



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

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 03 February 2022

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health and Aged Care

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Part 1—Preliminary

1 Name

This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 April 2022.	1 April 2022

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *National Health Act 1953*.

Note: See section 99YBA of the *National Health Act 1953*.

4 Schedule 2

Each instrument that is specified in Schedule 2 to this instrument is amended or repealed as set out in the applicable items in that Schedule, and any other item in that Schedule has effect according to its terms.

5 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) designated vaccine;
- (b) Secretary;
- (c) vaccine.

In this instrument:

Act means the *National Health Act 1953*.

amount includes a nil amount.

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approved ex-manufacturer price has the meaning given by subsection 84(1) of the Act.

ATAGI means the Commonwealth body known as the Australian Technical Advisory Group on Immunisation.

ATAGI advice has the meaning given by subsection 7(1).

ATAGI application has the meaning given by subsection 7(1).

ATAGI application due day has the meaning given by subsection 10(3).

Australian Register of Therapeutic Goods means the register maintained under section 9A of the *Therapeutic Goods Act 1989*.

brand has the meaning given by subsection 84(1) of the Act.

Committee means the Pharmaceutical Benefits Advisory Committee established under section 100A of the Act.

complex category ATAGI application fee has the meaning given by subsection 7(2).

cost-effectiveness test means an assessment of:

- (a) the extent (if any) to which the efficacy and toxicity of the therapy proposed in a submission for a disease or disorder differs from the efficacy and toxicity of any alternative therapy for the disease or disorder; and
- (b) the cost of the proposed therapy relative to the cost of the alternative therapy.

designated orphan drug has the same meaning as in the *Therapeutic Goods Regulations 1990*.

economic evaluation, for a submission and a drug, medicinal preparation or vaccine the subject of the submission, means data that is a comparative analysis of the costs and outcomes of:

- (a) the therapy to be provided by the drug, medicinal preparation or vaccine; and
- (b) any other therapy that the applicant nominates as an alternative therapy to the drug, medicinal preparation or vaccine.

evaluation category means an evaluation category referred to in the table in subsection 22(2).

high added therapeutic value: a drug, medicinal preparation or vaccine has **high added therapeutic value** if the drug, medicinal preparation or vaccine:

- (a) addresses a high and urgent unmet clinical need; and
- (b) is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapy.

listed brand of a pharmaceutical item has the meaning given by subsection 84(1) of the Act.

listed drug has the meaning given by subsection 84(1) of the Act.

list management application has the meaning given by paragraph 56(1)(a).

list management services has the meaning given by subsection 56(1).

medicinal food means food that is therapeutic goods within the meaning of paragraph (a) or (b) of the definition of ***therapeutic goods*** in subsection 3(1) of the *Therapeutic Goods Act 1989*.

MSAC means the body known as the Medical Services Advisory Committee.

notification:

- (a) for an ATAGI application—means a notification given under whichever of subsections 11(1), (2) and (3) is relevant to the ATAGI application or a notice of intent in relation to the ATAGI application; or
- (b) for a pre-submission meeting application—means a notification given under subsection 17(1); or
- (c) for a submission—means a notification given under whichever of subsections 33(1), (2) and (3) is relevant to the submission or a notice of intent in relation to the submission; or
- (d) for a pricing application—means a notification given under whichever of subsections 50(1), (2) and (3) is relevant to the pricing application or a notice of intent in relation to the pricing application; or
- (e) for a list management application—means a notification given under section 58.

PBS prescriber has the meaning given by subsection 84(1) of the Act.

pharmaceutical item has the meaning given by section 84AB of the Act.

pre-submission meeting application has the meaning given by paragraph 14(a).

pricing application has the meaning given by subsection 40(1).

pricing category means a pricing category referred to in the table in subsection 41(1).

pricing services has the meaning given by subsection 40(1).

reviewable decision has the meaning given by section 71.

submission means a submission referred to in subsection 21(1).

submission due day has the meaning given by subsection 31(3).

submission services has the meaning given by subsection 22(1).

Therapeutic Goods Administration means the part of the Department known as the Therapeutic Goods Administration.

Part 2—Pre-submission services

Division 1—Preliminary

6 Simplified outline of this Part

ATAGI advice

ATAGI may, on application (an ATAGI application) by a person, provide advice to the person to be included in the person's proposed submission to the Committee.

A fee is payable for the service of ATAGI providing the advice (unless a fee exemption applies or the fee is waived). The amount of the fee depends on whether the ATAGI application is categorised as complex or simple. A person may request the Secretary to decide whether the person's ATAGI application is in a simple category.

The person will generally need to have given the Department a notice of intent in relation to the ATAGI application at least 10 business days before the ATAGI application due day for the application.

The ATAGI application must be given to the Department on or before the ATAGI application due day.

ATAGI will not provide advice in response to the ATAGI application if a notice of intent in relation to the ATAGI application was not given, unless a notice of intent was not required because of an urgent public health need.

If a notice of intent in relation to a proposed ATAGI application is withdrawn soon after it is given, or an ATAGI application is withdrawn soon after it is made, the fee amount (if any) paid, except the amount of the deposit included in the fee amount, will be refunded. If no fee amount was paid before the withdrawal, a fee for the provision of administrative services by the Department in relation to the notice of intent or the ATAGI application will be payable.

Pre-submission meetings

The Department may, on application (a pre-submission meeting application) by a person, hold a pre-submission meeting with the person in relation to the preparation of the person's proposed submission to the Committee.

A fee is payable for the service of the Department holding the pre-submission meeting. The amount of the fee depends on the category of the pre-submission meeting.

If a pre-submission meeting application is withdrawn before a certain time, the fee amount (if any) paid for the service of the Department holding the meeting will be refunded in full.

Division 2—ATAGI advice

7 Fee for providing ATAGI advice

- (1) A person may make an application (an *ATAGI application*) for the service of ATAGI providing advice (*ATAGI advice*) to the person for the person to include in a proposed submission to the Committee that the Committee recommend to the Minister to exercise a power under section 9B of the Act.
- (2) Subject to section 8 of this instrument, the fee (the *complex category ATAGI application fee*) for providing the ATAGI advice to the person is \$181,500. This fee includes a deposit of \$430.

8 Reduced fee for ATAGI applications in simple category

Secretary may decide that ATAGI application is in simple category

- (1) The Secretary may, in writing and on request, decide whether or not a person's ATAGI application is in a simple category.

Note 1: The request must be included in the notice of intent for the ATAGI application or, if a notice of intent for the ATAGI application is not required, in the ATAGI application (see subsection (5)).

Note 2: A decision that the person's ATAGI application is not in a simple category is reviewable (see section 71).

Note 3: Regardless of subsection 7(2) and this section, in some circumstances the person will be fully exempt from paying a fee in relation to the ATAGI application (see section 67).

When is ATAGI application in simple category

- (2) The Secretary must decide under subsection (1) that a person's ATAGI application is in a simple category if:
 - (a) the person's ATAGI application is only proposing:
 - (i) that a new brand of vaccine be determined under subsection 9B(2) of the Act to be a designated vaccine; and
 - (ii) that the proposed determination is to specify the vaccine by reference to characteristics (other than brand) that are the same as, or similar to, those specified for another vaccine that is already a designated vaccine; or
 - (b) the person's ATAGI application is only proposing:
 - (i) to vary the circumstances specified in a determination under subsection 9B(2) of the Act in which a designated vaccine may be provided; and
 - (ii) that the variation is to extend the vaccine's eligible patient population to a new group of patients who are no more vulnerable to a poor outcome from either the relevant disease or the vaccine; or
 - (c) the Secretary is satisfied that providing the ATAGI advice to the person will not involve the degree of data analysis and consideration that would justify payment of the complex category ATAGI application fee.

Note: For examples of the characteristics referred to in subparagraph (a)(ii), see subsection 9B(3) of the Act.

- (3) For the purposes of paragraph (2)(a), **brand** has the same meaning as in section 9B of the Act.

Reduced fee for ATAGI applications in simple category

- (4) If the Secretary decides under subsection (1) that a person's ATAGI application is in a simple category, the fee for providing the ATAGI advice to the person is \$103,560. This fee includes a deposit of \$430.

Applicant who wants Secretary to decide whether ATAGI application is in simple category must include request in notice of intent or ATAGI application

- (5) A person (the **applicant**) who wants the Secretary to make a decision under subsection (1) must:
- (a) request this:
 - (i) in the notice of intent in relation to the proposed ATAGI application; or
 - (ii) if a notice of intent in relation to the proposed ATAGI application is not required—in the person's ATAGI application; and
 - (b) include reasons in the notice of intent or the ATAGI application (as the case may be) why the Secretary should do so.
- (6) The Secretary may, by written notice given to the applicant, seek further information from the applicant in relation to the applicant's request.
- (7) Giving a notice under subsection (6) seeking further information pauses the period of 15 business days referred to in subsection 11(3) for giving the notification in relation to the ATAGI application until the further information is given in accordance with the notice.

9 Notice of intent required for most ATAGI applications

When notice of intent is required

- (1) A person proposing to make an ATAGI application must give the Department a notice of intent in relation to the application unless the Secretary has decided under subsection (3) that a notice of intent is not required. The notice of intent must:
- (a) be in accordance with subsection (6); and
 - (b) be given at least 10 business days before the ATAGI application due day for the ATAGI application.

Note 1: Requiring a notice of intent allows ATAGI to properly prepare for the provision of advice in response to the ATAGI application.

Note 2: The ATAGI application must be given to the Department on or before the ATAGI application due day for the application (see paragraph 10(1)(b)).

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Exception if urgent public health need

- (2) If the person considers that the provision of advice by ATAGI in response to an ATAGI application is required to address an urgent public health need, the person may request the Secretary, in writing, to decide that a notice of intent in relation to the proposed ATAGI application is not required under subsection (1).
- (3) If the Secretary receives a request from a person under subsection (2) in relation to a proposed ATAGI application, the Secretary must:
 - (a) decide that a notice of intent in relation to the proposed ATAGI application is not required under subsection (1), or refuse to make that decision; and
 - (b) give the person written notice of the decision.

Note 1: If the Secretary refuses to make the decision requested, the Secretary must also comply with section 72.

Note 2: A refusal to make the decision requested is reviewable (see section 71).

- (4) The Secretary may decide under subsection (3) that a notice of intent in relation to the proposed ATAGI application is not required if the Secretary is satisfied that the provision of ATAGI advice in response to the ATAGI application is required to address an urgent public health need.

Consequence if notice of intent is required but not given

- (5) ATAGI will not provide advice in response to an ATAGI application if a notice of intent in relation to the application:
 - (a) is required under subsection (1); and
 - (b) is not given in accordance with that subsection.

Requirements for notice of intent

- (6) A notice of intent in relation to a proposed ATAGI application must:
 - (a) be in a form approved by the Secretary; and
 - (b) be given to the Department in a manner approved by the Secretary.

Note 1: If the person wishes the Secretary to make a decision under subsection 8(1) in relation to the proposed ATAGI application (simple category ATAGI applications), the request and reasons for the request must be included in the notice of intent (see subsection 8(5)).

Note 2: If the person giving the notice of intent considers that a fee exemption applies under section 67, the notice of intent must include the reasons for the exemption (see subsection 67(8)).

Note 3: If the person giving the notice of intent wishes to request waiver of the fee that would otherwise be payable, the request must be included in the notice of intent (see subsection 68(2)).

Note 4: Information about the approved form for a notice of intent in relation to a proposed ATAGI application and the approved manner for giving the notice of intent is accessible through the Department's website.

- (7) The Secretary may, in writing, approve:
 - (a) a form for a notice of intent in relation to a proposed ATAGI application; and
 - (b) a manner for giving the notice of intent to the Department.

10 Requirements for ATAGI applications

- (1) An ATAGI application must:
 - (a) be in a form approved by the Secretary; and
 - (b) be given to the Department:
 - (i) on or before the ATAGI application due day for the application; and
 - (ii) in a manner approved by the Secretary.

Note 1: If a notice of intent was not required to be given under subsection 9(1) and the applicant wishes the Secretary to make a decision under subsection 8(1) in relation to the ATAGI application (simple category ATAGI applications), the request and reasons for the request must be included in the ATAGI application (see subsection 8(5)).

Note 2: If the applicant considers that a fee exemption applies under section 67 and a notice of intent was not required to be given under subsection 9(1), the ATAGI application must include the reasons for the exemption (see subsection 67(7)).

Note 3: If the applicant wishes to request waiver of the fee that would otherwise be payable and a notice of intent was not required to be given under subsection 9(1), the request must be included in the ATAGI application (see subsection 68(2)).

Note 4: Information about the approved form for ATAGI applications and the approved manner for giving them to the Department is accessible through the Department's website.

- (2) The Secretary may, in writing, approve:
 - (a) a form for ATAGI applications; and
 - (b) a manner for giving ATAGI applications to the Department.

ATAGI application due day

- (3) The ***ATAGI application due day*** for an ATAGI application is the day published on the Department's website by which ATAGI needs to have received an ATAGI application for consideration at the meeting date specified in the ATAGI application.
- (4) The Secretary must ensure that the ATAGI application due days for future consideration by ATAGI of ATAGI applications are published on the Department's website.

11 Notification, including amount of fee payable

Notification after receipt of notice of intent—no simple category request and no fee exemption or waiver sought

- (1) If:
 - (a) the Department receives a notice of intent in relation to a proposed ATAGI application from a person under subsection 9(1); and
 - (b) the notice of intent does not include any of the following:
 - (i) a request for the Secretary to decide whether the ATAGI application is in a simple category;
 - (ii) reasons why section 67 applies to provide a fee exemption;
 - (iii) a request for waiver of the fee for providing ATAGI advice in response to the ATAGI application;

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the Secretary must, within 15 business days after the day the notice is received, notify the person, in writing:

- (c) that the Department has received the notice of intent; and
- (d) of the amount of the fee that is payable for the provision of ATAGI advice in response to the ATAGI application; and
- (e) of the manner for paying the fee.

