EXPLANATORY STATEMENT

Select Legislative Instrument 2009 No. 372

National Health Act 1953

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

Section 140 of the *National Health Act 1953* (the Act) provides in part, that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Division 4C of Part VII the Act enables fees to be charged for certain services provided by the Commonwealth Government (the Commonwealth) in order to recover the cost to the Commonwealth of providing those services. Those services relate to the exercise of certain powers of the Minister for Health and Ageing (the Minister) under section 9B of the Act (which relates to the National Immunisation Program (NIP)) and under Part VII of the Act (which relates to the Pharmaceutical Benefits Scheme, or (PBS)). The services include the functions of the Pharmaceutical Benefits Advisory Committee (the Committee) and its sub-committees; the functions of the Pharmaceutical Benefits Pricing Authority; and related functions performed by officers and administrative staff of the Department of Health and Ageing (the Department), and by contractors and sub-contractors of the Department.

Section 99YBA of the Act provides for regulations to set out the fees that are payable for those services, as well as other matters relating to the payment of those fees and the provision of those services, including some consequences of failing to pay a fee.

The Regulations prescribe application categories, fees and application procedures to applicants seeking a new or amended inclusion in the PBS or NIP. The Regulations also provide for exemption from fees, waiver of fees, and for review rights and procedures. The fees and procedures are administered by the Department.

The introduction of fees for applications seeking inclusions in the PBS or NIP was announced in the 2008-09 Budget. The *National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Act 2009*, which inserted Division 4C into Part VII of the Act, received Royal Assent on 22 July 2009.

Details of the Regulations are provided in the Attachment.

Consultation

Since 2005 when it was first announced, the Department of Health and Ageing has undertaken several rounds of consultations regarding the policy to recover the costs associated with the evaluation of medicines by the Pharmaceutical Benefits Advisory Committee. Consultations have focussed on those stakeholders expected to pay fees under the policy, that is pharmaceutical companies, and the peak industry representative organisations Medicines Australia and the Generic Medicines Industry Association. Inputs have been received from particular subsets of the industry where appropriate, such as from organisations interested in the listing of low volume or niche products (for example, Orphan Australia). Other interested stakeholders who have participated in the consultation process at various stages include PBS prescribers (for example, the Australian Medical Association),

consumers (for example, the Consumers' Health Forum) and pharmacists (for example, the Pharmacy Guild of Australia).

November 2005 – February 2007 Consultations

The PBS cost recovery policy was announced in the 2005-06 Budget, and was scheduled to commence on 1 July 2007. The first round of consultations commenced in late 2005 and included a paper outlining the broad issues for consideration, and subsequent meetings, followed by written advice to affected stakeholders.

April 2007 – August 2007 Consultations

The second round of consultations was based on a discussion paper which presented mechanisms for cost recovery (such as levies, fees and charges) and was distributed to all interested stakeholders. The Department received wide-ranging responses to the discussion paper and at the meetings that followed. However, there was a strong and consistent message from stakeholders that the preference was for a fees-only mechanism, structured as simply as possible, and with early announcement to facilitate business planning.

The Department responded by reflecting its costs in a fee schedule that had minimal fee points for administrative ease and efficiency. The time and resources associated with each step of the PBS listing process had been captured in an activity-based costing process, which allowed for evaluation and pricing fees per submission.

The commencement of cost recovery was deferred to 1 January 2008; however, Parliament was dissolved in 2007 before enabling legislation was introduced.

May 2008 – June 2008 Consultations

The Government announced in the 2008-09 Budget that cost recovery would be implemented on 1 July 2008. The Department undertook a third round of consultations, consisting of information sessions for pharmaceutical companies and meetings with Medicines Australia and Generic Medicines Industry Association.

The PBS Cost Recovery Bill 2009 was subject to Parliamentary process, including debate and two Senate Community Affairs Committee Inquiries between May and September 2008. The second Inquiry considered the draft regulations, which were provided to all stakeholders, including non-industry bodies such as the Australian General Practice Network, the Australian Medical Association and the Pharmacy Guild of Australia. Both inquiries recommended the passage of the enabling legislation.

September 2008 – October 2008 Consultations

A fourth round of consultations commenced in September 2008 where the Department met with stakeholders such as Palliative Care Australia, Medicines Australia and other interested parties to discuss the draft regulations and issues arising from the Inquiries.

