

## **EXPLANATORY STATEMENT**

Issued by the authority of the Minister for Health

*National Health Act 1953*

*National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2022*

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.

The Act enables fees to be charged to recover the costs of certain services provided by the Commonwealth. Under subsection 99YBA(1) of 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. This section 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).
- Part VII of the Act. This part 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 Pharmaceutical Benefits Advisory Committee (PBAC) and its sub-committees, and other services carried out by the Department of Health to assist the Minister to exercise the relevant powers under Part VII of the Act.

Subsection 99YBA(2) of the Act provides for regulations to set out the fees that are payable and manner of payment for those services. A prescribed fee is payable to the Commonwealth and must not be such as to amount to taxation. Subsection 99YBA(2) of the Act allows the regulations to set out other matters including the making of applications or submissions, exemptions from prescribed fees, the waiver, remission or refund of prescribed fees, the consequences of late payment or failing to pay a fee, and the review of decisions made under the regulations. A consequence of failing to pay a fee is that the Minister may refuse to exercise certain powers under the Act until the fee is paid.

### **Purpose**

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2022* (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 (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 Government. The regulations implement cost recovery arrangements whereby these evaluation costs are recouped from the pharmaceutical industry through fees.

The Regulations repeal and remake the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009* (the 2009 Regulations). This ensures that arrangements established under the 2009 Regulations continue to support the sustainability of the PBS and manage applications effectively.

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

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

The Regulations commence on 1 April 2022.

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

## **Consultation**

The Department consulted directly with key pharmaceutical industry groups as part of the process to remake the 2009 Regulations. Industry expressed support for the amendments in the Regulations. The Department will continue to consult regularly with the pharmaceutical industry on cost recovery arrangements, which are administered in accordance with the Regulations, including through bi-annual updates to the Cost Recovery Implementation Statement.

**Details of the *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2022***

Part 1—Preliminary

Section 1 – Name

Section 1 provides that the title of the instrument is the *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2022* (the Regulations).

Section 2 – Commencement

Section 2 provides that the Regulations commence on 1 April 2022.

Section 3 – Authority

Section 3 provides that the Regulations are made under the *National Health Act 1953* (the Act). Section 99YBA of the Act provide for the Regulations to set out 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.

Section 4 – Schedule 2

Section 4 provides that each instrument specified in Schedule 2 is amended or repealed as set out in the schedule. Any other item in Schedule 2 has effect according to its terms.

Section 5 – Definitions

Section 5 provides that, for the purpose of the Regulations, terms have the meaning given to them under this section.

Part 2—Pre-submission services

Division 1—Preliminary

Section 6 – Simplified outline of this Part

Section 6 provides a simplified outline of Part 2 – Pre-submission services. This part relates to services for the provision of the Australian Technical Advisory Group on Immunisation (ATAGI) advice and pre-submission meetings relating to the preparation of a future submission to the Pharmaceutical Benefits Advisory Committee (PBAC).

Division 2—ATAGI advice

Section 7 – Fee for providing ATAGI advice

Section 7 provides that a fee is payable for an application relating to the provision of advice by ATAGI. ATAGI is an entity that, among other roles, provides expert advice to a person, to be included in their submission to the PBAC.

## Section 8 – Reduced fee for ATAGI applications in simple category

Section 8 provides that the Secretary may decide that a person’s ATAGI application is in the simple category, where the person has made a written request, and certain criteria are met. This includes whether the person is seeking advice from ATAGI in relation to a vaccine that is substantially similar to an existing designated vaccine or the application does not involve a degree of analysis sufficient to justify the usual fee payable under section 7.

If the Secretary decides an ATAGI application is in the simple category, a reduced fee is prescribed. This ensures that the fee payable for receiving ATAGI advice has a reasonable relationship to the cost of the service provided by the Commonwealth to that person.

## Section 9– Notice of intent required for most ATAGI applications

Section 9 requires a person who proposes to make an application for ATAGI advice under section 10 to give the Department a notice of intent before the application is made. The purpose of requiring this notice is to ensure that the Department is able to resource and prepare to assess the application effectively once the application itself is provided.

The notice of intent must be provided to the Department at least 10 business days before the application due day specified on the Department’s website. The Department will not be required to assess the application for ATAGI services unless the notice of intent has been given. An exception to this is if the Secretary decides the notice of intent is not required in urgent public health situations. Section 9 also provides that a person must include a request and reasons in the notice of intent if they are seeking for the proposed ATAGI application to be in the simple category or wish to request fee exemption or a waiver of the fee.

## Section 10 – Requirements for ATAGI applications

Section 10 provides the process by which a person must make an application for ATAGI advice on or before the due day for consideration at the meeting date specified in the application, in the form and manner approved by the Secretary. Information about the due day, approved form and approved manner for ATAGI applications is published on the Department’s website.

## Section 11 – Notification, including amount of fee payable

Section 11 requires the Secretary to notify a person of certain matters within 15 business days after the Department has received a notice of intent made under section 9, or within 15 business days of an ATAGI application being submitted to which a notice of intent was not required. The notification must include the amount of fee payable by that person for their application in relation to receiving ATAGI advice. If the notice of intent or application includes a request for the simple category, reasons why a fee exemption might apply, or a request for a fee waiver, section 11 requires the Secretary to notify the person of the decision relating to that request within 15 days of receiving the ATAGI application and the amount of fee payable by that person in relation to receiving ATAGI advice.

