Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 May 2017

Ref No: SQ17-001060

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Sexual Dysfunction Medication

Type of Question: Hansard Page 119, 29 May 2017

Senator: Reynolds, Linda

Question:

Dr Skerritt: No. We have medicines for some very rare and unusual conditions for which no-one has ever written a condition.
Senator REYNOLDS: I think this is part of the problem, that blokes assessing these for women— Dr Skerritt: But we can still assess it.
Senator SINGH: It sounds very unfair—
CHAIR: Order!
Dr Skerritt: We do not have any guideline. We would very much welcome an application from this company, and it is welcome to pick up the phone and talk to us.
Senator REYNOLDS: I understand that the company has not—maybe you could take this on notice. Dr Skerritt: We will.
Senator REYNOLDS: I understand that the company has gone through a number of rounds of processes with the TGA, and something happens and then it has to go right back to the beginning again. If you could take that on notice—
Dr Skerritt: We will take it on notice.

Answer:

In order for a prescription medicine to be included in Australian Register of Therapeutic Goods (ARTG), a sponsor is required to submit an application to the Therapeutic Goods Administration (TGA) accompanied by a range of clinical and scientific data to support the quality, safety and efficacy of the product for its intended use. Inclusion of a prescription medicine in the ARTG cannot be facilitated in the absence of an application and subsequent approval from the TGA. In 1999, the TGA received a registration application for 'Andro-feme' for testosterone replacement therapy for confirmed testosterone deficiency in females. This application was withdrawn by the applicant prior to being considered at the Australian Drug Evaluation Committee (ADEC). On 8 November 2005, the TGA received an application to register two creams containing testosterone designed to deliver a systemic dose of testosterone following absorption through the skin (one product for males and one product for females). One of the products included was a resubmission for 'Andro-feme' with a newly proposed indication to treat menopausal women with low libido where non-hormonal aetiologies for sexual difficulties have been excluded and symptoms, particularly reduced sexual function, persist despite adequate transdermal oestrogen therapy. The resubmission of

the ‘Andro-feme’ application was again withdrawn by the applicant prior to being considered at the ADEC meeting as part of this registration process. Given the sponsor has withdrawn the applications for ‘Andro-feme’ and the TGA has not approved the product for its intended use, inclusion of the product in the ARTG cannot occur. The sponsor is required to resubmit a registration application so that the TGA may evaluate the complete dossier on the grounds of quality, safety and efficacy.