Submission to the Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

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Re: The Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

Dear Members of the Community Affairs Legislation Committee:

We would like to make the following points in support of this legislation:

The Therapeutic Goods Administration (TGA) is the appropriate body to assess the safety and efficacy of RU486 and, if safe and efficacious, to licence its use in Australia. It is clearly a matter of medical evidence whether or not RU486 is a safe drug for use in Australia. Assessing medical evidence is a specialised process requiring dedicated expertise and skills. In Australia, the TGA is the body authorised to exercise its expertise and skills in the assessment of new therapeutic agents. It is the best qualified authority to decide when, where, and with what support services this drug should be made available. This process of assessment should occur independently from the assessment of individual patients whose treatment may require the use of RU486.

As with other therapeutic agents, if RU486 is found to be safe and thus is licensed by the TGA, medical practitioners will have to make decisions about whether to prescribe that therapeutic agent in accordance with best medical practice and the law. Induced abortion is a legal, albeit heavily regulated, procedure in Australia; the licensing of RU486 will not alter this situation. What will change if RU486 is licensed is that Australian women and their medical practitioners will have an increased range of options from which to select the safest and most efficacious treatment for any particular patient. There is no evidence to suggest that licensing RU486 will increase the number of induced abortions occurring in Australia each year, merely that the method may change for some women.

Ministerial responsibility for approving RU486 is inappropriate on two grounds. First, the Minister does not have specific expertise in assessing the safety and efficacy of therapeutic agents. Second, seeking Ministerial approval for each use of the drug potentially breaches the confidentiality of the patient for whom its use is sought. There are no other medical procedures or treatments for which such an approval process is required, and as it is essential to avoid breaches of patient confidentiality, it is not morally acceptable and potentially discriminatory to require such approval for RU486.

Yours sincerely,
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