

Technical Alert

Labelling Update - TGO No. 92A Amendment Order amends TGO 92

An amendment order to amend the *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* (TGO 92) has now been registered on the Federal Register of Legislation (FRL). The amendment order can be found here: <u>Therapeutic Goods Order No. 92A – Therapeutic Goods Order No. 92 (Standard for labels of non-prescription medicines) Amendment Order 2017 (TGO 92A).</u>

The changes outlined in this Amendment Order will become incorporated into the next version of the TGO 92 that is expected to be registered on FRL in approximately one month's time.

There are no new requirements outlined in the amendment. There are clarifications and corrections to items included in Schedule 1 and 3, including editorial changes suggested by CMA as part of its response to addressing issues raised with regards to the interpretation of TGO 92.

The TGO 92A amendment:

- Provides that non-prescription medicines that not required to be included in the ARTG before their lawful supply under the health practitioner notification arrangement, under subsection 19(7A) of the Act (introduced recently by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017*), are not required to comply with the TGO 92;
- Clarifies the introductory text in Schedule 1 to the Order to confirm that multiple substance declarations can be made within the same sentence;
- Provides a note in Schedule 1 to the Order to exclude glycerol from the entry for sugar alcohols;
- Amends the entry for 'sorbates' in Schedule 1 to the Order to clarify its intent;
- Corrects the requirements for potassium declaration in Schedule 1 to the Order;
- Corrects the requirements for sodium declaration in Schedule 1 to the Order;
- Amends the units for bromelains in Schedule 3 to the Order, to allow insertion of 'million' before the unit 'PU" in Column 1 and before 'Papain units' in Column 2, to ensure the references are technically correct and consistent with agreed use; and
- Correctly reflects the name of the re-made TGO 69 (2017), which replaces the previous TGO 69.

More information about packaging and labelling generally can be found on the TGA website here.