

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: E12-076

OUTCOME1: Population Health

Topic: RU486

Type of Question: Hansard Page 50, 31 May 2012

Number of pages: 1

Senator: Senator Boswell

Question:

Can you provide copies of each of the summaries of adverse events? – NOTE that Senator Boswell is happy to get a summary of all adverse events.

Answer:

Since its approval under the Authorised Provider scheme in April 2006, a total of 832 reports of adverse events have been provided to the TGA as shown below (reports received to 25 June 2012).

Adverse event	No.
Ongoing pregnancy following treatment requiring Dilation and Evacuation or Dilation and Curettage	132
Significant post partum haemorrhage - requiring transfusion	23
Retained products of conception requiring Dilation and Curettage or Dilation & Evacuation	599
Cervical tear noted following initial dilatation	5
Uterine perforation or rupture	2
Nausea and vomiting	14
Infection/Suspected infection/Endometritis	29
Post partum haemorrhage – not requiring transfusion	28
Abdominal Pain	6
Fainting, dizziness, vomiting	2
Dehiscence of caesarean section scar	2
Death - sepsis	1