

Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for RU486) Bill 2005



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Introduction

Women's Health Victoria is an independent Victorian state-wide women's health promotion organisation run by women for women. We work to identify and respond to the health issues of the women of Victoria through a feminist perspective and a social model of health.

We are informed by, and encourage the validation of, women's experiences of health and ill-health. We promote women's right to control our own bodies in every aspect of health care and work to empower women and communities to act on health matters through the use of information.

Our women's health information Clearinghouse forms the core of our organisation. It provides the basis for our work representing women and facilitates access to health information to a range of users from diverse locations.

Women's Health Victoria welcomes the opportunity to make public comment to the Senate Community Affairs Committee on the TGA Amendment (Repeal of Ministerial Responsibility for RU486) Bill 2005.

Initial Public Hearings

WHV is concerned about the direction taken at the initial public hearings of this Inquiry. We understand that the issue that the Senate committee has been asked to consider is whether the Minister for Health should have power over the TGA with regard to the evaluation, registration or listing of abortifacients. In watching the live broadcast and reading Hansard, the attack of the integrity of invited witnesses and the use of the inquiry to argue about the ethics of abortion by some Senators was deeply disappointing. The violence towards women inherent in remakes made by Senator Joyce regarding how shooting pregnant women and killing the baby but not the mother would not be a crime¹ are extremely offensive and the Senator should withdraw them.

WHV recognises that there are a variety of views in the community with regard to abortion. However, we trust that future public hearings of this Inquiry will be about the essence of the bill under consideration- is it appropriate for the Minister for Health to decide how an objective federal agency assesses applications for the use of abortifacients.

TGA Process Supported

The Therapeutic Goods Administration (TGA) is recognised and quoted as a world leading independent expert authority. It is responsible for assessing the quality, efficacy and safety of drugs used in Australia as well as evaluating applications for the licensing of new drugs

¹ Joyce, B. Senate Community Affairs Legislation Committee Hansard, 15th December, p.C69

and treatments. Within the TGA, an expert advisory committee, the Australian Drug Evaluation Committee, has been undertaking these assessments for more than 40 years. This committee is entrusted with making significant decisions and has included providing sound judgements that have served Australia well. Within the current legislation, the TGA can move forward with the process of evaluation for all drugs bar one.

Process of Approval of Abortifacients

The Therapeutic Goods Act 1989² states that approval from the Health Minister is required to give approval for the evaluation, registration or listing of restricted goods. The interpretation of the Act outlines that abortifacients, of which mifepristone or RU486 is one, are the only restricted goods. This means that although we entrust control to the TGA with the licensing of every other therapeutic drug in Australia, due to a perceived ethical burden associated with the approval of abortifacients, the current legislation fails to allow the TGA to make objective decisions independent of the approval of the Minister for Health on these types of drugs.

However, abortifacients are not the only class of therapeutic drug whose application might be arouse a variety of opinions in the wider community. Many other treatments and drugs stimulate public debate. For example, some have expressed concern about organ transplant in those who may be perceived as 'less deserving' recipients. While this is not the view of Women's Health Victoria, those who mount such arguments raise issues about the validity of, for example, former smokers receiving lung transplants when others who have never smoked miss out on such life-saving transplants. However, regardless of a variety of opinions on who 'deserves' a transplant, we do not restrict transplants nor the use of anti-rejection drugs to recipients.

This is not a trivial comparison. It serves to demonstrate that in other areas of health care, differences in ethical positions should not and do not influence the approval or rejection of therapeutic drugs in Australia. As an independent expert authority, the TGA evaluates drugs for use on their merits and, unlike politicians, is free of the need to kowtow to the views of certain minority groups.

Independent Assessment and Individual Choice

Abortifacients such as mifepristone/RU486 should be used as medically indicated and we believe that individual women should be allowed to make the decision as to whether using them is appropriate in a given situation. The current legal situation means that the Health Minister of the day has power over aspects of women's reproductive choices. This is highly inappropriate. Members of parliament cannot bring the expertise and breadth of knowledge provided by the TGA and its advisory committees in determining the quality, efficacy and safety of therapeutic drugs and treatments.

WHV believes that, as with all other therapeutic drugs, the TGA must be allowed to assess the risks and benefits of mifepristone with regard to licensing it for use in Australia free of the interference or influence of the Minister of Health.

² Commonwealth of Australia. Therapeutic Goods Act 1989. Act No 21 of 1990 as amended.