Australian Government

Department of Health

Therapeutic Goods Administration

Guideline for the labelling of medicines

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TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.

- The 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 <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Scientific Evaluation	August 2014

Contents

1. Introduction

This guidance is to help sponsors and manufacturers of medicines meet Australian labelling requirements described in the Therapeutic Goods Order 79 *Standard for general requirements for the labelling of medicines* (TGO 79).

This guidance is not a legal interpretation of TGO 79 and covers current best practice for labelling in addition to requirements.

Where the words 'must' or 'required' are used, a legal requirement is being described.

This guidance applies to medicine labels that must comply with TGO 79. Exemptions are described in Section 5 of TGO 79. Other Commonwealth, State or Territory legislation also needs to be taken into account when labelling medicines.

You need to be careful that the labels do not function as advertisements for prescription medicines and pharmacist-only medicines that are not in Appendix H of the Poisons Standard. An advertisement includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods. Advertising on the label of other medicines needs to comply with part 5.1 of the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code.

2.   Labelling requirements

Labels are intended to communicate information that is critical to the prescriber, dispenser and consumer for the quality use of medicines. If it is difficult for health professionals or consumers to distinguish medicines or locate and understand critical safety information, then medication errors are likely to occur.

When we refer to labels, we are not referring to the Consumer Medicine Information or the Product Information documents, but to how the container and packaging are labelled.

2.1 General requirements

General requirements for medicine labels are described in section 7 of TGO 79. Required information on labels must be:

- in English [section 7(2)(a)]

- durable (defined in section 6) and legible [section 7(2)(c)]

- in colour or colours that contrast strongly with the background [section 7(2)(e)] - the use of colour is discussed in detail later in this document

- in text size not less than the equivalent of 6 point Arial, unless specified elsewhere in TGO 79 [section (7)(2)(d)].

In TGO 79, the font size applies a minimum size to letters such as 'a', digits and symbols such as '%' and addresses both the height and width of characters. The font description is not providing a system of measurement. Instead, the aim of the description is to identify a typically acceptable presentation that can be used as a benchmark and as a comparator to judge the legibility of fonts. The TGA will judge the acceptability of fonts by superimposing the labelling text in the font chosen by the sponsor onto the text in Arial.

2.2 Required information for labels

2.2.1 Information on the main label

The main label is the portion of the label where the name of the medicine is more or most conspicuously shown. A pack can have more than one main label if there are two or more portions of the label where medicine name is presented in equal conspicuousness or size.

Information required on the main label is described in section 9 of TGO 79. This information must be orientated in the same direction [section 9(4)]. Unless specified otherwise, the main label must include:

- name of the medicine [section 9(1)(a)] discussed in detail later in this document

- name of the active ingredients [section 9(1)(b)]

- quantity or proportion of active ingredients [section 9(1)(c)] – see the 'How to quantify active ingredients' of this document and section 11 of TGO 79 for specific information

- name of the dosage form [section 9(1)(d)]

- quantity of medicine [section 9(1)(e)] – no exceptions.

The name of the medicine and the name(s) of the active ingredient(s) must be presented in a continuous uninterrupted manner as a cohesive unit, unless otherwise specified [section 9(2)].

The name and quantity of each active ingredient are to be together on separate lines of text immediately below the name of the medicine [section 9(3)(a)]. The active ingredients and how much of each active ingredient is present must be identifiable in relation to all other material on the label [section 9(5)]. This may be achieved by a number of means including the size, colour and type of font chosen.

You may include more information than is required on the main label, but the information that is not required must not prevent compliance with TGO 79.

2.2.2 Specific requirements

There are specific requirements related to different properties of a medicine product. For any particular product, you need to check the requirements for:

- type of medicine

- specific routes

- specific ingredients

- type of packaging.

2.2.3 Information on a label

The following information must be on a label, unless specified otherwise, but does not have to be on the main label. This information is in section 8 of TGO 79:

- batch number and batch number prefix [section 8(1)(f)] – see section 6 for details

- expiry date and expiry date prefix [section 8(1)(g)] – see section 6 for details – preferably positioned with the batch number on an end or side panel

- storage conditions [section 8(1)(h)] – see section 11 (6)

- name and contact details of sponsor – required to be updated within a year of any change [section 8(1)(i)]

- declaration of any substances in Schedule 1 of TGO 79 (may be in a package insert for prescription medicines) [section 8(1)(j)

- any required warning statements [section 8(1)(k)]

- directions for use [section 8(1)(l)], except where one or more of the following are true:

    – it is a prescription medicine

    – the dose is usually determined by a health professional

    – there is insufficient space and a statement indicates that directions for use are in a package insert

- instructions for medicine preparation (if requires dissolving, dilution etc. before use) except if there is insufficient space and a statement indicates that directions for use are in a package insert [section 8(1)(m)

- statement of purposes [section 8(1)(n)], except where the medicine is one of the following:

- a prescription medicine

- supplied solely to a complementary healthcare practitioner for supply after affixing an instruction label following consultation and the label contains the words 'Practitioner Dispensing Only'.

All of the above need to be legible for the shelf-life of the product [section 7(2)(c)]; to achieve this, it is recommended that you use ink instead of embossing.

If the medicine has an AUST R or AUST L number, this also needs to be on the label (regulation 15 of the Therapeutic Goods Regulations 1990).

3. The name of a medicine

The 'name of the medicine' is defined in section 6 of TGO 79 and is usually the name intended to be on the certificate of registration or listing, where one exists.

3.1 How the name is displayed

When designing your label you must:

- display the medicine name as a cohesive unit in a continuous manner [section 9(2)], but the medicine name does not have to be on a single line if the label design or dimensions are such that the name will not fit on a single line

- not place any graphics or intervening text between the lines that contain the medicine name [section 9(2)]

- orient all of the medicine name in the same direction [section 9(4)].

We recommend that you:

- use fonts that are of similar size and style for all the words in the medicine name

- use different colours for certain components of the medicine name when it is useful to enhance the differentiation of the medicines within a range

When a registered medicine contains two or three active ingredients and it is impractical to fit the names and quantities of all the active ingredients on a single line on the main label, display the names and quantities of the active ingredients on more than one line.

- Place the names of the active ingredients immediately below the name of the medicine [section 9(3)(a)].

- Make the names appear as a cohesive unit [section 9(2)].

- Do not interrupt the names with other information or graphics [section 9(2)].

3.2 Names of active ingredients

The active ingredients and how much of each active ingredient is present must be identifiable in relation to all other material on the label, including any information that is not required to be there [subsection 9(5)]. This may be achieved by a number of means including the size, colour and type of font chosen.

