National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 1) 2023

I, Celia Street, Delegate of the Minister for Health and Aged Care, make the following Determination.

Dated 3 February 2023

Celia Street
First Assistant Secretary
Population Health Division
Department of Health and Aged Care
Delegate of the Minister for Health and Aged Care

Contents

1 Name

This instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 1) 2023*.

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	On 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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(1A)

Insert:

(1B) For item 108C of Schedule 1, the following number of doses and booster doses of a designated vaccine mentioned in that item 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:

(a) primary doses according to the following number of doses:

(i) if aged 12 months old or older at the start of their vaccine course – 2 doses;

(b) plus booster doses according to the following number and timing of doses:

(i) if they completed their primary doses at less than or equal to 6 years of age - 1 booster dose 3 years after completing the primary doses, and then 1 booster dose every 5 years after that; or

(ii) if they completed their primary doses at 7 years of age or older - 1 booster dose every 5 years after completing the primary doses.

2 Subsection 7(11)

Omit "218A,".

3 After subsection 7(13)

Insert:

(14) For item 218A of Schedule 1, three doses of a designated vaccine mentioned in that item may be provided to a person who:

(a) is at least 12 years of age but less than 26 years of age; and

(b) has impaired immunity;

with the three doses provided 6 to 12 months apart.

4 Part 1 of Schedule 1 (after table item 108B)

Insert:

108C	**Vaccine** Meningococcal *Neisseria meningitidis,* Meningococcal polysaccharide serogroups A, C, W-135 and Y conjugate serogroups A, C, W and Y **Circumstances** Vaccine may be provided to: (a) a child who is 12 months old; or (b) a person who is at least 14 years old but less than 20 years of age; or (c) a person aged at least 12 months old who has congenital or acquired asplenia (e.g. splenectomy); or hyposplenia); or (d) a person aged at least 12 months old who has complement deficiency; or (e) a person aged at least 12 months old undergoing eculizumab treatment.	MenQuadfi®	Injection (0.5mL)	After reconstitution, each of the following: (a) Meningococcal polysaccharide* group A 10.0 µg/dose (b) Meningococcal polysaccharide* group C 10.0 µg/dose (c) Meningococcal polysaccharide* group Y 10.0 µg/dose (d) Meningococcal polysaccharide* group W-135 10.0 µg/dose * Each of the four polysaccharides is conjugated to tetanus toxoid (approximately 55 µg /dose)	For persons that the circumstances in (a) and (b) of column 2 of this item apply: (a) 1 dose For persons that the circumstances in (c), (d) or (e) of column 2 of this item apply: (b) 2 doses of a primary course plus booster doses as described in the circumstances set out in subsection 7(1B).

5 Part 2 of Schedule 1 (table item 218A)

Repeal table item, substitute:

218A	**Vaccine** Human papillomavirus (HPV) (9-valent) **Circumstances** Vaccine may be provided to: (a) a person who is at least 12 years of age but less than 14 years of age; or (b) a person who is at least 12 years of age but less than 26 years of age who has not received a single dose of HPV vaccine.	Gardasil 9	Injection (0.5mL)	Each of the following: (a) HPV 6 L1 protein - 30µg; (b) HPV 11 L1 protein - 40µg; (c) HPV 16 L1 protein - 60µg; (d) HPV 18 L1 protein - 40µg; (e) HPV 31 L1 protein - 20µg; (f) HPV 33 L1 protein - 20µg; (g) HPV 45 L1 protein - 20µg; (h) HPV 52 L1 protein - 20µg; (i) HPV 58 L1 protein - 20µg.	1 dose

6 Part 3 of Schedule 1 (after table item 305A)

Insert:

305B	**Vaccine** Diphtheria, tetanus, pertussis and poliomyelitis, hepatitis B, and Haemophilus influenzae type b (DTPa-HB-IPV-Hib) **Circumstances** Vaccine may be provided to a child who is about 2, 4 and 6 months old, from 6 weeks of age.	Vaxelis®	Injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 20 IU; (b) tetanus toxoid — not less than 40 IU; (c) PT — 20 µg; (d) FHA — 20 µg; (e) PRN — 3 µg; (f) FIM — 3 µg; (g) Hepatitis B surface antigen— 10 µg; (h) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units; (i) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units; (j) inactivated poliovirus type 3 (Saukett) —32 D-antigen units (k) hepatitis B surface antigen — 10 µg; (l) *Haemophilus influenzae* type b polysaccharide (Polyribosylribitol Phosphate) — 3 µg (m) Conjugated to meningococcal protein2 — 50 µg	3 doses