

Submission to the Senate Community Affairs
Legislation Committee

Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial
Responsibility for approval of RU486) Bill 2005

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Introduction

RU486 is the common name for the drug mifepristone, a drug which amongst other uses can be used to induce a medical abortion (as opposed to a surgical abortion). RU486 is registered for use in the United States, Canada, the United Kingdom, New Zealand, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Luxembourg, the Netherlands, Norway, Spain, Sweden and Switzerland, not to mention China, Israel, Russia, South Africa, Taiwan, Tunisia and the Ukraine. It is not currently available in Australia.

As a result of amendments to the *Therapeutic Goods Act 1989* introduced in 1996 the Minister for health has an effective power of veto over the introduction of any drug into Australia which is intended for use as an abortifacient, such as RU486. While the amendments do not explicitly ban these drugs, they operate as a de facto ban due to their deterrent effect. Given that applying for the approval of a drug for use in Australia can involve substantial time and costs, it is likely that organisations which might be interested in making RU486 available in Australia would be deterred from doing so due to the Minister's power to block any application. Any veto by the Minister would mean that all costs incurred would thus have been wasted. As the current health Minister has been overt in his opposition to abortion as have many other members of parliament, it would seem a prudent decision to refrain from expending effort and financial resources in seeking approval for the use of a drug when it is unclear whether the basis for any decision would be opposition to abortion generally rather than the safety and efficacy of the drug per se.

Purpose of Current Bill

The purpose of the bill under inquiry is to remove the power of veto in relation to RU486 and other abortifacients from the Minister for Health and Ageing. As such, decisions in relation to the importation, listing, evaluation, registration and trial of medicines intended for use as abortifacients would be the responsibility of the Therapeutic Goods Administration (TGA) and would follow the same approval protocol applied to other drugs. This would remove uncertainty on the part of any group or organisation that might wish to make RU486 available in Australia as it would increase confidence that decisions would be made on the basis of an objective evaluation of the risks and benefits of the drug. This would therefore remove an additional barrier to the evaluation of RU486 for introduction into Australia, thereby increasing the likelihood that Australian women would eventually have access to an alternative to surgical abortion – an alternative that has been used safely by millions of women internationally.

The current bill does not change the existing legal status of abortion in Australia. Women and doctors would still need to comply with relevant state criminal codes regulating the procedure. While the bill does deal with drugs that are used for the purpose of aborting a pregnancy, it does not even make these drugs automatically available for use as abortifacients in Australia. The current bill only changes the assessment process for the drug to bring it in line with that used for all other medicines. That is, if the current bill was supported and a group or organization applied to make RU486 available for use in Australia and the TGA evaluated the drug as safe for use and it was subsequently made available under the conditions

determined by the TGA and other stakeholders, it would then allow women an alternative to a surgical abortion in circumstances where an abortion is legally allowed under existing Australian law and it was determined by the woman and her doctor that a medical abortion was an appropriate medical and clinical option.

This submission outlines why the Bill should be supported by all parliamentarians, regardless of individual moral positions on abortion.

Issues

Legal status of abortion in Australia

The practice of inducing abortions has existed for many years. The debate around the availability of abortion services remains controversial. This bill is not about changing the legal status of abortion. However, as the amendments to the *Therapeutic Goods Act 1989* that the current bill seeks to repeal only apply to medicines that are intended to induce abortions, it must be assumed that the primary concern of those proposing these amendments originally was to specifically expand the government's role in relation to abortion. Indeed it has been argued, both at the time the amendments were introduced and subsequently, that abortifacients require an additional level of scrutiny because they are used to terminate a pregnancy. Therefore in part this bill is concerned with what role the government should have in relation to decisions on terminating a pregnancy.

Laws governing abortion are the responsibility of the states and territories. Pregnant women do not currently have the legal right to an abortion on request in Australia, although under appropriate clinical circumstances a woman can access abortion within the law. With the exception of the ACT (where abortion is regulated like other medical procedures through the Health Act), abortion remains a criminal offence in all of the states and territories of Australia, unless it meets varying legal definitions of what is considered a 'lawful' exception to the crime.