3.3 Use of capital letters

The ARTG entry often uses uppercase letters for the name of the medicine. However:

- this is purely an administrative practice and it does not mean that the name appearing on the label needs to match the letter case entered in the ARTG

- whether to use upper or lower case for the name of the medicine on the label is at the sponsor's discretion.

For example, for a product with a certificate of 'THERAPAIN CHILDREN'S CHEWABLE paracetamol 250 mg tablets blister pack (reformulation)', the label name may be 'THERAPAIN CHILDREN'S CHEWABLE' or 'Therapain Children's Chewable' or 'Therapain children's chewable'.

The active ingredient name (paracetamol) and content (250 mg) will appear immediately under the name of the medicine; the dosage form 'tablets' will appear elsewhere within the main label; the container detail 'blister pack' is not required on the label as it is self-evident from the appearance of the container.

3.4 Font size of names

3.4.1 Names for registered medicines

For registered medicines with less than four active ingredients, the names and quantities of the active ingredients must be in a sans serif font at least the equivalent of 15 point Arial on the main label [subsection 9(7)a].

If a registered medicine has at least four active ingredients, the font size of the name and quantities of active ingredients depends on whether there is a Medicine Information panel:

- no Medicine Information panel (prescription medicines): in a sans serif font the equivalent of at least 12 point Arial on the main, side or rear label [subsection 9(8)a]

- with Medicine Information panel (most registered non-prescription medicines): in a sans serif font the equivalent of at least 6 point Arial within the medicine information panel.

3.4.2 Names on small and very small containers

On small containers (2.5 – 25 mL capacity), the font size of the name of the medicine and the names of the active ingredients is to be at least the equivalent of 8 point Arial and the quantity of active ingredients is to be at least the equivalent of 6 point Arial, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(4 and 14)].

On very small containers (no bigger than 2.5 mL capacity), the font size of the name of the medicine is to be at least the equivalent of 6 point Arial with other required information at least the equivalent of 4 point Arial, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(5) and 10(15)].

If there is more than one active ingredient, the name of the active ingredients do not need to be on a very small container, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(15)(g) and 10(5)(i)].

3.4.3 Font size for all other names

Names of medicines that are not registered and are not in small or very small containers are to be displayed in text size of not less than the equivalent of 6 point Arial [subsection 7(2)d].

4. How to quantify active ingredients

Labels are to provide consistent strength information for all medicines containing the same active ingredient. Section 11 of TGO 79 contains requirements about appropriate metric units and the expression of quantity or proportion of active ingredients, among other aspects of how to express information.

4.1 Salts, hydrates and solvates

For salts, hydrates and solvates, we recommend that you include the name of the salt, hydrate or solvate form on the label and do not repeat or emphasise this name unless there is a good reason to do so. The strength of an active ingredient will normally be expressed as the equivalent amount of the anhydrous free acid or free base and be consistent with international practice. If the active moiety is a quaternary ammonium cation (e.g. tiotropium), we recommend that the amount of the cation is labelled. We recommend the following:

- If only one salt is registered in Australia, include the name of the free acid or free base on all panels of the primary pack label and on the container label (e.g. fluoxetine) and on one panel of the primary pack include the salt (e.g. fluoxetine (as hydrochloride)).

- If there is more than one salt registered in Australia (e.g. erythromycin ethyl succinate and erythromycin lactobionate), include the name of the free acid or free base with the corresponding counter-ion in brackets on all panels of the primary pack label and on the container label (e.g. erythromycin (as ethylsuccinate) 400 mg).

- Instead of using brackets for the salt, you may also use a statement such as 'contains erythromycin ethylsuccinate equivalent to 400 mg erythromycin'.

- For a hydrate such as dapagliflozin propanediol monohydrate, this should be referred to as 'dapagliflozin 10 mg' in all cases except for the one case that names the hydrate, in which case this would be 'dapagliflozin propanediol monohydrate equivalent to 10 mg dapaglifozin'.

- If the strength of a hydrate or solvate relates to the solvated material, then the name of the active ingredient needs to include the solvate part of the name.

4.2 Established products

The principle of consistency between products containing the same ingredients is more important than following the above guidelines. This is particularly important when there is more than one sponsor of products with the same active ingredients.

For example, the quantity of active ingredient in metformin 500 mg tablets is expressed as the quantity of the salt (hydrochloride), even though the salt is not in the name. This is consistent with the British Pharmacopoeia monograph and changing this labelling would cause confusion. We recommend that new products containing metformin continue to quantify metformin in the way as metformin is quantified in current products.

4.3 Metric units

Express quantities using appropriate metric units [section 11(1)].

If possible, write the units in full. If you use an abbreviation, this is expected to be in standard SI abbreviations and symbols.

We recommend that for the word 'microgram', if there is insufficient space for the full word, use the abbreviation 'µg'. You may also use 'mcg' for medicines that are not prescription medicines. If there is sufficient space on the primary pack for the full word, but not on the container, then we recommend that you use the abbreviation on the container and 'microgram (µg)' or 'microgram (mcg)' on the primary pack.

4.4 Biological medicines

How to express the potency of biological medicines is described in Section 11(4) of TGO 79.

4.5 Enzymes

If a medicine contains an enzyme specified in Schedule 3 of TGO 79, then the activity needs to be expressed in terms of the units specified in Schedule 3 of TGO 79 [subsection 11(2)(b)(ii)].

4.6 Ethanol

If ethanol is present at 3% v/v or more, then the quantity of ethanol must be declared on the label as % v/v [Schedule 1 of TGO 79].

4.7 Radionuclide activity

How to express the activity of radionuclides in radiopharmaceutical preparations is described in Section 11(5) of TGO 79.

4.8 Sodium and potassium in oral medicines

For sodium and potassium in oral medicines, there is a requirement for quantification in milligrams of elemental sodium or potassium. This requirement applies when the daily dose contains more than 39 mg (1 mmol) potassium or more than 120 mg sodium [Schedule 1 of TGO 79].

4.9 Sugar alcohols

If the sugar alcohol content (such as erythritol, isomalt, lactitol, maltitol, mannitol, polydextrose, sorbitol, xylitol) exceeds 2 g per maximum recommended daily dose, then the quantity of sugar alcohol must be declared, along with a statement 'Products containing (name of sugar alcohol) may have a laxative effect or cause diarrhoea'[Schedule 1 of TGO 79].

4.10 Vitamin A

Medicines containing Vitamin A must now use the word 'microgram' when describing retinol equivalents [subsection 11(2)(j)(v)].

