

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 2023

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

Authority

Section 140 of the Act provides 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.

The Act specifies no conditions that need to be satisfied before the power to make the proposed regulations may be exercised.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instruction 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.

Background

The Act enables fees to be charged to recover the costs of certain services provided by the Commonwealth. Under the Act, payment of fees may be required for services that relate to the exercise of a power by the Minister under the following provisions:

- Section 9B of the Act which sets out 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. Services provided by the Commonwealth in relation to this section include those provided in connection with the National Immunisation Program (NIP), including activities of the Australian Technical Advisory Group on Immunisation (ATAGI) and the Pharmaceutical Benefits Advisory Committee (PBAC).
- Part VII of the Act which deals with matters related to the supply of and payments for pharmaceutical benefits and the Pharmaceutical Benefits Scheme (PBS). Services provided by the Commonwealth in relation to this part include the administration of the PBS, activities of the PBAC and its sub-committees, and other services carried out by the Department of Health and Aged Care (the Department) to assist the Minister to

exercise the relevant powers under Part VII.

The Act provides for regulations to set out the fees that are payable and the manner of payment for those services. A prescribed fee is payable to the Commonwealth and must not amount to taxation. The Act allows the regulations to set out other matters including:

- the making of applications for services provided under section 9B and Part VII,
- exemptions from prescribed fees for those services,
- the time that prescribed fees are due and payable,
- the manner of payment of prescribed fees,
- the payment of penalties in respect of late payment of prescribed fees,
- exemptions from prescribed fees,
- the waiver, remission or refund of prescribed fees,
- and the review of decisions made under the regulations.

The consequence of failing to pay a prescribed fee is that the Minister may refuse to exercise the relevant power under the Act until the fee is paid.

Purpose

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022* (the Principal Regulations) prescribe fees and matters relating to the making of applications or submissions for services provided by the Commonwealth in relation to the exercise of certain powers by the Minister under the Act.

The Department assesses the cost effectiveness of vaccines for inclusion on the NIP as well as drugs for listing on the PBS. Much of the assessment work is carried out by external evaluators at a cost to Commonwealth. The Principal Regulations implement cost recovery arrangements whereby these evaluation costs are recouped from the pharmaceutical industry through fees.

The purpose of the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023* (the Amendment Regulations) is to amend the Principal Regulations to:

- update cost recovery fees for the 2023-24 financial year in relation to applications for listing on the PBS and NIP; and
- provide a legislative basis for the new ‘Ministerial determination request’ charging pathway, that is to ensure applications requesting a determination from the Minister relating to another quantity of a brand of pharmaceutical item, under subsection 99AEKC(2) of the Act are also cost recovered.

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. Fees are calculated using an activity-based cost model. This ensures that the contemporary costs incurred by the Department when providing the applicant-requested PBS and NIP listing services, are accurately reflected in fees.

Commencement

The Amended Regulations commence on 1 July 2023.

Consultation

The changes in the Amended Regulations have been discussed with representatives of the pharmaceutical industry. Public consultation on the draft Cost Recovery Implementation Statement, which advises industry of the fee changes for the 2023-24 financial year, was undertaken in May 2023. Industry generally accepted the fee changes and did not raise any issues in relation to the new charges.

General

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

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

The Amendment Regulations are compatible with the rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility with human rights is set out in **Attachment B**.

Details of the proposed *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023*

Section 1 – Name

This section provides that the title of the Amendment Regulations is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023*.

Section 2 – Commencement

This section provides that the Amendment Regulations commence on 1 July 2023.

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 to the Amendment Regulations 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] – Subsection 7(2)

This item substitutes the ‘complex category ATAGI application fee’ amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year. The revised fees have been determined following the Department’s annual review of cost recovery fees. Fees are calculated using an activity-based cost model to reflect the efficient cost of providing services. This ensures that the contemporary costs incurred by the Department when providing the applicant-requested PBS and NIP listing services, are accurately reflected in fees.

This fee is charged by the Department to recover the cost of providing services in response to a ‘complex’ application for ATAGI advice.

ATAGI provides advice to support the PBAC’s evaluation of vaccines for the NIP, including on clinical, technical and implementation matters.

