MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Ian Chalmers
Chief Executive

17 September 2008

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

Dear Mr Humphery

I am pleased to present Medicines Australia's submission (with addendum) to the Australian Senate Community Affairs Committee Inquiry into Draft National Health (Pharmaceutical Benefits - Charges) Regulations 2008.

In this submission Medicines Australia has provided its views and recommendations relating both to the draft regulations and accompanying documentation and the consultation process that has occurred.

For the reasons detailed in its earlier submission and testimony, Medicines Australia continues to recommend that the Senate reject the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*.

Furthermore, the draft regulations and the explanatory statement do not remove the risk to patient access to medicines that was identified by the Senate Community Affairs Committee when it last considered the proposed cost-recovery arrangements for the PBS.

The time available to review such an important piece of regulation for Australian patients and the industry has been too short. This has meant that Medicines Australia has had less than three working days to analyse and comment on the documents.

Yours sincerely

Ian Chalmers.

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MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Submission

with *addendum*

Australian Senate Community Affairs Committee Inquiry into Draft National Health (Pharmaceutical Benefits - Charges) Regulations 2008

September 2008

Foreword to Submission and *Addendum*

The release on Friday, 12 September (4.22pm) of a revised set of regulations and an accompanying Explanatory Statement by the Department of Health and Ageing has necessitated the provision of an *addendum* to the submission prepared by MA. The timeframe allowed has not permitted a full revision of the submission.

The Addendum, providing initial comments on the new documentation and process, is followed by the Submission proper.

Addendum to Submission

Medicine's Australia would like to express its concern about the process in which consultation around these draft regulations has taken place. The requirement for an addendum to MA's submission is a direct result of the inadequate time available for sufficient consultation.

Stakeholders were initially given fewer than seven working days to provide commentary on the draft regulations to the Senate Committee. Subsequently, on the due-date for submissions to the Committee's review, stakeholders were provided with:

- a revised set of draft regulations
- an explanatory statement accompanying the revised draft regulations, providing an interpretive framework to these regulations.

Upon receipt of these, stakeholders were provided with an additional two working days to analyse and develop a position on the revised and new documents.

The Senate Community Affairs Committee hearing consequently was deferred for a week.

Whilst Medicines Australia – a membership based organisation required to consult within its structures before it can formally present a position on behalf of its membership – has attempted to accommodate these demands, this approach is not conducive to good policy making.

The actual consultation process also appears to be at odds with the Australian Government's policy requirements on consultation which requires all government agencies to ensure effective consultation with regulated parties at all stages of the regulatory cycle and realistic timeframes to allow stakeholders to provide a considered response.[1]

The *Best Practice Regulation Handbook* also states "all agencies with significant cost recovery arrangements will need to prepare a Cost Recovery

[1] Australian Government 2007, *Best Practice Regulation Handbook*, Canberra; Section 4.1, p.39

Impact Statement (CRIS)" and "all CRISs are required to be published online"[2]. To date, this has not occurred.

MA offers the Committee the following initial comments on the new documents. For the most part, the new documents do not address the concerns detailed in this submission. In particular, however, MA would like to draw attention to the following.

On the Consultation process

It is stated on **p.1** of the explanatory statement that:

> **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 *(sic)*, Palliative Care Australia, the Pharmacy Guild, the Australian Medical Association, Australian General Practice Network and the Royal Australian College of General Practitioners.

Medicines Australia has NOT been consulted by the Department of Health and Ageing about the draft Regulations during the stated timeframe

No meeting between the Department and MA has taken place on the draft regulations. MA has not yet had the opportunity to provide any written response to the Department, especially as this would occur in parallel to the present Senate Committee inquiry.

Medicines Australia does not believe the consultation process that has occurred meets the requirements of the Senators detailed in the reports and recommendations arising from the previous Senate Committee inquiry on the proposed cost-recovery arrangements. MA has been provided with both drafts of the regulations, but to date has not had sufficient opportunity to respond to those drafts.

On fee waivers

Whilst the Explanatory Statement seeks to provide additional interpretive context to the circumstances under which a waiver for a fee might be granted (i.e. the public interest criteria), the fundamental risk to patient access to medicines posed by the proposed cost-recovery arrangements has not changed.

