Michelle Swallow
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Community Affairs Senate Committee
Parliament House
Canberra ACT 2600

Dear Senators

Re: **Submission to the Community Affairs Senate Committee Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 from Family Planning Tasmania Inc.**

Family Planning Tasmania (FPT) is a provider of sexual and reproductive health services, including clinical, professional education/workforce development and health promotion services throughout Tasmania.

FPT supports the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 (herein the Bill). FPT 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. FPT believes that RU486 was unjustly isolated in the 1996 Amendments to the Therapeutic Goods Act 1989. FPT therefore strongly defends the role of the TGA as the independent statutory body responsible for the regulation of therapeutic goods in Australia.

The TGA takes a risk management approach to the consideration of therapeutic goods. FPT believes that the TGA's processes effectively take into account the potential dangers of any drug, and they would therefore 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. 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.

RU486 (Mifepristone) 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), is 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 the United States, France, China, United Kingdom, Sweden and in New Zealand and there is a significant body of knowledge and research about its use, safety and efficacy. Its availability as a treatment option is supported internationally by the World Health Organisation, the American Medical Association and the Federal Drug Administration in the USA, and in Australia by all relevant leading medical bodies, including the Royal Australian New Zealand College of Obstetricians and Gynaecologists, the Australian Medical Association and the Public Health Association of Australia.

FPT 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 person. FPT 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.

Yours sincerely

Michelle Swallow
Executive Director