Item [2] – Subsection 7(2)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

Under the Principal Regulations, fees for application services also include a non-refundable deposit amount. This fee is charged by the Department to cost recover administrative services by the Department in relation to an ATAGI application or the notice of intent for an ATAGI application.

Item [3] – Subsection 8(4)

This item substitutes the ‘simple category’ ATAGI fee amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

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

Item [4] – Subsection 8(4)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

Under the Principal Regulations, fees for application services also include a non-refundable deposit amount. This fee is charged by the Department to cost recover administrative services in relation to an ATAGI application or the notice of intent for an ATAGI application.

Item [5] – Subsection 12(4)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to an ATAGI application or the notice of intent for an ATAGI application.

Items [6] and [7] – Section 14 (table items 1 and 2)

Items 6 and 7 substitutes the fee amounts for a ‘first’ and ‘second or later’ PBAC presubmission meeting within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

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

Item [8] – Subsection 22(2) (table)

This item substitutes the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2023-24 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 the 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 notice of intent form.

Item [9] – Subsection 22(2) (note 4)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to a submission or notice of intent for a submission.

Item [10] – Subsection 35(6)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to a submission or notice of intent for a submission.

Items [11] through [15] – Subsection 41(1) (table items 1 through 5)

These items substitute the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2023-24 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 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 form.

Item [16] – Subsection 41(2)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

Under the Principal Regulations, fees for application services also include a non-refundable deposit amount. This fee is charged by the Department to cost recover administrative services in relation to a pricing application or the notice of intent for a pricing application.

Item [17] – Paragraph 41(3)(a)

This item substitutes the non-refundable deposit amount currently provided for within the Principal Regulations relating to Pricing Pathway A where a deed is not entered into because an applicant 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 [18] – Paragraph 41(3)(b)

This item substitutes the non-refundable deposit amount currently provided for within the Principal Regulations relating to Pricing Pathway B where a deed is not entered into because

an applicant 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 [19] – Paragraph 41(3)(c)

This item substitutes the non-refundable deposit amount currently provided for within the Principal Regulations relating to Pricing Pathway C where a deed is not entered into because an applicant 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 [20] – Subsection 51(5)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2023-24 financial year.

This fee is charged by the Department to cost recover administrative services in relation to a pricing application or notice of intent for a pricing application.

Item [21] Subsection 56(1) (table items 1 through 5)

These items substitute the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2023-24 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 applicants seeking to manage their listing on the PBS.

This item also substitutes references to the *National Health Act 1953* relating to requests from applicants seeking the discretion of the Minister to reduce, or not apply, a statutory price reduction. This ensures that these references remain contemporary and align with current administrative practice.

This item also provides the legislative basis to cost recover applications seeking a determination from the Minister for another quantity of a brand of pharmaceutical item, known as a Ministerial determination request. Under subsection 99AEKC(2) of the Act, the Minister can exercise their discretion to make a minimum stockholding determination of ‘another quantity’ where there are practical barriers to comply with the requirement to hold 4 or 6 months of stock. The quantity in a minimum stockholding determination may be a specified number of months stock by reference to the ‘usual demand’ for the brand.

List management options include:

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

Item [22] – Subsection 60(2)

This item substitutes 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 [23] – At the end of the Part 9

This item inserts a provision to clarify that the revised fees apply to all notices of intent, applications and submissions given on or after 1 July 2023.

This item also provides that the legislative basis to cost recover Ministerial determination requests does not commence until 1 July 2023.

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 2023

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023* (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 2023-24 financial year in relation to applications for listing on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP). The Amendment Regulations also provide the legislative basis to cost recover applications from sponsors requesting the Minister to determine a different quantity of a brand of pharmaceutical item, under subsection 99AEKC(2) of the *National Health Act 1953* (the Act).

The Amendment Regulations are made under section 140 of the Act. Section 140 provides 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 2022* (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 NIP.
- the Minister’s powers under Part VII broadly concern the listing process for applications for pharmaceuticals to be included in PBS.

Human rights implications

The Amendment Regulations engage Article 2, Article 9 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 social security and 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 these human rights by providing patients with subsidised access to medicines and vaccines. The Amendment Regulations ensure continued equitable access to PBS and NIP medicines and vaccines for Australians. 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.

Conclusion

The Amendment Regulations are 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 Mark Butler MP

Minister for Health and Aged Care