Medicine labelling: Update on the implementation of TGO91/92

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The drivers for change

Consistent location of important health information

Ensure important information is not obscured

Improve safety and quality use of medicines for consumers

Reduce medication errors

Key changes that were introduced with TGO 91 and 92

- Improved prominence of active ingredient
- More substances need to be declared
  - Crustacea
  - Fish
  - Eggs
  - Soya
  - Milk
  - Tree nuts

Other prescription medicine changes (TGO 91)

- Medicine name to be on at least 3 sides of the carton
- Mandatory 70x30 mm space for dispensing labels
- Small containers now 25 mL capacity
- Microgram and microlitre must be spelled out in full (no µ allowed except small and very small containers)

Other non-prescription medicine changes (TGO 92)

Medicine Information

Active Ingredient (in each tablet or xx mL)

AAN of antihistamine xxx mg

Uses

For temporary relief of sleeplessness.

Warnings

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

Do not

- use if you are pregnant or breastfeeding.
- take for more than a few days.

While using this product

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

Contains xxx

Directions for use

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

Other information

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

Display of Critical Health Information (CHI) for AUST R medicines

Use of 'active moiety' on main label instead of full ingredient name

Changes to container sizes

- Small containers now 25 mL capacity
- New medium container size up to 60 mL

Outline

- Registration and Listing numbers
- Schedule 1
- Cohesive units
- Batch and expiry information
- Ingredient names
- Concentrations
- Small containers

Displaying the AUST R or AUST L number

- Not a part of the labelling order – the requirement instead specified in regulation 15 of the Therapeutic Goods Regulations 1990

- Section 14 consent to supply therefore is not an option

- Section 19D of the Therapeutic Goods Act 1989 permits the Secretary (or the Secretary's delegate) to consent to the importation or supply of a TGA approved medicine without the relevant AUST number on the primary pack label

Displaying the AUST R or AUST L number (cont.)

- Consent would only be considered in situations where including the AUST number on the label of a medicine (either by printing or over-stickering) presents an unusual and unexpected challenge and immediate or timely supply of the medicine would address a national public health emergency, such as a pandemic declared by the World Health Organization (WHO)
- Options may include over-stickering
- **Reach out to the TGA**

Schedule 1

TGO 91/92, 8(1)(j) requires that, where a substance referred to in Schedule 1 is present in the medicine under the conditions outlined in Schedule 1, the name of the substance must be present on the labels. Further details are also outlined in the Guidance on TGO 91 and TGO 92 (see Section 1.5.9)

This example: each tablet contains 60 mg lactose; the maximum recommended daily dose of the medicine is 100 mg

Schedule 1 - Claims about absence of substances

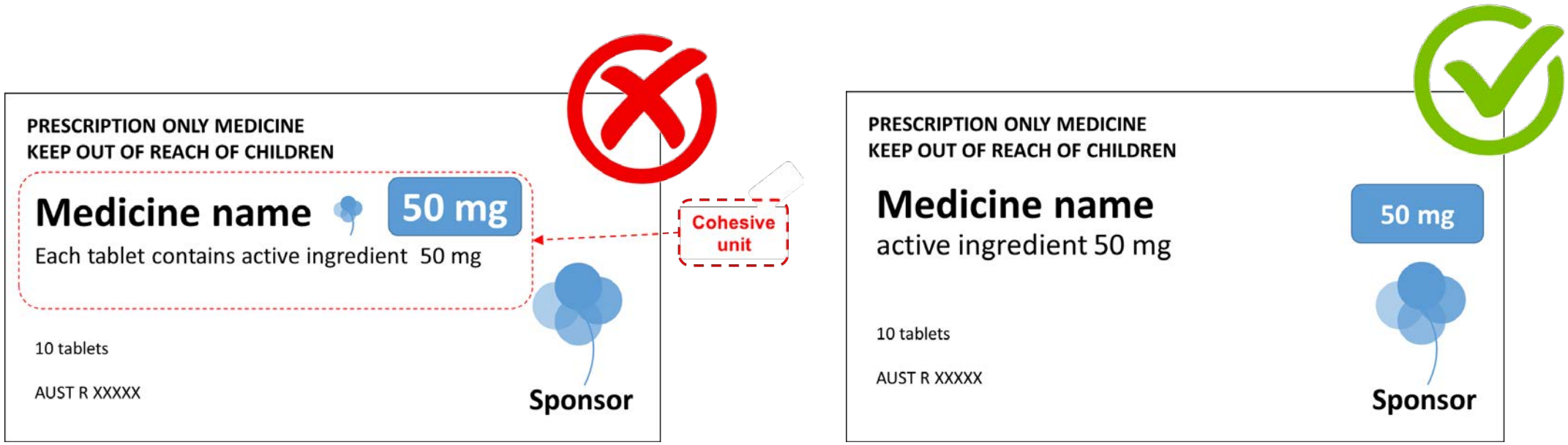
- Section 3.2.2, Medicine Labels Guidance on TGO 91 and TGO 92 states:

