

From: Andrew Oliver  
Sent: Wednesday, 21 November 2018 11:25 AM  
To: [REDACTED]  
Cc: [REDACTED] Caro Deluca [REDACTED]  
Subject: RE: \*Confidential: Re: Approval of vaccine funding for Northland meningococcal W outbreak

Hi Caroline,

The memo to the DG uses the same clinical arguments to support the option of immunising 9 month to 4 year olds and adolescents aged 14 – 19 years as we used in our funding decision paper. The additional email advice we sought from the Immunisation Subcommittee confirmed the clinical advice provided by the TAG and agreed these were the priority groups for the number of vaccine doses available.

In addition, we looked at vaccine availability, costs of different vaccines, cost effectiveness of targeting different age groups and available funding from the pharmaceutical budget to support immunising these priority groups compared to immunising the whole group under 20 years of age. As with any funding decision by PHARMAC, this is in the context of considering funding for all pharmaceuticals. PHARMAC’s decision fully considered our decision framework, the Factors for Consideration, that take into account the health need, health benefit, suitability and cost and savings to the individual, family, whanau and wider society and the health system.

Our analysis showed that the option of immunising the two identified priority groups was the most cost effective and most practical from a viewpoint of available vaccine and available funds to support the programme.

I would be happy to discuss on the phone if any clarification is needed.

Regards,  
Andrew

Andrew Oliver | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 10, 40 Mercer Street, Wellington  
[REDACTED] | P: +64 4 480 4990 | F: +64 4 480 4995 | [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

Please note: PHARMAC’s Reception is now located on level 10 until further notice.

From: [REDACTED] >  
Sent: Tuesday, 20 November 2018 1:58 PM  
To: Andrew Oliver <[REDACTED]>  
Cc: [REDACTED]  
Subject: \*Confidential: Re: Approval of vaccine funding for Northland meningococcal W outbreak

Many thanks Andrew -as discussed earlier today we are still awaiting sign off here but will advise you as soon as possible on decisions

Also as discussed attached in confidence is final copy of our memo that went to the DG. We would particularly like any extra input you can provide on the rationale for targeting the 2 age groups

Best wishes

[REDACTED]

Dr [REDACTED]  
Director of Public Health  
Population Health and Prevention  
Ministry of Health

[REDACTED]  
<http://www.health.govt.nz>  
[REDACTED]

From: Andrew Oliver <[REDACTED]>  
To: [REDACTED]  
Cc: [REDACTED]  
Date: 19/11/2018 12:51 p.m.  
Subject: Approval of vaccine funding for Northland meningococcal W outbreak

Hi [REDACTED]

I am pleased to advise that PHARMAC has approved the funding of up to 20,650 doses of quadrivalent meningococcal vaccine (Menactra) for the management of a meningococcal W disease outbreak in the Northland regions. The details of the approval are as follows:

A single dose of Menactra for children aged 9 months to 4 years and adolescents aged 14-19 years for the management of a meningococcal W disease outbreak in the Northland region, up to 20,650 doses in total;  
Note that this approval applies only to this outbreak situation and further requests to manage a different outbreak or extend the age groups covered would require further consideration by PHARMAC

Please advise PHARMAC when the Ministry of Health has made a decision on whether or not to proceed with the vaccination programme. Stock will be ordered as soon as the requirement is confirmed. The first 10,000 doses should arrive approximately one week after issuing the purchase order, the remaining 10,650 should arrive approximately 3 weeks after issuing the purchase order.

As previously discussed, it would be good to have a coordinated comms approach, particularly with media enquiries, and we would be happy for the Ministry to continue to lead this combined approach.

Regards,  
Andrew  
Andrew Oliver | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 10, 40 Mercer Street, Wellington  
[REDACTED] | P: +64 4 480 4990 | F: +64 4 480 4995 | [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

Please note: PHARMAC’s Reception is now located on level 10 until further notice.

\*\*\*\*\*  
This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager.  
This footnote also confirms that this email message has been swept by MIMESweeper for the presence of computer viruses.  
[www.clearswift.com](http://www.clearswift.com)  
\*\*\*\*\*  
\*\*\*\*\*

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.

If you have received this message in error, please notify the sender immediately and delete this message.

