

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Budget Estimates 2014-2015, 2/3 June 2014**

**Ref No:** SQ14-000887

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

**Topic:** TGA Approval Process

**Type of Question:** Written Question on Notice

**Senator:** McLucas, Jan

**Question:**

Can you, for the calendar year 2010, 2011, 2012 & 2013 provide data on the number of applications, approvals, rejections, length of application to approval/rejection and cost of assessment for products being assessed for 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 Therapeutic Goods Administration (TGA) as Type A medicine applications.

Please note, the following tables include information about Type A applications for the calendar years 2010- 2013. The data include the number of applications received per calendar year, the outcome of TGAs assessment, the average length of time take for the TGA to make its decision and the relevant fee.

Year decision was made	Number of Type A Applications	Average total approval time (working days)	Outcome of TGAs assessment
2010	33	348	33 Approved
2011	27	301	26 Approved, 1 Withdrawn
2012	24	284	22 Approved, 2 Withdrawn
2013	37	253	36 Approved, 1 Withdrawn

The following table provides the cost (fees) for Type A applications for the financial years 2010- 2013.

Financial year	Application fee	Evaluation fee	Total fee
2010-2011	n/a *	n/a *	\$ 192,400
2011-2012	n/a *	n/a *	\$ 198,900
2012-2013	\$ 42,000	\$ 168,100	\$ 210,100

\* Previously no separation between application fee and evaluation fee.