

# National Health (Immunisation Program — Designated Vaccines) Determination 2009 (No.3)<sup>1</sup>

#### National Health Act 1953

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

Dated twenty third ## December 2009

Mary Murnane
Deputy Secretary
Department of Health and Ageing
Delegate of the Minister for Health and Ageing

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#### 1 Name of Determination

This Determination is the *National Health (Immunisation Program — Designated Vaccines) Determination 2009 (No.3).* 

#### 2 Commencement

This Determination commences on the day after it is registered.

#### 3 Revocation

The National Health (Immunisation Program — Designated Vaccines) Determination 2009 (No. 2) 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 items 109 and 110 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.
- (2) For item 111 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.
- (3) 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).
- (4) For items 205 and 206 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 followup 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.

Part 1 Bacterial vaccines

### 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	Boostrix	Injection (0.5mL)	Each of the following:	1 dose	
	Diphtheria, tetanus and pertussis (adult/adolescent)			(a) diphtheria toxoid — not less than 2 IU;	(booster)	
	Circumstances			(b) tetanus toxoid — not less		
	Vaccine may be provided to a child who is at least 10 years but less than 18 years			than 20 IU;		
				(c) PT — 8 μg;		
				(d) FHA — $8 \mu g$ ;		
				(e) PRN — $2.5 \mu g$		
102	Vaccine	Adacel Injection (0.5mL)	Injection (0.5mL)	Each of the following:	1 dose	
	Diphtheria, tetanus and pertussis (adult/adolescent)				(a) diphtheria toxoid — not less than 2 IU;	(booster)
	Circumstances		(b) tetanus toxoid — not less			
	Vaccine may be provided to a child who is at least			than 20 IU;		
	10 years but less than 18 years			(c) PT — $2.5 \mu g$ ;		
				(d) FHA — 5 μg;		
				(e) PRN — $3 \mu g$		
				(f) FIM $2+3 - 5 \mu g$		

ltem	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses	
103	Vaccine	ActHib or	Refrigerated	Purified Hib capsular	1 dose	
	Haemophilus influenzae type b (Hib) (monovalent PRP-T)	Hiberix	lyophilised preparation for injection (0.5mL) with separate diluent	polysaccharide conjugated to tetanus toxoid — 10 μg	(booster)	
	Circumstances					
	Vaccine may be provided to a child who is about 12 months					
104	Vaccine	Pedvax	Vial for injection	Purified Hib capsular	3 doses	
	Haemophilus influenzae type b (Hib) (monovalent PRP-OMP)		(0.5mL)	polysaccharide conjugated to meningococcal protein — 7.5 μg		
	Circumstances			. 0		
	Vaccine may be provided to a child who is about 2, 4 or 12 months					
05	Vaccine	Meningitec	Injection (0.5mL)	Meningococcal group C	1 dose	
	Meningococcal C (conjugate)				oligosaccharide conjugated to diphtheria protein — 10 μg	
	Circumstances					
	Vaccine may be provided:					
	(a) to a child who is about 12 months; 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; and					
	(ii) who has not received a vaccine mentioned in this item or item 106 or 107					

Bacterial vaccines

tem	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
.06	Vaccine	Menjugate	Refrigerated	Meningococcal group C	1 dose
	Meningococcal C (conjugate)		lyophilised preparation for injection (0.5mL)	oligosaccharide conjugated to diphtheria protein — 10 µg	
	Circumstances		with separate diluent		
	Vaccine may be provided:				
	(a) to a child who is about 12 months; 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; and				
	(ii) who has not received a vaccine mentioned in this item or item 105 or 107				
07	Vaccine	NeisVac-C	eisVac-C Injection (0.5mL)	Meningococcal group C oligosaccharide conjugated to tetanus toxoid protein — 10 μg	1 dose
	Meningococcal C (conjugate)				
	Circumstances				
	Vaccine may be provided:				
	(a) to a child who is about 12 months; 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; and				
	(ii) who has not received a vaccine mentioned in this item or item 105 or 106				

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
108	Vaccine Pneumococcal (conjugate, 7-valent)	Prevenar	Injection (0.5mL)	Polysaccharides of Streptococcus pneumoniae	3 or 4 doses
	Circumstances			serotypes 4, 6B, 9V, 14, 18C, 19F and 23F conjugated to diphtheria protein — 2 µg of	
	Vaccine may be provided to:			each of serotypes 4, 9V, 14, 18C, 19F and 23F, and 4 μg of	
	(a) a child who is about 2, 4 or 6 months; or				
	(b) a child who is about 12 months and is a member of a medical risk group			serotype 6B	
109	Vaccine	Synflorix Injection (0.5mL)	Polysaccharides of	4 dose	
	Pneumococcal (conjugate, 10-valent)			Streptococcus <i>pneumoniae</i> serotypes 1, 4, 5, 6B, 7F, 9V, 14 and 23F conjugated to protein D (a surface protein from non-typeable <i>Haemophilus influenzae</i> ), 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.	
	Circumstances				
	Vaccine may be provided to a child who is about 2, 4 or 6 months, or 18 months				

