



Australian Government
Department of Health

Mr Tony Simovski
A/g Deputy Executive Director
Office of Best Practice Regulation

Dear Simovski

Therapeutic Goods Act 1989 – Determination un subsection 19A(3)

I am writing to the Office of Best Practice Regulation (OBPR) regarding the *Therapeutic Goods Act 1989 - Determination under subsection 19A(3)*, which, as per the *Legislation Act 2003*, had been scheduled to sunset on 1 October 2017. It has been decided that the instrument is to be remade without amendment. The instrument can be found at <https://www.comlaw.gov.au/Details/F2007B01106>. It is intended to repeal a redundant determination made under subsection 19A(3) at the same time.

The Department of Health certifies that there is a genuine need for the *Therapeutic Goods Act 1989 - Determination under subsection 19A(3)* to continue, that it is operating effectively and efficiently, and that therefore a Regulation Impact Statement is not required for this instrument to be remade.

The determination contains a list of 9 countries. The Secretary is able to approve the importing or supply of an unapproved medicine (in the event of a shortage or lack of supply of a medicine that has been registered by the Therapeutic Goods Administration) if, amongst other things, the unapproved medicine has been approved for general marketing in one of those countries. The assessment that the instrument is operating effectively and efficiently has been informed by a consultation process which involved 22 parties who had submitted subsection 19A(I) applications to the TGA during the 2014 and 2015 calendar years seeking approval to import or supply such unapproved medicines.

The consultation was undertaken over the period from 9 December 2015 until 15 January 2016. The TGA received 17 submissions, which accounted for 91% of section 19A applications received during 2014 and 2015.

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

If you have any queries about this advice, please contact Ms Mary McDonald on 6232 8087, or mary.mcdonald@tga.gov.au.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'John Skerritt'.

Adj. Professor John Skerritt
Deputy Secretary
Regulatory Services Group
24 March 2016