## Section 12 – Withdrawal of notice of intent or ATAGI application, and refund of fee or liability for deposit

Section 12 allows a person to withdraw their notice of intent or application for ATAGI advice by providing written notice to the Department. The Department must refund any fee paid, except the deposit amount, if the withdrawal is within 10 business days after receiving the notice under section 11. If the withdrawal occurs before any fee is paid, the applicant is liable for a fee covering administrative services by the Department relating to the notice of intent or the ATAGI application.

### Section 13 – Remaking ATAGI applications

Section 13 allows a person to remake an application for receiving advice from ATAGI. It also provides that the Regulations apply to the remade application as if it is a new application. This has the consequence that, for example, a new fee is payable with respect to the remade application.

### Division 3—Pre-submission meetings

#### Section 14 – Fees for holding pre-submission meetings

Section 14 provides that a fee is payable by a person for the service of the Department holding a pre-submission meeting with that person. The pre-submission meeting is intended to assist that person prepare a submission to the PBAC. Different fees apply for the first and subsequent pre-submission meetings related to the same submission to the PBAC.

#### Section 15 –Requirements for pre-submission meeting applications

Section 15 provides the process by which a person must make an application for a pre-submission meeting, and provide briefing papers for the meeting, in the form and manner approved by the Secretary. Information about the approved form and manner for giving the application is published on the Department’s website.

#### Section 16 – Agreeing to hold pre-submission meeting

Section 16 provides that the Secretary may agree to hold a pre-submission meeting after considering an application made under section 15. The Secretary may also decide not to agree to hold a pre-submission meeting.

#### Section 17 – Notification, including amount of fee payable

Section 17 requires the Secretary to notify a person of certain matters within 10 business days of receiving a pre-submission meeting application. This notification must include that the Department has received an application made under section 15 for a pre-submission meeting and whether the Secretary agrees to hold the meeting.

If the Secretary agrees to hold a meeting, a notification must be provided to the applicant not more than 20 business days before the meeting day setting out matters including the category of pre-submission meeting and the prescribed fees payable.

#### Section 18 – Withdrawal of pre-submission meeting application, and refund of fee

Section 18 allows a person to withdraw their application by providing written notice to the Department. It requires the Department to refund any fee paid by that person for the provision of a service under section 15 if the application is withdrawn before the end of last business day prior to meeting.

### Section 19 – Remaking pre-submission meeting applications

Section 19 allows a person to remake an application for a pre-submission meeting. It also provides that the Regulations will apply to the remade application as if it were a new application.

## Part 3—Submission services

### Division 1—Preliminary

#### Section 20 – Simplified outline of this Part

Section 20 provides a simplified outline of Part 3 – Submission services. This part relates to the provision of submission services in response to a person’s submission to the Committee or the Minister to exercise certain powers and the fees payable.

### Division 2—Submissions to the Committee or Minister and fees

#### Section 21 – Submissions to Committee or Minister in relation to exercise of certain powers

Section 21 provides that a person may prepare a submission requesting that the PBAC recommend or advise the Minister to exercise a relevant power under the Act. This section also provides that the person may make a submission requesting the Minister exercise a relevant power referred to in item 3.1 and item 2.5 of the table in Schedule 1 under certain circumstances. Submissions relevant to subsection 21(1)(b) and (c) do not require consideration by the PBAC.

Subsection 21(2) provides that a submission may include more than one request under certain circumstances.

#### Section 22 – Fees for providing submission services

Section 22 provides that the prescribed fees are payable for a submission made under section 21. This section sets out categories of submissions for which fees are prescribed. These fees are payable in exchange either for the service of the PBAC considering whether to make the recommendation requested by the person in accordance with section 21, or in exchange for the service of the Minister considering whether to exercise a power referred to in section 21.

Fees payable in respect to submissions made to the PBAC include a deposit covering administrative services by the Department relating to the notice of intent or the submission. In cases where a notice of intent in relation to an submission is withdrawn soon after it is given, or a submission is withdrawn soon after it is made, but no fee amount was paid before the withdrawal, the applicant is liable to pay the deposit amount outlined in subsection 22(2).

## Section 23 – Submissions in Category 1

Section 23 describes the types of submissions that meet the criteria for the ‘Category 1’ evaluation category. A submission is in this category if it includes a request in relation to one or more of the three following criteria:

- A first in class medicine or vaccine, or a medicine or vaccine for a new population [defined by subsection 23(2)]; or
- A drug, medicinal preparation, or vaccine with a Therapeutic Goods Administration (TGA) provisional determination related to the proposed population [defined by subsection 23(3)]; or
- A drug with a codependent technology that requires an integrated codependent submission to the PBAC and Medical Services Advisory Committee (MSAC) [defined by subsection 23(4) and (5)].

Category 1 submissions require the PBAC to apply the ‘cost-effectiveness test’. These submission types are expected to require additional interaction between the PBAC Secretariat and either TGA representatives, the ATAGI Secretariat, the MSAC Secretariat or the PBAC.

## Section 24 – Submissions in Category 2

Section 24 describes the types of submissions that meet the criteria for the ‘Category 2’ evaluation category. A submission is in this category if it includes a request in specified items of Schedule 1, requires the PBAC to apply the ‘cost-effectiveness’ test, and does not meet the criteria for a submission under section 23.

## Section 25 – Submissions in Category 3

Section 25 describes the types of submissions that meet the criteria for the ‘Category 3’ evaluation category. In general, this category is for requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine, and do not meet the criteria for a submission under section 23 and section 24.

