Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Labelling medicines to comply with TGO 91 and TGO 92

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Contents

Purpose

This guidance is to help sponsors and manufacturers of medicines meet the Australian labelling requirements described in the new labelling Orders.

There are different risks and information requirements associated with medicines prescribed by a medical practitioner (or used in a clinical setting) to those self-selected by consumers. As a result, the labels for these two types of medicines need to reflect the different contexts in which they're used.

In recognition of this, medicine label requirements are specified in two separate labelling Orders[1]:

- Therapeutic Goods Order No. 91 - *Standard for labels of prescription and related medicines* (TGO 91)
- Therapeutic Goods Order No. 92 - *Standard for labels of non-prescription medicines* (TGO 92)

Note

In addition to the Orders, other Australian legislation applies to medicine labels. For example, State or Territory legislation for medicines and poisons, and Commonwealth advertising requirements for therapeutic goods.

Guidance on this additional legislation is outside the scope of this document.

How to use the guidance

This guidance is not provided as a legal interpretation of TGO 91 or TGO 92. It includes clarification on, and information relating to, the mandatory requirements. It also includes additional information outlining best practice recommendations for medicine labels.

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

Note

Following this guidance is **not** a guarantee that your label is fully compliant.

Structure of the guidance

This guidance is divided into four parts.

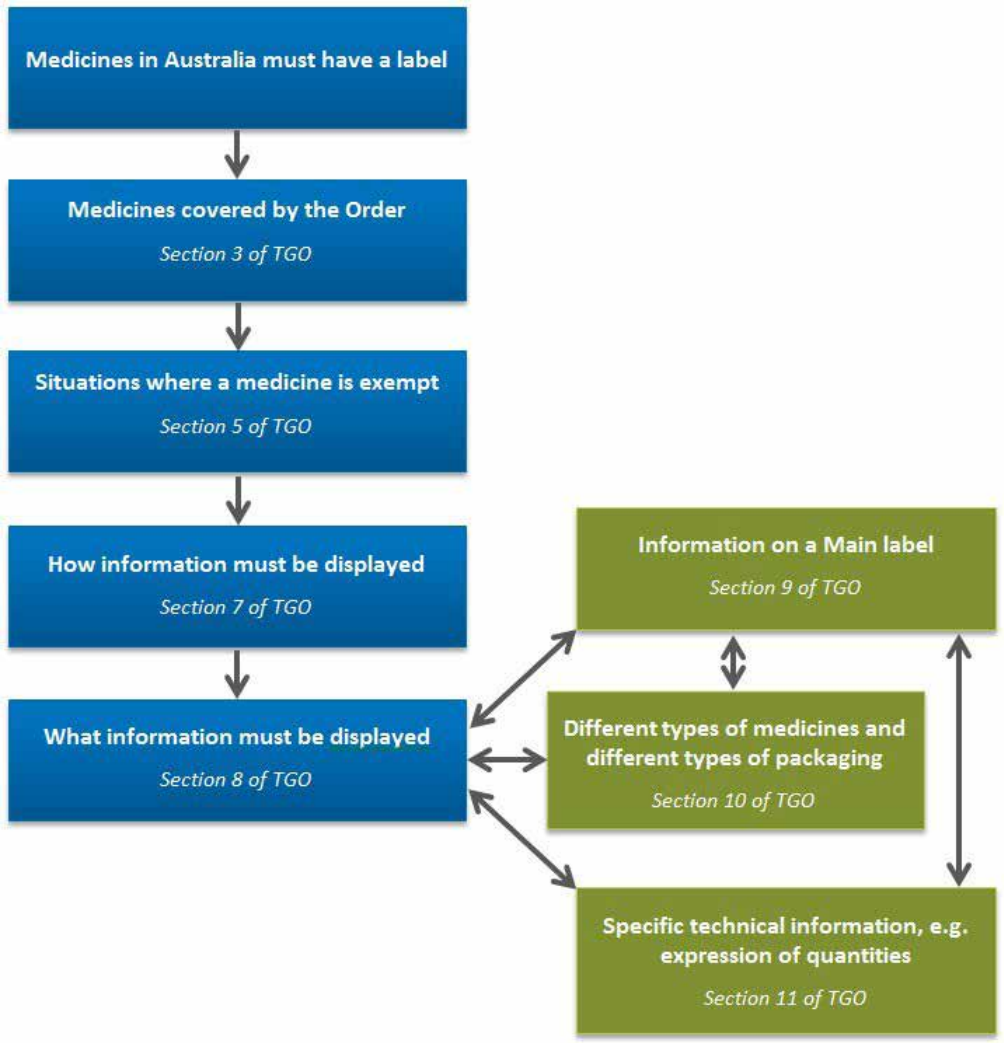
- **Using the Orders** describes the structure of the Orders and legal requirements that generally apply to all medicines.
- **Mandatory requirements - specific medicine types** provides guidance to assist you to identify the **mandatory** requirements that apply to certain types of medicines. For each type of medicine, there are references to specific relevant sections of the Orders.
- **Recommendations and best practice** provides guidance on the design of medicine labels and some 'best practice principles'. **This information is not mandatory** but is included to further improve the safe and quality use of medicines.
- **Tabulated display of CHI** provides guidance on the tabulated display of Critical Health Information. This includes **both** mandatory requirements and best practice guidance.

[1] Some medicines are exempt from the Orders, and these are described in section 5 of each Order.

Using the Orders

Labelling requirements depend on the type of medicine, how it is packaged and how it is used. However, there are common principles across all medicine types and therefore a common structure to the Orders.

Figure 1. Structure of both TGO 91 and TGO 92



Notable similarities and differences include:

- Section 7 is the same in both Orders.
- Sections 8 and 9 are different in the two Orders. This reflects the different ways that medicines are used. Consumers need additional information when self-selecting non- prescription medicines and therefore the requirements for these labels are different.
- There are also different types of non-prescription medicines. TGO 92 addresses this and there are different requirements within sections 8 and 9 of this Order for registered non- prescription medicines and listed non-prescription medicines. These differences reflect the low risk nature of listed medicines.

  For example, if you have a listed medicine you are not required to display Critical Health Information (CHI) in the tabulated format that is set out in section 8 of TGO 92.
- Sections 10 and 11 are different in the two Orders. You should review sections 10 and 11 to identify which requirements apply to your medicine, noting that more than one subsection may apply. Additionally, the requirements within sections 10 and 11 may affect how sections 8 and 9 apply to your medicine.

- TGO 91 and TGO 92 each have three schedules.
- Schedules 1 and 2 are the same in both Orders.

Schedules to the labelling Orders

TGO schedule	Description
Schedule 1	Lists the **substances** that you must declare on your label if they are present in your medicine.
Schedule 2	Lists **medicine ingredient names** that are being aligned with those used internationally and will be changing in the next few years.
Schedule 3 *(TGO 91 only)*	Lists ingredients that are **neuromuscular blocking agents** which, if present in a medicine, require a warning statement on the label.
Schedule 3 *(TGO 92 only)*	Lists the **units for quantities of enzymes** used as active ingredients in non-prescription medicines.

Medicines in Australia must have labels

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 to identify medicines, or to locate and understand critical safety information, then medication errors are more likely to occur.

What is covered by the term ‘label’?

When we refer to labels, we are not referring to the Consumer Medicine Information (CMI) or the Product Information (PI) documents. The labelling requirements apply to:

- the container
- any other packaging.

In some instances, information that cannot fit on the label is permitted by the Orders to be on a leaflet included in the medicine package (sometimes this is the CMI document). These leaflets will be assessed to ensure that the information fulfils the labelling requirements but are not considered to be a label in themselves. For example, PI/CMIs have specific formatting requirements and, if included as a leaflet, is not required to meet formatting requirements set out in the labelling Orders.

Labels as advertisements

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 labels of medicines needs to comply with part 5.1 of the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code.

Most prescription medicines cannot be advertised in Australia. You need to be careful that the labels for prescription medicines and pharmacist-only medicines do not function as advertisements - unless these medicines are in Appendix H of the Poisons Standard.

Note

All medicines supplied in Australia are subject to advertising requirements, even if they do not have to be on the Australian Register of Therapeutic Goods (ARTG).

Medicines covered by the Labelling Orders

Some types of information must be included on all labels, regardless of whether the medicines are prescription medicines, over-the-counter (OTC) medicines or listed medicines. Other information is particular to specific types of medicines.

To determine what information is required, you must first know which Order applies to your medicine.

Section 3 of each Order sets out the types of medicines covered by that Order.

TGO 91

This Order applies to prescription (and related) medicines, as defined in section 3 of TGO 91. This section refers to Schedule 10 to the *Therapeutic Goods Regulations 1990* (the Regulations).

Scheduling under the Poisons Standard

- If your medicine is subject to either Schedule 4 or Schedule 8 to the Poisons Standard, the medicine label must comply with TGO 91 (unless exempt, see section 5 of TGO 91).
- Medical devices that contain substances in Schedule 4, 8 or 9 to the Poisons Standard are not intended to be captured by TGO 91.
- If your composite pack contains a Schedule 4 or Schedule 8 medicine, the label on the pack must comply with TGO 91.

TGO 92

Any medicine that is not subject to TGO 91 must comply with TGO 92, unless exempt. If your medicine:

- is subject to either Schedule 2 or Schedule 3 to the Poisons Standard, the medicine label must comply with TGO 92.
- is not subject to a schedule to the Poisons Standard, it is likely that the medicine is subject to TGO 92. If in doubt, you will need to review section 3 of both Orders to determine which is applicable.

Exempt medicines

In some instances, a medicine may fit the criteria set out in section 3 of the Orders but is exempt from the requirements of that Order.

These circumstances are set out in section 5 of each Order and, in general, relate to how the medicine is supplied.

How information must be displayed

The mandatory information that must be provided on medicine labels, and the way this information is presented, makes an important contribution to the safe and quality use of medicines.

The requirements in section 7 of each of the Orders assist in making medicine labels easier to read and understand. This reduces the risk of errors by health professionals and facilitates consumer access to the information they need.

Note

All information required by the Orders needs to be legible for the shelf-life of the medicine.

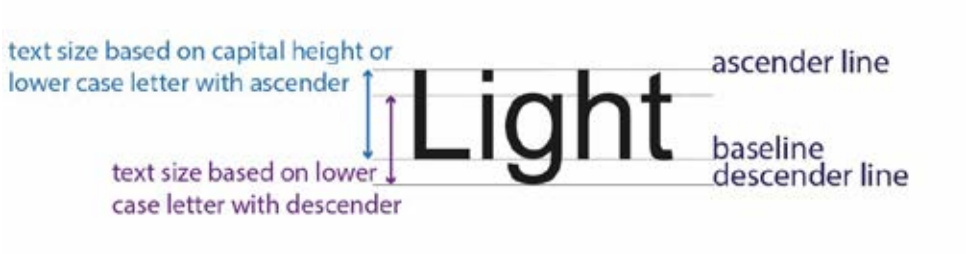
Text size

You must use a text size of not less than 1.5 millimetres for information that is required to be on medicine labels under the provisions of the Orders.

This minimum text size doesn't apply to a medicine's registration or listing number. The requirement for these to be on medicine labels is discussed in the section '**AUST R and AUST L number**' later in this guidance.

Section 6 of the Orders defines text size as the height of:

- upper case (capital) letters, or
- lower case letters having an ascender or descender.



In some specific circumstances, the Orders require certain information to be in minimum text sizes greater than 1.5 millimetres.

Text size for active ingredients

It is important that both health professionals and consumers can easily identify the active ingredients within a medicine. To help achieve this, there are specific requirements in the Orders for the text size you must use for displaying the names and amounts of active ingredients on your label.

Text sizes for registered medicines (prescription and non-prescription)

The names and amounts of active ingredients within a registered medicine must be displayed on the main label in a text size of not less than 3 millimetres. Exceptions to this requirement include where your medicine:

- contains multiple active ingredients, or
- is in a medium, small or very small container.

In these situations, this information may not fit the main label and can be moved to another label or panel. However, certain text height requirements may still apply.

Some examples of these situations are described below but you should refer to either TGO 91 or TGO 92 to determine the requirements for your particular medicine.

Example – Medium containers

It may be difficult to fit all the required information on labels on medium containers, but it's still important the active ingredients can be readily identified.

- If your medicine is **non-prescription and supplied in a medium container** (with a capacity of 60 millilitres or less), the names and quantities of active ingredients stated on a main label on the container must be in a text size of not less than 2.5 millimetres.
- If **this medicine is enclosed within a primary pack such as a carton**, the information on active ingredients must be in a text size of not less than 3 millimetres on the main label of the primary pack.

Example – Very small containers

If your medicine is **a prescription medicine, and it is in a very small container** (with a capacity of 3 millilitres or less), the name of the medicine must be displayed on the container label in a text size of not less than 1.5 millimetres.

The other information that you must include under the requirements of the labelling Order must be in a text size of not less than 1millimetre*.

**This size is smaller than the minimum text size otherwise required under the Orders.*

Example – Multiple active ingredients

If your registered medicine contains four or more active ingredients, you can include the information about the active ingredients on another panel or label.

Note: If you include this information on a **side or rear** panel or label, you **must use** a minimum text size of 2.5 millimetres.

Colour contrast

The information required on a medicine label must be in a colour (or colours) that contrasts strongly with the background it's printed on.

Dark text on a light background is easier to read, particularly for people with astigmatism (who make up a significant portion of the population). This is because of the 'halo' effect that occurs when light text is used on a dark background. Black on white may be the most legible contrast combination. There are tools to assist you to measure this (see colour contrast in **Part 3** of this guidance).

Highly reflective packaging (such as silver-foiled text) can be difficult to read as the reflection creates poor contrast. In some circumstances, highly reflective packaging will not be considered to meet colour contrast requirements.

Batch and expiry details

Batch and expiry details are often embossed or debossed on medicine labels. If you emboss or deboss these details, they are not required to be printed in ink. However, if you do print the batch or expiry details in ink, it must be in a colour that contrasts strongly with the background.

What information must be displayed

Certain information must be on any medicine label and this described by the requirements in section 8 of both Orders.

Medicines with more than one label

Many medicines have more than one label or different panels within one label. To reduce unnecessary replication of information in these instances, the Orders:

- define the 'main label' for a medicine (section 6)
- state the most important information you must display on the main label. The remaining required information can be displayed on other labels or panels.

There is one notable exception to this. TGO 91 requires prescription medicines to have the names of the medicine on at least three non-opposing sides of a carton. This allows pharmacists to easily identify medicines regardless of how they are stacked on shelves. This requirement is not relevant to medicines that are self-selected by consumers (so is not included in TGO 92).

Example: Names of medicine on at least three non-opposing sides of a carton

See our help card Tips on creating prescription medicine labels compliant with TGO 91 for further information about this example.

