Additional comments on the Inquiry into the Therapeutic Goods Amendment (repeal of Ministerial responsibility for approval of RU486) Bill 2005

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"If the Parliament wishes to stop terminations from happening then it should legislate to stop them. If it is not prepared to do that, it should not limit the options that women may have when they make the terrible decision to have the pregnancy terminated."

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It is our view that issues concerning the legality, morality and desirability of abortion in Australia are outside the terms of reference of this inquiry, being the responsibility of the various state and territory governments to decide. Of the remaining submissions received into the inquiry – those which address the terms of reference – opposition to the removal of Ministerial veto can be summed up by five main arguments:

- That the drug does not have "therapeutic value"; hence it does not come under the jurisdiction of the TGA (eg. 93, 420, 635);
- That the drug is unsafe, and that conflicting reports on the safety of the drug suggest that it is better to keep the drug out of the country until further research is done (eg. 74, 210, 1014);
- That the use of RU486 in the termination of a pregnancy is more traumatic for the woman than surgical abortion (eg. 11, 975, 1083);
- That allowing the drug to be made available will lead to an increase in the abortion rate (eg. 950, 975, 1012); and
- That the Health Minister should be responsible for making the decision because it encompasses more than just the safety of the drug (eg. 412, 628, 720).

That the drug does not have "therapeutic value", as pregnancy is not a disease; hence it does not come under the jurisdiction of the TGA

Ms Jill Michelson of Marie Stopes International writes (918):

"The Therapeutic Goods Administration (TGA) has to date overseen the evaluation and approval of over 50,000 therapeutic goods and therapies in Australia, making it the most experienced and qualified entity in the country.

The TGA is well resourced and positioned to make an evidence-based assessment based on clinical and professional criteria as to the efficacy of, as well as any risks pertaining to, the use of RU486.

As a member of the World Health Organisation (WHO) Collaborating Centre the TGA has access to counterpart bodies throughout the world, including in countries where RU486 has been approved and is currently in use, ensuring that the TGA has access to the most up-to-date information when making an assessment in relation to RU486.

Australia is well served by the TGA and the integrity and competence of their world's best practice standards."

The TGA assesses and monitors therapeutic goods that are available in Australia, to ensure that they are of an acceptable standard. Its purpose is to ensure that the Australian community has access to therapeutic

advances. It is a highly respected body, and as a member of the World Health Organisation (WHO) Collaborating Centre, the TGA has access to counterpart bodies in countries where RU486 has been assessed and approved for use.

The role of the TGA is to monitor the safety, quality and efficacy of medicines coming into Australia; its function does not rely on everyday usage of the word "therapeutic". Rather, the role of the TGA is defined by the Therapeutic Goods Act. From the TGA's own website:

> A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989).
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> Therapeutic use means use in or in connection with:
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> - preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
> - **influencing inhibiting or modifying a physiological process;**
> - testing the susceptibility of persons to a disease or ailment;
> - **influencing, controlling or preventing conception;**
> - testing for pregnancy; or
> - replacement or modification of parts of the anatomy.

The TGA is responsible for assessing the safety, quality and efficacy, and this role is not limited only to medically essential treatments. The TGA has a role in approving such goods as breast implants and some cosmetics, neither of which is used to prevent or treat disease.

Furthermore, it is clear that the decision to terminate a pregnancy is often taken for medical reasons. In the interests of these women, it is important that they should not be denied alternative methods of doing so, should they be deemed safe.

That the drug is unsafe, and that conflicting reports on the safety of the drug suggest that it is better to keep the drug out of the country until further research is done

The evidence that has been presented has demonstrated that, while no medical procedure is without risk, the risks of this particular drug are minimal. However, we assert that it should be the qualified professionals at the TGA that make the final assessment.

More importantly, that the evidence that has been provided by both sides of the argument is coming from the same sources, suggests to us that

this is in fact a question of interpreting the data and assessing the risks – a job we are confident in leaving to health professionals at the TGA.

