Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Outcomes of consultation on proposed changes to labelling of medicines supplied in Australia

Prescription and related medicines (replacing TGO 91)

Version 1.0, August 2026

Contents

Introduction

We asked for feedback on proposed changes to medicine labelling requirements to inform new standards that will replace:

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

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

We also sought feedback on planned updates to labelling guidance.

You can find an overview of the proposals, including a brief explanation of the background and reasons for the proposed changes in:

Medicine labels: Proposed changes to rules for the new standards replacing TGO 91 and TGO 92 (Version 1.2), published on the Consultation on proposed changes to labelling of medicines supplied in Australia webpage.

We thank respondents for their time and valuable input.

About this document: outcomes for prescription and related medicines

This document summarises the outcomes of the proposed changes for **prescription and related medicines** and how feedback will inform the development of the new standards. Outcomes may vary between prescription and non-prescription medicines due to differences in how they are regulated and used. A separate document outlining outcomes for non-prescription medicines is available on the consultation page.

The outcomes will not take effect until the new standards are finalised and implemented (by 1 October 2026). The new standards will include a 4-year transition period (proposal 72) to allow medicine sponsors and manufacturers time to update their labels. We will provide further information as we finalise and implement the new standards and guidance.

The sections below summarise the feedback by topic.

How we organised the proposed changes

In the consultation, we grouped the proposed changes by topic to make them easier to review and understand.

Some proposals appear under one topic but are relevant to others. This is because labelling requirements are interconnected and vary depending on the type of medicine, the size and type of packaging, and how the medicine is used.

Some proposed changes relate to guidance. Medicine labelling guidance may include:

explaining how to meet mandatory requirements in the standards

providing recommendations and best practice principles for designing medicine labels to support safe and quality use of medicines, which are not mandatory.

Each topic below includes a table summarising the proposals, feedback and outcomes for each consultation question. In some cases, we have also included the reasons for a decision. In the consultation paper, standard and guidance proposals were summarised in separate tables. In this document, they are presented together, with outcomes explaining whether each proposal will be included in the new standard, guidance, both, or neither.

Declaring allergens and other substances

We received a range of feedback on this topic, including support and implementation challenges.

Table 1: Declaring allergens and other substances – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
1	**Wheat** 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.	We received mixed feedback. Some respondents supported the proposal. Some respondents raised concerns or suggested exemptions (for example, for refined wheat-derived substances or to align closer with food labelling rules).	**Include in new standard (with changes).** Require wheat (and its hybridised strains) and wheat derived substances to be declared. In response to feedback, we will exclude alcohol distilled from wheat as it is a refined wheat-derived substance. Communicate[1] how labels will change to consumers and health professionals, including that updates will take time.
2	**Mollusc** Require marine mollusc to be declared as 'contains mollusc' or 'contains mollusc products' when present in the medicine for all routes of administration, irrespective of concentration.	We received support for this proposal, with few concerns raised.	**Include in new standard.** Require marine mollusc and substances derived from marine mollusc to be declared.
3	**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'.	We received mixed feedback. Some respondents supported the proposal to provide more detailed information to consumers. Some respondents raised concerns (for example, implementation challenges where the specific tree nut is not known when present as an impurity). Some respondents also considered that chestnut should not be required to be declared (for example, to align more closely with other rules such as food labelling rules).	**Include in new standard (with changes)**. Require the specific tree nut to be declared where known as 'contains [specific tree nut]' or 'contains [specific tree nut] products'. Where the specific tree nut is not known, continue to declare 'contains tree nuts' or 'contains tree nut products.' Do not require chestnuts to be declared. Communicate how labels will change, including that chestnut no longer needs to be declared as a tree nut.
4	**Lactose and milk products** For medicines that are inhaled into the lungs or administered by injection or infusion:	We received mixed feedback. Some respondents supported the proposal. Some respondents raised concerns (including about	**Include in new standard.** For inhaled, injected or infused medicines, require 'contains milk products' where lactose is from a milk source.

[1] We will provide general information about how labels will change. The tables highlight some key proposals that may need additional communication for stakeholders.

Q	Proposal	Feedback	What we will do
	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.	the balance of risk and benefit, and whether the statement should refer to milk, lactose, or both).	Referring to milk products is more relevant for people with milk allergy. Communicate how labels will change, including encouraging consumers to ask their health professional if they have questions about ingredients in their medicines.
5	**Sulfites** 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.	Feedback was mixed. Some respondents supported the proposal and some raised concerns about when sulfites would need to be declared.	**Include in new standard (with minor changes).** We will implement this proposal. Sulfites included as part of the final formulation will be required to be declared irrespective of their concentration. Incidental or upstream sulfites must be declared if present above 10 ppm.
6	**Gluten** Change the circumstance for gluten. Require gluten to be declared when present in a concentration of 3 ppm or more.	We received mixed feedback. Some respondents raised strong concerns including about implementation challenges such as existing testing methodologies, limited clinical benefit, and misalignment with some international regulators.	**Do not include in standard**. We will not implement this proposal due to implementation challenges for medicine sponsors and misalignment with some international regulations. No change to current requirements.
7	**Gluten source** Require the source of gluten to be declared. Guidance on label statements to meet the proposed requirements for both declaring wheat and declaring the source of gluten	We received mixed feedback. Some respondents raised concerns including potential difficultly in identifying source of low levels of gluten.	**Do not include in standard.** We will not implement this proposal. There will be no change to current requirements. **Do not include in guidance.** The proposed guidance is not needed for prescription medicines because the related standard proposal to declare the source of gluten will not proceed.
8	**Pollen, propolis and royal jelly (route of administration)** Require pollen, propolis and royal jelly to be declared for all routes of	We received mixed feedback, including support for declaring contact allergens. Some	**Include in new standard.** Require pollen, propolis and royal jelly to be declared for all routes of administration.

