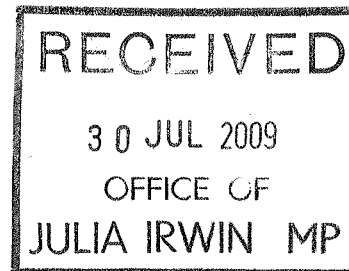


The Hon Mark Butler MP
Parliamentary Secretary for Health

Mrs Julia Irwin MP
Chair
Standing Committee on Petitions
PO Box 6021
Parliament House
CANBERRA ACT 2600



Dear Mrs Irwin *Julia*

Thank you for your letter of 11 June 2009 to the Minister for Health and Ageing, the Hon Nicola Roxon MP, regarding a petition in relation to the provision of Australian approved Product Information (PI) and Consumer Medicines Information (CMI) via a Therapeutic Goods Administration (TGA) website. As Parliamentary Secretary with executive responsibility for the TGA, I am responding on behalf of the Australian Government.

The proposal to make the PI and CMI documents available online from the TGA website is part of a business process review currently being undertaken by the TGA to improve access to information and enhance transparency around regulatory decision making. It will also mean that these documents will be available in a timely and reliable manner especially with respect to any safety updates. This practice is consistent with other comparable regulatory agencies such as the European Medicines Agency and the United States Food and Drug Administration. The business process review currently under way has been discussed with all major stakeholders including industry bodies and consumer groups.

The provision of the PI and CMI documents through the TGA website is seeking to enhance existing access arrangements and not to replace them. No change to the current system of distribution of these documents by sponsors or manufacturers of medicines is envisaged and the pattern of access by consumers, such as from the pharmacist when the medicine is dispensed, is not expected to be affected. It should be noted that some CMI documents are already available electronically from other sources such as the Pharmaceutical Benefits Scheme website, the National Prescribing Service website and the publication *MIMS*. Each source serves to provide access to the PI and CMI in a different context and thus has an overall complementary and beneficial role in the wider dissemination of this information to the public.

I trust that the above information is of use.

Yours sincerely

MARK BUTLER

24 JUL 2009