June 2009 – October 2009 Consultations

Following the Government's resubmission of the Bill to the House of Representatives in May 2009, the Department undertook further consultations with stakeholders, including non-industry groups such as the Pharmacy Guild of Australia and the Australian Medical Association.

Following passage of the enabling legislation through Parliament on 16 June 2009, consultations with industry occurred in June and September 2009 on implementation issues, including a commencement date, a draft Cost Recovery Impact Statement and the draft regulations. The Department held a further series of information sessions for the pharmaceutical industry in mid-October 2009.

Ongoing Information and Consultation Mechanisms

The Department will continue to consult with stakeholders on PBS cost recovery. Information is regularly provided through the PBS website (www.pbs.gov.au) and, in addition to existing communications channels with stakeholders, the Department operates a dedicated email enquiry system (pbscostrecovery@health.gov.au).

The Department has agreed with industry to establish a formal, ongoing consultative mechanism. Two meetings have occurred (3 June 2008 and 22 July 2009) and further meetings will be held on a regular annual basis. It is envisaged that this group will operate on a similar basis to the Therapeutic Goods Administration's Industry Consultative Committee and dovetail into the broader scope of the Access to Medicines Working Group (AMWG). The AMWG is an ongoing joint working group between Medicines Australia and the Department established in 2006 as a result of the reforms to the PBS. The purpose of the AMWG is to provide strategic oversight of joint activities undertaken by the Department and Medicines Australia to enhance the PBS processes, and to consider issues relating to timely and appropriate access to effective new medicines on the PBS following the PBS reforms. 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 on 1 January 2010.

ATTACHMENT

Details of the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009*

Part 1 – Preliminary

Regulation 1.1 – Name of Regulations

This regulation provides that the title of the Regulations is the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009*.

Regulation 1.2 – Commencement

This regulation provides that the Regulations commence on 1 January 2010.

Regulation 1.3 – Definitions

Regulation 1.3 provides that, for the purpose of the Regulations, terms have the meaning given to them in this regulation.

For the Regulations:

- *Act* means the *National Health Act 1953* (the Act)*;*
- *Brand* has the meaning given by the Act*;*
- *Committee* means the Pharmaceutical Benefits Advisory Committee;
- The *drug or vaccine* means the drug, medicinal preparation or vaccine which is the subject of the application;
- *Economic evaluation* means data that is a comparative analysis of the costs and outcomes of the therapy (to be provided by the drug or vaccine) and an alternative therapy nominated by the applicant;
- *Evaluation fee* means a fee prescribed by regulation 4.1;
- *Listed brand* has the meaning given by the Act;
- *Listed drug* has the meaning given by the Act;
- *Medicinal food* means a food that is a therapeutic good within the meaning of paragraphs (a) and (b) of the definition of 'therapeutic good' in section 3 of the *Therapeutic Goods Act 1989;*
- *Pharmaceutical item* has the meaning given by the Act;
- *Pricing fee* means a fee prescribed by regulation 4.2;
- *Secretary* has the meaning given by the Act, and for these regulations means the Secretary of the Department of Health and Ageing (the Department); and

- *Therapy*, for an application, means the clinical purpose stated in the application for a drug, medicinal preparation, additive or vaccine.

Part 2 – Applications

Division 2.1 – Evaluation categories for applications etc

Subdivision 1 - Preliminary

Regulation 2.1 – Scope of applications

Subregulation 2.1(1) provides that a person may make an application to request that the Committee make a recommendation or give advice as mentioned in Schedule 1 to the Regulations, or that the Minister for Health and Ageing take an action mentioned in an item or items in that Schedule.

Subregulation 2.1(2) allows for an application to include more than one item mentioned in Schedule 1 but only if the requests relate to the same drug, medicinal preparation or vaccine and each of the requests relates to the same disease or disorder. Applications that involve medicines and vaccines that are already included in the Pharmaceutical Benefits Scheme (PBS) may also relate to more than one item on Schedule 1.

Regulation 2.2 - Categories of applications

Regulation 2.2 provides that an application under this Part is in one of the following evaluation categories: major, minor, Committee Secretariat or new brand of existing pharmaceutical item.

