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

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

## Non-prescription medicines (replacing TGO 92)

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 non-prescription medicines

This document summarises the outcomes of the proposed changes for **non-prescription 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 prescription and related medicines is available on the consultation page.

The outcomes will not take effect until the new standards are finalised and implemented. The new standards will include a transition period 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 thesafe 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**<br>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).**<br>Require wheat (and its hybridised strains) and wheat derived substances to be declared.<br>In response to feedback, we will exclude alcohol distilled from wheat as it is a refined wheat-derived substance.<br>Communicate[1] how labels will change to consumers and health professionals, including that updates will take time. |
| 2 | **Mollusc**<br>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.**<br>Require marine mollusc and substances derived from marine mollusc to be declared. |
| 3 | **Tree nuts**<br>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.'<br>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).<br>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)**.<br>Require the specific tree nut to be declared where known as 'contains [specific tree nut]' or 'contains [specific tree nut] products'.<br>Where the specific tree nut is not known, continue to declare 'contains tree nuts' or 'contains tree nut products.'<br>Do not require chestnuts to be declared.<br>Communicate how labels will change, including that chestnut no longer needs to be declared as a tree nut. |
| 4 | **Lactose and milk products**<br>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.**<br>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).<br><br>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.<br><br>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.<br><br>Communicate how labels will change, including encouraging consumers to ask their health professional if they have questions about ingredients in their medicines. |
| 5 | **Sulfites**<br><br>Continue to require sulfites to be declared where added as an inactive ingredient/ excipient, regardless of concentration.<br><br>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).**<br><br>We will implement this proposal.<br><br>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**<br><br>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**.<br><br>We will not implement this proposal due to implementation challenges for medicine sponsors and misalignment with some international regulations.<br><br>No change to current requirements. |
| 7 | **Gluten source**<br><br>Require the source of gluten to be declared.<br><br>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 the source of low levels of gluten. | **Do not include in standard. Alternative action.**<br><br>**Include in guidance (with changes).**<br><br>We will not require the source of gluten to be declared.<br><br>Instead, guidance will recommend declaring the source on non-prescription medicines where known (for example, 'contains gluten from [source].'<br><br>Guidance will also include recommended wording for declaring gluten when wheat is also required to be declared. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| 8 | **Pollen, propolis and royal jelly (route of administration)**<br>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 received mixed feedback, including support for declaring contact allergens. Some respondents raised concerns about implementation if the pollen proposal (Q 9) is also implemented. | **Include in new standard (with changes).**<br>Require bee pollen, propolis and royal jelly to be declared for all routes of administration.<br>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.<br>(See also outcomes for question 9.) |
| 9 | **Pollen (when to declare)**<br>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 standard. Changes to guidance. Alternative action.**<br>We will not implement this proposal in response to stakeholder feedback and because pollen is common in the environment.<br>Guidance will recommend declaring pollen from other sources (not bee pollen) where an allergic risk is known. |
| 10 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 11 | **Aspartame and phenylalanine**<br>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).**<br>Require aspartame to be declared as 'contains aspartame (phenylalanine)'.<br>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**<br>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).**<br>We will update Note 5 under the above proposal (Q11) to clarify that phenylalanine does not need to be repeated.<br>Note 5 will also be updated to clarify that the entry applies to all medicines. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | | We may further reword Note 5 to improve clarity as the new standard is drafted. |
| 13 | **Hydroxybenzoates**<br>Require hydroxybenzoic acid esters to be declared on medicine labels as 'contains hydroxybenzoates (parabens)' when present in the medicine (instead of 'contains hydroxybenzoates').<br>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.') | We received mixed feedback, including 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.<br>Some respondents provided feedback about salicylates. | **Include in new standard (with changes).**<br>Require hydroxybenzoic acid esters to be declared as 'contains hydroxybenzoates (parabens)'. Clarify requirements to reflect current guidance.<br>Communicate how labels will change, including how the wording of this declaration will change. |
| 14 | **Antimicrobial preservatives**<br>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.**<br>We will proceed with this proposal. |
| 15 | **Antimicrobial preservatives – guidance**<br>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.**<br>We will not implement this proposal due to implementation challenges, including for substances with multiple functions. |
| 16 | **Other minor changes to Schedule 1** including:<br>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<br>clarify that lecithin derived from soya would need to declare the presence of soya beans. | We received mixed feedback. Some respondents supported the proposal while others raised questions about declaring soy from lecithin.<br>Some respondents requested allowing soya beans and soya bean products to be declared as 'soy'. | **Include in new standard (with changes).**<br>We will:<br>allow soya beans and soya bean products to also be declared as 'soy' or 'soy products'<br>make minor clarifications to Schedule 1 to improve clarity for medicine sponsors as the instruments are being drafted.<br>In guidance, recommend declaring the source of soy where the only source of soy is |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | | lecithin, for example 'contains soy (from lecithin)' or 'contains soy lecithin'. |