More than one layer of packaging

Medicines can also have more than one layer of packaging. If your medicine is supplied in a container which is in an outer primary pack such as a carton, there will be a main label on both the container and the carton. In certain situations the container will not be subject to the full requirements of sections 8 and 9.

Exactly what information is not needed on the container depends on the type of packaging. These requirements are specified in section 10 of the Orders.

Intermediate packaging

Intermediate packaging that obscures the labels of the containers, such as foil on a tray of ampoules inside a carton or a delivery device enclosing a container, must also be labelled – see section 8 of the Orders.

If the information on the label of the container(s) can still be seen and read easily, for example if only one panel of the intermediate packaging is opaque, additional labels are not required.

AUST R and AUST L number

Although not referred to in TGO 91 or TGO 92, the AUST R and AUST L numbers are still required on the labels of medicines that are on the ARTG.

This requirement to have the relevant registration number or listing number on medicine labels is specified in regulation 15 of the Regulations. This prescribes where on a medicine label the numbers must be placed and how they should be displayed.

The AUST R and AUST L number can be:

- oriented in any direction on the label because they are not information required by the Orders
- displayed in a text size that is smaller than the minimum text size otherwise required by the Orders. Section 7 of each Order identifies the legislative requirement for the inclusion of the AUST R or AUST L number on medicine labels.

Batch number and expiry date

Your medicine label must include the medicine's:

- batch number
- expiry date.

Each of these must be immediately preceded by a relevant prefix and examples are provided in section 6 of both Orders. Prefixes that cannot be used for expiry dates are also identified in section 6. Use of a combined batch number and expiry date prefix such as 'Lot/Exp' is generally not acceptable.

To 'precede' the batch number or expiry date, the prefixes must be above or to the left of the information.

Example: Prefix to precede batch number and expiry date

See our help card Tips on creating prescription medicine labels compliant with TGO 91 for example explanation.

The name of the dosage form

The name of the dosage form is the dosage form that has been entered onto the ARTG for the medicine.

Some dosage forms are written in reverse order for easy indexing in the TGA eBusiness Code Tables. In most cases, the word order should be changed to achieve plain English on labels, for example, ‘tablets, effervescent’ should be written ‘effervescent tablet’ on the label. There are several exceptions such as ‘injection, solution’ which should not be reversed.

The name of the medicine

The name of the medicine is defined in section 6 of both Orders as the name that appears on the ARTG certificate, with some qualification.

Often additional information appears with a tradename to more fully describe the medicine in the electronic record. Section 6 describes when it is acceptable to omit this information when stating the name of the medicine on a label. For example, additional descriptive information, such as the dosage form or a flavour, may only need to be included to differentiate between medicines in a range. In many instances dosage form or flavour information can be stated elsewhere on the label.

Note

If you are looking at the public ARTG summary document, the name that appears in the ‘Products’ field is the same as the name on the ARTG certificate

Changing sponsor or distributor details

The name and contact details of the medicine sponsor (or a nominated distributor) must be included on medicine labels.

In some cases, the sponsor or distributor details change during the lifetime of the medicine. For example, there can be a change in the contact details or a change in sponsorship.

Section 6 of the Orders includes a transition period of 12 months in the definition of 'name and contact details'. This allows existing labels, with the original details, to remain compliant with section 8 of the Orders while new labels are created.

If there is a change in sponsorship, the receiving sponsor may choose to supply medicines bearing the relinquishing sponsor's name and contact details on the label for a period of up to 12 months.

Substances that must be declared

You must declare on medicine labels the presence of certain excipients and impurities.

These are mostly found in Schedule 1 to the Orders, but other substances that must be declared include:

- any antimicrobial preservative in preparations for ophthalmic use
- any antimicrobial preservative in preparations for the skin or mucous membranes
- any excipient used in an injection
- some ingredients mentioned in the Required Advisory Statements for Medicine Labels (RASML)

Schedule 1 is not limited to excipients that are deliberately included in the medicine's formulation. In some instances you may need to test your medicine for traces of substances that may be involved in the manufacturing process but are not actual ingredients (e.g. sulfur present in stabilising agents or milk products as growth media).

Some entries in column 1 of Schedule 1 include example names underneath the primary substance name. These are examples only and should not be considered a complete list. You must determine whether any other substances in your medicine fit the definition and need to be declared. Sponsors should speak to their manufacturers about whether any declarable substances are an ingredient or component in the medicine or a known part of the manufacture of the medicine.

For more information about what consumers are expecting on their medicine labels, see the TGA 'Allergens and medicines'[2] page.

Determining when a substance is present

Not all entries in Schedule 1 include circumstances explaining when the substance doesn't need to be declared.

When there is no cut-off specified in the Schedule 1 entry, sponsors should declare the substance if:

- it has been added during any of the manufacturing processes (even as a manufacturing aid) and there is any likelihood that it remains in the finished goods
- it is a known component, or likely to be a component, of one of the ingredients in the medicine

Sponsors should assess the risk to consumers to determine whether a substance may be present and should be declared.

Tests to determine presence of an ingredient may not be sensitive enough to detect allergens but can be used to provide further information to consumers. Sponsors may choose to include additional information about the allergen on their label, website or Product Information/ Consumer Medicines Information documents. Information could include the level of residue detected, the measures taken to remove the substance or how the substance has been used in the manufacturing process. When including additional information, the statement, '*contains x'* must still be declared on the label as required by Schedule 1.

If it is unlikely that a substance is present, declarations should not be made simply as disclaimers. Sponsors are not required to introduce tests for *all* allergens.

[2] https://www.tga.gov.au/community-qa/allergies-and-medicines.

Declaring multiple substances

If your medicine has more than one substance that must be declared, these declarations can be combined to form simple sentences e.g. ‘contains sugars as lactose’ or ‘contains aspartame and sulfites’.

You should check all excipients in the formulation to determine if multiple substances need to be declared.

Example: Declaration of multiple substances.

In this example, each tablet contains 60 mg lactose and the maximum recommended daily dose is 100 mg. Lactose is listed in Schedule 1. The dosage form is for oral administration therefore column 3 is applicable and ‘lactose’ must be declared on the label (column 4).

Lactose is a sugar that has a glycaemic effect, so the entry ‘sugars – monosaccharides and disaccharides’ also applies. Because the maximum recommended daily dose of the medicine will contain more than 100 mg of lactose (i.e. 2 × 50 mg tablets = 2 × 60 mg lactose per tablet

= 120 mg lactose in maximum daily dose), column 2 and 3 are satisfied and ‘sugars’ must also be declared on the label.

Example: Declaration of multiple substances.

See our help card Tips on creating prescription medicine labels compliant with TGO 91 for example explanation.

Proprietary ingredients

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

Prescription medicines

For prescription medicines, there are two options for the declaration of the substances in Schedule 1. These can be either:

- declared on the label, or
- declared in the CMI and identified by a statement on the medicine’s label(s) that directs consumers to the CMI document.

In most cases, medicines that are required to declare substances in Schedule 1 will be expected to include the mandatory declaration on the medicine label to ensure the safe use.

However, it may be permissible to include a more general statement on your label directing consumers to review the CMI for further details. This statement **must specifically** alert consumers to the presence of a declarable substance in your medicine. This will help ensure that consumers can raise any concerns with their pharmacist or prescribing doctor before taking the medicine.

An example of a general statement that may be permitted is:

'This medicine contains substances that consumers are commonly allergic or sensitive to. For the list of these declarable substances, please refer to the Consumers Medicine Information leaflet, available from your pharmacist or go to www.tga.gov.au.'

Of course, when this statement is used on your labels you must ensure that the CMI is updated to include the required warning statement as set out in Schedule 1.

Specific entries

- **Benzoates** – this entry refers to benzoic acid and its simple salts. For example, benzoic acid, calcium benzoate, sodium benzoate and potassium benzoate should be declared. More complex esters, such as methyl benzoate, are not captured in this entry.
- **Egg** – prescription biological medicines are sometimes manufactured using substances such as chicken egg. These substances must be included on the label. Further information can be included on the CMI.
- **Hydroxybenzoic acid esters** – this entry refers only to parabens with 'hydroxybenzoate' in the Australian Approved Name. Salicylates should not be declared under this entry.
- **Phenylalanine** – The intention of note 5 of Schedule 1 was to ensure that consumers are aware of medicines that may contain phenylalanine in amounts that are of importance in the context of phenylketonuria (PKU). Ingredients high in protein, such as those mentioned in note 5, may have an impact on patients with PKU who are managing their phenylalanine intake. The intention is not to capture every complex ingredient that may contain phenylalanine as a trace component (e.g. gelatin).
- **Pollen** - There is no cut-off for pollen specified in Schedule 1, but it is **not** intended that pollen at background levels in the environment, to which consumers may be exposed in their everyday lives, be declared on medicine labels. The intention is to ensure consumers with pollen allergies are aware of medicines for which there is reasonable cause to suspect pollen may be present. Examples include, bee pollen products or herbal materials in medicines that include flowers.
- **Sorbates** – this entry refers to preservatives and does not include polysorbates.
- **Sugar alcohols** - you may include the quantity of the sugar alcohol as part of your declaration. You do not need to include 'contains sugar alcohols' if you choose to use the specific sugar alcohol name.

Machine-readable code and space for dispensing label

Machine-readable code (e.g. barcode)

Medicines covered by TGO 91 must have a machine-readable code on their label, unless they are in starter packs.

This machine-readable code will:

- facilitate electronic aids in dispensing
- act as a means of double-checking that the correct medicine is dispensed. To be effective, the code must be located where it:
- will not be covered by the pharmacist's dispensing label, **and**
- can still be scanned after the dispensing label has been affixed.

Multiple machine-readable codes

Medicines may include more than one machine readable code on their packaging. Some of the reasons that multiple machine readable codes may be present on the same package include:

- transitioning to 2D GS1 DataMatrix codes but still requiring linear EAN barcodes to support existing technology
- regulatory requirement for a 'track and trace' code from the country of manufacture.

Where multiple GS1 machine-readable codes are printed on a medicine package, all codes must encode the same Global Trade Item Number (GTIN). If a linear barcode (EAN-13) is on the pack, the GTIN-14 for the GS1 DataMatrix is created by adding a leading 0 (zero) to the GTIN-13 in the original barcode to ensure that the number remains the same.

Space for dispensing label

Most prescription medicines must also include a minimum space of 70 x 30 millimetres for the dispensing label. See section 10 of TGO 91 to determine whether the space needs to be on the container or primary pack of your medicine.

There are exemptions to this requirement if:

- the medicine is intended for use only in a clinical setting (i.e. supplied directly to hospitals for in-patient use only) or

it is precluded by the dimensions of the medicine's packaging. The size exemption does not apply if:

- the label can be redesigned to incorporate the space
- the label includes non-mandatory information that can be omitted to allow inclusion of the space.

If the full dispensing label space cannot fit on the label, it is expected that a smaller space will be included where possible.

Starter packs

If your medicine is a starter pack, you must have a space on the label that can be used to record dispensing details such as the:

- patient's name
- prescriber's name and telephone number
- directions for use
- date of supply.

You may pre-print this space with information to assist health professionals with patient instructions e.g. headings for patient name, dose etc., as described in Appendix L of the Poisons Standard.

Warnings

To ensure their safe use, many medicines require particular information to be communicated to consumers and health professionals.

As sponsor, you must ensure that you are aware of all relevant warnings and advisory statements when designing your label. In many instances, you must use specific wording for this information and it must be in a certain location on the label.

In addition to the requirements of the Orders, warning statements for medicines are mandated by other documents, including:

- the Poisons Standard
- RASML (registered as schedules to the Medicines Advisory Statements Specification (MASS)) (as amended from time to time)
- Conditions of registration or listing
- the Therapeutic Goods (Permissible Ingredients) Determination
- the Therapeutic Goods (Permissible Indications) Determination
- the Therapeutic Goods Advertising Code

- State or Territory legislation.

There are some best-practice warnings in Part 3 of this guidance and we strongly recommend you use them if they apply to your medicine.

Critical Health Information requirements

To ensure their safe use, medicines that are self-selected by consumers must have critical health information (CHI) on their label. Certain registered non-prescription medicines, must display the CHI in a tabulated format so that it is easier for consumers to locate, read and understand.

There are some exemptions to the requirements for tabulated CHI on registered non-prescription medicines - these are detailed in subsection 8(3) of TGO 92.

This requirement doesn't mean you must include additional information on your medicine label. If your label includes tabulated CHI, you can present some information required on the main label in an abbreviated form. See subsection 9(7) of TGO 92.

Part 4 of this guidance provides assistance on how you might present your CHI, including some examples.

Main label information

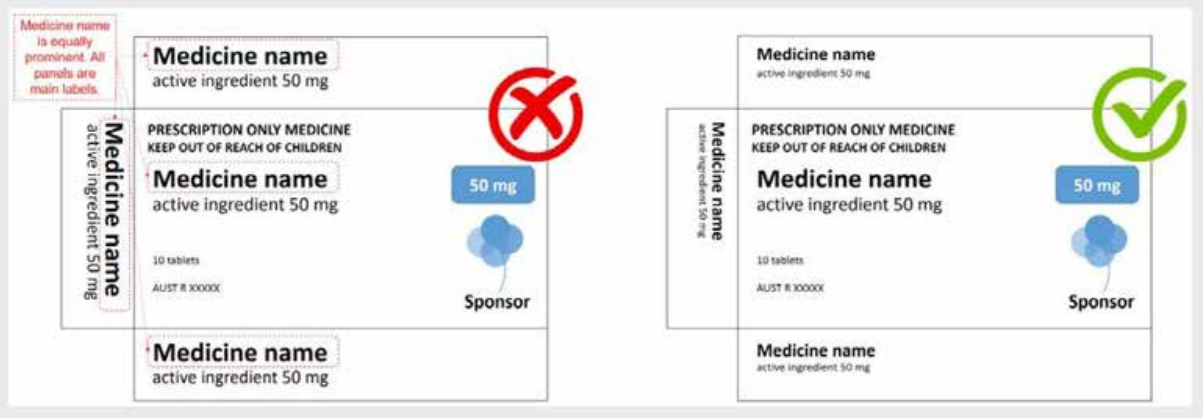
The 'main label' is the portion of the label where the name of the medicine is more or most conspicuously shown. This is defined in section 6 of both Orders.

A pack can have more than one main label if there are two or more portions of the label where the medicine name is presented in equal size or prominence.

In general, each layer of packaging also has a main label. Some specific container types do not require all main label information and formatting e.g. blister foils.

Section 9 of the Orders describes the information you must include on the main label. This mandatory main label information must all be oriented in the same direction.

Example: Increasing the prominence of the medicine name on the 'main label' compared to other portions of a carton label



See our help card Tips on creating prescription medicine labels compliant with TGO 91 for example explanation.

Prominence of active ingredients and medicine name

Clear unambiguous identification of medicines is critical in assisting in their safe use. The active ingredients and the name of the medicine must be easily identifiable and legible on a medicine label. To achieve this:

- The medicine name must be complete and clearly discernible (i.e. the complete name all in one place on the label). This will assist in differentiating medicines within a range.
- There must be consistency of location and presentation of active ingredient information.

The main label plays a critical role in communicating this information to medicine users. There are requirements in both Orders (subsections 9(2) and 9(3)) to ensure the prominence of the medicine name and active ingredients on the main label.

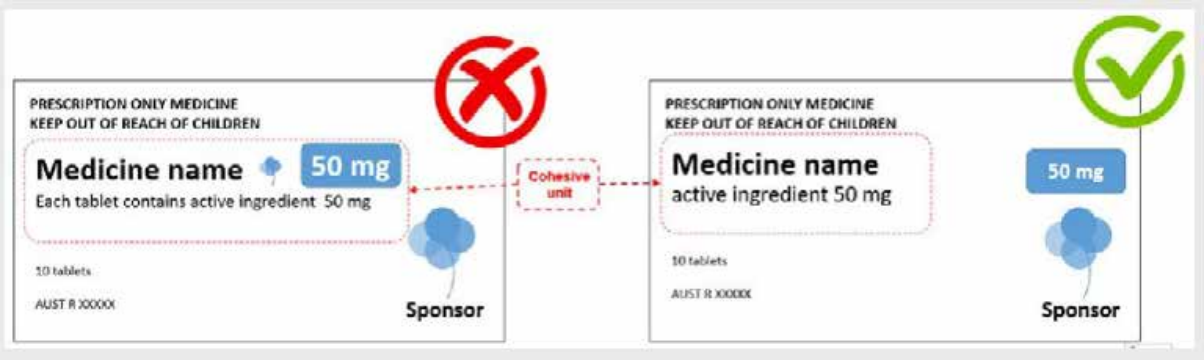
The relationship between the name of the medicine and the active ingredients on the label must not be interrupted by other information. However, there are particular medicines where additional information is needed to describe the active ingredients, for example composite packs and also certain types of active ingredients. Requirements for these medicines are included in subsection 9(3) of both Orders. Part 2 of this guidance describes these situations.

The medicine name

When designing your main label, you must:

- display the medicine name in an uninterrupted and continuous manner (the medicine name does not have to be on a single line if the label design or pack dimensions prevent this)
- ensure that the use of trademarks, graphics or additional text do not disrupt the medicine name. Use of the symbols ® and ™ are permitted next to the trade name
- ensure that no graphics or information interrupt the cohesive unit of the medicine name and the active ingredient.

Example: Cohesive (uninterrupted) unit for name of the medicine and the active ingredient



See our help card Tips on creating prescription medicine labels compliant with TGO 91 for example explanation

Identifying active ingredients

You must clearly identify the active ingredients present in your medicine by displaying this information in a certain place and in a specific text size. The required location and text size depends on:

- the type of medicine
- the type and size of container
- the type of packaging
- the number and type of active ingredients
- whether you have displayed the CHI in a tabulated format.

To determine the requirements for your medicine, you must read section 9 in conjunction with relevant subsections in section 10 of the Order that applies to your medicine.

To assist consumers in identifying active ingredients, you must place the ingredient name and its quantity or amount together. Text may wrap onto the following line if there are space constraints or if the legibility of the text will be adversely affected by being on the same line e.g. through the use of condensed fonts. If your medicine contains more than one active ingredient, each ingredient must be described on a separate line. The only exceptions are if your medicine is in a small or medium container and TGO 92 applies – see subsections 9(3) and 9(4) of TGO 92.

If your medicine name includes the full name of the active ingredient and its quantity, you do not need to duplicate this information on the main label.

The following table will assist you to comply with subsections 9(2) and 9(3) of the Orders.

Table 1. Prominence of active ingredients and medicine names

Permitted	Not permitted
Colour blocks, colour palettes, colour banners or patterns as background or near to medicine name and active ingredients where the legibility of the required information is not compromised	Colour palettes with poor colour contrast against the medicine name and active ingredients that make legibility difficult
	Background patterns that make legibility difficult
	Background graphics that interfere with legibility
Different font and differently sized fonts used for words that comprise the medicine name e.g. where there is branding across a range and font or colour is used to differentiate between medicines within the range and the entire medicine name is clear – although this needs to be considered in conjunction with other presentation factors	Distinguishing words, that are part of the medicine name, appearing in largely differing font where this results in the complete medicine name not being clearly discernible or easy to identify as a cohesive unit.
Shading, 3-D and other graphic effects applied to text/font of the medicine name	Graphic effects applied to text that disrupt the co-location of the medicine name and information on active ingredients or that make legibility difficult.
Logos, images or trademarks that feature graphic elements as part of their design placed above or adjacent to medicine name	Logos or images between words that comprise the medicine name.
To avoid disrupting or obscuring a trademark, placement of the active ingredients adjacent to, rather than below, the name of the medicine (i.e. when a trademarked design features the medicine name)	Logos between the medicine name and active ingredients.
Entire medicine name and active ingredients within a logo/distinct background block	Background logos or graphics that negatively affect legibility of active ingredients.

Permitted	Not permitted
	Distinguishing words that are part of the medicine name appearing in different locations e.g. ‘children’s’ for paediatric formulations; ‘sinus + pain’ for formulations with added ingredients within a product range (i.e. to distinguish between a medicine containing only phenylephrine from another in the same range that contains phenylephrine and paracetamol).
Wrapping of the name of the medicine onto more than one line, following usual English reading order (left to right, top to bottom)	The name of the medicine being discontinuous by being separated onto more than one line with large spaces between the words so that they do not appear to be linked (e.g. words within the name of the medicine changing justification as they wrap or leaving a large vertical gap between words).
	The name of the medicine being discontinuous by being presented in different lines that do not follow usual reading order (left to right, top to bottom).
	The name of the medicine being discontinuous by words differing in both font style and size so that they are not linked.
The words ‘per tablet’ or other dosage form after the active ingredient names and quantities Repeating active ingredient information elsewhere on the label using statements such as ‘each tablet contains X mg of *active ingredient name*’	Phrases such as ‘each tablet contains’ between the name of the medicine and the active ingredients.

Different types of medicine and different types of packaging

Some types of medicines, and certain containers, require particular consideration when designing labels.

Section 10 of each Order contains additional requirements, and qualifications to some requirements, for specific medicines or container types.

Your medicine may fit the description of more than one of these types. If so, more than one set of additional requirements will apply.

Example

A non-prescription medicine that:

- is a solution presented in a 10 millilitre container with a primary pack
- should be applied to a mucous membrane.

Which requirements apply?

Non-prescription medicine	TGO 92 applies (including the general requirements under sections 8, 9 and 11)
Presented in a 10 millilitre container with a primary pack	Requirements for primary packs of small containers (sections 8, 9 and 11) Requirements for small containers (subsection 10(7))
Is a solution intended to be applied to a mucous membrane	Requirements for preparations applied to skin/mucous membranes (subsection 10(2))

How to quantify active ingredients

Labels are to provide consistent strength information for all medicines containing the same active ingredient.

Section 11 of the Orders contains requirements about appropriate metric units and the expression of quantity or proportion of active ingredients, among other aspects of how to express information.

Metric units

You must:

- Express quantities using appropriate metric units, i.e. not in terms of a culinary spoonful (e.g. teaspoon, tablespoon, etc.).
- Always include the quantities of ingredients in the mandated units, in addition to any other dosage related quantities.

If possible, write the units in full.

Some classes of goods commonly express the quantities of active ingredients using non-metric units or non-mandated units. These units may be included as additional information on the label. They should not interrupt the main label requirements for expression of the active ingredient and the presentation must not be unacceptable.

Some medicines have specific requirements for expressing quantity of active ingredients in more than one unit. For example, injectable medicines intended for electrolyte replacement with a volume of 100 mL or less. For more information see Injections.

Use of abbreviations

Abbreviations are expected to be expressed in standard International System of Units (SI) abbreviations and symbols.

The use of 'µ' may be difficult to see in some print and size formats, and may be misread as 'm' ('mg' rather than micrograms). The word 'microgram' or 'microlitre' must be used in full, unless your medicine is covered by:

- TGO 91 **and** it is in a small or very small container, or
- TGO 92 **and** it is in a small container.

In these instances, if there is insufficient space for the full word, use the abbreviation 'µg' or 'µL'. 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 'microlitre (µL)' on the primary pack.

Quantity of the active ingredient in a suitable dose

If an article such as a calibrated dropper is packaged with your medicine, you may also include the quantity of the active ingredient in a suitable dose.

Example

If there is 20 mg *active ingredient* per millilitre and the dropper is calibrated to deliver 5 drops per millilitre, you may also include:

- 4 mg active ingredient per drop OR
- 5 drops contain 20 mg *active ingredient*

Mandatory requirements - specific medicine types

How your medicine meets the general requirements of section 8 of the relevant labelling Order is related to which requirements in sections 9 and 10 also apply. You should review these sections to determine the specific set of requirements for your medicine.

Section 11 of the Orders sets out general requirements on how information on the label must be expressed. This includes:

- how the quantities or amounts of active ingredients must be identified
- storage conditions.

It also includes specific requirements related to certain types of:

- dosage forms (e.g. transdermal patches, solid dosage forms and liquids)
- active ingredients (e.g. antibiotics and herbal ingredients).

The information in this Part of the guidance has been categorised to assist you in identifying specific subsections of 9, 10 and 11 that apply to your medicine.

Not all possible medicine types are identified.

More than one of the following medicine types may apply to your medicine. If there are multiple sets of requirements, you must comply with all of the relevant sections of the Orders.

Types of packaging

Blister, strip and dial dispenser packs

There are specific requirements for the information needed on blister, strip or dial dispenser packs that are supplied in a primary pack.

You should be aware that:

- The requirements for listed medicines and registered medicines differ.
- The requirements for all registered medicines are the same, regardless of whether your medicine is prescription or non-prescription.
- There are different requirements for certain types of blister or strip packs.

Information required every two (2) dosage units

Certain information must be repeated at least once every two dosage units if your medicine is supplied in a blister or strip where an individual segment containing a dosage unit can be readily detached.

The required information differs depending on how many active ingredients are in your medicine.

Only the name of the medicine must be repeated every two dosage units if your medicine is:

- a listed medicine that contains two or more active ingredients or
- a registered medicine that contains four or more active ingredients.

Otherwise, in addition to the name of the medicine, details of the active ingredient(s) must also be repeated at least once every two dosage units.

If your medicine is a composite pack and more than one formulation is in the same blister, the number of active ingredients in the medicine should be counted in the same way as for the main label (see Composite packs and medicine kits).

Relevant parts of the Orders

The requirements for blister, strip, or dial dispenser packs that are supplied in a primary pack can be found in:

- TGO 91, subsection 10(14)
- TGO 92, subsection 10(9).

Composite packs and medicine kits

Composite packs and kits are types of therapeutic goods that are defined in the Act. They comprise an outer package that contains more than one kind of medicine. These medicines may or may not be on the ARTG as separate goods.

Text between medicine name and active ingredients

To identify that there are multiple formulations within the composite pack or medicine kit, additional information on the active ingredients must be included on the medicine label. This affects the relationship between the medicine name and the active ingredients on a main label (see subsections 9(3) of TGO 91 and 9(6) of TGO 92).

Example

You could place the words ‘day formulation’ or ‘night formulation’ above each of the active ingredient lists.

Day formulation	Night formulation
Ingredient A – 500 milligrams	Ingredient A – 500 milligrams
Ingredient B – 30 milligrams	Ingredient B – 20 milligrams
Ingredient C - 1.2 milligrams	

Number of active ingredients

The total number of active ingredients present in the composite pack or medicine kit determines the location of information on active ingredients (see subsection 9(6) of TGO 91; subsections 9(6) and 9(7) of TGO 92).

Composite packs and medicine kits may contain two or more different formulations that share a common ingredient. These should be counted as demonstrated below:

Example

- Ingredient A and Ingredient B appear in both formulations
- This means they are counted as separate ingredients, meaning the medicine kit or composite pack has five (5) active ingredients in total.

Formulation 1	Formulation 2
Ingredient A – 500 milligrams	Ingredient A – 500 milligrams
Ingredient B – 30 milligrams	Ingredient B – 20 milligrams
Ingredient C - 1.2 milligrams	

The active ingredient information could therefore be included on a side label rather than the main label.

Composite packs

Medicines within a composite pack must be either combined before being administered or be taken in a particular sequence to achieve the intended therapeutic effect.

Where the composite pack contains medicines that are already on the ARTG as ‘separate and distinct’ goods:

- the individual components may retain their original AUST R or AUST L number on their respective packaging, use the new composite pack AUST R/L number or not include any AUST R/L number. To avoid confusion, if the individual component labels are to include the AUST R/L number of the composite pack, care should be taken to indicate that this number is in fact the AUST R/L of the composite pack and not that of the individual component.

- the outer package of the composite pack must be labelled with the new ARTG number (AUST R or AUST L) for that pack.

Relevant parts of the Orders

- Subsection 9(3) of both Orders
- TGO 91, subsection 10(16)
- TGO 92, subsection 10(11)

Medicine kits

- Under current legislation a medicine kit:
- includes at least one medicine that is on the ARTG
- **does not** include therapeutic devices.

The medicine kit itself is required to also be on the ARTG.

A package, and therapeutic goods in the package, constitutes a kit only if together they do not constitute a composite pack.

Non-prescription medicine kits

There are specific requirements for the label on the package if your medicine is a medicine kit comprising a package with at least one non-prescription medicine in it.

See subsections 9(3) and 10(6) of TGO 92.

Prescription and related medicines

Prescription medicines that are packaged with articles such as syringes or measuring cups are not regulated as medicine kits.

If your medicine includes an article such as these, you must describe it on the medicine label on the primary pack.

See subsection 8(5) of TGO 91.

Delivery devices

When medicine containers are enclosed within a delivery device, such as a canister within a pressurised metered dose inhaler, the label information required under the labelling Orders may be obscured. If the container cannot be removed from the device, then all the information required to be on the container must be on delivery device instead. This is the only situation where the container may not require a label.

This problem is avoided if all the information required to be on the container label is completely visible when the container is enclosed in the delivery device.

See subsections 8(3), 8(4) and 8(5) of TGO 91, subsections 8(4) and 8(5) of TGO 92 and further best practice guidance in **Recommendations and best practice** of this document.

Flexible intravenous (IV) bags

Large volume flexible bags are often labelled with text in different orientations. This is done to ensure quality and safe use of these medicines when delivered intravenously.

See subsection 9(7) of TGO 91 for the specific requirements for main labels on flexible bags.

There are also requirements for the expression of the quantity or proportion of active ingredients often included in IV bags. See subsections 11(2) and 11(6) of TGO 91.