Notification after receipt of notice of intent—fee exemption or waiver sought

(2) If:

- (a) the Department receives a notice of intent in relation to a proposed ATAGI application from a person under subsection 9(1); and
- (b) the notice of intent includes either of the following:
 - (i) reasons why section 67 applies to provide a fee exemption;
 - (ii) a request for waiver of the fee for providing ATAGI advice in response to the ATAGI application;

the Secretary must, within 15 business days after the day the notice of intent is received, notify the person, in writing:

- (c) that the Department has received the notice of intent; and
- (d) whether the fee exemption applies, or the fee is waived; and
- (e) if the request was for waiver and the fee is not waived—of the applicant's review rights under Part 8; and
- (f) if the fee exemption does not apply and the fee is not waived:
 - (i) of the amount of the fee that is payable for providing ATAGI advice in response to the ATAGI application; and
 - (ii) of the manner for paying the fee.

Note: If the notice of intent in relation to the proposed ATAGI application also includes a request for the Secretary to decide whether the ATAGI application is in a simple category, the Secretary's decision in response to the request will be included in the notification given under subsection (3) following receipt of the ATAGI application.

Notification after receipt of ATAGI application in relation to which simple category request relates or notice of intent was not required

(3) If the Department receives an ATAGI application, the Secretary must, within 15 business days after the day the ATAGI application is received, notify the applicant, in writing:

- (a) that the Department has received the ATAGI application; and
- (b) if the notice of intent in relation to the ATAGI application, or the ATAGI application (if a notice of intent in relation to the ATAGI application was not required), includes a request for the Secretary to decide whether the ATAGI application is in a simple category:
 - (i) of the Secretary's decision; and
 - (ii) if the decision is that the ATAGI application is not in a simple category—of the applicant's review rights under Part 8; and
- (c) if a notice of intent in relation to the ATAGI application was not required and the ATAGI application includes reasons why section 67 applies to

provide a fee exemption or a request for waiver of the fee for providing ATAGI advice in response to the ATAGI application:

- (i) whether the fee exemption applies, or the fee is waived; and
 - (ii) if waiver was requested and the fee is not waived—of the applicant’s review rights under Part 8; and
- (d) if the fee exemption does not apply and the fee is not waived:
- (i) of the amount of the fee that is payable for providing ATAGI advice in response to the ATAGI application; and
 - (ii) of the manner for paying the fee.

- Note 1: The period of 15 business days referred to in this subsection is paused if a notice is given under subsection 8(6) seeking further information in relation to a request for the Secretary to decide whether the ATAGI application is in a simple category (see subsection 8(7)).
- Note 2: The fee specified in a notification given under this section is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.
- Note 3: If a fee exemption does not apply and the fee is not waived, and the Secretary decides that the application is in a simple category, the reduced fee prescribed by subsection 8(4) is payable. In any other case, the complex category ATAGI application fee is payable.
- Note 4: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

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

Notice of intent or ATAGI application may be withdrawn at any time

- (1) Either of the following may be withdrawn by written notice given to the Department:
- (a) a notice of intent in relation to a proposed ATAGI application given under subsection 9(1);
 - (b) an ATAGI application.

Refund of fee amount that was paid

- (2) If:
- (a) a notification is given under subsection 11(1) or (2) after receipt of a notice of intent in relation to a proposed ATAGI application; and
 - (b) the notice of intent or the ATAGI application is withdrawn within 10 business days after the notification was given; and
 - (c) all or part of the fee for providing ATAGI advice in response to the ATAGI application was paid before the withdrawal of the notice of intent or the ATAGI application;

the fee amount paid, except the deposit included in the fee, must be refunded.

- (3) If:
- (a) a notification is given under subsection 11(3) after receipt of an ATAGI application; and

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- (b) the ATAGI application is withdrawn within 10 business days after the day the notification was given; and
- (c) all or part of the fee for providing ATAGI advice in response to the ATAGI application was paid before the withdrawal of the application; the fee amount paid, except the deposit included in the fee, must be refunded.

Liability for part of fee if no fee amount was paid

- (4) If:
 - (a) a notice of intent in relation to a proposed ATAGI application, or an ATAGI application, is withdrawn as described in paragraph (2)(b) or (3)(b); and
 - (b) no fee amount for providing ATAGI advice in response to the ATAGI application was paid before the withdrawal of the notice of intent or the ATAGI application;

the Secretary must notify the applicant, in writing, that a fee of \$430 is payable for the provision of administrative services by the Department in relation to the notice of intent or the ATAGI application.

Note 1: The fee specified in a notification given under this subsection is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

13 Remaking ATAGI applications

- (1) A person who has made an ATAGI application may remake the ATAGI application in the same or an amended form.

Example: A person responds to an ATAGI advice by amending, and remaking, the ATAGI application with the aim of receiving different ATAGI advice.

- (2) This instrument applies to the remade ATAGI application as if it were a new ATAGI application.

Note: This means, for example, that the remade ATAGI application will attract a new fee under section 7 or 8.

Division 3—Pre-submission meetings

14 Fees for holding pre-submission meetings

The fees referred to in the following table are prescribed for the service of the Department holding a pre-submission meeting with a person:

- (a) in response to an application (the *pre-submission meeting application*) by the person; and
- (b) in relation to the preparation of the person's proposed submission to the Committee that the Committee recommend to, or advise, the Minister to exercise a power referred to in an item of the table in Schedule 1.

Fees for providing service of holding pre-submission meeting		
Item	Category of pre-submission meeting	Fee (\$)
1	First meeting	15,700
2	Second or later meeting	21,350

15 Requirements for pre-submission meeting applications

- (1) A pre-submission meeting application, and briefing papers for the pre-submission meeting, must:
 - (a) be in a form approved by the Secretary; and
 - (b) be given to the Department in a manner approved by the Secretary.

Note 1: The briefing papers may be provided with the pre-submission meeting application or afterwards.

Note 2: Information about the approved form for pre-submission meeting applications and briefing papers for the meeting, and the approved manner for giving them to the Department, is accessible through the Department's website.

- (2) The Secretary may, in writing, approve:
 - (a) a form for:
 - (i) pre-submission meeting applications; and
 - (ii) briefing papers for pre-submission meetings; and
 - (b) a manner for giving pre-submission meeting applications and briefing papers for pre-submission meetings to the Department.

16 Agreeing to hold pre-submission meeting

The Secretary may, in writing, after considering a pre-submission meeting application for a pre-submission meeting, agree or not agree to the Department holding the pre-submission meeting with the applicant.

17 Notification, including amount of fee payable

- (1) Within 10 business days after the day the Department receives a pre-submission meeting application for a pre-submission meeting, the Secretary must notify the applicant in writing:

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- (a) that the Department has received the application; and
 - (b) whether the Secretary agrees or does not agree under section 16 to the Department holding a pre-submission meeting with the applicant.
- (2) If the Secretary agrees to the Department holding a pre-submission meeting with the applicant on a day less than 30 business days after the Secretary notifies the applicant under subsection (1), the notification under that subsection must also specify the matters referred to in subsection (4).
- (3) If the Secretary agrees to the Department holding a pre-submission meeting with the applicant on a day (the *meeting day*) at least 30 business days after the Secretary notifies the applicant under subsection (1), the Secretary must notify the applicant in writing of the matters referred to in subsection (4) not more than 20 business days before the meeting day.
- (4) The matters to be specified in a notification given under subsection (1) or (3) are:
 - (a) the category of the pre-submission meeting (see the table in section 14); and
 - (b) the amount of the fee that is payable for the service of holding the pre-submission meeting (see the table in section 14); and
 - (c) the manner for paying the fee.

Note 1: The fee specified in a notification given under this section is payable to the Commonwealth (see subsection 99YBA(4) of the Act).

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

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

- (1) A pre-submission meeting application may be withdrawn by written notice given to the Department.
- (2) If a pre-submission meeting application is withdrawn before the end of the last business day before the pre-submission meeting applied for is to be held, the fee (if any) paid for the service of holding the pre-submission meeting must be refunded to the applicant.

19 Remaking pre-submission meeting applications

- (1) A person who has made a pre-submission meeting application may remake the pre-submission meeting application in the same or an amended form.
- (2) This instrument applies to the remade pre-submission meeting application as if it were a new pre-submission meeting application.

Note: This means, for example, that the remade pre-submission meeting application will attract a new fee under section 14.

Part 3—Submission services

Division 1—Preliminary

20 Simplified outline of this Part

Submission services may be provided in response to a person's submission to the Committee or the Minister for those services. A fee is payable for providing the submission services (unless a fee exemption applies or the fee is waived). The amount of the fee depends on the evaluation category the submission is in, which depends on what the submission is for. If the submission is for more than one thing, the evaluation category is generally determined by the first provision of this Part about evaluation categories that applies to the submission.

If the person's submission is to the Committee, the person will generally need to have given the Department a notice of intent in relation to the submission at least 20 business days before the day (the submission due day) the Committee requires submissions for the Committee meeting that will be considering the submission. The submission due day depends on the evaluation category the submission is in.

The notice of intent in relation to the submission must state the likely evaluation category of the person's submission. The person will generally be charged a fee for the submission services based on this evaluation category.

If the Secretary later determines that the submission is in a different evaluation category, the person will be notified and any difference in the fee payable will be refunded or charged as appropriate.

If the person's submission is to the Committee, submission services will not be provided in response to the submission if a notice of intent in relation to the submission was not given, unless a notice of intent was not required because of an urgent public health need.

If a notice of intent in relation to a proposed submission is withdrawn soon after it is given, or a submission is withdrawn soon after it is made, in most cases, the fee amount (if any) paid, except the amount of the deposit included in the fee amount, will be refunded. If no fee amount was paid before the withdrawal, in most cases, a fee for the provision of administrative services by the Department in relation to the notice of intent or the submission will be payable.

Division 2—Submissions to the Committee or Minister and fees

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

- (1) A person may prepare a submission:
 - (a) that includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in an item of the table in Schedule 1; or
 - (b) for the Minister to exercise a power referred to in item 3.1 of the table in Schedule 1; or
 - (c) to which subsection 28(3) applies.

Note 1: Subsection 28(3) applies in relation to a submission that includes a request for 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 of a listed drug for oral administration in certain circumstances.

Note 2: For details about how to make a submission, see section 31.

Note 3: Submissions referred to in paragraph (a) of this subsection will be considered by the Committee.

- (2) A submission referred to in paragraph (1)(a) may include more than one request relating to the exercise of a power referred to in an item of Part 1 or 2 of the table in Schedule 1 if:
 - (a) each request relates to the same drug, medicinal preparation or vaccine; or
 - (b) the submission proposes therapy for a disease or disorder and each request relates to the same disease or disorder that is the subject of the proposed therapy.
- (3) If a submission referred to in paragraph (1)(a) includes 2 or more requests, the evaluation category the submission is in depends on the request that is covered by the earliest of the following sections of this Division (unless the submission has been remade after an earlier submission was unsuccessful because it did not resolve all issues that needed to be resolved).

22 Fees for providing submission services

- (1) This section prescribes fees for providing the following services (*submission services*):
 - (a) services provided by the Committee in considering whether to make the recommendation, or give the advice, referred to in paragraph 21(1)(a);
 - (b) services provided by the Commonwealth in assisting the Minister to consider whether to exercise the power referred to in paragraph 21(1)(b) or the power referred to in a submission to which subsection 28(3) applies.
- (2) The fee for providing submission services in response to a submission in an evaluation category referred to in column 1 of an item of the following table is the fee referred to in column 2 of that item. The fee includes the deposit referred to in column 3 of the item.

Fees and deposits for providing submission services			
Item	Column 1	Column 2	Column 3
	Evaluation categories of submissions	Fee (\$)	Deposit (\$)
1	Category 1	225,120	430
2	Category 2	170,050	430
3	Category 3	43,360	430
4	Category 4	33,980	430
5	Committee Secretariat category	12,270	430
6	New brand or new oral form of existing pharmaceutical item category	6,500	0
7	Standard re-entry pathway category	167,980	430
8	Early re-entry pathway category	42,010	430
9	Early resolution pathway category	42,160	430
10	Facilitated resolution pathway category	240,570	72,440

- Note 1: The evaluation category of a submission generally depends on what the submission requests or is for (see the following provisions of this Division). However, the evaluation category of a remade submission may depend on matters not resolved by the previous submission.
- Note 2: The following provisions of this Division are arranged so that only the first of them (in order of appearance in this Division) to apply to a submission determines the evaluation category of the submission (unless the submission has been remade after an earlier submission was unsuccessful because it did not resolve all issues that needed to be resolved).
- Note 3: The deposit referred to in column 3 of the table may be withheld from a refund of a fee paid for a submission if the submission is withdrawn soon after it is made or a notice of intent in relation to the submission is withdrawn soon after it is given (see section 35).
- Note 4: Except in certain cases, if a submission is withdrawn soon after it is made, or a notice of intent in relation to a submission is withdrawn soon after it is given, but no fee amount for providing submission services in response to the submission was paid before the withdrawal, the applicant is liable to pay the amount of \$430 (see section 35).

23 Submissions in Category 1

- (1) A submission is in Category 1 if:
- (a) the submission includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in an item of the table in Schedule 1; and
 - (b) subsection (2), (3), (4) or (5) applies in relation to the request or the submission.

Drug, medicinal preparation or vaccine first in class for new population or disease

- (2) This subsection applies to a request if it relates to:
- (a) a drug or medicinal preparation the intended effect of which is achieved by a distinct pharmacological, chemical, immunological or metabolic means that has not been considered before by the Committee; or

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- (b) a vaccine the intended effect of which is achieved by a distinct immunological means that has not been considered before by the Committee; or
- (c) a drug, medicinal preparation, or vaccine, that is for the treatment or prevention of a disease or disorder that has not been considered before by the Committee.

Drug, medicinal preparation or vaccine covered by a provisional determination

- (3) This subsection applies to a request if it relates to a drug, medicinal preparation, or vaccine, that is a medicine, within the meaning of the *Therapeutic Goods Act 1989*, in relation to which a provisional determination under section 22D of that Act is in force when the submission including the request is received by the Department.

