EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health and Aged Care

National Health Act 1953

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2021

The *National Health Act 1953* (the Act) makes provision in relation to 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 the following provisions:

- Section 9B of the Act, which 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.
- Part VII of the Act, which concerns pharmaceutical benefits and deals with matters including the supply of and payments concerning pharmaceutical benefits and the PBS.

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 the exercise of a power by the Minister under section 9B and Part VII of the Act.

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009* (the Principal Regulations) prescribe fees and matters relating 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 and Part VII of the Act. Much of the assessment work is out-sourced to external evaluators at a cost to Government, and the regulations implement cost-recovery arrangements whereby these evaluation costs and the costs the Department itself incurs in PBS approval and management are recouped from industry through fees provided in the regulations.

The purpose of the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2021* (the Amendment Regulations) is to:

- update cost recovery fees for the 2021-22 financial year in relation to applications for listing on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP); and
- amend the wording of Regulation 2.7 to include the words ‘medicinal preparation’ to enable applications that relate to medicinal foods to be submitted as a ‘Committee Secretariat’ category.

In line with Australian Government Cost Recovery Guidelines, the Principal Regulations are updated annually to ensure they accurately reflect the efficient costs of providing services.

The Amendment Regulations carry on the arrangements made by the Principal Regulations which sunset on 1 April 2022.

Details of the operation of the Amendment Regulations are provided in the Attachment.

The Amended Regulations commenced on 1 July 2021.

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

A Statement of Compatibility with Human Rights has been completed for the Amendment Regulation, 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.

Consultation

The changes in the Amendment Regulations have been discussed with representatives of Medicines Australia and the Generic and Biosimilar Medicines Association. Public consultation was undertaken on the draft Cost Recovery Implementation Statement to advise industry of the fee changes for the 2021-22 financial year.

ATTACHMENT

Details of the proposed *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2021*.

Section 2 – Commencement

This section provides for the Amendment Regulations to commence on 1 July 2021.

Section 3 – Authority

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

Section 4 – Schedule(s)

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

Schedule 1 – Amendments

Item [1] – Subregulation 1A.1(2)

This item substituted the 'usual ATAGI fee' amount within the Principal Regulations to reflect the revised fees for the 2021-22 financial year.

This fee is charged by the Department of Health (the Department) to recover the cost of providing services in response to a 'complex' application for Australian Technical Advisory Group on Immunisation (ATAGI) presubmission.

ATAGI provides advice to support the Pharmaceutical Benefits Advisory Committee's (PBAC's) evaluation of vaccines for the National Immunisation Program (NIP), including on clinical, technical and implementation matters.

Item [2] – Subregulation 1A.2(3)

This item substituted the 'partially exempt' ATAGI fee amount within the Principal Regulations to reflect the revised fees for the 2021-22 financial year.

This fee is charged by the Department to cost recover the services provided in response to a 'simple' application for ATAGI presubmission advice.

Items [3] and [4] – Subregulation 1A.7 (table items 1 and 2)

These items substituted the fee amounts for a 'first' and 'second' PBAC presubmission meeting within the Principal Regulations to reflect the revised fees for the 2021-22 financial year.

These fees are charged by the Department to recover the cost of holding a presubmission meeting with a sponsor to support development of their submission to the PBAC.

Items [5] through [14] – Subregulation 2.2(1) (table items 1 through 10, column 2)

These items substituted the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2021-22 financial year.

These fees are charged by the Department to recover the costs of the services provided in response to an application submission services:

a) for the PBAC to consider making a recommendation that may enable, amend or cease the public funding of a pharmaceutical or vaccine; or

b) to assist the Minister to determine a brand of pharmaceutical item.

There are six submission categories and four resubmission pathways for submissions to the PBAC.

Submission categories are determined based on the applicant's request in their submission. With the exception of Standard Re-entry Pathway, resubmission pathways are nominated by the PBAC following a 'not recommended' PBAC outcome. Applicants nominate their submission category or resubmission pathway via the Intent to Apply form (prior notice).

Under the Principal Regulations, fees for submission services also include a non-refundable deposit amount (prior notice fee) of $430. This fee remains unchanged.

Item [15] – Subregulation 2.7(2) (heading)

This item amended the wording of the heading of this paragraph to add the words 'medicinal preparations' after 'listed drugs'. This maintains consistency with changes to paragraph 2.7(2)(b) – refer item 16.

