

## **Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005**

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## ***The Australian Reproductive Health Alliance***

The Australian Reproductive Health Alliance (ARHA) mission is to promote public support for enhanced reproductive and sexual health in Australian and internationally, and to promote the advancement of the status of women and girls by:

- producing educational materials;
- organising seminars and workshops;
- preparing briefing materials for members of the press
- networking with parliamentarians, government and non-government agencies and other interested parties as required; and
- supporting and promoting alliances with opinion makers with comparable aims and objectives.

ARHA was established in 1995 following the International Conference on Population and Development held in Cairo in 1994. Since it began ARHA has been actively involved in sexual and reproductive health programs throughout the Asia Pacific region that broaden people's access to and information about good sexual and reproductive health policies, programs and services. ARHA has trained midwives in Pacific Island Countries, working with men in Pacific countries the Asian tsunami and Pakistan Earthquake. ARHA is a member of the Asia Pacific Alliance and through this network works with other environment and family planning NGO's to promote the linkages between population, development and family planning. ARHA has also established a secretariat for the Parliamentary Group on Population and Development and in 2005 ARHA was granted United Nations ECOSOC Status enabling it to participate in its own right at certain UN meetings and conferences. ARHA is an incorporated body that is governed by a board. Biographies of board and patrons have been attached (Annex 1: Biographies).

### **Previous submissions made by ARHA to the Government**

- Board of Taxation on the Definition of a Charity, September 20 2003
- National Drugs and Poisons Scheduling Committee on consideration of a proposal to reschedule from Schedule 4 to Schedule 3 when in a two tablet pack, of 0.75mg per tablet, for emergency postcoital contraception, May 20 2003
- Human Rights and Equal Opportunities Commission on the National Inquiry into Children in Immigration Detention, May 5 2002
- Inquiry into the Definition of Charities and Related Organisations, January 19 2001
- Joint Standing Committee on Treaties on Parliamentary Inquiry into the Kyoto Protocol, August 22 2000
- Senate Legal and Constitution Committee on the Sex Discrimination Amendment Bill (No.1) 2000, November 13 2000
- Human Rights and Equal Opportunity Commission on Pregnancy and Work Inquiry, February 19 1999

## ***Submission***

ARHA fully supports the principle that approval of a particular drug intended for use on people should be decided by a technically and professionally qualified entity such as the Australian Therapeutic Goods Administration (TGA) and its expert advisory committees. We consider this should be the over-riding principle, regardless of the particular drug or of the proposed use of the drug in question. The TGA provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicine for Australians. The TGA have already approved more than 50,000 therapeutic goods and therapies for use in Australia; there is no reason to have a separate process for one drug. There are a number of drugs could be regarded as religiously or socially contentious including for example those used in palliative care, which are not subject to singular scrutiny.

In Australia the TGA is the most appropriate body to address the safety and efficacy of all drugs, contentious or not. This is particularly relevant given the TGA's role as a World Health Organisation (WHO) Collaborating Centre within the Commonwealth Department of Health and Ageing. According to the Department's website, these Centres form part of the collaborative network set up by WHO in support of its policies and programs. The TGA's designation as a Collaborating Centre is based on the alignment of TGA activities and expertise with WHO aims and objectives. As a WHO Collaborating Centre for Drug Quality Assurance, the TGA also provides expert advice on the regulation of drug quality control and the licensing of drug manufacturers. It would seem therefore that the TGA is very well qualified and resourced to assess and evaluate RU486 and ideally placed to access existing WHO data and evaluations to inform decisions.

In 2005 the WHO listed RU486 as an essential medicine<sup>1</sup>. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Today mifepristone is available in 35 countries including the United States, New Zealand, Israel, France, Sweden and Britain and is used for a range purposes including as an abortifacient, commonly in the first 49 nine days of pregnancy<sup>2</sup>.

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<sup>1</sup> WHO Drug Information Vol 19, No. 3, 2005 p220

<sup>2</sup> Royal College of Obstetricians and Gynaecologists, National Clinical Guidelines, The Care of Women Requesting induced Abortion. London, RCOG, 2004

As abortion is already safely available in Australia (Annex 2: Legal Status of Abortion), and as the purpose of this inquiry is to review ministerial responsibility for approval of mifepristone, we have not addressed the wider issue of the benefits of providing a safe non-surgical option of termination of pregnancy to Australians in this submission.

