

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 30/31 May 2011

Question: E11-322

OUTCOME 1: Population Health

TOPIC: THIRD PARTY ASSESSORS

Written Question on Notice

Senator Fierravanti-Wells asked:

Why have the TGA now undertaken 3 separate reviews since 2008 into using third party conformity assessors for Australian Manufacturers, but are still yet to make any legislative changes to allow third party assessors? (Refer pg 37 hansard 31 May).

Answer:

The Therapeutic Goods Administration has not undertaken 3 reviews since 2008 into the use of third party conformity assessment bodies by Australian medical device manufacturers.

On 19 December 2008 the TGA commenced consultation on allowing the use of third party conformity assessment bodies in Australia. While the TGA was considering the submissions from the consultation process, the Health Technology Assessment (HTA) Review commenced.

Stakeholders were advised in November 2009 that a response to the third party assessment consultation would be issued by the TGA once the HTA Review was completed. The report of the HTA Review was released in February 2010.

Recommendation 8b of the HTA Review stated that the TGA should respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by Government by 2011.

Following the Federal election in mid 2010, the TGA released a discussion paper in October of that year on a package of proposed regulatory reforms, which included a proposal to allow Australian medical device manufacturers to use third party conformity assessment bodies.

A response paper is currently being developed.