This category includes submissions if, in considering the request, the PBAC will need to assess the applicant’s claim about the clinical need for and clinical effectiveness of the drug, medicinal preparation or vaccine, but an economic evaluation is not necessary to support the claims made in the submission. It also includes submissions seeking for the PBAC to recommend to, or advise, the Minister to exercise the power in item 2.18 in the table in Schedule 1 to make or amend a deed under section 85E of the Act.

Section 25 provides that a submission is in Category 3 if it is in relation to a medicinal preparation including somatropin (a growth hormone), requests the Minister to exercise the power referred to in item 3.1 in the table in Schedule 1 and makes a claim about the therapeutic benefit that is derived from the relationship between ingredients in the medicinal preparation.

While each different branded product of somatropin could be considered to be a generic product under section 28, submissions about somatropin are treated differently to other generic product submissions when received by the Department. They cannot be dealt with

administratively by the Department and instead require a submission to the PBAC. This is because somatropin is a biological product and each branded product of somatropin has not been deemed, by the TGA, to be substitutable for any other branded product of somatropin. The PBAC needs to be satisfied that each branded product of somatropin is substitutable for any other branded product of somatropin and therefore each application for somatropin requires consideration, as a separate agenda item, by the PBAC.

Section 25 also provides that a submission falls in Category 3 if it relates to medicinal food and it is not possible for the applicant to provide an economic evaluation because the patient population is too small.

#### Section 26 – Submissions in Category 4

Section 26 describes the types of submissions that meet the criteria for the ‘Category 4’ evaluation category. In general, a submission is in Category 4 if it does not meet the criteria for submissions under section 23, section 24 and section 25 and includes a request for one or more of the following:

- List a new form or manner of administration of a listed medicine [as defined by subsection 26(2)]; or
- A change to the maximum quantity and/or number of repeats of a listed medicine [as defined by subsection 26(3)]; or
- A change or addition to the prescriber type(s) of a listed medicine [as defined by subsection 26(4)]; or
- Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing [as defined by subsection 26(5)]; or
- Consideration as an exempt item [as defined by subsection 26(6)].

#### Section 27 – Submissions in Committee Secretariat category

Section 27 describes the types of submissions that meet the criteria for a submission in the ‘Committee Secretariat’ evaluation category. In general, a submission under section 27 is straightforward and does not require the PBAC to consider comparative effectiveness, cost-effectiveness, or clinical need as:

- there is no difference in patient safety or population for the new drug, medicinal preparation or vaccine in the submission compared to an already-listed pharmaceutical item; and
- there is no financial effect associated with the proposed change to the PBS.

Section 27 also provides that a submission that requests the Minister to exercise a power mentioned in item 3.1 in the table in Schedule 1 is in the Committee Secretariat category when the submission is in relation to a medicinal preparation that is a pharmaceutical item that either includes a glucose indicator or has the form of a glucose indicator.

While each glucose indicator product could be considered to be a generic product under section 28, submissions about glucose indicators are treated differently to other generic submissions when received by the Department. These submissions cannot be dealt with administratively by the Department and require a submission to the PBAC. This is because



there are a variety of different types of glucose test machines in use in Australia. Submissions about a glucose indicator are therefore not about an identical active ingredient.

Submissions in the Committee Secretariate category are not considered as a separate agenda item at a meeting of the PBAC. The Committee still decides the merit of each submission.

#### Section 28 – Submissions in new brand or new oral form of existing pharmaceutical item category

Section 28 provides that a submission falls into this category where it requests the Minister to exercise a power mentioned in items 3.1 of the table in Schedule 1 and where the request is not about a kind of medicinal preparation that includes somatropin or a glucose indicator. A submission under section 28 is commonly known as a submission about a generic product.

Section 28 also provides that a submission falls into this category where it requests the Minister to exercise the power referred to in paragraph (a) of item 2.5 of the table in Schedule 1 in relation to a new form for oral administration of a listed drug under certain circumstances. Such a submission would contain the same active moiety in the same quantity, request the same conditions as a currently listed form and provide a bioequivalence statement in support of the listing submission from the TGA.

#### Section 29 – Evaluation categories of certain remade submissions

Section 29 describes the types of submissions that meet the criteria for a submission to be remade where the PBAC has declined to take, or was of the view that the Minister should not take, the action sought by the previous submission. Section 29 defines four pathways available for reconsideration by the PBAC:

1. *Standard Re-entry Pathway* [as defined by subsection 29(3)] is the applicant-determined (default) resubmission pathway and also applies where:
  - the PBAC nominated a resubmission pathway and a person chooses not to accept the PBAC nominated resubmission pathway; or
  - an Early Re-entry Pathway or Early Resolution Pathway was nominated by the PBAC and a person decides to address issues other than those identified by the PBAC (including a subset of issues); or
  - a person decides to lodge later than the allowable timelines for the other pathways.
2. *Early Re-entry Pathway* [as defined by subsection 29(4)] may be nominated by the PBAC, where the PBAC considered that the remaining issues could be easily resolved; and the medicine or vaccine did not represent high added therapeutic value (HATV) for the proposed population. Applicants who accept this pathway must address the issues as outlined by the PBAC. To ensure early reconsideration, two lodgement deadlines apply for this pathway.
3. *Early Resolution Pathway* [as defined by subsection 29(5)] may be nominated by the PBAC, where the PBAC considered the medicine or vaccine represented HATV for the proposed population; and that the remaining issues could be easily resolved. Applicants who accept this pathway must address the issues as outlined by the PBAC. To ensure early reconsideration, two lodgement deadlines apply for this pathway.