This risk can be articulated as follows:

[2] http://www.finance.gov.au/obpr/consultation/gov-consultation.html

- Companies make rational decisions when allocating resources to the preparation of a submission to the PBAC many months prior to lodgement. It is unlikely that a company will lodge an application where the total costs for preparing the submission and submitting the application outweigh the benefits of listing. In calculating the cost and benefits of listings, companies also consider the opportunity-costs of diverting resources from one submission to another;
- The total cost to companies to prepare a submission currently ranges between $150,000 to $500,000 depending on the complexity of the clinical data and economic modelling;
- Whilst the regulations provide for full or partial fee waivers where this is in the 'public interest' (as determined by an Officer of the Commonwealth), the decision on whether a waiver is granted will only be made subsequent to a lodgement of a submission. **Such information will not be made available prior to the decision to prepare a submission.** The disincentives introduced by the cost-recovery arrangements have thus NOT been removed. The risk of access to medicines for small and underserved populations remains;
- There is still uncertainty around the circumstances in which a fee waiver might apply as specific criteria in the regulations for a range of fee waivers are still unclear. Moreover, in the context of fee waiver, the regulations (at 15(2), 8) state the following:

  "*Example of circumstances in which a fee could be waived*

  Listing change made of a request by the Committee"

  It is noteworthy that the example contained in the regulation itself is not mentioned in the Explanatory Statement.
- There are still no provisions in the regulations to remove the disincentive for companies to seek to expand the eligibility criteria for access to a PBS listed medicines as evidence develops. Such evidence takes many years to collect and the marginal benefit of seeking a listing diminishes as a medicine moves towards the end of its patent life. The proposed fees serve to exacerbate this existing feature of the system.

The revised draft regulations and the explanatory statement DO NOT remove the risk to access to medicines.

Given the unacceptable lack of consultation that has occurred to date and likely impact on patient access to medicines, Medicines Australia reiterates its recommendation to the Committee to reject the cost recovery proposal.

Furthermore, there has been insufficient consultation with all stakeholders. It is difficult to see how what consultation has occurred meets the requirements set out in the Government's own *Best Practice Regulation Handbook*[3].

[3] Australian Government 2007, *Best Practice Regulation Handbook*, Canberra

Medicines Australia Submission to the Australian Senate Community Affairs Committee Inquiry into Draft National Health (Pharmaceutical Benefits - Charges) Regulations 2008.

Executive Summary

For the reasons detailed in its earlier submission and testimony, Medicines Australia continues to recommend that the Senate **reject** the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008.*

Of paramount importance, is the fact that the proposed fee-for-submission based cost-recovery arrangements will undermine access to medicines for Australians. The arrangements will introduce an additional disincentive for companies to seek a listing, or expand the eligibility criteria for an existing listing, where the total costs for preparing the submission and submitting the application outweigh the benefits of listing for the company.

The access issue is most acute where companies are considering applying for additional or expanded indications. Whilst an imperfect system of waivers and exemptions might be designed for so-called orphan drugs and other small population medicines, no such system can remove the disincentives in this area. Whilst this will affect access across a wide range of medicines that Australians need, areas such as oncology that will be most affected.

Should, however, the Parliament wish to re-introduce this legislation in spite of this, Medicines Australia would like to ensure that the predictable risk to access to medicines on the PBS is, at a minimum, ameliorated by well formulated regulations that are informed by comprehensive consultation with all stakeholders, including industry and consumer groups.

The draft regulations *DO NOT* provide any certainty that the impact of this legislation on access to medicines will be minimised.

Medicines Australia **recommends** the Senate reject the Bill due to the impact on patient access to medicines and because the regulations do not address this problem. The Senate should also reject the Bill because the consultation process on the regulations has, to date, been insufficient.

Concerning the draft regulations, Medicines Australia **recommends** that:

1. substantive detail on the "public interest" and other criteria used to determine fee waivers be provided;
2. the process for granting fee waivers is clear and expeditious so that it does not serve to delay access to medicines by prolonging the listing process;

3. companies are given 6 to 12 months notice on whether a fee waiver will be granted in order to inform the business decision to develop and lodge a submission;
4. the disincentive to seeking expanded indications (i.e. eligibility criteria) for medicines is removed (for example by charging a fee only once per New Chemical Entity);
5. that companies do not bear the cost for errors that are attributable to the Department of Health and Ageing or those engaged by the Department of Health and Ageing during the assessment of a submission. In particular that companies are not charged for re-submissions where an error in an evaluation or assessment report may have been a contributing factor to a recommendation not to list by the PBAC;
6. current terminological and conceptual ambiguities in the regulations concerning the administration of the cost-recovery process be dealt with through extensive consultation with relevant stakeholders; and
7. numerous other concerns detailed in Section 3 of this submission are met through extensive consultation and re-drafting.

