Early medical abortion: legal and medical developments in Australia

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ABSTRACT

- Mifepristone is a safe, effective and relatively cheap drug that plays an important role in women's health care and is widely used for early medical abortion in many countries.
- The Therapeutic Goods Administration (TGA) can authorise mifepristone to be imported into and marketed in Australia. To date, no pharmaceutical company has applied to register mifepristone in Australia.
- The TGA can also permit medical practitioners to prescribe medicine that is not approved for marketing in Australia under the Authorised Prescribers scheme. The number of approvals for mifepristone has gradually increased, in spite of a complicated and protracted application process.
- Approval under the Authorised Prescribers scheme requires medical practitioners to comply with state or territory legislation. Abortion laws in Australia vary between jurisdictions, and in some states the law is unclear and confusing.
- The decriminalisation of abortion in all Australian jurisdictions would protect medical practitioners from criminal liability, promote the health interests of Australian women, and discourage the illegal importation of abortifacients that are being used without quality controls or medical supervision. The Victorian *Abortion Law Reform Act 2008* is one legislative model for this.

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See also pages 9, 13

There is no doubt that abortion is a controversial issue; it is also a common, safe and publicly subsidised medical procedure in Australia. Although there are no completely reliable national statistics, the Victorian Law Reform Commission (VLRC) accepted that the estimated annual number of abortions performed in Australia is between 80 000 and 85 000.[1] On the question of public opinion in Australia, the VLRC concluded that the majority support a woman's right to choose, but an undefined subset of these people also support restrictions based on the grounds for abortion and gestational age.[1] This finding strongly suggests that there is considerable support in Australia for a woman's right to choose an abortion early in an unintended pregnancy.

Most abortions performed in Australia are surgical first-trimester procedures,[1] and very few women have access to early medical abortions (EMAs), which are endorsed by both the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Royal College of Obstetricians and Gynaecologists in the United Kingdom.[2,3] An EMA refers to "an early pregnancy termination (usually before 9 weeks' gestation) performed without *primary* surgical intervention and resulting from the use of abortion-inducing medications".[4] The most common, most effective and safest medication is the combination of misoprostol and mifepristone (formerly RU486), which was first developed and marketed by French pharmaceutical company Roussel Uclaf in the 1980s.[5] Studies comparing EMA and surgical abortion have found that EMA has a lower completion rate; however, 90% of women avoid the risks associated with anaesthesia and surgical instrumentation of the uterus.[6-8]

The VLRC notes that the availability of EMA has not been shown to increase the rate of abortion; EMA has become an alternative to surgical abortion, not a replacement.[1] In the United States, the number of all abortions is decreasing and the number of mifepristone abortions is increasing. Mifepristone abortions represented about 14% of all abortions and 21% of early eligible abortions in 2007.[9] A recent study suggested that the use of mifepristone may have "contributed to a trend toward very early abortions" in the US.[9] In England and Wales, medical abortions accounted for about 38% of total abortions in 2008; the proportion had more than doubled in the previous 5 years. Of abortions performed between 3 and 8 gestational weeks, 51% were medical and 49% were surgical.[10] Internationally, EMA plays an important role in women's health care and will become even more relevant with the development of earlier and more accurate antenatal blood tests.[11] Furthermore, in countries where EMA is increasingly accepted, research is being conducted to improve the experience for women and develop a more convenient same-day regimen.[12]

Even though mifepristone is widely used overseas for early abortions, most women with an unintended pregnancy in Australia cannot make this choice because mifepristone is not registered on the Australian Register of Therapeutic Goods (ARTG) and is classified by the Therapeutic Goods Administration (TGA) as an unapproved drug. It has been reported that some Australian practitioners use the less effective methotrexate–misoprostol combination,[13] which most medical practitioners in the US and the UK abandoned after the mifepristone–misoprostol combination was approved by the relevant regulatory authorities.[5,10,12,14]

Here, I examine the legal and regulatory issues in Australia concerning the treatment of women dealing with an unintended pregnancy who would prefer to choose an EMA rather than a surgical abortion.[13,15-17]

