



RU486 for Australia?¹

Introduction

How safe is the abortion drug RU486? Should medical (as opposed to surgical) abortion using RU486 be allowed in Australia? Who is the appropriate authority to decide such matters? Questions such as these have become increasingly prominent in Australia as the result of recently proposed Australian Democrats amendments to the *Therapeutic Goods Act 1989* designed to make it possible for RU486 to be used here for medical abortion.²

Those wanting to make RU486 available in Australia have emphasised its wide availability overseas, evidence of its safety and efficacy compared with surgical abortion, and the possibility that it could alleviate problems of unequal access to abortion by women in rural areas and those for whom privacy is an issue for religious, ethnic or other reasons.³

Alternatively, others have tended to reject the notion that RU486 is essentially safe, and have suggested that, particularly in rural and remote areas without adequate levels of medical supervision and back-up care, its use places women at significant risk of ill-health.⁴

This Note provides a brief overview of RU486 and its use in medical abortion, an explanation of its current legislative status in Australia, and a brief analysis of the current debate about overturning legislative restrictions on RU486 and similar abortion drugs in Australia introduced at the instigation of Senator Brian Harradine in 1996.

Broadly, this Note suggests that there has been very little dispute in the current debate over the substantive ‘clinical facts’ of RU486 (such as its efficacy and possible side-effects). Rather, much of the debate has involved alternative *characterisations of the risk* associated with this form of medical abortion. This suggests that one of the key questions in the debate over RU486 is about who is the appropriate authority to evaluate the risk associated with this medicine and determine its appropriateness for authorised use in Australia.

This Note does *not* engage in discussion about the morality or ethics of abortion. While such issues are clearly important, they are beyond the scope of this paper.

RU486—an overview

What is RU486?

RU486 is the common name for the drug mifepristone, a synthetic steroid that can be used to induce what is known as medical abortion—an alternative method to surgical termination of pregnancy.⁵ RU486 has been approved for use in the United Kingdom, the United States, much of Western Europe, Russia, China, Israel, New Zealand, Turkey and Tunisia.⁶

RU486 works by blocking the effects of the hormone progesterone, which is crucial to starting and maintaining pregnancy. Without progesterone, the lining that covers the walls of the uterus breaks down. In the absence of progesterone, the uterus cannot hold onto the fertilised egg, making it impossible for pregnancy to continue.

Generally, in a medical abortion using RU486, the woman is given a specified dose of the drug by a qualified medical professional in a licensed facility.⁷ In most cases, the woman returns home and, two days later, returns to the clinic to be administered a prostaglandin (usually misoprostol).⁸ This causes the uterus to contract, thereby expelling the products of conception, usually within a few hours.⁹ According to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the experience for the woman ‘may be much like a spontaneous miscarriage, with some pain and bleeding to be expected’.¹⁰

RU486 is mainly used during the first nine weeks of pregnancy, though is also effective for second trimester termination, again in conjunction with a prostaglandin.¹¹

Safety and efficacy

Most reviews of the available evidence about RU486 suggest the following:

- medical abortion using the RU486/misoprostol combination will lead to a successful abortion in between 92 and 98 per cent of cases
- in the five to eight per cent of cases in which there has not been a successful abortion, the abortion will need to be completed surgically by a qualified physician
- in some cases, women will require urgent medical care for side-effects such as internal bleeding and infection of the retained products of conception, and

- safe medical abortion, like surgical abortion, requires the availability of an appropriate level of back-up medical care to address possible complications arising from the procedure.¹²

Comparison with surgical abortion

Supporters of medical abortion as an alternative to surgical abortion suggest that its advantages, when performed appropriately, include:

- no requirement for anaesthesia and no risk of perforation or damage to the cervix from instruments¹³
- evidence that it is ‘the most effective method of abortion at gestations of less than 7 weeks’,¹⁴ and
- evidence of its acceptability to many women as enabling greater involvement in the process than surgical abortion.¹⁵

Others have argued that the key point is not that one method of termination is inherently superior to another, but rather that women should have the opportunity to choose between the two methods on the basis of advice from qualified authorities. For example, the RANZCOG has argued that ‘best practice in the field includes the option of using mifepristone when termination of pregnancy is to be performed’.¹⁶

Legislative status in Australia

While it is commonly believed that RU486 is ‘banned’ in Australia, this is not strictly the case. In fact, RU486 belongs to a special category of drugs under the *Therapeutic Goods Act 1989* (the Act), known as ‘restricted goods’, which cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health.¹⁷ Further, any such written approval must ‘be laid before each House of the Parliament by the Minister within 5 sitting days of being given’.¹⁸

Restricted goods are defined under the Act as medicines ‘intended for use in women as abortifacients’.¹⁹ In other words, restricted goods provisions apply exclusively to medicines intended to induce an abortion. Medicines used for any purpose other than abortion are evaluated and regulated by the Therapeutic Goods Administration (TGA) without any requirement for approval from the Minister.

