



Australian Government
Department of Health

DEPUTY SECRETARY

2 November 2015

Mr Jason McNamara
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk@obpr.gov.au

Dear Mr McNamara

Therapeutic Goods Advertising Code 2007

I am writing to the Office of Best Practice Regulation (OBPR) regarding the Therapeutic Goods Advertising Code 2007, which, as per the *Legislative Instruments Act 2003*, is scheduled to sunset on 1 April 2017. However, the Department of Health has decided that the instrument is to be remade without significant amendment. The Therapeutic Goods Advertising Code is an essential component of the therapeutic goods advertising regulatory framework.

The Department of Health certifies that Therapeutic Goods Advertising Code is operating effectively and efficiently to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer. Accordingly a Regulation Impact Statement (RIS) is not required for this instrument to be remade with minor and technical amendments. The OBPR reference number is 19757.

The assessment that the regulation is operating effectively and efficiently has been informed by consultation processes more recently which involved the therapeutic goods industry and peak representative bodies from that industry, healthcare providers and consumers and the Therapeutic Goods Advertising Code Council (a statutory body established to provide a consultative forum on and make recommendations about the Code).

Please note the Code is expected to be reconsidered following the Government's response to Part 2 of the *Review of Medicines and Medical Devices Regulation*. A RIS may be required to be undertaken as part of this process.

I acknowledge that OBPR will publish this letter for transparency purposes.

If you have any queries about this advice, please contact Dr Larry Kelly on (02) 6232 8700, or Larry.kelly@tga.gov.au.

Yours sincerely

A handwritten signature in black ink, appearing to read 'John Skerritt', with a long, sweeping underline.

Adj. Professor John Skerritt
Regulatory Services Group