**EXPLANATORY STATEMENT**

Issued by the Authority of the Minister for Health

***National Health Act 1953***

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

* change and expand the circumstances in which Prevenar 13 and Pneumovax 23 (designated vaccines under existing items 110 and 112 respectively of Part 1 of Schedule 1 of the Determination) may be provided;
* expand the circumstances in which ActHIB or Hiberix (a designated vaccine under existing item 103 of Part 1 of Schedule 1 of the Determination) may be provided; and
* expand the circumstances in which Nimenrix (a designated vaccine under existing item 108A of Part 1 of Schedule 1 of the Determination) may be provided.

The Amendment Determination provides a whole-of-life pneumococcal vaccination schedule under the National Immunisation Program (NIP), including both Prevenar 13 and Pneumovax 23, for individuals most as risk of invasive pneumococcal disease.

The Amendment Determination also revises the circumstances for which vaccines (Nimenrix and ActHIB or Hiberix) for individuals most at risk of invasive meningococcal disease and Haemophilus influenzae type b (Hib) are available under the NIP.

These amendments are acting on new recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) and Pharmaceutical Benefits Advisory Committee (PBAC) in response to high pneumococcal disease rates 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 17 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 May 2019 and July 2019, the PBAC recommended amendments to the NIP, under the Actfor special risk groups and the prevention of invasive pneumococcal disease respectively.

In November 2018, the PBAC considered a preliminary research report on the vaccinations available (either funded under the NIP or PBS) and current clinical recommendations for asplenic individuals. ATAGI advice was requested on prevalence, incidence and likely uptake. In May 2019, The PBAC recommended that the following vaccinations be listed on the NIP schedule for patients with asplenia and hyposplenia – Meningococcal and meningococcal booster (Men ACWY), Pneumococcal (Prevenar 13 [single dose]) (13vPCV) and Pneumovax 23 [two subsequent doses]) (23vPPV) and Hib.

At the same meeting, PBAC also recommended Men ACWY for individuals with complement deficiencies and those undergoing eculizumab treatment following a submission from the Chief Medical Officer, which was supported by ATAGI. The PBAC considered that people with complement deficiency and undergoing eculizumab treatment had a high clinical need for vaccination, and that the cost-effectiveness in this population would not be worse than the current NIP listed population.

In July 2019, the PBAC recommended a whole-of-life pneumococcal vaccination schedule, including both Prevenar 13 and Pneumovax 23, as having acceptable cost-effectiveness for inclusion on NIP:

* All healthy non–Aboriginal and Torres Strait Islander adults ≥ 70 years: 13vPCV (single dose)
* All Aboriginal and Torres Strait Islander adults ≥50 years:  13vPCV (single dose) and 23vPPV (two subsequent doses approximately five years apart)
* In all persons ≥ 5 years of age newly diagnosed with a condition putting them at very high risk of pneumococcal infection: 13vPCV (single dose) and 23vPPV (two subsequent doses approximately five years apart).

Based on ATAGI’s advice on the high pneumococcal disease rates in certain high-risk infant populations, the following additions were also recommended to the infant pneumococcal program for children under five years of age:

* Non-Aboriginal and Torres Strait Islander children 2-12 months with very high risk of pneumococcal infection: an additional dose of 13vPCV (single dose) at 6 months (already funded for Aboriginal and Torres Strait Islander children) and 23vPPV (two subsequent doses approximately five years apart).
* Aboriginal and Torres Strait Islander children < 5 years living in Western Australia, Queensland, South Australia and Northern Territory (areas of high incidence): two additional doses of 23vPPV following the currently funded additional dose of 13vPCV at 6 months.
* Children 12 – 59 months newly diagnosed with a condition putting them at very high risk of pneumococcal infection: 13vPCV (single dose) and 23vPPV (two subsequent doses approximately 5 years apart).

*Government approval*

On 30 January 2020, the Minister for Health, the Hon Greg Hunt MP, approved the PBAC recommendations to amend the circumstances under which Pneumovax 23, Prevenar 13, Nimenrix, ActHIB and Hiberix can be provided through the NIP.

**Details**

The Determination commenced on 23 September 2014. 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 Instrument 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. 1) 2020***

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 1) 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 section 9B 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 Principal Determination).

**Item 1 – Before subsection 7(1)**

Item 1 inserts a new subsection 7(1A) which outlines the circumstances in which designated vaccines listed in item 108A of Schedule 1 of the Principal Determination may be provided, including numbers and timing of booster doses, under the National Immunisation Program (NIP).

**Item 2 – After paragraph 7(1)(a)**

Item 2 inserts revised circumstances after paragraph 7(1)(a) for which item 110 (Prevenar 13) of Schedule 1 in the Principal Determination may be provided for under the NIP.

**Item 3 – Subsection 7(2)**Item 3repeals subsection 7(2) in the Principal Determination and substitutes it with a new subsection 7(2). The new subsection 7(2) provides revised circumstances for which item 112 (Pneumovax 23) may be provided for under the NIP.

**Item 4 – Part 1 of Schedule 1 (item 103)**Item 4 repeals the circumstance in Part 1 of Schedule 1 (item 103, column headed “Vaccine and the circumstances in which vaccine may be provided”) and substitutes it with revised circumstances in which ActHib or Hiberix may be provided under the NIP.

**Item 5 - Part 1 of Schedule 1 (item 108A)**Item 5 repeals the circumstances in Part 1 of Schedule 1 (item 108A, column headed “Vaccine and the circumstances in which vaccine may be provided”) and substitutes it with revised circumstances in which Nimenrix may be provided under the NIP.

**Item 6 – Part 1 of Schedule 1 (item 108A)**Item 6 repeals the number and timing of doses for Part 1 of Schedule 1 (item 108A, column headed “Number and timing of doses”) and substitutes it with revised numbers and timings of doses in which Nimenrix may be provided under the NIP.

**Item 7 - Part 1 of Schedule 1 (item 110)**Item 7 Omits circumstance in Part 1 of Schedule 1 of the Principal Determination (table item 110, column headed “Vaccine and the circumstances in which Prevenar 13 may be provided) “(b) to a child who is about 6 months of age and is a member of a medical risk group”.

**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.1) 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. 1) 2020* (the Amendment Determination) varies the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1*) (the Principal 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.

The Amendment Determination will provide a whole-of-life pneumococcal vaccination schedule under the National Immunisation Program (NIP), including both Prevenar 13 and Pneumovax 23, for individuals most as risk of invasive pneumococcal disease.

The Amendment Determination also revises the circumstances for which vaccines for individuals most at risk of invasive meningococcal disease and Haemophilus influenzae type b are available under the NIP.

**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 maintains compliance with the right to health by continuing to provide free access for eligible people to designated vaccines. The Amendment Determination continues to support the attainment of the highest standard of health for all Australians, by protecting individuals and the community against vaccine preventable disease.

**Conclusion**

The Amendment Determination is compatible with human rights as it continues to promote the right to health.

**Hope Peisley**

**Assistant Secretary**

**Office of Health Protection**

**Department of Health**