  “Provided that it is true, you may include a statement on the label that your medicine does not contain certain substances of interest to a particular group of individuals (e.g. gluten free, sugar free, alcohol free, lactose free).”

- This can only be used if the formulation is completely free of the above mentioned substances
- If your medicine contains proprietary ingredients, check that these do not contain substances that need be declared, beware if you make an absence statement that you are sure
- Some free-from claims can be considered promotional statements, be careful how they are used
- Do not include free-from statements about active ingredients

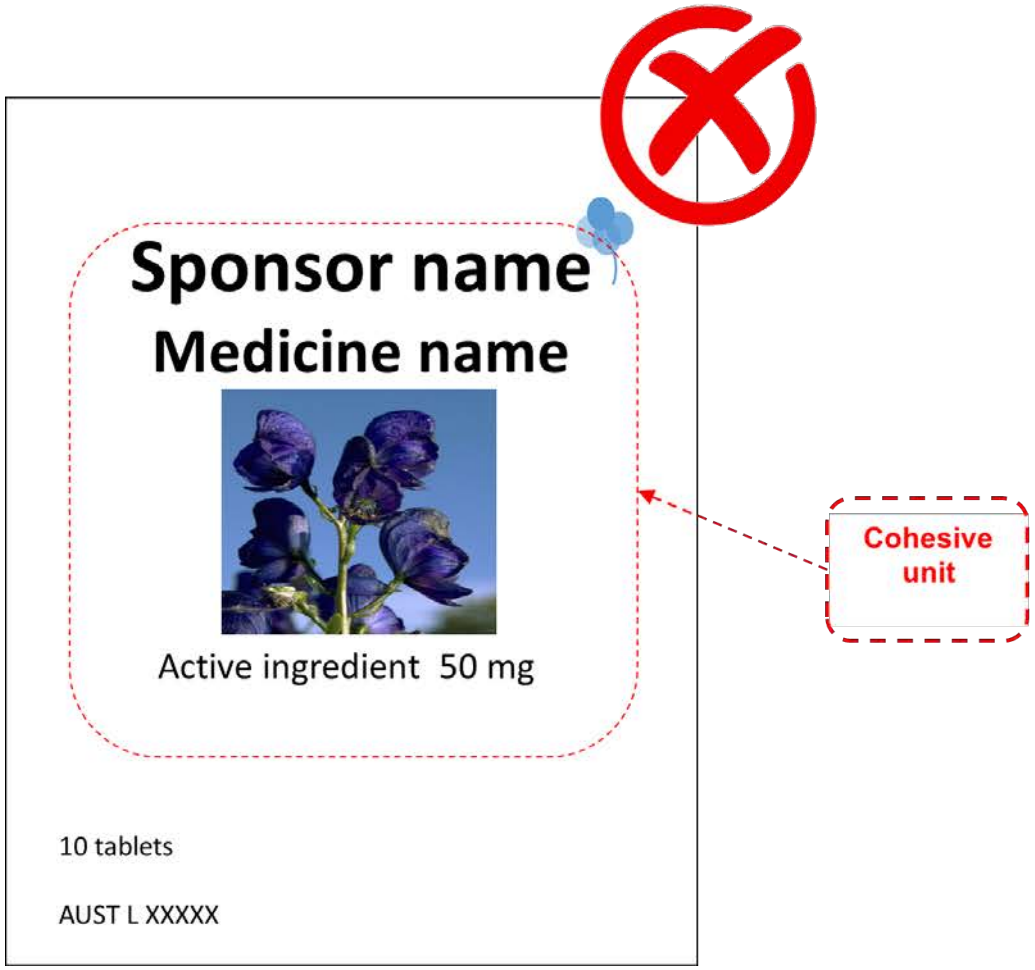
Cohesive units

Subsection 9(3) of TGO 91 and TGO 92 stipulates that the name of the medicine and the name of active ingredient(s) on the main label appear as a ‘cohesive unit’