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
110	Vaccine Pneumococcal (polysaccharide, 23-valent) Circumstances Vaccine may be provided in the circumstances set out in subsection 7 (1)	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
111	Vaccine Q fever	Q-Vax	Injection (0.5mL)	Killed <i>Coxiella burnetii</i> — 25 μg	1 dose
	Circumstances				
	Vaccine may be provided in the circumstances set out in subsection 7 (2)				

#### 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	VAQTA Paediatric/	Injection (0.5mL)	Hepatitis A virus protein —	2 doses, with
	Hepatitis A (monovalent)	Adolescent		25 units of the hepatitis A virus protein	the second dose given
	Circumstances				6 months after
	Vaccine may be provided to a child:				the first dose
	(a) who is an Aboriginal or a Torres Strait Islander; and				
	(b) who is at least 1 year but less than 5 years; and				
	(c) who lives in Queensland, Western Australia, South Australia or the Northern Territory				
202	Vaccine	H-B-Vax II	Vial for injection (1mL)	Hepatitis B surface antigen protein — 10 μg	2 doses, with the second dose given 4 to
	Hepatitis B (monovalent adult)				
	Circumstances				6 months after
	Vaccine may be provided to a child who is at least 10 years but less than 14 years				the first dose
203	Vaccine	Engerix-B	Vial for injection	Hepatitis B surface antigen	1 dose or
	Hepatitis B (monovalent paediatric)		(0.5mL)	protein — 10 μg	3 doses
	Circumstances				
	Vaccine may be provided in the circumstances set out in subsection 7 (3)				

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
204	Vaccine	H-B-Vax II	Vial for injection	Hepatitis B surface antigen	1 dose
	Hepatitis B (monovalent paediatric)		(0.5mL)	protein — 5 μg	

Circumstances

Viral vaccines

Vaccine may be provided to a newborn infant as soon as practicable after birth but no later than 7 days after birth

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
205	Vaccine	Fluvax or Vaxigrip	Injection (0.5mL)	Like strains of each of the	For children
	Influenza	or Influvac		following:	older than 6 months but
	Circumstances Vaccine may be provided in the circumstances set			<ul> <li>A (H1N1): an</li> <li>A/California/7/2009 (H1N1) -</li> <li>like strain, 15 μg HA per dose</li> </ul>	less than 9 years, 2 doses
	out in subsection 7 (4)			<ul> <li>A (H3N2): an A/Perth/16/2009 (H3N2) - like strain, 15 μg HA per dose</li> <li>B: a B/Brisbane/60/2008 - like strain, 15 μg HA per dose</li> <li>The following viruses are recommended as suitable vaccine strains:</li> <li>A/California/7/2009 (H1N1) (NYMC X-179A, NYMC X-181, NYMC X-181A, NIBRG-121, NIBRG-121xp)</li> <li>A/Perth/16/2009 (H3N2)- like virus (NYMC X-183)</li> <li>B/Brisbane/60/2008</li> </ul>	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  Note – For children aged between 6 months and less than 3 years the dose is 0.25ml

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Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
206	Vaccine	Fluvax Junior or	Injection (0.25mL)	Like strains of each of the	For children
	Influenza	Vaxigrip Junior		following:	older than 6 months but
	Circumstances			• A (H1N1): an A/California/7/2009 (H1N1) - like strain, 7.5 µg HA per dose	less than 3 years, 2 doses at least 1 month apart for the first vaccination
	Vaccine may be provided in the circumstances set out in subsection 7 (4)			<ul> <li>A (H3N2): an A/Perth/16/2009 (H3N2) - like strain, 7.5 μg HA per dose</li> <li>B: a B/Brisbane/60/2008 - like</li> </ul>	
				strain, 7.5 µg HA per dose	calendar year
				The following viruses are recommended as suitable vaccine	after that
				strains:	
				<ul> <li>A/California/7/2009 (H1N1) (NYMC X-179A, NYMC X- 181, NYMC X-181A, NIBRG- 121, NIBRG-121xp)</li> </ul>	
				<ul> <li>A/Perth/16/2009 (H3N2)- like virus (NYMC X-183)</li> </ul>	
				<ul> <li>B/Brisbane/60/2008</li> </ul>	

