



Australian Government

Department of Health
Therapeutic Goods Administration

10 September

Mr Wayne Poels
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet

Dear Mr Poels

Sunsetting of Therapeutic Goods Order No. 77 - Microbiological Standards for Medicines

I am writing to the Office of Best Practice Regulation (OBPR) regarding the Therapeutic Goods Order No. 77 - Microbiological Standards for Medicines, which, as per the Legislative Instruments Act 2003, had been scheduled to sunset on 1 October 2018. However, it has been decided that the instrument is to be remade without significant amendment.

The Australian Government Department of Health certifies that the Therapeutic Goods Order No. 77 - Microbiological Standards for Medicines is operating effectively and efficiently, and that therefore a Regulation Impact Statement is not required for this instrument to be remade.

The Department has undertaken self-assessment on the performance of the legislative instrument. The sunsetting review found that Therapeutic Goods Order No. 77 - Microbiological Standards for Medicines is fit for purpose and has operated effectively and efficiently since it came into force on 1 January 2010.

The self-assessment was informed by a public consultation process. The proposal to remake Therapeutic Goods Order No. 77 without substantially altering the current arrangements was available on the TGA web site for public comment from 6 February to 6 March 2018. Eight submissions were received during this consultation period. Most considered the Order to be efficient and effective, but technical modifications were requested.

A minor technical amendment will be made to the instrument - the addition of text to Clause 8 to refer to a medicine that is 'an aqueous multidose medicine'. The inclusion of this text will make clear the type of multidose medicines to which Clause 8 applies.

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

If you have any queries about this advice, please contact Tracey Duffy on 02 62328755 or via email, tracey.duffy@health.gov.au.

Yours sincerely

A handwritten signature in blue ink that reads "Jenny Francis". The signature is written in a cursive style with a large, looping initial "J".

Jenny Francis
A/g Deputy Secretary
Health Products Regulation Group (including the Therapeutic Goods Administration)