Q	Proposal	Feedback	What we will do
	administration rather than only when the medicine is for oral administration.	respondents raised concerns about implementation if the pollen proposal (Q 9) is also implemented.	We will update the standard to require declaration of bee pollen by changing 'pollen' to 'bee pollen' in Schedule 1. We will communicate how labels will change, including that labels that may currently declare pollen may no longer declare pollen (See also outcomes for question 9.)
9	**Pollen (when to declare)** Clarify in 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).	We received mixed feedback, including some support. Some respondents raised concerns, including about over-declaration of incidental pollen and misalignment with the food standard that specifies 'bee pollen.'	**Do not include in guidance. Alternative action.** We will not implement this proposal in response to stakeholder feedback. Instead, we will update the standard to change 'pollen' to 'bee pollen' in Schedule 1.
10	**Declaration statements for prescription medicines** 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.	We received mixed feedback, including some support for this proposal. Some respondents raised concerns such as implementation challenges.	**Do not include in standard**. **Alternative action.** Instead, include guidance recommending that declaration statements be displayed on the label unless there is insufficient space.
11	**Aspartame and phenylalanine** Require aspartame to be declared as 'contains aspartame (phenylalanine)' when present in the medicine (instead of 'contains aspartame').	We received mixed feedback. Some respondents supported clearly identifying that aspartame contains phenylalanine. Some respondents suggested changes to the statement or raised concerns, including overlap with other requirements.	**Include in new standard (with changes).** Require aspartame to be declared as 'contains aspartame (phenylalanine)'. Add a note to clarify that if both aspartame and phenylalanine are present separately, labels can state 'contains aspartame and phenylalanine' (or 'contains aspartame, phenylalanine'), rather than repeating phenylalanine.
12	**Phenylalanine** 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.	We received mixed feedback, including some support for this proposal. Some respondents suggested changes to Note 5. Some respondents did not support the proposal and raised concerns.	**Include in new standard (with changes).** We will update Note 5 under the above proposal to clarify that phenylalanine does not need to be repeated. We may further reword Note 5 to improve clarity as the new standard is drafted.
13	**Hydroxybenzoates**	We received mixed feedback, including	**Include in new standard.**

Q	Proposal	Feedback	What we will do
	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. (The guidance states: 'this entry refers only to parabens with 'hydroxybenzoate' in the Australian Approved Name. Salicylates should not be declared under this entry.')	support for this proposal as it makes the statement clearer for people more familiar with the term 'parabens'. Some respondents raised concerns or suggested changes to the statement. Some respondents provided feedback about salicylates.	Require hydroxybenzoic acid esters to be declared as 'contains hydroxybenzoates (parabens)'. xClarify standard to reflect that salicylates should not be declared under this entry. Communicate how labels will change.
14	**Antimicrobial preservatives** Only require the name of any antimicrobial preservative where it is not already declared on the label as part of Schedule 1 requirements.	We received a range of feedback including support for this proposal. Some respondents did not support it, preferring the current approach or raised other concerns.	**Include in new standard.** We will include this flexibility in the new standard as proposed
15	**Antimicrobial preservatives – guidance** Recommend that preservatives are declared on labels as 'Contains [name of preservative] as preservative.'	We received mixed feedback, including support for this proposal. Some respondents raised concerns including limited label space and substances present in trace amounts that do not function as a preservative in the final product.	**Do not include in guidance.** We will not implement this proposal due to implementation challenges, including for substances with multiple functions.
16	**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.	We received mixed feedback. Some respondents supported the proposal while others raised questions about declaring soy from lecithin. Some respondents requested allowing soya beans and soya bean products to be declared as 'soy'.	**Include in new standard (with changes).** We will: allow soya beans and soya bean products to also be declared as 'soy' or 'soy products' make minor clarifications to Schedule 1 to improve clarity for medicine sponsors as the instruments are being drafted. In guidance, recommend declaring the source of soy where the only source of soy is lecithin, for example 'contains soy (from lecithin)' or 'contains soy lecithin'
17	**More guidance**	We received a range of feedback, including	**Do not include in guidance.**

Q	Proposal	Feedback	What we will do
	More guidance including about declaring substances without cut-off limit in Schedule 1.	support for this proposal. Some respondents did not support it, conditionally supported it, or raised concerns including that guidance should not introduce new requirements or be inconsistent with accepted practice.	While we may make minor updates to guidance to clarify requirements or improve readability, this is a lower priority now that we plan to introduce a limit for residual sulfites, which was a key area of concern.
18	**Additional consultation question – declaring substances** 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. 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?	We received mixed feedback. Some respondents did not support adding more substances at this time, while some respondents suggested adding more.	**Do not include in standard.** We do not propose any further major changes to Schedule 1 at this time. We may consider some matters further in the future.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Active ingredients

We received a range of feedback on this topic from respondents.

