International Society for Cellular Therapy ISCT
TELEGRAFT

Australia – New Zealand Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

New Zealand

New Regulatory Regime

In October 2016, The Ministry of Health announced that they are working on a new and comprehensive regulatory regime to replace the Medicines Act of 1981 and includes significant sections on cell and tissue therapies (see section 8.3 of Paper 1 for a definition). Information can be found here:

http://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime

Australia

Consultation

The TGA is seeking comments on the proposed changes to Authorised Prescriber (AP) and Special Access Schemes (SAS) Category A and B submissions. Please forward your comments to the ANZ LRA, coordinated by anz.watchdog@celltherapysociety.org. The Consultation closes on 29 March 2017.

The Consultation announcement can be found here:

https://www.tga.gov.au/consultation/consultation-changes-accessing-unapproved-therapeutic-goods-through-authorised-prescriber-ap-and-special-access-schemes-sas

The PDF of the document can be found here:

https://www.tga.gov.au/sites/default/files/consultation-changes-accessing-unapproved-therapeutic-goods-through-authorised-prescriber-ap-and-special-access-schemes-sas.pdf