Technical Alert

TGO 91 and TGO 92 Updates

GMP Forum in Melbourne

Publication of Compositional Guidelines

TGO 91 and TGO 92 Updates

The TGA have released the updated guidance regarding implementation of the labelling orders TGO 91 and TGO 92.

The update provides more detailed guidance and is organised into four sections:
Part 1 describes the structure of the Orders and legal requirements that generally apply to all medicines.
Part 2 aids identification of legal mandatory requirements that apply to certain types of medicines.
Part 3 related to design of medicine labels and suggests some 'best practice principles', that are not mandatory, but may further improve the safe and quality use of medicines.
Part 4 provides guidance on the tabulated display of Critical Health Information (registered medicines only).

Specific changes to the guidance include: the application of transition arrangements, reference to other legislative instruments that contain warning statements, additional information related to the declaration of mandatory ingredients from Schedule 1 of the Orders, and use of multiple bar codes.

Transition arrangements

This updated guidance clarifies that whilst medicines released for sale and supply after 1 September 2020 must comply with TGO 91 or 92, that those medicines released for sale and supply **before 31 August 2020** can continue to supply TGO 69 compliant goods after 1 September 2020.

Release for supply is defined in the PIC/S guide as the final licensable step of manufacture, where each batch of finished medicinal product must be certified as having been manufactured in accordance with and Marketing Authorisation, and any other regulations relevant to the production, control and release of those medicinal products.

Warning Statements

Section 1.5 of the updated guidance advises sponsors that, in addition to warning statement contained in the Order, that other warning statements from additional instruments must be observed, including the following additions to the guidance: the Permissible Ingredient Determination, the Permissible Indications Determination and the Advertising Code.

Declaration of mandatory ingredients from Schedule 1

Section 1.5.9 of the guidance now includes some notes and qualifications to Schedule 1: “Substances or Groups of substances present in medicines that are required to be declared on the label of medicines”. Those that relate to complementary medicines are:

- **Benzoates**: the note clarifies which forms of benzoic acid captured by the label declaration. "For example, benzoic acid, calcium benzoate, sodium benzoate and potassium benzoate should be declared. More complex esters, such as methyl benzoate, are not captured in this entry."
- **Hydroxybenzoic acid esters –** the guidance notes that this entry in Schedule 1 refers only to parabens with 'hydroxybenzoate' in the Australian Approved Name. The specific names are listed in Schedule 1. The guidance also notes that salicylates should not be declared under this entry.
- **Phenylalanine –** The updated guidance provides a context to note 5 of Schedule 1 (page 37), which is to ensure that consumers are aware of medicines that might contain phenylalanine in quantities that are significant to the condition phenylketonuria (PKU). Ingredients high in protein, such as those mentioned in note 5, may have an impact on patients with PKU who are managing their phenylalanine intake. The intention is not to capture every complex ingredient that may contain phenylalanine as a trace component (e.g. gelatine).
- **Pollen –** the updated guidance in this section notes that a cut-off for pollen is not specified in Schedule 1, and it is only intended to alert consumers with pollen allergies to medicines where pollen may be present. For examples bee pollen products or herbal materials in medicines that include flowers. The guidance clarifies that the pollen label declaration is not intended to capture pollen at background levels in the environment, to which consumers may be exposed in their everyday lives, be declared on medicine labels.
- **Sorbates** – the updated guidance specifies that the label declaration for sorbates refers to preservatives, and does not include polysorbates.
- **Sugar alcohols** – regarding the declaration of sugar alcohols the guidance states that sponsors may include the quantity of the specific sugar alcohol as part of the declaration, AND do not need to include the statement 'contains sugar alcohols' where the specific sugar alcohol is named.

Use of multiple bar codes

The updated guidance acknowledges that there are situations where more than one code needs to be included on medicine packaging (for the purposes of sale) and provides guidance for these circumstances.

GMP Forum in Melbourne

The 2nd GMP Forum is being held on **21 November 2019** in Melbourne.

The event is hosted by the TGA in conjunction with the Royal Australian Chemical Institute (RACI), Australian Regulatory and Clinical Scientists (ARCS), Parenteral Drug Association (PDA) and the International Society for Pharmaceutical Engineering (ISPE), and will include content relevant to prescription, over-the-counter and complementary medicine sectors.

The TGA encourages personal/consultants employed by sponsors, manufacturers, small to medium size enterprises, who are involved with quality assurance, regulation, and risk assessment of medicines to attend.

Details:

Thursday, 21 November 2019

8:15am - 6:00pm AEDT
Pullman Melbourne Albert Park (the Pullman), 65 Queens Road, Melbourne, Victoria 3004

Registration:
Before Friday 18 October 2019
RACI - ARCS - PDA - ISPE members - $170
Non-members - $200
After 18 October 2019 - $430

Registrations close **Friday 1 November 2019**.

Payment and registration instructions are available on the webpage, along with additional information about accommodation at the Pullman Hotel.

Enquires about this event can be directed to Ms Karen Sivonen of the Manufacturing Quality Branch on 02 6221 6831 (tel), 02 02 6203 1451 (fax) or by email, GMPForum2019@health.gov.au

Publication of Compositional Guidelines: Resveratrol and Calcified *Lithothamnion species*

Resveratrol

The TGA have published a compositional monograph for Resveratrol, an ingredient used widely in complementary medicines and manufactured by bacterial fermentation of genetically modified baker's yeast (Cerevisiae).

The compositional guideline contains specific parameters related to appearance, water content, analytical method for identification, incidental constituents and microbiology.

Calcified Lithothamnion species

The TGA have also published a compositional monograph for Lithothamnion species (AAN) and Calcified Lithuanian tophiforme (AAN).

'*Lithothamnion spp*.' is derived from skeletal deposits of *Lithothamnion spp* (L. corallioides, L. tophiforme) sourced from the Atlantic Ocean.

'Calcified *Lithothamnion tophiforme*', the substance is the skeletal deposits of *Lithothamnion tophiforme* sourced from Arnarfjordur fjord in Iceland.

The compositional guideline contains specific parameters related to appearance, identification, incidental constituents and microbiology.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

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