Technical Alert

Updated TGA Guidance on TGO 92 Labelling Order – including Allergen & Substance Declarations

The TGA has published an update to the medicine labelling guidance, 'Medicine labels: Guidance on TGO 91 and TGO 92', on the TGA website. This version 1.1 of the guidance is the second version and replaces version 1.0 that was published in August 2016.

Changes to the guidance include:

- Addition of guidance on determining when a Schedule 1 substance is present - part 1.
- Corrections based on feedback and clarification of existing information.
- Addition of latex labelling in best practice - part 3.

Major changes to the document relevant to listed medicines are included in this technical alert. Changes to Section 4 (Consumer Health Information) may be of interest to sponsors of registered non-prescription medicines.

CMA will be providing a document highlighting the changes throughout the document to members of the email group CMA QRU (Quick Regulatory Updates). If you would like a copy of the highlighted document and are not on this email group, please request a copy at technical@cmaustralia.org.au.

TGO 92 error for listed medicines in small containers

The new guidance clarifies that there is an error in TGO 92 for listed medicines in small containers: The minimum text height for listed medicines presented in small containers is 1.5 millimetres, not 2 millimetres as stated by TGO 92. This will be corrected in future updates to the Order.

CMA has received advice that the post market section of the Complementary Medicines Branch will not be recognising this as a compliance breach. Therefore, Section 14 exemptions are not required to be submitted by sponsors who are using 1.5mm text height on small containers.

Guidance on labelling of Schedule 1 substances (including allergens)

The following clarification (p15) has been added to provide that where Schedule 1 names a group of substances (such as fish and fish products) and provides examples (such as tuna and cod-liver oil), those examples are not a comprehensive list of items that fall under that group:

> Some entries in column 1 of Schedule 1 include example names underneath the primary substance name. These are examples only and should not be considered a complete list. You must determine whether any other substances in your medicine fit the definition and need to be declared. Sponsors should speak to their manufacturers about whether any declarable substances are an ingredient or component in the medicine or a known part of the manufacture of the medicine.
>
> For more information about what consumers are expecting on their medicine labels, see the TGA 'Allergens and medicines' page.

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The following section has been added to Section 1 to clarify the declaration requirements of Schedule 1 ingredients. This section is of significance to sponsors as it indicates that a broader risk assessment of substances to be declared on labels is required. CMA and ASMI are currently working together to finalise an updated version of the questionnaire for raw material suppliers that is intended to reflect the below guidance.

Determining when a substance is present

Not all entries in Schedule 1 include circumstances explaining when the substance doesn't need to be declared.

When there is no cut-off specified in the Schedule 1 entry, sponsors should declare the substance if:

- it has been added during any of the manufacturing processes (even as a manufacturing aid) and there is any likelihood that it remains in the finished goods
- it is a known component, or likely to be a component, of one of the ingredients in the medicine

Sponsors should assess the risk to consumers to determine whether a substance may be present and should be declared.

Tests to determine presence of an ingredient may not be sensitive enough to detect allergens but can be used to provide further information to consumers. Sponsors may choose to include additional information about the allergen on their label, website or Product Information/ Consumer Medicines Information documents. Information could include the level of residue detected, the measures taken to remove the substance or how the substance has been used in the manufacturing process. When including additional information, the statement, '*contains x'* must still be declared on the label as required by Schedule 1.

If it is unlikely that a substance is present, declarations should not be made simply as disclaimers. Sponsors are not required to introduce tests for *all* allergens.

Declaring multiple substances

If your medicine has more than one substance that must be declared, these declarations can be combined to form simple sentences e.g. 'contains sugars as lactose' or 'contains aspartame and sulfites'.

Guidance on latex in medicine packaging

The following is a new section in the guidance:

3.1.2. Latex in medicine packaging

Some medicine packaging components, such as vial stoppers, are made with natural rubber latex. To reduce the risk of anaphylaxis and to assist consumers and health professionals in managing latex allergy, we recommend that all medicines containing rubber in their packaging:

- state the presence or absence of natural rubber latex on the label; and
- state the presence or absence of natural rubber latex in the Product Information (PI) and CMI.

For example, if your medicine container has a synthetic latex stopper, you should include the statement 'vial stopper not made with natural rubber latex'.

You should avoid using terms such as 'latex-free'.

Clarification on names of medicines and dosage forms.

The following are new sections of the guidance:

1.5.6 The name of the dosage form

The name of the dosage form is the dosage form that has been entered onto the ARTG for the medicine.

Some dosage forms are written in reverse order for easy indexing in the TGA eBusiness Code Tables. In most cases, the word order should be changed to achieve plain English on labels, for example, 'tablets, effervescent' should be written 'effervescent tablet' on the label. There are several exceptions such as 'injection, solution' which should not be reversed.

1.5.7 The name of the medicine

The name of the medicine is defined in section 6 of both Orders as the name that appears on the ARTG certificate, with some qualification.

Often additional information appears with a tradename to more fully describe the medicine in the electronic record. Section 6 describes when it is acceptable to omit this information when stating the name of the medicine on a label. For example, additional descriptive information, such as the dosage form or a flavour, may only need to be included to differentiate between medicines in a range. In many instances dosage form or flavour information can be stated elsewhere on the label.

ENDS

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