In addition, Medicines Australia **recommends** that:

8. the Government commit to and undertake extensive consultations with all stakeholders, including the industry, health professional organisations and consumer groups, to inform the re-drafting of the regulations to minimise the impact that this policy will have on access to medicines
9. as occurred with the introduction of TGA cost-recovery arrangements, PBS cost recovery be phased in over several years, starting 1 July 2009 and gradually increasing the schedule of fees over several years up to the full amounts specified in the draft regulations);
10. it becomes a legislative requirement that the cost-recovery arrangements for PBS listing process is independently reviewed after two years (as per the proposed amendment to the legislation moved by the Australian Greens[4]) to identify any negative impact that the policy has had on access to medicines;
11. as occurred with the introduction of TGA cost-recovery arrangements, that the PBS listing process is subject to increased quality assurance measures and efficiency improvements to ensure that the cost-recovery arrangements meet the stated policy objectives of the cost-recovery guidelines. [5]

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[4] National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Bill 2008-(S) Australian Greens 1.

[5] The Australian Government Cost Recovery Guidelines state that the Government's policy objectives for cost recovery include improving efficiency, accountability and transparency, as well as instilling cost consciousness

This multi-faceted approach to the introduction of cost recovery was clearly demonstrated with the launch of cost recovery specific to TGA activities. The TGA has been subject to cost recovery since 1991, initially at a level of 50% of its operating cost, subsequently increased to 75% in 1997-98, then to full cost recovery in 1998-99. The introduction of cost recovery for TGA

12. the fees collected through the cost-recovery arrangements are directly available and adjustable to fund agreed efficiency and quality improvements to the decision making, evaluation and listing process.
13. it is a legislative requirement that the total amount to be recovered each year must be agreed between DoHA and Medicines Australia; and reflect actual activity and resource use.
14. that a full regulatory impact statement be prepared prior to the implementation of the arrangements to assess the full impact that the proposed arrangements will have on decisions to seek a listing on the PBS.

And as per MA's previous submission that:

15. the Minister review and implement process improvements to PBS listing identified through the Access to Medicines Working Group.
16. the Australian Senate ensure that any cost-recovery arrangements for the PBS listing process conform to the Commonwealth Government's Cost Recovery Guidelines.

Introduction

Medicines Australia represents the innovative medicines industry in Australia. Our member companies comprise more than 80 percent of the prescription pharmaceuticals market, and are engaged in the research, development, manufacture, supply and export of prescription medicines.

The pharmaceuticals industry is a key industry in Australia which provides benefits to both Australians' health and the health of Australia's economy. Companies in this sector are constantly working to bring new and effective medicines to patients and invested around $752 million in local research and development in 2005-06

As a principal stakeholder, Medicines Australia (MA) welcomes the opportunity to present its position to the Australian Senate Community Affairs Committee's **Inquiry into Draft National Health (Pharmaceutical Benefits - Charges) Regulations 2008.**

MA has consistently maintained that the introduction of the proposed cost-recovery arrangements for PBS listing will undermine the timely and appropriate access to medicines that Australians need. Its reasons for objecting to this legislation can be found in its submissions and witness testimony to the recent Senate Community Affairs Committee review of the legislation enabling proposed arrangements.

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activities also led to significant improvements in TGA processes, that ultimately led to benefits for Australian patients. The most important of these were:

- the process became more efficient. Evaluation times were reduced from 2-5 years to 255 working days.
- the process became more accountable. Regular consultation with stakeholders enables the TGA to report on performance, consult on fees and charges, and discuss process changes. As a result, there has been increased confidence in the process and an improvement in the TGA/Industry relationship.