\*\*\*\*\*

---

This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

---

From: [REDACTED]  
Sent: Thursday, 15 November 2018 10:54 AM  
To: Andrew Oliver  
Subject: RE: Early draft of memo to DG Men W

Hi Andrew,

Good question, what Northland has proposed is based on their previous Men C programme in 2011 administered largely by public health nurses through primary care, outreach and community clinics and then possibly a schools-based programme

There will be additional costs, which we only have very rough estimates of The costs would include the immunisation benefit

Kind regards,

[REDACTED]

[REDACTED]

Manager, Communicable Diseases | Public Health Group | Ministry of Health | New Zealand

[REDACTED] | E: [REDACTED]



Surveillance, response and control of infectious diseases

From: Andrew Oliver <[REDACTED]>  
To: [REDACTED]  
Date: 15/11/2018 09:39 a.m  
Subject: RE: Early draft of memo to DG - Men W

Hi [REDACTED]

Quick question who would be administering the vaccine doses and would an immunisation benefit be payable? Context is that we normally note the Ministry cost of the immunisation benefit for listed vaccines. Are there any Ministry/DHB costs we should note in our decision paper?

Thanks,  
Andrew

Andrew Oliver | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 10, 40 Mercer Street, Wellington  
[REDACTED] | P: +64 4 480 4990 | F: +64 4 480 4995 | [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

Please note: PHARMAC's Reception is now located on level 10 until further notice.

[SEEMail]

From: [REDACTED]  
Sent: Tuesday, 13 November 2018 4:51 PM  
To: Andrew Oliver <[REDACTED]>  
Cc: Caroline De Luca <[REDACTED]>  
Subject: Early draft of memo to DG Men W

Hi Andrew,

I understand Caroline suggested we send you where we are at with our memo to the DG about the Men W response in Northland.

At this stage, we are still to complete the details of the proposed actions as well as the decision section but it would be useful to confirm if there is wording in here that could align with PHARMAC's Board/CE paper, or conversely if you have any wording that you could share with us!

Kind regards,

[REDACTED]

[REDACTED]

Manager, Communicable Diseases | Public Health Group | Ministry of Health | New Zealand

[REDACTED] | E: [REDACTED]



Surveillance, response and control of infectious diseases \*\*\*\*\*  
Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.  
If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.  
If you have received this message in error, please notify the sender immediately and delete this message  
\*\*\*\*\*

This e mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

\*\*\*\*\*  
This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager  
This footnote also confirms that this email message has been swept by MIMESweeper for the presence of computer viruses.  
[www.clearswift.com](http://www.clearswift.com)  
\*\*\*\*\*  
\*\*\*\*\*

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.

If you have received this message in error, please notify the sender immediately and delete this message.

\*\*\*\*\*

---

This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

---

From: Andrew Oliver  
Sent: Friday, 16 November 2018 9:48 AM  
To: [REDACTED]  
Subject: RE: Men W

Hi Laurence,  
It is in review now, so I would be hoping for early afternoon ish. Does that work for you?  
Regards,  
Andrew

Andrew Oliver | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 10, 40 Mercer Street, Wellington  
P: +64 4 460 4990 | F: +64 4 460 4995 | [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

Please note: PHARMAC’s Reception is now located on level 10 until further notice.

[SEEMail]

From: [REDACTED]  
Sent: Friday, 16 November 2018 9:41 AM  
To: Andrew Oliver <[REDACTED]>  
Subject: Men W

Hi Andrew,  
  
I hope your Friday is going well!

Do you have a rough estimate of when we may know the outcome of the decision on funding Menactra for the outbreak in Northland?

Kind regards,

[REDACTED]  
  
[REDACTED]  
Manager, Communicable Diseases | Public Health Group | Ministry of Health | New Zealand  
[REDACTED]



Surveillance, response and control of infectious diseases \*\*\*\*\*  
Statement of confidentiality: This e mail message and any accompanying  
attachments may contain information that is IN CONFIDENCE and subject to  
legal privilege  
If you are not the intended recipient, do not read, use, disseminate,  
distribute or copy this message or attachments  
If you have received this message in error, please notify the sender  
immediately and delete this message  
\*\*\*\*\*

This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

# PHARMAC

Pharmaceutical Management Agency

## MINISTER'S REPORT OCTOBER 2018

### COMMERCIAL IN CONFIDENCE

**Date** 5 December 2018  
**Hon Dr David Clark**  
**Attention** Minister of Health

#### Copies to:

PHARMAC Board  
Lead DHB CE, Pharmaceuticals  
Director-General of Health – Ministry of Health  
Manager Governance and Crown Entities Ministry of Health  
Senior Advisor, Governance and Crown Entities Ministry of Health

#### Contact (s)

Sarah Fitt, Chief Executive  
Alison Hill, Director Engagement and Implementation



## Key points

[illegible]



### **Meningococcal (groups A, C, Y and W-135) conjugate vaccine**

PHARMAC has worked closely with the Ministry of Health to put in place arrangements to protect the Northland community from meningococcal W (MenW) infection.

A vaccination campaign targeting under 5-year olds and 13 to 19-year olds will be implemented by Northland DHB in response to the MenW outbreak that has been declared in the region. 10,000 doses of meningococcal vaccine have arrived, with the remaining 10,650 due at the end of next week

These target age groups were identified following clinical advice from the Ministry of Health and our own expert clinical advisors, the Immunisation Subcommittee of Pharmacology and Therapeutics Advisory Committee (PTAC).

