EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2023

Purpose and operation

The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 2023* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) as described below.

Menquadfi

Remove reconstitution instructions from the designated vaccine listing for MenQuadfi®.

The Amendment Determination corrects an error on the listing of designated vaccine MenQuadfi® to reflect that MenQuadfi® is a fully liquid formulation and does not require reconstitution.

Shingrix

Repeal existing listing and add Shingrix® to the list of designated vaccines.

The Amendment Determination removes Zostavax and adds recombinant zoster vaccine (RZV), Shingrix® as the designated primary vaccine for the prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN) for non-Indigenous individuals aged ≥65 years, Aboriginal and Torres Strait Islander individuals aged ≥50 years and immunocompromised individuals aged ≥18 years with conditions at high risk of HZ infection.

In March 2023, the Pharmaceutical Benefits Advisory Committee (the PBAC) approved Shingrix® for non-Indigenous individuals aged 70 years and over. In July 2023, the PBAC considered, based on the reduced price proposed, that RZV is cost-effective, and the age for the primary program was lowered to 65 years with no upper limit.

Flucelvax

Add Flucelvax® Quad to the list of designated vaccines.

The Amendment Determination adds Flucelvax® Quad as a designated vaccine for the prevention of influenza virus. In September 2022, the PBAC approved quadrivalent cell-based influenza vaccine (QIVc), Flucelvax® Quad, as a designated vaccine for the prevention of 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.

These amendments implement new recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) and the PBAC.

Background

The National Immunisation Program (NIP)

The NIP is a joint initiative of the Commonwealth, State and Territory governments delivered under the Essential Vaccines Schedule. The NIP provides free vaccines to eligible people, including children, adolescents, the elderly, pregnant women, and Aboriginal and Torres Strait Islander people, to protect against 18 disease groups.

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.

Menquadfi
In November 2020, the PBAC recommended that MenQuadfi® vaccine should be a designated vaccine for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y for children aged 12 months, adolescents aged 14 to 19 years and at-risk individuals who are 12 months of age and older. MenQuadfi® was listed as requiring reconstitution in error, as it is a fully liquid formulation and does not require reconstitution.

Shingrix
In March 2023, the PBAC recommended that varicella virus recombinant vaccine (RZV, Shingrix®) be a designated vaccine for the purposes of the Act, for the prevention of HZ and PHN for non-Indigenous individuals aged ≥70 years (the primary program), Aboriginal and Torres Strait Islander individuals aged ≥50 years and immunocompromised individuals aged ≥18 years with conditions at high risk of HZ infection.

At its July 2023 meeting, the PBAC recommended the cohort be extended and the age for the primary program lowered to 65 years with no upper limit, due to a reduced price proposed by the vaccine sponsor.

Flucelvax
Flucelvax® Quad is a quadrivalent influenza vaccine that is manufactured in cell-culture from cell-derived candidate vaccine viruses and is commonly referred as QIVc. The traditional manufacturing process for influenza vaccines uses fertilised chicken eggs.

The PBAC's recommendation for listing Flucelvax® Quad was based on, among other matters, its assessment that the cost-effectiveness of QIVc would be acceptable with a price premium compared to egg-based quadrivalent influenza virus vaccines and the acknowledgment of potential benefits associated with the diversification of vaccine manufacturing.

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 and Aged Care for the supply of vaccines on the NIP.

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 November 2023.

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 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 vaccine on the NIP and the circumstances in which a designated vaccine should be provided, the 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. 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 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 with the PBAC.

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

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

The 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) 2023*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.1) 2023* (the Amendment Determination).

Section 2 - Commencement

Section 2 provides that the Amendment Determination commences on 1 November 2023.

