

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-072

OUTCOME 1: Population Health

Topic: RU486

Written Question on Notice

Senator Barnett asked:

Please provide copies of all adverse effects reports received by the TGA in relation to the use of RU486.

Answer:

The majority of adverse effect reports received by the TGA to date are summaries of adverse events that have occurred during the reporting period. As at 20 October 2010 only two (2) individual patient reports have been received. The de-identified information in these reports is provided below:

1. Report Date: 03/03/2008

Incomplete abortion requiring admission to hospital for dilation and curettage.
Patient recovered.

2. Report Date: 08/02/2010

Approximately 1 hour after taking mifepristone patient fainted with loss of consciousness for approximately 2 minutes. Patient regained consciousness and commenced vomiting for 5 minutes. Patient became dizzy and had palpitations. Diagnosed in emergency department as cardiovascular and circulatory vasosyncope.

These reactions are recognised as possible side effects of this medicine, for example they are listed in the New Zealand Product Information for this product.