The *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* (the Guidelines) version 4.1, which were last published on the Department's website in December 2008, provide substantial guidance to applicants about preparation of applications, the nature of evidence required and the required format for presenting the applicant's claims. The Guidelines, which are updated periodically, include a broad range of both clinical and economic information collated so as to demonstrate what is involved in obtaining a subsidy under the PBS. The updated versions are published following consultation with the pharmaceutical industry.

Subdivision 2 – Applications that are major

A *major* application 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. In general, a *major* application seeks to list new drugs or medicinal preparations for subsidy under the PBS, or to make substantial changes to current listings. Subdivision 2 provides the detail of the types of applications that fall into this category, with reference to the list of items in Schedule 1.

Regulation 2.3 – Major - applications to list

Regulation 2.3 provides that applications to the Committee to make a recommendation to the Minister to take action under some items in Schedule 1 are major applications. These items are 1.1, 1.3, 2.1, 2.3 and 2.10 in Schedule 1.

Regulation 2.4 – Major – health advantage test

Subregulation 2.4(1) provides that an application is in the major category if it includes a request to the Committee to make a recommendation to the Minister to take action under items 1.2, 2.2, 2.5 or 2.12 in Schedule 1 or to provide advice to the Minister is relation to item 2.15 in Schedule 1 where subregulation 2.4(2) applies to the request.

Subregulation 2.4(2) applies if the request requires the Committee to assess the extent of improvement in efficacy or reduction in toxicity of the therapy in the application over other therapy provided by any listed drug, special pharmaceutical product or designated vaccine; and the cost of the therapy in the application as it relates to other therapy; and the additional benefit provided by the improvement in efficacy or reduction in toxicity in relation to the additional cost of providing the therapy in the application.

Regulation 2.5 – Applications excluded from major category

Regulation 2.5 provide that an application is not in the major category where that application includes a request which meets the criteria for a major application under regulations 2.3 or 2.4 and also meets the criteria for a minor application under regulations 2.10 or 2.11 (minor – applications that are resubmissions and minor - medicinal foods).

Regulation 2.6 – Requirements for major applications

Regulation 2.6 provides that a major application must be supported by an economic evaluation.

Subdivision 3 – Applications that are minor

In general, *minor* applications to the Committee 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. Subdivision 3 provides the detail of the types of applications that fall into the minor category, with reference to the list of items in Schedule 1.

Regulation 2.7 – Minor – applications to change listings

Subregulation 2.7(1) provides that an application is in the minor category if it is not a major application under Subdivision 2 and 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.

Subregulation 2.7(2) provides that an application is in the minor category if it includes a request for the Committee to recommend to the Minister to take action mentioned in items 1.4, 2.4, 2.6, 2.8, 2.9, 2.11 or 2.14 of Schedule 1 and, if the application includes any other request, the application is not a major application.

Regulation 2.8 – Minor – clinical need and cost effectiveness test

Subregulation 2.8(1) provides that an application is in the minor category where the application is not in the major category and subregulation 2.8(2) applies to the request.

Subregulation 2.8(2) applies where the request to the Committee requires the Committee to assess an applicant's claim about the clinical need and clinical effectiveness of a request in the application and the request does not propose any changes to the unit price of a listed drug, special pharmaceutical product or vaccine or require the Committee to assess any cost implications for the supply of a drug, medicinal preparation or vaccine arising from a request.

Regulation 2.9 Minor – exceptions to the new brand of existing pharmaceutical items category

Regulation 2.9 provides that an application is in the minor category if it is about somatropin (a growth hormone), item 1 in the table in Schedule 2 and the applicant makes a claim about the therapeutic benefit that is derived from the relationship between ingredients in the medicinal preparation.

While each different branded product of somatropin could be considered to be a generic product under regulation 2.14, applications about somatropin are treated differently to other generic product applications when received by the Department. Applications cannot be dealt with administratively by the Department because somatropin is a biological product and each branded product of somatropin has not been deemed, by the Therapeutical Goods Administration, to be substitutable for any other branded product of somatropin. The Committee needs to be satisfied that each branded product of somatropin is substitutable for any other branded product of somatropin and therefore each application for somatropin requires consideration, as a separate agenda item, by the Committee.

Regulation 2.10 Minor – applications that are resubmissions

Regulation 2.10 provides that some applications to the Committee are in the minor category where paragraphs 2.10(a) to (e) are met.

