

## EXPLANATORY STATEMENT

### *National Health Act 1953*

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

##### **Authority**

Subsection 9B(1) of the *National Health Act 1953* (the Act) provides that the Minister may provide, or arrange for the provision of, designated vaccines and goods or services that are associated with, or incidental to, the provision or administration of designated vaccines.

Subsection 9B(2) provides that the Minister may, by legislative instrument, determine that a specified vaccine is a designated vaccine for the purposes of the Act. Subsection 9B(5) provides that in addition to specifying a vaccine, a determination may specify the circumstances in which the vaccine may be provided.

In addition to the power to make this instrument under section 9B of the Act, subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

##### **Purpose**

The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.1) 2023* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to:

##### *(Menquadfi)*

- add meningococcal serogroups A, C, W-135 and Y conjugate (MenQuadfi®), to the list of designated vaccines.

The Amendment Determination adds MenQuadfi® as a designated vaccine for the prevention of Invasive Meningococcal Disease (IMD) caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y for children aged 12 months, adolescents aged 14 to 19 years and at-risk individuals who are 12 months of age and older and are currently eligible for Nimenrix vaccination through the National Immunisation Program (NIP).

##### *(Vaxelis)*

- add diphtheria (D), tetanus (T), pertussis (P), hepatitis B (HB), poliomyelitis (IPV) and haemophilus influenzae Type B (Hib) Conjugate (DTPa-HB-IPV-Hib, Vaxelis®), to the list of designated vaccines.

The Amendment Determination adds Vaxelis® as a designated primary vaccine for the prevention of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b (Hib), for children at 2, 4 and 6 months of age and are currently eligible for Infanrix Hexa vaccine through the NIP.

The Pharmaceutical Benefits Advisory Committee (PBAC) noted that the inclusion of a hexavalent booster (DTPa-HB-IPV-Hib) at 18 months might be beneficial to overcome potential waning of long-term immunity to hepatitis B after the primary immunisation course,

noting that a booster for hepatitis B is currently not listed on the NIP. The submission did not propose listing of Vaxelis for use as a booster on the NIP.

These amendments are acting on new recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) and Pharmaceutical Benefits Advisory Committee (PBAC) in response to high pneumococcal disease rates in certain high-risk populations.

*(Gardasil)*

- variation to the circumstances to which the vaccine may be provided as a designated vaccine.

The Amendment Determination amends the listing of designated vaccine Gardasil®9, for the prevention of human papillomavirus from two doses to one dose for the adolescent vaccination program and extends the upper age limit for catch up vaccination to those up to and including 25 years of age. Immunocompromised people will continue to receive 3 doses, with the age limit also extended for those up to and including 25 years of age.

These amendments are acting on new clinical evidence and recommendations from ATAGI and PBAC that a single dose schedule of 9vHPV is likely to be non-inferior in terms of effectiveness to 2 doses. This aligns with recommendations made by the World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) and the United Kingdom's Joint Committee on Vaccination and Immunisation (JCVI).

## **Background**

### *The National Immunisation Program*

The NIP is a joint initiative of the Commonwealth and state and territory governments and is funded through a National Partnership on Essential Vaccines. The NIP provides free vaccines to eligible people to protect against 18 disease groups, including children, adolescents, the elderly, pregnant women and Aboriginal and Torres Strait Islander people.

### *Pharmaceutical Benefits Advisory Committee (PBAC) recommendations*

Subsection 9B(7) of the Act relevantly provides that a vaccine must not be specified in a determination under subsection 9B(2) unless the PBAC has recommended to the Minister that the vaccine be a designated vaccine.

### *Menquadfi*

In November 2020, PBAC recommended that MenQuadfi® vaccine should be a designated vaccine for the prevention of IMD caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y for children aged 12 months, adolescents aged 14 to 19 years and at-risk individuals who are 12 months of age and older.

### *Vaxelis*

In March 2022, the PBAC recommended that diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b conjugate vaccine (DTPa-HB-IPV-Hib, Vaxelis®) be a designated vaccine to be added to the NIP, for the purposes of the *National Health Act 1953* for the primary vaccination series against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type b for children at 2, 4 and 6 months of age and are currently eligible for Infanrix Hexa vaccine through the NIP .

The PBAC also considered Vaxelis to be suitable for catch-up for children under 10 years of age. The vaccine is not considered to be as part of the booster program on the NIP.

Once a vaccine is listed in the Determination, the supplier of that vaccine is eligible to participate in any procurement processes undertaken by the Department of Health for the supply of vaccines on the NIP.

### *Gardasil*

In December 2022, the PBAC recommended that human papillomavirus 9-valent vaccine (9vHPV), Gardasil®9 be varied from a two dose schedule to a one dose schedule on the NIP for the primary vaccination against human papillomavirus for Children aged at least 12 years of age but less than 14 years of age. They also recommended extending the catch up program to people up to and including the age of 25 years who have not received a single dose of HPV vaccine. Immunocompromised people will continue to receive 3 doses, with the age limit also extended for those up to and including 25 years of age.

### **Consultation**

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act, which makes recommendations to, and advises the Minister about, the determination of specified vaccines as designated vaccines under section 9B, for the NIP. The PBAC members are appointed from nominations by organisations and associations representing industry, consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications or experience in a field relevant to the functions of the PBAC that would enable them to contribute meaningfully to the deliberations of the PBAC.