Under 5-year olds are the group most affected once the disease spreads, while 13 to 19-year olds are most likely to be carriers of the meningococcal disease (but have no symptoms). Vaccinating these age groups will reduce or stop transmission of MenW to other unvaccinated people.

PHARMAC has also secured an additional 5000 doses of another quadrivalent meningococcal vaccine (Nimenrix), to fill any potential gap in supply that could occur while awaiting arrival of the second quantity of approximately 10,000 doses due at the end of next week.

These 5000 doses will arrive in New Zealand this week and will mean the total stock available to Northland will be 25,650 doses – sufficient to cover 100% of the age groups included in the vaccination programme (under-5 and 13 to 19-year olds).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]



From: [REDACTED]  
Sent: Monday, 19 November 2018 4:54 PM  
To: [REDACTED]  
Cc: Andrew Oliver; [REDACTED]  
Subject: Re: Approval of vaccine funding for Northland meningococcal W outbreak

Hi [REDACTED]  
I've been talking with Katie Sheriff at PHARMAC her phone number is [REDACTED] and email is simply [media@pharmac.govt.nz](mailto:media@pharmac.govt.nz)

Kind regards  
[REDACTED]  
[REDACTED]  
Senior Media Advisor  
Ministry of Health  
[REDACTED]  
[www.health.govt.nz](http://www.health.govt.nz)

From: [REDACTED]  
To: Andrew Oliver <a[REDACTED]>  
Cc: [REDACTED]  
Date: 19/11/2018 01:55 p.m.  
Subject: Re: Approval of vaccine funding for Northland meningococcal W outbreak

Hi Andrew,  
Many thanks for the confirmation, this is excellent news. Credit to you and the rest of the PHARMAC team for putting this together so rapidly.  
We will keep you updated in terms of a Ministry decision, and we will also ensure that your comms is linked in with ours (and Northlands). Who is the best person from PHARMAC to talk communications?  
Kind regards,  
[REDACTED]

[REDACTED]  
Manager, Communicable Diseases | Public Health Group | Ministry of Health | New Zealand



Surveillance, response and control of infectious diseases

From: Andrew Oliver <[REDACTED]>  
To: [REDACTED]  
Cc: [REDACTED]  
Date: 19/11/2018 12:51 p.m.  
Subject: Approval of vaccine funding for Northland meningococcal W outbreak

Hi [REDACTED]  
I am pleased to advise that PHARMAC has approved the funding of up to 20,650 doses of quadrivalent meningococcal vaccine (Menactra) for the management of a meningococcal W disease outbreak in the Northland regions  
The details of the approval are as follows:

A single dose of Menactra for children aged 9 months to 4 years and adolescents aged 14-19 years for the management of a meningococcal W disease outbreak in the Northland region, up to 20,650 doses in total;  
Note that this approval applies only to this outbreak situation and further requests to manage a different outbreak or extend the age groups covered would require further consideration by PHARMAC.

Please advise PHARMAC when the Ministry of Health has made a decision on whether or not to proceed with the vaccination programme. Stock will be ordered as soon as the requirement is confirmed. The first 10,000 doses should arrive approximately one week after issuing the purchase order, the remaining 10,650 should arrive approximately 3 weeks after issuing the purchase order.

As previously discussed, it would be good to have a coordinated comms approach, particularly with media enquiries, and we would be happy for the Ministry to continue to lead this combined approach.

Regards,  
Andrew  
Andrew Oliver | Therapeutic Group Manager  
PHARMAC | PO Box 10 254 | Level 10, 40 Mercer Street, Wellington  
P: +64 4 460 4990 | F: +64 4 460 4995 | [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

Please note: PHARMAC's Reception is now located on level 10 until further notice.

\*\*\*\*\*  
This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager.  
This footnote also confirms that this email message has been swept by MIMESweeper for the presence of computer viruses.  
[www.clearswift.com](http://www.clearswift.com)  
\*\*\*\*\*

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.

If you have received this message in error, please notify the sender immediately and delete this message.

