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Australia and New Zealand Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

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AUSTRALIA

TGA

Consultations

Remaking of standards and legislative instruments for human cell and tissue (HCT) products, blood and blood components

The TGA is seeking feedback on a proposal to remake some of the legislative instruments relating to human cell and tissue (HCT) products (including blood and blood components), which sunset in October 2021.

The consultation documents are available and relate to Therapeutic Goods Orders (TGO1) 83 (human musculoskeletal tissue), 84 (human cardiovascular tissue), 85 (human ocular tissue), 86 (human skin), the biologicals labelling standard TGO 87 and the infectious disease minimisation standard TGO 88 (Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products). The consultation closes on Sunday 11 July 2021 [1]

Proposed improvements to the Therapeutic Goods Advertising Code

The TGA is conducting a public consultation on options to improve the Therapeutic Goods Advertising Code (No.2) 2018 (the Code), which has been in force since January 2019. The TGA and stakeholders have identified opportunities for improvements to increase clarity for advertisers and other users of the Code. The consultation closes on Friday 18 June 2021. [2]

GMP

GMP forum

The third TGA GMP forum was held over three half days from Wednesday 12 May to Friday 14 May 2021 as a virtual event. It had a strong focus on GMP oversight during COVID-19 and covered GMP regulatory activities; inspection reliance; hybrid and remote inspections; update on the PIC/S Guide to GMP for Medicinal Products version 14; how to improve GMP compliance for listed products; inspection trends for non-sterile registered medicines, sterile medicines, investigational medicinal products; GMP compliance signal management. [3]

Guidance on the management of GMP compliance signals for domestic and overseas manufacturers of medicines and biologicals [4]

The TGA has published the above guidance on GMP compliance requirements (according to the Manufacturing Principles [5]) for manufacturing biologicals and medicines intended for supply in Australia and the TGA's framework for managing GMP compliance signals. GMP

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compliance signals (i.e., non-compliance alerts) come from a wide range of intelligence, data, information, internal and external sources, inspections and monitoring processes which indicate a departure from the manufacturing principles (or equivalent overseas standards) by a manufacturer. [4, 5]

COVID-19 vaccine safety related information
The TGA's COVID-19 vaccine weekly safety report for 3 June 2021 has been published along with all previous weekly safety reports. [6]

Zostavax vaccine related information
The TGA has required new warnings for Zostavax vaccine to address the risk of fatal disseminated vaccine strain varicella-zoster virus infection. A new boxed warning has been added to the Product Information (PI) with information about managing this risk, including pre-screening and risk-based assessment prior to use of the vaccine, and management of suspected cases. Zostavax is a live, attenuated varicella-zoster virus vaccine that is used to prevent shingles in patients aged 50 years and older and prevention of nerve pain associated with the virus in patients aged 60 years and older. It is included on the National Immunisation Program (NIP) for people aged 70 to 79 years. [7, 8]

Medical devices reforms: Conformity assessment bodies
The TGA is responsible for including medical devices in the Australian Register of Therapeutic Goods (ARTG). From 1 July 2021, Australian corporations will be able to apply to become an Australian Conformity Assessment Body ('AU CAB'). The TGA will publish guidance on how to apply and the scope of medical devices for which an AU CAB can issue a conformity assessment certificate. [9]

The determination of an AU CAB requires demonstrated competency and recognition for undertaking medical device conformity assessments and quality management system auditing.

It is expected that an AU CAB will be an Australian-based corporation operating under the systems and controls that have already been assessed as compliant by comparable overseas regulators through their parent and affiliated organisation's recognition, such as a Notified Body under EU Medical Device Regulation (EU MDR) or EU In Vitro Diagnostic medical devices Regulation (EU IVDR) [10], and as a Medical Device Single Audit Program (MDSAP) Auditing Organisation [11]. The MDSAP allows for recognised Auditing Organizations to conduct a single programme of regulatory audits of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program. The TGA has been a participating member of the MDSAP consortium since it was initiated as an International Medical Device Regulators Forum (IMDRF) work item in 2012. [11].

NEW ZEALAND
MINISTER OF HEALTH AND MEDSAFE

COVID-19 vaccine safety related information
MedSafe has published:

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1. **The June 21 Prescriber Update** which focuses particularly on the Comirnaty vaccine manufactured by Pfizer/BioNTech [12]. There are no updates to the missing information and the conditions placed on the provisional approval, but it notes that ongoing studies and will help address missing information and mentions:
    - 1.1 The publication of a **guidance on vaccination for patients with immunodeficiency or autoimmunity** by the Australasian Society of Clinical Immunology and Allergy [13]
    - 1.2 **Advice for the health sector published by the Ministry of Health**. [14]
    - 1.3 **An overview of the reports to the Centre for Adverse Reactions Monitoring (CARM) describing adverse events following immunisation (AEFI),** which is published on the Medsafe website. [15]
2. **Safety Report # 9 describing adverse events following immunisation with COVID-19 vaccines – 1 May 2021.** [16]
   281,005 doses have been administered (cumulative) and the following number of total Adverse Events Following Immunisation
    - 1,991 Total AEFI reports that were non-serious
    - 90 Total AEFI reports that were serious
    - 2,081 Total AEFI reports that were received (cumulative)
    -
3. **The Agenda for The 186th Meeting Of The Medicines Adverse Reactions Committee to be held on Thursday 10 June 2021** at 9 am[17]

GLOSSARY

Australian Register of Therapeutic Goods (ARTG): Therapeutic goods entered in the ARTG can be lawfully supplied in Australia (https://www.tga.gov.au/australian-register-therapeutic-goods)

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- **MEDSAFE**
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- **Consultation on proposed improvements to the Therapeutic Goods Advertising Code**
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