

**ISCT**

International Society for Cellular Therapy

**TELEGRAFT**

MEMBER NEWSLETTER

**Australia and New Zealand Legal and Regulatory Affairs****Watchdog Update****REGULATORY**  
WATCHDOGTGA changes to regulation of Autologous Cell and Tissue Products

The Therapeutic Goods Administration (TGA) announced in October 2017 that there will be changes to the current loophole that excludes from regulation, autologous cellular therapies that are manufactured by a medical practitioner (or by a person under their supervision) for a patient in their care. An update on their website in December 2017 ([link](#)) indicated that the new regulations will be drafted and submitted to Government for approval in 2018 and that detailed guidance on the new regulatory approach will be published early in 2018. No further information has been released to date.