Individually wrapped medicines

There are reduced labelling requirements for the wrappers of individually wrapped dosage units that are supplied in a primary pack.

The specific requirements depend on:

- the type of dosage unit (for example, lozenges, suppositories, herbal tea bags)
- whether the medicine is prescription or non-prescription.

Relevant parts of the Orders

The requirements for individually wrapped medicines that are supplied in a primary pack can be found in:

- TGO 91, section 10(13)
- TGO 92, section 10(8)

Medium containers

If your medicine is non-prescription and it is in a container with a capacity of 60 millilitres or less, but is not in a ‘small container’, TGO 92 defines it as being in a ‘medium container’.

See section 6 of TGO 92 for the definition of ‘medium container’.

Medicines with more than one active ingredient

Medicines that

- include more than one active ingredient, and
- are supplied in a medium container
- are not required to state the information about each active ingredient on separate lines on the main label. This applies to both the container and the associated primary pack.

See subsection 9(3) of TGO 92.

Medium container without additional outer packaging

Medicines supplied in medium containers without further outer packaging (i.e. a new primary pack), the name(s) and quantity information for the active ingredient(s) in the medicine can be displayed on the main label in a text size smaller than otherwise required under section 9.

See subsection 9(7) of TGO 92.

Metered dose medicines

If your medicine is packaged to deliver a metered dose (for example, dry powder inhalers or nasal sprays), there are two alternative ways to express the amount of active ingredient on the label.

Specific requirements for the expression of the quantity of the active ingredient in metered dose medicines are in subsection 11(2) of both Orders.

Dry powder inhalers

Since dry powder inhalers do not use ‘actuations’ it is acceptable to use an appropriate term such as ‘per inhalation’ when describing the quantity of the active ingredients. The quantity declared must be equivalent to the delivered dose.

Plastic ampoules

The capacity of plastic ampoules, how the ampoule is attached to the connecting strip and the type of medicine in the ampoule will determine how information is displayed on these containers.

The specific requirements are in subsection 10(15) of TGO 91 and subsection 10(10) of TGO 92.

Small containers

If your medicine is in a container with a capacity of 25 millilitres or less, both TGO 91 and TGO 92 define it as being in a ‘small container’.

For medicines in small containers that are supplied in an outer primary pack such as a carton, there are some allowances for the label on the container:

- Less information is required on the container label
- This information can be presented in smaller text sizes.

The primary pack of the small container must meet the full requirements of the Orders.

Relevant parts of the Orders

The requirements for small containers that are supplied in a primary pack can be found in:

- TGO 91, subsections 10(4) and 10(11)
- TGO 92, subsection 10(7).

Prescription medicines

Section 6 of TGO 91 defines a ‘small container’ and excludes ‘very small containers’ from this definition.

Non-prescription medicines

Medicines that:

- are subject to TGO 92,
- include more than one active ingredient, and
- are supplied in a small container
- are not required to state the information about each active ingredient on separate lines on the main label. This applies to both the container and the associated primary pack. See subsection 9(3) of TGO 92.

Medicines that:

- are subject to TGO 92,
- are supplied in a small container, and
- do not have any further outer packaging
- can display the name(s) and quantity information for the active ingredient(s) in a smaller text size on the main label. See subsection 9(7) of TGO 92.

Error in TGO 92 for listed medicines in small containers:

The minimum text height for **listed** medicines presented in small containers is 1.5 millimetres, not 2 millimetres as stated by TGO 92. This will be corrected in future updates to the Order.

Starter packs

Medicines that are starter packs must include:

- a statement to that effect on the label, and
- space for patient and doctor details. See subsection 10(10) of TGO 91.

Very small containers

If your medicine is a prescription or related medicine supplied in a container with a capacity of 3 millilitres or less, this is defined as being in a 'very small container'. See section 6 of TGO 91.

For medicines in very small containers that are supplied in a primary pack, there are some allowances for the label on the container:

- less information is required on the container label
- this information can be presented in smaller text sizes See subsections 10(5) and 10(12) of TGO 91.

Particular routes of administration

Haemofiltration and haemodiafiltration solutions

Haemofiltration and haemodiafiltration solutions have specific requirements for the placement of information on the main label of flexible bags.

There is specific information required to be included on the labels of these types of medicines. See subsections 9(7) and 10(7) of TGO 91.

Haemodialysis fluids used in renal replacement therapy where the movement of solutes is governed by diffusion are classified as medical devices, and are not within the scope of this Order.

Inhalations and nasal sprays

TGO 91 and TGO 92 have the same specific requirements for inhalations and nasal sprays.

Use of antimicrobial preservatives

Medicines for inhalation and nasal sprays must declare the presence of any antimicrobial preservative on the label of the container, and any associated primary pack.

Expressing the quantity or proportion of active ingredients

Medicines for inhalation have different requirements for the expression of the quantity or proportion of an active ingredient. This depends on whether your medicine is delivered as a metered dose or a discrete dosage unit.

See subsection 11(2) of both Orders for these requirements.

Relevant parts of the Orders

- TGO 91, subsection 10(9)
- TGO 92, subsection 10(2)

Injections

TGO 91 applies to medicines for injection. The capacity of the container determines which part of section 10 of TGO 91 applies:

Capacity	Relevant subsection of TGO 91
More than 100 millilitres	10(2)
100 millilitres or less	10(3)
25 millilitres or less	10(4)
3 millilitres or less	10(5)
Injections with a stated volume of fill of 100 millilitres or more	10(6)

Specific requirements for primary packs

If your injection is in a container with a capacity of less than 25 millilitres or a capacity less than 3 millilitres, the specific requirements in subsection 10(3) apply to the primary pack of your medicine but not the container label.

Injections in special packaging

If your injection is presented in a special type of packaging, additional requirements specified elsewhere in section 10 also apply (e.g. plastic ampoules that have a connecting strip – subsection 10(15)).

Injections requiring preparation before use

Subsection 8(1) of TGO 91 requires that certain preparation steps must be on all injection labels, or on a printed package insert in the primary pack of the medicine.

However, you are not required to have preparation steps on the container label where:

- your medicine is an injection in a container of capacity less than 25 millilitres and
- this information is on the label of the primary pack or package insert.

If preparation steps are in a package insert, you must include a statement on the label that those instructions are stated in the package insert. For example:

- ‘Please see package insert for instructions on how to prepare this medicine.’

Examples of a package insert include:

- the approved Product Information
- a leaflet detailing the instructions for preparation of injections administered by healthcare professionals.

For instructions for preparation package leaflets, a template is available at the TGA website - ‘Ensuring compliance after removing the product information insert’.

The package leaflet should:

- Be consistent with the preparation instructions before use stated in Section 4.2 of the approved Product Information.
- Have clear formatting to make it easy to read.

A package insert should be specific to the strength of the medicine. If there are multiple strengths of the medicine, and you want to include instructions for each in one package insert, ensure instructions are clear and the instructions for each strength is easy to identify.

Expressing the quantity or proportion of active ingredients

For medicines intended for electrolyte replacement with a volume of 100 mL or less:

- Section 10 and section 11 of TGO 91 include requirements on how you must express the quantity or proportion of active ingredients in injectable medicines intended for electrolyte replacement with a volume of 100 mL or less.
- These requirements were included in 2024 with a 2-year transition period. Applicable products imported or released for supply from 1 December 2026 must comply with the new requirements.
- The abbreviated unit ‘mmol’ for millimoles can be used when expressing quantity in millimoles.

Potassium chloride

For potassium chloride injectable medicines with a volume of 100 mL or less:

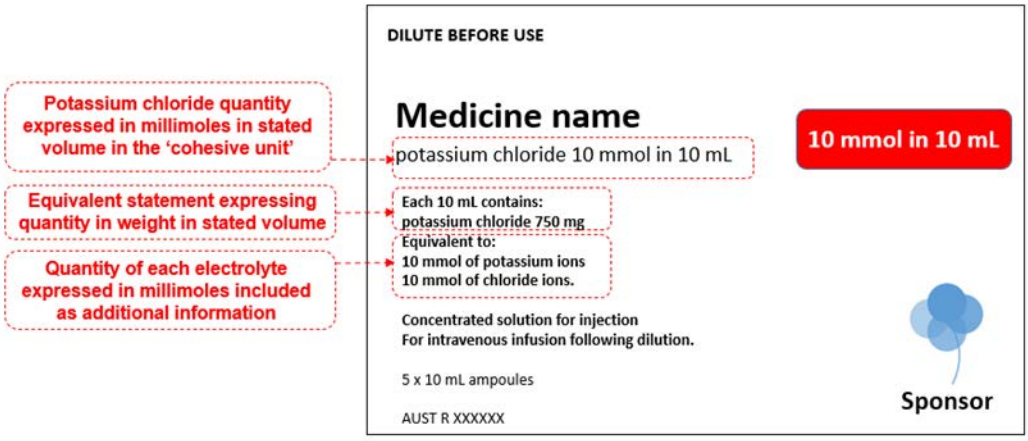
- the quantity or proportion of potassium chloride must be expressed as the number of millimoles in the stated volume of the injection in the container
- a statement must be included below the cohesive unit[3] to state the equivalent quantity of potassium chloride in weight (in relation to the stated volume of the injection).

You are not required to include the statement below the cohesive unit on the container label where:

- your medicine is in a container with a capacity of 25 mL or less, and
- this information is included on the label of the primary pack, and
- where the statement cannot be included due to the container size.

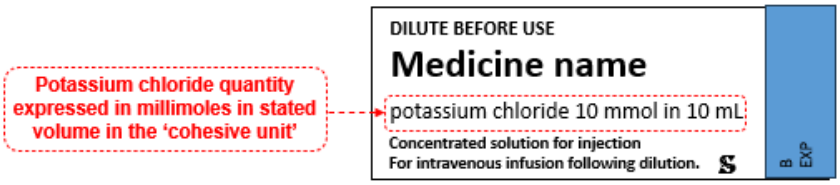
[3] Subsection 9(3) of TGO 91 and TGO 92 requires that the name of the medicine, active ingredients and quantity of active ingredients appear as a ‘cohesive unit’ on the main label without interruption of additional information, except in certain circumstances

Example: Expressing quantity of potassium chloride in medicines intended for electrolyte replacement with a volume of 100 mL or less on a primary pack main label.



Example of a main label on a primary pack expressing quantity of potassium chloride in millimoles in stated volume.[4] An equivalent statement is included below the cohesive unit to also show the equivalent quantity in weight in relation to the stated volume.

Example: Expressing quantity of potassium chloride in medicines intended for electrolyte replacement with a volume of 100 mL or less on a container main label where an equivalent statement is not included below the cohesive unit.



Example of a main label on a container expressing quantity of potassium chloride in millimoles in stated volume.[5] An equivalent statement is not included below the cohesive unit to support label readability as the size of the container precludes it.

There are also recommendations to uniquely identify injectable potassium medicines in **Potassium for injection or infusion**.

Other medicines

For medicines intended for electrolyte replacement with a volume of 100 mL or less (that are not potassium chloride):

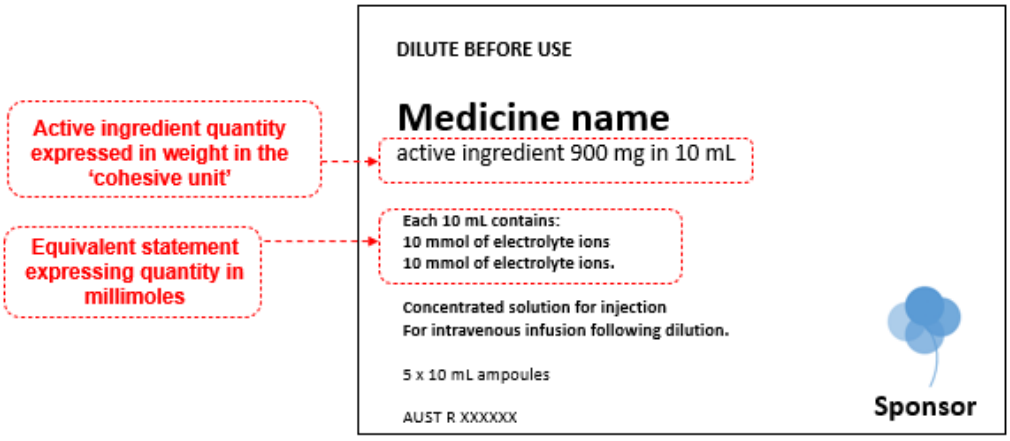
- The quantity or proportion of the active ingredients must be expressed as the stated weight in the stated volume of the injection in the container.
- A statement must be included below the cohesive unit to state the equivalent quantity of the active ingredients in millimoles (in relation to the stated volume of the injection).

An equivalent statement is always required for these medicines on the primary pack and on the container.

[4] This is an example only. This image may not be to scale and may not satisfy all the requirements and recommendations for potassium chloride medicines.

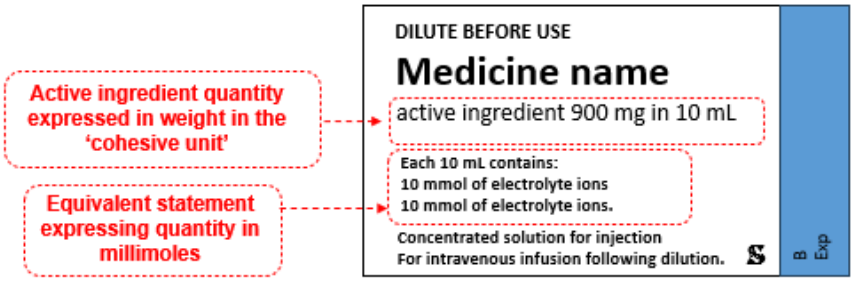
[5] This is an example only. This image may not be to scale and may not satisfy all the requirements and recommendations for potassium chloride medicines.

Example: Expressing quantity of an active ingredient that is not potassium chloride in medicines intended for electrolyte replacement with a volume of 100 mL or less on a primary pack main label.



Example of a main label on a primary pack expressing quantity of an active ingredient in weight in stated volume.[6] An equivalent statement is included below the cohesive unit to show the equivalent quantity in millimoles in relation to the stated volume.

Example: Expressing quantity of an active ingredient that is not potassium chloride in medicines intended for electrolyte replacement with a volume of 100 mL or less on a container main label.



Example of a main label on a container expressing quantity of an active ingredient in weight in stated volume. An equivalent statement is included below the cohesive unit to also show the equivalent quantity in millimoles in relation to stated volume.

Ophthalmic medicines

TGO 91 and TGO 92 have the same specific requirements for ophthalmic medicines.

- Labels must declare the presence (or absence) of any antimicrobial preservative (both the container label and any associated primary pack).
- If the medicine is for multidose use, the label must also include specific statements relating to this.

The specific requirements are in subsection 10(1) of both Orders.

Peritoneal dialysis solutions

Specific labelling requirements for peritoneal dialysis solutions are found in subsection 10(8) of TGO 91.

