



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guideline for over-the-counter medicines

Appendix 3: Guidelines on presentation aspects of OTC applications

Version 1.0, October 2012

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

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Version history

Version	Description of change	Author	Effective date
V1.0	<p>Update of ARGOM Chapters</p> <ul style="list-style-type: none">· 5A Product name· 5B Labelling· 5C Product Information· 5D Consumer Medicines Information· 5E Changes to Scheduling <p>Re-formatting of the above chapters as Appendix 3 – Guidelines on presentation aspects of OTC applications</p>	MAG – OTCME	October 2012

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Introduction

The presentation of over-the-counter (OTC) medicines is critical for their safe use. 'Presentation' is defined in Section 3 of the *Therapeutic Goods Act 1989*¹ (the Act) as 'the way in which the goods are presented for supply, including 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'. Presentation is one of the factors that must be taken into account by the TGA delegate in making decisions on the registration of medicines (Section 25 of the Act).

This part of the guidance document describes various aspects of presentation and gives guidance on what constitutes acceptable presentation for OTC goods. It is divided into five sections as follows:

1. [Unacceptable presentation](#)
2. [Product name](#)
3. [Labelling](#)
4. [Product Information \(PI\)](#)
5. [Consumer Medicine Information \(CMI\)](#)

¹ <http://www.tga.gov.au/industry/legislation.htm>

1. Unacceptable presentation

Section 3(5) of the *Therapeutic Goods Act 1989* states that:

“the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:

(a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have; or

(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or

(c) if the label of the goods does not declare the presence of a therapeutically active ingredient; or

(ca) if the therapeutic goods are medicine included in a class of medicine prescribed by the regulations for the purposes of this paragraph—if the medicine’s label does not contain the advisory statements specified under subsection (5A) in relation to the medicine; or

(d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or

(e) in prescribed cases.”

2. Product name



Note: The TGA is initiating a review of the labelling and packaging regulatory framework for prescription medicines, over the counter medicines and complementary medicines. This section ‘Product name’ will be revised pending the outcomes of the labelling and packaging review.

2.1 Interpretation of ‘name’

This section provides an interpretation of the meaning of ‘name’ as used in Schedule 16 of the Therapeutic Goods Regulations 1990² (the ‘Regulations’) and as applied to medicines. Under Schedule 16, goods are regarded as ‘separate and distinct’ if they differ from other goods in any of the following features:

- a. formulation, composition or design specification;
- b. strength or size (disregarding pack size);

² <http://www.tga.gov.au/industry/legislation.htm>

- c. dosage form or model;
- d. name;
- e. indications;
- f. directions for use;
- g. different container type (disregarding container size).

The 'name' is regarded as including the following [terms used are as defined in the *Therapeutic Goods Order No. 69 - General requirements for labels for medicines* (the Labelling Order)³]:

- *'Proprietary name' (the registered trade mark of the medicine or the unique name assigned to the medicine by the Sponsor and appearing on a label); or if there is no proprietary name,*
- *The 'Non-proprietary name' [the name used to describe the medicine in a specific standard. It includes the name of the dosage form (e.g. Paracetamol tablets BP). If no specific standard exists, a name comprising the name(s) of the active ingredient(s) and the name of the dosage form (e.g. Promethazine 25 mg tablets)]; and*
- *Any unique word or code given to the product; and*
- *Any registered trade mark or other name, mark or logo that uniquely identifies the product; and*
- *Any distinctive colour or label presentation.*

For products that are licensed with a 'generic' name (e.g. 'Cold Tablets' or 'Paracetamol Tablets'), the name of the Sponsor or distributor as it appears on the label (wherever it is located) is regarded as part of the 'name' of the product (e.g. a product labelled 'Cold Tablets' with the Sponsor identified on the label as 'Acme Pharmaceuticals' will be regarded as having the name 'Acme Pharmaceuticals Cold Tablets').

Products that have a different 'name' require a separate entry in the Australian Register of Therapeutic Goods (ARTG, the 'Register'). Retailers or marketing groups that wish to have products that are uniquely identified in the marketplace as their own will need to lodge separate applications to register or list these products.

2.2 'Umbrella'/Family brand names

'Umbrella' or 'family' branding describes the situation where a sponsor markets different products under the one brand name (e.g. Strepsils lozenges, Strepsils mouthwash, Strepsils 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' (see [Section 1 Unacceptable presentation](#)).

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.

³ <http://www.tga.gov.au/industry/legislation-tgo.htm>

In cases where the brand name is not strongly associated with a particular active or combination of actives and there are no significant differences in the safety, efficacy or dose regimen of the current and proposed products, the potential for confusion may be able to be addressed by clear differentiation of the packaging and labelling of the new product to the extent that it will be immediately apparent to consumers that they are dealing with a different product. In some cases this may require modification of the labels of the new product and all products in the existing range to include the name of the active ingredient as part of the product name using the same font style and size.

In assessing whether the use of an existing brand name for a new product with different active ingredients is acceptable, the following points are considered:

a. Association

The strength of association of the brand name with a particular active substance and/or therapeutic use:

- history of marketing and advertising;
- the extent of prescribing by medical practitioners and recommendation by pharmacists [including whether the brand is or has been listed on the Pharmaceutical Benefits Scheme (PBS)];
- the number and proportion of products within the brand range with a particular active substance;
- the presence of products within the brand range that have a different active substance(s).

b. Differentiation

Whether the presentation of the new product is sufficiently different to the existing product range to alert consumers to the fact that this is a different product, despite the similarity in product name:

- Wording (particularly the prominence of identification of the active ingredient) on the labels of proposed product and existing product(s);
- Pack colour, shape, size, layout and design;
- The dosage form: visual appearance, physical characteristics, smell and taste;
- The likelihood that consumers will mistake the new product for the existing one at the point of sale and at the point of use (e.g. at a child's bedside in the middle of the night).

c. Safety

- Consider the consequences if a consumer took the new product as if it were the existing product and vice-versa.
- Consider sub-groups for which there may be specific safety concerns, for example Consumer's with gastric ulcer or asthma if the products are confused.
- Consider the conditions the new product and existing products are intended to treat. If the conditions are different (e.g. the existing products are all antifungal and the new product is an antiviral), are there any safety concerns if a consumer confuses the products?

d. Efficacy

- Consider the consequences if a consumer took the new product as if it were the existing product and vice-versa.

- If the dose is different (amount, frequency or duration) or if the conditions to be treated by the existing and new products are different, are there any efficacy concerns if the consumer confuses the new and existing products?
- e. Other information
 - The classification of the product - is professional advice available / required at the point of sale?
 - The sponsor's proposals for advertising / consumer education / practitioner education.
 - Evidence of consumer testing to demonstrate adequate differentiation between the products.

2.3 'Own name' products

'Own name' products are those that are identified on the label as being associated with a particular retailer or marketing group. 'Own name' OTC products can be supplied under two alternative arrangements:

a. Separate registration/listing

Where a sponsor or retailer wants to label a product with a name that is unique to a particular retailer (e.g. 'Carter's Cold Tablets') a separate entry is required in the ARTG and the product will carry an Australian Registration/Listed number (AUST R/L) unique to that product.

b. Use of an existing registered/listed product

Under this arrangement some retailer identification may be included on the label of an existing registered/listed OTC product without requiring a separate entry in the ARTG. The product will continue to be registered in the ARTG by the original sponsor and carry the product's AUST R number.

In these instances, the product can be labelled with either or both of the following:

- On the main label, identifying details of the retailer in a font size not larger than that used for the active ingredients preceded by the words "*sold by*" or "*made for*" or "*manufactured for*" or "*distributed by*";
- On another part of the product (e.g. on the back label), identifying details of the retailer in a font size not larger than that used for the product name preceded by the words "*sold by*" or "*made for*" or "*manufactured for*" or "*distributed by*".

2.4 Professional endorsement

Pharmacists, pharmacy marketing groups, hospitals or other health professionals may wish to register or list products under their own name (e.g. 'Carter's Cold tablets' as above). Care needs to be taken to ensure that the name of the product, and any other information on the label, does not breach the 'professional endorsement' provisions of the

*Therapeutic Goods Advertising Code*⁴ (a label is an ‘advertisement’ as defined in Section 3 of the Act⁵).

The Code requires that advertisements must not contain or imply endorsement by ‘individual healthcare professionals’, other than where the emphasis is on ‘availability’ or by ‘hospitals and other facilities providing healthcare services’.

Certain medicines are usually only available through pharmacies [those included in Schedules 2 and 3 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP or Poisons Standard)⁶]. These medicines must include the signal heading “*Pharmacy Medicine*” or “*Pharmacist Only Medicine*”. These signal headings do not breach the Code because they describe the availability of the product – that is you must visit a pharmacy to purchase products in either category but must consult the pharmacist to purchase a ‘Pharmacist Only Medicine’ product.

Where names of products are proposed that include references to pharmacy or pharmacists or other healthcare professionals, it needs to be considered whether the reference is to ‘availability’ or whether it constitutes ‘endorsement’ by the pharmacist or by the ‘facility providing healthcare services’ (e.g. the pharmacy).

For instance, the words “*Pharmacy formula*” or “*Pharmacy Only*” would not be taken to breach the Code because they are a reference to ‘availability’. This interpretation only applies where a product is sold exclusively in pharmacies. If, for example, a paracetamol product bearing the name “*Pharmacy formula*” were to be sold in a supermarket, the reference to “*pharmacy*” could be interpreted as an endorsement by the pharmacy profession and would therefore be in breach of the Code.

Where a pharmacy marketing group has a name that clearly implies professional recommendation (e.g. “*Pharmacist Advice*”), the name and/or logo of the marketing group can only appear on product labels where it can be established that this name/logo is strongly linked with the point of supply. This could be the case in the following circumstances:

- Pharmacies subscribing to the marketing group are required to be identified with the name of the marketing group; and
- The products are not available to retail outlets that are not members of the marketing group; and
- The name/logo of the marketing group appears on the label in close proximity to the product’s name; or
- The name/logo of the marketing group appears elsewhere on the label and is a registered trade mark of the marketing group.

