DISSENTING REPORT BY COALITION SENATORS

NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL AND OTHER BENEFITS– COST RECOVERY) BILL 2008

Introduction

Coalition Senators make the following comments in relation to the majority report to reinforce issues of concern to the committee that we feel are not adequately reflected in the majority report.

Failure to produce Regulations

Coalition senators concur with the comments made in the majority report in paragraphs 1.14 to 1.17.

The committee was prevented from effectively scrutinising the effects of this legislation without access to the draft regulations that provide the operational mechanics of the measure.

Likewise witnesses appearing before the committee expressed concerns regarding the operation of the regulations. There had been no drafts of regulations provided during industry consultations

When questioned during hearings witnesses were not able to indicate an effective understanding of the operation of the measure.

Royal Australasian College of Physicians -

> **Senator COLBECK** –...Have you seen any regulations or a draft of regulations which are appended to the bill and are really what makes it work?
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> **Prof Carney** – No.
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> **Senator COLBECK** – So effectively all you have got at the moment is a bill that says, 'We are going to make regulations and this is how it is going to operate.'
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> **Prof Carney** – Yes. I do not have a feel for the detail. To me, if you can see what the potential problems are you can build a system with checks and balance…[1]

Pharmacy Guild of Australia -

> **Senator COLBECK** – Have you had any consultations or seen any draft regulations that relate to this measure?

1 *Committee Hansard* 28.7.08, p.CA11.

> **Mr Dowling** – No, and that is one of our primary concerns. We appreciate the exemptions that are mentioned in the paper, but we would certainly like to see the criteria around those regulations so we can be confident that our concerns will be addressed by them.[2]

Palliative Care Australia -

> **Senator BOYCE**—I have one last question. I am not entirely sure about this—perhaps you can tell me if you are. Are you confident about the stage at which you would be aware of whether there would be cost recovery regarding a specific submission? I realise that there are definitions of an orphan drug now; I understand that that definition may yet change. Are you confident that you would know in a timely way whether a submission would be charged or not for assessment by the PBAC?
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> **Mr Shaw**—Not under the information that we have available to us now. The problem that Professor Ravenscroft referred to is that there is so much discretion left to the delegate, to the department, in this. It is not going to be transparent and clear up-front, in a sense.[3]

Likewise members of the committee were restricted in the questions that they could ask due to a lack of knowledge of the content and operation of the regulations. With respect to the Minister's statement regarding parliamentary scrutiny of the regulations (paragraph 1.18 of majority report). Coalition Senators note that the scrutiny of the parliament is effectively restricted to acceptance or rejection of the regulations. The parliament has limited power to alter regulations except in a specific range of criteria.[4]

Coalition Senators note that a request was taken on notice by the Department for the provision of draft regulations, however as of the date of tabling there had been no response or indication that information may be provided to the committee.

Access to Low-Volume Products and Indications

Of particular concern to Coalition Senators were medications used in paediatric, palliative and Indigenous care where a high proportion of medications are used "off label".

In its submission to the committee the Department of Health and Ageing provided information relating to the treatment of "orphan drugs" as classified by the TGA, however there was considerable evidence provided to the committee in submissions and in evidence during the inquiry regarding the effect of the measure on medicines used "off label".

Witnesses from the Royal Australasian College of Physicians and Palliative Care Australia, provided information to the committee that medicines used in the treatment of three major groups were often used "off label":

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2 *Committee Hansard* 28.7.08, p.CA19.

3 *Committee Hansard* 28.7.08, pp.CA43-4.

