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Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medicine labels

Proposed changes to rules for the new standards replacing TGO 91 and TGO 92

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Introduction

Overview

Medicine labels communicate information to health professionals and consumers that is critical to support the safe and quality use of medicines. If it is difficult to identify medicines, or to locate and understand important information, then medication errors are more likely.

Different types of medicines need different information on their labels. Medicines vary in risk, how they are supplied and the regulatory framework that applies. As a result, there are 2 sets of requirements for medicine labelling; one for prescription and equivalent medicines, and one for non-prescription medicines (registered over-the-counter, listed, assessed listed and registered complementary and complementary medicines).

Medicines entered in the Australian Register of Therapeutic Goods (ARTG) for supply in Australia must comply with the requirements for labels set out in:

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

TGO 91 and TGO 92 set out the type of information required to be included on the label, the conditions under which these requirements apply, as well as general standards, to support the safe and quality use of medicines.[1]

We intend to introduce new standards for medicine labels, including updated requirements, before 1 October 2026. This is because TGO 91 and TGO 92 will sunset on this date, and we consider medicine label rules remain necessary to support the safe and quality use of medicines. Most legislative instruments are automatically repealed 10 years after commencement under the *Legislation Act 2003*. This automatic repeal is called 'sunsetting' and helps to ensure legislative instruments stay up to date.

Why your views matter

The rules set out in TGO 91 and TGO 92 help to make important information easier to find on medicine labels. However certain aspects of these labelling rules need further improvements to help medicines be used correctly and safely, or to provide more clarity to medicine sponsors.

We are seeking feedback to help ensure the proposed new rules support the safe and quality use of medicines. We also want to know if the proposed rules are clear for medicine sponsors.

Some key aims of the proposals include:

- Update the substances and warnings that must be declared on medicine labels.
- Improve information available on non-prescription medicine labels to help consumers make informed choices.
- Clarify rules for medicine sponsors.
- Modernise the standards. For example, by introducing requirements for the use of QR codes as these technologies are now widely used by consumers.

[1] Read more about the quality use of medicines in Background – Medicine labels in this paper, and in Australia's National Medicines Policy and National Strategy for Quality Use of Medicines.

- Reduce the number of applications for exemptions from TGO 91 and 92 requirements under Section 14 of the *Therapeutic Goods Act 1989* by aligning requirements with accepted medicine labelling practices.

Scope and priorities

This consultation is about the requirements for medicine labels to be included in the new standards that will replace TGO 91 and TGO 92.

Other medicine labelling rules required under separate legislation are outside the scope of this consultation. For more information see Background – Rules for medicine labels in this paper.

Standards for medicine labels facilitate the safe and appropriate use of medicines by consumers and health professionals by ensuring appropriate labelling. We also acknowledge, based on nearly a decade of real-world experience with TGOs 91 and 92, that there are opportunities to improve labelling requirements to further support the quality use of medicines and provide more clarity for medicine sponsors.

Overall, we consider that TGO 91 and TGO 92 are working well. Therefore, this consultation is focused on certain aspects that may need improvements. You can read more in Proposed changes to labelling rules.

Labelling requirements need to be carefully considered to avoid introducing inconsistencies or unintended risks to medicine safety.

A range of improvements have been suggested by various stakeholders since the introduction of TGO 91 and TGO 92. We have considered these suggestions taking into account available resources, time constraints, complexity, interconnected issues and challenges in catering for all individual medicines.[2].

We have prioritised and limited the proposed changes to labelling rules based on feedback we received in the 2023 targeted consultation. Prioritising areas for improvement is important to allow sufficient time to review interrelated rules and develop well considered solutions in collaboration with stakeholders, helping to ensure medicines are used correctly and safely. We consider that it is important to make improvements to limited high priority areas, rather than delaying the introduction of the new standards to address all minor issues. Additionally, some reforms would involve changes to systems or legislation beyond the reach of the labelling requirements and are therefore beyond the scope of this project. Importantly, reforms not pursued at this time are not being ruled out and may be considered after the new standards are made. Overall, we are proposing several changes, but many are minor.

Where appropriate, and where legislative changes are not needed, we plan to publish guidance on the new labelling standards to give medicine sponsors more clarity on some aspects of labelling.

Have your say

We want to know if you think the proposals support the safe and quality use of medicines and are clear.

Your feedback will help to inform how certain information will be displayed on medicine labels in the future.

We invite you to give your feedback by completing our online survey on the TGA Consultation Hub, which includes the questions outlined in this consultation paper. The question numbers in the online survey match the questions numbers in this paper. You are welcome to give us feedback on all parts

[2] Sponsors of medicines can seek a Section 14 consent where a specific labelling requirement may not be appropriate for a given medicine.

of this consultation, or only on the parts that are important to you. We will publish responses on the TGA Consultation Hub, unless you request that your response be kept confidential.

Depending on the feedback received on this consultation, we may also seek further feedback from respondents on proposals. If you are happy to be contacted, please let us know in the online survey.

If you have any questions about this consultation, please contact TGA.Scientific@health.gov.au.

Background

Medicine labels

Before you use any medicine, you should read the medicine label carefully and follow all instructions. If you are unsure or have other health conditions or take other medications, then you should also consult a health professional. For more information about some important things you should look for on the medicine label, read What's on my medicine label?

The design and content of medicine labels can have a significant impact on the safe and quality use of those medicines. Labels must clearly identify a particular medicine and provide sufficient information to allow people to make safe and informed decisions about its use. Clear and consistent placement of important information helps a medicine be selected properly and used safely. If it is difficult for a health professional, consumer or carer to identify and select a medicine, or to locate and understand critical information, then unintentional medication errors or misuse of medicines can occur.

Labelling that supports the safe and quality use of medicines is part of the intended outcomes of Australia's National Medicines Policy. Quality use of medicines is sometimes explained as the correct use of medicines.[3] Along with medicine safety, it is a National Health Priority. Quality use of medicines includes choosing treatment options, choosing suitable medicines, and using medicines safely and effectively. More information is available in the National Medicines Policy and National Strategy for Quality Use of Medicines.

Rules for medicine labels

Current labelling requirements for medicines supplied in Australia are set out in:

- 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)

and were implemented under section 10 of the *Therapeutic Goods Act 1989*.

TGO 91 and TGO 92 were implemented in 2016 to replace Therapeutic Goods Order No. 69 - General requirements for labels for medicines (TGO 69). Medicine sponsors were given 4 years to comply with the new rules. Medicines released for supply from 1 September 2020 had to comply with the rules set out in TGO 91 and TGO 92.

Guidance is available on the TGA website to help medicine sponsors and manufacturers meet the requirements of TGO 91 and TGO 92. See Labelling medicines to comply with TGO 91 and TGO 92. This guidance also includes a section on 'Recommendations and best practice'. Compliance with this section is not mandatory but is included to help improve the safe and quality use of medicines.

Certain medicine types may require more information than others and TGO 91 and TGO 92 have specific rules for the information needed in different circumstances. For example, in certain

[3] Department of Health and Aged Care, 'National Medicines Policy 2022 (plain language)', DHAC, Australian Government, 2022, accessed 23 June 2025.

circumstances less information is required on a container when it is supplied in an outer primary pack[4].

Other rules that apply to the labelling and packaging of medicines that are outside the scope of this consultation include:

- Therapeutic Goods (Medicines Advisory Statements) Specification 2021 which sets out Required Advisory Statements for Medicine Labels (RASML) for specified non-prescription medicines, including over the counter and registered complementary medicines.
- Label advisory statement requirements within the Permissible ingredients determination.
- Labelling requirements in relation to Permitted indications for listed medicines.
- The Poisons Standard, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which sets the level of control on the availability of poisons, including rules on certain advertising, labelling and packaging requirements.
- Therapeutic Goods (Medicines - Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021 which includes rules about the display of information in data matrix codes on the medicine label.
- The rules for displaying the AUST R, AUST L or AUST L(A) number on a medicine label outlined in the Therapeutic Goods Regulations 1990.
- The rules about unacceptable presentation in section 3(5) of the *Therapeutic Goods Act 1989*.

Updating rules for medicine labels

TGO 91 and TGO 92 are due to sunset on 1 October 2026, which gives an opportunity to review and update requirements to help ensure the instruments are still fit for purpose.

Clear medicine labels are an important factor in the safe and quality use of medicines. Developing and updating medicine label rules to ensure clarity across different types of medicines is complex.

Labelling rules need to be well considered to avoid introducing inconsistencies, or unintended risks to medicine safety.

Changes to medicine labels take time. When we update labelling rules, we introduce transition periods to allow medicine sponsors time to update labels while ensuring the medicine's availability in the community. New labels usually appear gradually as new stock is distributed, and existing stock is sold.

The new standards to replace TGO 91 and TGO 92 can also be updated in the future if needed to support the correct and safe use of medicines. For example, after TGO 91 and TGO 92 were introduced, and in collaboration and consultation with stakeholders including health professionals and medicine sponsors, we:

- introduced warning statements for neuromuscular blocking agents in 2018
- updated requirements and guidance for labels of injectable medicines in 2024.

2023 targeted consultation on priorities for labelling improvements

We carried out a targeted consultation from August to September 2023 on priorities for future improvements to medicine labels to support the safe and quality use of medicines. Thank you to

[4] The *Therapeutic Goods Act 1989* defines primary pack as: 'the complete pack in which the goods, or the goods and their container, are to be supplied to consumers'. See Understanding packaging definitions for medicines.

everyone who provided feedback in the targeted consultation. The feedback we received helped us develop the proposals included in this consultation paper.

Priorities frequently raised to support the safe and quality use of medicines or to improve clarity to medicine sponsors included review of the:

- declaration of substances on medicine labels
- active ingredient expression
- dosage form expression
- presentation of the name of the medicine (sometimes called product name, trade name or brand name).

We considered all feedback before developing proposals for updates to labelling rules.

We are not proposing to address some of the issues raised at this time, including where:

- the benefits to be gained in one amendment do not offset additional risks in other areas
- some matters raised may need new legislation or changes to legislation outside of TGO 91 and TGO 92.

In addition, stakeholders raised concerns regarding selection errors for some medicines with similar labels or packaging. Suggestions relating to this concern included limiting or reserving certain colours to certain types of medications. While this has value, we are not pursuing legislative changes at this time for the following reasons:

- Restricting certain colours on labels or packaging for specific medicines can itself increase the risk of supply disruption.
- Reliance on a certain colour for identification risks selection errors if used as a shortcut to identify a medicine.[5] While colour-coding medicines may be helpful in some situations, the selection should always be made on medicine name.
- Assigning exclusive colours to specific medicines would inevitably make those medicines look similar, increasing the risk of selection errors among those medicines.
- Reading the medicine label carefully is important to identify and select the correct medicine. Guidance for health professionals on the safe selection and storage of medicines is available including the Australian Commission on Safety and Quality in Health Care's Principles for the safe selection and storage of medicines.[6]

Labelling medicines to comply with TGO 91 and TGO 92 includes some general design principles and recommendations in respect to colour. Additional proposals regarding medicine differentiation are discussed in the Differentiating medicines section of this paper.

Proposed changes to rules for the new standards

This consultation paper outlines the main changes we are proposing to labelling requirements in the new instruments replacing TGO 91 and TGO 92. It also explains why we are proposing to make these changes.

For a consolidated summary list of proposed changes to requirements, see Appendix 1 in this paper.

[5] World Health Organization. 'Medication safety for look-alike, sound-alike medicines', WHO, 2023, accessed 22 July 2025.
[6] Australian Commission on Safety and Quality in Health Care, 'Principles for the safe selection and storage of medicines: Guidance on the principles and survey tool', ACSQHC, 2020, accessed 22 July 2025.

We may also make other minor changes to requirements to give more clarity to medicine sponsors as the instruments are being drafted.

The proposed changes focus on improvements to support the safe and quality use of medicines as we develop the new standards. We are also proposing to make minor changes to address inconsistencies or errors and provide clarity to medicine sponsors where there is a simple clear solution. See also: Scope and priorities.

In the development of these proposals, we have considered feedback from stakeholders including from the targeted consultation. As you consider the proposals, please also consider the current context and operating environment of the instruments including:

- changes to related policy or legislation since TGO 91/ 92 were made in 2016, including updates to the National Medicine Policy and active ingredient prescribing
- other changes such as technological advancements (for example, increased consumer use of QR codes).

Proposed transition periods

In general, we are proposing a transition period of up to 3 years for the changed requirements, giving medicine sponsors time to update their labels. This would mean that medicines manufactured or imported 3 years after the new Orders are registered must comply with the new requirements. New labels may not appear for some time after this as new stock is distributed and existing stock is sold. We note that medicine labels are typically changed every three years as part of business-as-usual activities, allowing many changes to be made without exceptional costs.

The proposal for non-prescription medicines with large solid oral dosage forms includes a shorter transition period of 2 years. This is because a safety warning is needed sooner. We have also previously consulted on this issue. As a result, medicine sponsors are likely to be familiar with aspects of the proposal and expecting new requirements. We invite your feedback on the proposed transition periods later in this paper.

Planned guidance updates

Where appropriate, and where legislative changes are not needed, we plan to use guidance to give medicine sponsors more clarity on certain aspects of labelling. Some plans for the new guidance are included in this paper, and a consolidated summary list of planned guidance updates is provided in Appendix 2. The new guidance will also reflect changes to requirements implemented in the new instruments.

We intend to publish new guidance soon after we introduce the new standards. In addition, we plan to change some of the structure of the current guidance, see guidance structure.

Topics covered in the proposed changes

The proposed changes to medicine labelling rules and some of the planned changes to guidance are outlined under the following topics:

- 1. Declaring allergens and other substances
- 2. Active ingredients
- 3. Name of the medicine
- 4. Dosage form
- 5. Warning statements and advisory information

- 6. QR codes, machine-readable codes and instructions for preparation
- 7. Other information displayed on labels, such as space for a dispensing label, batch numbers and expiry dates and sponsor contact details
- 8. Specific medicine types, including requirements for certain types of active ingredients, packaging and route of administration
- 9. Label presentation and design
- 10. General requirements including application, exemptions, definitions and transition periods
- 11. Guidance structure.

Please note that some proposals included under a certain topic may also be relevant to other topics. This is because labelling rules are interconnected and requirements vary depending on the type of medicine, the size and type of packaging, and how the medicine is used.

1. Declaring allergens and other substances

Certain substances or ingredients in medicines must be declared on the label for safety purposes. For example, potential allergens such as egg must be declared if they are likely to be in the medicine as 'Contains egg'. For more information, see our Allergies and medicines page.

The substances that must be declared on medicine labels, and the circumstances in which they need to be declared, are mostly found in Schedule 1 of TGO 91 and TGO 92. Some substances only need to be declared when they are present above a specified amount, as very small quantities may pose an acceptable level of risk.

Declarations required on prescription medicine labels may be made in the Consumer Medicine Information (CMI) leaflet instead of on the label. In this case, there will be a statement on the label referring to the CMI.

It is important that certain substances are declared, as medicine labels do not always list all the ingredients in the medicine. There are other ways to find information on ingredients in a medicine. For example, since TGO 91 and TGO 92 were introduced, information about some ingredients in medicines is now available by downloading the ARTG Public summary for each medicine. However, some potential allergens, such as ingredients in a flavour, fragrance or colour mixture, may not be included in some of this information. Also, consumers may not be aware that certain ingredient names refer to the substance they are seeking information about. For example, consumers may not be aware that the ingredient names *Triticum aestivum* and *Triticum durum* are species of wheat.

Therefore, we encourage consumers to ask their doctor or pharmacist if they have any questions about ingredients in their medicines. If ingredient information is important, consumers and health professionals may need to get in touch with the medicine company. Their contact details are on the medicine label. You can also contact the TGA to ask if a particular substance is in a medicine. For more information see Allergies and medicines and What ingredients are in my medicine?

There are different rules for declaring certain substances on food labels. Since TGO 91 and 92 were introduced, Food Standards Australia New Zealand (FSANZ) have introduced new rules for declaring allergens on food. The latest changes came into force on 25 February 2024. Food packaged and labelled before 25 February 2024 which complies with the previous requirements can continue to be sold until 25 February 2026, and as such might have different allergen labelling to foods packaged and labelled after this date. Read more about food allergen labelling for consumers and allergen labelling for food businesses.

Separate to those described in Schedule 1, other substances, such as the antimicrobial preservative present in ophthalmic medicines, must be declared on labels. In addition, Required Advisory Statements for Medicine Labels (RASML) may require some substances to be declared for specified non-prescription medicines.

TGO 91 and TGO 92 has specific rules for the information needed on different types of medicine packaging. Less information is required on some packaging where space is not available, provided it is supplied in a primary pack that includes the full declaration. For example, substances do not need to be declared on the blister pack of tablets or on a small vial supplied in an outer carton. The primary pack of these medicines (the packaging that you see sitting on the shelf that is supplied to the user) will have the substance declaration.

As outlined in the scope and priorities, this consultation focuses on specific aspects of TGO 91 and TGO 92 that may need improvement. It highlights opportunities to improve specific parts of TGO 91 and TGO 92. While several changes to Schedule 1 are proposed, it does not include a full review of Schedule 1. The new standards that replace TGO 91 and TGO 92 can be updated in the future as needed to support the safe and quality use of medicines.

For declaration of substances, we propose a transition period of 3 years from the start of the new standards to support the safe use of medicines, as these generally include safety of medicines. This means that medicines manufactured or imported from 1 October 2029 must follow the proposed new rules. However new labels might take some time to appear as new stock is distributed, and existing stock is sold.

1.1 Substances to be declared

The substances that must be declared on medicine labels are mostly listed in Schedule 1 of TGO 91 and TGO 92. At present there are some differences between the substances that must be declared on medicines and food.

We are proposing some additions and changes to the substances that must be declared on medicine labels, to better align the rules for food and medicine labels and make declaration statements clearer for consumers.

Wheat

Wheat and its hybrids (such as triticale) are required to be declared on food labels under the new food rules because they can cause allergic reactions.[7]

Currently, medicine labels do not need to declare wheat.

Wheat allergy is different to coeliac disease and gluten intolerance.[8] For consumers allergic to wheat, the presence of the proteins in wheat is more relevant information than the presence of gluten.[9] (Gluten must be declared on medicine labels and will continue to be required).

Proposed changes – wheat

To align medicine labelling with food labelling rules and give important information to people with wheat allergy, we propose the following change:

- Require wheat (and its hybridised strains) to be declared on medicine labels as ‘contains wheat’ or ‘contains wheat products’ when present in the medicine for all routes of administration.

We do not propose to set a threshold or concentration level for declaring wheat. Wheat, if present, would need to be declared regardless of the amount present in the medicine.

[7] FSANZ (Food Standards Australia New Zealand), *Allergen labelling for food businesses*, FSANZ website, 2022, accessed 23 June 2025; Australia New Zealand Food Standards Code – Schedule 9 – Mandatory advisory statements and declarations.
[8] Allergy & Anaphylaxis Australia, *Wheat*, A&AA website, 2024, accessed 23 June 2025.
[9] FSANZ (Food Standards Australia New Zealand), ‘Approval report – Proposal P1044’, FSANZ , 2020, accessed 23 June 2025.

Question – wheat

1. Do you agree with proposed change to require wheat (and its hybridised strains) to be declared on medicine labels? *(Yes, partially agree, no, unsure)*. Please explain your answer. Please also tell us how this change may affect you.

Marine mollusc

Mollusc is required to be declared on the label of listed medicines if they contain certain ingredients, as specified by the Therapeutic Goods (Permissible Ingredients) Determination. Listed medicines containing ingredients that are marine mollusc or marine mollusc products such as mussel, oyster, sepia or squid oil need to include the statement 'contains mollusc' or 'contains mollusc products'.

Food labels must also declare marine mollusc as 'mollusc'.

Proposed changes – mollusc

To align labelling requirements across different types of medicines and with food labelling rules, we propose to:

- Require marine mollusc to be declared on the label as 'contains mollusc' or 'contains mollusc products' when present in the medicine for all routes of administration.