MA has undertaken a review of the regulations and argues that they do **not** remove the risk to access to medicines on the PBS posed by the introduction of cost-recovery arrangements. The regulations fail to remove the disincentives for companies to seek a PBS listing for a medicine and/or expanded indication(s) where the total costs for preparing the submission and submitting the application outweigh the benefits of listing for the company.

MA therefore reiterates its recommendation to the Senate to reject the Bill due to its impact on patient access to medicines.

MA's submission is presented in two parts: a critical commentary on the draft regulations under review; followed by a series of recommendations aimed at ameliorating the predictable and negative effects of the proposed cost-recovery arrangements.

1. Critical Commentary on Draft National Health (Pharmaceutical Benefits - Charges) Regulations 2008.

MA has reviewed the draft regulations and presents the following critical commentary on them.

General Comments:

- the Regulations fail to protect access to medicines where the total costs for preparing the submission and submitting the application outweigh the benefits of listing for the company. In particular:
    - the Regulations lack any detail on the criteria to be used in the determination of waivers to be applied to fees where this is in the "public interest";
    - there are no provisions in the regulations to remove the disincentive for companies to seek to expand the eligibility criteria for access to a PBS listed medicines as evidence develops. Such evidence takes many years to collect and the marginal benefit of seeking a listing diminishes as a medicine moves towards the end of its patent life. The proposed fees serve to exacerbate this existing feature of the system.
    - the Regulations have the potential to support the delay by the Department or the PBAC of an application for PBS listing. Potential delays in reviews of fee categories and payments, and resulting interruptions to the evaluation process could result in an application not being considered at the meeting for which it was submitted.
- the Regulations are replete with poorly defined or ambiguous terms and concepts related to the listing process. Terms such as 'substantive', 'public interest' and 'financially unviable' should all be defined within the Regulations to reduce the potential for misunderstandings arising in their application. These are all topics that require further debate and consultation with Industry and other stakeholders.

- There is no assignment of responsibility within the Department in terms of notification of fee category, determination of waiver status etc. This creates an unreasonable level of uncertainty for industry as to who in Government will be the arbiters of such matters. This uncertainty is compounded by the level of subjectivity within the current Regulations.
- The Regulations appear to enshrine in legislation documents and guidance from the Department of Health and Ageing with respect to applications for listing and pricing which heretofore were non-binding guidance. This is an unreasonable shift in the nature of that listing process and there has been insufficient time to consider the full implications of this significant change.
- Through re-submission fees, industry is expected to bear the costs of errors, including those originating during the Department of Health and Ageing review, where this has contributed to a PBAC recommendation not to list. This is not acceptable.

Specific Comments

Part 1 Preliminary

Section 3: Definitions

Regulation (1) pp 2

1. PBAC Guidelines – the latest version is December 2007, not September 2002.
2. the PBPA Pricing Authority Manual is currently under review.

Consideration needs to be given to the impact of continuous updates to both documents over time and how this will impact on the standing of the Regulations.

Other definitions that could also be included are: 'new drug', 'Department', and 'biosimilar'.

Regulation (2) pp 3

1. Subregulation (a), *'new nutritional product'* is not defined.
2. *"(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*

   There is an internal inconsistency in this subregulation. Since the Committee is the PBAC, then the PBAC cannot be used to define what is a major submission since the Committee will not consider the application until 17 weeks after submission – much later than the 14 days stipulated for notification of sponsors of the fee category to which they are allocated.

3. Subregulations (d) and (e) appear to be new definitions of what constitutes a major submission which are not in the PBAC Guidelines under definition of a **major** submission.
4. In subregulation (e), *'substantive'* is not defined.

Regulation (3) pp 3

1. Subregulation (g), *'substantive'* is not defined.

Regulation (4) pp 4

1. Subregulations (b) and (c) define what constitutes a Secretariat Listing.

   However, the Regulations do not discuss who is to bear the fees of such listings. On occasion the PBAC makes recommendations upon advice from the Secretariat &/or non-Industry stakeholders. MA believes that industry should not be responsible for costs associated with this work, and believe the regulations need to be amended to this effect. A general statement as to who will bear the fees in relation to Secretariat listings is required.

Section 4: Purpose of Regulations, pp 4

"Initial listing" is not defined. Taken as written, this would imply that cost-recovery is only applicable when a medicine is first listed.