[6] This is an example only. This image may not be to scale and may not satisfy all the requirements and recommendations for these medicines.

As these medicines are usually large volume injections, there are other relevant requirements in subsection 10(2) and subsection 11(2).

Topical medicines

Topical medicines must declare the presence of any antimicrobial preservative on the label of the container and any associated primary pack.

The definition of 'topical use' can include medicines such as nasal sprays and nasal inhalations. Non-prescription topical medicines have requirements to include specific warning statements such as 'Caution: Not to be swallowed' or 'For external use only' but use of these on nasal medicines can be confusing for consumers. A statement to the effect of 'For nasal use only' can be used instead.

Relevant parts of the Orders

- TGO 91, subsection 10(9)
- TGO 92, subsection 10(2)

Expressing the quantity or proportion of active ingredients

There are also specific requirements on how you must express the quantity or proportion of active ingredients in medicines used on skin or mucous membranes.

See subsection 11(2) of both Orders.

Transdermal patches

There are specific requirements for the expression of the amounts of active ingredients in transdermal patches. You must include:

- the total quantity of active ingredient
- the quantity of active ingredient released in a specific time period on the medicine label.

See section 11(2) of both Orders.

Types of active ingredients

Antibiotics

There are specific requirements if you use potency units as a measure of the medicine's activity. See subsection 11(2) of TGO 91.

Neuromuscular blocking agent-containing medicines

There are specific labelling requirements for medicines that contain an ingredient that is a neuromuscular blocking agent.

See section 6 and subsection 10(8A) of TGO 91.

Ingredients that are neuromuscular blocking agents (including salts thereof) are listed in Schedule 3 to TGO 91.

The warning statement described in subsection 10(8A) of TGO 91 must be displayed on 'fluorescent red' or 'warm red' background colours. The colour identifiers for these background colours are:

- fluorescent red
  - RGB: 253.121.86

  - CMYK: 0.52.65.1
  - Pantone: 811
- warm red;
  - RGB: 245.64.41
  - CMYK: 0.75.90.0
  - Pantone: Warm Red

Note:

The Pantone Matching System is an example of a suitable commercially available product. Mention of this product in the guidance is not an endorsement.

Container constraints

There are reduced requirements for medicines in particular containers. These are:

- injections in a container with a capacity of 3 mL or less
  - the warning statement can be shortened to ‘Warning: Paralyser’ or ‘Paralyser’.
- plastic ampoules
  - the warning can shortened and be printed in any text colour, with or without the background colour.

See paragraph 10(8A)(b) for details of reduced requirements.

Biological medicines

Biological medicines are defined in section 6 of TGO 91. If your medicine:

- is a vaccine, or
- satisfies all four of the other criteria in that definition and is not exempt, it must meet the requirements of TGO 91.

There are also specific requirements for biological medicines, see subsection 11(3) of TGO 91.

If your medicine is a peptide, protein or polysaccharide-based and is not a prescription medicine, it is **not** considered a ‘biological medicine’ for labelling purposes.

Your medicine must meet the requirements of TGO 92.

Herbal medicines

Section 6 of TGO 92 provides specific definitions for herbal materials and herbal preparations to assist you in interpreting the specific requirements of the Order.

The type of herbal ingredient in your medicine determines how you must express the quantity of the active ingredient on the label. The requirements for each type are in subsection 11(2) of TGO 92.

Identifying the active ingredient in herbal medicines

The active ingredient in a medicine is defined in section 6 of TGO 92. This definition must not be interpreted to mean a component within a herbal material or herbal preparation.

In most cases, to correctly identify herbal ingredients, you must state the species name (Latin binomial), plant part and preparation on the label. This is the full approved name as described in the Australian Approved Names List; see the TGA approved terminology for medicines document for more information.

Example

A medicine that contains St John's wort would name *Hypericum perforatum* as the active ingredient in the ARTG entry for the medicine, and on the medicine label. The chemical 'hypericin' could be identified on the label as additional information (often this is identified as a 'herbal component') but this is not the name of the active ingredient.

Additional information for herbal preparations

Your main label needs to include information that relates the amount of active ingredient in your medicine to the amount of herbal material from which it was prepared. See subsection 11(2) of TGO 92.

Where no standardisation is claimed

Herbal material

If the active ingredient in your medicine is a herbal material, its quantity must be expressed as the weight of that material.

Example - *Camellia sinensis* dry leaf 500 mg

Herbal preparation

If the active ingredient in your medicine is a herbal preparation, its quantity must be expressed as the:

- weight of that preparation, and
- equivalent weight of the herbal material from which it was prepared.

Examples

- *Camellia sinensis* leaf dry extract 5 mg, derived from *Camellia sinensis* leaf dry 500 mg (or words to that effect).
- *Camellia sinensis* leaf dry ext. 5 mg, from *C. sinensis* leaf dry 500 mg (or words to that effect)
- *Camellia sinensis* dry leaf extract 5 mg, from 500 mg dry leaf (green tea)

Where standardisation 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. Where standardisation of the herbal material or herbal preparation is claimed on the label of the medicine, it affects the way that the quantity or proportion of the active ingredient must be expressed. You should use the term 'minimum' on your label.

Standardised herbal material

If the active ingredient in your medicine is a standardised herbal material, then the quantity of the active ingredient must be expressed as:

- the minimum dry weight or minimum fresh weight of herbal material, and
- the quantity of standardised constituent(s) in the herbal material.

Examples

- *Camellia sinensis* leaf dry 500 mg minimum, standardised to contain catechins 30 mg.
- *Camellia sinensis* dry leaf 500 mg (min), stand. to contain catechins 30 mg
- *Camellia sinensis* dry leaf 500 mg (min), contains catechins stand. 30 mg

Standardised herbal preparation

If the active ingredient in your medicine is a standardised herbal preparation, then the quantity of the active ingredient must be expressed as:

- the weight of that preparation,
- the minimum weight of the herbal material from which it was prepared, and
- the quantity of standardised constituent(s) in the herbal preparation.

Examples

- *Camellia sinensis* leaf dry extract 5 mg, derived from *Camellia sinensis* leaf dry 500 mg minimum, standardised to contain catechins (of *Camellia sinensis*) 30 mg (or words to that effect)
- *Camellia sinensis* ext. 5 mg, from 500 mg (min) dry leaf, contains std. catechins 30 mg
- *Camellia sinensis* ext. 5 mg, from 500 mg (min) dry leaf, contains 30 mg of std. catechins

If you include statements on standardised components on your label, you should present this information as clearly as possible. This might include stating the standardised component on a separate line.

Homoeopathic medicines

Section 6 of TGO 92 provides specific terminology to assist in understanding the labelling requirements for homoeopathic medicines:

- homoeopathic medicine

- homoeopathic potency
- the meaning of ‘name of an active ingredient’ when the active ingredient is a homoeopathic preparation.

Label statement

A statement describing the medicine as homoeopathic is required on the labels of all medicines containing homoeopathic preparations.

The requirements for the wording and location of this information are in subsections 10(3) and 10(4) of TGO 92.

Medicines with both homoeopathic and non-homoeopathic ingredients

If your medicine contains both homoeopathic ingredients and active ingredients in material doses, these must be distinguished on the medicine label.

Section 10(4) of TGO 92 includes some example statements that can be used to differentiate the types of ingredients.

Expressing the quantity or proportion of homoeopathic preparations

Specific requirements for the expression of the quantity or proportion of homoeopathic preparations are in subsection 11(3) of the TGO 92.

Minerals for supplementation

If the formulation of your medicine includes a mineral intended as a supplement (i.e. to increase the user’s intake of that mineral), the amount of the mineral element must be declared on the label.

You must state the:

- name of the active ingredient, and
- name and quantity of the element intended for mineral supplementation. This applies to both prescription and non-prescription medicines.

This requirement applies to all mineral supplements. It does not rely on the inclusion of an explicit statement such as ‘for supplementation’ (or similar) to be on the label.

You may choose to include the amount of active ingredient in addition to the above information.

Examples

1. An oral preparation that includes calcium for supplementation would express the calcium component on the label as both the:
   - scientific name (AAN), e.g. calcium carbonate
   - name of the elemental mineral and its quantity, e.g. equivalent to calcium 500 mg
2. An oral preparation containing *calcium pantothenate* (Vitamin B5) that has **not been included for mineral supplementation** does not have to include the amount of elemental calcium on the label because that ingredient has not been included in the formulation to add calcium to the diet.

Sunscreens

Most sunscreens that are regulated as medicines are listed, rather than registered, on the ARTG.

Listed sunscreens

The names and quantities of the active ingredients do not have to appear on the main label if your sunscreen is a listed medicine.

Subsection 9(6) of TGO 92 provides the alternative of including this information on either the side or rear labels. It does not matter how many active ingredients are in your medicine.

Sunscreens in small containers

If your medicine is a sunscreen **and** is in a container with a capacity of 25 millilitres or less, some information can be displayed in text sizes smaller than the usual requirements.

These requirements are in subsection 10(5) of TGO 92.

Vitamin supplements

TGO 91 and TGO 92 have the same specific requirements for medicines containing vitamins.

Inclusion of common names of vitamins

Medicines containing an active ingredient that is a vitamin can use the word ‘vitamin’ (or a suitable abbreviation), together with the common name of that vitamin, on the main label. This additional information does not affect the relationship between the name of the medicine and the name of active ingredients required under subsection 9(3) of the Orders.

The quantity of the active ingredient applies only to the amount of the actual ingredient and not to the amount of the base vitamin.

> **Example** – 671 mg d-alpha-tocopherol (vitamin E)

Relevant parts of the Orders

- TGO 91, subsection 11(6)
- TGO 92, subsection 11(5)

Vitamin A medicines

Medicines containing Vitamin A (or a derivative of Vitamin A) as an active ingredient must express its quantity in microgram retinol equivalents.

See subsection 11(2) of both Orders.

Vitamins, minerals and herbal ingredients

If your medicine contains active ingredients that are vitamins, minerals for supplementation or herbal materials or preparations, you may need to include additional information on your label.

Number of active ingredients

If your medicine includes these types of ingredients, they may be described with additional information as permitted or required by the Orders. This affects when the information on active ingredients can be included on a side or rear panel rather than on the main label (see subsection 9(5) of TGO 92).

Text between medicine name and active ingredients

Similarly, this additional information on the active ingredients may affect the relationship between the medicine name and the active ingredients on a main label (see subsections 9(3) of TGO 91 and 9(6) of TGO 92).

Recommendations and best practice

This part of the Guidance describes best practice principles and provides additional information to assist you in developing medicine labels.

This part of the Guidance is **non-mandatory** best practice.

In addition to the legislated requirements for medicine labels, there are other features of label design that may affect the quality use of medicines. Some of these are addressed in this Part to assist you in designing a medicine label.

This information is not mandatory and is intended to serve the purpose of improving safe and quality use of medicines.

General design principles

When designing your label, think about the end user of your medicine. Labels are used by different people under different circumstances. You should consider:

- age of users
- target patient group
- literacy of users
- visual acuity

This Part of the guidance will assist you with some of these considerations.

User-centred design of labels

You should consider the end user of your medicine and any specific considerations in relation to the type of goods.

For example, if your medicine is to assist people with poor vision, consider using larger text than the minimum requirement.

Inclusion of additional, non-mandatory information may assist consumers in their choice of medicine. Some consumers are interested to know certain additional information about a medicine.

Consumers often ask about:

- Whether there are any animal products in the medicine
- Where the medicine was made (see the Australian Competition & Consumer Commission's (ACCC) guidance on country of origin claims)
- What the packaging is made of (e.g. is the vial stopper made from latex?)
- Whether the packaging is recyclable
- Details of the full formulation

You should consider including this type of information on a label.

Latex in medicine packaging

Some medicine packaging components, such as vial stoppers, are made with natural rubber latex. To reduce the risk of anaphylaxis and to assist consumers and health professionals in managing latex allergy, we recommend that all medicines containing rubber in their packaging:

- state the presence or absence of natural rubber latex on the label; and
- state the presence or absence of natural rubber latex in the Product Information (PI) and CMI.

For example, if your medicine container has a synthetic latex stopper, you should include the statement 'vial stopper not made with natural rubber latex'.

You should avoid using terms such as 'latex-free'.

Colour contrast

Colour contrast is an important tool in ensuring legibility of text for consumers, particularly for those who experience visual impairment.

The Vision Australia colour contrast analyser can be used to assist you in determining whether your proposed text is acceptable. This is available on the Vision Australia website.

Batch number and expiry date

Although not required by the Orders, you should consider printing the batch number and expiry date details where this would improve legibility. Legibility of embossed batch and expiry is particularly difficult on clear or translucent packaging. If the batch and expiry details must be embossed, a darkened background is preferred.

Colour

We recommend the use of colour to help differentiate medicines within a sponsor's medicine line, but it should not be the only element that is used. Colour differentiation is different from colour coding.

Our recommendations with respect to colour are similar to those of the FDA Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.

Colour differentiation

We recommend using colour to make features on a medicine label stand out and help distinguish one item from another. In some circumstances, colour can be used to bring attention to:

- the name of the medicine
- the strength of the medicine
- important precautions.

We recommend that you:

- use fonts that are of similar size and style for all the words in the medicine name
- only use different colours for certain components of the medicine name when it is useful to enhance the differentiation of the medicines within a range.

Using other aspects in addition to colour

Individuals can perceive colours differently, some people are colour-blind and colours can look different in different lighting conditions. For these reasons, if colour was the only element used to

distinguish medicines within a sponsor's medicine line it may be difficult or confusing to identify the goods and we may 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 used to distinguish medicines.

Related guidance

See guidance for information about colour differentiation for prescription medicines.

Colour coding

Colour coding is where colour is used to designate a specific meaning. However, because colour coding has contributed to medication errors in the past, it needs to be used with care. When colour is used as a shortcut to identifying a medicine, people sometimes don't read the label and this leads to mistakes.

We recommend that:

- Colour coding is only used when this coding has already been established on TGA-approved labels or is a requirement specified in the Orders.
- Where colour coding is used on a medicine label, it should be applied to all labels and packaging, such as the immediate container and the primary pack.

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 does not mean that the name appearing on the label needs to match the letter case entered in the ARTG.

- It is at the sponsor's discretion whether to use upper or lower case for the name of the medicine on the label.
- Care should be taken with all-capital text because it is often harder to read.

Example

ARTG certificate name: 'THERAPAIN CHILDREN'S CHEWABLE paracetamol 250 mg tablets blister pack (reformulation)'.

Label name can be:

- 'Therapain Children's Chewable', or
- 'Therapain children's chewable', or
- 'THERAPAIN CHILDREN'S CHEWABLE' (use of all capitals not recommended)

Use of sentences

We recommend using sentences (starting with a capital letter) to present the information on your label. Use a mix of upper and lower-case letters.

