Submission to the Senate Community Affairs Legislation Committee Inquiry Into Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

Introduction

The Royal Women's Hospital supports the enactment of the *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill*. We believe that the Therapeutic Goods Administration is the appropriate statutory authority to take responsibility for the evaluation, approval and regulation of mifepristone, formally known as RU468, and other abortifacients. The following submission provides information about the provision of medical abortion as part of comprehensive health care for women.

Royal Women's Hospital

The Royal Women's Hospital (RWH) is the largest specialist hospital in Australia dedicated to improving the health of all women. Each year, RWH cares for more than 300 000 women from 165 different nationalities, who follow 42 different religious faiths and speak 60 different languages. The RWH is committed to providing the highest quality of clinical care, information and support available.

Improving Women's Health and Wellbeing

Comprehensive women's health care includes the provision of abortion services. It is estimated that a third of Australian women will have an abortion at some stage in their lives[1]. A woman's decision about her pregnancy needs to be informed by accurate, unbiased information about all of her options.

The World Health Organisation (WHO) reports that abortion is one of the safest medical procedures when performed by health professionals with proper equipment, correct technique and sanitary standards[2]. Restrictive legislation is associated with a high incidence of unsafe abortion[3]. Even where abortion is legal, access to services may be hampered by services of poor quality, or that are insufficient to meet demand or inadequately distributed[4]. It is women who are most vulnerable to poverty, discrimination and coercion who are at particular risk of unsafe abortion[5].

According to RANZCOG, a comprehensive literature review has found that abortion rarely causes immediate or lasting psychological harm in healthy women[6].

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[1] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Termination Of Pregnancy A Resource for Health Professionals November 2005,* *http://www.ranzcog.edu.au/womenshealth/termination-of-pregnancy.shtml,* p.5

[2] World Health Organisation (WHO), 'Chapter 1 - Safe abortion services: the public health challenge', *Safe Abortion: Technical and Policy Guidance for Health Systems*, http://www.who.int/reproductive-health/publications/safe_abortion/safe_abortion.pdf, p.14

[3] WHO, 'Legal Framework of Abortion'*, Unsafe Abortion Global and Regional Estimates of Incidence of Unsafe Abortion and Associated Mortality in 2000 –4th Edition,* http://www.who.int/reproductive-health/publications/unsafe_abortion_estimates_04/estimates.pdf, p.3

[4] WHO, 'Legal Framework of Abortion'*, Unsafe Abortion,* ibid, p.3

[5] WHO, 'Safe Abortion Services: the Public Health Challenge', *Safe Abortion: Technical and Policy Guidance for Health Systems*, http://www.who.int/reproductive-health/publications/safe_abortion/safe_abortion.pdf, p.14

[6] RANZCOG, ibid, p.25

Mifepristone's Proven Role In Fertility Control

The large majority of terminations occur in the first trimester of pregnancy[7]. In Australia, providers of abortion services perform termination of early pregnancy largely through surgery[8].

Research clearly shows that mifepristone, taken in conjunction with synthetic prostaglandins such as misoprostol, can be safely used to induce medical abortion[9]. Although alternatives to mifepristone are available, they are less effective[10]. In the first trimester, medical and surgical abortions have similar outcomes in terms of their safety and efficacy[11]. The Royal College of Obstetricians and Gynaecologists reports mifepristone and misoprostol as an appropriate, safe and effective method for mid-trimester medical abortion[12]. The RWH believes that access to medical abortion via mifepristone is a safe, reliable, non-invasive and effective option that should be made available to Australian women.

Women's Preferences

The RWH believes that for many women a medical abortion, which can be performed earlier in pregnancy than surgical abortion, would be preferable. Our experience is that women contact our service early in their pregnancy and are dismayed when they find out they will have to wait until they are at least 6½ weeks pregnant before they can have a surgical termination. Some women undergoing a termination of pregnancy want a safe alternative to surgery and to avoid being anaesthetised, which can cause a sense of a loss of control. In addition, an increasing number of women contact RWH requesting a medical abortion, knowing that it is available in New Zealand, the United Kingdom and the United States, as well many other countries in Europe and Asia.

