

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012

Question: E12-074

OUTCOME 1: Population Health

Topic: RU486

Type of Question: Hansard Page 49, 31 May 2012

Number of pages: 1

Senator: Senator Boswell

Question:

Is the TGA aware that the FDA strongly recommends the use of those particular antibiotics in association with the use of Mifopristol for medical abortions?

Answer:

As at 19 July 2011, post market safety information for Mifeprex (mifepristone), published on the US Food and Drug Administration (FDA) website states:

“FDA does not have sufficient information to recommend the use of prophylactic antibiotics for women having a medical abortion. Reports of fatal sepsis in women undergoing medical abortion are very rare (approximately 1 in 100,000). Prophylactic antibiotic use carries its own risk of serious adverse events such as severe or fatal allergic reactions. Also, prophylactic use of antibiotics can stimulate the growth of “superbugs,” bacteria resistant to everyday antibiotics. Finally, it is not known which antibiotic and regimen (what dose and for how long) will be effective in cases such as the ones that have occurred”.