

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2025

Purpose and operation

The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2025* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to list Prevenar 20 as a designated vaccine for the prevention of pneumococcal disease in children.

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

Listing of Prevenar 20

In November 2023, the PBAC recommended adding Prevenar 20 as a designated vaccine on the National Immunisation Program (the NIP) for the prevention of pneumococcal disease in children in alignment with the current paediatric pneumococcal schedule, which centres on the currently listed designated vaccine Prevenar 13 (item 110).

Subject to this, the Australian Technical Advisory Group on Immunisation (ATAGI) undertook a review of the paediatric pneumococcal vaccine schedule. The aim of the review was to streamline the currently highly complex schedule, improve equity and provide access to the best available vaccine for children aged 17 years and younger. As part of the review's recommendations, ATAGI recommended to list Prevenar 20 as a designated vaccine on the NIP for the same paediatric populations that are eligible for Prevenar 13 (item 110). In addition, ATAGI also recommended that access to three primary doses and a booster dose (3+1 schedule) for Prevenar 20 is expanded to all Aboriginal and Torres Strait Islander children irrespective of location.

In May 2025, the PBAC noted the updated ATAGI recommendations for the paediatric pneumococcal immunisation schedule on the NIP for those aged 17 years and under including the recommendation to list Prevenar 20 as a designated vaccine. The PBAC recommended it would be appropriate to remove restrictions regarding location in specific states and territories in the listings for Aboriginal and Torres Strait Islander children.

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.

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 2025*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2025*.

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 subsection 9B(2) 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 – After subsection 7(1)

Item 1 inserts a new subsection 7(1C) after subsection 7(1) of the Determination to specify circumstances in which the designated vaccine Prevenar 20 may be provided to a child. This includes children who are about 6 months old and are Aboriginal and Torres Strait Islander, and children who are about 6 months old and have at least one of the medical conditions that are listed in paragraph 7(1C)(b). It also includes children who have been diagnosed with at least one of the listed medical conditions that are specified in paragraphs 7(1C)(c) and 7(1C)(d) at a certain age.

Item 2 – After item 111 of the table in Part 1 of Schedule 1

Item 2 inserts new table items 111A and 111B in Part 1 of Schedule 1 to provide that Prevenar 20, a vaccine for the prevention of pneumococcal disease in children, is a designated vaccine for the purposes of the *National Health Act 1953*.

Table item 111A has the effect that a maximum of 3 doses of Prevenar 20 may be provided to a child at the following intervals: about 2 months, 4 months and 12 to 24 months old.

Table item 111B has the effect that a single additional dose of Prevenar 20 may be provided to a child in one of the circumstances set out in the new subsection 7(1C). A child should only ever receive one additional dose, even if they are eligible under more than one of the circumstances set out in subsection 7(1C). For example, if a child who is an Aboriginal person or Torres Strait Islander receives an additional dose under paragraph 7(1C)(a), and

develops one of the medical conditions listed in paragraph 7(1C)(b) at a later age, they should not receive another dose (i.e. they should only ever receive a total of 4 doses, not 5).

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 2025

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 *National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2025* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to list Prevenar 20 as a designated vaccine for the prevention of pneumococcal disease in children.

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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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