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MEMBER NEWSLETTER

Australia and New Zealand Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

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AUSTRALIA

TGA

Consultations

Updates to the human tissue specific standards Therapeutic Goods Orders

Consultation documents are expected in April 2021 for consultations on proposed updates to the human tissue specific standards Therapeutic Goods Orders (TGO) 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). [1]

Proposed regulatory options for medical devices containing nanomaterials.

The EU introduced a new medical device regulatory framework from 2017 (EU Regulation on medical devices (2017/745), which included new requirements around nanomaterials. The TGA is consulting on whether the Australian medical device regulatory framework should be aligned to the EU framework for medical devices containing nanomaterials, and how this could occur. The consultation closes on 9 April 2021. [2]

GMP Forum

The third TGA GMP forum will be held over three half days on Wednesday, 12 May - Friday, 14 May 2021. It will be held as a virtual event due to the ongoing uncertainty as a result of the COVID-19 pandemic. It will be a free event. [3]

Zolgensma

On 24 February 2021 the TGA approved Zolgensma (onasemnogene abeparvovec) for the treatment of paediatric patients less than 9 months of age with symptomatic or pre-symptomatic spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and 1 to 3 copies of the SMN2 gene. It was entered into the Australian Register of Therapeutic Goods (ARTG) on 4 March 2021. [4]

Procurement guidance

The TGA has published guidance for health procurement teams in hospitals, aged care residential facilities and other facilities about therapeutic goods and medical devices. It covers

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what is a medical device, an 'exempt' therapeutic good and an 'excluded' good; the ARTG and reporting problems with therapeutic goods. [5]

COVID-19 vaccines

Provisional approval of Astra Zeneca COVID-19 vaccine

On 16 February 2021, the TGA published that it granted provisional approval to AstraZeneca Pty Ltd for its COVID-19 vaccine, making it the second COVID-19 vaccine to receive regulatory approval in Australia. It is included in the ARTG for the active immunisation of individuals 18 years and older for the prevention of COVID-19 caused by SARS-CoV-2. The provisional approval is valid for two years and means the vaccine can now be legally supplied in Australia. The approval is subject to strict conditions such as the requirement for AstraZeneca to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment [6]. The Australian Public Assessment Report for the vaccine was also published on 16 February 2021 [7]. The Office of the Gene Technology Regulator (OGTR) issued a licence (DIR 180) to AstraZeneca for the importation, transport, storage and disposal of the vaccine [8]. The TGA has also given approval for the vaccine to be manufactured in Australia by CSL-Seqirus [9] and on the 23 March it approved the release of the first four batches totaling 832,200 doses for supply. [10]

Approval of updated storage conditions for the Pfizer COVID-19 vaccine

The TGA has approved updated storage conditions for the Pfizer COVID-19 vaccine (COMIRNATY - BNT162b2). A storage condition of - 20±5°C for up to 2 weeks (even during transportation) within the 6 month shelf life when stored at -90 to -60°C has been approved. An updated Product Information Sheet is anticipated to be submitted by Pfizer and published on the TGA website shortly. [11]

Fast tracking authorisations of modified COVID-19 vaccines for variants

The TGA has adopted Access Consortium guidance for fast-tracking authorisations of modified COVID-19 vaccines for variants. [12]

Safety relevant information on COVID-19 vaccines

The TGA is monitoring the situation regarding in a small number of people, predominantly overseas (in the United Kingdom and Europe) who have presented with clotting disorders following vaccination with the AstraZeneca vaccine. On 2 April, one case has been reported in Australia and is being investigated by the TGA. [13, 14]

International Medical Device Regulators Forum (IMDRF) seeks submissions on proposed guidance on the process used to evaluate Conformity Assessment Bodies performance

