National Health (Pharmaceutical Benefits — Charges) Regulations 2008[1]

Select Legislative Instrument 2008 No.

I, PHILIP MICHAEL JEFFERY, 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 2008

Governor-General

By His Excellency's Command

[DRAFT ONLY – NOT FOR SIGNATURE]
Minister for Health and Ageing

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Part 1 Preliminary

1 Name of Regulations

These Regulations are the *National Health (Pharmaceutical Benefits — Charges) Regulations 2008*.

2 Commencement

These Regulations commence on ^***date to be inserted***^.

3 Definitions

(1) In these Regulations:

Act means the *National Health Act 1953*.

brand has the meaning given by section 84 of the Act.

Committee means the Pharmaceutical Benefits Advisory Committee.

new brand, for a pharmaceutical item, means a brand of the pharmaceutical item that:

(a) contains the same active molecule as a listed brand of pharmaceutical item; and

(b) is bioequivalent or biosimilar to a listed drug or listed brand of the pharmaceutical item.

PBAC Guidelines means the *Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee*, published in September 2002.

Pricing Authority manual means the *Policies, procedures and methods used in the pricing of pharmaceutical products*, published by the Pharmaceutical Benefits Pricing Authority in December 2006.

(2) For Schedule 1, an application is in the ***major*** category if:

(a) it is for the listing of a new drug or medicinal item, including a combination drug, a new nutritional product, a new vaccine or a new orphan drug; or.

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(b) the Committee considers that it would make a substantial change to a current listing of a drug or medicinal product, including a new indication or a de-restriction; or

(c) it is for the review of comparative cost effectiveness of a currently listed drug in relation to its therapeutic relativity or price advantage; or

(d) it seeks a price advantage for a new form of a currently listed drug; or

(e) it is a resubmission of a matter mentioned in paragraph (a), (b), (c) or (d) and the Committee considers that it introduces a substantive change to the previous submission.

(3) For Schedule 1, an application is in the ***minor*** category if it is for any or the following:

(a) a new form or manner of administration for a listed drug or medicinal item;

(b) a minor change to the circumstances of use of a listed drug or medicinal item;

(c) listing a new type of unit, strength or other aspect of form of a pharmaceutical item containing a listed drug or medicinal item for which:

(i) a price advantage is not requested; or

(ii) the likely volume and proportion of use is expected to be small;

(d) minor changes to the circumstances of use of a listed drug or medicinal item, including changing the maximum quantity per prescription or the number of repeats per prescription;

(e) to justify the clinical need for the listing of a drug or medicinal item, or a form of it;

(f) to clarify the wording of a restriction, without changing the intended use;

(g) a resubmission without substantive changes to the original application.

(4) For Schedule 1, an application is in the ***Secretariat listing*** category if:

(a) it would be in the minor category; and

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(b) the Chair and the Secretary of the Committee agree that the listing or change to an existing listing should be recommended by the Committee; and

(c) the listing or change is recommended by the Committee without it being considered as a separate agenda item at a meeting of the Committee.

4 Purpose of Regulations

The purpose of these Regulations is to provide for cost recovery by the Department for the costs of the process of initial listing of drugs on the pharmaceutical benefits scheme, and designation of vaccines on the national immunisation program, and variations of existing listings and designations.

Part 2 Applications

5 Evaluation categories

When the Department receives an application mentioned in Schedule 1:

(a) it must tell the applicant within 14 days which evaluation category it considers appropriate for the application; and

(b) the fee for an application of that evaluation category is payable to the Department.

6 Withdrawal of application

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

(2) If the application is withdrawn within 14 days after it was lodged, the Department must refund any lodgment fee paid.

7 Resubmission of applications

If the Committee decides not to make a recommendation requested by an application:

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

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(b) the application is subject to a lodgment fee as if it were a new application.

Part 3 Fees

8 Lodgment fees

(1) For section 99YBA of the Act, the fee for lodgment of an application is the amount mentioned in Schedule 1 for the evaluation category that applies to the application.

(2) For item 2 of Schedule 1, an application is to be considered by the Committee if it complies with the PBAC Guidelines.

9 Pricing fees

(1) This regulation applies to an application for a recommendation:

(a) to list the original brand of a pharmaceutical item or medicinal preparation; or

(b) to designate an original brand of a vaccine.

(2) When a price agreement is made under section 85AD of the Act or, if there is no agreement, a price determination is made under section 85B or the Act, the pricing fee mentioned in Schedule 2 for the kind of application is payable.

10 Independent review fee

(1) This regulation applies if the Committee decides not to recommend, under section 101 of the Act, that:

(a) a drug or medicinal preparation be made available as a pharmaceutical benefit or special pharmaceutical product; or

(b) an additional indication be determined for a listed drug.

(2) The fee for an independent review of the Committee's decision is $119 500.

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Note The Australia–United States Free Trade Agreement provides for an independent review for an applicant whose submission to the Committee has not resulted in a recommendation to list a drug on the Pharmaceutical Benefits Scheme, or to extend a listing of an already listed drug: see the Independent Review (PBS) website at http://www.independentreviewpbs.gov.au.

(3) There is no fee for submission to the Committee of the result of a review mentioned in subregulation (2).

11 Payment of fees

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

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

(b) within 14 days after the Department gives notice of the amount of the fee.

(2) However, the Department may agree in writing to accept partial payments.

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

(a) 14 days after being told of the amount; or

(b) a longer period allowed by the Department.

(4) 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 14 days after the later of:

(a) payment of the fee; and

(b) determination by the Department of the amount of fee that is payable.

12 Delay in payment of fees

If a 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 lodged by the applicant, until the fee is paid or no longer payable.

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13 Indexation of fees

A fee payable under these Regulations is increased on 1 July in each year in the following way:

wage cost index 3 – 1.25%

where:

wage cost index is [***to be defined in terms of the Wage Cost Index published by the Australian Bureau of Statistics.***]

Part 4 Exemptions and waivers

14 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:

(i) because of an approval granted under section 19A of the *Therapeutic Goods Act 1990*; or

(ii) because of a national emergency;

(c) to offer a price reduction;

(d) to change the name of the manufacturer;

(e) to remove a drug or brand of a pharmaceutical item from the pharmaceutical benefits scheme or vaccines from the national immunisation program;

(f) to change the pack size with no price implications;

(g) to change wording at the request of Medicare Australia;

(h) a mandated change because of a Government initiative.

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

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15 Waiver of fees

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

(2) The Department 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.

Example of circumstances in which a fee could be waived

Listing change made because of a request by the Committee.

Part 5 Review of decisions

16 Notice of review rights

When the Department makes a decision about a fee under these Regulations, it must, within 14 days after making the decision, give the applicant written notice with the following information:

(a) the terms of the decision;

(b) the reasons for the decision;

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

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

17 Internal review

(1) An applicant may apply in writing to the Department for review (***internal review***) of a decision about a fee.

(2) The application must:

(a) be made within:

(i) 14 days after the applicant received notice of the decision; or

(ii) another period allowed by the Department; and

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

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(3) The original decision maker or, if he or she is not available, another officer in the Department:

(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 after doing so, 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 Department for review of the decision made under subregulation (3).

(5) The Department:

(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 Department revokes the decision — make any other decision the Department 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 Department may suspend any work on the initial application while an application is being considered under this regulation.

18 Review by Administrative Appeals Tribunal

(1) The applicant may apply to the Administrative Appeals Tribunal for review of a decision by the Department under these Regulations.

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(2) The Department may suspend any work on the initial application 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 6 Transitional

19 Transitional

No fee under these Regulations is payable for an application:

(a) received by the Department before [***date to be inserted***]; and

(b) for which a price agreement or price determination was made before [***date to be inserted***].

Schedule 1 Lodgment fees

(regulation 8)

Item	Application	Evaluation category	Lodgment fee ($)
1	For a drug or medicinal item to be declared under subsection 85 (2) of the Act or for a special arrangement to be made under section 100 of the Act	(a) major	119 500
		(b) minor	12 500
		(c) Secretariat listing	1 000
		(d) new brand of existing pharmaceutical item	500
2	For an application for variation of a declaration under subsection 85 (2) of the Act or a special arrangement under section 100 of the Act — if the application is to be considered by the Committee	(a) major	119 500
		(b) minor	12 500
		(c) Secretariat listing	1 000

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3	For an application for variation of a declaration under subsection 85 (2) of the Act or a special arrangement under section 100 of the Act — if the application is not to be considered by the Committee	new brand of existing pharmaceutical item	500
4	For an application for the Committee to recommend a determination under section 9B of the act that a specified vaccine is a designated vaccine	(a) major	119 500
		(b) minor	12 500
		(c) Secretariat listing	1 000
5	For an application for the Committee to advise the Minister about a proposed variation of a determination under section 9B of the Act	(a) major	119 500
		(b) minor	12 500
		(c) Secretariat listing	1 000

Schedule 2 Pricing fees

(regulation 9)

Item	Application	Pricing fee ($)
1	**Tier 1** (a) the applicant relies on a claim of cost minimisation (or at least 'no worse than' according to the PBAC Guidelines); and (b) the pricing is based on a comparison of the effectiveness of a dose of the drug or medicinal item with that of another drug or medicinal item; and (c) the prices to pharmacist proposed are worked out in accordance with the Pricing Authority manual	6 000
2	**Tier 2** The applicant: (a) relies on: (i) a claim of cost minimisation, if pricing is not in worked out in accordance with the Pricing Authority manual; or (ii) acceptable incremental cost effectiveness; or (b) requests a change to a current listing and the	25 000

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	estimated net cost to the PBS is less than $10 million for each of the first 4 years of listing	
3	**Tier 3** The net cost to the PBS of implementing the PBAC recommendation is estimated by the Department and the Department of Finance and Deregulation to be least $10 million in any of the first 4 years of listing	25 000

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.

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