\*\*\*\*\*

---

This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

---

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

**To:** Director of Operations  
**From:** Manager Pharmaceutical Funding  
**Date:** 19 November 2018

---

**Proposal to fund a regional outbreak response to meningococcal disease (W strain) in Northland**

**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 approve the funding of a single dose of quadrivalent meningococcal vaccine (Menactra) for children aged 9 months to 4 years and adolescents aged 14 19 years for the management of a meningococcal W disease outbreak in the Northland region, up to 20,650 doses at a total net cost to the Combined Pharmaceutical Budget (CPB) of [REDACTED]

**resolve** to approve the purchase orders for Menactra for 20,650 doses at a price of [REDACTED] per dose (ex-manufacturer, excl. GST) (Appendix 1);

**note** that this approval applies only to this outbreak situation and further requests to manage a different outbreak or extend the age groups covered would require further consideration by PHARMAC;

**note** that this use of Menactra for outbreak management would occur outside of a Pharmaceutical Schedule listing and stock would be directly distributed from ProPharma to Northland region to be managed by Public Health;

**resolve** that no consultation was necessary because this proposal is to secure an interim emergency supply of quadrivalent meningococcal vaccine for the management of a declared meningococcal W outbreak in Northland. The proposed transaction is an urgent response to address a public health need at the request of the Ministry of Health Public Health Group

<b>SUMMARY OF PROPOSAL</b>				
<b>Market data</b>	<b>Year ending</b>	<b>30 Jun 2018</b>	<b>30 Jun 2019</b>	<b>30 Jun 2020</b>
<b>Number of patients</b>		20,650	0	0
<b>Number of Maori or PI people</b>		7,145	0	0
<b>Community Pharmaceuticals</b>	Subsidy (gross)	██████████	\$0	\$0
	Net pharmaceutical cost	██████████	\$0	\$0
	Net present value	██████████		
<b>Hospital Pharmaceuticals</b>	Expenditure (gross)	\$0	\$0	\$0
	Net pharmaceutical cost	\$0	\$0	\$0
	Net present value	\$0		
<b>Total CPB impact</b>	Expenditure (gross)	██████████	\$0	\$0
	Net pharmaceutical cost	██████████	\$0	\$0
	Net present value	██████████		
<b>Other DHB costs</b>	Net cost to DHBs	\$0	\$0	\$0
<b>Distribution costs</b>	Net distribution costs	██████████	\$0	\$0
<b>Total</b>	Total net cost to DHBs	██████████0	\$0	\$0
	Net present value	██████████		

Notes:

1. Subsidy (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 1 year using an annual discount rate of 8%.
6. There are no expected costs in out years as the proposal is for a one-off programme.
7. Calculations are in A1209464.



**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

- There has been a significant increase in group W meningococcal disease (Men W) in New Zealand since the second half of the 2017 calendar year. The Northland District Health Board population has been the most affected by this increase, with the overall rate in this region now 8.1 per 100,000 and the rate for Māori is 22.7 per 100,000.
- In consultation with PHARMAC, the Ministry of Health (MoH) convened a technical advisory group (TAG) meeting via teleconference on 8 November 2018, including members of the Immunisation Subcommittee of PTAC, to provide advice on a response to the high Men W rates in Northland. The MoH was concerned that there had been 3 deaths in the last 4 months and the rates were close to those required to declare an outbreak. The TAG considered that there was an outbreak and recommended that a Northland immunisation response should be implemented and identified priority groups for vaccination. The MoH declared an outbreak of Men W disease in Northland region on 8 November 2018.
- Similar increases of Men W have been seen in other countries, including the UK and Australia. The particular strain of Men W causing this spread is associated with a high mortality and affects all age groups. It may also present with atypical gastrointestinal related symptoms which may delay diagnosis and treatment.
- There are two quadrivalent meningococcal vaccines registered in New Zealand: Menactra (supplied by Sanofi) and Nimenrix (supplied by Pfizer). Nimenrix is not currently supplied in New Zealand. PHARMAC staff contacted the suppliers of these vaccines and determined that Sanofi would be able to supply 20,650 doses of Menactra, 10,000 within approximately one week and the remaining 10,650 doses within 3 weeks of a purchase order being issued, however, further supply of Menactra would be subject to approximately 18 months lead time, so would not be available in a suitable timeframe to address the current outbreak. Pfizer advised that it could supply up to 33,000 doses of Nimenrix within a few weeks.
- PHARMAC staff note that the cost of Nimenrix is significantly higher than Menactra, and there is no direct evidence to quantify the additional benefits of vaccinating the whole Northland population aged under 20 years compared to vaccinating the identified priority childhood and adolescent groups.
- PHARMAC staff have considered three options for providing vaccine to manage the Northland Men W outbreak (see Table below). This took into account the clinical advice received, the availability of vaccine, cost and cost effectiveness of different options, and the available budget. On balance, PHARMAC staff recommend option one. PHARMAC staff note that the current budget position, based on the latest (November 2018) expenditure report and the October 2018 forecast, does not permit large investments and option one would provide a cost effective investment with an affordable budget impact. The Immunisation Subcommittee of PTAC was consulted by email and members support the proposed approach.
- There is a degree of urgency in implementing an outbreak response as the school year finishes in early December. The proposed programme could still allow for a school vaccination programme to catch the junior high school students who have not yet finished for the year.
- The MoH is planning to submit a decision memo to the Director General of Health on 19 November 2018 to seek approval to proceed with the implementation of an

emergency immunisation programme in Northland Incorporating PHARMAC's funding decision would be useful.



