

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

**Question:** E12-016

**OUTCOME 1:** Population Health

**Topic:** ANTIMICROBIAL RESISTANCE

**Type of Question:** Hansard Page 24, 17 October 2012

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**Senator:** Senator Di Natale

**Question:**

What has the TGA done to implement recommendation No. 9 in the JETACAR report - specifically:

- a) The inclusion of microbial resistance safety data, including the propensity for promoting resistance and cross-resistance as a basic requirement of the assessment of all new antibiotics by the TGA;
- b) The implementation of a definition by a recognised authority of the threshold rates of resistance to human antibiotics and the circumstances in which usage should be investigated and mitigation procedures implemented; and
- c) The inclusion of national human antibiotic resistance prevalence data in the product information, with a regular update every five years.

Provide, in detail, a response to each of these individual points outlined in recommendation No. 9.

**Answer:**

- a) Sponsors of antibacterial medicinal products for human use are required by Therapeutic Goods Administration (TGA) to provide antimicrobial resistance risk assessments in their initial registration applications or applications to extend the use of the registered products. This has been undertaken since 2001.
- b) The Department of Health and Ageing supports the National Antimicrobial Utilisation Surveillance Program (NAUSP), managed by the South Australia Department of Health. NAUSP collects, analyses and reports trends on inpatient antimicrobial usage data at a national and individual hospital level on approximately 50 per cent of tertiary referral hospital beds. NAUSP provides information to support the development of strategies to minimise antimicrobial resistance.

- c) Since April 2009, Risk Management Plans have been required as part of all new applications to register medicinal products (including antibiotics) and major variations to registered products. Under Risk Management Plans, summaries of global bacterial resistance patterns are being routinely included in the Periodic Safety Update Reports, which are required to be submitted to the TGA at specified intervals. The TGA has asked sponsors submitting such applications involving antibiotics to include protocols for the post-marketing gathering of Australian-specific antimicrobial resistance information. The Risk Management Plans do not impact on the majority of widely used antibiotics which were registered before 2006 and the TGA is now re-examining the issue.