Australian Immunisation Handbook

Responses to Public Consultation Submissions

Changes to the recommended use of meningococcal vaccine to prevent meningococcal infection

Public consultation period: 15 June 2022 to 17 July 2022

Contents

1. Introduction

Public consultation for the revised meningococcal vaccine recommendations in the Australian Immunisation Handbook (the Handbook) was conducted over a 4 week period from 15 June 2022 to 17 July 2022, during which time the draft recommendations were available on the Citizen Space website. The Immunisation Branch invited a range of stakeholders, committees, working groups and interested people to provide submissions. A list of organisations formally invited to comment on the draft guidelines is provided in Appendix A.

This report outlines the public consultation comments received on the revised meningococcal vaccine recommendations. 15 submissions were received using the submission template provided on Citizen Space. Of these, 8 were on behalf of an organisation or jurisdiction and 7 were from individuals.

The Australian Technical Advisory Group on Immunisation (ATAGI) considered all responses from the public consultation in August 2022 and, where necessary, revised the recommendations in accordance with the submissions. Comments from the public consultation submissions and the ATAGI responses are summarised in the following section.

This report was submitted to the National Health and Medical Research Council (NHMRC) on 30 September 2022, reviewed at its meeting on 23 November 2022, and approved on 6 December 2022.

2. Summary of comments received through public consultation on updated meningococcal vaccination recommendations for inclusion in the Handbook

	Organisation	Comment	Proposed Action	Rationale
1a	Victorian Department of Health	Testing was undertaken on healthy people and follow-up extended to 26 months. It will be important to ascertain the durability of response and whether only 1 booster dose is required for those at risk, especially young children with immunodeficiency.	**Reviewed. No change in recommendation made**	A single booster dose of MenB (meningococcal B) vaccine is recommended because the evidence is not sufficient to assess the value of multiple booster doses. The evidence regarding duration of protection after a booster dose will continue to be monitored to guide future recommendations about subsequent booster doses for individuals who remain at ongoing risk.
1b		Reaching part-time laboratory staff with these new recommendations, and also perhaps determining the risk particularly among lab staff who would rarely have exposure to the organism.	**Reviewed. No change in recommendation made**	The recommendation is made for laboratory workers who frequently handle *Neisseria meningitidis* and not all laboratory staff. This recommendation is long standing and should be part of standard workplace health and safety guidelines for pathology staff.
2a	Individual	As a nurse immuniser I believe that the uptake of MenB would be far greater if it was integrated into the National Immunisation Program and as part of the 'No Jab No Pay Policy'. Because MenB is not part of the 'No Pay No Pay Policy' Indigenous parents often decline.	**Reviewed. No change in recommendation made**	The Pharmaceutical Benefits Advisory Committee (PBAC) assesses the cost-effectiveness of vaccines to determine if they can be included in the National Immunisation Program (NIP). For MenB vaccine, this is currently restricted to Indigenous infants and people with certain medical conditions. Matters related to the 'No Jab No Pay Policy' are managed by the Australian Government Department of Health and Aged Care and are outside the scope of this public consultation document.
3	Individual	No	**Reviewed. No change in recommendation made**	Comment noted with thanks.

