Technical Alert

Announcement: Comparable Overseas Bodies Announced

Consultation: Export of Therapeutic Goods

Technical Guidance on GMP for Medicinal Cannabis

Comparable Overseas Regulators

The Medicines and Medical Devices Review (MMDR) identified a need for the TGA to recognise the evaluations of international regulators when assessing OTC and complementary medicines and new substances for listed medicines, as a measure to streamline business processes by removing duplication of efforts. This has been one of the lengthier and complex recommendations to implement, however, in response to this recommendation the TGA has now announced the list of recognised comparable overseas bodies (COBs); criteria for identifying COBs; and a process for accepting reports from COBs.

The COB report-based process is already open for applications and can, under the specified circumstances, be used to evaluate:

- 'AUST R' registered complementary medicines
- 'AUST LA' assessed listed medicines
- Substances for use as ingredients in 'AUST L' listed medicines.

Important notes:

- Medicines and substances in reports must have received full marketing approval from the comparable overseas bodies following a 'de novo' (new) application, not an extension of an existing approval. Unless justified the application or marketing approval should not have been delayed, deferred, rejected, refused, cancelled or withdrawn.
- Members who have access to a COB report can assess its suitability against the 'Stage 2' criteria.
- The ability to use a report should be discussed at a pre-submission meeting with the TGA.
- New COBs can be identified and added to the existing list with a set of 'Stage 1' criteria used to establish sufficient similarity between TGA and the overseas body.
- The list of initial COBs is below, with the full criteria and approval for each on the TGA website. The list of COBs and criteria for each may change depending on suitability.

EU – European Food Safety Authority (EFSA)
EU – European Medicines Agency (EMA)
EU – Joint FAO/WHO Expert Committee on Food Additives (JECFA)
EU – Scientific Committee on Consumer Safety (SCCS)
US – Cosmetic Ingredient Review (CIR)
US – Food and Drug Administration (FDA) , Center for Drug Evaluation and Research (CDER)
Australia – Food Standards Australia New Zealand (FSANZ)
Australia – National Industrial Chemicals and Assessment Scheme (NICNAS)
Canada – Health Canada (HC)
Singapore – Health Sciences Authority (HSA)
Japan – Pharmaceutical and Medical Devices Agency (PMDA)

Consultation: Export of Therapeutic Goods

The TGA is seeking feedback regarding a guidance document related to the export of medicines from Australia. The document provides guidance on all aspects of the process, including: regulation, controlled substances, export only medicines, the application process and export certificates. In particular, the TGA seeks feedback on the following proposals which related to export certificates:

1. Is it of benefit to allow submission of electronic schedules to accompany a Certificate of Pharmaceutical Product (CPP) or a Certificate of Listed Product (CLP) application?
    - The TGA currently requires all export documents to be provided in hard copy, as this was a requirement of importing countries over 15 years ago
    - The TGA would like to allow the option to submit electronic documents (where acceptable to the importing country)

2. Is it of benefit for the TGA to provide traceable post for all hard copy certificates? (this option may incur an appropriate fee increase)

This consultation is relevant to:

- Australian sponsors planning to export medicines for commercial purposes
- Authorised agents action on behalf of a sponsor
- People planning to export medicines for non-commercial use

The consultation period will **close on 3 February 2020**. The TGA webpage contains the consultation documents as well as instructions on how to make a submission (Note: there is a separate consultation document for the export of devices). Members are encouraged to participate in the consultation and forward any comments to lucy.lang@cmaustralia.org.au

Technical Guidance on GMP for Medicinal Cannabis

The TGA have released the final version of the Technical guidance on the interpretation of the PIC/S Guide to GMP for Medicinal Cannabis products. At this stage, please note that unless down-scheduled, cannabis remains classified as a registered S4 'prescription only' medicine when included in the ARTG. However most medicinal cannabis products currently remain unapproved therapeutic goods that can only be accessed through special access pathways:- the authorised prescriber scheme, the Special Access Scheme (SAS), or clinical trials in certain circumstances.

There are **two licences** that operate under different legislation which may be required if you are manufacturing medicinal cannabis **in Australia**:

- Licence to manufacture therapeutic goods (GMP) issued by the TGA; **and/or**
- Narcotic manufacture licence issued by the ODC

Overseas manufacturers should be covered by a current GMP clearance or certification.
GMP level requirements for API and registered medicines would also be expected.
The full guidance document is available here on the TGA website.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au. ENDS