You should only use all-capital letters when they are mandated by other regulatory requirements, such as RASML.

Use of Braille and other languages

Text in languages or characters other than English may also be included on labels, as long as the information:

- is true and correct
- does not breach legislation on content that is permitted on medicine labels (such as the Therapeutic Goods Advertising Code)
- does not impact the readability of required information.

If your label includes text or characters from another language, you should ensure that:

- this does not cause clutter or overcrowding of the label
- the other language text is consistent with the required English language text
- the label, including the name of the medicine, does not include or imply any additional indications
- interpretation of the text or characters is valid and appropriate.

Machine-readable code

We recommend that all medicine labels include a machine-readable code, although they are only mandatory for prescription medicines.

You can include information such as batch and expiry details and country of manufacture in a 2D data matrix code. Your label should include a statement to alert users of this information, for example, 'Please scan this code for more information about this medicine'.

QR codes

A Quick Response (QR) code is a type of matrix code that can be read on a mobile phone.

You may use QR codes to provide consumers with information relating to the medicine. You may also use QR codes to provide health professionals with information about medicines that are administered by healthcare professionals.

However, QR codes cannot be used to replace information that must be on the label but may be used in addition to physical labelling.

We recommend you place QR codes on a back or side panel so it does not distract from critical information on the main label.

Considerations when using QR codes for consumers

If you include a QR code, we recommend that you include a statement close to the QR code stating its purpose, 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 CMI is available from pharmacists or the TGA website.

The QR code may:

- Provide a link directly to the CMI document, which is consistent with the most recent approved PI document. We prefer you to link to the CMI available from the TGA Business Services (TBS) website.
- Direct the consumer to a company website if the website is acceptable (see **Acceptable web addresses** in this guidance), and complies with all advertising restrictions.

Considerations when using QR codes for medicines administered by healthcare professionals

If you include a QR code, we recommend that you include a statement close to the QR code stating its purpose, for example;

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

The QR code may:

- Be used in addition to printed instructions for preparation for medicines, but not in place of printed instructions for injectable medicines administered by a healthcare professional.
- Link directly to the current, approved Product Information document on a website controlled by the sponsor.
- Direct the health professional to a company website if the website is acceptable (see Acceptable web addresses in this guidance). Any information must be linked to or provided in accordance with TGA legislation including the *Therapeutic Goods Act 1989* and the Therapeutic goods advertising code.

If a QR code contains a number or link that is unique to the unit of medicine it is printed on, the unit is considered to be serialised and the requirements of Therapeutic Goods (Medicines – Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021 apply. For more information see: Understanding serialisation and data matrix codes.

Acceptable web addresses

A label may include the address of a company website, 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 medicine type.

To ensure this occurs, 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 medicine (including any direct links from the website) is consistent with information approved by the TGA for that medicine.

Blister strips – frequency of information

In some instances, blister strips are manufactured with perforations (or are marked in some way) to assist the consumer or medical practitioner to detach individual dosage units.

When dosage units are detached, it is important that label information can still be read. To address this, there is a specific requirement for how often critical information must be repeated for blisters or strips where an individual segment containing the dosage unit can be readily detached.

It is recognised that blister strips are often cut up, even if there is no intention for individual dosage units to be supplied in this way. To help ensure the quality and safe use of these medicines, we recommend repeating the required information at least once every two dosage units whenever possible.

We also recommend that the particulars on the label remain visible until the last dose is removed. This may best be achieved using a random display where the information appears frequently across the blister strip.

Related guidance

- General guidance on **prescription medicines in blister strips** section in this guidance.
- Information on the **specific legislated requirements relating to blister packs** section in this guidance.

Inclusion of additional information on labels

You may include more information on a label than is required by the Orders. However, the additional information must not prevent compliance with the Orders.

Full formulation disclosure

The Orders do not require all excipients to be declared on the medicine label (except for injections). You may choose to include the full formulation details to better inform consumers about their medicines.

Disclosure of excipients

You may wish to declare excipients other than those required by the labelling Orders. If you do this, you will need to 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 medicine.

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

Claims about absence of substances

Provided that it is true, you may include a statement on the label that your medicine does not contain certain substances 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, check with the manufacturer or supplier to make sure that it does not contain anything claimed to be absent on the label.

You may include a statement that the medicine 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.

Claims about absence of substances are considered promotional statements and are **not permitted** in the Critical Health Information table.

Do not include statements about the medicine being ‘free from’ an active ingredient that is not in the medicine.

For example, a label for paracetamol 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.

Changes in formulation or appearance

To alert consumers, we recommend including the statement 'New Appearance' on the label if your medicine has been marketed in Australia and you change its appearance. 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 has changed but not the appearance, we recommend including the statement 'New Formulation' on the label.

International labels

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

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
- bulk finished product prior to packaging and for commercial distribution and supply.

A presentation is considered to be a bulk pack 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 (TGO 80) and Therapeutic Goods Order No. 95 - Child- resistant packaging requirements for medicines 2017 (TGO 95).

Non-prescription medicines information

Critical health information for listed medicines

Presentation of CHI in a tabulated format is not a requirement for some registered non- prescription medicines or for any listed medicine. However, we recommend that you use this format whenever possible for all non-prescription medicines supplied in Australia. This will assist consumers to become more familiar with CHI, and where to find it.

If you choose to use the tabulated format for CHI on, for example, the label of a listed medicine, display the CHI in the same way that is required for higher risk non-prescription medicines.

Otherwise the medicine's presentation may be considered unacceptable under the requirements of the Act.

Both the **best-practice** information and **mandatory requirements** for the display of CHI are co-located in **Tabulated display of CHI** of this guidance for ease of reference.

Prescription medicines information

Expressing names of active ingredients and strength

The name and amount of an active ingredient present in a medicine must be clearly stated on the medicine label to assist in quality use of medicines. This information must accurately reflect the medicine's formulation and may therefore include reference to chemical components such as salts, waters of hydration and solvates.

Active ingredients present as salts, hydrates or solvates

For active ingredients that are present as salts, hydrates or solvates, include the name of the salt, hydrate or solvate form on the main label. It may not be necessary to repeat or emphasise this name elsewhere.

Expressing the strength of a medicine

The strength of the medicine will normally be expressed as the equivalent amount of the active ingredient in the anhydrous free acid or free base form and be consistent with international practice. We recommend the following:

Example	Recommendation
Only one salt is registered in Australia and the strength of the medicine is expressed in terms of the free base or the free acid.	Include the name of the salt in brackets, e.g. fluoxetine 20 mg (as hydrochloride).[1] If the available label space precludes this, you can simply use the name of the free base/acid (e.g. fluoxetine 20 mg) on labels other than the main label. Your main label must include the name of the salt.
More than one salt is 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 labels.[1]
The active ingredient is present as the salt of a base or acid and it is established that the strength is labelled in terms of the formulated amount of that salt.	Use the name of the salt on all labels (e.g. metformin hydrochloride 500 mg and raloxifene hydrochloride 60 mg).
The active ingredients are present as a hydrate or solvate (such as dapagliflozin propanediol monohydrate), where the strength of the medicine is expressed on the solvent-free basis.	Include the hydrate or solvate in brackets, as in the case for a salt, e.g. dapagliflozin 10 mg (as propanediol monohydrate). If the available label space precludes this, you may omit the name of the solvate (e.g. dapagliflozin 10 mg) on labels other than the main label. Your main label must include the name of the solvate.

Example	Recommendation
The strength of the medicine is expressed in terms of the hydrated or solvated material.	The name of the active ingredient must include this information, e.g. indapamide hemihydrate 2.5 mg.
The active moiety is a quaternary ammonium cation e.g. tiotropium (as bromide monohydrate).	The expression of the active ingredient is labelled as per a salt and the strength of the medicine is expressed as the amount of the cation (e.g. tiotropium).

[1] Instead of using brackets for the salt, solvate or hydrate, you may also use a statement such as 'contains dapagliflozin propanediol monohydrate, equivalent to 10 mg dapagliflozin'.

Consistency of labelling active ingredient and strength for both innovator and generic versions

It is also important that the names of active ingredients and the strengths of prescription medicines are consistently labelled for both the innovator medicine and any generic formulation of that medicine. That is, the:

- references to the name of the active ingredient
- order of multiple active ingredients (if relevant)
- expression of the strength of the medicine is established by the innovator medicine.

Using colour to differentiate strength (prescription medicines)

For medicines 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 medicines and lighter shades might be used for lower strength medicines.

Different colour schemes might also be chosen for the different strengths, for example:

- Innovator Medicine Name 5 mg (blue colour scheme to denote strength)
- Innovator Medicine Name 10 mg (green colour scheme to denote strength).

When the innovator medicine uses colour differentiation to distinguish between strengths, 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 to denote strength)
- Generic Medicine Name 10 mg (green colour scheme to denote strength).

Specific recommendations

There are recommendations for use of certain colours for specific medicines. See section **Potassium for injection or infusion** of this guidance.

The recommendation for consistency of colour schemes between innovator and generic medicine ranges applies only to colour features to distinguish on the basis of strength. This consistency should NOT be applied to the entire label presentation as it may result in confusion between goods. This would be considered ‘unacceptable presentation’ under section 3(5) of the Act.

Fixed Dose Combination products

For combination products, the quantities of the active ingredients should be clearly visible and may be incorporated in the product name, for example, ‘*XYZ 20/10*’. This is particularly important when there are several strengths within a range.

Delivery devices

Delivery devices, such as pressurised metered dose inhalers, have different labelling requirements depending on whether the canister can be removed.

If the canister can be removed from the device, consumers may not be aware of this and not realise that important information is obscured. The CMI should state that the canister can be removed to view the full label.

Pharmacist’s dispensing label space

You should leave as much space as possible to allow the pharmacist's dispensing label to be affixed to your medicine without obscuring information already on the pack. Some dispensing systems use labels measuring 80 x 40 millimetres which is larger than the minimum space mandated in TGO 91.

Remember, after the pharmacist has labelled the pack, the following essential information should remain visible:

- Batch number
- Expiry date
- Storage instructions
- Product name
- Strength
- Name of the active ingredient(s)
- Dosage form
- Barcode (EAN barcode)
- Signal headings
- Warning statements
- AUST R number

Words to the effect 'Place label here' should be placed in the designated dispensing label space. Ideally, if there are mandatory warning labels required, space should be provided.

Small containers

If the medicine is packaged in a small container (such as eye drops), consider using a cardboard backboard on the primary pack that would allow space for a dispensing label.

Consistency with the Product Information for blister strips

We recommend that the overall design of a blister strip label is consistent with the instructions for prescription medicines that are provided within the 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.

Starter packs of prescription medicines

There are specific labelling requirements for starter packs of your prescription medicine. The definition of a starter pack that is included in TGO 91 aligns with that given in the Medicines Australia Code of Conduct Edition 18.

Sizes of starter packs

TGO 91 defines the size of starter packs based on the:

- most commonly prescribed PBS quantity, or
- smallest trade pack.

Where it is not practical to produce a ⅓ pack, the smallest trade pack can be used. Examples of this may be ear and eye drops or medicines in small containers. Reasons such as cost or availability are not accepted as being impractical.

Dispensing label space

The dispensing label space that is required for prescription medicines should be used by a practitioner to record relevant details as required in Appendix L of the Poisons Standard.

You may leave this space blank or pre-print it with the relevant headings.

Methotrexate-containing medicines

Methotrexate is sometimes taken once weekly and other times more frequently; this has resulted in medication errors. For medicines 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.

Vinca alkaloids-containing medicines

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’.

Potassium for injection or infusion

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

Clear differentiation of injectable potassium medicines from other medicines and intravenous fluids is recommended to help mitigate some of the risks associated with the use of these medicines as recommended below under ‘Medicines for injection or infusion after dilution’.

Medicines for injection or infusion after dilution

For medicines that are 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 total content in millimoles in the stated total volume, for example, 10 mmol in 10 mL.

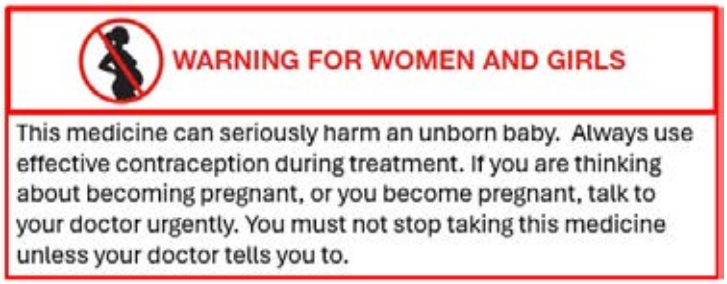
Premixed bags

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 total content in millimoles in the stated total volume, for example, 40 mmol in 500 mL
- provide a clear space at least equivalent to the maximum font size around main description and key information (such as diluent and volume).

Products containing valproic acid and valproate salts

Products containing valproic acid or any of its salts should include the following warning:



Neuromuscular blocking agent-containing medicines

There are specific labelling requirements for medicines that contain neuromuscular blocking agents. These requirements are outlined in subsection 10(8A) of TGO 91.

We recommend that the warning statement is:

- displayed in greater than the minimum 1.5 mm text size where possible
- displayed on the main label of the primary pack
- displayed in a combination of upper case and sentence case (i.e. WARNING: Paralysing agent)
- the permitted abbreviations are only used if there is insufficient space to include the full warning statement.

Example

A medicine contains rocuronium bromide. 'Rocuronium' is a neuromuscular blocking agent listed in Schedule 3 to TGO 91.

The medicine is:

- an injection packaged in a 3 mL glass ampoule
- supplied in an outer carton.

The carton label includes the full warning statement for neuromuscular blocking agents, in black text on a fluorescent red background:

WARNING: Paralysing agent

The sponsor chooses to include this warning on the main label of the carton to improve visibility and reduce the risk of medication errors.

Due to constraints of the size of the container label, the full warning statement does not fit, so a shortened version has been used:

WARNING: Paralyser

Tabulated display of CHI

Certain registered non-prescription medicines must comply with the requirements of subsection 8(2) of TGO 92. This prescribes the presentation of tabulated Critical Health Information (CHI) for these medicines. To allow sponsors some flexibility in design, not all aspects of its presentation are subject to mandatory requirements.

However, it is important that all aspects are considered when designing the label, and therefore both **mandatory** requirements and **best practice** guidance have been co-located in this section for ease of reference.

Mandatory requirements are described using **must**.

Critical Health Information – CHI

Critical health information (CHI) is information that is important for the safe use of non- prescription medicines. It should be easy for consumers to find and understand this information when they read a medicine label.

What information does it cover?

Section 6 of TGO 92 defines which of the information required under subsection 8(1) is considered CHI.

CHI comprises:

- the names of all active ingredients in the medicine
- the quantity or proportion of all active ingredients in the medicine
- intended purpose of the medicine
- relevant warning statements
- substances required to be declared on a label and any associated statements (Schedule 1 to the Orders)
- directions for use.

