International Society ISCT Cell & Gene Therapy

TELEGRAFT

MEMBER NEWSLETTER

Australia and New Zealand Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Gabrielle O'Sullivan, PhD, MPH
Executive Officer, Royal Prince Alfred Hospital Institutional Biosafety Committee
Royal Prince Alfred Hospital, Australia

TGA

New standard for disinfectants

The TGA has made a new 'Standard for Disinfectants' (TGO 104) to replace the previous 'Standard Disinfectants and Sterilants' (TGO 54), which sunset on 1 April 2019. The new Standard clarifies the requirements for hard surface disinfectants and labelling and provides guidance on the evaluation of disinfectants. Compliance obligations and penalties will commence on 29 March 2021, allowing a reasonable period to implement labelling changes. [1]

Evaluations of new biological entities – Beovu and Ajovy

The TGA has approved Brolucizumab (rbe) (Beovu, Novartis) for entry onto the Australian Register of Therapeutic Goods (ARTG). Brolucizumab is a humanized monoclonal single-chain Fv (scFv) antibody fragment that binds to vascular endothelial growth factor A (VEGF-A) isoforms. It is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD). [2]

The TGA has published the Australian Public Assessment Report (AusPAR) for Fremanezumab (Ajovy, Teva), which was entered into the ARTG on 20 September 2019. Fremanezumab is a humanized monoclonal antibody that binds calcitonin gene-related peptide (CGRP) and is indicated for the preventive treatment of migraine in adults. [3]

Therapeutic goods entered in the ARTG can be lawfully supplied in Australia. An AusPAR provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. The TGA aims to publish an AusPAR within 12 weeks of the new entry on the ARTG.

New regulatory model for faecal microbiota transplant (FMT) products

The TGA has provided details of a new regulatory model by which the collection, manufacture and supply of faecal microbiota transplant (FMT) products are to be regulated in Australia from 2020 [4, 5]. The TGA has consulted on draft standards for FMT products [6], and the new regulatory amendments for FMT products implemented on 1 January 2020 have a transition period of 12 months (i.e. commencing from 1 January 2021). All FMT products are regulated as biologicals. This includes significantly processed products that are derived from human stool. Where a strain(s) of microorganisms, known to be present in stool, is characterised and grown from established isolates with standardised consistency, these may be regulated as medicines, rather than as biologicals [5].

International Society ISCT Cell & Gene Therapy
TELEGRAFT
MEMBER NEWSLETTER

Presentations on GMP
The TGA has published presentations made at the 2nd Industry Forum on Good Manufacturing Practice (GMP) held on 21 November 2019 [7], including a presentation on GMP for new and emerging technologies: Advanced Therapy Medicinal Products (ATMPs) [8].

New science strategy
The Health Products Regulation Group (HPRG) in the Department of Health has published a new regulatory science strategy to ensure regulatory scientists are prepared for future challenges and emerging technologies. The strategy sets the direction over the next five-years for scientists in TGA, which regulates medicines and medical devices, and the Office of Drug Control (ODC), which regulates the import, export and manufacture of controlled drugs as well as the cultivation of medicinal cannabis. [9]

Pilot programme to increase international collaboration on inspections
TGA and its international partners are launching a pilot programme to increase their cooperation in the inspection of manufacturers of sterile medicines for human use. This collaboration will allow TGA, the European Medicines Agency (EMA), EU national authorities (France and the United Kingdom), the United States Food and Drug Administration (FDA), Health Canada, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and the World Health Organization (WHO) to share information on GMP inspections of manufacturers of sterile medicines who are located outside the participating countries, and to organise joint inspections for manufacturing sites of common interest. The products in scope are sterile medicinal products of chemical origin for human use and certain therapeutic biotechnology-derived products (such as monoclonal antibodies and recombinant proteins). Products currently out of the scope of this pilot are vaccines, cell and gene therapies and plasma-derived pharmaceuticals. [10]

Quality testing project
A testing project was performed by TGA Laboratories in 2018-19 to monitor the quality compliance and batch-to-batch consistency of Gardasil 9 being supplied in Australia. This project was initiated as part of routine surveillance testing of the quality of the vaccine and not in response to any specific safety concerns. The samples reported on passed the tests and meet quality standards. [11]

Advertising
On 20 November 2019, the TGA issued a direction notice to Cat Media concerning its advertising of Fatblaster Clinical. The notice requires the cessation of claims or representations that imply that Fatblaster Clinical can assist with weight loss [12]. The TGA has also published comprehensive information and guidance on its Advertising Code [13].