Paragraph 2.10(a) provides where it is resubmitted under regulation 2.20 (see below).

Paragraph 2.10(b) provides where it was previously evaluated by the Committee in the major category.

Paragraph 2.10(c) provides where it does not include data that is a reconstruction of a modelled economic evaluation previously considered by the Committee or a new methodological basis to support a variable in a modelled economic evaluation previously considered by the Committee.

Paragraph 2.10(d) provides where the request satisfies the requirements for a major application under Subdivision 2.

Paragraph 2.10(e) provides that if it includes a request not previously considered by the Committee – that request does not satisfy the requirements for a major application under Subdivision 2.

Regulation 2.11 Minor – medicinal foods

Regulation 2.11 provides that an application is in the minor category if it usually satisfies the requirement to be in the major category, but it solely relates to a medicinal food, and where it is not possible for the applicant to provide an economic evaluation because the patient population is too small.

Subdivision 4 – Other categories

Regulation 2.12 Applications that are Committee Secretariat

A *Committee Secretariat* listing is a type of minor category 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.

Regulation 2.12 specifies the types of applications that fall into the Committee Secretariat category, with reference to the list of items in Schedule 1. This application category also includes applications that are not minor nor major under Subdivision 2 or 3.

Regulation 2.13 – Committee Secretariat – exceptions to the new brand of pharmaceutical item category

Regulation 2.13 provides that an application to the Minister to take action mentioned in items 3.1 or 3.2 in Schedule 1 is in the Committee Secretariat category when the application is about a kind of pharmaceutical item 2 mentioned in Schedule 2 (a glucose indicator).

While each glucose indicator product could be considered to be a generic product under Regulation 2.14 (below), applications about glucose indicators are treated differently to other generic applications when received by the Department. Applications cannot be dealt with administratively by the Department because not all glucose indicator products are exactly the same as there are a variety of different types of glucose test machines in use in Australia. Applications about a glucose indicator are therefore not about an identical active ingredient. The applications are, however, straightforward and are not considered as separate agenda items by the Committee.

Regulation 2.14 - Applications that are a new brand of an existing pharmaceutical item

An application in the *new brand of an existing pharmaceutical item* category is commonly known as an application about a generic product.

Regulation 2.14 provides that an application falls into this category where it requests the Minister to take action mentioned in items 3.1 and 3.2 of Schedule 1 and where the request is not about a kind of medicinal preparation mentioned in Schedule 2 (somatropin or a glucose indicator).

Subdivision 5 – Evaluation categories

Regulation 2.15 Matters requiring consideration

Regulation 2.15 ensures that where there is an element of discretion used in determining the relevant evaluation category, the views of the Chairperson of the Committee are taken into account.

Subregulation 2.15(1) specifies that for each of the items listed in the table in this regulation, the Secretary must, for the purposes of determining the evaluation category of an application under Division 2.1, be satisfied that each of the matters in the item requires consideration. If the Secretary is satisfied of this, then the Secretary consults with the Chairperson of the Committee before making a decision about the matter (as listed in the table).

Subregulation 2.15(2) provides that for the purpose of determining an evaluation category of an application under regulation 2.11 (minor – medicinal foods) the Secretary must be satisfied that it is not possible for the applicant to provide an economic evaluation because the patient population is too small.

Division 2.2 – Application procedure

Regulation 2.16 - How to apply

Subregulation 2.16(1) specifies that an application mentioned in Division 2.1 must be made in writing, in an approved form, to the Secretary and sent to the office of the Department administering the Committee.

Subregulation 2.16(2) specifies that an application under regulation 2.9, 2.13 or 2.14 must be made in writing to the Secretary and sent to the office of the Department administering the applications about items 3.1 or 3.2 in Schedule 1 (generic products).

Subregulation 2.16(3) provides that the Secretary may, in writing, approve forms for use in making applications under the Regulations.

Regulation 2.17 – Notification

Regulation 2.17 provides for the Department to notify applicants of certain matters once it receives an application.

Subregulation 2.17(1) requires that the Department notify the applicant of certain matters in writing within 14 days of receiving an application. These matters include acknowledging receipt of the application, information about whether a fee exemption or waiver has been granted (if requested), any decision made by the Secretary about the evaluation category of the application, the amount of the evaluation fee and the applicant's review rights under Part 6 of the Regulations.

Subregulation 2.17(2) provides that the fee for an application, or any part of the fee that has not been waived, is payable to the Department unless a fee exemption has been granted or the fee has been completely waived (exemptions and waivers are provided for in Part 5 of the Regulations).

Regulation 2.18 – Assessment of applications

Subregulation 2.18(1) provides that the Committee may request further information from the applicant.

Subregulation 2.18(2) provides that the Committee may request the Secretary to initiate a review of the decision about the evaluation category of an application under regulation 6.3 (Internal review – Secretary), if it is unable to assess the application without further information.

Regulation 2.19 – Withdrawal of application

Subregulation 2.19(1) specifies that an application may be withdrawn by written notice to the Department.

Subregulation 2.19(2) provides that any evaluation fee paid must be refunded where the application is withdrawn within 14 days after notice is given under regulation 2.17.

Regulation 2.20 – Resubmission of applications

Regulation 2.20 provides that a resubmitted application be treated as if it were a new application for the purposes of the Regulations.

Paragraph 2.20(a) provides that an applicant may resubmit an application in the same or an amended form when the application has not been recommended by the Committee or when the Committee has not given the advice requested [as provided for under paragraph 2.1(1)(a)].

Paragraph 2.20(b) provides that the resubmitted application is subject, as if it were a new application, to Division 2.1 and a fee under regulation 4.1.

Part 3 – Pricing

Division 3.1 – Pricing

Regulation 3.1 – Applications to which this Part applies

Regulation 3.1 provides that Part 3 applies to major or minor applications (as mentioned in Subdivision 2 or 3 of Part 2), and to Committee Secretariat applications (as mentioned in regulation 2.12 or 2.13), subject to paragraphs (a) and (b).

Paragraph 3.1(a) provides that regulation 3.1 applies where the Committee provides advice or makes a recommendation to the Minister and paragraph (b) applies.

Paragraph 3.1(b) provides that the recommendation or advice [in paragraph (a)] results in the Minister making or varying a price agreement or price determination with the applicant about an item listed or seeking a listing, or arranging for a price for which a designated vaccine may be supplied or making or varying an agreement with the applicant in relation to the price of a special pharmaceutical product.

Division 3.2 – Pricing categories for applications

Regulation 3.2 – Pricing categories

Regulation 3.2 provides that applications under Part 3 are categorised as complex, simple or Pricing Secretariat.

Regulation 3.3 – Complex pricing category

Regulation 3.3 provides that certain types of pricing decisions are in the complex pricing category.

Subregulation 3.3(1) provides that the complex pricing category applies to a claim to which subregulation (2) applies and the resulting price for a drug, medicinal preparation or vaccine is higher than the price for an equivalent amount of a listed drug, special pharmaceutical product or designated vaccine nominated by the applicant in the application as an alternative therapy; or the Committee considers is clinically comparable to the drug, medicinal preparation or vaccine.

Subregulation 3.3(2) applies if the applicant claims that the use of the drug, medicinal preparation or vaccine provides a significant improvement in the efficacy or reduction in toxicity compared to the alternative therapy or therapies as provided by a listed drug, special pharmaceutical product or designated vaccine and the application requests a higher price compared to the alternative therapy or therapies and the Committee's recommendation accords with these claims.

Subregulation 3.3(3) provides that an application is in the complex pricing category if paragraph (a), (b) or (c) applies.

Paragraph 3.3(a) applies if the application included a request for a review of an existing price and the resulting price is higher.

Paragraph 3.3(b) applies if, when the application was made, it included 'a claim of cost minimisation' (which is defined in regulation 3.6) and the Committee's advice or recommendation to the Minister did not accord with that claim.

Paragraph 3.3(c) applies if there is an agreement between the applicant and the Commonwealth (other than an agreement mentioned at paragraph 3.1(b)) containing risk-sharing arrangements or other requirements relating to the supply of the drug, medicinal preparation or vaccine.

Regulation 3.4 – Simple pricing category

Regulation 3.4 provides that certain types of pricing decisions are in the simple pricing category if the requirements of the following paragraphs are met.

Paragraph 3.4(a) applies if an application is not in the complex pricing category.

