Women's Abortion Action Campaign
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Submission to Senate Community Affairs Legislation Committee

Reference: *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU 486) Bill 2005*

Prepared by:
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Executive Summary

Recommendations

1. **THAT the Committee recommend that Ministerial approval for 'restricted goods' and specifically for RU486 be repealed and that evaluation, monitoring, and approval processes for drugs such as RU486 be brought into line with the evidence-based assessment used for all other medicines in Australia, that is, these drugs be evaluated by the Therapeutic Goods Administration.**

2. **THAT there is no case for the continued singling out of abortifacient drugs as 'restricted goods' nor is there any case which can be made for these drugs to require Ministerial approval. Rather they should be subject to the same approval processes as for all other drugs in Australia, that is, by the Therapeutic Goods Administration.**

3. **THAT the Committee recommends, if RU486 is eventually approved for distribution by the Therapeutic Goods Administration, that it be available to all Australian women whether located in metropolitan or rural or remote areas.**

4. **THAT we support the Rural Doctors Association of Australia statements in their presentation to the Committee on 15th December 2005 that: "*the rural and remote medical workforce operate an advanced scope of practice and deal with a lot of emergencies which includes pregnancy, miscarriage and other sequelae of pregnancy*".**

5. **THAT to deny rural and remote women access to this drug would breach the Convention for the**

Elimination of Discrimination Against Women (CEDAW). Further, it implies that the rural and remote medical workforce is not to be trusted to administer this drug appropriately. Such an implication is an anathema.

6. **THAT, concurrent with recommendation 3, 4 and 5 and if the TGA should approve distribution of RU486, the Federal Government provide funding to each state and territory to establish a statewide telephone information and referral service which would provide pregnancy options counselling in a non-judgemental and non-directive manner.**

7. **THAT, concurrent with recommendation 3, 4, 5 and 6 the statewide telephone information and referral services also have a Unit which provides back-up medical advice to regional, rural and remote medical workforce staff in regard to matters relating to counselling, administration of and monitoring of RU486.**

8. **THAT, if the TGA were to approve the use of RU486, the Abortion Providers Federation of Australasia and the Australian Women's Health Network be invited by the Joint Consultative Committee of Obstetrics to participate in the drafting of protocols for the use of RU486 across Australia.**

9. **THAT, if the TGA were to approve the use of RU486, there be a Medicare item number for it and that it be no less in quantity than the current amount available for item 35643 (suction curettage). In addition, that a Medicare item number for counselling (by appropriately trained counsellors) be created and that the amount for that item number be no less than $120 (for 60 minutes counselling).**

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Context

Prior to 1996, **all** drugs whether abortifacient in their effect or not, were evaluated by the Therapeutic Goods Administration (TGA) before they could be approved for use in Australia. The political arrangement which Senator Brian Harradine was able to negotiate in that year set up an aberration of process for just one set of drugs – abortifacient drugs.

This arrangement was made to satisfy the aims of a very small minority of the Australian population.

Women's Abortion Action Campaign has absolutely no problem with the fact that some (a very small percentage) in the Australian population oppose abortion – we understand completely the perspective of those who vehemently oppose abortion and we understand their sense of abhorrence of abortion. We are mindful of the views of those who oppose abortion, notwithstanding the strength of our commitment to the view that abortion is a woman's right to choose.

What we cannot understand is the abuse of power which lead to the 1996 arrangement being made. We cannot understand the continued abuse of power which allows Ministerial responsibility for evaluation of just one set of drugs at the same time that all other drugs, not abortifacient in their effect, must go through a stringent evaluation process by the TGA.

The *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005* provides a welcome opportunity for the Federal Parliament to reverse the aberration which has been in place over the past 9 (and a bit) years.

Recommendation 1

Women's Abortion Action Campaign recommends that the Committee recommend that Ministerial approval for 'restricted goods' and specifically for RU486 be repealed and that evaluation, monitoring, and approval processes for medications such as RU486 be brought back into line with the evidence-based assessment used for all other medicines in Australia, that is, these drugs be evaluated by the Therapeutic Goods Administration. There is no case for singling out abortifacient drugs

Currently, Section 23AA of the *Therapeutic Goods Act 1989* states that "restricted goods (that is, abortifacient drugs) must not be evaluated or registered or listed **without the written approval of the Minister**".