It is important to acknowledge that the Australian Medical Association (AMA) (1003), The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) (401, 401a, 401b, 401c, 401d) and Rural Doctors Association of Australia (RDAA) (911) all endorse the use of RU486 for medical termination of pregnancy.

Further questions about the circumstances under which RU486 may be administered should also be determined by the relevant professionals. In recommending that the Health Minister's veto power be removed we do not assert that there should be any less regulation of this drug than with any other.

Therefore, we support the move to remove the Health Minister's veto power, so that the safety of the drug, and recommendations for its correct use, can be determined by those most qualified to do so. In doing so, we do not make any claims as to the safety or otherwise of this drug. Rather, we recognise that this is a technical question that should remain outside the realm of politics.

That the use of RU486 in the termination of a pregnancy is more traumatic for the woman than surgical abortion

Some submissions have argued that this method of termination is more traumatic for the woman, while others have argued that this is a preferable option.

From the research we have been presented with, it seems that the choice between surgical and medical abortion is a matter of personal preference and control. Despite the varying results of research into the effects of abortion on the woman, there seems to be a universal recognition of the fact that abortion is always more traumatic when it is not freely chosen and fully informed.

For this reason alone, it is clear that, should the TGA declare the drug safe, providing women with another option for her to consider will be a positive move.

Furthermore, it has been argued that for women who cannot get access to surgical abortion, and those for whom privacy and control are primary considerations, being forced to make costly and conspicuous visits to abortion clinics, often being accosted by protestors, is in itself a highly traumatic experience (204, 606, 901, 911).

That allowing the drug to be made available will lead to an increase in the abortion rate

This claim has been made in a number of the submissions to the inquiry, however no supporting evidence has been provided to show that this has been the case in any of the many countries where RU486 has been made available. Evidence was presented that suggested that the introduction of RU486 in countries such as the UK, US, Germany and Sweden, the overall abortion rates remained stable or actually declined (402, 917, 1003).

The evidence also indicates an increase in the number of early terminations, as medical abortions can be performed earlier in the pregnancy than surgical abortions can. Some countries have recorded a steady rise in the numbers of medical abortions, however this has coincided with a decrease in the number of surgical abortions being performed, suggesting that for many women this is the preferred option.

There is no evidence, however, to suggest that allowing RU486 into Australia will in any way conflict with the important policy goal of reducing the total number of terminations.

Further to this, it remains our view that if the concern is for women's physical and mental health, then making it more difficult to obtain appropriate medical care is not an acceptable response.

That the Health Minister should be responsible for making the decision because it encompasses more than just the safety of the drug

Questions of the legality and availability of abortion fall to the state and territory governments. Allowing the Federal Government to exert control over the availability of RU486 for reasons other than safety gives is allowing it to override the laws of the majority of states and territories, which have ruled that abortion be allowed under certain circumstances (705, 1005).

It has been argued that the Federal Government should not be required to "rubber stamp" the decisions made by state and territory governments (729). However this is not the question that we are being asked to address. Although the current Health Minister has made it clear that he will not allow abortifacients into the country, the Ministerial veto will continue to apply to all subsequent Health Ministers.

There are many medications the uses of which have social and ethical implications, for example Viagra, birth control pills and medications involved in IVF. However, the need for ministerial approval is limited to abortifacients, and it is our view that this additional level of scrutiny

provides the Health Minister with a level of power that should be outside of his or her role.

Conclusion

To summarise, while there have been plenty of reasons offered as to why RU486 should not be made available in Australia, we remain unconvinced that the Health Minister should have the unique power to make that decision. In order to determine the safety of the drug, it is clear that the health of Australian women depends on appropriately qualified professionals making such decisions based on an ongoing, careful assessment of the evidence-based research, and therefore we recommend the Bill be passed to allow this to take place.

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