

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 30/31 May 2011

Question: E11-324

OUTCOME 1: Population Health

TOPIC: THIRD PARTY ASSESSORS

Written Question on Notice

Senator Fierravanti-Wells asked:

Does the TGA understand that the delay in adopting recommendations regarding the use of third party conformity assessors for Australian Manufacturers is making Australian SME's less internationally competitive and causing financial strain due to the delays in assessments? (refer pg 37 hansard 31 May).

Answer:

The Therapeutic Goods Administration is required to ensure that both Australian and overseas manufacturers can demonstrate that both the device and the manufacturing processes used to make the device conform to the requirements of relevant therapeutic goods legislation.

The provisions in the legislation are designed to ensure that medical devices which are safe and perform in accordance with their intended purpose are placed on the market, consistent with the TGA's mandate of ensuring the public health and safety of Australians through the regulation of therapeutic goods, including medical devices.

A decision on whether to allow Australian manufacturers to use third party conformity assessors is a proposal being considered as part of the proposed reforms into medical device regulation and is therefore a matter for the Government.