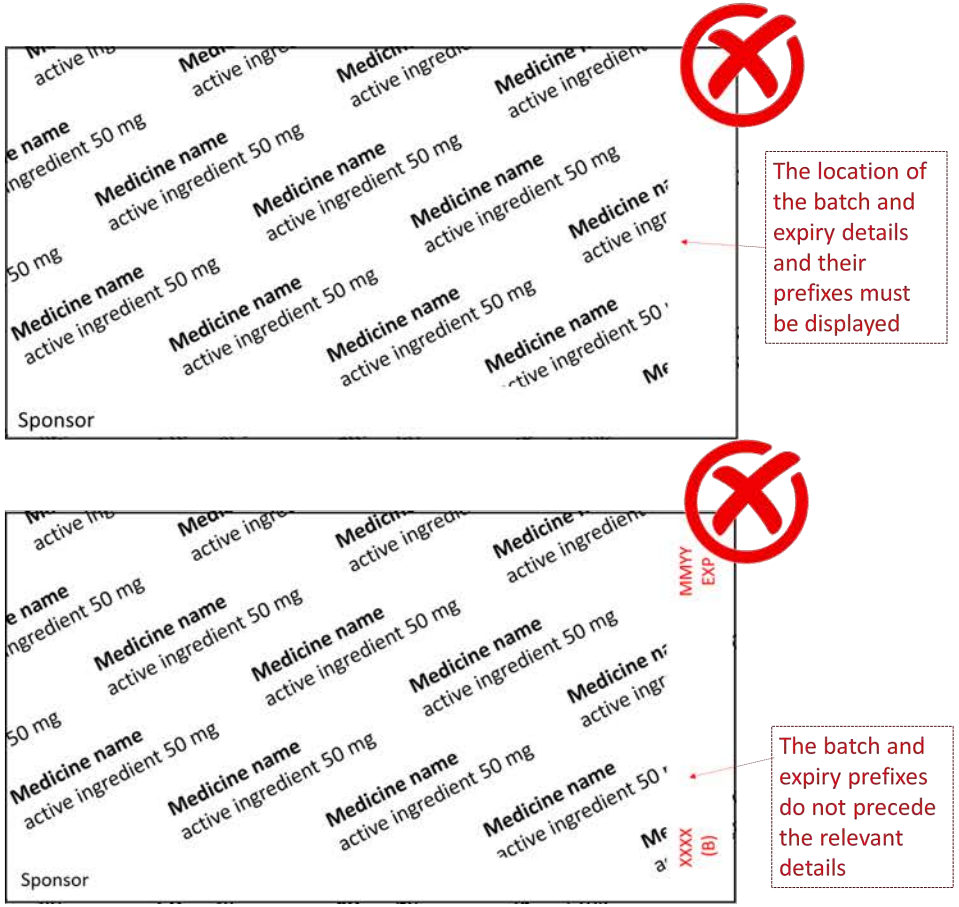
Cohesive units

Must not be separated by any text or graphics, except where additional information is permitted under the Orders



