



National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 04 April 2019

Peter Cosgrove
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019*.

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 July 2019.	1 July 2019

Note: This table relates only to the provisions of this instrument as originally made.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*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

1 Regulation 1.3

Insert:

amount includes a nil amount.

ATAGI means the Commonwealth acting through the Australian Technical Advisory Group on Immunisation.

ATAGI application means an application under Division 1A.1.

Australian Register of Therapeutic Goods has the same meaning as in the *Therapeutic Goods Act 1989*.

2 Regulation 1.3 (definition of *Committee*)

After “means”, insert “the Commonwealth acting through”.

3 Regulation 1.3

Insert:

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

4 Regulation 1.3 (definition of *economic evaluation*)

After “an application”, insert “under Part 2”.

5 Regulation 1.3 (definition of *evaluation fee*)

Repeal the definition.

6 Regulation 1.3

Insert:

list management application means an application under Part 3A.

list management services means services provided as described in regulation 3A.1.

meeting application means an application under Division 1A.2.

notification, for an application, means a notification given under:

- (a) for an ATAGI application—regulation 1A.4; or
- (b) for a meeting application—regulation 1A.10; or
- (c) for an application under Part 2 for which prior notice is required under subregulation 2.15(1)—subregulation 2.17(1) about the prior notice of the application; or
- (d) for an application under Part 2 for which prior notice is not required under subregulation 2.15(1)—subregulation 2.17(2); or

- (e) for a pricing application for which prior notice is given as described in paragraph 3.10(1)(a)—subregulation 3.12(1) about the prior notice of the pricing application; or
- (f) for a pricing application for which prior notice is not given as described in paragraph 3.10(1)(a)—subregulation 3.12(2); or
- (g) for a list management application—regulation 3A.3.

Part 2 submission means a submission referred to in subregulation 2.1(1).

pricing application means an application under Part 3.

7 Regulation 1.3 (definition of *pricing fee*)

Repeal the definition.

8 Regulation 1.3

Insert:

pricing services means services provided as described in subregulation 3.2(1).

submission due day has the meaning given by subregulation 2.16(3).

submission services means services provided as described in subregulation 2.2(1).

9 Regulation 1.3 (definition of *therapy*)

After “an application”, insert “under these Regulations”.

10 Regulation 1.3

Insert:

usual ATAGI fee has the meaning given by subregulation 1A.1(2).

11 After Part 1

Insert:

Part 1A—Pre-submission services

Division 1A.1—Providing ATAGI advice

1A.1 Fees for providing ATAGI advice

- (1) ATAGI may provide advice to a person:
 - (a) in response to an application (the **ATAGI application**) by the person; and
 - (b) for the person to include in a proposed Part 2 submission to the Committee that the Committee recommend to the Minister that the Minister exercise a power under section 9B of the Act.
- (2) For the purposes of section 99YBA of the Act, the fee (the **usual ATAGI fee**) prescribed for providing the ATAGI advice to the person is:
 - (a) if the notification for the person’s ATAGI application is given during the financial year starting on 1 July 2019—\$295,420; or

- (b) if the notification for the person's ATAGI application is given during the financial year starting on 1 July 2020—\$300,440.

Note: This fee is indexed for later financial years (see regulation 4.7).

1A.2 Partial exemption from usual ATAGI fee for simple ATAGI applications

Person may be partially exempt from usual ATAGI fee

- (1) The Secretary may, in writing and on request, decide whether or not to partially exempt a person from the usual ATAGI fee.

Note 1: A decision not to partially exempt a person is reviewable (see regulation 6.1A).

Note 2: Regardless of this regulation, in some circumstances the person will be fully exempt from the usual ATAGI fee (see regulation 5.1).

- (2) The Secretary must decide under subregulation (1) to partially exempt the person 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 as 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 entire usual ATAGI fee.

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

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

Fee payable if a person is partially exempt

- (3) If a person is partially exempt under subregulation (1), the fee for providing the ATAGI advice to the person is reduced to:

- (a) if the notification for the person's ATAGI application is given during the financial year starting on 1 July 2019—\$175,570; or
- (b) if the notification for the person's ATAGI application is given during the financial year starting on 1 July 2020—\$178,550.

Note: This reduced fee is indexed for later financial years (see regulation 4.7).

ATAGI application must indicate if partial exemption is requested

- (4) A person who wants the Secretary to make a decision under subregulation (1) must request this in the person's ATAGI application, and include reasons in the ATAGI application why the Secretary should do so.
- (5) The Secretary may, by written notice given to the applicant, seek further information from the applicant in relation to the applicant's request.
- (6) Giving such a notice seeking further information pauses the 21-day period mentioned in subregulation 1A.4(1) for the ATAGI application until the further information is given in accordance with the notice.

1A.3 How to make an ATAGI application

- (1) An ATAGI application must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) be sent to the office of the Department administering ATAGI.

Note: The address for the office administering ATAGI can be found on the Department's website.

- (2) The Secretary may, in writing, approve a form for use in making ATAGI applications.

1A.4 Notification (including invoicing of fees)

- (1) Within 21 days after the day the Department receives an ATAGI application, the Secretary must notify the applicant in writing:
 - (a) that the Department has received the application; and
 - (b) if the applicant requests a fee exemption under regulation 1A.2 or 5.1:
 - (i) whether the fee exemption applies; and
 - (ii) for a request under regulation 1A.2—of the applicant's review rights under Part 6; and
 - (c) of the amount of the fee that is payable for the service of ATAGI providing advice in response to the application; and
 - (d) of the manner for paying that fee.
- (2) The fee for the service is payable to the Department unless a fee exemption applies under regulation 5.1.

Note 1: If a fee exemption under regulation 1A.2 applies, the reduced fee referred to in paragraph (1)(c) (and subregulation 1A.2(3)) is payable.

Note 2: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

1A.5 Withdrawal of an ATAGI application

- (1) An ATAGI application may be withdrawn by written notice to the Department.
- (2) If the ATAGI application is withdrawn within 14 days after the day notice about the application is given under regulation 1A.4, the Department must refund any fee paid for the service of ATAGI providing advice in response to the application.

1A.6 Resending ATAGI applications

- (1) An applicant for an ATAGI application may remake and resend the ATAGI application in the same or an amended form.

Example: An applicant responds to an ATAGI advice by amending, and resending, the ATAGI application with the aim of receiving different ATAGI advice.

- (2) These Regulations apply to the resent application as if it were a new application.

Note: This means, for example, that the resent application will attract a new fee under regulation 1A.1.