Early medical abortion: overseas experience

RU486 was licensed as Mifegyne (Exelgyn Laboratories, Paris, France) in the UK in 1991 without any major controversy, but the licensing of RU486 in the US and New Zealand was more complicated. In the US, obtaining approval from the Food and Drug Administration (FDA) was very controversial, and mifepristone was banned by the government from 1988 to 1993. In 1993, President Clinton directed the FDA to review the scientific basis of the ban and, once it was subsequently lifted, Roussel Uclaf transferred the US rights to a New York non-profit organisation, the Population Council, that performed the clinical study required for FDA approval. However, US pharmaceutical companies would not market mifepristone due to the threat of boycott. A small

company, Danco Laboratories, was incorporated solely to manufacture and market mifepristone. To this day, details of Danco's headquarters and operations are kept secret because of security issues. In 2000, the FDA gave its final approval for the use of mifepristone under the trade name Mifeprex in the US.[18,19]

In New Zealand, established pharmaceutical companies refused to become involved with mifepristone in the 1990s because of international events and the small market. Five specialist medical practitioners experienced in abortion care overcame this obstacle by forming Istar, a non-profit company, in 1999. Istar signed an agreement with the French manufacturer Exelgyn to import Mifegyne, and in 2001 the use of Mifegyne for early abortions was approved by the Ministry of Health.[20]

Early medical abortion: the Australian experience

In 1994, the TGA permitted Monash University and Family Planning Victoria to participate in World Health Organization international trials designed to compare the efficacy of two different regimens of mifepristone followed by misoprostol for medical abortion.[5,21] A separate survey associated with the WHO trial found that 38 Australian respondents were satisfied with the method, and concluded that "medical abortion provided women with a more active role in the process, thus allowing them to achieve a certain degree of autonomy".[22]

These and other trials triggered public controversy in Australia,[20] leading to the anti-abortion independent senator Brian Harradine successfully moving an amendment to the *Therapeutic Goods Act 1989* (Cwlth) in 1996. The *Therapeutic Goods Amendment Act 1996* (Cwlth) gave the Minister for Health and Ageing the right to veto applications to import an abortifacient drug into Australia and required ministerial approval to be tabled in Parliament. Consequently, no applications to import and market mifepristone in Australia were made by pharmaceutical companies — presumably because potential sponsors judged it not worth the trouble and expense.[23] This political interference with the risk management role of the TGA led to a de-facto ban on the use of mifepristone for EMAs, as Australian women were denied the choice of a safe alternative to surgical abortion.[24]

A decade later, after a cross-party vote in federal Parliament, the *Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Act 2006* (Cwlth) removed the special requirement for ministerial approval to import and market mifepristone for the purpose of EMA.

Therapeutic Goods Administration authorisation

Before medication such as mifepristone can be commercially supplied in Australia, it must be entered on the ARTG. For a therapeutic good to be entered on the ARTG, a sponsor company must apply to the TGA, so that the TGA may evaluate the quality, safety and efficacy of the medication. To date, mifepristone "has not yet been sponsored by a pharmaceutical company for use in Australia [but] a sponsor may emerge for mifepristone in the near future".[25] No doubt, the political history, small market and Australian abortion laws have deterred potential sponsors.

Under the Therapeutic Goods Act, ss. 18, 19 (1), (4) and (5), the TGA is required to authorise the use of unapproved medicines not registered on the ARTG, such as mifepristone, and one pathway for this is the TGA's Authorised Prescribers scheme. Under this scheme, medical practitioners can be authorised to access drugs that are not approved for marketing. The TGA can authorise individual medical practitioners with relevant training and expertise to prescribe an unapproved drug for a specified class of patients suffering from a life-threatening or otherwise serious illness or condition (Therapeutic Goods Act ss. 19 [5], 31B [3]; *Therapeutic Goods Regulations 1990* [Cwlth] r. 12B).[17] Medical practitioners applying for authorisation must provide clinical reasons, evidence about the seriousness of the condition, and the justification for using the unregistered product in preference to other available treatments. Applicants must be engaged in clinical practice in or outside a hospital and have the endorsement of a hospital ethics committee or appropriate specialist college. The role of the ethics committee is very important; it must assess the safety of the product and the suitability of the applicant medical practitioner, and provide a letter of endorsement to support the application. TGA authorisation is subject to a number of other conditions, including:

