



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

The Royal Women's Hospital and Family Planning Victoria are major providers of health care to women. We give unreserved backing to the proposed Bill, the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005, which would assign responsibility for evaluation, approval and regulation of RU486 and other abortifacients to the Therapeutic Goods Administration.

The Royal Women's Hospital and Family Planning Victoria support the repeal of the 1996 amendments to the *Therapeutic Goods Act 1989 (Com)* 'the Act'. These amendments constructed a special category of restricted goods for abortifacients¹ and provided the Minister for Health with a unique power of veto over the importation of these restricted goods². The Royal Women's Hospital and Family Planning Victoria believe that these amendments have created a major anomaly in the regime established under the Act for the evaluation, approval and regulation of therapeutic goods³. These legislative provisions undermine the integrity of the system established by the Therapeutic Goods Administration (TGA) to protect and promote public health through safe and efficacious use of high quality, therapeutic drugs in Australia.

The Royal Women's Hospital and Family Planning Victoria submit that it ought to be up to the country's drug regulator, the TGA, not a Minister of the Crown, to decide if RU486 should be available for use in Australia. The TGA is the specialist statutory body authorised to evaluate, approve and regulate therapeutic drugs in the public interest, after a rigorous and robust assessment of scientific evidence and an examination of the risks inherent in any drug proposed for marketing in Australia. The Australian parliament has endowed the TGA with all the necessary powers, authority and resources to evaluate and assess research results regarding the quality, safety and efficacy of a specific drug and to advise practitioners and the community on its safe and effective use⁴.

Singling out abortifacients for Ministerial approval does not improve the safety of drug regulation and prescribing in Australia. The TGA has established a solid risk assessment framework that provides doctors, health service providers, pharmaceutical companies and consumers with clarity about the process for regulating access to new drugs⁵. The TGA has well-established processes for evaluating drugs for inclusion on the Register of

¹ S. 3(1) Interpretation, *Therapeutic Goods Act 1989 (Com)*

² S. 6AA Importation of Restricted Goods, *Therapeutic Goods Act 1989 (Com)*

³ *Regulation Of Therapeutic Goods In Australia, Overview*, <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm>

⁴ *The Therapeutic Goods Administration's Risk Management Approach To The Regulation Of Therapeutic Goods Version 1 of July 2004*, <http://www.tga.gov.au/about/tgariskmnt.pdf>

⁵ *Therapeutic Goods Act 1989, Medicines Regulation and the TGA*, Department of Health and Ageing, September 2004, <http://www.tga.gov.au/docs/pdf/medregs.pdf>

Therapeutic Goods. Practitioners and the broader health sector are confident that a rigorous and robust process is applied. In contrast, the current legislative provisions give the Minister unfettered and absolute discretion to veto the importation of RU486 without considering evidence proving its efficacy.

The TGA's approval process is subject to clear standards of accountability and transparency for evaluating clinical evidence. Its risk assessment procedures ensure that decisions about access to unproven drugs are protected from vested interests, whether from consumers with chronic or life threatening illnesses, or manufacturers mindful of profit margins, who may seek to influence decisions on access to drugs. The public's interests are also protected by the TGA's governance structure and accountability process, which require reporting through the Minister to parliament. It is not appropriate that current legislative provisions should construct an exception to this legislative framework. The current exceptions confer on the Minister responsibility for decisions regarding the safety and efficacy of a class of drug, when the parliament has already established an appropriate mechanism, ensuring accountability and transparency.

Most drugs and medicines are potentially harmful when used improperly. Clinical protocols informed by expert information and advice are recognised as the most effective means of ensuring safe and appropriate use of drugs that can have harmful side effects. Below are some examples of advice and conditions included in product information approved by the Therapeutic Goods Administration:

GONADOTROPHINS

"Treatment with (gonadotrophin for ovulation induction) should be initiated under the supervision of a doctor experienced in the treatment of fertility problems."

OXYTOCIN

"Administration should only be under hospital conditions, and all patients receiving intravenous oxytocin must be under continuous observation by trained personnel with a thorough knowledge of the drug and qualified to identify complications. A doctor qualified to manage any complications must be immediately available."

METHOTREXATE is marketed with the following prominent *Boxed Warning*,

"Because of the potential to cause severe toxicity, methotrexate therapy requires close supervision with particular caution to distinguish between daily and weekly dosage regimens. Weekly dosage prescriptions should specify a particular day of the week"⁶

Australia's health care system regularly manages situations of comparable risk to that posed by RU486. As with many other medical procedures, protocols can be developed to ensure that women have access to medical care, according to the level of risk, following administration of the drugs. For example New Zealand has developed comprehensive guidelines for the use of mifepristone for medical abortion⁷.

⁶ Sourced from MIMS ONLINE, <http://www.mims.com.au/>

⁷ Carol Shand, Hazel Irvine, Vasudha Iyengar, *Guidelines for the Use of Mifepristone Medical Abortion In New Zealand Report of a Technical Committee to the Abortion Supervisory Committee*, September 2004, http://www.abortion.gen.nz/docs/ASC_Technical_Committee_Report_24_Aug04.pdf

Medical abortion should not be self-administered without medical supervision. The experience of medical abortion is described as being very much like miscarriage, which is the natural outcome of around one in six pregnancies. It is our experience that women recognise the symptoms of miscarriage and access medical advice; complications requiring urgent treatment are uncommon. Current trends are to reduce surgical interventions for miscarriage by awaiting spontaneous miscarriage or using drugs in at least some cases⁸.

Similarly, the risk of serious haemorrhage or life-threatening complications following a medical abortion is extremely small⁹. Further, since these rare outcomes are known they can be anticipated, and women can be alerted about early symptoms and when to seek further care. For example, women from remote and rural areas undergoing medical abortion may need to remain within close proximity of a health service that has the capacity to provide care for women with early miscarriage, for the duration of the treatment period. This is common practice in health service delivery for residents of rural and remote communities experiencing a variety of medical complications.

In conclusion, enactment of the *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005* by Parliament will remove the major inconsistency that exists under the current law and omits a drug from the TGA's normal evaluation, approval and regulation process. The TGA's approval process is based on scientific evidence, which examines and evaluates the quality, safety and effectiveness of drugs. The TGA's risk assessment framework provides clarity and transparency of process and protection from vested interests. The 1996 amendments impose an exception to the agreed standards and criteria for assessing drugs for use in Australia. The TGA is the appropriate body for assessing the risks associated with RU 486, and approving and regulating its use.

⁸ Alexandros Sotiriadis, George Makrydimas, Stephanie Papatheodorou, John Ioannidis, 'Expectant, Medical or Surgical Management of First Trimester Miscarriage: A Meta-Analysis', *American College of Obstetricians and Gynaecologists*, Vol 15(5), May 2005, pp.1104-1113

⁹ Royal Australian New Zealand College of Obstetrician and Gynaecologists (RANZCOG), *Termination Of Pregnancy A Resource for Health Professionals*, <http://www.ranzcog.edu.au/womenshealth/termination-of-pregnancy.shtml>, November 2005