Women's Hospitals Australasia
ABN: 50 065 080 239

16 January 2005

Submission from Women's Hospitals Australasia

Reference: Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of Ru486) Bill 2005.

Women's Hospitals Australasia (WHA) is a not for profit organization that supports women's hospitals and services in their pursuit of excellence in the provision of clinical care. It does so by conducting benchmarking exercises and forums to explore issues of current concern by sharing local knowledge and emerging evidence underpinning best practice.

Mifepristone (Ru486) is a drug that opposes the effects of the female hormone progesterone. Progesterone has a number of actions but its principal function appears to be stabilisation of the pregnant uterus by preventing contractions of the uterus.

Mifepristone's mechanism of action has led to it being studied as a therapeutic agent in the following situations relating to pregnancy:

- Emergency post coital contraception
- Medical termination of pregnancy in the first trimester
- Medical management of missed or incomplete first trimester miscarriage
- Medical termination of pregnancy in the second trimester
- Induction of labour at term

On the basis of the clinical trials available, mifepristone can be recommended – in combination with a prostaglandin agent – for medical first trimester termination of pregnancy and management of first trimester miscarriage. Medical termination of pregnancy may be more successful at emptying the uterus than surgical treatment at early gestations (below 9 weeks) and medical management of such situations may have important economic benefits over surgery.

The use of mifepristone (along with a prostaglandin) for first trimester termination of pregnancy is supported by evidence based guidelines released by organisations such as The Royal College of Obstetricians and Gynaecologists, London and the International Planned Pregnancy Federation.

The authors of the reviews and guidelines cited above all emphasised that the relevant studies were conducted in hospital settings and women managed as outpatients had – and should continue to have - ready access to hospital facilities that include the ability to conduct an emergency surgical evacuation of the uterus. This important caveat was also expressed by the Food and Drug Administration (FDA) when it approved the drug for use in the United States in 2000. Since FDA approval mifepristone has been used in as many as 460,000 terminations.

In November 2004 the FDA drew attention to the potentially fatal complications of using mifepristone to terminate early pregnancies. This warning came after one death occurred from a ruptured undiagnosed ectopic pregnancy and two deaths occurred from sepsis. In July 2005 the FDA announced it was aware of four deaths due to sepsis following the use of mifepristone for early termination of pregnancy. All of the deaths were due to an organism called *Clostridium sordellii* and all presentations were unusual in that fever was absent and cramping and low blood pressure were the main presenting features. An article describing these deaths was published in the New England Journal of Medicine (NEJM) in December 2005. The accompanying NEJM editorial estimates that the risk of such a tragedy occurring is less than 1 per 100,000 terminations. This figure compares with a risk of death of approximately 0.1 per 100,000 surgical terminations at a similar gestation. These risks are significantly lower than the maternal risk of carrying a pregnancy to term (8 to 10 per 100,000 pregnancies).

WHA has confidence in the processes and procedures of the Therapeutic Goods Administration of the Department of Health and Ageing (TGA). We expect that the TGA studies the available published literature and monitors the actions of overseas regulatory authorities such as the FDA. WHA feels that mifepristone should be considered by the TGA and supports its use under strict medical supervision in appropriate clinical environments.

In circumstances under which termination of pregnancy is lawfully conducted WHA supports the ready access to appropriate termination of pregnancy services that include:

- Privacy and confidentiality,
- Sensitive counseling and provision of information,
- Pre procedure medical assessment, discussion of options and obtaining of informed consent,
- Conduct of the procedure according to best practice evidence based guidelines by appropriately trained clinicians in appropriate facilities,
- Post procedure information and counseling.

WHA draws the Committee's attention to the activities of the New Zealand Abortion Supervisory Committee. This committee has the responsibility of keeping under review all provisions of abortion law in New Zealand. This includes:

- licensing institutions for the performance of abortions,
- appointment of certifying consultants to consider cases, and
- tabling an annual report to Parliament that includes detailed statistical information relating to all abortions performed in the previous calendar year.

WHA recommends the collection of appropriate statistics regarding the number of terminations performed in Australia, the reasons for such terminations, the methods used and the complications observed.

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