## Options considered

	Targeted approach	Doses required and BIA
Option One	<p>Children aged 9 months – 4 years and adolescents aged 14 – 19 years, with maximum uptake of 87.6%.</p> <p>One dose of Menactra for the two main target groups</p>	<p>Obtain 20,650 doses of Menactra.</p> <p>The cost to the CPB would be [REDACTED] (in 2018/19 FYR). There would also be distribution costs of [REDACTED] for extra deliveries</p>
Option Two	<p>All children aged 9 months – 4 years and adolescents aged 14 – 19 years with 100% uptake in these groups.</p> <p>One dose of Menactra for children except those 12 months to 2 years who could have Nimenrix.</p> <p>One dose of Nimenrix for children aged 12 months to 2 years to provide a full immune response.</p>	<p>Obtain 20,650 doses of Menactra and 5,000 doses of Nimenrix.</p> <p>The total cost to the CPB would be [REDACTED] (in 2018/19 FYR), [REDACTED] for 20,650 doses of Menactra and [REDACTED] for 5,000 doses of Nimenrix</p> <p>Additional distribution costs would be [REDACTED].</p>
Option Three	<p>All children aged 9 months to people aged under 20 years old, estimated to be 47,050 people.</p> <p>One dose to all people aged under 20 years – Menactra for children aged 9 months to 12 months, and 4 years to 19 years. Nimenrix for children aged 12 months to 2 years to provide a full immune response.</p>	<p>Obtain 20,650 doses of Menactra and 30,000 doses of Nimenrix</p> <p>The total cost to the CPB would be [REDACTED] (in 2018/19 FYR), [REDACTED] for 20,650 doses of Menactra and [REDACTED] for 30,000 doses of Nimenrix.</p> <p>Additional distribution costs would be [REDACTED]</p>

**Proposal**

- To secure supply of 20,650 doses of Menactra (meningococcal ACWY vaccine) for use in the current Men W outbreak in Northland. The groups that would be vaccinated would be all Northland children aged 9 months to 4 years and adolescents aged 14–19 years. Sanofi has advised that 20,650 doses would be the upper limit of what it could supply at short notice, and this would provide 87.7% coverage of these groups. This would require a purchase order to Sanofi for a one-off purchase of 20,650 doses for [REDACTED].
- There would also be distribution costs of [REDACTED] for extra deliveries from HCL to ProPharma Whangarei, paid out of PHARMAC's operations budget under the vaccines national storage agreement with HealthCare Logistics.
- The vaccine stock would be imported and delivered to Healthcare Logistics (HCL). HCL would then distribute the vaccine to the ProPharma Whangarei branch for further distribution to vaccinators are required. ProPharma Whangarei only have capacity to store approximately 1,000 doses of Menactra, so a series of deliveries from HCL would be required.
- Implementation would be managed by the DHB with support from the MoH Immunisation team and Communicable disease team.

**Agreement (if applicable)**

- The current Menactra supply agreement with Sanofi, dated 25 July 2016 (Objective reference ZA114162), provides for the supply of additional vaccine for use in outbreaks, at the same price as the subsidised supply, but with reasonable allowance for PHARMAC to cover additional freight expenses.

(Agreement attached in Appendix 2)



## Health Need

### Disease

- Meningococcal disease is caused by *Neisseria meningitidis*, a gram negative bacterium, and is an important cause of sepsis and meningitis. Worldwide, the most important serogroups of meningococci are groups A, B, C, W135 and Y. Groups B and C are the important types seen in children and young adults in New Zealand. Transmission from person to person is by respiratory droplets or direct contact with nasopharyngeal secretions, from a carrier or case. Those particularly at risk of meningococcal disease are children aged under five years, although all age groups can be infected.
- There has been a steady increase in the number of meningococcal cases (all serotypes) in New Zealand since 2014, from 46 cases in 2014 to 112 cases in 2017 and 96 cases year to date in 2018.
- Although group B serotype remains the most prevalent group, there has been an increase in the number of cases of Men W in NZ since the second half of 2017. Prior to 2017, there were zero to six cases a year. In 2017, there were 12 cases reported including three deaths, and in 2018 (until 5 November) there have been 24 reported cases, including four deaths. Cases have been reported in 10 DHBs across New Zealand with the largest number reported from Northland (7 cases) followed by 3 cases in each of Waitemata, Auckland and Canterbury DHBs.
- Similar increases of Men W have been seen in other countries, including the UK and Australia. The particular strain of Men W causing this spread is associated with a high mortality and affects all age groups. It may also present with atypical gastrointestinal related symptoms which may delay diagnosis and treatment.
- The rate of Men W in the Northland population for all ethnicities under 15 years is now 8.1 per 100,000 population, and the rate for Māori under 15 years is 22.7 cases per 100,000 population. The rate for Māori now meets the definition for a community outbreak as set out in the Communicable Disease Control Manual (three or more confirmed cases of the same strain (group and serotype) within a 3-month period and an age-specific incidence or specific community population incidence of approximately 10 per 100,000, where there is no other obvious link between the cases).
- Seven of the 24 cases of Men W in 2018 have occurred in Northland, including three deaths. These cases are distributed across the DHB region and with an age range from 11 months to 61 years. During September and October there were 4 cases of Men W in Northland, with 2 deaths; 3 of the 4 cases were aged under 20 years.
- The number of people in each of the target age groups recommended for vaccination by the TAG are as follows:

Age group	Numbers in group
9 months - 4 years	10,000
14 years - 19 years	13,550
All under 20s (ie 9 months to 19 years)	47,000



#### Availability and suitability of existing treatments

- Both Menactra and Nimenrix are quadrivalent vaccines that are registered with Medsafe and would provide protection against Men W infection. Only Menactra is currently supplied in New Zealand, but the suppliers have advised that emergency stocks of both vaccines could be sourced.
- Menactra is currently listed in the National Immunisation Schedule for close contacts of cases and immunocompromised groups. PHARMAC is also currently assessing some significant other funding applications for meningococcal vaccines (MenB universal childhood vaccination and Men C universal childhood and/or adolescent vaccination). The Immunisation Subcommittee recommended that MenB vaccine be funded with a medium priority for universal infant vaccination as part of the Infant Immunisation Schedule (minutes available [here](#)). This application will be considered by PTAC at its February 2019 meeting. The Immunisation Subcommittee will be further considering the Men C application at its March 2019 meeting.
- In meningococcal outbreak situations, the usual response is to provide antibiotic chemoprophylaxis with oral antibiotics ciprofloxacin and rifampicin to close contacts of cases.

#### Health need of others

- Meningococcal infection is transmitted from person to person through aerosol droplets, respiratory secretions and saliva, so immunisation of groups with high carriage rates reduces the risk of meningococcal infection and subsequent transmission to family or whānau members with strains covered by the vaccine used.

#### Impact on Māori health areas of focus and health outcomes

- Men W infection rates in Northland are higher in Māori people compared with the total population. In people aged under 20 years, Māori had the highest disease rate over a 14 week period from 15 July 2018, with a rate of 12.4 per 100,000 compared with 6.3 per 100,000 for all ethnicities.
- Northland has a much higher proportion of Māori compared to the national average. Māori make up 34.6% of the Northland population, compared to 15.8% for the national average.
- From an implementation aspect, it would be important to start delivering the school based vaccination programme before the school holidays commence in early December. The senior secondary school students have already finished classes for the year, but the junior students are still in class.



## Health Benefit

- The proposed vaccine (Menactra) is effective against meningococcal disease serotypes A, C, Y and W 135. It is indicated for vaccination of individuals from 9 months to 55 years of age. The most common reported side effects for children and adolescents are injection site pain, irritability, headache and fatigue.
- [Mills et al NZMJ 2013;126:30-8](#) reports on the Northland emergency Men C vaccination programme implemented in 2011. That programme achieved overall coverage of 73% of all people aged under 20 years. Northland Men C rates declined after the programme and have remained low since then.

## *TAG advice*

The MoH convened a technical advisory group (TAG) meeting via teleconference in early November 2018, including members of the Immunisation Subcommittee (summary minutes from discussion in Appendix 3).

- The TAG recommended that, ideally, the whole Northland population under 20 years of age should be immunised with a quadrivalent meningococcal vaccine (50,000 people). Within this overall group, there were two priority groups: children aged 9 months – 4 years (10,000 people); and adolescents aged 14 – 19 years (10,000 people).
- The TAG considered that both Menactra and Nimenrix vaccines would be suitable for use in the recommended outbreak response, noting that Menactra is licenced for use from 9 months of age and Nimenrix is licenced for use from 12 months of age.

## *Immunisation Subcommittee advice*

Email advice from the Immunisation Subcommittee of PTAC was sought (13 November 2018, Appendix 4) regarding the proposed outbreak response and targeted approach.

