

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2010-11, 23 February 2011

Question: E11-009

OUTCOME 1: Population Health

Topic: AUST R AND AUST L

Written Question on Notice

Senator Siewert asked:

- a) Does the TGA consider that there is a good understanding among the general public of the difference between AUST R and AUST L products?
- b) If not, what is the TGA doing to educate the public about the difference between these products?

Answer:

- a) The TGA has received some feedback to suggest a level of confusion within the general public of the difference between AUST R (Registered) and AUST L (Listed) products.

Listed medicines are considered low risk medicines that are evaluated and approved for marketing in Australia based on assessment of safety and manufacturing quality. They have not been assessed for efficacy by the TGA, however sponsors are expected to hold this evidence and to make it available to the TGA upon request. In line with their low-risk nature, Listed medicines may only contain pre-approved, low-risk ingredients and may only make limited therapeutic claims.

In order for a Registered medicine to be available to the Australian consumer, a sponsor is required to submit an application to the TGA accompanied by scientific data to support the quality, safety and efficacy of the product for its intended use. The TGA reviews the data, and may seek the advice of an independent expert advisory committee, before making a decision to approve or reject a new product.

- b) The TGA is progressing an internet site redevelopment to implement a user-centred website that provides consistent, accurate and appropriate information from the TGA in a manner that is easy to locate, access and understand.