| 17 | **More guidance**<br>More guidance including about declaring substances without cut-off limit in Schedule 1. | We received a range of feedback, including 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. | **Do not include** in **guidance.**<br>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, and pollen is being updated to bee pollen, which were the key areas of concern. |
| 18 | **Additional consultation question – declaring substances**<br>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.<br>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 (at this time).**<br>We do not propose any further major changes to Schedule 1 at this time.<br>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**<br>Allow the active ingredient name to appear without the hydration or solvate state on the main label in the cohesive unit where:<br>the strength of the active ingredient is not based on the hydrated or solvated form | 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 | **Include in new standard (with changes).**<br>For registered medicines, we may make minor changes to existing provisions to also allow for solvation states.<br>For listed medicines, the hydration or solvation state may be omitted from the name of an active ingredient on the |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | the hydration or solvate state is not important for the safe use of the medicine.<br><br>Require the full name of the active ingredient (as included in the Australian Approved Names List) to be displayed elsewhere on the label. | active ingredients not listed on the main label. Some respondents raised the existing provisions in paragraph 9(7)(d) of TGO 92 for registered non-prescription medicines. | main label where the strength of the active ingredient is not based on the hydrated or solvated form and it is not important to the safe use of the medicine. Some respondents suggested extending this approach to side or rear panels. However, we will not do so because it could result in important information being omitted entirely from the label.<br><br>We will develop guidance to help sponsors understand requirements.<br><br>We will also communicate how labels may change. |
| 20 | **Salts**<br><br>Allow the active ingredient name to be expressed without the salt state in the cohesive unit when:<br><br>the strength of the active ingredient is based on the free base or acid<br><br>the salt is not important to the safe use of the medicine.<br><br>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.<br><br>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:<br><br>more than one salt of the active ingredient is registered in Australia<br><br>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, managing labels if a new salt is registered and existing TGO 92 provisions for registered non-prescription medicines. | **Include in new standard (with changes).**<br><br>We will adopt this proposal, with some changes.<br><br>For registered medicines, we will retain the existing provisions, with minor changes consistent with the approach adopted for hydrates and solvates.<br><br>For listed medicines, the salt state may be omitted from the name of an active ingredient on the main label where it is not important to the strength or safe use of the medicine. Some respondents suggested extending this approach to side or rear panels. However, we will not do so because it could result in important information being omitted entirely from the label.<br><br>We will develop guidance to help sponsors understand requirements. Guidance will include information about arrangements where more than one salt exists.<br><br>We will also communicate how labels may change. |
| 21 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 22 | **Active ingredient prominence for registered medicines** | We received mixed feedback. Some respondents supported the proposal. Some | **Include in guidance.** |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | 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. | 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. | Existing font size minimum requirements will continue to apply.<br>Guidance will recommend (not expect) a 50% size of the name. |
| 23 | **Active ingredient location for listed medicines**<br>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 received a range of feedback including support for this proposal. Some respondents partially supported the proposal, did not support it, or raised concerns. Concerns included reduced prominence of active ingredient information, such as vitamins on labels, and the risk that consumers could unintentionally exceed the recommended daily dose by taking multiple products containing the same active ingredient.<br>Some respondents also requested clarification about whether the existing provisions in paragraph 9(6)(a) for sunscreen preparations will be retained. | **Include in new standard.**<br>While we acknowledge the concerns raised, this proposal is a minor change to simplify an existing requirement. Many listed medicines can already display active ingredients and their quantities on a side or rear panel if they contain at least two vitamin, mineral or herbal active ingredients.<br>We have considered some concerns about active ingredient prominence as part of other proposals (see Q 36).<br>We intend to retain the existing provision that allows sunscreen medicines to display active ingredients and their quantities on a side or rear panel, regardless of the number of active ingredients. |
