

24.09.01

*24 26/09/02

Terry Lee

24/09/2002 12:03

To: Dennis Hartley/TGA/Health@Health_gov_au

cc:

Subject: Proposed Amendment of the Excluded Goods Order

Another new matter Dennis

----- Forwarded by Terry Lee/TGA/Health on 24/09/2002 11:59 -----



Rob Keane

24/09/2002 10:24

To: Terry Lee/TGA/Health@Health_gov_au

cc:

Subject: Proposed Amendment of the Excluded Goods Order

I would like to arrange a time to discuss briefly the involvement of the Legal Branch in a proposed amendment of the Excluded Goods Order. The proposed amendment relates to a resolution from the Therapeutics Policy and Planning Committee meeting of 10 September. The paper that went to that meeting is attached.

The Legal Branch has not been involved in this issue up until this point and this involvement is essential. Some of the issues I would like to discuss are:

1. allocation of a legal officer for the project;
2. the process for amending the Order;
3. the potential issues associated with the CAB amendments to the devices aspects of the Order, including the possibility of concurrence of these amendments;
4. the precise amendments to the Order, including the issues associated with substances used for treating or purifying the drinking water of animals (not humans).

I realise that you are busy and I don't wish to take up too much of your time with this preliminary discussion of the issue. I cease employment with the TGA on Friday and I would like to get this project to a stage where I can hand it to another OCM staff member, who can then liaise with Legal to finalise the project.

Rob Keane ext 8718



TPPC meeting.do

→ John Hall
back 14/10

David Briggs
x 8439

TPPC Meeting 10/9/02

3.8 AMENDMENT OF THE THERAPEUTIC GOODS (EXCLUDED GOODS) ORDER [PIO CESARIN]

The Committee endorsed a proposed amendment to the Therapeutic Goods (Excluded Goods) Order which would result in therapeutic goods for use in purification or treatment of drinking water being included within the scope of therapeutic goods legislation where therapeutic claims are made for such goods.

It was agreed that the amendment should apply only to substances used for purification or treatment of drinking water and not to the equipment in which they may be used.

