SUPPLEMENTARY SUBMISSION TO SENATE INQUIRY INTO THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL RESPONSIBILITY FOR RU-486) BILL 2005

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Following my submission to the Inquiry of 14 December I wish to make a supplementary submission. This is because I believe that there may have been some confusion over the medical evidence presented at the Committee hearing of 15 December concerning exactly how early-pregnancy medical abortion is carried out, and in particular what women undergoing this procedure can expect to happen.

All regimens reported in the overseas literature confine medical abortion in which the expulsion of the products of conception is planned to take place outside a hospital or clinic, to pregnancies of 63 days (nine weeks) in length or less, dated from the first day of the woman's last menstrual period and confirmed by ultrasound scan. At 8-9 weeks the developing embryo is no more than 1.5 cm in length; at 5-7 weeks it is considerably smaller. Pregnancy can be accurately diagnosed with a home pregnancy test at four weeks since the last menstrual period. Most abortions, medical or surgical, take place before 8 weeks of pregnancy.

All regimens for early medical abortion require the woman (after appropriate discussion, counselling and examination by a medical practitioner) to take an oral dose of mifepristone (RU 486) in front of the doctor or a person under the supervision of the doctor i.e. a registered nurse. Subsequently, usually 1-3 days later depending upon the particular regimen, the woman is administered misoprostol or a similar drug either orally or vaginally. In many places this administration also takes place in a hospital or clinic and the abortion proceeds at that site, however overseas studies have been carried out in which the woman herself vaginally administers misoprostol and

undergoes abortion at home; these studies have found that this process is safe and very acceptable to women.

In my application currently with the Therapeutic Goods Administration to become an Authorised Prescriber of mifepristone I have included a planned protocol which involves vaginal insertion of misoprostol by myself or my colleague in our consulting rooms in Cairns; after one hour's observation in the rooms the woman will be able to go home within Cairns (at a distance of not more than 8 km from the consulting rooms) in the company of a designated support person who undertakes to stay with her until the abortion process is complete. 24 telephone access to emergency care from myself or my colleague will be available and suitable transport must be available to the woman should she require to come to the consulting rooms or a hospital. Medical abortion will only be carried out if these conditions are met.

In 90-95% of cases administration of these two drugs results in expulsion of all the products of conception within 4-8 hours. The effect of mifepristone is to totally interrupt the pregnancy so that what is expelled consists of the tiny embryo - probably not identifiable - placental tissue, membrane and blood clot. The process is very similar to a spontaneous miscarriage, something which many women undergo every day in this country. The woman experiences temporary heavy bleeding, heavier than a normal menstrual period but nevertheless manageable with the use of sanitary pads which would then be disposed of in the same way as the woman deals with pads and tampons used for menstruation. Pain requiring strong analgesics is experienced by about 60% of women and it is usual to anticipate this and provide analgesia in all regimens.

Some women will require a further dose of misoprostol about 8 hours after the initial dose to complete the abortion, and some will take longer than 8-12 hours for the process to be complete. Some bleeding continues following medical abortion, as it does following surgical abortion, miscarriage and normal birth, but this generally reduces rapidly in amount over a number of days and is acceptable to most women. A small proportion of women will need further medical examination either to remove products of conception which are present in the cervix or vagina or to undergo a surgical evacuation of the uterus in an operating theatre. At all times a woman

undergoing a medical abortion with mifepristone/misoprostol outside a hospital/clinic setting must have immediate access to emergency care as a very small number will have vaginal bleeding heavy enough to warrant immediate surgical treatment and rarely, blood transfusion.

The embryo expelled in an early medical abortion is always less than 1.5 cm in length and will, in the days since the mifepristone was administered, have undergone considerable resorption. Women will not see large recognisable fetal parts in the tissue and fluid passed.

Mifepristone is also used overseas for abortions later in pregnancy and is particularly effective for late termination for fetal abnormality. In this case the drug should be administered *in hospital* and the woman should remain *in hospital* until the abortion is complete. Women undergoing later termination require expert nursing and medical care and access to intravenous therapy, suitable analgesia and an operating theatre if needed. In later terminations a recognisable fetus is certainly often passed and women require the support of nursing and other staff through this process. There is no place for late medical abortion outside a hospital setting.

I would emphasise to the members of the Committee that numerous overseas studies have shown the process of medical abortion to be very acceptable to women, while nevertheless not influencing their decision for abortion – rates of abortion have remained the same in countries where medical abortion has become available. Women of reproductive age are accustomed to regular vaginal bleeding and often to a degree of pain with this and so may be less daunted by the prospect of the realities of medical abortion than some of the male members of the Committee might imagine. Medical abortion can also increase a woman's sense of control over the process of abortion; she may in addition appreciate the degree of privacy and lack of invasion which medical abortion provides in contrast to surgical abortion. However it is recognised in all overseas studies that many women will continue to opt for surgical abortion when they have a choice of the two methods.

It is unfortunate that this debate has focused on abortion rather than the terms of the Inquiry which deal with the unusual power of the Minister for Health and Ageing to

continue the ban on mifepristone rather than allowing the drug to be assessed by the TGA. However since this is the case I would like to make one further medical observation on the topic of abortion generally. It has been said to the media that medical abortion is “the worst possible way to have an abortion.” As an obstetrician and gynaecologist with more than thirty years full-time caring for women I can assure you that this is not the case. The worst possible way to have an abortion is illegally and unsafely, as still happens in many parts of the world, leading to the deaths of some 150.000 women world-wide each year. I have personally witnessed women dying or chronically ill from unsafe illegal abortion, as a medical student in Ireland in the late 1960s, when poor Irish women were unable to afford the trip to England where the 1967 Abortion Act was in place. I have also seen women dead from illegal abortion, or permanently damaged by its effects, when working in Papua-New Guinea, and in New South Wales in the 1970s and early 80s, amongst immigrant women who did not realise that safe abortion was unable or who were unable to access it. Under no circumstances should the current abortion services for Australian women be in any way curtailed or threatened so that even a single woman feels compelled to seek an unsafe solution to an unplanned pregnancy.