National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2009[1]

Select Legislative Instrument 2009 No. 372

I, QUENTIN BRYCE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *National Health Act 1953*.

Dated 14 December 2009

QUENTIN BRYCE
Governor-General

By Her Excellency's Command

NICOLA ROXON
Minister for Health and Ageing

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Part 1 Preliminary

1.1 Name of Regulations

These Regulations are the *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2009*.

1.2 Commencement

These Regulations commence on 1 January 2010.

1.3 Definitions

In these Regulations:

Act means the *National Health Act 1953*.

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

Committee means the Pharmaceutical Benefits Advisory Committee.

economic evaluation, for an application and a drug, medicinal preparation or vaccine the subject of the application (the ***proposed drug or vaccine***), means data that is a comparative analysis of the costs and outcomes of:

(a) the therapy to be provided by the proposed drug or vaccine; and

(b) any other therapy that the applicant nominates as an alternative therapy to the proposed drug or vaccine.

evaluation fee means a fee prescribed by regulation 4.1.

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

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

medicinal food means food that is a therapeutic good within the meaning of paragraphs (a) and (b) of the definition of therapeutic goods in section 3 of the *Therapeutic Goods Act 1989*.

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

pricing fee means a fee prescribed by regulation 4.2.

Secretary has the meaning given by subsection 4 (1) of the Act.

therapy, for an application, means the clinical purpose stated in the application for a drug, medicinal preparation or vaccine.

Part 2 Applications

Division 2.1 Evaluation categories for applications etc

Subdivision 1 Preliminary

2.1 Scope of applications

(1) A person may make an application as follows:

(a) requesting that the Committee make a recommendation or give an advice, as mentioned in Schedule 1, that the Minister take an action mentioned in an item in Schedule 1;

(b) for the Minister to take an action mentioned in an item in Part 3 of Schedule 1.

(2) An application mentioned in paragraph (1) (a) may include more than 1 request, listed in an item in Parts 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.

2.2 Categories of applications

An application under this Part is in 1 of the following evaluation categories:

(a) major;

(b) minor;

(c) Committee Secretariat;

(d) new brand of existing pharmaceutical item.

Note See the document titled *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee*, published by the Department, which can be found on the Department's website at http://www.health.gov.au.

Subdivision 2 Applications that are major

2.3 Major — applications to list

An application is in the major category if it includes a request for the Committee to make a recommendation that the Minister take an action mentioned in item 1.1, 1.3, 2.1, 2.3, or 2.10 in Schedule 1.

2.4 Major — health advantage test

(1) An application is in the major category if:

(a) it includes a request for the Committee:

(i) to make a recommendation that the Minister take an action mentioned in item 1.2, 2.2, 2.5 or 2.12 in Schedule 1; or

(ii) to give advice to the Minister in relation to a matter mentioned in item 2.15 in Schedule 1; and

(b) subregulation (2) applies to the request.

(2) For subregulation (1), this subregulation applies if the request requires the Committee to assess:

(a) the extent of improvement in efficacy or reduction of toxicity of the therapy proposed in the application compared with therapy provided by any listed drug, special pharmaceutical product or designated vaccine; and

(b) the cost of the therapy proposed in the application compared with the cost of the other therapy; and

(c) the additional benefit, described in paragraph (a), in relation to the additional cost of providing the therapy proposed in the application.

2.5 Applications excluded from major category

An application that includes a request to which regulation 2.3 or 2.4 applies is not in the major category if regulation 2.10 or 2.11 applies to it.

2.6 Requirements for major applications

An application to which regulation 2.3 or 2.4 applies must be supported by an economic evaluation.

Subdivision 3 Applications that are minor

2.7 Minor — applications to change listings

(1) An application is in the minor category if:

(a) the application is not a major application under Subdivision 2; and

(b) it includes a request for the Committee to give advice to the Minister in relation to a matter mentioned in item 2.15 in Schedule 1.

(2) An application is in the minor category if:

(a) it includes a request for the Committee:

(i) to make a recommendation that the Minister take an action mentioned in item 1.4, 2.4, 2.6, 2.8, 2.9, 2.11 or 2.14 in Schedule 1; or

(ii) to give advice to the Minister in relation to a matter mentioned in item 2.16 in Schedule 1; and

(b) if the application includes any other request — the application is not a major application under Subdivision 2.