'Other information'

To provide flexibility in designing the table of CHI and the label, some 'other information' can be included in the table. This information is not mandatory to include in the tabulated format.

Paragraph 8(2)(e) of TGO 92 details the 'other information' that is not 'critical health information' but may be of importance to some consumers. This information should also be easy to locate and understand. This 'other information' comprises:

- storage conditions (such as safe storage advice e.g. keep out of reach of children or mandatory temperature information e.g. store below 25°C)
- any tamper evident features of the pack/container
- sponsor or distributor contact details
- a full list of the medicine's ingredients.

If you choose to include a full list of ingredients under this heading, any substances required to be declared under Schedule 1 must still appear under the 'Warnings' heading.

If you decide not to include the 'other information' heading in the table of CHI, you must include any mandatory information, such as storage conditions, elsewhere on the label.

Display of CHI – Mandatory requirements

You must include the critical health information (CHI) in a consistent location and format on the labels of most registered non-prescription medicines.

Subsection 8(2) of TGO 92 specifies certain requirements for displaying CHI. You must display CHI in a tabulated format and the information **must**:

- be under relevant headings
- be in a particular order
- have a white or other contrasting background
- be in only one colour (both text and associated punctuation)
- be black or another dark colour

The table containing CHI **must not**:

- contain any additional information, other than that specified
- use fonts, bolding or colours to highlight parts of the CHI (except for headings/subheadings or when it is mandatory)
- contain logos or graphics that break up or interfere with the CHI
- include marketing information, such as 'free from' claims

There are only a few mandatory formatting requirements for the tabulated display of CHI. You have flexibility to design a format that suits medicines supplied in different types of packs and pack sizes and use colour palettes that are consistent with branding or have been developed as part of user-testing performed during product development.

Medicines not required to use tabulated CHI display

Medicines that are exempt from using the tabulated CHI display on their labels are specified in subsection 8(3) of TGO 92.

Options within tabulated CHI display

You have the option to include some additional information within the tabulated display of CHI.

Paragraphs 8(2)(d) and (e) of TGO 92 specify types of information that are not required by the Order but can be included in the table.

These are:

- Words describing the pharmacological category or principal intended actions of the active ingredient(s)
- Safety related information such as:
  - allergen advice
  - advice about keeping the medicine out of reach of children
  - non-mandatory cautions or warnings.

Headings

You must present the CHI under appropriate headings.

You can choose the words to use in each heading, however they must have the same meaning as the headings described in paragraph 8(2)(b) of TGO 92.

Headings should be of sufficient prominence to distinguish them from the critical health information text. Headings do not have the same formatting requirements as the CHI but must contrast strongly with the background. You can use bolding, different coloured background or text to present the headings).

Order of CHI

You must display the CHI headings in the following order (specified in subsection 8(2) of TGO 92):

- Name and quantity of the active ingredient(s)
- Indications
- Warnings
- Directions for use
- Other information (this section of the CHI is optional).

Warnings

You must include all mandated warnings and advisory statements that apply to your medicine under this heading in the CHI tabulated display. This includes declarations of substances identified in Schedule 1 to TGO 92.

If you must include multiple statements, these can be grouped under sub-headings to improve readability.

Advisory statements such as ‘drink plenty of water’ can be included under this heading.

Schedule 1 declarations, such as declaration of allergens, must be included under the warnings heading, even if the ingredient appears in a full list of ingredients elsewhere in the table.

Signal headings required by the Poisons Standard do not need to be included in the table.

Directions for use

Directions for use are critical to ensure the safe use of medicines for different target populations using the same medicine, or people using the same medicine for different purposes.

Directions for use must include information on:

- appropriate doses of the medicine
- the method of administration or use of the medicine
- the frequency and duration of treatment for each statement of purpose or indication for the medicine
- the use of the medicine by people of particular ages or those with particular medical conditions.

If required, the approved dosage directions must include additional information such as the maximum daily dose for each age group or frequency and duration for each target population to ensure safe use of your medicine.

Warnings specifically about the directions for use, such as the duration of use or patient age, may appear under this heading.

Dosing for liquid, solid or semi-solid medicines

You:

- **must** label the dose of your medicine in metric units (e.g. 5 mL, 10 g).
- **must** state the equivalent metric units if your dosage instructions use a calibrated or standardised measuring implement that is included with your medicine.
- **must not** state the dosage in terms of culinary spoonsful (e.g. teaspoon, tablespoon, etc.); these spoons are not standardised or calibrated.

Lengthy directions

If you cannot fit your directions for use into the display of CHI, you must include these on a package insert.

Consistent with section 8 of TGO 92, if you do this, you must include a statement under the ‘directions for use’ heading that refers consumers to the package insert, e.g. ‘*please refer to package insert for instructions on how to use this medicine*’ or words to that effect.

Different ways to name active ingredients on the main label

If your medicine label includes CHI in the tabulated display, you are not required to use the full Australian Approved Name (AAN) to identify the active ingredients on the main label. You may choose to use an abbreviated name instead.

Many approved names are lengthy because they include chemical components (such as waters of hydration or salts) in addition to the therapeutically relevant moiety. To assist readability for consumers, this additional scientific information can be omitted from the main label of your medicine if the full approved name is displayed as CHI.

You can only use the active moiety in place of the full approved name if the moiety is part of the approved name.

Therefore, this approach is associated with chemical ingredients that use an 'Australian Approved Name' and is not relevant to complex complementary medicine substances.

For example, if your medicine contains 'oxymetazoline hydrochloride' as an active ingredient, the main label could state 'oxymetazoline' immediately under or next to the medicine name. If you choose to do this, you must not include any quantity information with the abbreviated name on the main label (full AAN and the quantity will need be included in the table of CHI).

If your medicine contains more than one active ingredient and one of those is identified using the active moiety without quantity information, you must not include quantity information for any of the active ingredients on the main label.

Display of CHI - Best practice

If your medicine is in a container that is supplied in an outer pack (i.e. primary pack) that meets the requirements of subsection 8(2), you do not have to duplicate the CHI tabulated display on the container label (inner label).

- Where space permits we recommend also using the specified CHI presentation on the container label.
- Where there is insufficient space on the container label and the information cannot be presented in a tabulated form, we recommend that you present the information in the same order as in the CHI on the primary pack.

Simple language

We recommend wording your CHI succinctly and in plain English wherever specific wording is not mandated.

Title

We recommend using the heading **Medicine information** (in larger text) for the table containing the CHI.

Border

We recommend techniques to highlight the information and improve readability such as:

- box-borders (if space permits)
- colour shades in or around the table.

Headings

We recommend that you highlight your headings using techniques such as:

- bold fonts (appropriate size)
- shading
- shaded coloured bars or text boxes across the width of the panel different colours on a strongly contrasting background
- bullet points (in the same colour as the heading text)
- **Do not** use narrow letters or narrow word spacing
- **Do not** use multiple colours or colours that are dark as the back ground for the CHI panel
- **Do not** use white text on dark coloured background for the CHI (except for the headings/subheadings).

Use of sentences and capital letters

We recommend using sentences to present the CHI. Use a mix of upper and lower-case letters, starting sentences with a capital letter.

Do not use all-capital text. A mix of upper and lowercase characters is easier to read.

The exception is when capital letters are mandated by other regulatory requirements, such as RASML.

Active ingredient purpose

The pharmacological category or principal intended action of the active ingredients (the active ingredient purpose, e.g. 'antihistamine' or 'analgesic') can be included in the table of CHI. This is not to be confused with the medicine purpose or indications.

Grouping warnings

We strongly recommend you group warnings under subheadings such as:

- 'Do not use if''
- 'Ask a doctor or pharmacist before use if you'
- 'Stop use and ask a doctor if'.

Text and font for warnings

For subheadings under the Warnings section, we recommend using bold font and text size that is not bigger than the heading.

You can present the subheading and warning as a continuous sentence (instead of a bullet) with the subheading in bold font when there is only one warning under a subheading. For example, '**Do not use** if you are pregnant'.

RASML requirements

Make sure the meaning of the RASML warning does not change when you group warnings under a subheading.

You may need to make minor changes to either the subheadings or the warning statements to comply with RASML.

Directions for use

We recommend:

- Using the 'Directions for use' section for advisories about dose or directions for use.

Specifying age groups

You can express the directions for use as a sentence unless there are different dosages for different age groups.

You should use a table format when there are more than two dosages or age groups recommended for your medicine.

If your medicine is not for use in children, we recommend that you:

- specify that the dose is an adult dose (e.g. 'Adult dose: 10 mL')
- include the statement 'For adults only' or words appropriate for your medicine.

Directions for symptomatic relief

Include the following qualifiers if the medicine is for symptomatic relief (e.g. cough and cold preparations) and does not require a course of treatment:

- 'when necessary'
- 'as required'

Continuation of CHI presentation

The CHI presentation should be a single panel in one field of view.

If this is not possible because of the packaging (e.g. smaller packs, cartons for tube presentations), you can use more than one table, column or panel for the required information but you must retain the order of information required by TGO 92.

We recommend:

- Highlighting the table on each panel with techniques such as boxed borders or shading.
- Placing the word 'continued…' at the right bottom corner of the first panel.
- Titling the subsequent tables 'Medicine Information (continued)'

If you use more than one panel, we recommend using arrow heads (▻ or ◅) at the end of 'continued…' to mark the direction of the continuation.

Examples of CHI presentation

The following examples, using common OTC active ingredients, are intended to show how the CHI tables can be set out. Different presentations include:

- Absence or use of borders
- use of coloured backgrounds
- use of coloured texts for headings
- continuation of CHI when more than one table is required.

The 'indications' under the 'Uses' heading in some examples below are only intended to show how they can be organised. Of course, indications included under this section on your medicine must be consistent with the ARTG entry.

The examples below only include the mandatory statements required for each relevant active ingredient at the time of preparing this guidance document. The CHI tables are permitted to include warning/advisory statements that are not mandated in RASML. In some instances the TGA may request the inclusion of additional warning/advisory statements. As warning/advisory statements and scheduling status of medicines change regularly, you must consult the latest publications to ensure that your medicines labels meet all applicable regulatory requirements.

Paracetamol tablets (showing the optional 'Purpose' of the active ingredient):

Medicine Information

Active Ingredient (in each tablet)	**Purpose**
Paracetamol 500 mg.....	Analgesic

Uses

For the temporary relief of pain associated with xxxxx
Reduces fever

Warnings

Do not

û (*as relevant to the scheduling status of the medicine*) give to children 6 years of age or less OR give to children under 12 years of age
û take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist

Unless advised by a doctor, do not use

û for longer than a few days at a time if you are an adult
û in children and adolescents for longer than 48 hours at a time

While using this product

§ Keep to the recommended dose
§ 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

! Contains xxx, xxx. Products containing xxx can cause xxx. (*as relevant*)

Directions for use

Adults and children 12 years of age and over: Take 1-2 tablets every 4-6 hours as necessary with water. Do not take more than 8 tablets in 24 hours.

Other information

Store below xx°C away from light.
Do not use if the tamper evidence seal is broken or missing.
Distributed by:
xxxx

Paracetamol and phenylephrine hydrochloride combination (showing the optional 'purpose' of the active ingredients):

Medicine Information

Active Ingredient (in each tablet) **Purpose**
Paracetamol xxx mg ....Analgesic
Phenylephrine hydrochloride x mg .....Decongestant

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

ü Reduces fever

Warnings
Do not use
û if you are taking other products containing paracetamol unless advised to do so by a doctor or pharmacist
û in children under 12 years of age.

See your doctor or pharmacist before use if
û you have high blood pressure or heart problems or are taking antidepressant medication
û you are pregnant or likely to become pregnant

Unless advised by a doctor
û do not take this medicine for longer than a few days at a time if you are an adult
û do not give this medicine to children and adolescents for longer than 48 hours at a time

While using this product
§ Keep to the recommended dose
§ 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

! Contains xx.

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

Other information
Store below xx °C away from light. Do not use if tamper evidence seal is broken or missing.
Distributed by:

xxxxxx

Hydrocortisone and clotrimazole cream (the CHI table is continued on the other panels of the carton and the CHI table is without the optional Other Information section):

Medicine Information
Active ingredients: Clotrimazole 1% w/w, Hydrocortisone 1% w/w
What this medicine is used for For the treatment of fungal skin infections when inflammation is prominent. This includes conditions such as § fungal infected dermatitis § intertrigo § Candida nappy rash Continued ....▼

Medicine Information (continued)
Warnings **Do not use** in the eyes or for acne. If irritation occurs discontinue use.
Unless a doctor has told you to, do not use § for more than 7 days § for children under 2 years old § under occlusive dressings
For external use only.
Contains hydroxybenzoates as preservatives. Continued…▼

Medicine Information (continued)
How to use this medicine - Clean and dry the affected area thoroughly. Rub gently into the affected area and surrounding skin 2-3 times daily. Once inflammation has subsided apply a cream containing only the single anti-fungal agent for 14 days after symptoms disappear.

Paracetamol, phenylephrine and diphenhydramine combination (showing the optional 'purpose of the active ingredients'):

Medicine Information

Active Ingredient (in each tablet)	**Purpose**
Paracetamol xxx mg.....	....Analgesic
Phenylephrine hydrochloride x mg.....	Decongestant
Diphenhydramine hydrochloride x mg ……	Antihistamine

What this medicine is used for

For the temporary relief of xxxx etc.

Warnings

Do not use

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

§ in children under xx years of age.

See your doctor or pharmacist before using this medicine if

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

§ you are pregnant or likely to become pregnant.

§ using in children (*under x or aged x to xx*) years of age.

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 and adolescents for longer than 48 hours at a time.

While using this medicine

§ Keep to the recommended dose

§ Phenylephrine may cause sleeplessness.

§ Diphenhydramine may cause drowsiness. If affected do not drive a vehicle or operate machinery.

§ Diphenhydramine may increase the effects of alcohol, therefore alcohol should be avoided.

§ 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.

! Contains xxx

How to take this medicine

Adults and children xx years of age and over: Take x tablets every xx hours as necessary with water. Do not take more than xx tablets in 24 hours.

Other information

Store below xx °C. Do not use if the tamper evidence seal is broken or missing.

Distributed by:

xxxxx

Ibuprofen for oral use:

Medicine Information

Active Ingredient (in each tablet or xx mL)
Ibuprofen xx mg

What this medicine is used for
For the temporary relief of pain and inflammation associated with xxxxx.
Also reduces fever.

Warnings

Do not use if
§ you have a stomach ulcer, impaired kidney function or heart failure § you are allergic to ibuprofen or other anti-inflammatory medicines § you are trying to become pregnant or during the first 6 months of pregnancy except on the doctor's advice. Do not use at all during the last 3 months of pregnancy.

Unless advised by a doctor do not use
§ if you have asthma.
§ (*as relevant to scheduling status*) if you are aged 65 years or over.
§ (*as relevant to scheduling status*) in children 6 years of age or less.
§ for more than a few days at a time.