5. Use of colour

Required information must be in colour or colours that contrast strongly with the background [section 7 of TGO 79]. Text is easier to read when there is a large difference in contrast between the text and the background; black on white has the greatest contrast.

Dark text on a light background is easier to read than light text on a dark background for people with astigmatism (who make up a significant portion of the population), because of the 'halo' effect.

We recommend that colour be used to help differentiate products, but it should not be the only element that distinguishes products within a sponsor's product line. Colour differentiation is different from colour coding, which needs to be used with care, because it has contributed to medication errors in the past.

Our recommendations with respect to colour are similar to those of the FDA <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf>.

5.1 Colour differentiation

We recommend using colour to make features on a medicine label stand out and help distinguish one item from another. We recommend using colour to bring attention to:

- the name of the medicine

- the strength of the medicine

- important precautions.

For products that differ in strength, but otherwise have the same name, colour may be used to emphasise the strength, so as to differentiate between different labels. Stronger colours might be used for higher strength products and lighter shades might be used for lower strength products. Different colour schemes might also be chosen for the different strengths. For example:

- Innovator Medicine Name 5 mg (blue colour scheme)

- Innovator Medicine Name 10 mg (green colour scheme).

When the innovator medicine uses colour differentiation, we recommend to sponsors of generic medicines to use the same colour scheme as the innovator to differentiate the strengths of their products. A generic of the above example would be:

- Generic Medicine Name 5 mg (blue colour scheme)

- Generic Medicine Name 10 mg (green colour scheme).

If colour were to be used as the only element to distinguish products within a sponsor's product line, the TGA would consider the label to be capable of misleading of confusing as to the identification of the goods, and so the TGA would consider this to be unacceptable under section 3(5) of the Act. We recommend that other features such as font type, size and shape are also be used to distinguish products. This is because individuals can perceive colours differently; some individuals are colour-blind; and colours can look different in different lighting conditions.

5.2 Colour coding

Colour coding is when colour is used to designate a specific meaning. We recommend that colour coding is only used when this coding has already been established on TGA-approved labels. Colour coding needs to be used with care, because it has contributed to medication errors in the past. When colour is used as a shortcut to identifying a medicine, people sometimes don't read the label, and this leads to mistakes.

An example of colour coding that we recommend is the use of red letters for pre-mixed bags containing potassium for injection or infusion.

An example of where we do not recommend the use of colour coding is on labels approved by the TGA of anaesthetics. Colour coding systems are used in a hospital setting on user-applied labels for anaesthetics, but we are concerned about this system being extended to TGA-approved labels.

# 6.	Different types of medicine

Different types of medicine include:

- prescription medicines

- registered non-prescription medicines

- listed medicines

- sunscreens

- homoeopathic medicines.

6.1 Prescription medicines

6.1.1 Font size of names

For registered medicines with less than four active ingredients, the name and quantity of the active ingredients is to be in a sans serif font at least the equivalent of 5 point Arial on the main label [subsection 9(7)(a)].

For prescription medicines with at least four active ingredients the active ingredient names and quantities must be in a sans serif font that is the equivalent of at least 12 point Arial on the main, side or rear label [subsection 9(8)(a)].

6.1.2 Machine readable code and space for dispensing label

A machine-readable code (defined in section 6) must be on the label of medicines in schedules 4 or 8 of the Poisons Standard and blood products in Appendix A of the Poisons Standard [subsection 8(1)(p)]. The intention is that this machine readable code will facilitate electronic aids in dispensing and act as a means of double-checking that this is the correct product to be dispensed. We anticipate that this machine readable code will usually be an EAN barcode. To be effective, it must be located so that it will not be covered by the pharmacist's dispensing label and can still be scanned after the pharmacist has affixed the dispensing label.

These medicines must also include on the primary pack a minimum space of 70 x 30 millimetres for the dispensing label, unless precluded by the dimensions of the primary pack [subsection 8(1)(q)].

6.1.3 Declaring substances in Schedule 1 of TGO 79

For prescription medicines the substances in Schedule 1 of TGO 79 do not have to be declared on the label, they may be declared on a leaflet inserted in the primary pack [subsection 8(1)(j)].

6.2 Registered non-prescription medicines – Medicine Information panel

Registered non-prescription medicines (with the exception of medicines for injection) must have a Medicines Information panel on the label of the primary packaging. The Medicine Information panel must also appear on the label of the container if the capacity of the container is greater than 25 millilitres [section 10(20) of TGO 79].

The format of the Medicine Information panel is shown in Schedule 2. In addition, there is a written description of the requirements that apply to the Medicine Information panel in section 10(20) of TGO 79.

6.2.1 Title

The Medicine Information panel must be titled Medicine Information in a font size that is not less than the fonts used for the headings within the panel [section 10(20)(c)].

6.2.2 Border

TGO 79 does not mandate the use of a box border around the Medicine Information panel. However, we recommend using a box-border where space permits, because this will help with the organisation or readability of the information.

6.2.3 Only include required information

The medicine information panel must not be broken up or interfered with by logos or graphics. It may contain information that is not required by TGO 79, but the optional heading 'Other information' must be used [section 10(2)(b)(iii)].

6.2.4 Headings

Headings must be highlighted by the use of appropriately sized bold fonts, shading, box-borders, colour or other suitable means [section 10(20)(f)]. We encourage you to use shaded coloured bars or text boxes that extend the width of the panel.

Headings must be left-justified [section 10(20)(i)].

6.2.5 Use of coloured or bold text

With the exception of headings, all information in the Medicine Information panel must be black text against a white background [section 10(20)(d)].

We recommend that you do not highlight parts of the information in the Medicine Information panel by using bold fonts or colours, except when mandated in TGO 79 or by RASML.

6.2.6 Use of sentences and capital letters

You must use sentences to present the information, with a capital letter at the beginning of each sentence [section 10(20)(j)]. The use of all-capital text is not permitted, because large amounts of information displayed in upper-case letters are difficult to read. The exception is when capital letters are mandated by other regulatory requirements, such as Required Advisory Statements for Medicine Labels (RASML).

6.2.7 Order of information

Information within the panel must be presented under the specified headings in the following order [section 10(20)(e)]:

- Ingredients

- 'Uses' or 'What this medicine is used for'

- Warnings

- Directions for use

- Other information

6.2.7 Ingredients

How to express the quantity of active ingredient is discussed in the section 'How to quantify active ingredients' and is legislated in section 11 of TGO 79.

For registered non-prescription medicines with more than four ingredients, this is the only place that the names of active ingredients are required [section 9(8)(b)].