Co-dependent submission relating to testing

- (4) This subsection applies to a submission relating to a drug, medicinal preparation or vaccine if:
 - (a) determining the existence of:
 - (i) the proposed circumstances for writing a prescription for supply of the drug or medicinal preparation under Part VII of the Act; or
 - (ii) the proposed circumstances for provision of the vaccine under section 9B of the Act;will depend on provision of a medical service using technology before administration of the drug, medicinal preparation or vaccine starts or is continued; and
 - (b) it is proposed that there be an item of the table, within the meaning of the *Health Insurance Act 1973*, for the medical service; and
 - (c) the submission includes a request for MSAC to recommend that such an item be included in the table (as well as the request referred to in paragraph (1)(a) of this section for the Committee); and
 - (d) in considering their respective requests, both the Committee and MSAC will need to do a cost-effectiveness test (whether or not the Committee or MSAC will need to assess anything else).

Co-dependent submission relating to administration

- (5) This subsection applies to a submission relating to a drug or medicinal preparation if:
 - (a) administration of the drug or medicinal preparation proposed to be provided under the Act will involve the provision of a medical service; and
 - (b) it is proposed that there be an item of the table, within the meaning of the *Health Insurance Act 1973*, for the medical service; and
 - (c) the submission includes a request for MSAC to recommend that such an item be included in the table (as well as the request referred to in paragraph (1)(a) for the Committee); and
 - (d) in considering the request for the Committee, the Committee will need to do a cost-effectiveness test (whether or not the Committee will need to assess anything else); and

- (e) in considering the request for MSAC, MSAC will need to assess the cost of the therapy proposed in the submission for a disease or disorder relative to the cost of any alternative therapy for the disease or disorder (whether or not MSAC will need to assess anything else).

24 Submissions in Category 2

A submission is in Category 2 if:

- (a) it includes a request that the Committee:
 - (i) recommend to, or advise, the Minister to exercise a power referred to in item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 2.5, 2.6 or 2.13 of the table in Schedule 1; or
 - (ii) advise the Minister in relation to a power referred to in item 2.15 of the table in Schedule 1; and
- (b) in considering the request, the Committee will need to do a cost-effectiveness test; and
- (c) if the request relates to a drug or medicinal preparation—the drug or preparation is not a medicinal food the patient population for which is too small for the person making the submission to be able to provide a meaningful economic evaluation for the submission; and
- (d) the submission is not in Category 1.

25 Submissions in Category 3

- (1) A submission is in Category 3 if:
 - (a) subsection (2), (3), (4) or (5) applies to the submission; and
 - (b) the submission is not in Category 1 or Category 2.

Submissions including certain requests

- (2) This subsection applies to a submission if it includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in item 1.4, 2.4, 2.7, 2.12, 2.14, 2.15, 2.17 or 2.18 of the table in Schedule 1.

Submissions involving assessment of clinical need and effectiveness of drug, medicinal preparation or vaccine

- (3) This subsection applies to a submission if:
 - (a) it includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in item 1.2, 2.2 or 2.6 of the table in Schedule 1; and
 - (b) in considering the request, the Committee will need to assess the applicant's claim about the clinical need for, and clinical effectiveness of, the drug, medicinal preparation or vaccine to which the request relates; and
 - (c) the submission does not:
 - (i) propose any change to the unit price of a listed drug or designated vaccine; or

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- (ii) need the Committee to assess any implications arising from the request for the cost of supplying or providing the drug, medicinal preparation or vaccine.

Submissions for determination of brand of medicinal preparation with somatropin

- (4) This subsection applies to a submission if:
 - (a) it is for the Minister to exercise a power referred to in item 3.1 of the table in Schedule 1 in relation to a medicinal preparation including somatropin; and
 - (b) it includes a claim about the therapeutic benefit derived from the relationship between ingredients in the medicinal preparation.

Submissions relating to medicinal food

- (5) This subsection applies to a submission if it includes a request relating to a drug, or medicinal preparation, that is a medicinal food the patient population for which is too small for the person making the submission to be able to provide a meaningful economic evaluation for the submission.

26 Submissions in Category 4

- (1) A submission is in Category 4 if:
 - (a) subsection (2), (3), (4), (5) or (6) applies to the submission; and
 - (b) the submission is not in Category 1, Category 2 or Category 3.

Form or manner of administration of listed drugs and equivalent pharmaceutical items

- (2) This subsection applies to a submission if:
 - (a) it includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in item 2.5 of the table in Schedule 1; and
 - (b) it is not a submission to which subsection 28(3) applies.

Changes to maximum quantity or number of repeats

- (3) This subsection applies to a submission if it includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in item 2.7 of the table in Schedule 1 so as to vary a determination under paragraph 85A(2)(a) or (b) of the Act.

Determinations affecting who may prescribe pharmaceutical benefits or pharmaceutical items

- (4) This subsection applies to a submission if it includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in item 2.8 or 2.9 of the table in Schedule 1.

Prescriber bag supplies

- (5) This subsection applies to a submission if it includes a request that the Committee recommend to the Minister to exercise a power referred to in item 2.11 of the table in Schedule 1.

Exempt items

- (6) This subsection applies to a submission if it includes a request that the Committee advise the Minister to exercise a power referred to in item 2.16 of the table in Schedule 1.

27 Submissions in Committee Secretariat category

- (1) A submission is in the Committee Secretariat category if:
- (a) subsection (2), (3) or (4) applies to the submission; and
 - (b) the submission is not in Category 1, Category 2, Category 3 or Category 4.

New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk

- (2) This subsection applies to a submission if:
- (a) it includes a request that the Committee recommend to, or advise, the Minister to exercise a power referred to in item 1.2, 2.2, 2.5 or 2.6 of the table in Schedule 1; and
 - (b) it demonstrates that there is no increase in risk to a patient associated with using a listed drug, medicinal preparation or designated vaccine as a result of the proposed exercise of the power.

Pharmaceutical benefits that can no longer be supplied early

- (3) This subsection applies to a submission that includes a request that the Committee recommend to the Minister to exercise the power referred to in item 2.10 of the table in Schedule 1.

New brand of glucose indicator pharmaceutical item

- (4) This subsection applies to a submission for the Minister to exercise a power referred to in item 3.1 of the table in Schedule 1 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.

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

- (1) A submission is in the new brand or new oral form of existing pharmaceutical item category if:
- (a) subsection (2) or (3) applies to the submission; and
 - (b) the submission is not in Category 3 or the Committee Secretariat category.

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New brand of existing pharmaceutical item

- (2) This subsection applies to a submission for the Minister to exercise a power referred to in item 3.1 of the table in Schedule 1.

New oral form of listed drug

- (3) This subsection applies to a submission if:
- (a) it includes a request for 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 of a listed drug for oral administration; and
 - (b) it seeks the same listing conditions, and contains the same active moiety in the same quantity, as an existing form of the listed drug; and
 - (c) evidence of bioequivalence between the new form of the listed drug and the existing form of the listed drug is provided with the submission.

29 Evaluation categories of certain remade submissions

- (1) This section applies to a submission (the **current submission**) if:
- (a) the current submission is a remaking, under section 36, of an amended submission (the **previous submission**) that was the most recent submission made before the current submission; and
 - (b) the previous submission was not in:
 - (i) the Committee Secretariat category; or
 - (ii) the new brand or new oral form of existing pharmaceutical item category; and
 - (c) the Committee declined to take, or was of the view that the Minister should not take, the action sought by the previous submission, because of issues (the **outstanding issues**) arising from the previous submission.
- (2) This section has effect in relation to the current submission despite whichever of sections 23, 24, 25, 26, 27 and 28 applies to it.

Standard re-entry pathway category

- (3) The current submission is in the standard re-entry pathway category if:
- (a) after considering the previous submission, the Committee either:
 - (i) considered that the outstanding issues could not be resolved easily and identified the outstanding issues in a communication to the applicant; or
 - (ii) made a suggestion described in paragraph (4)(a), (5)(a) or (6)(a); and
 - (b) either:
 - (i) the notice of intent in relation to the current submission given under section 30; or
 - (ii) if a notice of intent in relation to the current submission was not required under that section—the current submission; states that the current submission is likely to be in the standard re-entry pathway category.

Early re-entry pathway category

- (4) The current submission is in the early re-entry pathway category if:
- (a) after considering the previous submission, the Committee:
 - (i) considered that the drug, medicinal preparation or vaccine to which the previous submission related did not have high added therapeutic value; and
 - (ii) considered that the outstanding issues could be resolved easily; and
 - (iii) suggested to the person who made the previous submission that the person remake the submission, as a submission in the early re-entry pathway category, to resolve the outstanding issues; and
 - (iv) identified the outstanding issues in the suggestion; and
 - (b) the only material differences between the current submission and the previous submission are to address the outstanding issues; and
 - (c) the remaking of the current submission occurs after the suggestion and no later than the second submission due day after the suggestion for submissions in the early re-entry pathway category; and
 - (d) either:
 - (i) the notice of intent in relation to the current submission given under section 30; or
 - (ii) if a notice of intent in relation to the current submission was not required under that section—the current submission;
states that the current submission is likely to be in the early re-entry pathway category.

Early resolution pathway category

- (5) The current submission is in the early resolution pathway category if:
- (a) after considering the previous submission, the Committee:
 - (i) considered that the drug, medicinal preparation or vaccine, to which the previous submission related had high added therapeutic value; and
 - (ii) considered that the outstanding issues could be resolved easily; and
 - (iii) suggested to the person who made the previous submission that the person remake the submission, as a submission in the early resolution pathway category, to resolve the outstanding issues; and
 - (iv) identified the outstanding issues in the suggestion; and
 - (b) the only material differences between the current submission and the previous submission are to address the outstanding issues; and
 - (c) the remaking of the current submission occurs after the suggestion and no later than the second submission due day after the suggestion for submissions in the early resolution pathway category; and
 - (d) either:
 - (i) the notice of intent in relation to the current submission given under section 30; or
 - (ii) if a notice of intent in relation to the current submission was not required under that section—the current submission;
states that the current submission is likely to be in the early resolution pathway category.

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Facilitated resolution pathway category

- (6) The current submission is in the facilitated resolution pathway category if:
- (a) after considering the previous submission, the Committee:
 - (i) considered that the drug, medicinal preparation or vaccine to which the previous submission related had high added therapeutic value; and
 - (ii) considered that a workshop involving the person who made the previous submission and one or more members of the Committee was desirable to discuss the outstanding issues; and
 - (iii) suggested to the person who made the previous submission that the workshop be held and that the person later remake the submission, as a submission in the facilitated resolution pathway category, to resolve the outstanding issues; and
 - (b) the workshop was held at which the outstanding issues were discussed; and
 - (c) the remaking of the current submission occurs after the workshop and no later than the second submission due day after the workshop for submissions in the facilitated resolution pathway category; and
 - (d) either:
 - (i) the notice in relation to the current submission given under section 30; or
 - (ii) if a notice of intent in relation to the current submission was not required under that section—the current submission;states that the current submission is likely to be in the facilitated resolution pathway category.

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

30 Notice of intent required for most submissions

When notice of intent is required

- (1) A person proposing to make a submission in an evaluation category (other than the new brand or new oral form of existing pharmaceutical item category) must give the Department a notice of intent in relation to the submission unless the Secretary has decided under subsection (3) that a notice of intent is not required. The notice of intent must:
 - (a) be in accordance with subsection (6); and
 - (b) be given at least:
 - (i) 20 business days before the submission due day for the submission; or
 - (ii) if the submission is to be in the early re-entry pathway category or the early resolution pathway category—5 business days before the submission due day for the submission; or
 - (iii) if the submission is to be in the facilitated resolution pathway category because a workshop is to be held as described in subsection 29(6)—10 business days before the workshop is to be held.

Note 1: Requiring a notice of intent allows the Commonwealth to properly prepare for the provision of submission services in response to the submission.

Note 2: The submission must be given to the Department on or before the submission due day for the submission (see paragraph 31(1)(c)).

Exception if urgent public health need

- (2) If the person proposing to make the submission considers that the provision of submission services in response to the submission is required to address an urgent public health need, the person may request the Secretary, in writing, to decide that a notice of intent in relation to the submission is not required under subsection (1).
- (3) If the Secretary receives a request from a person under subsection (2) in relation to a proposed submission, the Secretary must:
 - (a) decide that a notice of intent in relation to the proposed submission is not required under subsection (1), or refuse to make that decision; and
 - (b) give the person written notice of the decision.

Note 1: If the Secretary refuses to make the decision requested, the Secretary must also comply with section 72.

Note 2: A refusal to make the decision requested is reviewable (see section 71).

- (4) The Secretary may decide under subsection (3) that a notice of intent in relation to the proposed submission is not required if the Secretary is satisfied that the provision of submission services in response to the submission is required to address an urgent public health need.

Part 3 Submission services

Division 3 Procedure for making submissions and giving notice of intent

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Consequence if notice of intent is required but not given

- (5) Submission services will not be provided in response to a submission if a notice of intent in relation to the submission:
- (a) is required under subsection (1); and
 - (b) is not given in accordance with that subsection.

Requirements for notice of intent

- (6) A notice of intent in relation to a proposed submission must:
- (a) be in a form approved by the Secretary; and
 - (b) state, with reasons, why the proposed submission is likely to be in a particular evaluation category; and
 - (c) be given to the Department in a manner approved by the Secretary.

Note 1: If the person giving the notice of intent considers that a fee exemption applies under section 67, the notice of intent must include the reasons for the exemption (see subsection 67(8)).

Note 2: If the person giving the notice of intent wishes to request waiver of the fee that would otherwise be payable, the request must be included in the notice of intent (see subsection 68(2)).

Note 3: Information about the approved form for a notice of intent in relation to a proposed submission and the approved manner for giving the notice to the Department is accessible through the Department's website.

- (7) The Secretary may, in writing, approve:
- (a) a form for a notice of intent in relation to a proposed submission; and
 - (b) a manner for giving the notice of intent to the Department.

31 Requirements for submissions

Procedural requirements for submissions

- (1) A submission must:
- (a) be in a form approved by the Secretary; and
 - (b) if a notice of intent in relation to the submission was not required to be given under subsection 30(1)—state, with reasons, why the submission is likely to be in a particular evaluation category; and
 - (c) be given to the Department:
 - (i) if there is a submission due day for the submission—on or before that day; and
 - (ii) in a manner approved by the Secretary.

