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

made under subsection 9B (2) and (5) of the

National Health Act 1953

I, JULIANNE QUAINE, Delegate of the Minister for Health, make this Determination under subsections 9B (2) and (5) of the *National Health Act 1953*.

Dated 29 August 2014

Julianne Quaine
Assistant Secretary
Immunisation Branch
Department of Health
Delegate of the Minister for Health

Federal Register of Legislative Instruments F2014L01255

Contents

1 Name of Determination

This Determination is the *National Health (Immunisation Program — Designated Vaccines) Determination 2014 (No.1)*.

2 Commencement

This Determination commences on the day after it is registered.

3 Revocation

The *National Health (Immunisation Program — Designated Vaccines) Determination 2012 (No.1)* is revoked.

4 Definitions

µg means microgram.

Act means the *National Health Act 1953*.

$CCID_{50}$ means cell culture infectious dose 50%, being the quantity of an infectious agent that when inoculated onto a number of susceptible cell cultures will infect 50% of the individual cultures.

FHA means filamentous haemagglutinin.

FIM 2+3 means fimbrial agglutinogens 2+3.

IU means International Unit.

member of a medical risk group means a person mentioned in any of the following paragraphs:

(a) a person who has congenital immune deficiency (including symptomatic IgG subclass or isolated IgA deficiency) other than a person who requires monthly immunoglobulin infusion;

(b) a person who has sufficient immune reconstitution for a vaccine response to be expected and is receiving a course of:

  (i) immunosuppressive therapy, including corticosteroid therapy equivalent to greater than 2mg/kg per day of prednisone for more than 2 weeks; or

  (ii) radiation therapy;

(c) a person who has compromised splenic function because of:

  (i) sickle haemoglobinopathies; or

  (ii) congenital or acquired functional or anatomical asplenia;

(d) a person who has an HIV infection, either before or after the development of AIDS;

(e) a person who has:

  (i) renal failure; or

  (ii) relapsing or persistent nephrotic syndrome;

(f) a person who has Down's syndrome;

(g) a person who has heart disease associated with cyanosis or cardiac failure;

(h) a person who was a premature infant and who has, or has had, chronic lung disease;

(i) a person who was born at less than 28 weeks gestation;

(j) a person who has cystic fibrosis;

(k) a person who has insulin-dependent diabetes mellitus;

(l) a person who has proven or presumptive cerebrospinal fluid leak;

(m) a person who has an intracranial shunt;

(n) a person who has a cochlear implant.

PFU means plaque forming units.

PRN means pertactin.

PT means pertussis toxoid.

$TCID_{50}$ means tissue culture infectious dose 50%, being the quantity of an infectious agent that when inoculated onto a number of susceptible tissue cultures will infect 50% of the individual cultures.

5 Designated vaccines

For subsection 9B (2) of the Act, a vaccine mentioned in column 2 of Schedule 1 is a designated vaccine.

6 Circumstances in which designated vaccines may be provided

For subsection 9B (5) of the Act, a designated vaccine may be provided in the circumstances mentioned for it in Schedule 1.

7 Circumstances in which designated vaccines may be provided — particular vaccines

(1) For item 110 of Schedule 1, a designated vaccine in that item may be provided in the following circumstances:

(a) a dose of the vaccine may be provided to a child:

(i) who is an Aboriginal or a Torres Strait Islander; and

(ii) who is at least 12 months but not more than 18 months; and

(iii) who lives in Queensland, Western Australia, South Australia or the Northern Territory;

(2) For item 112 of Schedule 1, a designated vaccine mentioned in that item may be provided in the following circumstances:

(a) a first dose of the vaccine may be provided to a person:

(i) who is not an Aboriginal or a Torres Strait Islander; and

(ii) who is at least 65 years;

(b) a first dose of the vaccine may be provided to a person:

