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Medical abortion: it is time to lift restrictions

Lifting the special drug status applied to medical abortion medications will enable equitable access

In 2016, the Committee on Economic, Social and Cultural Rights — a collection of human rights experts tasked with interpreting these rights — asserted that abortion services are an integral part of the right to health in its groundbreaking interpretation of the right to sexual and reproductive health.¹

Mifepristone, still often referred to in the media as RU486, was licensed by the Therapeutic Goods Administration for use in Australia in 2012 and added to the Pharmaceutical Benefits Scheme in 2013.^{2,3} Mifepristone is used in conjunction with misoprostol for both early medical abortion (up to 9 weeks' gestation) and later medical abortion in hospital, and this drug combination is now the gold standard for these procedures.^{4,5} The safety, efficacy and acceptability to women of medical abortion using mifepristone compare favourably with these aspects of surgical abortion.⁶

The use of mifepristone was the subject of political controversy in a number of countries, but this was particularly the case in Australia. Specific legislation — the 1996 Harradine amendment to the *Therapeutic Goods Act of 1989* (Cwlth) — was the result of a deal done between the independent senator Brian Harradine and then Prime Minister John Howard, who gave his support to Harradine's legislation restricting the import and use of mifepristone in Australia in return for Harradine's support for the partial privatisation of Telstra.⁷⁻⁹ This amendment meant that, for 10 years, Australian women were not only unable to access the drug but they also knew very little about its increasingly wide and safe use overseas.^{8,9}

The Harradine amendment was overturned by a cross-party group of women senators introducing a bill, first in the Senate and then in the House of Representatives in 2006. However, the controversy surrounding the drug meant that no pharmaceutical company operating in Australia was prepared to manufacture or market it here. This problem was at least partially solved by the use of the Authorised Prescriber legislation of the Therapeutic Goods Administration, which allows doctors to import from overseas, for use in their private practices, safe and effective drugs licensed elsewhere but not in Australia.¹⁰⁻¹² By 2012, more than 80 doctors across the country were authorised prescribers of mifepristone, and several large studies and a number of smaller ones had shown mifepristone use in Australia, as elsewhere, to be safe and effective and highly acceptable to women.^{4-6,10-12}

Meanwhile, French physician and pharmaceutical manufacturer André Ulmann, a long-time activist for women's access to medical abortion in many parts of the world, had been building an application to the Therapeutic Goods Administration for the full licensing of mifepristone in Australia (Dr André Ulmann, CEMAG Care, France, personal communication, October 2012). This required the compiling of an extensive dossier supporting the safety and efficacy of the drug — work supported in part by Marie Stopes International Australia. The approval for the drug was finally granted in 2012;² however, its registration was accompanied by an onerous risk management plan that placed conditions and restrictions on how the drug would be prescribed and dispensed for medical abortion.

The company MS Health, which sponsors the drug, is a separate entity from Marie Stopes International Australia. Doctors wishing to prescribe mifepristone must register (at no cost) with MS Health and must complete a 2–3-hour online education program in order to become registered prescribers.² Exemptions from this program have been granted

to Fellows and advanced diplomates of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, but these doctors must still be registered prescribers and registrations must be renewed regularly. Registered prescribers need to liaise with pharmacists who have themselves been registered with MS Health. Unlike other licensed drugs, mifepristone is not universally available in Australian pharmacies.^{2,13} The company must provide a 24-hour telephone aftercare service and was also required to complete a phase 4 study of the first 15 000 patients treated. At present, MS Health is the sole distributor of mifepristone in Australia.

There may have been some justification for all these requirements in 2012, when the drug was (fairly) new in Australian practice. It has now been licensed for more than 6 years and over 100 000 medical abortions have been performed using it. Four large studies and several smaller ones examined its use in Australia, confirming the results of a large number of international studies.^{3-6,10-12,14-17} There is also a large study detailing the safe use of medical abortion provided via telemedicine across Australia.¹⁴ Used correctly with misoprostol (administered buccally in Australia) up to 9 weeks' gestation for outpatient (usually in-home) early medical abortion, the drug combination brings about successful expulsion of products of conception in over 95% of cases.^{11,12,15,16} Side effects are generally minimal and tolerable when women are well informed about them, and complications, the most important ones being incomplete abortion requiring surgery, haemorrhage, and infection, occur in 4.8%, 0.13% and 0.11%¹⁶ of patients, respectively. In Australia, the results for the use of mifepristone later in the pregnancy also equate well with those of overseas studies.^{10,17}

There is no good reason why mifepristone, which has minimal side effects and is supplied uniquely as a single tablet, needs to remain indefinitely as a special drug — a status that contributes to the stigmatisation of abortion itself and of the many women who make the decision to terminate a pregnancy. The procedure of medical abortion can be easily managed by any medical practitioner, including in rural practice, who routinely cares for women presenting with spontaneous miscarriage. No extra procedural skills are required, provided the practitioner can refer those women needing surgical evacuation of incomplete abortion to an appropriate hospital.^{6,8,14}

Registered medical practitioners are allowed to freely prescribe a wide range of drugs; they have been trained to do so, are expected to discriminate between those drugs they are familiar with and those they need to find information about, and are well aware of how to find that information. The various insulins, for example, require expert knowledge of diabetes, blood chemistry, dosage, likely effects and side effects on the part of the prescriber, but no mandatory training and registration are needed for their prescription. Graduation from medical school and an expectation that doctors undertake continued professional development to ensure their skills and knowledge provide up-to-date medical services are considered sufficient. The same standards should be applied to mifepristone.

The continuation of the special status of mifepristone contributes to the poor public sector provision of early medical abortion, which is restricted to a few facilities in major centres. Recent research shows that Australian women who are disadvantaged socially, economically or geographically continue to have limited access to both medical and surgical abortion.¹⁸ General practitioners (GPs) are the group most suited to use early medical abortion as part of a holistic women's reproductive health care. However, while numbers of registered prescribers are slowly rising,¹⁸ we believe that GPs who might otherwise prescribe it are put off by the need for special registration, even though most GPs want women requesting termination of pregnancy to be able to readily access safe effective services. This reluctance contributes to the ongoing stigma around abortion both within the profession and in society as a whole.

It is time for mifepristone to be relieved of its special status and made available universally for prescription by registered medical practitioners who wish to do so and be likewise supplied by all pharmacies. Medical abortion is now available to women in many parts of Australia, but not all. Despite the introduction of telemedicine abortion services, these are not available to all women, especially in rural and remote areas, and in particular to Indigenous women, who often present later and have to travel further to access abortion care. It is time to make mifepristone and early medical abortion accessible to all Australian women.

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