Many women from rural and regional Victoria contact our service for a surgical abortion, which can mean up to 2 or 3 days away from family, work and friends. They report that access to abortion services in regional parts of Australia is restricted by limited service providers, the cost of seeing a private practitioner and the lack of privacy in small communities. Access to mifepristone could assist in reducing these barriers, protecting women's confidentiality while also enabling them to draw on the support of their partner, family or friends.

A research study of medical abortion with a selected group of 38 Australian women reported high levels of satisfaction with this method, with those who had had a prior surgical abortion finding the medical approach more acceptable[13]. Nevertheless, some women will continue to want surgery, and both options should be made available. Several other studies have shown that women value choice, have a strong preference for one or other approach, and are more likely to be satisfied with a method they choose[14].

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[7] RANZCOG, ibid, p. 5
[8] RANZCOG, ibid, p.8
[9] RANZCOG, ibid, p.16
[10] RANZCOG, ibid, p.4
[11] RANZCOG, ibid, p. 21-22
[12] Royal College of Obstetricians and Gynaecologists, *The care of women requesting induced abortion*, *Evidence-based Clinical Guideline No.7*, September 2004, http://www.rcog.org.uk/resources/Public/pdf/induced_abortionfull.pdf, pp.56 -57
[13] Pam M Mamers, Anna L Lavelle, Amanda J Evans, Sandra M Bell, Jen R Rusden and David L Healy, 'Women's satisfaction with medical abortion with RU486', *MJA*, 167(6), September 1997, http://www.mja.com.au/public/issues/sep15/mamers/mamers.html, pp.316-317
[14] RANZCOG, ibid, pp.23-24

Evidence About the Number of Abortions In Australia

There is no evidence to show that the availability of mifepristone in Australia will increase the number of abortions being performed[15]. Instead, the RWH anticipates that medical abortions will replace a proportion of the surgical abortions currently undertaken. It is likely that health services that introduce medical abortion will initially experience high levels of demand for this treatment until it becomes more generally available. The RWH believes that knowledge about women's health would be improved by the collection of national data on termination of pregnancy in Australia.

Evidence Based Practice For Medical Terminations

In the event that the *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill* is passed, and the Therapeutic Goods Administration's evaluation of the evidence results in access to mifepristone in Australia, the RWH would establish protocols and train relevant staff to make this treatment available to women, as appropriate. Approaches to counselling and decision-making about abortion would not change. Clinical practice, information and support would be informed by international evidence about best practice.

Gynaecologists are suitably trained to supervise medical abortion and to recognise and manage any complications. Care may be delivered in partnership with midwives, counsellors and General Practitioners according to appropriate protocols. Protocols would be established regarding all of the steps required for medical abortion:

- Prescription and administration of mifepristone (including location and supervision)
- Return for prostaglandin administration
- Prescription and administration of prostaglandin (including location and supervision)
- Observation period
- Follow up plans for women who proceed to complete abortion
- Follow up plans for women who do not complete abortion during the observation period.

This protocol would include the requirement that all women accessing this procedure would be discharged from the RWH with advice and written information, including:

- A telephone number to contact in case of emergency
- Symptoms that might be expected
- Arrangements for emergency care if needed, and
- A follow-up appointment.

Conclusion

Access to abortion services should be provided on the basis of health care need, and should not be limited by socio-economic circumstances, geographic isolation or age. Mifepristone with prostaglandin is a proven safe and effective method of abortion that should be available through our health care system to Australian women.

[15] Rachel K. Jones and Stanley K. Henshaw, 'Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden', *Perspectives on Sexual and Reproductive Health*, 34(3), May/June 2002, http://www.guttmacher.org/pubs/journals/3415402.pdf, p.156