REPLACEMENT EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025

Purpose and operation

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025* (the Amendment Regulations) amend the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations* 2022 (the Regulations). The Amendment Regulations update the withdrawal timeframes and non-refundable deposit amounts for applications, or notices of intent to submit an application, for applicants seeking pricing services for the listing of new medicines, or changes to listing arrangements for existing medicines, on the PBS. The Amendment Regulations also insert provisions that allow the Secretary to request further information from applicants to assist in the consideration of requests for fee waivers under the Regulations.

Background

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

The *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations* 2022 (the Regulations) are made under section 140 of the Act. The 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 of Health, Disability and Ageing (the department) assesses the cost effectiveness of vaccines for inclusion on the National Immunisation Program (NIP) and drugs for listing on the Pharmaceutical Benefits Scheme (PBS). Much of the assessment work is carried out by external evaluators at a cost to Government. The Regulations implement cost recovery arrangements whereby these evaluation costs are recouped from the pharmaceutical industry through fees. In line with Australian Government Cost Recovery Policy, the Regulations are updated annually to ensure they accurately reflect the efficient costs of providing services.

The updates that are to be given effect by the Amendment Regulations ensure that cost recovery arrangements remain consistent with the requirements of the Australian Government Cost Recovery Policy and provide appropriate timeframes for pharmaceutical sponsors to withdraw applications without incurring full application fees.

Authority

The Act provides for regulations to set out the fees that are payable and manner of payment for those 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 to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Act enables fees to be charged to recover the costs of certain services provided by the Commonwealth. Relevantly, under the Act, payment of fees may be required for services that relate to the exercise of a power by the Minister under Section 9B and Part VII of the Act. Section 9B 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. Part VII deals with matters related to the supply of and payments for pharmaceutical benefits and the Pharmaceutical Benefits Scheme (PBS).

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

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.

Commencement

The Amendment Regulations commence on 1 March 2025.

Consultation

Medicines Australia, the primary representative group for the innovator pharmaceutical industry, have been consulted on the Amendment Regulations. This consultation was facilitated via the Access to Medicines Working Group, which is comprised of representatives from Medicines Australia and several pharmaceutical companies. An exposure draft was provided for consideration in January 2025. Medicines Australia advised that they did not have any concerns with the Amendment Regulations. Public consultation was not considered necessary as industry groups make up the entirety of the stakeholders affected by the Amending Regulations.

General

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

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

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

ATTACHMENT A

Details of the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025*

Section 1 - Name

Section 1 provides that the title of the instrument is the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025* (the Amendment Regulations).

Section 2 - Commencement

Section 2 provides that the Amendment Regulations commence 1 March 2025.

Section 3 - Authority

Section 3 provides that the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025* are made under the *National Health Act 1953*.

Section 4 - Schedule(s)

Section 4 provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 - Amendments

Schedule 1 details the amendments to the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022*.

Item [1] - Subsection 41(2)

This item omits references to subsections 49(3) and 51(2) regarding refunds excluding deposits and substitutes with a reference to subsection 51(2) only. This change provides that partial refunds (excluding non-refundable deposits) are available to applicants who withdraw their application for the Commonwealth to provide pricing services within 30 business days.

Item [2] - Subsection 41(3)

This item inserts a reference to subsection 49(3), providing that applicants who do not submit a pricing application within 30 days following submission of a notice of intent are liable for the corresponding non-refundable deposit amount set out in subsection 41(3).

Item [3] - At the end of subsection 41(3)

This item provides that items 4 and 5 of the table in subsection are inclusive of a $455 non-refundable deposit amount.

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

Item [4] - Subsection 49(3)

This item omits a reference to subsection 41(2) and substitutes a reference to subsection 41(3) providing an appropriate refund amount should an applicant not provide a pricing application within 30 days following submission of a notice of intent.

Item [5] - Paragraphs 51(2)(b), (3)(b) and (4)(b)

This item omits references to 10 business days and substitutes with references to 30 business days, thereby providing applicants with additional time to withdraw a pricing application before becoming liable for the full application fee.

Item [6] - Section 66 (at the end of the paragraph beginning "The Secretary may")

This item inserts wording into the simplified outline providing that the department's Secretary may seek further information from an applicant to consider a request for a fee waiver.

Item [7] - At the end of section 68

This item inserts subsection 68(5) to clarify that the department's Secretary may, by written notice, seek further information from an applicant to assist their decision whether to waive one or more fees payable for the provision of services relating to an ATAGI application, submission or pricing application.

The purpose of this provision is to ensure that decisions on applications for fee waivers are based on all relevant information. The Secretary may request further information relating to the criteria for determining a fee waiver under the Regulations. The applicant may decide to provide the further information detailed in the notice.

The notice of request for further information does not affect the timeframe for making a decision on the fee waiver and advising of the fees payable by the applicant for an ATAGI application, submission or pricing application under the Regulations.

A decision under subsection 68(1) of the Regulations to not waive a fee for which an application for a waiver has been made, is a reviewable decision under section 71 of the Regulations.

Item [8] - At the end of section 69

This item inserts subsection 69(5) to clarify that the department's Secretary may, by written instrument, seek further information from an applicant to assist their decision whether to waive one or more fees payable for the provision of listing management services in response to a list management application.

The purpose of this provision is to ensure that decisions on applications for fee waivers are based on all relevant information. The Secretary may request further information relating to the criteria for determining a fee waiver under the Regulations. The applicant may decide to provide the further information detailed in the notice.

The notice of request for further information does not affect the timeframe for making a decision on the fee waiver and advising of the fees payable by the applicant for list management services provided in response to a list management application under the Regulations.

A decision under subsection 69(1) of the Regulations to not waive a fee for which an application for a waiver has been made, is a reviewable decision under section 71 of the Regulations.

Item [9] - At the end of Part 9

This item provides the amendments made by the Amendment Regulations are added after Part 9 as Division 5. This includes the definitions of amending regulations being these regulations and commencement day being 1 March 2025 for the newly added Division 5, which is in section 88. The newly added section 89 has the application provision for these Amendment Regulations to clarify that these administrative amendments apply to all notices of intent, applications and submissions given on or after 1 March 2025.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025* (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 Amendment Regulations

The Amendment Regulations update the withdrawal timeframes and non-refundable deposit amounts for applications, or notices of intent to submit an application, from pharmaceutical sponsors seeking pricing services from the department for the listing of new medicines, or changes to listing arrangements for existing medicines on the PBS. These updates ensure that cost recovery arrangements remain consistent with the requirements of the Australian Government Cost Recovery Policy and provide appropriate timeframes for pharmaceutical sponsors to withdraw applications without incurring full application fees. The Amendment Regulations also specify that the department may request further information of pharmaceutical companies to assist in the consideration of requests for fee waivers.

The Amendment Regulations are made under section 140 of the *National Health Act 1953* (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 provisions 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.

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.

Right to Health

This supports the right to the enjoyment of the highest attainable standard of physical and mental health contained in article 12(1) of the ICESCR. Whilst the UN Committee on Economic Social and Cultural Rights has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. In addition, the right to health must meet certain key requirements, including that health care must be scientifically and medically appropriate and of good quality.

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
The Minister for Health, Disability and Ageing