Australian Government
Department of Health
Therapeutic Goods Administration

Listed medicine presentation and labels

Australian regulatory guidance

Version 1.1, September 2020

TGA Health Safety Regulation

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Contents

Listed medicine presentation

Applicants of all listed medicines are required to certify [against subsections 26A(2)(c) for listed medicines or 26AB(2)(c)of the Act for listed assessed medicines] that the presentation [as per definition under Section 3(1) of the Act] of the medicine is not unacceptable.

Section 3(1) of the *Therapeutic Goods Act 1989* provides the definition of presentation:

> '**Presentation**' in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods

Some aspects of the product that are considered to comprise the 'presentation' include (but are not limited to):

- the medicine name
- the medicine label, including: symbols and pictures; the name; indications; directions for use; warning and cautionary statements; logos
- packaging
- dosage form
- advertising material

Unacceptable presentation of a listed medicine

A listed medicine can be cancelled from the ARTG if the medicine's presentation is found to be unacceptable. Section 3(5) of the Act and 3(A) of the *Therapeutic Goods Regulations 1990* state when the presentation of a good is considered unacceptable.

Examples of unacceptable presentations include, but are not limited to:

- Therapeutically active ingredients are present in the formulation but not declared as such on the label (and/or misleadingly declared as 'excipients' in the application).
- Statements are made attributing a therapeutic role to ingredients that have not been declared as active ingredients, that is: excipient ingredients.
- Statements or pictures suggest that the product has uses or actions different from, or in addition to, the indications for use included in the ARTG.
- Presentation of a product is in a form likely to result in it being confused with food, for example: in confectionery-like novelty shapes and packaging.
- Product names are used that are likely to be misleading as to the composition of the medicine.
- The appropriate dosage for all age-groups in the likely target population is not stated, for example: 'adults', 'children 6-12 years' etc., as appropriate.
- The dosage form or directions are inappropriate for the target population, for example: a capsule dosage form is not appropriate for infants.
- Warning or cautionary statements needed for proper usage of the product are omitted.

- A reformulated product that does not have labelling adequately informing the consumer that it has different active ingredients from the product previously supplied under that name.
- Claims are made that a formulation is 'hypo-allergenic' or 'non-irritant', unless the sponsor holds supportive evidence from clinical tests that can be produced on request.
- Claims are made that a product is free from certain substances, for example: 'free from artificial colours' if not true.

Advertising of listed medicines

For information about the advertising of medicines, go to:

- Advertising to the public: complying with the Therapeutic Goods Advertising Code
- Australian Regulatory Guidelines for Advertising Therapeutic Goods

Listed medicine labels

A product's 'label' includes the label attached to the container (for example: bottle, tube, sachet or blister pack) and the primary pack (for example: carton). Sponsors must ensure the product label and any printed information supplied with the medicine (for example: a package insert) complies with all relevant legislation before it can be supplied in Australia, including advertising requirements.

Specific documents relating to medicine labelling requirements include:

- the Therapeutic goods labelling order as current and in force
- Part 5-1 (Advertising and generic information) of the *Therapeutic Goods Act 1989*
- Therapeutic Goods Advertising Code
- *Therapeutic Goods Regulations 1990*
- Therapeutic Goods (Permissible Ingredients) Determination
- Therapeutic Goods (Permissible Indications) Determination
- Required Advisory Statements for medicine Labels (RASML)
- the Poisons Standard (the SUSMP) (note: Australian states and territories vary in the way they adopt the Poisons Standard)
- TGA approved terminology for medicines

In relation to medicine labels, listed medicine sponsors should note:

- Non-corporate graphics, logos or symbols on labels should be consistent with the product's approved details, including being appropriate for the claimed therapeutic use of the product. For example: an illustration of a baby would be inappropriate for a product with a dose range starting at 2 years.
- Statements of comparative advertising, professional recommendations, endorsements, sponsorship must all be compliant with the Therapeutic Goods Advertising Code.
- Reference to other products: reference in labelling to a sponsor's other products may be permitted, provided that the products are included in the ARTG (or exempt).
- Negative disclosure statements such as 'gluten free' or 'sugar free' must be true of all ingredients in the medicine, including proprietary ingredients. The statement 'sugar free' is acceptable where no sugars (such as fructose or sucrose) are included.
- The inclusion of internet addresses on labelling is only acceptable where the information on the website (including any direct links from that website) is consistent with the information included in the ARTG for that product. Websites are considered advertising and are subject to the Therapeutic Goods Advertising Code.
- As a general guideline, label flashes such as 'New Formulation' or 'Now with …' should not be used to describe any product, presentation or therapeutic indication/claim which has been available and promoted in Australia for more than 12 months.
- An excipient ingredient need not be nominated on a medicine label, unless it is a restricted ingredient, for example: included in the Poisons Standard; or included in Schedule 1 of Therapeutic goods labelling order 92, as current and in force (which lists substances required to be mandatorily declared on medicine labels).

- Where a sponsor chooses to disclose a (non-mandatory) excipient on a medicine label, then all excipients must be disclosed, that is: declaration of excipients on a medicine label cannot be selective.
- Products that are supplied in Australia and also exported to another country may include international product registration numbers (in addition to the ARTG number) required by the importing country.

TGA assessment of medicine labels

Medicine labels for listed medicines are not submitted at the time of listing and are therefore not approved by the TGA. However, listed medicine labels may be reviewed as part of random and targeted compliance reviews—see Listed medicine compliance reviews.