2.8 Minor — clinical need and effectiveness test

(1) An application that includes a request for the Committee to make a recommendation that the Minister take an action mentioned in item 1.2, 2.2, 2.5 or 2.12 in Schedule 1 is in the minor category if:

(a) the application is not a major application under Subdivision 2; and

(b) subregulation (2) applies to the request.

(2) For subregulation (1), this subregulation applies if:

(a) the request requires the Committee to assess an applicant's claim about the clinical need and clinical effectiveness of a request in the application; and

(b) the request does not:

(i) propose any changes to the unit price of a listed drug, special pharmaceutical product or designated vaccine; or

(ii) require the Committee to assess any cost implications for the supply of a drug, medicinal preparation or vaccine arising from a request.

2.9 Minor — exceptions to new brand of existing pharmaceutical item category

An application for the Minister to take an action mentioned in item 3.1 or 3.2 in Schedule 1 is in the minor category if:

(a) the application is about a kind of medicinal preparation mentioned in item 1 of the table in Schedule 2; and

(b) the applicant makes a claim about the therapeutic benefit that would be derived from the relationship between ingredients in the proposed medicinal preparation.

2.10 Minor — applications that are resubmissions

An application is in the minor category if:

(a) it is resubmitted under regulation 2.20; and

(b) it was previously evaluated by the Committee in the major category; and

(c) it does not include, in support of a request that was previously considered by the Committee, data that is:

(i) a reconstruction of a modelled economic evaluation previously considered by the Committee; or

(ii) a new methodological basis to support a variable in a modelled economic evaluation previously considered by the Committee; and

(d) the request satisfies the requirements for a major application under a provision in Subdivision 2; and

(e) if it includes a request that was not previously considered by the Committee — that request does not satisfy the requirements for a major application under a provision in Subdivision 2.

2.11 Minor — medicinal foods

An application is in the minor category if:

(a) it includes a request that satisfies the requirements for a major application under a provision in Subdivision 2; and

(b) the request relates to a drug or medicinal preparation that is a medicinal food; and

(c) it is not possible for the applicant to comply with the requirement under regulation 2.6 to provide an economic evaluation because the patient population is too small; and

(d) no other request in the application:

(i) relates to a drug or medicinal preparation that is not a medicinal food; and

(ii) meets the criteria for a major application under a provision in Subdivision 2.

Subdivision 4 Other categories

2.12 Applications that are Committee Secretariat

(1) An application is in the Committee Secretariat category if:

(a) it is an application for the Committee to make a recommendation that the Minister take an action mentioned in item 2.7 or 2.13 in Schedule 1; and

(b) if the application includes any other request — the application is neither a minor nor a major application under Subdivision 2 or 3.

(2) An application that includes a request for the Committee to make a recommendation that the Minister take an action mentioned in item 1.2, 2.2, 2.5 or 2.12 in Schedule 1 is in the Committee Secretariat category if:

(a) the application demonstrates that the risk to a patient, associated with using a drug, medicinal preparation or vaccine, is not greater than the risk of using a listed drug, a special pharmaceutical product or a designated vaccine; and

(b) the application is neither a minor nor a major application under Subdivision 2 or 3.

2.13 Committee Secretariat — exceptions to new brand of existing pharmaceutical item category

An application for the Minister to take an action mentioned in item 3.1 or 3.2 in Schedule 1 is in the Committee Secretariat category if the application is about a kind of medicinal preparation mentioned in item 2 of the table in Schedule 2.

2.14 Applications that are new brand of existing pharmaceutical item

An application for the Minister to take an action mentioned in item 3.1 or 3.2 in Schedule 1 is in the new brand of existing pharmaceutical item category if the application is not about a kind of medicinal preparation mentioned in Schedule 2.

Subdivision 5 Evaluation categories

2.15 Matters requiring consideration

(1) For each kind of application mentioned in an item in the following table the Secretary must, for the purpose of determining the evaluation category of an application under this Division:

(a) be satisfied that each of the matters in the item requires consideration; and

(b) consult with the Chairperson of the Committee before making his or her decision about a matter.