(i) who is an Aboriginal or a Torres Strait Islander; and

(ii) who is at least 15 years but less than 50 years; and

(iii) who:
(A) has heart disease; or
(B) has kidney disease; or
(C) has lung disease; or
(D) has asthma; or
(E) has diabetes; or
(F) has an immune compromising condition; or
(G) in the opinion of a medical practitioner, consumes alcohol excessively; or
(H) smokes tobacco;

(c) a first dose of the vaccine may be provided to a person:
(i) who is an Aboriginal or a Torres Strait Islander; and
(ii) who is at least 50 years; and
(iii) who has not received a dose of the vaccine under paragraph (b);

(d) a second dose of the vaccine may be provided to a person mentioned in paragraph (a), (b) or (c) 5 years after the first dose was provided to the person under paragraph (a), (b) or (c);

(e) a third dose of the vaccine may be provided to a person mentioned in paragraph (b) after the later of the following:
(i) the end of 5 years after the second dose was provided to the person under paragraph (d);
(ii) the person turns 50;

(f) a dose of the vaccine may be provided to a child:
(i) who is an Aboriginal or a Torres Strait Islander; and
(ii) who is at least 18 months but not more than 24 months; and
(iii) who lives in Queensland, Western Australia, South Australia or the Northern Territory;

(g) a dose of the vaccine may be provided to a child:
(i) who is at least 4 years but less than 6 years; and
(ii) who is a member of a medical risk group.

(3) For item 113 of Schedule 1, a designated vaccine mentioned in that item may be provided to a person:
(a) who is at least 15 years; and
(b) who is one of the following:
(i) an abattoir worker;
(ii) a sheep shearer;
(iii) a sheep, dairy or beef cattle farmer;
(iv) an employee of a sheep, dairy or beef cattle farmer;
(v) a member of the family of a sheep, dairy or beef cattle farmer who works on the sheep, dairy or beef cattle farm;
(vi) an employee of a tannery; and

(c) who has had a Q-Vax skin test and has received a negative result for that test; and

(d) who has had a *Coxiella burnetii* antibody serum study and has received a negative result for that study.

(4) For item 203 of Schedule 1, a designated vaccine mentioned in that item may be provided in the following circumstances:

(a) a dose of the vaccine may be provided to a newborn infant as soon as practicable after birth but no later than 7 days after birth;

(b) a first dose of the vaccine may be provided to a child who is at least 10 years but less than 14 years;

(c) a second dose of the vaccine may be provided to a child mentioned in paragraph (b) 1 month after the first dose was provided to the child under paragraph (b);

(d) a third dose of the vaccine may be provided to a child mentioned in paragraph (b) 5 months after the second dose was provided to the child under paragraph (c).

(5) For items 205, 208, 209 and 210 of Schedule 1, a designated vaccine mentioned in those items may be provided to:

(a) a person who is at least 65 years; or

(b) an Aboriginal and Torres Strait Islander person who is at least 15 years; or

(c) a person who is at least 6 months

(i) who:

(A) has cardiac disease including cyanotic congenital heart disease, coronary artery disease and congestive heart failure; or

(B) has a chronic respiratory condition including suppurative lung disease, bronchiectasis, cystic fibrosis, chronic obstructive pulmonary disease, chronic emphysema and severe asthma; or

(C) has another chronic illness requiring regular medical follow-up or hospitalisation in the preceding year, including diabetes mellitus, chronic metabolic diseases, chronic renal failure, haemoglobinopathies and impaired immunity (including drug-induced immune impairment); or

(D) has a chronic neurological condition, including multiple sclerosis, spinal cord injuries, seizure disorders or other neuromuscular disorders; or

(E) has impaired immunity, including HIV infection; or

(F) is aged 6 months to 10 years and is receiving long-term aspirin therapy; or

(G) is pregnant.

(6) For item 206 of Schedule 1, a designated vaccine mentioned in that item may be provided to a person who is at least 65 years of age.