There is no requirement to declare all excipients on medicine labels. Only those excipients specified in TGO 79 are required to be declared in the Ingredients section of the panel. In order to avoid confusion with the active ingredients, we recommend that the required excipients are listed as 'Also contains xxx, xxx'. In the case of antimicrobial preservatives, the words "as antimicrobial preservatives" may be added after the name of the excipient.

6.2.8 Uses

We recommend that indications in the panel are worded succinctly; they must not include promotional or marketing statements. Where appropriate, such statements may be placed elsewhere on the label.

6.2.9 Warnings

Many medicines are required to contain warning statements. These warning statements are usually required to be in the Medicine Information panel for registered non-prescription medicines, although occasionally they are permitted to be in a package insert. Warning statements are specified in:

- TGO 79

- Regulatory advisory statements for medicine labels (RASML)

- ARGOM Appendix 5 Guidelines on OTC applications for specific substances

- correspondence from the TGA during the evaluation of an application.

Where relevant, the warning statements must be grouped under subheadings such as 'Do not use if', 'Ask a doctor or pharmacist before use if you' and 'Stop use and ask a doctor if' [section 10(20)(g)]. These subheadings must be presented in bold fonts and must use text sizes that are smaller than the text size used for the headings [section 10(20)(g)]. A horizontal hairline must be used below each of the subheadings in the 'Warnings' section [section 10(20)(h)].

If there is only one warning statement under a subheading, then the subheading and warning can be presented as a continuous sentence (instead of a bullet); in these cases the subheading segment of the sentence must still be in bold font.

When using subheadings to group warning statements, make sure that the meaning and intent of RASML warning statements is maintained. In some instances it may be necessary to make minor modifications to either the subheadings or the warning statements themselves in order to comply with the Required Advisory Statements for Medicine Labels.

6.2.9.1 Use in pregnancy warning

For non-prescription medicines for oral use, a warning statement is required if the medicine contains an active ingredient included in category B, C or D in the *TGA Prescribing medicines in pregnancy database* [subsection 8(1)(k)].

If the ingredient is in category B1, B2, B3 or C, then the warning statement is:

'If pregnant or likely to become pregnant, consult a pharmacist or doctor before use', or words to this effect.

If the ingredient is in category D, then the warning statement is:

'Do not use this medicine if pregnant or likely to become pregnant', or words to this effect.

If the medicine is the subject of other specific warnings (such as RASML), then they take precedence over the advisory statements listed above.

If all active ingredients are category A or uncategorised, a pregnancy advisory statement is not required.

6.2.10 Directions for use

Ensure that the 'Directions for use' section in the medicine Information panel includes information on:

- the dose

- the dosage frequency for each target population for which the product is intended

- maximum daily dose for each age group, where relevant.

6.2.10.1 Advisory statements related to dose

We recommend that any advisory statements related to dose or directions for use are in the 'Directions for use' section and precede the actual dosage instructions. Examples of such statements are:

- Do not exceed the recommended dose

- Maximum of 8 tablets in 24 hours

- Do not give to children below 12 years of age

- Not recommended for children under 6 years.

6.2.10.2 Specifying age groups

When the directions for use do not include different dosages for different age groups, they can simply be presented in a sentence. However, when more than two different dosages or age groups are involved, we recommend using a tabulated format.

If the product is not intended for use in children, we recommend that you:

- specify that the dose is an adult dose (e.g. 'Adult dose: 10 mL').

- label as 'For adults only'.

6.2.10.3 Directions for symptomatic relief

If the medicine is indicated for symptomatic relief (e.g. cough and cold preparations) and a course of treatment is not required, we recommend that you include after the dosage information a qualifier such as:

- 'when necessary'

- 'as required'.

6.2.10.4 Referring to medical advice

We recommend that you only include in a Medicine Information panel a statement such as 'Do not give to this age group except on medical advice' if the product has a TGA-approved Product Information (PI) that includes dosage information to help a doctor or pharmacist determine the appropriate dose.

If such Product Information does not exist, we recommend that the label should state 'Do not give to this age group'.

6.2.10.5 Dosing for liquid, solid or semi-solid products

For liquid, solid and semi-solid products, label the dose in metric units (e.g. 5 mL, 10 g) [section 11(1)].

Do not state the dosage in terms of culinary 'spoonfuls' (e.g. teaspoon, dessertspoon, tablespoon etc.); these spoons are not standardised or calibrated.

6.2.10.6 Lengthy directions

Where the directions for use are lengthy and cannot be accommodated on the primary pack label, these should be included in a package insert with the primary pack [section 8(1)(l)(iii)]. Include a statement on the label to the effect of 'please refer to package insert for detailed information on how to use this medicine'.

6.2.11 Other information in the panel

'Other information' is less critical than the information required to be in the panel.

Inclusion of the 'other information' section is optional, but allows the co-location of other information with information that is required in the panel where space permits. Although the other information may not be required in the Medicine Information panel, some of it is required to be on the label somewhere (such as storage conditions, sponsor name and address).

Other appropriate information includes tamper-evident features and sugar-free claims.

6.2.12 Continuation of the medicine information panel

Where space permits, the medicine information panel is to be a single panel in one field of view. However, for certain packaging (such as smaller packs) this may be impossible. In these situations, the medicine information can be provided in more than one panel [section 10(20)(l)].

When more than one panel is used, we recommend that you use a box-border for each panel. You must:

- retain the format and order of information required by TGO 79

- place the word 'continued…' at the right bottom corner of the preceding panel

  call subsequent panels 'Medicine Information (continued)'

For situations when more than one additional panel is used, we recommend that you mark the direction of the continuation with arrow heads (▷ or ◁) at the end of 'continued…'.

6.2.13 Examples of Medicine Information panels

Below are examples of compliant Medicine Information panels.

6.2.13.1 Complying with RASML in panel

In this example of a carton label for ibuprofen 200 mg tablets (containing lactose as an excipient), the subheadings under the warnings heading have been modified to be consistent with the RASML:

- 'Ask a doctor or pharmacist before use if' was amended to 'Ask a doctor before use'

- 'Stop use and ask a doctor if' was modified to 'Stop use and see your doctor immediately if'

Also, in this example the directions for use are presented in a table.

Medicine Information

Ingredient(s)

Each tablet contains the active ingredient
 - Ibuprofen 200mg
Also contains lactose.

