Technical Alert

Required Advisory Statements for Medicine Labels (RASML)
Removal of requirements that apply solely to listed medicines

An updated edition of the Medicines Advisory Statements Specification (the '2017 Specification') has been registered on the Federal Register of Legislation (FRL).
The 2017 Specification includes an updated version of RASML No. 3, effective 1 July 2017, and will also include a fully updated version of RASML No.4, which will come into effect 1 January 2019.

As usual, the 2017 Specification allows for an 18-month transition period for adoption of the advisory statements in RASML No. 4 (new and amended) onto medicine labels. During this transition period, from 1 July 2017 to 1 January 2019, affected medicine labels may comply with either RASML No. 3 (as amended) or with RASML No. 4.
However, there are some important changes for our industry to note.

Removal of requirements that apply solely to listed medicines

The changes in the RASML No. 3 include the **removal of all requirements that apply solely to listed medicines.** These requirements are being removed from the RASML because the relevant requirements are now included in the Therapeutic Goods (Permissible Ingredients) Determination ('the 26BB Determination'), and the Specification does not apply to listed medicines that are compliant with the S26BB Determination.

Removal of these requirements from the RASML is consistent with the intent of the section 26BB Determination in regards to labelling requirements for listed medicines, and avoids duplication.

Further information about this change and the other changes that will be included in the Updated Medicines Advisory Statement Specification can be found on the TGA website at:
Medicines Advisory Statements Specification Updates

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