We do not propose to specify a concentration level for declaring mollusc. As with the current arrangement for listed medicines, labels would be required to declare mollusc when added at any level.

Question – mollusc

2. Do you agree with proposed change to require mollusc to be declared on medicine labels? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.

Tree nuts

Tree nuts are currently required to be declared on medicine labels. However, the rules for declaring tree nuts on medicine labels differs from the food labelling rules.

Medicines must declare tree nuts and tree nut products as 'contains tree nuts' or 'contains tree nuts products' when present. In addition, TGO 91 and TGO 92 lists some ingredients that are included as tree nuts or tree nut products in Schedule 1, such as almond oil, *Juglans nigra*, macadamia nut oil, *Macadamia ternifolia*, *Prunus dulcis*, walnut. Note 8 also states that tree nuts include almond, Brazil, cashew, chestnut, and walnut.

TGO 91 and TGO 92 do not include a complete list of tree nuts that must be declared. This may make it unclear for medicine sponsors to know which tree nuts are covered by the requirement.

Food labelling rules require a specific list of tree nuts to be declared individually as the specific nut[10]. These are:

- almond

[10] Australia New Zealand Food Standards Code – Schedule 9 – Mandatory advisory statements and declarations.

- Brazil nut
- cashew
- hazelnut
- macadamia
- pecan
- pine nut
- pistachio
- walnut.

These are the tree nuts that commonly trigger food allergic reactions in Australia.[11] FSANZ reported that consumer evidence indicates consumers prefer specific tree nuts to be declared rather than the generic term 'tree nuts'.[12] Foods are not required to declare chestnut.

Peanuts are different to tree nuts.[13] Peanuts are already required to be declared on medicine and food labels.

Proposed changes – tree nuts

To align more closely with food labelling rules, clarify requirements for medicine sponsors and give consumers more detailed information about the presence of tree nuts, we propose the following changes:

- Require the following to be declared individually as the specific tree nut when present in medicines:
  - almond
  - Brazil nut
  - cashew
  - hazelnut
  - macadamia
  - pecan
  - pine nut
  - pistachio
  - walnut.

For example, if almond is present in the medicine, this would need to be declared on the label as 'contains almond' or 'contains almond products', rather than 'contains tree nuts.'

As chestnut is currently required to be declared on medicine labels as 'contains tree nuts' or 'contains tree nut products', we also propose to:

- Require chestnut to be declared as 'contains chestnut' or 'contains chestnut products'.

Note: water chestnuts are different to chestnuts and would not need to be declared.

[11] Allergy & Anaphylaxis Australia, *Tree nut*, A&AA website, 2024, accessed 24 June 2025.
[12] FSANZ (Food Standards Australia New Zealand), 'Approval report – Proposal P1044', FSANZ , 2020, accessed 26 June 2025.
[13] Allergy & Anaphylaxis Australia, *Peanut*, A&AA website, 2024, accessed 26 June 2025.

Question – tree nuts

3. Do you agree with the proposed change to require tree nuts to be declared as the specific tree nut on medicine labels? *(Yes, partially agree, no, unsure)*. Please explain your answer and tell us how this change may affect you.

Lactose and milk products

Milk and milk products are required to be declared on the label when present in the medicine.

Lactose is required to be declared when present in medicines when intended for oral administration.

We require these substances to be declared on medicines for different reasons as milk allergy and lactose intolerance are different conditions.[14]

There is a risk that lactose can be contaminated with milk protein. However, the Australasian Society of Clinical Immunology and Allergy (ASCIA) state: '*The chance of a person with cow's milk protein allergy reacting to pure lactose sugar in medications that has been contaminated with cow's milk is very low.*'[15]

Medicine sponsors do not need to declare lactose in medicines that are inhaled into the lungs. However, if the lactose contains milk protein, this is important information for people with milk allergies. The Product Information (PI) and Consumer Medicine Information (CMI) may include details about lactose and milk protein residue. Declaring the presence of milk protein on the label makes it clearer for health professionals and consumers.[16]

Injections must list all excipient ingredients on the primary pack label. Therefore, lactose would be included on the primary pack label if present in the medicine. However, the label does not need to include a statement about milk protein.

We have also received feedback that the requirements for lactose need to be clearer, especially when declaring multiple substances.

'Note 4: Lactose' for Schedule 1 in TGO 91 and TGO 92 states if a medicine contains lactose obtained from milk, that it does not need the 'contains milk product' statement. 'Note 6: Sugars – monosaccharides and disaccharides' includes '*where lactose is present in the medicine, the entries under 'lactose', 'sugars –monosaccharides and disaccharides' and 'milk and milk products' (if of dairy origin) each apply*.'

Proposed changes – lactose and milk products

We propose changes to give medicine users more information about the presence of milk proteins and clarify requirements for medicine sponsors, especially for inhalers and injections.

We propose:

- For medicines that are inhaled into the lungs or administered by injection or infusion:
  - Require 'contains milk products' to be declared for medicines containing lactose from milk origin. This may involve changing both the content in Schedule 1 and in note 4.

[14] Allergy & Anaphylaxis Australia, *Milk/Dairy*, A&AA website, 2025, accessed 30 June 2025.
[15] Australasian Society of Clinical Immunology and Allergy, *ASCIA Dietary Guide - Cow's Milk Protein (Dairy) Allergy*, ASCIA website, 2023, accessed 30 June 2025.
[16] J Robles, L Motheral, Hypersensitivity Reaction After Inhalation of a Lactose-Containing Dry Powder Inhaler - PMC, The Journal of Pediatric Pharmacology and Therapeutics, 2014, 19(3):206–211, doi:10.5863/1551-6776-19.3.206, accessed 30 October 2025.

- Continue to require medicines with an oral route of administration containing lactose (and no other milk product) to only declare 'contains lactose' on the label.
- Amend Note 6, by changing 'dairy origin' to 'animal origin' to clarify that this includes milk from all animals.

If the proposed changes are implemented, we would also update the guidance to reflect the changes.

Question – lactose and milk products

4. Do you agree with the proposed change to require injectable medicines and medicines inhaled into the lungs to state 'contains milk products' if they contain lactose from milk origin? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.

1.2 When substances are declared

Some substances only need to de declared if there is a certain amount of the substance in the medicines.

Other entries in Schedule 1 do not specify circumstances or a cut off limit for when substances need to be declared. These substances need to be declared irrespective of the concentration or amount present in the medicine. Labelling medicines to comply with TGO 91 and TGO 92 gives medicine sponsors some guidance about determining when a substance is present. For example:

'*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.*

Schedule 1 lists the route of administration for when substances must be declared.

Updates to the guidance will improve clarity of the current requirements.

Sulfites

Sulfites are used in some foods, drinks and medicines as preservatives.[17] Some people have a sulfite sensitivity.[18]

Sulfites are required to be declared on labels when present in the medicine as 'contains sulfites'. 'Sulfites' are sometimes spelt as 'sulphites', for example, when declared on food labels.

Sulfites are required to be declared on labels in Australia when present in the medicine, regardless of concentration. In contrast, for foods in Australia, 'sulphites' only need to be declared for added 'sulphites' in concentrations of 10 mg/kg (10 ppm) or more.[19]

We have received feedback from medicine sponsors that there are challenges with declaring sulfites under the current rules with concerns they are required to declare sulfites when small amounts could be present that are below the levels that tests can detect, which may make the statement less meaningful.

[17] Allergy & Anaphylaxis Australia, *Sulphite sensitivity*, A&AA website, n.d., accessed 1 July 2025.
[18] Australasian Society of Clinical Immunology and Allergy, *Sulfite Sensitivity*, ASCIA website, 2024, accessed 1 July 2025.
[19] Australia New Zealand Food Standards Code – Schedule 9 – Mandatory advisory statements and declarations.

Internationally, for medicines, the United States Food and Drug Administration (FDA) requires sulphites to be declared when added as an inactive ingredient, regardless of the amount added.[20] The European Medicines Agency (EMA) requires 'sulphites' to be declared on medicine labels if added to a medicine as an excipient.[21]

Proposed changes – sulfites – circumstances when needs to be declared

In consideration of both international rules for medicines and rules for food labels in Australia, and to give clearer rules for medicine sponsors, we propose to:

- Continue to require sulfites to be declared where added as an inactive ingredient/excipient, regardless of concentration.
- Where sulfites have not been intentionally added but may be present as an impurity, they must be declared when present at 10 mg/kg (10 ppm) or more.

Question – sulfites

5. Do you agree with the proposed change to when sulfites must be declared on medicine labels? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.

Gluten

People with coeliac disease must follow a gluten-free diet.[22] Gluten is currently required to be declared on medicine labels when it is present in the medicine at a concentration of 20 parts per million (ppm) or more.

The current food rules require gluten to be declared if it is present in food containing wheat (and its hybrids such as triticale), barley, oats, or rye.[23]

In New Zealand, Medsafe lowered the threshold for declaring gluten on medicine from 20 ppm to 3 ppm,[24] to align more closely with the sensitivity of medicine manufacturing tests for detecting gluten in medicines.

Medsafe also requires the source of gluten to be declared on medicine labels.

Proposed changes – gluten – circumstances when needs to be declared and source

To align with New Zealand rules for medicines and more closely with rules for food, we propose to:

- Change the circumstance for gluten. Require gluten to be declared when present in a concentration of 3 parts per million (3 ppm) or more.
- Require the source of gluten to be declared. This means that gluten would be declared as 'contains gluten from [specify source]', rather than just 'contains gluten'.

[20] § 201.22 Prescription drugs containing sulfites; required warning statements.
[21] European Medicines Agency, Excipients in the labelling and package leaflet of medicinal products for human use', EMA, 2018, accessed 1 July 2025; European Medicines Agency, 'Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use', EMA, 2024, accessed 1 July 2025.
[22] Coeliac Australia, *Coeliac disease*, Coeliac Australia website, 2023, accessed 2 July 2025.
[23] Australia New Zealand Food Standards Code – Schedule 9 – Mandatory advisory statements and declarations.
[24] Medsafe, 'Proposed warning statements for substances (eg, allergens) in medicines that may cause undesirable reactions – Consultation', Medsafe, 2020, accessed 2 July 2025.

We plan to give sponsors guidance on label statements to meet the proposed requirements for both declaring wheat and declaring the source of gluten.

Questions – gluten

6. Do you agree with the proposed change to when gluten must be declared on medicine labels? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.
7. Do you agree with the proposed change to require the source of gluten to be declared? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you. Any suggestions for guidance on meeting both the wheat declaration and gluten source requirements are welcome.

Pollen, propolis and royal jelly

Column 3 of Schedule 1 of TGO 91 and TGO 92 lists the route of administration for when substances must be declared.

Some substances need to be declared for all routes of administration. However, other substances only need to be declared if the route of administration is 'oral'. For these substances, they would need to be declared if they were in a medicine that was, for example, a tablet to be swallowed, but not in a medicine that was, for example, a cream to be applied to the skin.

Under TGO 91 and 92, pollen, propolis and royal jelly only need to be declared when the route of administration of the medicine is oral.

However, the Therapeutic Goods (Permissible Ingredients) Determination requires all listed medicines containing pollen or royal jelly to include a certain warning statement, regardless of route of administration. All listed medicines containing propolis also must include a warning statement, but the There is ambiguity whether pollen should be declared in non-oral dosage forms as well as whether pollen needs to be declared when it is present as part of a plant component (such as a flower) in addition to when the pollen is sourced from bees.

Proposed changes – pollen, propolis and royal jelly (route of administration)

To align labelling requirements more closely with the Permissible Ingredients requirements for listed medicines and provide more clarity for medicine sponsors, we propose to:

- Change the requirements for declaring pollen, propolis and royal jelly. Require pollen, propolis and royal jelly to be declared for all routes of administration, rather than only when the medicine is for oral administration.

We also propose to clarify the requirements for pollen in the guidance by stating that:

- Pollen, when present, should be declared irrespective of its source (isolated pollen, bee pollen or when present as a component of a flower or other plant part).

Questions – pollen, propolis and royal jelly

8. Do you agree with the proposed change to require pollen, propolis and royal jelly to be declared for all routes of administration, rather than only when the

medicine is for oral administration? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.

9. Do you agree with the proposed guidance to clarify that pollen should be declared irrespective of its source? *(Yes, partially agree, no, unsure).* Please explain your answer and give us your suggestions for the guidance.

1.3 How substances are declared

Declaring substances for prescription medicines

For prescription medicines, substances that must be declared must appear on either the label on the pack or in the Consumer Medicine Information (CMI) leaflet. For over-the counter and listed medicines, substances must be declared on the label. For more information see Allergies and medicines.

We have received feedback that it could be beneficial to consumers to require the statement on the label for prescription medicines. There are some concerns that if declaration statements are not on the label that healthcare providers or patients could incorrectly assume that the substance is not in the medicine. Some declaration statements such as 'contains gluten' may be shorter than a statement instructing the reader to refer to the CMI.

Proposed changes – prescription medicine declaration statements

To support consistency in the location of substance declaration statements, we propose to:

- Require declaration statements for prescription medicines to be included on the medicine label unless there is insufficient space to do so.

The current allowances for certain sized containers would continue.

Question – prescription medicine declaration statements

10. Do you agree with the proposed change to require declaration statements for prescription medicines to be included on the label (unless there is not enough space), instead of also allowing the label to direct a consumer to the CMI? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.

Aspartame and phenylalanine

Aspartame is an artificial sweetener containing phenylalanine. Phenylalanine affects people with the rare genetic disorder phenylketonuria.[25]

Aspartame is required to be declared on medicine labels as 'contains aspartame' under Schedule 1 of TGO 91 and TGO 92.

Phenylalanine is also listed in Schedule 1. Medicines containing phenylalanine are required to state 'contains phenylalanine' on the label with Note 5 providing some examples of when phenylalanine needs to be declared. Some stakeholders have told us that this note could be confusing to medicine sponsors and manufacturers.

[25] FSANZ (Food Standards Australia New Zealand), *Warning and advisory statements*, FSANZ website, 2016, accessed 28 July 2025.

Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires specified non-prescription medicines, including over the counter and registered complementary medicines containing aspartame to include on the label:

- 'Phenylketonurics are warned that this product contains aspartame (phenylalanine).'

Foods containing aspartame or aspartame-acesulphame salt, must declare that the food contains phenylalanine.[26]

Proposed changes – aspartame and phenylalanine

To make declaration statements clearer that aspartame contains phenylalanine and to align with the warning statement required for certain medicines under Required Advisory Statements for Medicine Labels (RASML), we propose to:

- change the current requirement for declaring aspartame to require aspartame to be declared on medicine labels as 'contains aspartame (phenylalanine)' when present in the medicine (instead of 'contains aspartame').

To give more clarity to medicine sponsors, we also propose to:

- change the note related to phenylalanine to give more clarity to medicine sponsors by clarifying that the entry applies to all medicines and reflect that in guidance.

Questions – aspartame and phenylalanine

11. Do you agree with the proposed change to declare aspartame as 'contains aspartame (phenylalanine)' on medicine labels, instead of 'contains aspartame'? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.
12. Do you agree with the proposal to clarify the requirements for declaring phenylalanine? *(Yes, partially agree, no, unsure).* Please explain your answer. Also tell us:
    a. Your suggestions for changing Note 5 in the Order or updating the guidance to clarify requirements.
    b. How changes to requirements for declaring phenylalanine may affect you.

Hydroxybenzoates (parabens)

Hydroxybenzoic acid esters are required to be declared on medicine labels as 'contains hydroxybenzoates'. As listed in Schedule 1 of TGO 91 and TGO 92, hydroxybenzoic acid esters includes substances such as ethyl hydroxybenzoate, methyl hydroxybenzoate and propyl hydroxybenzoate. These substances are sometimes called 'parabens', including by health professionals.

Labelling medicines to comply with TGO 91 and TGO 92 gives medicine sponsors guidance about declaring hydroxybenzoates. It states that hydroxybenzoic acid esters in Schedule 1 '*refers only to parabens with 'hydroxybenzoate' in the Australian Approved Name. Salicylates should not be declared under this entry.*'

[26] Australia New Zealand Food Standards Code – Schedule 9 – Mandatory advisory statements and declarations.

Proposed changes – hydroxybenzoates

To provide more clarity to health professionals and consumers, we propose to:

- change the current requirement for declaring hydroxybenzoates by requiring hydroxybenzoic acid esters to be declared on medicine labels as 'contains hydroxybenzoates (parabens)' when present in the medicine (instead of 'contains hydroxybenzoates').

We also propose to clarify the requirements for declaring hydroxybenzoic acid esters in Schedule 1 to reflect what is currently included in the guidance about salicylates.

Question – hydroxybenzoates (parabens)

13. Do you agree with the proposed change to declare hydroxybenzoic acid esters as 'contains hydroxybenzoates (parabens)' on medicine labels, instead of 'contains hydroxybenzoates'? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you. If you have any comments about our proposal to clarify requirements to reflect the guidance about salicylates, please include them.

1.4 Minor changes or clearer requirements for declaring substances

Antimicrobial preservatives

The name of antimicrobial preservatives must be declared on medicine labels when used in the following:

- ophthalmic medicines
- preparations for use on the skin and/or mucous membranes
- inhalations and nasal sprays.

These requirements are outlined in:

- subsection 10(1) of TGO 91 and TGO 92 (for ophthalmic medicines)
- subsection 10(9) of TGO 91 and subsection 10(2) of TGO 92 (for preparations for use on the skin and/or mucous membranes, and inhalations and nasal sprays).

The full name of the antimicrobial preservative is sometimes included on the label under these requirements. For example, 'contains sodium benzoate'.

Schedule 1 also lists some substances that must be declared that may be used as preservatives. For example, benzoates, including sodium benzoate, must be declared as 'contains benzoates'. We have received feedback that the requirements for declaring antimicrobial preservatives may be inconsistent with these Schedule 1 requirements.

A general descriptor such as 'contains benzoates' may be clearer to consumers than 'contains sodium benzoate'.

Some example labels currently in the guidance show 'Contains xxx as preservative' in the tabulated Critical Health Information for non-prescription registered medicines. We plan to continue to encourage preservatives to be declared in this way.

Proposed changes – antimicrobial preservatives

To make rules clearer for medicine sponsors, we propose to:

- Only require the name of any antimicrobial preservative where it is not already declared on the label as part of Schedule 1 requirements. This may involve minor changes to the wording of the requirements currently included in:
  - subsection 10(1) and 10(9) of TGO 91
  - subsection 10(1) and 10(2) of TGO 92.

We also plan to recommend in guidance that preservatives are declared on labels as 'Contains [name of preservative] as preservative'.

Questions – antimicrobial preservatives

14. Do you agree with the proposed change to labelling requirements for declaring antimicrobial preservatives? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how this change may affect you.
15. Do you agree with the planned guidance to recommend that preservatives are declared on labels as 'Contains [name of preservative] as preservative'. *(Yes, partially agree, no, unsure)*. Please explain your answer.

Other minor changes for declaring substances

We also propose other minor changes to make the rules clearer for medicine sponsors including:

- Clarify the statements that must be included on labels. For example, by clarifying the intent of column 4 of Schedule 1 where 'or' is included.
- Clarify that lecithin derived from soya would need to declare presence of soya beans.

Question – other minor changes

16. Do you agree with clarifying the intent of Column 4 in Schedule 1 and clarifying the requirements for lecithin? *(Yes, partially agree, no, unsure).* Please explain your answer and tell us how these changes may affect you.

In addition to the proposed changes to requirements for declaring substances on medicine labels, we also plan to update labelling guidance to give:

- More guidance about declaring substances without a cut-off limit in Schedule 1.

Question – guidance

17. Do you agree with the plan to give more guidance about declaring substances without a cut-off? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. If you have any suggestions for the guidance about declaring substances, please include them.