What this medicine is used for

For the temporary relief of pain associated with
▪ headache ▪ migraine headache ▪ tension headache ▪ sinus pain ▪ dental procedures ▪ backache ▪ muscular aches and pains ▪ period pain
Reduces fever

Warnings

Do not use if

▪ you have a stomach ulcer ▪ you are allergic to ibuprofen or other anti-inflammatory medicines ▪ you are in the last 3 months of pregnancy

Ask a doctor before use if

▪ you have asthma ▪ you are in the first 6 months of pregnancy ▪ you are taking other medicines containing ibuprofen or other anti-inflammatory medicines

Stop use and see your doctor immediately if

▪ you get an allergic reaction

Directions for use

▪ do not use for more than a few days at a time unless a doctor has told you to ▪ do not exceed the recommended dose ▪ excessive use can be harmful

Adults and children 12 years and over	Take 2 tablets initially, then 1-2 tablets every 4 to 6 hours as necessary. Do not take more than 6 tablets in 24 hours.
Children 7-12 years	Take 1 tablet every 6 to 8 hours as necessary. Do not take more than 4 tablets in 24 hours
Children under 7 years of age	Do not use

Other information

Store below 30 degrees away from light.
Supplied by xx.

6.2.13.2 Additional subheadings in the warnings section

In this carton label for paracetamol and phenylephrine tablets the additional subheading 'While using this product' has been included in the Warnings section.

Medicine Information

Ingredients

Each tablet contains the active ingredient
- Paracetamol 500mg
- Phenylephrine hydrochloride 5mg

Uses

For the temporary relief of symptoms of cold & flu including ▪ headache ▪ body aches & pain ▪ sore throat ▪ blocked or runny nose
Reduces fever

Warnings

Do not use if

▪ you are taking other products containing paracetamol unless advised to do so by a doctor or pharmacist

Ask your doctor or pharmacist before use if

▪ you have high blood pressure or heart problems or are taking antidepressant medication

Unless advised by a doctor

▪ do not take this medicine for longer than a few days at a time if you are an adult

▪ do not give this medicine to children over 12 years for longer than 48 hours at a time

While using this product

▪ This product may cause sleeplessness.

▪ If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage

Directions for use

▪ Keep to the recommended dose

Adults and children over 12 years of age: Take 2 tablets every 4-6 hours as necessary with water. Do not take more than 8 tablets in 24 hours.

Do not give to children under 12 years of age.

Other information

Store below 30 degrees away from light.

Supplied by xxxx.

.2.13.3 Example of the continuation of a Medicine Information panel

In this example of a carton label for hydrocortisone and clotrimazole cream, the panel has to be split into two because of limited space.

First panel

Medicine Information

Ingredients

Active ingredients: clotrimazole 1% w/w, hydrocortisone 1% w/w
Also contain hydroxybenzoates as preservatives.

Uses

For the treatment of fungal skin infections when inflammation is prominent. This includes conditions such as ▪ fungal infected dermatitis ▪ intertrigo ▪ Candida nappy rash

Continued...

Subsequent panel

Medicine Information (continued)
Warnings
Do not use ▪ in the eyes ▪ for acne
Unless a doctor has told you to, do not use ▪ for more than 7 days ▪ for children under 2 years old ▪ under occlusive dressings
If irritation occurs discontinue use.
Directions for use
Clean and dry the affected are thoroughly. Rub gently into the affected area and surrounding skin 2-3 times daily. Once inflammation has subsided apply a cream containing a single anti-fungal agent only, for 14 days after symptoms disappear.

6.2.13.4 Example of clear directions for use

In this carton label for oxymetazoline hydrochloride nasal spray the directions for use clearly specify that the dose is only in adults and children over 6 years. The maximum of 2 doses in 24 hours is also clearly specified.

Medicine Information
Ingredient(s)
Each mL contains 0.5mg oxymetaxoline hydrochloride Also contains benzalkonium chloride as a preservative.
Uses
For symptomatic relief of nasal and nasopharyngeal congestion associated with the common cold, hayfever and sinusitis.
Warnings
Do not use ▪ in children children under 6 years of age ▪ for more than 3 days
Ask your doctor or pharmacist before use if using for children between 6-12 years of age
Consult a doctor if congestion persists
Directions for use
Adults and children over 6 years of age: 2-3 sprays in each nostril every 10-12 hours as necessary. Maximum 2 doses in 24 hours.

6.3 Listed medicines

With the exception of listed medicines in small or very small containers, all text required to be on labels of listed medicines is to be the equivalent of at least 6 point Arial [subsection 7(2)(d)].

6.4 Sunscreens

For sunscreen preparations in containers no bigger than 25 mL, the text on the container may be reduced to a text size of not less than the equivalent of 4 point Arial, with the exception of the sun protection factor, which must be no less than the equivalent of 6 point Arial [subsection 10(11)].

6.5 Homoeopathic medicines

6.5.1 Statement describing medicines as homoeopathic

For medicines that contain homoeopathic preparations, the main label on the container and the main label on the primary pack (if any) must include a statement in text size that is not less than 50% of the text size of the name of the medicine and (in any event) not less than the equivalent of 8 point Arial:

- to the effect that the medicine is a homoeopathic medicine, if all the active ingredients are homoeopathic preparations [subsection 10(9)]

- to the effect that the medicine contains homoeopathic preparations, if the medicine contains active ingredients that are homoeopathic preparations and other active ingredients that are not homoeopathic preparations [subsection 10(9)].

This statement is intended to assist consumers with the appropriate selection of a medicine and minimise confusion that can arise with self-selection; this will facilitate the quality use of medicines.

6.5.2 Homoeopathic potency

The 'name of an active ingredient' is defined in section 6, and for homoeopathic preparations includes the homoeopathic potency, which is also defined in section 6.

How to express the quantity or proportion of active ingredients for homoeopathic preparations is detailed in section 11(3).

6.5.3 Differentiation of homoeopathic and non-homoeopathic active ingredients

For medicines that contain active ingredients that are not homoeopathic as well as homoeopathic preparations, you must clearly differentiate the homoeopathic active ingredients [subsection 10(10)].

Suggestions on how to make this distinction:

- include the statement 'contains homoeopathic preparations of' adjacent to the list of homoeopathic ingredients

- preface the name of the homoeopathic active ingredient with the term 'homoeopathic'.

7. Medicines applied using specific routes

7.1 For skin or mucous membranes

The name of any antimicrobial preservative needs to be included on the label of preparations for the skin or mucous membranes [section 10(7)].

7.2 For ophthalmic use

The name of any antimicrobial preservative needs to be included on the label of preparations for ophthalmic use. Other requirements are also specified in section 10(1) for preparations for ophthalmic use.

