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Palliative Care Australia

10 September 2008

Mr Elton Humphery
Committee Secretary
Senate Community Affairs Committee
Parliament House
Canberra ACT 2600

by email: community.affairs.sen@aph.gov.au

Dear Mr Humphery

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

Thank you for the invitation to comment on the draft National Health (Pharmaceutical Benefits – Charges) Regulations 2008.

PCA advocates that, should the Bill proceed, the regulations should be clear, comprehensive, and only finalised after extensive consultation with all stakeholders, including sector groups such as PCA, industry and consumer groups.

While we acknowledge that we have been sent the current draft regulations by the Department of Health and Ageing, we are not convinced that this amounts to the sort of engagement that would be necessary to meet the criteria of "extensive consultation with all stakeholders, including sector groups such as PCA, industry and consumer groups."

The draft regulations are lacking in any substantive details about the listing process, particularly with regard to how decisions are to be made about fee category and determination of waiver status, and about who will have the power to make these decisions, and under what criteria.

Terms such as 'substantive', 'public interest' and 'financially unviable' are all used very loosely, without definition. Our view is that a proper consultation process, engaging all stakeholders, is imperative to allay concerns about the process. 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.

As we stated to you in our evidence on 28 July 2008, the Pharmaceutical Benefits Advisory Committee (PBAC) assessment process currently encourages the initial listing of most medicines to one major indication. This is for the very good reason that

this is the indication that the initial evidence-base for the new medicine supports. Subsequent submissions may be required for other uses. This is particularly true for drugs used for palliative care.

This is the PBAC process that has evolved over time, and by and large works well. To tamper with it under the notion that subsequent applications are an indication of a poor quality initial application is to risk the vital role that the PBS plays in our health system.

Given that palliative medicines comprise a small patient base, it is reasonable to assume that such additional indications will be less likely to be sought if there is a substantial cost barrier imposed, or even that the research and data collection will be undertaken to obtain the necessary additional evidence.

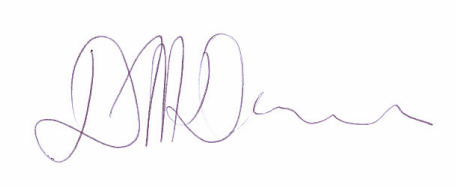
Accordingly, Palliative Care Australia remains concerned about the detrimental effect of the measure on access to new medicines for small group populations such as palliative care patients.

Palliative Care Australia recommends:

- consultation on the whole cost recovery measure, including any regulations, should be substantive with all stakeholders (including sector groups such as PCA, industry and consumer groups) before any cost recovery measure is further proceeded with;
- substantive detail on the "public interest" and other criteria used to determine fee waivers be provided in the regulations after substantive consultation;
- the process for granting fee waivers must clear and should not serve to delay access to medicines by prolonging the listing process;
- the disincentive to seeking expanded indications for medicines for small patient groups is removed;
- there should be no disincentive to seek listing for palliative indications once evidence supports this.

Palliative Care Australia would be pleased to appear at your public hearing on Monday 15 September 2008, should the committee wish.

Yours sincerely



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