Medicine labels for registered complementary medicines are evaluated pre-market. In evaluating a new registered complementary medicine (and in a listing compliance review of listed complementary medicines) all aspects of the medicine presentation, including proposed labelling and package inserts, are assessed for compliance with the various legislative requirements (including advertising requirements). This is to ensure clarity is provided for consumers in relation to the medicine and its proposed use.

Listed medicine label names

Medicine labels are required to display the name of the medicine as it appears on the Certificate of Registration or Certificate of Listing. Inclusion of a brand name, as part of the 'name of the product' in the ARTG will result in this being considered 'the name of the medicine' for the purposes of TGO 92. Similarly, it would be clear that the name, inclusive of the brand name component, would be used to identify the goods for recall purposes. Generally, the TGA would anticipate that a brand name would be included on the ARTG because it is intended to uniquely identify the medicine and is an effective means to uniquely identify the goods for recall purposes.

Umbrella branding

'Umbrella' or 'family' branding describes the situation where a sponsor markets different products under the one brand name (e.g. Brand X lozenges, Brand X mouthwash, Brand X Family Cough Medicine). The use of a well-known brand name on new products with different active ingredients for either the same or a different indication could cause the consumer or health care practitioner to confuse the current products and the new product. In these circumstances, the 'presentation' of the product may be 'unacceptable'. Where the brand name is strongly associated with a particular active and there are significant differences in the safety, efficacy or dose regimen of the current and proposed products, the new product will not be accepted under the proposed trade name.

Transition arrangements regarding subsection 9(2) of TGO 92

Therapeutic Goods Order No. 92 (TGO 92) includes requirements to ensure easy readability and identification of key health information such as active ingredients. These requirements aim to address key concerns from consumers, health practitioners and Poison Centres around easy identification of medicines and the active ingredients in those medicines.

To achieve this subsection 9(2) of TGO 92 requires that:

- the medicine name be presented in an uninterrupted and continuous manner (i.e. the complete name all in one place on the label).
- the use of trademarks, graphics or additional text must not disrupt the medicine name. This will ensure that the medicine name is clearly recognisable.

Some non-prescription medicines sponsors have raised concerns due to having difficulty complying with the TGO 92 requirements for the presentation of the medicine name because their medicine label includes a long standing brand name or branding either within or adjacent to the name of the medicine that uniquely identifies a range of products from that sponsor. In some cases, inclusion of a 'distinguishing mark' such as a registered trademark, a graphic image, icon or logo, a brand name, slogan or tagline, within or adjacent to the medicine name may cause the medicine's label to be non-compliant with subsection 9(2) of TGO 92.

The TGA has established a process for sponsors of non-prescription medicines (which include complementary and OTC medicines) to request consent for non-compliance with subsection 9(2) of Therapeutic Goods Order No. 92 relating to the presentation of the name of the medicine on product labels.

This is an interim measure to assist industry to transition to the requirements for TGO 92. Consideration of potential amendments to the requirements relating to the presentation of the name of the medicine on product labels will occur in 2020-2021. Products must meet a set of requirements to be eligible for consideration under this measure. For more information, please see:

- Consent to supply therapeutic goods that do not comply with subsection 9(2) of Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicine - requirements for presentation of the medicine name

Labelling requirements for specific ingredients/listed medicines

Table 1: Labelling requirements for specific ingredients/medicines

Ingredient/medicine	Labelling requirement
Labelling associated with proprietary ingredients in all listed medicines	If the label of a medicine that includes a proprietary ingredient includes a negative disclosure statement (for example: 'sugar free'), sponsors must ensure that the substance referred to in the negative disclosure statement is not contained in any proprietary ingredient in the product formulation. The onus is on the sponsor to obtain this assurance from the supplier. Sponsors must also ensure that their medicine label complies with all the requirements of the Therapeutic goods labelling order as current and in force, including the declaration of excipient ingredients that must be declared on the medicine label.
Labelling 'For practitioner dispensing only' products	Sponsors may choose to supply their products in a dispensing pack solely to healthcare practitioners with the words 'for practitioner dispensing only', or words to that effect, included on the label. These medicines must meet the all applicable statutory requirements. This includes that labelling (apart from indications) must meet the requirements of the Therapeutic goods labelling order and the Therapeutic Goods Advertising Code (unless the appropriate exemption or approval to do otherwise has been granted). The only difference between 'for practitioner dispensing only' products and other listed or registered complementary medicines is that the former do not need to include a statement of their purpose/therapeutic indication on the label [refer to TGO 92 Section 8(1)(n)]. These medicines should only be supplied to an individual after consultation with a healthcare practitioner, at which time, the healthcare practitioner attaches a label to the medicine providing instructions for use for that individual alone.
Specific labelling requirements for homoeopathic preparations	All commercially supplied homoeopathic medicines in Australia, regardless of whether they are included in the ARTG, must: • comply with advertising requirements set out in Therapeutic Goods Advertising Code and other therapeutic goods legislation • be labelled in compliance with the general requirements for labels and the specific requirements for homoeopathic medicines in the Therapeutic goods labelling order as current and in force), and any other applicable official standards.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication. Information on labelling and presentation extracted from ARGCM version 8.0: • Information on presentation extracted from page 27 and pages 49–51 • Information on advertising replaces page 29. Information on advertising removed and reference to advertising guidelines provided • Information on labels extracted from pages 27– 28. • Information on proprietary ingredients extracted from page 25. • Information on practitioner only products extracted from page 16. • Information on homoeopathic labelling extracted from page 21. New sections and information provided on: • TGA assessment of medicine labels • Listed medicine label names • Umbrella branding • Transition arrangements for TGO 92	Complementary & OTC Medicines Branch	May 2020
V1.1	Removed reference to TGO 69 from page 8	Complementary & OTC Medicines Branch	September 2020

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