Division 1A.2—Holding pre-submission meetings

1A.7 Fees for holding pre-submission meetings

For the purposes of section 99YBA of the Act, the following fee is prescribed for the service of the Department holding a pre-submission meeting with a person:

- (a) in response to an application (the *meeting application*) by the person; and
- (b) in relation to the preparation of the person's proposed Part 2 submission to the Committee that the Committee recommend to, or advise, the Minister that the Minister exercise a power mentioned in an item in Schedule 1.

Fee for providing the service of holding a pre-submission meeting			
Item	Category of pre-submission meeting to be held	Fee if the notification for the application is given during the financial year starting on 1 July 2019	Fee if the notification for the application is given during the financial year starting on 1 July 2020
1	First meeting	\$16,090	\$16,290
2	Second or a subsequent meeting	\$21,090	\$21,360

Note: These fees are indexed for later financial years (see regulation 4.7).

1A.8 How to apply for a pre-submission meeting

- (1) A meeting application, and briefing papers for the meeting, must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) be sent to the office of the Department arranging such meetings.

Note 1: The briefing papers could be provided with the meeting application or afterwards.

Note 2: The address for the office arranging pre-submission meetings can be found on the Department's website.

- (2) The Secretary may, in writing, approve forms for:
 - (a) meeting applications; or
 - (b) briefing papers for pre-submission meetings.

1A.9 Agreeing to hold a pre-submission meeting

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

1A.10 Notification (including invoicing of fees)

- (1) Within 14 days after the day the Department receives both a meeting application and briefing papers for a pre-submission meeting, the Secretary must notify the applicant in writing:
 - (a) that the Department has received the application and briefing papers; and
 - (b) whether the Secretary agrees under regulation 1A.9 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, the notice under subregulation (1) must also state:
 - (a) the category of the pre-submission meeting; and
 - (b) the amount of the fee that is payable for the service of holding the pre-submission meeting; and
 - (c) the manner for paying that fee.
- (3) The fee for the service is payable to the Department.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

1A.11 Withdrawal of a meeting application

- (1) A meeting application may be withdrawn by written notice to the Department.
- (2) If the meeting application is withdrawn before the earlier of:
 - (a) the 15th day after the day notice about the application and briefing papers is given under regulation 1A.10; and
 - (b) the last business day before the day the pre-submission meeting relating to the application is to be held;the Department must refund any fee paid for the service of holding the pre-submission meeting.

1A.12 Resending meeting applications

- (1) An applicant for a meeting application may remake and resend the meeting application in the same or an amended form.
- (2) These Regulations apply to the resent application as if it were a new application.

Note: This means, for example, that the resent application will attract a new fee under regulation 1A.7.

12 Part 2 (heading)

Repeal the heading, substitute:

Part 2—Submission services

Division 2.1A—Preliminary

2.1A Simplified outline of this Part

Submission services are provided in response to a person's submission to the Committee or Minister (also known as an application for those services). The amount of the fee payable for providing the submission services depends on the evaluation category of the person's application.

If the person's application is to the Committee, and is in the major or minor evaluation category, the person will need to have given the Department prior notice at least 28 days before the day the Committee requires applications for the relevant Committee meeting that will be considering the application. The day that the Committee requires applications will be different depending on the evaluation category of the person's application.

This prior notice must include the evaluation category that the application is likely to be in. The person will generally be invoiced a fee for the submission services that reflects this evaluation category.

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

Submission services will not be provided in response to the person's application if this prior notice is not given. The only exception to this is if the Secretary is satisfied that prior notice is not required because the submission services are required to address an urgent public health need.

13 Division 2.1 of Part 2 (heading)

Repeal the heading, substitute:

Division 2.1—Submissions to the Committee or Minister etc.

14 Subdivision 1 of Division 2.1

Repeal the Subdivision, substitute:

Subdivision 1—Fees and associated applications

2.1 Which submissions (also known as applications for services) are relevant?

- (1) A person may prepare a submission (the *application*):
 - (a) that includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in an item in Schedule 1; or
 - (b) for the Minister to exercise a power mentioned in an item of Part 3 of Schedule 1.

- (2) An application may include more than one request relating to the exercise of a power mentioned in an item of Part 1 or 2 of Schedule 1, but only if:
- (a) each of the requests relates to the same drug, medicinal preparation or vaccine; or
 - (b) the application proposes therapy for a disease or disorder and each of the requests relates to the same disease or disorder that is the subject of the proposed therapy.

Note: For details about how to apply, see regulation 2.16.

2.2 Fees for submission services

- (1) For the purposes of section 99YBA of the Act, the following fees are prescribed:
- (a) a fee for the services provided by the Committee in considering whether to make the recommendation, or give the advice, referred to in paragraph 2.1(1)(a);
 - (b) a fee for the services provided by the Commonwealth in assisting the Minister to consider whether to exercise the power referred to in paragraph 2.1(1)(b).

Fee for providing submission services			
Item	Submission services provided in response to an application in this evaluation category:	Fee if the notification for the application is given during the financial year starting on 1 July 2019	Fee if the notification for the application is given during the financial year starting on 1 July 2020
1	Major	\$179,510	\$225,180
2	Minor, otherwise than because of regulation 2.9	\$27,310	\$40,470
3	Minor, because of regulation 2.9	\$26,920	\$40,070
4	Committee secretariat	\$5,940	\$10,880
5	New brand of existing pharmaceutical item	\$2,910	\$5,320

- (2) Each of the fees in items 1 and 2 of the table includes a deposit of:
- (a) if the notification for the application is given during the financial year starting on 1 July 2019—\$390; or
 - (b) if the notification for the application is given during the financial year starting on 1 July 2020—\$400.

Note: These fees and deposits are indexed for later financial years (see regulation 4.7).

15 Regulation 2.3 and subparagraph 2.4(1)(a)(i)

Omit “make a recommendation that the Minister take an action”, substitute “recommend to the Minister that the Minister exercise a power”.

16 Subparagraph 2.4(1)(a)(ii) and paragraph 2.7(1)(b)

Omit “give advice to the Minister in relation to a matter”, substitute “advise the Minister in relation to a power”.

17 Subparagraph 2.7(2)(a)(i)

Omit “make a recommendation that the Minister take an action”, substitute “recommend to the Minister that the Minister exercise a power”.

18 Subparagraph 2.7(2)(a)(ii)

Omit “give advice to the Minister in relation to a matter”, substitute “advise the Minister in relation to a power”.

19 Subregulation 2.8(1)

Omit “make a recommendation that the Minister take an action”, substitute “recommend to the Minister that the Minister exercise a power”.

20 Regulation 2.9

Omit “take an action”, substitute “exercise a power”.

21 Paragraphs 2.10(a) and (b)

Repeal the paragraphs, substitute:

- (a) it is resented under regulation 2.19; and
- (b) it was previously in the major category; and

22 Paragraph 2.12(1)(a) and subregulation 2.12(2)

Omit “make a recommendation that the Minister take an action”, substitute “recommend to the Minister that the Minister exercise a power”.

23 Regulations 2.13 and 2.14

Omit “take an action”, substitute “exercise a power”.

24 Subdivision 5 of Division 2.1

Repeal the Subdivision.

25 Division 2.2

Repeal the Division, substitute:

Division 2.2—Application procedure including prior notice

2.15 Prior notice needed for major or minor applications to the Committee

Prior notice required

- (1) A person proposing to make and send an application in an evaluation category in item 1 or 2 of the table in subregulation 2.2(1) must give the Department prior notice of the application:
 - (a) in accordance with subregulation (5); and
 - (b) at least 28 days before the application’s submission due day.

Note 1: Requiring this prior notice allows the Commonwealth to properly prepare for the provision of submission services in response to the application.

Note 2: The application will need to be sent to the Department on or before this submission due day (see paragraph 2.16(1)(c)).

Exception if an urgent public health need

- (2) However, prior notice of the application is not required under subregulation (1) if the Secretary decides under subregulation (3) that providing submission services in response to the application is required to address an urgent public health need.
- (3) The Secretary may, in writing, decide whether or not providing submission services in response to the application is required to address an urgent public health need.

Note: A decision that providing the submission services is not required to address an urgent public health need is reviewable (see regulation 6.1A).

Consequence if prior notice is required but not given

- (4) Submission services will not be provided in response to an application if prior notice of the application:
 - (a) is required under subregulation (1); and
 - (b) is not given in accordance with that subregulation.

How to provide prior notice

- (5) A prior notice under subregulation (1) must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) state, with reasons, why the proposed application is likely to be in a particular evaluation category; and
 - (c) be sent to the office of the Department administering the Committee.

Note: The address for the office administering the Committee can be found on the Department's website.

- (6) The Secretary may, in writing, approve forms for use in giving a prior notice under subregulation (1) of an application under this Part.

2.16 How to apply for submission services*Procedural requirements for applications*

- (1) An application under this Part must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) if prior notice of the application is not required under subregulation 2.15(1)—state, with reasons, why the application is likely to be in a particular evaluation category; and
 - (c) be sent, on or before the application's submission due day (if any), to:
 - (i) for an application that is likely to be in an evaluation category because of regulation 2.9, 2.13 or 2.14—the office of the Department administering applications about item 3.1 in Schedule 1; or
 - (ii) otherwise—the office of the Department administering the Committee.

Note: The addresses for the offices mentioned in paragraph (c) can be found on the Department's website.

- (2) The Secretary may, in writing, approve forms for use in making applications under this Part.

Submission due day

- (3) For an application under this Part that:

- (a) is for the Committee; and
- (b) is likely to be in a particular evaluation category;

the **submission due day** is the day by which the Committee needs to have received applications in that evaluation category for the Committee meeting that is to consider the application.

Note: The submission due day for applications in one evaluation category could be different from that for applications in another evaluation category.

- (4) The Secretary must ensure that the submission due days for future Committee meetings are published on the Department's website.

2.17 Notification (including invoicing of fees)

Notices relating to proposed major or minor applications for the Committee

- (1) Within 14 days after the day the Department receives a notice under subregulation 2.15(1) from a person about a proposed application, the Secretary must notify the person in writing:
- (a) that the Department has received the notice; and
 - (b) based on the statement in the notice about the evaluation category of the proposed application—of the amount of the fee that is payable for providing submission services in response to the proposed application; and
 - (c) of the manner for paying that fee.

The fee for the submission services is payable to the Department.

Note 1: The fee must be paid within a period starting when this notification is given (see paragraph 4.1(1)(b)).

Note 2: For the table in subregulation 2.2(1), the financial year for working out the fee is the financial year in which this notification is given (see paragraph (c) of the definition of **notification** in regulation 1.3).

Note 3: If it is later found that a fee exemption or waiver under regulation 5.1 or 5.2 applies, a refund may be payable (see subregulation 4.1(4)).

Notices relating to applications

- (2) Within 21 days after the day the Department receives an application under this Part, the Secretary must notify the applicant in writing:
- (a) that the Department has received the application; and
 - (b) if the applicant requests a fee exemption or waiver under regulation 5.1 or 5.2:
 - (i) whether the fee exemption applies, or the fee is waived or partially waived; and
 - (ii) in relation to a request for a waiver—of the applicant's review rights under Part 6; and
 - (c) if prior notice of the application is not required under subregulation 2.15(1):
 - (i) of the amount of the fee payable for providing submission services in response to the application, worked out based on the statement in the application about its evaluation category; and

(ii) of the manner for paying that fee.

- (3) If paragraph (2)(c) applies, the fee for the submission services, or any part of the fee that has not been waived, is payable to the Department unless:

- (a) a fee exemption applies; or
- (b) the fee is waived in its entirety.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

2.18 Withdrawal

Prior notices or applications may be withdrawn at any time

- (1) Either of the following may be withdrawn by written notice to the Department:
- (a) a notice (a **prior notice**) under subregulation 2.15(1) given about a proposed application;
 - (b) an application under this Part.

When a withdrawal will result in a refund

- (2) If the prior notice is withdrawn within 14 days after the day a notification is given under subregulation 2.17(1) about the prior notice, the Department must refund any fee paid for providing submission services in response to the proposed application except for the deposit referred to in subregulation 2.2(2).
- (3) If all of the following apply:
- (a) prior notice of the application is not required under subregulation 2.15(1);
 - (b) a notification is given under subregulation 2.17(2) about the application;
 - (c) the application is withdrawn within 14 days after the day that notification is given;
- the Department must refund any fee paid for providing submission services in response to the application.

2.19 Resending applications

- (1) An applicant for an application under this Part may remake and resend the application in the same or an amended form. These Regulations apply to the resent application as if it were a new application.

Note: This means, for example, that the resent application will attract a new fee under regulation 2.2.

- (2) Despite subregulation (1) and regulation 2.15, prior notice under subregulation 2.15(1) of the resent application is not required if the Secretary agrees to this under subregulation (3) of this regulation.

Note: Prior notice will also not be required if the resent application is in one of the evaluation categories in items 3 to 5 of the table in subregulation 2.2(1).

- (3) The Secretary may, by written notice given to the applicant, agree that prior notice under subregulation 2.15(1) of the resent application is not required if the Secretary is satisfied that:
- (a) the absence of prior notice would not unduly affect the provision of submission services in response to the resent application; and

-
- (b) the resent application would be in the minor category (see Subdivision 3 of Division 2.1) for consideration at the next meeting of the Committee.

Division 2.3—Validating evaluation categories and assessing applications

2.20 Validating an application's evaluation category

- (1) After having:
- (a) had regard to the matters in Division 2.1; and
 - (b) consulted with the Chair of the Committee;
- the Secretary may, in writing, determine that an application under this Part is in one of the evaluation categories mentioned in that Division.

Note: The Secretary may initiate a review of the decision to make the determination (see regulation 6.3).

- (2) If the evaluation category determined under subregulation (1) for the application is different from the evaluation category used to work out the fee notified to the person under regulation 2.17 (or previously under this regulation), the Secretary must notify the person in writing accordingly.

- (3) A notice under subregulation (2) to the person must state:
- (a) the amounts of the fees payable for the submission services that relate to each of those evaluation categories; and
 - (b) the fee amounts already paid, or refunded, (if any) for the submission services; and
 - (c) the fee amount that is to be refunded to, or is payable by, the person that reflects the amounts referred to in paragraphs (a) and (b); and
 - (d) the manner for paying any amount referred to in paragraph (c) that is payable by the person; and
 - (e) the applicant's review rights under Part 6 in relation to the determination under subregulation (1).

Any fee amount notified under paragraph (c) as being payable is payable to the Department.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

- (4) For the purposes of paragraph (3)(a), the fee payable for the submission services that relates to the new evaluation category determined under subregulation (1) is worked out as if that fee had been notified to the person during the same financial year as that in which the notification for the application was given to the person.

2.21 Assessing applications

- (1) The Committee or the Minister may request further information from the applicant about an application under this Part.
- (2) If the Committee, or the Minister, (the **assessor**) is unable to assess such an application without further information, the assessor may ask the Secretary to consider:

- (a) making a determination under subregulation 2.20(1) about the application; or
- (b) reviewing under regulation 6.3 a determination under subregulation 2.20(1), or a decision under subregulation 5.2(1), about the application.

26 Part 3

Repeal the Part, substitute:

Part 3—Pricing services

Division 3.1—Preliminary

3.1 Simplified outline of this Part

Pricing services may be sought after a meeting of the Committee that results in the Committee making a positive recommendation, or giving positive advice, as part of providing submission services under Part 2.

The pricing services will be provided in response to a person's pricing application. The amount of the fee payable for providing the pricing services depends on the category of the person's pricing application.

The person will need to have given the Department at least 7 days prior notice of the pricing application.

This prior notice must include the category that the pricing application is likely to be in. The person will generally be invoiced a fee for the pricing services that reflects this category.

If the Secretary later decides 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 invoiced as appropriate.

Pricing services will be delayed if this prior notice is not given. The only exception to this is if the Secretary is satisfied that prior notice is not required because the pricing services are required to address an urgent public health need.

The pricing application will need to be sent to the Department within 42 days after this prior notice is given.

Division 3.2—Fees and associated applications

3.2 Applications for pricing services

- (1) A person may apply (the *pricing application*) for the Commonwealth to provide services (*pricing services*) in assisting the Minister to consider whether to exercise one or more powers under section 85AD, 85B or 85E of the Act in relation to one or more drugs or medicinal preparations.

Note: For details about how to apply, see regulation 3.11.

- (2) However, the person may only make the pricing application if the Committee has made a positive recommendation, or given positive advice, in response to a single Part 2 submission made to the Committee by the person that covers all of those drugs or medicinal preparations.

Note 1: A single submission can only cover multiple drugs or medicinal preparations in the case set out in paragraph 2.1(2)(b).

Note 2: A separate pricing application is required for a drug or medicinal preparation covered by a separate submission to the Committee. This means separate fees under regulation 3.3 are payable for providing pricing services relating to the drugs or medicinal preparations covered by separate submissions to the Committee.

3.3 Fees for providing pricing services

- (1) For the purposes of section 99YBA of the Act, the following fee is prescribed for the pricing services provided by the Commonwealth in response to the pricing application.

Fee for providing pricing services			
Item	Pricing services provided in response to this category of pricing application:	Fee if the notification for the application is given during the financial year starting on 1 July 2019	Fee if the notification for the application is given during the financial year starting on 1 July 2020
1	Pricing Pathway A	\$119,310	\$120,810
2	Pricing Pathway B	\$92,530	\$93,700
3	Pricing Pathway C	\$58,180	\$58,920
4	Pricing Pathway D	\$13,550	\$19,910
5	Pricing Secretariat	\$6,140	\$10,890

- (2) Each of these fees includes a deposit of:
- if the notification for the pricing application is given during the financial year starting on 1 July 2019—\$390; or
 - if the notification for the pricing application is given during the financial year starting on 1 July 2020—\$400.

Note: These fees and deposits are indexed for later financial years (see regulation 4.7).

3.4 Pricing Pathway A applications

A person's pricing application is in the Pricing Pathway A category if:

- as part of the Committee's recommendation or advice responding to the person's Part 2 submission covering the drugs or medicinal preparations to which the pricing application relates, the Committee finds that:
 - 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
 - the drugs or medicinal preparations address a high and urgent unmet clinical need; and
 - it would be in the public interest for a pricing application relating to the drugs or medicinal preparations to be in this category; and
- the pricing application states that the application is to be in this category.

Note: Prior notice of the pricing application will also need to state that the pricing application is to be in this category (see subregulation 3.10(5)).

3.5 Pricing Pathway B applications

- (1) A person's pricing application is in the Pricing Pathway B category if:
 - (a) the pricing application seeks the entering into of a deed under section 85E of the Act for 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 about the following (the ***pricing terms***):
 - (i) reimbursing the Commonwealth;
 - (ii) providing the Commonwealth with information;
 that are substantially similar to those appropriate for the new drugs; and
 - (c) the pricing application is not in the Pricing Pathway A category.

Note: Regulation 3.7 is relevant to paragraph (b).

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

3.6 Pricing Pathway C applications

- (1) A person's pricing application is in the Pricing Pathway C category if:
 - (a) the pricing application seeks the entering into of a deed under section 85E of the Act for 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 about the following (the ***pricing terms***):
 - (i) reimbursing the Commonwealth;
 - (ii) providing the Commonwealth with information;
 that are substantially similar to those appropriate for the new drugs; and
 - (c) the pricing application is not in the Pricing Pathway A category.

Note: Regulation 3.7 is relevant to paragraph (b).

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

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

- (1) This regulation applies for the purposes of paragraphs 3.5(1)(b) and 3.6(1)(b).

