

1 February 2006

Thank you for contacting me about the Private Member's Bill shortly to be considered by the Parliament which proposes that the process for approval of the use of RU486 in Australia should be determined by the Therapeutic Goods Administration (TGA) and not by the Minister for Health.

In the case of all drugs other than those deemed "restricted goods", the TGA is regarded by the Government as the appropriate authority to determine whether or not a drug is safe for use in Australia. Specifically, the TGA identifies, assesses and evaluates the risks posed by therapeutic goods and, on the basis of its investigations, decides whether a drug should be approved for use. If a drug is approved, the TGA then monitors and reviews the risk over time. The approach required of the TGA means that decisions about whether drugs are allowed to be used in Australia are entirely based on clinical and medical evidence.

RU486 is defined as a "restricted good" under the Therapeutic Goods Act 1989. Restricted goods cannot even be evaluated by the TGA without the written approval of the Minister for Health.

Since RU486 was classified as a restricted good in 1996, there has been an accumulation of data about the risks and benefits of RU486 when used as an abortifacient and also in its use in treating certain types of cancers, including brain tumours.

While the current legislation can allow the TGA to grant approval for RU486 to be imported under its special access scheme, in practice this scheme is unworkable.

For example, under these special access provisions, the TGA recently granted a cancer patient a permit to import RU486 to enable her to arrest the growth of her tumour. Tragically, the reality is that this patient cannot actually use the drug to treat her condition.

This is because, although the import permit had been granted, RU486 is still deemed restricted and therefore, without Ministerial approval, the TGA could not evaluate it. Without such evaluation, the TGA could not provide the normal assurances about drug use on which doctors depend for their indemnity requirements.

Unfortunately for the cancer patient concerned, this means that she still cannot use the drug because doctors have so far refused to prescribe it.

In my opinion, all drugs proposed for use in Australia should be assessed by the independent medical experts at the TGA and not be subject to the approval of one individual, the Minister for Health.

This would ensure that if RU486 were to be approved for use in Australia by the TGA, it would have been thoroughly evaluated in terms of its potential risks and benefits and would also be subject to on-going rigorous monitoring and review.

Thank you once again for your correspondence and your interest in this important matter.

Yours sincerely

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