



Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

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Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

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House: House of Representatives

Portfolio: Health and Ageing

Commencement: On Royal Assent

Purpose

This Bill proposes to amend the *Therapeutic Goods Act 1989* to make it possible to evaluate, register, list or import abortifacients (medicines intended to induce an abortion) such as RU486 (mifepristone) for use in Australia without the approval of the Minister for Health and Ageing.

Background

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.¹

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.

According to one recent estimate, RU486 has been approved for use in 35 countries, including the United Kingdom, the United States, much of Western Europe, Russia, China, Israel, India, New Zealand and Tunisia.²

A more detailed overview of RU486 and issues related to its use in medical abortion can be found in the Parliamentary Library Research Note *RU486 for Australia?*, available at <http://www.aph.gov.au/library/pubs/rn/2005-06/06rn19.htm>.

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Regulation of medicines in Australia

Therapeutic goods such as medicines are regulated under *Therapeutic Goods Act 1989* (the Act). The purpose of the Act is to ensure the quality, safety, efficacy (where appropriate) and timely availability of therapeutic goods.³ Regulatory arrangements for therapeutic goods under the Act are the responsibility of the Therapeutic Goods Administration (TGA), a unit of the Department of Health and Ageing.⁴

Any medicine available for general sale in Australia must be included on the Australian Register of Therapeutic Goods (ARTG). There are also a range of programs whereby conditional access can be granted to products not listed on the ARTG, including the Special Access Scheme, the Authorised Prescriber Scheme and exemptions under clinical trials schemes.⁵

The TGA is responsible for administering the provisions of the Act and maintaining the ARTG and the various conditional access programs.

TGA regulatory approach

Therapeutic goods on the ARTG are regulated according to a ‘risk management’ approach. This means that the evaluated risk associated with a particular medicine or medicinal ingredient determines the type of assessment process used by the TGA. The concept of risk is based on an assessment of the ‘potential of a product to do harm to those it is intended to help, or to others (such as children) who may come into contact with it—regardless of whether the harm results from following or disregarding the directions for use’.⁶

Higher risk therapeutic goods (Registered medicines), such as those used to treat serious conditions, or which need to be used under a doctor’s supervision, are subject to a high level of scrutiny and evaluation by TGA to determine their quality, safety and efficacy. **Lower risk** therapeutic goods (Listed medicines) are assessed by the TGA for quality and safety *but not* efficacy. That is, the TGA does not evaluate Listed medicines prior to supply to determine whether they are effective.⁷

Legislative status of RU486

RU486 belongs to a special category of drugs under the Act, known as ‘restricted goods’, which cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing.⁸ Medicines used for any purpose other than abortion can be regulated by the TGA and (if approved) imported by a manufacturer or distributor (known as the sponsor) without any requirement for approval from the Minister.

The restricted goods provisions were incorporated into the Act in 1996 as a result of amendments introduced in the *Therapeutic Goods Amendment Bill 1996* by Senator Brian

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Harradine (the ‘Harradine amendments’). Senator Harradine and others speaking in support of the amendments argued that these provisions were necessary because abortifacients amounted to a special category of drugs for which an additional layer of public scrutiny was required.⁹

Refer to the Parliamentary Library Research Note *RU486 for Australia?*, available from <http://www.aph.gov.au/library/pubs/rn/2005-06/06rn19.htm> for further details.

Basis of policy commitment

Through the amendments in this Bill, Senators Allison, Moore, Nash and Troeth are seeking to make it possible for abortifacients such as RU486 to be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing. If successful, ultimate responsibility for approving RU486 would be taken from the Minister and returned to the TGA.

In her Second Reading speech, Senator Nash argued that the TGA, rather than the Minister, is the appropriate body for making such a decision:

The [TGA] has the knowledge and expertise to conduct the evaluation of RU486 for quality, safety and efficacy. That is why the TGA has been entrusted to evaluate more than 50,000 therapeutic goods that have already come before it.¹⁰

Further, the Explanatory Memorandum to the Bill noted that the TGA’s role in regulating the risks associated with medicines make it the appropriate body for evaluating RU486:

The TGA is specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods that come into Australia, applying any measures necessary for treating the risks posed, and monitoring and reviewing the risks over time.

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. It is therefore reasonable to assume that it is also qualified to manage the risks associated with medications such as RU486.¹¹

It is also evident that an underlying purpose of the Bill is to remove what some see as an impediment created by the current arrangements to sponsors making an application for approval of RU486. According to the Explanatory Memorandum, ‘it is reasonable to assume that [the amendments in the Bill] 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’.¹²

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Commentary and analysis

The debate about the possible use of RU486 for medical abortion in Australia has been strongly contested by numerous members of parliament, interest groups and press commentators both prior to, and since, the introduction of this Bill in December 2005. Much of this debate has been conducted as part of the Senate *Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005*.¹³ This debate has not been restricted to the substantive issue raised by this Bill—that is, who is the appropriate authority to decide whether RU486 should be available in Australia? Rather, it has been, to some extent a debate about the legitimacy of abortion, in which RU486 has come to play a symbolic role.