Question – other substances

This consultation focuses only on certain labelling requirements that may need improvements, as we believe TGO 91 and TGO 92 are working well. There is limited time before the new standards are introduced, and labelling rules must be carefully considered to avoid inconsistencies or unintended risks to medicine safety. We may only consider adding more substances or making further changes to Schedule 1 (beyond what we are already proposing) if time allows and it is essential for medicine safety.

18. Do you think any more substances should be added to Schedule 1, or any more changes made to requirements for declaring substances, that are critical to support medicine safety? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

2. Active ingredients

Active ingredients are the substances in a medicine with a therapeutic effect. They are typically required to be stated, and quantified, below or next to the product name on the label. Where the medicine contains multiple active ingredients (such as a multivitamin) these ingredients can be found on the back of the label or on a side panel. Registered non-prescription medicines also state the active ingredients in the critical health information table.

TGO 91/ 92 describes how active ingredients must be displayed on medicine labels.

For example, subsection 9(3) of TGO 91 and TGO 92 requires that the name of the medicine[27], active ingredients and quantity of active ingredients appear as a 'cohesive unit' on the main label[28] without interruption of additional information (Figure 1), except in certain circumstances. The purpose of these requirements is to support clear and easy identification of the active ingredients by a consumer or health care professional.

Figure 1: Cohesive unit of the name of the medicine, active ingredients and quantity of active ingredients.

Example of a main label on a primary pack showing the 'cohesive unit' of the name of the medicine, active ingredient and quantity of active ingredient.[29]

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

[28] 'Main label' is defined in TGO 91 as:
(a) where there are two or more labels or two or more portions of a single label - that label or portion of the label where the name of the medicine is more or most conspicuously shown; or
(b) where the name of the medicine is equally conspicuous on two or more labels or portions of a label – each label or portion.

[29] Label images included in the paper are examples only. The images may not be to scale and may not satisfy all the requirements and recommendations for medicine labels.

Proposed changes to requirements for the presentation of some types of active ingredients, such as vitamins and herbal medicines, is discussed later in this paper.

2.1 Hydrates, solvates and salts

Currently medicine labels must include the name of active ingredients that accurately reflects the medicine's formulation. This means the name of the active ingredient on the label may include chemical components such as salts, hydrates and solvates.

Hydrates and solvates

The full molecule name and hydration or solvate state may be long and hard to fit on some labels.

In many cases, the hydration or solvate may not affect the therapeutic activity of the active ingredient and may not be important for health professionals or consumers. For example, clinical guidelines may refer to 'cefalexin monohydrate' simply as 'cefalexin'.

However, sometimes the strength of the medicine is based on the hydrated or solvated form. In these cases, including the hydration or solvate in the active ingredient name helps ensure the strength is accurate.

Proposed changes – hydrate and solvate expression

To make labels clearer for consumers and health professionals, we propose to:

- allow the active ingredient name to appear without the hydration or solvate state on the main label in the cohesive unit where:
  - the strength of the active ingredient is not based on the hydrated or solvated form
  - the hydration or solvate state is not important for the safe use of the medicine
- however, still require the full name of the active ingredient (as included in the Australian Approved Names List) to be displayed elsewhere on the label.

If implemented, updated guidance will reflect the new requirements.

Salts

Like hydrates and solvates, salts in active ingredient names can make medicine names long and hard to fit on labels. Sometimes the salt is not clinically important. For example, clinical guidelines may refer to 'fluoxetine hydrochloride' simply as 'fluoxetine'.

Currently, the main label must include the salt name. If only one salt is approved for the active ingredient, the salt can be included in brackets on prescription medicines, for example, 'fluoxetine (as hydrochloride)'. If space is limited, the guidance states that just 'fluoxetine' can be shown on labels other than the main label.

However, unlike hydrates, salts are often clinically important to the medicine. Different iron salts, for example, have differing properties and may not be interchangeable. In these cases, stating the salt of the active ingredient in the cohesive unit is crucial to medicine selection.

In addition, some medicines, such as metformin hydrochloride, the strength is expressed in terms of the amount of the salt. In these cases, the salt name must stay on the label to ensure the stated strength is accurate.

Proposed changes – salts

We propose to:

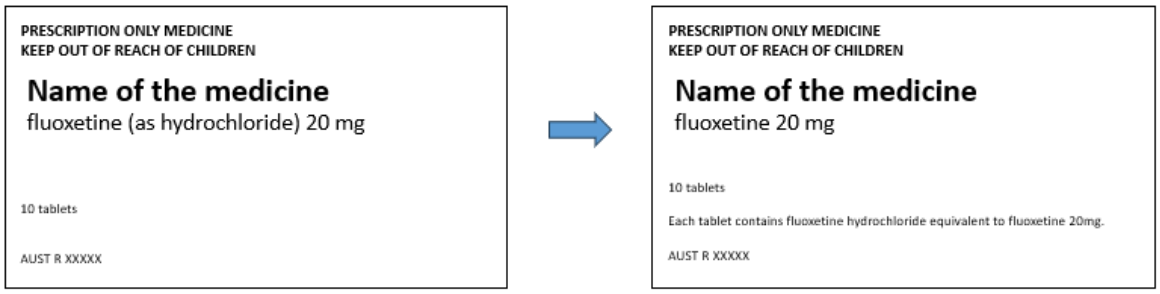
- allow the active ingredient name to be expressed without the salt state on the main label in the cohesive unit when:
  - the strength of the active ingredient is based on the free base or acid
  - the salt is not important to the safe use of the medicine
- however, still require the full name of the active ingredient (as included in the Australian Approved Names List) to be placed elsewhere on the label (for example, a side panel) if the salt is omitted from the cohesive unit.

This proposed change is illustrated in Figure 2 below.

We plan to update the guidance to reflect these changes, including circumstances where the salt should be included in the cohesive unit. For example, the salt name should remain when:

- more than one salt of the active ingredient is registered in Australia
- the salt may contribute a clinically significant amount of electrolyte, such as sodium.

Figure 2: Example main label of proposed change for expressing salt active ingredients[30].



Questions – hydrates, solvates and salts

19. Do you agree with the proposed changes to how active ingredients that are hydrates and solvates can be shown in the cohesive unit on the main label? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.
20. Do you agree with the proposed changes to how active ingredients that are salts can be shown in the 'cohesive unit' on the main label? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Also tell us:
    a. how these changes may affect you
    b. when the salt name should be required in the cohesive unit.

2.2 Vaccines

Vaccine labels are often small, making it hard to fit all the active ingredient information.

Some vaccines contain multiple active ingredients, even with active ingredients targeting different diseases. Others include ingredients targeting different strains or serotypes of the same disease. For

[30] Illustrative only, not a fully compliant label. This example shows that the full name has been placed elsewhere on the main label. Alternatively, the full name of the active ingredient could appear in another location on the label, such as a side panel.

example, some vaccines to help prevent against pneumococcal disease contain a mixture of inactive parts from over 20 of the most common types of pneumococcal bacteria. In these cases, sponsors cannot always list every active ingredient on the container or primary pack label as required by TGO 91 due to limited space. Consequently, sponsors are currently required to obtain consents to supply under S14/A provisions for these labels.

We have received feedback that in these situations it may be helpful for the label to clearly show the number of strains with the vaccine type descriptor, such as 'pneumococcal vaccine 20-valent'. However, TGO 91 requirements may limit where some of this information can appear.

Proposed changes – vaccine active ingredients

We are proposing changes to clarify how active ingredients are displayed on vaccine labels when space is limited. These changes aim to ensure people can still access this important information in other ways.

We also propose changes to include a short, clear product description to help identify the vaccine type when there are multiple active ingredients.

Our proposal includes the following.

Active ingredients when label space is limited

- Allow injectable vaccines in containers with a capacity of 3 millilitres or less, containing either:
  - 4 or more active ingredients, or
  - an active ingredient formulated with 4 or more strains, serotypes or variants (multiple valences), to:
    - not list all active ingredients on the label where space precludes this.
- Allow carton and container labels for vaccines containing 4 or more active ingredients (or an active ingredient with 4 or more strains, serotypes or variants) to omit listing all active ingredient names and quantities on the label if all of the following apply:
  - the vaccine is an injection in a container with a capacity of 3 millilitres or less and
  - the label includes a statement directing users to the Product Information (PI) for a full list of active ingredients (including specific strains/ serotypes, and their corresponding quantities)
  - the label of the primary pack includes a QR code or website address linking to the PI if it is not physically included. The QR code or web address must remain active and link to the current approved PI for the shelf life of the medicine.

For vaccines containing 3 or fewer active ingredients, the main label must continue to show the names and quantities of each active ingredient. Sponsors may still repeat or include extra active ingredient information on the side or rear label/ panel.

Vaccine descriptor

- Allow all injectable vaccines to:
  - interrupt the 'cohesive unit' on the main label with a vaccine descriptor.
- The vaccine descriptor:
  - should be included after the name of the medicine and before the active ingredients
  - must accurately describe the vaccine

- may include the following information where it is not already included in the name of the medicine:
  - the disease for which the vaccine is indicated (for example ‘pneumococcal’)
  - the type of vaccine or further description (for example ‘conjugate’, ‘polysaccharide’, ‘inactivated’)
  - the number of strains or serotypes or variants (for example, monovalent, quadrivalent, 13-valent).

For example, the vaccine descriptor may include terms such as ‘20-valent’ after the name of the medicine, such as ‘Trade name pneumococcal conjugate vaccine 20-valent’.

Planned guidance – vaccines

We plan to give medicine sponsors guidance on these requirements, including:

- suggested wording for directing users to the PI
- suggested presentations for vaccine descriptors (for example, using a different font to distinguish the name of the medicine from the vaccine descriptor)
- example labels.

Question – vaccines

21. Do you agree with the proposed changes to labelling requirements for displaying vaccine active ingredients and vaccine descriptors? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Also tell us how these changes may affect you and share any suggestions for the improving the guidance.

2.3 Active ingredient size and location

Active ingredients need to be shown clearly and consistently on medicine labels. The requirements for text size and location depend on several factors including the type of medicine, the size of the number and type of active ingredients. These requirements are outlined in Sections 9 and 10 of the current Orders.

TGO 91 and TGO 92 required active ingredients to be more prominent on medicine labels to make them easier to find.

Active ingredient prominence for prescription and related medicines, and other registered medicines

After TGO 91 and 92 were made, the Australian government introduced active ingredient prescribing. Under this practice, doctors nominate the active ingredient rather than the brand name for the prescription. Accordingly, since February 2021, prescriptions for most Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS medicines must show their active ingredients. This means most medicines are prescribed according to their active ingredient rather than brand name.

Clear and prominent display of active ingredients on labels supports consumers to identify the medicine when the brand name is not used on the script.

Proposed guidance – active ingredient prominence for registered medicines

To further support the prominence of active ingredients, we propose to include more clarity on their display in relation to the 'name of the medicine' (sometimes called the brand name) for prescription and other registered medicines. We propose to:

- Recommend that on the main label of the primary pack, the text size of the active ingredient should be at least 50% of the name of the medicine height, or 3 mm, whichever text size is greater.

Note: The presentation of the name of the medicine is discussed later in this paper, see Name of the medicine presentation for prescription and related medicines.

Question – active ingredient prominence

22. Do you agree with the proposed guidance on font size for active ingredients in relation to the name of the medicine on registered medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

Active ingredient location for non-prescription medicines

Some medicines with multiple active ingredients list those ingredients on a side or rear panel instead of the main label. Section 9 of TGO 92 sets out the rules for this. Some sponsors have asked for less restrictions on these requirements.

Subsection 9(5) of TGO 92 currently allows sponsors to display active ingredients and their quantities on a side or rear panel if at least two of the ingredients are vitamins, minerals or herbal preparations. Subsection 9(6) sets out further rules for listed medicines. For example, active ingredients can also be displayed on the side or rear panel if there are four or more of any type.

Additional requirements such as subsection 9(7) apply to registered medicines, affecting when active ingredients can be displayed on the side or rear panel.

Some other rules about where active ingredients need to be shown on labels of registered non-prescription medicine (over-the-counter [OTC] and registered complementary medicines [RCM]) could also be clearer. For example, if the name of the medicine includes the full name of the active ingredient and its quantity, it may not need to be repeated on the main label of some registered non-prescription medicines.

Proposed changes – active ingredient location for non-prescription medicines

We propose minor changes to TGO 92 requirements for displaying active ingredient information. These changes would allow more listed medicines to show ingredients on a side or rear panel. This may help when there is limited space on the main label.

We propose:

- For listed medicines, update the requirements to allow active ingredients to appear on a side or rear panel when the medicine contains at least two active ingredients (of any type).

We also plan to give medicine sponsors more guidance, including:

- For registered non-prescription medicines, clearer guidance about when sponsors do not need to repeat the name of the active ingredient below the name of the medicine (when the name of the active ingredient and its quantity is clearly included in the name of the medicine).

Questions – active ingredient location for non-prescription medicines

23. Do you agree with the proposed changes to where active ingredients can be shown on listed medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.

24. Do you agree with the guidance plan for registered non-prescription medicines about when active ingredients do not need to be repeated below the name of the medicine? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

2.4 Active ingredient quantity expression

TGO 91 and 92 set out how to express the quantity of active ingredients in medicines. We are proposing changes for certain ingredients or classes of medicines to improve clarity and support their safe use.

Insulin

Insulin products come in different strengths and formulations. This can cause confusion and increase the risk of selecting the wrong product, which may harm patients. For example, insulin glargine is available in multiple concentrations. Errors and harm have been reported from using high concentration insulin glargine by mistake. [31]

TGO 91 already requires the potency of liquid biological medicines to be expressed as potency units in section 11(3). However, there is no requirement, nor guidance, regarding the prominence or position of the potency value.

Proposed guidance – displaying insulin concentration

We plan to update the guidance to support clear and prominent display of insulin concentration on labels.

We plan to:

- recommend insulin medicines display international units per mL prominently on the label, for example displaying ‘100 IU/mL’ or ‘300 IU/mL’ near the name of the medicine. We plan to give medicine sponsors examples in the guidance.’
- encourage sponsors through guidance to display the concentration on the individual pens in the largest possible font

Questions – insulin

25. Do you agree with the proposed guidance about displaying insulin concentration on medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. In your response, include:
    a. Comments on how to make insulin concentration clear on labels for health professionals and consumers. If possible, give examples of labels you think are clear or not clear.

[31] Australian Commission on Safety and Quality in Health Care, ‘ Safer insulin prescribing: Guidance for Australian prescribers ‘, ACSQHC, 2022, accessed 1 September 2025.

b. Suggestions to improve the guidance.

Injections

For single-use injectable solutions, it is important for medicine safety that the total amount of active ingredient in the total volume of the medicine is clearly stated.

For example, stating the active ingredient as ‘50 mg in 1 mL’ or ’50 mg/1 mL’ tells a health professional that the vial or ampoule contains 50 mg in total. In contrast, ‘50 mg/mL’ does not make the total amount clear.

TGO 91 outlines how to express the quantity of active ingredients in injectable medicines in paragraph 11(2)(f). For example, injectable solutions intended for single use must express the quantity of active ingredients in the total volume, as outlined in subparagraph 11(2)(f)(v). However, some of these requirements could be updated to improve clarity and safety.

Proposed requirements and planned guidance – injection active ingredient quantity expression in stated volume

Our proposal includes:

- continue to require single-use injectable solutions to express the quantity of active ingredients in the stated volume of fill in the container
- require injectable solutions intended for single use with a total stated volume of 1 mL to express the volume of fill in numbers. For example, the active ingredient must be stated as ‘50 mg in 1 mL’, not ‘50 mg/mL’. (This requirement would also permit, for example, ‘50 mg/1 mL’, but this should be displayed as ‘50 mg in 1 mL’, where space allows)
- clarify which types of injections must state the quantity of the active ingredient in the total volume. For example, we propose to: remove ‘concentrated solution for injection’ from 11(2)(f)(i). This is because concentrated injections must already be expressed in the total volume of the medicine.

We also plan to strengthen the guidance to support clear and standardised expression. For example:

- single-use injectable solutions should be expressed as, for example, ‘50 mg in 1 mL’, rather than ‘50 mg/1 mL’, where space allows
- vaccines and antivenoms should be expressed as ‘X microgram per Y mL dose', where space allows.

Questions – expressing the quantity of active ingredients in injections

26. Do you agree with the proposed change to require single-use injectable solutions with a total stated volume of 1 mL to show the volume of fill in numbers? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you. If you have any comments on the proposal to remove ‘concentrated solution for injection’ from 11(2)(f)(i) (because concentrated injections must be expressed in the total volume of the medicine), please share them.
27. Do you agree with the proposed guidance on how to express quantity of active ingredients in single-use injectable medicines? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

Units for active ingredient quantities

TGO 91 and 92 set out requirements for units to quantify active ingredients but some of the requirements may benefit from clearer direction to support the safe use of medicines.

Note: proposed changes to expressing the quantity of vitamin active ingredients is discussed later in this paper.

Microgram abbreviation

Section 11 of both Orders includes a note about when the abbreviation 'µg' may be used for microgram.

Proposed changes – microgram

We propose strengthening the requirement for displaying 'microgram' in full wherever possible. This is because 'µg' can be mistaken for 'mg'.[32]

We propose that:

- 'microgram' must be displayed in full unless it does not fit on the label and is a label on a small (for TGO 92) or a small or very small container (for TGO 91)[33].

Question – microgram

28. Do you agree with the proposed change to require 'microgram' to be shown in full, unless it does not fit on the label of a small or very small container? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.

Injectable medicines active ingredient quantity units

Paragraph 11(2)(f) of TGO 91 sets out how to show the quantity of active ingredients in injectable medicines. Most injectable medicines must show the quantity in weight, which reflects how they are used in clinical practice. However, some medicines, such as oxytocin, are dosed in units.

Proposed changes – injectable medicines active ingredient quantity expression

We propose updating the requirements to reflect clinical practice and current labelling practices.

We propose:

- For injectable medicines intended for use as a single dose, that the quantity of active ingredients must be shown as either:
  - the stated weight of the active ingredient in the stated volume of fill of the injection in the container, or
  - if the dose is measured in units in clinical practice, as the number of units expressed as:
    - International Units (IU)
    - a unit defined in an applicable default standard, or

[32] Australian Commission on Safety and Quality in Health Care, 'Recommendations for safe use of medicines terminology', ACSQHC, 2024, accessed 21 July 2025.
[33] Small container is defined in TGO 92 as a container that has a capacity less than or equal to 25 millilitres. Very small container is defined in TGO 91 as a container having a capacity less than or equal to 3.0 millilitres.

- where IU or pharmacopeial monographs have not been established, as the unit in the approved product details for the medicine.

Question – units for injectable medicines

29. Do you agree with the proposed changes to how the quantity of active ingredients in injections is expressed (in either weight or units)? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.

Parenteral nutritional therapy quantity units

Paragraph 11(2)(f) also covers how to show the quantity of active ingredients in injectable medicines used for parenteral nutritional therapy.

Stakeholders told us the current requirements can be improved to align with clinical practice. Currently, the quantity of active ingredients in nutritional therapy is required to be shown in millimoles. However, for some components, such as amino acids, expressing the quantity in weight may be more useful for health professionals.

Proposed changes – parenteral nutritional therapy active ingredient quantity

We propose updating the requirements to reflect clinical practice and current labelling practices as follows:

- for the components of injectable nutritional therapy that are not electrolytes, that the quantity of active ingredients must be shown as:
  - the stated weight of the active ingredient in the stated volume of fill of the injection in the container.

Question – parenteral nutritional therapy quantity units

30. Do you agree with the proposed changes to how the quantity of components in parenteral nutritional therapy (excluding electrolytes) is expressed? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.

Retinol equivalents for prescription medicines

TGO 91 requires preparations containing vitamin A or a derivative of vitamin A to also express the quantity in terms of microgram retinol equivalents. This is outlined in subparagraph 11(2)(k)(i). However, this requirement captures retinoids such as acitretin, tretinoin and isotretinoin, for which expressing the dose in retinol equivalents is not appropriate.

