Committee Secretary Community
Affairs Committee Department of
the Senate Parliament House
CANBERRA ACT 2600

Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 - Submission by Carolyn Mongan

Dear Sir,

The following is my submission in respect of the above Bill. I have dealt with three issues in particular: firstly, the inaccuracy of the Explanatory Memorandum; secondly, Costing; and thirdly, Ministerial Control.

Inaccuracy of the Explanatory Memorandum

Having read the explanatory memorandum for the above Bill, I am concerned that the memorandum does not accurately represent either the current arrangements relating to RU486 or the effect of the Bill.

Paragraph 4 of the Explanatory Memorandum states:

> *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.*

To accurately represent the current situation, whereby drugs of this class can be, and have been, trialled and used for other purposes, this paragraph should read:

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

Paragraph 6 of the Explanatory Memorandum states:

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

I understand that this is not the case. There are, as I understand it, several other drugs in that category. They are: *Alprostadil; Carboprost; Dinoprost; Dinoprostone; Gemeprost; Misoprostol;* and Prostaglandins Vaccines against human chorionic gonadotrophin. These are all items that are categorized as *restricted goods,* which are defined as follows:

> *"Restricted goods" are defined to be drugs within Regulation 2 of the Therapeutic Goods Regulations (including progesterone antagonists and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients. (TGA News Issue 22 (October 1996) Legislation update)*

Paragraph 8 of the Explanatory Memorandum states:

> *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.*

To claim that the TGA has a role in *applying any measures necessary for treating the risks posed, and monitoring and reviewing the risks over time,* is, in my opinion, overstating the responsibilities of the TGA. I have included the following extract from the TGA's website, which outlines that the TGA evaluates goods for 'quality, safety and efficacy:

> ## Regulating medicines
>
> Australian manufacturers of all medicines must be licensed under Part 4 of the *Therapeutic Goods Act 1989* and their manufacturing processes must comply with the principles of GMP (Good Manufacturing Practice).
>
> Medicines assessed as having a higher level of risk (prescription medicines, some non-prescription medicines) are evaluated for quality, safety and efficacy and are registered on the Australian Register of Therapeutic Goods (ARTG). Medicines having a lower risk (consumer medicines purchased over the counter such as complementary medicines including vitamins) are assessed for quality and safety. In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are all taken into account.
>
> Once approved for marketing in Australia, medicines are included in the ARTG and can be identified by the AUST R number (for registered medicines) or an AUST L number (listed medicines) that appears on the packaging of the medicine.

This information is available at the following internet address:

> http://www.tga.gov.au/docs/html/tga/tgaginfo.htm

It is therefore clear, that the TGA has no role in the administration of the drug, once it is listed, that is, it cannot set conditions or procedures for on how, where, when or why it is to be used; this would be left to the medical practitioner.

Paragraph 10 of the Explanatory Memorandum states:

> *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.*

With regard to the first sentence, I simply respond that the current requirement to refer the final approval to the Minister for Health and Aging, does not alter the role of the TGA nor the evaluation framework that the TGA would apply to RU486, had an application been received.

With regard to the second sentence, it is highly speculative and hardly likely that the requirement for Ministerial approval is deterring the current owner of the patent from applying to have the drug evaluated for marketing in Australia.

Costing

I am concerned there has not been enough research done to cost the impact of the Bill. With the publicity currently being given to surgical waiting list, there is a clear incentive for medical practitioners to 'gently' pressure women into choosing a medical abortion, and thereby free-up surgical facilities for other procedures. This could impact on the balance of State and Federal funding. Has this been addressed?

Ministerial Control

I believe that the current requirement for Ministerial control should continue to apply for the following reasons:

- the Minister would have the authority to set a protocol for the use of such drugs, to ensure that they were appropriately used, for example that they were not administered, as an abortifacient, to a woman who was more than one hour's travel from a suitable emergency facility;
- the Minister could ensure that women were not encouraged by medical practitioners to accept a medical abortion rather than a surgical abortion, in order to 'free-up' theatres for other surgery, especially in regional or remote areas; and
- the Minister could ensure that if such drugs were introduced, that appropriate monitoring and follow-up was introduced.

I would be grateful if you would put my submission before the Committee to consider.

Yours sincerely,

Carolyn Mongan