

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-355

OUTCOME 2: Access to Pharmaceutical Services

Topic: PHARMACEUTICALS AND PHARMACEUTICAL SERVICES

Written Question on Notice

Senator Fierravanti-Wells asked:

The 2010 Memorandum of Understanding between Government and Medicines Australia provides for government to use best endeavours to make decisions on medicines listings within six months of pricing agreements being finalised.

- a) Has that provision been met?
- b) Are there any medicines recommended by the PBAC that have finalised pricing agreements more than six months ago and are still waiting for PBS listing?
- c) Please name those medicines, what are they for, how many patients are being impacted by the delay in PBS listing?

Answer:

- a) Yes, with the exception being the Pharmaceutical benefits Scheme (PBS) listing of cetuximab (Erbix<sup>®</sup>) which was dependent on a K-RAS generic test being submitted for Medical Services Advisory Committee consideration for listing on the Medicare Benefits Scheme.
- b) Yes.
- c) The extension to the PBS listing of dabigatran (Pradaxa<sup>®</sup>) for the treatment of atrial fibrillation. However, Cabinet did consider the listing of this medicine within the timeframes committed to in the Memorandum of Understanding.

At its March 2011 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended to extend the PBS listing of dabigatran for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation (a condition associated with an abnormal heart rhythm) on the basis of acceptable cost-effectiveness, but it also raised a number of concerns that require further investigation and assessment. These issues include:

- the fact that dabigatran derives its advantage over warfarin when warfarin is not taken as prescribed or the dosage for the patient is not correct; and

- the benefit of dabigatran observed in the clinical trial may or may not be reflected for every patient.

The Government has therefore commissioned Emeritus Professor Lloyd Sansom AO, the former Chair of the PBAC, to conduct a further analysis to inform the Government on options for improving the health outcomes of patients treated with anticoagulation therapies, including optimizing the use of currently available treatments in Australia as well as the future role of newer therapies for the treatment of atrial fibrillation, such as dabigatran.

The number of patients who may have been prescribed this medicine in the first full year of PBS listing is Cabinet-in-confidence.