Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-460

OUTCOME 2: Access to Pharmaceutical Services

Topic: PRADAXA

Written Question on Notice

Senator Fierravanti-Wells asked:

How many additional hospital, doctor visits and blood tests will be required for each year that Pradaxa is not available for patients?

Answer:

The answer to this question is not known for a number of reasons.

- Dabigatran is not side-effect free, and has safety issues that need to be managed, such as difficult-to-control internal bleeding and implications for people with reduced renal function.

- These side effects could lead to hospitalisation and additional doctor visits. The Therapeutic Goods Administration has issued a safety advisory alert based on the increase in bleeding-related adverse events reports and is in discussions with the sponsor of dabigatran with respect to renal function monitoring and monitoring of patients who are at risk of bleeding – thrombin time aPTT (activated partial thromboplastin time).

- The efficacy of dabigatran is subject to patients complying with the twice-daily regimen versus once a day regimen for other treatments.

- The Pharmaceutical Benefits Advisory Committee advised that dabigatran derives its advantage over warfarin when warfarin is used
  sub-optimally.