EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2024

Purpose and operation

The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2024* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to:

- list Abrysvo as a designated vaccine for the prevention of respiratory syncytial virus (RSV) in infants from birth through to 6 months of age through the immunisation of pregnant women; and
- amend the eligible cohort for the influenza vaccine Flucelvax Quad to include all children aged at least 6 months but less than 5 years, and to children who are at least 6 months of age and who are at increased risk of influenza disease complications.

These amendments act on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) and the Pharmaceutical Benefits Advisory Committee (PBAC).

Listing of Abrysvo

In September 2024, the PBAC recommended adding Abrysvo as a designated vaccine on the National Immunisation Program for the prevention of RSV in infants from birth through to 6 months of age by active immunisation of pregnant women. This is the first time a vaccine for the prevention of RSV will be listed on the Determination.

Amendment to the listing of Flucelvax

On 1 November 2023, Flucelvax Quad was added to the Determination as a designated vaccine for the vaccination against influenza in Aboriginal and Torres Strait Islander people aged 5 to 65 years, people at increased risk of influenza disease complications aged 5 to 65 years, and pregnant women.

In March 2024, the PBAC recommended expanding the eligible cohort for the Flucelvax Quad vaccine to include all children aged at least 6 months but less than 5 years, and to children who are at least 6 months of age and who are at increased risk of influenza disease complications.

Background

The National Immunisation Program (NIP)

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, including children, adolescents, the elderly, pregnant women, and Aboriginal and Torres Strait Islander people.

PBAC recommendations

Subsection 9B(7) of the *National Health Act 1953* (the Act) relevantly provides that a vaccine must not be specified in a determination under subsection 9B(2) of the Act unless the PBAC has recommended to the Minister that the vaccine be a designated vaccine.

Authority

Subsection 9B(1) of 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.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

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.

Commencement

The Amendment Determination commences on the day after it is registered.

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 under 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 of the Act for the purposes of 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 designated vaccine on the NIP and the circumstances in which the vaccine should be provided, the PBAC considers 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 receives advice from 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 to have their vaccine listed, 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 for consideration alongside the company submission.

It was considered that further consultation on the Amendment Determination was unnecessary due to the nature of the consultation that had already taken place with the PBAC.

General

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

Details of this Amendment Determination are set out in **Attachment A**.

This Amendment Determination is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

ATTACHMENT A

Details of the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2024*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2024.*

Section 2 - Commencement

Section 2 provides that this instrument commences the day after it is registered.

Section 3 - Authority

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

Section 4 - Schedules

Section 4 provides that this instrument is amended as set out in Schedule 1.

Schedule 1 - Amendments

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

Item 1 – Before paragraph 7(9A)(a)
Item 1 inserts a new paragraph 7(9A)(aa) before paragraph 7(9A)(a) of the Determination to specify that the designated vaccine Flucelvax Quad, may be provided to a child who is at least 6 months of age but less than 5 years of age. This change expands the eligibility cohort to enable all children in this age bracket to access the vaccine.

Item 2 – Paragraph 7(9A)(a)
Item 2 amends paragraph 7(9A)(a) for the designated vaccine Flucelvax Quad to omit the words "5 years of age" and substitute it with "6 months of age". This change expands the eligibility cohort to include Aboriginal or Torres Strait Islander children aged at least 6 months of age.

Item 3 – Paragraph 7(9A)(b)
Item 3 amends paragraph 7(9A)(b) for the designated vaccine Flucelvax Quad to omit the words "5 years of age" and substitute it with "6 months of age". This change expands the eligibility cohort to include children aged at least 6 months of age and who have an illness or condition outlined in subparagraphs 7(9A)(b)(i) to 7(9A)(b)(v).

Item 4 – Paragraph 7(9A)(c)
Item 4 amends paragraph 7(9A)(c) for the designated vaccine Flucelvax Quad to omit the words "5 years of age" and substitute it with "6 months of age". This change expands the

eligibility cohort to children aged at least 6 months of age and who are receiving long-term aspirin therapy.

Item 5 – Part 2 of Schedule 1 (table item 210A, column headed "number and timing of doses")

Item 5 amends table item 210A in Part 2 of Schedule 1 for the designated vaccine Flucelvax Quad to omit the words "5 years of age" and substitute it with "6 months of age". This change expands the eligibility cohort to children aged at least 6 months of age to be able to access 2 doses at least 1 month apart for the first vaccination and 1 dose per calendar after that.

Item 6 – In the appropriate position in Part 2 of Schedule 1 (table)

Item 6 inserts a new table item 222 in Part 2 of Schedule 1 to provide that Abrysvo, a vaccine for respiratory syncytial virus (RSV) stabilised prefusion F subunit, is a designated vaccine for the purposes of the *National Health Act 1953*. Abrysvo may be provided to a person who is pregnant and new table item 222 provides for the number of timing of doses during pregnancy.

ATTACHMENT B

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) 2024

This Disallowable 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 Disallowable Legislative Instrument

The purpose of the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2024* (the Amendment Determination) is to amend the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to:

- list Abrysvo as a designated vaccine for the prevention of respiratory syncytial virus (RSV) in infants from birth through to 6 months of age through the immunisation of pregnant women; and
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Human Rights Implications

The 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 because it promotes the right to health.

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