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International Society for Cellular Therapy ISCT

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Australia & New Zealand Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Australia

The TGA has publicly posted the presentation given at the International Society for Cellular Therapy Australia and New Zealand Regional Meeting, 12 November 2016. Ian Prosser, Senior Medical Adviser, provided an overview of how products are regulated, discussed the Excluded Goods Order and the recent consultation on the exclusion of some autologous cell therapies. The full presentation, including transcript, can be found at the link below.

https://www.tga.gov.au/tga-presentation-international-society-cellular-therapy-australia-and-new-zealand-regional-meeting-12-november-2016

TGA sought comments on the draft guidance for varying a biological included in the Register. http://www.tga.gov.au/consultation/consultation-guidance-variations-biologicals-included-register This Consultation "Guidance on variations to biologicals included in the Register" closed on 11 November 2016. An update is needed and relevant as there is currently only a loose understanding about what constitutes a notifiable variation and how such variations would be charged. The process of notification of variations has an impact on costs and workload for a licenced manufacturer of Biological products on the ARTG register, particularly where the variation relates to a change in test method by an external provider.

The TGA recently released several consultation documents in response to recommendations from the Review of Medicines and Medical Devices Regulation http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation (MMDR). While these draft documents may not be directly relevant to Biologicals, Dr Tony Manderson, Principal Adviser, Cell & Tissue Therapies Unit, Scientific Evaluation Branch, has indicated that it is possible that the same principles could be applied to biologicals.

1. New expedited pathways for the registration of prescription medicines https://www.tga.gov.au/consultation/consultation-expedited-pathways-prescription-medicines. If similar pathways were applied to biologicals it could impact greatly on entry into market for products with unmet need and that meet the specified criteria, and somewhat similar to other countries that have commenced implementation of similar strategies (eg. Japan, Canada and USA). This generally would support the global harmonisation of efforts within cell therapy groups in Australia and worldwide.

2. The proposed criteria to identify comparable overseas regulators in the regulation of prescription medicines https://www.tga.gov.au/consultation/consultation-criteria-comparable-overseas-regulators. The TGA propose defined criteria to identify comparable overseas regulators in the regulation of prescription medicines. Thus TGA will identify overseas agencies that have similar regulatory framework that aligns with that of the TGA and have MOUs with these comparable overseas regulators (CORs).

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This would allow sharing of the reports from CORs to facilitate expedited or more rapid assessment of new products. If used efficiently, this could impact greatly on the number of biological products entering the market and perhaps reduce overheads.

Both these consultations closed on 12 December 2016.

The TGA is seeking comments from interested parties on draft guidance documents and on whether or not EU guideline EMEA/149995/2008 should be adopted in Australia. Where TGA are recommending the adoption of EU guidelines in Australia it is rational, particularly when these are large generic documents and when adopted in Australia will provide relevant information to manage Biologicals.

- Consultation: Guidance on biovigilance responsibilities of sponsors of biologicals https://www.tga.gov.au/consultation-guidance-biovigilance-responsibilities-sponsors-biologicals
- Consultation: Guidance on risk management plans for medicines and biologicals https://www.tga.gov.au/consultation-guidance-risk-management-plans-medicines-and-biologicals
- Consultation on adoption of a European Union guideline EMEA/149995/2008 in Australia https://www.tga.gov.au/consultation-adoption-european-union-guideline-australia

These consultations close on 16 December 2015.

The TGA is seeking comments on the appropriate body or bodies for the handling of complaints under a new complaints-management system for therapeutic goods advertisements directed to the public, and other recommended reforms to the advertising regulatory framework. This is very relevant with the autologous cell therapy issues in Australia and worldwide. The advertising Biologicals consultation will be interesting to follow to see if any positive outcomes can be achieved.

- Consultation: The regulatory framework for advertising therapeutic goods - November 2016 https://www.tga.gov.au/consultation/consultation-regulatory-framework-advertising-therapeutic-goods-november-2016

This consultation closes on 21 December 2016.