Table 2: Active ingredients – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
19	**Hydrates and solvates** 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	We received a range of feedback on this proposal, including support. Some respondents did not support it, conditionally supported it, or raised concerns including potential inconsistencies or reduced benefit for medicines with multiple active ingredients not listed on the main label.	**Include in new standard.** We will implement this proposal. We will develop guidance, which may include a decision tree, to help sponsors understand requirements. Communicate how labels will change.

Q	Proposal	Feedback	What we will do
	Australian Approved Names List) to be displayed elsewhere on the label. Update guidance to reflect proposed changes to hydrates and solvates.		
20	**Salts** 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. 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.	We received a range of feedback on this proposal, including support. Some respondents did not support it, conditionally supported it, or raised concerns including potential inconsistencies or managing labels if a new salt is registered.	**Include in new standard.** We will implement the proposal and state that if the salt is omitted from the cohesive unit, the full salt name must be included elsewhere on the label. **Include in guidance (with changes).** We will implement the proposal and clarify that if the salt is omitted from the cohesive unit, the full salt name must be included elsewhere on the label. Guidance will include information about arrangements when a salt affects the use of the medicine.
21	**Vaccines** 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 container and primary pack label where there is not enough space, in certain circumstances. For example, this may apply where the label directs users to the PI and the primary pack includes a QR code or website linking to the PI, the PI is not physically included).	We received a range of feedback, including support. Some respondents conditionally supported the proposal, did not support it, raised concerns or suggested changes, such as making the rules consistent for trivalent and quadrivalent influenza vaccines.	**Include in new standard (with changes).** We will implement the proposal for the primary pack, but reduce the threshold to 3 or more active ingredients to align the rules for trivalent and quadrivalent influenza vaccines. Existing requirements for very small containers will be maintained. We may also update other requirements to align rules for trivalent and quadrivalent influenza vaccines. For example, we may review when vaccines can include multiple active ingredients on a side

Q	Proposal	Feedback	What we will do
	Allow all injectable vaccines to interrupt the 'cohesive unit' on the main label with a vaccine descriptor (in certain circumstances). 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.		panel rather than the main label. **Include in guidance (with changes).** We will update the guidance to reflect the revised requirements.
22	**Active ingredient prominence for registered medicines** 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.	We received mixed feedback. Some respondents supported the proposal. Some respondents preferred a stronger approach, such as making it a mandatory requirement rather than a guidance recommendation. Some respondents did not support the proposal or raised concerns such as increased complexity for medicine sponsors and potential impacts on readability.	**Do not include in guidance.** We will not include this recommendation, as it may create confusion for medicine sponsors. Existing font size requirements will continue to apply.
23	Not applicable to prescription and related medicines.		See non-prescription medicines document.
24	Not applicable to prescription and related medicines.		See non-prescription medicines document.
25	**Insulin** 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.	We received a range of feedback, including support, partial support and respondents who were unsure. Some respondents prefer 'units' to 'IU' due to concerns that 'IU' can be mistaken for other abbreviations or numbers.	**Include in guidance (with changes).** We will implement this proposal, with some changes. We will recommend 'units' instead of 'IU' to support clarity, but 'IU' will remain acceptable.
26 & 27	**Injections – expressing active ingredient quantity in the stated volume** Require injectable solutions intended for single use with a total	We received a range of feedback, including support for this proposal. Some respondents did not support the proposal or	**Include in new standard.** We will implement the proposals.

Q	Proposal	Feedback	What we will do
	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). Remove 'concentrated solution for injection' from 11(2)(f)(i) (because concentrated injections must be expressed in the total volume of the medicine). 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.	raised concerns, including limited label space and unnecessary label changes. Some respondents considered that these medicines should always be expressed as, for example '50 mg in 1 mL' Others considered that '50 mg/1 mL' should continue to be acceptable.	**Include in guidance (with changes).** We will implement the proposal. We will update the guidance to clarify that both '50 mg in 1 mL' and '50 mg/1 mL' are acceptable. Where space allows, we recommend using '50 mg in 1 mL'.
28	**Microgram abbreviation** 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 or very small container.	We received mixed feedback. Some respondents supported the proposal. Some respondents did not support it, partially supported it or raised concerns. Concerns included that expressing 'microgram' in full may make labels harder to read, particularly on labels with limited space, even when the term fits. Some respondents suggested other abbreviations.	**Include in new standard (with changes).** We will require 'microgram' to be written in full, except on small and very small containers, which may use 'µg'. In guidance, we will continue to recommend writing 'microgram' in full where there is sufficient space. We will also extend this proposal to microlitres and require 'microlitre' to be written in full, except on small and very small containers, which may use 'µL'. While we did not specifically consult on this change, it aligns with and strengthens the existing requirements and is consistent with the equivalent proposal for micrograms, which was subject to consultation.
29	**Injections – active ingredient quantity units**	We received a range of feedback, including support for the proposal because it	**Include in new standard.** We will adopt this proposal.