(7) For item 207 of Schedule 1, a designated vaccine mentioned in those items may be provided to:

(a) a person who is at least 65 years; or

(b) an Aboriginal and Torres Strait Islander person who is at least 15 years; or

(c) a person who is at least 5 years

(i) who:

(A) has cardiac disease including cyanotic congenital heart disease, coronary artery disease and congestive heart failure; or

(B) has a chronic respiratory condition including suppurative lung disease, bronchiectasis, cystic fibrosis, chronic obstructive pulmonary disease, chronic emphysema and severe asthma; or

(C) has another chronic illness requiring regular medical follow-up or hospitalisation in the preceding year, including diabetes mellitus, chronic metabolic diseases, chronic renal failure, haemoglobinopathies and impaired immunity (including drug-induced immune impairment); or

(D) has a chronic neurological condition, including multiple sclerosis, spinal cord injuries, seizure disorders or other neuromuscular disorders; or

(E) has impaired immunity, including HIV infection; or

(F) is aged 5 to 10 years and is receiving long-term aspirin therapy; or

(G) is pregnant.

Schedule 1 Designated vaccines and circumstances in which vaccines may be provided

(sections 5 and 6)

Part 1 Bacterial vaccines

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
101	**Vaccine** Diphtheria, tetanus and pertussis (adult/adolescent) **Circumstances** Vaccine may be provided to a child who is at least 10 years but less than 18 years old.	Boostrix	Injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 2 IU; (b) tetanus toxoid — not less than 20 IU; (c) PT — 8 µg; (d) FHA — 8 µg; (e) PRN — 2.5 µg	1 dose (booster)
102	**Vaccine** Diphtheria, tetanus and pertussis (adult/adolescent) **Circumstances** Vaccine may be provided to a child who is at least 10 years but less than 18 years old.	Adacel	Injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 2 IU; (b) tetanus toxoid — not less than 20 IU; (c) PT — 2.5 µg; (d) FHA — 5 µg; (e) PRN — 3 µg (f) FIM 2+3 — 5 µg	1 dose (booster)

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
103	**Vaccine** *Haemophilus influenzae* type b (Hib) (monovalent PRP-T) **Circumstances** Vaccine may be provided to a child who is about 12 months old.	ActHib or Hiberix	Refrigerated lyophilised preparation for injection (0.5mL) with separate diluent	Purified Hib capsular polysaccharide conjugated to tetanus toxoid — 10 μg	1 dose (booster)
104	**Vaccine** *Haemophilus influenzae* type b (Hib) (monovalent PRP-OMP) **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 12 months old.	Pedvax	Vial for injection (0.5mL)	Purified Hib capsular polysaccharide conjugated to meningococcal protein — 7.5 μg	3 doses
105	**Vaccine** *Haemophilus influenzae* type b (Hib) and Meningococcal C **Circumstances** Vaccine may be provided to a child who is about 12 months old.	Menitorix	Refrigerated lyophilised preparation for injection (0.5mL) with separate diluent	Each of the following : (a) Hib capsular polysaccharide conjugated to tetanus toxoid- 5 μg (b) Group C meningococcal polysaccharide conjugated to tetanus toxoid- 5 μg	1 dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
106	**Vaccine** Meningococcal C (conjugate) **Circumstances** Vaccine may be provided: (a) to a child who is about 12 months old; or (b) in the period commencing on 1 January 2006 and ending at the end of 30 June 2007, to a person: (i) who, on 1 January 2003, was at least 1 year but less than 20 years of age; and (ii) who has not received a vaccine mentioned in this item or item 106 or 107	Meningitec	Injection (0.5mL)	Meningococcal group C oligosaccharide conjugated to diphtheria protein — 10 μg	1 dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
107	**Vaccine** Meningococcal C (conjugate) **Circumstances** Vaccine may be provided: (a) to a child who is about 12 months old; or (b) in the period commencing on 1 January 2006 and ending at the end of 30 June 2007, to a person: (i) who, on 1 January 2003, was at least 1 year but less than 20 years of age; and (ii) who has not received a vaccine mentioned in this item or item 105 or 107	Menjugate	Refrigerated lyophilised preparation for injection (0.5mL) with separate diluent	Meningococcal group C oligosaccharide conjugated to diphtheria protein — 10 µg	1 dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
108	**Vaccine** Meningococcal C (conjugate) **Circumstances** Vaccine may be provided: (a) to a child who is about 12 months old; or (b) in the period commencing on 1 January 2006 and ending at the end of 30 June 2007, to a person: (i) who, on 1 January 2003, was at least 1 year but less than 20 years of age; and (ii) who has not received a vaccine mentioned in this item or item 105 or 106	NeisVac-C	Injection (0.5mL)	Meningococcal group C oligosaccharide conjugated to tetanus toxoid protein — 10 μg	1 dose