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

- (2) The pricing terms in an existing deed will be substantially similar to those appropriate for the new drugs if, under those terms, the new drugs can share an existing subsidisation cap with the drugs or medicinal preparations in the existing deed.

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- (3) The pricing terms in an existing deed will be substantially similar to those appropriate for the new drugs if:
- (a) the Committee's recommendation or advice responding to the person's Part 2 submission 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 that submission of the kind referred to in subparagraphs 3.8(2)(a)(i), (ii) and (iii).

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

- (4) Despite subregulations (2) and (3), the pricing terms in an existing deed will not be substantially similar to those appropriate for the new drugs if:
- (a) those terms relate to further clinical testing, or to the collection of further clinical data on the effectiveness, of drugs or medicinal preparations; or
 - (b) those terms, to the extent that they reimburse the Commonwealth, include taking into account the clinical response of patients to drugs or medicinal preparations; or
 - (c) those terms include an existing subsidisation cap that cannot be shared with the new drugs; or
 - (d) those terms, to the extent that they reimburse 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 subregulations are not exhaustive

- (5) This regulation does not set out the only circumstances in which the pricing terms in an existing deed will be, or will not be, substantially similar to those appropriate for the new drugs.

3.8 Pricing Pathway D applications

- (1) A person's pricing application is in the Pricing Pathway D category if:
- (a) subregulation (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 for the drugs or medicinal preparations to which the pricing application relates (the **new drugs**); and
 - (c) the pricing application is not in the Pricing Pathway A category.
- (2) This subregulation applies to the pricing application if the pricing application:
- (a) notes that the person's Part 2 submission to the Committee covering the new drugs included 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

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- (b) notes that the claims are consistent with the Committee's recommendation or advice to the Minister responding to that submission; and
 - (c) suggests a price based on the claims.
- (3) This subregulation applies to the pricing application if:
- (a) the pricing application notes that the person's Part 2 submission to the Committee covering the new drugs:
 - (i) claimed that the use of the new drugs provides a significant improvement in the efficacy or reduction in toxicity compared to any alternative therapy; and
 - (ii) requested for the new drugs a higher price per treatment, or price per unit, than that for an alternative therapy; and
 - (b) the pricing application requests for the new drugs a higher price per treatment, or price per unit, than that for:
 - (i) the alternative therapy referred to in subparagraph (a)(ii); or
 - (ii) another alternative therapy if, as part of the Committee's recommendation or advice (the *Committee's response*) responding to that submission, the Committee finds that the other therapy is clinically comparable to the new drugs; and
 - (c) the claim in paragraph (a) and the requests in paragraphs (a) and (b) are consistent with the Committee's response.
- (4) This subregulation applies to the pricing application if:
- (a) the pricing application notes that the person's Part 2 submission to the Committee covering the new drugs included 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 responding to that submission.
- (5) This subregulation applies to the pricing application if:
- (a) the pricing application notes that the person's Part 2 submission to the Committee covering the new drugs included 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 responding to that submission.

3.9 Pricing Secretariat applications

A person's pricing application is in the Pricing Secretariat category if it is not in the Pricing Pathway A, B, C or D category.

Division 3.3—Application procedure including prior notice

3.10 Prior notice of pricing applications needed

Prior notice required

- (1) A person proposing to make and send a pricing application:
 - (a) must give the Department prior notice of the pricing application in accordance with subregulation (5); and
 - (b) must do so at least 7 days before the day the person sends the proposed pricing application to the Department.

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

Note 2: The pricing application will need to be sent to the Department within 42 days after this prior notice is given (see paragraph 3.11(1)(d)).

Exception if an urgent public health need

- (2) However, prior notice of the pricing application is not required under subregulation (1) if the Secretary decides under subregulation (3) that providing pricing services in response to the pricing application is required to address an urgent public health need.
- (3) The Secretary may, in writing, decide whether or not providing pricing services in response to the pricing application is required to address an urgent public health need.

Note: A decision that providing the pricing services is not required to address an urgent public health need is reviewable (see regulation 6.1A).

Consequence if prior notice is required but not given

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

The pricing services will not begin to be provided until at least 7 days after the day the pricing application is sent to the Department.

How to provide prior notice

- (5) A prior notice under subregulation (1) must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) state, with reasons, why the proposed pricing application is to be in a particular category; and
 - (c) be sent to the office of the Department arranging pricing services.

Note: The address for the office arranging pricing services can be found on the Department's website.

- (6) The Secretary may, in writing, approve forms for use in giving a prior notice under subregulation (1) of a pricing application.

3.11 How to apply for pricing services

- (1) A pricing application must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) if prior notice of the pricing application is not given as described in paragraph 3.10(1)(a)—state, with reasons, why the pricing application is to be in a particular category; and
 - (c) be sent to the office of the Department arranging pricing services; and
 - (d) if prior notice of the pricing application is given as described in paragraph 3.10(1)(a)—be sent to that office of the Department within 42 days after the day the prior notice is so given.

Note: The address for the office arranging pricing services can be found on the Department's website.

- (2) If:
 - (a) prior notice of a proposed pricing application is given as described in paragraph 3.10(1)(a); but
 - (b) the proposed pricing application is not sent as required under paragraph (1)(d) of this regulation;
 the Department must refund any fee paid for providing pricing services in response to the proposed pricing application except for the deposit referred to in subregulation 3.3(2).

Note: If the person still seeks the pricing services, the person will need to give prior notice again under regulation 3.10 of a new pricing application.

- (3) The Secretary may, in writing, approve forms for use in making pricing applications.

3.12 Notification (including invoicing of fees)

Notices relating to proposed pricing applications

- (1) Within 14 days after the day the Department receives a notice as described in paragraph 3.10(1)(a) from a person about a proposed pricing application, the Secretary must notify the person in writing:
 - (a) that the Department has received the notice; and
 - (b) based on the statement in the notice about the 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 that fee.

The fee for the pricing services is payable to the Department.

Note 1: The fee must be paid within a period starting when this notification is given (see paragraph 4.1(1)(b)).

Note 2: For the table in subregulation 3.3(1), the financial year for working out the fee is the financial year in which this notification is given (see paragraph (e) of the definition of **notification** in regulation 1.3).

Note 3: If it is later found that a fee exemption or waiver under regulation 5.1 or 5.2 applies, a refund may be payable (see subregulation 4.1(4)).