	Organisation	Comment	Proposed Action	Rationale
4	Individual	MenB should be included as part of the childhood immunisation schedule. It should not be presented as an option for parents. All children should have access to this vaccine for free.	**Reviewed. No change in recommendation made**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. For MenB vaccine, this is currently restricted to Indigenous infants and people with some medical conditions. Other groups are not eligible to receive funded vaccine doses as their meningococcal disease risk is not sufficient to meet cost-effectiveness thresholds.
5a	Individual	I don't think there are any further risks or unintended consequences that could arise from changes to the MenB vaccination. To include people of non-Indigenous status would be of greater benefit as people from this cohort are also at risk of contracting meningococcal disease; as you would well be aware it doesn't discriminate on race.	**Reviewed. No change in recommendation made**	Funding for MenB vaccination is provided for individuals in population groups identified at greatest risk of invasive meningococcal disease (IMD). Aboriginal and Torres Strait Islander people have a higher risk of disease than healthy non-Indigenous people. Other people are still recommended to receive MenB vaccine at ages when their risk of disease is greatest (eg infancy and adolescence). These people are not recommended to receive a booster dose of MenB vaccine as the risk of IMD is low in this group, and primary vaccination is likely to provide adequate protection. There is a lack of data on the clinical benefit of a booster dose in these people.
5b		The entire NIP needs to be reviewed. The amount of undue stress it causes clinicians who have to administer 3 and sometimes 4 vaccines at one time on children is unnecessary. I understand that there is science and research that has gone into why the schedule is the way it is – but explaining that to parents in a manner they will 1) understand and 2) accept is another matter. It is both traumatic for the patient, the parents and the clinicians.	**Reviewed. No change in recommendation made**	Comment is outside the scope of this public consultation document.
5c		As per Question 7. But also, why is Rotarix the only vaccine that is given as an oral preparation? How nice would it be if other vaccines could be given this way as well? Is there any research into this?	**Reviewed. No change in recommendation made**	Comment is outside the scope of this public consultation document.
6a	Individual	The recommendation of a booster dose will provide ongoing protection. The only unintended consequence will be the financial imposition placed upon the consumer as the vaccine is not PBS listed.	**Reviewed. No change in recommendation made**	This is a funding issue and outside the scope of this public consultation document. A booster dose in those groups for which it is recommended will need to undergo assessment by the PBAC and meet cost-effectiveness thresholds to be funded under the NIP.

	Organisation	Comment	Proposed Action	Rationale
6b		There needs to be clear communication regarding this for professionals who treat especially medical-at-risk persons.	**Reviewed. No change in recommendation made**	The *Australian Immunisation Handbook* meningococcal chapter will contain detailed information on the MenB booster dose. Communication strategies will be managed by the Department of Health and Aged Care as per standard processes.
7a	WA Primary Health Alliance	Considerations for implementation would include a document similar to the pneumococcal vaccination clinical decision tree – this is a very useful tool for general practitioners and practice nurses. This could be used with meningococcal ACWY [MenACWY] and B vaccinations to ensure those providers are able to deliver the correct vaccines to the correct patient and ensure they complete the correct dosing schedule.	**Reviewed. No change in recommendation made**	A clinical decision tree for meningococcal vaccination will be considered.
7b		It is also helpful to have a comprehensive list of the medical conditions to review while the patient is present, to confirm their eligibility. It should be inclusive of interchangeability of vaccines and the possibility of delivering with others on the current schedule with any increased risk of adverse reactions.	**Reviewed. No change in recommendation made**	The list of medical conditions for people at increased risk of IMD can be found in the *Australian Immunisation Handbook*. Currently MenB vaccines are not interchangeable, and completion of primary courses and booster doses should be done using the same vaccine. Men B booster doses may be co-administered with other vaccines although providers should be aware of the risk of an increase in local or systemic adverse reactions.
7c		It may be also be useful to also include travel recommendations for these vaccines, now that we are seeing an increase in travel overseas post COVID lockdowns.	**Reviewed. No change in recommendation made**	Vaccination information for travellers can be found in the *Australian Immunisation Handbook*. In general, MenB vaccine (in contrast to MenACWY vaccine) is not considered to be required for travel.
8a	Department of Health and Human Services Victoria	ATAGI identifies a lack of data to support heterologous primary and booster doses. Recommendation for a homologous approach is contingent upon specific vaccine availability. See comments relating to vaccine safety under Question 7.	**Reviewed. No change in recommendation made**	The recommendation for homologous primary and booster doses is based on available evidence. As indicated, there is insufficient evidence to recommend a heterologous schedule.
8b		Training and communication strategies Clarification is required of the Commonwealth's lead role in the provision of resources, guidance for clinicians, guidance for state and jurisdictions (including management of interval and vaccine error), educational resources and communication strategy. State and jurisdictional communication strategies will be required to support the rollout.	**Reviewed. No change in recommendation made**	Implementation matters will be managed by the Australian and state and territory health departments and are outside the scope of this public consultation document.

