

**Technical Alert 18.12.2019**

**TGA response to online publication of excipient ingredients**  
**Update to the Uniform Recall Procedure for Therapeutic Goods**  
**TGA E-learning Modules for Listed Medicines published**  
**Update to Advertising Guidance**  
**GMP Webinar Presentation Published**

**TGA response to online publication of excipient ingredients**

In August 2019, the TGA opened a consultation [Increased online access to ingredient information](#) proposing to publish medicine excipients on ARTG records (but not labels). The TGA have advised that due to around 400 consumer responses in favour of excipient publication, that there is the intention to proceed with the proposal. This is with the exception of excipients contained with flavour, fragrance or colour proprietary ingredients that would be identified using the generic terms 'flavour', 'fragrance' and 'colour'. CMA is continuing to express our raise concerns around IP in response to the proposed publication to examine whether there are acceptable modifications.

**Update to the Uniform Recall Procedure for Therapeutic Goods**

An updated version of the Uniform Recall Procedure for Therapeutic Goods (URPTG) has been published on the [TGA website](#).

The updates in this version include the following, with 2 & 4 relevant to complementary medicines:

1. Additional clarity on the provision of surgeon contact details for implanted therapeutic goods
2. **Amendments related to the online notification of recall and non-recall actions (including the use of GS1 Australia's Recall Health portal)**
3. Removal of the placeholder referring to the "National Patient Contact Principles for Patients with Implanted Medical Devices subject to Hazard Alerts"; and
4. **A second example template for the sponsor's customer letter.**

This version also includes several other minor editorial amendments.

**TGA E-learning Modules for Listed Medicines**

In November this year, CMA provided feedback to the TGA on some provisional e-learning modules. These modules have now been [published](#).

The TGA has advised that they have made some minor amendments in response to feedback such as: amending wording; changing graphics; providing links to permitted indications guidance, and inclusion of brief statements on the justification of evidence.

Feedback from industry about the justification for evidence and specific and non-specific indications is to be incorporated into subsequent modules.

## Advertising Code Guidance Update: cancelled and suspended goods

The TGA [Advertising Guidance webpage](#) has been updated to include information about the advertising of suspended or cancelled goods.

The website specifically states that the following types of goods cannot be advertising:

- therapeutic goods not entered on the ARTG, which includes,
- cancelled or suspended therapeutic goods (even those goods are available under the special access scheme or other unapproved goods access pathways).

The database of suspended goods can be accessed [here](#), although please note that suspensions are currently not applied or rarely applied to listed medicines.

Due to the introduction of the Standards Provisions Act and amendments to the Therapeutic Goods Act in 2018, the TGA now have powers to apply infringements and penalties to advertising issues including the advertising of medicines that have been cancelled or suspended.

## Publication of webinar: GMP clearance applications - Common Pitfalls

Following the webinar of 6 December 2019, the TGA have [published this slide presentation](#) which summarises common deficiencies identified in GMP clearance applications, along with suggestions of how to improve application quality and reduce common errors that typically may delay applications.

## Resources

- [Publication of excipient ingredients](#)
- [URPTG update](#)
- [E-learning modules for TGA listed medicines](#)
- [Advertising Guidance updated](#)
- [GMP Clearance applications presentation](#)

**Members are encouraged to forward any identified issues to [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au) for attention by the Committee Secretariat.**

**ENDS**