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
207	Vaccine	M-M-R II	Refrigerated lyophilised	Each of the following live attenuated viruses:	2 doses
	Measles, mumps and rubella  Circumstances		preparation for injection (0.5mL)	(a) measles virus (Edmonston strain) — 1000 TCID50;	
	Vaccine may be provided to a child who is about 12 months or 4 years			(b) mumps virus (Jeryl Lynn strain) — 5000 TCID50;	
	12 monuis of 4 years			(c) rubella virus (Wistar RA 27/3 strain) — 1000 TCID50	
208	Vaccine	Priorix Refrigerated lyophilised preparation for injection (0.5mL)	Each of the following live	2 doses	
	Measles, mumps and rubella		preparation for	attenuated viruses:  (a) measles virus (Schwarz	
	Circumstances			strain) — $10^{3.0}$ CCID <sub>50</sub> ;	
	Vaccine may be provided to a child who is about 12 months or 4 years				(b) mumps virus (RIT 4385 derived from the Jeryl Lynn strain) — 10 <sup>3.7</sup> CCID <sub>50</sub> ;
				(c) rubella virus (Wistar RA 27/3 strain) — $10^{3.0}$ CCID <sub>50</sub>	
209	Vaccine	IPOL	Injection (0.5mL)	Each of the following killed whole	No more than
	Poliomyelitis			polioviruses:	4 doses
	Circumstances			(a) type 1 (Mahoney) — 40 D-antigen units;	
	Vaccine may be provided to a child who is about 2, 4 or 6 months or 4 years, if all other vaccines containing poliovirus are unsuitable			<ul> <li>(b) type 2 (MEF-1) —</li> <li>8 D-antigen units;</li> <li>(c) type 3 (Saukett) —</li> <li>32 D-antigen units</li> </ul>	

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
210	Vaccine	Varilrix	Refrigerated lyophilised preparation for injection (0.5mL)	Live attenuated Oka strain of the	1 dose
	Varicella			varicella-zoster virus — 10 <sup>3.3</sup> PFU	
	Circumstances				
	Vaccine may be provided to:				
	(a) a child who is about 18 months; or				
	(b) a child who is at least 10 years but less than 14 years, if the child:				
	(i) has not had varicella; and				
	(ii) has not been vaccinated against varicella				
211	Vaccine	Varivax	Refrigerated	Live attenuated Oka/Merck strain of the varicella-zoster virus — at least 1350 PFU	1 dose
	Varicella	Refrigerated	lyophilised preparation for		
	Circumstances		injection (0.5mL)		
	Vaccine may be provided to:				
	(a) a child who is about 18 months; or				
	(b) a child who is at least 10 years but less than 14 years, if the child:				
	(i) has not had varicella; and				
	(ii) has not been vaccinated against varicella				

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
212	Vaccine	Gardasil	Injection (0.5mL)	Each of the following:	3 doses
	Human papillomavirus (HPV)			(a) HPV 6 L1 protein — 20 μg;	
	Circumstances			<ul> <li>(b) HPV 11 L1 protein — 40 μg;</li> <li>(c) HPV 16 L1 protein — 40 μg;</li> <li>(d) HPV 18 L1 protein — 20 μg</li> </ul>	
	Vaccine may be provided to:				
	(a) a female who is at least 12 years but less than 14 years; or				
	(b) a female who, between 1 March 2007 – 30 June 2009, is at least 13 years but less than 27 years and has received at least one before 1 July 2009				
213	Vaccine	Cervarix	Injection (0.5mL)	Each of the following:  (a) HPV 16 L1 protein - 20μg;  (b) HPV 18 L1 protein - 20μg	3 doses
	Human papillomavirus (HPV)				
	Circumstances			(b) 111 v 18 L1 protein - 20µg	
	Vaccine may be provided to: a female who is at least 12 years but less than 14 years				

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses			
214	Vaccine	Rotarix	Rotarix		Oral suspension (1.5mL) in oral	Human rotavirus vaccine, live attenuated, RIX 4414 strain	2 doses:	
	Rotavirus		applicator (G1P[8]) — not less than 10 <sup>6</sup>	$(G1P[8])$ — not less than $10^6$	(a) first dose			
	Circumstances			$CCID_{50}$	given at			
	Vaccine may be provided to a child who:				6 to 14 weeks of			
	(a) is about 2 or 4 months							age;
								(b) second
						dose given at		
					14 to 24			
					weeks of			
					age			

Formulation	Active ingredient and strength	Number and timing of doses
Oral solution (2.0mL)	Live pentavalent reassortant vaccine containing each of the following:  (a) G1 — 2.2 x 10 <sup>6</sup> IU;  (b) G2 — 2.8 x 10 <sup>6</sup> IU;  (c) G3 — 2.2 x 10 <sup>6</sup> IU;  (d) G4 — 2.0 x 10 <sup>6</sup> IU;  (e) P1 (8) — 2.3 x 10 <sup>6</sup> IU	timing of doses  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
		(2.0mL) vaccine containing each of the following:  (a) G1 — 2.2 x 10 <sup>6</sup> IU;  (b) G2 — 2.8 x 10 <sup>6</sup> IU;  (c) G3 — 2.2 x 10 <sup>6</sup> IU;  (d) G4 — 2.0 x 10 <sup>6</sup> IU;

