



National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.2) 2020

I, Hope Peisley, delegate of the Minister for Health, make the following Determination.

Dated 2 June 2020

Hope Peisley
Assistant Secretary
Immunisation Branch
Office Of Health Protection
Chief Medical Officer Group
Department of Health

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1 Name

This instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2020*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsections 9B(2) and (5) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)

1 After subsection 7(12)

Insert:

- (13) For item 114 of Schedule 1, a designated vaccine mentioned in that item may be provided in the following circumstances:
- (a) the following number of doses and booster doses may be provided to a person who is an Aboriginal and Torres Strait Islander:
 - (i) if aged at least 2 months of age at start of vaccine course – 2 primary doses with at least 8 weeks between doses and a booster aged at least 12 months;
 - (ii) if aged under 2 years of age at start of vaccine course and the person has not received a dose of the vaccine under subparagraph (i) – 2 primary doses with at least 8 weeks between doses and a booster at least 8 months after the second dose was provided;
 - (b) a person who is an Aboriginal and Torres Strait Islander; and
 - (i) who has one of the following medical conditions known to increase the risk of Invasive Meningococcal Disease (IMD):
 - (A) defects in, or deficiency of, complement components, including factor H, factor D or properdin deficiency; or
 - (B) current or future treatment with eculizumab (a monoclonal antibody directed against complement component C5); or
 - (C) functional or anatomical asplenia, including sickle cell disease or other haemoglobinopathies, and congenital or acquired asplenia; or
 - (D) HIV, regardless of disease stage or CD4⁺ cell count; or
 - (E) haematopoietic stem cell transplant;
 - (ii) may be provided the following number of doses and booster doses:
 - (A) if aged at least 2 months of age at start of vaccine course – 3 primary doses with at least 8 weeks between doses and a booster aged at least 12 months;
 - (B) if aged under 2 years of age at start of vaccine course – 3 primary doses with at least 8 weeks between doses and a booster at least 6 months after the third dose was provided;

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- (c) The following number of doses and booster doses may be provided to a person who has congenital or acquired asplenia (e.g. splenectomy) or hyposplenia, a person who has complement deficiency or a person undergoing eculizumab treatment:
- (i) if aged 6 weeks to 5 months of age at start of vaccine course – 3 primary doses with at least 8 weeks between doses and a booster dose aged at least 12 months;
 - (ii) if aged between 6 and 11 months at start of vaccine course – 2 primary doses with at least 8 weeks between doses and a booster dose aged at least 12 months;
 - (iii) if aged at least 12 months of age at start of vaccine course – 2 primary doses with at least 8 weeks between doses.

2 Part 1 of Schedule 1 (after table item 113)

Insert:

114	Vaccine	Bexsero	Injection (0.5mL)	50 µg <i>Neisseria meningitidis</i> serogroup B Neisseria heparin binding antigen fusion protein	As described in subsection 7(13)
	Multicomponent meningococcal group B (4CMenB)				
	Circumstances				
	Vaccine may be provided in the circumstances set out in subsection 7 (13)			50 µg <i>Neisseria meningitidis</i> serogroup B Neisseria adhesion A protein	
				50 µg <i>Neisseria meningitidis</i> serogroup B factor H binding protein fusion protein	
				25 µg outer membrane vesicles from <i>Neisseria meningitidis</i> serogroup B strain NZ98/254 (measured as amount of total protein containing the PorA P1.4)	