Proposed guidance – retinol equivalents

We propose updating guidance to clarify expectations regarding 11 (k)(i) of TGO 91 for some prescription medicines.

We propose:

- clarify in guidance that for the purposes of expressing retinol equivalents, acitretin, tretinoin and isotretinoin, are not considered derivatives of vitamin A and do not need to also express active ingredient quantity in terms of microgram retinol equivalents.

Questions – retinol equivalents

31. Do you agree with the proposed guidance to clarify expectations about expressing some active ingredients in retinol equivalents for prescription medicines? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

Specified units for enzymes

TGO 92 outlines how to state the amount of active ingredients that are enzymes. These requirements are in subparagraph 11(2)(i)(iii) and Schedule 3, which lists the activity unit for each enzyme.

The requirements may need to be updated to reflect enzymes that are allowed in listed medicines under the Therapeutic Goods (Permissible Ingredients) Determination.

Proposed changes – specified units for enzymes

We are proposing updates to Schedule 3 to make requirements clearer and more consistent and include new activity units for certain enzymes, as shown in Table 1.

Table 1: Proposed additions to specified units for enzymes

Activity unit	Unit description	Enzymes
million PU/g	Million Papain units per gram	Bromelains
million PU	Million Papain units	Papain
million PU/g	Million Papain units per gram	Papain

Question – specified units for enzymes

32. Do you agree with the proposed changes to TGO 92 requirements for stating the amount of active ingredients that are enzymes? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.

Probiotics and postbiotics quantity units

TGO 92 sets out how to quantify active ingredients that are biological organisms, such as probiotics. These requirements are in subparagraph 11(2)(i)(v).

We may need to update the requirements because some of these active ingredients are live organisms, while others are not.

Sponsors can find some information on selecting appropriate units for probiotics in Demonstrating the quality of listed probiotic medicines.

Proposed changes – quantifying biological organisms in non-prescription medicines

We propose updating the requirements to clearly distinguish between live and non-viable biological active ingredients, such as probiotics and postbiotics. This will help ensure consistent labelling and accurate information for consumers.

We propose to:

- continue the current requirements in TGO 92 for live biological organisms:

  - as the number of organisms present per metric unit for liquids and powders and as the number of organisms present per dosage unit for other dosage forms

- require the quantity of active ingredients that are non-viable biological organisms to be expressed as:
  - the number of non-viable organisms present per metric unit for liquids and powders and as the number of non-viable organisms present per dosage unit for other dosage forms.

Question – probiotics and postbiotics quantity units

33. Do you agree with the proposed changes to TGO 92 requirements for expressing the quantity of active ingredients that are non-viable organisms? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes will affect you.

Dual presentation of units

Some active ingredients are expressed in more than one way in clinical practice. For example, Australian treatment guidelines for vitamin D replacement are stated in both micrograms and international units.

Some medicine labels show both units for these types of active ingredients, while others show only one.

Planned guidance – dual presentation of units for some medicines

We plan to update the guidance to recommend that active ingredients such as colecalciferol (vitamin D3) are labelled with both micrograms and international units.

Question – dual presentation of units

34. Do you agree with the planned guidance to recommend that active ingredients such as colecalciferol (vitamin D3) are labelled using both micrograms and international units? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

2.5 Potassium for injection or infusion

Potassium for injection is considered a high-risk medicine due to the risk of a fatal outcome when administered inadvertently or incorrectly.[34]

Sections 10 and 11(2) of TGO 91 makes specific requirements for regarding the presentation of potassium chloride content and concentration in injectable medicines but this does not include provision for font colour.

The current labelling guidance includes recommendations for labelling potassium for injection or infusion in a way that uniquely identifies them, such as red lettering on premixed bags. Red lettering is currently commonly included on potassium infusion bags.

[34] Clinical Excellence Commission, *High-Risk Medicines*, CEC website, 2025, accessed 4 September 2025; Australian Commission on Safety and Quality in Health Care, *High risk medicines*, ACSQHC website, 2025, accessed 4 September 2025.

However, as it is not mandated, there is a risk of inconsistency between medicines of this type, potentially leading to confusion and increase risk of administration errors.

Proposed changes – Potassium for injection or infusion font colour

We are proposing changes to requirements that:

- mandate common labelling practices, such as using red lettering
- improve clarity of expectations for medicine sponsors
- ensure consistency across products.

We propose:

- Where potassium is the principal active ingredient in an injectable medicine (for example, 10 mmol potassium chloride and 0.29% sodium chloride 100 mL) that at least the name of the medicine, active ingredient and quantity must be in red font.

This change would apply to concentrated potassium in vials and ampoules, as well as premixed bags.

We also plan to update the guidance to reflect these proposed changes, including to remind sponsors that the red font must comply with section 7 for visibility and legibility.

Question – potassium for injection or infusion

35. Do you agree with the proposed change to require red font for certain information when potassium is the principle active ingredient in an injectable medicine? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Also tell us:
    a. how these changes may affect you
    b. how the proposed requirements or guidance could be clearer about when red font would be required
    c. other suggestions for the guidance about injectable potassium medicines.

2.6 Clarifying how active ingredients must be displayed

We have received feedback that certain requirements could be more clearly described.

Proposed changes – minor updates for active ingredient requirements

We propose minor updates to clarify how active ingredients and their quantities must be displayed on prescription and listed medicine labels.

We propose for listed and prescription medicines to:

- make it clearer that when active ingredients and their quantities are included on the side or rear panel as permitted under section 9, that the relevant requirements of subsection 9(3) still apply including:
  - the active ingredient name and quantity cannot be interrupted with additional information not permitted for the cohesive unit on the main label
  - the cohesive unit requirements to list the name and quantity of each active ingredient on separate lines of text also applies to the side panel.

Note: a planned correction to the minimum text size requirements in TGO 92 for listed medicines in small containers is outlined later in this paper, see text size.

Question – minor updates about active ingredients for listed and prescription medicines

36. Do you agree with the proposed change to clarify requirements when active ingredients and their quantities are shown on a side or rear panel? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you.

2.7 Planned guidance updates – active ingredients

In addition to the proposed changes to requirements and planned guidance updates already mentioned, we also plan to give sponsors more guidance on how to show active ingredients and their quantities on labels.

In the new guidance we plan to include:

- More examples of best practice labels, covering aspects such as:
  - expressing active ingredients that are salts in prescription medicines
  - meeting cohesive unit requirements, including for combination prescription medicine products
  - using colour and colour blocks to help differentiate strengths
  - displaying strength on a separate line in certain circumstances to make it more visible for suitable medicines.
- Advice for liposomal medicines where there is a risk of medication errors. The term 'liposomal' or 'pegylated liposomal' should be included on the main label (and in the name of the medicine on the ARTG), in line with other regulators[35].
- A reminder to avoid trailing zeros. For example, 1 mg is preferable to 1.0 mg as it has a risk of being mistaken for 10 mg.
- Guidance on limited circumstances when active ingredient quantity rounding may be appropriate on labels.
- Clearer guidance on expressing active ingredient quantities for different dosage forms or presentations of biological medicines.

Question – planned guidance about active ingredients

37. Do you agree with the planned updates to guidance on expressing active ingredients, including more example labels, advice for liposomal medicines, and reminders to avoid trailing zeros? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

[35] European Medicines Agency Change of name of liposomal medicines at high risk of medication errors | European Medicines Agency (EMA), European Medicines Agency website, 2019, accessed 18 July 2025.

3. Name of the medicine

Medicines must have the 'name of the medicine' on the label. This may be the product name or brand name or trade name[36].

Subsection 9(2) of TGO 91 and 92 requires labels to present the name of the medicine on the main label in a 'continuous, uninterrupted manner and not be broken up by additional information or background text.' Section 9(3) requirements include that the name of the medicine, active ingredients and quantity of active ingredients appear as a *cohesive unit* on the main label. The purpose of these requirements is to support clear and easy identification of a medicine, including the name of the medicine and its active ingredients by a consumer or health care professional.

The ARTG name may contain information to fully describe the medicine in the electronic ARTG record. Section 6 of TGO 91 and 92 describes when it is acceptable to omit some of this information when stating the name of the medicine on a label. For example, descriptive information, such as the dosage form or a flavour, may only need to be included on the label to differentiate between medicines in a range. In many instances dosage form or flavour information can be stated elsewhere on the label.

Some proposals related to the name of the medicine are discussed earlier in this paper. For example, see the section on insulin.

3.1 Name of the medicine presentation for prescription and related medicines

It is important that the unique name of a medicine is clear and easy to identify. This is especially important for prescription medicines where there may be many medicines with the same active ingredients but supplied by different entities. The trade name must, among other considerations, be unique.

The main label of a prescription medicine usually includes the name of the medicine below the signal heading required by the Poisons Standard for the relevant scheduling classification, but this is not mandatory and may lead to inconsistent presentation of labels.

TGO 91 also requires prescription medicines to also display the name of the medicine on 3 non-opposing sides of a carton.

Proposed changes – name of the medicine presentation for prescription and related medicines

We propose changes to support clear identification of medicines and provide more clarity to medicine sponsors. We propose to:

- require the 'name of the medicine' to be immediately below the signal heading as a a cohesive unit with the active ingredient (where a signal heading is required to be stated on the label under the Poisons Standard)
- require the name of the medicine on the label to be unique. For example, where the sponsor or distributor name is included in the ARTG name and this is needed to differentiate the medicine from other medicines, it would need to be included in the name of the medicine on the label and be presented in a continuous uninterrupted manner.

We also plan to provide more guidance including:

[36] The commercial name given to the goods by the manufacturer; and under which they are supplied (Regulation 2, Therapeutic Goods Regulations 1990).

- updating label examples in guidance to make it clearer when and how the sponsor's name can be included separately on the label. For example, where the medicine has a unique name that does not include the sponsor's name, then the sponsor's name can be included in the bottom right corner of the main label
- more guidance about fixed dose combination products including that strengths of fixed-dose combination products should be included in the name of the medicine. For example, a product with two actives at strengths of 10 mg and 5 mg should be presented as, 'Trade name 10/5'
- guidance about active ingredient prominence in relation to the name of the medicine. See Active ingredient size and location.
- more guidance on 'main label', including in relation to the Poisons Standard signal heading. (See also proposed changes to main label definition later in this paper)
- recommend that while only the 'name of the medicine' is required on at least 3 non-opposing sides of a carton, that the whole 'cohesive unit' including the name of the active ingredients and quantity of active ingredients is displayed on at least 3 non-opposing sides.

Question – name of the medicine presentation for prescription and related medicines

38. Do you agree with the proposed changes to requirements for presenting the name of the medicine on prescription and related medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Also tell us:
    a. how these changes may affect you
    b. if you think any medicine, such as fluid bags, should be excluded from this proposal
    c. your suggestions or comments on the planned guidance for presenting the name of the medicine on prescription labels.

3.2 Name of the medicine presentation for non-prescription medicines

Some non-prescription medicines have long-standing branding, such as a symbol or icon, in, or adjacent to, the name of medicine that may be helpful to uniquely identify a range of products. This presentation may not be compliant with the current TGO 92 requirements. As an interim measure, the TGA has accepted some labels with certain branding by providing Section 14 consents to supply medicines that do not comply with TGO 92 requirements. Targeted consultation with some affected sponsors of non-prescription medicines in 2022 highlighted that this matter needed more consideration, and it was decided to postpone action until the standard replacing TGO 92 was being introduced.

Proposed changes – presentation of the name of the medicine for non-prescription medicines

To give more clarity to non-prescription medicine sponsors on acceptable presentation of the name of the medicine, we propose to:

- Change the requirements for non-prescription medicines to permit the name of the medicine to be interrupted by a distinguishing mark or graphic related to the medicine's branding, or spatially separated in certain circumstances with the following limitations:

- Distinguishing marks must be related to the medicine's branding.
- Slogans and taglines are not permitted for registered medicines.
- A Slogan and taglines and/or spatial separation of the naming elements is permitted for non-prescription medicines only where the name of the medicine is legible, and readily and unambiguously relatable to its ARTG entry.

To achieve this, we propose to include a definition for a 'distinguishing mark' in the new standard replacing TGO 92:

> **distinguishing mark**, in relation to a range of therapeutic goods supplied by a person, means a trade mark (whether a registered trade mark or not) or other mark that relates to a brand of a medicine and is used, or intended to be used, to distinguish the range of the goods from goods supplied by the same person or another person, and includes the following or any combination of the following:
>
> a. where the medicine is a Registered medicine - any numeral, letter, word, name, brand, a graphic image or icon, or logo; or
>
> b. where the medicine is a Listed medicine - any numeral, letter, word, name, brand, a graphic image or icon, logo, or a slogan or tagline.
>
> Note: A distinguishing mark may be in plain or stylised form.

We will also revise the requirements replacing those included in subsection 9(2) and 9(3) to accommodate this.

We also plan to give medicine sponsors guidance including:

- Examples of acceptable label layouts and positioning of the name of the medicine.

Question – name of the medicine presentation for non-prescription medicines

39. Do you agree with the proposed changes to how the name of the medicine can be presented on non-prescription medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes might affect you. In your response, please include:
    a. any comments or suggestions regarding the proposed definition of 'distinguishing mark'
    b. any suggestions for the guidance on how to present the name of the medicine on non-prescription labels.

4. Dosage form

Dosage form is the pharmaceutical form in which a product is presented for therapeutic administration, for example, a tablet, capsule, or cream.

A medicine's dosage form is important information for health professionals and consumers. For example, consumers may refer to the dosage form on a label to choose a product with their preferred dosage form if multiple dosage forms are available.

Medicine labelling requirements consider the essential information needed to support consumer understanding and clarity so as not to crowd the label, while also ensuring key safety information is available. Additional Information about dosage form might be available from Public Summary document from the ARTG, but the label of a medicine is usually the first point of interaction between a consumer and a medicine.

For modified release dosage forms, suffix abbreviations such as XR (extended release) are encouraged to aid in identifying the medicine from immediate release.

4.1 Name of the dosage form

TGO 91 and 92 require the name of the dosage forms to be included on labels.

Section 6 of TGO 91 and 92 defines the name of the dosage form to include the name of the dosage form as entered, or proposed to be entered, in the ARTG in relation to the medicine.

Additional qualifiers and descriptors may be used to better define the nature of the dosage form and these should provide clarity to the consumer. For example, using 'sustained release tablet' from the product name rather than the option of 'tablet, modified release' available in the TGA eBusiness Code Tables.

Sometimes the dosage form name is simplified on the label, for example from 'hard capsule' to 'capsule'. Extra information about a dosage form may also be included.

We received mixed feedback in the 2023 targeted consultation about displaying the name of the dosage form on the label. This included the full description of the name of the dosage form being required on labels so that it was clear, for example, if a tablet is coated. Other feedback considered that the full description should not be required, or only in certain circumstances, for example where it is an important functional characteristic. Consistency in the expression of dosage form was also voiced, including more standardisation of dosage form expression. A review of the TGA eBusiness Code Tables was also proposed but this would be a substantive undertaking and beyond the scope of review of labelling requirements.

The guidance provides some information about when dosage forms in the TGA eBusiness Code Tables should be reversed to achieve plain English. We have received feedback that the guidance about displaying the name of the dosage form could be improved.

Proposed changes – name of the dosage form

We are considering updates to rules for medicines to balance clear expression of dosage form with some minor changes and some flexibility to reflect current practice.

We propose:

- change the requirement for including dosage form on labels to allow the 'name of the dosage form' (as currently defined) or the name of the pharmaceutical form that is consistent with the 'name of the dosage form'.

Planned guidance – name of the dosage form

To support consistency in the expression of dosage form where possible, and support proposed changes to requirements, we plan to update guidance to include:

- where some descriptors such as 'hard' can be omitted unless these additional descriptors are an important functional characteristic. For example, 'hard capsule' may be shown on the label as 'capsule'
- the full dosage form should be included in many cases, especially where it may be useful information for consumers. For example, consumers might want to know that tablets are coated, or capsules are soft
- more examples about how to express dosage forms on labels when they are written in reverse order for easy indexing in the TGA eBusiness Code Tables. For example, this may include updating the 'injection, solution' example to reflect current label practice

- examples of expressing dosage forms on medicine labels that the TGA would consider acceptable as being consistent with the name of the dosage form under the proposed updated requirements. For example, that 'hard capsule' can be expressed as 'capsule' on the medicine label
- more guidance about modified release dosage forms and why terms such as 'sustained release', 'prolonged release', 'delayed release', are sometimes used instead of 'modified release'. This may include that the name of the dosage form on generic medicines needs to be consistent with innovator. Also, sometimes terms are adopted from pharmacopeial monographs. We may also include some information about suffix abbreviations in the name of the medicine and how this is especially important on certain containers such as blister packs that are not required to include the name of the dosage form due to space limitations.

Question – dosage form

40. Do you agree with the proposed changes to requirements for expressing the dosage form name on medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Also tell us:
    a. how these changes may affect you
    b. your suggestions or comments on the planned guidance for expressing dosage form names.

5. Warning statements and advisory information

To ensure their safe use, many medicines require particular information to be communicated to consumers and health professionals. Warning statements on medicines inform consumers of specific risks associated with their use.

TGO 91 and TGO 92 require warning statements to be included on the medicine label.

'Warning statements' is defined in section 6 of both Orders. Importantly, the definitions differ between the two Orders to reflect the types of medicines each one covers and the legislation that applies to those medicines.

The labelling guidance provides further information about warning statements. In addition to TGO 91 and TGO 92, other documents mandate warning statements. These include RASML and the Therapeutic Goods (Permissible Ingredients) Determination.

Declaring allergens and other substances is a separate topic discussed earlier in this paper.

5.1 Modified release and enteric coated medicines

Modified release tablets and capsules change how active ingredients are released in the body. They are sometimes described as 'sustained release', 'slow release', or 'extended release'. Often, these medicines contain a higher dose that is released into the body more slowly. These medicines should not be crushed or chewed as this may lead to an immediate or uncontrolled release of drug substance.[37]

Such medicines often include warning the statements 'Swallow capsules whole' and 'Do not crush or chew' (or equivalent). These statements are not mandatory and not all modified release and enteric coated medicines include such a statement. Inconsistent presence of these types of statements could be confusing to medicine users and represent a safety risk. For prescription medicines, pharmacists

[37] Advanced Pharmacy Australia, *Don't Rush to Crush +* [eMIMS], June 2025, accessed 4 August 2025.

may also include a cautionary advisory label stating ‘Swallow whole. Do not crush or chew.’ Such labels are not usually included on other types of medicines.

Proposed changes – warning statement for modified release and enteric coated medicines

To improve consistency in the use of warning statements on medicine labels about modified release and enteric coated medicines whose action requires the dosage form to be swallowed whole, we propose to:

- require modified release and enteric coated dosage forms to include on the label:
  - a statement denoting the approved method of administration such as ‘Swallow whole’ and a warning statement against other methods of administration such as ‘Do not crush or chew.’

We also propose to provide guidance about preferred or acceptable statements. For example, statements with additional information would also be acceptable such as:

- ‘Swallow whole. Do not crush or chew’.

Question – modified release and enteric coated medicines

41. Do you agree with requiring a statement such as ‘Swallow whole, do not crush or chew’ on labels of medicines that are modified release or enteric coated formulations for oral administration? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you. If you have any comments about the proposed guidance, please share them.

5.2 Warning statements for prescription medicines

Section 6 of TGO 91 defines ‘warning statements’ as any of the following:

- statements specified in a standard that applies to the medicine
- statements required by the Secretary as a condition of registration
- statements specified in the Poisons Standard.

The guidance recommends additional warning statements for some medicines. These mostly apply to prescription medicines, such as products containing valproates and vinca alkaloids.

Planned guidance – warning statements for prescription medicines

We plan to update the guidance on warning statements to support the safe use of prescription medicines including:

- Strengthening recommendations for some warning statements, such as those for vinca alkaloids.
- Advising sponsors of generic medicines to consider warning statements included on the innovator product. For example, if the reference product for a generic medicine includes a cytotoxic warning, a generic medicine is expected to include a similar warning.
- Clarify warning statements expected on prescription medicine labels.