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
109	**Vaccine** Pneumococcal (conjugate, 7-valent) **Circumstances** Vaccine may be provided to: (a) a child who is about 2, 4 or 6 months old; or (b) a child who is about 12 months of age and is a member of a medical risk group	Prevenar	Injection (0.5mL)	Polysaccharides of *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23F conjugated to diphtheria protein — 2 µg of each of serotypes 4, 9V, 14, 18C, 19F and 23F, and 4 µg of serotype 6B	3 or 4 doses
110	**Vaccine** Pneumococcal (conjugate, 13-valent) **Circumstances** Vaccine may be provided: (a) to a child who is about 2, 4 or 6 months old; and (b) to a child who is about 12 months of age and is a member of a medical risk group; or (c) Vaccine may be provided in the circumstances set out in subsection 7 (1)	Prevenar 13	Injection (0.5mL)	Polysaccharides of *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F - 2.2 µg of each of serotype, and 4.4 µg of serotype 6B	3 or 4 doses for a primary course or a single supplementary dose.

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
111	**Vaccine** Pneumococcal (conjugate, 10-valent) **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old, or 18 months old.	Synflorix	Injection (0.5mL)	Polysaccharides of Streptococcus *pneumoniae* serotypes 1, 4, 5, 6B, 7F, 9V, 14 and 23F conjugated to protein D (a surface protein from non-typeable *Haemophilus influenzae*), serotype 18C conjugated to tetanus toxoid protein and serotype 19F conjugated to diptheria toxoid protein – 1 μg of each 1, 4, 6B, 7F, 9V, 14 and 23F and 3 μg of 4, 18C and 19F.	4 dose
112	**Vaccine** Pneumococcal (polysaccharide, 23-valent) **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7 (2)	PneumoVax 23	Injection (0.5mL)	Polysaccharides of *Streptococcus pneumoniae* serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F — 25 μg of each serotype	1 to 3 doses

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
113	**Vaccine** Q fever **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7 (3)	Q-Vax	Injection (0.5mL)	Killed *Coxiella burnetii* — 25 µg	1 dose

Federal Register of Legislative Instruments F2014L01255

Part 2 Viral vaccines

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
201	**Vaccine** Hepatitis A (monovalent) **Circumstances** Vaccine may be provided to a child: (a) who is an Aboriginal or a Torres Strait Islander; and (b) who is at least 1 year old but less than 5 years of age; and (c) who lives in Queensland, Western Australia, South Australia or the Northern Territory	VAQTA Paediatric/ Adolescent	Injection (0.5mL)	Hepatitis A virus protein — 25 units of the hepatitis A virus protein	2 doses, with the second dose given 6 months after the first dose
202	**Vaccine** Hepatitis B (monovalent adult) **Circumstances** Vaccine may be provided to a child who is at least 10 years old but less than 14 years of age.	H-B-Vax II	Vial for injection (1mL)	Hepatitis B surface antigen protein — 10 μg	2 doses, with the second dose given 4 to 6 months after the first dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
203	**Vaccine** Hepatitis B (monovalent paediatric) **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7 (4)	Engerix-B	Vial for injection (0.5mL)	Hepatitis B surface antigen protein — 10 µg	1 dose or 3 doses
204	**Vaccine** Hepatitis B (monovalent paediatric) **Circumstances** Vaccine may be provided to a newborn infant as soon as practicable after birth but no later than 7 days after birth.	H-B-Vax II	Vial for injection (0.5mL)	Hepatitis B surface antigen protein — 5 µg	1 dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
205	**Vaccine** Influenza **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7 (5)	Vaxigrip or Influvac or Fluarix	Injection (0.5mL)		For children older than 6 months but less than 9 years, 2 doses at least 1month apart for the first vaccination and 1 dose per calendar year after that. For persons 9 years and above, 1 dose per calendar year. Note – For children aged between 6 months and less than 3 years the dose is 0.25ml