7.3 For injection

Specific labelling instructions for medicines for injection are divided into:

- nominal volume greater than 100 millilitres [subsection 10(2)]

- nominal volume of 100 millilitres or less [subsection 10(3)]

- container capacity of 25 millilitres or less [subsection 10(4)]

- container capacity of 2.5 millilitres or less [subsection 10(5)].

The approved route must be on the label of medicines for injection or infusion.

The quantity of the medicine must be stated on all labels [subsection 8(1)(e)]. The way to express the quantity of an active ingredient in medicine for injection is described in section 11(2)(f).

For a medicine for injection the quantity of active ingredient is expressed:

- as the quantity in one millilitre, if the volume is greater than one millilitre and the medicine is for multidose use

- as the quantity in a suitable dose volume, if the volume is less than or equal to one millilitre and the medicine is for multidose use

- as the quantity in the stated volume, if the volume is small and is usually intended to be a single dose.

7.4 Peritoneal dialysis solutions

Specific labelling requirements for peritoneal dialysis solutions are described in section 10(6).

8. Medicines with specific ingredients

8.1 Excipients

Some excipients are required to be on the label (or a package insert for prescription medicines, subsection 8(1)(j)).

TGO 79 does not require all excipients to be declared on the medicine label. You have three choices:

- only declare the excipients and impurities specified in TGO 79

- declare all of the ingredients

- justify the specific inclusion of some ingredients and not others - selective disclosure of individual excipients may imply that the excipient contributes to the therapeutic activity of the product.

Reference to a colour, fragrance or flavour (e.g. red capsule, strawberry flavour) is generally considered to be acceptable without justification.

8.1.1 Substances that must be declared

You must declare on the primary pack label the presence of excipients specified in TGO 79. These are mostly found in Schedule 1 of TGO 79, but other excipients and impurities that must be declared include:

- any antimicrobial preservative in preparations for ophthalmic use [section 10(1)]

- any antimicrobial preservative in preparations for the skin or mucous membranes [section 10(7)]

- residual antibiotic in biological medicines [section 10(8)]

- adjuvants in biological medicines [section 10(8)].

If your formulation includes a proprietary ingredient, we recommend that you check with the manufacturer or supplier to find out if it contains any Schedule 1 excipients that must be declared on the label.

8.1.2 Claims about absence of ingredients

Provided that the statement is true, you may include a statement on the label that the product does not contain certain ingredients of interest to a particular group of individuals (e.g. gluten free, sugar free, alcohol free, lactose free). If your formulation includes a proprietary ingredient, we recommend that you check with the manufacturer or supplier to make sure that it does not contain any component claimed to be absent on the label.

For registered medicines, provide a written assurance in your application that the product is free from the substance.

You may include a statement that the product contains no sugar (e.g. 'sugar free') if the formulation does not include:

- sucrose, glucose, fructose, maltose or honey

- other sugars with the potential to increase tooth decay or affect people with diabetes.

We recommend that you do not include statements about the medicine being free from an active ingredient that is not in the medicine. For example, a paracetamol tablet label should not include a statement that it is free from aspirin, because such statements can cause confusion. They may also breach advertising regulations by implying that the medicine is safer by virtue of being free from the named active ingredient.

8.2 Potassium for injection or infusion

We recommend that you package all concentrated potassium products for injection or infusion in a manner that uniquely identifies them.

For products for injection or infusion after dilution that contain potassium, best practice is:

- for ampoules, include a black block of colour on the 'twist off' tab at the top of the ampoule

- for ampoules, label the end with 'KCl', or equivalent, in large lettering

- for vials, the cap of the vial should have a black 'twist off' seal

- clearly label the containers as 'Potassium Chloride' or the relevant salt

- include the instruction 'dilute before use'

- display the strength prominently as both total content in millimoles and strength in millimoles/litre.

For premixed bags containing potassium, we recommend:

- use only **red lettering** for labelling

- write 'Potassium' in letters vertically on the left hand side of the panel as well as horizontally, both in the largest font used on the label

- display the words "Potassium chloride' (or equivalent) in large letters on the label

- display the strength prominently as both total content in millimoles and strength in millimoles/litre next to the word 'Potassium'

- provide a clear space at least equivalent to the maximum font size around main description and key information (such as diluent and volume).

8.3 Vinca alkaloids

We recommend that you label medicines containing vinca alkaloids prominently with, 'To be given intravenously only' followed by, 'Fatal if given by any other routes'.

8.4 Methotrexate

Methotrexate is sometimes taken once weekly and sometimes more frequently; this has resulted in medication errors. For products containing methotrexate we recommend that you:

- use the warning 'Check dose and frequency - methotrexate is usually taken once a week'

- consider packaging methotrexate in indication-specific weekly or daily packs to assist in reducing errors.

8.5 Herbal materials and preparations

Herbal materials are a plant or part of a plant that is whole, fragmented, cut or ground, whether it is fresh or dried. Herbal preparations are ingredients derived from processing of a herbal material (section 6 of TGO 79).

For herbal materials, you must state the species name (Latin binomial), plant part and preparation (e.g. *Hypericum perforatum* herb top extract dry) and provide any herbal component names for which claims are made.

Quantities of herbal ingredients must be expressed as both extract weight (if known) and equivalent fresh or dry weight (section 11(2)(j)(ii). This enables the consumer to gain meaningful information from the label in relation to the 'strength', 'concentration' or quantified levels in general, of the herbal ingredients in the medicine.

8.5.1 Where standardisation of a herbal material or preparation is claimed

Standardisation is the process in which the content of a specific chemical constituent(s) has been determined in a herbal material or herbal preparation (section 6). Where standardisation of the herbal material [subsection 11(2)(j)(ii)(A)] or herbal preparation [subsection 11(2)(j)(iii)(C)] is claimed on the label of the medicine, then the quantity or proportion of an active ingredient to be included on a label must be expressed:

- for standardised herbal **material**, as both of the following

    - the minimum dry weight or minimum fresh weight of herbal material

    - the quantity of standardised component(s) in the herbal material.

- for standardised herbal **preparation**, all of the following

    - the quantity of herbal preparation in the dosage unit (tablet, capsule etc.), for example, '*Camellia sinensis* leaf extract dry 50 mg'

    - the minimum dry weight or minimum fresh weight of herbal material from which the preparation is derived, for example, 'derived from *Camellia sinensis* leaf dry 1.5 g'

    - the quantity of standardised component(s) in the herbal preparation, for example, 'standardised to catechins (of *Camellia sinensis*) 30 mg'.

Where a label makes claims in relation to herbal ingredients being standardised then we recommend that you state the quantity of the standardised component(s) as a separate statement.

