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:
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> > Where the patient population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted.
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> 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).