| 24 | **Active ingredient location for registered non-prescription medicines**<br>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). | We received a range of feedback, including support for this proposal. Some respondents did not support the proposal or raised concerns such as inconsistent presentation of active ingredient information.<br>Some respondents suggested extending the proposal to listed medicines. | **Include in guidance.**<br>For registered non-prescription medicines, guidance will clarify that when the name of the medicine already includes the name and quantity of an active ingredient, the active ingredient and quantity do not need to be repeated on the main label.<br>We will not extend this proposal to listed medicines because they are regulated differently from registered medicines.<br>Guidance will be updated to reflect this. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| 25 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 26 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 27 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 28 | **Microgram abbreviation**<br>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 container. | We received mixed feedback. Some respondents supported the proposal. Some respondents did not support it, partially supported it or raised concerns.<br>Concerns included that expressing 'microgram' in full may make labels harder to read, particularly on labels with limited space, even when the term fits.<br>Some respondents suggested other abbreviations for microgram, such as 'microg', to help prevent 'µg' being mistaken for 'mg'. | **Include in new standard (with changes).**<br>We will require 'microgram' to be written in full, except on small and medium containers, which may use 'mcg' or 'µg'.<br>In guidance, we will continue to recommend writing 'microgram' in full on small and medium containers where there is sufficient space, and to use 'mcg' over 'ug'.<br>We considered requests to allow 'microg' as an alternative abbreviation. However, we will not make further changes at this time. Where 'microgram' cannot be written in full, 'µg' may continue to be used because it aligns with the current requirements and existing medicine labels.<br>We will also extend this proposal to microlitres and require 'microlitre' to be written in full, except on 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 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 30 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 31 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 32 | **Specified units for enzymes**<br>Include new activity units for certain enzymes in Schedule 3 (specified units for enzymes), as shown in Table 1 of consultation paper. | We received a range of feedback, including support for this proposal.<br>Suggestions included expressing less common unit names in full rather | **Include in new standard.**<br>We will proceed with this proposal.<br>In guidance, we will also recommend using 'papain unit' |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | than using abbreviated terms. | rather than 'PU' where practical. |
| 33 | **Probiotics and postbiotics quantity units**<br>Require the quantity of active ingredients that are non-viable biological organisms to be expressed as:<br>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. | We received a range of feedback. Some respondents suggested other approaches or raised issues related to existing labelling practices, test methods, and whether further consultation was needed. | **Do not include in standard (at this time).**<br>**Further consideration.**<br>Feedback raised a range of issues. We may consider this proposal further in the future. |
| 34 | **Vitamin D – dual presentation of units**<br>Recommend that active ingredients such as colecalciferol (vitamin D3) are labelled with both micrograms and international units. | We received a range of feedback including support for this proposal. Some respondents partially agreed, did not agree or raised concerns including about dual units potentially causing confusion, which ingredients the proposal would apply to, and how dual units could be presented. | **Do not include in guidance (at this time).**<br>We will not implement this proposal due to concerns that it could cause confusion. Sponsors can continue to include appropriate additional information on the label where it is presented clearly. |
| 35 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 36 | **Minor requirement updates about active ingredients for listed medicines**<br>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:<br>the active ingredient name and quantity cannot be interrupted with additional information not permitted for the cohesive unit on the main label<br>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 the proposal or raised concerns. Concerns included challenges with listing active ingredients on separate lines (especially on small containers) and impacts of uninterrupted cohesive unit requirements on providing additional ingredient information, such as herbal common names. | **Include in new standard (with changes).**<br>We consider that the current requirements for listed medicines need to be clearer to support clear and prominent active ingredient information and help consumers identify and understand the active ingredients in their medicines.<br>We will implement the proposal with changes. The requirements will be consolidated and made clearer to make them easier to understand and apply.<br>We will introduce exemptions to allow additional information to interrupt the cohesive unit in certain circumstances<br>We will also exempt some medicines from the requirement to list active ingredients on separate lines., eg . |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | | We will provide guidance to help medicine sponsors understand and apply the requirements. |
| 37 | **Guidance updates about active ingredients** including:<br>avoiding trailing zeros (for example, do not display 1 mg as 1.0mg)<br>when rounding active ingredient quantities may be appropriate. | 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).**<br>We will develop updated guidance and consider consultation feedback.<br>Although we may not be able to provide draft guidance before implementation, we may make further updates to 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 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 39 | **Name of the medicine presentation for non-prescription medicines**<br>Change 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.<br>Add a definition of 'distinguishing mark'.<br>Examples of acceptable label layouts and positioning of the name of the medicine. | We received a range of feedback, including some support for this proposal. Some respondents partially supported it or did not support it, provided suggestions, or raised concerns including that it may make labels less readable for consumers. | **Include in new standard (with changes).**<br>**Include in guidance (with changes).**<br>We will permit the name of a medicine to be interrupted by a mark or graphic related to the medicine's branding, or to be spatially separated in limited circumstances.<br>Slogans and taglines will not be permitted to interrupt the name of a registered medicine. For listed medicines, taglines may interrupt the name of the medicine in certain circumstances<br>While we acknowledge concerns raised, these requirements are intended to reflect current labelling practices that the TGA considers acceptable. |