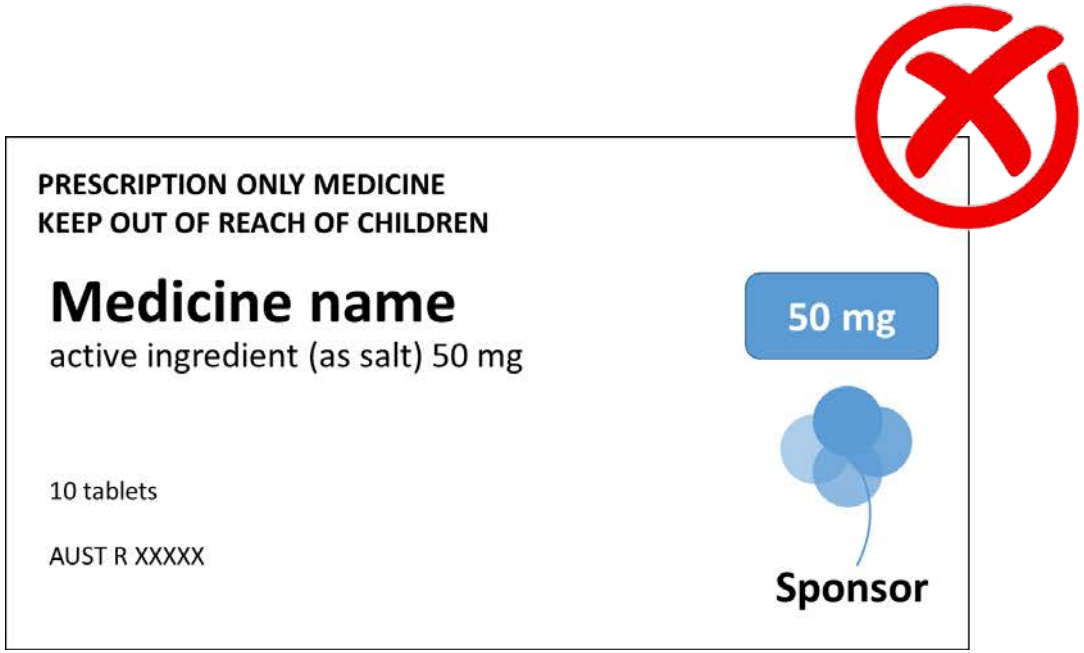
Batch and expiry prefixes

TGO 91 requires that the labels include the batch number of the medicine preceded by the batch number prefix; and the expiry date of the medicine, preceded by the expiry date prefix.



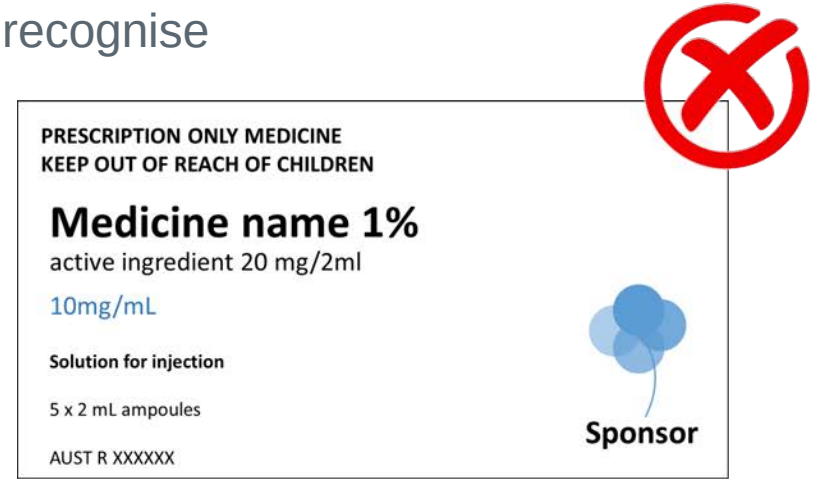
Ingredient names

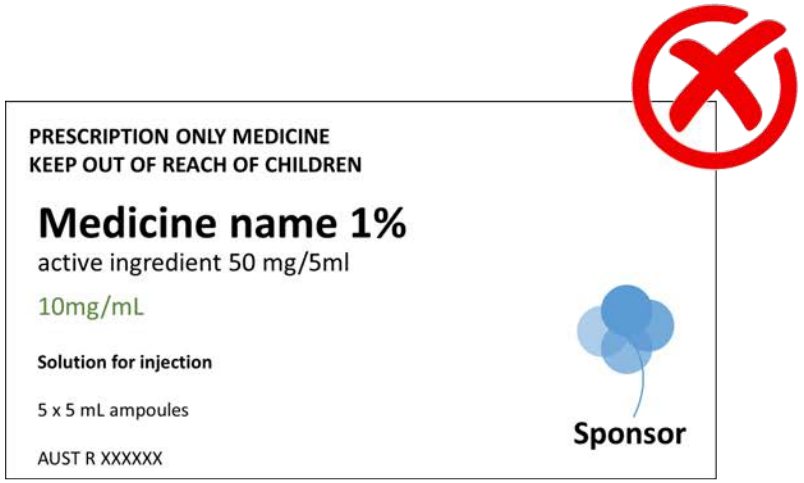
The name and amount of an active ingredient present in a medicine must be clearly stated on the medicine label to assist in quality use of medicines



