

RU486 registration welcomed, but more detailed information needed

Neil Bramwell

THE wider availability of early medical abortion following TGA registration of mifepristone and misoprostol last week has been welcomed, but with caveats.

Mifepristone (RU486) has been available in Australia since 2006 through the TGA Authorised Prescriber Scheme but, under the provisions of registration, the drug will now be distributed through MS Health, a not-for-profit pharmaceutical subsidiary of Marie Stopes International Australia (MSIA).

Only medical practitioners recognised by MS Health as

having completed their own free online training module, developed as part of a risk management program, will be able to prescribe the drugs for abortion.

The favourable safety profile of RU486 was demonstrated in a study of >13,000 women who had a medical termination (up to 63 days' gestation but most at 6–7 weeks) between 2009 and 2011 at MSIA clinics.

This showed clinic administration of mifepristone with later self-administration of buccal misoprostol to complete the abortion had a low failure rate (3.5%), and low rates of haemorrhage (0.1%)


and known or suspected infection (0.2%). One woman, who did not seek medical advice despite signs of infection, died from sepsis.

But Professor Caroline de Costa, in an *MJA* editorial written with fellow Cairns gynaecologist Dr Michael Carrette, while acknowledging the regimen was “safe and effective” also expressed concern over some reported outcomes that had implications for the national provision of mifepristone.

“Access to a telephone helpline alone is insufficient, especially for women in rural areas,” they wrote, adding that arrangements

for emergency care in the rare event of complications needed documentation.

Women in poor socioeconomic circumstances, without suitable home support, might be better served by surgical abortion, they stated.

Professor de Costa told *MO* she wanted more information on several issues including the planned price but also the fact that the mifepristone approval in Australia was for early medical abortions up to seven weeks' gestation, whereas there may be a demand up to nine weeks. 

MJA 2012;197:257-58;282-86