

FIAPAC - International Federation of Professional Abortion and Contraception Associates
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Re: Submission for the Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

Sir,

Please allow me to comment on the current debate on medical abortion and more specifically on the Inquiry into TGA.

Please understand these comments on the basis of my professional background as:

- being a specialist in Obstetrics and Gynaecology
- having more than 20 years of clinical experience in medicine and 10 years clinical experience with medical as well as surgical abortion
- being a member of the Research Group on Reproductive Health at the prestigious Karolinska University Hospital in Stockholm (www.reproductivehealthresearch.org/) and having recently finished a PhD there on „Improving medical abortion” (<http://diss.kib.ki.se/2005/91-7140-458-9/>)
- being president of the international non-profit association FIAPAC (International Federation of Professional Abortion and Contraception Associates, www.fiapac.org) and
- the published literature in medical peer reviewed journals.

The current debate on the abortion pill mifepristone, formerly also called RU 486, in Australia resembles very much a virtual discussion. Most people do not have any real experience with this treatment, neither professional nor personal. Therefore many contributions are more based on personal fantasies than on facts.

Please allow me therefore to complete the current debate, based on my personal experience in treating women with mifepristone since more than 10 years now.

Background and worldwide experiences:

The drug has been approved in 31 countries so far, since its first marketing in France in 1988. Since, more than 1.5 million women have been treated with mifepristone in Europe alone.

The well documented efficacy and safety of medical abortion has let the leading professional bodies to include it in their evidence based guidelines (WHO, RCOG in the UK, Planned Parenthood Association of America, ANAES in France etc.) Please find a

list of guidelines at the link section of www.fiapac.org.

Furthermore mifepristone has recently been included in the List of Essential Drugs of WHO. This list contains the most basic drugs, which WHO recommends all countries to approve. Or in the words of WHO, it “presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions”.

(www.who.int/medicines/publications/essentialmedicines/en/index.html)

The treatment of medical abortion resembles the course of a spontaneous miscarriage. In clinical terms it cannot be distinguished from so called „corpus luetum insufficiency” which is a common cause of miscarriage.

However medical abortion has the advantage of being a planned intervention as compared to a spontaneous miscarriage, which can happen at any time in pregnancy.

Mifepristone is also approved in most European countries for late abortions done for medical reasons and is recommended for this indication by several evidence-based clinical guidelines like the RCOG in the UK and WHO. Furthermore, mifepristone followed by a prostaglandin has become the standard for this indication in many European countries. It has several advantages over the older regimen, consisting of prostaglandin alone: less side effects, less health risks for the woman, shorter duration until delivery and far less pain. Unfortunately the outdated regimen using prostaglandin alone is still the standard of care in those countries where mifepristone is not available. Approving mifepristone for this indication is urgently needed if evidence based medicine is to be applied for women in the difficult situation of undergoing a medically indicated late abortion.

Mifepristone is also highly effective and far superior to all alternatives for cervical priming prior to a surgical intervention.

Advantages and disadvantages of medical abortion:

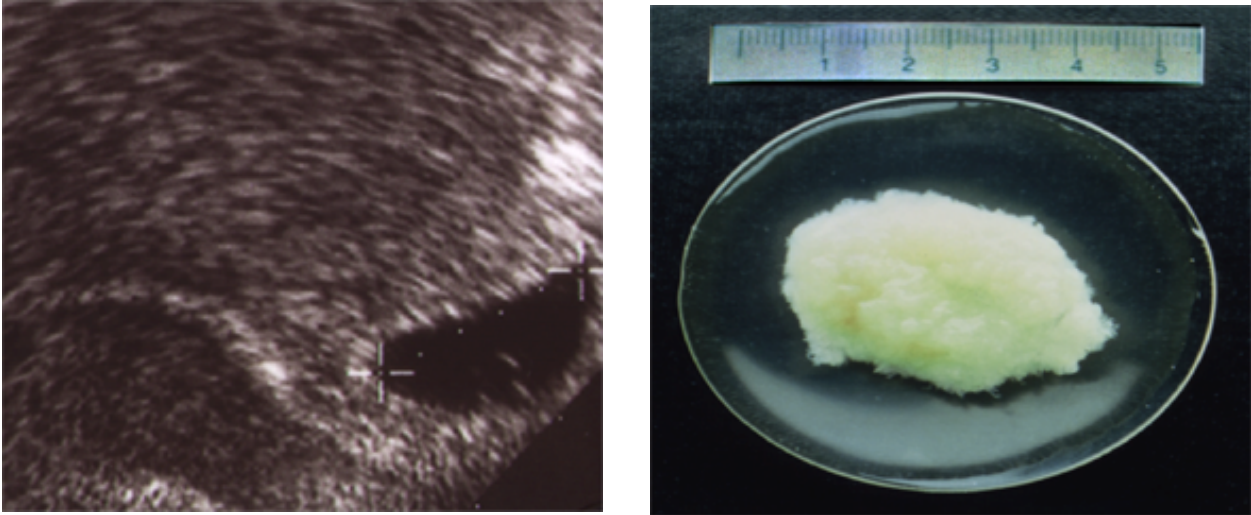
Women choose medical abortion over the surgical method mainly for three reasons.

