EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2024

Purpose

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

- expand the eligibility cohort for Shingrix to include a broader population of immunocompromised individuals at increased risk of herpes zoster (HZ) infection;
- amend the formula for Menveo from a solution and powder for reconstitution to a solution for injection; and
- amend the circumstances to enable listed meningococcal, pneumococcal and *Haemophilus influenzae* type b (Hib) vaccines to be provided if a person is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan).

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

Amendment to the listing of Shingrix

In November 2023, Shingrix was listed as a designated vaccine for individuals who are at least 65 years of age, for Aboriginal and Torres Strait Islander individuals who are at least 50 years of age and for immunocompromised individuals who are at least 18 years of age with conditions at high risk of HZ infection.

The Amendment Determination further extends the eligibility criteria to immunocompromised individuals who are at least 18 years of age and considered to be at an increased risk of HZ infection due to an underlying condition and/or undergoing immunomodulatory or immunosuppressive treatments.

This change supports the 2024-25 Budget measure *Supporting Ongoing Access to Vaccines* to expand the eligibility of Shingrix for the prevention of HZ and postherpetic neuralgia in individuals at a moderate to high risk of severe infection.

Amendment to the listing of Menveo

In September 2020, Menveo was listed as a designated vaccine as a solution and powder for reconstitution for the prevention of Invasive Meningococcal Disease (IMD) caused by Neisseria meningitidis serogroups A, C, W-135 and Y.

The Amendment Determination lists a new formula of the same Menveo vaccine to a solution for injection. The circumstances in which this vaccine can be provided have not changed.

Amendment to listed Meningococcal, Pneumococcal and Hib vaccines
The PBAC recommended listing Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab. Individuals undergoing treatment or those who will commence treatment with Empavali may become severely immunocompromised and would need access to currently listed vaccines for meningococcal, pneumococcal and Hib.

The Amendment Determination amends the circumstances for currently listed meningococcal, pneumococcal and Hib vaccines to specify that these vaccines may also be provided to an individual who is undergoing treatment, or will commence treatment, with Empavali.

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, older adults, 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 1 September 2024.

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 deliberation process. As part of the PBAC process, patients, carers, members of the public, health professionals and 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 the Amendment Determination was unnecessary due to the nature of the consultation that had already taken place through 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 2024*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination 2024.*

Section 2 - Commencement

Section 2 provides that this instrument commences on 1 September 2024.

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 – After subsection 7(14)
Item 1 inserts a new subsection 7(15) after subsection 7(14) of the Determination to specify circumstances in which the designated vaccine Shingrix, which is listed under item 217A in Part 2 of Schedule 1, may be provided to a person who is at least 18 years of age and who is considered at increased risk of herpes zoster (HZ).

This includes if the person has:

- an underlying health condition that is outlined in paragraph 7(15)(a); or
- a malignancy, autoimmune or inflammatory condition and is receiving immunomodulatory or immunosuppressive treatments that are specified in paragraph 7(15)(b).

Item 2 – Part 1 of Schedule 1 (table item 103, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 2 amends the circumstances for table item 103 of Schedule 1 to provide that the designated vaccines ActHib or Hiberix may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 3 – Part 1 of Schedule 1 (table item 104, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 3 amends the circumstances for table item 104 of Schedule 1 to provide that the designated vaccine Pedvax may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 4 – Part 1 of Schedule 1 (table item 105, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 4 amends the circumstances for table item 105 of Schedule 1 to provide that the designated vaccine Menitorix may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 5 – Part 1 of Schedule 1 (table items 106, 107 and 108, columns headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 5 amends the circumstances for table items 106, 107 and 108 of Schedule 1 to provide that the designated vaccines Meningitec, Menjugate and NeisVac-C may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 6 – Part 1 of Schedule 1 (table item 108A, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 6 amends the circumstances of table item 108A of Schedule 1 to provide that the designated vaccine Nimenrix may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 7 – Part 1 of Schedule 1 (table item 108B, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 7 amends the circumstances of table item 108B of Schedule 1 to provide that the designated vaccine Menveo may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 8 – Part 1 of Schedule 1 (table item 108B, column headed "Active ingredient and strength")
Item 8 amends table item 108B of Schedule 1 to omit reference to "reconstituted" for the designated vaccine Menveo. This change lists a new formula of a solution for injection, instead of a solution and powder for reconstitution.