Note 1: If the person making the submission considers that a fee exemption applies under section 67 and a notice of intent was not required to be given under subsection 30(1), the submission must include the reasons for the exemption (see subsection 67(7)).

Note 2: If the person making the submission wishes to request waiver of the fee that would otherwise be payable and a notice of intent was not required to be given under subsection 30(1), the request must be included in the submission (see subsection 68(2)).

Note 3: Information about the approved form for a submission and the approved manner for giving the submission to the Department is accessible through the Department's website.

- (2) The Secretary may, in writing, approve:
 - (a) a form for submissions; and
 - (b) a manner for giving submissions to the Department.

Submission due day

- (3) The **submission due day** for a submission that:
 - (a) is for consideration by the Committee; and
 - (b) is likely to be in a particular evaluation category;is the day published on the Department's website by which the Committee needs to have received submissions in that evaluation category for the Committee to consider at the meeting date specified in the submission.
- (4) The Secretary must ensure that the submission due days for future Committee consideration of submissions are published on the Department's website.

32 Economic evaluation to support submission in Category 1 or Category 2

A submission in, or likely to be in, Category 1 or Category 2 must be accompanied by an economic evaluation for the submission.

33 Notification, including amount of fee payable

Notification after receipt of notice of intent—no fee exemption or waiver sought

- (1) If the Department receives a notice of intent in relation to a proposed submission from a person under subsection 30(1), the Secretary must, at least 10 business days before the submission due day for the submission, notify the person in writing:
 - (a) that the Department has received the notice of intent; and
 - (b) based on the statement in the notice of intent about the evaluation category the proposed submission is likely to be in—of the amount of the fee that is payable for providing submission services in response to the proposed submission; and
 - (c) of the manner for paying the fee.

Note 1: The fee must be paid within a period starting when this notification is given (see paragraph 62(1)(b)).

Note 2: If it is later found that a fee exemption or waiver under section 67 or 68 applies, a refund may be payable (see subsection 62(4)).

Notification after receipt of notice of intent—fee exemption or waiver sought

- (2) However, if the notice of intent includes either of the following relating to the fee for providing submission services in response to the proposed submission:
 - (a) reasons why section 67 is expected to apply to provide an exemption from the fee;
 - (b) a request for waiver of the fee;

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then the Secretary must, at least 5 business days before the submission due day for the submission, notify the person in writing:

- (c) that the Department has received the notice of intent; and
- (d) whether the fee exemption applies, or the fee is waived; and
- (e) if waiver was requested and the fee is not waived—of the person’s review rights under Part 8; and
- (f) if the fee exemption does not apply and the fee is not waived:
 - (i) of the amount of the fee that is payable for providing submission services in response to the proposed submission, based on the statement in the notice of intent about the evaluation category the submission is likely to be in; and
 - (ii) of the manner for paying the fee.

Notification after receipt of submission in relation to which notice of intent was not required

- (3) If the Department receives a submission from a person in relation to which a notice of intent was not required to be given under subsection 30(1), the Secretary must, within 15 business days after the day the submission is received, notify the person in writing:
 - (a) that the Department has received the submission; and
 - (b) if the submission includes reasons why section 67 applies to provide a fee exemption or a request for waiver of the fee for providing submission services in response to the submission:
 - (i) whether the fee exemption applies, or the fee is waived; and
 - (ii) if waiver was requested and the fee is not waived—of the person’s review rights under Part 8; and
 - (c) if the fee exemption does not apply and the fee is not waived:
 - (i) of the amount of the fee that is payable for providing submission services in response to the submission; and
 - (ii) of the manner for paying the fee.

Note 1: The fee specified in a notification given under this section is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

34 Secretary may refuse to accept incomplete submission

- (1) The Secretary may refuse to accept a submission from a person if the submission is so incomplete that it does not provide an adequate basis for:
 - (a) preparing a recommendation or advice requested by the submission; or
 - (b) deciding whether to exercise a power to which the submission relates.
- (2) If, under subsection (1), the Secretary refuses to accept a submission from a person:
 - (a) the Secretary must, within 10 business days, notify the person, in writing, of this decision; and

- (b) the Commonwealth may refuse to provide any submission services in response to the submission; and
- (c) the fee (if any) paid for providing submission services in response to the submission, except the deposit included in the fee, must be refunded.

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

Notice of intent or submission may be withdrawn at any time

- (1) Either of the following may be withdrawn by written notice given to the Department:
 - (a) a notice of intent in relation to a proposed submission given under subsection 30(1);
 - (b) a submission.

Refund of fee amount that was paid

- (2) If:
 - (a) a notification is given under subsection 33(1) after receipt of a notice of intent in relation to a proposed submission; and
 - (b) the notice of intent or the submission is withdrawn:
 - (i) on or before the submission due day for the submission; or
 - (ii) if the proposed submission is likely to be in, or the submission is in, the early re-entry pathway category, the early resolution pathway category or the facilitated resolution pathway category—within 10 business days after the day the notification was given; and
 - (c) all or part of the fee for providing submission services in response to the submission was paid before the withdrawal of the notice of intent or the submission;

the fee amount paid, except the deposit included in the fee, must be refunded.

Note: See also subsection (5) in relation to refund of the fee relating to a submission in the facilitated resolution pathway category.

- (3) If:
 - (a) a notification is given under subsection 33(2) after receipt of a notice of intent in relation to a proposed submission; and
 - (b) the submission is withdrawn within 10 business days after the day the notification was given; and
 - (c) all or part of the fee for providing submission services in response to the submission was paid before the withdrawal of the submission;

the fee amount paid, except the deposit included in the fee, must be refunded.

Note: See also subsection (5) in relation to refund of the fee relating to a submission in the facilitated resolution pathway category.

- (4) If:
 - (a) a notification is given under subsection 33(3) after receipt of a submission; and

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- (b) the submission is withdrawn within 10 business days after the day the notification was given; and
 - (c) all or part of the fee for providing submission services in response to the submission was paid before the withdrawal of the submission;
- the fee amount paid, except the deposit included in the fee, must be refunded.

Note: See also subsection (5) in relation to refund of the fee relating to a submission in the facilitated resolution pathway category.

- (5) Despite subsection (2), (3) or (4), the Department need not make a refund under that subsection relating to a proposed submission in the facilitated resolution pathway category if the withdrawal occurs after the last business day before the workshop (including on or after the day of the workshop) referred to in subsection 29(6) in connection with the submission.

Liability for part of fee if no fee amount was paid

- (6) If:
 - (a) a notice of intent in relation to a proposed submission, or a submission, is withdrawn as described in paragraph (2)(b), (3)(b) or (4)(b); and
 - (b) no fee amount for providing submission services in response to the submission was paid before the withdrawal of the notice of intent or the submission;

the Secretary must notify the person who gave the notice of intent or made the submission, in writing, that a fee of \$430 is payable for the provision of administrative services by the Department in relation to the notice of intent or the submission.

- (7) Subsection (6) does not apply in relation to:
 - (a) a submission in the new brand or new oral form of existing pharmaceutical item category; or
 - (b) a notice of intent in relation to a proposed submission in the facilitated resolution pathway category, or a submission in that category.

Note: Subsection (8) deals with liability for the fee relating to a submission in the facilitated resolution pathway category.

- (8) If:
 - (a) a notice of intent in relation to a proposed submission in the facilitated resolution pathway category, or a submission in that category, is withdrawn after the last business day before the workshop (including on or after the day of the workshop) referred to in subsection 29(6) in connection with the submission; and
 - (b) no fee amount for providing submission services in response to the submission was paid before the withdrawal of the notice of intent or the submission;

the Secretary must notify the person who gave the notice of intent or made the submission, in writing, that a fee of \$72,440 is payable for the provision of services relating to the preparation and delivery of the workshop.

Note 1: The fee specified in a notification given under subsection (6) or (8) is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

36 Remaking submission

- (1) A person who has made a submission may remake the submission in the same or an amended form.
- (2) This instrument applies to the remade submission as if it were a new submission.

Note: This means, for example, that the remade submission will attract a new fee under section 22.

Division 4—Determining evaluation category and assessing submissions

37 Determining evaluation category that submission is in

- (1) After having had regard to the matters in Division 2 of this Part and consulting with the Chair of the Committee, the Secretary may, in writing, determine that a submission is in one of the evaluation categories.

Note: The Secretary may initiate a review of the decision to make the determination (see section 74).

- (2) To avoid doubt, the Secretary may determine under subsection (1) that a submission is in an evaluation category (the *determined category*) other than the category that the submission, or the notice of intent in relation to the submission given under subsection 30(1), states that the submission is likely to be in, even if the determined category is an evaluation category described in section 29 (about evaluation categories of certain remade submissions).
- (3) If the Secretary determines, under subsection (1), that a submission is in a different evaluation category from the evaluation category used to work out the fee notified, under section 33 (or previously under this section), to the person who made the submission, the Secretary must notify the person, in writing, accordingly.
- (4) A notification to a person under subsection (3) must specify:
 - (a) the amounts of the fees payable for the submission services that applied when the notification for the submission was given under section 33; and
 - (b) the fee amounts (if any) already paid, or refunded, for the submission services; and
 - (c) the fee amount that is to be refunded to, or is payable by, the person based on the amounts referred to in paragraphs (a) and (b); and
 - (d) the manner for paying the amount (if any) referred to in paragraph (c) that is payable by the person; and
 - (e) the person's review rights under Part 8 in relation to the determination under subsection (1).

Note 1: The fee specified in a notification given under subsection (3) is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

38 Assessing submissions

- (1) The Committee or the Minister may request further information from a person who has made a submission to assess the submission.
- (2) If the Committee or the Minister is unable to assess a submission without further information, the Committee or the Minister may ask the Secretary to consider:

- (a) determining, under subsection 37(1), the evaluation category the submission is in; or
- (b) reviewing, under section 74:
 - (i) a determination under subsection 37(1) of the evaluation category the submission is in; or
 - (ii) a decision under subsection 68(1) (waiver of fees) in relation to the submission.

Part 4—Pricing services

Division 1—Preliminary

39 Simplified outline of this Part

Pricing services in relation to one or more drugs or medicinal preparations may be sought after a meeting of the Committee that results in the Committee making a positive recommendation, or giving positive advice, in relation to the drugs or medicinal preparations.

Pricing services may be provided in response to a person's pricing application. A fee is payable for providing the pricing services (unless a fee exemption applies or the fee is waived). The amount of the fee depends on the category of the person's pricing application.

The person will generally need to have given the Department a notice of intent in relation to the proposed pricing application at least 5 business days before making the application.

The notice of intent must state the category that the pricing application is likely to be in. The person will generally be charged a fee for the pricing services based on this category.

If the Secretary later determines that the pricing application is in a different category, the person will be notified and any difference in the fee payable will be refunded or charged as appropriate.

Pricing services will be delayed if a notice of intent in relation to the pricing application was not given, unless a notice of intent was not required because of an urgent public health need.

The pricing application must be given to the Department within 30 business days after the notice of intent is given.

If a notice of intent in relation to a proposed pricing application is withdrawn soon after it is given, or a pricing application is withdrawn soon after it is made, in most cases, the fee amount (if any) paid, except the amount of the deposit included in the fee amount, will be refunded. If no fee amount was paid before the withdrawal, a fee for the provision of administrative services by the Department in relation to the notice of intent or the pricing application will be payable.

Six months after a pricing application is made, the Commonwealth may cease to provide the pricing services applied for if the Secretary is satisfied that negotiations relevant to the pricing services have not concluded successfully and are not continuing because of the applicant's inaction. If the ceased services relate to a proposed deed, a refund of part of the fee is available.

Division 2—Pricing applications and fees

40 Applications for pricing services

- (1) A person may make an application (a **pricing application**) for the Commonwealth to provide services (**pricing services**) in assisting the Minister to consider whether to exercise one or more powers, under subsection 85(2), (2A) or (3), paragraph 85(7)(b) or section 85AD, 85B or 85E of the Act, in relation to one or more drugs or medicinal preparations (the **relevant drugs or medicinal preparations**) if the Committee has made a positive recommendation, or given positive advice, covering all the relevant drugs or medicinal preparations.

Note: The Committee may make a recommendation or give advice in response to a submission, or otherwise under the Act, for the purpose of assisting the Minister to consider whether to exercise one or more powers under a provision of the Act referred to in this subsection in relation to one or more drugs or medicinal preparations.

- (2) If the person has made one or more submissions covering the relevant drugs or medicinal preparations, the person must make a separate pricing application in relation to each submission.

Note 1: A single submission may cover multiple drugs or medicinal preparations only in the circumstances set out in paragraphs 21(2)(a) and (b).

Note 2: A separate pricing application must be made in relation to a drug or medicinal preparation covered by a separate submission to the Committee. Separate fees under section 41 are payable for providing pricing services relating to the drugs or medicinal preparations covered by separate submissions to the Committee.

Note 3: For details about how to make a pricing application, see section 49.

41 Fees for providing pricing services

- (1) The fee for providing pricing services in response to a pricing application in a pricing category referred to in column 1 of an item of the following table is the fee referred to in column 2 of that item.

Fees for providing pricing services		
Item	Column 1	Column 2
	Pricing categories of pricing applications	Fee (\$)
1	Pricing Pathway A category	142,540
2	Pricing Pathway B category	112,810
3	Pricing Pathway C category	74,680
4	Pricing Pathway D category	20,460
5	Pricing Secretariat category	12,690

- (2) For the purposes of subsections 49(3) and 51(2) (about refunds excluding deposits), each fee prescribed by an item of the table in subsection (1) of this section includes a deposit of \$430.

- (3) For the purposes of subsections 51(4) and 54(2) (about a refund excluding a deposit if a deed is not entered into):

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- (a) the fee prescribed by item 1 of the table in subsection (1) of this section includes a deposit of \$134,200; and
- (b) the fee prescribed by item 2 of the table in subsection (1) of this section includes a deposit of \$104,470; and
- (c) the fee prescribed by item 3 of the table in subsection (1) of this section includes a deposit of \$66,340.