Part 2 Applications

Section 5: Evaluation categories

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

Will sponsors be issued with an invoice for fee payment at the time of notification of the applicable category (this would be required by companies to comply with standard accounting procedures)? This is not clear in the regulations.

Section 6: Withdrawal of application

Regulation (2) pp 4

1. *"If the application is withdrawn within 14 days after it was lodged, the Department must refund any lodgement fee paid."*

   This timeframe is inappropriate and should be revised. As a decision to withdraw an application may be dependent upon the Department's assignment of evaluation category **and** the

Department has 14 days from receipt of submission to advise the applicant of the evaluation category (and not withstanding subsequent delays due to dispute over assignment of evaluation category), the situation may arise where the sponsor wishes to withdraw but is ineligible for a refund.

In addition, it is unreasonable that a sponsor be charged the full fee for evaluation of a submission if they do not proceed through that entire evaluation process. The fee structure therefore needs to be more transparent so that if an application is withdrawn at any time after 14 days, the sponsor is eligible for a refund equal to the amount of the fee apportioned to the remaining evaluation process.

Section 7: Resubmission of applications

Subregulation (b) pp 5

1. *"the application is subject to a lodgement fee as if it were a new application."*

   The language in this subregulation may be misinterpreted so that any resubmission may be charged the same fee as the initial submission regardless of whether or not it is in the same category (i.e. a major submission that is resubmitted as a minor incurs the fee of a major). Alternative text is required.

Part 3 Fees

Section 8: Lodgement fees

Regulation (2), pp 5

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

   The intent of this subregulation is not clear. The literal interpretation is that in order for an application to change/vary a listing to be considered by the Committee it must meet the PBAC Guidelines. Does this mean that it must comply with the Guidelines completely, or with the provisions in the Guidelines for what constitutes a change in a listing that needs to be considered by the Committee? From the language above, the former interpretation could be assumed to apply. Does this therefore mean that the Guidelines are now mandated requirements? If the interpretation is the latter, then it should be reflected in the text of this subregulation. This also has the potential to change the nature of the PBAC Guidelines, but the implications of this have yet to be fully determined.

Section 9: Pricing fees

Regulation (1), pp 5

1. *"(a) to list the original brand of a pharmaceutical item of medicinal preparation; or (b) to designate an original brand of a vaccine."*

   This requires further clarification – for example, what occurs with listing of subsequent brands, and subsequent indications/ formulation that may lead to revised pricing? What is the definition of *'original brand'?*

Section 10: Independent review fee

Regulation (2), pp 5

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

   The process and tasks associated with an Independent Review are likely to be significantly different from those of a PBAC evaluation. MA believes that the fact that the fee for an independent review is exactly the same as that for an initial evaluation of a major submission is too simplistic. The complexity of an independent review may vary from relatively straightforward to extremely complex. Fees should be structured and detailed accordingly.

   Consideration could also be given as to whether to propose that where an Independent Review finds in favour of the sponsor, that the fees for that review be refunded to the sponsor. Any benefits to sponsors in this regard need to be weighted against potential disincentives it may create with regard to Review findings.

Section 11: Payment of fees

Regulation (1), pp 6

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

   The period for payment of fees should be made consistent with that applied for TGA fees (28 days) as it is consistent with sponsors' internal accounting procedures.

Regulation (2), pp 6

1. *"(2) However the Department may agree in writing to accept partial payments."*

Details/requirements with regards to *'partial payments'* need to be specified in the Regulations.

Regulation (3), pp 6

1. *"(b) A longer period allowed by the Department."*

   Details/requirements with regards to *'longer period'* need to be specified in the Regulations.

Section 12: Delay in payment of fees

It is debateable that the Committee would not review a submission for which the fee has not been paid. However, it is totally unreasonable that they would not review any other submissions from that applicant (even if the fees on the others have been paid).

Section 13: Indexation of fees

1. *"A fee payable under these Regulations is increased on 1 July in each year."*

   Once stabilised (pending any negotiated phasing in) fees should remain constant until a review of the impact/ appropriateness of the Cost Recovery legislation has been conducted. Clarification is required of the source and intent of the 1.25% adjustment (Wage Cost Index 3?). Moreover, the application of indexation of fees in this instance is out of step with other Departmental procedures with regard to indexation of PBS prices.

Part 4 Exemptions and Waivers

Section 14: Exemptions

Regulation (1), pp 7

The list of allowable exemptions should be expanded to include changes to wording requested by anyone other than the Sponsor (not just Medicare Australia), and situations where a submission is invited by the PBAC, or is as a direct response to a request for information (such as in a cost-effectiveness review) from the PBAC, its evaluation Sub-Committee, or the Department.

1. Subregulation (h), *'mandated change'* is not defined.

Section 15: Waiver of fees

Regulation (2), pp 8

1. Subregulation (1), *'part'* is not defined, nor is its determination.

"The Department may waive a fee payable under these Regulations if the application involves the public interest and payment of the fee would make the application financially unviable."

This section needs significant revision in order to address the concerns regarding access raised by Senate Community Affairs Committee, and the lack of a definition of *'public interest'*.

In addition, clarification with regards to the point in the process where a sponsor is advised that the fee will be waived is required. The draft Regulations state that this will occur within the initial 14 days post submission. However, Medicines Australia believes that this is far too late and that the proposed timing will not alleviate the potential access issues identified in the original Senate Committee inquiry.

To gain PBS listing, a company must provide high-level evidence establishing both clinical effectiveness and relative cost-effectiveness. Pharmaceutical companies already face considerable expense in the preparation of major submissions to the PBAC. Medicines Australia's best estimates of the direct cost is a range between **$150,000 to $500,000** depending upon the complexity of the submission. Therefore, companies will require certainty around a waiver at least 6 – 12 months before they submit their application – i.e. before they dedicate time, resources and costs to generating the PBAC submission.

Part 5 Review of decisions

Section 17: Internal review

Regulation (7), pp 9

- *"The Department may suspend any work on the initial application while an application is being considered under this regulation".*

  It is unreasonable that the evaluation process be suspended while any disputes over fees are being resolved/addressed. This adds to further delays to the listing process and potentially can delay the evaluation and listing of a new medicine over an administrative argument over fee structures.

Schedule 2: Pricing Fees

Items 2 and 3, p 11-12.

Pricing submissions vary in their degree of complexity, and are Tiered accordingly. Given the the differing resource/administrative requirements for Tier 2 and 3 submissions, it seems unreasonable that they attract the same fee. This needs revision.

2. Requirements for ameliorating the predictable and negative effects of the proposed cost-recovery arrangements.

The table below outlines Medicines Australia's recommendations for ameliorating the predictable and negative effects of the proposed cost-recovery arrangements. These recommendations not only address the issues identified specific to the draft Regulations, but also look to protect access to medicines via the PBS – a serious issue identified in the original Senate Committee Inquiry, and reflected in the reports of all Committee members. A number of the suggested changes can be introduced within the regulations proper. Others, however, will require amendments to the Bill or other policy support for their implementation.

Draft Regulation	Recommended Amendment
Part 1 – Preliminary	
	▪ Amend start date to July 1, 2009 ▪ Amend introduction to phasing over a 3 year period (July 1, 2009 to July, 2011) – as happened with the introduction of TGA Cost Recovery.
Section 3 (1)	▪ Amend publication date of PBAC Guidelines from September 2002 to December 2007, &/or ▪ Amend wording to reflect potential for updates to both the PBAC Guidelines and PBPA Manual ▪ Include definitions of: - *new drug* - *Department* - *biosimilar* - *nutritional product* - *substantial* - *substantive* - *original brand* - *mandated change* - *part* - *public interest* - *financially unviable* - *initial listing*
Section 3 (2)(b)	▪ Amend to reflect the fact that the *'Committee'* does not consider the application until 17 weeks post submission – 15 weeks post the draft regulations timing for notification of sponsors of the fee category.
Section 3 (4)(b)&(c)	▪ Amend to reflect that industry is not responsible for costs associated with non-industry stakeholder generated minor submissions &/or Secretariat decisions. ▪ Amend to ensure that that companies do not bear the cost for errors that are attributable to the Department of Health