Q	Proposal	Feedback	What we will do
	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 – where IU or pharmacopeial monographs have not been established, as the unit in the approved product details for the medicine.	reflects current labelling practices and makes requirements clearer. Some respondents did not support the proposal or only partially supported it. Some respondents stated that international units should be written in full or that 'units' should be used instead of 'IU' because 'IU' can be mistaken for other abbreviations or numbers.	However, the guidance will recommend using 'units' instead of 'IU'.
30	**Parenteral nutritional therapy – active ingredient quantity units** 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.	We received a range of feedback, including support for this proposal.	**Include in new standard.**
31	**Retinol equivalents for prescription medicines** Clarify in guidance that for the purposes of expressing retinol equivalents on labels, 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.	We received a range of feedback, including support for this proposal because it clarifies how these medicines should be expressed on labels and reflects current labelling practice. Some respondents raised questions or concerns.	**Include in guidance.** We will implement this proposal. This proposal only clarifies existing labelling practice. It does not change other warnings or contraindications.
32	Not applicable to prescription and related medicines.		See non-prescription medicines document.
33	Not applicable to prescription and related medicines.		See non-prescription medicines document.
34	**Vitamin D – dual presentation of units** Recommend that active ingredients such as colecalciferol (vitamin D3) are labelled with both	We received a range of feedback including support for this proposal. Some respondents partially agreed, did not agree or raised concerns including	**Do not include in guidance (at this time).** We will not implement this proposal due to concerns that it could cause confusion.

Q	Proposal	Feedback	What we will do
	micrograms and international units.	about dual units potentially causing confusion, which ingredients the proposal would apply to, and how dual units could be presented.	
35	**Potassium for injection or infusion** 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. 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.	We received a range of feedback, including support for this proposal. Some respondents partially supported the proposal, did not support it or raised concerns, including about colour contrast, readability, particularly for people with colour vision deficiency, and manufacturing limitations. Some respondents also considered that this should be guidance only.	**Include in new standard.** We will implement proposal. **Include in guidance (with changes).** Guidance will also clarify 'principal active ingredient' and provide examples of what meets and does not meet the requirements. We acknowledge concerns raised. However, we consider that this proposal aligns with some current labelling practices and supports greater consistency.
36	**Minor requirement updates about active ingredients for prescription medicines** 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.	We received mixed feedback. Some respondents supported the proposal, including for reasons related to clear and consistent active ingredient information on labels. Some respondents did not support it or raised concerns. Concerns included challenges with listing active ingredients on separate lines, particularly for small containers, and the impact of uninterrupted cohesive unit requirements on providing additional ingredient information, such as herbal common names.	**Do not include in new standard.** We will not implement this proposal for prescription medicines. We consider it more important to prioritise clarifying these requirements for listed medicines, which are more likely to contain multiple active ingredients and are regulated differently from prescription medicines.
37	**Guidance updates about active ingredients** including: more example labels (for example about expressing active ingredient salts, meeting cohesive unit requirements for combination prescription medicine products, and using colour or colour blocks to differentiate strengths)	We received a range of feedback, including support for this proposal. Some respondents partially supported or did not support the proposal, provided suggestions, or indicated they would be better placed to comment if draft guidance was available for review.	**Include in guidance (with changes).** We will develop updated guidance with more example labels and consider consultation feedback. Although we may not be able to provide draft guidance before implementation, we may make further updates to

Q	Proposal	Feedback	What we will do
	advice on labelling liposomal medicines including using 'liposomal' or 'pegylated liposomal' on the main label (and ARTG name) avoiding trailing zeros (for example, do not display 1 mg as 1.0mg) when rounding active ingredient quantities may be appropriate expressing active ingredient quantities for biological medicines.		the guidance in the future if needed.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Name of the medicine

We received a range of feedback on this topic, including support, suggestions and concerns.

Table 3: Name of the medicine – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
38	**Name of the medicine presentation for prescription and related medicines** Require the name of the medicine and active ingredient information (the cohesive unit) to be immediately below the signal heading (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. Guidance on the name of the medicine including: label examples guidance about displaying the name of fixed dose combination products (for example, including strengths such as 'Name 10/5'	We received a range of feedback, including some support for this proposal. Some respondents supported only aspects of the proposal, partially supported it, did not support it, provided suggestions, or raised concerns such as implementation challenges. Feedback included that some products have space between the signal heading (and associated cautionary statement) and the cohesive unit.	**Include in new standard (with changes).** We will implement this proposal to require that there is no text between the Poisons Standard signal headings and cautionary statements and the cohesive unit. We will also implement in the standard the requirement for the full name of the medicine to be presented in a continuous and uninterrupted manner in the cohesive unit. **Include in guidance (with changes).** We will adopt this proposal with changes. We will also update the guidance and label examples to reflect revised requirements.