42 Pricing applications in Pricing Pathway A category

A pricing application is in Pricing Pathway A category if:

- (a) as part of the Committee's recommendation or advice covering the drugs or medicinal preparations to which the pricing application relates, the Committee found that:
 - (i) the drugs or medicinal preparations are expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapy; and
 - (ii) the drugs or medicinal preparations address a high and urgent unmet clinical need; and
 - (iii) it would be in the public interest for a pricing application relating to the drugs or medicinal preparations to be in this category; and
- (b) the pricing application, or the notice of intent (if any) in relation to the proposed pricing application, states that the application is to be in this category.

Note: See subsection 48(6) and paragraph 49(1)(b).

43 Pricing applications in Pricing Pathway B category

- (1) A pricing application is in Pricing Pathway B category if:
 - (a) the pricing application seeks the entering into of a deed under section 85E of the Act relating to the drugs or medicinal preparations to which the pricing application relates (the *new drugs*); and
 - (b) no deed under that section is in force (between the Commonwealth and any person) that contains terms (the *pricing terms*) about the following:
 - (i) reimbursing the Commonwealth;
 - (ii) providing the Commonwealth with information;that are substantially similar to the pricing terms that are appropriate for the new drugs; and
 - (c) the pricing application is not in Pricing Pathway A category.

Note: Section 45 is relevant to paragraph (b).

- (2) For the purposes of paragraph (1)(b), the pricing terms are appropriate for the new drugs if they are consistent with the Committee's recommendation or advice covering the new drugs.

44 Pricing applications in Pricing Pathway C category

- (1) A pricing application is in Pricing Pathway C category if:

- (a) the pricing application seeks the entering into of a deed under section 85E of the Act relating to the drugs or medicinal preparations to which the pricing application relates (the **new drugs**); and
- (b) a deed under that section is in force (between the Commonwealth and any person) that contains terms (the **pricing terms**) about the following:
 - (i) reimbursing the Commonwealth;
 - (ii) providing the Commonwealth with information;that are substantially similar to the pricing terms that are appropriate for the new drugs; and
- (c) the pricing application is not in Pricing Pathway A category.

Note: Section 45 is relevant to paragraph (b).

- (2) For the purposes of paragraph (1)(b), the pricing terms are appropriate for the new drugs if they are consistent with the Committee's recommendation or advice covering the new drugs.

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

- (1) This section applies for the purposes of paragraphs 43(1)(b) and 44(1)(b).

When pricing terms are substantially similar to those appropriate for the new drugs

- (2) The pricing terms in an existing deed under section 85E of the Act are substantially similar to the pricing terms (the **new pricing terms**) that are appropriate for the new drugs if, under the new pricing terms:
 - (a) the new drugs can share an existing subsidisation cap with the drugs or medicinal preparations to which the existing deed relates; or
 - (b) the new drugs are cost-minimised to the drugs or medicinal preparations to which the existing deed relates.
- (3) The pricing terms in an existing deed under section 85E of the Act are substantially similar to the pricing terms appropriate for the new drugs if:
 - (a) the Committee's recommendation or advice covering the new drugs suggested that the pricing terms in the existing deed would be appropriate for the new drugs; and
 - (b) this suggestion relates to claims in the relevant pricing application of the kind referred to in subparagraphs 46(2)(a)(i), (ii) and (iii).

When pricing terms are not substantially similar to those appropriate for the new drugs

- (4) Despite subsections (2) and (3), the pricing terms in an existing deed under section 85E of the Act are not substantially similar to the pricing terms (the **new pricing terms**) appropriate for the new drugs if:
 - (a) the new pricing terms relate to further clinical testing, or to the collection of further clinical data on the effectiveness, of the new drugs; or

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- (b) the new pricing terms, to the extent that they provide for reimbursing the Commonwealth, include taking into account the clinical response of patients to the new drugs; or
- (c) the pricing terms in the existing deed include an existing subsidisation cap that cannot be shared with the new drugs; or
- (d) the new pricing terms, to the extent that they provide for reimbursing the Commonwealth, relate to Commonwealth expenditure on a therapy that involves using the new drugs in combination with any of the drugs or medicinal preparations covered by the existing deed.

Circumstances in the above subsections are not exhaustive

- (5) This section does not set out the only circumstances in which the pricing terms in an existing deed under section 85E of the Act are, or are not, substantially similar to the pricing terms appropriate for the new drugs.

46 Pricing applications in Pricing Pathway D category

- (1) A pricing application is in Pricing Pathway D category if:
 - (a) subsection (2), (3), (4) or (5) applies to the pricing application; and
 - (b) the pricing application does not seek the entering into of a deed under section 85E of the Act relating to the drugs or medicinal preparations to which the pricing application relates (the *new drugs*); and
 - (c) the pricing application is not in Pricing Pathway A category.
- (2) This subsection applies to the pricing application if:
 - (a) it includes one or more of the following claims about the new drugs and an alternative therapy:
 - (i) a claim that the effectiveness of specified doses of the new drugs is equivalent to specified doses of the alternative therapy;
 - (ii) a claim that the new drugs will provide similar health benefits to those provided by the alternative therapy;
 - (iii) a claim that the new drugs may be supplied at the same or a lower price per treatment, or price per unit, as that for the alternative therapy; and
 - (b) it notes that the claims are consistent with the Committee's recommendation or advice to the Minister in relation to the new drugs; and
 - (c) it suggests a price based on the claims.
- (3) This subsection applies to the pricing application if:
 - (a) it claims that the use of the new drugs provides a significant improvement in the efficacy or reduction in toxicity compared to an alternative therapy; and
 - (b) it requests for the new drugs a higher price per treatment, or price per unit, than that for:
 - (i) the alternative therapy referred to in paragraph (a); or
 - (ii) another alternative therapy if, as part of the Committee's recommendation or advice to the Minister in relation to the new

- drugs, the Committee found that the other therapy is clinically comparable to the new drugs; and
- (c) the claim in paragraph (a) and the request in paragraph (b) are consistent with the Committee's recommendation or advice to the Minister in relation to the new drugs.
- (4) This subsection applies to the pricing application if:
- (a) it includes a request for a review of the existing price for a listed drug; and
 - (b) the resulting price requested in the pricing application is consistent with the Committee's recommendation or advice to the Minister in relation to the listed drug.
- (5) This subsection applies to the pricing application if:
- (a) it includes both of the following claims about the new drugs and an alternative therapy:
 - (i) a claim that the new drugs will provide similar health benefits to those provided by the alternative therapy;
 - (ii) a claim that the new drugs may be supplied at the same or a lower price per treatment, or price per unit, as that for the alternative therapy; and
 - (b) the claims are consistent with the Committee's recommendation or advice to the Minister in relation to the new drugs.

47 Pricing applications in Pricing Secretariat category

A pricing application is in the Pricing Secretariat category if it is not in any other pricing category.

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

48 Notice of intent required for most pricing applications

When notice of intent is required

- (1) A person proposing to make a pricing application must give the Department a notice of intent in relation to the pricing application unless the Secretary has decided under subsection (3) that a notice of intent is not required. The notice of intent must:
 - (a) be in accordance with subsection (6); and
 - (b) be given at least 5 business days before the day the person gives the proposed pricing application to the Department.

Note 1: Requiring the notice of intent allows the Commonwealth to properly prepare for the provision of pricing services in response to the pricing application.

Note 2: The pricing application must be given to the Department within 30 business days after the notice of intent is given (see subsection 49(2)).

Exception if urgent public health need

- (2) If the person considers that the provision of pricing services in response to the pricing application is required to address an urgent public health need, the person may request the Secretary, in writing, to decide that a notice of intent in relation to the proposed pricing application is not required under subsection (1).
- (3) If the Secretary receives a request from a person under subsection (2) in relation to a proposed pricing application, the Secretary must:
 - (a) decide that a notice of intent in relation to the proposed pricing application is not required under subsection (1), or refuse to make that decision; and
 - (b) give the person written notice of the decision.

Note 1: If the Secretary refuses to make the decision requested, the Secretary must also comply with section 72.

Note 2: A refusal to make the decision requested is reviewable (see section 71).

- (4) The Secretary may decide under subsection (3) that a notice of intent in relation to the proposed pricing application is not required if the Secretary is satisfied that the provision of pricing services in response to the pricing application is required to address an urgent public health need.

Consequence if notice of intent is required but not given

- (5) The provision of pricing services in response to a pricing application will be delayed if a notice of intent in relation to the pricing application:
 - (a) is required under subsection (1); and
 - (b) is not given in accordance with that subsection.

The pricing services will not begin to be provided until at least 5 business days after the day the pricing application is given to the Department.

Requirements for notice of intent

- (6) A notice of intent in relation to a proposed pricing application under subsection (1) must:
- (a) be in a form approved by the Secretary; and
 - (b) state, with reasons, why the proposed pricing application is likely to be in a particular pricing category; and
 - (c) be given to the Department in a manner approved by the Secretary.

Note 1: If the person giving the notice of intent considers that a fee exemption applies under section 67, the notice of intent must include the reasons for the exemption (see subsection 67(8)).

Note 2: If the person giving the notice of intent wishes to request waiver of the fee that would otherwise be payable, the request must be included in the notice of intent (see subsection 68(2)).

Note 3: Information about the approved form for a notice of intent in relation to a pricing application and the approved manner for giving the notice of intent to the Department is accessible through the Department's website.

- (7) The Secretary may, in writing, approve:
- (a) a form for a notice of intent in relation to a pricing application; and
 - (b) a manner for giving the notice of intent to the Department.

49 Requirements for pricing applications

- (1) A pricing application must:
- (a) be in a form approved by the Secretary; and
 - (b) if a notice of intent in relation to the pricing application was not required to be given under subsection 48(1)—state, with reasons, why the pricing application is to be in a particular pricing category; and
 - (c) be given to the Department in a manner approved by the Secretary.

Note 1: If the applicant considers that a fee exemption applies under section 67 and a notice of intent was not required to be given under subsection 48(1), the pricing application must include the reasons for the exemption (see subsection 67(7)).

Note 2: If the applicant wishes to request waiver of the fee that would otherwise be payable and a notice of intent was not required to be given under subsection 48(1), the request must be included in the pricing application (see subsection 68(2)).

Note 3: Information about the approved form for a pricing application and the approved manner for giving the pricing application to the Department is accessible through the Department's website.

- (2) If a notice of intent in relation to the pricing application was given under subsection 48(1), the pricing application must be given to the Department within 30 business days after the day the notice of intent was given.

- (3) If:
- (a) a notice of intent in relation to a proposed pricing application is given by a person under subsection 48(1); and
 - (b) the proposed pricing application is not given to the Department before the end of the period referred to in subsection (2) of this section;

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the fee amount (if any) paid for providing pricing services in response to the proposed pricing application, except the deposit referred to in subsection 41(2) included in the fee, must be refunded.

Note: If the person still seeks the pricing services, the person must give a new notice of intent in relation to a proposed new pricing application under section 48.

- (4) The Secretary may, in writing, approve:
- (a) a form for pricing applications; and
 - (b) a manner for giving pricing applications to the Department.

50 Notification, including amount of fee payable

Notification after receipt of notice of intent—no fee exemption or waiver sought

- (1) If the Department receives a notice of intent in relation to a proposed pricing application from a person under subsection 48(1), the Secretary must, within 10 business days after the day the notice of intent is received, notify the person in writing:
- (a) that the Department has received the notice of intent; and
 - (b) based on the statement in the notice of intent about the pricing category of the proposed pricing application—of the amount of the fee that is payable for providing pricing services in response to the proposed pricing application; and
 - (c) of the manner for paying the fee.

Note 1: The fee must be paid within a period starting when this notification is given (see paragraph 62(1)(b)).

Note 2: If it is later found that a fee exemption or waiver under section 67 or 68 applies, a refund may be payable (see subsection 62(4)).

Notification after receipt of notice of intent—fee exemption or waiver sought

- (2) However, if the notice of intent includes either of the following relating to the fee for providing pricing services in response to the proposed pricing application:
- (a) reasons why section 67 is expected to apply to provide an exemption from the fee;
 - (b) a request for waiver of the fee;
- then the Secretary must, within 15 business days after the day the notice of intent is received, notify the person in writing:
- (c) that the Department has received the notice of intent; and
 - (d) whether the fee exemption applies, or the fee is waived; and
 - (e) if waiver was requested and the fee is not waived—of the applicant's review rights under Part 8; and
 - (f) if the fee exemption does not apply and the fee is not waived:
 - (i) of the amount of the fee that is payable for providing pricing services in response to the proposed pricing application, based on the statement in the notice of intent about the pricing category the pricing application is likely to be in; and
 - (ii) of the manner for paying the fee.

Notification after receipt of pricing application in relation to which notice of intent was not required

- (3) If the Department receives a pricing application in relation to which a notice of intent was not required to be given under subsection 48(1), the Secretary must, within 15 business days after the day the pricing application is received, notify the applicant in writing:
- (a) that the Department has received the application; and
 - (b) if the pricing application includes reasons why section 67 applies to provide a fee exemption or a request for waiver of the fee for providing pricing services in response to the pricing application:
 - (i) whether the fee exemption applies, or the fee is waived; and
 - (ii) if waiver was requested and the fee is not waived—of the applicant’s review rights under Part 8; and
 - (c) if the fee exemption does not apply and the fee is not waived:
 - (i) of the amount of the fee that is payable for providing pricing services in response to the pricing application; and
 - (ii) of the manner for paying the fee.

Note 1: The fee specified in a notification given under this section is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

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

Notice of intent or pricing application may be withdrawn at any time

- (1) Either of the following may be withdrawn by written notice given to the Department:
- (a) a notice of intent in relation to a proposed pricing application given under subsection 48(1);
 - (b) a pricing application.