Notices relating to pricing applications

- (2) Within 21 days after the day the Department receives a pricing application, the Secretary must notify the applicant in writing:
 - (a) that the Department has received the pricing application; and
 - (b) if the applicant requests a fee exemption or waiver under regulation 5.1 or 5.2:
 - (i) whether the fee exemption applies, or the fee is waived or partially waived; and
 - (ii) in relation to a request for a waiver—of the applicant's review rights under Part 6; and
 - (c) if prior notice of the pricing application is not given as described in paragraph 3.10(1)(a):
 - (i) of the amount of the fee payable for providing pricing services in response to the pricing application, worked out based on the statement in the pricing application about its category; and
 - (ii) of the manner for paying that fee.
- (3) If paragraph (2)(c) applies, the fee for the pricing services, or any part of the fee that has not been waived, is payable to the Department unless:
 - (a) a fee exemption applies; or
 - (b) the fee is waived in its entirety.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

3.13 Withdrawal

Prior notices or pricing applications may be withdrawn at any time

- (1) Either of the following may be withdrawn by written notice to the Department:
 - (a) a notice (a **prior notice**) given as described in paragraph 3.10(1)(a) about a proposed pricing application;
 - (b) a pricing application.

When a withdrawal will result in a refund

- (2) If the prior notice is withdrawn within 14 days after the day a notification is given under subregulation 3.12(1) about the prior notice, the Department must refund any fee paid for providing pricing services in response to the proposed pricing application except for the deposit referred to in subregulation 3.3(2).
- (3) If all of the following apply:
 - (a) prior notice of the pricing application is not given as described in paragraph 3.10(1)(a);
 - (b) a notification is given under subregulation 3.12(2) about the pricing application;
 - (c) the pricing application is withdrawn within 14 days after the day that notification is given;the Department must refund any fee paid for providing pricing services in response to the pricing application.

Division 3.4—Validating categories of pricing applications

3.14 Validating a pricing application's category

- (1) After having had regard to the matters in regulations 3.4 to 3.9, the Secretary may, in writing, determine that a pricing application is in one of the categories mentioned in those regulations.
 Note: The Secretary may initiate a review of the decision to make the determination (see regulation 6.3).
- (2) If the category determined under subregulation (1) for a pricing application is different from the category used to work out the fee notified to the person under regulation 3.12 (or previously under this regulation), the Secretary must notify the person in writing accordingly.
- (3) A notice under subregulation (2) to the person must state:
 - (a) the amounts of the fees payable for the pricing services that relate to each of those categories; and
 - (b) the fee amounts already paid, or refunded, (if any) for the pricing services; and
 - (c) the fee amount that is to be refunded to, or is payable by, the person that reflects the amounts referred to in paragraphs (a) and (b); and
 - (d) the manner for paying any amount referred to in paragraph (c) that is payable by the person; and
 - (e) the applicant's review rights under Part 6 in relation to the determination under subregulation (1).
 Any fee amount notified under paragraph (c) as being payable is payable to the Department.
 Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).
- (4) For the purposes of paragraph (3)(a), the fee payable for the pricing services that relates to the new category determined under subregulation (1) is worked out as if that fee had been notified to the person during the same financial year as that in which the notification for the pricing application was given to the person.

Part 3A—List management services

3A.1 Fees for providing list management services

- (1) For the purposes of section 99YBA of the Act, the fee set out in an item of the following table is prescribed for the Commonwealth providing services (the ***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 under a provision of Part VII of the Act set out in that item of the table.

Fee for providing list management services			
Item	List management services provided in assisting the Minister exercise a power under this provision of Part VII of the Act:	Fee if the notification for the application for those services is given during the financial year starting on 1 July 2019	Fee if the notification for the application for those services is given during the financial year starting on 1 July 2020
1	(a) subsection 85AD(1) (about price agreements); or (b) section 85B (about price determinations); in relation to a listed brand of a pharmaceutical item if subregulation (2) applies.	\$2,330	\$2,370
2	(a) subsection 99ACB(6A); or (b) subsection 99ACB(6B); or (c) subsection 99ACBA(1); or (d) subsection 99ACD(7A); or (e) subsection 99ACD(7B); or (f) subsection 99ACE(5); or (g) subsection 99ACE(5A); or (h) subsection 99ACEA(1); or (i) subsection 99ACF(3); or (j) subsection 99ACF(3AA); or (k) subsection 99ACF(3AB).	\$3,480	\$3,540

Note: Each of these fees is indexed for later financial years (see regulation 4.7).

(2) This subregulation 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 Part 2 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.

3A.2 How to apply for list management services

- (1) A list management application must:
 - (a) be made in writing, in the approved form, to the Secretary; and
 - (b) be sent to the office of the Department providing those services.

Note: The address for the office providing those services can be found on the Department's website.

- (2) The Secretary may, in writing, approve forms for use in making list management applications.

3A.3 Notification (including invoicing of fees)

- (1) Within 14 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 relate; and
 - (c) if the applicant requests a fee exemption or waiver under regulation 5.1 or 5.2:
 - (i) whether the fee exemption applies, or the fee is waived or partially waived; and
 - (ii) in relation to a request for a waiver—of the applicant's review rights under Part 6; and
 - (d) of the amount of the fee that is payable for providing those services; and
 - (e) of the manner for paying that fee.
- (2) The fee for the list management services, or any part of the fee that has not been waived, is payable to the Department unless:
 - (a) a fee exemption applies; or
 - (b) the fee is waived in its entirety.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

3A.4 Withdrawal of a list management application

- (1) A list management application may be withdrawn by written notice to the Department.
- (2) If the application is withdrawn within 14 days after the day notice about the application is given under regulation 3A.3, the Department must refund any fee paid for the provision of list management services relating to the application.

27 Part 4 (heading)

Repeal the heading, substitute:

Part 4—Fees: common rules and independent review fee**28 Regulations 4.1 and 4.2**

Repeal the regulations, substitute:

4.1 Payment of fees

- (1) A fee payable under these Regulations for services provided by the Commonwealth in response to an application must be paid:
 - (a) in full to the Commonwealth; and
 - (b) before the end of the following period of days starting on the day that the Department gives notice under these Regulations to the applicant that the fee is payable:
 - (i) if the notice is given under subregulation 2.17(1) about prior notice of a proposed application under Part 2 that, when sent to the Department, includes a request for the Secretary to waive under subregulation 5.2(1) all or part of the fee—42 days;
 - (ii) if the notice is given under subregulation 3.12(1) about prior notice of a proposed pricing application that, when sent to the Department, includes a request for the Secretary to waive under subregulation 5.2(1) all or part of the fee—42 days;
 - (iii) otherwise—28 days.
- (2) However, the Secretary may agree, in writing, to accept payment by instalments.
- (3) If, because of a decision notified under these Regulations to a person, the person has paid a fee amount under these Regulations that falls short of the amount mentioned in that notice as being payable, the person must pay the Commonwealth an amount equal to the shortfall within:
 - (a) 28 days after the day of that notice; or
 - (b) a longer period allowed by the Secretary.