Q	Proposal	Feedback	What we will do
	guidance on active ingredient prominence in relation to the name of the medicine. 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.		
39	Not applicable to prescription and related medicines.		See non-prescription medicines document.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Dosage form

Respondents expressed a range of views on this topic, including support, suggestions and concerns.

Table 4: Dosage form – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
40	**Name of the dosage form** 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'. Guidance on how to express dosage forms on labels including: about proposed changes and to support consistency in dosage form expression more guidance about modified release dosage forms.	We received a range of feedback, including support for this proposal. Some respondents partially supported the proposal or did not support it, provided suggestions, or raised concerns including about potential discrepancies with the TGA code tables. Some respondents also highlighted the need for quality guidance.	**Include in new standard.** We will implement this proposal to provide greater flexibility and reflect current labelling practice, while maintaining consistency with the TGA code tables where possible. **Include in guidance.** To support consistent expression of dosage forms, guidance will encourage use of the full dosage form where it may be useful to consumers and identify circumstances where omission may be inappropriate. A review of the TGA eBusiness Code Tables is beyond the scope of review of labelling requirements but may be considered in the future.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Warning statements and advisory information

Feedback on this topic was varied and included support, suggestions and concerns.

Table 5: Warning statements and advisory information – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
41	**Modified release and enteric coated medicines** 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'. Guidance about preferred or acceptable statements.	We received a range of feedback, including support for this proposal. Some respondents partially supported the proposal or did not support it. Concerns raised included the suitability of the proposal for all modified release and enteric coasted medicines, and whether it would provide accurate information in all cases. Some respondents noted that this information may already be provided by pharmacists, including through dispensing labels. Some respondents suggested changes to the wording of the statement.	**Include in new standard (with changes).** We will implement the proposal to include the requirement of a warning statement for modified release and enteric coated medicines of 'Do not crush or chew' where crushing or chewing would alter the modified release properties of the medicine. **Include in guidance** We will also provide guidance on appropriate warning statements and when they should be used.
42	**Warning statements for prescription medicines** Updates to guidance for prescription medicines including: strengthening recommendations for some warning statements, for example for vinca alkaloids advising sponsors to consider warning statements on the innovator product clarifying warning statements expected on prescription medicine labels.	We received a range of feedback on this proposal, including some support. Some respondents partially supported the proposal or did not support it. Concerns raised included occupational safety and whether medicines that are mutagenic, teratogenic or reprotoxic should be required to include specific label statements. Some respondents considered it should be mandatory for generic medicines to include the same warnings as the innovator medicines, while others noted challenges and tracking changes to innovator labels. Some respondents gave suggestions for the guidance. Some raised questions about consistency with the Poisons Standard or whether the Poisons Standard warnings are required on labels.	**Include in guidance (with changes).** We will implement this proposal and consider suggestions when developing the guidance. We plan to provide additional guidance to give sponsors greater clarity about the Poisons Standard warning statements when designing prescription medicine labels.
43	Not applicable to prescription and related medicines.		See non-prescription medicines document.
44	Not applicable to prescription and related medicines.		See non-prescription medicines document.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

QR codes, machine-readable codes and instructions for preparation

We received a range of views on this topic, including support, suggestions, concerns and alternative approaches.

Table 6: QR codes, machine-readable codes and instructions for preparation – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
45	**QR codes** New requirements for QR codes including a statement to explain purpose, requirements for the linked website and content accessed via the QR code. More guidance recommendations about using QR codes.	We received a range of feedback on this proposal, including some support. Some respondents partially supported the proposal or did not support it. Some respondents indicated they would support the proposal if it was included as guidance rather than mandatory requirements. Some concerns raised related to geoblocking and the limited space available on labels to include a statement explaining the purpose of the QR code.	**Include in new standard (with changes).** We will adopt this proposal with changes. We will require content accessed through a QR code on a medicine label to be controlled by the sponsor and not require a login, payment or any other barrier beyond scanning the code. **Include in guidance (with changes).** The guidance will provide further recommendations. Some guidance may be specific to certain medicine types.
46	**Machine-readable code with GTIN** More guidance on using machine-readable codes, such as considerations relating to how a medicine is used when including machine-readable codes on the label, the types of labels that may benefit from a code, and the placement and annotation of machine-readable codes.	We received a range of feedback, including support for this proposal. Some respondents wanted the proposal to go further, for example, by mandating machine-readable codes containing a GTIN on non-prescription medicines. Some partially supported the proposal or did not support it. Some respondents also raised concerns and questions, including whether the guidance would be voluntary, or requested more detail or additional exclusions.	**Include in guidance (with changes).** We will implement this proposal and consider suggestions when developing guidance.
47 & 48	**Instructions for preparation before use of injectable products administered by healthcare professionals** For injectable medicines administered by healthcare	We received mixed feedback in response to question 47, including support, partial support and strong opposition.	**Include in new standard (status quo):** Noting the concerns raised, we will maintain the status quo, requiring injectables to have instructions for use to be

