The Senate

Standing Committee on Community Affairs

Draft National Health (Pharmaceutical Benefits — Charges) Regulations 2008

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MEMBERSHIP OF THE COMMITTEE

42nd Parliament

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Senator Gary Humphries	LP, Australian Capital Territory

Participating Members

Senator the Hon Richard Colbeck	LP, Tasmania
Senator Steve Fielding	FFP, Victoria
Senator Scott Ryan	LP, Victoria

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DRAFT NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – CHARGES) REGULATIONS 2008

THE INQUIRY

1.1 On 4 September 2008 the Parliamentary Secretary to the Minister for Health and Ageing, Senator McLucas, tabled in the Senate draft National Health (Pharmaceutical Benefits – Charges) Regulations 2008 and referred the draft regulations to the Community Affairs Committee (the Committee) for inquiry and report by 2 October 2008.

1.2 The Committee received 9 submissions relating to the Regulations and these are listed at Appendix 1. The Committee considered the Regulations at public hearings in Canberra on 22 and 25 September 2008. Details of the public hearings are referred to in Appendix 2. The submissions and Hansard transcript of evidence may be accessed through the Committee's website at http://www.aph.gov.au/senate_ca.

BACKGROUND

1.3 The National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008 (the Bill) was introduced into the Senate on 16 June 2008. The Bill was referred to the Committee and the Committee's report was presented on 22 August 2008.

1.4 The Bill proposed to implement cost recovery arrangements for the services and activities related to listing medicines on the Pharmaceutical Benefits Scheme (PBS) or designating vaccines for the National Immunisation Program (NIP). In its report, the Committee noted that the actual operation and implementation of the cost recovery arrangements were to be prescribed by regulation with the Bill simply providing a framework authorising the creation of the Regulations but did not contain any detail.[1]

1.5 As the Regulations were not available for consideration during the inquiry, both witnesses and the Committee voiced concern that it was difficult to appropriately assess the implications of the proposed arrangements. The Committee reiterated its view that subordinate legislation should be made available in conjunction with primary legislation, in order to facilitate comprehensive examination of legislation and its impact on stakeholders.

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1 Senate Community Affairs Committee, *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*, p.3.

1.6 In relation to specific issues raised during the inquiry, the Committee noted that there were challenges facing groups trying to obtain listings for low-volume medicines and indications. The Committee recommended that:

> …the regulations should incorporate specific measures, whether through exemptions or waivers or some other form, to ensure that there is no disincentive for companies to lodge applications to list low-volume medicines, or to change or extend the indications of listed medicines.[2]

1.7 On 22 August 2008 the Department of Health and Ageing (DoHA) provided draft Regulations to the Committee in response to requests at the public hearing into the Bill held on 28 July. However, the Committee had by then already completed its inquiry and presented its report. The draft Regulations were formally tabled in the Senate on 4 September. DoHA subsequently provided an updated version of the draft Regulations, together with a table summarising the changes made to the earlier draft, as part of its submission to this inquiry.[3] They are reproduced at Appendix 3.

THE DRAFT REGULATIONS

1.8 The purpose of the draft 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 DoHA. The Regulations set out the fees and conditions under which this will be achieved.

1.9 The Regulations include definitions of applications to the Pharmaceutical Benefits Advisory Committee (PBAC):

- major applications are those which involve substantially more effort to evaluate and consider and seek to list new drugs or medicinal preparations for subsidy under the PBS or to make substantial changes to current listings. The Regulations provide the detail of the types of applications that fall into this category;
- minor applications 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 and details of the types of applications which fall into this category are provide in the Regulations;
- committee secretariat listing is a minor application that is straightforward and not considered as a separate item at a PBAC meeting;
- new brand of a pharmaceutical item applications arise if the form of the drug and manner of administration is already listed, that is, a generic product; and
- Pricing Authority Secretariat Listing concerns an application for a price change which is recommended by the Pricing Authority without it being

2 Senate Community Affairs Committee, *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*, p.19.

3 *Submission* 5, Attachments B and C (DoHA).

considered as a separate agenda item at a meeting of the Pricing Authority and is not the subject of price negotiation.

