

Submission to the Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005.

Submission From

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Dear Members of the Community Affairs Legislation Committee,

The Pregnancy Advisory Centre was established by the South Australian Health Commission in 1992. The role of the Centre is to provide services on a statewide basis for women in relation to unplanned pregnancy.

The service provides pregnancy diagnosis, counselling, first and second trimester termination of pregnancy, contraception and follow up services.

The Centre employs Medical Officers, Specialist Anaesthetists, Nurses, Social Workers and Administrative staff.

Services are provided for over 2,500 women per year.

16% of our clients travel from country areas to use the service.

Women are provided with high quality services to address their immediate and ongoing needs.

The Centre operates with clear evidence based guidelines and protocols to ensure optimum outcomes for women emotionally and physically.

75% of procedures are done at 10 weeks or less.

The following points are made in support of the proposed legislation:

1. Role of the Therapeutic Goods Administration.

The Therapeutic Goods Administration is an independent, expert body tasked with "...assessment and monitoring activities to ensure therapeutic goods in Australia are of an acceptable standard with the aim of ensuring the Australian community has access, within a reasonable time, to therapeutic advances."

Since its development in the 1980s RU486 (Mifepristone) has been in use in many countries, developed and developing, and there is now a substantial body of evidence that is based on clinical trials and clinical use about its indications, efficacy, safety and acceptability.

Mifepristone represents a therapeutic advance for many indications and its approval or otherwise should rest with the Therapeutic Goods Authority - the appropriately qualified and resourced body.

2. Indications for Mifepristone

Medical Abortion - Given in combination with a prostaglandin analogue (misoprostol), Mifepristone provides a safe and effective method of medical abortion. There is ongoing research into the most appropriate management regimes for the use of Mifepristone in the induction of medical abortion.

Early Medical Abortion - various treatment regimes have been developed and are provided in various clinical settings that result in complete medical abortion for at least 95% of women up to 63 days (9 weeks) gestation.

It can be used as early as a woman knows she is pregnant whereas a woman must wait until the 5th or 6th week of pregnancy for a surgical abortion. It is our experience at the Centre that once a woman knows she is pregnant and has made a clear decision that it is distressing for her to then have to wait sometimes up to 2 weeks for a procedure.

Women are aware of medical abortion and do request that we provide it for them for a number of very valid reasons that include:

- Fear of surgery

- Fear of anaesthesia

- Less embarrassing - particularly for vulnerable women including those who have experienced sexual abuse and assault

- A more natural process

- More private

- A feeling of greater control

The international literature reports a very similar picture of reasons why 30 - 50% of women choose medical abortion in favour of surgical abortion. The literature also reports the high value that women place on having this choice.

In clinical practice we are often aware when consulting women that medical abortion would be the most appropriate method, including occasions where, for clinical reasons, medical abortion would provide a safer method than a surgical procedure and accompanying anaesthesia.

We are also aware of the many women who travel from regional centres for a surgical procedure for whom medical abortion, with regional hospital back up services, could be provided closer to women's homes and support networks.

In no country has the introduction of Mifepristone been found to increase abortion numbers.

Contraception - Mifepristone has application as emergency contraception. Early work is indicating that it has a role in the treatment of the irregular bleeding that can be a side effect of long acting progesterone contraceptives. This irregular bleeding is a significant cause of discontinuance of these very effective contraceptive methods.

Other Medical Indications - There are a number of indications for the use of Mifepristone in the treatment of Cushings syndrome, treatment of inoperable meningiomas, breast and prostate cancer and endometriosis.

RECOMMENDATION

That the amendment now tabled in the Senate addressing the Therapeutic Goods Act Amendment of 1996 removes the reference to the restrictive definition of RU486 and the approval required of the Federal Minister for Health and therefore return assessment and regulation of this class of drugs to the TGA.