Where the above does not apply and the sponsor’s name implies professional recommendation, that name cannot be used as part of the product name but can be included in small font, not on the main label, as part of the sponsor’s name and address as required by the Therapeutic Goods Order No. 69 (TGO 69) - *General requirements for labels for medicines*⁷, without breaching the Code.

Products that have names that breach the professional recommendation provisions of the *Therapeutic Goods Advertising Code* will not be approved. Names that have been accepted to date include ‘Chemists’ Own’, ‘XX Chemists’, ‘Health Care Chemist’, ‘XXX Pharmacy’,

⁴ <http://www.tga.gov.au/industry/legislation-tgac.htm>

⁵ <http://www.tga.gov.au/industry/legislation.htm>

⁶ <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>

⁷ <http://www.tga.gov.au/industry/legislation-tgo.htm>

'Pharmacist', 'Pharmacist Formula', 'Pharmacy Formula', 'Pharmacy Health' and 'Pharmacist Advice'.

3. Labelling

A product's label (as defined in the Act⁸) includes the label attached to the container (e.g. bottle, tube or blister pack), the primary pack (e.g. carton) and any printed information supplied with the container or primary pack (e.g. package insert).

Copies of all draft product labels (including package insert) should be provided with applications to register new products or vary the labelling of current products. Where the only difference in labelling between pack sizes is the quantity, only one set of labels need to be submitted, provided that an assurance to that effect is supplied with the application.

If possible, full scale, full colour draft labels or mock-ups of the proposed pack should be provided with the application to allow a thorough assessment of the product's presentation. If colour labels cannot be provided at the time of submission of the application, text or black and white label mock-ups should be provided. However, colour labels will be required for evaluation prior to approval of the product. This will allow the TGA to fully evaluate aspects of the labels such as umbrella branding issues, the appropriateness of any proposed label graphics, and the presentation of indications and other label claims. In the case of products where 'umbrella branding' issues apply (refer to [Section 2.2 'Umbrella'/Family brand names](#)), colour labels will be required as early as possible during the evaluation process. The colour labels or mock-ups should be provided in hard copy and in electronic copy.

Labels should comply with the latest versions of the following documents:

- Therapeutic Goods Order No. 69 (TGO 69) - *General requirements for labels for medicines* (the Labelling Order)⁹
- *Required advisory statements for medicine labels* (RASML)¹⁰
- *ARGOM Appendix 5 Guidelines on OTC applications for specific products*¹¹
- *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP)¹²
- *Therapeutic Goods Act 1989*¹³ and *Therapeutic Goods Regulations 1990*¹⁴
- *Therapeutic Goods Advertising Code*¹⁵
- *Code of practice for the tamper-evident packaging (TEP) of therapeutic goods*¹⁶

Other Commonwealth and State/Territory legislation may need to be taken into account when labelling medicines, for example, the *Competition and Consumer Act 2010*, Part 5-3, Country of origin representations¹⁷, *Commerce (Trade Descriptions) Act 1905* and

⁸ <http://www.tga.gov.au/industry/legislation.htm>

⁹ <http://www.tga.gov.au/industry/legislation-tgo.htm>

¹⁰ <http://www.tga.gov.au/industry/labelling-rasml.htm>

¹¹ <http://www.tga.gov.au/industry/otc-argom-app5.htm>

¹² <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>

¹³ <http://www.tga.gov.au/industry/legislation.htm>

¹⁴ <http://www.tga.gov.au/industry/legislation.htm>

¹⁵ <http://www.tga.gov.au/industry/legislation-tgac.htm>

¹⁶ <http://www.tga.gov.au/industry/packaging-tamper-evident-cop.htm>

¹⁷ <http://www.accc.gov.au/content/index.phtml/itemId/654658>

Commerce Imports Regulations 1940¹⁸, Therapeutic Goods Order No. 80 (TGO 80) - *Child-resistant packaging requirements for medicines*¹⁹, Trade Measurement²⁰, Packaging Covenant²¹.

Note: The above list is indicative only.

3.1 Statement of ingredients

The Labelling Order²² specifies how active ingredients should be declared on labels. The Labelling Order also requires the disclosure of specified excipients (e.g. those that are known to cause adverse effects in some individuals; antimicrobial preservatives in products for topical use) and specifies how these are to be declared on labels.

Selective disclosure of excipients, other than those required to be disclosed by the Labelling Order, must be justified (e.g. flavours, colours). Where the selective disclosure of individual excipients could imply that the excipient may have a therapeutic activity, this will not be accepted. Claims relating to excipients will be assessed by the TGA on a case-by-case basis in the context of the overall registered product.

3.1.1 Absence of excipient

A product label may include a statement that the product does not contain an excipient known to cause adverse effects in some individuals (e.g. gluten free, sugar free, alcohol free, lactose free), provided the statement is true. If including any statements that the product is 'free from...', the sponsor should provide written assurance in their submission that the product is free from the stated substance.