	Organisation	Comment	Proposed Action	Rationale
8c		Vaccine safety There is potential for an increase in AEFI [adverse events following immunisation], creating an additional burden to surveillance, reporting and clinical management. This potential has not been quantified in this paper. There is potential risk of administration error with stratified age-based intervals and vaccine choice for booster doses. Clear clinical guidance for booster doses, including minimum accepted intervals is required. Guidance must also be available to states and jurisdictions to manage interval and vaccine errors.	**Reviewed. No change in recommendation made**	The *Australian Immunisation Handbook* meningococcal chapter will contain detailed information on the expected adverse events of a MenB booster dose. As the recommendation for a booster dose of MenB vaccine applies to limited population groups, it is not anticipated that there will be a large burden of AEFI reported. In addition to the guidance that will be provided in the *Handbook*, further communication strategies will be managed by the Department of Health and Aged Care.
8d		Administration systems Amendments to the Australian Immunisation Register (AIR) must occur prior to MenB booster rollout to support recording, facilitate surveillance, and optimise jurisdictional reporting.	**Reviewed. No change in recommendation made**	Immunisation providers will be able to enter a booster dose of MenB vaccine into the AIR upon implementation.
8e		Funding Funding considerations for the MenB booster doses are not included in this ATAGI paper. A number of medical conditions described by ATAGI of being higher risk for IMD are not currently funded under the NIP as they do not meet cost-effectiveness evaluation. Individuals at risk through occupational exposure are not funded through the NIP. Identification of risk groups (and specific medical conditions) to receive an NIP-funded booster will facilitate rollout of the proposed changes. If the booster doses are to be funded through NIP, clarify whether this will include both Bexsero (currently funded) and Trumenba vaccines. Bexsero is the only MenB vaccine licensed in Australia for those aged <10 years.	**Reviewed. No change in recommendation made**	This is a funding issue and outside the scope of this public consultation document. At this time, no MenB vaccine has been assessed by the PBAC for cost-effectiveness for use as a booster dose and will not be in the NIP.
8f		Although notification rates for MenB disease have decreased in the period to 2020, highest risk groups include those aged under 5 years. Is there any intention to extend the primary schedule to all infants and children under 5 years? Recommendations 1. Quantify any additional potential burden for surveillance, reporting and AEFI management (projection using historical data with primary MenB schedule) 2. Confirm the Commonwealth's lead role in the provision of resources, guidance for clinicians, guidance for state and jurisdictions (including interval and vaccine error), educational resources and communication strategy. 3. Confirm funding provision and specific cohorts covered in the NIP for MenB boosters. 4. Confirm any changes to NIP to include funding for Trumenba MenB vaccines.	**Reviewed. No change in recommendation made**	Comment is outside the scope of this public consultation document. The *Australian Immunisation Handbook* recommends infants and children aged <2 years receive a primary series of MenACWY and MenB vaccines. In addition to the guidance that will be provided in the *Handbook*, further communication strategies will be managed by the Department of Health and Aged Care. At this time, no MenB vaccine has been assessed by the PBAC for cost-effectiveness for use as a booster dose and will not be in the NIP.

	Organisation	Comment	Proposed Action	Rationale
9a	Individual	Potential benefits would include the vaccines being given to the patients who require them, as opposed to the medical practitioner needing to recommend them, write prescriptions and then the patients organising to have them administered. There would be no discrimination on the basis of affordability. These patients require a number of added vaccines which are already provided to them at no cost to the individual; it would simplify their treatment to have MenB vaccines added to their regime.	**Reviewed. No change in recommendation made**	This is a funding issue and outside the scope of this public consultation document. The PBAC assess the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, no MenB vaccine has been assessed by the PBAC for cost-effectiveness for use as a booster dose and will not be in the NIP.
10a	Queensland Health	No No	**Reviewed. No change in recommendation made**	Comment noted with thanks.
11a	NT Health – Public Health Directorate	None identified Nothing further to add	**Reviewed. No change in recommendation made**	Comment noted with thanks.

