EXPLANATORY STATEMENT

National Health Act 1953

National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 4) 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.4) 2020* (the Amendment Determination) amends the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* (the Determination) to extend the current temporary listing of Hepatitis B surface antigen recombinant vaccine, Engerix-B (adult formulation), for use in adolescents and adults until 30 June 2022, due to an ongoing shortage of the National Immunisation Program (NIP) listed adult formulation of H-B-Vax ll for the same indication and population.

This amendment implements recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC).

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.

Engerix-B
Merck Sharp and Dohme (Merck) has been experiencing global manufacturing and supply shortages of their Hepatitis B vaccines for a number of years. Merck manufactured vaccines are sponsored by Seqirus for supply in Australia. Merck have advised that the current shortage may not be resolved until August 2021.

Hepatitis B vaccines are currently listed on the NIP under the Determination for the following cohorts:

Authorised Version Explanatory Statement registered 10/12/2020 to F2020L01560

- Individuals up to the age of 14 years can receive either Seqirus' H-B-Vax II (paediatric formulation) or GlaxoSmithKline's (GSK) Engerix-B (paediatric formulation); and
- Catch up cohorts, including all 10-19 year olds, and refugees and humanitarian entrants of all ages, can receive Seqirus' H-B-Vax II (adult formulation).

In July 2018, the PBAC recommended the temporary listing of Engerix-B (adult formulation) for use in adolescents and adults on the NIP until either the shortage of H-B-Vax II (adult formulation) has been resolved, or 31 December 2019, whichever were to occur first. The PBAC considered:

- Engerix-B (adult formulation) is registered with the Therapeutic Goods Administration for active immunisation against Hepatitis B virus infection;
- Engerix-B (adult formulation) is sufficiently interchangeable with H-B-VAX II (adult formulation) as per the advice of the Australian Technical Advisory Group on Immunisation (ATAGI); and
- that the temporary listing would ensure ongoing coverage for the catch up populations that are eligible for the vaccine under the NIP.

In August 2019, PBAC recommended an extension to the temporary listing for Engerix-B (adult formulation) and was subsequently extended until 31 December 2020, given the ongoing shortage. In the most recent out-of-session consideration of August 2020 (tabled at the September PBAC meeting), PBAC recommended a further extension of the temporary listing until 30 June 2022 to enable continued management of the shortage.

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*.

Authorised Version Explanatory Statement registered 10/12/2020 to F2020L01560

ATTACHMENT 1

Details of the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No. 4) 2020*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Immunisation Program – Designated Vaccines) Amendment Determination (No.4) 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 – Part 2 of Schedule 1 (table item 202A, column headed "Vaccine and the circumstances in which vaccine may be provided")

Item 1 repeals the circumstances in Part 2 of Schedule 1 (table item 202A, column headed "Vaccine and the circumstances in which vaccine may be provided") and substitutes it with revised circumstances in which Engerix-B may be provided under the NIP.

Authorised Version Explanatory Statement registered 10/12/2020 to F2020L01560

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.4) 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. 4) 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 extends the current temporary listing of Hepatitis B surface antigen recombinant vaccine, Engerix B (adult formulation), for use in adolescents and adults until 30 June 2022 due to an ongoing shortage of the National Immunisation Program (NIP) listed adult formulation of H-B-Vax ll for the same indication and population.

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.

Darius Everett
Acting Assistant Secretary
Immunisation and Communicable Diseases Branch
Department of Health