Inclusion of a statement that the product contains no sugar (e.g. 'sugar free') is acceptable provided the formulation does not include sucrose, glucose, fructose, maltose, honey or other sugars with a cariogenic potential or the potential to affect people with diabetes.

If the formulation includes a proprietary ingredient, the sponsor should check with the manufacturer or supplier of the proprietary ingredient to ascertain that it does not contain any component it is claimed to be 'free of' on the label. The sponsor should also check whether the proprietary ingredient contains any specified excipient that must be declared on the labels, in accordance with the Labelling Order²³.

3.2 Directions for use and dosage

Directions for use must clearly identify the dose and dosage frequency for each target population for which the product is intended (e.g. '*Adults and children over 12 years: two tablets twice daily; Children 6 to 12 years: one tablet twice daily*'). For the appropriate use of some products, a statement regarding '*duration of use*' should be included in the directions for use on the labels. If the product is not intended for use in children, the label should specify that the dose is an *adult* dose (e.g. '*Adult dose: 10 mL*'). The maximum daily dose for each age group should be included where appropriate.

¹⁸ Commonwealth government legislation available on <http://www.comlaw.gov.au>

¹⁹ <http://www.tga.gov.au/industry/legislation-tgo.htm>

²⁰ <http://www.measurement.gov.au/TradeMeasurement/Pages/default.aspx>

²¹ <http://www.environment.gov.au/settlements/waste/covenant/index.html>

²² <http://www.tga.gov.au/industry/legislation-tgo.htm>

²³ <http://www.tga.gov.au/industry/legislation-tgo.htm>

3.2.1 Dosing for adults and/or children over a specified age

Where the labelling only includes doses for adults and/or children over a specified age (e.g. adults and children 12 years and over; adults and children 6 years and over; children 6-12 years), the labels should include a statement such as *'Do not give to children under xx years / months'* or *'Not recommended for children under xx years / months'*.

3.2.2 Directions to seek advice from doctor or pharmacist

Inclusion of a label statement such as *'Do not give to children under xx years / months except on medical advice'* or *'Not recommended for use in children under xx years / months except on the advice of a doctor (or pharmacist)'* is only acceptable if the product has a TGA-approved published product information (PI) that the doctor or pharmacist can refer to in determining the appropriate dose for this age group.

3.2.3 Directions for symptomatic relief

The directions for products which are intended for symptomatic relief (e.g. cough and cold preparations) should include a qualifier such as 'as required' or 'when necessary' after the specific dosage frequency (e.g. *'take one tablet in the morning when necessary'*). The directions *'as required'* or *'when necessary'* are not acceptable on their own.

3.2.4 Dosing for liquid, solid or semi solid products

For liquid products, recommended doses should be able to be measured using commonly available metric measures. If the recommended doses cannot be measured using a readily available metric measure, a suitable measure should be provided in the pack. Sponsors intending to supply a measure with the product should refer to the *ARGOM Appendix 2 Guidelines on quality aspects of OTC application: Section 8.1 Measuring devices or other dose delivery devices*²⁴.

For solid or semi-solid dose forms such as powders or gels, if the labelled dose corresponds to the quantity contained in one or more *level 5 mL* medicinal measuring spoons, a dosage stated in that way would be acceptable (e.g. *'Adult dose: one level 5 mL medicinal measuring spoonful...'*).

References to a culinary 'spoonful' (e.g. teaspoon, dessertspoon, tablespoon, etc.) will not be accepted.

3.3 Warning statements and contraindications

Product labels must include the advisory statements required by the *Required Advisory Statements for Medicine Labels (RASML)*²⁵. Statements specified in *ARGOM Appendix 5 Guidelines on OTC applications for specific products*²⁶ should also be included on the label and/or package insert, as appropriate. The TGA may request the inclusion of other warning statements and/or contraindications on the product label and/or package insert during evaluation of an application to register or vary the registration of a product.

²⁴ <http://www.tga.gov.au/industry/otc-argom-app2.htm>

²⁵ <http://www.tga.gov.au/industry/labelling-rasml.htm>

²⁶ <http://www.tga.gov.au/industry/otc-argom-app5.htm>

3.4 Pregnancy warning statement

Where a product contains active ingredient(s) that are included in category 'B' (including 'B1', 'B2', 'B3') or category 'C' in the *Prescribing medicines in pregnancy* database on the TGA website²⁷, the primary pack label should include a statement advising consumers who are pregnant or who may become pregnant to check with their doctor or pharmacist before taking or using the medicine. Inclusion of this statement on the primary pack label will allow consumers who are pregnant or who may become pregnant to see this information before purchasing the product. This statement is not required on the labels of products for which all the active ingredient(s) are in category 'A'.

The primary pack labels of products that contain active ingredient(s) that are in category 'D' or category 'X' in the *Prescribing medicines in pregnancy database* must include a statement advising consumers who are pregnant or who may become pregnant that they should not use this product. In some cases (e.g. products for use as nicotine replacement therapy), the TGA may accept use of a substance in category 'D' during pregnancy, on the basis of risk-benefit analyses.

