Sexual Health & Family Planning Australia

328-336 Liverpool Road Ashfield NSW 2131

Ph: 02 8752 4348
Fax: (02) 9716 7234
E-mail: fpa@fpa.net.au

ABN: 20 860 935 679

Submission to the Community Affairs Senate Committee Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 from Sexual Health and Family Planning Australia

Sexual Health & Family Planning Australia (SH&FPA) is the federal body for family planning organisations in Australia. SH&FPA's member organisations are the state based family planning organisations, which play a vital role in the provision of sexual and reproductive health services, including clinical, professional education and health promotion services throughout Australia.

Sexual Health and Family Planning Australia (SH&FPA) supports the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 (herein the Bill). SH&FPA believes that the responsibility for approving all drugs should fall to the specialist statutory body the Therapeutic Goods Administration (TGA). The current arrangement requiring Ministerial approval undermines the purpose for which the TGA was established - to ensure that all therapeutic goods available to Australians are proven in their quality, safety and efficacy. The TGA is trusted to independently administer all other drugs in Australia, to identify, assess and evaluate the risks posed by therapeutic goods and regulate their availability based on scientific evidence. SH&FPA believes that RU486 was unjustly isolated in the 1996 Amendments to the Therapeutic Goods Act 1989. SH&FPA strongly defends the role of the TGA as the independent statutory body responsible for the regulation of therapeutic goods in Australia.

The Australian Drug Evaluation Committee (ADEC) provides expert independent, scientific advice on all drugs to the TGA. SH&FPA believes that ADEC's advice constitutes an appropriate, objective, apolitical conclusion based on the efficacy, quality and safety of a drug and its suitability for use by Australians. That this expert body is not trusted to provide adequate advice on this matter seems to refute the whole proposition of evidence based scientific scrutiny in the provision of appropriate drug supply to the Australian community. The democratic political process requires that the government act in the interest of the constituency it represents and should not rely on the decision of one person, while denying

the advice of a properly constituted expert body and in doing so deny a scientifically proven medical choice to Australians. It is not appropriate that the availability of any drug should rest on the decision of a single individual.

The TGA takes a risk management approach to the consideration of therapeutic goods to ensure that the Australian community's expectation that 'therapeutic goods are safe, and of high quality, to a standard equal to that in comparable countries'[1]. SH&FPA believes that the TGA's processes effectively take into account the potential dangers of any drug. Their own acknowledgement that 'medicines used to treat serious conditions, or which need to be used under a doctor's supervision, are subjected to a high level of scrutiny and evaluation to determine their quality, safety and efficacy'[2] indicates to SH&FPA that the TGA will seriously consider the allegations of RU486's status as a drug posing high risk to women.

An objective of the Therapeutic Goods Act 1989 is to provide for the 'timely availability of therapeutic goods'[3]. The issue of timely availability of therapeutic goods is undermined by the current legislative anomaly that requires Ministerial approval for this group of drugs to even be considered for approval by the TGA. This requirement for Ministerial approval creates an additional and unnecessary time barrier in making therapeutic advances enabled by this group of drugs available to Australians.

Mifepristone (RU486) belongs to a class of compounds called antiprogestins. Antiprogestins counteract the action of the hormone progesterone and when given in conjunction with prostaglandin (a drug that stimulates uterine contractions), are effective at inducing the abortion of a pregnancy of up to seven week's duration. RU486 has been used for more than 20 years for medical terminations in countries such as France, China, United Kingdom, Sweden, New Zealand and the United States and there is a significant body of knowledge and research about its use, safety and efficacy.

There are other possible therapeutic uses for RU 486 other than as an abortifacient; they include:

Contraception

RU 486 inhibits ovulation and acts to prevent implantation. It is a safe and effective method of emergency contraception, there is also potential to utilise this compound as a regular

[1] Therapeutic Goods Administration (2004) The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods, Canberra: Australian Government, p 4.
[2] Therapeutic Goods Administration (2004) Medicines Regulation and the TGA, Canberra: Australian Government, p 4.
[3] Therapeutic Goods Act 1989, Section 4.

method of oestrogen-free contraception. This would present an advantage to those women who are unable to use contraception that contains oestrogen.

Non-Contraceptive Uses of Antiprogestins

RU 486 has also been utilised in the treatment of large, inoperable meningiomas (a type of brain tumour) and in Cushing's Syndrome - a disorder of the adrenal gland. It has also been used in the treatment of breast and prostate cancer and there are indications it may be useful in the management of glaucoma and depression. RU 486 also appears to have a role in the management of a number of gynaecological conditions. These include the treatment of endometriosis and as a means of reducing the size of uterine fibroids.

Use of RU 486 to control bleeding in those using Progestogen-only methods of Contraception

Since the early 1990s there has been a marked increase in the number of long-acting progestogen-only contraceptive methods available and in the number of women choosing to use them. Such methods include injectable contraception as well as contraceptive implants and progestogen-bearing intrauterine devices. A major problem however with all progestogen-only contraceptive methods is that they tend to disrupt the regular menstrual cycle and unacceptable bleeding patterns represent the commonest reason for women discontinuing their use.

Preliminary studies, such as that undertaken in Australia by a SH&FPA member organisation, with approval from the TGA[4], indicate that the use of RU 486 may be an effective treatment option for women experiencing irregular bleeding while using progestogen only contraceptive methods. Many of these long-acting methods such as the implants and progestogen-bearing IUD are relatively expensive contraceptive methods for either the consumer herself or for the Health System that subsidises their cost. A reliable way of treating irregular vaginal bleeding in a woman using progestogen-only contraception who was otherwise suited to the method would be therefore useful from both a clinical and economic perspective.

These potential advances in treatment for cancer, endometriosis and irregular bleeding as well as an alternative means of terminating pregnancy, as permitted by law in Australia, have been effectively unavailable to Australians under the current arrangements. SH&FPA believes that the changes proposed in the Bill are necessary to rectify this objectionable situation.

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[4] Wiseberg, E., Hickey, M. et.al. (2006) 'A pilot study to assess the effect of three short-term treatments on frequent and/or prolonged bleeding compared to placebo in women using Implanon' *Human Reproduction,* 21, 1, pp. 295-302.

SH&FPA strongly supports the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 being considered by this inquiry to maintain the principle that regulation of therapeutic goods in Australia is based on scientific evidence considered by independent experts, not decisions made by one individual. SH&FPA believes that the approval process for the class of drug currently known as 'restricted goods' within the Therapeutic Goods Act, which includes RU486, should be brought into line with that of all other drugs in Australia.

Dr Edith Weisberg
Director of Research
Sydney Centre for Reproductive Health Research
Research Division of FPA Health
Spokesperson for Sexual Health and Family Planning Australia

328-336 Liverpool Road, Ashfield NSW 2131
Phone: (02) 8752 4342
Email: edithw@fpahealth.org.au