Item	For an application in:	... the matters requiring consideration are:
1	the major category mentioned in subregulation 2.4 (1)	each of the matters in paragraphs 2.4 (2) (a), (b) and (c)
2	the minor category mentioned in regulation 2.8	each of the matters in paragraphs 2.8 (2) (a) and (b)
3	the minor category mentioned in regulation 2.9	the matter in paragraph 2.9 (b)
4	the Committee Secretariat category mentioned in subregulation 2.12 (2)	the matter in paragraph 2.12 (2) (a)

(2) The Secretary must, for the purpose of determining the evaluation category of an application under regulation 2.11, be satisfied of the matter in paragraph 2.11 (c).

Division 2.2 Application procedure

2.16 How to apply

(1) An application mentioned in Division 2.1 must:

(a) be made in writing, in the approved form, to the Secretary; and

(b) be sent to the office of the Department administering the Committee.

Note The address for the office administering the Committee can be found in the document titled *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* published by the Department. The document is available from the Department's website at http://www.health.gov.au.

(2) An application mentioned in regulation 2.9, 2.13 or 2.14 must:

(a) be made in writing, in the approved form, to the Secretary; and

(b) be sent to the office of the Department administering applications about item 3.1 or 3.2 in Schedule 1.

Note At the commencement of these Regulations, the office administering applications about item 3.1 or 3.2 in Schedule 1 is the Listings Unit in the Pharmaceutical Evaluation Branch of the Pharmaceutical Benefits Division. The address of the Listings Unit can be found on the Department's website at http://www.health.gov.au.

(3) The Secretary may, in writing, approve forms for use in making applications under these Regulations.

2.17 Notification

(1) When the Department receives an application, it must notify the applicant, in writing, within 14 days:

(a) that it has received the application; and

(b) if the applicant requests a fee exemption or waiver under regulation 5.1 or 5.2 — whether the fee exemption is granted, or the fee is waived or partially waived; and

(c) of any decision made about the evaluation category of the application by the Secretary under Division 2.1; and

(d) the evaluation category of the application; and

(e) the amount of the evaluation fee for the application; and

(f) the applicant's review rights under Part 6.

(2) The fee for the application, or any part of a fee that has not been waived, is payable to the Department unless:

(a) a fee exemption is granted; or

(b) the fee is waived in its entirety.

Note Part 4 provides for the payment of fees.

2.18 Assessment of applications

(1) The Committee may request further information from the applicant.

(2) The Committee may ask the Secretary to initiate a review of a decision under regulation 6.3 if it is unable to assess the application without further information.

2.19 Withdrawal of application

(1) An application may be withdrawn by written notice to the Department.

(2) If the application is withdrawn within 14 days after notice is given under regulation 2.17, the Department must refund any evaluation fee paid.

2.20 Resubmission of applications

If the Committee decides not to make a recommendation or not to give advice requested in an application:

(a) the applicant may re-submit the application in the same or an amended form; and

(b) the resubmitted application is subject, as if it were a new application, to:

(i) Division 2.1; and

(ii) a fee under regulation 4.1.

Part 3 Pricing

Division 3.1 Pricing

3.1 Applications to which this Part applies

This Part applies to an application mentioned in Subdivision 2 or 3 of Part 2, or regulation 2.12 or 2.13, if:

(a) the Committee advises or makes a recommendation to the Minister; and

(b) the advice or recommendation results in:

(i) the Minister making or varying a price agreement with the applicant under section 85AD of the Act; or

(ii) the Minister making a price determination under section 85B of the Act; or

(iii) the Minister arranging for a price for which a designated vaccine may be supplied under section 9B of the Act; or

(iv) the Minister making or varying an agreement with the applicant about the price of a special pharmaceutical product for its supply under section 100 of the Act.

Note There are no fees payable under these Regulations for price agreements and determinations being made as a result of applications in the ***new brand of existing pharmaceutical item*** evaluation category: see regulation 2.18.

