

**SUBMISSION TO THE SENATE COMMUNITY
AFFAIRS LEGISLATION COMMITTEE**

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

Prepared and Submitted by:

**Children by Choice Association Incorporated
237 Lutwyche Rd
PO Box 2005 Windsor Qld 4030
Australia
T: 07 3357 5570
F: 07 3857 6246
E: deba@childrenbychoice.org.au**

**Authorised on behalf of the Children by Choice Management
Committee and members by:**



**Debbie Andrews
Acting Coordinator**

Summary Points

1. The Therapeutic Goods Administration is qualified to assess and manage the risks associated with RU486.
2. The risks associated with RU486 fall within acceptable limits.
3. Women report increased satisfaction and acceptability of medical abortion.
4. Making a non-surgical option available will not increase the abortion rate.
5. The majority of Australians support a woman's right to choose abortion.

Executive Summary and Recommendation

Children by Choice Association Inc is a counselling, information and education service that provides clients with unbiased information on all unplanned pregnancy options; abortion, adoption and parenting. Our mission is to support the empowerment of women to take control of their sexual and reproductive health choices. We achieve this by providing a Queensland-wide telephone counselling service as well as a Brisbane-based face-to-face counselling service for pregnant women, their partners, and support people. We also deliver education and training to high school students, tertiary students, and health and allied health professionals.

Inherent within our service provision is the underlying principle that each woman is the expert on her own life, and therefore the person best equipped to make decisions regarding her sexual and reproductive health. For this reason, we believe that all women should have access to safe and affordable pregnancy termination services should this be their chosen option in the event of an unplanned pregnancy. Although there are several termination clinics operating throughout Queensland, the vast size of this state means that often women living in remote rural areas have to travel great distances to access pregnancy termination services. For this reason, we believe that the introduction of RU486 would make pregnancy termination services more readily accessible to Queensland women. Furthermore, we believe that women should be entitled to choice in regard to pregnancy termination options and therefore support the introduction of medical termination for Australian women.

For these reasons, Children by Choice recommends that the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 be passed to allow the Therapeutic Goods Administration (TGA) to take responsibility for the evaluation and regulation of the use of RU486 in Australia.

1. The Therapeutic Goods Administration is qualified to assess and manage the risks associated with RU486.

The TGA is regarded by the Government as having the knowledge and expertise to assess and monitor therapeutic goods used in Australia to ensure they are of an acceptable standard (TGA, 2005). Currently the TGA evaluates more than 50,000 therapeutic goods for quality, safety, and efficacy. However current legislation specifies that RU486 is the only medication which is not subject to evaluation by the TGA. It is the belief of Children by Choice that all medical decisions should be made on the basis of rigorous and up-to-date medical evidence. It is therefore difficult to understand why the decision regarding the safety and acceptability of RU486 is left with the Minister for Health, who has no medical knowledge or training on which to base such a judgement. As the explicit function of the TGA is to manage the risks associated with therapeutic goods, it is our belief that the TGA is the most appropriate body to assess the risks associated with RU486.

2. No medication or medical procedure is risk-free. However the risks associated with RU486 fall well within acceptable limits.

RU486 is a safe, effective medication that is registered for use in 33 countries around the world, including the United Kingdom, New Zealand, and the United States. It has been used by over 2 million women worldwide. Several respected Australian, International, and World Health bodies support the availability of RU486 including:

- The World Health Organisation
- The Royal Australian New Zealand College of Obstetricians and Gynaecologists
- The Public Health Association of Australia
- The Royal College of Obstetricians and Gynaecologists (UK)
- The Australian Medical Association
- The American Medical Association
- Federal Drug Administration (US)
- The Rural Doctors Association of Australia
- Federation of International Gynaecology and Obstetrics (FIGO)
- American College of Obstetricians and Gynaecologists

Concerns have been raised regarding the link between RU486 and four recent deaths of American women from unusual bacterial infections. Following these deaths, the US Food and Drug Administration investigated these cases and concluded that RU486 remains a safe method of medical abortion and can continue to be used (FDA, 2005). The risk of infection is inherent within all medical procedures and should always be addressed with clients to ensure informed consent is obtained. However, the Royal Australian New Zealand College of Obstetricians and Gynaecologists has noted that the risk of infection may be lower in medical than surgical abortions (RANZCOG, 2005).

A further factor to consider when discussing the safety of medication is its adverse drug event rate. This rate for RU486 is 0.137%, which is very low (NARAL, 2004). Several other non-prescription medications readily available in Australia have much higher rates, such as allergy medication Claratyne which has an adverse drug event rate of 12% (87 times higher than RU486) (NARAL, 2004). Undoubtedly any concerns regarding the safety of RU486 should be investigated to ensure the wellbeing of those using this medication. However, this investigation should be undertaken by the experts in this field, the TGA, and should take into consideration the vast literature from around the world which confirms the safety and effectiveness of RU486.