As indicated above, the restricted goods provisions do not amount to a direct ban on RU486 or other abortifacients. A sponsor seeking approval to market an abortifacient can apply through the same process as exists for all prescription medicines in Australia—that is, an application would need to be submitted with supporting data to demonstrate the quality, safety and effectiveness of the drug. The key difference as a result of the restricted goods provisions is that, in addition to the supporting data, written ministerial approval is required before a restricted good, such as RU486, can be evaluated by the TGA.

Why restricted goods?

The restricted goods provisions were incorporated into the Act in 1996 as a result of amendments introduced to the *Therapeutic Goods Amendment Bill 1996* by Senator Brian Harradine (the ‘Harradine amendments’). These amendments were supported by both the Liberal-National government and the Labor opposition.

The stated intent of the Harradine amendments was to make the Minister for Health, rather than the TGA (the statutory body usually responsible for approval of medicines in Australia) ultimately responsible for decisions in relation to the evaluation, registration, listing or importation of abortifacients. This was on the grounds that abortifacients amounted to a special category of drugs for which an additional layer of public scrutiny was required.

At the time, Senator Harradine raised particular concerns about the safety of RU486—for example, he claimed that it could have long-term effects on the tissue of the cervix and uterus.²⁰ Senator Harradine and others speaking in support of the amendments also suggested that it is not sufficient to only assess the appropriateness of such drugs in relation to scientific criteria such as safety and efficacy because abortion is a sensitive community issue.²¹

On the other hand, many participants in the debates surrounding the TGAB 1996 argued that the *actual* intent of the amendments was to ban RU486 from Australia. For example, Senator Meg Lees argued that the creation of an extra stage in the approval process would deter potential sponsors (such as manufacturers, clinicians or clinical researchers) from seeking to bring RU486 into Australia.²²

A *de facto* ban on RU486?

However, despite the fact that it is possible under current arrangements to apply for approval to market RU486, no such application has ever been lodged in Australia.²³ Indeed, some have argued that potential sponsors of RU486 have been deterred from applying for approval to market the drug in Australia as a result of the Harradine amendments.²⁴ Given the fact that an application could be blocked from TGA evaluation by the Minister, it is possible that potential sponsors have made the judgement that making an application is not worth the trouble (there are often significant costs involved in putting together supporting evidence for an application to the TGA).

The view that potential sponsors of RU486 have been deterred by the Harradine amendments is probably lent further credence by the fact that RU486 is currently licensed for use in a large number of countries and there would most likely be reasonable demand for the drug in Australia. According to a RANZCOG review of relevant literature, given the choice, a substantial proportion of women prefer medical methods of abortion.²⁵

A question of risk

As noted above, in recent months the debate surrounding RU486 has intensified as a result of renewed attempts to make this form of medical abortion available in Australia. It is notable that this debate has been underpinned by the issue of risk—that is, the question of whether the potential benefits of making medical abortion available are outweighed by the potential harms (in this case, to the health of women).

On the one hand, those in favour of making medical abortion using RU486 available have argued that its use constitutes a relatively low safety risk for women.²⁶ For example, Australian Medical Association (AMA) President, Mukesh Haikerwal, has argued that RU486 ‘certainly is safe and has been used overseas for many years now, with over a million women having been treated’.²⁷

Alternatively, others have argued that safety risks associated with RU486 are significant.²⁸ For example, in written advice to the Health Minister, the Chief Medical Officer (CMO), Professor John Horvath, stated that use of RU486 for abortion ‘carries a significantly *higher* risk [than surgical abortion] of later adverse events’, and that use of medical abortion by GPs in situations where there was not an ‘established relationship with an obstetric service that could deal with emergency complications outside normal clinic hours ... would substantially increase the risks to women undergoing termination’.²⁹ On the basis of this advice, the Minister stated that he would not seek to change the current regulatory arrangements in relation to RU486.³⁰

It should be noted, however, that AMA Executive Councillor and obstetrician, Dr Andrew Pesce, responded to the CMO’s advice by arguing that women would only be able to access medical abortion ‘under the supervision and advice of a doctor who would be responsible for managing the entire termination process’.³¹

Nevertheless, while different characterisations of the potential risks of medical abortion have been presented, the basic facts about clinical outcomes (such as efficacy and possible side-effects) do not appear to be in dispute. Rather, the main area of dispute in the current debate over RU486 has tended to be about *whether these ‘clinical facts’ in relation to this form of medical abortion can be said to constitute an acceptable risk to the health of women.*

In other words, the current debate over RU486 in Australia is essentially over questions of risk management. This is a key point because the management of risk associated with medicines is an explicit function of the TGA.