Refund of fee amount that was paid

- (2) If:
- (a) a notification is given under subsection 50(1) or (2) after receipt of a notice of intent in relation to a proposed pricing application; and
 - (b) the notice of intent or the pricing application is withdrawn within 10 business days after the notification was given; and
 - (c) all or part of the fee for providing pricing services in response to the pricing application was paid before the withdrawal of the notice of intent;
- the fee amount paid, except the deposit referred to in subsection 41(2) included in the fee, must be refunded.
- (3) If:

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- (a) a notification is given under subsection 50(3) after receipt of a pricing application; and
- (b) the pricing application is withdrawn within 10 business days after the day the notification was given; and
- (c) all or part of the fee for providing pricing services in response to the pricing application was paid before the withdrawal of the application; the fee amount paid must be refunded.

(4) If:

- (a) a notice of intent in relation to a proposed pricing application, or a pricing application, is withdrawn as described in paragraph (2)(b) or (3)(b); and
- (b) the proposed pricing application, or pricing application, was or would have been for pricing services relating to the entering into of a deed under section 85E of the Act (whether or not other pricing services were or would have been applied for); and
- (c) all or part of the fee for providing pricing services in response to the pricing application was paid before the withdrawal of the notice of intent or the pricing application;

the fee amount paid, except the relevant deposit referred to in subsection 41(3), must be refunded.

Liability for part of fee if no fee amount was paid

(5) If:

- (a) a notice of intent in relation to a proposed pricing application, or a pricing application, is withdrawn as described in paragraph (2)(b) or (3)(b); and
- (b) no fee amount for providing pricing services in response to the pricing application was paid before the withdrawal of the notice of intent or the pricing application;

the Secretary must notify the applicant, in writing, that a fee of \$430 is payable for the provision of administrative services by the Department in relation to the notice of intent or the pricing application.

Note 1: The fee specified in a notification given under this subsection is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

Division 4—Determining pricing category of pricing applications

52 Determining pricing category that pricing application is in

- (1) After having had regard to the matters in sections 42 to 47, the Secretary may, in writing, determine that a pricing application is in one of the pricing categories.

Note: The Secretary may initiate a review of the decision to make the determination (see section 74).

- (2) If the Secretary determines, under subsection (1), that a pricing application is in a different pricing category from the pricing category used to work out the fee notified to the applicant under section 50 (or previously under this section), the Secretary must notify the applicant, in writing, accordingly.

- (3) A notification under subsection (2) to an applicant must specify:

- (a) the amounts of the fees payable for the pricing services that applied when the notification for the pricing application was given under section 50; and
- (b) the fee amounts (if any) already paid, or refunded, for the pricing services; and
- (c) the fee amount that is to be refunded to, or is payable by, the applicant based on the amounts referred to in paragraphs (a) and (b); and
- (d) the manner for paying the amount (if any) referred to in paragraph (c) that is payable by the applicant; and
- (e) the applicant's review rights under Part 8 in relation to the determination under subsection (1).

Note 1: The fee specified in a notification given under subsection (2) is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

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

53 Cessation of pricing services 6 months after pricing application is made

The Commonwealth may cease to provide the pricing services applied for in a pricing application if 6 months has passed since the pricing application was made and the Secretary is satisfied that:

- (a) an agreement or understanding has not been reached with the applicant in relation to the assistance to be provided to the Minister to consider whether to exercise a power to which the pricing services relate; and
- (b) negotiations relevant to the pricing services are not proceeding because of the applicant's inaction.

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

- (1) This section applies if:
 - (a) a pricing application was made for pricing services relating to the entering into of a deed under section 85E of the Act; and
 - (b) under section 53 of this instrument, the Commonwealth ceases to provide the pricing services; and
 - (c) when the Commonwealth ceased to provide the pricing services, the deed had not been entered into.
- (2) The fee amount (if any) paid for providing the pricing services in response to the pricing application, except the relevant deposit referred to in subsection 41(3) included in the fee, must be refunded.

Part 5—List management services

55 Simplified outline of this Part

List management services may be provided by the Commonwealth, on application (a list management application) by a person, in assisting the Minister to consider whether to exercise certain powers under Part VII of the Act.

A fee is payable for the provision of the list management services (unless a fee exemption applies or the fee is waived).

If the list management application is withdrawn before a certain time, in most cases, the fee amount (if any) paid for providing list management services in response to the application will be refunded in full.

If the list management application sought the entering into of a deed with the person to replace an expired deed and it is decided not to enter into the replacement deed, part of the fee amount paid will be refunded.

56 Fees for providing list management services

- (1) The fee for providing services (*list management services*):
- (a) in response to an application (the *list management application*) by a person; and
 - (b) in assisting the Minister to consider whether to exercise a power described in column 1 of an item in the following table;
- is the fee referred to in column 2 of that item.

Fees for providing list management services		
Item	Column 1	Column 2
	Powers of Minister under the Act	Fee (\$)
1	Power under: (a) subsection 85AD(1) (about price agreements) of the Act; or (b) section 85B (about price determinations) of the Act; relating to a listed brand of a pharmaceutical item if subsection (2) of this section applies	5,080
2	Power under subsection 85E(1) of the Act (as affected by subsection 33(3) of the <i>Acts Interpretation Act 1901</i>) to vary a deed entered into under subsection 85E(1) of the Act	1,980
3	Power under subsection 85E(1) of the Act to enter into a deed with a person replacing an expired deed entered into with the person under that subsection	10,410
4	Power under any of the following provisions of the Act (relating to pricing): (a) subsection 99ACB(6A); (b) subsection 99ACB(6B);	7,090

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Fees for providing list management services

Item	Column 1	Column 2
	Powers of Minister under the Act	Fee (\$)
	(c) subsection 99ACBA(1); (d) subsection 99ACD(7A); (e) subsection 99ACD(7B); (f) subsection 99ACE(5); (g) subsection 99ACE(5A); (h) subsection 99ACEA(1); (i) subsection 99ACF(3); (j) subsection 99ACF(3AA); (k) subsection 99ACF(3AB)	

- (2) This subsection applies if:
- (a) either:
 - (i) a price agreement under section 85AD of the Act is in force between the person and the Minister for the listed brand of the pharmaceutical item; or
 - (ii) determinations under subsections 85B(2) and (3) of the Act are in force for the listed brand of the pharmaceutical item; and
 - (b) since that agreement or those determinations entered into force, the Committee has not made a recommendation, or given advice, in response to a submission made by the person in relation to:
 - (i) the listed brand of the pharmaceutical item; or
 - (ii) the drug in the pharmaceutical item; and
 - (c) in the list management application, the person is seeking:
 - (i) through the exercise of the power in subsection 85AD(1) of the Act—an increase in the approved ex-manufacturer price of the listed brand of the pharmaceutical item; or
 - (ii) the making of a determination under subsection 85B(3) of the Act, or the increase in a price earlier determined under that subsection, in relation to the listed brand of the pharmaceutical item.

57 Requirements for list management applications

- (1) A list management application must:
- (a) be in a form approved by the Secretary; and
 - (b) be given to the Department in a manner approved by the Secretary.

- Note 1: If the applicant considers that a fee exemption applies under section 67, the list management application must include the reasons for the exemption (see subsection 67(7)).
- Note 2: If the applicant wishes to request waiver of the fee that would otherwise be payable, the request must be included in the list management application (see subsection 69(2)).
- Note 3: Information about the approved form for a list management application and the approved manner for giving the list management application to the Department is accessible through the Department’s website.

-
- (2) The Secretary may, in writing, approve:
- (a) a form for list management applications; and
 - (b) a manner for giving list management applications to the Department.

58 Notification, including amount of fee payable

Within 15 business days after the day the Department receives a list management application, the Secretary must notify the applicant in writing:

- (a) that the Department has received the application; and
- (b) of the Ministerial power in Part VII of the Act to which the list management services sought by the list management application relate; and
- (c) if the list management application includes reasons why section 67 applies to provide a fee exemption or a request for waiver of the fee for providing list management services in response to the list management application:
 - (i) whether the fee exemption applies, or the fee is waived; and
 - (ii) if waiver was requested and the fee is not waived—of the applicant’s review rights under Part 8; and
- (d) if the fee exemption does not apply and the fee is not waived:
 - (i) of the amount of the fee that is payable for providing the list management services in response to the list management application; and
 - (ii) of the manner for paying the fee.

Note 1: The fee specified in a notification given under this section is payable to the Commonwealth (see subsection 99YBA(4) of the Act) unless the fee is waived under section 68 of this instrument.

Note 2: Part 6 deals with the payment of fees, including the time for payment (see paragraph 62(1)(b)).

59 Withdrawal of list management application, and refund of fee

- (1) A list management application may be withdrawn by written notice given to the Department.
- (2) If the list management application is withdrawn within 10 business days after the day the notification in relation to the application was given under section 58, the fee (if any) paid for providing list management services in response to the application must be refunded.

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

- (1) This section applies if:
 - (a) a list management application by a person sought the exercise of the power referred to in item 3 of the table in subsection 56(1) to enter into a deed (the *replacement deed*) with the person replacing an expired deed; and
 - (b) all or part of the fee prescribed by that item for providing list management services in response to the list management application has been paid; and
 - (c) the Department becomes aware of a decision (whether by the Minister, the person, or as agreed between them) not to enter into the replacement deed.

Part 5 List management services

Section 60

- (2) The amount of \$8,340 must be refunded to the person.

Part 6—Fees: common rules and independent review fee

61 Simplified outline of this Part

A fee that is payable under this instrument for services provided by the Commonwealth must be paid:

- (a) in full to the Commonwealth before the end of 28 days starting on the day the notification that the fee is payable is given under this instrument; or
- (b) by instalments if the Secretary has agreed to accept payment of the fee by instalments.

If a fee that is payable under this instrument by a person (other than a fee for an independent review of certain decisions by the Committee) is not paid before the time the fee must be paid, the Commonwealth may:

- (a) refuse to consider any submission or application made (or to be made) by the person under this instrument; or
- (b) refuse to provide any services in response to a submission or an application under this instrument until the fee is paid or is no longer payable.

A person may seek an independent review of certain decisions by the Committee. A fee is payable for the independent review.

If a submission or an application for services made under this instrument is withdrawn and no services have been provided, or the Secretary decides that the Commonwealth cannot provide the services to which a submission or an application for services made under this instrument relates, the Secretary must decide whether the fee (if any) paid for the services is to be refunded or, if no fee was paid, whether to remit the fee.

62 Payment of fees

- (1) A fee payable under this instrument for services provided by the Commonwealth in response to a submission or an application made under this instrument must be paid:
 - (a) in full to the Commonwealth; and
 - (b) unless the Secretary has agreed, under subsection (2), to accept payment of the fee by instalments—before the end of 28 days starting on the day the Department gives a notification under this instrument that the fee is payable.
- (2) The Secretary may agree, in writing, to accept payment by instalments.
- (3) If, because of a decision notified under this instrument to a person, the person pays a fee amount under this instrument that is less than the amount referred to in

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the notification as being payable, the person must pay the Commonwealth an amount equal to the shortfall within:

- (a) 28 days after the day of the notification; or
- (b) a longer period allowed by the Secretary.

Note: The notification by the Secretary could be, for example:

- (a) a notification relating to a different evaluation category or pricing category determined under subsection 37(1) or 52(1); or
- (b) a notification under section 75 about an underpayment because of a replacement decision made as part of a review under Part 8.

- (4) If a person pays a fee amount under this instrument that is more than the amount notified by the Secretary as being payable, the Commonwealth must refund to the person an amount equal to the excess within 20 business days after the later of:

- (a) the day the person paid the fee amount; and
- (b) the day the Secretary notified the person of the amount payable.

Note: The notice by the Secretary could be, for example:

- (a) a notification relating to a different evaluation category or pricing category determined under subsection 37(1) or 52(1); or
- (b) a notification under subsection 33(2) or (3) of a decision under subsection 68(1) to waive the fee; or
- (c) a notification under section 75 about an overpayment because of a replacement decision made as part of a review under Part 8.

- (5) This section does not apply in relation to a fee prescribed by section 64 (independent review fee).

63 Delay in paying fee

- (1) If a fee payable under this instrument by a person is not paid before the time the fee must be paid, the Commonwealth may do either or both of the following until the fee is paid or is no longer payable:
 - (a) refuse to consider a submission or application made (or to be made) by the person under this instrument;
 - (b) refuse to provide any services relating to a submission or an application made under this instrument.

Note 1: Paragraph (a) means, for example, that the Committee or ATAGI could refuse to consider the person's current or future submissions or applications made under this instrument until the fee is paid or is no longer payable.

Note 2: The Commonwealth could, instead of or in addition to refusing to do these things, seek to recover the unpaid fee as a debt (see subsection 99YBA(5) of the Act).

- (2) This section does not apply in relation to a fee prescribed by section 64 (independent review fee).

64 Independent review fee

- (1) A person may seek an independent review of a decision by the Committee in response to a submission not to recommend to, or advise, the Minister:
 - (a) to declare a drug or medicinal preparation under subsection 85(2) of the Act; or

- (b) to determine, under subsection 85(7) of the Act, further circumstances in which a prescription for the supply of a pharmaceutical benefit may be written.
- (2) A submission in relation to which an independent review is sought must:
- (a) be submitted in the form in which it was originally considered by the Committee; and
 - (b) have been rejected by the Committee in its entirety.
- (3) The fee for the independent review is the same as the fee that would have been payable under Part 3 of this instrument for submission services:
- (a) provided in response to a submission that is in Category 2 evaluation category; and
 - (b) for which a notification under that Part is given at the same time as the submission is submitted under this section.
- (4) The fee for the independent review must be paid in full to the Commonwealth at the time the submission is submitted under this section.
- Note: The independent review will not commence until the fee is paid.
- (5) There is no fee for the Committee to reconsider a submission following the independent review.

Note: Information about independent reviews is accessible through the PBS website at <http://www.pbs.gov.au>.