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

- (a) a notice relating to a different category determined under subregulation 2.20(1) or 3.14(1); or
- (b) a notice under regulation 6.4 about an underpayment because of a replacement decision made as part of a review under Part 6.

- (4) If a person pays a fee amount under these Regulations that exceeds the amount notified by the Secretary as being payable, the Commonwealth must refund to the person an amount equal to the excess within 28 days after the later of:
 - (a) the day of that payment by the person of the fee amount; and
 - (b) the day of that notice by the Secretary of the amount payable.

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

- (a) a notice relating to a different category determined under subregulation 2.20(1) or 3.14(1); or
- (b) a notice under subregulation 2.17(2) of a decision under subregulation 5.2(1) to waive all or part of the fee; or
- (c) a notice under regulation 6.4 about an overpayment because of a replacement decision made as part of a review under Part 6.

- (5) This regulation does not apply in relation to a fee mentioned in regulation 4.3.

4.2 Delay in paying a fee

- (1) If a fee payable under these Regulations 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 no longer payable:

- (a) refuse to consider any application sent (or to be sent) by the person under these Regulations;
- (b) refuse to provide any services relating to such an application.

Note 1: Paragraph (a) means, for example, that the Committee or ATAGI could refuse to consider the person's current or future applications under these Regulations until the fee is paid or 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 regulation does not apply in relation to a fee mentioned in regulation 4.3.

29 Subregulation 4.3(3)

Repeal the subregulation, substitute:

- (3) For the purposes of section 99YBA of the Act, the fee prescribed for the provision by the Commonwealth of an independent review in response to an application under this regulation is the same as the fee that would be payable under Part 2 for submission services:
 - (a) provided in response to an application under Part 2 that is in the major evaluation category (see table item 1 in subregulation 2.2(1)); and
 - (b) for which a notification under that Part is given at the same time as the time the application under this regulation is submitted.

This fee for the independent review must be paid in full to the Commonwealth at the time the application under this regulation is submitted.

Note: The independent review will not commence until the fee is paid.

30 Regulations 4.4 to 4.6

Repeal the regulations.

31 Subregulation 4.7(1)

Insert:

fee includes:

- (a) so much of a fee under Part 2 that is specified by subregulation 2.2(2) to be a deposit; and
- (b) so much of a fee under Part 3 that is specified by subregulation 3.3(2) to be a deposit.

32 Subregulation 4.7(1) (definition of *relevant financial year*)

Omit "30 June 2011", substitute "30 June 2021".

33 Before subregulation 5.1(1)

Insert:

Exemptions for services

34 Subregulation 5.1(1)

Omit "No fee is payable for an application for any of the following matters", substitute "No fee is payable under these Regulations for services if the application for the services relates to, or is for, any of the following matters".

35 Paragraph 5.1(1)(a)

Repeal the paragraph.

36 Subregulation 5.1(2)

Repeal the subregulation, substitute:

- (2) Subregulation (1) does not apply in relation to:
- (a) services under Division 1A.2 (about pre-submission meetings); or
 - (b) services under regulation 4.3 (about independent reviews).

Exemption for submission services relating to designated orphan drugs

- (3) No fee is payable under these Regulations for submission services provided in response to a person's application under Part 2 proposing a therapy involving the use of one or more drugs or medicinal preparations if:
- (a) on the day the application is sent to the Department under Part 2, subregulation (4) applies to each of those drugs or medicinal preparations; and
 - (b) this subregulation has not already applied to submission services provided in response to an earlier application under Part 2 by the person proposing the same therapy involving the use of any of those drugs or medicinal preparations.
- (4) This subregulation 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, both of the registration fees for doing so have been or would be waived under paragraph 45(12)(c) of the *Therapeutic Goods Regulations 1990* because of the drug being 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 both of the registration fees for doing so were waived under paragraph 45(12)(c) of the *Therapeutic Goods Regulations 1990* because the drug was a designated orphan drug.
- (5) For the purposes of paragraphs (4)(b) and (c), the registration fees are the fees described in paragraph 23B(2)(b) and subsection 24(1A) of the *Therapeutic Goods Act 1989*.

Application for the services should include reasons why any exemption applies

- (6) An applicant for services who considers that subregulation (1) or (3) applies to the fee for the services, must include with the application for the services reasons why that subregulation would apply.

37 Subregulations 5.2(1) and (2)

Repeal the subregulations, substitute:

Waiver of fees under Division 1A.1 or Part 2 or 3

- (1) The Secretary may, in writing and on request, decide whether or not to waive all or part of one or more fees:

- (a) payable by a person under Division 1A.1 or Part 2 or 3; and
- (b) for services that directly or indirectly relate to a Part 2 submission.

The request must be included in the person's application under Part 2 or 3 for any of the services referred to in paragraph (b).

Note: A request to waive fees payable under Division 1A.1 for ATAGI advice would need to be included in a related application for services under Part 2 or 3.

- (2) The Secretary must decide under subregulation (1) to waive all or part of one or more those fees if:

- (a) the submission involves the public interest; and
- (b) payment of all of those fees would make the submission financially unviable.

38 Subregulation 5.2(3)

Omit "application" (wherever occurring), substitute "submission".

39 At the end of regulation 5.2

Add:

- (4) If:

- (a) as described in subregulation (1), a person requests the Secretary to waive all or part of a fee for services that directly or indirectly relate to a Part 2 submission; and
- (b) the Secretary decides under subregulation (1) not to do so;

the person may not later request the Secretary to waive all or part of that fee.

Waiver of fees for list management services

- (5) The Secretary may, in writing and on request, decide whether or not to waive all or part of the fee payable by a person under Part 3A for list management services provided in response to a list management application.

- (6) The request must be included in the list management application.

- (7) The Secretary must decide under subregulation (5) to waive all or part of the fee if:

- (a) the list management application involves the public interest; and
- (b) payment of the fee would make that application financially unviable.

- (8) Subregulation (3) applies to:

- (a) subregulation (7); and
 - (b) a list management application referred to in subregulation (7);
- in a corresponding way to the way that subregulation (3) applies to subregulation (2) and a submission referred to in subregulation (2).

40 Before regulation 6.1

Insert:

6.1A Reviewable decisions

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

- (a) a decision under subregulation 1A.2(1) not to partially exempt a person (about ATAGI applications);
- (b) a decision under subregulation 2.15(3) that providing submission services in response to an application is not required to address an urgent public health need;
- (c) a decision under subregulation 2.20(1) determining the evaluation category of an application under Part 2;
- (d) a decision under subregulation 3.10(3) that providing pricing services in response to a pricing application is not required to address an urgent public health need;
- (e) a decision under subregulation 3.14(1) determining the category of a pricing application;
- (f) a decision under subregulation 5.2(1) or (5) (about waiving fees);
- (g) a decision under subregulation 6.3(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).