Q	Proposal	Feedback	What we will do
	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. Guidance to reflect proposed changes, including: acceptable statements to describe the purpose of the QR code when used in place of printed instructions for preparation examples of medicines where it may not be appropriate to use a QR code instead of physical instructions for preparation.	Some respondents considered that physical instructions should remain mandatory where preparation is required to support safe use. Some did not support the proposals due to concerns about relying on electronic access to information when preparing or administering medicines. Some respondents supported or partially supported the proposal for a range of reasons, including international alignment and that most healthcare professionals have access to medicines information through other sources. In response to question 48, respondents provided examples of medicines for which it may or may not be appropriate to permit a QR code in place of physical instructions.	either printed on the label, or on a package insert. **Include in guidance:** Guidance will note that QR codes may be applied in addition to, but not in place of, physical instructions for use.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Other information displayed on labels

Feedback on this topic was varied and included support, suggestions and concerns.

Table 7: Other information displayed on labels – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
49	**Batch number and expiry date – embossing and debossing** 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.	We received mixed feedback on this proposal. Some respondents supported the proposal, noting that embossed batch numbers and expiry dates can be difficult to read. Some respondents partially supported or did not support the proposal. Concerns raised included the cost of changing manufacturing technology, which could affect medicine supply. Some respondents also raised concerns about	**Do not include in standard. Alternative action.** We will not implement this proposal due to concerns raised about potential impacts on medicine supply. Instead, we will update guidance to remind sponsors that the existing legibility requirements apply to batch numbers and expiry dates, that this information must remain legible throughout the product's shelf life, and that poorly resolved or illegible

Q	Proposal	Feedback	What we will do
		impacts on tubes and other commonly embossed containers that may also be the 'primary pack'. Feedback indicated that the consultation paper did not clearly communicate that the proposal was intended to apply only to primary pack cartons.	embossing may breach the standard.
50	**Batch number and expiry date – prefixes** Update requirements to allow for some printing or packaging limitations, including allowing the identifier to 'accompany' (rather than necessarily 'precede') the batch number and expiry date. Guidance to reflect proposed changes, including: the identifiers 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 examples of acceptable and unacceptable identifiers, including how identifiers may 'accompany' the batch and expiry. Other guidance, for example, recommending including a space for 'open date' on certain medicines with short term in-use, such as eye drops.	We received a range of feedback, including support for this proposal. Some respondents partially supported or did not support the proposal. Some respondents also requested more detail, for example about the meaning of 'accompanying', or raised questions or concerns, including about the risk of confusion if batch numbers and expiry dates are difficult to distinguish.	**Include in new standard.** We will implement this proposal. While we acknowledge the concerns raised, greater flexibility is needed where limited label space makes it difficult to meet the current requirements for batch number and expiry date prefixes. **Include in guidance.** Guidance will clarify requirements and provide examples to support consistent implementation and the clear presentation of batch numbers and expiry dates.
51	**Sponsor or distributor name and contact details** 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). Guidance, including:	We received a range of feedback, including support for this proposal. Some respondents wanted the proposal to go further, for example, by requiring more than one contact method or always requiring sponsor contact details. Some respondents partially supported or did not support the proposal. Concerns raised included limited label space and the	**Include in new standard.** We will implement this proposal. **Include in guidance (with changes).** We will update guidance to reflect these changes and consider stakeholder suggestions when developing guidance.

Q	Proposal	Feedback	What we will do
	ensure compliance with other relevant legislation (for example, the address of the sponsor or distributor may be required by the SUSMP) recommendations to support accessible contact details, including, multiple contact methods, sponsor contact details (even where a distributer is listed), clearly identified distributors and additional Australian contact details via a QR code.	need to update labels more often if contact details change.	
52	**Excipient ingredients on vaccine labels with limited space** 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. Guidance on proposed changes, including suggested wording to direct users to the PI and when an excipient mix name can be used if the full list does not fit.	We received a range of feedback on this proposal, including some support. Some respondents partially supported the proposal or did not support it. Concerns raised concerns included not having excipient information on the label. Some respondents gave suggestions for the guidance or provided feedback on the use of QR codes in this situation.	**Include in new standard.** We will implement this proposal. **Include in guidance.** We plan to provide guidance on wording to direct users to Product Information (PI), the use of QR codes, and excipient mixes. While we acknowledge the concerns raised, this approach may reflect current labelling practice for some medicines. Schedule 1 substances will continue to be required to be declared.
53	**Diluents in injectable medicines** More guidance on clearly displaying diluents on labels for products such as intravenous infusion bags and other injectables.	We received a range of feedback, including some support. Some respondents partially supported the proposal or did not support it. Some raised concerns or gave suggestions, including making labels clearer when a medicine is supplied with a separate diluent. Some feedback focused on compatible diluents used for administration, which was outside the scope of this proposal.	**Include in guidance.** We will implement this proposal and consider suggestions when developing the guidance. This proposal relates to diluents that are supplied as part of the medicine product, whether included in the formulation or provided separately with the product. Current guidance does not provide detailed expectations for diluents, and we sought feedback on whether more guidance is needed. Existing requirements require injections to include the name and quantity of each excipient, including diluents, except in certain circumstances.