12a	Individual	Provision of a booster MenB vaccine dose 3 years after a 4-dose schedule in those <7 years of age would need to be better justified. A booster interval of 5 years which is independent of age would be preferable for consistency for primary care providers. I'm unaware of any data supporting a closer interval in children <7 years of age compared to those >7 years although I appreciate this may be difficult to assess. We are continuing to evaluate the 4CMenB [multicomponent meningococcal B] vaccine program in South Australia (SA). At 3 years post introduction of the program there are no cases in anyone with an immunocompromising condition, despite a few cases in children who have received 1 or 2 doses of 4CMenB vaccine. The 3-year data is included below and was presented at the Communicable Diseases Immunisation Conference (CDIC), on 21st June 2022. *Infants* Vaccine impact: 62% reduction in the incidence of MenB in infants aged 12 weeks to 11 months (IRR [incidence rate ratio]: 0.38, 95%CI: 0.19–0.75, p=0.005) Vaccine effectiveness: 3 doses No MenB cases in those who had received 3 or 4 doses, VE [vaccine effectiveness] =100% (unable to assess variance) 1 and 2 dose(s) 1 MenB case received 2 doses; 2 MenB cases received 1 dose Screening method 48% (OR [odds ratio]: 0.52, 95%CI: 0.09–3.13, p=0.476) for 1 dose 93% (OR: 0.07, 95%CI: 0.01–0.71, p=0.024) for 2 doses Case-control method using 20 AIR controls 41% (OR: 0.59, 95%CI: 0.10–3.68, p=0.576) for 1 dose 91% (OR: 0.09, 95%CI: 0.01–0.93, p=0.043) for 2 doses *Adolescents* Vaccine impact: 78% reduction in the incidence of MenB in adolescents aged 15–18 years (IRR: 0.22, 95%CI: 0.07–0.67, p=0.008) Vaccine effectiveness 1 MenB case had received 2 doses Screening method 84% (OR: 0.16, 95%CI: 0.02–1.49, p=0.108) for 2 doses Case-control method (using 20 AIR controls) 89% (OR: 0.11, 95%CI: 0.01–1.12, p=0.062) for 2 doses In addition, a new published paper on fHbp vaccine (Trumenba) longer-term immunogenicity and safety in children 1–10 years of age is in press (*Lancet Infectious Diseases*). I am happy to provide this paper if it is of interest as it is not yet publicly available (I am first author).	**Reviewed. No change in recommendation made**	No studies were identified that directly assess the optimal timing of booster doses. The timing of MenB booster doses is recommended to align with the timing of MenACWY vaccine boosters to simplify implementation. The timing of the MenACWY booster is recommended 3 years after the primary schedule for people aged <7 years and 5 years for people aged ≥7 years.