3.5 'Fast' or 'rapid' claims

All 'fast' or 'rapid' claims must be supported by appropriate data. The examples below are provided for guidance only. The ultimate acceptability of any 'fast' or 'rapid' claims must be evaluated within the overall context of the product.

Fast or rapid claims are appropriate only when they are made in relation to a condition or symptom where speed of onset is relevant (e.g. pain). Such claims may not be appropriate for chronic conditions or those not requiring immediate relief or if the pharmacokinetics or mechanism of action of the medicine precludes a fast action.

In general, claims that imply fast action or fast relief should be supported by clinical data. However, in some circumstances (described below), dissolution data can be used to support certain fast or rapid claims.

Circumstances when clinical or pharmacokinetic data are required:

- Where the words 'rapid' or 'fast' are intended or likely to be taken to be part of the product name, the applicant is expected to provide clinical efficacy data which compares the efficacy of the product against an appropriate Australian comparator demonstrating significantly earlier onset of clinically relevant efficacy. If a product is to be taken with food, then efficacy studies in the fed and fasted states are also required.
- Claims of fast absorption require pharmacokinetic data. Where the claims imply 'faster absorption', comparative pharmacokinetic data are required against the product or products with which the comparison is being made. Comparative dissolution data alone cannot be used to support such claims.

Circumstances when dissolution data alone may support certain fast or rapid claims:

- Where appropriate to the dosage form and indication (e.g. an analgesic tablet for relief of pain), 'fast' claims may be included on the label on the basis of dissolution data showing > 70% dissolution of the active ingredient(s) within 15 minutes. To support

²⁷ <http://www.tga.gov.au/hp/medicines-pregnancy-categorisation.htm>

the claim, dissolution testing should be performed at expiry (or on aged samples from the stability trials). Where the product has not been tested at expiry, the available stability data on aged samples should not indicate that the product is likely to fail dissolution (NLT 70% in 15 minutes) at expiry. If the data provided indicate that the dissolution limits (NLT 70% in 15 minutes) may not be met, then the 'fast' claim will not be accepted.

Note: Fast relief of fever or inflammation are considered to be inappropriate claims and will not be accepted.

- Where 'fast' or 'rapid' action claims are justified on the basis of dissolution data, such claims are to be linked to the symptoms/conditions that are relieved and are to be displayed/included as part of the indications on the label (e.g. "*For fast relief of itchy eyes associated with hay fever*"). Unqualified or stand alone 'fast' or 'rapid' claims that are prominently displayed on the label are likely to mislead the consumers and are therefore considered to be unacceptable.

Dissolution data alone cannot be used to support a 'fast' claim if the medicine is of a known slow onset, or if the pharmacokinetics or mechanism of action of the medicine precludes a fast action. For example, a medicine like loperamide which acts in the lower intestine may dissolve quickly but cannot be accurately described as fast because of the length of time required before the onset of action.

For fast or rapid claims not included in these scenarios, contact the TGA to discuss the data requirements.

3.6 Distinctiveness of labels

To reduce the possibility of confusion among consumers, the presentation of new products (including pack design, font size and type, logos, etc.) should be such that the new products are clearly distinguishable from existing products.

3.7 Graphics, logos and symbols

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;
- a graphic highlighting joints would be inappropriate for a product that is indicated for use only on soft tissue injuries.

3.8 Reference to other products

Situations where other products may be referred to in labelling include:

- reference to more suitable dosage forms within the same range for different age groups (see *ARGOM Appendix 5 Guidelines on OTC applications for specific products: Paediatric products – Solid dose products*²⁸)
- reference to another product that can be used in conjunction with the product, where appropriate
- reference to a sponsor's other products within the same product range that have the same trade name as the current product, where appropriate.

Note: The products referred to must be approved for supply in Australia.

References to other products which are capable of confusing the consumer (e.g. inclusion on the front panel of a label of the statement '*from the makers of Xxx*' or that it has '*the same active ingredient as Xxx*' may lead some consumers to think the product *is* 'Xxx') is unacceptable.

3.9 Comparison

Statements comparing a product with other products or treatments will only be accepted where satisfactory evidence is provided to support the claim. These claims must also comply with Clause 4.5 of the *Therapeutic Goods Advertising Code*²⁹. See also the ASMI Code of Practice, clauses 5.1.3 and 5.2³⁰.

3.10 Endorsements

Labels must not contain or imply endorsement of the product except as permitted by the *Therapeutic Goods Advertising Code* (Clause 4.6)³¹.

The sponsor should remove an endorsement from the labelling (by way of a notification application to the TGA) once the endorsement is no longer applicable.

3.11 Sponsorship

Labels may include reference to sponsorship of the product (e.g. Pink Ribbon Campaign, Cancer Council Australia, Surf Life Saving Australia) when in compliance with clause 4.6 of the *Therapeutic Goods Advertising Code*³². Sponsors should provide evidence that claims relating to any such sponsorship are true, for example, a letter from the relevant organisation showing that claims relating to any such sponsorship are true.