- The authorised prescriber must obtain written informed consent from each patient (or the legal guardian) after advising the patient that the drug is not approved in Australia. The informed consent form should include information about the product, as well as the benefits, risks and side effects, the possibility of unknown risks and side effects, and alternative treatments that are already available.
- The authorised prescriber must continue to have an appropriate endorsement.
- The authorised prescriber must comply with relevant state or territory legislation.[17]

These conditions reflect consent laws relevant to all medical procedures and do not impose an undue burden on medical practitioners; however, as I will discuss, the requirement to comply with abortion laws may be problematic in some states.

Two gynaecologists, Professor de Costa and Dr Carrette from the Cairns Base Hospital, have documented their experience with an application under the Authorised Prescribers scheme.[24] In December 2005, 2 months before the Harradine Amendment was repealed, and after the Cairns Base Hospital Ethics Committee had granted approval, de Costa and Carrette applied to the TGA for permission to prescribe mifepristone (with misoprostol) to appropriate patients residing in Cairns for induced abortion up to 9 weeks' gestation. Their application was supported by an evidence-based list of medical conditions that would be a major threat to the life or health of a pregnant woman continuing with the pregnancy. In April 2006, the TGA authorised the applicants to prescribe mifepristone, and in June 2006 they were given a permit to import 40 tablets from Istar. The authorisation limited the treatment to women in Cairns with life-threatening or otherwise serious medical conditions exacerbated by pregnancy. De Costa and Carrette found the TGA application process complex and protracted, but also professional and thorough. They noted that there

> is an urgent need for a more proactive approach from individual doctors, professional bodies and Health Departments, at both state and federal level, to make mifepristone widely used and largely uncontroversial, as it is in other countries.[24]

The TGA does not publish information about authorised prescribers, and the public have to rely on sources such as newspapers and media releases for this information.[26] In August 2009, Melbourne newspaper *The Age* reported that 61 medical practitioners in Australia were authorised to prescribe mifepristone.[27]

1 Abortion statutes in Australian states and territories

Jurisdiction	Early medical abortion legislation
Australian Capital Territory	*Health Act 1993* ss. 80–84
New South Wales	*Crimes Act 1900* ss. 82–84
Northern Territory	*Medical Services Amendment Act 2006* s. 11
Queensland	*Criminal Code Act 1899* ss. 224–226, 282
South Australia	*Criminal Law Consolidation Act 1935* ss. 81, 82, 82A (3)
Tasmania	*Criminal Code Act 1924* ss. 134, 135, 164
Victoria	*Abortion Law Reform Act 2008*
Western Australia	*Criminal Code Act 1913* s. 199 *Health Act 1911* s. 334 ◆

State and territory abortion laws

Box 1 refers to the legislation governing EMA throughout Australia. All state and territory laws have been repealed, reformed or modified by parliaments and courts to make provision for some form of lawful abortion.[16] The abortion laws vary between jurisdictions and can be divided into two main categories: "reform" jurisdictions and "offence/defence" jurisdictions.

Box 2 shows the grounds for EMA in both reform and offence/defence jurisdictions. In the reform jurisdictions — Australian Capital Territory, Victoria and Western Australia — the decision to have a first-trimester abortion is essentially a matter to be decided between the woman and her medical practitioner.

In the offence/defence jurisdictions, where the law varies, there are concerns about legal boundaries. Statutes in South Australia, the Northern Territory and Tasmania appoint doctors as gatekeepers and impose various requirements, such as the need for two medical signatures or statutory informed consent, but generally abortions are lawful if medical practitioners act in good faith and comply with the conditions set out in the relevant statute. In New South Wales, the Menhennitt ruling, that was established in the Victorian case *R v Davidson*,[28] followed by Levine J in *R v Wald* and upheld in *CES v Superclinics (Australia) Pty Ltd*, provides a defence if a doctor forms a bona fide belief that an abortion is necessary to preserve the woman's life, health or wellbeing.[28-31] Abortions are not always unlawful, and the case law demonstrates that it is difficult for the Crown to establish beyond reasonable doubt that a defendant did not form a bona fide belief, except in extreme situations such as *R v Sood*, which concerned the offence of termination of a viable fetus.[31]