Q	Proposal	Feedback	What we will do
54	Not applicable to prescription and related medicines.		See non-prescription medicines document.
55	**Space for a dispensing label** Update the current requirements for dispensing label space to 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). In guidance, 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.	We received mixed feedback on this proposal to increase the space available for dispensing labels. Feedback ranged from support for aligning with commonly used dispensing label sizes to help keep key information visible, to concerns about space constraints and resources required to redesign labels. Some respondents suggested that the guidance should go further to also encourage sufficient space for ancillary labels. We also received feedback calling for greater international harmonisation of labelling requirements to support timely responses to potential medicine shortages. For the proposed guidance recommendation, we received a range of feedback, from support to concerns about ambiguity and additional burden for sponsors.	**Do not include in standard.** We will not implement this proposal to increase space available for dispensing labels due to concerns raised in the consultation. Existing requirements for dispensing label space will remain unchanged. **Do not include in guidance.** Guidance will continue to note that typical dispensing stickers are 80 x 40 millimetres.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Specific medicine types

Respondents provided a range of feedback on this topic.

Table 8: Specific medicine types – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
56	Not applicable to prescription and related medicines.		See non-prescription medicines document.
57	Not applicable to prescription and related medicines.		See non-prescription medicines document.
58	Not applicable to prescription and related medicines.		See non-prescription medicines document.
59	**Printed plastic ampoules** New labelling requirements for printed plastic ampoules. If the active ingredient is clearly included in the name of the medicine, it	We received a range of feedback on this proposal including some support. Some respondents partially supported the proposal or	**Include in new standard.** We will implement this proposal. **Include in guidance.**

Q	Proposal	Feedback	What we will do
	won't need to be repeated below the medicine name. Carton (primary pack) labels must meet the full requirements in the new labelling standard. Guidance, including examples of acceptable printed plastic ampoule labels.	did not support it and raised concerns. Concerns included whether active ingredient information would be clear enough to support active ingredient prescribing and whether the proposal goes far enough to address space constraints.	We will update guidance. We acknowledge concerns about label clarity. However, the proposal reflects accepted label practice for some prescription medicines.
60	**Blister packs supplied inside a primary pack** More guidance on labelling blister packs, including: 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.	We received a range of feedback on this proposal, including support. Some respondents partially supported or did not support the proposal. Respondents also raised concerns and provided suggestions, including a preference for a harmonised approach with other markets, a request for more guidance on heat-sealed packs in wallets or sleeves, and a suggestion that 2D data matrix codes could be used to provide information.	**Include in guidance.** We will implement this proposal through guidance and consider relevant suggestions when developing the guidance.
61	**Concentrated injections** 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.	We received a range of feedback, including support for this proposal to clarify requirements. Some respondents raised concerns or provided suggestions, including using positive statements such as 'dilute before use' rather than negative statements.	**Include in new standard.** When developing guidance, we will consider suggestions about use of positive statements when determining any recommendations.
62	**Injections – route of administration** More guidance on labelling injections, including route of administration statements, their prominence and abbreviations.	We received a range of feedback on this proposal, including support. Some respondents provided suggestions, including that the route of administration should be written in full, except where there is insufficient label space. Suggestions also included label examples where label space is limited, guidance on the placement of the route of administration, an abbreviation list, and presenting the route of administration as a positive statement.	**Include in guidance.** We will consider suggestions when developing guidance.

Q	Proposal	Feedback	What we will do
63	Not applicable to prescription and related medicines.		See non-prescription medicines document.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Label presentation and design

We received a range of feedback including support, suggestions and concerns.

Table 9: Label presentation and design – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
64	**Colour contrast** Guidance to: 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.	We received mixed feedback on this proposal, including support, partial support and opposition. Some respondents provided suggestions for improvement. Views on the recommended ratio varied, with some supporting it and others raising concerns such as that it may be too restrictive, difficult to apply to some types of packaging, or require exceptions.	**Include in guidance.** We will consider suggestions when developing the guidance on colour contrast requirements and recommendations.
65	**Graphics on prescription medicines** Guidance, including: graphics on prescription medicines 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.	We received a range of feedback, including support for this proposal. Some respondents partially supported or did not support it. Views on the use of graphics related to indications were mixed. Some respondents raised concerns that graphics may detract from critical medicine information, while others considered that they may help patients identify medicines or be informative.	**Include in guidance (with changes).** Clarify that graphics on prescription medicines are discouraged and provide clear expectations for when they are used.
66	**Differentiating medicines** Guidance for prescription medicines, including: minor updates about differentiating medicine strengths and formulations and avoiding unacceptable presentation	We received broad support for this proposal, with few respondents expressing opposition or partial support. Some respondents noted concerns about medicines with similar labels or packaging, with one suggestion that the proposal should go further	**Include in guidance.** Consider stakeholder suggestions when developing the guidance. Other proposals may also support medicine differentiation, including proposals related to insulin (Q 25), potassium for injection or

