

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

## **EXPLANATORY MEMORANDUM**

A Bill for an Act to repeal Ministerial approval and to leave approval with the Therapeutic Goods Administration over access to RU486, and for related purposes.

The purpose of this bill is to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

In 1996 amendments to the Therapeutic Goods Act were passed that placed medications such as RU486 in a special group of drugs known as 'restricted goods'.

According to the 1996 amendments restricted goods cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing.

In addition, any such written approval must be laid before each House of the Parliament by the Minister within 5 sitting days of being given.

RU486 is the only medicine that is subject to the restricted goods condition.

Medicines used for any purpose other than abortion are evaluated and regulated by the Therapeutic Goods Administration (TGA) alone and do not require additional approval from the Minister for Health and Ageing.

The TGA is specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods that come into Australia, applying any measures necessary for treating the risks posed, and monitoring and reviewing the risks over time.

The TGA is regarded by the government as being qualified to manage the risks associated with any therapeutic good that is used (or proposed for use) in Australia. It is therefore reasonable to assume that it is also qualified to manage the risks associated with medications such as RU486.

Removal of the restricted goods provisions in the Act would mean that RU486 could be evaluated within the same framework as applies to all other medicines. It is reasonable to assume that this may provide potential sponsors of the drug with greater confidence that an application for approval would be worth pursuing—in that the determining factor in the process would be an evidence-based evaluation by the TGA of the merits and risk profile of the drug.

The amendments to the Therapeutic Goods Act 1989 in this Bill will bring the approval process for medications such as RU486 into line with the evidence-based assessment used for all other medicines in Australia.