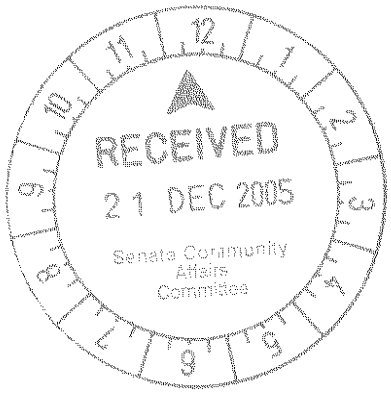
PUBLIC HEALTH ASSOCIATION
of Australia Inc
ABN 41 062 894 473

Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
CANBERRA ACT 2600



Dear Sir/Madam

SUBMISSION FROM THE PUBLIC HEALTH ASSOCIATION OF AUSTRALIA TO THE INQUIRY INTO THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU 486) BILL 2005

The Public Health Association of Australia (PHAA) is a forum for the promotion of the health of the public as well as being a professional resource for public health personnel. The Association provides opportunities for the exchange of ideas, knowledge and information on public health and actively undertakes advocacy for public health policy, development, research and training.

The PHAA believes that prevention of unwanted and unplanned pregnancies is an important public health goal. We also know that no method of prevention is infallible; therefore there will always be a need for emergency contraception and safe, legal termination services. We believe that Australian women should have the right to an informed choice of a full range of methods for termination of pregnancy like those available to women in most developed countries.

We therefore strongly urge the government to overturn the ban on the availability of Mifepristone, also known as RU486. RU486 is a non-surgical method of termination which is extremely effective in the first trimester, is available in most western countries, but not in Australia. As it can be used earlier than most other methods of termination, i.e. earlier than nine weeks, women may experience less psychological stress than those from later methods.

What is the evidence for the safety of RU 486?
An impressive roll-call of Australian, International and World Health Bodies argue that Mifepristone is safe, effective and well tolerated by women and support the wide availability of RU 486. They include:

* 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

20 Napier Close Deakin, ACT Australia, 2600 PO Box 319 Curtin, ACT Australia, 2605
Tel: (02) 6285 2373 Fax: (02) 6282 5438 Email: phaa@phaa.net.au www.phaa.net.au

* The American Medical Association
* American Association for Advancement of Science
* Federal Drug Administration (US)
* The Rural Doctors Association Australia
* Federation of International Gynaecology and Obstetrics (FIGO)
* American College of Obstetricians and Gynaecologists
* Cochrane Collaboration

Experience of Mifepristone use in rigorous studies has shown that it is safe, effective, cheap to produce and highly acceptable to women. There is no rigorous evidence that Mifepristone causes any greater harm to women than other forms of termination if taken in accordance with appropriate medical guidelines and indeed is safer than carrying a pregnancy to term.

This view is supported by the Royal College of Obstetricians and Gynaecologists' Guideline '*The care of women requesting induced abortion' Evidence-based clinical guideline number 7*, two Cochrane reviews, one by Say et al (2005), that compared medical and surgical methods, and the other by Kulier (2004) that examined medical methods of emergency contraception. In addition this evidence has been further supported by a large case study undertaken by Ashok (1999).

What are the risks?
No drug is risk-free. The health risks associated with RU 486 fall well within acceptable limits. RU 486 has been used by over 21 million women worldwide in more than 30 countries, including the United Kingdom, New Zealand and the United States. According to the Royal Australian New Zealand College of Obstetricians and Gynaecologists, the risk of mortality and serious complications with abortion are "rare" and in some cases may be lower with medical abortion.
(see: http://www.ranzcog.edu.au/womenshealth/pdfs/Termination-of-pregnancy.pdf <http://www.ranzcog.edu.au/womenshealth/pdfs/Termination-of-pregnancy.pdf>).