	Organisation	Comment	Proposed Action	Rationale
		Consistency of a recommendation for a 5-year interval from the last dose irrespective of age would assist immunisation providers and is unlikely to impact on vaccine effectiveness.		
12b		1. Consideration of a 4-dose (as opposed to current 3-dose) schedule for Aboriginal and Torres Strait Islander infants The current NIP schedule for Aboriginal infants is a 3-dose schedule. As Aboriginal infants have a higher risk (X6–X10) than non-Indigenous infants, consideration should be given to including them as a cohort that should be recommended a 3+1 schedule. I don't have access to national data but I am aware of a meningococcal disease case in an Aboriginal infant who had received 2 primary doses and was not old enough for a 12-month dose. It would be important to determine whether there are other cases in Aboriginal infants 6–12 months of age who have developed meningococcal B disease despite a 2-dose primary schedule, for consideration of a 4-dose schedule in Aboriginal infants for better protection.	**Reviewed. No change in recommendation made**	At this time a 4-dose schedule is not considered necessary for Aboriginal and Torres Strait Islander infants. Although the risk of IMD is higher in Aboriginal and Torres Strait Islander infants, the immune response to a 3-dose schedule is adequate. Some groups are recommended to have a 4-dose schedule as they do not respond as well to a 3-dose schedule.
12c		2. Consideration of inclusion of Aboriginal adolescents for a funded MenB vaccine program under the NIP An additional group with increased risk of meningococcal disease for consideration include Aboriginal children 5–14 years of age. As presented by Katrina Clark at CDIC on 22nd June, Aboriginal children 5–14 years of age have a X20 higher risk of meningococcal disease and X10 for MenB disease compared to non-Indigenous children. Average annual notification rate for IMD in the 5–14-year age group over the 2016–2019 period was 4.65 per 100,000 per year in Aboriginal and Torres Strait Islander children/adolescents vs 0.23 per 100,000 per year in other (non-Indigenous + not stated/missing), giving a rate ratio of 20.0 (95%CI: 11.7–34.5). The MenB IMD notification rate was 1.5 per 100,000 per year in Aboriginal and Torres Strait Islander children/adolescents aged 5–14 years and 0.2 per 100,000 per year in other children/adolescents (RR: 9.7, 95% CI: 4.1–21.7) (personal communication Associate Professor Frank Beard) from a publication submitted to *Communicable Diseases Intelligence* (Jackson J, Sonneveld N, Rashid H, Karpish L, Wallace S, Whop L, et al. Vaccine preventable diseases and vaccination coverage in Aboriginal and Torres Strait Islander people, Australia, 2016–2019). In addition to the impact on meningococcal disease in SA included in the section 6 response above, we have also measured vaccine effectiveness through cross-protection against gonorrhoea in adolescents 15–17 years of age. Consideration of a MenB vaccine program for 14-year-old Aboriginal adolescents (Year 9) potentially could reduce the risk of both these diseases and assist in Closing the Gap. Vaccine impact in adolescents: 30% reduction in the incidence of gonorrhoea in adolescents aged 15–17 years (IRR: 0.70, 95%CI: 0.43–1.14, p=0.152) Vaccine effectiveness: 153 out of 823 gonorrhoea cases (born between 31 January 1998 and 30 April 2006) received MenB vaccination 1 dose (N=31) 2 doses (N=119)	**Reviewed. No change in recommendation made**	This is a funding issue related to primary MenB vaccination and outside the scope of this public consultation on MenB boosters. Some groups are not eligible to receive funded vaccine doses as their meningococcal disease risk is not sufficient to meet cost-effectiveness thresholds set by the PBAC.

	Organisation	Comment	Proposed Action	Rationale
		3 doses (N=3) Case-control method (using chlamydia controls) VE=37% (OR: 0.63, 95%CI: 0.50–0.80, p<0.001) for 2 doses Case-control method (using 20 AIR controls) VE=64% (OR: 0.36, 95%CI: 0.28–0.45, p<0.001) for 2 doses Screening method VE=73% (OR: 0.27, 95%CI: 0.22–0.34, p<0.001) for 2 doses In addition to our published paper, Wang B et al. *Lancet Infectious Diseases* 2022;22(7):1011–1020, there are now a further 3 published papers showing evidence of 4CMenB providing cross-protection against gonorrhoea in addition to the original paper from New Zealand using the MeNZB vaccine. References Abara W et al. *Sexually Transmitted Diseases* 2020;47(2):S46–S47 Longtin J et al. *Open Forum Infectious Diseases* 2017;4(Suppl 1):S734–S735 Wang B et al. *Lancet Infectious Diseases* 2022;22(7):1011–1020 Bruxvoort KJ et al. *Clinical Infectious Diseases* 2022 Jun 1:ciac436 Petousis-Harris H et al. *The Lancet* 2017;390:1603–1610 I am very happy to provide these data to ATAGI in a formal presentation if helpful.		
13	Department of Health WA	There may be potential confusion for providers, as Indigenous infants are eligible for a MenB vaccine primary course through the NIP but not listed as eligible for a booster dose. This should be explained in the *Immunisation Handbook* updates. As per response to Question 6, implementation may be confusing for providers, as Indigenous infants are one of the two groups eligible under the NIP for a MenB vaccination primary course, but are not recommended to receive a booster dose, whereas the other two groups, which are people who have certain medical conditions that increase their risk of meningococcal disease and laboratory workers who have ongoing exposure to the bacteria that causes meningococcal disease, are recommended to receive a booster dose. The introduction of a booster dose for the two identified high-risk groups is supported based on the evidence and rationale provided. However, it is not clear from the summary why Indigenous children are not recommended to receive a MenB booster dose. Waning immunity will also occur for Indigenous infants, and their inclusion in the National Immunisation Schedule as a group eligible for free MenB vaccination is based on their increased risk of disease. From 2016 to 2018 IMD notification rates in Indigenous people were reported to be 5-fold higher than for non-Indigenous people and 15% of notifications were in Indigenous people (https://www.ncirs.org.au/sites/default/files/2022-06/Summary%20of%20National%20Surveillance%20Data%20on%20Vaccine%20Preventable%20Diseases%20in%20Australia%2C%202016%E2%80%932018_0.pdf).	**Reviewed. No change in recommendation made**	Aboriginal and Torres Strait Islander infants have not been included in the population at increased risk of IMD as the risk is age based and the risk declines with age. Individuals with certain medical conditions that put them at continued risk of IMD have been recommended to receive a booster dose.