They want to:

- avoid a surgical intervention
- keep control over their body
- have the abortion done as early in pregnancy as possible without any unnecessary delay.

The last aspect is of special importance for them. Embryonic cardiac activity develops around 6 1/2 weeks gestation and most women will come for an abortion before this stage, provided they have unrestricted access to medical abortion. And for many this method is the only option as most providers are reluctant to perform a surgical abortion at that early gestation. (see pictures 1 and 2)

Furthermore most women are highly satisfied with their choice of medical abortion after the treatment as has been confirmed by several studies.



Picture 1 and 2: Gestational sac at 6 weeks gestation in the uterine cavity and expelled after medical abortion; no embryonic cardiac activity yet (www.abtreibung.at/media/Fruchtsack_6_Wochen.jpg)

Medical abortion is as effective and safe as the surgical method. However women undergoing medical abortion witness the blood loss and also perceive it to be heavier than women undergoing surgical abortion with vacuum aspiration (Holmgren 1992). Two studies compared the blood loss with surgical abortion and found significantly more bleeding in medical abortion but no significant change in haemoglobin levels (Chan et al., 1993, Prasad et al., 1995). Also, clinical measures showed no significant difference in blood loss between surgical and medical abortion in another big study (Harper et al., 1998).

A very small percentage of women requires curettage for heavy bleeding (less than 1 %) and provisions have to be made for these few cases. However sudden heavy bleeding is also an inherent risk at any time in normal pregnancy. Therefore no specific backup measures have to be taken for medical abortion, in places where women are sufficiently followed for normal ongoing pregnancies.

The rate of backup curettage in experienced centres is below 2%, all reasons taken together. This is rather low compared to the results of a recent study giving a figure of 5% for complications after surgical abortions. (Zhouet et al. 2002)

Infection after medical abortion:

There have been 4 tragic death cases in the US due to septic shock over the last years. Surprisingly all of them occurred in California. A number of unsubstantiated theories have been raised, but no casual relationship with mifepristone has been found so far by the CDC and FDA, even after thorough examination. See:

www.cdc.gov/mmwr/preview/mmwrhtml/mm5429a3.htm.

As tragic as these cases are, one has to see them in perspective. Nothing of this kind has been reported in Europe in the last 15 years and more than 1.5 million women being treated. And it is safe to assume that tragic cases like these ones would have been reported, given the high public awareness on this topic.

Mifepristone a gender issue?

Mifepristone is available since more than 16 years now. It took many years for the approval in those countries where it is available. However most women in the world still have no access to this safe and effective drug.

There is another drug, which was recently approved within a couple of weeks almost worldwide. The approval has not been delayed although the drug has been associated with a high number of death cases: 130 American citizens died during the first 6 months of marketing. Surprisingly these death cases have caused only limited public debate and not a single country has so far pulled the drug from the market. It is left for speculation whether there is an underlying gender aspect explaining the different handling of mifepristone and Viagra®.

(Please see the FDA homepage for more details on the mentioned death cases:

www.fda.gov/cder/consumerinfo/viagra/safety3.htm

Medical abortion in rural areas

Medical abortion has been approved long ago and is since widely used in many countries ranging from Western Europe to the US, Tunisia to Vietnam and Taiwan to South Africa. The regimen has proven to be safe and effective under very different circumstances. It is quite difficult to understand the fear expressed in the minutes to the Minister of Health that it „would substantially increase the risk for women” in rural areas in Australia, when there is so much evidence to the contrary.

Would not doctors working in rural areas be in the best position to judge which of all available treatments are best for a given patient? And would it not be the role of the health authorities to make all safe and effective treatment options available to the doctors so that they can choose in the best interest of a their patients?

Living in a remote area obviously reduces access to health care facilities. However this is true for all health aspects, including for example spontaneous pregnancy. It seems important to underline that the availability of medical abortion does not add any additional health risk for women living in an area where a spontaneous pregnancy can sufficiently be followed.

In conclusion:

Mifepristone has become the standard of care for several indications in a number of countries. Consequently all evidence-based recommendations include mifepristone and WHO has included it into the List of Essential Drugs.

It is therefore difficult to understand why a developed country like Australia would delay or restrict access to mifepristone despite the overwhelming evidence and experience documenting its safety and effectiveness. Furthermore is difficult to understand why a developed country would install a professional body for the examination of new drugs, like the TGA when their evidence based decisions are then subject to the personal judgement of the Minister of Health. With all due respect for his decisions, but this potential for overruling decisions of a professional body seems to be in conflict with evidence base medicine. And the fact that this power to possibly overturn a vote of the TGA is limited to mifepristone, clearly is a gender issue and a disservice for Australian

women as it limits their right to freely choose the treatment that is in their best interest. In fact it would seem reasonable that women would start legal actions against health authorities that are withholding this beneficial and safe drug against all medical evidence.

With best regards

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(submitted by email)
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