Unless advised by a doctor or a pharmacist, do not
§ use with other products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines you are taking regularly.
§ give to children suffering from dehydration through diarrhoea and/or vomiting (*as relevant to the patient population*).

While using this medicine
§ do not exceed the recommended dose. Excessive or prolonged use can be harmful and increase the risk of heart attack, stroke or liver damage.
§ if you get an allergic reaction, stop taking and see your doctor immediately.

! Contains xxx, xxx. Products containing xxx can cause xxx.

Directions for use
Adults and children 12 years of age and over: Take xx tablets every 4-6 hours as necessary with water. Do not take more than xx tablets in 24 hours.
Children 7-11 years: take x tablet every 6 to 8 hours as needed. Do not take more than xx tablets/ in 24 hours.
For liquid preparations intended for children it is recommended that the dosing information is presented in a table consistent with the ARGOM.

Other information
Store below xx °C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Ibuprofen and paracetamol combinations:

Medicine Information

Active Ingredient (in each tablet)

Ibuprofen xxx mg
Paracetamol xxx mg

Uses

For the temporary relief of pain and inflammation associated with xxxxx.
Also reduces fever.

Warnings

Do not use

§ if you have a stomach ulcer, impaired kidney function or heart failure § if you are allergic to ibuprofen or other anti-inflammatory medicines § if you are pregnant or trying to become pregnant § in children under 12 years of age.

Unless advised by a doctor do not use

§ if you have asthma
§ if you are aged 65 years or over
§ for longer than a few days at a time if you are an adult
§ in children and adolescents for longer than 48 hours at a time.

Unless advised by a doctor or a pharmacist

§ do not use with other products containing paracetamol, ibuprofen, aspirin or other anti-inflammatory medicines or with medicines you are taking regularly.

While using this product

§ do not exceed the recommended dose. Excessive or prolonged use can be harmful and increase the risk of heart attack, stroke or liver damage.
§ if you get an allergic reaction, stop taking and see your doctor immediately.
§ 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.

! Contains xxx, xxx. Products containing xxx can cause xxx.

Directions for use

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

Other information

Store below xx °C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Aspirin for pain relief:

Medicine Information

Active Ingredient (in each tablet)
Aspirin xxx mg

Uses
For the temporary relief of pain and inflammation associated with xxxxx.
Also reduces fever.

Warnings

Do not use if
§ you have a stomach ulcer § you are allergic to aspirin or other anti-inflammatory medicines.

Unless advised by a doctor, do not use
§ if you have asthma.
§ in children under 12 years of age.
§ in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.
§ for more than a few days at a time.
§ for thinning the blood or for your heart.
§ during the first 6 months of pregnancy. Do not use at all during the last 3 months of pregnancy

Unless advised by a doctor or a pharmacist
§ do not use with other products containing aspirin or anti-inflammatory medicines or with medicines you are taking regularly.

While using this product
§ if you get an allergic reaction, stop taking and see your doctor immediately.

Contains xxx.

Directions for use
Adults and children 12 years of age and over: Take xx tablets every xx hours as necessary with water. Do not take more than xx tablets in 24 hours.

Other information
Store below xx°C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Aspirin for prevention of cardiovascular disease or inhibition of platelet aggregation:

Medicine Information
Active Ingredient (in each tablet) Aspirin xxx mg
Uses To reduce the risk of heart attack and stroke in patients with known cardiovascular or cerebrovascular disease, by helping to prevent blood clotting.
Warnings **For use under medical supervision only –** see your doctor before taking for thinning the blood or for your heart.
Do not use if § you have a stomach ulcer § you are allergic to aspirin or other anti-inflammatory medicines.
Unless advised by a doctor do not use § if you have asthma. § in children under 12 years of age. § in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever. § during the first 6 months of pregnancy. Do not use at all during the last 3 months of pregnancy.
Unless advised by a doctor or a pharmacist § do not use with other products containing aspirin or anti-inflammatory medicines or with medicines you are taking regularly.
While using this product § if you get an allergic reaction, stop taking and see your doctor immediately.
! Contains xxx, xxx.
Directions for use Adults: Take 1 tablet daily. Swallow whole tablet (*as relevant*). Do not crush or chew (*as relevant*).
Other information Store below xx°C. Do not use if the tamper evidence seal is broken. Distributed by: xxxx

Diclofenac (oral):

Medicine Information

Active Ingredient (in each tablet)
Diclofenac xxx mg

Uses
For the temporary relief of pain and inflammation associated with xxxxx.

Warnings

Do not use if
§ you have a stomach ulcer § you have impaired kidney function § you have heart failure § you are allergic to diclofenac or other anti-inflammatory medicines.

Unless advised by a doctor do not use
§ if you have asthma.
§ in children under 12 years of age.
§ for more than a few days at a time.
§ if trying to become pregnant or during the first 6 months of pregnancy. Do not use at all during the last 3 months of pregnancy.

Unless advised by a doctor or a pharmacist
§ do not use with other products containing diclofenac, aspirin or anti-inflammatory medicines or with medicines you are taking regularly.
§ (*if also indicated for children under 12 years of age*) do not use in children suffering from dehydration through diarrhoea and/or vomiting.

While using this product
§ if you get an allergic reaction, stop taking and see your doctor immediately § do not exceed the recommended dose. Excessive or prolonged use can be harmful and increase the risk of heart attack, stroke or liver damage.

Contains xxx.

Directions for use
Adults and children 12 years of age and over: Take xx tablets every xx hours as necessary with water. Do not take more than xx tablets in 24 hours
Children 7-11 years: take x tablet every xx hours as needed. Do not take more than x tablets in 24 hours.

Other information
Store below xx°C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Diclofenac (dermal):

Medicine Information

Active Ingredient (in each mL or g)
Diclofenac xxx mg (or % w/w etc)

Uses
For the temporary relief of pain and inflammation associated with xxxxx.

Warnings
Do not use if
û you are allergic to diclofenac or other anti-inflammatory medicines.
Unless advised by a doctor or a pharmacist
û do not use with other medicines you are taking regularly.

While using this product
§ if you get an allergic reaction, stop using and see your doctor immediately.

Contains xxx as preservative.
For external use only.

Directions for use
Adults and children 12 years of age and over: Apply xx to the affected area and rub in gently. Repeat every xx hours as necessary.

Other information
Store below xx°C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Doxylamine combined with paracetamol and phenylephrine hydrochloride:

Medicine Information

Active Ingredient (in each tablet)
Purpose
Paracetamol xxx mg ..... Analgesic
Phenylephrine hydrochloride xmg ..... Decongestant
Doxylamine succinate x mg .....Antihistamine

Uses
For the temporary relief of xxxx etc.

Warnings
Do not
§ use if you are taking other products containing paracetamol unless advised to do so by a doctor or pharmacist.
§ (as relevant) give to children under xx years of age.

See your doctor or pharmacist before use if
§ you have high blood pressure or heart problems or are taking antidepressant medication.
§ you are pregnant or likely to become pregnant.
§ using in children (under x or aged x to xx) years of age.

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 and adolescents for longer than 48 hours at a time.

While using this product
§ Keep to the recommended dose.
§ Phenylephrine may cause sleeplessness.
§ Doxylamine may cause drowsiness. If affected do not drive a vehicle or operate machinery.
§ Doxylamine may increase the effects of alcohol, therefore alcohol should be avoided.
§ 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.

! Contains lactose.

Directions for use
Adults and children xx years of age and over: Take x tablets every x hours as necessary with water. Do not take more than x tablets in 24 hours.

Other information
Store below xx °C away from light.
Distributed by:
xxxx

Antihistamines (such as diphenhydramine hydrochloride, promethazine hydrochloride and doxylamine succinate) as a sleep aid:

Medicine Information

Active Ingredient (in each tablet or xx mL)
AAN of antihistamine xxx mg

Uses
For temporary relief of sleeplessness.

Warnings
This product should be taken only on the advice of the doctor or pharmacist.

Do not
§ use if you are pregnant or breastfeeding.
§ take for more than a few days.

While using this product
§ This medicine is intended to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery.
§ Avoid alcohol.

Contains xxx

Directions for use
Adults and children xx years of age and over: Take xx tablets/xx mLs 20 minutes before going to bed, when necessary. Do not give to children under xx years of age.

Other information
Store below xx°C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Loperamide hydrochloride:

Medicine Information

Active Ingredient (in each tablet)
Loperamide hydrochloride xx mg

Uses
For the temporary relief of xxx.

Warnings

Do not
§ take if you have a medical condition where constipation should be avoided.
§ give to children under 12 years of age.

See your doctor or pharmacist before use
§ if you are pregnant or breastfeeding.
§ if you have a fever, severe stomach pain, bloody diarrhoea or ongoing condition affecting the bowel.

While using this product
§ if the condition persists after two days of treatment, seek medical advice as soon as possible.
§ drink plenty of fluids as fluid and electrolyte depletion may occur with diarrhoea. If dehydration is suspected seek medical attention.

! Contains xxx, xxx.

Directions for use
Adults and children 12 years of age and over: Take xx tablet(s) initially, then x tablet after each loose bowel motion as needed. Do not exceed xx tablets in a 24 hour period.

Other information
Store below xx °C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Naproxen/Naproxen sodium:

Medicine Information

Active Ingredient (in each tablet)
Naproxen xxx mg *OR* Naproxen sodium xxx mg

Uses
For the temporary relief of xxx

Warnings

Do not use if
§ you have a stomach ulcer, impaired kidney function or heart failure § you are allergic to naproxen or other anti-inflammatory medicines § you are trying to become pregnant or during the first 6 months of pregnancy except on the doctor's advice. Do no use at all during the last 3 months of pregnancy.

Unless advised by a doctor or a pharmacist
§ do not use with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines you are taking regularly.
§ (*if also indicated for children under 12 years of age*) do not give to children suffering from dehydration through diarrhoea and/or vomiting.

Unless advised by a doctor do not use
§ if you have asthma.
§ for more than a few days at a time.

While using this product
§ do not exceed the recommended dose. Excessive or prolonged use can be harmful and increase the risk of heart attack, stroke or liver damage.
§ if you get an allergic reaction, stop taking and see your doctor immediately.

! Contains xxx, xxx.

Directions for use
Adults and children xx years of age and over: Take xx tablets/mLs every x hours as necessary.

Other information
Store below xx °C.
Do not use if the tamper evidence seal is broken.
Distributed by:
xxxx

Phenylephrine/pseudoephedrine for oral use:

Medicine Information
Active Ingredient (in each tablet) AAN of active ingredient xx mg
Uses For the temporary relief of xxxx.
Warnings **Do not** û give to children under x years of age (as relevant) *OR* û give to children aged 11 year or between x and 11 years of age except on the advice of a doctor, pharmacist or a nurse practitioner.
See your doctor or pharmacist before use if û you have high blood pressure or heart problems or are taking antidepressant medication.
While using this product § This product may cause sleeplessness (*for pseudoephedrine add* – if taken up to several hours before going to bed).
! Contains xx.
Directions for use Adults and children 12 years of age and over: Take x tablets every x hours as necessary with water. Do not take more than x tablets in 24 hours.
Other information Store below xx °C. Distributed by: xxxx

Topical nasal decongestant preparations such as those containing the following active ingredients:

- Naphazoline
- Oxymetazoline
- Phenylephrine
- Xylometazoline.

Medicine Information
Active Ingredient (in each drop/spray/dose or as %, as relevant) AAN of the active ingredient xx mg
Uses For the temporary relief of xxx.
Warnings **Unless advised by a doctor or a pharmacist** do not use for more than 3 days at a time.
If congestion persists see your doctor or pharmacist.
Frequent or prolonged use may cause nasal congestion to recur or worsen.
Do not give to children under xx (or between xx and xx years of age) except on the advice of a doctor, pharmacist or a nurse practitioner.
Do not swallow *OR* For nasal use only.
! Contains xxx, xxx.
Directions for use Adults and children xx years of age and over: Spray xx times or instil xx drops into each nostril every x hours as necessary. Do not exceed xx doses in 24 hours.
Other information Store below xx °C away from light. Do not use if the tamper evidence seal is broken. Distributed by: xxxx

Vasoconstrictor eye drops including

- Naphazoline
- Oxymetazoline
- Phenylephrine
- Tetrahydrozoline
- Tramazoline
- Tymazoline
- Xylometazoline.

Medicine Information
Active Ingredient (in each drop/dose or as % as relevant) AAN of the active xx mg
Uses For the temporary relief of xxx.
Warnings **Do not use** if you have glaucoma or other serious eye conditions. **Consult a doctor or pharmacist** § if you are using other eye products. § if symptoms persist. Prolonged use may be harmful. Do not swallow OR For external use only. Discard 4 weeks after opening OR Once opened, this medicine should not be used after 4 weeks. **! Contains** xxx, xxx.
Directions for use Adults and children xx years of age and over: Instil xx drops every x hours as necessary.
Other information Store below xx °C away from light. Do not use if the tamper evidence seal is broken. Distributed by: xxxx

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration (Scientific Evaluation Branch)	31 August 2016
V1.1	Corrections based on feedback and clarification of existing information. Addition of latex labelling in best practice – part 3. Addition of guidance on determining when a Schedule 1 substance is present – part 1.	Therapeutic Goods Administration (Scientific Evaluation Branch)	May 2018
V2.0	Addition of information about warning statements for neuromuscular blocking agents in parts 1, 2 and 3. Minor corrections based on stakeholder feedback.	Therapeutic Goods Administration (Scientific Evaluation Branch)	June 2018
V2.1	Additional information to provide clarity on: • Transition period • Declaration of benzoates • Reference to the CMI for Schedule 1 declarable substances • Multiple barcode guidance Minor corrections based on stakeholder feedback.	Therapeutic Goods Administration (Scientific Evaluation Branch)	July 2019
V2.2	Minor update to information due to end of the transition period	Therapeutic Goods Administration (Scientific Evaluation Branch)	September 2020
V2.3	Update to include examples related: • Medicine name on the main label	Therapeutic Goods Administration (Scientific Evaluation Branch)	March 2021
V2.4	Addition of information about: • Expressing the quantity or proportion of active ingredients for injections, including complying with requirements for injectable medicines intended for electrolyte replacement (with a volume of 100 mL or less) that were amended in 2024.	Therapeutic Goods Administration (Scientific Evaluation Branch)	December 2024

Version	Description of change	Author	Effective date
	• Injections requiring preparation before use, including providing instructions for preparation for injectable medicines administered by healthcare professionals. • QR codes, including using QR codes for medicines administered by healthcare professionals. Minor corrections based on stakeholder feedback about: • Potassium for injection or infusion		
V2.5	Addition of requirements for a warning on valproate-containing products	Therapeutic Goods Administration (Scientific Evaluation Branch)	

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