Question – warning statements for prescription and related medicines

42. Do you agree with the planned guidance updates about warning statements on labels of prescription and related medicines? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us your suggestions for the guidance.

5.3 Non-prescription medicines with large solid oral dosage forms

The size and shape of a medicine can affect its safety. Large tablets or capsules may pose a choking risk.

In 2024, we consulted on giving consumers more information about large solid oral dosage forms on labels of listed medicines. This is because the TGA has received reports of serious choking related adverse events involving large dosage forms. Most of these reports involved listed medicines.

Thank you to everyone who gave feedback on the 2024 consultation. We considered it carefully and in response to feedback we have updated our proposed requirements. This includes widened size limits for dosage forms that will need a warning. The warning will therefore apply only to the largest tablets or capsules, which present the greatest choking risk.

We also now propose to apply these requirements to all non-prescription medicines to help consumers, choose and use these medicines safely.

These proposals would not apply for dosage forms not intended to be swallowed whole (such as chewable dosage forms and lozenges) if there are clear directions not to swallow them whole.

Proposed changes – non-prescription medicines with large solid oral dosage forms

We are proposing changes to requirements for non-prescription medicines:

- to help consumers identify large solid oral dosage forms on labels
- in consideration of the 2024 consultation feedback.

Our proposal includes the following.

Large dosage form warning statement proposal

- Medicines subject to TGO 92 (non-prescription medicines) with large solid oral dosage forms must include the following warning statement if they exceed certain size limits:
  - ‘Warning: large [short name of dosage form].
- The warning statement is required if the dosage form exceeds the following dimensions:
  - Round tablets: diameter over 13 mm.
  - Non-round dosage forms other than capsules with either:
    - length or largest dimension greater than 22.4 mm, or
    - width, widest dimension or diameter greater than 10.5 mm.
  - Capsules, either:

- length or largest dimension is greater than 24.1 mm
- width, widest dimension or diameter is greater than 9.5 mm.

Direction to swallow with water proposal

- If a warning statement is required, the label must also display in the directions for use section the statement:
  - "Swallow with water' (or words to that effect).

Proposed transition period

We propose a transition period of about 2 years from the start of the new standards. This period is shorter than what we propose for the rest of the labelling standard as these label updates are important for safety.

Medicines manufactured or imported from the 1 October 2028 must follow the proposed new rules. However new labels might take some time to appear as new stock is distributed, and existing stock is sold.

Guidance updates

The guidance will be updated to reflect these changes. Sponsors can include additional directions to support safe administration.

Question – non-prescription medicines with large solid oral dosage forms

43. Do you agree with the proposed requirements for non-prescription medicines that are large solid oral dosage forms? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes might affect you. If you have any suggestions or comments about the planned guidance, please include them.

5.4 Warning statement visibility for listed medicines

Most registered non-prescription medicines are required to include certain information, including warnings, in a Critical Health Information (CHI) table. This is outlined in subsection 8(2) of TGO 92 and was introduced to help make medicine information clearer. Information about warnings is displayed under an easy to recognise heading such as 'warnings'.

Listed medicines are not required to include a CHI table. However, as outlined in the guidance, we recommend all non-prescription medicines supplied in Australia use this format whenever possible.

We have received reports from consumers experiencing adverse events where they have not noticed or easily located waring statements on listed medicines.

The definition of warning statement in TGO 92 notes that warning statements required by the Permissible Ingredients Determination must be included on the label (as this is a determination made under 26BB(1)(b) of the Act). A similar reminder for the Permissible Indications Determination is not included as this was introduced after TGO 92 was made which may result in mandatory statement being omitted from labels .

Proposed changes – warning statements for listed medicines

To support warning statements to be clearly visible, we propose to:

- Require listed medicines to prominently display all warning statements.

We also propose to add to the definition of warning statement in TGO 92 to make it clearer that the label statements required by the Permissible Indications Determination are considered warning statements.

We plan to give medicine sponsors examples of prominently displayed warning statements in the guidance. For example, display in a coloured text box.

Question – warning statement visibility for listed medicines

44. Do you agree with the proposed changes to displaying warning statements on labels of listed medicines? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you. If you have any comments about the planned guidance for displaying warning statements on listed medicines, please include them.

6. QR codes, machine-readable codes and instructions for preparation

6.1 QR codes

QR codes can appear on medicine labels to give people access to more information about the medicine but do not replace any information that is legally required to be printed on the label.

Sponsors can find more details about using QR codes in the labelling guidance.

There is also some information about QR codes in Understanding serialisation and data matrix codes on medicines. 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 serialised. In this case, the label must also include a DataMatrix code that contains the serial number, as required under Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021.

QR code purpose and use

QR codes and other machine-readable codes are increasingly being used on medicine labels to provide additional information. However, TGO 91 and TGO 92 are largely silent on QR codes or the online content they link to.

We include recommendations about QR code use in our labelling guidance. For example, we recommend that sponsors include a short statement near the QR code to explain its purpose.

Proposed changes – QR codes

We are proposing changes to clarify requirements for including QR codes on medicine labels.

We propose that if a QR code is displayed on the medicine label:

- A short statement must be included near the QR code to explain its purpose.
- The QR code must:
  - link to a website whose content is controlled by the sponsor (for example, the sponsor's publicly available website)
  - not link to a website that requires a login, payment, has a geoblock or any other restriction to access the content.

- The content accessed via the QR code must:
  - be consistent with information approved by the TGA for that medicine (for example, if the QR links to the Product Information, it must show the current approved version)
  - not contradict or misalign with any information on the medicine label
  - not breach the Therapeutic Goods Advertising Code
- If the QR code links to a list of excipients, it must be consistent with the ARTG entry. The label and site linked to the QR code must include all excipients.

We also plan to give medicine sponsors recommendations on using QR codes. For example:

- If the QR code has multiple purposes, the linked website should clearly identify the types of information, for example, by using a clear menu, navigation structure or information tree.
- QR codes can serve non-marketing purposes, such as authenticity verification and stock traceability (however, other requirements such as a need for a DataMatrix code under TGO 106 may then apply).

We are also proposing additional requirements for using QR codes in certain situations. See instructions for preparation before use.

Question – QR codes

45. Do you agree with the proposed requirements for using QR codes on medicine labels? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes might affect you. If you have any suggestions or comments about the planned guidance, please include them.

6.2 Machine-readable code with GTIN

Prescription medicine labels must include a machine-readable code, such as linear barcode, that encodes a Global Trade Item Number (GTIN). This requirement applies unless the medicine is a starter pack or meets specific exemptions under TGO 91.

These codes can help pharmacists and health professionals in several ways when there are the appropriate systems in place, including to:

- confirm the correct medicine is dispensed
- verify the correct medicine is administered
- support electronic systems, including for inventory management.[38]

The labelling guidance gives sponsors information about machine-readable codes, including some information about managing multiple codes.

Non-prescription medicines do not have the same requirements as prescription medicines. However, most have a machine-readable code to support standard retail processes. We currently recommend, but do not mandate, that all medicines include a machine-readable code.

[38] Australian Commission on Safety and Quality in Health Care, 'Barcoding and other scanning technologies to improve medication safety in hospitals', ACSQHC, 2017, accessed 22 September 2025; Australian Commission on Safety and Quality in Health Care, 'Principles for the safe selection and storage of medicines: Guidance on the principles and survey tool', ACSQHC, 2020, accessed 22 July 2025.

We have received feedback that more medicine labels should include a machine-readable code. For example, labels on oral liquid bottles used in hospitals could benefit from having a machine-readable code with a GTIN to support safe administration.

There are additional requirements for data matrix codes and if the medicine is serialised under TGO 106. For more information, see Understanding serialisation and data matrix codes on medicines.

Planned guidance – machine-readable codes

This includes:

- consideration as to how a medicine is used when including machine-readable codes on the label
- placement and annotation of machine readable codes

Question – machine-readable codes

46. Do you agree with the planned guidance for using machine-readable codes on medicine labels? (*Yes / Partially agree / No / Unsure*). Please explain your answer. If you have any comments about requirements for machine-readable codes, please include them.

6.3 Instructions for preparation before use

If a medicine must be prepared before use, the label must include preparation instructions. Some injectable products need preparation before use, such as diluting or reconstituting. Health professionals need clear instructions on how to prepare and store these medicines. For example, how to dilute concentrated injections or reconstitute powders for injection. These instructions help ensure the medicines are prepared and stored correctly, which is essential for their safety and efficacy.

If there is not enough space on the label, the instructions can go in a package insert inside the primary pack. The label must clearly state that the instructions are in the insert.

These requirements are outlined in paragraph 8(1)(l) of TGO 91 and paragraph 8(1)(m) of TGO 92. There are also some allowances for certain sized containers. For example, injections in a container with a capacity of 25 millilitres or less, are not required to include preparation steps if the information is on the label of the primary pack or package insert.

Medicine sponsors have asked us to change the requirements for providing instructions for preparation when these instructions cannot fit on a label for injections administered by healthcare professionals. Some sponsors want to use electronic formats such as QR codes on the label that link to the approved Product Information (PI) document, instead of providing a package insert.

Benefits of using a QR code to access the instructions for preparation may include a reduction in manufacturing complexity and reduced risk of medicine shortages. It may help deliver the intended benefits of recent changes to the Product Information (PI) as a package insert for injectable products.

Previous consultation of this proposal in 2024 resulted in concerns over accessibility of electronic-only instructions for preparation at the time of medicine administration. These concerns resulted in the proposal being deferred to be considered further as part of the remake of TGOs 91 and 92. With additional discussion between stakeholders in the intervening time we are prepared to reconsider this proposal and advance it if accessibility concerns no longer stand.

Read more about the 2024 consultation at Updates to Australian medicine labelling rules to support medicine safety.

This year, the TGA is separately consulting on changing the requirements for the inclusion of Product Information as a package insert for consumer administered injectables. We are not currently proposing changes to labelling requirements for these types of medicines.

Proposed changes – instructions for preparation of injectable products administered by healthcare professionals

If accessibility issues no longer exist we are proposing changes to providing instructions for preparation only to injectable products administered by healthcare professionals. Where they have other ways to access information about preparing and storing these medicines, in addition to a package insert or PI insert.

We propose:

- For injectable medicines administered by healthcare professionals and where the Secretary, when registering or varying a registration, considers it appropriate:
  - Allow QR codes on labels that link to approved electronic instructions as an option for providing approved preparation instructions instead of a package insert where preparation information cannot fit on the label.
  - As proposed in 6.1 QR codes, if a QR code is used to provide instructions for preparation, the label must include a statement near the code explaining its purpose.
  - If a QR code is used and the medicine is a powder for reconstitution, a direction that the medicine must be reconstituted must still be included on the label. (The requirements in 10(3)(c) for a direction on the label not to administer a concentrated solution undiluted in would also continue).

QR codes may not be permitted instead of physical preparation instructions in certain cases. For example, it may not be appropriate for:

- new medicines
- medicines with complex preparation steps.

We welcome feedback on types of injectable medicines and conditions that should or should not need physical preparation instructions.

We also propose that if a QR code is used instead of physical instructions for preparation the QR code must link to instructions for preparation that are consistent with the approved Product Information (PI) and are easy to locate (for example, an information tree).

To give health professionals time to adjust, we propose a delayed start to these changes. This would allow an electronic format to replace of physical preparation instructions approximately 2 years after the new labelling standard replaces TGO 91 for some medicines. This is to allow healthcare providers, who will administer these medicines, to have time (should they need it) to put in place processes to minimise any risk associated with not having physical instructions for preparation in the pack or on the label.

We plan to give sponsors guidance on:

- Acceptable statements to describe the purpose of the QR code. For example, ‘Scan this code for the Product Information’ or ‘Scan this code for instructions on how to prepare this medicine’.
- Examples of medicines where it may not be appropriate to use a QR code instead of physical instructions for preparation.

Questions – instructions for preparation of injectable products administered by healthcare professionals

47. Do you agree with the proposed changes to requirements to allow some injectable medicines administered by healthcare professionals to use a QR code instead of providing printed instructions for preparation? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes might affect you. In your response, please include:

    a. Comments about accessibility concerns raised in the previous consultation. For example, if you believe that the accessibility concerns raised in the previous consultation are no longer applicable, what evidence or data do you have to support this?

    b. Any suggestions or comments for the associated guidance.

48. If the proposed changes to requirements for instructions for preparation for injectable medicines administered by healthcare professionals were implemented, which medicines do you think should or should not be allowed to use a QR code instead of printed preparation instructions? For example, should anaesthetic agents have printed instructions?

7. Other information displayed on labels

Certain information must be on all medicine labels. This is described by the requirements in section 8 of both Orders.

7.1 Batch number and expiry date

Medicine labels must include both the batch number and expiry date.

Batch numbers help identify products during a recall. Medicines should not be used after their expiry date, as they may no longer work or could be unsafe.

Section 7 of TGO 91 and 92 requires label information to be easy to read. Information must be clearly visible and in colours contrasting with the background.

Expiry dates and batch numbers appear in different ways on medicine labels in Australia. While some are printed, others, especially on foil blisters, are permitted by Section 7 to be embossed or debossed. In this instance no colour contrast is required.

People have told us that embossed expiry dates can be hard to read and easily made illegible by opening the pack.

Additionally, batch numbers and expiry dates must include a prefix such as ‘Batch’ or ‘Exp’, as set out in Sections 6 and 8. The prefix must be before the batch number and expiry date. Some sponsors have told us that they need more flexibility with this requirement because of printing or packaging limitations for certain medicines.

Proposed changes – batch number and expiry date

Embossing and debossing proposal

We are proposing changes as a step towards improving how batch and expiry dates are displayed while recognising that it may be difficult to make changes on some types of packaging.

We propose to:

- Stop allowing embossed or debossed batch numbers and expiry dates on the primary pack, unless they are also printed or clearly contrast with a dark background.
- Continue to allow embossing or debossing on foil blisters and other containers included in a primary pack.

Prefix proposal

We also propose some changes to the requirements for batch number and expiry prefixes to allow for some printing or packaging limitations. We propose:

- replacing 'expiry date prefix' with 'expiry date identifier' in the definitions section of both orders, generally retaining the characteristics of the 'expiry date prefix' defined in TGO 91 and 92 while allowing it to accompany rather than necessarily precede the expiry date
- replace 'batch number prefix' with 'batch number identifier', generally retaining the characteristics of the 'batch prefix' defined in TGO 91 and 92 while allowing it to accompany rather than necessarily precede the batch number
- replace 'prefix' and/or 'preceding' with 'accompanying' throughout the orders where batch and expiry information is required.

We propose to update the guidance to:

- recommend that the identifier should clearly and individually precede the batch number and expiry date where possible
- state that a combined batch number and expiry date identifier such as 'Lot/Exp' may be acceptable on small and very small containers or where there are other space limitations
- provide acceptable and unacceptable examples of the identifier and what constitutes acceptable 'accompanying' of the batch and expiry
- give medicine sponsors more guidance on batch number and expiry date including expiry information for packages once opened. For example, including a space for 'open date' on certain medicines with short term in-use, such as eye drop.

Questions – batch number and expiry date

49. Do you agree with the proposed changes to stop allowing embossing or debossing batch numbers and expiry dates on the primary pack, unless they are also printed or clearly contrast with a dark background? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes might affect you.
50. Do you agree with the proposed changes to requirements for prefixes of batch numbers and expiry dates? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes may affect you. If you have any suggestions or comments about the planned guidance for batch numbers and expiry dates, please include them.

7.2 Sponsor or distributor name and contact details

Medicine labels must show the name and contact details of the sponsor or distributor of the medicine. The sponsor is the company responsible for supplying the medicine in Australia. Including this

information helps consumers and health professionals identify who to contact if there are questions or concerns about the product.

Section 6 of the TGO 91 and TGO 92 defines 'name and contact details' which includes 'sufficient information to allow the sponsor or distributor to be uniquely identified so as to facilitate public contact.' The contact details must include information such as the city or suburb of the sponsor or distributor's main business location in Australia. A phone number, website or email address may also be included.

The address of the sponsor or distributor is not required by the labelling standards, but may be required by other legislation such as the Poisons Standard (the SUSMP) and Trade Measurement Laws. Sponsors should be familiar with the requirements of other, non-therapeutic goods-specific labelling legislation.

Section 6 also provides a 12-month period where the previous contact details may be supplied, allowing sponsors to use existing labels with the original details while they create new labels.

We have received some feedback that these requirements are unclear or could be improved.

Separate to the labelling standards, the Poisons Standard (the SUSMP) also requires medicine labels containing scheduled ingredients to include the name and address of the manufacturer or distributor on the label. As outlined in section 32, the address must be a physical address.

Proposed changes – sponsor or distributor name and contact details

We propose changes to reflect common communication methods used today and support consumers and health professionals to contact the sponsor when needed. We also want to make requirements clearer for medicine sponsors.

We propose:

- Not to the exclusion of any other legislation, to require at least one of the following Australian contact details to facilitate public contact, including complaints or adverse events:
  - Toll free phone number
  - Email address
  - Website address (with contact details on the website).

Medicines subject to the SUSMP also have additional requirements to include the name and address of the manufacturer or distributor.

We will also plan to include in updated guidance:

- Ensure compliance to any other relevant legislation that makes labelling requirements regarding contact details such as the SUSMP and Trade Measurement laws.
- We recommend that multiple contact methods are included on the label to facilitate contact by consumers preferring different communication methods.
- While distributor contact details may be included on the label instead of sponsor contact details, the sponsor has legal obligations for adverse event reporting and it is recommended to be included on the label to facilitate public contact.
- Where a distributor is included on the label, it is recommended to be preceded by words to identify that it is the distributor such as 'distributed by' or 'distributor'.
- Encourage sponsors to give more Australian contact details in addition to those printed on the label via a QR code.

If you have any concerns, please let us know in your response to the consultation questions. It also may reduce the need for sponsors to change labels if they change addresses.

These proposals do not change the existing requirements for sponsor address and contact details in the Product Information.

Question – sponsor or distributor name and contact details

51. Do you agree with the proposed changes to sponsor or distributor contact details on medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes might affect you. In your response, include:
    a. The contact details you think should appear on medicine labels.
    b. Any suggestions or comments about the planned guidance.

7.3 Excipient ingredients

Medicines often contain ingredients other than the active ingredients. These are called excipients or inactive ingredients. Examples include preservatives and tablet coatings.

Medicine labels do not usually list all excipients. However, some types of medicines are required to include this information in some cases. For example, injections must include excipients on the primary pack.

For many medicines, it would be difficult to fit all the excipient names on the label due to space limitations.

There are other ways to find out ingredient information. This is mentioned above in this paper in Declaring allergens and other substances. For more information, also see:

- Types of ingredients
- About active and inactive medicine ingredients
- I can't find what I'm looking for! on our Allergies and medicines page.

Excipient ingredients on vaccine labels with limited space

Vaccine containers are often small, which limits the space available for labelling and some excipients have long names.

Under TGO 91, injection labels must include the name and quantity of each excipient ingredient. Injections in containers with a capacity of 25 millilitres or less don’t need to include this information on the label if it appears on the primary pack.

Proposed changes – vaccine excipient ingredients

We are proposing changes to clarify how excipient information is provided on vaccine labels when space is limited. These changes aim to ensure people can still access this important information.

We propose that for injectable vaccines:

- The requirement to list the name and quantity of each excipient on the primary pack does not apply if:
  – the full list cannot fit due to the size of the primary pack, and

- the label includes a statement directing the user to the Product Information (PI) for a full list of excipients.

We plan to give medicine sponsors guidance including:

- suggested wording to direct users to the PI. For example, 'See the Product Information for a full list of excipients'
- advice on when the name of an excipient mix can be included if the full list of excipients does not fit.

