EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.2) 2019

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.2) 2019* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to:

- add VaxiGrip Tetra to the list of designated vaccines for the prevention of influenza and the circumstances, including the specified population of patients to which they may be provided; and
- extend the listing of Engerix-B (adult formulation) for use in adolescents and adults in the list of designated vaccines until either the shortage of H-B-Vax II (adult formulation) has been resolved, or 31 December 2020, whichever occurs first. The current period specified is 31 December 2019.

Background

<u>*Pharmaceutical Benefits Advisory Committee (PBAC) recommendations*</u>

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.

In July 2019, the PBAC recommended the addition of VaxiGrip Tetra to the current National Immunisation Program (NIP) for the prevention of influenza for the following populations:

- children aged 6 months to <5 years, who are not currently eligible through the NIP; and
- at-risk individuals who are currently eligible for seasonal influenza vaccination through the NIP.

In August 2019, the PBAC recommended that the temporary listing of Engerix-B (adult formulation) for use in adolescents and adults on the NIP should continue until either the

shortage of H-B-Vax II (adult formulation) has been resolved, or 31 December 2020, whichever were to occur first.

Government approval
On 18 October 2019, the Minister for Health, the Hon Greg Hunt MP, approved the PBAC recommendations to add VaxiGrip Tetra to the current NIP and extend the temporary listing of Engerix-B. This will take effect from the day after the Amendment Determination is registered.

Details
The Determination commenced on 23 September 2014. 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.

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. PBAC also receives advice from the Australian Technical Advisory Group on Immunisation 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 Instrument was unnecessary due to the nature of the consultation that had already taken place.

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

The Amendment Determination commences on the day after registration.

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

ATTACHMENTS

DETAILS ON THE *NATIONAL HEALTH (IMMUNISATION PROGRAM – DESIGNATED VACCINES) AMENDMENT DETERMINATION (NO. 2) 2019*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2019* (the Amendment Determination).

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 section 9B 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 Principal Determination).

Item 1
Item 1 inserts a new subsection 7(8B).

Section 7 of the Principal Determination provides for the circumstances in which particular designated vaccines set out in Schedule 1 to the Principal Determination may be provided.

New subsection 7(8B) specifies the circumstances in which the designated vaccine mentioned in the new item 207F of Schedule 1 (VaxiGrip Tetra) may be provided. This subsection provides that the vaccine can be provided to the following persons:

(a) a person who is at least 65 years old; or
(b) an Aboriginal or Torres Strait Islander who is at least 6 months old; or
(c) a child who is at least 6 months old but less than 5 years old; or
(d) a person who is at least 6 months old who

(i) has cardiac disease including cyanotic congenital heart disease, coronary artery disease and congestive heart failure; or
(ii) has a chronic respiratory condition including suppurative lung disease, bronchiectasis, cystic fibrosis, chronic obstructive pulmonary disease, chronic emphysema and severe asthma; or
(iii) 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

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

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

(vi) is less than 11 years and is receiving long term aspirin therapy; or

(e) a woman who is pregnant.

Item 2

Item 2 amends subparagraph (iii) in relation to the circumstances in which Hepatitis B (Monovalent vaccine) with the Brand Engerix –B can be provided (refer to item 202A in Part 2 of Schedule 1) by omitting the year "2019" and substituting it with the year "2020". This ensures that the temporary listing of Engerix-B (adult formulation) for use in adolescents and adults on the NIP continues until 31 December 2020 or until the shortage of H-B-Vax II (adult formulation) has been resolved, whichever occurs first.

Item 3

Item 3 inserts a new item 207F in Part 2 of Schedule 1. Item 207F in Part 2 of Schedule 1 provides the details of the VaxiGrip Tetra vaccine and the circumstances in which this vaccine can be provided under the NIP. The circumstances are those set out in new subsection 7(8B).

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.2) 2019

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. 2) 2019* (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.

The Amendment Determination adds the quadrivalent influenza vaccine, VaxiGrip Tetra, to the National Immunisation Program (NIP) for children aged 6 months to <5 years, who are not currently eligible through the NIP; and at-risk individuals who are currently eligible for seasonal influenza vaccination through the NIP.

The Amendment Determination also extends the temporary listing of Engerix-B (adult formulation) for use in adolescents and adults on the NIP until either the shortage of H-B-Vax II (adult formulation) has been resolved, or 31 December 2020, whichever were to occur first.

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 maintains compliance with the right to health by continuing to provide free access for eligible people to designated vaccines. The Amendment Determination continues to support the attainment of the highest standard of health for all Australians, by protecting individuals and the community against vaccine preventable disease.

Conclusion

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

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