the summary of information about the proposed changes to eight vaccines

Out of scope

Out of scope

SUMMARY OF PROPOSAL				
Brand Name	Multiple	**Chemical Name**	Multiple	
Therapeutic Group	National Immunisation Schedule	**Pharmaceutical Type**	Vaccines	
Supplier	Multiple			
MOH Restrictions	Immunisation Schedule			
Market data	**Year ending**	**30 Jun 2021**	**30 Jun 2022**	**30 Jun 2023**
	Number of new patients	Withheld under section 9(2)(j)		
Combined Pharmaceutical Budget	Expenditure (gross)	Withheld under section 9(2)(j)		
	Net cost to CPB	Withheld under section 9(2)(j)		
	Net present value	Withheld under section 9(2)(j)		
Other DHB costs	Net distribution costs	Withheld under section 9(2)(j)		
	Net cost to DHBs	Withheld under section 9(2)(j)		
Total	Total cost to DHBs	Withheld under section 9(2)(j)		
	Net present value (5 year)	Withheld		

Notes:
1. Expenditure (gross) = forecast of spending at the proposed price and subsidy.
2. Net cost to DHBs = forecast of change in spending compared with status quo.
3. All pharmaceutical costs are ex manufacturer.
4 All costs are ex-GST
5. NPV is calculated over 5 years using an annual discount rate of 8%.
6. Calculations are in A1270670.

Executive Summary

- This is the second of four papers relating to the Vaccines RFP and addresses decisions to be made in relation to vaccines which would result in changes to the brands, dosing schedules and/or eligibility criteria
- Following a Request for Proposals (RFP) for vaccines issued on 20 November 2018, PHARMAC has reached five provisional agreements with four suppliers, GlaxoSmithKline NZ Ltd (GSK), Out of scope
  Out of scope
- The proposals in this paper are for:
  - Awarding supply bids for eight vaccines with proposed changes to the funded brand or eligibility criteria;
  - Amendments to the eligibility criteria for five vaccines:
    Out of scope
    - tetanus and pertussis vaccine;

    Out of scope
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    Out of scope
- Overall, the proposals are estimated to result in a saving to the CPB of Withheld under section 9(2)(i) NPV (5 years, 8%) for these vaccines
- Implementation of any changes to the National Immunisation Schedule is the responsibility of the Ministry of Health's Immunisation team PHARMAC staff work closely with this team and meet with key members of the team on a monthly basis. The Immunisation Team has advised that it is able to support the implementation of the changes set out in this proposal.

The Proposal

In summary, through provisional agreements with a number of suppliers, this proposal would result in the following vaccine brand, eligibility and dose changes:

Brand Changes

Vaccine	*Current brand*	*Proposed brand*
Out of scope		
Out of scope		
Adult diphtheria and tetanus vaccine	ADT Booster (Seqirus)	Replaced via expanding access to Boostrix see below

Eligibility and Dose Changes

Vaccine	*Proposed Change*	*Rationale for Change*	*Cost to CPB over 4 year supply period NPV (4 years 8%)*
Diphtheria, tetanus and pertussis (Tdap) vaccine (Boostrix)	Tdap (Boostrix) vaccine would replace the Adult diphtheria and tetanus vaccine (ADT Booster), and its eligibility criteria would be amended to restrict the tetanus booster at age 45 to individuals who have not received 4 tetanus vaccinations in their lifetime	Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b)(ii), Withheld under section Clinical advice was supportive of this change	$ Withheld under
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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, 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

Diphtheria, tetanus and pertussis

Need

Diphtheria is a notifiable disease and characteristically involves membranous inflammation of the upper respiratory tract, with the involvement of other tissues, especially the myocardium and peripheral nerves The major complication of diphtheria is respiratory obstruction, although the majority of deaths are due to the effects of diphtheria toxin on various organs. Of particular importance are the effects of the toxin on the myocardium (leading to myocarditis and heart failure), peripheral nerves (resulting in demyelination and paralysis), and kidneys (resulting in tubular necrosis).

Tetanus is a nervous system disorder characterized by muscle spasms that is caused by the toxin producing anaerobe Clostridium tetani, which is found in the soil. Tetanus can present in one of four clinical patterns: generalized, local, cephalic or neonatal. Although tetanus is now rare in more affluent countries, the disease remains a threat to all unvaccinated people *C tetani* spores cannot be eliminated from the environment, so immunisation and proper treatment of wounds and traumatic injuries are important for tetanus prevention

Pertussis (whooping cough) is highly infectious and is one of the most infectious vaccine preventable diseases In the initial stages of infection an irritating cough develops that can progress to severe paroxysms of coughing. The most common complications are secondary infections such as otitis media and pneumonia, and the physical sequelae of paroxysmal coughing (eg subconjunctival haemorrhages, petechiae, central nervous system haemorrhages, pneumothoraces and herniae).

Health Benefit

The proposed change of vaccine for patients requiring a diphtheria and/or tetanus booster from ADT to dTaP would result in a small health benefit to patients who would receive a pertussis dose that is not included in the incumbent vaccine.

Limiting eligibility for a tetanus booster dose at 45 years of age to people who have not received at least 4 previous tetanus doses in their lifetime would not result in a change to health benefit. In March 2019, the Immunisation Subcommittee considered that many people received more tetanus doses in their lifetime than was required, so it would be appropriate to remove this dose for people who have received at least 4 previous doses. It considered that there was not very high uptake of this dose and the dose at 65 years of age was more important.

The Subcommittee considered that dTaP was a suitable option for those patients who require a tetanus booster, but stressed that it was not necessary for this group to receive a pertussis dose with the tetanus booster The Subcommittee considered that there could be a small group of vaccine-averse patients who might currently accept a diphtheria and tetanus dose, but may not accept a dose that also includes pertussis.

Suitability

dTaP (Boostrix) is approved by Medsafe for use in the New Zealand market and is one of the incumbent vaccines There would be no change to the presentation of the vaccine

Costs and Savings

Health related costs and savings to the person

The vaccines are proposed to be listed on the Pharmaceutical Schedule at no price or subsidy as they are purchased by PHARMAC and supplied to vaccinators free of charge The Ministry of Health pays vaccinators an immunisation service subsidy, so the patient should not incur any costs from vaccination.

Cost and savings to Pharmaceutical expenditure

The proposal would result in a Withheld under section NPV (4 years, 8%) to the CPB over the four year sole supply period. Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii)

Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(ba)(ii)

Costs and savings to the rest of the health system

It is anticipated that there would be no change to the costs and savings to the rest of the health system as a result of this proposal.

Cost Effectiveness

The proposed price increase would reduce the cost effectiveness of dTaP vaccine supplied by GSK However there is a clinical need for this vaccine and it would still be likely to provide good value for money