

Technical Alert

Microbiological Updates

NEW Therapeutic Goods Order No. 98 – Microbiological Standards for Medicines 2018

TGA hosting Stakeholder Forum on Faecal Microbiota Transplantation

NEW Therapeutic Goods Order No. 98 – Microbiological Standards for Medicines 2018.

The existing 'Therapeutic Goods Order No. 77 – Microbiological Standards for Medicines' is due to 'sunset' on 1 October 2018. This means that the Order will automatically expire due to default Government requirements for legislation.

The TGA have re-made this Standard into the new '**Therapeutic Goods Order No. 98 - Microbiological Standards for Medicines**', available on the Federal Register of Legislation [here](#). The new TGO 98 goes into effect on **1 October 2018**.

After consultation, the TGA determined that the TGO 77 has operated effectively and efficiently since it came into force in January 2010, and it continues to do so. Therefore, they have re-made the Order with only minimal changes for clarification and the new Order should not require any changes to existing processes.

Section 8 (preservative efficacy) has been clarified that it is only for **aqueous** multidose preparations, rather than multidose preparations.

For member who wish to view the tracked changes between the old and new Order, CMA has saved a copy [here](#).

Please also note that the TGA have not made changes in respect of probiotics in this Order. If you would like to discuss technical issues with the Order related to probiotic goods, contact technical@cmaustralia.org.au



TGA hosting Stakeholder Forum on Faecal Microbiota Transplantation

The TGA is hosting a free stakeholder [forum](#) to confirm their understanding of the health care sector engaged in the collection, manufacture and supply of material used in faecal microbiota transplantation (FMT).

The forum will be of interest to health care practitioners, patients and patient representatives, industry and State and Territory Government representatives interested in the regulation of FMT materials.

The forum seeks to clarify if and how the FMT sector can meet the current regulatory requirements for materials used in FMT. Feedback from participants at the forum will be used to inform whether product specific requirements and standards for the collection, manufacture and supply of FMT material are required.

When: **10 October 2018**

Time: **10:00 - 4.00pm** (lunch provided)

Where: **Melbourne**, Department of Health offices, Level 8, 595 Collins Street

Speakers:

- Professor Thomas Borody | Centre for Digestive Diseases, Sydney
- Dr Sam Costello | The Queen Elizabeth Hospital, Adelaide
- Professor Jane Andrews | Royal Adelaide Hospital, Adelaide
- Adjunct Professor David Van Der Poorten | Westmead Hospital, Sydney
- Professor Michael Kamm | St Vincents Hospital, Melbourne
- Dr David Andresen | St Vincents Hospital, Sydney

Register [here](#).

ENDS