Technical Alert

Branding and Labelling Update: Specialised Application Process to be announced by the TGA to assist complementary medicine sponsors with TGO 92.

CMA are very pleased to announce that through CMA advocacy, working with direct CMA member involvement, the TGA have agreed to offer industry a specialised application process that is intended to provide relief to sponsors whose pre-existing, reasonably presented brand logos/trademarks on medicine labels would be adversely affected by a particular part of the TGO 92.

This specialised application process is being designed to be practical to achieve and relatively low cost. It will help sponsors during the next few years to maintain some existing elements of brand logos/trademarks, which allows the TGA additional time to examine the possibility of more permanent options for additional branding flexibility for non-prescription medicine sponsors. Both the short term and long term processes will continue to have some conditions, to ensure that the guiding principles of the TGO 92 – to have improved clarity of labels and medicine names for consumers – will continue to be met.

Background

The ***Therapeutic Goods Oder No 92 Standard for labels of non-prescription medicines*** came into effect in September 2016, with a four year transition period, with a final implementation date of September 2020.

The listed complementary medicine in particular, generally experienced some delays in implementing the Order early, as many sponsors were waiting for the introduction of "permissible indications" before proceeding with major label changes. When the TGO 92 was implemented by complementary medicine sponsors on a wider scale, it became clear that:

- There was confusion about whether the brand name needed to be on the ARTG, or only the individual product name.
- There was confusion about whether the TGO 92 requirements applied to brand names as well as product names, and how significantly this affected brand logos.
- It later became evident that there were some adverse and unintended consequences for brand logos and domestic as well as international brand trademarks. Such consequences included:
    - "Non-compliance" of important brand logo/trademark elements, such as small graphics or taglines. This affected brand whose brand name was included on the ARTG. This is due to Section 9(2) of the TGO 92, which states:

      'The name of the medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information or background text',

      where the 'name of the medicine' has the meaning set out in the TGO 92, primarily, that it is the **name appearing on the ARTG Certificate of Listing or Registration** (not including certain items such as the strength or pack size).

The wording of section 9(2), has unfortunately introduced some unintended consequences for some brands and sponsors, meaning that some brand logos or trademarks would be considered "non-compliant" due to the presence of small graphics or trademarks, even though these items do not significantly distract the consumer from having a clear and accessible medicine name on a product label.

After considerable discussion of the issue between CMA, TGA, and some affected members, the TGA have been understanding of industry's concerns that there are branding circumstances where the guiding principles of the TGO 92 to have clearer labels are met, even though there is the presence of some small graphics and taglines that would "technically" breach Section 9(2) of the TGO 92.

To help resolve this issue, the TGA are offering two processes:

1. In the shorter term (next several years), a specialised application process for sponsors to apply for a limited-time consent under Section 14 of the Act, to supply products that have brand logos or trademarks that are unable to meet the exacting requirements of Section 9(2) of the TGO 92.
2. This allows sponsors relief, while in the longer term, the TGA can examine and consult upon possibilities for some improved permanent flexibility for brands in the TGO 92 labelling order.

Member Questions and Comments

The TGA have not yet publicly announced this. **If you have any questions or comments about this process**, please contact CMA directly Lucy.Lang@cmaustralia.org.au, not the TGA, until more information is published on their website.

The process to apply for brand relief before TGO 92 takes full effect.

1. If your brand is included on the ARTG Certificate(s) of Listing.

Full details of the process will be announced by the TGA in coming weeks. The preview of this process is as follows. We have provided this information to the best of our knowledge following our meeting with the TGA, but please note that until the TGA finalise the process, it is possible some small changes may occur.

- If your brand is on the ARTG and your TGO 92 medicine labels, including the brand logo/trademark, already meet the requirements of Section 9(2) of the TGO 92, then you do not need to take any action.
- Sponsors who have a brand name logo/trademark for an existing range of products on their ARTG Certificates of Listing, who are concerned that their brand will be unable to meet Section 9(2) requirements of the TGO 92, can make an application to the TGA for consent to supply the products with TGO 92 labels that are not fully complying with Section 9(2), due to small or reasonable brand logo/trademark elements.
- The TGA will publish a specialised form for sponsors to use for this process.
- The TGA will publish certain condition or parameters that must be met for the application to be approved by the TGA. These are still being finalised, however, as an example, if you have an existing brand graphic or tagline, there still will be some limitations on its presentation, such as the text size of a tagline, or whether a graphic would cause significant problems with the consumer recognition of the name of the medicine. As most brand names already take a sensible approach, we are expecting that most (if not all) brand logo/trademark presentations would be likely to be approved through this process.
- However, for sponsor certainty, CMA recommends providing applications as soon as possible after the TGA publish the specialised application forms. In the (hopefully unlikely) scenario that an

application is rejected, this would mean brand changes would still be necessary to have TGO 92 compliant labels by September 2020.

- The timeframe for approving applications may vary depending on the number of applications and other TGA work, however, please be aware that timeframes of 4-6 weeks might be expected.
- The applications for this specialised process are only intended to be **specifically** in relation to Section 9(2) of the TGO 92, to help sponsors preserve logos and trademarks that were unintentionally affected. The TGA are **not inviting** wide-scale applications in regard to other TGO 92 issues.
- The TGA are not inviting applications in relation to any new logos or trademarks that would not comply with Section 9(2). The applications are intended for **existing** brand logos or trademarks.
- Cost: A Section 14/14A application currently costs $480. The TGA will allow a "group application" for a brand range to help lower costs for sponsors. For example, if you have a brand range that has 25 products with the identical brand logo/trademark presentation on every product, they will allow a single application, rather than require 25 applications. However, the single application would be expected to provide all 25 labels (whether in final printed form, or final draft form).
- A section 14/14A application can only be for medicines that are already on the ARTG. If members have brand name ranges where NPD is occurring further down the track, then new applications will need to be made for the new products after they come onto the ARTG. Sponsors could choose to do an application for **each** new product, or they could wait to apply for a **group** of new products at one time – however please note that these new products that are not fullying complying with TGO 92 should not be supplied until the Section 14/14A "consent" application is approved.
- The label assessment through this specialised application will only consider this aspect of the TGO 92. The labels will not be reviewed by the TGA for other aspects of TGO 92 compliance. However, the TGA wishes to remind sponsors that a label complying with TGO 92 must comply with *all* aspects of the TGO 92, in other words, a reminder that labels cannot 'mix and match' requirements between the old TGO 69 and the new TGO 92.

2. If your brand is not included on the ARTG.

If your brand is not included on the ARTG, then the TGO 92 requirements of Section 9(2) do not currently apply to your brand. However, other relevant pieces of legislation may apply as to whether the brand should be included on the ARTG or not.

There have been some conflicting messages as to whether there is any legal expectation under the Therapeutic Goods Act that brand names should, under most circumstances, be included on the ARTG record. Due to this issue of ongoing uncertainty and confusion over the legal compliance requirements, CMA are seeking further clarification from the TGA to ensure that sponsors would not encounter any "unexpected" compliance issues in the next few years regarding medicine naming, which could become extremely costly and difficult for sponsors if they were approached about naming and branding issues that were not expected *after* the introduction of TGO 92. We are hoping that this would not be the case. However, if we become aware of any clarifications provided by the TGA in the near future, through existing cases that are occurring which might affect any existing sponsors, we have requested that this would also be approached in a clear, practical, helpful, and low cost way for industry members.

ENDS