

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 30/31 May 2011

Question: E11- 325

OUTCOME 1: Population Health

Topic: MEDICAL DEVICE COMPLIANT AUDIT BACKLOG

Written Question on Notice

Senator Fierravanti-Wells asked:

- a) What is the current backlog of applicants currently waiting for a medical device compliance audit?
- b) What is the reason for the current delays in assessment for Australian Medical devices?
- c) Is the backlog larger than it was at 30 June 2010?
- d) how many devices are awaiting a compliance audit?
- e) How long is the current backlog?
- f) How long is the current waiting list?
- g) How many devices have been waiting for more than the following timeframes?
  - 1 Month
  - 2 Months
  - 3 Months
  - 6 Months
  - 9 Months
  - 12 Months
  - Longer than 12 Months

(refer pg 37 Hansard 31 May)

Answer:

The Australian regulations do not refer to “compliance audits”, and as such, the following answers have been prepared on the premise that the Senator’s questions relate to TGA conformity assessment applications for medical devices.

- a) As at 21 June 2011, the TGA has 152 conformity assessment applications under review, all at various stages of assessment.
- b) The TGA has completed a total of 84 conformity assessment applications so far in the 2011 calendar year, at an average processing time of 94 TGA work days.

The TGA applies the following target processing times:

- 90 TGA work day target time for applications involving an assessment of a manufacturer's quality management system.
- 120 TGA work day target time for applications involving examination of the design of a high risk device.
- 180 TGA work day target time for applications that are also referred to the Advisory Committee for Medical Devices (ACMD) for advice. The ACMD meets on a quarterly basis.

Although the TGA is generally meeting its target time frames, there has been a significant increase in the number of applications received in the second half of 2010.

- c) There were approximately 103 conformity assessment applications under review at 30 June 2010. Therefore, there are currently 50 per cent more conformity assessment applications under review than the same time last year. This is primarily due to a significant increase in the number of applications received in the second half of 2010.
- d) See answer to item a)
- e) See answer to item a).
- f) See answer to item a) and g).
- g) The average processing time for all 152 conformity assessment applications currently under review is 77 TGA work days. These can be broken down into the following timeframes:

<b>Processing Timeframe Range</b>	<b>Number of applications currently under review</b>
1 - 30 TGA work days	40
31 - 60 TGA work days	24
61 - 90 TGA work days	36
91 - 120 TGA work days	19
121 - 180 TGA work days	26
180+ TGA work days	7
<b>Average time = 77 TGA work days</b>	<b>Total = 152 applications</b>