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Submission to the Senate Finance and Public Administration References Committee inquiry on the Government's administration of the Pharmaceutical Benefits Scheme (PBS)

The AMA opposes Government decisions to defer listing of medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC).

Australia is a prosperous country that can afford to fund the latest safe, clinically effective and cost-effective medicines that sick people need. The AMA is aware that the Government pays a high price by international comparison for many off-patent medicines that are subsidised for patient consumption via the PBS.

PBAC process

The PBAC assessment and pricing process is world class. PBAC is an independent expert body that includes health economists and medical experts.

PBAC is legally required to consider the effectiveness and cost of a proposed PBS listing compared with other therapies. Therefore, when recommending listings to the Minister for Health and Ageing, PBAC also advises the Pharmaceutical Benefits Pricing Authority about how the new listing compares with alternative medicines and/or current standard care in terms of cost-effectiveness ('value for money').

To assess value for money, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of a proposed medicine compared with other medicines already listed on the PBS for the same, or similar, indications. Where there is no listed alternative, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of the proposed medicine compared to standard medical care. On the basis of community usage, PBAC recommends maximum quantities and prescription repeats and may also recommend restrictions as to the indications where a PBS subsidy is available.

A new medicine may be recommended for listing if it is:

- needed for the prevention or treatment of significant medical conditions not already covered, or inadequately covered, by medicines in the existing listing and is of acceptable cost-effectiveness;
- more effective or less toxic (or both) than a medicine already listed for the same indications and is of acceptable cost-effectiveness; and/or
- at least as effective and safe as a medicine already listed for the same indications and is of similar or better cost-effectiveness.

A new medicine that is less effective and/or more toxic than a medicine already listed for the same indication(s) might be considered for listing. In such a circumstance, other supportive factors would be needed to justify a recommendation, for example, if the new medicine would decrease the

overall costs of therapy and/or if it were restricted to a subsequent line of therapy after the more effective or less toxic therapy.

Recommendations to list a new medicine are unlikely if its:

- use might increase problems of abuse or dependence; or
- sole use would be to treat an individual patient whose response to, or need for, a medicine is unique.

Removal of a medicine from the list may occur if:

- a more effective or equally effective but less toxic medicine becomes available;
- evidence becomes available that the effectiveness of the medicine is unsatisfactory;
- evidence becomes available that the toxicity or abuse potential of the medicine outweighs its therapeutic value;
- the medicine has fallen into disuse or is no longer available; and/or
- treatment with the medicine is no longer deemed cost-effective compared with other therapies.

PBAC follows due process in considering the removal of a medicine, including consulting with affected stakeholders.

Successive Governments have relied on this rigorous, scientific PBAC assessment to inform PBS listing decisions. Consequently, PBS funding decisions by Government have been fair, equitable, evidence-based and transparent. It has saved successive Governments from being lobbied by special interest groups to fund particular medicines and from having to make politically difficult decisions.

New process

As far as the AMA can tell from Government announcements, there appears to be two criteria that Cabinet is now using to defer listing medicines on the PBS after PBAC has recommended the listing:

- the medicines are for conditions for which there are existing treatments already available on the PBS; and
- the circumstances do not permit listing.

The AMA considers both criteria to be inappropriate. In respect of the first criterion, the AMA considers it is a false 'saving' as the market for that type of medicine does not grow but sales of the medicine in question are funded by reduced sales in its direct competitors.

In respect of the second criterion, because there is no transparency about the exact circumstances that will permit listing, Cabinet decisions to list medicines on the PBS are now purely political.

False savings

Medical practitioners will prescribe medicines when it is clinically appropriate for the treatment of the patient.

Access to a range of proven medicines funded under the PBS allows medical practitioners to make decisions about the optimal medical treatment of the patient, based on the patient's particular clinical circumstances, without patients having to make decisions about what they can afford. As stated above, PBAC assesses the clinical effectiveness and cost-effectiveness of medicines against

existing treatments. Only those that qualify against these two measures are recommended for listing. It is a false saving to not list the new, alternative treatment when there will be PBS outlays for the existing medicines.

