

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.1) 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.1) 2019* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014(No. 1)* (the Determination) to expand the circumstances in which Fluarix Tetra® (a designated vaccine under existing item 207A of Part 2 of Schedule 1 of the Determination) may be provided.

Background

Pharmaceutical Benefits Advisory Committee (PBAC) recommendations

In March 2019, the PBAC recommended changes to the existing subsection 9B(2) determination for Fluarix Tetra® to expand the circumstances in which that vaccine may be provided for the National Immunisation Program (NIP). The recommended change will lower the age of persons to whom Fluarix Tetra® can be provided under the NIP from 3 years to 6 months (the person must also meet other eligibility criteria, which are not changed by the recommendations).

Government approval

On 29 March 2019, the Minister for Health, the Hon Greg Hunt MP, approved the PBAC recommended changes to the existing NIP listing for Fluarix Tetra®. 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 subsection 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*.

Authority: Subsection 9B of the
National Health Act 1973

DETAILS ON THE NATIONAL HEALTH (IMMUNISATION PROGRAM – DESIGNATED VACCINES) AMENDMENT DETERMINATION (NO. 1) 2019

1. Name of Determination

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

2. Commencement

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

3. Authority

Section 3 provides that the Amendment Determination is made under subsection 9B of the *National Health Act 1953*.

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

Item 1 inserts new subsection 7(7A) after existing subsection 7(7). New subsection 7(7A) specifies the circumstances in which the designated vaccine mentioned in item 207A of Schedule 1 (Fluarix Tetra®) may be provided. Prior to this amendment, the circumstances in which the designated vaccine mentioned in item 207A of Schedule 1 (Fluarix Tetra®) may be provided were specified under subsection 7(8).

Under subsection 7(8), as it applied to item 207A of Schedule 1 (Fluarix Tetra®) prior to the amendment, the circumstances at paragraphs (b),(c) and (d) applied to persons at least 3 years old. Under new subsection 7(7A), the circumstances at paragraphs (b),(c) and (d) apply to persons who are at least 6 months old. In all other respects, the circumstances that apply to item 207A of Schedule 1 (Fluarix Tetra®) are unchanged by the amendment.

Item 2

Item 2 amends existing subsection 7(8) so that subsection 7(8) no longer applies to item 207A of Schedule 1 (Fluarix Tetra®). The circumstances in which item 207A of Schedule 1 (Fluarix Tetra®) may be provided are now specified by new subsection 7(7A).

Item 3

Item 3 amends Part 2 of Schedule 1 (table item 207A, column headed “Vaccine and the circumstances in which vaccine may be provided”) to omit the reference to subsection 7(8) and substitute a reference to subsection 7(7A). The circumstances in which item 207A of Schedule 1 (Fluarix Tetra®) may be provided are now specified by new subsection 7(7A). Subsection 7(8) no longer applies to item 207A of Schedule 1 (Fluarix Tetra®).

Item 4

Item 4 amends Part 2 of Schedule 1 (table item 207A, column headed “Number and timing of doses”) so that the number and timing of doses that applied to “children 3 years and older but less than 9 years”, prior to the amendment, now applies to “children 6 months and older but less than 9 years”. This change is required for consistency with new subsection 7(7A), which is inserted by item 3.

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) 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. 1) 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 expands the circumstances in which Fluarix Tetra® (a designated vaccine already listed in Item 207A of Schedule 1 of the Determination) can be provided, to include persons aged 6 months and over who meet the specified circumstances. Prior to the amendment, Fluarix Tetra® could only be provided to persons aged 3 years and over who met the specified circumstances. In all other respects, the circumstances in which Fluarix Tetra® can be provided are unchanged by the amendment.

Human Rights Implications

This Amendment Determination engages the right to health as set out in Article 2 and 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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