Thus, the current situation is that the TGA cannot even evaluate abortifacient drugs or, specifically RU486, without the Minister giving written approval. Even were the Minister to give written approval for an evaluation process to be undertaken his written approval is still then needed for the drugs to be registered or listed, no matter what the outcome of the evaluation process may be.

It is obvious that the current provisions in the *Therapeutic Goods Act 1989* are, in effect, designed **to create a barrier** to approval. They are not designed with anything else in mind.

We reiterate the current provisions are there to satisfy the aims of a very small minority of the Australian population.

Given that the remainder of the *Therapeutic Goods Act 1989* is specifically about the powers of the TGA to evaluate, register or list, monitor and even subsequently withdraw drugs if post-marketing surveillance were to identify adverse reactions in the larger population, subsection 3(1); Sections 6AA, 6AB and 23AA; and subsection 57(9) stand out even more as aberrations.

Abortion is legal in every state and territory, whether by common law ruling or by statute. The abortion operation should be treated like every other medical procedure. Likewise every drug which has an abortifacient effect, in terms of their approval process, should be evaluated like all other drugs are. There is no case for the continued singling out of abortifacient drugs.

Recommendation 2

Women's Abortion Action Campaign (WAAC) recommends that there is no case for the continued singling out of abortifacient drugs as 'restricted goods' nor is there any case which can be made for these drugs to require Ministerial approval. Rather they should be subject to the same approval processes as for all other drugs in Australia, that is, by the Therapeutic Goods Administration.

Access for all

Some suggestions have been made that, even if RU486 were approved for distribution, it should not be available for women in rural and remote areas due to transport and other health infrastructure shortfalls. Arguments have also been raised that rural and remote women would be endangered if they had access to RU486 because of language, culture and, even, because of weather conditions.

These arguments, in essence, are an attack on the integrity of the rural and remote medical workforce to say nothing of an attack upon the capability of women to judge whether a particular method of abortion is suitable to them and their circumstances.

We have read the transcript of the Inquiry's public hearing held on 15th December 2005 and we can only but agree with the presentation made by the Rural Doctors Association of Australia that the rural and remote medical workforce operates an advanced scope of practice and is capable of following appropriate protocols for administration and monitoring of RU486 should it become available in Australia.

Recommendation 3

THAT the Committee recommends, if RU486 is eventually approved for distribution by the Therapeutic Goods Administration, that it be available to all Australian women whether located in metropolitan or rural or remote areas.

Recommendation 4

THAT we support the Rural Doctors Association of Australia statements in their presentation to the Committee on 15th December 2005 that: "*the rural and remote medical workforce operate an advanced scope of practice and deal with a lot of emergencies which includes pregnancy, miscarriage and other sequelae of pregnancy*". Therefore, the rural and remote medical workforce is capable of administering and monitoring RU486 within appropriate protocols.

Recommendation 5

THAT to deny rural and remote women access to this drug would breach the Convention for the Elimination of Discrimination Against Women (CEDAW). Further, it implies that the rural and remote medical workforce is not to be trusted to administer this drug appropriately. Such an implication is an anathema.

Appropriate levels of non-judgemental and non-directive counselling support needed for all Australian women, particularly women in rural and remote Australia

All Federal Government funding around pregnancy counselling so far made available since the Government was elected in 1996 has been directed toward services which are anti-abortion in their outlook.

No federal funding has gone toward pregnancy counselling services which are non-judgemental and non-directive in their approach yet supportive of a woman's right to choose abortion.

Some members of the Senate Committee of Inquiry may feel it is a contradiction in terms to assert that pregnancy counselling services which are supportive of a woman's right to choose abortion can be non-directive.

This could not be farther from the truth. The women's health movement in Australia has a very long and proud tradition of approaching pregnancy counselling from a perspective which commences with respect for each woman and respect for her value system. In the 31 years that women's health centres have received government funding, there is not one whit of evidence that those centres have 'talked' women into having an abortion.

Recommendations around the need for non-judgemental and non-directive counselling support have been made in two major Australian reports:

We Women Decide by Barbara Buttfield, Margie Ripper and Lyndall Ryan published in 1992 – a comparative study of access to abortion in South Australia, Queensland and Tasmania over the late 1980's; and the

*Information paper regarding termination of pregnanc*y published 1997 by the National Health and Medical Research Council (NHMRC) – this report was prepared by an Expert Panel appointed by the Keating government in 1992 – a new government was in power by the time its report was tabled – the report of the Expert Panel was initially tabled in 1996 then withdrawn and republished nearly a year later as an 'Information Paper'. The fact that it was the findings of

an Expert Panel which had been meeting and scanning an extensive range of documents – both Australian and international – over more than three years was downplayed and disregarded.