²⁸ <http://www.tga.gov.au/industry/otc-argom-app5.htm>

²⁹ <http://www.tga.gov.au/industry/legislation-tgac.htm>

³⁰ <http://www.asmi.com.au/about/ASMI-Code-of-Practice.aspx>

³¹ <http://www.tga.gov.au/industry/legislation-tgac.htm>

³² <http://www.tga.gov.au/industry/legislation-tgac.htm>

Where the sponsorship includes a potential restricted representation³³, e.g. Cancer Council Australia, prior approval for the use of the restricted representation must be sought in writing from the TGA.

3.12 Internet addresses

The inclusion of internet addresses on labelling is only acceptable if the sponsor provides an assurance that the information about the product included on the website (including any direct links from that website) is consistent with the information approved by the TGA for that product. If such an assurance cannot be provided, the internet address should be deleted from the labelling.

3.13 International labels

Products that are supplied in Australia and also exported to another country may include overseas product registration numbers required by the importing country. Labels intended for export only should be submitted to the Exports Section of the TGA.

3.14 Foreign language text on labels

For labels on medicines supplied in Australia a certified English translation of any other language must be provided to verify that the text is consistent with the English language text and that the label, including the product name, does not include or imply any additional indications.

3.15 Package inserts

Package inserts are considered part of product labelling (refer to the definition of 'Label' in the Act) and require approval by the TGA. A package insert should be provided if the primary pack label does not contain all the information which the TGA considers to be necessary for the safe and appropriate use of the product by the majority of consumers (including indications, directions for use, and important contraindications and precautions). The TGA may request the provision of a package insert in cases where this applies, if the sponsor has not already submitted a package insert.

A package insert may be in the form of a consumer medicine information (CMI) document if there is an approved product information (PI) document for the product (refer to '[Section 4 Product information](#)' and '[Section 5 Consumer medicine information](#)').

3.16 Requirements for labels and or package inserts following changes to scheduling classification

When the classification of a product is changed following a decision by the delegate, changes will be required for the labels, package inserts, PI and CMI (see also '[Section 4.2](#)

³³ <http://www.tga.gov.au/industry/advertising-restricted-representations.htm>

[Requirements for the PI following changes to scheduling classification](#)’ and ‘[Section 5.1 Requirements for the CMI following changes to scheduling classification](#)’). The sponsor is responsible for ensuring that labelling and any other changes arising out of a rescheduling decision are submitted for approval by the TGA (see ‘[Section 3.17 Changes to labels and/or package inserts](#)’, ‘[Section 4.4 Changes to the PI](#)’ and ‘[Section 5.2 Changes to the CMI](#)’). The products must not be supplied under the new scheduling arrangements prior to the effective date as specified in the SUSMP.

3.17 Changes to the labels and/or package inserts

Changes to the labels or package inserts of existing products will require approval from the TGA³⁴. Relevant changes to labels should be highlighted (e.g. through the provision of ‘track changes’ labels or a table detailing all the proposed changes).

Where changes are made to a package insert, a variation application should be submitted to the TGA requesting approval of the amended package insert. Approval by the TGA will be required if a package insert is no longer to be provided by the sponsor with the product.

4. Product Information (PI)

Product information (PI) is a term used to describe the technical information approved by the TGA and intended for distribution to health professionals. It may be distributed via publications such as Medical Information Management System (MIMS).

The PI presents a scientific, objective account of the medicine’s usefulness and limitations for the benefit of health professionals recommending or prescribing the product. The PI must be consistent with the data supporting the application. It does not include promotional material (refer to the ASMI’s Code of Practice³⁵ for further information regarding promotional material).

Paragraph 23(2)(ba) of the Act³⁶ requires an application for the registration of a ‘restricted medicine’ to include product information for that medicine, otherwise it would be considered “not effective”.

Restricted medicines are defined in the *Restricted Medicine Specification 2011*³⁷ and include:

- prescription medicines in Schedules 4 and 8 of the current Poisons Standard³⁸, and
- medicines in Schedule 3 of the current Poisons Standard and which are only available from a pharmacist.

³⁴ Refer to the application process for variation to the register (to be finalised)

³⁵ <http://www.asmi.com.au/about/ASMI-Code-of-Practice.aspx>

³⁶ <http://www.tga.gov.au/industry/legislation.htm>

³⁷ <http://www.tga.gov.au/industry/legislation-pi.htm>

³⁸ <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>

The secretary may also require applications in relation to other medicines not in Schedule 3, 4 or 8 of the current Poisons Standard to have approved product information. Examples where this may occur include:

- Products with active ingredients that are new chemical entities (NCEs) that at the time of the application have not been scheduled
- Products with new indications and/or new directions for use that have been approved on the basis of clinical data
- Products where a PI has been required by the TGA delegate following recommendation by the Advisory Committee on Non-prescription Medicines (ACNM) [previously Medicines Evaluation Committee (MEC)](e.g. all nicotine replacement products, some 'new' combinations of active ingredients)
- Products that are not scheduled but by reason of circumstances under which it is used such as in hospital setting or require medical supervision i.e. in medical and/or dental procedures. Examples include sucralfate and topical anaesthetics for use in medical procedures.

