Complementary Medicines Australia

Technical Alert

Therapeutic Goods Order No. 95 - *Child-resistant packaging requirements for medicines 2017* (TGO 95)

The Therapeutic Goods Order No. 80 (TGO 80), entitled '*Child-Resistant Packaging Requirements for Medicines*' is due to sunset (expire) on 1 October 2018. The TGO 80 will be succeeded by the Therapeutic Goods Order No. 95 – '*Child-resistant Packaging Requirements for Medicines*' (TGO 95), which commenced on the Federal Register of Legislation (FRL) on 5 December 2017.

The implementation of TGO 95 includes a transition period until **30 September 2018**. During this time, sponsors can choose between complying with the requirements of TGO 80 or the TGO 95. From **1 October 2018**, all medicines supplied in Australia to which this Order applies, must comply with the requirements of TGO 95.

No perceived impact on complementary medicines.

TGO 95 makes minor changes, of which there is no perceived changes for complementary medicines. There are no amendments to Part 2 of Schedule 1, which lists individual substances contained in complementary medicines, such as iron compounds.

The changes to the Order affect three registered medicines on the ARTG. The sponsors of these medicines were included in a targeted consultation, and a Regulatory Impact Statement was reviewed favourably by the Office of Best Practice Regulation (OBPR).

Compared to the TGO 80, the new TGO 95:

- Removes examples of substances in Part 1 of Schedule 1, leaving only the classes of medicines to which the Order applies in Part 1;
- Removes Part 3 of Schedule 1 altogether which was simply an alphabetical listing of substances from Part 1. The purpose of this change is to prevent the Order being misinterpreted as an exhaustive list of substances, and to promote the use of the World Health Organization Anatomical Therapeutic Chemical (WHO ATC) classification system, to identify by class the substances to which the Order applies.
- Includes additional substances, podophyllum/podophyllotoxin and alpha blockers (prescription medicines), in Schedule 1 to the Order.
- Updates the international packaging standards referenced in the Order to reflect the current editions of the standards which are listed in part 9 of the Order.
- Makes minor editorial amendments, e.g. to reflect current Australian Approved Names and new TGA advisory committee structure.

ENDS