Each of these major studies made a substantial range of recommendations. Both reports, in slightly differing ways, recommended funding be provided by each state and territory government to establish a statewide telephone counseling and information service.

Both reports recognised women's needs for better access to information and counselling about pregnancy options and, specifically, information about abortion and how to access it if their decision was to terminate their pregnancy.

The recommendations in both these reports have been consistently ignored by both the Federal Government and state and territory governments with the exception of Queensland which provides funding to the statewide pregnancy counselling service, Children by Choice.

Again, we concur with the Rural Doctors Association of Australia in their submissions made to the Senate Committee on 15th December 2005. Specifically the comments by Dr Page in regard to the need for rural and remote women to have access to counselling by phone.

This counsellling must be non-judgemental and non-directive yet well informed about the abortion procedure and abortion methodology. In the context of pregnancy options counselling and pregnancy decision-making, much of it is correcting misinformation women have picked up from various sources as it is about counselling around feelings and emotions.

For many women, just having the correct information is enough to allow them to go back to their (hopefully supportive) partner and/or family and/or trusted friends to resolve their situation with a pregnancy.

For example, if a woman is hoping to have a termination by RU486 and it proves that it is not possible because of her location or because of lack of services in her area appropriate counselling and information support would be necessary not only to understand the reasons why access is not possible but also to assist her to make whatever arrangements need to be made to travel elsewhere for either a termination by the RU486 method or by suction curettage.

Access for women who are in rural and remote parts of Australia has always been an issue of concern. Women from rural and remote areas, if they wish to access termination of pregnancy, have always incurred more costs than women in metropolitan areas because of costs such as: travel, accommodation, childcare, living expenses whilst away and the cost of the actual abortion operation.

Recommendation 6

THAT, concurrent with recommendation 3, 4 and 5 and if the TGA should approve distribution of RU486, the Federal Government provide funding to each state and territory to establish a statewide telephone information and referral service which would provide pregnancy options counselling in a non-judgemental and non-directive manner.

Recommendation 7

THAT, concurrent with recommendation 3, 4, 5 and 6, the statewide telephone information and referral services also have a Unit which provides back-up medical advice to regional, rural and remote medical workforce staff in regard to matters relating to counselling, administration of and monitoring of RU486.

An abortion is an abortion is an abortion

In much of the discussion and argumentation about access to abortifacient drugs such as RU486, it has been implied that women are not capable of understanding the drug's regimen even when explained by medical workforce staff and that they will move to using it in a way which would be against the protocols.

Nothing could be farther from the truth. **Women do not make the decision to have a termination of pregnancy lightly.** Many commentators seem to have forgotten that having an abortion by a different methodology does not make it 'less' in some way in the minds of women.

Women will still be going through the same issues they go through now when having a suction curettage operation – that is, does the doctor know what he/she is doing? what are the clinic staff like? how will I know what is normal after the operation and what is not? how will I feel on the day and in the week after the operation? what is a normal bleeding pattern? this has been a hard decision for me, I've had no support but I know that I am making the best decision that I can – but what about afterwards? are there any services I can talk with about my feelings? and so on.

Whether an abortion operation is performed via a chemical method or by the suction curettage method the issues remain the same. **This makes it even of greater paramount that counselling support is readily available – either by telephone via a funded statewide counselling and information service or on site with and as part of the medical workforce staff.**

Likewise, it needs to be remembered that whilst abortion is legal in all states and territories (either by common law ruling or by statute) there are still provisions in the respective state/territory *Crimes Acts* or *Criminal Code*s (with the exception of the ACT – the ACT is the only state which has repealed provisions from its Crimes Act) which relate to abortion.

The existence of these provisions, even though they and their interpretation have been clarified either by common law ruling (Victoria, NSW and Qld) or by statute (NT, SA, WA and Tasmania) make doctors nervous. The possibility of being arrested and charged with performing a so-called 'unlawful' abortion is still present for all doctors who perform abortions in Australia, except doctors in the ACT.

