Technical Alert

Using Restricted Representations in Advertising

Permitted indications: e-learning modules released

Compositional Guideline: *Streptococcus salivarius*

Using Restricted Representations in Advertising

Summary

The TGA have updated the guidance regarding the use of restricted representations in advertising and on medicine labels, including how to apply to use a restricted representation, and launched a new online application process to replace paper-based applications.

A restricted representation is a "**serious form of disease, condition, ailment or defect**" that cannot be referred to in advertising on any medicine in any context, unless specifically approved, or permitted for use by the TGA prior to use.

In particular, the guidance clarifies that applications to make restricted representations/reference to serious diseases or conditions are not required where the reference is contained or required in mandatory label warning, contraindication or advisory statement. This is particularly relevant to those sponsors who have been asked by the TGA in recent times to obtain a restricted representation for the use of a TGA required warning statement that includes a restricted representation on a medicine label, as the guidance now clarifies that this is not required.

Approval and permission to use restricted representations

There are two ways a restricted representation may be used in advertising. It can approved by the Secretary (under section 42DF of the Therapeutic Goods Act 1989). Alternatively, permission may be granted by the Secretary in the absence of an application (under section 42DK of the Act).
Approval or permission to use a restricted representation may be granted to advertisements for a specific product or substance, a group of products (eg sunscreens), or products containing a specific substance (eg folate).

When considering applications to use restricted representations in advertising, the Secretary (or delegate) is required to take into account the public interest criteria set out in the Code and the advice of any relevant Committee, and be satisfied that the representation is accurate and balanced; is not misleading or likely to be misleading.

Permitted indications: e-learning modules released

A set of e-learning modules have been added to the Permitted Indications TGA webpage related to the transition arrangements for permitted indications, as well as instructions on how to use permitted indications in the TGA Business Services portal.

The modules are:

Module 1: Overview of permitted indications and transition arrangements

Module 2: How to remove indications and add permitted indications for your existing medicine

Module 3: Selecting parent indications and linking indications

Compositional Guideline for *Streptococcus salivarius*

The TGA have published a compositional guideline for the bacterium Streptococcus salivarius which is found in normal human oral microflora, and which can be cultivated and used in listed medicines. The compositional guideline contains specific parameters related to appearance, particle size, morphology, biochemical profile and virulence.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS