Australian Government
Department of Health
Therapeutic Goods Administration

Appendix 1 - Guidelines for advertisements for medicines containing Schedule 3 substances

Version 1.0, May 2018

TGA Health Safety Regulation

This document is for Reference only.

It is not for consultation or comments.

Reference only.

Contents

Background

As documented in the recently revised Scheduling Policy Framework (SPF) (www.tga.gov.au/scheduling-news) medicines containing substances from Schedule 3 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP or Poisons Standard) will now be permitted to be advertised unless it is determined that advertising is not appropriate for a particular substance. Substances will be considered on a case-by-case basis and included in Appendix H following a decision by a Delegate of the Secretary of the Department of Health (the Delegate).

A person must not include in any advertisements, except those in genuine professional or trade journals to healthcare professionals or the wholesale therapeutic goods trade, any reference to a substance included in Schedule 3 of the Poisons Standard, unless the substance is also listed in Appendix H of the Poisons Standard (see Paragraph 3.1 Part 3 Poisons Standard) and Part 2 of the Therapeutic Goods Regulations 1990 (the Regulations).

Advertisements for Schedule 3 substances are required to comply with other relevant provisions of the Therapeutic Goods Advertising Code (the Code), the *Therapeutic Goods Act 1989* and the Regulations.

Purpose

The purpose of this document is to:

1. Provide guidance for the Delegate and stakeholders for determining if a Schedule 3 substance is not suitable for advertising;
2. Provide additional guidance for parties advertising medicines containing Schedule 3 substances.

Role of the Delegate

Once a substance has been added to Schedule 3, in accordance with the SPF, the Delegate will consider if there is any compelling reason for the substance not to be advertised directly to consumers.

If there is no overriding reason to prevent the substance from being advertised, it will be added to Appendix H of the Poisons Standard. Substances considered unacceptable for advertising will be listed on the Scheduling webpage.

The Delegate may also consider an application to reconsider a substance that is in Schedule 3 but has not been included in Appendix H.

Factors to be considered by the Delegate

When deciding if there is a reason for not permitting a substance to be advertised, the Delegate will consider the potential impact on public health as follows:

a. Is there potential for inappropriate use, abuse, diversion that may be exacerbated by advertising?

b. Are there potential interactions with the substance (drug-drug, drug-food) that require increased patient education to ensure safe use?

c. Are there additional risks associated with the dosage form that may impact on safe use?

d. Any other information that may be relevant, for example the substance has sedating properties, or there are safer alternatives available.

On balance, if the potential impact on public health is determined to be adverse were advertising to the public to be allowed, the Delegate may choose to not add a substance to Appendix H. The factors listed from a-d (above) are intended as a guide to assist in determining the potential public health impact, and may not be relevant in all cases. Conversely, additional factors might be relevant in specific cases.

The process

For substances being considered by the Delegate for inclusion in Schedule 3, their suitability for inclusion in Appendix H will be considered concurrently. There will be no specific application or criteria to be addressed. During the public consultation phase of the scheduling process stakeholders will be asked to provide comment on the potential inclusion of the substance in Appendix H.

The need to seek advice from the Advisory Committee for Medicines Scheduling regarding inclusion in Appendix H will be at the Delegate's discretion.

Where a substance has been determined to be unsuitable for advertising, interested parties may make a submission to the Delegate to reconsider the substance addressing the reasons given for not adding the substance to Appendix H.

Mandatory requirements for product advertising

In accordance with the Code, advertisements for products containing Schedule 3 substances must include the following statement:

"***Ask your pharmacist, they must decide if this product is right for you***"[1].

There may be other mandatory requirements for advertisements of Schedule 3 products specified in the Code, for example analgesics, that stakeholders must comply with.

Schedule 3 substances may also be captured by the restricted representations of the Code, and stakeholders must comply with these requirements when preparing their advertisements.

[1] This statement was included in the recent consultation on the draft Therapeutic Goods Advertising Code 2018 which closed on 27 April 2018. The final approved wording may still change.

Adverse events

The inclusion of detailed adverse event information in advertisements for medicines containing Schedule 3 substances is not mandatory. However, for stakeholders who wish to include side effects in their advertisements, the following is recommended:

1. Inclusion of adverse events in an advertisement should not obscure the key take out message(s). For advertisements for medicines containing Schedule 3 substances, the key take out message is the emphasis on the role of the pharmacist.
2. Any presentation of adverse events should be clear and easily understood. This means that the font should be easily read and understood, or audio delivery can be clearly heard and understood.

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