

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2016 - 2017, 1 March 2017

Ref No: SQ17-000391

OUTCOME: 5 - Regulation, Safety and Protection

Topic: TGA Drug warning labels

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

Please confirm how many complaints/adverse event reports the TGA has received from use of the asthma medication ‘Singulair’?

Answer:

The active ingredient in Singulair is montelukast. The Database for Adverse Event Notifications (DAEN) shows that there are 339 adverse event reports between January 2000 and 16 December 2016 which have been associated with products containing montelukast in children, adolescents and adults. Of these, 196 relate to psychiatric events. Included in these figures are 262 adverse event reports that relate specifically to Singulair, 155 of which relate to psychiatric events.

(NB DAEN search results do not include information from the previous three months. This is to allow TGA time to review any new reports submitted and code the information).