Australian Government

Department of Health and Ageing

DEPUTY SECRETARY

Mr Elton Humphery
Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Mr Humphery,

Thank you for your letter of 8 September 2008 to Ms Halton inviting the Department to comment, as part of a short inquiry by the Committee into the regulations for the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008.

Please find attached the following information:

Attachment A – a draft Explanatory Statement for the regulations

Attachment B – an updated version of the draft regulations, subsequent to that provided on 22 August 2008

Attachment C – a table explaining updates in the version provided at Attachment B.

The purpose of an Explanatory Statement is to assist in understanding the intended function of a Bill or regulations. It is a factual document prepared for information purposes only. As is the case with regulations, an Explanatory Statement cannot be finalised prior to the passage of the Bill.

The Explanatory Statement provided here, as a consultation draft, has been prepared to correspond and reflect the Government's intended function of the regulations. Both the Explanatory Statement and the regulations remain subject to change while consultation over the regulations continues, technical issues in the regulations are addressed and pending the outcome of the Committee's inquiry.

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

Select Legislative Instrument 2008 No.

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 2008

Governor-General

By Her Excellency's Command

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

CONSULTATION DRAFT

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.

PBAC Guidelines means the *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* (version 4.2), published in December 2007.

Pharmaceutical Benefits Pricing Authority means the body of that name created by Ministerial direction on 1 January 1988.

Pricing Authority means the Pharmaceutical Benefits Pricing Authority.

Pricing Authority manual means the *Pricing 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

(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 application.

(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 ***Committee Secretariat listing*** category if:

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

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

(5) For Schedule 1, an application is in the ***new brand of pharmaceutical item*** category if the form of the drug and manner of administration is already listed.

(6) For Schedule 2, an application is in the ***Pricing Authority Secretariat listing*** category if:

(a) the Chair and the Secretary of the Pricing Authority agree that the price requested by the applicant for the listing or change to an existing listing should be recommended, without the need for negotiation; and

(b) the requested price is recommended by the Pricing Authority without it being considered as a separate agenda item at a meeting of the Pricing Authority or being subject to price negotiation.

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

(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 or vary the listing of the original brand of a pharmaceutical item or medicinal preparation; or

(b) to designate or vary the designation of 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.

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

(1) 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.

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

(a) withhold listing the drug or medicinal preparation on the Schedule of Pharmaceutical Benefits;

(b) commence debt recovery action.

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 means an Australian Government indexation mechanism applicable to the Department and designed to take account of variations in both wage and non-wage costs for a particular year.

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 public health event of national significance;

(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.

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

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

(1) 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.

(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) After a review under subregulation 17 (5), an applicant may apply to the Administrative Appeals Tribunal for review of a decision by the Department under these Regulations.

(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 received by the Department 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) Committee 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) Committee Secretariat listing	1 000
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) Committee Secretariat listing	1 000
5	For an application for the	(a) major	119 500

	Committee to advise the Minister about a proposed variation of a determination under section 9B of the Act	(b) minor	12 500
		(c) Committee Secretariat listing	1 000

Schedule 2 Pricing fees

(regulation 9)

Item	Application	Pricing fee ($)
1	**Pricing Authority Secretariat listing**	1 000
2	**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) PBAC accepts what is being claimed in (a) and (b); and (d) the prices to pharmacist proposed are determined in accordance with the Pricing Authority manual	6 000
3	**Simple minor** A pricing negotiation that requires consideration by the Pricing Authority, and for which there is no increased cost for government	6 000
4	**Tier 2** The applicant: (a) relies on: (i) a claim of cost minimisation, if pricing is not 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 estimated net cost to the PBS is less than $10 million for each of the first 4 years of listing	25 000

Item	Application	Pricing fee ($)
5	**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
6	**Complex minor** A pricing negotiation that requires consideration by the Pricing Authority, and for which: (a) there is increased cost for government; or (b) there is a requirement to validate dose relativity; or (c) risk-sharing arrangements are to be determined between the Department and the applicant	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.

Please do not hesitate to contact the Department, should you need any further information. The contact officer is Mr Roger Busch, Director, Policy Implementation and Budget Section. Mr Busch can be contacted on (02) 6289 5136.

Yours sincerely

David Learmonth
Deputy Secretary

15 September 2008

Attachment A

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits – Charges) Regulations 2008 (No.)

Section 99YBA of the *National Health Act 1953* (the Act) provides that the Governor-General may make regulations for certain services provided by the Commonwealth which are associated with the exercise of powers by the Minister in relation to Part VII of the Act (the Pharmaceutical Benefits Scheme (PBS)), and section 9B of the Act, (the National Immunisation Program (NIP)).

Subsection 99YBA(2) provides, among other things, that a fee can be prescribed for these services.

Section 99YBB provides for the consequences if prescribed fees are not paid, including that the Minister may refuse to exercise certain powers.

Services associated with these powers include performance of the functions by the Pharmaceutical Benefits Advisory Committee (the Committee) and its sub-committees, the Pharmaceutical Benefits Pricing Authority, and related services performed by officers of the Department of Health and Ageing (the Department), contractors and sub-contractors.

The purpose of the Regulations is to allow for the charging of fees to applicants seeking to list an item on the PBS or under the NIP, or to amend a listing. These fees will be administered by the Department of Health and Ageing.

The Regulations set out the fees and conditions under which this will be achieved.

Consultation about the Regulations occurred in late August and September 2008. Stakeholders were invited to provide comments on the Regulations to the Department. Stakeholders consulted included Medicines Australia, Generic Medicines Industry Association, the Consumers Health Forum, the Royal Australian College of Physicians, Palliative Care Australia, the Pharmacy Guild, the Australian Medical Association, Australian General Practice Network and the Royal Australian College of General Practitioners.

In addition, there were three rounds of consultation with industry between 2005-2008 over proposed administrative processes and fee mechanisms.

Details of the Regulations are provided in the Attachment.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

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

The Regulations commence [date to be inserted].

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits – Charges) Regulations 2008*

Part 1 – Preliminary

Regulation 1 – Name of Regulations

Regulation 1 will provide that the title of the Regulations is the *National Health (Pharmaceutical Benefits – Charges) Regulations 2008.*

Regulation 2 – Commencement

Regulation 2 will provide that the Regulations commence on [date to be inserted].

Regulation 3 – Definitions

Regulation 3 will provide that for the purpose of these Regulations, terms have the meaning given to them by this regulation.

Terms used to describe categories of applications to the Pharmaceutical Benefits Advisory Committee (the Committee) such as, *major* and *minor* are used widely between industry and the Department of Health and Ageing. They are well understood and reflect current and longstanding practice as set out in the *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (version 4.2) December 2007*. These Guidelines were developed, as a result of ongoing consultation with the pharmaceutical industry and are periodically updated.

A *major* application to the Committee involves substantially more effort to evaluate and consider than a *minor* application. Both major and minor category applications are considered as full agenda items at a meeting of the Committee. A *major* application seeks to list new drugs or medicinal preparations for subsidy under the Pharmaceutical Benefits Scheme, or to make substantial changes to current listings. The Regulations provide the detail of the types of applications that fall into this category.

A *minor* application to the Committee will include those for new forms of an already listed drug or medicinal preparation, or changes to the conditions for prescription or supply of existing pharmaceutical benefits. The Regulations will provide the detail of the types of applications that fall into the minor category.

A *Committee Secretariat listing* is a minor application that is straightforward and not considered as a separate agenda item at a meeting of the Committee. The Committee still decides the merit of each application.

For Schedule 1, an application is in the *new brand of a pharmaceutical item* category if the form of the drug and manner of administration is already listed. This is what is commonly known as a generic product.

A *Pricing Authority Secretariat Listing* concerns an application for a price change which is recommended by the Pricing Authority without it being considered as a separate agenda item at a meeting of the Pricing Authority and is not the subject of price negotiation.

Regulation 4 – Purpose of Regulations

Regulation 4 will set out the purpose of these Regulations, which is to allow for the charging of fees to applicants seeking to list an item on the pharmaceutical benefits scheme (PBS) or under the national immunisation program (NIP), or to amend a listing. These fees will be administered by the Department of Health and Ageing.

Part 2 – Applications

Regulation 5 – Evaluation categories

Paragraph (a) will establish that when the Department receives an application of any type mentioned in Schedule 1, it must advise the applicant, within 14 days of receiving the application, which evaluation category applies.

Paragraph (b) will require the Department to advise the applicant of the fee for that evaluation category within 14 days of receiving the application.

The classification an application has for a lodgement fee (which relates to evaluation of the application) will not necessarily determine the applicable pricing category and fee payable for pricing.

Regulation 6 – Withdrawal of application

Paragraph (1) will specify that an application referred to in Schedule 1 may be withdrawn by written notice of the applicant to the Department.

Paragraph (2) will provide that where the application is withdrawn within 14 days after lodgement, any lodgement fee paid must be refunded.

Regulation 7 – Resubmission of applications

Paragraph (a) will acknowledge that an applicant may resubmit an application that is not recommended by the Committee, in the same or an amended form.

Paragraph (b) will result in a further lodgement fee, as though the resubmission were a new application. Any resubmission can be considered under the waiver paragraphs at regulation 15.

Part 3 – Fees

Regulation 8 – Lodgement fees

Paragraph (1) will establish that the fees payable for the lodgement and evaluation of applications are those set out in Schedule 1 for the relevant evaluation category.

Paragraph (2) will specify that an item in Schedule 1 is required to be considered by the Committee if it complies with the *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (version 4.2) December 2007* (the Guidelines).

Regulation 9 – Pricing fees

Paragraph (1) will mean that regulation 9 (which covers pricing fees) applies to all applications for a recommendation to list or vary the listing of a drug or medicinal preparation, or to designate or vary a vaccine.

Paragraph (2) will result in the charging of fees in accordance with Schedule 2 when a price agreement is made under section 85AD of the Act or, a price determination is made under section 85B of the Act.

No fees will be payable for pricing negotiation initiated as a result of administrative processes of the Department. For example, annual pricing reviews, Weighted Average Monthly Treatment Costs, and price reductions required under statutory price reductions that are not required to be negotiated.

Regulation 10 – Independent review fee

Paragraph (1) will mean that regulation 10 applies to an application for independent review of a Committee decision not to recommend listing of a drug or medicinal preparation, or the requested circumstances in which a drug or medicinal preparation should be made available as a pharmaceutical benefit or special pharmaceutical product.

Paragraph (2) will establish that the fee for an independent review of the Committee's decision is $119 500.

Paragraph 3 will provide that a resubmission to the Committee as a direct result of an independent review will not attract a fee.

Regulation 11 – Payment of fees

Paragraph (1) will specify that fees are payable in full at the time of payment, which is within 14 days of the Department providing notice of the amount due.

Paragraph (2) will allow for the Department to agree, in writing, with an applicant to the payment of a fee in instalments.

Paragraph (3) will specify that where a fee has been paid in advance of notice of Department's notice the amount payable, but for a lesser amount, the applicant must pay the difference within 14 days of notice of the higher amount, or, a longer period as may be allowed by the Department.

Paragraph (4) will require the Department, where an applicant has made an advance payment that was more than the fee payable, to refund the difference within 14 days of either the payment of the fee, or determination of the amount payable by the Department, whichever is the latter.

Regulation 12 - Delay in payment of fees

Regulation 12 will allow the Committee to refuse to consider an application, or any other application by the same applicant, until the relevant fee is paid, or no longer payable.

Debt recovery action may also be commenced under subsection 99YBA(5) of the *National Health Act 1953*. Further, under section 99YBB of the *National Health Act 1953* the Minister may refuse to exercise a power in relation to the application (or another application for a service for which a fee is payable under the Regulations) until the prescribed fee is paid.

Regulation 13 – Indexation of fees

Regulation 13 will allow for the indexation of fees on an annual basis using a wage cost index developed by the Department of Finance and Deregulation. This is an Australian Government indexation mechanism, which applies to the Department of Health and Ageing and is designed to take account of variations in both wage and non-wage costs for a particular year.

Part 4 – Exemptions and waivers

Regulation 14 – Exemptions

Paragraph (1)(a) will allow for a drug designated as an orphan drug under regulation 16J of the *Therapeutic Goods Regulations 1990* to be exempt from fees.

Paragraph (1)(b) will allow for other drugs that are exempt from entry on the Australian Register of Therapeutic Goods because of a temporary supply approval (under section 19A of the *Therapeutic Goods Act 1989*), and for drugs to be included on the PBS in a national emergency (as defined in the *National Health Security Act 2007),* to also be exempt from fees.

Paragraphs (1)(c)–(h) will specify for other types of applications where no fee is payable.

Paragraph (2) will require that an applicant who wishes the Department to consider whether an exemption applies, must include information in the application about why an exemption would apply. This information could include, for example, details of an orphan drug designation.

Regulation 15 – Waiver of fees

Paragraph (1) will allow for the applicant to apply for a full or partial waiver of fees payable under the Regulations.

Paragraph (2) will require that an application for a full or partial waiver involve the public interest and be financially unviable if a fee was payable.

It is intended that considerations in assessing the public interest will include in particular, the contribution of the application to a particular disease state/s and the patient population involved, for example, where the patient population is likely to be small and utilization of the drug, medicinal preparation or vaccine is likely to be highly targeted, such as in Aboriginal and Torres Strait Islander communities and/or for people undergoing palliative care.

The assessing officer will take into account information supplied by the applicant, information held or obtained by the Department and information in the public domain when considering waiver of fees. The officer assessing the application for waiver will need to be satisfied that, based on the available information, proceeding with the application would not be financially viable if the applicable fee is payable. The type of information the officer may take into account will include:

- the potential utilization of the drug or medical preparation or vaccine,
- the price requested;
- whether the Committee or the Department invited the application; and
- whether alternate products are already subsidised under the Pharmaceutical Benefits Scheme, or designated under the National Immunisation Program.

Decisions about fee waivers will be made on a case-by-case basis. Rights for review of the waiver decision will be available under Part 5 of the Regulations.

Part 5 – Review of decisions

Regulation 16 – Notice of review rights

Paragraph (1) will require that the Department give notice in writing, within 14 days of making a decision about a fee, the terms of the decision and the reasons, including an explanation of the applicant's review rights.

Paragraph (2) will mean that a failure to comply with Paragraph 1 does not affect the validity of the decision.

Regulation 17 – Internal review

Paragraph (1) will allow an applicant to apply in writing to the Department for a review (internal review) of a decision about a fee, including a fee category or a decision about a fee exemption or waiver.

Paragraph (2)(a) will state that this application must be made within 14 days of the applicant receiving notice of the decision, or within another period allowed by the Department.

Paragraph (2)(b) will require the applicant to detail the grounds on which the applicant relies in applying for the review.

Paragraph (3)(a) will require that the decision must be reviewed by the original decision-maker, or another officer in the Department if that person is not available, within 14 days of the request being received.

Paragraph (3)(b) will mean the decision could be affirmed, revoked or varied by the original decision maker. If the decision is to be revoked, this paragraph will allow for any other decision to be made as thought appropriate by the review officer.

Paragraph (3)(c) will require that within 14 days of reviewing the decision, the applicant must be advised of the result in writing.

Paragraph (4) will allow for the applicant, within 14 days after receiving that advice to apply in writing to the Department to have the decision made following the review by the Officer involved in paragraph 3(a) reviewed further by a different person.

Paragraph (5)(a) will require that the Department review the decision within 14 days after receiving this request.

Paragraph (5)(b) will mean that the Department could affirm, revoke or vary the reviewable decision. If the decision is to be revoked, this paragraph will allow for any other decision thought to be appropriate.

Paragraph (5)(c) will require that the Department, within 14 days of reviewing the decision in paragraph (3), provide written notice to the applicant of the decision.

Paragraph (6) will require that the person in the Department who carries out the review under paragraph (5), must not have been involved in the original decision or the internal review decision made under Paragraph 3.

Paragraph (7) will provide that the Department may suspend work on the application while a decision under this regulation is being considered.

Regulation 18 – Review by Administrative Appeals Tribunal

Paragraph (1) will provide for applicants to apply to the Administrative Appeals Tribunal for a review of a decision made by the Department under these Regulations after any internal review rights under regulation 17 have been completed.

Paragraph (2) will provide that the Department may suspend work on an application for listing while an application is being considered under this regulation.

Paragraph (3) will provide that, for regulation 18, *decision* means the same as it does in the *Administrative Appeals Tribunal Act 1975.*

Part 6 - Transitional

Regulation 19 – Transitional

Regulation 19 will provide that no fee will be payable for an application received by the Department before [insert date]. This will give certainty as to which applications will be subject to the fees payable under the Regulations.

Schedule 1 – Lodgement fees

Schedule 1 sets out, for the purposes of regulation 8, the fees for each evaluation category for lodgement applications mentioned in the Schedule.

The lodgement fees for an application falling within the *major* category will be $119,500, a *minor* category $12,500, a *Committee Secretariat Listing* $1,000 and for a *new brand of pharmaceutical item* category $500.

Item 1 will apply to an application to list a drug or medicinal preparation for subsidy under the PBS, and for an arrangement to be made for supply of a special pharmaceutical product under section 100 of the Act, where the application must be considered by the Committee.

Item 2 will apply to applications seeking to vary the declaration for a drug or medicinal preparation listed for subsidy under the PBS, or vary an arrangement applying to a special pharmaceutical product under section 100 of the Act, in cases where the application is to be considered by the Committee.

Item 3 will apply to applications, in respect of a *new brand of a pharmaceutical item*, to vary the declaration of a drug or medicinal preparation listed for subsidy under the Pharmaceutical Benefits Scheme, or vary an arrangement applying to a special pharmaceutical product under section 100 of the Act, in cases where the application is not to considered by the Committee.

Item 4 will apply to applications to the Committee to recommend the designation of a vaccine under section 9B of the Act for the National Immunisation Program.

Item 5 will apply to applications to the Committee to vary a determination of a vaccine designated under section 9B of the Act for the National Immunisation Program.

Schedule 2 – Pricing fees

Schedule 2 sets out, for the purposes of regulation 9, the fees that will be charged on the completion of a pricing agreement or determination.

The pricing fee for *major* category items includes reference to pricing Tiers. Definitions for pricing Tiers were developed in consultation with the pharmaceutical industry, and in particular Medicines Australia. The concept of pricing Tiers applies only to applications in the *major* category.

Item 1 will apply to pricing for a *Pricing Authority Secretariat Listing.* The fee will be $1,000.

Item 2 will apply to applications that are in the *major* category, where the pricing category is determined to be a Tier 1 (one). The pricing fee will be $6,000. Tier 1 pricing applies to applications that rely on a claim of cost minimisation, which is where the pricing for a brand of a pharmaceutical item that has the relevant drug is based on a comparison of the effectiveness of a dose with an existing brand of a pharmaceutical item that has the relevant drug or medicinal preparation.

Item 3 will apply to applications that are in the *minor* category, where the pricing application requires consideration by the Pricing Authority and where there is no net financial implication for government. The pricing fee will be $6,000.

Item 4 will apply to applications that are in the *major* category, where the pricing category is determined to be a Tier 2 (two) and where the estimated cost to the PBS is less than $10 million for each of the fist 4 years of the changed price for the listing or arrangement. The pricing fee will be $25,000. Tier 2 pricing applies to applications that rely upon:

- a claim of cost minimisation in circumstances where the pricing is not worked out in accordance with the Pricing Authority manual; or
- acceptable (to the Committee) incremental cost effectiveness. Incremental cost effectiveness is the ratio of the extra costs of introducing a new medicine (or introducing a change in the use of an existing medicine) divided by the improvement in health outcomes it produces. Or;
- a request for a change to a current price of a brand of pharmaceutical item that has a drug or medicinal preparation that is listed for subsidy under the Pharmaceutical Benefits Scheme, or to a price applying to a special pharmaceutical product,

Item 5 will apply to applications that are in the *major* category, where the pricing category is determined to be a Tier 3 (three). The pricing fee will be $25,000. Tier 3 pricing applies to applications that rely upon the items outlined in Tier 2, but where the estimated cost of listing the brand for subsidy under the Pharmaceutical Benefits Scheme, or the price applying to a special pharmaceutical product, is more than $10 million for any of the first 4 years of the changed price for the listing or arrangement.

Applications where the estimated cost to the PBS is more than $10 million for any of the first four years of listing, or change to a listing, require consideration by Cabinet. The fee for a price negotiation under Tiers 2 and 3 will be the same, as the cost of preparing the Cabinet submission will not be passed onto applicants, as it is an administrative process required by government.

Item 6 will apply to applications that are in the *minor* category, where the pricing application requires consideration by the Pricing Authority and where there:

- is a net financial implication for government; and/or
- is a requirement to validate the dose-relativity of the drug or medicinal preparations; and/or
- the Department and applicant enter into a price rebate or price volume Deed.

The pricing fee for Item 6 will be $25,000

Attachment C

A summary of updates to draft regulations for the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008

Current Situation

1. A version of the draft regulations was provided to the Senate Community Affairs Committee on 22 August 2008.
2. The office of Legislative Drafting and Publishing has recently provided an updated version that incorporates comments from the Department of Health and Ageing on the previous draft.

Explanation of Changes

The table below summarises the amendments made to the draft regulations since a version was provided to the Senate Community Affairs Committee.

Schedule 2 (pricing fees) has been expanded to ensure that all types of pricing agreements are defined in the regulations. The main change is the addition of a new (lower) fee for pricing agreements that do not require negotiation. This pricing point was introduced into Schedule 2 as the previous version did not cater for straightforward pricing agreements that required no negotiation. Inserting the new lower point ensures that applicants will not be inappropriately charged a higher fee.

Regulation Reference	**Amendment**	**Rationale**
Schedule 2 Pricing Fees	A new price point '*Pharmaceutical Benefit Pricing Authority Secretariat listing*' category has been added. (Defined in Regulation 3(6). The fee for applications in the PBPA Secretariat listing category is $1000.	To ensure that pricing agreements that require no price negotiation are not inappropriately charged.
Schedule 2 continued	Insertion of two new pricing definitions – *simple minor* and *complex minor*. The cost of a 'Simple Minor' submission will be the same as for a Tier 1: $6,000. The cost of 'Complex Minor' submission will be the same as Tiers 2 and 3: $25,000.	To ensure pricing agreements reached on applications in the *minor* lodgement category can be charged a fee. The pricing terminology referring to Tiers only applies to application in the *major* lodgement categories. Inserting the additional definitions ensures that all pricing agreements can be charged the appropriate fee reflecting the activity

		required.
Technical Changes		
3 (1) Definitions PBAC Guidelines	Reference to PBAC Guidelines now reads *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (version 4.2) December 2007.*	There is a legal requirement for the full title of the guidelines to appear in order for them to have legal effect.
3 (1) Definitions Pharmaceutical Benefits Pricing Authority (PBPA)	Regulations now include a definition for the PBPA	The PBPA makes recommendations to the Minister about pricing of new pharmaceutical items (and other matters as appropriate) and therefore needs definition for the purpose of Schedule 2.
3 (1) Definitions *Pricing Authority manual*	This term has been revised to reflect its full and correct title: *Pharmaceutical Benefits Pricing Authority Manual, Pricing Procedures and methods used in the pricing of pharmaceutical products, December 2006.*	There is a legal requirement for the full title of the manual to appear for its legal effect.
3 (2) Definitions Consistency of terminology	Submission replaced by application.	Consistency
3 (4) Definitions Secretariat listing category	This term has been revised to: *For Schedule 1, an application is in the <u>Committee</u> Secretariat listing category if:* (listed requirements not reproduced here).	The inclusion of the word 'Committee' into the term differentiates it from the new term: *PBPA Secretariat Listing category*, which arises from the need for additional pricing points.
3 (4) Definitions (a) – (c) requirements for a *Committee* Secretariat listing category	Sub-paragraph (b) has been amended by removing the words '…by the Committee'	This revision represents the legislative and current administrative practice more accurately.
3 (5) Definitions New brand	Revision of the definition for 'new brand of pharmaceutical item'	Definition revised for technical accuracy.
3 (6) Definitions Pricing Authority Secretariat Listing	Insertion of new definition	Required to define the lowest pricing agreement fee category.

9 (1) Pricing Fees Listing of pharmaceutical items or designating vaccines	Paragraphs 1 (a) and (b) amended to also specify that variations to listings attract fees.	Drafting error omitted the word vary. The amendment to subparagraph (1) means it now reflects the full range of functions pricing fees cover.
12 Delay in payment of fees Consequences	Inclusion of additional wording to reflect the legislation.	This regulation has been expanded to provide more information about the full range of actions permitted under the legislation when a fee is not paid.
13 Indexation of fees Wage cost index	More detail of wage cost index parameters included.	This revision was made to provide information and detail about context.
14 Exemptions National emergency	Now defined as 'a public health event, as defined by the *National Health Security Act 2007*.	This revision has been made to ensure accuracy.
1**8 Review by Administrative Appeals Tribunal** (AAT)	Sub regulation 18 expanded to reflect graded steps to processes of review.	To ensure that recourse to the AAT can only happen after the process of internal review is complete.
19 Transitional	Paragraph (b) removed	The full sense of the intended meaning for this subparagraph was already encompassed in paragraph (a).
Schedule 2 Pricing Fees 1 Tier 1 (c)	To make evident that PBAC must accept the claims made by sponsors in submissions in order to make a positive recommendation.	This reflects the current operation of PBAC and its relationship with the PBPA.
1 Tier 1 (c) – now (d)	Insertion of the word *'determined'*. .	Technical accuracy.