Denying access to medicines that are proven to be both clinically useful and cost-effective is a crude and blunt instrument to attempt to control PBS outlays. The AMA notes that the Government has not attempted to quantify the net savings it expects to make by deferring listing medicines where existing treatments are already available on the PBS.

Circumstances that permit listing

When first announcing that the Government had deferred the listing of seven medicines recommended by PBAC in February 2011, the Minister for Health and Ageing said that the medicines would be reconsidered "when circumstances permit". Now, only four months later, one of those medicines, 'Duodart' (for treatment of an enlarged prostate), will be listed.

It is not clear what circumstances have changed in that short time to permit the listing of 'Duodart'. Further, the Government has not explained why it has decided to now list this one medicine ahead of the other six that were similarly deferred in February 2011.

While the Government's basis for deferring listing medicines on the PBS is unclear, the listing process can only be political. The AMA considers these listing processes and decisions must be fair, equitable and transparent, and not subject to political interference.

The AMA contends that Cabinet Ministers are not qualified to make decisions about which PBAC recommended medicines should not be listed, or those that should be listed ahead of others.

In addition, the AMA is not aware that Cabinet is provided with a cost benefit analysis of the impact of deferring the listing of medicines that takes into account direct and indirect costs and benefits to patients, the health care system and to the Australian economy.

Other ways to reduce PBS cost outlays

There are other measures that can reduce unnecessary PBS outlays.

Firstly, the Government should ensure that current PBS subsidised medications are recorded on the Personally Controlled Electronic Health Record (PCEHR). Making this information available to all prescribers through the PCEHR will reduce PBS outlays for duplicate scripts and have the added benefit of reducing adverse medications events. This measure has the potential to provide significant savings and ensure the quality use of medicines.

Secondly, the Government should cease implementation of the 'continued dispensing' measure in the 5th Community Pharmacy Agreement that will permit pharmacists to dispense PBS medicines without a prescription from a medical practitioner and without reference to the patient's treating medical practitioner. Only medical practitioners are adequately trained to make assessments about a patient's clinical condition, the need to begin treatment with a prescription medication, and consequently to continue, adjust or cease that treatment.

It is likely that the 'continued dispensing' measure will add to PBS outlays because pharmacists will continue to dispense medicines that the treating medical practitioner had not intended to prescribe for the patient *ad infinitim*.

Thirdly, the Government should withdraw prescribing rights under the PBS from non-medical practitioners.

Fourthly, the Government should refrain from:

- providing any other non-medical practitioners with prescribing rights under the PBS; and
- extending the schedule of medications that non-medical practitioner prescribers can currently prescribe.

Fifthly, the Government should ensure the mandatory price disclosure rules are being properly observed and include any one-off discounting. The price disclosure rules are designed to recoup savings for Australian taxpayers where there are significantly better trade terms from wholesalers resulting in prices much lower than the PBS subsidy. The Government should prevent any bulk purchasing that may occur in the first month of the price disclosure year, which could have the effect of minimising the savings from the price disclosure measure (see *Generics and the Crystal Ball*, Australian Journal of Pharmacy Vol 92 February 2011).

Other matters

The 2011-12 Federal Budget provides $11.4m over two years to expand the role of the Medical Services Advisory Committee (MSAC) to assess the safety, quality and fee levels of medical services. MSAC assessments will be used to inform decisions about whether medical services should be subsidised under the Medicare Benefits Schedule (MBS).

The AMA is concerned that the Government will take the same approach with MSAC decisions as it has with PBAC decisions. The medical profession has already seen lengthy and unexplained delays between MSAC recommendations and the listing of the services on the MBS, for example, the MSAC recommendation for endoscopic argon plasma coagulation for gastrointestinal bleeding and oesophageal stents was endorsed by the Minister in May 2008 but MBS funding did not commence until 1 May 2010.

Conclusion

The Government must make it clear to the Australian people that it is winding back its PBS and MBS funding policies. The long held fundamental basis of both programs, which is universal access to necessary medical care and treatment are seriously threatened because of delays in funding proven medical treatments.

Regarding PBS listings, the Government must act on the advice of its own independent expert committee to ensure patients have affordable access to the medicines that have been found to be safe, clinically effective and cost-effective.

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