	and Ageing or those engaged by the Department of Health and Ageing during the assessment of a submission. In particular that companies are not charged for re-submissions where an error in an evaluation or assessment report has contributed to a recommendation not to list by the PBAC.
Part 2 – Applications	
Section 5 & 6	▪ Revise timeframe to account for fact that draft Regulations allow the Department 14 days to define category, yet sponsors only have the same 14 days to withdraw in order to be eligible for refund of lodgement fee. ▪ Amend to allow for refund equal to the amount of fee apportioned to the remaining evaluation process.
Section 7	▪ Amend to ensure that fees for resubmissions are in line with required work-load, not *'as if it were a new application'*.
Part 3 – Fees	
Section 8 (2)	▪ Amend to prevent potential misinterpretation that the *'PBAC Guidelines'* are now mandated requirements.
Section 9 (1)	▪ Amend to cover subsequent brands, subsequent indications, subsequent formulations.
Section 10 (2)	▪ Amend to allow refund to sponsor should the Independent Review find in favour of the sponsor.
Section 11 (1)	▪ Revise the period of payment of fees to 28 days – to be in line with TGA Cost Recovery fee requirements.
Section 11 (2)	▪ Amend to include details/ requirements specific to *"partial payments"*.
Section 11 (3)	▪ Amend to include details/ requirements specific to *"longer period"*.
Section 12	▪ Amend to restrict any evaluation penalty to *'the application'* only.
Section 13	▪ Amend to keep fees fixed and linked to specific services. ▪ Amend to explain the source and intent of the 1.25% adjustment.
Section 14 (1)	▪ Amend to add *'to remove an indication of a drug from the PBS'*.

Part 4 – Exemptions & Waivers	
Section 14	▪ Amend to include exemptions for the following: - paediatric medicines - medicines for ATSI - medicines for palliative care patients - medicines used in oncology settings ▪ Amend to remove disincentive for sponsors to change or extend indications of listed medicines
	▪ Add Regulation to ensure that exemption and/or waivers are covered by the Government; and that fees for non-exempt submissions are not adjusted to cover cost of exemptions/ waivers.
Section 15	▪ Amend to clearly outline the process for granting fee waivers, and one whereby sponsors are provided with certainty around their waiver application at the pre-submission stage – i.e. 6-12 mths and $150K-$500K before submission.
Part 5 – Review of Decisions	
Section 17 (7)	▪ Amend to allow evaluation process to proceed while any disputes over fees are being resolved.
Part 6 – Transitional	
Schedule 1	▪ Amend fee structure to negate generic 'free-rider' effect; NB identified in Cost-Recovery Guidelines as a reason for rejecting cost-recovery arrangements.
Schedule 2	▪ Reduce Tier 2 fee to allow stepped costings across Tier 1 to Tier 3 – in line with stepped work requirements.
Schedule 2	▪ Add Regulation linking Tiered pricing fees to defined PBS listing times post PBAC approval.
Other	
	▪ Amend Legislation to require an independent review of the cost-recovery arrangements to examine, as per the proposed Australian Green's amendment:

	(a)the average number of times a submission is presented before gaining approval and the reasons provided for requiring applicants to resubmit; (b) the average cost of submissions by type of submission (major/minor/generic according to Department of Health and Ageing classifications); (c) the number of applications received for non-orphan drugs that are highly specialised, low volume and target a small population, including applications for specific formula requirements, unplanned activity discovery and the addition of an indication for a medicine; (d) the number of complaints received from sponsors/applicants; (e) the number of fee waivers given to applicants and the reasons why waivers were given; (f) the length of time taken for submissions to be approved. (g) the number of applications that fail to gain a listing, the reasons why and the types of drugs concerned; (h) any increase in operating costs of the Pharmaceutical Benefits Advisory Committee; (i) any increase in the cost of pharmaceutical benefits scheme medications to patients; (j) any other matters considered relevant. ▪ Amend legislation to ensure that the fees collected through the cost-recovery arrangements are directly available and adjustable to fund agreed efficiency and quality improvements to the decision making, evaluation and listing process. ▪ Amend legislation to ensure that the total amount to be recovered each year *must* be agreed between DoHA and Medicines Australia; and reflect actual activity and resource use. ▪ Ensure that the PBS listing process is subject to increased quality assurance measures and efficiency improvements to ensure that the cost-recovery arrangements meet the stated policy objectives of the Cost-recovery Guidelines. (as occurred with the introduction of TGA cost-recovery ▪ Amend legislation to ensure government reforms PBS listing process to reduce time to listing and number of re-submissions to PBAC.