### ***Mifepristone in Australia***

Following approval from the Therapeutic Goods Administration in March 1994, Monash University and Family Planning Victoria participated in a WHO international multicentre, double-blind, randomised controlled trial of RU486. The purpose of the study was to test the efficacy and side effects of Mifepristone when used as emergency contraception and as an abortifacient.

Although the trial was suspended, researchers had enough data to show that women who participated in the test were satisfied with the method and most found the associated level of pain acceptable. Women who had previously had surgical abortions reported that the medical method was more acceptable. Reasons given by Australian women for choosing medical abortion included; avoidance of an anaesthesia and increased autonomy; that medical abortion is more “natural” and emotionally acceptable and that it is less stressful. Australian women who participated in the trial also reported feeling more involved in the process and therefore able to achieve a greater sense of control. For many women in the trial, the non-clinical approach used during the medical abortion was also seen as psychologically preferable<sup>3</sup>.

The trials were suspended after intervention by the Health Minister in 1995 following concerns about inadequate patient consent. There were 12 other nations involved in the WHO trial and in no other nation was there such legal and bureaucratic scrutiny. The then head of the federal health department was taken to court by the Right to Life organisation for allowing the trials and one of the doctors involved was investigated by police following unsubstantiated claims of misuse of the drug<sup>4</sup>.

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<sup>3</sup> Marners, et al. 1997 “Women’s satisfaction with medical abortion with RU486” MJA 1997; 167: 316-317

<sup>4</sup> Davies, Julie-Anne “Bitter Pill” The Bulletin, 7/12/2005

## ***Annex 1 – Board Biographies***

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### ***Heather Macdonald***

#### *President*

- MSc Primary Health Care, DCH – Graduate Diploma of Community Health, State Registered Midwife, State Registered Nurse England
- 25 years experience in international aid development and project management specializing particularly in health promotion; non-communicable disease; maternal and child health; and primary health care
- Nurse practitioner with the Royal Flying Doctor Service, followed by extensive work with State Health Departments in SA and NSW managing health promotion initiatives
- Consultant for the World Health Organisation (European Office) in Health Promotion
- Health Adviser to AusAID for a period of 8 years

### ***Jim Redden***

#### *Vice President*

- Senior Program Director for the Institute of International Business, Economics and Law at the University of Adelaide.
- Since 2000, member of the Australian Ministerial WTO Advisory Committee advising on international trade and sustainable development issues and participated in the Doha and Cancun WTO Ministerial meetings as part of the Australian Government's official delegation
- Worked closely with the Trade Minister, Mark Vaile to ensure Australia's support for a WTO deal that would increase developing country access to affordable medicines.
- From 1998 – 2004 Policy Director for the Australia Council for International Development.
- Currently manages trade related training and capacity building programs in developing countries and lectures at the University of Adelaide on international trade and on corporate social responsibility.

### ***Dr Harry Cohen***

#### *Committee Member*

- MB and BS University of Adelaide Medical School, 1955
- Foundation Fellow of the Royal Australian College of Obstetricians and Gynecologists
- Head of Dept. of Gynecology – Royal Perth Hospital
- Consultant – King Edward Memorial Hospital
- AM recipient 1995

### ***Margaret O'Callaghan***

#### *Committee Member*

- 1998 - 2005 appointed UNFPA representative to Zambia
- 1993 appointed UNFPA representative in Papua New Guinea
- Joined AusAid in 1987, working in PNG, Japan, Fiji, Solomon Islands, Vanuatu and Western Samoa
- Bachelor of Applied Science (Health Education)
- Project Officer, ACT Health Authority
- Co-author "Our Daily Fix – Drug use and Abuse in Australia" (1981)
- Counsellor and state representative of Nursing Mothers Association of Australia

***Dr Margaret Valadian***

*Vice-President*

- BscSt (Social Work), MEd (Communications), Master of Social Welfare, Hon DLit.
- Previously Director of the Centre for Indigenous Development, Education and Research, University of Wollongong
- Previously Director of the Aboriginal Education Centre, University of Wollongong.
- Co-Founder and Co-Director of the Aboriginal Training and Cultural Institute.

***Natascha McNamara***

*Treasurer*

- Multidisciplinary background in Economics, Business/Administration, Education and Arts
- Experience in paid and voluntary work with the Private Sector, Commonwealth / State Governments, Legal profession, Catholic Church, the Tertiary Education institutions and Aboriginal communities and organisations
- Experience in Taxation, Commercial and Administrative Law and Laws relating to incorporation and management of organisations.