The debate surrounding the Bill has been conducted around three main questions:

- is RU486 when used in medical abortion safe enough to be used by women in Australia?,
- is the Minister or the TGA the most appropriate authority for deciding whether RU486 should be made available in Australia for use in medical abortion?
- is there an established relationship between availability of RU486 for medical abortion and an increase in the overall abortion rate in countries where it has become available?

As noted above, the debates surrounding each of these questions have been underpinned by existing assumptions about the legitimacy of abortion in general (rather than restricted to particular issues associated with RU486).

Safety of RU486

As noted in the in the Parliamentary Library Research Note *RU486 for Australia?*, 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). Indeed, there appears to be continuing agreement over 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.¹⁴

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Rather the key point of dispute has been over whether the above constitutes an acceptable or unacceptable level of risk to the safety of women.

While the issue of safety is clearly important, the debate over the level of risk associated with RU486 when used in medical abortion tends to reinforce the argument that the TGA should have some role in determining whether the drug should become available in Australia for that purpose. A similar point was made by Dr David van Gend, Secretary of the World Federation of Doctors Who Respect Human Life, in the Senate Inquiry into the Bill. In response to concerns about the safety of RU486 raised by Senator Joyce, Dr van Gend, who while being opposed to the Bill, stated that he did not want ‘to get into an auction of side effects. That is for the TGA. That is for the [Obstetrics and Gynaecological] College. It is nothing to do with politicians, respectfully’.¹⁵

Appropriate authority and accountability

The issue of whether the TGA is sufficiently accountable to the public to be charged with ultimate decision-making power in relation to abortifacients has been raised by a number of participants in the debate over this Bill. For example, Federal Minister for Health and Ageing, Mr Tony Abbott, has argued that the issue of access to RU486 ‘is such an important thing that it shouldn’t be left in the hands of the ... unaccountable bureaucrats’.¹⁶ Further, Dr van Gend has argued that:

Parliament is again to debate the regulation of RU486, but this time the stated aim is to remove this professional proper accountability. So, once more a departmental official can approve RU486 without the Minister taking policy responsibility or the parliament knowing. With this amendment Bill for repeal of Ministerial authority for approval of RU486, the parliament is being asked to support an amendment which undermines, for ideological reasons, proper ministerial accountability on a matter of public importance. It would be a triumph of underhandedness over transparency in public life. If this Bill were passed, it would be an abandonment by parliament of their responsibility to grapple with difficult social and ethical questions, instead hiving the issues off to unelected scientists and officials who are not accountable for contentious decisions.¹⁷

Arguments about the need for greater accountability through parliamentary scrutiny of decisions related to RU486 were also prominent in the debates surrounding the 1996 amendments to the Act that brought about the current legislative arrangements in relation to abortifacients. To what extent, though, can the current arrangements be said to provide for such accountability?

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, this would *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 would neither necessarily be

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informed nor have the capacity for any oversight of such a decision. As Senator Allison has argued, at the present time:

the Minister can decide to refuse an application and not indicate to the parliament that he has done so and that he can agree to grant exemptions or approval without providing the reasons to parliament ... There is no way that the parliament can disallow his decision. There is no way the parliament can debate it or have a vote on it.¹⁸

Thus, while there may be sound arguments for having greater accountability in relation to decisions to evaluate, register, list or import abortifacients, it is reasonable to argue that the current arrangements provide for greater restrictions but only limited parliamentary accountability. Greater parliamentary accountability could, however, be provided through changes such as requiring the Minister to table decisions not to approve applications and/or making any decisions in relation to abortifacients disallowable. Such changes may even have been contemplated recently by Mr Abbott when he recently argued that in relation to abortifacients ‘there should be the accountability of a ministerial decision and the possibility of subsequent parliamentary disallowance.’¹⁹

Increased accessibility of abortion

The possibility of increased availability of abortion following any decision to approve RU486 for use in medical abortion in Australia has also figured prominently in the recent debate.

For example, some in favour of approving RU486 have argued that it may make abortion more accessible to women who have traditionally not had such access (such as women in rural areas). This has led to concerns being raised about the health risks this might present to women in these areas and the subsequent emphasis by medical experts on the need to ensure that there is an appropriate level of back-up medical care to address possible complications arising from medical abortion using RU486.