Clear expression of concentration

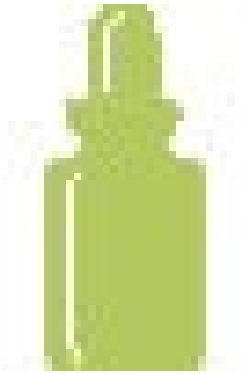
To eliminate the risk of confusion or incorrect dosing, the strength should be clear and easy to recognise





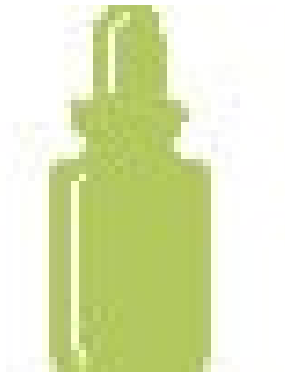
Small containers

- Both Orders contain details for small containers (Capacity is 25 mL or less)
- When a small container is supplied in an outer primary pack such as a carton there are allowances for the label:
    - Less information required on the container label
    - Smaller text sizes can be used for the required information
- The primary pack MUST meet the full requirements of the order



Small containers

- TGO 92 permits medicines with more than one active ingredient supplied in a small container to display information with more flexibility, including:
    - Listing active ingredients on the same line
    - When there is no outer carton, using a smaller text size (1.5 mm)



