

13 April 2009

Committee Secretary  
Senate Community Affairs References Committee  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Dear Committee Secretary

I am pleased to present Medicines Australia's submission to the Australian Senate Community Affairs References Committee inquiry into *Consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme*.

Medicines Australia represents the innovative medicines industry in Australia. Our member companies comprise more than 80 per cent of the Australian prescription pharmaceuticals market and are engaged in the research, development, manufacture, supply and export of prescription medicines. As such, Medicines Australia is an important partner in any policy that affects the regulation, manufacture, distribution and utilisation of pharmaceuticals in Australia.

Medicines Australia welcomes the wider scrutiny into a number of existing "policy levers" which permit high cost and unpredictable Government interventions into Australia's highly efficient pharmaceuticals market. As argued in the submission, these interventions have social and business costs that greatly outweigh the value of any short-term fiscal savings to the Government that they might generate.

Importantly, interventions, such as the formation of Therapeutic Groups and the Cabinet Review process, also potentially put the health of patients at risk: the first, by increasing the out-of-pocket costs of patients, assuming that patients can switch from one medicine to another, and introducing financial considerations into a doctor's prescribing decision; and the second, by delaying the listing of potentially life-saving and cost-effective medicines by up to 12 months.

Such Government interventions also serve to undermine business confidence in the Australian pharmaceuticals market putting future investment at risk. The use of Therapeutic Groups, in particular, undermines pricing predictability and introduces unnecessary volatility to a high cost and highly competitive market.

As cost-saving measures they are also not needed, especially after the introduction of PBS Reform. Efficiency and long-term sustainability are "hard-wired" into the PBS listing process itself resulting in Australia's total expenditure on pharmaceuticals being lower than nearly all other OECD countries. It should be no surprise to the Senate Committee that recent OECD research also showed that ***Australia pays the fourth lowest prices for innovative or originator medicines relative to economy wide-prices in the whole of the OECD and that prices for originator medicines are 81% of the OECD average.***

For these reasons and others, Medicines Australia is recommending that:

1. the Australian Government abolish the Therapeutic Group policy and legislative provisions relating to it as this policy:
  - a. potentially places patient interests at risk by:
    - i. transferring a proportion of the costs of important medicines from the Government to the patient and therefore increasing the risk of non-compliance;
    - ii. assuming without appropriate evidence that an individual patient is able to switch to another medicine within the Therapeutic Group without detriment to the patient's health;
    - iii. introducing financial considerations into a doctor's decision to prescribe a medicine most suited to an individual patient's clinical needs;
  - b. is not required to ensure the long-term sustainability of the PBS, the efficiency of which is underpinned by both rigorous cost-effectiveness analysis and growing price competition in the off-patent market;
  - c. undermines industry confidence in the Australian business environment by permitting the government to intervene at any point in time without consultation in the market putting ongoing investment at risk.
2. the Australian Government provide clear definitions and guidance on all legislation or policy that might compromise Australians' timely access to medicines. In particular, the Government had an obligation to ensure that the term "interchangeability on a patient basis" be clearly defined and guidance provided on the evidence required to establish such a link between medicines
3. the Australian Government, before intervening in the pharmaceuticals market, conduct appropriate consultations with affected parties and ensure at all times that due process is followed
4. the Australian Government work with industry to implement a formal price disclosure dispute resolution and audit process to avoid delays implementing further price disclosure price reductions
5. the Australian Government increase the threshold at which Cabinet approval is required for the listing of demonstrated cost-effective medicines on the PBS from the current \$10 million to \$20 million; and index future adjustments to reflect economy-wide price
6. the Australian Government commit to reduce the time it currently takes to achieve a PBS listing for those medicines for which Cabinet approval is required.

I would also welcome the opportunity to present Medicines Australia position before a Committee hearing as the issues before this inquiry are sufficiently complex and important to merit this.

Please do not hesitate to contact me should you require any additional information or clarification of any matter presented in this submission.

Yours sincerely



Dr Brendan Shaw  
Chief Executive