

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-290

OUTCOME 1: Population Health

Topic: MEDICAL DEVICES

Written Question on Notice

Senator Fierravanti-Wells asked:

- a) Can the Department give an update as to the response paper to the “Reforms to the Medical Devices Regulatory Framework” which included the proposal to allow Australian Medical Device Manufacturers to use third party conformity assessment bodies?
- b) At the Budget Estimates on 31 May, you stated that this response paper was “currently being developed”. Why has it taken so long?

Answer:

- a) The response was released on the Therapeutic Goods Administration website on 23 September 2011, titled “Reforms to the medical devices regulatory framework: Proposals”.
- b) The range of comments received as part of the reform consultation process needed to be carefully considered in the context of the complex regulatory arrangements for medical devices, in order to achieve a balance between improved regulation and continued timely availability of medical devices.