Item 9 – Part 1 of Schedule 1 (table item 108C, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 9 amends the circumstances of table item 108C of Schedule 1 to provide that the designed item MenQuadfi® may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 10 – Part 1 of Schedule 1 (table item 109, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 10 amends the circumstances of table item 109 of Schedule 1 to provide that the designated vaccine Prevenar may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 11 – Part 1 of Schedule 1 (table item 110, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 11 amends the circumstances of table item 110 of Schedule 1 to provide that the designated vaccine Prevenar 13 may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 12 – Part 1 of Schedule 1 (table item 111, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 12 amends the circumstances of table item 111 to provide that the designated vaccine Synflorix may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 13 – Part 1 of Schedule 1 (table item 112, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 13 amends the circumstances of table item 112 of Schedule 1 to provide that the designated vaccine PneumoVax 23 may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 14 – Part 1 of Schedule 1 (table item 114, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 14 amends the circumstances of table item 114 of Schedule 1 to provide that the designated vaccine Bexsero may be provided for the treatment of an adult with paroxysmal nocturnal haemoglobinuria who has an inadequate clinical response or is intolerant to treatment with eculizumab or ravulizumab, and who is commencing treatment with, or will have ongoing treatment with, Empavali (pegcetacoplan).

Item 15 – Part 2 of Schedule 1 (table item 217A, column headed "Vaccine and the circumstances in which vaccine may be provided", subheading "Circumstances")
Item 15 amends the circumstances of table item 217A of Schedule 1 to provide that the designated vaccine Shingrix may be provided to a person who is at least 18 years of age and is considered at increased risk of herpes zoster, and if the person has an underlying health condition or is receiving immunomodulatory or immunosuppressive treatments, where the circumstances for these requirements are outlined under new subsection 7(15).

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

- expand the eligibility cohort for Shingrix to include a broader population of immunocompromised individuals at increased risk of herpes zoster (HZ) infection;
- amend the formula for Menveo from a solution and power for reconstitution to a solution for injection; and
- amend the circumstances to enable listed meningococcal, pneumococcal and *Haemophilus influenzae* type b (Hib) vaccines to be provided if a person is undergoing treatment, or will commence treatment, with Empavali (pegcetacoplan).

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

Amendment to the listing of Shingrix

The Amendment Determination further extends the eligibility criteria to immunocompromised individuals who are at least 18 years of age and who are considered to be at an increased risk of HZ infection due to an underlying condition and/or undergoing immunomodulatory or immunosuppressive treatments.

The change supports the 2024-25 Budget measure *Supporting Ongoing Access to Vaccines* to expand the eligibility of Shingrix for the prevention of HZ and postherpetic neuralgia in individuals at a moderate to high risk of severe infection.

Amendment to the listing of Menveo

Menveo is currently listed as a designated vaccine as a solution and powder for reconstitution for the prevention of Invasive Meningococcal Disease (IMD) caused by Neisseria meningitidis serogroups A, C, W-135 and Y. The Amendment Determination lists a new formula of the same Menveo vaccine to a solution for injection. The circumstances in which this vaccine can be provided have not changed.

Amendment to listed Meningococcal, Pneumococcal and Hib vaccines
The PBAC recommended listing Empavali (pegcetacoplan) for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who have an inadequate clinical response or are intolerant to treatment with eculizumab or ravulizumab. Individuals undergoing treatment or those who will commence treatment with Empavali may become severely immunocompromised and would need access to currently listed vaccines for meningococcal, pneumococcal and Hib.

The Amendment Determination amends the circumstances for currently listed meningococcal, pneumococcal and Hib vaccines to specify that these vaccines may also be provided to an individual who is undergoing treatment, or will commence treatment, with Empavali.

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 designated vaccines and protecting individuals and the community against vaccine preventable disease.

Conclusion
The Amendment Determination is compatible with human rights as it promotes the right to health.

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