Division 3.2 Pricing categories for applications

3.2 Pricing categories

An application to which this Part applies is in 1 of the following pricing categories:

(a) complex;

(b) simple;

(c) Pricing Secretariat.

3.3 Complex pricing category

(1) An application is in the complex pricing category if:

(a) it includes a claim to which subregulation (2) applies; and

(b) the resulting price for a drug, medicinal preparation or vaccine is higher than the price for an equivalent amount or unit of a listed drug, a special pharmaceutical product or a designated vaccine that:

(i) the applicant nominates in the application as presenting an alternative therapy; or

(ii) the Committee considers is clinically comparable to the drug, medicinal preparation or vaccine the subject of the application.

(2) This subregulation applies if an applicant claims that:

(a) the use of a drug, medicinal preparation or vaccine provides a significant improvement in the efficacy or reduction in toxicity compared to any alternative therapy provided by:

(i) a listed drug; or

(ii) a special pharmaceutical product; or

(iii) a designated vaccine; and

(b) the applicant requests a higher price compared to the alternative therapy; and

(c) the Committee's recommendation is in accordance with the claim.

(3) An application is in the complex pricing category if:

(a) it includes a request for a review of the existing price for a listed drug, a special pharmaceutical product or a designated vaccine and the resulting price is higher; or

(b) the following apply:

(i) when the application was made, it included a claim of cost minimisation;

(ii) the Committee's recommendation or advice to the Minister was not in accord with the claim; or

(c) there is an agreement, between the applicant and the Commonwealth (other than an agreement or arrangement mentioned in paragraph 3.1 (b)), containing risk-sharing arrangements or other requirements relating to the supply of a drug, medicinal preparation or vaccine.

3.4 Simple pricing category

An application is in the simple pricing category if:

(a) regulation 3.3 does not apply to the application; and

(b) when the application was made, it included:

(i) a claim that the effectiveness of a specified dose of a drug, medicinal preparation or vaccine the subject of the application is equivalent to the dose of a listed drug, special pharmaceutical product, or designated vaccine; and

(ii) a claim of cost minimisation; and

(c) the Committee's recommendation or advice to the Minister was in accord with the claims; and

(d) the resulting price is based on the claims.

3.5 Pricing Secretariat pricing category

An application is in the Pricing Secretariat pricing category if neither regulation 3.3 nor regulation 3.4 applies to it.

3.6 Claims of cost minimisation

For this Division, an applicant makes a ***claim of cost minimisation*** if the applicant claims that a drug, medicinal preparation or vaccine:

(a) would provide similar health benefits to those provided by a listed drug, a special pharmaceutical product or a designated vaccine (the ***other drug or vaccine***); and

(b) may be supplied at the same, a similar or a lower price per unit of the other drug or vaccine.

Division 3.3 Pricing procedure

3.7 When a pricing fee is payable

A pricing fee is payable under regulation 4.2:

(a) when an agreement or a determination mentioned in paragraph 3.1 (b) is made or varied; or

(b) for vaccines — when a price mentioned in subparagraph 3.1 (b) (iii) is recommended.

3.8 Notification

(1) The Department must notify an applicant in writing, within 14 days after the occurrence of the following events:

(a) the day any of the following come into effect:

(i) an agreement mentioned in subparagraph 3.1 (b) (i), (iii) or (iv);

(ii) a determination mentioned in subparagraph 3.1 (b) (ii);

(b) if a price mentioned in subparagraph 3.1 (b) (iii) is recommended — the day of the recommendation;

(c) any decision made about a pricing category by the Secretary under Division 3.2;

(d) if the applicant requests a fee exemption or waiver under Part 5 relating to a pricing fee — a decision about the request.

(2) The notification must include information about the applicant's review rights under Part 6.

(3) The pricing fee for the application, or any part of the fee that has not been waived, is payable to the Department unless:

(a) a fee exemption is granted; or

(b) the fee is waived in its entirety.

Part 4 Fees

4.1 Evaluation fees

For section 99YBA of the Act, the fee for making an application under Part 2 is the amount mentioned in Schedule 3 for the evaluation category of the application.