1.10 The Regulations establish the fees payable as follows:

- lodgement fees: apply for lodgement of an application. Schedule 1 of the Regulations sets out the fees for each evaluation category for lodgement applications mentioned in the Schedule;
- pricing fees: apply 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 or where a price agreement is made under section 85AD or a determination is made under section 85B of the National Health Act. Pricing fees are set out in Schedule 2 of the Regulations; and
- independent review fees: apply to an application for independent review of a PBAC 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.

1.11 Fees are payable in full at the time of payment, which is within 14 days of the DoHA providing notice of the amount due. DoHA may agree to the payment of fees in instalments. Regulation 12 allows the PBAC to refuse to consider an application or any other application by the same applicant until the relevant fee is paid, or no longer payable. Fees will be indexed annually using a wage cost index.

1.12 The Regulations allow for exemptions and waivers. Exemptions will be allowed for a drug designated as an orphan drug; for drugs that are exempt from entry on the Register of Therapeutic Goods because of a temporary supply approval and for drugs included on the PBS in a national emergency; and for other types of applications listed in the Regulations such as to change the name of the manufacturer of the drug. Applicants may apply to DoHA for a full or partial waiver of fees. Fees may be waived in full or part if the application involves the public interest and payment of the fee would make the application financially unviable.

1.13 Part 5 of the Regulations provides for the review of decisions about fees through an internal review by the Department. Review by the Administrative Appeals Tribunal is available for decisions made by the Department under the Regulations after any internal review rights have been completed.

Update to the draft regulations

1.14 DoHA provided the Committee with an undated version of the draft Regulations as part of its submission. The amendments include technical changes and amendments to Schedule 2 (pricing fees). The amendments to Schedule 2 are to ensure that all types of pricing agreements are defined in the Regulations and include a new (lower) fee for pricing agreements that do not require negotiation.

ISSUES

Consultation with stakeholders

1.15 Witnesses raised the issue of insufficient consultation in relation to the draft Regulations. The Explanatory Statement indicated that consultations about the Regulations occurred in late August and September 2008; that stakeholders were invited to provide comments on the Regulations to DoHA; and that a number of groups were consulted. Ms Donna Daniell of Palliative Care Australia (PCA) stated:

> I sent an email on Monday last week saying that we would like these consultations to include something more than just sending out a bald letter, and that possibly a face-to-face meeting in which we could talk through some of the issues might be nice. [DoHA], to their credit, got back to us very promptly, and the result of that was the face-to-face meeting last Friday morning, at which we spent half an hour or so talking through the issue.[4]

1.16 Medicines Australia commented that it had not been consulted by DoHA about either the draft Regulations or the Explanatory Statement.[5] Further, it was Medicines Australia's view that the industry had been caught 'on the hop' as it considered that earlier discussions in relation to cost recovery had been shelved.[6]

1.17 Mr Timothy Vines noted that cost recovery regulation and cost recovery ideas have been considered since the 2005 budget and that while they were subsequently dropped, 'the industry was put on notice that this was certainly a direction that we were moving towards, and with 15 years of cost recovery mechanisms for the Therapeutic Goods Administration there was at least a precedent there for cost recovery in a health policy area'.[7]

1.18 DoHA reiterated that extensive consultations had taken place over a substantial period of time:

> Medicines Australia, along with others, have had numerous opportunities over time to talk about this in a variety of fora and, in relation to the latest exchange in terms of the draft coming on top of all of that previous consultation, there was that invitation there. It was in the context of relatively marginal changes to the scheme that was out in the public domain before that, and if Medicines Australia had wished anything further in that context they were quite able to pick up the phone, as they were invited to do and as they do on many issues where they wish to engage us. They most

4 *Committee Hansard*, 22.09.08, p.CA1 (Ms D Daniell, PCA).

