EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Determination 2026

Purpose and operation

The *National Health (Immunisation Program – Designated Vaccines) Determination 2026* (the Determination) revokes and remakes the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)*, which sunsets on 1 October 2026.

The purpose of the Determination is to specify, for the purposes of subsection 9B(2) of the *National Health Act 1953* (the Act), the vaccines that are designated vaccines and the circumstances in which those vaccines are designated vaccines under the National Immunisation Program (NIP).

The Determination is substantially the same as the *National Health (Immunisation Program - Designated Vaccines) Determination 2014 (No.1)* and includes minor amendments to improve clarity and consistency. These amendments update or remove obsolete references, refine definitions, renumber provisions, incorporate relevant circumstances into Schedule 1 and revoke 19 designated vaccines that are no longer available through the NIP. These amendments are administrative in nature and do not alter policy or vaccine access arrangements through the NIP.

Remaking the Determination ensures the ongoing operation of the NIP by enabling the Australian Government to continue providing free vaccines to eligible people, helping to reduce the incidence of vaccine-preventable diseases.

Background

The National Immunisation Program

The NIP is a joint initiative of the Commonwealth and State and Territory governments and is funded through the Essential Vaccines Schedule. The NIP provides free vaccines to eligible people, including children, adolescents, older adults, 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) of the Act unless the PBAC has recommended to the Minister that the vaccine be a designated vaccine.

Section 9B(8) of the Act provides that before revoking or varying the Determination in such a way that a vaccine ceases to be a designated vaccine, the Minister must obtain the written advice of the PBAC in relation to the proposed revocation or variation. Section 9B(9) provides that the advice is to be tabled in each House of Parliament with the revocation or variation.

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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 Determination commences on 1 October 2026.

Consultation

Key stakeholders within the Department of Health, Disability and Ageing (the department) were consulted to ensure that the Determination will operate effectively and efficiently. No significant issues were raised through consultation.

The department also consulted the Attorney-General's Department in relation to the remake of the Determination.

To align with subsections 9B(8) and 9B(9) of the *National Health Act 1953* (the Act), the PBAC provided its written advice on the revocation of 19 designated vaccines. The PBAC supported the removal of the vaccines identified for delisting and did not raise any concerns.

General

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

Details of the Determination are set out in **Attachment A**.

This 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**.

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ATTACHMENT A

Details of the *National Health (Immunisation Program – Designated Vaccines) Determination 2026*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Determination 2026.*

Section 2 - Commencement

Section 2 provides that this instrument commences on 1 October 2026.

Section 3 - Authority

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

Section 4 - Schedules

Section 4 provides that each instrument that is specified in Schedule 2 to this instrument is amended or repealed as set out in the applicable items in that Schedule, and any other item in that Schedule has effect according to its terms.

Section 5 - Definitions

Section 5 defines key terms used in the Determination and gives shortened reference to the Act.

Section 6 – Designated Vaccines

Section 6 sets out a vaccine specified in Schedule 1 is determined to be a designated vaccine for the purposes of subsection 9B(2) of the Act.

Section 7 – Circumstances

Section 7 sets out the circumstances in which a designated vaccine may be provided, for the purpose of subsection 9B(5) of the Act.

Section 8 – Catch-up doses for persons less than 10 years old

Section 8 sets out the circumstances in which catch-up doses of designated vaccines may be provided to persons who are less than 10 years old.

Section 9 – Catch-up doses for persons at least 10 years old but less than 20 years old

Section 9 sets out the circumstances in which catch-up doses of designated vaccines may be provided to persons who are at least 10 years old but less than 20 years old.

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Section 10 – Catch-up doses for visa-holders at least 20 years old

Section 10 sets out the circumstances in which catch-up doses of designated vaccines may be provided to persons who are at least 20 years old and hold one of the visas specified in this section.

Schedule 1 – Designated Vaccines and Circumstances

Schedule 1 sets out the designated vaccines and the circumstances in which they may be provided. Part 1 outlines bacterial vaccines and the circumstances in which they may be provided. Part 2 outlines viral vaccines and the circumstances in which they may be provided. Part 3 outlines combined bacterial and viral vaccines and the circumstances in which they may be provided.

Schedule 2 – Repeals

Schedule 2 repeals the whole of the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)*, as it is due to sunset on 1 October 2026.

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) Determination 2026

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) Determination 2026* (the Determination) revokes and remakes the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)*, which sunsets on 1 October 2026.

The purpose of the Determination is to specify, for the purposes of subsection 9B(2) of the *National Health Act 1953* (the Act), the vaccines that are designated vaccines and the circumstances in which those vaccines are designated vaccines under the National Immunisation Program (NIP).

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Remaking the Determination ensures the ongoing operation of the NIP by enabling the Australian Government to continue providing free vaccines to eligible people, helping to reduce the incidence of vaccine-preventable diseases.

Human Rights Implications

The 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 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.

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Conclusion

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

The Hon Jason Clare MP
Minister for Education
for the Minister for Health and Ageing