	Organisation	Comment	Proposed Action	Rationale
14a	Australian College of Nursing (ACN)	ACN commends ATAGI for guidelines that are clear and easy to read. For ACN members, the risks that IMD poses to those in the at-risk groups far outweigh any adverse effects that the vaccine might have. Those contracting IMD can die quickly before the disease is detected. Protecting those in the 'increased risk' group is supported. ACN members also strongly supported providing a booster shot of the MenB vaccine to laboratory workers at occupational risk of *Neisseria meningitidis*.	**Reviewed. No change in recommendation made**	Comment noted with thanks.
14b		Several members raised their concerns over the health risks to people already managing existing health conditions and the possible interactions the MenB vaccine could have with existing medications. Suggest that more research is needed to determine whether the MenB vaccine adversely impacts existing medical conditions or affects health outcomes for people at higher risk. This would require monitoring of this target group well into the future.	**Reviewed. No change in recommendation made**	The only contraindications to meningococcal vaccines are: • anaphylaxis after a previous dose of any meningococcal vaccine • anaphylaxis after any component of a meningococcal vaccine At this time, there are no data that have raised concerns about interaction of MenB vaccines with pre-existing medical conditions. Monitoring for safety signals for all therapeutic products is conducted by the Therapeutic Goods Administration (TGA).
14c		ACN members raised concerns over whether the public will perceive the vaccination to be effective in preventing IMD. More generally, concerns were raised over the lack of awareness of IMD in the general population and therefore suggested there may be little understanding of the health benefits of having a vaccine and/or a booster. Members suggested that a health promotion campaign is needed to address public concerns, improve public health literacy, and ensure that those recommended for the vaccine and booster know the benefits of vaccinating and the risks of catching IMD.	**Reviewed. No change in recommendation made**	Comment is outside the scope of this public consultation document. Communication strategies will be managed by the Department of Health and Aged Care.
14d		ACN members stressed the need for reliable feedback on any unforeseen reactions and/or incidents of anaphylaxis. Good data collection should be mandatory, with the ability to input data at any location where MenB vaccines are administered.	**Reviewed. No change in recommendation made**	Comment is outside the scope of this public consultation document As for other vaccines, adverse events should be reported to the TGA (https://www.tga.gov.au/reporting-adverse-events).