Part 3 Combined bacterial and viral vaccines

#### 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	Infanrix-IPV	Injection	Each of the following:	4 doses		
	Diphtheria, tetanus, pertussis and poliomyelitis		(0.5mL)	(a) diphtheria toxoid — not less than 30 IU;			
	Circumstances			<ul> <li>(b) tetanus toxoid — not less than 40 IU;</li> <li>(c) PT — 25 μg;</li> </ul>			
	Vaccine may be provided to a child who is about 2,			(d) FHA — 25 µg;			
	4 or 6 months, or between 3 years and 6 months and 4 years		(e) PRN — 8 μg;				
	1 years					(f) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units;	
				<ul><li>(g) inactivated poliovirus type 2</li><li>(MEF-1) — 8 D-antigen units;</li></ul>			
				(h) inactivated poliovirus type 3 (Saukett) —32 D-antigen units			

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses	
302	Vaccine	Quadracel	Vial for	Each of the following:	4 doses	
	Diphtheria, tetanus, pertussis and poliomyelitis		(0.5 mL)	(a) diphtheria toxoid — not less than 30 IU;		
	Circumstances			(b) tetai	<ul><li>(b) tetanus toxoid — not less than 40 IU;</li><li>(c) PT — 20 ug:</li></ul>	
	Vaccine may be provided to a child who is about 2,			. 63		
	4 or 6 months, or between 3 years and 6 months and 4 years			(e) PRN — 3 $\mu$ g;		
	· years			(f) FIM $2+3 - 5 \mu g$ ;		
			(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		

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				
303	Vaccine	Infanrix-Penta	Injection	Each of the following:	3 doses				
	Diphtheria, tetanus, pertussis, poliomyelitis and		(0.5mL)	(a) diphtheria toxoid — not less than 30 IU;					
	hepatitis B			(b) tetanus toxoid — not less than 40 IU;					
	Circumstances			(c) PT — 25 μg;					
	Vaccine may be provided to a child who is about 2,			(d) FHA — 25 μg;					
	4 or 6 months			(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;
				<ul><li>(i) recombinant hepatitis B surface antigen — 10 μg</li></ul>					

Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses
304	Vaccine	Pediacel	Injection	Each of the following:	3 doses
	Diphtheria, tetanus, pertussis, poliomyelitis and		(0.5mL)	(a) diphtheria toxoid — not less than 30 IU;	
	Haemophilus influenzae type b (Hib)			(b) tetanus toxoid — not less than 40 IU;	
	Circumstances			(c) PT — 20 μg;	
	Vaccine may be provided to a child who is about 2,			(d) FHA — 20 μg;	
	4 or 6 months			(e) PRN — $3 \mu g$ ;	
			(f) FIM $2+3 - 5 \mu g$ ;		
			(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;		

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Item	Vaccine and the circumstances in which vaccine may be provided	Brand	Formulation	Active ingredient and strength	Number and timing of doses	
305	Vaccine	Infanrix-Hexa	(0.5mL) (a combination pack (c)	Each of the following:	3 doses	
	Diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and <i>Haemophilus influenzae</i> type b (Hib)			<ul><li>(a) diphtheria toxoid — not less than 30 IU;</li><li>(b) tetanus toxoid — not less than 40 IU;</li></ul>		
	Circumstances			(c) PT — 25 µg;		
	Vaccine may be provided to a child who is about 2, 4 or 6 months			<ul><li>(d) FHA — 25 μg;</li><li>(e) PRN — 8 μg;</li></ul>		
	4 Of O Months			(f) inactivated poliovirus type 1 (Mahoney) — 40 D-antigen units;		
				(g) inactivated poliovirus type 2 (MEF-1) — 8 D-antigen units;		
					<ul><li>(h) inactivated poliovirus type 3</li><li>(Saukett) — 32 D-antigen units;</li></ul>	
				<ul><li>(i) recombinant hepatitis B surface antigen — 10 μg;</li></ul>		
				<ul><li>(j) purified Hib capsular polysaccharide conjugated to tetanus toxoid — 10 μg</li></ul>		
306	Vaccine	Comvax	Vial for	Each of the following:	3 doses	
	Hepatitis B and <i>Haemophilus influenzae</i> type b (Hib)		injection (0.5mL)	<ul><li>(a) Hepatitis B surface antigen — 5μg;</li><li>(b) purified Hib capsular polysaccharide</li></ul>		
	Circumstances			conjugated to meningococcal protein — 7.5µg		
	Vaccine may be provided to a child who is about 2, 4 or 12 months			1-0		

#### Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <a href="http://www.frli.gov.au">http://www.frli.gov.au</a>.