Indeed, the adverse drug event rate for RU 486 is very low at 0.137%. This compares with the over-the-counter drug Claratyne which has an adverse event rate of 12% (87 times higher than Mifepristone).

RANZCOG also notes that infection using medical abortion "may be less frequent than with suction curettage method of abortion". This is relevant to discussions surrounding the recent deaths of four American women from an unusual bacterial infection. In the December 1st Edition of the New England Journal of Medicine Dr Robert Greene, a Professor of Obstetrics, Gynaecology, and Reproductive Biology at Harvard Medical School, Boston and the Director of Obstetrics at Massachusetts General Hospital, Boston, has argued that the overall mortality rate associated with medical abortion is small (1:100,000) and no different to that posed by surgical abortion. Given that it remains unclear if the infection was associated with abortion using RU 486, and RU 486 has been used by millions of women in Europe and China with no reported instances of the infection, Greene argues against regulators restricting or banning the drug, though he stresses the importance of women being informed about the small risk of this infection before giving consent.

(see: http://content.nejm.org/cgi/content/full/353/22/2317?query=TOC <http://content.nejm.org/cgi/content/full/353/22/2317?query=TOC>).

The US FDA recently affirmed the safety of medical abortion for American women and authorised its continued use.

Are there equity and access issues?
Medical abortion, like surgical, requires appropriate medical supervision and women in most states will still need to persuade a medical practitioner their abortion is "necessary" for them to comply with relevant state criminal codes regulating the procedure. There is also evidence that women seeking termination are more likely to socio-economically disadvantaged. We support the conclusions reached by da Costa in her MJA article (2005, 183(7): 387-380) that provides an insight into how the availability of this drug in Australia might help to overcome many of the inequalities of access to abortion, in particular for poorer women and those located in rural and remote Australia.

Will this increase the abortion rate?
Overseas experience shows that that the availability of medical abortion does not increase the overall number of abortions that take place, as was recently acknowledged in a recent briefing paper by the Australian Christian Lobby.
(See: http://www.acl.org.au/pdfs/load_pdf_public.pdf?pdf_id=437&from=)

The introduction of RU 486 in Germany 1999 has seen a steady rise in the number of women choosing a medical abortion, but a relatively steady rate of abortion over all. Increasing numbers of American women are also choosing medical over surgical abortion, but the US recently recorded its lowest overall rate of abortion in 30 years. In Sweden, abortion rates actually declined after medical abortion was introduced.
(See: http://www.agi-usa.org/pubs/journals/3415402.pdf)

Why is the appropriate approval process for medicines not being used?
The Therapeutics Goods Administration - not politicians, religious leaders or political activists - should decide if RU 486 poses an unacceptable level of risk to Australian women. Australia is much-admired for its thorough expert assessment and regulatory process for pharmaceutical license and we see no reason why RU486 should not be assessed in the same way.
A recent research note by the federal parliamentary library service says that given that the current debate over RU 486 is "essentially over questions of risk management" and that management of the risks associated with medicines is an "explicit function of the TGA", that the Government should step back and let the TGA do its job: "The TGA is regarded by the Government as being qualified to manage the risks associated with any therapeutic good that is used (or proposed for use) in Australia. From this, one could reasonably assume that it is also qualified to manage the risks associated with RU486".
(see:http://www.aph.gov.au/library/pubs/RN/2005-06/06rn19.htm)

The PHAA urges you to consider the weight of medical evidence, and the importance of good governance to a healthy democracy in determining your vote on whether or not the impediments to the assessment of RU 486 by the Therapeutics Goods Administration

alone should be removed. We strongly encourage you to place the determination of safety and efficacy of all medicines in the hands of the Therapeutic Goods Administration and to ensure that such determinations are not made by Ministers.

I would be happy to meet with your staff to discuss this issue should that prove useful. I can be contacted on (02) 62852373 or at plaut@phaa.net.au.

Yours sincerely,

Pieta Laut

Pieta Laut
Executive Director
19.12.05