The IMDRF working group on Good Regulatory Review Practices seeks to develop guidance that establishes good regulatory review practices for Regulatory Authorities and/or Conformity Assessment Bodies (CABs), and to promote global harmonisation in the premarket review processes. It is seeking comments on a proposed guidance document, which outlines the process used to evaluate CAB performance and the possible outcomes if performance issues are identified. Interested parties should make submissions by 19 April 2021, using a provided template, directly to the IMDRF working. [15, 16]

MITOCHONDRIAL DONATION

Mitochondrial donation is not currently allowed in Australia. The Australian Government is proposing to introduce mitochondrial donation in a staged and closely monitored way and has

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consulted on the proposal [17, 18]. A bill will be introduced to Parliament to enable this and MPs and Senators will be allowed a conscience vote on it. [19]

CONSULTATION ON IMPLEMENTATION OF THE OUTCOMES OF THE THIRD REVIEW OF THE AUSTRALIAN GENE TECHNOLOGY REGULATORY SCHEME

The Australian Government has consulted on the Regulatory Impact Statement outlining options for implementing the outcomes of the Third Review of the Australian Gene Technology Regulatory Scheme [20]. The Review took place from 2017-2018 and supported continuation of the Scheme with adjustments to futureproof it and make it more flexible and responsive to technological advances. Legislation will be forthcoming with further consultation.

RESEARCH

The NHMRC has released a statement [21] on the Nature paper '*Modelling human blastocysts by reprogramming fibroblasts into iBlastoids'* published by Monash University's Polo Laboratory [22]. The NHMRC statement states that the research '*involved the creation of human-embryo like structures by reprogramming adult human skin cells. These structures are called iBlastoids by the research group because they are artificially induced and closely resemble human blastocysts (an early stage of human embryo development). iBlastoids are not generated from the fertilisation of an egg by a sperm. They are artificially created by reprogramming adult human skin cells. iBlastoids can be created in large numbers in the laboratory, which is expected to allow researchers to more easily study early human development. In the Australian context, research on early human embryonic development has been limited to using 'excess' embryos created during ART treatment. Research opportunities have therefore been limited by the low number of available 'excess' embryos, as well as ethical concerns over the use of embryos created by fertilisation in research*.'

NEW ZEALAND

MINISTER OF HEALTH AND MEDSAFE

COVID Vaccines

On February 3rd 2021, the Minister of Health provisionally consented to the sale, supply or use in New Zealand of the new medicine COVID-19 vaccine, COMIRNATY BNT162b2 (mRNA) manufactured by Pfizer Manufacturing Belgium NV for prevention of COVID-19 disease caused by SARS-CoV-2 in adults and adolescents from 16 years of age and older [23]. On March 8th the government announced the vaccine roll-out plan for everyone in New Zealand aged 16 and over using the Pfizer/BioNTech vaccine. Following this announcement, MedSafe has published risk management plans (RMPs) setting out the known safety information for a medicine and measures to monitor the safety of the medicine. RMPs include a summary of the known safety profile and risks, activities to minimise the risks, and plans to gain more information on the medicine.

The Janssen (Ad26.COV2.S) and the AstraZeneca COVID-19 vaccines are being processed through an abbreviated application pathway and awaiting further data to be provided by the sponsor. [24]

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Consultations

Update the New Zealand Code of Good Manufacturing Practice

MedSafe is adopting the new PIC/S Guide to Good Manufacturing Practices (GMP) PE009-14 to ensure alignment with global regulators and best practice [25]. This will exclude annexes 3, 4, 5, 12 and 16. In February 2021 MedSafe published the consultation plan, which is expected to conclude in November 2021. [26]

Medicines Classification Committee

MedSafe published the agenda for the 66th meeting of the medicines classification committee to be held in Wellington on 11 May 2021. [27]

ISCT ANZ REGIONAL MEETING

The Australia and New Zealand Regional ISCT Meeting was held virtually on Friday 26 February 2021 as a free event to ISCT members. [28]

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NEW ZEALAND

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ISCT ANZ VIRTUAL REGIONAL MEETING