

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 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.2) 2020* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to add multicomponent meningococcal group B (4CMenB) to the list of designated vaccines.

This designated vaccine is for the prevention of Invasive Meningococcal Disease (IMD) caused by *Neisseria meningitidis* group B strains for the following specified population of patients:

- Aboriginal and Torres Strait Islander infants aged at least 2, 4 and 12 months, with a catch up program for children under 2 years of age;
- Aboriginal and Torres Strait Islander infants with medical conditions known to increase the risk of IMD aged at least 2, 4, 6 and 12 months, with a catch up program for children under 2 years of age; and
- Persons with specified medical conditions known to increase the risk of IMD, with the number of doses to be provided dependent on the age of the person at the start of the vaccine course.

These amendments are acting on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) and Pharmaceutical Benefits Advisory Committee (PBAC) in response to the high incidence of IMD caused by *Neisseria meningitidis* group B strains in certain high-risk populations.

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 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.

In November 2019, the PBAC decided to recommend to the Minister (under section 101(4B) of the Act that 4CMenB should be a designated vaccine for the purposes of section 9B of the Act.

Based on PBAC recommendations the NIP will provide:

- for Aboriginal and Torres Strait Islander infants, two primary doses for infants aged at least 2 and 4 months with at least 8 weeks between doses and a booster dose aged at least 12 months, with a three year catch up program for children aged under 2 years old;
- for Aboriginal and Torres Strait Islander infants with medical conditions known to increase the risk of IMD, three primary doses for infants aged at least 2, 4 and 6 months with at least 8 weeks between doses and a booster aged at least 12 months, with a three year catch up program for children aged under 2 years old;
- for persons with specified medical conditions (persons with asplenia, hyposplenia, complement deficiency, or those undergoing treatment with eculizumab) known to increase the risk of IMD:
 - Infants 6 weeks to 5 months of age at the start of the vaccine course - three primary doses with at least 8 weeks between doses and a booster aged at least 12 months;
 - Children between 6 and 11 months of age at the start of the vaccine course – two primary doses with at least 8 weeks between doses and a booster aged at least 12 months;
 - Persons aged at least 12 months of age at the start of the vaccine course – two primary doses with at least 8 weeks between doses.

As a result of the inclusion of 4CMenB on the NIP at 2, 4 and 12 months, the 12 months NIP schedule point visit for Indigenous children could include up to six injections. Therefore, ATAGI have investigated and recommended moving the 12 month schedule point for the Hepatitis A vaccination from 12 months to 4 years.

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. 2) 2020*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 2) 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 – After subsection 7(12)

Item 1 inserts a new subsection 7(13) (after subsection 7(12)) which specifies the circumstances in which the designated vaccine listed in item 114 of Schedule 1 of the Determination may be provided, including the number and timing of doses, under the National Immunisation Program (NIP).

Item 2 – Part 1 of Schedule 1 (after table item 113)

Item 2 inserts a new item 114 in Part 1 of Schedule 1 (after table item 113). Item 114 in Part 1 of Schedule 1 determines that the multicomponent meningococcal group B (4CMenB) vaccine is a designated vaccine for the purposes of the Act. Additionally, it specifies the circumstances in which the vaccine can be provided.

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) 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. 2) 2020* (the Amendment Determination) varies the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)* (the Determination), and determines, under subsection 9B(2) of the *National Health Act 1953* (the Act), that multicomponent meningococcal group B (4CMenB) 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 will list 4CMenB on the National Immunisation Program (NIP), for the prevention of Invasive Meningococcal Disease (IMD) caused by *Neisseria meningitidis* group B strain for the following specified population of patients to which they may be provided:

- Aboriginal and Torres Strait Islander infants aged at least 2, 4 and 12 months, with a catch up program for children under 2 years of age;
- Aboriginal and Torres Strait Islander infants with medical conditions known to increase the risk of IMD aged at least 2, 4, 6 and 12 months, with a catch up program for children under 2 years of age; and
- Persons with specified medical conditions known to increase the risk of IMD, with the number of doses to be provided dependent on the age of the person at the start of the vaccine course.

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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