Question – vaccine excipient ingredients

52. Do you agree with the proposed changes for showing vaccine excipients on labels with limited space? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes might affect you. If you have any suggestions or comments about the planned guidance, please include them.

Diluents in injectable medicines

Injections must include the name and quantity of each excipient ingredient, including diluents. except in certain circumstances. This is outlined in section 10 of TGO 91.

The diluents used in medicines, such as in intravenous infusion bags, are important information for health professionals when administering these medicines. Current guidance is silent on expectations regarding the presentation of diluents on labels. More guidance may be needed.

Guidance – diluents in injectable medicines

We are seeking feedback on providing more guidance for sponsors on clearly displaying diluents on labels for products such as intravenous infusion bags and other injectables.

Question – diluents in intravenous infusion bags

53. Do you think more guidance is needed on displaying diluents in injectable medicines? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Please include in your answer:
    a. Comments about how to make diluent information clear for health professionals on medicine labels. If possible, please give examples of labels you think are clear or not clear.
    b. Suggestions for improving the guidance.

Excipient ingredients – non-prescription medicines

Consumers may be better informed to make appropriate choices regarding medicine selection by having information about excipient ingredients on the medicine label, or a way to easily access it.

Proposed changes – excipient ingredients in non-prescription medicines

We are proposing changes to improve information about excipients on non-prescription medicine labels. This will help consumers understand where and how to find information about excipients.

We propose to require on non-prescription medicine labels any one of the following:

- the name of each excipient

- a statement explaining how to find excipient information (this could include a QR code in certain circumstances, see proposed requirements for QR codes)
- a statement directing consumers to the ARTG Public Summary
- we propose that small and medium containers would not need to include this information if they are enclosed in a primary pack that meets all labelling requirements.

We plan to give medicine sponsors guidance on acceptable wording for these statements. For example, 'For a full list of ingredients please download the ARTG public summary for this medicine.'; 'Please note that, ingredients in flavour, fragrance or colour ingredient mixes are not shown in the ARTG summary.'

Question – excipient ingredients in non-prescription medicines

54. Do you agree with the proposed changes to require either a list of excipients or a statement about how to find excipients on non-prescription medicine labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how these changes might affect you. If you have any suggestions or comments about the planned guidance, please include them.

7.4 Space for a dispensing label

Where prescription medicine labels can accommodate it, space must be reserved on the label for the pharmacist to attach a dispensing label. Sponsors can find guidance in Labelling medicines to comply with TGO 91 and TGO 92.

Space for a dispensing label is not required in some circumstances, such as where the medicine is intended for use only in a clinical setting, or where the label cannot accommodate the space needed due to other requirements.

Medicines such as injectables typically administered by healthcare professionals are sometimes dispensed direct to the end-user or carer and must have a dispensing label attached, for example, in some palliative care settings.

It is important to keep key information on the label visible after the pharmacist adds their dispensing label. Where space for a dispensing label is required, the label must include at least 70 x 30 millimetres of clear space. However, pharmacy systems typically use dispensing labels that are 80 x 40 millimetres.

Proposed changes – Space for a dispensing label

To help keep important information visible on prescription medicine labels and reflect the common size of dispensing labels used in Australia, we propose to:

- update the current requirements for dispensing label space, require a minimum size of 80 x 40 millimetres
- continue the current exceptions. For example, dispensing label space is not required if the medicine's packaging is too small to allow it

We also plan to continue to give guidance to medicine sponsors that:

- the size exemption does not apply if:
  - the label can be redesigned to include the required space
  - the label includes non-mandatory information that can be removed to make room for 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.

We propose to update guidance to recommend including space for a dispensing label when:

- a medicine is intended only for use in a clinical setting but may still be dispensed to a patient.

Question – space for a dispensing label

55. Do you agree with the proposed changes to requirements for including space on prescription medicine labels for a dispensing label? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and describe how these changes might affect you. If you have any suggestions or comments about the planned guidance, please include them.

8. Specific medicine types

TGO 91 and 92 outline specific requirements for certain types of medicine, including some types of:

- active ingredients
- packaging
- routes of administration.

8.1 Types of active ingredients

Vitamins in non-prescription medicines

Vitamins must be listed on labels by their approved scientific names. These names may not be familiar to most consumers. For example, labels must use ‘cyanocobalamin’ instead of the more common name ‘vitamin B12’. Some labels also include common names like ‘vitamin B12’, but this is optional.

Some warning statements use a common name such as ‘vitamin B12’, but the label may only show the scientific name. This difference could be confusing for consumers.

We received feedback that people want common names on vitamin labels. However, we recognise that some labels have limited space, such as those on small containers or medicines that contain many active ingredients, like multivitamins. We also need to make sure the information about each vitamin, including how much is in the medicine, is clear.

The labelling standards currently allow the common name of vitamins to be included between the approved name of the active ingredient and the quantity of that active ingredient. These requirements are in subsection 9(3) and 11(5) of TGO 92.

Displaying vitamin names on medicine labels is subject to strict controls set out in the Therapeutic Goods Act 1989 (Act), the Therapeutic Goods Regulations 1990 and the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code). Under this framework, representing or referring to goods as a vitamin is a 'prohibited representation' unless the goods are composed of, or contain a substance specified in Part 3 of Schedule 2 to the Regulations, or are a salt or derivative of that substance. These controls are not part of this consultation.

Proposed changes – vitamins – expressing active ingredients on non-prescription medicines

We are proposing changes to make information about vitamin active ingredients clearer for consumers on medicine labels.

Our proposal includes:

- For active ingredients that are vitamins listed in Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990, (vitamin active ingredients), require both the common name (for example, 'Vitamin B12') and the approved name of the active ingredient (for example, cyanocobalamin) on non-prescription medicine labels.
- Require the names of vitamin active ingredients to be presented with the common name first, followed by the approved name in brackets, then the quantity of the vitamin. For example:
  - Vitamin B12 (from cyanocobalamin) 10 micrograms.
  - Vitamin C (from calcium ascorbate) 85 mg.
    - (Note: the quantity for the Vitamin C example is displayed as 85 mg ascorbic acid as Vitamin C from 100 mg calcium ascorbate dihydrate).
- Change the requirements for expressing the quantity of vitamin active ingredients.
  - Require the quantity of active ingredients that are vitamins listed in Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990 to be expressed as:
    - the total quantity of the vitamin (as listed in Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990) in the medicine
    - as a currently accepted unit of proportion for the vitamin included in the eBS code tables. For example, metric units, International Units, Retinol Equivalents as relevant to specific vitamins.
  - Where there is more than one active ingredient contributing to the total quantity of a common name, allow these to be grouped under the common name. For example:
    - Vitamin C (from calcium ascorbate and sodium ascorbate) 500 mg.
    - Vitamin B6 (from pyridoxine hydrochloride and pyridoxine 5-phosphate) 50 mg.
- Not allow abbreviations of the word vitamin, such as 'Vit'.
- Include in guidance, that the requirements for labelling vitamins are also subject to other legislation such as Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990.

Question – vitamins

56. Do you agree with the proposed changes for showing vitamin active ingredients on non-prescription medicine labels? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes might affect you.

Herbal medicines

The type of herbal ingredient in a medicine determines how its quantity must be shown on the label. These requirements are set out in subsection 11(2) of TGO 92.

For example, if an active ingredient is a standardised herbal preparation, then the label must show all the following:

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

Examples are included in the guidance, such as:

- *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
- *Camellia sinensis* ext. 5 mg, from 500 mg (min) dry leaf, contains 30 mg of std. catechins.

Standardisation is a process where the content of specific chemical constituents has been determined in an herbal material or herbal preparation. For some herbal medicines, the weight of the raw material used in a batch may vary according to the content of the standardised component.

Showing minimum weight of the herbal material may prevent misleading consumers. However, medicine sponsors have told us these requirements can cause problems. For example, they may not align with some manufacturing requirements.

Proposed changes – standardised herbal materials and preparations

We are proposing changes to improve consistency in requirements for medicine sponsors.

We propose to:

- Change the current requirements for expressing the quantity of a standardised herbal material to include the following:
  - the dry or fresh weight of herbal material (that is, the ‘average’ dry or fresh weight), and
  - the quantity of standardised constituent(s) in the herbal material.
- Change the current requirements for expressing the quantity of a standardised herbal preparation to include the following:
  - the weight of that preparation and
  - the dry or fresh weight of the herbal material from which the preparation was derived and
  - the quantity of standardised constituent(s) in the herbal preparation.

Planned guidance – herbal medicines

We also plan to clarify the guidance about expressing herbal medicines on labels. This may include:

- examples to avoid duplication of information
- more guidance about including additional information on labels such as:
  - herbal ingredient components
  - herbal common names.

Question – herbal medicines

57. Do you agree with the proposed changes for labelling herbal medicines to allow ‘average’ weight instead of minimum weight in certain circumstances? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes might affect you. If you have comments about the planned guidance for herbal medicines, please include them.

Sunscreens

Sunscreen labels give consumers important information. Read more about interpreting sunscreen labels on our website.

Therapeutic sunscreens regulated by the TGA must meet all labelling requirements for therapeutic goods including TGO 92. Our guidance on understanding the regulation of therapeutic sunscreens includes some information about labelling requirements.

Standards Australia publish an Australian/New Zealand Sunscreen Standard (*Australian/New Zealand Standard (AS/NZS) 2604:2021*) for sunscreens which provides the testing requirements for sunscreens marketed in Australia and some labelling requirements relating to sunscreen performance and directions for use. The standard includes specific directions for use label instructions for spray and pump packs sunscreens, but does not refer to other dosage forms.

Proposed changes – sunscreens

In the new standard replacing TGO 92, we propose to consolidate the labelling requirements relating to sunscreen usage instructions from the sunscreen standard with additional information to manage risks associated with any type of dosage form.

- All sunscreen labels must:
  - Clearly indicate the product is only for dermal application on unbroken skin.
  - Provide applicable storage directions for products, for example, protect from direct light, heat.
  - Include the following statements (or words to this effect):
    - ‘Apply generously to the skin 20 minutes before skin exposure, then reapply frequently, and after swimming, sweating or towelling’.
    - ‘Wait for 15 minutes after application before swimming or putting on clothes.’

We also propose that sunscreens in the following dosage forms must also include certain statements on the label (or words to this effect):

- For dosage forms with a risk of inhalation (for example, sprays, foams/mousses):
  - ‘Use in a well-ventilated area.’
  - ‘Avoid inhalation.’
- For dosage forms with a risk of contact with eyes, nose or mouth (for example, sprays, foams/mousses):
  - ‘Do not spray/ apply directly to the face. Spray/ apply onto hands and then apply to the face.’
- For dosage forms that require even distribution of the active ingredients (for example, sprays) before application:
  - ‘Shake well before use.’
- For dosage forms that can be dispersed by environmental conditions (such as sprays, mousses), one of the following:
  - ‘Apply out of the wind.’
- For dosage forms with a risk of inadequate application (for example, sprays, roll-on):
  - ‘Apply generously and evenly on all exposed skin.’
- For sunscreens administered as a spray:

– ‘Hold container 10 to 15 cm away from the body.’

Question – sunscreens

58. Do you agree with the proposed changes to requirements for sunscreen labels? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. How might these changes affect you?

8.2 Types of packaging

Medicine containers and packaging vary in size. Some have very limited space for labels. TGO 91 and 92 outline labelling rules for certain types of packaging and include some allowances for medicines supplied in small containers, or where there is not enough space to include all required label information.

Printed plastic ampoules

Some medicines in plastic ampoules do not meet the current labelling requirements because the label space is very small. This mostly affects products where the text is stamped directly onto the ampoule. To allow supply of these medicines, the TGA has granted Section 14 consents.

The previous labelling standard [39] allowed the product name, name of the active ingredients and quantity to be abbreviated on plastic ampoules in some circumstances. For example, the product name might include the active ingredient, so it is not listed again below the product name.

These rules changed when TGO 91 and TGO 92 were introduced to make it easier to find important information on medicine labels.

Specific requirements for plastic ampoules are outlined in subsection 10(15) of TGO 91 and subsection 10(10) of TGO 92. Updating these requirements to reflect accepted labelling practice will reduce the need for Section 14 consents to supply.

Proposed changes – printed plastic ampoule

We propose changes to requirements that reflect accepted labelling practice for plastic ampoules. The proposal includes:

- Where the active ingredient is clearly included in the name of the medicine, it does not need to be repeated below the medicine name.
- Carton (primary pack) labels must meet the full requirements in the new labelling standard.

Guidance will include examples of acceptable printed ampoule labels to help sponsors apply the rules.

Question – printed plastic ampoules

59. Do you agree with the proposed changes for printed plastic ampoules to not require the active ingredient name to be printed if it is included in the medicine name? *(Yes / Partially agree / No / Unsure)*. Please explain your answer and tell us how the changes might affect you. Please include in your answer:

[39] Therapeutic Goods Order No. 69 - General requirements for labels for medicines

a. Comments about making these labels clear for health professionals. If possible, please give examples of printed plastic ampoule labels you think are clear or unclear.

b. Suggestions or comments about the planned guidance.

Blister, strip and dial dispenser packs

Blister, strip and dial dispenser packs must include specific information when supplied inside a primary pack. They usually show less information than the primary pack. Important usage information may be lost if the blister label does not contain enough information to be reunited with the correct primary pack.

Planned guidance – blister packs

We plan to give sponsors more guidance on how to label blister packs to support the safe use of medicines and improve clarity of requirements. This includes:

- For modified release medicines, ensure the pack shows this, for example, in the medicine's name.
- Print information in a pattern so that it stays readable while the pack is in use.

Question – blister packs

60. Do you agree with the planned guidance for labelling blister packs? (*Yes / Partially agree / No / Unsure*). Please explain your answer.

8.3 Route of administration

TGO 91 and 92 outline specific requirements for certain routes of administration (how the medicine is given).

Injections

TGO 91 requires injection labels to include specific information. The container's capacity determines some of these requirements.

For example, subsection 10(3) of TGO 91 requires a statement on concentrated injections in containers of 100 millilitres or less. The label must include a direction not to administer the solution undiluted, for example, 'dilute before use.' TGO 91 does not require this for injections in containers over 100 millilitres, but these are rarely concentrated.

Subsections 8(1) and 9(1) require the label to show how the injection is given (the route of administration). Because label space is often limited, abbreviations are sometimes used, such as 'IM' for intramuscular.

We propose a minor change to make the rules clearer. This will also cover the rare case where a concentrated injection is in a container larger than 100 millilitres.

Proposed changes – direction to not administer concentrated injections undiluted

We propose:

- If a medicine is a concentrated solution of injection in a container over 100 millilitres, the label must include:
  - a direction not to administer the solution undiluted.

Planned guidance – injection route of administration

We plan to give sponsors more guidance on how to label injections to support the safe use of medicines. This includes guidance about:

- route of administration statements
- prominence of the route of administration
- abbreviations for route of administration, for example, recommending acceptable abbreviations outlined in Recommendations for safe use of medicines terminology.

Question – injections

61. Do you agree with the proposed changes to requirements for including a statement on concentrated injections? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes might affect you.
62. Do you agree that more guidance is needed on showing the route of administration on injectable medicine labels? *(Yes / Partially agree / No / Unsure).* Please explain your answer and give us your suggestions for the guidance.

Listed medicines with a vaginal route of administration

Some medicines used vaginally must include certain statements on the label as set out in RASML. Other medicines used vaginally may also need warning statements to help ensure they are used safely.

In general, ingredients permitted for use in listed medicines have not been evaluated for safety in pregnancy when administered intravaginally, nor whether there is a risk to fertility/foetus. Medicines administered via vaginal routes have the potential for higher exposure and systemic absorption. Additionally, vaginal routes of administration pose significant pharmacokinetic issues in pregnancy, as the venous plexus communicates with the uterine venous plexus directly and so drug exposure 'locally' to the foetus can potentially be higher than by systemic pharmacokinetics.

Proposed changes – Listed medicines with a vaginal route of administration

We propose changes to requirements to support the safe use of medicines.

We propose:

- Listed medicines with a vaginal route of administration must have the following label statement:
  - 'Do not use if pregnant or likely to become pregnant'.

Question – listed medicines with a vaginal route of administration

63. Do you agree with the proposal to require a label statement for listed medicines with a vaginal route of administration? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes might affect you.

9. Label presentation and design

Section 7 of TGO 91 and TGO 92 outlines the general rules for labels, including presentation.

Labelling medicines to comply with TGO 91 and TGO 92 provides guidance and some best practice recommendations for label design.

9.1 Colour contrast

Paragraph 7(2)(e) of both Orders requires that label information be in a colour (or colours) that strongly contrast with the background. There are some exceptions for batch numbers and expiry dates, elsewhere in this paper.

The guidance aims to help sponsors meet these requirements and gives some recommendations about colour contrast. Stakeholders have told us that this guidance needs improvements.

Planned guidance – colour contrast

We plan to update the guidance to:

- encourage use of a colour contrast tool
- remove references to a specific tool
- recommend a colour contrast ratio of at least 4.5:1 between the foreground and background colours.

Question – colour contrast

64. Do you agree with the planned guidance updates about colour contrast? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

9.2 Graphics on prescription medicines

TGO 91 has limited rules about the use of graphic on prescription medicine labels. Subsection 9(3) requires that graphics must not interrupt the cohesive unit of the medicine name and active ingredient.

Labelling medicines to comply with TGO 91 and TGO 92 gives sponsors some guidance about using graphics in relation to subsection 9(2) and 9(3) of TGO 91, however guidance is largely limited to the positioning and interference risk of graphics. Guidance regarding acceptable graphic depictions on labels is not covered.

Planned guidance – graphics on prescription medicines

We plan to update the guidance to help sponsors use graphics appropriately. This includes guidance regarding:

- graphics on prescription medicines, which are generally discouraged. If used, graphics should be considered carefully to ensure they are informative and not promotional, misleading or suggesting an indication or other restricted representation.
- tablet and capsule images are permitted only if they are accurately printed or embossed/debossed.

Question – graphics on prescription medicines

65. Do you agree with the planned guidance updates about graphics on prescription medicines? *(Yes / Partially agree / No / Unsure).* Please explain your answer and tell us what you think should be included in the guidance.

9.3 Differentiating medicines

Clear identification of medicines is important to support their safe use. TGO 91 and 92 include requirements to ensure the medicine name and information about active ingredients are prominent and clear on the main label (in subsections 9(2) and 9(3)). These and other requirements help to assist in distinguishing between different medicines.

Reading the medicine label carefully is important to identify and select the correct medicine. Guidance for health professionals on the safe selection of medicines is available, including the Australian Commission on Safety and Quality in Health Care's Principles for the safe selection and storage of medicines.

In addition to legislated requirements for medicine labels, Labelling medicines to comply with TGO 91 and TGO 92 includes some recommendations and best practice guidance to support the safe and quality use of medicines. This includes some recommendations about the use of colour in differentiating medicines. However, the guidance is perfunctory or silent on several aspects of medicine differentiation.

Planned guidance updates – differentiating medicines

To further support differentiating medicines, we plan to update the guidance to include:

- minor updates to give more guidance about differentiating medicine strengths and formulations and unacceptable presentation.
- consider clinical use and environment of your medicine when designing labels. For example, if your medicine is used in an environment with neuromuscular blocking agents that have requirements for red colouring, avoid red colouring on your medicine.
- recommend white packaging to emphasise the colour that is used on labels.

Some of our proposed changes or guidance included in other sections of this consultation paper may also help with differentiating medicines. For example:

- Mandating common labelling practices such as red lettering for potassium for injection or infusion.
- Planned or proposed guidance:
  - Recommend insulin medicines display international units per mL prominently on the label (see Insulin).
  - More guidance or example labels about using colour block (see Planned guidance updates – active ingredients).
  - Information about liposomal medicines where there is a risk of medication errors (see Planned guidance updates – active ingredients).

See also 2023 targeted consultation on priorities for labelling improvements for some of our considerations about some of the feedback we received to help to differentiate medicines.