5 *Committee Hansard*, 22.09.08, p.CA16 (Mr W Delaat, Medicines Australia).

6 *Committee Hansard*, 22.09.08, p.CA16 (Mr W Delaat, Medicines Australia).

7 *Committee Hansard*, 22.09.08, p.CA7 (Mr T Vines).

> certainly pick up the phone and come and talk to us, and we are of course very open to doing that at any point.[8]

Impact on patient access to medicines

1.19 Witnesses again commented that the cost recovery measures would impact adversely on patient access to medicines. Medicines Australia argued that if access to certain medicines is put at risk, 'this current fee-for-submission proposal should not be supported'.[9] Professor Shane Carney also commented that there is a 'real worry' that the fee will act as a disincentive for pharmaceutical companies.[10]

1.20 Mr Vines provided a counter argument. He noted that that the pharmaceutical industry received significant financial reward as well as enjoying financial certainty in listing a medication. He concluded that the proposed fee schedule would 'constitute a relatively minor financial inconvenience to companies seeking to list a medication on the PBS'.[11]

1.21 Mr Vines also argued that attaching a value to a submission to the PBAC may result in some additional benefits. He noted that at the present time, 47 per cent of major submissions are rejected by the PBAC and may be a result of poor drafting of submissions. Perhaps a fee 'would give pause to therapeutic and pharmaceutical companies before putting in a submission to ensure that it actually conforms to the cost effectiveness and cost minimisation guidelines and specifications set down in the PBAC guidelines that are referred to'.[12]

1.22 DoHA also commented on industry claims concerning additional costs to consumers. DoHA noted that many factors, both international and domestic, impact on the costs of developing a drug, marketing it, educating doctors around it and bringing it to market, as well as price considerations. DoHA concluded that the impact of cost recovery was 'an extremely small amount of money' compared with the costs to develop a drug and that:

> There are a range of other considerations that companies take into account in deciding at what price point to pitch their drug in different markets, for that matter. In all of those contexts, it is just not possible to say that the costs of PBS cost recovery would, in a mechanistic way, be passed on. In any event, what the consumer pays in this country is regulated in terms of the copayment. So, in all of this, I think it is very hard to draw a link.[13]

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8 *Committee Hansard*, 25.09.08, p.CA10 (Mr D Learmonth, DoHA).

9 *Committee Hansard*, 22.09.08, p.CA15 (Mr W Delaat, Medicines Australia).

10 *Committee Hansard*, 25.09.08, p.CA2 (Prof S Carney, Royal Australasian College of Physicians).

11 *Committee Hansard*, 22.09.08, p.CA8 (Mr T Vines).

12 *Committee Hansard*, 22.09.08, p.CA8 (Mr T Vines).

13 *Committee Hansard*, 25.09.08, p.CA18 (Mr D Learmonth, DoHA).

Lodgement fees

1.23 Schedule 1 of the Regulations contain the fees to be charged for the various evaluation categories. GMiA commented that the proposed fees for new brands of existing pharmaceutical items 'reflect the level of activity involved in the listing of these products on the PBS'.[14]

Waiver of fees

1.24 Regulation 15 allows for an application to the Department to waive all or part of a fee payable under the Regulations. The Department may waiver the fee 'if the application involves the public interest and payment of the fee would make the application financially unviable'. The example of circumstances in which the fee would be waived is given as a listing change made because of a request by the PBAC.

1.25 The Explanatory Statement provides further detail on the considerations in assessing public interest including '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 Island communities and /or for people undergoing palliative care'. The Explanatory Statement also lists the type of information to be taken into account when assessing the application for a fee waiver.[15]

1.26 Concerns were raised about a number of aspects of the fee waiver regulation.

Access to low-volume products and indications

1.27 During the inquiry into the Bill, a significant concern was the impact of cost recovery fees on the accessibility of low-volume medications and the extension of indications for listed medications. PCA noted that the Explanatory Statement included the patient population as a consideration in an assessment of a waiver of fees under Regulation 15 but that this 'was not acceptable to us because it does not really mean anything at the end of the day'.[16]

1.28 PCA advised the Committee that it had met with DoHA to discuss its concerns and that the Department had taken up its suggestion for an amendment to the draft Regulations:

> …the Acting Assistant Secretary of the Pharmaceutical Evaluation Branch, Mrs Diana McDonell, has confirmed to us by email that the department has taken on board our suggestions that more specific wording be included in regulation 15 dealing with the waiver of cost recovery fees for applications

14 *Submission* 6, p.1 (GMiA).