Depending on where a pregnant woman lives, she may be able to obtain a termination if a doctor, or in some cases two doctors, decide that continuation of the pregnancy would cause greater risk to the health of the woman than if the pregnancy was terminated. Fetal abnormality is not sufficient grounds for abortion in some jurisdictions, even in cases where the abnormality is lethal. Even where the law permits termination of pregnancy there are restrictions on where abortions can be performed, who can perform them and what other requirements are placed on women before an abortion can be undertaken.

While current Australian abortion laws are inconsistent and result in substantial uncertainty that leave doctors and women vulnerable to criminal prosecution, they have historically been interpreted in such a way that an abortion is available to a woman seeking termination of her pregnancy - if she has access to a service to perform the procedure, has undergone any mandated counselling, has the financial resources to meet the costs associated with the procedure and has medical agreement that the termination is necessary under the requirements of the particular state or territory in which she lives.

As previously mentioned, this Bill will not change any of the current legal restrictions or requirements surrounding abortion. It is only concerned with removing special barriers which have been imposed on the evaluation and approval of an alternative method of abortion. It is unethical for the government to block, either directly or indirectly, the assessment of potentially safe alternatives for legal medical procedures.

Expertise to evaluate safety and efficacy of medicines

The Australian community expects that the medicines approved for use in Australia are safe and effective. Evaluating a medicine well is not a simple task and requires careful, impartial examination of the evidence, using a standardised process in an explicit manner. No medication, or medical procedure, is risk free and those involved in examining the evidence surrounding the potential benefits and risks of a medicine require the requisite skills and knowledge to be able to appraise the quality of the available evidence, including its quality, potential biases and robustness.

The TGA is the statutory body responsible for the approval of all medicines in Australia, other than those known as ‘restricted drugs’. Restricted drugs are a special category which contains only those medicines intended to induce an abortion. The TGA is considered by the government as being qualified and resourced to assess and manage the risks associated with all other therapeutic goods that are used (or proposed for use) in Australia, including medicines with severe side effects such as those used in chemotherapy. The TGA has the technical and professional resources to

- identify, assess and evaluate the risks posed by medicines and other therapeutic goods;
- apply any measures necessary for treating the risks posed; and
- monitor and review the risks over time.

For further details on the TGA’s risk management approach see attachment A.

Given the above, the TGA would appear to be qualified to assess and manage any risks associated with abortifacients. In contrast it would appear unlikely that an individual member of parliament or any subgroup of the parliament or indeed the parliament as a whole would have the necessary skills, knowledge and resources to undertake this task. This is presumably why the TGA was established in the first place.

The impartiality of an organisation such as the TGA would appear to be particularly important in the area of abortion where there is already evidence that the scientific process is manipulated and research findings misrepresented to justify an anti-choice agenda and further restrict access to contraception and abortion.

In the current context it is noteworthy that the World Health Organisation, the UK Royal College of Obstetricians and Gynaecologists, the American College of Obstetricians and Gynaecologists, the Australian Medical Association, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Rural Doctors’ Association, all organizations with specific medical expertise, have examined the scientific evidence and concluded that RU486 should be available to women.

Need for Ministerial/Parliamentary Accountability

The current bill does not address the ethical issue of whether women should or should not be able to access abortion or even under what circumstances they should be able to terminate a pregnancy. The issue is not who approves or disapproves of the act of aborting a pregnancy.

This Bill is about governance. It concerns whether decisions about the availability of a medicine should be made by an objective scientific agency with expertise in assessing the risks and benefits of medicines or whether the personal views of parliamentarians, specifically the health minister in this case, should be allowed to determine the potential entry of a medicine into Australia.