4. *Facilitated Resolution Pathway* [as defined by subsection 29(6)] may be nominated by the PBAC, where the PBAC considered the medicine or vaccine represented HATV for the proposed population and where the PBAC determined specific matters could be resolved through a workshop. Applicants who accept this pathway will have the opportunity to attend a solution-focussed workshop with one or more members of the PBAC to explore feasible options to address the issues identified by the Committee. To ensure the reconsideration in a timely manner following the workshop, two lodgement deadlines apply for this pathway.

### Division 3—Procedure for making submissions and giving notice of intent

#### Section 30 – Notice of intent required for submissions

Section 30 provides that lodgement of a notice of intent is required for all submissions to the PBAC. The purpose of requiring this notice is to ensure that the Department is able to resource and prepare to assess the application effectively once the application itself is provided. The Department will not be required to assess the submission unless the notice of intent has been given. An exception to this is if the Secretary decides the notice of intent is not required in urgent public health situations or the submission is made under section 28.

Section 30 also provides the timeframes in which a person must give the Department the required notice of intent prior to lodgement. Lodgement timeframes for notice of intent vary depending on which on the evaluation category of the submission.

For submissions made under section 23, 24, 25, 26, 27 and subsection 29(3) (Category 1, 2, 3, 4, Committee Secretariat category and Standard Re-entry Pathway), notice of intent is required at least 20 business days prior to the submission due day.

For submissions made under subsection 29(4) and (5) (Early Re-entry Pathway and Early Resolution Pathway categories), notice of intent is required at least 5 business days before lodgement.

For submissions made under subsection 29(6) (Facilitated Resolution Pathway category), notice of intent is required at least 10 business days before the workshop is held.

Section 30 requires that a notice of intent in relation to a proposed submission be made in the manner and form approved by the Secretary and state, with reasons, why the proposed submission is likely to be in a particular evaluation category.

#### Section 31 – Requirements for submissions

Section 31 specifies that a submission mentioned in Part 3 must be made in the form and manner approved by the Secretary by the submission due day. Information about the approved form and manner for giving the submission and the submission due day is published on the Department's website.

#### Section 32 – Economic evaluation to support submissions in Category 1 or Category 2

Section 32 provides the requirement for an economic evaluation to be included in applications made under section 23 (Category 1) and section 24 (Category 2).

### Section 33 – Notification, including amount of fee payable

Section 33 requires the Secretary to notify a person of certain matters after the Department receives a notice of intent for a proposed submission, or a submission from this person under section 30 if a notice of notice is not required.

Subsection 33(1) provides that following receipt of a notice of intent in relation to a proposed submission, the Secretary must notify the person at least 10 business days before the submission due day for the proposed submission. The notification must acknowledge receipt of the notice of intent, include the amount of fee payable to provide submission services based on the proposed category in the notice of intent and how to pay the fee.

Subsection 33(2) provides that if the notice of intent for a proposed submission includes reasons for an exemption of fees [as defined by section 67] or a request for a waiver of the fee, the Secretary must notify the person at least 5 business days before the submission due day for the proposed submission. The notification must acknowledge receipt of the notice of intent, state whether fee exemption applies or whether the fee is waived, review rights under Part 8, specify any fee payable and how to pay the fee.

Subsection 33(3) provides that if a notice of intent for a proposed submission is not required, the Secretary must notify the person within 15 business days of receiving an submission. The notification must acknowledge receipt of the submission, state whether a fee exemption or waiver has been granted (if requested), specify any fee payable and how to pay the fee.

### Section 34 – Secretary may refuse to accept incomplete submission

Section 34 provides that the Secretary may refuse to accept a submission from a person to the PBAC on the basis it is incomplete and does not contain the information required for PBAC consideration. In these circumstances, the Department will notify the person within 10 business days after the Secretary has made a decision to refuse to accept a submission and refund any fee paid except for the deposit amount.

### Section 35 – Withdrawal of notice of intent or submission, and refund of fee or liability for deposit

Section 35 allows a person to withdraw their notice of intent or submission by providing written notice to the Department. The Department must refund any fee paid except the deposit amount if the notice of intent or submission is withdrawn on or before the submission due day or within 10 business days of notification given, whichever occurs earlier.

The Department must refund any fee paid except the deposit amount if a person withdraws their submission within 10 business days after receiving a notification under subsection 33(2) relating to a fee exemption or fee waiver or under subsection 33(3) where an exception to the notice of intent was granted.

The Department need not make a refund of any fee paid if a proposed submission in the

Facilitated Resolution Pathway is withdrawn after the last business day before the workshop (including on or after the day of the workshop).

If a notice of intent or a submission is withdrawn and no fee amount has been paid, the applicant will be liable for a fee covering administrative services by the Department in relation to the notice of intent or the submission. This ensures that the administrative costs are consistently recovered from persons regardless of whether the fee amount had been paid prior to withdrawal.

#### Section 36 – Remaking submission

Section 36 provides that this instrument applies to a remade submission as if it is a new submission and a new fee will apply under section 22.

#### Division 4—Determining evaluation category and assessing submissions

##### Section 37 – Determining evaluation category that submission is in

Section 37 provides that, after consultation with the Chair of the Committee, the Secretary is able to determine that a submission made under Part 3 is within one of the categories mentioned in Part 3. The Secretary must have regard to specified matters before making this determination.