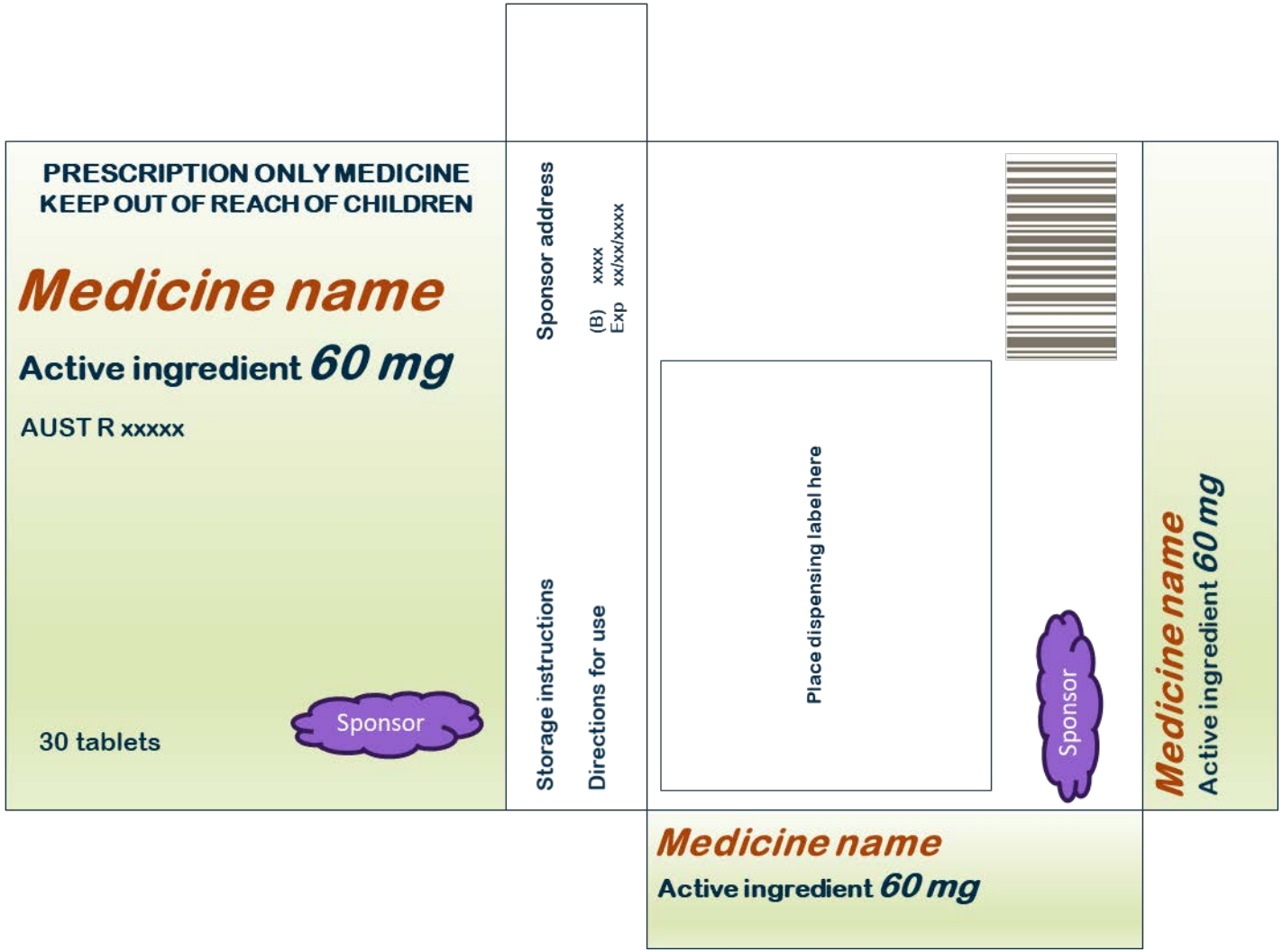
Audience time

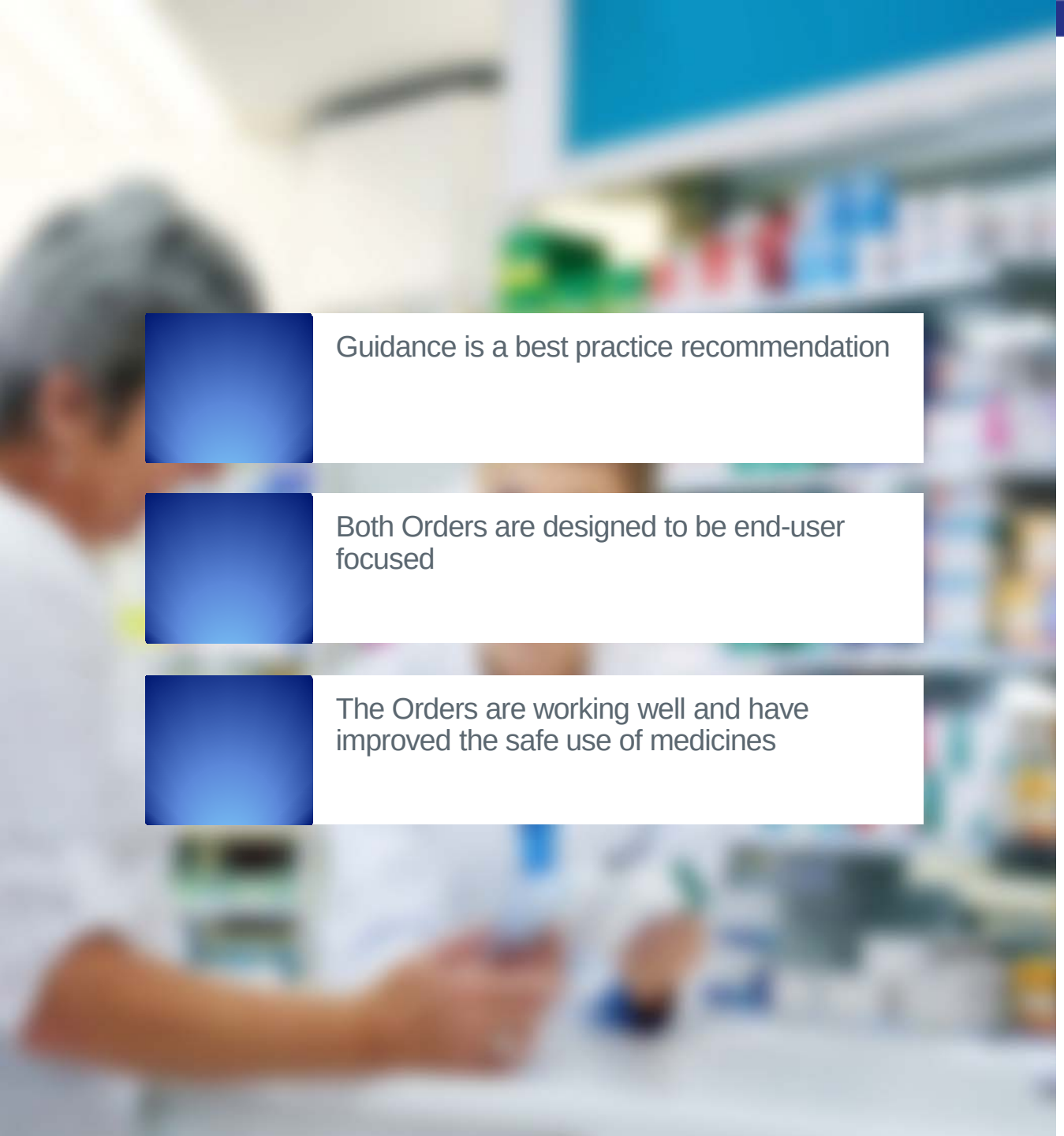
1. Does this label meet all of the requirements of TGO 91?