8.5.2 Where no standardisation is claimed

For medicines containing herbal material or preparations with no claims of standardisation, the quantity or proportion of an active ingredient to be included on a label must be expressed for:

- herbal material, as the weight of the herbal material [subsection 11(2)(ii)]

- a herbal preparation that is an essential oil, as the quantity of the essential oil [subsection 11(2)(iii)A]

- a herbal preparation that is a juice (fresh, concentrated, dry or diluted), as both of the following:

    - the amount of juice in the dosage unit (tablet, capsule etc.)

– the minimum dry weight or fresh weight of the herbal material from which the juice was derived [subsection 11(2)(iii)B].

- any other herbal preparation, as both of the following:

    – the amount of the herbal preparation in the dosage unit (tablet, capsule etc.)

    – the dry or fresh weight of the herbal material from which the preparation was derived [subsection 11(2)(iii)D].

9.   Different types of packaging

Some types of products and containers require particular considerations when designing labels. Section 10 of TGO 79 contains additional requirements and qualifications to some requirements for specific products or container types.

9.1 Effect of opening packaging

Information required to be on the label must not be damaged, defaced, destroyed, or removed when the packaging is opened [subsection 7(3)9b]. Exceptions are made for blister packs, strip packs and sachets.

9.2 Cartons

If a medicine is packaged in a primary pack that is a carton, the name of the medicine must appear on at least three non-opposing sides of the carton [subsection 8(1)(r)].

9.3 Intermediate packaging

Opaque intermediate packaging, such as foil packaging of a tray of ampoules inside a carton, must [section 8(2)] be labelled with:

- name of the medicine

- name of the active ingredients

- quantity or proportion of active ingredients

- batch prefix and batch number

- expiry date and expiry prefix

- name or registered trademark of the sponsor.

Transparent intermediate packaging is exempt from TGO 79 [subsection 5(2)].

9.4 Composite packs

For composite packs [section 10(19)]:

- the expiry date of the pack must be the earliest expiry date of the individual medicines in the pack

- the storage conditions of the pack must be the most restrictive storage conditions of the individual medicines in the pack.

9.5 Medicine kits and starter packs

In TGO 79, labelling requirements for medicine kits and starter packs can be found in:

- section 10(12) for medicine kits

- section 10(13) for starter packs.

9.6 Delivery devices

Sometimes a medicine container is fully enclosed within a disposable delivery device that obscures the label on the container from view. When this is the case, a visible surface of the delivery device must be labelled according to the same requirements that apply to the container label [section 8(3)].

9.7 Metered dose products

For metered dose products such as pressurised inhalers, dry powder inhalers and nasal sprays, the quantity of an active ingredient must be expressed on the label [subsection 11(2)(i)] as:

- delivered dose (when this has been established) – defined in section 6 as the dose delivered to the patient

- metered dose (when subject to a pharmacopoeial monograph)

- if delivered dose is unknown and medicine is supplied as discrete dosing units, such as capsules, then the quantity of active ingredient in a dosage unit.

In addition, the name of any antimicrobial preservative must be included on the label of preparations for inhalation and metered nasal sprays [section 10(7)].

9.8 Individually wrapped medicines

Provided that the individually wrapped medicines are in a primary container appropriately labelled:

- tablets, capsules, cachets, pessaries, suppositories, singles doses of powders or liquid, and transdermal patches must be labelled with batch number and expiry date (as well as name of the medicine, name and quantity of each active ingredient, and sponsor name or trademark) on each wrapper, sachet or blister [section 10(16)(a)]

- pastilles and lozenges need only have the name of the medicine on each individual wrapper [section 10(16)(b)]

- a transdermal patch, after application to the patient, must be identifiable by a code, name of medicine, or name of active ingredient [section 10(16)(c)].

9.9 Transdermal patches, intrauterine or implanted drug delivery systems

The label on transdermal patches, intrauterine or implanted drug delivery systems must state the total quantity of active ingredient in addition to the quantity of active ingredient released in a specific time period [section 11(2)].

9.10 Blister, strip and dial dispenser packs

The labelling requirements for blister, strip and dial dispenser packs (defined in section 6) differ if the pack is a calendar pack or contains multiple formulations [section 10(17)].

9.10.1 Requirements for blister, strip and dial packs

All blister, strip and dial dispenser packs must be labelled with the following [section 10(17)(a)]:

- name of the medicine

- the batch prefix and batch number

- the expiry prefix and expiry number

- the sponsor name or trademark.

We recommend that the particulars on the label remain visible to the consumer until the last dose is removed.

The name and quantity of each active ingredient must be included on strip, blister or dial dispenser packs if:

- the medicine is listed and there is only one active ingredient [section 10(17)(b)(ii)]

- the medicine is registered and there are less than four active ingredients [section 10(17)(b)(i)].

If the blister or strip pack is **not a calendar pack** and does not contain multiple formulations, then, irrespective of whether an individual segment can be readily detached, **every two dosage units** the strip or blister must contain the following information [section 10(17)(c)]:

- the name of the medicine

- the name and quantity of each active ingredient for listed medicines with one active ingredient and for registered medicines with less than four active ingredients.

Where it is not possible to apply all the information over each blister pocket, a random display of the information should appear frequently across the blister pack.

9.10.2 Consistency with the PI

We recommend that the overall design of a blister pack label is consistent with the instructions provided within the Product Information (PI) document. We recommend that you:

- do not present and sequence doses in ways that do not match the approved usual dosage; for example, if the approved dosing regimen is variable, such as once or twice daily, then the labelling must not imply a fixed dose of twice a day

- do not number each blister cell in sequence, such that a blister pack containing 28 doses is numbered from 1 to 28; such numbers may be confused for the strength of the oral dosage form or the days of the month—when appropriate, use calendar packs, especially for medicines administered on a chronic basis according to a once-daily dosing regimen

- do not provide more doses than needed for a single course of treatment; this can lead to excessive duration of therapy. For example, a product used once daily for five days should only contain five tablets.

9.11 Small and very small containers

Less content is required on the labels of small (2.5 – 25 mL capacity) and very small containers (no bigger than 2.5 mL capacity), and the required font sizes are smaller than for larger containers, provided that the containers are in a primary pack that complies with TGO 79. Labelling requirements are described for:

- injections in small containers: section 10(4)

- injections in very small containers: section 10(5)

- small containers (not including injections): section 10(14)

- very small containers (not including injections): section 10(15)

- plastic ampoules: section 10(18).

9.11.1 Content requirements

Provided that the primary pack complies with TGO79, on small containers (2.5 – 25 mL capacity) and very small containers (no bigger than 2.5 mL capacity) the labels do not need to include:

- storage conditions

- contact details of sponsor

- declaration of any substances in Schedule 1 of TGO 79

- directions for use

- instructions for medicine preparation

- statement of purposes.

In addition, very small containers do not need to be labelled with the name of the dosage form, although the route must be specified if the medicine is for injection. If there is more than one active ingredient, very small containers do not need to be labelled with:

- name of the active ingredients

- quantity or proportion of active ingredients unless this is essential to distinguish very small containers containing medicines with different quantities of active ingredients.

9.11.2 Font size on small containers

On small containers (2.5 – 25 mL capacity), the font size of the names of the medicine and the active ingredients is to be at least the equivalent of 8 point Arial and the quantity of active ingredients must be at least the equivalent of 6 point Arial, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(4 and 14)].

9.11.3 Font size on very small containers

On very small containers (no bigger than 2.5 mL capacity), the font size of the name of the medicine must be at least the equivalent of 6 point Arial with other required information at least the equivalent of 4 point Arial, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(5) and 10(15)].

If there is more than one active ingredient, the name of the active ingredients do not need to be on a very small container, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(15)(g) and 10(5)(i)].

9.11.4 Plastic ampoules

The labelling of plastic ampoules is described in section 10(18):

- different sized ampoules are described by container capacity (8 millilitres and 25 millilitres)

- some labelling requirements must be on every ampoule, irrespective of whether or not the seal is broken on detaching an ampoule:
    - name of the medicine
    - name and quantity of active ingredients
    - batch number prefix and batch number
    - expiry date prefix and expiry date
    - the approved route(s) of administration followed by the word 'only', or warnings about unapproved routes

- labelling requirements not listed above, such as sponsor name and contact details, may be divided between the ampoule and the connecting strip if the capacity of the ampoule is 8 millilitres or less.

9.12 Bulk packaging

By bulk packaging we mean medicine packaging for commercial distribution and supply in Australia; we are not referring to packaging used to hold bulk intermediates during manufacturing, or packaging used to hold bulk finished product prior to packaging and labelling for commercial distribution and supply.

A presentation is considered to be a bulk pack in instances where the number of dosage units enclosed within a container exceeds the number of units considered reasonable for the treatment of one individual for a clinically justified period of time.

We recommend that you label bulk packs with a statement such as: '**For Dispensing Only. Not For Individual Patient Supply**'. When labelled like this, bulk packs are exempt from the requirement for child-resistant packaging; see Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines*.

10. Optional information

You are allowed to put information on your labels in addition to the required information, so long as the optional material does not result in a lack of compliance with legislated requirements.

10.1 Use of Braille and other languages

The required label information must be written in the English language [section 7(2)(b)]. Text in languages or characters other than English may also be included on labels.

If your label includes text or characters from another language, we recommend that:

- this does not cause clutter or overcrowding of the label

- you provide a certified English translation of the information to enable the TGA to verify that the:

    – other language text is consistent with the English language text

    – the label, including the name of the medicine, does not include or imply any additional indications

    – the interpretation of the terms is valid and appropriate

10.2 International labels

If your medicine is supplied in Australia and also exported to another country, you may include overseas product registration numbers if they are required by the importing country.

10.3 Optional QR Codes and web addresses

Prescription medicines are required to contain a machine readable code on the label [section 8(1)(p)]. The intention is that the machine readable code will facilitate electronic aids in dispensing and act as a means of double-checking that this is the correct product to be dispensed.

Any medicine label may also include a QR code and a web address.

10.3.1 QR codes

A Quick Response (QR) code is a type of matrix bar code that can be read on a mobile phone. You may use QR codes to provide consumers with information relating to the medicine.

We recommend that the QR code is located on the back or side panel so that it does not distract from critical information on the main label. If you include a QR code, we recommend that you include a statement close to the QR code stating the purpose of the QR code, for example:

- 'Please scan this code to obtain a copy of the Consumer Medicines Information'

- 'Please scan this code for more information about this medicine' (only when the information is not the CMI).

If the QR code takes the consumer to the CMI, then we recommend that you include a statement informing patients that the Consumer Medicine Information is available from pharmacists.

The QR code may:

- provide a link directly to the Consumer Medicine Information (CMI) document, which must be the up-to-date and consistent with the most recent approved PI document; it is preferred if you link to the CMI available from the TGA eBS website

- direct the consumer to a company website if the website is acceptable (see below) and complies with all advertising restrictions.

For registered medicines, you will need to provide written assurance of the above.

10.3.2 Acceptable web addresses

A label may include the address of a company website, or a QR code or other machine readable code that directs users to a company website. The website must comply with the advertising restrictions for that particular type of medicine. In order for this to be the case, we recommend that websites identified on labels are such that:

- the sponsor has full control over the content

- the website address is Australian (that is, ends with '.au' or other justified suffixes that reflect Australian ownership of the address)

- information on the website is consistent with the *Therapeutic Goods Advertising Code* (or other advertising restrictions that apply to the medicine)

- information about the product (including any direct links from the website) are consistent with information approved by the TGA for that product.

For registered medicines, you will need to provide written assurance of the above.

11. Changes and labels

11.1 Changing sponsor

You may lodge a request to transfer the sponsorship of an ARTG entry.

If the receiving sponsor chooses to supply medicine bearing the relinquishing sponsor's name and contact details on the label, this is acceptable for a period of up to 12 months [section 8(i) of TGO 79]. In this situation we recommend that there is:

- a written arrangement between the relinquishing sponsor and the receiving sponsor agreeing to the continued use of the relinquishing sponsor's name and contact details

- prompt forwarding to the receiving sponsor of all correspondence received by the relinquishing sponsor relating to the medicine for which sponsorship has been transferred.

11.2 Changes in formulation or appearance

If a medicine has been marketed in Australia and you change the appearance of the medicine, we recommend including the statement 'New Appearance' on the label to alert consumers. A change in appearance might be because:

- a physical characteristic has changed, such as the introduction of a score line

- the formulation has changed, resulting in a physical change such as the colour of the tablet.

If the formulation is changed and the appearance has not changed, we recommend including the statement 'New Formulation' on the label. If you are doing this for a registered medicines, then do one of the following:

- include this statement in the mock-up labels provided to the TGA in an application

- provide assurance that this statement will be over-stickered on the label under Good Manufacturing Practice (GMP).

For registered medicines, we expect your application to include a justification of the time period that the statement 'New Appearance' or 'New Formulation' will remain on the label. Usually, this time period would correspond to one shelf-life cycle. However, other justifications may be accepted.

Therapeutic Goods Administration

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Reference/Publication #R14/643926