4.2 Pricing fees

(1) This regulation applies if:

(a) the applicant and the Minister make an agreement mentioned in paragraph 3.1 (b); or

(b) the Minister makes a price determination mentioned in subparagraph 3.1 (b) (ii); or

(c) the Minister provides for a price recommendation mentioned in subparagraph 3.1 (b) (iii).

(2) For section 99YBA of the Act, the fee for the agreement, determination or price recommendation is the amount mentioned in Schedule 4 for the pricing category of the application on which the agreement, determination or recommended price is based.

4.3 Independent review fee

(1) An applicant may seek an independent review of a decision by the Committee not to make a recommendation that the Minister:

(a) declare a drug or medicinal preparation under subsection 85 (2) of the Act; or

(b) specify further circumstances, requested in an application, in which a prescription for the supply of a pharmaceutical benefit may be written under subsection 85 (2A) of the Act.

(2) The application 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 an application to the Department for an independent review of the Committee's decision is $119 500 and is payable at the time the application is submitted.

(4) There is no fee for the Committee to reconsider an application following the independent review.

Note See the Independent Review (PBS) website at http://www.independentreview.pbs.gov.au.

4.4 Payment of fees

(1) An evaluation fee that is payable under these Regulations must be paid:

(a) in full to the Department at the time of payment; and

(b) within 28 days after the Department gives notice to the applicant of its receipt of an application under regulation 2.17; and

(c) in accordance with the notice.

(2) A pricing fee that is payable under subregulation 4.2 (1) must be paid:

(a) in full to the Department at the time of payment; and

(b) within 28 days after the Department gives notice to the applicant of the making of an agreement, determination or price recommendation under regulation 3.8; and

(c) in accordance with the notice.

(3) However, the Secretary may agree, in writing, to accept payment by instalment.

(4) If an applicant pays a fee before being told by the Secretary the amount of fee that is payable and the amount paid is less than the amount payable, the applicant must pay the difference within:

(a) 28 days after being notified of the amount under regulation 2.17; or

(b) if the applicant makes a written request to the Secretary — another period allowed by the Secretary.

(5) If an applicant pays more than the fee that is payable, the Department must refund to the applicant the amount that has been overpaid within 28 days after the later of:

(a) payment of the fee; and

(b) notification by the Department of its receipt of the application under regulation 2.17.

4.5 Delay in payment of evaluation fee

(1) If the evaluation fee for an application is not paid within the time required for its payment, the Committee may refuse to consider the application or any other application submitted by the applicant until the fee is paid or no longer payable.

(2) For a fee mentioned in subregulation (1), the Department may do either or both of the following:

(a) suspend taking any action relating to the application;

(b) commence debt recovery action.

Note For example, the Department may withhold listing the drug or medicinal preparation the subject of the application on the Schedule of Pharmaceutical Benefits.

4.6 Delay in payment of pricing fee

(1) If the pricing fee for an application is not paid within the time required for its payment, the Committee may refuse to consider any other application submitted by the applicant, whether in existence at the time or not, until the fee is paid or is no longer payable.

(2) For a fee mentioned in subregulation (1), the Department may commence debt recovery action.

4.7 Indexation of fees

(1) In this regulation:

CPI number means the All Groups Consumer Price Index number (that is, the weighted average of the 8 Australian capital cities) published by the Australian Statistician.

earlier CPI number, for a financial year, means the CPI number for the last March quarter before the beginning of the financial year.

latest CPI number, for a financial year, means the CPI number for the last March quarter before the end of the financial year.

relevant financial year means a financial year beginning after 30 June 2011.

(2) If, in a relevant financial year, the latest CPI number is greater than the earlier CPI number, a fee under these Regulations is taken to increase, on 1 July of the next financial year, in accordance with the following formula:

$$\frac{\text{fee} \times \text{latest CPI number}}{\text{earlier CPI number}}$$

(3) If a fee increased under subregulation (2) would be an amount of dollars and cents, the amount is to be rounded to the nearest whole dollar and, if the amount to be rounded is 50 cents, the amount is to be rounded down.

Note The Department publishes information about fees and their indexation under this regulation on its website at http://www.pbs.gov.au.

