

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2014-2015, 2/3 June 2014

Ref No: SQ14-000882

OUTCOME: 7 – Health Infrastructure, Regulation, Safety & Quality.

Topic: TGA Approval Process

Type of Question: Written Question on Notice

Senator: McLucas, Jan

Question:

What is the average and median length of time between application and approval for products to be added to the ARTG?

Answer:

The term ‘products’ is taken to mean applications for New Chemical Entities (NCEs) and New Biological Entities (NBEs), also known internationally as New Active Substances (NASs). These are referred to by the TGA as Type A medicine applications.

The following table provides the average and median time taken by the TGA to reach a decision about Type A applications for the calendar years 2011- 2013.

Year decision was made	Number of Type A Applications	Average total approval time (working days)	Median total approval time (working days)
2011	27	301	284
2012	24	284	248
2013	37	253	250

Further information on TGA Performance Indicators is available on the TGA website at:
<http://www.tga.gov.au/about/tga-kpi.htm>