The Secretary may determine that the submission is in a different category to that initially notified to the person under section 33. The purpose of this determination is to ensure the fee paid by the person under section 22 continues to have a reasonable relationship to the cost of the services provided by the Commonwealth. This determination can be made when the Secretary is in a position to assess the entirety of the service provided to the person.

This section requires the Secretary to notify the person after making a determination under subsection 37(1). The notification must state the amount that may be refunded to or is payable by the person, how the fee is to be paid and the person's review rights under Part 8.

##### Section 38 – Assessing submissions

Section 38 provides that the PBAC can request further information from a person about a submission to the Committee under Part 3. It also allows the assessor of the submission to request that the Secretary consider making a determination under subsection 37(1) as to which category the submission should be in or otherwise review a previous determination or decision about the submission.

#### Part 4—Pricing services

##### Division 1—Preliminary

##### Section 39 – Simplified outline of this part

Section 39 provides a simplified outline of Part 4 – Pricing services. This part relates to the provision of pricing services and fees payable in response to a person's pricing application

where the pricing application is in relation to a positive recommendation or positive advice from the PBAC.

## Division 2—Pricing applications and fees

### Section 40 – Applications for pricing services

Section 40 allows a person to make an application for the Commonwealth to provide pricing services in assisting the Minister to consider whether to exercise certain powers in the Act. For example, a person can request that the Commonwealth assist the Minister to negotiate or make an appropriate determination in relation to that person's drugs or medicinal preparations.

Under section 85AD of the Act, the Minister and the responsible person for the pharmaceutical item may agree as to the appropriate maximum price of that pharmaceutical item. Under section 85B of the Act, the Minister may determine an appropriate maximum price for a pharmaceutical item if the Minister and the responsible person have been unable to agree. Under section 85E of the Act, the Minister may enter into a deed with the responsible person in relation to pharmaceutical items, which could include an agreement for the Commonwealth to be reimbursed in relation to the provision of pharmaceutical benefits.

A person can only make an application for pricing services under section 40 if the PBAC has previously made a positive recommendation or given positive advice that covers all of the drugs or medicinal preparations in the pricing application. The PBAC may make a recommendation or give advice in response to a submission or otherwise under the Act.

Subsection 40(2) requires that a separate pricing application must be made in relation to a drug or medicinal preparation covered by a separate submission to the PBAC and separate fees will apply. A single submission may cover multiple drugs or medicinal preparations only in certain circumstances.

### Section 41 – Fees for providing pricing services

Section 41 prescribes the amount of fees payable by a person for the Commonwealth to provide services in response to a pricing application. The fee payable will depend on the category of the pricing application. The categories of application are related to the complexity and resourcing requirements of the pricing services to be provided to the person. Section 41 also provides that different deposit amounts are included in the fees for pricing services for different application categories.

### Section 42 – Pricing applications in Pricing Pathway A category

Section 42 describes when a person's pricing application is in the 'Pathway A' category. An application will be in this category if, as part of the PBAC's recommendation or advice, the Committee found that drugs or medicinal preparations are expected to provide a substantial and clinically relevant improvement in efficacy, or reduction in toxicity, over any alternative therapies; address an urgent and high clinical need; and where it is in the public interest for a pricing application relating to the drug or medicinal preparation to be in this category.

### Section 43 – Pricing applications in Pricing Pathway B category

Section 43 describes when a person’s application is in the ‘Pathway B’ category. An application will only be in this category if it seeks the Minister to enter into a deed under section 85E of the Act in relation to the relevant drugs or medicinal preparations.

Additionally, there must be no deed currently in force between the Commonwealth and any person about reimbursing the Commonwealth or providing information to the Commonwealth that contains terms that are substantially similar to the pricing terms that are appropriate for the drugs or medicinal preparations that the person’s application relates to (the new drugs).

Refer to section 45 for circumstances where terms in an existing deed made under section 85E of the Act will be substantially similar to those appropriate for the new drugs.

An application for pricing services will not be in Pathway B if it is in Pathway A.

### Section 44 – Pricing applications in Pricing Pathway C category

Section 44 describes when a person’s application is in the ‘Pathway C’ category. As for Pathway B applications, an application will only be in this category if it seeks the Minister to enter into a deed under section 85E of the Act.

However, for Pathway C to apply there must be a deed currently in force between the Commonwealth and any person with terms that are substantially similar to those that are appropriate for the new drugs.

An application for pricing services will not be in Pathway C if it is in Pathway A or B.

### Section 45 - When pricing terms are substantially similar to those appropriate for the new drugs

Section 45 sets out certain circumstances when terms in a deed currently in force are or are not substantially similar to those that may apply to the new drugs.

The terms of an existing deed relating to reimbursing the Commonwealth or providing information to the Commonwealth will be substantially similar terms appropriate for the new drugs if:

- the new drugs can share an existing subsidisation cap with the drugs or medicinal preparations to which the existing deed relates; or
- the new drugs are cost-minimised to the drugs or medicinal preparations to which the existing deed relates; or
- the PBAC’s recommendation or advice to the Minister suggested that terms in the existing deed would be appropriate for the new drugs.

However, the terms of an existing deed will not be substantially similar to those appropriate for the new drugs if the terms relate to further clinical testing or requirements for the provision of further clinical data, or include taking the clinical response of patients into account in calculating reimbursement amounts. They also will not be substantially similar if they include a subsidisation cap that cannot be shared with the new drugs or, in calculating

the amount of reimbursement to the Commonwealth, take into account expenditure of therapies that involve using the new drugs in combination with drugs covered by the existing deed.

