



Australia and New Zealand Legal and Regulatory Affairs

Watchdog Update



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The TGA has consulted on a proposal to remake Therapeutic Goods Order No. 77 – Microbiological Standards for Medicines (TGO 77) without technical amendment.

<https://www.tga.gov.au/consultation/consultation-remaking-tgo-no-77-microbiological-standards-medicines>

The Order applies to medicines for human use that are within the operation of the Therapeutic Goods Act 1989, unless exempted. TGO 77 has been in force since 1 January 2010 and it is considered to operate effectively and efficiently. Hence the proposal to remake it without technical amendment.

The TGA has updated the information on its website on the regulation of autologous cells and tissues, including stem cells.

<https://www.tga.gov.au/autologous-cell-and-tissue-products>

The update outlines the timing of upcoming changes in the regulation of autologous cells in response to previous public consultations, global concern with direct to consumer advertising of unproven autologous stem cell interventions and concerns about risks to patient safety due to the increasing complexity of treatments offered. The changes are anticipated to commence in mid-2018.

The Therapeutic Goods (Manufacturing Principles) Determination 2018 came into effect on 1 January 2018

<https://www.legislation.gov.au/Details/F2017L01574>

It replaces the Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2013 and sets out minimum requirements for the manufacture of therapeutic goods other than medical devices.

ISCT

International Society for Cellular Therapy

TELEGRAFT

MEMBER NEWSLETTER



The TGA has published its Prescription medicines and biologicals: TGA annual summary
<https://www.tga.gov.au/prescription-medicines-and-biologicals-tga-annual-summary-2017>

This is an annual report on prescription medicines added to the Australian Register of Therapeutic Goods (ARTG).

The new Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.0, October 2017) came into effect on Monday, 15 January 2018

<https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg-v20>