

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-294

OUTCOME 1: Population Health

Topic: THIRD PARTY CONFORMITY ASSESSORS

Written Question on Notice

Senator Fierravanti-Wells asked:

This issue of the use of third party conformity assessors was first raised by the TGA in 2008. Does the TGA consider a 3 year delay in dealing with this issue reasonable?

Answer:

In late 2008 the Therapeutic Goods Administration (TGA) released a discussion paper requesting comment relating to the use of third party conformity assessment bodies (CABs) for medical devices manufactured in Australia. Subsequent to the release of the TGA's consultation papers the Government announced its decision to review all aspects of the Commonwealth's Health Technology Assessment (HTA) processes. The terms of reference for the HTA review made it clear that TGA's own processes for assessment of medical devices prior to market entry, including the possible use of third party CABs, were within the scope of the HTA review. For this reason TGA considered it premature to proceed with some of the issues raised in the consultation papers within the timeframes originally proposed.

The report on the Review of Health Technology Assessment in Australia (the Report) has now been released. In response to the recommendations of the Report, the TGA proposed a number of regulatory reforms, which encompass this issue.

The use of third party conformity assessment bodies for Australian manufactured devices has not been accepted in these reforms. This issue is also the subject of a recommendation in the recently released report on the Senate Inquiry into the regulatory standards for the approval of medical devices in Australia. The Government's response to the Senate Inquiry recommendations will be made in due course.