Question – differentiating medicines

66. Do you agree with the planned guidance updates about differentiating medicines? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. If you have suggestions for improving the guidance about differentiating medicines, please share them.

10. General requirements including application, exemptions, definitions and transition periods

TGO 91 and TGO 92 follow the same structure. This helps to make it easy to find certain requirements. For example, section 5 of both Orders lists exemptions. The guidance explains this in more detail.

Some stakeholders told us the Orders could be clearer. Following this consultation, we plan to develop the new labelling standards to replace TGO 91 and TGO 92. The new standards may look different to reflect best practices for developing legal instruments. Our goal is to also make the requirements clearer.

10.1 Medicines subject to TGO 91 and TGO 92

Section 3 outlines the medicines subjected to each Order.

Prescription and related medicines that are 'osmotic pumps'

In TGO 91, section 3 lists some exceptions. For example, medical gases and certain blood products are not covered by TGO 91.

'Osmotic pumps' are listed in TGO 91 as not being covered by TGO 91. This term may mean different things. There are some oral dosage forms that may be referred to as 'osmotic pumps' that the TGA do not exempt from TGO 91.

Proposed changes – 'osmotic pump' prescription medicines

We are proposing changes to clarify requirements and expectations.

We propose:

- Remove exception for 'osmotic pumps'. This means the new prescription medicine labelling standard would apply to prescription and related medicines as defined in Section 3 of TGO 91 that are considered 'osmotic pumps'.

Question – 'osmotic pumps'

67. Do you agree with the proposal to remove the exception for osmotic pumps? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how this change may affect you.

10.2 Exempt medicines

Some medicines meet the criteria of section 3 of the Orders but are exempt in certain circumstances. This is outlined in section 5 of each Order. For example, export only medicines do not have to comply

with TGO 91 or TGO 92. There are also some exemptions to specific requirements in the Orders. The current legislation has created situations where the exemptions are utilised outside of what was intended.

Exemptions for non-prescription medicines made up or compounded for an individual, or supplied during treatment

Exemptions for non-prescription medicines prepared by complementary healthcare practitioners and pharmacists

Some medicines prepared by complementary health practitioners do not have to comply with TGO 92.

This is outlined in paragraph 5(1)(m) which exempts medicines that are:

- 'made up or compounded extemporaneously, for a specific and individual case, by a complementary healthcare practitioner in the lawful practice of his or her profession.'

Only medicines prepared by some complementary healthcare practitioners, as defined in section 6 of TGO 92, are exempt. *'Complementary healthcare practitioner means a person described in paragraph 42AA(1)(c) of the Act.'*

Medicines made up or compounded by a pharmacist in the lawful practice of their profession are also exempt under paragraph 5(1)(k) of TGO 92.

Exemptions for non-prescription medicines supplied during treatment

TGO 92 also exempts some medicines supplied by a health professional during treatment.

Paragraph 5(1)(l) exempts medicines:

- 'supplied, in the course of treating a patient, by a health professional in the lawful practice of his or her profession.'

Only medicines supplied by health professionals, as defined in section 6 of TGO 92, are exempt. Health professional is defined in TGO 92 as including the following:

a. '*a health practitioner of any kind registered under a law of a State or Territory that provides for the registration of health practitioners of that kind; and*

b. *a biomedical engineer, prosthetist or rehabilitation engineer'.*

There is a risk that this exemption could be misunderstood or used inappropriately. Finished products not included on the ARTG should not be sold under this exemption.

Proposed change – Exemptions for non-prescription medicines made up or compounded for an individual, or supplied during treatment

We are proposing changes to clarify requirements. We propose to:

- Remove the exemption in paragraph 5(1)(l) of TGO 92 – 'supplied, in the course of treating a patient, by a health professional in the lawful practice of his or her profession.'
- Change the exemption in paragraph 5(1)(k) of TGO 92 for medicines made up or compounded extemporaneously from 'pharmacist' to 'health professional' to capture additional health professionals as defined in TGO 92.
- Keep the exemption in paragraph 5(1)(m) for medicines prepared by certain complementary health practitioners.

We are not proposing changes to the definition of complementary health practitioners at this time. Reviewing definitions linked to or included in other legislation is beyond the scope of this consultation.

Question – exemptions for non-prescription medicines

68. Do you agree with the proposed changes to exemptions for non-prescription medicines made up or compounded for an individual, or supplied during treatment? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how these changes may affect you. In your response, please include:

    a. circumstances and examples where medicines should or should not be exempt from TGO 92 in the course of treating a patient by a health professional

    b. if medicines made or compounded by health professionals should be exempt from TGO 92, which health professionals should this apply to.

Purpose of the medicine on the label (for non-prescription medicines)

Most medicines covered by TGO 92 must show the intended purpose (what the medicine is used for) on the label.

Paragraph 8(1)(n) outlines that the purpose is not needed when the medicine is:

- 'supplied solely to a complementary healthcare practitioner for supply to a person after affixing by the practitioner of an instruction label on the medicine following a consultation with that person'
- includes the statement 'For Practitioner Dispensing Only' on the label.

However, some of these medicines may be available for purchase online or in retail stores and sold without instructions being affixed to the medicine label by the retailer, with the consequence that a consumer may purchase and own a product without an intended purpose on the label. This raises concerns about how the exemption is being used, and if it should be continued.

Proposed changes – purpose of the medicine on the label

We are proposing changes to make medicine labels clearer for consumers.

We propose to:

- Require the purpose of the medicine to be stated on the label for medicines that are' For Practitioner Dispensing Only' by removing the exception of 8(1)(n)(i) in TGO 92.

Note that sponsors may still choose to include 'practitioner only' on their medicine label for business/marketing purposes and practitioners may still choose to provide additional directions for use to their patient following consultation, as per their professional association's code of conduct.

Question – purpose of the medicine (non-prescription medicines)

69. Do you agree with the proposed changes to require the purpose of the medicine on the label for non-prescription medicines that are 'For Practitioner Dispensing Only'? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how this change may affect you.

10.3 Text size

TGO 91 and TGO 92 set out the minimum text size for information required on medicine labels. The required size depends on several factors, including the type of information, the type of medicine and the size of the container. These requirements are explained in the guidance.

Text size for listed medicines in small containers

TGO 92 contains an error for listed medicines in small containers.

Paragraph 7(2)(d) states that listed medicines must display label information in a minimum text size of 1.5 millimetres. The exception is the AUST L number, which must be at least 1 millimetre.

However, subsection 10(7) incorrectly states that some information must be displayed in a minimum text size of 2 millimetres.

As clarified in the guidance, the correct minimum text height for listed medicines in small containers is 1.5 millimetres—not 2 millimetres.

Proposed changes – text size for listed medicines in small containers

We plan to correct the minimum text size requirements in TGO 92 for listed medicines in small containers. The minimum text size will be confirmed as 1.5 millimetres.

We will also update the guidance to reflect this change.

Question – text size for listed medicines in small containers

70. Do you agree with the planned changes to correct the text size requirements for listed medicines? (*Yes / Partially agree / No / Unsure*). Please explain your answer.

10.4 Main label definition

Medicines often have more than one label or different panels in one label. To avoid information being repeated unnecessarily on the medicine label, TGO 91 and TGO 92:

- define the ‘main label’ for a medicine (in section 6)
- set out the key information that must appear on the main label. Other required information can appear on other labels or panels.

Main label is defined in TGO 91 and TGO 92 as:

a. where there are two or more labels or two or more portions of a single label - that label or portion of the label where the name of the medicine is more or most conspicuously shown; or

b. where the name of the medicine is equally conspicuous on two or more labels or portions of a label – each label or portion;

The Poisons Standard also defines ‘main label’. This definition is more recent:

a. the part of the label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and

b. if there are 2 or more labels:

i. the label or the part of the label where the product name is more or most conspicuously shown; or

ii. if the product name is equally more or most conspicuously displayed on more than one of those labels—each of the labels on which the product name is equally more or most conspicuously displayed.

Proposed changes – main label definition

We propose:

- Align the definition of main label in the labelling orders with the definition in the Poisons Standard.

Question – main label definition

71. Do you agree with the proposal to change the definition of main label in TGO 91 and TGO 92 to match that of the Poisons standard (the SUSMP)? (*Yes / Partially agree / No / Unsure*). Please explain your answer and tell us how this change might affect you.

10.5 Transition periods for the new labelling standards

We propose a 3-year transition period for most changes. For labelling changes for large dosage forms, the proposed transition period is 2 years. You can read more in proposed transition periods.

Question – transition periods

72. Do you agree with the proposed transition periods for the new labelling standards? (*Yes / No, I think they should be shorter/ No, I think they should be longer/ Neither agree nor disagree / Unsure*). Please explain your answer. Tell us how the transition periods may affect you. In your answer, please include:
    a. if any proposed changes would be problematic to implement in the proposed timeframe
    b. if any proposals would benefit from longer or shorter transition periods.

11. Guidance structure

11.1 Guidance on labelling requirements and best practice recommendations

The current guidance 'Labelling medicines to comply with TGO 91 and TGO 92' helps sponsors and manufacturers meet the labelling requirements of both Orders.

It also includes recommendations and best practice principles for developing medicine labels to support the safe and quality use of medicines. These recommendations are not mandatory.

While there are 2 Orders to cover different medicine types, there is only one guidance document.

Planned guidance updates – structure and general plans

We plan to update the guidance to make it clearer and more useful for sponsors. Our plans include:

- splitting the guidance to reflect different types of medicines and different Orders
- an increased focus on how to label medicines with examples, with more references to other legislation and TGA guidance.

Question – guidance structure

73. Do you agree with the plan to update the structure of the guidance to reflect different types of medicines and different Orders? *(Yes / Partially agree / No / Unsure)*. Please explain your answer. Please also share any other suggestions or comments about the structure of the guidance.

Question – general feedback

This consultation focuses only on certain labelling requirements that may need improvements, as we believe TGO 91 and TGO 92 are working well. There is limited time before the new standards are introduced, and labelling rules must be carefully considered to avoid inconsistencies or unintended risks to medicine safety. We may only consider further suggested changes to requirements and guidance (beyond what we are already proposing) if time allows and it is essential for medicine safety.

74. Do you think any more changes should be made to medicine labelling requirements in the new standards replacing TGO 91 and TGO 92, that are critical to support medicine safety? *(Yes / Partially agree / No / Unsure)*. Please explain your answer.

75. If you have any other comments or general feedback about medicine labelling requirements, please include them here.

Appendices

Appendix 1: Summary list of proposed changes to labelling requirements

We have grouped and summarised the proposed changes to labelling requirements under the standards that will replace TGO 91 and TGO 92.

The table shows whether we think the proposals will increase, decrease or not affect the regulatory requirements for medicine sponsors. We welcome your feedback on how the changes may affect you. In particular, please consider the impact of the proposed transition periods, which gives medicine sponsors time to update labels, often as part of broader updates.

We have listed provisions from TGO 91 and TGO 92 that relate to the proposals. Please note that the structure of the new standards may be different. Also, some proposals are for new requirements which may be included in a different part of the new standards than indicated in the table.

Table 2: Summary list of proposed changes to labelling requirements and location in this consultation paper

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
1R	**Declaring allergens and other substances**					
1R.1	Require wheat (and its hybridised strains) to be declared as 'contains wheat' or 'contains wheat products' when present in the medicine for all routes of administration, irrespective of concentration.	All	Schedule 1	Schedule 1	1.1 Substances to be declared – Wheat	Increase

[40] We have given each proposal an ID number to help us track them. These numbers are different to section numbers in the paper and question numbers.
[41] TGA comments on how we expect the proposals will affect the regulatory requirements for medicine sponsors. While the regulatory requirements for some proposals may be increasing, the proposed transition periods allow sponsors to update their labels, often as part of regular broader business-as-usual label updates.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
1R.2	Require marine mollusc to be declared as 'contains mollusc' or 'contains mollusc products' when present in the medicine for all routes of administration. We propose not to specify a certain concentration for when mollusc needs to be declared.	All	Schedule 1	Schedule 1	Marine mollusc	Nominal increase but effectively no change as all medicines containing mollusc are listed medicines. No registered medicines currently contain mollusc products.
1R.3	Change requirement for declaring tree nuts. Require the following to be declared as the individual tree nut using these names: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio, walnut. For example, if almond is present in the medicine, it would need to be declared as 'contains almond' or 'contains almond products', instead of 'contains tree nuts' or 'contains tree nut products.' Require chestnuts to be declared as 'contains chestnut' or 'contains chestnut products'.	All	Schedule 1	Schedule 1	Tree nuts	Increase (better alignment with FSANZ labelling requirements).
1R.4	For medicines that are inhaled into the lungs or administered by injection or infusion: • Require 'contains milk products' to be declared for medicines containing lactose from milk origin. This may involve changing both the content in Schedule 1 and in note 4. Continue to require medicines with an oral route of administration containing lactose (and no other milk product) to only declare 'contains lactose' on the label. Amend Note 6, by changing 'dairy origin' to 'animal origin' to clarify that this includes milk from all animals.	All	Schedule 1	Schedule 1	Lactose and milk products	Increase

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
1R.5	Continue to require sulfites to be declared where added as an inactive ingredient/ excipient, regardless of concentration. Where sulfites have not been intentionally added but may be present in the medicine as an impurity, only require sulfites to be declared when present at 10mg/kg (10 ppm) or more.	All	Schedule 1	Schedule 1	1.2 When substances are declared – Sulfites	Decrease – fewer products will need to declare sulfites.
1R.6	Change the circumstance for gluten. Require gluten to be declared when present in a concentration of 3 ppm or more. Require the source of gluten to be declared.	All	Schedule 1	Schedule 1	Gluten	Increase
1R.7	Require pollen, propolis and royal jelly to be declared for all routes of administration rather than only when the medicine is for oral administration.	All	Schedule 1	Schedule 1	Pollen, propolis and royal jelly	Increase. However, listed medicines are already required to include a warning statement, regardless of route of administration under the Therapeutic Goods (Permissible Ingredients) Determination.
1R.8	Require declaration statements on the medicine label (rather than allowing a statement on the label to refer to the CMI), unless there is insufficient space to do so.	Prescription medicines	8(1)(j)	N/A	1.3 How substances are declared – Declaring substances for prescription medicines	Increase. Many medicines may already comply.
1R.9	Require aspartame to be declared as 'contains aspartame (phenylalanine)' when present in the medicine (instead of 'contains aspartame'). Change the note related to phenylalanine to give more clarity to medicine sponsors. Clarify that the entry applies to all medicines and reflect that in guidance.	All	Schedule 1	Schedule 1	Aspartame and phenylalanine	Increase

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
1R.10	Require hydroxybenzoic acid esters to be declared on medicine labels as 'contains hydroxybenzoates (parabens)' when present in the medicine (instead of 'contains hydroxybenzoates'). Clarify the requirements for declaring hydroxybenzoic acid esters to reflect what is currently included in the guidance about salicylates.	All	Schedule 1	Schedule 1	Hydroxybenzoates (parabens)	Increase
1R.11	Only require the name of any antimicrobial preservative where it is not already declared on the label as part of Schedule 1 requirements.	All	10(1) 10(9)	10(1) 10(2)	1.4 Minor changes or clearer requirements for declaring substances – Antimicrobial preservatives	Decrease
1R.12	Other minor changes to Schedule 1 including: • Clarify the statements that must be included on labels. For example, by clarifying the intent of column 4 of Schedule 1 where 'or' is included. • Clarify that lecithin derived from soya would need to declare presence of soya beans.	All	Schedule 1	Schedule 1	Other minor changes for declaring substances	No change

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
2R	**Active ingredients**					
2R.1	Allow the active ingredient name to appear without the hydration or solvate state on the main label in the cohesive unit where: • the strength of the active ingredient is not based on the hydrated or solvated form • the hydration or solvate state is not important for the safe use of the medicine. Require the full name of the active ingredient (as included in the Australian Approved Names List) to be displayed elsewhere on the label.	All	9(1)(b)	9(1)(b)	2.1 Hydrates, solvates and salts – Hydrates and solvates	Decrease
2R.2	Allow the active ingredient name to be expressed without the salt state in the cohesive unit when: • the strength of the active ingredient is based on the free base or acid • the salt is not important to the safe use of the medicine. Require the full name of the active ingredient (as included in the Australian Approved Names List) to be placed elsewhere on the label if the salt is removed from the cohesive unit.	All	9(1)(b)	9(1)(b)	Salts	Decrease