4 See Odgers' Australian Senate Practice, 11th edition, 2004, Delegated Legislation and Disallowance, pp.321-343.

Royal Australasian College of Physicians –

> **Prof Carney**- …I would think that the majority of medications being used in children would not have good data on their use, certainly at the time when the medication was approved. Most of that has really been off label.
> …
> **Prof. Carney** - One of the troubles of new medication is that there are often populations where it has not been trialled. We presume that when a medication comes out it works in the indigenous population the same as everyone else. The industry tries to have new products tested in various countries, and you might get a few Indigenous people who might be involved in one of those trials, but I do not think you could get meaningful information. We just presume that it works for them the same as it does in a Caucasian.[5]

Palliative Care Australia –

> **Prof. Ravenscroft**—The drugs often do exist. Here is the nub: the clinical studies that have been done on the drugs have not been for palliative care purposes. What has to happen is that the data needs to be generated for those drugs. The department of health has funded multicentre trials, which are ongoing at the moment, to gather that data. So we are going to get some more data. But what will actually happen is that those drugs, when there is sufficient data, will go to the TGA and will cop a cost-recovery fee—and I am not yet sure who is going to pay that because the data is being collected by groups of palliative care physicians. Then when they go to PBAC they will cop another cost-recovery system. What we are saying is that these costs are going to kill these drugs.
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> **Senator BOYCE**—We have had a number of witnesses who are quite confident that the legislation in its final form will allow sufficient flexibility to accommodate orphan drugs, extensions of indicators into small volume markets and so forth. What are your comments on that?
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> **Prof. Ravenscroft**—My personal comment is that to leave this open for the bureaucracy to make these decisions may end up producing a result that is less than satisfactory for the patients who need these drugs. I think it would be much better if an exclusion was made in the legislation for palliative care patients who need these drugs.
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> …
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> **Senator COLBECK**—We heard this morning that most of the drugs used in paediatric care were used off label. What proportion of drugs used in palliative care would be used in a similar way?
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> **Prof. Ravenscroft**—Very perceptive, Senator. I do not have the actual figure, but the figure was quite large.

5 *Committee Hansard* 28.7.08, pp.CA11-12.

> **Senator COLBECK**—Would it be fair to say, again, most?
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> **Prof. Ravenscroft**—I would say probably half, but the advent of the PBAC's palliative care section in the PBS book has made a huge difference because it has actually given us some drugs for longer periods than are usually available for people who do not have palliative care indications. So that has been a really positive thing, and it has given us the opportunity also to advertise to doctors that that section is available. Over the last four years there has been a great leap in the understanding of the PBAC about palliative care drugs and their willingness to help with their better recognition, and they have really been most cooperative in looking at drugs with us to see if we could find data that was adequate for their purposes. I think this legislation really counters that a fair bit.[6]

Coalition Senators appreciate the work of PBAC in its efforts to support the listing of medications and indications used in the spheres of paediatrics and palliative care through the formation of Medicines Advisory Groups

The point of raising these applications in this form is to emphasise that there is considerable work currently underway, at the instigation of the PBAC, that may potentially trigger the payment of fees.

Again the lack of regulations has made it difficult for the committee to gain a real understanding of the financial effect in this process

Consultation

Coalition Senators do not consider it reasonable to assert that there was merely a seamless process of consultation that has occurred for this measure from its initial announcement by the previous government in 2005 to the decision of new government elected in 2007 to proceed.

Not only has there been a new government elected with different policies, there have been a number of events that occurred during the intervening period, including a major renegotiation of prices paid for products supplied under the PBS that provides a projected saving of $3 billion to government over 10 years.

Since November 2007 there has been no policy indication from the new government as to their policy intentions on cost recovery for listing on the PBS.

This is confirmed in evidence given to the committee by Medicines Australia:

> **Senator COLBECK** – I want to go back to the original consultation process. We have heard during evidence today that there was an initial proposal that was announced in 2005-06 with respect to a possible measure of this nature, followed by a consultation paper, I think. Have you had any consultations other than that consultation process with the department, this side of the election?

6 *Committee Hansard* 28.7.08, pp.CA42, 45-6.

