



The Royal Australasian
College of Physicians

Submission to the Australian Senate Community Affairs Legislation Committee

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

Following an invitation to the Royal Australasian College of Physicians (the College) for a written submission relating to the above mentioned Bill, the matter was examined by members of the relevant committees of the College, namely the Therapeutics Advisory Committee and the Pharmaceutical Policy Working Party.

College Fellows on these committees felt that RU486 should find its place in the usual way in which all other Therapeutic Goods are dealt with under Law. Neither the approval of RU486 nor the work of the Therapeutic Goods Administration (TGA) should be subject to the political interference they may be open to if Ministerial responsibility were to remain.

Advice received from these College committees indicates that there are no efficacy or safety arguments for an arrangement whereby the Minister for Health and Ageing must micromanage the business of the TGA. This drug regulatory anomaly should therefore be removed.

Accordingly, the College firmly supports the Bill to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the TGA.

Yours sincerely,

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President
The Royal Australasian College of Physicians

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