Women's Abortion Action Campaign cannot see there being a massive increase in the number of doctors willing to perform abortions even if RU486 were available. An abortion is an abortion is an abortion. To provide termination of pregnancy, whether by chemical means or by suction curettage, a doctor needs an infrastructure to support that service.

There will not be a mad rush by doctors to begin administering and monitoring Ru486. The practicalities are too great – counselling support is necessary, enough staff to be able to deal with ongoing inquiries from women as their chemical termination proceeds (and having enough staff does not come cheap!) and so on.

Ensuring, if you are not set up to perform a suction curettage, that you have a back up system of where to refer women to if the possibility of retained products after administration of RU486 eventuates – these are huge practical problems which are not easily overcome, particularly if one is working in a rural or remote area.

This makes it of even greater paramount that a statewide service is available in each state/territory to provide back up advice and support for the few doctors who will be willing to administer and monitor RU486 outside the existing network of reputable abortion providers.

Recommendation 8

> **THAT, if the TGA were to approve the use of RU486, the Abortion Providers Federation of Australasia and the Australian Women's Health Network be invited by the Joint Consultative Committee of Obstetrics to participate in the drafting of protocols for the use of RU486 across Australia.**

RU486 will not make abortion cheaper for women

RU486 will simply provide a different method of abortion for women who happen to be lucky enough to be in the window period in which it is most efficacious and who would prefer it as a method to suction curettage. Administration and monitoring of RU486 will not be 'easier' from a medical perspective nor will it be 'easier' or less risky in terms of liability, nor will it be cheaper.

Notwithstanding our questioning of the safety and efficacy of RU486 in the early years of its development in our magazine *Right to Choose* (see copy of attached articles we published about RU486 over the period 1982 – 1990) we believe that it has been proven since then to be appropriate for use by some women provided they have been informed about the side effects, what they should expect and in what time frame, what back up and support is being provided by the abortion service, what counselling support there is and so on.

If an abortion service is administering and monitoring RU486 it will not be able to 'get away' with less staff, less cost and therefore less fee to the woman. If an abortion service is following protocols similar to that in New Zealand or those in the European countries, there is no way it will be cheaper for the abortion service or for women to have an RU486 chemical abortion as opposed to suction curettage.

Women deserve this level of support and the Medicare system must reflect this level of support which will need to be provided by abortion services.

Recommendation 9

THAT, if the TGA should approve RU486 for use, there be a Medicare item number for it and that it be no less in quantity than the current amount available for item 35643 (suction curettage). In addition, that, a Medicare item number for counselling by appropriately trained counsellors be created and that the amount for that item number be no less than $120 (for 60 minutes counselling).

ATTACHMENTS TO SUBMISSION BY WOMEN'S ABORTION ACTION CAMPAIGN TO SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE RE RU486

ATTACHMENT 1

Background information about Women's Abortion Action Campaign

Women's Abortion Action Campaign (WAAC) was formed in August 1972 by the Women's Liberation Movement. Our aims are:

- that abortion is a woman's right to choose;
- the repeal of all abortion laws;
- free safe abortion on demand;
- free, safe contraception on demand; and
- no forced sterilization.

We are an activist group organising public meetings, protests, rallies, petition drives, lobbying, submissions in support of the above aims.

WAAC publishes a women's health action magazine, *Right to Choose*. *Right to Choose* was initially published from 1973 to 1980-81 in a newspaper format; from 1980-81 to 1992 it was published in an A4 magazine format on a regular basis. Since 1992 it has been published in 1998 and then on an occasional basis.

From 1982 *Right to Choose* covered the early development of RU486 (see attached copy of relevant articles from back issues) – we approach new drugs from a perspective of being skeptical that they will provide a technological fix to what is perceived to be a problem.

Notwithstanding our questioning of the safety and efficacy of RU486 in the early years of its development we believe that it has been proven since then to be appropriate for use by some women provided they have been informed about the side effects, what they should expect and in what time frame, what back up and support is being provided by the abortion service, what counselling support there is and so on.

Other attachments will follow by fax. They are:

Photocopy of article re RU486 from Issue #25 *Right to Choose* Spring 1982
Photocopy of article re Prostaglandins from Issue #25 *Right to Choose* Spring 1982
Photocopy cover and article re RU486 issue #31 *Right to Choose* Summer 1989-90
Photocopy cover and article re RU486 issue #32 *Right to Choose* Autumn 1990
Graphic