- Members considered that the two priority groups to vaccinate in Northland are children aged 9 months – 4 years and adolescents aged 14 – 19 years. In addition, it would be ideal to vaccinate all people under 20 years of age.
- Members considered that administering one dose of Menactra in children aged 9 months – 2 years would provide an adequate immune response during an outbreak situation, even though two doses are recommended in this age group to provide full immunity. Although a second dose at a later date would be preferred, it was not essential.
- Members considered that if Nimenrix was available, it would provide better protection for toddlers than a single dose of Menactra and would be preferred for this reason. However, it also noted that in this option, children aged 9 – 12 months would not be vaccinated or would require Menactra.
- Members noted that herd immunity was achieved for Men C in the Netherlands by vaccinating everyone under 20 years of age, and sustaining vaccination of young children after that. Members considered that a targeted approach vaccinating people aged under 20 provides cost effectiveness because it potentially protects people

outside the targeted age groups. The Subcommittee noted that >50% of Men W cases in the last 5 years were in people aged over 20 years.

**Advisor Conflicts of Interest**

No relevant conflicts of interest have been declared by any of the clinical advisors who contributed to the above advice.

**Suitability**

- Menactra is a quadrivalent meningococcal vaccine that provides protection against serotypes A, C, Y and W 135. It is indicated for use in people aged from 9 months to 55 years. Menactra is registered for distribution in New Zealand and is listed in the Pharmaceutical Schedule for immunocompromised people and close contacts of meningococcal cases (types A,C,Y and W)
- Approximated half of the proposed doses would be provided in standard export packaging, in packs of 5 vials. This presentation is not currently approved by Medsafe and would require approval to distribute. Medsafe has indicated that it would be able to provide a priority assessment to expedite availability of vaccine for the management of an outbreak.
- Nimenrix is a quadrivalent meningococcal vaccine that provides protection against serotypes A, C, Y and W 135. It is indicated for use in people aged from 12 months to 55 years. Nimenrix is registered for distribution in New Zealand but is not currently supplied in the New Zealand market.



## Costs and Savings

- The cost of the proposed outbreak response would be [REDACTED] as a one-off cost to the CPB in the 2018/19 financial year as there would be a fixed number of vaccine doses provided that would be delivered over a short time frame of approximately 2 months. There are no expected costs in out years as any further requests for vaccination would be considered separately
- The current budget position, based on the latest (November 2018) expenditure report and the October 2018 forecast, is such that there is currently no headroom for significant investments in the current or next financial years. PHARMAC staff note that the request from the MoH's Public Health Group to conduct a Men W outbreak management programme is a public health issue and PHARMAC has a responsibility to assist the MoH in providing vaccines to manage disease outbreaks. There has already been media attention around the Northland outbreak and the Minister of Health has expressed interest in the response

## Cost effectiveness

- Cost effectiveness for all three possible funding options was considered. The proposed option would be the most cost effective and would have the least budget impact. Options two and three would be less cost effective due to the higher cost of Nimenrix vaccine and the larger target groups. Option three would be more cost effective than option two; however, it would have a significantly higher budget impact.
- Conservative estimates of cost-effectiveness (expressed as QALYs per \$1m) for each age based sub population for the proposal using Menactra, are as follows: 9 months to 4 years [REDACTED]  
[REDACTED]
- The base-case estimates assume that the vaccination programme would result in 50% to 60% of the targeted population being directly protected, by combining coverage and vaccine effectiveness. It is also assumed that if the vaccination programme does not proceed, Northland would experience the same number and age-distribution of cases as has occurred in the 12 months to date. With the programme, 50% to 60% of the outbreak cases would be prevented in the targeted age-groups
- The base-case estimate understates several health benefits: First, it is possible that vaccinating one age group will reduce cases in other groups, by reducing transmission. Second, we have only counted cases prevented in the first 12 months. Cost effectiveness would be better if the programme also prevents cases in later years either by creating enduring immune response, or by reducing the number of carriers in the populations.
- The estimates also assume different levels of 'carriage' (i.e., infants are estimated to have much lower levels of contact with each other compared to contact between those aged 14 to 19 years) and thus lower conferred herd immunity amongst the sub-population. Lastly, they do not consider immunity provided by the vaccination beyond 12 months (which would further improve cost-effectiveness).
- For option two, conservative estimates of cost effectiveness (expressed as QALYs per \$1m) for each age-based sub-population in this option are as follows:
  - 12 months to 2 years approximately [REDACTED]
  - 2 years to 4 years approximately [REDACTED]

- 14 to 19 years [REDACTED]  
some Nimenrix would be required to be used in this group so this would be an overestimate.
- For option three, conservative estimates of cost-effectiveness (expressed as QALYs per \$1m) for each age-based sub-population in this option are as follows:
  - 12 months to 2 years – [REDACTED]
  - 2 years to 19 years [REDACTED]  
vaccine (up to 20,600 doses); and
  - all remaining patients under 20 years [REDACTED]  
using Nimenrix.
  - Lastly, the estimated cost effectiveness for those under 20 years assumes no other vaccination groups (interaction effects are hard to account for).