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
206	**Vaccine** Influenza **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7 (6)	Intanza 15 micrograms	Injection (0.1mL)		For persons aged 65 years and over. 1 dose per calendar year.
207	**Vaccine** Influenza **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7 (7)	Fluvax	Injection (0.5mL)		For children older than 5 years but less than 9 years, 2 doses at least 1 month apart for the first vaccination and 1 dose per calendar year after that. For persons 9 years and above, 1 dose per calendar year.

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
208	**Vaccine** Influenza **Circumstances** Vaccine may be provided to a child that is older than 6 months but less than 3 years, in the circumstances set out in subsection 7 (5)(c).	Vaxigrip Junior	Injection (0.25mL)		For children older than 6 months but less than 3 years, 2 doses at least 1 month apart for the first vaccination and 1 dose per calendar year after that.

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
209	**Vaccine** Influenza **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7(5).	Agrippal	Injection (0.5mL)		For children older than 6 months but less than 9 years, 2 doses at least 1month apart for the first vaccination and 1 dose per calendar year after that. For persons 9 years and above, 1 dose per calendar year. Note – For children aged between 6 months and less than 3 years the dose is 0.25ml

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
210	**Vaccine** Influenza **Circumstances** Vaccine may be provided in the circumstances set out in subsection 7(5).	Fluvirin	Injection (0.5mL)		For children older than 6 months but less than 9 years, 2 doses at least 1month apart for the first vaccination and 1 dose per calendar year after that. For persons 9 years and above, 1 dose per calendar year. Note – For children aged between 6 months and less than 3 years the dose is 0.25ml

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
211	**Vaccine** Measles, mumps and rubella **Circumstances** Vaccine may be provided to a child who is: a. about 12 months old; or b. about 4 years of age if MMRV was not given at 18 months; or c. about 18 months old when administered concurrently with a monovalent varicella vaccine.	M-M-R II	Refrigerated lyophilised preparation for injection (0.5mL)	Each of the following live attenuated viruses: (a) measles virus (Edmonston strain) — 1000 TCID50; (b) mumps virus (Jeryl Lynn strain) — 5000 TCID50; (c) rubella virus (Wistar RA 27/3 strain) — 1000 TCID50	1 or 2 doses
212	**Vaccine** Measles, mumps and rubella **Circumstances** Vaccine may be provided to a child who is; a. about 12 months old; or b. about 4 years of age if MMRV was not given at 18 months; or c. about 18 months old when administered concurrently with a monovalent varicella vaccine.	Priorix	Refrigerated lyophilised preparation for injection (0.5mL)	Each of the following live attenuated viruses: (a) measles virus (Schwarz strain) — $10^{3.0}$ $CCID_{50}$; (b) mumps virus (RIT 4385 derived from the Jeryl Lynn strain) — $10^{3.7}$ $CCID_{50}$; (c) rubella virus (Wistar RA 27/3 strain) — $10^{3.0}$ $CCID_{50}$	1 or 2 doses

