

16th January 2006



Mr Elton Humphrey
Committee Secretary
Community Affairs Committee

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Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

Dear Mr Humphrey,

Thank you for the opportunity to present our position in relation to the *Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005*.

Under the terms of reference, the inquiry is considering whether or not 'to transfer the responsibility for regulatory approval of RU486 from the Minister for Health and Ageing to the Therapeutic Goods Administration'.

Marie Stopes International holds the view that any drug which is intended for clinical use within Australia should be duly evaluated and assessed by an independent advisory committee of technically and professionally qualified experts.

The Therapeutic Goods Administration (TGA) has to date overseen the evaluation and approval of over 50,000 therapeutic goods and therapies in Australia, making it the most experienced and qualified entity in the country.

The TGA is well resourced and positioned to make an evidence-based assessment based on clinical and professional criteria as to the efficacy of, as well as any risks pertaining to, the use of RU486.

As a member of the World Health Organisation (WHO) Collaborating Centre the TGA has access to counterpart bodies throughout the world, including in countries where RU486 has been approved and is currently in use, ensuring that the TGA has access to the most up-to-date information when making an assessment in relation to RU486.

Australia is well served by the TGA and the integrity and competence of their world's best practice standards.

Marie Stopes International sees no reason to have a separate process for RU486. Furthermore, Marie Stopes International disagrees that any one person, in this case the Minister for Health and Aging, is better qualified and positioned to assess the suitability of RU486 for clinical use in Australia.

While we respect the right of Ministers to hold their own personal views on issues such as medical abortion, these views should not impact on independent, professional duties such as those overseen by the TGA.

The TGA has a proven and credible record in addressing the safety and efficacy of drugs to be used in Australia. To this end, Ministerial responsibility for approval of RU486 should be repealed from the Minister for Health and Ageing and transferred to the TGA.

Ms Jill Michelson
Acting CEO
Marie Stopes International

[Providing choices in reproductive healthcare](#)

Marie Stopes International

Marie Stopes International is a not-for-profit sexual and reproductive healthcare provider, with centres in the ACT, Queensland, New South Wales and Western Australia. The organisation offers a range of services, including abortion, vasectomy, sexually transmitted infection check-ups and contraception. Surplus proceeds from Australian activities support the work of Marie Stopes International Partnerships, which delivers sexual and reproductive health services to more than four million people in over 37 countries.

Marie Stopes International's experience with RU486

Marie Stopes International Partnerships deliver sexual and reproductive health services in over 37 countries, including medical abortion.

In the United Kingdom and South Africa, where RU486 is an approved drug, Marie Stopes International performs medical abortions up to 9 weeks of gestation. Early Medical abortions for 2005 totalled about 4000. In 2004, 24% of all abortions performed at Marie Stopes International Centres in the United Kingdom, up to 9 weeks LMP, were medical abortions.

Medical abortion is a clinically viable option in early stages of pregnancy and one which many women prefer to surgical abortion.

Medical abortions are performed in compliance with international clinical protocols. The Marie Stopes International protocols for medical abortion require that medical abortions should only be undertaken in centres which have adequate access to medical facilities equipped to provide emergency treatment of haemorrhage, incomplete abortion and emergency resuscitation.

Complication rates are comparable with surgical abortion.