

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2012-2013, 17 & 19 October 2012

Question: E12-246

OUTCOME 1: Population Health

Topic: RISPERIDONE

Type of Question: Written Question on Notice

Number of Pages: 1

Senator: Senator Fierravanti-Wells

Question:

The Food and Drug Administration of the United States has banned the use of risperidone since 2005, what are the reasons for the continuing use of, and the prevalence of the administration of antipsychotic drugs such as risperidone with respect to the aged, especially with patients in nursing care with dementia and Alzheimer's disease.

Answer:

The Food and Drug Administration (FDA) has not banned the use of risperidone; however the FDA has not approved risperidone for use in patients with dementia-related behavioural disturbances. Risperidone has several approved indications for use in adults in Australia, including "for the treatment of behavioural disturbances in dementia". Some dementia patients have episodes of disturbed behaviour that pose a substantial risk to their own safety and the safety of the people caring for them. The approval of risperidone in Australia for the treatment of behavioural disturbances in dementia was based on a thorough assessment of the data regarding use in this patient population. The Product Information documents for all atypical antipsychotic medications, including risperidone, carry a precaution to warn prescribers that an increased risk of mortality in elderly patients given these medications has been observed in clinical trials. In addition, the Product Information documents for all products containing risperidone carry a precaution to warn prescribers that an increase in the risk of cerebrovascular stroke in elderly patients with dementia prescribed risperidone has also been identified. The Product Information also recommends a lower dosage for elderly patients with dementia, and states that 'as with all symptomatic treatments, the continued use of risperidone must be evaluated and justified on an ongoing basis'.

Whilst the Therapeutic Goods Administration (TGA) provides detailed Product Information to promote the safe and effective use of prescription medicines in Australia, the TGA does not regulate the prescribing habits of medical professionals.

The TGA considers that, when prescribed in accordance with the Product Information, the benefits of risperidone outweigh the risks in this patient population.