Others have raised concerns about the possibility that availability of RU486 for medical abortion could lead to an increase in the overall abortion rate. It should be noted, however, that there is very little evidence available from which to draw conclusions about the connection between availability of medical abortion and the overall abortion rate. However, the very few studies that have addressed this question appear to indicate that, in the countries assessed, the availability of medical abortion has not led to an increase in the abortion rate.

For example, one study considered trends in abortion rates across France, Great Britain and Sweden (as measured as the number of abortions (at all gestations) per 1,000 women aged between 15-44).²⁰ The study found that the abortion rate in France, England and Wales remained stable from the date of approval of RU486, to the most recent year data was available. In France the abortion rate of 13 per 1,000 women in 1987 was the same as the abortion rate in 1997. In England and Wales, the rate of abortion of 16 per 1,000

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women in 1990 was the same in 2000. In Sweden, the abortion rate fell slightly—from 21 per 1,000 women in 1990 (the year before its introduction) to 18 per 1,000 women in 1999. In Scotland the rate rose slightly from 9 per 1,000 in 1990 to 11 per 1,000 in 2000.

Party positions

Unlike the 1996 amendments to the Act that brought in the current restrictions relating to abortifacients, the government and the opposition have both declared a free vote in relation to this Bill.²¹ As such, none of the major parties have officially declared positions on the Bill.

Members of the government to have stated positions on the Bill include Deputy Prime Minister, Mr Mark Vaile (opposed), Mr Abbott (opposed), Government Leader in the Senate, Senator Nick Minchin (opposed), Dr Sharman Stone (in favour) and Dr Mal Washer (in favour).²² The Prime Minister, Mr Howard, has said that he remains undecided.²³

Members of the opposition reported to have declared positions on the Bill include Opposition Leader in the Senate, Senator Chris Evans (in favour), Senator Jan McLucas (in favour), Senator Steve Hutchens (opposed) and Senator Helen Polley (opposed).²⁴ The Leader of the Opposition, Mr Kim Beazley, and the Shadow Minister for Health and Ageing, Ms Julia Gillard, do not appear to have publicly declared positions on the Bill—though, Ms Gillard has stated that ‘the base Labor position and my position on this is that RU486 ought to be treated like every other medication and that is [that] the safety and the circumstances in which it can be used should be determined by the Therapeutic Goods Administration’.²⁵

The Greens and Democrats support the Bill, while Family First Senator Steve Fielding is opposed.²⁶

Potential technical problem One issue not dealt with in the Bill, is the fact that under the *Customs (Prohibited Imports) Regulations 1956* (the Regulations), abortifacients may not be imported without the written permission of the Secretary of the Department of Health and Ageing.

The relevant regulation is 5H(2), which says importation of any good listed in Schedule 8 is prohibited unless it is authorised in writing by the Secretary or a person authorised by the Secretary. **Schedule 8 of the regulations lists ‘Abortifacients, that is, substances that purport to produce abortion’.**

This suggests that, even if the RU486 Bill was to pass through the Parliament (thereby removing the ‘restricted goods provisions’ relating to abortifacients from the Act and the TGA was to approve an application from a sponsor to include RU486 on the ARTG, the sponsor would still require the permission of the Secretary (or authorised officer) of the Department of Health and Ageing before importation of the drug could occur.

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It is unclear from the regulations whether permission from the Secretary (or authorised officer) requires only one (open-ended) instrument giving permission or whether, alternatively, the sponsor needs to obtain permission every time the drug is imported.

A further issue to be aware of, is that under regulation 5H(3) the Secretary (or authorised officer) could potentially impose conditions on the permission which make importation difficult.

One way of addressing the above issues would be to **amend the Act (through an amendment to the RU486 Bill) to ensure that the reference to abortifacients in Schedule 8 of the above Regulations did not apply to abortifacients approved for use in Australia by the TGA**. A possible wording for the amendment could be:

notwithstanding anything in the Customs (Prohibited Imports) Regulations 1956, if approved for use in Australia by the TGA, abortifacients will not require the permission of the Secretary of the Department of Health or authorised officer prior to importation.

This would mean that, if the TGA decided to include RU486 on the ARTG, there would be no additional requirement for permission to import the drug.

Main provisions

Schedule 1—Amendment of the *Therapeutic Goods Act 1989*

Subsection 3(1) repeals the definition of ‘restricted goods’.

Section 6AA repeals the section relating to importation of restricted goods.

Section 6AB repeals the section stating that Regulations exempting restricted goods from the operation of a Part of this Act must not take effect before the expiration of the time within which a House of the Parliament may disallow the regulations.

Section 23AA repeals the section relating to evaluation or registration or listing of restricted goods.

