MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

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

Dear Mr Humphery

Following the Australian Senate Community Affairs Committee hearing into the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*, I am pleased to present supplementary information as requested by the Senators during Medicines Australia's witness testimony.

The information attached concerns medicines and indications for medicines that will be placed "at-risk" by the proposed cost-recovery arrangements. These examples highlight how, when added to the substantial existing administrative costs, the fees will influence the business decisions of companies on whether to seek PBS listing for small volume products and/or indication expansions.

The examples reflect the issues that Medicines Australia (MA) has raised in its submission and testimony to the Committee.

MA does not believe that a system of exemptions can adequately deal with the types of delays cost recovery would cause. The issue is the potential lack of alignment of PBS reimbursement eligibility criteria with the best available clinical trial evidence. This evidence only becomes available over the full life of a medicine and is almost never available at the time of first listing. There is a real risk that the introduction of cost-recovery will significantly reduce access to medicines many Australians need, thus undermining the objectives of Australia's National Medicines Policy.

MA also believes that the system of exemptions currently under consideration does not adequately deal with the problem of restricting access to medicines for small, vulnerable groups, including children, the dying and ATSI populations. The Department of Health and Ageing has confirmed that the cost of these "exemptions" will be transferred to non-exempt submissions in the form of higher fees. Such an approach simply hides these disincentives from the public.

I ask Committee members to consider closely MA's argument that the proposed arrangements run contrary to the Government's own cost-recovery guidelines (***not*** the Productivity Commission guidelines frequently cited by the Department).

In short, the Guidelines themselves point to reasons why this proposal should be rejected, namely, these arrangements:

- are *NOT* cost-effective – they do not increase "cost-awareness" in the responsible agency as all monies 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 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.

MA believes that the proposal to introduce cost-recovery in the PBS is poorly conceived; especially in the absence of any extensive and systematic consultation with key stakeholders **on the merits of the policy.** Should the arrangements proceed, even in the face of such arguments, Medicines Australia would expect to be consulted as to how they could be implemented in a way that ameliorates any threats to access to medicines, and on what improvements to the PBS listing process may flow from attaching fees to a submission process which has been designed to provide the Australian Government with information on how best to direct its resources.

I look forward to further discussions on this matter.

Yours sincerely

Ian Chalmers

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TABLE 1: COMPANY EXAMPLES

Medicine	PBAC Submission Purpose	PBAC Meeting	Submitted Under Cost Recovery
Terbinafine (TERBINAFINE TABLETS)	• For PBS access to nystatin for Aboriginal or Torres Strait Islander patients with fungal and yeast infections where topical treatment has failed.	• Nov 2007	Had cost-recovery measures been in place in 2007, Novartis would have needed to consider the following factors before making a decision on whether to make a submission to the PBAC: • Dut y of care for the patient group affected • Com mercial considerations: i) due to the relatively small population eligible for treatment, 10 years of sales would have been required before cost recovery fees would not have been recouped by Novartis Australia ii) while it would take Novartis well over 10 years to recover the costs, the sponsors of generic terbinafine would receive an immediate benefit. If the submission had not gone ahead the capacity of the PBS to meet the needs of indigenous Australians would not have improved
Alendronate sodium (various brands)	• For widened PBS access to alendronate to all patients with clinically defined osteoporosis. Specifically patients with a BMD T- score of less than, or equal to, -2.5 (regardless of age). • The intended listing would ensure PBS access to alendronate is in line with clinical guidelines.	• March 2008 (rejected)	Under normal circumstances, a company such as MSD might consider lodging a resubmission with the PBAC to address its concerns. However, under cost-recovery, there would be limited incentive for MSD, or any of the generic companies who supply alendronate sodium, to resubmit this application - given that alendronate sodium is subject to considerable generic competition. If MSD is unable to resubmit, an estimated 175,000 men and women with osteoporosis over the age of 70 will not receive PBS access to this medicine should PBS cost recovery be implemented
Meloxicam (MOBIC®)	• For widened PBS access to meloxicam specific to symptomatic relief of rheumatoid arthritis	• March 2008 (rejected) • April	Post rejection of its original PBAC submission, BI lodged a resubmission with the PBAC. This resubmission was successful. However, under a cost-recovery scheme, there would have been

		2008	limited incentive for BI, or any of the generic companies who supply meloxicam, to pursue PBS listing. If BI hadn't resubmitted their application, then the PBS restriction for meloxicam would have remained out of step with clinical guidance
Sodium valproate (EPILIM) Syrup	• For PBS access to different dosage forms of sodium valproate for the treatment of epilepsy.	• Various	While the potential patient benefits of having access to different dose forms of sodium valproate are significant, the commercial benefits are limited. Under PBS cost recovery, sanofi-aventis or any of the generic companies who supply sodium valproate, are unlikely to apply for new, improved dose forms of sodium valproate
Methylnaltrexone (RELISTOR®)	• For PBS access to methylnaltrexone for treatment of opioid-induced constipation in patients receiving palliative care	• March 2009	It is anticipated that Wyeth will be submitting an application for PBS reimbursement of methylnaltrexone in late 2008 or early 2009. Should PBS cost recovery proceed, Wyeth will need to weigh up the likelihood of success against potential commercial returns should its initial submission be unsuccessful. This is not a decision the company will make lightly. Under PBS cost recovery, access to this important medicine for palliative care patients may be compromised
Sildenafil citrate (REVATIO)	• For PBS access to sildenafil for a small subset of patients with pulmonary arterial hypertension (PAH)	• Nov 2008	Pfizer estimates that < 175 patients per year will benefit from the PBS listing of sildenafil for the treatment of PAH. As such, the commercial return in a given year for this indication is limited. Under a PBS cost recovery scheme, Pfizer would have given serious consideration as to whether or not to submit this application.