Risk management and the TGA

The TGA’s risk management role means that it is specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods, applying

any measures necessary for treating the risks posed, and monitoring and reviewing the risks over time.³²

The key point here is that the TGA is regarded by the government as being qualified to manage the risks associated with any therapeutic good that is used (or proposed for use) in Australia. From this, one could reasonably assume that it is also qualified to manage the risks associated with abortifacients such as RU486.

However, as noted above, as a result of the Harradine amendments in 1996, the power to make assessments of this kind in relation to abortifacients has been effectively taken out of the hands of the TGA and given to the Minister for Health. It is notable that abortifacients are the only such medicines to which this arrangement applies. At the same time, it should also be noted that for Senator Harradine and those who supported his amendments to the Act in relation to RU486 in 1996, the creation of this unusual arrangement was appropriate given community sensitivity to the issue of abortion.

Conclusion

The current legislative amendments proposed by the Australian Democrats are aimed at making RU486 available in Australia by removing the restricted goods provisions from the *Therapeutic Goods Act 1989*.

Removal of the restricted goods provisions would mean that RU486 could be evaluated within the same framework as applies to all other medicines. It is reasonable to assume that this may provide potential sponsors of the drug with greater confidence that an application for approval would be worth pursuing—in that the determining factor in the process would be an evidence-based evaluation by the TGA of the merits and risk profile of the drug.

At the same time, removal of the restricted goods provisions would mean that the additional layer of scrutiny (that is, the requirement for Ministerial approval and notification of Parliament) that currently exists in relation to applications for marketing of RU486 would no longer exist.

However, this is not the same as saying that the process for evaluating applications for abortifacients would become less transparent or accountable. Under current arrangements, the Minister is simply required to *notify* the Parliament of a decision to *approve* an application for evaluation by the TGA. Given the fact that such a decision would not be disallowable by the Parliament, this does *not* amount to a significant level of parliamentary scrutiny. Further, the Minister is *not* required to table decisions *not to approve* such applications, meaning that the Parliament is neither necessarily informed of these, nor does it have the capacity for any oversight of such decisions.

Essentially, current arrangements mean that the Minister for Health alone decides whether applications for evaluation of abortifacients such as RU486 can proceed

through the usual processes of the TGA. It could be argued that this situation is at odds with the evidence-based framework generally used to assess other medicines in Australia.

While it could also be argued that special arrangements are necessary in the case of RU486, given community sensitivity to the issue of abortion, it should be noted that the current arrangements do not necessarily provide for significant parliamentary scrutiny of applications to evaluate, register, list or import RU486 for use in medical abortion. Rather, this power currently resides entirely with the Minister for Health.

Endnotes

1. Thanks to the following people for their assistance with the production of this paper: Dr Kenneth Clark, President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); Professor Caroline de Costa, Department of Obstetrics and Gynaecology, James Cook University; Kerrilie Rice, Policy and Research Officer, Women's Health Victoria; and the colleagues from the Parliamentary Library who provided advice and feedback during an internal workshop. I am also grateful to the Department of Health and Ageing for comments and information provided during the preparation of this paper.
2. *Therapeutic Goods Amendment Bill 2005* (Amendments to be moved by Senators Allison and Stott Despoja on behalf of the Australian Democrats in committee of the whole). See also Senator Lyn Allison, 'Democrats to reverse ban on abortion drug', *media release*, 3 October 2005.
3. See, for example, C. de Costa, 'Medical abortion for Australian women: it's time', *Medical Journal of Australia*, vol. 183, no. 7, 2005, pp. 378–80; Mukesh Haikerwal, 'AMA President outlines medical support for RU486', *Radio National Breakfast*, ABC Radio National, 8 November 2005; and Sharman Stone MP, cited in S. Maiden, 'Liberals press for conscience vote over abortion drug', *Australian*, 17 November 2005.
4. See, for example, Senator Alan Eggleston and Senator the Hon. Ron Boswell, 'Senators oppose abortion drug because it requires access to emergency help unavailable in some rural areas', *media release*, 13 November 2005; Hon. Tony Abbott MP, Minister for Health and Ageing, cited in M. Metherell, 'Ban on abortion pill to stay', *Sydney Morning Herald*, 16 November 2005.
5. While RU486 can potentially be used for the purposes of emergency (or 'morning after') contraception, it is *not* what is commonly known as the 'morning after pill'. In this country, the term 'morning after pill' is generally used to refer to the drug Postinor-2 (levonorgestrel), a post-coital emergency contraceptive.
6. de Costa, op. cit., p. 378.
7. R. Jones and S. Henshaw, 'Mifepristone for early medical abortion: experiences in France, Great Britain and Sweden', *Perspectives on Sexual and Reproductive Health*, vol. 34, no.3, May/June 2002, pp. 156–7; Abortion Supervisory Committee (New Zealand), *Guidelines for the use of mifepristone in medical abortion in New Zealand*, August 2004, pp. 13–14.
8. *ibid.*
9. RANZCOG, *Termination of pregnancy: A resource for health professionals*, November 2005, p. 16.
10. *ibid.*
11. de Costa, op. cit., p. 378.
12. See, for example, World Health Organisation (WHO), *Safe abortion: technical and policy advice for health systems*, WHO, Geneva, 2003, pp. 35–39; Royal College of Obstetricians and Gynaecologists (RCOG), *The care of women requesting induced abortion*, Evidence-based Clinical Guideline No. 7, RCOG, London, September 2004, pp. 51–54. Available online: see http://www.rcog.org.uk/resources/Public/pdf/induced_abortionfull.pdf (accessed 27 November 2005); Department of Health and Ageing, *RU-486 (mifepristone)—medical abortion*, Minute to the Minister, November 2005; de Costa, op. cit.

