Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-451

OUTCOME 2: Access to Pharmaceutical Services

Topic: PHARMACEUTICALS AND PHARMACEUTICAL SERVICES

Written Question on Notice

Senator Fierravanti-Wells asked:

a) How does this new, ad hoc, opaque process mirror the rigour and integrity of the world renowned PBAC process?

b) What is the new review intended to look at, and how does this differ from what the PBAC has already examined in determining that Pradaxa is safe and cost-effective for at risk stroke patients?

c) What are the guidelines or criteria for this new review?

d) What is the timing of the review? When will it report and how soon will Australian patients get access to a medicine recommended by the PBAC?

Answer:

a) The Government is acting on the advice provided by the Pharmaceutical Benefits Advisory Committee (PBAC). Reviews of existing or potential new listings are not new.

Over the past ten years, the PBAC has made a number of recommendations or observations in its minutes that have lead to reviews of particular drugs or treatments being instigated.

In 2009, PBAC concerns about the unjustifiably large proportion of patients who were deemed eligible to continue biological disease modifying anti-rheumatoid drugs (bDMARDs) led to a review of this group of medicines on the Pharmaceutical Benefits Scheme (PBS). The results of this review were announced in the 2010 Budget.

In 2008, following a recommendation to list clopidogrel for patients with acute coronary syndrome, the PBAC requested a review of the cost effectiveness of clopidogrel in an area of high clinical need. This review was considered in March 2009, and the Minister received a recommendation for an extension to the listing which was subsequently made.

In 2002, the former government relied on overall PBAC advice to reject the listing of Viagra® on the PBS, noting the Committee's concerns that, whilst the drug had been found to be both clinically effective and cost effective, the Committee had concerns about the high annual cost of the potential listing.

Other drugs that have been subject to review include Herceptin®, and the ACE inhibitor and ATRA groups of drugs.

b), c) and d)
At its March 2011 meeting, the PBAC recommended extending the current PBS listing of Pradaxa to include the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation (a condition associated with an abnormal heart rhythm).

However, in recommending the listing of Pradaxa on the PBS for patients at risk of stroke because they have atrial fibrillation, the PBAC noted the following:

- Pradaxa derives its advantage over warfarin when warfarin is used sub-optimally;
- improving the use of warfarin by means of an education campaign aimed at prescribers, pharmacists and patients would be less costly;
- the benefit of Pradaxa observed in the clinical trial may or may not be wholly reflected in the Australian population;
- a number of patients who are reluctant to take warfarin because of its stringent monitoring requirements and interactions with other drugs and foods may be treated with Pradaxa. This would likely lead to additional benefits and costs not measured in the trial;
- low risk patients currently managed on aspirin may be inappropriately transferred to Pradaxa; and
- listing Pradaxa would cost the budget up to $1 billion over the forward estimates.

Based on this advice, on 30 September 2011 the Government announced that it would commission Emeritus Professor Lloyd Sansom AO, the former Chair of the PBAC, to inform the Government on options for improving the health outcomes of patients treated with anticoagulation therapies, including optimising the use of currently available treatments in Australia as well as the future role of newer therapies for the treatment of atrial fibrillation.

The Terms of Reference for the Review are:

a. To report on current and future options for improving the health outcomes of patients with atrial fibrillation treated with oral anticoagulants.
b. To report on modes of health system delivery which may be used to optimise the use of currently available anticoagulants.
c. To report to what extent optimisation of the use of currently available anticoagulant treatments used in patients with atrial fibrillation would improve health outcomes and at what cost.
d. To examine the future role of newer anticoagulant therapies for atrial fibrillation.
e. To report on any other matter relevant to items (a) to (d) above and on any other matters referred to it by the Minister.

A reference group will be established to assist Professor Sansom in the consideration of matters arising from the Review. The reference group will comprise experts in clinical and drug utilisation areas to provide the breadth of clinical input necessary to address the Terms of Reference of the Review, including, but not limited to a cardiologist, neurologist, clinical haematologist, epidemiologist, pharmacist, geriatrician and consumer representation.

The expected timeframe and process for the Review is as follows:

- Literature reviews and research – October to January.
- Calls for submissions to be made in December, and be expected in by end of January.
- Reference group to be in place by December.
- Stakeholder engagement February to May.
- Report to PBAC in July 2012.