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
2R.3	Allow injectable vaccines in containers with a capacity of 3 millilitres or less, containing 4 or more active ingredients (or an active ingredient formulated with 4 or more strains, serotypes or variants) to: • not list all active ingredients on the label in certain circumstances (such as referring to PI and including a QR code). Allow all injectable vaccines to interrupt the 'cohesive unit' on the main label with a vaccine descriptor (in certain circumstances).	Prescription medicines	9(1)(b) 9(1)(c) 9(3) 10(5)	N/A	2.2 Vaccines	Decrease
2R.4	For listed medicines, update the requirements to allow active ingredients to appear on a side or rear panel when the medicine contains at least two active ingredients (of any type).	Listed medicines	N/A	9(5) 9(6)	2.3 Active ingredient size and location – Active ingredient location for non-prescription medicines	No change. Improve clarity.
2R.5	Require injectable solutions intended for single use with a total stated volume of 1 mL to express the volume of fill in numbers. For example, the active ingredient must be stated as '50 mg in 1 mL', not '50 mg/mL'. (This requirement would also permit, for example, '50 mg/1 mL', but this should be displayed as '50 mg in 1 mL', where space allows).	Prescription medicines	11(2)(f)	N/A	2.4 Active ingredient quantity expression – Injections	Increase Most medicines are expected to already meet proposed requirements.
2R.6	Remove 'concentrated solution for injection' from 11(2)(f)(i) (because concentrated injections must be expressed in the total volume of the medicine).	Prescription medicines	11(2)(f)	N/A	2.4 Active ingredient quantity expression – Injections	No change. Improve clarity and reflect current practices.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
2R.7	For medicines quantified in micrograms, 'microgram' must be displayed in full unless it does not fit on the label and is a label on a small (for TGO 92) or small or very small container (for TGO 91).	All	11(1)	11(1)	Units for active ingredient quantities – Microgram abbreviation	Increase
2R.8	For injectable medicines intended for use as a single dose, that the quantity of active ingredients must be shown as either: • the stated weight of the active ingredient in the stated volume of fill of the injection in the container, or • if the dose is measured in units in clinical practice, as the number of units.	Prescription medicines	11(2)(f)	N/A	Injectable medicines active ingredient quantity units	No change. Improve clarity and reflect current practices. Most medicines are likely to already meet proposed requirements.
2R.9	For the components of injectable nutritional therapy that are not electrolytes, that the quantity of active ingredients must be shown as the stated weight of the active ingredient in the stated volume of fill of the injection in the container.	Prescription medicines	11(2)(f)	N/A	Parenteral nutritional therapy quantity units	No change or minor change. Improve clarity and reflect current practices. Most medicines are likely to already meet proposed requirements.
2R.10	Include new activity units for certain enzymes in Schedule 3 (specified units for enzymes), as shown in Table 1.	Non-prescription medicines	N/A	11(2)(i) Schedule 3	Specified units for enzymes	No change or minor change. Improve clarity and reflect current practices.
2R.11	Require the quantity of active ingredients that are non-viable biological organisms to be expressed as: • the number of non-viable cells present per metric unit for liquids and powders and as the number of non-viable cells present per dosage unit for other dosage forms.	Non-prescription	N/A	11(2)(i)(v)	Probiotics and postbiotics quantity units	Minor change. Improve clarity.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
2R.12	Where potassium is the principal active ingredient in an injectable medicine (for example, 10 mmol potassium chloride and 0.29% sodium chloride 100 mL) that at least the name of the medicine, active ingredient and quantity must be in red font.	Prescription medicines	Section 10	N/A	2.5 Potassium for injection or infusion	Increase. Most impacted medicines may already meet proposed requirements.
2R.13	Make it clearer that when active ingredients and their quantities are included on the side or rear panel as permitted under section 9, that the relevant requirements of subsection 9(3) still apply including: • The active ingredient name and quantity cannot be interrupted with additional information not permitted for the cohesive unit on the main label. • The cohesive unit requirements to list the name and quantity of each active ingredient on separate lines of text also applies to the side panel.	All	9(3) 9(6)	9(3) 9(5) 9(6) 9(7)	2.6 Clarifying how active ingredients must be displayed	Minor change. Improve clarity.
3R	**Name of the medicine**					
3R.1	Require the name of the medicine and 'cohesive unit' to be immediately below the signal heading. Require the name of the medicine on the label to be unique. For example, where the sponsor or distributor name is included in the ARTG name and this is needed to differentiate the medicine from other medicines, it would need to be included in the name of the medicine on the label and be presented in a continuous, uninterrupted manner.	Prescription	New	N/A	3.1 Name of the medicine presentation for prescription and related medicines	Increase (depending on outcome). Most medicines already meet proposed requirements.
3R.2	Change requirements for non-prescription medicines to permit the name of the medicine to be interrupted by a distinguishing mark related to the medicine's branding in certain circumstances. Add a definition of 'distinguishing mark'.	Non-prescription	N/A	9(2) 9(3)	3.2 Name of the medicine presentation for non-prescription medicines	Decrease. Improve clarity and reflect some current labels.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
4R	**Dosage form**					
4R.1	Change the requirement for including dosage form on labels to allow the 'name of the dosage form' (as currently defined) or the name of the pharmaceutical form that is consistent with the 'name of the dosage form'.	All	8(1)(d)	8(1)(d)	4.1 Name of the dosage form	Decrease
5R	**Warning statements**					
5R.1	Require modified release and enteric coated tablets, capsules and granules for oral administration to include on the label: • A statement denoting the approved method of administration such as 'Swallow whole' and a warning statement against other methods of administration such as 'Do not crush or chew'.	All	New	New	5.1 Modified release and enteric coated medicines	Increase. Some medicines may already meet the requirements.
5R.2	Medicines subject to TGO 92 with large solid oral dosage forms must include a warning statement, image of dosage form (if the container is not transparent), and a direction to swallow with water, if they exceed certain size limits. Transition period of 2 years.	Non-prescription	N/A	New	5.3 Non-prescription medicines with large solid oral dosage forms	Increase Note: for listed medicines, proposal is a decrease from the proposed requirement in 2024.
5R.3	Require listed medicines to prominently display all warning statements.	Listed medicines	N/A	Section 8	5.4 Warning statement visibility for listed medicines	Increase.
6R	**QR codes, machine-readable codes and instructions for preparation**					
6R.1	New requirements for QR codes including a statement to explain purpose, requirements for the linked website and content accessed via the QR code.	All	New	New	6.1 QR codes	Increase, most proposed requirements are currently in guidance.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
6R.2	For injectable medicines administered by healthcare professionals that are manufactured or imported after 1 September 2029 and where the Secretary, when registering or varying a registration, considers it appropriate: • Allow QR codes on labels that link to approved electronic instructions instead of a package insert where preparation information cannot fit on the label – in certain circumstances.	Prescription medicines – Injectable medicines administered by healthcare professionals	8(1)(l)	N/A	6.3 Instructions for preparation before use – Instructions for preparation of injectable products administered by healthcare professionals	Decrease
7R	**Other information displayed on labels**					
7R.1	Cease embossed or debossed batch numbers and expiry dates on the primary pack, unless they are also printed or clearly contrast with a dark background.	All	Section 7	Section 7	7.1 Batch number and expiry date	Increase
7R.2	Update requirements for batch number and expiry date prefixes to allow for some printing or packaging limitations. Allow the batch number and expiry date identifier to 'accompany' rather than necessarily 'precede' the batch number and expiry date.	All	Section 6 Section 8	Section 6 Section 8	7.1 Batch number and expiry date	Decrease
7R.3	Require at least one of the following Australian contact details to facilitate public contact: • Phone number • Email address • Website address (with contact details on the website). Note: The address of the sponsor or distributor may be required by other legislation such as the SUSMP and Trade Measurement Laws.	All	Section 6 8(1)(i)	Section 6 8(1)(i)	7.2 Sponsor or distributor name and contact details	Increase, however most medicines already meet requirements to meet current requirements for 'sufficient information to allow the sponsor or distributor to be uniquely identified so as to facilitate public contact '.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
7R.4	For injectable vaccines, the name and quantity of each excipient is not required on the primary pack if: • The full list cannot fit due to the size of the primary pack. • The label includes a statement directing the user to the Product Information (PI) for a full list of excipients.	Prescription medicine	10(3)	N/A	7.3 Excipient ingredients – Excipient ingredients on vaccine labels with limited space	Decrease
7R.5	Medicines subject to TGO 92 must include on the label either, the name of each excipient or a statement explaining how to find excipient information (for example, via QR code).	Non-prescription medicines	N/A	New	Excipient ingredients – non-prescription medicines	Increase for labels not including a QR code.
7R.6	Update the current requirements for dispensing label space. Require a minimum size of 80 x 40 millimetres. Continue the current exceptions. For example, dispensing label space is not required if the medicine's packaging is too small to allow it. (If the full space cannot fit, we will continue to expect a smaller space to be included where possible).	Prescription medicines	8(2)	N/A	7.4 Space for a dispensing label	Nominal increase. However, where a larger dispensing label space cannot fit, medicine sponsors do not need to change labels.
8R	**Specific medicine types**					
8R.1	For active ingredients that are vitamins and listed in Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990 require both the common name (for example, 'Vitamin B12') and the approved name of the active ingredient (for example, cyanocobalamin) on medicine labels. Require the common name to be presented first. Change the requirements for expressing the quantity of vitamin active ingredients. Not allow abbreviations of the word 'vitamin.'	Both	Section 9	Section 9	8.1 Types of active ingredients – Vitamins in non-prescription medicines	Increase. Increase/decrease depending on circumstance. Improve clarity Some medicine labels may already comply with the proposed requirements.

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
8R.2	Change the current requirements for expressing the quantity of a standardised herbal material or standardised herbal preparation to permit use of 'average' dry or fresh weight instead of minimum.	Non-prescription medicines	N/A	11(2)	Herbal medicines	Decrease.
8R.3	Require sunscreens to include certain statements on the label.	Non-prescription medicines	N/A	New	Sunscreens	Increase Improve clarity. Some medicine labels may already comply with some of the proposed requirements.
8R.4	New labelling requirements for printed plastic ampoules. If the active ingredient is clearly included in the name of the medicine, it won't need to be repeated below the medicine name. Carton (primary pack) labels must meet the full requirements in the new labelling standard.	All	10(15)	N/A	8.2 Types of packaging – Printed plastic ampoules	Decrease
8R.5	If a medicine is a concentrated solution of injection in a container over 100 millilitres, the label must include a direction not to administer the solution undiluted.	Prescription medicines	10(2)	N/A	8.3 Route of administration – Injections	No change or minor increase. Minor change to improve clarity and cover rare case.
8R.6	Listed medicines with a vaginal route of administration must include the statement 'Do not use if pregnant or likely to become pregnant'.	Listed medicines	N/A	Section 10?	Listed medicines with a vaginal route of administration	Increase.
9	**Label presentation and design**					
	(No proposed changes to requirements. See summary list of planned guidance in Appendix 2.)					
10R	**General requirements including application, exemptions, definitions and transition periods**					

ID[40]	Proposed change	Medicine type	TGO 91	TGO 92	Location/ details	Regulatory requirement comments[41]
10R.1	Remove exception for 'osmotic pumps'.	Prescription medicines	3(1)(a)(iii)	N/A	10.1 Medicines covered by TGO 91 and TGO 92	No change. For example, oral tablet prescription medicines that might be considered 'osmotic pumps' are expected to comply with TGO 91.
10R.2	Remove the exemption in paragraph 5(1)(l) of TGO 92 'supplied, in the course of treating a patient, by a health professional in the lawful practice of his or her profession.' Change the exemption in paragraph 5(1)(k) of TGO 92 for medicines made up or compounded extemporaneously from 'pharmacist' to 'health professional'.	Non-prescription medicines	N/A	5(1)(l) 5(1)(k)	10.2 Exempt medicines	Increase
10R.3	Require the purpose of the medicine to be stated on the label for medicines that are' For Practitioner Dispensing Only' by removing the exception of 8(1)(n)(i) in TGO 92.	Non-prescription medicines	N/A	8(1)(n)	Purpose of the medicine on the label (for non-prescription medicines)	Increase
10R.4	Correct the minimum size text size requirements in TGO 92 for listed medicines in small containers.	Listed medicines	N/A	10(7)	10.3 Text size	No change. Decrease in requirements but guidance clarifies expectations.
10R.5	Update definition of main label to align with the definition in the Poisons Standard.	All	Section 6	Section 6	10.4 Main label definition	No change

List of proposed changes to labelling requirements.

Appendix 2: Summary list of planned guidance updates

We plan to publish new guidance to reflect the new instruments replacing TGO 91 and TGO 92. We also plan to use guidance to give medicine sponsors more clarity on some aspects of labelling.

Some of the specific plans for the new guidance included in this paper are grouped and summarised in the following table.

Table 3: Summary list of planned updates to guidance and location in this consultation paper

ID	Proposed or planned guidance update	Medicine type	Details and location
1G	**Declaring allergens and other substances**		
1G.1	Guidance on label statements to meet the proposed requirements for both declaring wheat and declaring the source of gluten.	All	1.2 When substances are declared – Gluten
1G.2	Clarify the requirements for declaring pollen by stating in the guidance that: • Pollen, when present, should be declared irrespective of its source (isolated pollen, bee pollen or when present as a component of a flower or other plant part).	All	Pollen, propolis and royal jelly
1G.3	Clarify requirements for declaring phenylalanine.	All	1.3 How substances are declared –Aspartame and phenylalanine
1G.4	Recommend that preservatives are declared on labels as 'Contains [name of preservative] as preservative.'	All	1.4 Minor changes or clearer requirements for declaring substances – Antimicrobial preservatives
1G.5	More guidance about declaring substances without cut-off limit in Schedule 1.	All	Other minor changes for declaring substances
2G	**Active ingredients**		
2G.1	Update guidance to reflect proposed changes to hydrates, solvates and salts, including circumstances where the salt name should remain as it is important to the safe use of the medicine, such as when: • more than one salt of the active ingredient is registered in Australia • the salt may contribute a clinically significant amount of electrolyte, such as sodium.	All	2.1 Hydrates, solvates and salts

ID	Proposed or planned guidance update	Medicine type	Details and location
2G.2	Guidance on proposed changes to requirements for expressing vaccine active ingredients, including: • suggested wording for directing users to the PI • suggested presentations for vaccine descriptors (for example, using a different font to distinguish the name of the medicine from the vaccine descriptor) • example labels.	Prescription medicines	2.2 Vaccines
2G.3	Recommend that on the main label of the primary pack the text size of the active ingredient should be at least 50% of the name of the medicine height, or 3 mm, whichever text size is greater.	Registered medicines	2.3 Active ingredient size and location
2G.4	For registered non-prescription medicines, clearer guidance about when sponsors do not need to repeat the name of the active ingredient below the name of the medicine (when the name of the active ingredient and its quantity is clearly included in the name of the medicine).	Registered non-prescription medicines	Active ingredient location for non-prescription medicines
2G.5	Recommend insulin medicines display international units per mL prominently on the label, for example displaying '100 IU/mL' or '300 IU/mL' near the name of the medicine, with examples. Encourage sponsors to display the concentration on the individual pens in the largest possible font.	Prescription medicines	2.4 Active ingredient quantity expression – Insulin
2G.6	Strengthen the guidance to support clear and standardised expression. For example: • Single-use injectable solutions should be expressed as, for example, '50 mg in 1 mL', rather than '50 mg/1 mL', where space allows. • Vaccines and antivenoms should be expressed as 'X microgram per Y mL dose', where space allows.	Prescription medicines	Injections
2G.7	Clarify in guidance that for expressing retinol equivalents, acitretin, tretinoin and isotretinoin, are not considered derivatives of vitamin A and do not need to also express active ingredient quantity in terms of microgram retinol equivalents.	Prescription medicines	Retinol equivalents for prescription medicines
2G.8	Recommend that active ingredients such as colecalciferol (vitamin D3) are labelled with both micrograms and international units.	All	Dual presentation of units
2G.9	Update guidance to reflect proposed changes for potassium for injection or infusion, including to remind sponsors that the red font must comply with section 7 for visibility and legibility.	Prescription and related medicines	2.5 Potassium for injection or infusion

ID	Proposed or planned guidance update	Medicine type	Details and location
2G.10	More example labels in the guidance including about: • expressing active ingredients when present as salts • meeting cohesive unit requirements, including for combination prescription medicine products • using colour or colour blocks to help differentiate strengths.	Prescription medicines	2.7 Planned guidance updates – active ingredients
2G.11	Advice for liposomal medicines where there is a risk of medication errors. The term 'liposomal' or 'pegylated liposomal' should be included on the main label (and in the name of the medicine on the ARTG), in line with other regulators.	Prescription medicines	2.7 Planned guidance updates – active ingredients
2G.12	Trailing zeros should be avoided. For example, 1 mg should not be displayed as 1.0mg as it has a risk of being mistaken for 10 mg.	All	2.7 Planned guidance updates – active ingredients
2G.13	Guidance on limited circumstances when active ingredient quantity rounding may be appropriate on labels.	All	2.7 Planned guidance updates – active ingredients
2G.14	Clearer guidance on expressing active ingredient quantities for different dosage forms or presentations of biological medicines.	Prescription medicines	2.7 Planned guidance updates – active ingredients
3G	**Name of the medicine**		
3G.1	Guidance on the name of the medicine including: • Label examples to make it clearer when and how the sponsor's name can be included separately on the label. For example, where the medicine has a unique name that does not include the sponsor's name, then the sponsor's name can be included in the bottom right corner of the main label. • More guidance about fixed dose combination products including that strengths of fixed-dose combination products should be included in the name of the medicine. For example, 'Name 10/5'. • Guidance about active ingredient prominence in relation to the name of the medicine.	Prescription medicines	3.1 Name of the medicine presentation for prescription and related medicines

ID	Proposed or planned guidance update	Medicine type	Details and location
3G.3	Recommend that while only the 'name of the medicine' is required on at least 3 non-opposing sides of a carton, that the whole 'cohesive unit' including the name of the active ingredients and quantity of active ingredients is displayed on at least 3 non-opposing sides.	Prescription medicines	3.1 Name of the medicine presentation for prescription and related medicines
3G.2	Examples of acceptable label layouts and positioning of the name of the medicine for non-prescription medicines.	Non-prescription medicines	3.2 Name of the medicine presentation for non-prescription medicines
4G	**Dosage form**		
4G.1	More guidance on how to express dosage forms on labels including: • Guidance to support proposed changes and support consistency in dosage form expression. • More guidance about modified release dosage forms.	All	4.1 Name of the dosage form
5G	**Warning statements**		
5G.1	Examples of preferred or acceptable statements to comply with proposed requirement for including a statement on modified release and enteric coated tablets medicines.	All	5.1 Modified release and enteric coated medicines
5G.2	Updates to guidance for prescription medicines including: • Strengthen recommendations for some warning statements, such as those for vinca alkaloids. • Advise sponsors to consider warning statements included on innovator product. • Clarify warning statements expected on prescription medicine labels.	Prescription medicines	5.2 Warning statements for prescription and related medicines
5G.3	Updates to reflect proposed requirements for non-prescription medicines with large solid oral dosage forms.	Non-prescription medicines	5.3 Non-prescription medicines with large solid oral dosage forms
5G.4	Examples of prominently displayed warning statements for listed medicines.	Listed medicines	5.4 Warning statement visibility for listed medicines

ID	Proposed or planned guidance update	Medicine type	Details and location
6G	**QR codes, machine-readable codes and instructions for preparation**		
6G.1	More advice when using QR codes.	All	6.1 QR codes
6G.2	More guidance on using machine-readable codes such as other labels that may benefit from including a code.	All/ non-prescription	6.2 Machine-readable code with GTIN
6G.3	Guidance to reflect proposed changes, including on acceptable statements to describe the purpose of the QR code when used in place of printed instructions for preparation.	Prescription medicines – injectable products administered by healthcare professionals	6.3 Instructions for preparation before use – Instructions for preparation of injectable products administered by healthcare professionals
7G	**Other information displayed on labels**		
7G.1	Guidance to reflect proposed changes to batch number and expiry date identifiers including that: • the identifier should clearly and individually precede the batch number and expiry date where possible • a combined batch number and expiry date identifier such as 'Lot/Exp' may be acceptable on small and very small containers or where there are other space limitations.	All	7.1 Batch number and expiry date
7G.2	More guidance on batch and expiry, for example, recommending a space for 'open date' on certain medicines such as eye drops..	All	7.1 Batch number and expiry date
7G.3	Guidance to reflect proposed changes, including encouraging giving more Australian contact details via a QR code. Guidance to include 'distributed by' or similar when the company on the label is the distributor, not the sponsor.	All	7.2 Sponsor or distributor name and contact details
7G.4	Guidance on proposed changes for vaccine excipient ingredients, including suggested wording to direct users to the PI.	Prescription medicines – vaccines	7.3 Excipient ingredients – Excipient ingredients on vaccine labels with limited space
7G.5	Additional guidance on clearly displaying diluents on labels for products such as intravenous infusion bags.	Prescription and related medicines	Diluents in injectable medicines

ID	Proposed or planned guidance update	Medicine type	Details and location
7G.6	Guidance on acceptable wording when directing consumers to a list of excipients.	Non-prescription medicines	Excipient ingredients – non-prescription medicines
7G.7	Updates to reflect proposed changes for dispensing label space. Recommend including space for a dispensing label when a medicine is intended only for use in a clinical setting but may still be dispensed to a patient.	Prescription medicines	7.4 Space for a dispensing label
8G	**Specific medicine types**		
8G.1	Make it clearer to medicine sponsors that the requirements for labelling vitamins are also subject to Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990.	All	8.1 Types of active ingredients – Vitamins in non-prescription medicines
8G.2	Examples to avoid duplication of information when expressing herbal medicines. More guidance on including additional information on labels such as herbal ingredient components and herbal common names.	Non-prescription medicines	Herbal medicines
8G.3	Guidance on proposed requirements for sunscreens.	Non-prescription medicines – sunscreens	Sunscreens
8G.4	Examples of acceptable printed plastic ampoule labels.	All	8.2 Types of packaging – Printed plastic ampoules
8G.5	More guidance on how to label blister packs.	All	Blister, strip and dial dispenser packs
8G.6	More guidance on labelling injections, including route of administration statements and abbreviations.	Prescription medicines	8.3 Route of administration – Injections
9G	**Label presentation and design**		

ID	Proposed or planned guidance update	Medicine type	Details and location
9G.1	Encourage use of a colour contrast tool but remove references to a specific tool. Recommend a colour contrast ratio of at least 4.5:1 between the foreground and background colours.	All	9.1 Colour contrast
9G.2	Graphics not encouraged on prescription medicines and need to be carefully considered to ensure they are not promotional, misleading etc. Tablet images are permitted only if they are accurately printed or embossed/ debossed.	Prescription medicines	9.2 Graphics on prescription medicines
9G.3	More guidance about differentiating medicines and unacceptable presentation.	Prescription medicines	9.3 Differentiating medicines
10G	**General requirements including application, exemptions, definitions and transition periods**		
10G.1	Update guidance to reflect planned change to correct the minimum text size requirements in TGO 92 for listed medicines in small containers.	Listed medicines	10.3 Text size
11G	**Guidance structure**		
11G.1	Split the guidance to reflect different types of medicines and different Orders. Increased focus on how to label medicines, with more references to other legislation and TGA guidance.	All	11.1 Guidance on labelling requirements and best practice recommendations

Version history

Version	Description of change	Author	Effective date
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