Paragraph 3.4(b) applies if, when the application was made, it included a claim that the effectiveness of a specified dose of the drug, special pharmaceutical product or vaccine subject to the application is equivalent to the dose of a listed drug, special pharmaceutical product or designated vaccine and (the application) makes a claim of cost minimisation.

Paragraph 3.4(c) applies if the Committee's recommendation or advice to the Minister was in accord with the claim.

Paragraph 3.4 (d) applies if the resulting price is based on the claim.

Regulation 3.5 – Pricing Secretariat pricing category

Regulation 3.5 provides that an application is in the Pricing Secretariat category if it is not in either the complex or simple pricing categories.

Regulation 3.6 – Claims of cost minimisation

Regulation 3.6 provides that, for the purposes of Division 3.2, an applicant makes a 'claim of cost minimisation' if the applicant claims that the drug, medicinal preparation or vaccine

provides similar health benefits as those provided by the other drug or vaccine and may be supplied at the same, a similar or a lower price per unit.

Division 3.3 – Pricing procedure

Regulation 3.7 – When a pricing fee is payable

Pricing fees are only payable following the conclusion of price negotiations.

Regulation 3.7 specifies that a pricing fee is payable (under regulation 4.2) when an agreement or determination mentioned in paragraph 3.1(b) is made or varied or, for vaccines, when a price mentioned in subparagraph 3.1(b)(iii) is recommended.

Regulation 3.8 – Notification

Subregulation 3.8(1) requires the Department to notify applicants of certain matters within 14 days of the occurrence of events specified in paragraphs 3.8(1)(a), (b), (c) and (d).

Paragraph 3.8(1)(a) provides for events on completing pricing agreements or determinations mentioned in regulation 3.1.

Paragraph 3.8(1)(b) provides for events covering completing price recommendations (for vaccines) mentioned in regulation 3.1.

Paragraph 3.8(1)(c) provides for events about decisions made by the Secretary about a pricing category under Division 3.2.

Paragraph 3.8(1)(d) provides for events following a decision about a fee exemption or fee waiver in relation to a pricing fee.

Subregulation 3.8(2) requires that the notification include information about the applicant's review rights (under Part 6 of the Regulations).

Subregulation 3.8(3) provides that the pricing fee for an application, or any part of the fee that has not been waived, is payable unless a fee exemption has been granted or unless the fee has been completely waived (exemptions and waivers are provided for in Part 5 of the Regulations).

Part 4 – Fees

Regulation 4.1 – Evaluation fees

Regulation 4.1 provides that the fee for making an application under Part 2 is the amount mentioned in Schedule 3 for the category of the application.

Regulation 4.2 – Pricing fees

Subregulation 4.2(1) provides that pricing fees only apply if an applicant and the Minister make an agreement mentioned in paragraph 3.1(b); or the Minister makes a price determination mentioned in subparagraph 3.1(b)(ii); or the Minister provides for a price recommendation mentioned in subparagraph 3.1(b)(iii).

Subregulation 4.2(2) provides that the fee for the agreement, determination or recommendation is the amount mentioned in Schedule 4 for the pricing category on which the agreement, determination or recommendation is based.

Regulation 4.3 – Independent review fee

Regulation 4.3 provides that fees are payable for independent reviews of certain decisions of the Committee.

Subregulation 4.3(1) provides that an applicant may seek an independent review of a decision by the Committee not to make a recommendation that the Minister declare a drug or medicinal preparation under subsection 85(2) of the Act, or 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.

Subregulation 4.3(2) provides that an application submitted for independent review must be submitted in the form in which it was originally considered by the Committee and have been rejected by the Committee in its entirety.

Subregulation 4.3(3) provides that the fee for the independent review is $119,500 which is payable at the time the application is submitted for independent review.

Subregulation 4.3(4) provides that there is no fee for the Committee to reconsider an application following the independent review.

Regulation 4.4 – Payment of fees

Subregulation 4.4(1) specifies that an evaluation fee is payable in full at the time of payment, which is within 28 days of the Department providing notice of the amount due.

Subregulation 4.4(2) specifies that a pricing fee is payable in full at the time of payment, which is within 28 days of the Department providing notice of the amount due.

Subregulation 4.4(3) allows for the Secretary to agree, in writing, with an applicant to the payment of a fee in instalments.

Subregulation 4.4(4) provides that where a fee has been paid in advance of notice of the amount that is payable, but the payment made was for a lesser amount than the fee payable, the applicant must pay the difference within 28 days of notice of the higher amount or a longer period, as may be allowed by the Secretary.

Subregulation 4.4(5) requires the Department to refund the applicant an amount that has been overpaid where an applicant has made an advance payment that was more than the payable fee. This is required within 28 days of the latter of either payment of the fee or notification by the Department that it has received the application.

Regulation 4.5 – Delay in payment of the evaluation fee

Subregulation 4.5(1) provides for the Committee to refuse to consider the application, or any other application by the same applicant, until the relevant application fee is paid or no longer payable.

Subregulation 4.5(2) provides, in the event an application fee is not paid, for the Department to suspend taking any action relating to the application or to commence debt recovery action, as provided for in subsection 99YBA(5) of the Act.

Regulation 4.6 – Delay in payment of pricing fee

Subregulation 4.6(1) provides that, if the pricing fee is not paid in the required time, the Committee may refuse to consider any other application by the same applicant, until the relevant pricing fee is paid or no longer payable.

Subregulation 4.6(2) provides, in the event a pricing fee is not paid, for the Department to commence debt recovery action, provided for in subsection 99YBA(5) of the Act.

Regulation 4.7 – Indexation of fees

Regulation 4.7 provides for the annual indexation of fees, on 1 July each year, based on increases in the Consumer Price Index as detailed in the regulation.

The first indexation event, under this regulation, occurs on 1 July 2011.

Part 5 – Exemptions and waivers

Regulation 5.1 – Exemptions

Regulation 5.1 provides that no fee is payable for an application for any of the matters listed in paragraphs 5.1(a) to (m).

Paragraphs 5.1(a) to (c) relates to applications that still require active decision making and use of resources (in considering the merits of the application) even though no fee is payable. Paragraph (a) provides for when a drug is designated as an orphan drug under regulation 16J of the *Therapeutic Goods Regulations 1990*; paragraph (b) provides for when a drug is 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 paragraph (c) provides for when the Secretary considers that the supply of a drug, medicinal preparation or vaccine is necessary for certain public health reasons, including under the *Quarantine Act 1908*.

Paragraphs 5.1(1)(d) to (m) provides for other types of applications where no fee is payable. These types of applications involve minimal decision making, administrative action and use of resources by the Department or the Committee.

Subregulation 5.1(2) provides that, where an applicant wishes the Secretary to consider if an exemption applies, the applicant must include information in their application about why an exemption apply to their application.

Regulation 5.2 – Waiver of fees

Subregulation 5.2(1) allows for the applicant to apply for a full or partial waiver of fees payable under the Regulations.

Subregulation 5.2(2) provides that the Secretary may waive all or part of a fee if the application involves the public interest and payment of the fee makes the application financially unviable.

Without limiting subregulation (2), subregulation (3) sets out information about whether an application involves the public interest.

It is intended that considerations in assessing the public interest includes 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 utilisation 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 takes 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 needs to be satisfied that, based on the available information, proceeding with the application is not financially viable if the applicable fee is payable. The type of information the officer may take into account includes:

- the potential utilisation 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 PBS, or designated under the NIP.

Decisions about fee waivers are made on a case-by-case basis. Decisions made under regulation 5.2 are reviewable under Part 6 of the Regulations.

Part 6 – Review of decision

Regulation 6.1 – Notice of review rights

Subregulation 6.1(1) requires the Secretary to give an applicant written notice of a decision and a statement setting out the particulars of the applicant's review rights, within 14 days after making a decision about a fee under these Regulations.

Subregulation 6.1(2) requires the notice to include particulars of how and where the applicant may respond to the notice.

Subregulation 6.1(3) provides that failure to comply with subregulation (2) does not invalidate the decision.

Regulation 6.2 – Internal review

Subregulation 6.2(1) provides that an applicant may apply in writing to the Secretary for a review (to be known as an 'internal review') of a decision about the evaluation category, the pricing category or the waiver of a fee.

Paragraph 6.2(2)(a) provides that the application must be made within 14 days of the applicant receiving notice of the decision, or within another period allowed by the Secretary.

Paragraph 6.2 (2)(b) requires the applicant to detail the grounds on which the applicant relies in applying for the review.

Paragraph 6.2(3)(a) requires the original decision-maker, or another officer authorised by the Secretary, to review that decision within 14 days of receiving the request.

Paragraph 6.2(3)(b) allows for the reviewable decision to be affirmed, revoked or varied and in the case of revocation, for any other decision to be made as thought appropriate by the review officer.

Paragraph 6.2(3)(c) requires the Department to give written notice to the applicant within 14 days of reviewing the decision.

Subregulation 6.2(4) allows for the applicant, within 14 days after receiving notice under paragraph (3)(c), to apply in writing to the Secretary to have the internal review decision reviewed.

Paragraph 6.2(5)(a) requires the Secretary to review the decision within 14 days after receiving that request.

Paragraph 6.2(5)(b) provides that the Secretary may affirm, revoke or vary the reviewable decision and in the case of revocation, make any other decision thought to be appropriate.

Paragraph 6.2(5)(c) requires that the Secretary provide written notice to the applicant, within 14 days of reviewing the decision in subregulation (3).

Subregulation 6.2(6) requires that the person in the Department who carries out the review under subregulation (5), must not have been involved in the original decision or the internal review decision made under subregulation 3.

Subregulation 6.2(7) provides that the Department may suspend work on the initial application while a decision under this regulation is being considered.

Regulation 6.3 – Internal Review - Secretary

Subregulation 6.3(1) provides that the Secretary may initiate a review at any time about a decision about the evaluation category, pricing category or waiver of a fee.

Subregulation 6.3(2) provides that the Secretary may require the reviewable decision to be affirmed, revoked or varied and in the case of revocation, for any other decision to be made as thought appropriate by the Secretary.

Subregulation 6.3(3) requires the Secretary to advise the applicant in writing within seven days of making a decision under subregulation 2.

Regulation 6.4 – Fee adjustment

Regulation 6.4 requires the Secretary to refund an overpayment within 28 days of a review decision, if there is an overpayment of a fee as a result of a decision following an internal review or review by the Secretary.

Regulation 6.5 - Review by Administrative Appeals Tribunal

Subregulation 6.5(1) provides for applicants to apply to the Administrative Appeals Tribunal for a review of decision made by the Department under these Regulations after any internal review rights under regulation 6.2(5) have been exhausted.

Subregulation 6.5(2) provides that the Department may suspend work on the initial application while an application is being considered under this regulation.

Subregulation 6.5(3) provides that, for regulation 6.5, *decision* means the same as it does in the *Administrative Appeals Tribunal Act 1975.*

Part 7 – Application Provision

Regulation 7.1 – Application of these Regulations

Regulation 7.1 provides that these regulations apply to applications received by the Department after 31 December 2009.

Schedule 1 – Applications

Part 1 – Vaccines

Part 1 of Schedule 1 lists matters about which an applicant may request the Committee make a recommendation to the Minister or provide advice to the Minister in relation to the designating of vaccines under subsection 9B(2) of the Act, dealt with in the Regulations.

Part 2 – Pharmaceuticals

Part 2 of Schedule 1 lists matters about which an applicant may request the Committee make a recommendation to the Minister or provide advice to the Minister in relation to the listing of pharmaceutical items or special pharmaceutical products on the *Schedule of Pharmaceutical Benefits*, dealt with in the Regulations.

Part 3 – Existing pharmaceutical items or special pharmaceutical products

Part 3 of Schedule 1 lists matters about which an applicant may request the Minister to list a generic medicine on the *Schedule of Pharmaceutical Benefits*, dealt with in the Regulations.

Schedule 2 – Medicinal preparations

Schedule 2 lists those pharmaceutical items or special pharmaceutical products, that when an application is made to the Minister to take action mentioned in items 3.1 or 3.2 in Schedule 1 (relating to determining a brand for a pharmaceutical item or specifying or vary the form or manner of administration of a special pharmaceutical product) are in the Committee Secretariat application category.

Schedule 3 – Evaluation fees

Schedule 3 lists the applicable application evaluation fees for Part 2 of the Regulations.

Schedule 4 – Pricing fees

Schedule 4 lists the applicable pricing fees for Part 3 of the Regulations.