

Item 5 Issues arising from permitted indications industry consultation

Issue

The TGA is finalising a list permitted indications for use in listed medicines. The following issues have arisen during stakeholder consultation:

- Traditional Chinese Medicine Indications not being understood by general consumer.

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Background

From January 2018, to be eligible for listing on Australian Register of Therapeutic Goods (ARTG), listed medicines can only use indications from the permitted indications list. A 'free text field' for entering indications is not available for listed medicine entries.

'Indications' are statements that describe a therapeutic use for a medicine. In relation to listed medicines, a 'therapeutic use' means 'use in, or in connection with, influencing, inhibiting or modifying a physiological process in persons'.

Permitted indications are indications that have been assessed against a set of criteria and determined to be appropriate for low risk listed medicines that are not assessed pre-market. Permitted indications have a consistent structure and terminology to describe the therapeutic uses for listed medicines. All permitted indications contain a therapeutic action and a therapeutic target.

Only low level indications that are compliant with the regulatory requirements are included on the permitted indications list, based on the following criteria:

The indication must be:

- low risk- the indication can only refer to
 - health maintenance
 - health enhancement
 - prevention or alleviation of a non-serious vitamin or mineral dietary deficiency
 - a non-serious form of a disease, condition, ailment or defect
- consistent with the treatment paradigm –scientific or tradition of use
- capable of complying with the Advertising Code when included on promotional materials.

The purpose of establishing the list of permitted indications is to:

- Ensure that listed medicines can only make low level indications that are suitable for medicines that do not undergo pre market assessment.
- Provide transparency for sponsors on what indications are suitable for listed medicines to help prevent inadvertent non-compliance.

- Avoid consumers being misled by inappropriate indications on listed medicine labels.

The draft list of permitted indications was published on the TGA website in July 2017 for public comment, closing on 31 October 2017. ACCM advice is sought on the following issues raised in the stakeholder comment period.

Advice sought

Issue 1: TCM indications

A number of submissions expressed concern in relation to the inclusion of paradigm specific terminology for Traditional Chinese Medicine (TCM) indications, stating that these are not understood by the general consumer and therefore inappropriate to be included in the list. Examples are provided in the table below:

TCM specific indications
Clear/expel Damp-Heat in Bladder
Clear/cool Blood Heat
Clear/dry/drain/eliminate/resolve/dry Dampness
Clear/expel Dampness transforming into Phlegm
Clear/dispel/transform Body Fluid
Clear/drain Damp Heat in Gall Bladder

TGA comment:

TCM specific indications have been included in the list recognition that traditional terminology is required for persons familiar with the TCM paradigm to use the medicines appropriately.

Proposed policy:

TGA proposes to include a general requirement that medicines using indications with paradigm specific terminology (e.g. TCM and Ayurvedic medicine indications) include an advisory statement on their label with words to the effect of:

‘Please seek the advice of a traditional [insert paradigm] practitioner to ensure this medicine is right for you’

In addition, TGA Guidance material will recommend that TCM sponsors include a general plain English indication along with the traditional terminology on the medicine’s label.

Advice sought:

ACCM is requested to comment on whether the following label statement, or words to the effect of, should be required on indications with parading specific terminology to mitigate concerns that such indications are not understandable to the general consumer.

‘Please seek the advice of a traditional [insert paradigm] practitioner to ensure this medicine is right for you’