Part 5 Exemptions and waivers

5.1 Exemptions

(1) No fee is payable for an application for any of the following matters:

(a) a drug that is designated as an orphan drug under regulation 16J of the *Therapeutic Goods Regulations 1990*;

(b) 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*;

(c) if the Secretary considers that the supply of a drug, medicinal preparation or vaccine is necessary for the management of:

(i) a public health event of national significance; or

(ii) a public health emergency under section 2B or 12A of the *Quarantine Act 1908*;

(d) to offer a price reduction;

(e) to change the name of the responsible person;

(f) to revoke a determination under subsection 9B (2) of the Act;

(g) to vary a determination under subsection 9B (2) of the Act so that a vaccine ceases to be a designated vaccine;

(h) to revoke a declaration under subsection 85 (2AA) of the Act;

(i) to vary a declaration under subsection 85 (2A) of the Act so that a drug or medicinal preparation ceases to be a listed drug;

(j) to revoke an arrangement under subsection 100 (2) of the Act;

(k) to vary an arrangement under section 100 of the Act so that a drug or medicinal preparation ceases to be covered by the arrangement;

(l) to change the pack size with no price implications under section 85AD of the Act;

(m) to vary a declaration, determination, arrangement or other legislative instrument made under Part VII or section 9B of the Act:

(i) at the request of Medicare Australia or the Therapeutic Goods Administration; or

(ii) that is a mandated change because of a Government initiative.

Note ***public health event of national significance*** is defined in section 3 of the *National Health Security Act 2007*.

(2) An applicant who wants the Secretary to consider whether subregulation (1) applies to an application must include with the application information about why subregulation (1) would apply.

5.2 Waiver of fees

(1) An applicant may apply to the Secretary to waive all or part of a fee payable under these Regulations.

(2) The Secretary may waive a fee, or part of a fee, payable under these Regulations if the application involves the public interest and payment of the fee would make the application financially unviable.

(3) Without limiting subregulation (2), the 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 6 Review of decisions

6.1 Notice of review rights

(1) When the Secretary makes a decision about a fee under these Regulations, the Secretary must, within 14 days after making the decision, give the applicant:

(a) written notice of the decision; and

(b) a statement setting out particulars of the applicant's review rights.

(2) The notice must include particulars about how the applicant may respond to the notice.

(3) Failure to comply with subregulation (1) does not affect the validity of the decision.

6.2 Internal review

(1) An applicant may apply in writing to the Secretary, in accordance with the notice mentioned in regulation 6.1, for review (***internal review***) of a decision about:

(a) the evaluation category of an application; or

(b) the pricing category of an application; or

(c) the waiver of a fee.

(2) The application must:

(a) be made within:

(i) 14 days after the applicant received notice of a decision made under regulation 2.15, Part 3 or regulation 5.1, 5.2 or 6.3; or

(ii) if the applicant makes a written request to the Secretary — another period allowed by the Secretary; and

(b) set out the grounds on which the applicant relies.

(3) The original decision maker or, if he or she is not available, an officer authorised by the Secretary:

(a) must review the decision within 14 days after receiving the request; and

(b) may:

(i) affirm, vary or revoke the reviewable decision; and

(ii) if he or she revokes the decision — make any other decision he or she thinks appropriate; and

(c) must, within 14 days of receiving the request, give written notice to the applicant.

(4) The applicant may, within 14 days after receiving notice under paragraph (3) (c), apply in writing to the Secretary, in accordance with the notice, for review of the decision under subregulation (3).

(5) The Secretary:

(a) must review the decision within 14 days after receiving the request; and

(b) may:

(i) affirm, vary or revoke the reviewable decision; and

(ii) if the Secretary revokes the decision — make any other decision the Secretary thinks appropriate; and

(c) must, within 14 days after doing so, give written notice to the applicant.

(6) For subregulation (5), the person in the Department who carries out the review must not have been involved in the original decision or the decision under subregulation (3).

(7) The Secretary may suspend any work on the initial application to which the review relates, while an application is being considered under this regulation.

6.3 Internal review — Secretary

(1) The Secretary may, at any time, initiate review of:

(a) a decision made under Part 2 about the evaluation category of an application; or

(b) a decision made under Part 3 about the pricing category of an application; or

(c) the waiver of a fee.

(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.

(3) The Secretary must give written notice to the applicant within 7 days after making a decision under subregulation (2).

6.4 Fee adjustment

If there is overpayment of a fee as a result of a decision made under the following provisions, the Secretary must, within 28 days after making the decision, refund the overpaid amount:

(a) paragraph 6.2 (3) (b);

(b) if the applicant makes an application mentioned in subregulation 6.2 (4) — paragraph 6.2 (5) (b);

(c) subregulation 6.3 (2).

6.5 Review by Administrative Appeals Tribunal

(1) After a review under subregulation 6.2 (5), an applicant may apply to the Administrative Appeals Tribunal for review of a decision by the Secretary under these Regulations.

(2) The Department may suspend any work on the initial application to which the review relates, while an application is being considered under this regulation.

(3) In this regulation:

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

Part 7 Application provision

7.1 Application of these Regulations

These Regulations apply to applications received by the Department after 31 December 2009.

Schedule 1 Applications

(Division 2.1)

Part 1 Vaccines

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) 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) to change a circumstance in which the vaccine may be provided but not so as to add a new circumstance

Part 2 Pharmaceuticals

2.1 To declare a drug or medicinal preparation under subsection 85 (2) of the Act

2.2 To vary a declaration made under subsection 85 (2) of the Act

2.3 To specify circumstances, or vary an existing specification to add a new circumstance, in which a prescription for the supply of a pharmaceutical benefit may be written under subsection 85 (2A) of the Act

2.4 To vary an existing specification to change the circumstances in which a prescription for the supply of a pharmaceutical benefit may be written under subsection 85 (2A) of the Act but not so as to add a new circumstance

2.5 To determine, or vary an existing determination of, a form of a listed drug under subsection 85 (3) of the Act

2.6 To determine matters, or vary an existing determination of matters, for the writing of prescriptions by a specified class of persons under subsection 85A (2) of the Act

2.7 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

2.8 To make a determination about the supply of a pharmaceutical benefit under section 93 of the Act

2.9 To make a special arrangement under section 100 of the Act to provide for the supply of special pharmaceutical products

2.10 To specify a circumstance in which a special pharmaceutical product 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

2.11 To vary the circumstances in which a special pharmaceutical product may be supplied in an existing special arrangement made under section 100 of the Act but not so as to add a new circumstance

2.12 To specify in an existing special arrangement made under section 100 of the Act a form and manner of administration of a special pharmaceutical product

2.13 To vary the specification of a form and manner of administration of a special pharmaceutical product in an existing special arrangement made under section 100 of the Act

2.14 To specify matters, or vary an existing specification of matters, about maximum quantity or number of units or maximum repeats for supply of a special pharmaceutical product in an existing special arrangement under section 100 of the Act

2.15 Under subsection 101 (4AC) of the Act, advice that relates to the exercise of a power by the Minister under subsection 99ACC (3) of the Act to agree on a new price for a single brand of a combination item

2.16 Under subsection 101 (4AB) of the Act, advice that relates to the exercise of a power by the Minister to determine that a pharmaceutical item is an exempt item under section 84AH of the Act

Part 3 Existing pharmaceutical items or special pharmaceutical products

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

3.2 To specify, in a special arrangement made under section 100 of the Act, a form and manner of administration of a special pharmaceutical product that has the same active ingredient and the same form and manner of administration as an existing special pharmaceutical product

Schedule 2 Medicinal preparations

(regulations 2.9 and 2.13)

1. The medicinal preparation is a pharmaceutical item or a special pharmaceutical product that includes a substance, or has the form, mentioned in the following table:

Item	Substance or form
1	somatropin
2	a glucose indicator

Schedule 3 Evaluation fees

(regulation 4.1)

Item	Evaluation category of application	Fee ($)
1	Major	119 500
2	Minor	12 500
3	Committee Secretariat	1 000
4	New brand of existing pharmaceutical item	500

Schedule 4 Pricing fees

(regulation 4.2)

Item	Pricing category of application	Fee ($)
1	Complex	25 000
2	Simple	6 000
3	Pricing Secretariat	1 000

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au.