***Cait Calcutt***

*Secretary*

- Bachelor of Arts (Social Science) – Curtin University of Technology
- Certificate of Information Technology – TAFE Perth 1995
- Coordinator of Children by Choice

***Jane Hearn***

*Committee Member*

- Visiting Fellow, Australian National University
- Principal lawyer responsible for the ACT Human Rights Act 2004
- International Human Rights Section of the Office of International Law, Attorney Generals Department
- Law Group of Federal Parliament
- UN High Commissioner for Human Rights in Cambodia
- Founding Editor of Human Rights Defender

***Wendy McCarthy***

*Patron*

- Chancellor of University of Canberra, Chair PLAN, Director PLAN International, Chair McGrath Estate Agents, Chair New South Wales Ministerial Participation Council, Deputy Chair Sydney Community Foundation.
- An Officer of the Order of Australia for outstanding contributions to community affairs, women's affairs and the Bicentennial celebrations
- 1996 Honorary Doctorate from the University of South Australia
- Has worked with government, corporations and community based organisations in education, health conservation and heritage, media, women's affairs, public health and waste management

***Marie Coleman***

*Patron*

- Former senior public servant in federal departments covering health, child care, social policy (20 years)
- Public Service Medal in 1989 for contributions to public administration.
- Journalist
- Consultant
- Recipient Commonwealth Honors System's Centenary Medal for services to public administration
- Recipient Centenary Medal of the Australian Institute of Public Administration for services to public administration
- Victorian Parliament's Honor Roll of Women

***Jack Caldwell***

*Patron*

- Currently Emeritus Professor and Visiting Fellow
- 1993 – 1997 Australian National University, University Fellow
- 1998 – 1993 Associate Professor of National Centre Epidemiology Public Health
- 1977 – 1998 Head of Demography, Australian National University

## ***Annex 2 Legal Status of Abortion in Australia***

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<b>State or Territory</b>	<b>Legal Status</b>
New South Wales	An abortion is not legal if it prevents a serious risk of danger to a woman's life or physical or mental health based on social, economic or medical grounds
Queensland	An abortion is lawful if it is performed to save a woman's life
Victoria	A pregnancy can be lawfully terminated to protect a woman from serious danger to her health or life
Australian Capital Territory	Abortion has been removed from the criminal code and is governed by the 1998 Medical Practitioners Act
Northern Territory	A pregnancy can be lawfully terminated to protect a woman from serious danger to her physical or mental health
South Australia	A pregnancy can be lawfully terminated to protect a woman from serious danger to her physical or mental health
Western Australia	Abortions occur within the jurisdictions of both the Health and Criminal codes
Tasmania	A pregnancy can be lawfully terminated to protect a woman from serious danger to her physical or mental health

Table data from Queensland Parliamentary Library "Abortion Law Reform: An Overview of Current Issues" Research Brief No 2003/09



Annex 3 - Countries where Mifepristone is approved for use

# Mifepristone Approval

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<b>1988</b> <ul style="list-style-type: none"><li>■ China</li><li>■ France</li></ul>	<b>1999</b> <ul style="list-style-type: none"><li>■ Austria</li><li>■ Belgium</li><li>■ Denmark</li><li>■ Finland</li><li>■ Germany</li><li>■ Greece</li><li>■ Israel</li><li>■ Luxembourg</li><li>■ Netherlands</li><li>■ Spain</li><li>■ Switzerland</li></ul>	<b>2000</b> <ul style="list-style-type: none"><li>■ Norway</li><li>■ Russia</li><li>■ Taiwan</li><li>■ Tunisia</li><li>■ Ukraine</li><li>■ US</li></ul>	<b>2002</b> <ul style="list-style-type: none"><li>■ Azerbaijan</li><li>■ Belarus</li><li>■ Georgia</li><li>■ India</li><li>■ Latvia</li><li>■ Uzbekistan</li><li>■ Vietnam</li></ul>	<b>2003</b> <ul style="list-style-type: none"><li>■ Estonia</li></ul>
<b>1991</b> <ul style="list-style-type: none"><li>■ UK</li></ul>		<b>2001</b> <ul style="list-style-type: none"><li>■ New Zealand</li><li>■ South Africa</li></ul>		<b>2004</b> <ul style="list-style-type: none"><li>■ Guyana</li><li>■ Moldova</li></ul>
<b>1992</b> <ul style="list-style-type: none"><li>■ Sweden</li></ul>				<b>2005</b> <ul style="list-style-type: none"><li>■ Albania</li><li>■ Hungary</li></ul>