Item [16] – Paragraph 2.7(2)(b)

This item added the words 'medicinal preparations' after 'listed drugs', to provide for applications in relation to medicinal foods to be submitted as a 'Committee Secretariat' category.

Items [17] through [21] – Subregulation 3.3(1) (table items 1 through 5)

These items substituted the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2021-22 financial year.

These fees are charged by the Department to recover the costs of the services provided in response to an application for pricing services.

There are five different pricing pathways (pricing application categories) to progress a positive PBAC recommendation – Pricing Pathway A; Pricing Pathway B (new deed); Pricing Pathway C (existing deed); Pricing Pathway D (no deed); and Pricing Secretariat.

Pricing Pathway A requires the PBAC to recommend that it is appropriate for a submission to follow this pathway. All other pricing pathways are determined based

on the listing arrangements required. Applicants nominate their pricing pathway via the Notice of Intent for Pricing form (prior notice).

Under the Principal Regulations, fees for submission services also include a non-refundable deposit amount (prior notice fee) of $430. This fee remains unchanged.

Item [22] – Paragraph 3.3(3)(a)

This item substituted the refund amount currently provided for within the Principal Regulations relating to the Pricing Pathway A where a deed is not entered into because a sponsor withdraws their pricing application or there has been no active negotiation for 26 weeks. Only the rebate management component of the pricing pathway fee is refunded.

Item [23] – Paragraph 3.3(3)(b)

This item substituted the refund amount currently provided for within the Principal Regulations relating to the Pricing Pathway B where a deed is not entered into because a sponsor withdraws their pricing application or there has been no active negotiation for 26 weeks. Only the rebate management component of the pricing pathway fee is refunded.

Item [24] – Paragraph 3.3(3)(c)

This item substituted the refund amount currently provided for within the Principal Regulations relating to the Pricing Pathway C where a deed is not entered into because a sponsor withdraws their pricing application or there has been no active negotiation for 26 weeks. Only the rebate management component of the pricing pathway fee is refunded.

Items [25] through [28] – Subregulation 3A.1(1) (table items 1 through 4)

These items substituted the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2021-22 financial year.

These fees are charged by the Department to recover the costs of the services provided in response to an application for list management services. List management services includes activities that are directly requested by sponsors seeking to manage their listing on the PBS.

List management options include:

- Price increase requests including brand premium requests;
- Ministerial discretion requests;
- Deed renewal requests; and
- Deed variation requests.

Item [29] – Subregulation 3A.5(2)

This item substituted the amount currently provided for within the Principal Regulations which is refunded by the Department where an applicant withdraws their deed renewal application and a deed arrangement has not been entered into.

Item [30] – In the appropriate position in Part 7

This item inserted an application provision to clarify that the revised fees apply to all applications for which notification is given on or after 1 July 2021.

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 (Fees) Regulations 2021

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2021* (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 update cost recovery fees for the 2021-22 financial year in relation to applications for listing on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP).

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 the 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 or Part VII of the Act.

The Amendment Regulations amend the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009* (the Principal Regulations). The Amendment Regulations provide for fees for services provided by the Commonwealth in relation to an exercise of power by the Minister under section 9B or Part VII of the Act:

- The Minister's powers under section 9B of the Act broadly relate to the National Immunisation Program (NIP).
- The Minister's powers under Part VII broadly concern the listing process for applications for pharmaceuticals to be included in the Pharmaceutical Benefits Scheme (PBS).

Human rights implications

The Amendment Regulations engage Article 2 and 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 PBS and NIP are benefit schemes, which assist with advancement of this human right by providing patients with subsidised access to medicines. By accurately recovering the costs of assessing applications for subsidy, the Commonwealth ensures that the medicine and vaccine assessment process remains financially sustainable and contributes to a viable and well-functioning PBS. This mean that Australians will

continue to have access to safe, effective medicines which, in turn, promotes the various rights to health in the Conventions.

Conclusion

This Legislative Instrument is compatible with human rights. Human rights continue to be protected by ensuring the PBS and NIP are financially sustainable and will continue to assess applications for subsidy of medicines and vaccines which benefit the health of Australian citizens.

The Hon Greg Hunt MP

Minister for Health and Aged Care