### **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.

PHARMAC staff do not, however, consider it appropriate to consult on the recommendations contained in this paper as the proposed transaction is an urgent response to address a public health need at the request of the MoH Public Health Group

### **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.

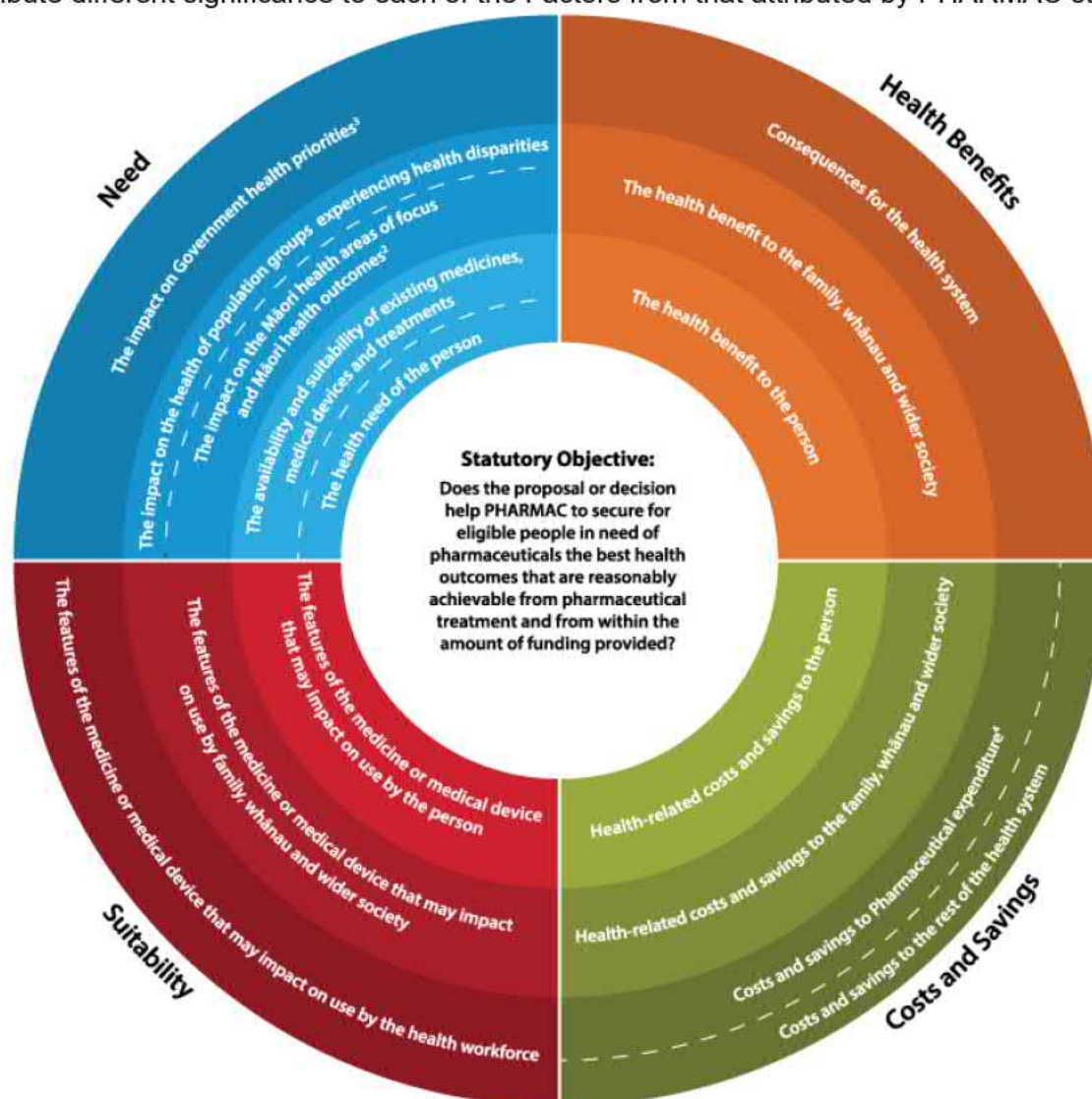
### **Implementation**

Section 49(b) requires PHARMAC to take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the pharmaceutical schedule. As this transaction addresses a Northland region disease outbreak response, notification would be to the MoH's Public Health Group, which would implement the immunisation response in Northland. There is a high degree of media attention to meningococcal disease the present time, so PHARMAC's media team would coordinate with the MoH's media team to provide relevant information to the media. The MoH would lead the media response.



## 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

<sup>1</sup> 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](#).

<sup>2</sup> The current Māori health areas of focus are set out in PHARMAC's [Te Whaioranga Strategy](#)

<sup>3</sup> Government health priorities are currently communicated to PHARMAC by the Minister of Health's [Letter of Expectations](#)

<sup>4</sup> Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate)

<sup>5</sup> 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.