Section 45 does not limit the circumstances in which the terms of an existing deed relating to reimbursement of the Commonwealth or the provision of information to the Commonwealth are, or are not, substantially similar to terms appropriate for the new drugs.

#### Section 46 – Pricing applications in Pricing Pathway D category

Section 46 describes when a person's application is in the 'Pathway D' category. An application is in this category if it is not in the Pathway A category, the application does not seek entry into a deed under section 85E of the Act, and the remaining criteria in section 46 are satisfied. These criteria broadly relate to the complexity of the application. This ensures that any fee payable by the person for an application in this category has a reasonable relationship to the cost of the service provided to the person.

#### Section 47 – Pricing applications in Pricing Secretariat category

Section 47 describes when a person's application is in the 'Pricing Secretariat' application category. An application is in this category if it is not in Pathway A, B, C or D. This category is intended for the simplest of applications.

#### Division 3—Procedure for making pricing applications and giving notice of intent

#### Section 48 – Notice of intent required for most pricing applications

Section 48 requires a person to give the Department a notice of intent of their pricing application before it is made. The purpose of requiring this notice is to ensure that the Department is able to resource and prepare to assess the application effectively once the application itself is provided.

A person may submit their pricing application a minimum of 5 business days and a maximum of 30 business days after lodging the notice of intent. The Department will not be required to assess the application for pricing services unless the notice of intent has been given, unless the Secretary decides the notice of intent is not required in urgent public health situations. Section 48 also sets out the requirements for how the notice of intent is to be given.

#### Section 49 – Requirements for pricing applications

Section 49 sets out how an application for pricing services must be made in the form and manner approved by the Secretary. Information about the approved form and manner for a pricing application is published on the Department's website.

If the applicant wishes to request a fee waiver or put forward reasons why a fee exemption might apply, this must be included in the notice of intent (where required).

#### Section 50 – Notification, including amount of fee payable

Section 50 requires the Secretary to notify a person of certain matters after the Department

has received a notice of intent for a proposed pricing application. Generally, this notification must be given 10 business days after the notice of intent was received and include the amount of fee payable by that person for their proposed pricing application.

If the notice of intent includes reasons why a fee exemption applies, or requests a fee waiver, the Secretary is required within 15 business days to notify the person of the decision relating to that request.

If no notice of intent is required, the Secretary must notify the person of certain matters within 15 business days after the pricing application was received.

#### Section 51 – Withdrawal of notice of intent or pricing application, and refund of fee or liability for deposit

Section 51 allows a person to withdraw their notice of intent or pricing application by providing written notice to the Department. The Department must refund any fee paid by the person in relation to pricing services in certain circumstances. In cases where a notice of intent or a pricing application is withdrawn soon after it is made, but no fee amount for providing pricing services in response to the application was paid before the withdrawal, the applicant is liable to pay the deposit amount outlined in subsection 41(2) to cover administrative services by the Department in relation to the notice of intent or the application.

#### Division 4—Determining pricing category of pricing applications

##### Section 52 – Determining pricing category that pricing application is in

Section 52 provides that the Secretary is able to determine that an application made under Part 4 is within one of the categories listed under section 42 to section 47.

The Secretary may determine that the application is in a different category to that initially notified to the person under section 50. The purpose of this determination is to ensure the fee paid by the person under section 41 has a reasonable relationship to the cost of the services provided by the Commonwealth when the Secretary is in a position to assess the entirety of the service provided to the person.

This Section also provides how the Secretary is to give notice to the person of this determination, including the amount that may be refunded to the person, the amount that may be payable by the person, as well as the person's review rights under Part 8.

#### Division 5—Cessation of pricing services 6 months after pricing application is made

##### Section 53 – Cessation of pricing services 6 months after pricing application is made

Section 53 provides that the Secretary is able to cease pricing services after 6 months (26 weeks) where there is not active negotiation between the applicant and the Department.

To recommence pricing services where pricing services had ceased, a person is required to lodge a new notice of intent and pricing application and a new fee is payable dependent on the listing arrangements sought.



As pricing services can only be ceased where a person is not actively negotiating with the Department to reach in-principal agreement on listing arrangements, the decision to cease pricing services after 6 months in these circumstances is not a reviewable decision under Part 8.

#### Section 54 – Refund if deed not made within 6 months after pricing application is made

Section 54 provides that in circumstances where a deed arrangement between the applicant and the Commonwealth has not been entered into and pricing services have ceased under section 53, any fees paid in relation to pricing services other than the deposit must be refunded.

#### Part 5—List management services

##### Section 55 – Simplified outline of this Part

Section 55 provides a simplified outline of Part 5 – List management services. This part relates to the provision of list management services in response to a person’s list management application and the fees payable.

##### Section 56 – Fees for providing list management services

Section 56 establishes a fee for list management services provided by the Commonwealth in relation to an exercise of power by the Minister under the relevant parts of the Act. List management services are provided by the Commonwealth at the request of a person, which are intended to assist the Minister to make a decision about the price of a pharmaceutical item to agree, determine or increase the maximum price of pharmaceutical items.

The fee for services provided in relation to deed management such as deed variations and deed renewals are outlined at item 2 and 3 of the fee table.

##### Section 57 – Requirements for list management applications

Section 57 specifies that an application for list management services must be in the form and manner approved by the Secretary. If a person wishes to request a fee exemption or waiver, reasons for this request must be included in the application. Information about the approved form and manner for giving the application is published on the Department’s website.

