

EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health

National Health Act 1953

*National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment
(Vaccine Advice) Regulations 2019*

The *National Health Act 1953* (the Act) relates to the provision of pharmaceutical, sickness and hospital benefits and medical and dental services.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted or are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 99YBA(1) of the Act provides that the regulations may make provision in relation to services provided by the Commonwealth in relation to the exercise of a power by the Minister under section 9B of the Act:

- Section 9B of the Act provides that the Minister may provide, or arrange for the provision of, designated vaccines and goods and services associated with or incidental to the provision or administration of designated vaccines. The Minister may also specify designated vaccines under section 9B.

Services provided by the Commonwealth in relation to section 9B include services provided in connection with the National Immunisation Program, including the activities of the Australian Technical Advisory Group on Immunisation (ATAGI).

Subsection 99YBA(2) enables regulations to be made that make provision in relation to matters including the prescribing of fees, the making of applications, and exemptions from the prescribed fees, in relation to services provided by the Commonwealth in relation to the exercise of a power by the Minister under section 9B of the Act.

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009* (the Principal Regulations) currently prescribe fees and make provision in relation to the making of applications for services provided by the Commonwealth in relation to the exercise of a power by the Minister under section 9B of the Act.

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment Regulations 2019*, made on 4 April 2019, amend the Principal Regulations with effect from 1 July 2019. The amendments include the imposition of a fee in relation to the provision of advice by ATAGI for the purposes of the designation of a vaccine under section 9B of the Act.

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Vaccine Advice) Regulations 2019* (the Amendment Regulations) amend the Principal Regulations to defer the commencement date for the new fees for the provision of ATAGI services from 1 July 2019 to 1 July 2020.

Consultation

The Department of Health has implemented new cost recovery processes in relation to fees charged under section 99YBA of the Act. The document *Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NIP (1 July 2019 – 30 June 2020)* was released for public consultation on www.pbs.gov.au from 1 February to 17 February 2019 to support implementation of the cost recovery arrangements. Feedback during this process, from relevant industry bodies including Medicines Australia and its Vaccine Interest Group members, led the Commonwealth to agree to defer the commencement date for new fees for ATAGI services.

The amendments in the Amendment Regulations give industry sufficient time to plan and budget for the fees associated with seeking ATAGI advice.

No general public consultation was undertaken in the development of the Amendment Regulations.

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Regulations commence immediately after the commencement of the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment Regulations 2019*. Those regulations commence on 1 July 2019.

Details of the Amendment Regulations are provided in [Attachment A](#).

A Statement of Compatibility with Human Rights has been completed for the Amendment Regulations, in accordance with the *Human Rights (Parliamentary Scrutiny) Act 2011*. The Statement's assessment is that the measures in the Amendment Regulations are compatible with human rights. A copy of the Statement is at [Attachment B](#).

ATTACHMENT A

Details of the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Vaccine Advice) Regulations 2019*

Section 1—Name of Regulations

This section provides that the name of the Amendment Regulations is the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Vaccine Advice) Regulations 2019*.

Section 2—Commencement

This section provides for the Amendment Regulations to commence immediately after the commencement of the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment Regulations 2019*. Those regulations commence on 1 July 2019.

Section 3—Authority

This section provides that the Amendment Regulations are made under the *National Health Act 1953*.

Section 4—Schedules

This section provides that each instrument specified in the Schedule is amended or repealed as set out in the Schedule and that any other item in the Schedule has effect according to its terms.

Schedule 1—Amendments

Item [1]—regulation 1.3

This item inserts a new definition into regulation 1.3 of the Principal Regulations to provide for a definition of ‘ATAGI advice’.

ATAGI provides expert advice, including on clinical, technical and implementation matters, to be included in a person's application to the Pharmaceutical Benefits Advisory Committee seeking a recommendation that a vaccine be designated under section 9B of the Act. Designated vaccines are included in the National Immunisation Program (NIP).

Item [2]—regulation 1A.1

This item repeals regulation 1A.1 of the Principal Regulations and substitutes a new regulation that provides that a fee is payable for receiving advice from ATAGI if the application for the advice is made on or after 1 July 2020.

Presently, no fee is payable in respect of the provision of advice by ATAGI. It is not intended for regulation 1A.1 to affect applications to ATAGI made prior to 1 July 2020, and those applications will continue not to attract a fee.

Regulation 1A.1 provides that for applications made on or after 1 July 2020, and for which the Department provides notification of receipt of the application during the financial year starting on 1 July 2020, the fee is \$300,440.

Item [3]—subregulation 1A.2(3)

This item repeals subregulation 1A.2(3) of the Principal Regulations and substitutes it with a new subregulation that provides that if a person is partially exempt under subregulation 1A.2(1) from the usual fee payable under regulation 1A.1, a reduced fee of \$178,550 is payable.

Subregulation 1A.2(1) of the Principal Regulations requires the Secretary to grant a partial exemption from the usual ATAGI fee in certain circumstances, including where the application does not involve a degree of analysis sufficient to justify the usual fee.

This reduced fee applies in relation to an application made on or after 1 July 2020 and for which the Department provides notification of receipt of the application during the financial year starting on 1 July 2020.

It is not intended for the subregulation to affect applications to ATAGI made prior to 1 July 2020 and those applications continue not to attract a fee.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Vaccine Advice) Regulations 2019

The Amendment Regulations are 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 Regulations

The Amendment Regulations are made under section 140 of the *National Health Act 1953* (the Act). Section 140 provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act. Subsection 99YBA(2) of the Act further provides that regulations may make provision in relation to matters including the prescribing of fees, the making of applications, and exemptions from the prescribed fees, in relation to services provided by the Commonwealth under section 9B of the Act.

Services provided by the Commonwealth in relation to section 9B include services provided in connection with the National Immunisation Program (NIP), including the activities of the Australian Technical Advisory Group on Immunisation (ATAGI).

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment Regulations 2019*, made on 4 April 2019, amend the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009* (Principal Regulations) with effect from 1 July 2019. This amendment includes the imposition of a fee in relation to the provision of advice by the ATAGI for the purposes of the designation of a vaccine under section 9B of the Act.

The Amendment Regulations amend the Principal Regulations to defer the commencement date for the new fee for the provision of ATAGI services from 1 July 2019 to 1 July 2020.

Human rights implications

The changes made by the Amendment Regulations do not affect a person's entitlement to receive health services subsidised by the Commonwealth, nor do they limit the vaccines that may be designated under section 9B of the Act and be made available on the NIP.

Deferring the commencement date for imposing the fee in relation to the provision of advice by the ATAGI will allow industry to plan and budget for the imposition of the

fee. This may prevent unintended consequences such as potential delays to applications for new listings on the NIP.

Conclusion

The Amendment Regulations are compatible with human rights. Human rights continue to be protected by supporting processes for listing new vaccines on the NIP, which promotes the right to the enjoyment of the highest attainable standard of physical and mental health.

**The Hon Greg Hunt
Minister for Health**