Queensland abortion law is more complex and uncertain. The wording in the *Criminal Code Act 1899* differs from that in the other states. The common law defence of necessity does not generally apply to the Queensland Criminal Code, but the Menhennitt ruling has been accepted by the Queensland courts.[15,32-36] Nevertheless, it has been argued that there are still uncertainties about the extent to which the Menhennitt ruling applies in Queensland.[15] The surgical benefits defence under s. 282 of the Queensland Criminal Code has also been interpreted as providing a defence, but before 2009 it only covered surgical abortions. In 2009, the Queensland surgical benefits defence was amended to "allow the treatment to be administered medically (for example, through the prescription of drugs) as an alternative to surgical treatment" if an abortion is lawfully indicated.[37] Health professionals acting under the lawful direction of a medical practitioner are

2 Grounds for early medical abortion in each Australian state and territory, by jurisdiction category

Jurisdiction	Grounds for early medical abortion
Reform jurisdictions	
Australian Capital Territory	Request of woman — all abortions must be carried out by a doctor in an approved medical facility.
Victoria	Request of woman — if the doctor has a conscientious objection to abortion, the woman must be referred to another doctor who does not hold a conscientious objection.
Western Australia	Informed consent or for medical, psychological or social reasons. Dependent minors under 16 years of age must have one parent informed and given the opportunity to participate in medical consultation, unless Children's Court makes an exemption order.
Offence/defence jurisdictions	
South Australia	Defence: lawful if two doctors form a bona fide opinion that the pregnancy would involve a greater risk of injury to a woman's life or physical or mental health than terminating a pregnancy; or where there is a substantial risk that the born child would be seriously handicapped. Social factors may be taken into account. Abortions must be performed in a prescribed facility.
Northern Territory	Similar to SA, but one of the medical practitioners must be a gynaecologist or obstetrician unless impracticable. Legal guardian must give consent if the woman is under 16 years of age or lacks capacity.
Tasmania	Similar to SA, but statutory informed consent required.
New South Wales	Defence: lawful if a medical practitioner honestly believes on reasonable grounds that termination is necessary to preserve the woman from serious danger to her life or physical or mental health, taking economic and social grounds into account.
Queensland	Two defences: under the common law, an abortion may be lawful if necessary in similar circumstances to those in NSW. A statutory "surgical/medical benefits defence" applies where a person performs in good faith and with reasonable care and skill a surgical operation or medical treatment to "preserve the mother's life" when reasonable, having regard to the patient's state at the time and her circumstances. ◆

covered by the amendment. The 2009 amendment has not yet been tested in court.

Conclusions

Mifepristone (in combination with misoprostol) is a proven safe and effective drug for early abortion that is cheaper than surgery. TGA approval is necessary to import mifepristone but, to date, no pharmaceutical company has applied to register mifepristone in Australia. Medical practitioners or a non-profit organisation with an interest in women's health could investigate establishing a non-profit corporation along the lines of the New Zealand Istar model. However, there are some differences between the Australian and New Zealand systems that could make the cost prohibitive.

According to media reports,[26,27] the TGA is approving more applications for individual medical practitioners under the Authorised Prescribers scheme; however, information about the number of successful or unsuccessful applications is not available to the public. The TGA must be satisfied that an applicant seeking to use mifepristone for EMA will comply with abortion laws. This condition should not be problematic in the reform jurisdictions (ACT, Vic and WA), but it is not clear how this condition is interpreted in the offence/defence jurisdictions (NSW, NT, Qld, SA and Tas), and there is no public information available about the TGA process. Clearly, the regulatory framework governing mifepristone prescription rights would be less complex if states and territories throughout Australia decriminalised abortion laws. The Victorian *Abortion Law Reform Act 2008* is one legislative model for this. Repealing these laws would protect medical practitioners from criminal liability, promote the health interests of Australian women and discourage the illegal importation of abortifacients that are being used without quality controls or medical supervision — reminiscent of the "backyard" abortions of yesteryear.

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Competing interests

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