##### Section 58 – Notification, including amount of fee payable

Section 58 requires the Secretary to notify a person of certain matters after the Department has received their application for list management services. This notification must be given 15 business days after the list management application was received and include the amount of fee payable by that person for their list management application.

##### Section 59 – Withdrawal of a list management application, and refund of fee

Section 59 provides that a list management application may be withdrawn by written notice to the Department. It also provides for the Department to refund any fee paid by the person for

providing list management services if the application is withdrawn within 10 business days after the notification is given.

#### Section 60 – Refund of part of fee if replacement for expired deed not made

Section 60 requires the Department to refund part of the fee paid for a person's list management application, where a decision is made not to enter into a deed arrangement between the person and the Commonwealth to replace an expiring deed.

This is in addition to the refund of list management fees paid if an application is withdrawn within 10 business days after the notification is given.

#### Part 6—Fees: common rules and independent review fee

##### Section 61 – Simplified outline of this Part

Section 61 provides a simplified outline of Part 6 – Fees: common rules and independent review fee. This part relates to common rules that apply to all fees payable to the Commonwealth under the Regulations. This include fees payable in response to a person's request for submission or application services or an independent review of certain decisions made by the PBAC.

##### Section 62 – Payment of fees

Section 62 outlines common rules for all fees payable to the Commonwealth under the Regulations. This includes that the fee must be paid in full to the Commonwealth and within a 28 calendar day period after the Secretary gives notice to the person that the fee is payable. It also allows the Secretary to accept payment by instalment or to grant a longer period for the payment of an amount of a fee. It also requires the Secretary to refund an amount of fee paid to the Commonwealth in certain circumstances.

##### Section 63 – Delay in paying fee

Section 63 provides that if a fee payable under the Regulations has not been paid by the time it is due and payable, the Commonwealth may refuse to consider any application made under the Regulations or provide any service in relation to the submission or application until the fee has been paid.

##### Section 64 – Independent review fee

Section 64 provides that fees are payable for independent reviews of certain decisions of the PBAC. A person may seek an independent review of certain decisions by the PBAC. The application submitted for independent review must be submitted in the form in which it was originally considered by the PBAC and was not recommended by the Committee in its entirety. The fee payable for an independent review is the same as the fee payable for a Category 2 submission under Part 3 and must be paid in full to the Commonwealth at the time the application to seek an independent review under section 64 is submitted.

##### Section 65 – Refund or remission of fees if services not provided

Section 65 provides that the Secretary must decide whether or not to refund a fee amount paid if the request for a service is withdrawn before the service has been provided or the Secretary decides that the service in relation to the application cannot be provided.

This section also provides that if no fee had been paid for the service in relation to the application, the Secretary must decide whether the fee is to be remitted.

#### Part 7—Exemptions and waivers

##### Section 66 – Simplified outline of this Part

Section 66 provides a simplified outline of Part 7 – Exemptions and waivers. This part relates to circumstances which fee exemption or waiver would apply to a person's request for submission services or application services.

##### Section 67 – Exemptions

Section 67 provides the circumstances in which an exemption from fees payable for a service under Parts 2, 3, 4 or 5 applies.

Some of these circumstances relate to submissions or applications that require active decision making and use of resources even though no fee is payable (e.g. submissions or applications relating to the management of a public health event of national significance, a biosecurity emergency or designated orphan drugs). Other circumstances include types of services that involve minimal decision making, administrative action and use of resources by the Department or the PBAC.

This section also provides the circumstances in which a fee exemption is not available. These circumstances include fees for pre-submission meetings and independent reviews, as these are optional parts of the PBS listing processes.

##### Section 68 – Waiver of fees for provision of ATAGI advice, submission services or pricing services

Section 68 provides that the Secretary may decide to waive the fees payable for the provision of services relating to an ATAGI application, submission, or pricing application. The Secretary must be satisfied that the application or submission involves the public interest and payment of the fee would be financially unviable.

This section also sets out some of the circumstances that may be considered by the Secretary to involve the public interest, including that the application:

- is for a drug, medicinal preparation or vaccine that represents a suitable therapy for a patient population that is not large enough to make the application or submission financially viable; and
- the drug or vaccine is to be used for palliative care, or as a paediatric medicine, or for medical treatment of Aboriginal and/or Torres Strait Islander peoples.

##### Section 69 – Waiver of fees for provision of list management services

Section 69 provides that a person could request the waiver of some, or all list management fees specified in Part 5. Such a request must be made as part of the application for list management services. The Secretary must be satisfied that the list management application involves the public interest and payment of the fee makes the application financially unviable.

## Part 8—Review of decisions

### Section 70 – Simplified outline of this Part

Section 70 provides a simplified outline of Part 8 – Review of decisions. This part provides that certain decisions may be reviewed internally or, following internal review, by the Administrative Appeals Tribunal.

### Section 71 – Reviewable decisions

Section 71 provides the decisions that are reviewable decisions for the purposes of this instrument.

### Section 72 – Notice of review rights

Section 72 provides that if the Secretary makes a reviewable decision under subsection 9(3), 30(3), 48(3) or 74(2), the Secretary is required to give the person affected by this decision a written notice and statement setting out the person's review rights within 10 business days of making this decision.

### Section 73 – Internal review

Section 73 provides that a person may in certain circumstances, apply in writing to the Secretary for a review (known as an 'internal review') of a reviewable decision. The application must be made within 10 business days of the person receiving notice of the decision, or within another period allowed by the Secretary. The person must detail the grounds on which the person relies in applying for the review.