> **Mr Chalmers** – The answer is no. We were aware of the initial proposal, which was much wider than just cost recovery in our industry. That was in the 2005-06 budget. In 2007 there was a paper presented to us inviting comments on alternative models for payment of the fee, but there was no consultation about the appropriateness of cost recovery. Our industry provided a response in terms of potential fee structures, but at no point was there broader investigations, such as there is now, of the appropriateness of this measure.
> I also note that, having lodged that submission well over a year ago, nothing further was heard from the government, although the current minister for health did place on the record in the House of Representatives her view that this measure would at the very least not be appropriate.[7]

In fact this comment is the only indication that industry has had from the government as to its position on this initiative which was made during debate on the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007* when the now minister said as shadow minister on 31 May 2007

> The PBAC needs to be independent of government and of industry, and we cannot see the justification for this move to the cost recovery model. I have asked the government to reconsider this approach given the risk to the independence of the PBAC, or even to consider if cost sharing, perhaps between the government and industry, being the major stakeholders in the PBAC, would be more appropriate. I note the AMA has recently backed this call to ensure that independence is maintained.[8]

It is not unreasonable for industry to expect that this would be the position of the new Government.

Cost Recovery

Coalition Senators note that industry groups have raised significant concerns that the cost recovery measures will cause delays, reduce incentives and may run contrary to the *Australian Government Cost Recovery Guidelines* as outlined in the majority report at paragraphs 1.73 – 1.76 and 1.78 – 1.80.

Item 15 of the Cost Recovery Guidelines stipulate:

> Agencies with significant CR arrangements should ensure that they undertake appropriate stakeholder consultation, including with relevant departments.

It is the view of Coalition Senators that the Government has not met this element of the cost recovery guidelines.

Further to this point, Medicines Australia noted in its supplementary submission that the cost recovery measures appeared to run counter to the *Australian Cost Recovery Guidelines* as they:

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7 *Committee Hansard* 28.7.08, pp.CA51-2.

8 Ms Roxon, *House of Representatives Hansard*, 31.5.07, p.12.

- are NOT cost-effective – they do not increase "cost-awareness" in the responsible agency as all moneys go into consolidated revenue; and importantly they are not accompanied by any proposals and/or performance targets to ensure improvement in the efficiency or timeliness of the PBS listing process;
- are inconsistent with the intent of Government [*National Medicines*] Policy, which is to facilitate timely access to the medicines that Australians need, at a cost individuals and the community can afford – the PBS is essentially a government procurement program;
- will unduly stifle competition and industry innovation principally by the exacerbation of existing 'free rider' effects;
- disregard the public good characteristics of the PBS listing process;
- disregard the significant spillover benefits to the broader community of the PBS listing process, and
- fail to acknowledge other policy reasons for funding it, in particular that the PBS is an integral part of Australia's tax-payer funded, universal health system.[9]

Medicines Australia has submitted in its supplementary submissions that the Department of Health and Ageing frequently cited the Productivity Commission guidelines rather than the *Australian Government Cost Recovery Guidelines* and has suggested that an assessment of the proposed arrangements in accordance with the *Australian Government Cost Recovery Guidelines* should be undertaken.

The only public policy statement of the Government prior to the budget announcement (which did not support the implementation of cost recovery) also places the measure at odds with the guidelines.

Concerns were also raised that the proposed system of exemptions to cost recovery measures on submissions would not adequately deal with the types of delays cost recovery would cause. Medicines Australia submitted in its supplementary submission that exemptions granted for listing for low-volume drugs or indication expansions would be passed on to other non-exempt submissions, thus hiding the disincentive from the public. It is noted in the majority report in paras 1.50-1.52 that the exemptions would be contained in the regulations and the absence of the regulations has meant adequate scrutiny of the proposal and the exemptions has not been possible.

9 Medicines Australia, *Submission* 7, Additional information dated 12.8.08, p.2.

Conclusion

Coalition Senators do not believe that the government has allowed sufficient consultation or scrutiny of this measure to support passage of the legislation. Accordingly Coalition Senators **recommend that the Senate not support this bill** at this time.

Senator Gary Humphries
Deputy Chair

Senator Judith Adams

Senator Sue Boyce

Senator the Hon Richard Colbeck

Senator Scott Ryan