65 Refund or remission of fees if services not provided

- (1) This section applies if:
- (a) a person made a submission or an application under this instrument for the provision of services by the Commonwealth; and
 - (b) either:
 - (i) the submission or the application is withdrawn before any services are provided; or
 - (ii) the Secretary decides that the Commonwealth cannot provide the services to which the submission or application relates.
- (2) If all or part of the fee for the provision of the services was paid, the Secretary must:
- (a) decide whether or not the fee amount paid is to be refunded to the person; and
 - (b) notify the person, in writing, of the decision as soon as practicable after making it.
- Note: A decision not to refund the fee is reviewable (see section 71).
- (3) If no fee for the provision of the services was paid, the Secretary must:
- (a) decide whether to remit the fee; and
 - (b) notify the person, in writing, of the decision as soon as practicable after making it.

Note: A decision not to remit the fee is reviewable (see section 71).

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- (4) This section does not apply in relation to a submission if the submission is withdrawn in the circumstances provided by section 35.

Note: Section 35 deals with refunds or liability for part of the fee if a notice of intent in relation to a submission, or a submission, is withdrawn in the circumstances provided by that section.

- (5) This section does not apply in relation to an application for services made under this instrument if the application is withdrawn in the circumstances provided by section 12, 51 or 59.

Note: Those sections deal with refunds or liability for part of the fee if a notice of intent in relation to an application for services under Part 2, 4 or 5, or an application for services under Part 2, 4 or 5, is withdrawn in the circumstances provided by section 12, 51 or 59.

Part 7—Exemptions and waivers

66 Simplified outline of this Part

Exemptions

Exemptions from the liability to pay a fee apply in certain cases.

A person who has made a submission or an application for services under this instrument, and who considers that a fee exemption applies in relation to the provision of the services must include in the submission or application or, if required, in the notice of intent in relation to the proposed submission or application, the reasons why the fee exemption applies.

Waiver of fees

The Secretary may, on request by a person, decide to waive a fee payable by the person in relation to the provision of services to which a submission or an application under this instrument relates. The request must be included in the person's submission or application for the services or, if required, in the notice of intent in relation to the proposed submission or application.

67 Exemptions

Exemptions for services—general

- (1) No fee is payable under this instrument for the provision of services if the submission or application for the services relates to:
 - (a) a drug that is exempt from entry in the Australian Register of Therapeutic Goods because of an approval granted under section 19A of the *Therapeutic Goods Act 1989*; or
 - (b) the supply of a drug, medicinal preparation or vaccine that the Secretary considers is necessary for the management of:
 - (i) a public health event of national significance (within the meaning of the *National Health Security Act 2007*); or
 - (ii) a biosecurity emergency that is declared to exist under subsection 443(1) of the *Biosecurity Act 2015*; or
 - (iii) a human biosecurity emergency that is declared to exist under subsection 475(1) of the *Biosecurity Act 2015*.
- (2) No fee is payable under this instrument for the provision of services if the submission or application for the services seeks any of the following:
 - (a) to offer a price reduction;
 - (b) to change the name of the responsible person (as defined by subsection 84(1) of the Act) for a brand of a pharmaceutical item;
 - (c) to vary a determination under subsection 9B(2) of the Act so that a vaccine ceases to be a designated vaccine;

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- (d) to revoke a determination under subsection 9B(2) of the Act;
 - (e) to vary a special arrangement under subsection 100(2) of the Act so that a drug or medicinal preparation ceases to be covered by the arrangement;
 - (f) to revoke a special arrangement under subsection 100(2) of the Act;
 - (g) to vary a declaration under subsection 101(4AAA) of the Act so that a drug or medicinal preparation ceases to be a listed drug;
 - (h) to revoke a declaration under subsection 101(4AAA) of the Act;
 - (i) to decrease the pack quantity (the *existing pack quantity*) of a listed brand of a pharmaceutical item if the amount that is to be the appropriate maximum price of the decreased pack quantity to be agreed under section 85AD of the Act will be calculated proportionally based on the approved ex-manufacturer price of the existing pack quantity on the day before the agreement under that section takes effect;
 - (j) to increase the pack quantity of a listed brand of a pharmaceutical item if the price for the increased pack quantity will be based on the proportional ex-manufacturer price worked out under section 85D of the Act;
 - (k) to vary a declaration, determination, arrangement or other legislative instrument made under section 9B or Part VII of the Act:
 - (i) at the request of Services Australia or the Therapeutic Goods Administration; or
 - (ii) that is a mandated change because of a Government initiative.
- (3) Subsections (1) and (2) do not apply in relation to:
- (a) services under Division 3 of Part 2 (about pre-submission meetings); or
 - (b) services under section 64 (about independent reviews).

Exemption for submission services relating to designated orphan drugs

- (4) No fee is payable under this instrument for submission services provided in response to a person's submission proposing a therapy involving the use of one or more drugs or medicinal preparations if:
- (a) on the day the submission is given to the Department, subsection (5) applies to each of those drugs or medicinal preparations; and
 - (b) this subsection has not already applied to submission services provided in response to an earlier submission by the person proposing the same therapy involving the use of any of those drugs or medicinal preparations.
- (5) This subsection applies to a drug or medicinal preparation (the *drug*) on a day if:
- (a) on that day, the drug is a designated orphan drug; or
 - (b) both:
 - (i) on that day, the Secretary is yet to decide whether to include the drug in the Australian Register of Therapeutic Goods in response to an application made by the person on or before that day; and
 - (ii) were the drug to be so included, the registration fees for doing so would be waived under paragraph 45(12)(c) of the *Therapeutic Goods Regulations 1990* because the drug is a designated orphan drug; or
 - (c) less than 12 months before that day, the drug was included in the Australian Register of Therapeutic Goods and the registration fees for

doing so had been waived under paragraph 45(12)(c) of the *Therapeutic Goods Regulations 1990* because the drug was a designated orphan drug.

- (6) For the purposes of paragraphs (5)(b) and (c) of this section, the registration fees are the fees described in paragraph 23B(2)(b) and subsection 24(1A) of the *Therapeutic Goods Act 1989*.

Including reasons for exemption in submission or application or notice of intent

- (7) A person who has made a submission or an application for services under this instrument and who considers that subsection (1), (2) or (4) applies to provide a fee exemption for the services must include in the submission or application the reasons why that subsection applies to provide a fee exemption, unless the person has complied with subsection (8).
- (8) If a person:
- (a) proposes to make an ATAGI application, a submission or a pricing application in relation to which the person expects subsection (1), (2) or (4) to apply to provide a fee exemption; and
 - (b) is required by section 9, 30 or 48 (as applicable) to give the Department a notice of intent in relation to the proposed ATAGI application, submission or pricing application;
- the person must include in the notice of intent the reasons why subsection (1), (2) or (4) of this section is expected to apply to provide a fee exemption.

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

- (1) The Secretary may, in writing and on request by a person made in accordance with subsection (2), decide whether or not to waive one or more fees payable by the person for the provision of services in response to the person's ATAGI application, submission or pricing application.

Note: A decision not to waive a fee that is payable is reviewable (see section 71).

- (2) The request must be made:
- (a) in the person's ATAGI application, submission, or pricing application (as applicable); or
 - (b) if, under section 9, 30 or 48 (as applicable), a notice of intent is required in relation to the proposed ATAGI application, submission or pricing application—in the notice of intent.
- (3) The Secretary must decide under subsection (1) to waive one or more of the fees if:
- (a) the ATAGI application, submission or pricing application involves the public interest; and
 - (b) payment of all of the fees would make the ATAGI application, submission or pricing application financially unviable.
- (4) Without limiting subsection (3), an ATAGI application, submission or pricing application involves the public interest if:

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- (a) it concerns a drug, medicinal preparation or vaccine that would represent suitable therapy for a patient population; and
- (b) the patient population is not large enough to make the ATAGI application, submission or pricing application financially viable; and
- (c) the drug, medicinal preparation or vaccine is to be used:
 - (i) for palliative care; or
 - (ii) as a paediatric medicine; or
 - (iii) for medical treatment of Aboriginal or Torres Strait Islander peoples.

69 Waiver of fees for provision of list management services

- (1) The Secretary may, in writing and on request by a person made in accordance with subsection (2), decide whether or not to waive the fee payable by the person under Part 5 for list management services provided in response to a list management application.

Note: A decision not to waive a fee that is payable is reviewable (see section 71).

- (2) The request must be included in the list management application.
- (3) The Secretary must decide under subsection (1) to waive the fee if:
 - (a) the list management application involves the public interest; and
 - (b) payment of the fee would make the application financially unviable.
- (4) Without limiting subsection (3), a list management application involves the public interest if:
 - (a) it concerns a drug, medicinal preparation or vaccine that would represent suitable therapy for a patient population; and
 - (b) the patient population is not large enough to make the application financially viable; and
 - (c) the drug, medicinal preparation or vaccine is to be used:
 - (i) for palliative care; or
 - (ii) as a paediatric medicine; or
 - (iii) for medical treatment of Aboriginal or Torres Strait Islander peoples.

Part 8—Review of decisions

70 Simplified outline of this Part

Certain decisions under this instrument may be reviewed internally and by the Administrative Appeals Tribunal.

71 Reviewable decisions

This Part applies to the following decisions (*reviewable decisions*) of the Secretary:

- (a) a decision under subsection 8(1) that an ATAGI application is not in a simple category;
- (b) a refusal under subsection 9(3) to decide that a notice of intent in relation to a proposed ATAGI application is not required;
- (c) a refusal under subsection 30(3) to decide that a notice of intent in relation to a proposed submission is not required;
- (d) a decision under subsection 37(1) determining the evaluation category that a submission is in;
- (e) a refusal under subsection 48(3) to decide that a notice of intent in relation to a proposed pricing application is not required;
- (f) a decision under subsection 52(1) determining the pricing category that a pricing application is in;
- (g) a decision under subsection 65(2) not to refund a fee;
- (h) a decision under subsection 65(3) not to remit a fee;
- (i) a decision under subsection 68(1) or 69(1) not to waive a fee that is payable;
- (j) a decision under subsection 74(2) (about decisions made on reviews initiated by the Secretary).

Note: The decision could be made by a delegate of the Secretary (see subsection 6(5) of the Act).

72 Notice of review rights

- (1) If the Secretary makes a reviewable decision referred to in paragraph 71(b), (c), (e) or (j), the Secretary must, within 10 business days after making the decision, give the person affected by the decision:
 - (a) written notice of the decision; and
 - (b) a statement setting out particulars of the person's review rights.
- Note: Notice of these things for the other kinds of reviewable decisions is given under other provisions of this instrument.
- (2) The notice must include particulars about how the person may respond to the notice.
- (3) Failure to comply with subsection (1) does not affect the validity of the decision.

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73 Internal review

Initial internal review

- (1) If a reviewable decision is made, the person affected by the decision may apply, in writing, to the Secretary for review of the decision.
- (2) The application must:
 - (a) be made within:
 - (i) 10 business days after the applicant received notice under this instrument of the reviewable decision; or
 - (ii) such longer period (if any) allowed by the Secretary; and
 - (b) set out the reasons for making the application.
- (3) A person authorised under subsection (6) must, within 10 business days after receiving the application:
 - (a) review the reviewable decision; and
 - (b) make a decision (the **initial review decision**):
 - (i) to affirm or vary the reviewable decision; or
 - (ii) to revoke the reviewable decision, and make any other decision that the person thinks appropriate; and
 - (c) give the applicant written notice of the initial review decision.

Further internal review

- (4) The applicant may, within 10 business days after receiving notice of the initial review decision under paragraph (3)(c), request the Secretary, in writing to review the initial review decision.
- (5) The Secretary, or a person authorised under subsection (6), (the **further reviewer**) must, within 10 business days after receiving the request under subsection (4):
 - (a) review the initial review decision and decide (the **further review decision**):
 - (i) to affirm or vary the initial review decision; or
 - (ii) to revoke the initial review decision, and make any other decision that the further reviewer thinks appropriate; and
 - (b) give written notice to the applicant of the further review decision.

Persons authorised by the Secretary

- (6) The Secretary may, in writing, authorise an SES employee, or an acting SES employee, in the Department to act under subsection (3) or (5).
- (7) However:
 - (a) a person must not review a reviewable decision under subsection (3) if the person was involved in making the reviewable decision; and
 - (b) a person must not review an initial review decision under subsection (5) if the person was involved in making:
 - (i) the initial review decision; or
 - (ii) the reviewable decision to which the initial review decision relates.

Discretion to suspend any services to which the review relates

- (8) If an application or request for review is being considered under this section, the Commonwealth may suspend any services under this instrument to which the reviewable decision relates.

74 Secretary may initiate internal review

- (1) The Secretary may, at any time, initiate a review of a reviewable decision (other than an earlier decision under subsection (2)).

Note: The review could be initiated by a delegate of the Secretary (see subsection 6(5) of the Act).

- (2) The Secretary may:
- (a) affirm, vary or revoke the reviewable decision; and
 - (b) if the Secretary revokes the reviewable decision—make any other decision the Secretary thinks appropriate.

Note: Notice must be given of a decision under this subsection (see subsection 72(1)).

75 Notice of fee adjustment

If a person has underpaid or overpaid a fee as a result of a decision made under any of the following provisions, the Secretary must, within 20 business days after the decision was made, notify the person accordingly:

- (a) paragraph 73(3)(b) (an initial review decision);
- (b) paragraph 73(5)(a) (a further review decision);
- (c) subsection 74(2) (a Secretary-initiated review decision).

Note: A further payment, or a refund, may be required (see subsections 62(3) and (4)).

76 Review by the Administrative Appeals Tribunal

- (1) Applications may be made to the Administrative Appeals Tribunal for review of a decision under paragraph 73(5)(a) of the further reviewer referred to in that paragraph.
- (2) If such an application is being considered by the Administrative Appeals Tribunal, the Commonwealth may suspend any services under this instrument to which the decision relates.

Part 9—Application and transitional provisions

Division 1—Application of this instrument as originally made

77 Definitions for this Division

In this Division:

commencement day means the day this instrument commences.

old Regulations means the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009*, as in force immediately before the commencement day.

services means any of the following:

- (a) ATAGI advice;
- (b) the service of the Department holding a pre-submission meeting with a person;
- (c) submission services;
- (d) pricing services;
- (e) list management services.

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

This instrument applies to a submission or an application (including a remade submission or application) for the provision of services that is received by the Department on or after the commencement day.