2. In the previous example (right), which parts of TGO 91 are not met?
   a) Cohesive unit
   b) Schedule 1 substances
   c) Prominence of medicine name
   d) Medicine name on three non-opposing sides
   e) Location of batch and expiry details

Audience time

1. Does the label meet all of the requirements of TGO 91?





Guidance is a best practice recommendation

Both Orders are designed to be end-user focused

The Orders are working well and have improved the safe use of medicines

Final Considerations

- The guidance provides recommendations on best practice – there will always be exceptional circumstances and we can work together to ensure labels provide the end-user with the best experience
- Clarity is the key – labels need to be clear to reduce the risk of dosing mistakes by end-users in clinical and home settings
- The current versions of TGO 91 and 92 have had a positive impact on the safe use of medicine, future changes will be to further enhance this impact

Medicine labelling: Minor amendments & future plans

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April 2023 minor amendments

To support dual labelling transition to sole medicine ingredient names

International harmonisation of ingredient names (IHIN) - Dual labelling transition to sole medicine ingredient names

Minor amendments to TGO 91 and TGO 92 made in April 2023

Dual labelling period for most names ended 30 April 2023.

Medicine sponsors have 3 years to update labels to show only the new name at end of dual labelling period.

Transition periods included in TGO 91 and TGO 92 (via amendment instrument) to allow sponsors time to update labels and ensure compliance with requirements. Text size allowances continued.

Transition period for most dual labelled ingredients started 1 May 2023, ending 30 April 2026. Affected medicines released for supply from 1 May 2026 must reflect sole names.

The future

Considerations and Priorities for improvement to medicine labels

Considerations for future labelling requirement updates

Many improvements were made to Australian medicine labels with the implementation of TGO 91 and TGO 92.

Updating labelling requirements considerations:

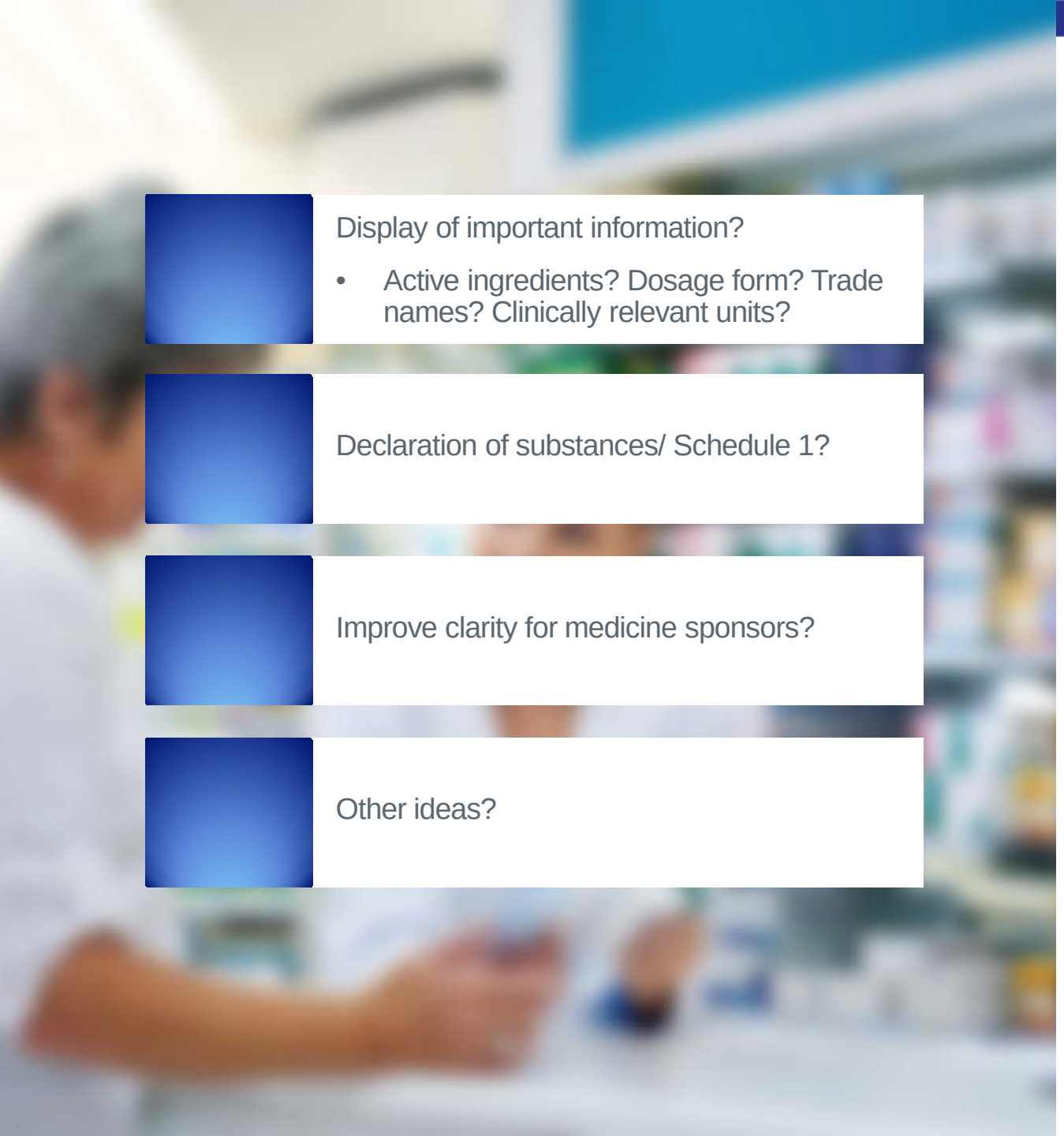
- Developing and updating rules for medicine labels can be complex to achieve clear labels across different types of medicines.
- Rules need to be well considered to avoid introducing unnecessary inconsistencies, or unintended risks to medicine safety.
- Some potential areas of improvement to medicine labels may require a multifaceted approach and could involve more than just amendments to TGO 91 and TGO 92.
- Interconnection of issues.
- Labelling supports the safe and quality use of medicines.

Priorities for future improvements to medicine labels

Potential areas of improvement to TGO 91 and TGO 92 requirements

Prioritising areas for improvement

- The TGA is aware of some potential areas of improvement of medicine labelling rules.
- Prioritising future areas for improvement will assist in allocating sufficient time to review interrelated rules and develop solutions to address important matters.
- Targeted consultation planned in mid 2023 to hear ideas and priorities on future improvements. Feedback will help to inform the priorities for future updates to medicine labelling rules and the development of proposals to be included in a future public consultation.



Display of important information?

- Active ingredients? Dosage form? Trade names? Clinically relevant units?

Declaration of substances/ Schedule 1?

Improve clarity for medicine sponsors?

Other ideas?

Priorities for future improvements

Targeted consultation 2023

We want to know:

- How can Australian medicine labels be further improved to support the safe and quality use of medicines?
- What are the priorities for future updates to medicine labelling rules?
- What are the main challenges for medicine sponsors with meeting the current rules for labels of medicines supplied in Australia?

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration