

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-174

OUTCOME 1: Population Health

Topic: RU486

Type of Question: Written Question on Notice

Senator: Senator Madigan

Question:

RU486, Registration with Therapeutic Goods Administration and eligibility for listing under Pharmaceutical Benefits Scheme.

What is the precedent for the Therapeutic Goods Administration for granting approval to import a drug to a company established exclusively for the importation of only that drug, and whose parent company has a vested interest in its usage? This is case with the establishment of Marie Stopes Health by one of Australia's leading abortion providers, Marie Stopes International, and the TGA approval of the importation of RU486.

Answer:

Drugs on the Australian Register of Therapeutic Goods (ARTG) that are captured under the Customs (Prohibited Imports) Regulations 1956 (the Regulations) require an import permit. The Therapeutic Goods Administration (TGA) grants import permits to sponsor companies who wish to import therapeutic goods included on the ARTG which are included in the Regulations.

Marie Stopes Health is the sponsor of the mifepristone product, which is a prohibited import without a permit, on the ARTG, thus the import permits are issued to this company. The company is then able to distribute the therapeutic good as any sponsor company could, in conjunction with the requirements for registration of the product as imposed by the TGA.

This is not a precedent as there are other drugs which require an import permit who have a sole Australian sponsor.