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TELEGRAFT MEMBER NEWSLETTER

Australia and New Zealand Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Australia

TGA Media Release regarding changes to regulation of Autologous Cell and Tissue Products

On 24 October 2017 the Therapeutic Goods Administration (TGA) announced 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. The exclusion was created for autologous HPC collection, processing, cryopreservation, storage and subsequent reinfusion that is an evidence-based treatment which is almost exclusively performed in the hospital setting with some oversight, in the form of accreditation, by the National Association of Testing Authorities (NATA). However, this exclusion has allowed unproven autologous cellular therapies to proliferate in Australia without any regulatory oversight. This area is of growing global concern with direct to consumer advertising of unproven autologous stem cell interventions, many with risks to patient safety due to increasing complexity of the treatments offered. Consequently, the TGA has recently proposed the following changes:

- No direct advertising to consumers of autologous cell and tissue products, but advertising of services (that do not mention specific products) will still be permitted.
- Exclude from TGA regulation autologous cell and tissue products that are manufactured and used in a hospital by a medical practitioner, for a patient under their care.
- Introduce TGA regulation, with exemptions from some requirements, for autologous cell and tissue products that are minimally manipulated, for homologous use only, and manufactured and used outside a hospital by a medical/ dental practitioner, for a patient under their care.
- Regulate under the Biologicals Regulatory Framework autologous cell and tissue products that are manufactured and used outside an accredited hospital, and are more than minimally manipulated, or for non-homologous use.

Implementation of these changes is likely to commence early in 2018. Access the full media release via this link.