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**<br>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'.<br>Guidance on how to express dosage forms on labels including:<br>about proposed changes and to support consistency in dosage form expression<br>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. | **Standard: Include in new standard.**<br>**Guidance: Include in guidance.**<br>We will implement this proposal to provide greater flexibility, while maintaining consistency with the TGA code tables where possible.<br>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.<br>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**<br>Require modified release and enteric coated tablets, capsules and granules for oral administration to include on the label:<br>a statement denoting the approved method of administration such as 'Swallow whole' and a warning statement against other methods | 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 | **Standard: Include in new standard (with changes).**<br>**Guidance: Include in guidance (with changes).**<br>We will proceed with this proposal, with some changes. We will require modified release and enteric coated medicines to include an appropriate statement where crushing or chewing would alter the modified release properties of the medicine. In response to feedback, this |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | of administration such as 'Do not crush or chew'.<br><br>Guidance about preferred or acceptable statements. | that this information may already be provided by pharmacists, including through dispensing labels. Some respondents suggested changes to the wording of the statement.<br><br>For non-prescription medicines, some respondents suggested changes to the wording of the statement or considered that it should be included with directions for use rather than as a warning. | statement is to be included as part of the directions for use, rather than requiring it to be presented as a warning statement.<br><br>We will also provide guidance on appropriate statements, including when they should be used and where they should appear on the label. |
| 42 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 43 | **Large solid oral dosage forms**<br><br>Non-prescription medicines with tablets, capsules or other solid oral dosage forms that exceed specified size thresholds must include the warning statement 'Warning: large [short name of dosage form]' and a direction to swallow with water.<br><br>If the container is not transparent, labels must also include an actual-size image of the dosage form next to the warning statement, together with the words 'actual size'.<br><br>The requirements will not apply to dosage forms that are not intended to be swallowed whole, such as chewable tablets and lozenges, where clear directions are provided not to swallow them whole.<br><br>Sponsors will have a 2-year transition period to comply with the new requirements<br><br>Guidance will be updated to reflect the new requirements. | We received mixed feedback, with respondents expressing a range of views. Some respondents supported the proposal, some partially supported it, some did not support it, some wanted the proposal to go further and some sought changes or additional exemptions. Concerns raised included implementation challenges, including with the 2-year transition period. Similar concerns were also raised in the question about transition periods (Q 72).<br><br>Some respondents also raised concerns about choking risk or sought a clearer rationale for increasing the proposed size thresholds since the previous consultation in 2024. Some respondents suggested larger or different size thresholds. | **Standard: Include in new standard (with changes).**<br><br>**Guidance: Include in guidance (with changes).**<br><br>We will implement the proposed size thresholds for the warning statement and direction to swallow with water. Having considered the feedback received during this consultation, we continue to consider the proposed thresholds appropriate. Exemptions will exist for dosage forms that are not intended to be swallowed whole.<br><br>Small and medium containers, containers supplied in a compliant primary pack, or primary packs where the dosage form is visible will not require an image.<br><br>Stickers on container lids solely for the purpose of meeting the large dosage form |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | | warning and image requirements will be permitted.<br>The transition period will be extended to align with the transition period for the new labelling standard. |
| 44 | **Warning statements for listed medicines**<br>Require listed medicines to prominently display all warning statements.<br>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.<br>Guidance examples of prominently displayed warning statements. | We received mixed feedback on this proposal. Some respondents supported the proposal because it would make warning statements more visible on listed medicines.<br>Some respondents partially supported the proposal or did not support it. Some raised concerns about the proposed requirements or requested more information about how sponsors would comply with them. Some respondents also suggested a 'warning' heading instead of displaying warnings in a coloured text box.<br>Some respondents raised concerns about the Permissible Indications proposal, such as noting that it may require a warning statement on the label when an indication is included in the ARTG entry but not on the label itself. | **Standard: Include in new standard (with changes).**<br>**Guidance: Include in guidance (with changes).**<br>We will proceed with this proposal with changes.<br>To make it clearer how sponsors must prominently display warning statements, we will require listed medicines to display all warning statements under, or immediately following, an appropriate heading or prefix such as 'Warnings'.<br>We will update the definition of warning statements to clarify that label statements required by the Permissible Indications Determination are considered warning statements. We will also clarify that these label statements are only required where the related indication appears on the label.<br>We will update the guidance to reflect these changes. |