Subsection 57(9) repeals the subsection stating that the Minister must not delegate his or her powers or functions under section 6AA or 23AA.

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Concluding comments

This Bill is particularly controversial, especially given its broader association with the sensitive social issue of abortion and the fact that many people on either side of the abortion debate have views that are strongly held. Those who support the Bill believe that the appropriate body for making decisions in relation to the evaluation, registration, listing or importation of abortifacients is the TGA, rather than the Minister for Health and Ageing. In other words, they argue that abortifacients should be treated like all other medicines in Australia. Those against the Bill argue that decisions about abortifacients, like RU486, require an additional layer of accountability of the kind currently provided by the restricted goods provisions in the Act. As argued above, however, while the current arrangements provide restrictions on abortifacients, it is questionable whether they could be said to offer a significant degree of parliamentary accountability (given that they are not disallowable and that the Minister is not required to table decisions not to approve such drugs).

Endnotes

1. 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.
2. [List of mifepristone approval](http://www.gynuity.org/index.html), Gynuity Health Products website <http://www.gynuity.org/index.html>
3. *Medicines Regulation and the TGA*, Therapeutic Goods Administration, Department of Health and Ageing, September 2004, p. 1.
4. This responsibility is exercised in cooperation with State and Territory Governments and industry. There are five main processes used by the TGA in regulating therapeutic goods: pre-market evaluation and approval; development, maintenance and monitoring of the systems for listing medicines; licensing of manufacturers; post-market monitoring; and assessment of medicines for export.
5. In 2005, two Queensland-based gynaecologists, Caroline de Costa and Michael Carrette, submitted an application to become Authorised Prescribers of RU486. See, for example, M. Price, ‘Doctor’s push for abortion drug’, *Australian*, 20 October 2005. The Authorised Prescriber program enables the TGA to grant medical practitioners authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients (identified by their medical condition). The medical practitioner can prescribe that product for that condition to individual patients in their immediate care without further TGA approval.
6. *Medicines Regulation and the TGA*, op. cit., p. 4.

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7. *ibid*, p. 4.
8. *Therapeutic Goods Act 1989*, sections 23AA(1) and 6AA.
9. 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.
10. Senator Fiona Nash, [Therapeutic Goods Amendment \(Repeal of Ministerial responsibility for approval of RU486\) Bill 2005: Second Reading Speech](#), Senate, *Debates*, 8 December 2005, p. 1.
11. [Therapeutic Goods Amendment \(Repeal of Ministerial responsibility for approval of RU486\) Bill 2005: Explanatory Memorandum](#), p. 1.
12. *ibid*.
13. Submissions to the Inquiry can be accessed from http://www.aph.gov.au/Senate/committee/clac_ctte/ru486/submissions/sublist.htm, accessed 6 February 2006. Transcripts from the Inquiry hearings can be accessed from http://www.aph.gov.au/Senate/committee/clac_ctte/ru486/hearings/index.htm, accessed 6 February 2006.
14. 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; C. de Costa, ‘Medical abortion for Australian women: it’s time’, *Medical Journal of Australia*, vol. 183, no. 7, 2005, pp. 378–80.
15. *Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005*, p. 75.
16. ‘Abortion drug issue one of principle: Abbott’, *Australian Associated Press*, 1 February 2006.
17. *Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005*, p. 66.
18. *Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005*, p. 71.
19. ‘Abortion drug issue one of principle: Abbott’, *Australian Associated Press*, 1 February 2006.
20. R. Jones and S. Henshaw, ‘Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden’, *Perspectives on Sexual and Reproductive Health*, Volume 34, Number 3, May/June 2002, p. 156.
21. M. Grattan and N. Khadem, ‘Howard cautious as vote on abortion drug nears’, *The Age*, ^ Febraury 2006.

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22. See L. Wright, 'Vaile says 'no' to pill', *Sunday Herald Sun*, 5 February 2006; 'Abbott stand on abortion pill', *Daily Telegraph*, 2 February 2006; N. Khadem, '2006: the issues to watch', *The Age*, 2 February 2006; S. Peatling, 'Lobbying storm in abortion pill debate', *Sydney Morning Herald*, 7 February 2006.
23. M. Grattan and N. Khadem, op. cit.
24. See J. Topsfield and N. Khadem, 'Fear and fury on eve of RU486 vote', *The Age*, 7 February 2006; H. Low Choy, 'Polley defies poll majority', *Hobart Mercury*, 3 February 2006.
25. J. Gillard, Shadow Minister for Health, *TRANSCRIPT DOORSTOP INTERVIEW—8:15am—Parliament House, Canberra. Monday 6 February 2006*, media release, 6 February 2006.
26. J. Topsfield and N. Khadem, op. cit.

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