



**SUBMISSION TO THE SENATE
COMMUNITY AFFAIRS LEGISLATION
COMMITTEE INQUIRY INTO THE
THERAPEUTIC GOODS AMENDMENT
(Repeal of Ministerial responsibility for
approval of RU486) BILL 2005**

AUSTRALIAN MEDICAL ASSOCIATION

CANBERRA

JANUARY 2006

This submission is made in support of the proposed Bill for an Act to repeal Ministerial responsibility for approval of RU486, and related purposes.

The AMA believes that the proposed amendments to the Therapeutic Goods Act 1989 will benefit the Australian population as a whole and Australian women in particular.

The AMA, as a body representing nearly 28,000 doctors, takes great care when developing policy on a wide range of issues and took great care whilst discussing and developing the policy relevant to this issue. AMA membership is wide and reflects the diversity of opinion on this issue that is found in the general public.

Following a review of the literature we revised our position on Termination of Pregnancy at the last meeting of our Federal Council in November 2005. The revised section of our Position Statement on Reproductive Health and Reproductive Technology 1998 is reproduced below:

1. **The AMA respects the rights of doctors to hold differing views regarding termination of pregnancy.**
2. **Where the law permits termination of pregnancy, the procedure and the associated anesthesia should, as with any other medical intervention, be performed by appropriately trained medical practitioners, in premises approved by a recognized health standards authority.**
3. **Where the law permits termination of pregnancy, non-surgical forms of termination (such as RU486/mifepristone) should be made available as an alternative to surgical abortion in cases where they are medically deemed to be the safest and most appropriate option based on the appropriate clinical assessment.**
4. **It is the doctor's responsibility to provide patients with information regarding the potential health risks and psychological consequences which can arise from continuation of and termination of pregnancy.**

The revision made was to remove a short section which stated:

4. The AMA acknowledges the need for further research into non-surgical forms of termination and replaced it with 3. above:

3. **Where the law permits termination of pregnancy, non-surgical forms of termination (such as RU486/mifepristone) should be made available as an alternative to surgical abortion in cases where they are medically deemed to be the safest and most appropriate option based on the appropriate clinical assessment.**

In this revision we took great care to make no judgment about the rights and wrongs of abortion as many of our members do not support abortion, however we all support the need for **where abortion is legal** for it to be performed safely and to the highest

possible standard to ensure that women who choose this option do not suffer unnecessary harm.

The change to the AMA's Position was made because we now believe the necessary research on non-surgical forms of abortion has been done and has reassured us that the risks to a woman of using RU486 is acceptably low. There have been a few deaths but sadly there are also a few deaths from surgical abortions too. Indeed reproductive health is fraught with danger

The AMA's review of the present literature lead us to the same position as the Royal Australia and New Zealand College of Obstetrics and Gynecology, that non-surgical forms of abortion based on the use of RU486 are sufficiently safe that they should be made available to Australia women within, of course, a therapeutic relationship and with all necessary services and support. There is no expectation that the rigorous service provision that ensures surgical abortions are very safe would be relaxed when the medical option is available.

The AMA therefore calls upon the government to remove the effective ban of RU486 by repealing the part of the Therapeutics Goods Act which was added in 1996 giving Ministerial responsibility for approving evaluation, registration, listing or importing of "restricted goods" in Australian and defining "restricted goods" as medicines "intended for use in women as abortifacients".

These are the only drugs to require this kind of Ministerial approval. This section of the Act has effectively banned the entry of RU486 into Australian not only for use as abortifacients but also for the number of other possible uses such as an emergency contraceptive, as treatment for endometriosis and the treatment of some breast and brain tumors.

The AMA believes that the TGA is best placed to decide upon the safety of all medications and therapeutic products including RU486 and should be given the opportunity to judge the safety and efficacy of this medication as it does all others. It is the best qualified authority to decide when and where and with what support services this drug should be made available. They must exert their judgment freely, fairly away from undue pressure. The AMA's judgment is that the TGA will find the drug to be as safe as many others that are available in Australia and that the safety profile is acceptable.

Although the AMA believes that this medical alternative for a surgical procedure, where legal, should be available to Australian women it would of course accept the verdict of the TGA on the safety of RU486 both for use in inducing abortion but also in the other possible use areas mentioned above.

Women would of course need to be provided with sufficient information to make an informed choice between surgical and medical abortion once they have decided that abortion is what they want. It is certainly far safer to terminate a pregnancy with RU 486 than to take the pregnancy to term but the women will need to know of the rare possibility of death and the much more common issues of prolonged bleeding and the possibility of needing a surgical intervention to remove any retained products of conception which is in between 5 and 8% of cases.

The AMA understand that there is concern at the number of abortions performed every year in Australia but do not believe that making RU486 available will have a significant impact on the number of abortions performed. RU486 was introduced into the UK in the middle of 1991. The abortion rate per 1,000 women aged 15-44 in 1990 was 15.50 in 1991 it was 15.04 and in 1992 it was 14.59. The rate of abortion pre the introduction of RU486 was not again reached until 1996 which we do not believe can be attributed to the introduction of RU486 in 1991.

Restricting access to RU486 in the unsupported expectation that this will reduce the number of abortions performed is not reasonable. The AMA supports actions the government is proposing and should consider to take others to reduce the demand for abortions, such as better sex education in primary and secondary schools, improving access to effective modern contraception and emergency contraception on the PBS, making the work environment more conducive to having children by increasing the availability of child care and making it more affordable by allowing childcare costs to be claimed as an expense and therefore paid pre-tax and mandating 6 months paid maternity leave and a whole raft of other supports that are not relevant to this inquiry.

The AMA's request is that Senators consider the merits of the issues to hand and that restricting access to RU 486 will not keep the numbers of abortions down. Women have always accessed abortions and will continue to do so. By making RU486 available you will remove the need for surgery for some. However in reality most will probably continue to use surgical abortion services.