Technical Alert

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TGA Public Consultation & Survey: Options for the implementation of a claimer for efficacy assessed non-prescription medicines

On 10 May 2018 the TGA released the consultation document detailing the options for implementing a positive label claimer for TGA pre-assessed non-prescription medicines, including complementary medicines (Listed Assessed and Registered). This consultation arises from Recommendation Forty-Five of the Review of Medicines and Medical Devices:

Australian Government Response to the Review of Medicines and Medical Devices Regulation

Recommendations	*Government response*
Recommendation Forty-Five: The Panel recommends that where a medicinal product is listed in the ARTG following an assessment by the NRA of an application under Option Two, the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indication(s).	The Commonwealth **accepts-in-principle** Recommendation Forty-Five, noting that the design and use of the promotional statements will require careful consideration by the TGA and further consultation with stakeholders.

The February 2017 consultation on reforms to complementary medicines included a proposal to allow sponsors to claim on the product label that products which have been pre-assessed (in the Listed Assessed pathway) have been assessed by the TGA for efficacy. As this option was strongly supported, the current consultation is being undertaken to determine the most appropriate presentation of the claimer. The scope has been expanded from Listed Assessed medicines only to all classes of non-prescription medicines, and the consultation asks which classes the claimer should apply to.

Submission may be made in writing, however, to increase the level of engagement from stakeholders, the TGA have provided the ability to respond by survey.

The following information is being asked:

- Do you support the introduction of a claimer?
- Which classes of medicines should be able to use the label claimer?
- The visual identity and size, colour and location of the label claimer.
- The expression of any associated label statement.

Submissions to the **consultation** including the **survey** close on **Thursday 21 June 2018.**

Priority Sponsor Review of Arbutin-containing Herbal Products

The TGA have previously advised sponsors that changes in the upcoming June version of the Permissible Ingredients Determination will require the mandatory declaration of arbutin in herbal products including *Achillea millefolium, Arctostaphylos uva-ursi* (leaf)*, Chimaphila umbellate, Kalmia latifolia, Ledum palustre, Origanum majorana, Pyrus communis, Pyrus pyrifolia, Rhododendron ferrugineum, Turnera diffusa, Vaccinium vitis-idaea* (leaf).

Preparations containing hydroquinone or its derivative – arbutin – is included in Schedule 4 of the Poisons Standard when for therapeutic use. Due to the inclusion in the schedule, the TGA have indicated that they are unable to provide a transition period for this change to the Determination. Although they have not stated whether they will be progressing compliance assessment, sponsors may wish to prioritise internal reviews of any listed medicines that contain arbutin-containing herbs for oral use including *Arctostaphylos uva-ursi (leaf) and Turnera diffusa.*

CMA will be continuing to assess the situation in relation to arbutin-containing herbs and we encourage any views to be forwarded to the Secretariat at technical@cmaustralia.org.au .

Delayed changes to Caffeine in Listed Medicines – for further review

Earlier this year the TGA flagged changes to listed medicines containing caffeine within the forthcoming June version of the Permissible Ingredients Determination. The changes were proposed as follows:

'*The maximum daily dose must provide no more than 600 milligrams of caffeine. Divided preparations for internal use must contain no more than 100 milligrams of caffeine per dosage unit'*.

However, we have become aware that the proposed change was not in alignment with the view of all areas of the TGA in regards to the required restrictions for caffeine-containing ingredients. In particular, the dosing requirements and advisory statements for listed medicines would have been significantly more relaxed than those for registered medicines (as well as for comparably regulated products overseas and FSANZ formulated caffeinated beverages). This could have resulted in a situation where consumers may have accidentally misused caffeine-containing products, as well as a situation where other areas of the TGA would have required further changes to the caffeine-containing listed medicines within a short period of time, creating regulatory complications for new products in development.

The TGA have advised that any amendments for caffeine related products will be delayed until the next Determination, in order for the TGA to conduct a more thorough review of the regulatory requirements for these products. The TGA will communicate this delay to sponsors shortly.

CMA members have expressed concerns over high-dose caffeine products inadvertently causing adverse effects if not used appropriately. CMA will continue to assess within regulatory working groups what is an effective level of regulation that is accordance with international best practice on caffeine-containing products while also avoiding unnecessary or onerous restrictions.

CMA submission on Plain English Allergen Labelling in foods

CMA's submission to the Food Standard Australia New Zealand (FSANZ) consultation on Proposal P1044 - Plain English Allergen Labelling (PEAL) is available on the CMA Submission page (PDF). While recognising there will always be some differences between appropriate allergen labelling for foods and complementary medicines, CMA has supported the alignment of terminology and grouped allergen categories where there are opportunities to do so, to simplify arrangements for both consumers and industry.

Mandatory Labelling of Lupin on Food Products in effect 26 May 2018

On 25 May 2017, in response to a risk assessment, Food Standards Australia New Zealand (FSANZ) updated the Food Standards Code requiring lupin to be declared when present in a food, as an ingredient or component of ingredients, including food additives and processing aids. Industry was granted a 12 month transition period to comply.

From **26 May 2018**, all foods must comply with the new requirement.

Resources related to this decision

- Food Standards (Proposal P1026 – Lupin as an Allergen) Variation, was made on 22 May 2017 and updated Food Standard 1.2.3. This can be viewed here.
- The original proposal and risk assessment can still be viewed here on the FSANZ website.
- Lists of foods that may contain lupin are published on the FSANZ website here.
- The Media Release can be located here.

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

ENDS