79 Prior notice of certain applications given before commencement day

(1) If:

- (a) before the commencement day, a person had given prior notice of an application for the provision of submission services under Part 2 of the old Regulations; and
- (b) either:
 - (i) the Department had not received the application for the provision of the submission services before the commencement day; or
 - (ii) the Department had received the application for the provision of the submission services before the commencement day, but the assessment of the application had not been completed before the commencement day;

the person is taken, on and after the commencement day, to have given a notice of intent under section 30 of this instrument in relation to a submission for the provision of the submission services.

(2) If:

- (a) before the commencement day, a person had given prior notice of a pricing application for the provision of pricing services under Part 3 of the old Regulations; and
- (b) either:
 - (i) the Department had not received the pricing application for the provision of the pricing services before the commencement day; or
 - (ii) the Department had received the pricing application for the provision of the pricing services before the commencement day, but the assessment of the application had not been completed before the commencement day;

the person is taken, on and after the commencement day, to have given a notice of intent under section 48 of this instrument in relation to a pricing application for the provision of the pricing services.

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

- (1) If:
 - (a) an application for the provision of submission services made under Part 2 of the old Regulations was received by the Department before the commencement day; and
 - (b) the Secretary had not given a notification relating to the application, or the prior notice of the application (if any), under the old Regulations before the commencement day; and
 - (c) the application had not been withdrawn before the commencement day;this instrument applies in relation to the application as if it were a submission made under Part 3 of this instrument for the provision of the submission services.

Note 1: A notification will be given under section 33 of this instrument for the application or the prior notice of the application (if any).

Note 2: Other provisions in this instrument will also apply in relation to the submission, for example, section 34 (Secretary may refuse to accept incomplete submission), section 35 (withdrawal of notice of intent or submission, and refund of fee or liability for deposit), section 36 (remaking submissions), section 37 (Secretary may determine evaluation category that submission is in) and section 38 (assessing submissions).

- (2) If:
 - (a) an application for the provision of services (the *relevant services*) made under the old Regulations (other than an application for the provision of submission services made under Part 2 of the old Regulations) was received by the Department before the commencement day; and
 - (b) the Secretary had not given a notification relating to the application, or the prior notice of the application (if any), under the old Regulations before the commencement day; and
 - (c) the application had not been withdrawn before the commencement day;this instrument applies in relation to the application as if it were an application made under this instrument for the provision of the relevant services.

Note 1: A notification will be given under section 11, 17, 50 or 58 (as the case requires) of this instrument for the application or the prior notice of the application (if any).

Part 9 Application and transitional provisions

Division 1 Application of this instrument as originally made

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- Note 2: Other provisions in this instrument will also apply in relation to the application, for example:
- (a) in relation to an ATAGI application—section 12 (withdrawal of notice of intent or ATAGI application, and refund of fee or liability for deposit) and section 13 (remaking ATAGI applications); and
 - (b) in relation to a pre-submission meeting application—section 18 (withdrawal of pre-submission meeting application, and refund of fee) and section 19 (remaking pre-submission meeting applications); and
 - (c) in relation to a pricing application—section 51 (withdrawal of notice of intent or pricing application, and refund of fee or liability for deposit), section 52 (Secretary may determine pricing category that pricing application is in), section 53 (cessation of pricing services 6 months after pricing application is made) and section 54 (refund if deed not made within 6 months after pricing application is made); and
 - (d) in relation to a list management application—section 59 (withdrawal of list management application, and refund of fee) and section 60 (refund of part of fee if replacement for expired deed not made).

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

- (1) If:
- (a) an application for the provision of submission services made under Part 2 of the old Regulations was received by the Department before the commencement day; and
 - (b) the Secretary had given a notification relating to the application, or the prior notice of the application (if any), under the old Regulations before the commencement day; and
 - (c) the application had not been withdrawn before the commencement day; and
 - (d) the assessment of the application had not been completed before the commencement day;
- this instrument applies:
- (e) in relation to the application—as if it were a submission made under Part 3 of this instrument for the provision of the submission services; and
 - (f) in relation to the notification—as if it had been given under section 33 of this instrument.

- Note: Other provisions in this instrument will also apply in relation to the submission and the notification, for example, section 34 (Secretary may refuse to accept incomplete submission), section 35 (withdrawal of notice of intent or submission, and refund of fee or liability for deposit), section 36 (remaking submissions), section 37 (Secretary may determine evaluation category that submission is in) and section 38 (assessing submissions).

- (2) If:
- (a) an application for the provision of services (the *relevant services*) made under the old Regulations (other than an application for the provision of submission services made under Part 2 of the old Regulations) was received by the Department before the commencement day; and
 - (b) the Secretary had given a notification relating to the application, or the prior notice of the application (if any), under the old Regulations before the commencement day; and

- (c) the application had not been withdrawn before the commencement day;
and
- (d) the assessment of the application had not been completed before the commencement day;

this instrument applies:

- (e) in relation to the application—as if it were an application made under this instrument for the provision of the relevant services; and
- (f) in relation to the notification—as if it had been given under section 11, 17, 50 or 58 (as the case requires) of this instrument.

Note: Other provisions in this instrument will also apply in relation to the application, for example:

- (a) in relation to an ATAGI application—section 12 (withdrawal of notice of intent or ATAGI application, and refund of fee or liability for deposit) and section 13 (remaking ATAGI applications); and
- (b) in relation to a pre-submission meeting application—section 18 (withdrawal of pre-submission meeting application, and refund of fee) and section 19 (remaking pre-submission meeting applications); and
- (c) in relation to a pricing application—section 51 (withdrawal of notice of intent or pricing application, and refund of fee or liability for deposit), section 52 (Secretary may determine pricing category that pricing application is in), section 53 (cessation of pricing services 6 months after pricing application is made) and section 54 (refund if deed not made within 6 months after pricing application is made); and
- (d) in relation to a list management application—section 59 (withdrawal of list management application, and refund of fee) and section 60 (refund of part of fee if replacement for expired deed not made).

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

- (1) This section applies if:
 - (a) a person had made an ATAGI application under Division 1A.1 of the old Regulations for the provision of services that directly or indirectly related to a proposed Part 2 submission under the old Regulations; and
 - (b) the person had not made the related Part 2 submission before the commencement day; and
 - (c) the person wishes to request the Secretary to waive the fee payable by the person for the provision of services in response to the ATAGI application.
- (2) The person must include the request for waiver of the fee:
 - (a) in the related submission made by the person under Part 3 of this instrument; or
 - (b) if, under section 30 of this instrument, a notice of intent is required in relation to the proposed related submission—in the notice of intent.
- (3) The Secretary must notify the person, in writing, of the following:
 - (a) whether the fee is waived;
 - (b) if the fee is not waived:
 - (i) the person's review rights under Part 8 of this instrument; and
 - (ii) the amount of the fee that is payable for the provision of services in response to the ATAGI application; and

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(iii) the manner for paying the fee.

- (4) The information required to be notified under subsection (3) must be included in the notification given under section 33 of this instrument in relation to:
- (a) the related submission; or
 - (b) if applicable, the notice of intent in relation to the proposed related submission.

83 Review of decisions made under the old Regulations

- (1) Without limiting its operation apart from this section, Part 8 of this instrument applies, as modified under subsections (2) to (4) of this section, in relation to a reviewable decision that was made under the old Regulations.
- (2) For the purposes of applying Part 8 of this instrument in relation to a reviewable decision that was made under the old Regulations:
- (a) section 71 of this instrument applies as if it included a reference to each decision referred to in regulation 6.1A of the old Regulations; and
 - (b) subparagraph 73(2)(a)(i) of this instrument applies as if “this instrument” were omitted and “the old Regulations” were substituted; and
 - (c) subsection 74(1) of this instrument applies as if “subsection (2)” were omitted and “subregulation 6.3(2) of the old Regulations” were substituted; and
 - (d) subsection 76(1) of this instrument applies as if it also provided that applications may be made to the Administrative Appeals Tribunal for review of a decision under paragraph 6.2(5)(a) of the old Regulations of the further reviewer referred to in that paragraph.
- (3) If:
- (a) the Secretary had made a reviewable decision referred to in paragraph 6.1A(b), (d) or (g) of the old Regulations; and
 - (b) the Secretary had not, before the commencement day, given the person to whom the reviewable decision relates the information required by section 6.1 of the old Regulations in relation to the reviewable decision;
- section 72 of this instrument applies as if the reference to a reviewable decision in subsection (1) of that section were a reference to a reviewable decision referred to in paragraph 6.1A(b), (d) or (g) of the old Regulations.

Note: The effect of this subsection is that the Secretary will be required to comply with section 72 of this instrument in relation to the reviewable decision.

- (4) If:
- (a) the Secretary was required to notify a person under regulation 6.4 of the old Regulations about an underpayment or an overpayment that has occurred as a result of a reviewable decision referred to in that regulation; and
 - (b) the Secretary had not, before the commencement day, notified the person as required by that regulation;
- section 75 of this instrument applies as if:

- (c) the reference to paragraph 73(3)(b) of this instrument were a reference to paragraph 6.2(3)(b) of the old Regulations; and
- (d) the reference to paragraph 73(5)(a) of this instrument were a reference to paragraph 6.2(5)(a) of the old Regulations; and
- (e) the reference to subsection 74(2) of this instrument were a reference to subregulation 6.3(2) of the old Regulations.

Note: The effect of this subsection is that the Secretary will be required to comply with section 75 of this instrument in relation to the reviewable decision and the overpayment or underpayment.

84 Things done under the old Regulations

- (1) Without limiting any other provision in this Part, if:
 - (a) a thing was done for a particular purpose under the old Regulations; and
 - (b) the thing could be done for that purpose under this instrument;the thing has effect for the purposes of this instrument as if it had been done for that purpose under this instrument.
- (2) Without limiting subsection (1), a reference in that subsection to a thing being done includes a reference to a notice, application or other instrument being given or made.

Schedule 1—Powers of the Minister under the Act

Note: See sections 14, 21, 23, 24, 25, 26, 27, 28, 30 and 31.

Powers under the Act that the Minister may be requested to exercise

Item	Powers under the Act
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Part 1—Vaccines

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| 1.1 | To specify a vaccine to be a designated vaccine in a determination under subsection 9B(2) of the Act |
| 1.2 | To vary the determination of a designated vaccine under subsection 9B(2) of the Act to change the way in which a vaccine has been specified |
| 1.3 | To vary the determination of a designated vaccine under subsection 9B(2) of the Act to add a new circumstance in which the vaccine may be provided |
| 1.4 | To vary the determination of a designated vaccine under subsection 9B(2) of the Act to change a circumstance in which the vaccine may be provided but not so as to add a new circumstance |

Part 2—Pharmaceuticals

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| 2.1 | To declare a drug or medicinal preparation under subsection 85(2) of the Act and, if applicable, subsection 85(2A) of the Act |
| 2.2 | To vary a declaration made under subsection 85(2) of the Act and, if applicable, subsection 85(2A) of the Act |
| 2.3 | To determine circumstances, or vary an existing determination to add a new circumstance, in which a prescription for the supply of a pharmaceutical benefit may be written under subsection 85(7) or paragraph 85(8)(b) of the Act |
| 2.4 | To vary an existing determination to change the circumstances in which a prescription for the supply of a pharmaceutical benefit may be written under subsection 85(7) or paragraph 85(8)(b) of the Act but not so as to add a new circumstance |
| 2.5 | To determine, or vary a determination about: <ul style="list-style-type: none"> (a) a form of a listed drug under subsection 85(3) of the Act; or (b) the manner of administration of a form of a listed drug under subsection 85(5) of the Act |
| 2.6 | To determine, or vary a determination, under paragraph 85(8)(a) of the Act, that a pharmaceutical benefit (other than a pharmaceutical benefit that has a drug covered by subsection 85(2A) of the Act) can only be supplied under special arrangements under section 100 of the Act |
| 2.7 | To determine matters, or vary an existing determination of matters, under subsection 85A(2) of the Act, with respect to the writing of prescriptions by a specified class of persons for the supply of a pharmaceutical benefit |
| 2.8 | To specify, or vary the specification of, a class of persons in a determination made under subsection 85A(1) or (2) of the Act |
| 2.9 | To determine for the purposes of subsection 88(1), (1A), (1C), (1D) or (1E) of the Act a pharmaceutical benefit the supply of which a PBS prescriber referred to in that subsection is authorised to write a prescription, or to vary such a determination |
| 2.10 | To vary the specification of a pharmaceutical item under subsection 84AAA(2) of the Act so that it no longer applies to a pharmaceutical benefit |
| 2.11 | To make a determination about the supply of a pharmaceutical benefit under section 93, 93AA or 93AB of the Act |

Powers under the Act that the Minister may be requested to exercise

Item Powers under the Act

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| 2.12 | To make or vary a special arrangement under section 100 of the Act to provide for the supply of pharmaceutical benefits |
| 2.13 | To specify a circumstance in which a pharmaceutical benefit may be supplied in a special arrangement made under section 100 of the Act, or to vary an existing special arrangement to specify a new circumstance |
| 2.14 | To vary the circumstances in which a pharmaceutical benefit may be supplied in an existing special arrangement made under section 100 of the Act but not so as to add a new circumstance |
| 2.15 | To agree on a new price for a single brand of a combination item under subsection 99ACC(3) of the Act

Note: The Committee may advise the Minister about this under subsection 101(4AC) of the Act. |
| 2.16 | To determine that a pharmaceutical item is an exempt item under section 84AH of the Act

Note: The Committee may advise the Minister about this under subsection 101(4AB) of the Act. |
| 2.17 | To revoke or vary, under subsection 101(4AAE) of the Act, a declaration under subsection 85(2A) of the Act so that a listed drug is generally available for supply under Part VII of the Act rather than available only under special arrangements under section 100 of the Act |
| 2.18 | To enter into a deed with a person under section 85E of the Act or to vary a deed entered into with a person under section 85E of the Act |

Part 3—Existing pharmaceutical items

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| 3.1 | To determine a brand under subsection 85(6) of the Act for a pharmaceutical item that has a listed brand |
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Schedule 2—Repeals

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009

1 The whole of the instrument

Repeal the instrument.