15 Explanatory Statement, p.6.

16 *Committee Hansard*, 22.09.08, p.CA2 (Mr B Shaw, PCA).

> dealing with small population groups. They will ask the drafter to include words with the following meaning in the regulations as an indication of the type of application where fees could be waived…It says, referring to regulation 15, that they will put a further example that says:
>
> > Where the patient population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted.
>
> This is the criteria for which the waiver of the fees would qualify. PCA is happy with this outcome.[17]

Lack of clarity

1.29 Medicines Australia commented that there was a lack of any detail on the criteria to be used in the determination of fee waivers where this is in the 'public interest'.[18] Medicines Australia did not consider that it was sufficient to include details in the Explanatory Statement and 'certainly we would not be satisfied with the current explanation of what is in the public interest within the current regulations. It is very short on detail, and even the explanatory notes do not give clarity to that issue.'[19] Medicines Australia concluded that uncertainty still remains in relation to waivers 'as specific criteria in the regulations for a range of fee waivers are still unclear'.[20]

1.30 PCA also commented that there were no definitions for terms such as 'substantive', 'public interest' and financially unviable' used in Regulation 15. PCA noted that as these concepts 'are vital to whether the cost recovery measure will adversely affect access to important medicines, they should all be defined within the Regulations, after a process of meaningful stakeholder consultation'.[21]

1.31 DoHA commented that the Regulations contain a broad principle for public interest and noted that many factors would bear on the public interest decision, including the nature and size of the target population, the price of the drug that is required, and what else exists on the PBS or is otherwise available. As a consequence 'it is a little difficult to try and specify too much within that or you run the risk of creating a barrier that will have unintended consequences'.[22]

Timing of waiver decision

1.32 Medicines Australia raised concerns about the timing of the decision to grant a full or partial wavier. It noted that a waiver will be granted subsequent to the

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17 *Committee Hansard*, 22.09.08, p.CA1 (Ms D Daniell, PCA).

18 *Committee Hansard*, 25.09.08, p.CA14 (Mr W Delaat, Medicines Australia).

19 *Committee Hansard*, 25.09.08, p.CA20 (Mr W Delaat, Medicines Australia).

20 *Submission* 8, p.4 (Medicines Australia).

21 *Submission* 2, p.1 (PCA).

22 *Committee Hansard*, 25.09.08, p.CA16 (Mr D Learmonth, DoHA).

lodgement of an application. However, companies make decisions about the viability of medicines six or 12 months ahead of an actual submission and 'it is too late for companies to have that decision about a waiver being made at the point of making the submission because, by then, you have already had those up-front costs so you are hardly going to incur those costs without any certainty that the product is going to be waived'.[23] Medicines Australia concluded that 'disincentives introduced by the cost-recovery arrangements have thus NOT been removed'.[24]

1.33 The AMA also commented that the full information needed to make a waiver decision will not be available until after the PBAC has assessed the application and made its recommendation on listing. The waiver decision will thus be based on expected outcomes.[25]

1.34 The Department responded that there is not 'quite the uncertainty there as perhaps imagined'.[26] Presubmission meetings take place between companies and DoHA well before the lodgement date and an indication can then be given as to whether a waiver would be available. While that indication is not a guarantee, DoHA stated:

> …we can give them a clear indication of our disposition towards waiver at that point, as we do about other matters in relation to the submission. I think they ought to have some reasonable confidence in that. The difficulty lies in what they actually subsequently present. If what they actually subsequently present is something different to what they had anticipated at the presubmission meeting, we would have to look at it, obviously, and make the formal decision. But in the presubmission meetings they would be talking to the same people who would be taking the matters into account formally and who would be making the decision initially in relation to fee-waiver. So I think they can get a pretty good indication as early as they would wish to, in terms of a presubmission meeting, as to what the disposition will be.[27]

Making waiver decision

1.35 The Australian Medical Association (AMA) argued that the Minister, not the Department, should make waiver decisions and that the Minister's decisions about waiver applications should be tabled in Parliament because of the public interest test.[28] The AMA stated that:

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23 *Committee Hansard*, 25.09.08, p.CA15 (Mr W Delaat, Medicines Australia); see also *Submission* 8, p.4 (Medicines Australia).

24 *Submission* 8, p.4 (Medicines Australia).

25 *Submission* 7, p.3 (AMA).

26 *Committee Hansard*, 25.09.08, p.CA16 (Mr D Learmonth, DoHA).

27 *Committee Hansard*, 25.09.08, p.CA8 (Mr D Learmonth, DoHA); see also p.CA17.

28 *Submission* 7, p.3 (AMA).

> If the policy intention of the PBS is to be maintained, then the AMA believes the public interest test in the waiver provisions in the regulations must be considered by the minister. This will ensure that the minister has direct responsibility for personally considering the short- and long-term public good issues. The consequences are important. This should not be delegated to non-elected officials. It will also make the decision transparent.[29]

1.36 The Committee has considered the AMA's comments and considers that it is appropriate that fee waiver decisions remain with the Department. The Explanatory Statement details the considerations to be taken into account in assessing the public interest thus ensuring a consistent and transparent approach. In addition, the waiver decision is reviewable under Part 5 of the Regulations.

CONCLUSION

1.37 The Committee has examined the draft Regulations and considers that they satisfactorily address the issues that were raised during the Committee's earlier inquiry into the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008.

1.38 The Committee further considers that it would have saved considerable time and effort for both the Committee and the Senate had the draft Regulations been available during the earlier inquiry into the Bill.

Senator Claire Moore
Chair

October 2008

29 *Committee Hansard*, 22.09.08, p.CA11 (Mr F Sullivan, AMA); see also *Submission* 7, p.3 (AMA).

DISSENTING REPORT BY COALITION SENATORS

Introduction

Coalition Senators do not support the conclusion of the majority report that the draft regulations "satisfactorily address the issues that were raised during the Committee's earlier inquiry into the National Health Amendment (Pharmaceutical and other Benefits – Cost Recovery) Bill 2008" because clearly that contention is not supported by the weight of evidence presented to the committee.

Clearly there remains significant opposition to the proposal to move to cost recovery, and the concerns surrounding that proposal have not been mitigated by the release of the draft regulations.

This was best articulated by Professor Carney, Chair of the Therapeutics Advisory Committee, Royal Australasian College of Physicians

> **Prof. Carney**—I would first like to thank you for allowing the college and myself to comment on this PBAC funding cost recovery model again. The last time, when I was in Canberra and commented on this, I mainly tried to raise various issues and did not really come up with a decision as to what the college and its affiliated speciality societies felt about the proposal. Since then, I have had a chance to talk not only within the college, including my therapeutics committee, which met two days ago, but also to a number of affiliated specialty societies—not all, but a fair number including oncology, rheumatology, paediatrics, geriatrics, nephrology, cardiology and a couple of others. We have a large number of the various specialty groups, specialist physicians around the country who are associated with the college. Following those discussions, ***I can say with some confidence that there is no support for the proposal before the Senate at the moment.*** (emphasis added)

and

> **CHAIR**—My understanding is that you still have concerns, the ones you had when you originally gave evidence. You do not, at this stage, feel as though you have had them addressed?
>
> **Prof. Carney**—No, I have not. I see the system as unchanged and with the potential for getting worse. I can understand the government's problems in the Senate at the moment; we all read about that in the paper—probably a bit too much! But I wonder whether the amount of money the government will get from it is really going to be worth it in the long term.