Q	Proposal	Feedback	What we will do
	considering clinical use and environment when designing labels recommending white packaging to emphasise the colour that is used on labels.	and mandate differentiation between medicines Some respondents noted that caution is needed when using colour as a differentiation strategy, stating that it may work against safe medicine selection if overused or used inconsistently and should not be relied on as the primary control. Some respondents provided suggestions for the guidance or requested more examples of acceptable differentiation, particularly in different clinical use and healthcare environments. Some respondents emphasised the importance of flexibility when applying differentiation principles.	infusion (Q 35), and active ingredient guidance including on using colour and colour blocks to help differentiate strengths and labelling liposomal medicines (Q 37).

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

General requirements including application, exemptions, definitions and transition periods

Feedback on this topic ranged from support to suggested changes and concerns.

Table 10: General requirements including application, exemptions, definitions and transition periods – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
67	**Osmotic pumps** Remove exception for 'osmotic pumps' from prescription medicine standard.	We received limited feedback on this proposal, including some support. Several respondents considered the proposal not applicable to them or their products. Feedback generally did not identify issues with the proposed approach.	**Include in new standard.** We will implement this proposal by removing the exception for osmotic pumps from the prescription medicine standard. Medicines that are considered 'osmotic pumps' are already expected by the TGA to comply with existing labelling requirements. Removing the exception will clarify this expectation in the new standard.
68	**Exemptions for non-prescription medicines**	We received mixed feedback on this proposal including support, partial support, opposition and	**Do not include in standard.**

Q	Proposal	Feedback	What we will do
	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'.	uncertainty. Concerns included the potential impacts on health professionals supplying extemporaneously compounded medicines, uncertainty about how the proposed changes would operate in practice, and ambiguity or inconsistency in the existing requirements and definitions.	**Alternative action extended to prescription medicines.** **Further consideration for non-prescription medicines.** We will not implement this proposal at this time. However, we may update the wording of the exemptions to clarify expectations, including corresponding exemptions in the prescription medicine standard. We may also consider this proposal further in the future for non-prescription medicines.
69	Not applicable to prescription and related medicines.		See non-prescription medicines document.
70	Not applicable to prescription and related medicines.		See non-prescription medicines document.
71	**Main label definition** Update the definition of main label in the labelling standards to align with the definition in the Poisons Standard.	We received broad support for this proposal. Some respondents only partially supported the proposal and raised questions such as its suitability for medicines to which the Poisons Standard does not apply.	**Include in new standard.** Align the definition with the Poisons Standard, while ensuring it remains appropriate for all medicines.
72	**Transition periods** A 3-year transition period would apply to most changes.	We received a range of feedback on this proposal, including support and support for a shorter transition period. Many respondents called for a longer transition period, including to support medicine supply, reduce regulatory burden and align with previous labelling standard transition periods.	**Include in new standard (with changes).** Provide a 4-year transition period to give sponsors time to update labels and support medicine supply. New medicines will need to comply with the new requirements. Communicate how labels will change to consumers and health professionals, including that updates will take time.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Guidance structure and general feedback

We received a range of general feedback, including comments on the guidance structure.

Table 11: Guidance structure and general feedback – consultation feedback and outcomes

Q	Proposal	Feedback	What we will do
73	**Guidance structure**	We received broad support for this proposal.	**Include in guidance**.

Q	Proposal	Feedback	What we will do
	Split the guidance to reflect different types of medicines and different Orders. Increase focus on how to label medicines, with more references to other legislation and TGA guidance.		Publish separate guidance for each Order as soon as practicable after registration.
74	**Additional consultation question – other changes** 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. 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?	We received mixed feedback on this question. Some respondents considered that no further changes were needed, noting that many changes had already been proposed and cautioning against introducing amendments too quickly due to the risk of unintended inconsistencies. Some respondents raised concerns that they considered should be addressed through the labelling requirements or guidance.	**Do not include in standard (at this time).** We do not propose any further changes to the requirements at this time. We may consider some matters further in the future. We may also consider some relevant suggestions when developing the guidance.
75	**Additional consultation question – general comments or feedback** If you have any other comments or general feedback about medicine labelling requirements, please include them here.	We received a range of general feedback, comments and suggestions.	We do not propose any further changes to the requirements at this time. We may consider some matters further in the future. We may also consider some relevant suggestions when developing the guidance.

This table summarises the proposals, feedback and outcomes for consultation questions related to this topic.

Next steps

We will now progress to finalising and implementing the new standards. We will also publish supporting guidance as soon as practicable.

Some proposals that are not progressing at this time may be considered further after the new standards are made. Guidance may also be updated over time in response to stakeholder feedback or changes in labelling practice.

Version history

Version	Description of change	Author	Effective date
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