

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2014-2015, 2/3 June 2014

Ref No: SQ14-000891

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

Topic: TGA Approval Process

Type of Question: Written Question on Notice

Senator: McLucas, Jan

Question:

Have there been any recent instances where a drug has been approved by either the USFDA or EMA but refused by the TGA?

Answer:

Yes. The Therapeutic Goods Administration is not able to provide details because those applications are considered commercially sensitive.