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
213	**Vaccine** Measles, mumps, rubella and varicella **Circumstances** Vaccine may be provided to a child who is about 18 months of age	Priorix-Tetra	Powder for injection vial with diluent syringe (0.5mL)	Each of the following live attenuated viruses: (a) measles virus (Schwarz strain) – $10^{3.0}$ CCID50 (b) mumps virus (RIT 4385 strain,derived from Jeryl Lynn strain) - $10^{4.4}$CCID50 (c) rubella virus (Wistar RA 27/3 strain) – $10^{3.0}$ CCID50 (d) varicella virus (Oka strain) - $10^{3.3}$ PFU	1 dose
214	**Vaccine** Measles, mumps, rubella and varicella **Circumstances** Vaccine may be provided to a child who is about 18 months of age	ProQuad	Injection (0.5mL)	Each of the following live attenuated viruses: (a) measles virus derived from Enders' attenuated Edmonston strain) – $10^{3.0}$ TCID50 (b) mumps virus (Jeryl Lynn™ (B Level) strain) - $10^{4.3}$TCID50 (c) rubella virus (Wistar RA 27/3 strain) – $10^{3.0}$ TCID50 (d) Varicella-zoster virus (Oka/Merck strain) - $10^{3.99}$ PFU	1 dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
215	**Vaccine** Poliomyelitis **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old or 4 years of age, if all other vaccines containing poliovirus are unsuitable	IPOL	Injection (0.5mL)	Each of the following killed whole polioviruses: (a) type 1 (Mahoney) — 40 D-antigen units; (b) type 2 (MEF-1) — 8 D-antigen units; (c) type 3 (Saukett) — 32 D-antigen units	No more than 4 doses
216	**Vaccine** Varicella **Circumstances** Vaccine may be provided to: (a) a child who is about 18 months old; or (b) a child who is at least 10 years old but less than 14 years of age, if the child: (i) has not had varicella; and (ii) has not been vaccinated against varicella.	Varilrix	Refrigerated lyophilised preparation for injection (0.5mL)	Live attenuated Oka strain of the varicella-zoster virus — $10^{3.3}$ PFU	1 dose

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
217	**Vaccine** Varicella **Circumstances** Vaccine may be provided to: (a) a child who is about 18 months old; or (b) a child who is at least 10 years old but less than 14 years of age, if the child: (i) has not had varicella; and (ii) has not been vaccinated against varicella.	Varivax Refrigerated	Refrigerated lyophilised preparation for injection (0.5mL)	Live attenuated Oka/Merck strain of the varicella-zoster virus — at least 1350 PFU	1 dose
218	**Vaccine** Human papillomavirus (HPV) **Circumstances** Vaccine may be provided to: (a) a person who is at least 12 years old but less than 14 years of age; or (b) A male who, between 1 February 2013 and 31 December 2015, is at least 13 years old but less than 16 years old.	Gardasil	Injection (0.5mL)	Each of the following: (a) HPV 6 L1 protein — 20 µg; (b) HPV 11 L1 protein — 40 µg; (c) HPV 16 L1 protein — 40 µg; (d) HPV 18 L1 protein — 20 µg	3 doses

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
218	**Vaccine** Human papillomavirus (HPV) **Circumstances** Vaccine may be provided to: a female who is at least 12 years old but less than 14 years of age.	Cervarix	Injection (0.5mL)	Each of the following: (a) HPV 16 L1 protein - 20μg; (b) HPV 18 L1 protein - 20μg	3 doses
220	**Vaccine** Rotavirus **Circumstances** Vaccine may be provided to a child who: (a) is about 2 or 4 months old.	Rotarix	Oral suspension (1.5mL) in oral applicator	Human rotavirus vaccine, live attenuated, RIX 4414 strain (G1P[8]) — not less than 10^6 $CCID_{50}$	2 doses: (a) first dose given at 6 to 14 weeks of age; (b) second dose given at 14 to 24 weeks of age