OTHER NEWS

Expanded access to Kymriah
On 28 January, the Federal Health Minister announced expanded access to Kymriah [14]. Between 200 and 250 additional cancer patients with Diffuse Large B Cell Lymphoma, Transformed Follicular Lymphoma and Primary Mediastinal B Cell Lymphoma, are expected to benefit from access to the CAR T-cell therapy, Kymriah, each year.

CTPL agreement with Novartis to produce Kymriah in Melbourne
Also on 28 January, Cell Therapies Pty Ltd (CTPL) announced that it has signed an agreement

International Society ISCT Cell & Gene Therapy
TELEGRAFT
MEMBER NEWSLETTER

with Novartis to produce Kymriah® in Melbourne. This will enable the first Australian on-shore commercial manufacture and supply of this therapy and will remove a major bottle-neck of international transport while patients benefit from substantially less time needed from blood collection to reinfusion [15].

[1] Therapeutic Goods Order 54 - Standard for Disinfectants and Sterilants (TGO 54), https://www.tga.gov.au/therapeutic-goods-order-54-standard-disinfectants-and-sterilants-tgo-54, published on 28 January 2020

[2] Beovu (Brolucizumab (rbe), Novartis), https://www.tga.gov.au/apm-summary/beovu, approved on 15 January 2020, entered into ARTG on 16 January 2020, published on 24 January 2020

[3] Australian Public Assessment Report (AusPAR): Fremanezumab, https://www.tga.gov.au/auspar/auspar-fremanezumab, published on 24 January 2020

[4] TGA regulation of faecal microbiota transplant (FMT) products in Australia, https://www.tga.gov.au/tga-regulation-faecal-microbiota-transplant-fmt-products-australia, published on 15 September 2019

[5] Faecal Microbiota Transplant (FMT) product regulation, Australian Regulatory Guidelines for Biologicals (ARGB), https://www.tga.gov.au/publication/faecal-microbiota-transplant-fmt-product-regulation, published on 6 January 2020

[6] Consultation: Draft standards for faecal microbiota transplant (FMT) products, https://www.tga.gov.au/consultation/consultation-draft-standards-faecal-microbiota-transplant-fmt-products, published on 15 January 2020

[7] TGA presentations: The 2nd Industry Forum on Good Manufacturing Practice (GMP), 21 November 2019, https://www.tga.gov.au/tga-presentations-2nd-industry-forum-good-manufacturing-practice-gmp-21-november-2019, published on 16 January 2020

[8] GMP for new and emerging technologies: Advanced Therapy Medicinal Products (ATMPs), https://www.tga.gov.au/presentation-gmp-new-and-emerging-technologies-advanced-therapy-medicinal-products-atmps, published on 16 January 2020

[9] New science strategy prepares regulatory scientists for the future, https://www.tga.gov.au/new-science-strategy-prepares-regulatory-scientists-future, published on 20 January 2020

[10] Launch of international pilot programme on inspection of manufacturers of sterile medicines, https://www.tga.gov.au/launch-international-pilot-programme-inspection-manufacturers-sterile-medicines, published on 19 December 2019

[11] TGA Laboratories testing report: Gardasil 9 Human Papillomavirus (HPV) vaccine monitoring, https://www.tga.gov.au/tga-laboratories-testing-report-gardasil-9-human-papillomavirus-hpv-vaccine-monitoring, published on 31 January 2020

[12] Direction about advertisements: Cat Media Pty Ltd, https://www.tga.gov.au/direction-about-advertisements-cat-media-pty-ltd, 24 December 2019

International Society ISCT Cell & Gene Therapy
TELEGRAFT
MEMBER NEWSLETTER

[13] Advertising: Advertising Code and guidance, https://www.tga.gov.au/advertising-advertising-code-and-guidance, published on 13 December 2019

[14] Expanded access to cutting edge CAR T-cell therapy, Media release from the Minister for Health The Hon Greg Hunt MP, https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/expanded-access-to-cutting-edge-car-t-cell-therapy, published on 28 January 2020

[15] Kymriah® to be manufactured at Cell Therapies Pty Ltd, marking Australia's first on-shore commercial production of CAR T therapy, https://www.celltherapies.com.au/kymriah-to-be-manufactured-at-cell-therapies-pty-ltd-marking-australias-first-on-shore-commercial-production-of-car-t-therapy/, Accessed 29 January 2020