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**<br>New requirements for QR codes including a statement to explain purpose, requirements for the linked website and content accessed via the QR code. | We received a range of feedback on this proposal, including some support. Some respondents partially supported the proposal or did not support it. Some | **Standard: Include in new standard (with changes).**<br>**Guidance: Include in guidance (with changes).** |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | More guidance recommendations about using QR codes. | 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. | We will adopt this proposal with changes.<br>We will require content accessed through a QR code on a medicine label to not require a login, payment or any other barrier beyond scanning the code. For listed medicines, the content accessed through the QR code must be controlled by the sponsor or the TGA, as these medicines are regulated differently.<br>The guidance will provide further recommendations. Some guidance may be specific to certain medicine types. |
| 46 | **Machine-readable code with GTIN**<br>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).**<br>We will implement this proposal and consider suggestions when developing guidance. |
| 47 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 48 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |

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** | We received mixed feedback on this proposal. | **Do not include in standard. Alternative action.** |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | 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.<br>Continue to allow embossing or debossing on foil blisters and other containers included in a primary pack. | 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.<br>Some respondents also raised concerns about 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. | We will not implement this proposal due to concerns raised about potential impacts on medicine supply.<br>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 embossing may breach the standard. |
| 50 | **Batch number and expiry date – prefixes**<br>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.<br>Guidance to reflect proposed changes, including:<br>the identifiers should clearly and individually precede the batch number and expiry date where possible<br>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<br>examples of acceptable and unacceptable identifiers, including how identifiers may 'accompany' the batch and expiry.<br>Other guidance, for example, recommending including a space for 'open date' on certain | 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. | **Standard: Include in new standard.**<br>**Guidance: Include in guidance.**<br>We will implement this proposal.<br>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.<br>Guidance will clarify requirements and provide examples to support consistent implementation and the clear presentation of batch numbers and expiry dates. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | medicines with short term in-use, such as eye drops. | | |
| 51 | **Sponsor or distributor name and contact details**<br>Require at least one of the following Australian contact details to facilitate public contact:<br>phone number<br>email address<br>website address (with contact details on the website).<br>Guidance, including:<br>ensure compliance with other relevant legislation (for example, the address of the sponsor or distributor may be required by the SUSMP)<br>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. | 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.<br>Some respondents partially supported or did not support the proposal. Concerns raised included limited label space and the need to update labels more often if contact details change. | **Include in new standard.**<br>**Include in guidance (with changes).**<br>We will implement this proposal.<br>We will update guidance to reflect these changes, including recommending an Australian toll-free number or current email address. Guidance will clarify where a website address is used, the contact details should be prominently displayed on the home webpage. |
| 52 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 53 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 54 | **Excipient ingredients in non-prescription medicines**<br>Require non-prescription medicines to include either the name of each excipient or a statement explaining how to find excipient information (for example, via QR code).<br>Guidance on acceptable wording when directing consumers to a list of excipients. | We received mixed feedback on this proposal including support, partial support and strong opposition. Concerns raised included that the proposal was not practical, particularly for labels with limited space, that it could overwhelm consumers or clutter labels, and that the proposed options may not be accessible to all consumers. Some respondents suggested alternative approaches, such as consumer education. | **Do not include in standard.**<br>**Alternative action.**<br>We will not implement this proposal at this time due to concerns raised.<br>We may consider education to help consumers and health professionals find excipient information on the publicly accessible version of the Australian Register of Therapeutic Goods (ARTG). |
| 55 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |

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 | **Vitamins in non-prescription medicines**<br>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.<br>Change the requirements for expressing the quantity of vitamin active ingredients.<br>Not allow abbreviations of the word 'vitamin.'<br>Guidance clarifying that vitamin labelling is also subject to Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990. | We received a range of feedback on this proposal, including support to make vitamin active ingredient information clearer for consumers, as well as partial support and opposition.<br>Some respondents raised concerns about the proposed format, including whether it clearly indicated what the strength related to. Some respondents requested greater flexibility in presenting vitamin information.<br>Some respondents commented on the use of the terms 'as' and 'from' before the approved name, noting that the appropriate term may depend on the vitamin source.<br>Some respondents did not support restricting abbreviations of the word 'vitamin' because of concerns about limited label space and crowding. | **Standard: Do not include in standard (at this time). Further consideration.**<br>**Guidance: Include in guidance (with changes).**<br>We will not implement the proposed changes to labelling requirements at this time. This proposal is linked to other legislation that needs to be reviewed or amended to fully support the intended outcomes.<br>However, we may include relevant information in the guidance, including clarification that vitamin labelling is also subject to Schedule 2 Part 3 of the Therapeutic Goods Regulations 1990. |
| 57 | **Herbal medicines**<br>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.<br>Guidance, which may include:<br>examples to avoid duplication of information when expressing herbal medicines<br>advice on including additional information on labels such as herbal ingredient components and herbal common names. | We received a range of views on this proposal, including support, partial support and opposition. Some respondents raised concerns, suggested changes, or requested greater flexibility, such as allowing either minimum or average dry or fresh weight. | **Include in new standard.**<br>**Include in guidance.**<br>We will implement this proposal. We will update the guidance and consider suggestions when developing it. |
| 58 | **Sunscreens** | We received a range of feedback on this proposal, | **Include in new standard (with changes).** |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | Require sunscreens to include certain statements on the label.<br>Guidance on proposed requirements for sunscreens. | including support for clear and standardised sunscreen labelling, as well as partial support and opposition. Some respondents raised concerns including that the times mentioned in some statements could be confusing or appear inconsistent. Some respondents also provided suggestions for improvement. | **Include in guidance (with changes).**<br>We will remove the statements identified by industry as new requirements.<br>The new standard will replicate the current requirements in the Permissible Ingredients Determination and the AS/NZ sunscreen standard for sunscreen instructions for use, with the intent of consolidating sunscreen labelling instructions into the one legislative instrument.<br>Label requirements for different dosage forms will be principle based, with sponsors being responsible for ensuring that their labels are appropriate for therapeutic sunscreens and support their safe use.<br>Guidance will be updated to reflect new requirements. |
| 59 | **Printed plastic ampoules**<br>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.<br>Carton (primary pack) labels must meet the full requirements in the new labelling standard.<br>Guidance, including examples of acceptable printed plastic ampoule labels. | We received a range of feedback on this proposal including some support. Some respondents partially supported the proposal or 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. | **Include in new standard.**<br>**Include in guidance.**<br>We acknowledge concerns about label clarity. However, the proposal reflects accepted label practice for some registered medicines.<br>For listed medicines, we consider this proposal appropriate for printed plastic ampoules as we recognise there are significant space constraints with this container type.<br>These requirements align with the expectations for registered non-prescription medicines (see Q24). |
| 60 | **Blister packs supplied inside a primary pack**<br>More guidance on labelling blister packs, including:<br>for modified release medicines, ensure the pack shows this (for example, in the medicine's name) | 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 | **Include in guidance.**<br>We will implement this proposal through guidance and consider relevant suggestions when developing the guidance. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | print information in a pattern so that it stays readable while the pack is in use. | 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. | |
| 61 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 62 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 63 | **Listed medicines with a vaginal route of administration**<br>Listed medicines with a vaginal route of administration must include the statement 'Do not use if pregnant or likely to become pregnant'. | We received mixed feedback on this proposal, including support, partial support and opposition.<br>A number of respondents raised concern that this statement would prevent consumers using a medicine based on health practitioner's advice. Accordingly, these respondents recommended the statement should include wording such as 'unless directed by your health practitioner.'<br>Some feedback suggested that some respondents were not aware that the scope of the proposal was limited to listed medicines, which do not have a Consumer Medicine Information (CMI) leaflet.<br>Other feedback suggested that the statement should not be required for specific ingredients. The TGA considers that, where sponsors have evidence supporting the safe use of their medicine in pregnancy, there are existing measures by which they can request an exemption from this requirement for their medicine. | **Include in new standard (with changes).**<br>In response to concerns, further targeted consultation was conducted regarding the wording of the required statement.<br>Listed medicines with a vaginal route of administration will be required to include the statement 'Do not use if pregnant or [trying/likely] to become pregnant unless directed by your health practitioner.' |

