Technical Alert

NEW TGO 101 in effect on 31 March 2019; Important Changes to Note

The TGA have signed off a NEW Standard for Tablets, Capsules and Pills, which was recently publicly consulted on the TGA website. The new standard "TGO 101" replaces the current "TGO 78" as of **next Sunday, 31 March 2019**. There are new changes and new requirements, we recommend members read the summary below and familiarise themselves with changes, pending TGA training.

The NEW ***Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TG0 101) Order 2019:***

- **DOWNLOAD HERE** from CMA's website.

Note: content limits of vitamins, minerals, enzymes and probiotics are unchanged from existing.

Official Publication:

TGO 101 will be registered on the Federal Register of Legislation prior to coming into effect.

A link to the Order will be on the TGA website once registered.

The supporting guidance document will be published by **Friday 5 April.**

Effect:

The document is effective on **31 March 2019**.
Requirements that carry forward from existing requirements, and changes *other than those* noted below with a transition period, will be immediately in effect.

NEW Requirements with Transition Period to March 2021:

1. **Elemental impurities (heavy metals) – for Tablets and Capsules.**
   We are pleased that the TGA have accepted CMA's recommendation to not proceed with the original, concerning consultation options for elemental impurities, but to:
   A. Adopt USP <2232> for elemental impurities; and
   B. Provide an alternative option to use ICH-Q3D if preferred; and
   C. Provide a transition period for implementation (**March 2021**).
   We note that pills have been given a separate elemental impurities requirement within Schedule 2, Part 6 of the Order (more below).

2. **Residual Solvents**
   The TGA are adopting the European Pharmacopoeia requirements for residual solvents, with a 2-year transition to **March 2021**.

3. **Reintroduction of Pills (note – Traditional Chinese Medicines)**

   The Order reintroduces requirement for Pills, which will especially have an effect on Traditional Chinese Medicines that are presented in pill form. The requirements relate to:

   - Appearance
   - Water content
   - Weight variation
   - Disintegration
   - Assay of each active ingredient
   - Elemental impurities. We note that these requirements, *in addition* to those outlined above for Tablets and Capsules, also have a set of concentration limits provided:
     - Arsenic - a maximum concentration of 2 parts per million
     - Cadmium - a maximum concentration of 1 part per million;
     - Lead a maximum concentration of 5 parts per million;
     - Mercury a maximum concentration of 0.2 parts per million.

Other Important Changes:

1. **Choice of, and application of Standards**

The new TGO specifically outlines that there are **two choices** that a sponsor/manufacturer can choose from in the application of standards to a medicine – refer to Section 8 of the document. As many complementary medicines do not have an individual monograph for a specific tablet or capsule, in those cases the choice would automatically be A. In all circumstances, sponsors/manufacturers have the ability to choose A as summarised below.

A. As per Section 8(2) and 8(1)(b) of the document:

   Use the **"*Australian Specific Requirements*" (Division 3 of TGO 101)**

   <u>TOGETHER WITH</u>

   The **general chapters*** of one of the following **default standards**:
   - the ***British Pharmacopoeia*** **(BP);** or
   - the ***European Pharmacopoeia*** **(EP);** or
   - the ***United States Pharmacopeia National Formulary*** **(USP-NF).**

B. As per 8(1)(a) of the document: If there is **an individual monograph for a specific tablet or capsule**, then you can still choose A as per above *or* you can choose to:

   Following the requirements specified in that individual monograph, subject to **Division 2** of the TGO 101, which includes the specific TGA requirements for:

   - **Dissolution of folic acid for registered and listed medicines**
   - Other dissolution requirements for registered medicines
   - **Uniformity relating to dosage units and weight**

Note on applying General Chapters of a Pharmacopoeia as well as the TGO's requirements.

The TGA have stated that the requirement to use General Chapters *in addition to* the TGO is a carryover of existing requirements from the Therapeutic Goods Act, but we understand that this may be different to the understanding of the sector, based on activities to date with the TGA.

CMA are currently following up on this with both the TGA and our manufacturing committee, however please reach out to us with any specific comments or concerns in relation to this matter.

2. **Expansion of some requirements.**

   Some TGO requirements (e.g. Disintegration) have been expanded to permit the choice of tests from different monographs, such as the choice to use the USP-NF for a specific test in addition to the BP or EP.

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