

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 & 30 May 2017

Ref No: SQ17-001045

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Medicinal Cannabis- Special Access Scheme Category B

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

If there are 119 SAS applications in total, and 89 approved, and none declined (as we heard in evidence) what has happened to the remaining 30. What is the reason for the delay? What is the average delay? Who is responsible for the delay?

Answer:

The question uses two figures from different overall time frames and to clarify please note:

From **1st January 2016 to 26th May 2017** the TGA received **119** applications for SASB, of which **66** were approved and none of which were rejected as per Adj Prof Skerritt's testimony.

From **7th May 1992 to 26th May 2017** the TGA received **161** applications for SASB of which **89** were approved.

For the period 1st January 2016 to 26th May 2017 the applications received and their outcome is in the following table

Number of applications received	119
Number of applications approved	66
Number of applications rejected	0
Number of applications pending	34
Number of applications withdrawn	19

The 34 applications pending as of 26 May 2017 are a result of the Therapeutic Goods Administration (TGA) requesting further information from the medical practitioner to assist with the delegate making an informed decision. Information requested may include clarification of specific product being applied for, efficacy and safety data to support the proposed use of the product and details of the intended monitoring for the patient

The total average time elapsed for Special Access Scheme Category B pending applications from 1 January 2016 to the 26th of May 2017 is 88 days. However, all pending applications are currently with the applicant to provide further information to support their application and not with the TGA.