Coalition Senators note that it has not been practice to release draft regulations prior to the passage of legislation and appreciate that the committee has had the opportunity to provide this scrutiny on behalf of the Senate. We are concerned however that the draft regulations were not released until after the committee had reported.

We also concur with the majority report that considerable time and effort would have been saved by the committee and the Senate had the draft regulations been available during the earlier inquiry into the Bill.

Consultation

There remains a considerable difference of opinion between the Department of Health and Ageing (DoHA) and industry over the definition and quality of consultation on the draft regulations.

We reiterate our view that it is unreasonable to assert that there was a seamless process of consultation between the two governments pre- and post the 2007 election.

We further express concern that the perception that forwarding the draft regulations to certain members of industry with an invitation to respond with any issues is genuine consultation, particularly given that the consultation process had been questioned in the previous inquiry.

This is born out by the fact that only two of those circulated (12) responded to the information circulated.

Medicines Australia stated the following in relation to previous experience of consultation with the Department

> **Senator COLBECK**—So, from your experience of consultation with the department, you would have difficulty in calling this 'consultation'?
>
> **Mr Delaat**—Absolutely. We would have great difficulty in defining this as consultation.

A similar response was received from the Australian Medical Association with the added perspective that the interaction of the measure with the Senate process had influenced expectations to consultation.

> **Senator COLBECK**—Basically, I think we are on the same track. Can I go back to your interactions with the department since the last hearings and in particular since the report came out? What communications has there been between the AMA and the department in respect of the issue of initially the draft regs and then the second incarnation that had the explanatory notes attached?
>
> **Mr Sullivan**—We received those from the department by way of its normal dissemination of information. I have not had direct dealings with the department. We have not had any interaction with the department in the interim.
>
> **Senator COLBECK**—Were there any specific requests that came with the documentation? You were basically just provided with that as part of an information process?
>
> **Mr Sullivan**—It is my understanding that it is the latter: the dissemination of information from the department.
>
> **Senator COLBECK**—So it could not be called a consultation process.
>
> **Mr Sullivan**—We have not been consulted per se. Like many groups we have been watching the political debate in the Senate and we responded accordingly to this process. Therefore our understanding of how things will work is the same as everybody else's.

> **Senator COLBECK**—So your response has effectively been to this committee process rather than necessarily the department or the government at this particular time?
>
> **Mr Sullivan**—That is correct.

These responses reinforce previous concerns expressed by Coalition Senators regarding consultation on this measure.

Operation of Regulations

It was obvious from evidence that the provision of the draft regulations has given industry and those interacting with the Pharmaceutical Benefits Scheme a much better understanding of the operations of the measure than briefings provided by the department, and that the process had prompted some amendments.

It is clear however that the release of the regulations had not allayed concerns regarding the concept of cost recovery for the PBS.

> **Mr Sullivan**—…the AMA would like to reiterate its concern about the government policy to introduce cost recovery for the Pharmaceutical Benefits Advisory Committee process. There is no net benefit to the Australian people in requiring pharmaceutical companies to pay application fees for PBS listing processes. These companies will simply factor this cost into their listing prices and claim them as legitimate business expenses for tax purposes. The potential consequence for the Australian people is that companies will decide there is no business case to bring a low-volume, low-priced product to the Australian market. These will be medications for small populations, medications for palliative care, oncology and our Indigenous Australians, for example.

and

> **Senator COLBECK**—You say that the draft regs do not adequately address your concerns. Fundamentally, can that be changed or do you have a basic view that cost recovery is not the process to be undertaken with respect to this particular measure?
>
> **Mr Sullivan**—Yes. In the spirit of the AMA's engagement we are trying to make something we think is not so good maybe slightly better. As we said in our first submission and I tried to reiterate, we do not believe cost recovery should apply in this field.

The Department had also indicated that the regulations were framed and would operate in a similar manner to those of the Therapeutic Goods Administration (TGA), the terms and procedures of which industry is quite familiar.

