Description: Commonwealth Coat of Arms

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

**as amended**

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

National Health Act 1953

**Compilation start date:** 1 June 2015

**Includes amendments up to:** National Health (Immunisation Program - Designated Vaccines) Variation Determination 2015 (No.1)

**About this compilation**

**This compilation**

This is a compilation of the *National Health (Immunisation Program - Designated Vaccines) Determination 2014 (No.1)* as in force on 1 June 2015. It includes any commenced amendment affecting the legislation to that date.

This compilation was prepared on 1 June 2015.

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of each amended provision.

**Uncommenced amendments**

The effect of uncommenced amendments is not reflected in the text of the compiled law but the text of the amendments is included in the endnotes.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Modifications**

If a provision of the compiled law is affected by a modification that is in force, details are included in the endnotes.

**Provisions ceasing to have effect**

If a provision of the compiled law has expired or otherwise ceased to have effect in accordance with a provision of the law, details are included in the endnotes.

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1. Name of Determination

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

2 Commencement

This Determination commences on 23 September 2014.

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*.

***CCID50*** 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*** meanspertactin.

***PT*** means pertussis toxoid.

***TCID50*** 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 and/or 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 and/or 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 and/or 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 and/or 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 and/or 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/or Torres Strait Islander person who is:

(i) aged at least 6 months but less than 5 years; or

(ii) 15 years or older; 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/or 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  102A | 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.  Vaccine  Diphtheria, tetanus and pertussis (child)  Circumstances  Vaccine may be provided to a child who is about 18 months of age. | Adacel  Infanrix | Injection (0.5mL)  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  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 | 1 dose (booster)  1 dose (booster) |
| 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 |
| 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 |
| 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 |
| 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 |
| 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:   1. to a child who is about 2, 4 or 6 months old; and 2. to a child who is about 12 months of age and is a member of a medical risk group; or 3. 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. |
| 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 |
| 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 |

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 Aboriginal and/or 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 |
| 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 |
| 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 |
| 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. |
| 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. |
| 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 |
| 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 |
| 211 | Vaccine  Measles, mumps and rubella  Circumstances  Vaccine may be provided to a child who is:   1. about 12 months old; or 2. about 4 years of age if MMRV was not given at 18 months; or 3. 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;   1. about 12 months old; or 2. about 4 years of age if MMRV was not given at 18 months; or 3. 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) — 103.0 CCID50;  (b) mumps virus (RIT 4385 derived from the Jeryl Lynn strain) — 103.7 CCID50;  (c) rubella virus (Wistar RA 27/3 strain) — 103.0 CCID50 | 1 or 2 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:   1. measles virus (Schwarz strain) – 103.0 CCID50 2. mumps virus (RIT 4385 strain,derived from Jeryl Lynn strain) - 104.4CCID50 3. rubella virus (Wistar RA 27/3 strain) – 103.0 CCID50 4. varicella virus (Oka strain) - 103.3 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:   1. measles virus derived from Enders’ attenuated Edmonston strain) – 103.0 TCID50 2. mumps virus (Jeryl Lynn™ (B Level) strain) - 104.3TCID50 3. rubella virus (Wistar RA 27/3 strain) – 103.0 TCID50 4. Varicella-zoster virus (Oka/Merck strain) - 103.99 PFU | 1 dose |
| 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 — 103.3PFU | 1 dose |
| 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 |
| 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:   1. HPV 16 L1 protein - 20μg; 2. 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 106 CCID50 | 2 doses:  (a) first dose given at 6 to 14 weeks of age;  (b) second dose given at 14 to 24 weeks of age |
| 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 106 IU;  (b) G2 — 2.8 x 106 IU;  (c) G3 — 2.2 x 106 IU;  (d) G4 — 2.0 x 106 IU;  (e) P1 (8) — 2.3 x 106 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 |

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 |
| 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 |
| 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 |
| 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 |
| 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](http://www.comlaw.gov.au/).

Endnotes

Endnote 1—About the endnotes

The endnotes provide details of the history of this legislation and its provisions. The following endnotes are included in each compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Endnote 5—Uncommenced amendments

Endnote 6—Modifications

Endnote 7—Misdescribed amendments

Endnote 8—Miscellaneous

If there is no information under a particular endnote, the word “none” will appear in square brackets after the endnote heading.

**Abbreviation key—Endnote 2**

The abbreviation key in this endnote sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended the compiled law. The information includes commencement information for amending laws and details of application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision level. It also includes information about any provisions that have expired or otherwise ceased to have effect in accordance with a provision of the compiled law.

**Uncommenced amendments—Endnote 5**

The effect of uncommenced amendments is not reflected in the text of the compiled law, but the text of the amendments is included in endnote 5.

**Modifications—Endnote 6**

If the compiled law is affected by a modification that is in force, details of the modification are included in endnote 6.

**Misdescribed amendments—Endnote 7**

An amendment is a misdescribed amendment if the effect of the amendment cannot be incorporated into the text of the compilation. Any misdescribed amendment is included in endnote 7.

**Miscellaneous—Endnote 8**

Endnote 8 includes any additional information that may be helpful for a reader of the compilation.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| ad = added or inserted | pres = present |
| am = amended | prev = previous |
| c = clause(s) | (prev) = previously |
| Ch = Chapter(s) | Pt = Part(s) |
| def = definition(s) | r = regulation(s)/rule(s) |
| Dict = Dictionary | Reg = Regulation/Regulations |
| disallowed = disallowed by Parliament | reloc = relocated |
| Div = Division(s) | renum = renumbered |
| exp = expired or ceased to have effect | rep = repealed |
| hdg = heading(s) | rs = repealed and substituted |
| LI = legislative instrument | s = section(s) |
| LIA = *Legislative Instruments Act 2003* | Sch = Schedule(s) |
| mod = modified/modification | Sdiv = Subdivision(s) |
| No = Number(s) | SLI = Select Legislative Instrument |
| o = order(s) | SR = Statutory Rules |
| Ord = Ordinance | Sub-Ch = Sub-Chapter(s) |
| orig = original | SubPt = Subpart(s) |
| par = paragraph(s)/subparagraph(s) |  |
| /sub-subparagraph(s) |  |

Endnote 3—Legislation history

| Name | FRLI registration or gazettal | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| National Health (Immunisation Program — Designated Vaccines) Determination 2014 (No.1) | F2014L01255 | 23 Sept 2014 | \_ |
| National Health (Immunisation Program - Designated Vaccines) Variation Determination 2014 (No.1) | F2014L01822 | 1 Jan 2015 | \_ |
| National Health (Immunisation Program - Designated Vaccines) Variation Determination 2015 (No.1) | F2015L00715 | 1 June 2015 | \_ |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| s. 7 ………………………….  Sch 1, Part 1, Item 102A ......  Sch 1, Part 2 ……………….. | am. F2014L01822  ad. F2015L00715  am. F2014L01822 |
|  |  |
|  |  |

Endnote 5—Uncommenced amendments [none]

Endnote 6—Modifications [none]

Endnote 7—Misdescribed amendments [none]

Endnote 8—Miscellaneous [none]