4.1 Form

As a part of an application to register a 'restricted medicine', a draft product information document must be lodged in a form approved by the secretary under section 7D of the *Therapeutic Goods Act 1989* (the Act)³⁹. This is the *Form for providing product information for a restricted medicine or other medicine in relation to which the Secretary requires product information to be provided* (the Form)⁴⁰. The form must also be used if the Secretary has given the applicant notice as referred to in subparagraph 25(1)(da)(ii) requiring the application to give the Secretary a product information.

The Form requires that the draft PI provided in relation to the medicine must be set out under the specified heading in the specified order.

Additional notes for OTC medicines are provided below in Section 4.1.1.

4.1.1 Additional notes

In the situation where there is no product information available in relation to a particular heading in the form (e.g. clinical trial data) for OTC medicines, the section need not be completed and words to the effect of "This information is not available" should be included under the heading.

In addition, for the following headings in the Form, further clarification and explanations are provided:

(i) Name of the medicine

The CAS Registry number should be provided for each therapeutically active ingredient.

(ii) Description

This section should also include

- A list of the active ingredients (using AANs) expressed quantitatively

³⁹ <http://www.tga.gov.au/industry/legislation.htm>

⁴⁰ <http://www.tga.gov.au/industry/legislation-pi-form.htm>

- A list of the excipients (using AANs) expressed qualitatively

(iv) Clinical trials

For OTC products which are not registered on the basis of clinical trial data, this heading need not be completed. However, this information is required if a new indication, direction of use, new patient population are approved on the basis of clinical trial data.

(v) Indications

The therapeutic application means the approved use of the medicine and the PI 'Indications' must be consistent with the indications to be included in the ARTG.

(vi) Contraindications

This section should also include:

- Hypersensitivity to the active ingredient(s), to any active ingredients of the same or similar pharmacological/ chemical class (where relevant), and to the excipients.

(vii) Precautions

This section should also include:

- Examples of the circumstances where caution and dosage adjustment is required including "Use in renal impairment" and "Use in hepatic impairment" (to be included where applicable).

(ix) Adverse effects

This section should include warnings of possible adverse effects (adverse reactions) that may occur under normal circumstances of use, or in particular circumstances such as use in patients with renal, hepatic or cardiac failure, the elderly or children. These effects should be quantified (giving frequency in terms of severity and clinical importance) where known.

The PI should include information on adverse events observed in post-marketing data, where this information is available.

Information on adverse effects observed in clinical trials should be included in the PIs of products that were approved on the basis of data that included clinical trials, and in the PIs of products where new indications and/or directions for use were approved on the basis of clinical trial data. In these cases, the PI could include information on adverse events observed in the clinical trials for both active and placebo (or comparative treatment) groups and set out as required in the approved form.

Where terms in the approved form such as 'rare', 'uncommon' (etc.) are used, the meaning should be consistent with the Council for International Organizations of Medical Sciences (CIOMS)⁴¹ definitions:

- very common ³ 10%
- common ³ 1% and < 10%
- uncommon ³ 0.1% and < 1%
- rare ³ 0.01% and < 0.1%
- very rare < 0.01%

⁴¹ <http://www.cioms.ch>

(x) Dosage and administration

Dosage information should be consistent with the dosage instructions on the labels. The directions for use of products intended for symptomatic relief should include a qualifier such as 'as required' or 'when necessary'.

Where relevant, the following information should also be included:

- doses for different age groups
- maximum daily doses (for each age group, where appropriate)
- maximum recommended duration of use

For OTC medicines, some of the subheadings included in this section in the approved form need not be completed if these details have not been approved by the TGA or did not constitute part of the data evaluated by the TGA.

(xi) Overdosage

For OTC medicines, a statement advising contacting the Poisons Information Centre for advice would be required, and where possible, the symptoms, signs and recommended treatment of overdosage or accidental poisoning.

4.1.2 Core PI documents

The TGA and the Australian Self Medication Industry (ASMI) have developed core PI documents based on information in standard reference texts and previously evaluated and approved PIs for a number of OTC ingredients^{42, 43}, and these may also be used as a reference.

4.2 Requirements for the PI following changes to scheduling classification

4.2.1 Schedule 3 Pharmacist only medicines

All applications to register 'Pharmacist Only Medicine' (Schedule 3) products must be accompanied by a draft PI document, in the approved form, which will be evaluated as part of the application. References should be provided for all technical information, for example, doses, contraindications, precautions, and adverse effects.

Submission of a draft PI will also be required with variation applications arising when a product is rescheduled to 'Pharmacist Only Medicine' (Schedule 3) (e.g. down-scheduling from 'Prescription Only Medicine' (Schedule 4) or up-scheduling from 'Pharmacy Medicine' (Schedule 2) or unscheduled).