The proposed similarity between the two processes however was an additional point of concern with those at the coal face dealing directly with patients

> **Senator COLBECK**—I understand what you are saying but given that a lot of the precedents and process that is proposed for the PBAC process is lifted from the TGA process that would I presume reinforce your concerns?
>
> **Prof. Carney**—Yes. It would be just be PBAC running the way TGA does. That is my big concern because we are finding it extremely difficult. As I said certain groups now put it on their websites. You will find if you go to the MOG website, which is one of the groups, you will see medications. If you look at the indications approved by TGA, and you look at theirs, they are quite different. Because they have decided

that for their members and their patients they will put it down as they see it. There are legal issues in this of course. I do not quite know how they are going to be resolved. It is an area of confusion but again I would not want to see PBAC end up being in a situation where they are tied by having to get the money and then having to rely on industry who are going to say, 'What's in it for us?'

Conclusion

Coalition Senators reaffirm their view that cost recovery not be pursued, with that view supported by the overwhelming weight of evidence at both inquiries conducted into this measure.

Senator Gary Humphries

Senator Judith Adams

Senator Sue Boyce

Senator Richard Colbeck

Senator Scott Ryan

APPENDIX 1

Submissions received by the Committee

1 Pharmacy Guild of Australia (ACT)

2 Palliative Care Australia (ACT)

Supplementary information

- Opening statement tabled at hearing 22.9.08

3 Vines, Mr Timothy and Faunce, A/Professor Thomas (ACT)

4 Nordin AO, Professor B E C (SA)

5 Department of Health and Ageing (ACT)

Supplementary information

- Stakeholder mailing list tabled at hearing 25.9.08

6 Generic Medicines Industry Australia Pty Ltd (GMiA) (NSW)

7 Australian Medical Association (AMA) (ACT)

8 Medicines Australia (ACT)

9 Greensmith, Mr Barry (NSW)

APPENDIX 2

Public Hearings

Monday, 22 September 2008
Parliament House, Canberra

Committee Members in attendance

Senator Claire Moore (Chair)
Senator Rachel Siewert (Deputy Chair)
Senator Judith Adams
Senator Catryna Bilyk
Senator the Hon Richard Colbeck
Senator Steve Fielding
Senator Mark Furner
Senator Gary Humphries
Senator Scott Ryan

Witnesses

Palliative Care Australia
Ms Donna Daniell, Chief Executive Officer
Mr Bruce Shaw, National Policy Director

Mr Timothy Vines

Australian Medical Association
Mr Francis Sullivan, Secretary General

Medicines Australia
Mr Will Delatt, Chairman
Mr Brendan Shaw, Executive Director, Health, Policy and Research
Mr Andrew Bruce, Reimbursement Strategies Manager

Thursday, 25 September 2008
Parliament House, Canberra

Committee Members in attendance

Senator Claire Moore (Chair)
Senator Rachel Siewert (Deputy Chair)
Senator Judith Adams
Senator Sue Boyce
Senator the Hon Richard Colbeck
Senator Mark Furner
Senator Gary Humphries
Senator Scott Ryan

Witnesses

The Royal Australasian College of Physicians
via teleconference
Professor Shane Carney

Department of Health and Ageing

Mr David Learmonth, Deputy Secretary

Ms Sue Campion, Acting First Assistant Secretary, Pharmaceutical Benefits Division

Mrs Diana Macdonell, Acting Assistant Secretary, Pharmaceutical Evaluation Branch

Mr Roger Busch, Director, Policy Implementation and Budget Section, Pharmaceutical Evaluation Branch

APPENDIX 3

National Health (Pharmaceutical Benefits – Charges) Regulations 2008 – updated draft

Summary of updates to draft Regulations

Source: Submission 5, Attachments B and C (DoHA)

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

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(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

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(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.

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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.

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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

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(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*;

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(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.

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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.

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(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*.

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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

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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

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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.

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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.