41 Subregulation 6.1(1)

Repeal the subregulation, substitute:

- (1) When the Secretary makes a reviewable decision referred to in paragraph 6.1A(b), (d) or (g) about a person, the Secretary must, within 14 days after making the decision, give the person:
 - (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 these Regulations.

42 Subregulation 6.1(2)

Omit "applicant", substitute "person".

43 Regulation 6.2

Repeal the regulation, substitute:

6.2 Internal review

Initial internal review

- (1) If a reviewable decision is made about a person, the person may apply in writing to the Secretary for review of the reviewable decision.
- (2) The application must:
 - (a) be made within:
 - (i) 14 days after the applicant received notice under these Regulations of the reviewable decision; or
 - (ii) any longer period allowed by the Secretary; and

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- (b) set out the reasons for making the application.
 - (3) The following person (the **initial reviewer**):
 - (a) if the original decision maker of the reviewable decision is available—that person;
 - (b) otherwise—a person authorised under subregulation (6);
 must, within 14 days after receiving the application:
 - (c) review the reviewable decision and decide (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 initial reviewer thinks appropriate; and
 - (d) give written notice to the applicant of the initial review decision.

Further internal review

- (4) The applicant may, within 14 days after receiving notice under paragraph (3)(d), request in writing to the Secretary, in accordance with the notice, that the Secretary review the initial review decision.
- (5) The Secretary, or a person authorised under subregulation (6), (the **further reviewer**) must, within 14 days after receiving the request:
 - (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) For the purposes of subregulation (3) or (5), the Secretary may in writing authorise an SES employee, or acting SES employee, in the Department to act under that subregulation.
- (7) However, disregard a person's authorisation for the purposes of subregulation (5) if the person was involved in making:
 - (a) the initial review decision; or
 - (b) the reviewable decision from which the initial review decision was made.

Discretion to suspend any services to which the review relates

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

44 Regulation 6.3

Repeal the regulation, substitute:

6.3 Internal review—Secretary

- (1) The Secretary may, at any time, initiate a review of a reviewable decision (other than an earlier decision under subregulation (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 decision; and
- (b) if the Secretary revokes the decision—make any other decision the Secretary thinks appropriate.

Note: Notice must be given of a decision under this subregulation (see subregulation 6.1(1)).

45 Regulation 6.4

Repeal the regulation, substitute:

6.4 Notice of fee adjustment

If a person has underpaid or overpaid a fee as a result of a decision made under the following provisions, the Secretary must, within 28 days after making the decision, notify the person accordingly:

- (a) paragraph 6.2(3)(c) (an initial review decision);
- (b) paragraph 6.2(5)(a) (a further review decision);
- (c) subregulation 6.3(2) (a Secretary-initiated review decision).

Note: A further payment, or a refund, will then be required (see subregulations 4.1(3) and (4)).

46 Regulation 6.5

Repeal the regulation, substitute:

6.5 Review by the Administrative Appeals Tribunal

- (1) Applications may be made to the Administrative Appeals Tribunal for review of a decision under paragraph 6.2(5)(a) of the further reviewer referred to in that paragraph.
- (2) While such an application is being considered by the Administrative Appeals Tribunal, the Commonwealth may suspend any services under these Regulations to which the decision relates.

47 Part 7 (heading)

Repeal the heading, substitute:

Part 7—Application and transitional provisions

48 At the end of Part 7

Add:

7.2 Application and transitional provisions for the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019*

- (1) The amendments made by the amending instrument apply in relation to an application made under these Regulations on or after 1 July 2019, even if a related application under these Regulations was made before that day.

Example: An application under Part 3 is made on 10 July 2019 that relates to an application under Part 2 that was made in January 2019. The amendments made by the amending instrument will apply in relation to the application under Part 3.

- (2) However, these Regulations apply with the modifications described in subregulation (3) in relation to an application made under Part 2 on or after 1 July 2019 that:
- (a) is in the major evaluation category (see Subdivision 2 of Division 2.1); and
 - (b) is for consideration at the Committee meeting in November 2019.

Note: This means the amendments made by the amending instrument apply in relation to these particular Part 2 applications with the modifications in subregulation (3).

- (3) These Regulations apply in relation to the application (the ***transitional application***) as if:
- (a) the fee in item 1 of the table in subregulation 2.2(1) did not include an amount equal to the deposit referred to in subregulation 2.2(2); and
 - (b) prior notice of the transitional application were not required under subregulation 2.15(1).
- (4) Despite the amendments made by the amending instrument:
- (a) the old Regulations (other than Part 3) continue to apply on and after 1 July 2019 in relation to an application:
 - (i) made under Part 2 of the old Regulations; and
 - (ii) for which a notice under regulation 2.17 of the old Regulations has been given before 1 July 2019;
 as if those amendments had not been made; and
 - (b) Part 3 of the old Regulations continues to apply on and after 1 July 2019 in relation to an application:
 - (i) made by a person under Part 2 of the old Regulations; and
 - (ii) for which the Commonwealth has notified the person in writing before 1 July 2019 that the Commonwealth will begin pricing negotiations in response to a pricing offer sent by the person;
 as if those amendments had not been made; and
 - (c) the old Regulations continue to apply on and after 1 July 2019, in relation to an application submitted under regulation 4.3 of the old Regulations before 1 July 2019, as if those amendments had not been made.

Example: A notice is sent under regulation 2.17 of the old Regulations in early 2019 about a person's application under Part 2, and the Commonwealth notifies the person on 1 June 2019 that related pricing negotiations will begin. The old Regulations will continue to apply to anything done on and after 1 July 2019 in relation to the application or the pricing negotiations. For example:

- (a) an application to waive the evaluation fee or pricing fee would be made under subregulation 5.2(1) of the old Regulations; and
- (b) a notice about the Minister exercising a power relating to the pricing offer would be made under regulation 3.8 of the old Regulations.

- (5) An application under Part 2 of the old Regulations ceases to have effect on 1 July 2019 unless it is covered by subregulation (4).
- (6) In this regulation:

amending instrument means the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019*.

old Regulations means these Regulations (apart from this Part) as in force immediately before 1 July 2019.

49 Items 2.15 and 2.16 in Schedule 1

Repeal the items, substitute:

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.

50 Schedules 3 and 4

Repeal the Schedules.