Australia and New Zealand Legal and Regulatory Affairs
Watchdog Update

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On 29 March the TGA published updated guidance on Risk Management Plans for medicines and biologicals. The guidance is for sponsors of prescription medicines and biologicals making applications to enter or vary Australian Register of Therapeutic Goods (ARTG) entries. It describes the risk management plan requirements and has new content, new Australia-Specific Annex and a new form [1]. Therapeutic goods entered in the ARTG can be lawfully supplied in Australia [2].

On 15 March the TGA published information about how it manages complaints about therapeutic goods advertising and how to make a complaint if an ad for a therapeutic product breaches the Advertising Code [3].

The TGA is undertaking review and reform of the Australian regulatory requirements for medical devices classification. When undertaking such reviews, it has regard among other things, to the international best regulatory practice and any emerging issues. As part of the review, it is considering the EU regulatory framework. On 6 March it requested comments on a number of consultation papers including, among others, a paper on proposed medical device classification for human cells, tissues and organs storage solutions and IVF media [4]. Comments will close on 29 April 2019 and feedback will be released following consideration of submissions [5].

The TGA has provided further information relevant to the International Organization for Standardization (ISO) 2016 revision to ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes which has replaced the previous version from 2003 [6]. The 3-year transition period for ISO 13485 (full transition to the 2016 version of the standard) ended on 1 March 2019. The TGA published a notification of this transition period on its website on 9 August 2016.

References
3. TGA, How we stop advertisers from taking advantage of vulnerable consumers
4. TGA Consultation: Proposed medical device classification for human cells, tissues and organs storage solutions and IVF media”,