13. Reproductive Choice Australia, *Mifepristone—'RU-486'*, Briefing Paper, August 2005, p. 3. Available online: see <http://www.comcen.com.au/~welnsu/pages/RU486.doc> (accessed 27 November 2005).
14. RCOG, *The care of women requesting induced abortion*, op. cit., p. 11.
15. P. Mammers, A. Lavelle, A. Evans, S. Bell, J. Rusden and D. Healy, 'Women's satisfaction with medical abortion with RU486', *Medical Journal of Australia*, vol. 167, 1997, pp. 316–17. See also B. Faucher, N. Baunot and P. Madelenat, 'The efficacy and acceptability of mifepristone medical abortion with home administration misoprostol provided by private providers linked to the hospital: a prospective study of 433 patients', *Gynaecology, Obstetrics and Fertility*, vol. 33, 2005, pp. 220–7.
16. RANZCOG, 'RANZCOG supports AMA in the RU486 debate', *media release*, 9 November 2005.
17. *Therapeutic Goods Act 1989*, section 23AA(1).
18. *ibid.*, section 23AA(2).
19. *ibid.*, section 3.
20. Senator Brian Harradine, 'Senator proposes amendments to the importation of RU486', *Daybreak*, ABC Radio National, 20 May 1996.
21. For example, in explaining why the ALP would not be opposing the amendments, ALP Senator Belinda Neal argued in Committee that Labor wished to 'ensure that each house of parliament and the public at large are notified'. Senator Belinda Neal, 'In committee speech: Therapeutic Goods Amendment Bill 1996 (No. 2)', Senate, *Debates*, 9 May 1996, p. 623.
22. Senator Meg Lees, 'Third reading speech: Therapeutic Goods Amendment Bill 1996 (No. 2)', Senate, *Debates*, 21 May 1996, p. 827.
23. Department of Health and Ageing, op. cit., p. 1.
24. See, for example, Dr Adrienne Freeman cited in R. Rouse, 'Concern over "abortion pill" access', *Medical Observer Weekly*, 16 July 2004, p. 8.
25. RANZCOG, *Termination of pregnancy. A resource for health professionals*, op. cit., p. 23.
26. See, for example, Haikerwal, op. cit.; Allison, 'Democrats to reverse ban on abortion drug', op. cit.; de Costa, op. cit.; Reproductive Choice Australia, op. cit.
27. Haikerwal, op. cit.
28. See, for example, Department of Health and Ageing, op. cit.; Eggleston and Boswell, op. cit.; Hon. Tony Abbott MP, Minister for Health and Ageing, cited in Metherell, op. cit.; A. Shanahan, 'Misleading campaign against Abbott's rejection of RU486 abortion pill', *Canberra Times*, 19 November 2005.
29. Department of Health and Ageing, op. cit., pp.1–2.
30. Hon. Tony Abbott MP, Minister for Health and Ageing, cited in Metherell, op. cit.
31. A. Pesce, 'Health minister's RU-486 advice skewed, incomplete and ignores the needs of the majority of Australian women', *media release*, Australian Medical Association, 15 November 2005.
32. Therapeutic Goods Administration (TGA), *The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods*, TGA, July 2004, p. 4.

Luke Buckmaster Social Policy Section Information and Research Service

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