EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 3) 2020

Authority
Subsection 9B(1) of the *National Health Act 1953* (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.

In addition to the power to make this instrument under section 9B of the Act, 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.

Purpose
The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.3) 2020* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to:

- expand the circumstances in which quadrivalent inactivated influenza vaccine (QIV), Fluarix Tetra (Fluarix Tetra) (a designated vaccine under existing item 207A of Part 2 of Schedule 1 of the Determination) may be provided; and
- add meningococcal serogroups A, C, W-135 and Y oligosaccharides conjugate (Menveo), to the list of designated vaccines.

The Amendment Determination further extends the current listing of FluarixTetra, for the prevention of seasonal influenza to include children aged at least 6 months old but less than 5 years old who are currently eligible for influenza vaccination under the National Immunisation Program (NIP). The circumstances in which this vaccine may be provided aligns with the current NIP listings for Vaxigrip Tetra (item 207F) and FluQuadri (item 207B) QIVs and as a result repetitive subsections have been repealed to reflect this.

The Amendment Determination adds Menveo as a designated vaccine for the prevention of Invasive Meningococcal Disease (IMD) caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y in adolescents as part of a school based immunisation program for year 10 students (aged at least 14 years old, but less than 17 years old) and via a catch-up program for adolescents aged at least 14 years old, but less than 19 years old.

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

Background
The National Immunisation Program

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 to protect against 18 disease groups, including children, adolescents, the elderly, 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) unless the PBAC has recommended to the Minister that the vaccine be a designated vaccine.

Fluarix Tetra
In July 2020, the PBAC recommended a further extension to the listing of the Fluarix Tetra on the Determination, for the prevention of seasonal influenza, to include vaccination of children aged at least 6 months old, but less than 5 years old.

Based on PBAC recommendations the NIP will provide the designated vaccine to the following eligible groups:

(a) a person who is at least 65 years old or

(b) an Aboriginal or Torres Strait Islander person who is at least 6 months old; or

(c) a child who is at least 6 months old but less than 5 years old; or

(d) a person who is at least 6 months old 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; or

(e) a person who is at least 6 months old but is less than 11 years old and is receiving long-term aspirin therapy; or

(f) a woman who is pregnant.

Menveo
In July 2018, PBAC recommended that Menveo vaccine should be a designated vaccine for the prevention of IMD caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y as a single dose for adolescents as part of a school based immunisation program for year 10 students (aged at least 14 years old, but less than 17 years old) and via a catch-up program for a single dose for adolescents aged at least 14 years old, but less than 19 years old.

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 for the supply of vaccines on the NIP.

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, for 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, 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 received advice from the 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 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 this Amendment Determination was unnecessary due to the nature of the consultation that had already taken place.

Details of the Amendment Determination are set out in Attachment 1.

The Amendment Determination commences on the day after registration.

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

ATTACHMENT 1

Details of the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 3) 2020*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.3) 2020.*

Section 2 - Commencement

Section 2 provides that the Amendment Determination commences on the day after its registration.

Section 3 - Authority

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

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

Item 1 – Subsection 7(7A)

Item 1 repeals subsection 7(7A) in the Determination.

Item 2 - Subsection 7(8)

Item 2 omits "207B" and substitutes it with "207A, 207B and 207F". Subsection 7(8) specifies the circumstances in which the designated vaccines listed in items 207A, 207B and 207F of Schedule 1 of the Determination may be provided under the NIP.

Item 3 – Subsection 7(8B)

Item 3 repeals subsection 7(8B) in the Determination.

Item 4 – Part 1 of Schedule 1 (after table item 108A)

Item 4 inserts a new item 108B in Part 1 of Schedule 1 (after table item 108A). Item 108B in Part 1 of Schedule 1 determines that the Meningococcal (Groups A, C, W-135 and Y) Oligosaccharide CRM197 Conjugate Vaccine (Menveo) is a designated vaccine for the purposes of the Act. Additionally, it specifies the circumstances in which the vaccine can be provided.

Item 5 – Part 2 of Schedule 1 (table item 207A, column headed "Vaccine and the circumstances in which vaccine may be provided", under the subheading "Circumstances")

Item 5 amends the circumstances in Part 2 of Schedule 1 (table item 207A, column headed "Vaccine and the circumstances in which vaccine may be provided", under the subheading "Circumstances") and substitutes it with the new subsection 7(8) which provides for the revised circumstances in which Fluarix Tetra may be provided under the NIP.

Item 6 – Part 2 of Schedule 1 (table item 207F, column headed "Vaccine and the circumstances in which vaccine may be provided", under the subheading "Circumstances")

Item 6 amends the circumstances in Part 2 of Schedule 1 (table item 207F, column headed "Vaccine and the circumstances in which vaccine may be provided", under the subheading "Circumstances") and substitute it with the new subsection 7(8) which provides for the circumstances in which VaxiGrip Tetra may be provided under the NIP.

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.3) 2020

This 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 Legislative Instrument

The *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 3) 2020* (the Amendment Determination) varies the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1*) (the Determination), which determines, under subsection 9B(2) of the *National Health Act 1953* (the Act), that a specified vaccine in the instrument is a designated vaccine for the purposes of the Act. Additionally the Amendment Determination specifies under subsection 9B(5) of the Act, the circumstances in which the vaccine can be provided.

The Amendment Determination expands the circumstances in which Fluarix Tetra can be provided for the prevention of seasonal influenza under the National Immunisation Program (NIP) to include vaccination of children aged at least 6 months old, but less than 5 years old.

The Amendment Determination will list Menveo on the NIP, for the prevention of Invasive Meningococcal Disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y as a single dose for adolescents as part of a school based immunisation program for year 10 students (aged at least 14 years old, but less than 17 years old) and via a catch-up program for a single dose for adolescents aged at least 14 years old, but less than 19 years old.

Human Rights Implications

This 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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