To this extent the purpose of the drug and the particular views of individual members of parliament are irrelevant. It should not matter whether the drug is intended to induce an abortion or treat cancer or diabetes. Nor should it matter whether it is the current health minister or some other parliamentary individual or structure that is responsible for sanctioning a particular medicine. As previously mentioned however, the special conditions on the evaluation and approval of a potential medicine for introduction into Australia only apply to abortifacients. Therefore in part the issue is what role the government should have in decisions about abortion.

For more than two decades, there has been consistent evidence that the majority of Australians support access to abortion. The 2003 Australian Survey of Social Attitudes conducted by the Australian National University found that 81% of Australians support a woman's right to choose and only 9% are opposed. There appears to be broad community support for medical decisions to be made by those most closely affected by them after discussion with the appropriate health professional.

Parliamentarians, like all Australians, are entitled to differing views regarding abortion and there are clearly members of parliament with religious and moral views that oppose abortion. Nevertheless politicians are not entitled to use the power of the state and legislation to impose their own personal moral positions on the entire community.

Although there has been some public debate on the need to reduce the number of abortions (some would argue debate that has been manufactured by those who wish to suggest there is a crisis that necessitates restricting access to abortion), allowing parliamentarians to block access to non-surgical abortion, if determined to be safe, would not appear to be either an effective or ethical way of achieving this outcome. Evidence from European countries where RU486 has been available for some time demonstrates that the introduction of medical abortion has little effect on the number or rate of abortions overall. However, it does have the benefit of increasing the percentage of abortions that occur earlier in the pregnancy, which is safer for the woman.

The most effective strategy to reduce the number of crisis pregnancies and subsequent abortions would be to prevent unwanted pregnancies in the first place. Lifelong, evidence based sexual and reproductive health education and access to the effective and affordable use of contraception are essential to achieving a reduction in the

number of unplanned pregnancies and abortions. However there will always be crisis pregnancies and women will continue to require access to safe and legal terminations.

Parliamentarians have a political responsibility to ensure the safety and quality of healthcare and to ensure equitable access to lawful services and procedures. They also have a responsibility to distinguish between their personal views and the appropriate role of the government and the law.

As abortions are legal under specific circumstances in Australia, there would appear to be no reason that the government should be involved in determining what technique is used for conducting a legal medical procedure. Decisions about whether a pregnant woman has a vaginal or caesarean birth are made on the basis of individual medical and clinical factors by the woman and her doctor, not on the basis of the personal views of parliamentarians. Decisions about whether a pregnant woman has a surgical or medical abortion should also be between women and their doctors.

Conclusion

The debate about this bill should be distinguished from the debate about abortion more generally. Abortion is legal under certain circumstances in all Australian states and territories. If a safe non-surgical abortion technique is available Australian women should not be prevented from having access to it.

There would appear to be no legitimate reason why RU486 and other abortifacients should be subject to special arrangements with regard to their approval for use in Australia. The TGA has the expertise to assess whether RU486 is a safe and effective means for non-surgical abortion. If an organisation applies to make RU486 available in Australia and it is approved for use by the TGA Australian women can have confidence that the drug is safe and of high quality. If the TGA determines that it is not safe then the drug will not be allowed to be used in Australia.

There would appear to be no appropriate role for the parliament, either an individual Minister or the parliament as a whole, in determining whether RU486 and other abortifacients are safe and effective or whether they should be available to Australian women. Parliamentarians do not have the skills, knowledge or expertise to evaluate a drug's safety. Nor are they in a position to determine whether a surgical or non-surgical abortion would be more medically and clinically appropriate for any individual woman. This is a decision which needs to be made by a woman and her doctor. The role of government is to ensure that the community has access to safe and legal healthcare, not to prevent that access based on personal views.

Maintaining the current veto power held by the health Minister or replacing it with an alternative that still inserts an additional step in the approval process which is not based on evidence based medical criteria will maintain the existing deterrent effect put in place by the 1996 amendments. The *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for approval of RU486) Bill 2005* should be passed.