

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-107

OUTCOME 1: Population Health

Topic: Thalidomide

Written Question on Notice

Senator Boyce asked:

Is the Minister aware that the rigid protocols developed for the safe prescribing of thalidomide through the thalidomide risk management program (i-access®) could be diluted by the entry of alternate presentations of thalidomide by generic manufacturers?

Answer:

A condition of marketing approval of any form of thalidomide is strict compliance with a Risk Management Program (RMP) to reduce the risk of exposure in pregnancy. Therefore, any application to register a generic form of thalidomide must include a RMP, which would include strict controls on supply that were equivalent to those contained in Celgene Pty Ltd's "i-access" program.