4.2.2 Down-scheduling from Schedule 4 Prescription only medicines to Schedule 3 Pharmacist only medicines

For those products that have been down-scheduled from 'Prescription Only Medicine' (Schedule 4) status, where no changes have been made to the TGA-approved PI (other than a change to the poisons schedule section of the PI), a copy of the PI should be included in the application, together with an assurance that no changes (other than a

⁴² <http://www.tga.gov.au/industry/otc-pseudoephedrine-rescheduling-080915.htm>

⁴³ <http://www.asmi.com.au/industry/Consumer-Medicine-Information.aspx>

change to the poisons schedule) have been made. Changes to the PI will be needed if only some of the prescription indications are approved for the OTC product (e.g. cases where the acceptable OTC indications are restricted on the basis of an SUSMP⁴⁴ schedule entry), and to ensure that the directions for use are consistent with those on the proposed OTC product labelling. Other aspects of the PI may also need to be updated in accordance with the approved form.

4.2.3 Down-scheduling from Schedule 3 Pharmacist only medicines

Where products are down-scheduled to 'Pharmacy Medicine' (Schedule 2) or unscheduled status, sponsors are encouraged to retain the existing PI, and maintain its currency. Sponsors should consider quality use of medicine (QUM) principles if the deletion of a PI is proposed. In any case, deletion of a current PI will require approval by the TGA – such a change will not be approved for products for which the Secretary has specifically required a PI, unless adequately justified by the sponsor.

4.4 Changes to the PI

Where changes are made to the PI, a variation application should be submitted to the TGA requesting approval of the amended PI⁴⁵. Relevant changes to PI should be highlighted (e.g. through the provision of 'track changes' labels or a table detailing all the proposed changes).

For applications to vary an entry on the ARTG or change the conditions to which the inclusion of the medicine is subject, and require a change to the existing product information, must include a draft product information document in the application.

5. Consumer Medicine Information (CMI)

The Therapeutic Goods Regulations 1990⁴⁶ require that sponsors supply Consumer Medicine Information (CMI) with all 'Pharmacist Only Medicine' (Schedule 3) products.

The CMI must be:

- written in English
- clearly legible
- written in language that can easily be understood by consumers
- consistent with the approved or proposed PI.

The CMI must comply with the requirements specified in Schedule 13 of the Regulations⁴⁷, although the information does not have to be set out as listed there. CMIs must not include promotional material (refer to the ASMI Code of Practice⁴⁸ for further information

⁴⁴ <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>

⁴⁵ Refer to the application process for variation to the register (to be finalised)

⁴⁶ <http://www.tga.gov.au/industry/legislation.htm>

⁴⁷ <http://www.tga.gov.au/industry/legislation.htm>

⁴⁸ <http://www.asmi.com.au/about/ASMI-Code-of-Practice.aspx>

regarding promotional material). The CMI may be provided in the primary pack (e.g. as a leaflet in the carton) or 'in another manner' (e.g. in electronic form via pharmacy computers).

The sponsor is responsible for writing, updating, and distributing the CMI to the point of supply of a medicine to the patient. The information contained in the CMI should be easily read and understood by the Australian consumers. Sponsors are encouraged to utilise relevant guidance documents which provide advice on writing for consumers as well as refer to Core CMIs. Information on relevant guidance documents and the Core CMIs are available from the Australian Self Medication Industry (ASMI) website⁴⁹.

5.1 Requirements for the CMI following changes to scheduling classification

5.1.1 Schedule 3 Pharmacist only medicines

All applications to register new 'Pharmacist Only Medicine' (Schedule 3) products should be accompanied by a draft CMI document which will be evaluated as part of the application.

Submission of a draft CMI will also be required with variation applications arising when a product is rescheduled to 'Pharmacist Only Medicine' (Schedule 3) (e.g. down-scheduling from 'Prescription Only Medicine' (Schedule 4) or up-scheduling from 'Pharmacy Medicine' (Schedule 2) or unscheduled).

5.1.2 Down-scheduled from Schedule 4 Prescription only medicines to Schedule 3 Pharmacist only medicines

Products that have been down-scheduled from 'Prescription Only Medicine' (Schedule 4) status should already have a PI and CMI. Where no changes to the current CMI are proposed, the sponsor should provide a copy of the current CMI, together with an assurance that no changes have been made. Changes to the CMI may be needed if only some of the prescription indications are approved for the OTC product, and to ensure that the directions for use are consistent with those on the proposed product labelling. Other aspects of the CMI may also need to be updated.

5.2 Changes to the CMI

Where changes are made to the CMIs that are supplied as a package insert, a variation application should be submitted to the TGA requesting approval of the amended CMI⁵⁰. Changes to CMIs that are not supplied as a package insert need not be approved by the TGA, provided all changes are consistent with the approved PI and product labelling. Where a change is required as a result of an amendment to the PI, the CMI should be updated without delay to ensure that it is consistent with the PI, as required by Schedule 13 of the Regulations.

Relevant changes to CMI should be highlighted (e.g. through the provision of 'track changes' labels or a table detailing all the proposed changes).

⁴⁹ <http://www.asmi.com.au/industry/Consumer-Medicine-Information.aspx>

⁵⁰ Refer to the application process for variation to the register (to be finalised)

Changes to CMIs that are supplied as a package insert are treated in the same way as changes to product labelling.

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