

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

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Dear Community Affairs Committee Members,

The Australian population expects the drugs they access to have passed rigorous assessment, supported by evidence-based research, before the decision whether or not to release them onto the market is made. This assessment is the responsibility of the Therapeutic Goods Administration (TGA).

The one exception to this process is the abortifacient, RU-486, with the Federal Minister for Health able to prevent it being provided to Australians, without any reference to the TGA. It is difficult to support banning any drug without assessment, and this holds true in the case of RU-486, particularly as there are other TGA assessed abortifacients in use in Australia. I submit that there is no valid reason for this anomaly and it should be removed so that RU-486 is subjected to the same medical evaluation and approval process as all other medicines.

The evidence from overseas experience with RU-486 supports its safety, with the risk of mortality and serious complications being 'rare'. In some cases risks may actually be lower than with surgical abortion.¹

Health bodies supporting the availability of RU486 include:

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

For example, AMA President, Mukesh Haikerwal, has stated that RU-486 “certainly is safe and has been used overseas for many years now, with over a million women having been treated.”²

The argument that the use of RU-486 in rural areas would place women at significant risk disregards the fact that the drug is administered under medical supervision and that its effect is, according to the RANZCOG, “much like a spontaneous miscarriage.”³ In many areas access to surgical abortion involves travel to major hospitals, involving a great deal of time and extra cost. Many rural areas have small hospitals equipped to deal with pregnancy and spontaneous abortion and these hospitals could also provide back up for women needing assistance with medical abortions.

The current debate in Australia seems to have little to do with the clinical facts on RU-486, and more to do with the ethics of abortion. This is despite the findings of the 2003 Australian Survey of Social Attitudes conducted by the Australian National University that 81% of Australians support a woman’s right to choose whether to proceed with a pregnancy or not, with only 9% against abortion.

As safe abortion is legally obtainable in Australia it does not make sense to ban one method of termination outright on moral rather than medical grounds. The argument is not that one method of termination is necessarily superior to another but that women, in consultation with their medical practitioners, should have the choice of a full range of safe methods.

RU-486 could be part of this choice and should be reviewed on medical grounds by the TGA, using the same framework and standards employed when evaluating other drugs. It is not appropriate for members of parliament to decide on the safety of any drug – that is the role of the TGA.

There is no justification for subjecting RU-486 to moral restrictions and considerations not shared by the majority of Australians. The right to choose enables the individual to decide on the course of action which best fits her circumstances, ethics and beliefs.

I therefore request that responsibility for RU-486 be removed from the Minister and the political process and invested in the appropriate body, the Therapeutic Goods Administration, and that this is set as the standard procedure for evaluation of all drugs.

Joan Barry

¹ <http://www.ranzcog.edu.au/womenshealth/pdfs/Termination-of-pregnancy.pdf>

² Haikerwal, op.cit

³ RANZCOG, Termination of pregnancy: A resource for health professionals; Nov 2005, p.16