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**<br>Guidance to:<br>encourage use of a colour contrast tool but remove references to a specific tool<br>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.**<br>We will consider suggestions when developing the guidance on colour contrast requirements and recommendations. |
| 65 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |
| 66 | Not applicable to non-prescription medicines. | | See prescription and related medicines document. |

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**<br>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. Extend to non-prescription medicines.**<br>We will implement this proposal by removing the exception for osmotic pumps from the prescription medicine standard.<br>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.<br>We will also extend this proposal to non-prescription medicines. While we did not specifically consult on removing the equivalent TGO |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | | 92 exemption, feedback on the similar TGO 91 proposal generally did not identify concerns. |
| 68 | **Exemptions for non-prescription medicines**<br>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.'<br>Change the exemption in paragraph 5(1)(k) of TGO 92 for medicines made up or compounded extemporaneously from 'pharmacist' to 'health professional'. | We received mixed feedback on this proposal including support, partial support, opposition and 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. | **Do not include in standard (at this time).**<br>**Further consideration.**<br>We will not implement this proposal at this time. However, we may update the wording of the exemptions to clarify expectations.<br>We may also consider this proposal further in the future. |
| 69 | **Purpose of the medicine on the label (for non-prescription medicines)**<br>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. | We received a range of feedback, including support for this proposal. Some respondents partially supported or did not support or raised concerns. | **Include in new standard.**<br>Remove the exception for medicines supplied as 'For Practitioner Dispensing Only'. As a result, these medicines will be required to include the purpose of the medicine on the label. |
| 70 | **Text size for listed medicines in small containers**<br>Correct the minimum size text size requirements in TGO 92 for listed medicines in small containers.<br>Confirm a minimum text size of 1.5 millimetres.<br>Update guidance to reflect this change. | We received broad support for this proposal, with few respondents expressing opposition or partial support. | **Include in new standard.** |
| 71 | **Main label definition**<br>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.**<br>Align the definition with the Poisons Standard, while ensuring it remains appropriate for all medicines. |
| 72 | **Transition periods**<br>A 3-year transition period would apply to most changes.<br>A 2-year transition period would apply to labelling changes for large dosage forms. | We received a range of feedback on the proposed 3-year transition period, including support and calls for a shorter transition period. Many respondents called for a longer transition period, including to support medicine supply, reduce | **Include in new standard (with changes).**<br>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. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | | regulatory burden and align with previous labelling standard transition periods.<br>Some respondents raised concerns that the 2-year transition period for large dosage forms may be insufficient, could affect supply, and would result in different transition periods for different requirements. Similar concerns were raised in the question about large dosage forms (Q 43). | For large dosage forms, the transition period will be extended to align with the transition period for the new labelling standard (see also Q 43). 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**<br>Split the guidance to reflect different types of medicines and different Orders.<br>Increase focus on how to label medicines, with more references to other legislation and TGA guidance. | We received broad support for this proposal. | **Include in guidance**.<br>Publish separate guidance for each Order as soon as practicable after registration. |
| 74 | **Additional consultation question – other changes**<br>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.<br>Do you think any more changes should be made to medicine labelling requirements in the new | We received mixed feedback on this question.<br>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.<br>Some respondents raised concerns that they considered should be addressed through the labelling requirements or guidance. | **Do not include in standard (at this time).**<br>We do not propose any further changes to the requirements at this time. We may consider some matters further in the future.<br>We may also consider some relevant suggestions when developing the guidance. |

| Q | Proposal | Feedback | What we will do |
|---|---|---|---|
| | standards replacing TGO 91 and TGO 92, that are critical to support medicine safety? | | |
| 75 | **Additional consultation question – general comments or feedback**<br>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.<br>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 |
|---|---|---|---|
| V1.0 | Original publication | Medicines Regulation Division | August 2026 |

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au