

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-291

OUTCOME 1: Population Health

Topic: THERAPUETIC GOODS ADMINISTRATION (TGA) DISCUSSION PAPER

Written Question on Notice

Senator Fierravanti-Wells asked:

The original discussion paper (“Reforms to the Medical Devices Regulatory Framework”) was released in October 2010, and a basic 1 page response was released 23 September 2011 on the TGA Website at <http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm>

- a) Do you consider 12 months to be an unreasonably long period of time for the TGA to release such a basic response to the discussion paper?

This one page response claims that with regard to third party conformity assessors “These proposals remain under consideration and further consultation will occur on amended versions of these proposals”

- b) Can you elaborate on this “further consultation”?
- c) When will this consultation occur?
- d) When will the “amended versions of these proposals be released”?

Answer:

- a) No. The original discussion paper received 77 submissions, which the TGA provided a summary of in February 2011, this can be found at <http://www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm#overview> This occurred within three months of release of the paper. There then occurred detailed consideration of the submissions and a Senate Inquiry that have impacted the timelines of the response.
- b) Consultation on outstanding reform proposals, including the one relating to third party assessors, will shortly be occurring through direct consultation between the TGA and stakeholders to resolve particular outstanding concerns and develop alternative options where appropriate.
- c) The consultation is an ongoing process working in conjunction with consumers, health professionals and industry, recognising the TGA’s responsibilities to ensure quality, safety and efficacy of therapeutic goods.
- d) Formal release of a proposal or options for proposals will be for Government to determine once consultations have been finalised.