This section also allows for the person, within 10 business days after receiving the initial review decision, to request the Secretary to have the internal review decision reviewed.

### Section 74 – Secretary may initiate internal review

Section 74 provides that the Secretary may initiate a review at any time about a reviewable decision. The Secretary may decide for the reviewable decision to be affirmed, revoked or varied and in the case of revocation, for any other decision to be made as thought appropriate by the Secretary.

### Section 75 – Notice of fee adjustment

Section 75 requires the Secretary to notify a person within 20 business days of a review decision, if there is an overpayment or underpayment of a fee as a result of a decision following an internal review.

## Section 76 – Review by the Administrative Appeals Tribunal

Section 76 provides for applicants to apply to the Administrative Appeals Tribunal for a review of a decision after any internal review rights have been exhausted.

The Department may suspend services relating to an application for review that is being considered by the Administrative Appeals Tribunal.

## Part 9—Application and transitional provisions

### Division 1—Application of this instrument as originally made

#### Section 77 – Application of this instrument

Section 77 provides that, for the purpose of the Regulations, terms have the meaning given to them under this section. Section 78 – Submission or applicant for the provision of services received on or after commencement day

#### Section 78 – Submission or application for the provision of services received on or after commencement day

Section 78 provides that this instrument applies to a submission or an application, including a remade submission or application for the provision of services received by the Department on or after 1 April 2022.

#### Section 79 – Prior notice of certain applications given before commencement day

Section 79 provides that this instrument applies to prior notice given for an application for submission services under Part 2 of the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009* (the 2009 Regulations), or for pricing services under Part 3 of the 2009 Regulations as it would apply to a notice of intent given under section 30 or section 48 of this instrument respectively if, before 1 April 2022:

- the Department had received the prior notice but had not received the relevant application; or
- the Department had received the prior notice and the relevant application, but the assessment of the application had not been completed.

#### Section 80 – Application for services received, but notification not given, before commencement day

Section 80 provides that this instrument applies to an application for services made under the 2009 Regulations as it would apply to a submission or application made for relevant services under this instrument if, before 1 April 2022:

- the Secretary had not given a notification in relation to the application or relevant prior notice given; and
- the application made had not been withdrawn.

## Section 81 – Application for services received, and notification given, before commencement day

Section 81 provides that this instrument applies to an application for services made under the 2009 Regulations as it would apply to a submission or application made for relevant services under this instrument if, before 1 April 2022:

- the Secretary had given a notification in relation to the application or relevant prior notice given; and
- the application had not been withdrawn; and
- the assessment of the application had not been completed.

## Section 82 – ATAGI application made, but waiver of fee not requested, before commencement day

Section 82 provides that if a person had made an ATAGI application under Division 1A.1 of the 2009 Regulations and the relevant Part 2 application under the 2009 Regulations had not been made before 1 April 2022, if the person wishes to seek a fee waiver for ATAGI application services, the request for waiver of fees must be included in the Part 3 submission or the notice of intent required for the Part 3 submission under this instrument.

Section 82 also provides that the Secretary must give a notification under section 33 of this instrument to notify the person whether the fee is waived. If the fee is not waived, the person will be notified of their review rights, the amount of fee payable and manner for paying the fee.

## Section 83 – Review of decisions made under the old Regulations

Section 83 provides the circumstances in which Part 8 of this instrument would apply to reviewable decisions made under the 2009 Regulations.

## Section 84 – Things done under the old Regulations

Section 84 provides that without limiting any other provision in Part 9, if a thing was done under the 2009 Regulations for a particular purpose that can also be done under this instrument, this instrument would apply to the thing as if it had been done for that purpose under this instrument. This includes a reference to a notice, application or other instrument being given or made.

## Schedule 1—Powers of the Minister under the Act

### Part 1—Vaccines

Part 1 of Schedule 1 lists matters dealt with in this instrument about which a person may request the PBAC make a recommendation to the Minister or provide advice to the Minister in relation to the designating of vaccines under subsection 9B(2) of the Act.

## Part 2—Pharmaceuticals

Part 2 of Schedule 1 lists matters dealt with in this instrument about which a person may request the PBAC make a recommendation to the Minister or provide advice to the Minister in relation to the listing of pharmaceutical items or special pharmaceutical products on the Schedule of Pharmaceutical Benefits.

## Part 3—Existing pharmaceutical items

Part 3 of Schedule 1 lists matters about which a person may request the Minister to list a generic medicine on the Schedule of Pharmaceutical Benefits, dealt with in the Regulations.

## Schedule 2—Repeals

This Schedule repeals the 2009 Regulations.

### **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) Regulations 2022*

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 Regulations**

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2022 (the Regulations)* repeal and remake the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009*. This ensures that arrangements established under the 2009 Regulations continue to support the sustainability of the PBS and manage applications effectively.

The purpose of the Regulations is to prescribe fees and matters relating to the making of applications or submissions 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:

- 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 of the Act broadly concern the listing process for applications seeking inclusion in the Pharmaceutical Benefits Scheme (PBS).

### **Human rights implications**

The Regulations engage Article 2 and Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 for subsidised access by patients to medicines and vaccines. 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. Fees for submissions and applications that are financially unviable and are in the public interest can be waived at the discretion of the Secretary. The cost recovery arrangements mean that Australians will continue to have access to safe, effective medicines and vaccines 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