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
221	**Vaccine** Rotavirus **Circumstances** Vaccine may be provided to a child who: (a) is about 2, 4 or 6 months old.	RotaTeq	Oral solution (2.0mL)	Live pentavalent reassortant vaccine containing each of the following: (a) G1 — 2.2 x 10^6 IU; (b) G2 — 2.8 x 10^6 IU; (c) G3 — 2.2 x 10^6 IU; (d) G4 — 2.0 x 10^6 IU; (e) P1 (8) — 2.3 x 10^6 IU	3 doses: (a) first dose given at 6 to 14 weeks old; (b) second dose given at 14 to 24 weeks old; (c) third dose given before 32 weeks old

Federal Register of Legislative Instruments F2014L01255

Part 3 Combined bacterial and viral vaccines

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
301	**Vaccine** Diphtheria, tetanus, pertussis and poliomyelitis **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old, or between 3 years and 6 months and 4 years of age.	Infanrix-IPV	Injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 30 IU; (b) tetanus toxoid — not less than 40 IU; (c) PT — 25 µg; (d) FHA — 25 µg; (e) PRN — 8 µg; (f) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units; (g) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units; (h) inactivated poliovirus type 3 (Saukett) —32 D-antigen units	4 doses

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
302	**Vaccine** Diphtheria, tetanus, pertussis and poliomyelitis **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old, or between 3 years and 6 months and 4 years of age.	Quadracel	Vial for injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 30 IU; (b) tetanus toxoid — not less than 40 IU; (c) PT — 20 µg; (d) FHA — 20 µg; (e) PRN — 3 µg; (f) FIM 2+3 — 5 µg; (g) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units; (h) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units; (i) inactivated poliovirus type 3 (Saukett) — 32 D-antigen units	4 doses

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
303	**Vaccine** Diphtheria, tetanus, pertussis, poliomyelitis and hepatitis B **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old.	Infanrix-Penta	Injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 30 IU; (b) tetanus toxoid — not less than 40 IU; (c) PT — 25 µg; (d) FHA — 25 µg; (e) PRN — 8 µg; (f) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units; (g) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units; (h) inactivated poliovirus type 3 (Saukett) — 32 D-antigen units; (i) recombinant hepatitis B surface antigen — 10 µg	3 doses

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
304	**Vaccine** Diphtheria, tetanus, pertussis, poliomyelitis and *Haemophilus influenzae* type b (Hib) **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old.	Pediacel	Injection (0.5mL)	Each of the following: (a) diphtheria toxoid — not less than 30 IU; (b) tetanus toxoid — not less than 40 IU; (c) PT — 20 µg; (d) FHA — 20 µg; (e) PRN — 3 µg; (f) FIM 2+3 — 5 µg; (g) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units; (h) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units; (i) inactivated poliovirus type 3 (Saukett) — 32 D-antigen units; (j) purified Hib capsular polysaccharide conjugated to tetanus toxoid — 10 µg	3 doses

Federal Register of Legislative Instruments F2014L01255

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
305	**Vaccine** Diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and *Haemophilus influenzae* type b (Hib) **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 6 months old.	Infanrix-Hexa	Injection (0.5mL) combination pack	Each of the following: (a) diphtheria toxoid — not less than 30 IU; (b) tetanus toxoid — not less than 40 IU; (c) PT — 25 µg; (d) FHA — 25 µg; (e) PRN — 8 µg; (f) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units; (g) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units; (h) inactivated poliovirus type 3 (Saukett) — 32 D-antigen units; (i) recombinant hepatitis B surface antigen — 10 µg; (j) purified Hib capsular polysaccharide conjugated to tetanus toxoid — 10 µg	3 doses
306	**Vaccine** Hepatitis B and *Haemophilus influenzae* type b (Hib) **Circumstances** Vaccine may be provided to a child who is about 2, 4 or 12 months old.	Comvax	Vial for injection (0.5mL)	Each of the following: (a) Hepatitis B surface antigen — 5µg; (b) purified Hib capsular polysaccharide conjugated to meningococcal protein — 7.5µg	3 doses

Note
All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See www.comlaw.gov.au.