	Organisation	Comment	Proposed Action	Rationale
15a	GSK	GSK welcome the recommendation of a booster dose for individuals with specified medical conditions at increased risk of IMD. Two potential unintended consequences are outlined below for consideration: 1) This new proposed recommendation of an additional booster dose of MenB vaccine for the *Australian Immunisation Handbook* (AIH) will result in an inconsistency with the National Health (Immunisation Program – Designated Vaccines) Determination ('Determination'), which would not have been updated with this additional booster dose for those at increased risk of invasive meningococcal B disease due to specified medical conditions. Until the Determination is changed, individuals would not be able to receive this additional booster dose of MenB vaccine as part of the funded NIP in individuals with specified medical conditions +/– people with ongoing occupational risk of exposure. As such, the additional booster dose would result in 'out-of-pocket' cost for the individual.	**Reviewed. No change in recommendation made**	This is a funding issue and is beyond the scope of the *Australian Immunisation Handbook*. To be added to the Immunisation Program – Designated Vaccines Determination (and consequently the NIP) the vaccine first needs to be assessed for cost-effectiveness as a booster by the PBAC. At this time, no MenB vaccine has been assessed by the PBAC for cost-effectiveness for use as a booster dose and will not be in the NIP.
15b		2) The use and definition of the term 'booster' is inconsistent between the TGA-approved product information (PI), the Determination and the AIH recommendation for Bexsero. The PI and Determination refer to the last dose of the primary course as a booster dose. However, with this proposed recommendation, the AIH specifies a single 'booster' dose after completion of the full primary course. This may create confusion for immunisation providers when reading the PI and/or AIH regarding the need and/or timing of booster doses. Furthermore, this language inconsistency appears throughout the meningococcal disease page where the primary course wording has no mention of a 'booster' within the primary course (different to the PI nomenclature). GSK propose that a clause is added to the AIH to highlight this discrepancy between the PI and AIH as a footnote in the relevant sections or in the 'Variations from product information' section of the AIH, or at ATAGI's discretion to update this nomenclature in line with the approved PI and Determination.	**Reviewed. Change made to recommendation**	Changes to the PI or Immunisation Program – Designated Vaccines Determination are beyond the scope of this public consultation document. Terminology used in the *Australian Immunisation Handbook* will be reviewed for clarity and any necessary variations from the PI will be clearly outlined.
15c		Additional requests for consideration Request for review 1: The following sentence (on page 5 and 6): 'Bexsero and Trumenba are not interchangeable for primary or booster vaccines. The same vaccine should be used for all primary vaccine doses, and the same vaccine should be used for a booster dose'. The second use of 'The same vaccine should be used' seems to be duplicative and GSK suggest its removal for succinctness, greater clarity and consistency. The proposed revised sentence will read as 'Bexsero and Trumenba are not interchangeable for primary or booster vaccines. The same vaccine should be used for all primary vaccine doses as well as the booster dose'.	**Reviewed. Change made to recommendation**	The sentence has been revised to 'The same vaccine should be used for all primary vaccine doses as well as any booster dose'.

	Organisation	Comment	Proposed Action	Rationale
15d		Request for review 2: In order to clearly distinguish between primary series and booster recommendations (on page 6) in the recommendations table ('Table. Recommendations for MenB vaccine for people with a specified medical condition that increases their risk of invasive meningococcal disease') and also to minimise risk for confusion of which vaccine to use for booster dose in accordance to age, GSK propose the addition of subheadings within the table: – add subheading 1 of 'Primary series according to age at first vaccination and MenB vaccine brand' followed by the listing of the primary series information. – add subheading 2 of 'Booster dose according to age at primary series and MenB vaccine brand' followed by the listing of the booster dosing information. Due to the online form limitations of not being able to present this suggested change in a table format, we have emailed through a visual illustration of the table to the Secretariat for consideration.	**Reviewed. No change in recommendation made**	To comply with accessibility guidelines for tables on websites, we are not able to include subheadings. The table for MenB vaccines has been set out in a similar manner to the one for MenACWY vaccines.
15e		The information below is provided as a background update in relation to upcoming Bexsero PI changes (being considered by the TGA currently). GSK have received a clinical evaluation report which recommends approval for an additional Bexsero booster dose: – in toddlers 12 months to 23 months (1 dose with an interval of 12 months to 23 months between the primary series and booster dose) – in children 2 years to 10 years, adolescents (from 11 years) and adults, a booster dose should be considered in individuals at continued risk of exposure to meningococcal disease based on official recommendations	**Reviewed. No change in recommendation made**	Comment noted with thanks.

3. Appendix A – Public Consultation Distribution List

An email was sent on 15 June 2022 to the following organisations and committees to provide advice on the public consultation:

- Australian Association of Practice Management
- Australian Health Protection Principal Committee
- Australian Technical Advisory Group on Immunisation
- Communicable Diseases Network Australia
- Consumers Health Forum of Australia
- Jurisdictional Immunisation Coordinators
- Primary Health Networks
- Pharmaceutical Benefits Advisory Committee
- National Health and Medical Research Council
- Royal Australian College of Physicians