3. Women report increased satisfaction and acceptability of medical abortion.

A number of studies have noted that women often report that they are satisfied with medical abortion, find the associated pain acceptable, and would consider this option in the future if further pregnancy terminations were required (Berer, 2005; Mamers et al, 1997; MJA, 1997). Furthermore, when asked to compare the medical and surgical termination procedures, several women have indicated increased satisfaction with the

medical approach (Mamers et al, 1997). IPAS, a well-respected international reproductive health care organisation notes on its website that “Women who have a choice of methods [of abortion] report greater satisfaction with their abortion care” (IPAS, 2005). As the research has indicated that medical abortion is safe, effective, and more acceptable to many women than surgical abortion, this should undoubtedly be an option for Australian women.

On a daily basis, the counselling staff at Children by Choice speak with women seeking information on pregnancy termination services. Often these women discuss the option of medical termination as a preferred option and are disappointed that such services are not available within Australia. These women, in line with those mentioned in the studies above, suggest that medical abortion feels like a more “natural” process, is less stressful, and would reduce their fears regarding complications or risks to future fertility. As an unplanned pregnancy and pregnancy termination can be a difficult time for many women, it is imperative that we provide women with information and options that will make this experience less stressful. As the aforementioned studies have shown, providing women with the option of medical pregnancy termination would assist in achieving this goal.

4. Making a non-surgical option available to women will not increase the abortion rate.

The decision to terminate a pregnancy is often a difficult one, made after careful consideration of several competing factors. Women will often consider factors such as their financial situation, housing, support, relationship stability, career, education, emotional readiness, ages, values regarding options, and their general readiness to parent. It is careful consideration of these factors that leads to a decision to terminate a pregnancy, rather than consideration of abortion procedures. As long as contraceptives continue to have failure rates and circumstances such as domestic violence, incest, relationship breakdowns and sexual assault continue to exist, there will remain a need for pregnancy termination services. Introducing RU486 and increasing women’s options with abortion will not change the reasons that women choose to terminate a pregnancy. Instead it will give women more choices and control in an often difficult time.

With the introduction of RU486, women will still require medical supervision during their pregnancy termination. Furthermore, in order to comply with relevant state laws regarding abortion, many women will still need to explain to a doctor why a pregnancy termination is “necessary” in their situation, and must still receive detailed information regarding the procedure and its associated risks in order to provide informed consent. In this regard, the procedures involved in obtaining a pregnancy termination will remain largely unchanged. It is anticipated that the only changes in the process will be positive ones, such as a reduction in travel cost and expense.

Overseas experience has demonstrated that the introduction of RU486 has not increased the overall number of abortions that take place (Jones and Henshaw, 2002). With the introduction of RU486 in Scotland, Sweden, England and Wales, the proportion of

abortions performed using this method has steadily increased while the overall abortion rates remain stable (Jones and Henshaw, 2002). This result further supports the assertion that RU486 is an effective and acceptable method of pregnancy termination for many women. Its introduction into Australia would provide more choice for women choosing abortion, but will not increase the number of women accessing pregnancy terminations.

5. The vast majority of Australians support a woman's right to choose abortion and believe that abortion is a private matter between a woman and her doctor.

The 2003 Australian Survey of Social Attitudes conducted by the Australian National University found that 81% of Australians support a woman's right to choose abortion and only 9% do not. While there may be vocal opponents to abortion, these results demonstrate that the majority of Australians are in support of reproductive choice. Furthermore, 7220 people have shown their support for the introduction of RU486 by signing a petition to remove the current ban on its importation (GetUp, 2006).

The central question regarding this bill is whether or not the TGA should have control over the introduction of RU486 into Australia, not whether or not abortion is acceptable. However, many opponents of this bill have argued that RU486 should not be available in Australia as abortions should not be allowed to take place. Furthermore, this unusual arrangement for the importation of RU486 was initially considered appropriate because of community sensitivity to the issue of abortion. Although this is not the central issue with regard to this bill, it remains important to note that the majority of Australians do support a woman's right to choose abortion and believe that abortion is a private matter to be discussed between a woman and her doctor. In accordance with this widely-held belief, Children by Choice considers that it is not appropriate for politicians to be involved in decisions regarding RU486. We urge all political parties to respect the privacy of every woman, and allow each woman to make her own decision around an unplanned pregnancy in consultation with a trained health professional.

Recommendation

For the aforementioned reasons, Children by Choice recommends that the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 be passed to allow the TGA to take responsibility for the evaluation and regulation of the use of RU486 in Australia.

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