Section 3 - Authority

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

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

Item 1 – After subsection 7(9)

Item 1 inserts a new subsection 7(9A) after subsection 7(9) of the Determination. For item 210A of Schedule 1, subsection 7(9A) specifies the persons to whom the designated vaccine Flucelvax may be provided. The persons to whom a Flucelvax may be provided under this provision are:

(a) an Aboriginal or Torres Strait Islander who is at least 5 years of age but less than 65 years of age;

(b) a person who is at least 5 years of age but less than 65 years of age and who:

(i) has cardiac disease including cyanotic congenital heart disease, coronary artery disease and congestive heart failure; or

(ii) has a chronic respiratory condition including suppurative lung disease, bronchiectasis, cystic fibrosis, chronic obstructive pulmonary disease, chronic emphysema, and severe asthma; or

(iii) has another chronic illness requiring regular medical follow-up or hospitalisation in the preceding year, including diabetes mellitus, chronic metabolic diseases, chronic renal failure, haemoglobinopathies and impaired immunity (including drug-induced immune impairment); or

(iv) has a chronic neurological condition, including multiple sclerosis, spinal cord injuries, seizure disorders or other neuromuscular disorders; or

(v) has impaired immunity, including HIV infection;

(c) a person who is at least 5 years of age but less than 11 years of age and is receiving long-term aspirin therapy;

(d) a woman who is pregnant.

Item 2 – Part 2 of Schedule 1 (table item 108C, column headed "Active ingredient and strength")

Item 2 amends table item 108C of Part 2 of Schedule 1 of the Determination to omit the reference to reconstitution in the listing for designated vaccine MenQuadfi®. This corrects an error on the listing of MenQuadfi®, reflecting that it is a fully liquid formulation and does not require reconstitution.

Item 3 – Part 2 of Schedule 1 (after table item 210)

Item 3 inserts a new table item 210A into Part 2 of Schedule 1 to determine that influenza vaccine Flucelvax® Quad is a designated vaccine for the purposes of the Act, which may be provided in the circumstances set out in the new subsection 7(9A).

Item 4 – Part 2 of Schedule 1 (table item 217A)

Item 4 repeals table item 217A of Part 2 of Schedule 1 of the Determination and inserts a new item 217A into Part 2 of Schedule 1. This has the effect of removing the listing for Zostavax, and instead determining that the herpes zoster and post-herpetic neuralgia vaccine (recombinant zoster virus, Shingrix®) is a designated vaccine for the purposes of the Act. Item 4 also specifies the persons to whom this vaccine can be provided:

(a) at least 65 years of age; or

(b) at least 50 years of age and an Aboriginal and/or Torres Strait Islander; or

(c) at least 18 years of age and who:

(i) has had a haemopoietic stem cell transplantation or is scheduled to receive a haemopoietic stem cell transplantation; or

(ii) has had a solid organ transplant or is scheduled to receive a solid organ transplant and is on immunosuppressive therapy; or

(iii) has an active haematological malignancy; or

(iv) has advanced or untreated HIV with CD4 counts < 250/ μL or a higher CD4 count unable to be established on effective anti-retroviral therapy.

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) 2023

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 (No. 2) 2023* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1*) (the Determination). The Determination determines under subsection 9B(2) of the *National Health Act 1953* (the Act) that a specified vaccine is a designated vaccine for the purposes of the Act, and specifies under subsection 9B(5) of the Act the circumstances in which the vaccine can be provided.

The Amendment Determination implements new recommendations from the Australian Technical Advisory Group on Immunisation and the Pharmaceutical Benefits Advisory Committee as follows:

- Corrects an error on the listing of designated vaccine MenQuadfi® to reflect that MenQuadfi® is a fully liquid formulation and does not require reconstitution;
- Removes Zostavax and adds Shingrix® as a designated primary vaccine for the prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN) for non-Indigenous individuals aged ≥65 years, Aboriginal and Torres Strait Islander individuals aged ≥50 years, and immunocompromised individuals aged ≥18 years with conditions at high risk of HZ infection; and
- Adds Flucelvax® Quad as a designated vaccine to prevent 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.

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 as it promotes the right to health.

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