When recommending the listing of a vaccine on the NIP and the circumstances in which a designated vaccine should be provided, PBAC takes into account the target population for which the vaccine has been approved for use in Australia and its clinical effectiveness, safety and cost-effectiveness. The PBAC also received advice from the ATAGI regarding the clinical aspects of the disease and the vaccine.

Pharmaceutical companies are consulted throughout the process of the listing of their vaccine on the NIP and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process.

As part of the PBAC process, patients, carers, members of the public, health professionals or members of consumer interest groups may provide comments and feedback on vaccines being considered by the PBAC via a web interface or in writing over a period of six weeks prior to PBAC meetings. These are provided to the PBAC in a de-identified form for consideration alongside the company submission.

It was considered that further consultation for this Amendment Determination was unnecessary due to the nature of the consultation that had already taken place.

Details of the Amendment Determination are set out in Attachment 1.

The Amendment Determination commences on the day after registration.

The Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

**Details of the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 1) 2023* (Amendment Determination)**

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.1) 2023*.

Section 2 - Commencement

Section 2 provides that the Amendment Determination commences on the day after its registration.

Section 3 - Authority

Section 3 provides that the Amendment Determination is made under subsections 9B(2) and (5) of the *National Health Act 1953*.

Section 4 - Schedules

Section 4 provides that the Amendment Determination amends the instrument specified in a schedule to the Amendment Determination, and any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1 - Amendments

Schedule 1 varies the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination).

**Item 1 – After subsection 7(1A)**

Item 1 inserts a new subsection 7(1B) after subsection 7(1A) in the Determination. Subsection 7(1B) specifies the circumstances in which the designated vaccine listed in item 108C of Schedule 1, MenQuadfi®, may be provided under the NIP to persons with certain medical conditions.

**Item 2 –Subsection 7(11)**

Item 2 omits item 218A of Schedule 1, HPV 9 Valent vaccine Gardasil®9, from subsection 7(11) in the Determination, which specifies additional circumstances the vaccine may be provided under, as these no longer apply to this item.

**Item 3 – After subsection 7(13)**

Item 3 inserts a new subsection in the Determination. Subsection 7(14) specifies the circumstances in which the designated vaccine listed in item 218A of Schedule 1, HPV 9 Valent vaccine Gardasil®9, may be provided under the NIP to persons with impaired immunity.

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

Item 4 inserts a new item 108C in Part 1 of Schedule 1 (after table item 108B). Item 108C in Part 1 of Schedule 1 determines that the meningococcal serogroup A, C, W-135 and Y

Polysaccharide Tetanus Toxoid Conjugate (MenACWY-TT) vaccine (MenQuadfi®) is a designated vaccine for the purposes of the Act. Additionally, it specifies the circumstances in which the vaccine can be provided.

#### **Item 5 – Part 2 of Schedule 1 (table item 218A)**

Item 5 repeals the table item and substitutes a revised item 218A in part 2 of Schedule 1 which determines that HPV 9 Valent vaccine Gardasil®9 is a designated vaccine for the purposes of the Act. Additionally, it specifies the circumstances in which the vaccine can be provided.

The changes to this item are the doses from 2 doses to 1 dose and an increase in the upper age limit for catch up vaccinations.

#### **Item 6 – Part 3 of Schedule 1 (after table item 305A)**

Item 6 inserts a new item 305B in Part 3 of Schedule 1 (after table item 305A). Item 305B in Part 3 of Schedule 1 determines that the diphtheria (D), tetanus (T), pertussis (P), hepatitis B (HB), poliomyelitis (IPV) and haemophilus influenzae Type B (Hib) Conjugate (DTPa-HB-IPV-Hib, Vaxelis®) is a designated vaccine for the purposes of the Act. Additionally, it specifies the circumstances in which the vaccine can be provided.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

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

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Legislative Instrument**

The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 1) 2023* (the Amendment Determination) varies the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)* (the Determination), which determines, under subsection 9B(2) of the *National Health Act 1953* (the Act), that a specified vaccine in the instrument is a designated vaccine for the purposes of the Act. Additionally the Amendment Determination specifies under subsection 9B(5) of the Act, the circumstances in which the vaccine can be provided.

The Amendment Determination adds MenQuadfi® on the National Immunisation Program (NIP), for the prevention of Invasive Meningococcal Disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y as a designated vaccine for children aged 12 months, adolescents aged 14 to 19 years and at-risk individuals who are 12 months of age and older and are currently eligible for Nimenrix vaccination through the NIP.

The Amendment Determination adds Vaxelis® as a designated primary vaccine for the prevention of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib), for children at 2, 4 and 6 months of age and are currently eligible for Infanrix Hexa vaccine through the NIP.

The Amendment Determination amends the listing of designated vaccine Gardasil®9, for the prevention of human papillomavirus from two doses to one dose for the adolescent vaccination program and extends the upper age limit for catch up vaccination to those up to and including 25 years of age. Immunocompromised people will continue to receive 3 doses, with the age limit also extended for those up to and including 25 years of age.

#### **Human Rights Implications**

This Amendment Determination engages the right to health as set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Amendment Determination supports the right to the attainment of the highest standard of health, by providing free access for eligible people to a designated vaccine and protecting individuals and the community against vaccine preventable disease.

#### **Conclusion**

The Amendment Determination is compatible with human rights as it promotes the right to health.