Australian Government
Department of Health
Therapeutic Goods Administration

Tips on creating prescription medicine labels compliant with TGO 91

Help Card

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TGA Health Safety Regulation

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Contents

Medicine name on the main label – TGO 91 help card 5

Cohesive unit of medicine name and active ingredient name – TGO 91 help card 7

Medicine name on three non-opposing sides – TGO 91 help card 9

Schedule 1 substances – TGO 91 help card 11

Location of batch and expiry details – TGO 91 help card 13

This help card is for sponsors, distributors and retailers responsible for designing and updating prescription medicine product labels.

The examples provided are not representative of all requirements in TGO 91 for all product types. This advice is general in nature and is given without prejudice.

To understand the labelling requirements in TGO 91, ensure you read:

- Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91)
- Medicine labels: Guidance on TGO 91 and 92

Medicine name on the main label – TGO 91 help card

Requirements

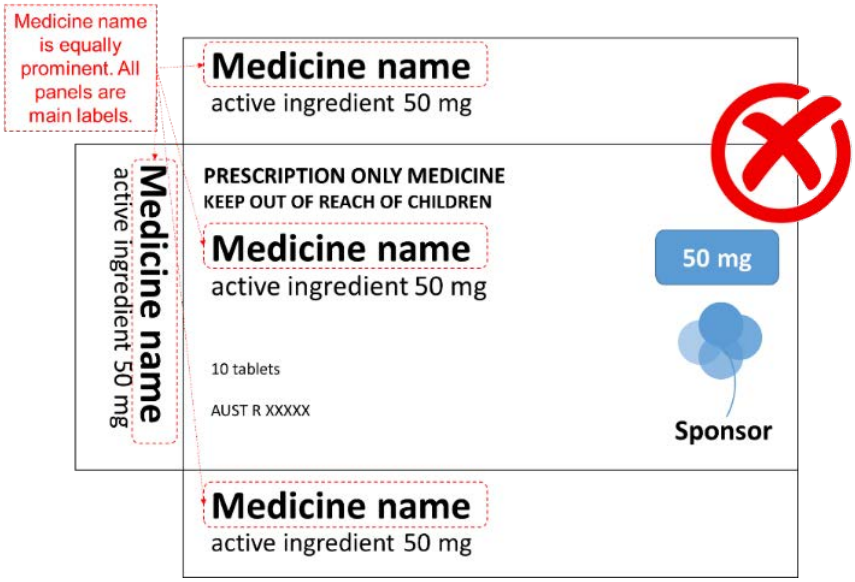
The main label is the portion where the name of the medicine is more or most conspicuously shown (Section 6 of TGO 91). Where the name of the medicine is equally conspicuous on two or more portions of a label, each portion is the main label and all information required on the main label, must be repeated on all portions.

Information that must be included on main labels is defined in Section 9 of TGO 91. Additionally, the main label must include the AUST R number (*Therapeutic Goods Regulations 1990*) and relevant signal heading relating to the relevant scheduling classification (Poisons Standard) for the medicine.

Further details are outlined in Guidance on TGO 91 and TGO 92 (see Section 1.7).

Question

What is wrong with the following example?



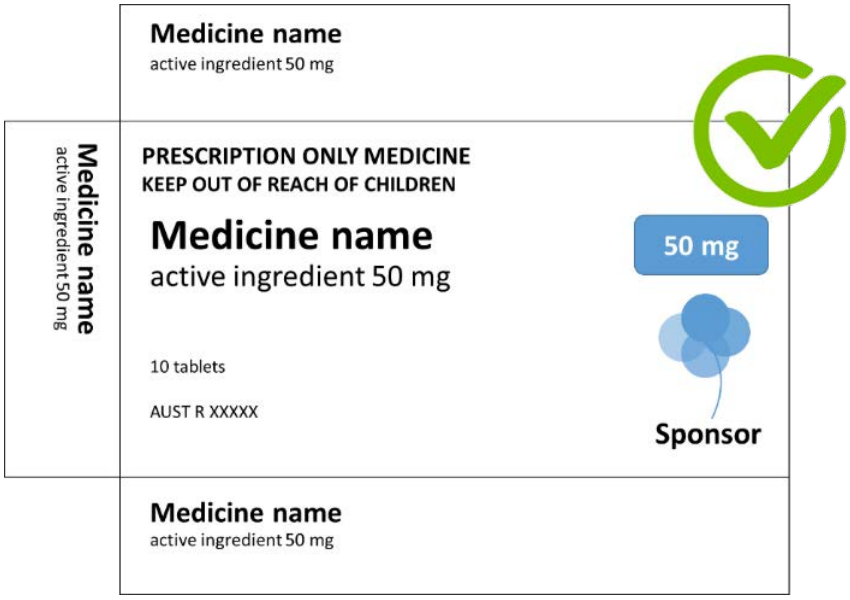
Answer

The medicine name is equally conspicuous (that is, same text size and formatting) on all four portions of the label shown.

Therefore, all four portions are main labels and must include the AUST R number, the signal heading and caution statements, and all 'main label' information stated in Section 9 of TGO 91, including the name of the dosage form and the quantity of the medicine.

Solution

Increase the prominence of the medicine name on the main label. This makes your main label obvious by using different text sizes for the medicine name. You could increase the text size of the medicine name on the main label or decrease the text size on other portions.



Example only, not to scale

If you want two (or more panels) to have equally prominent medicine names, then each panel must include all 'main label' information.

Cohesive unit of medicine name and active ingredient name – TGO 91 help card

Requirements

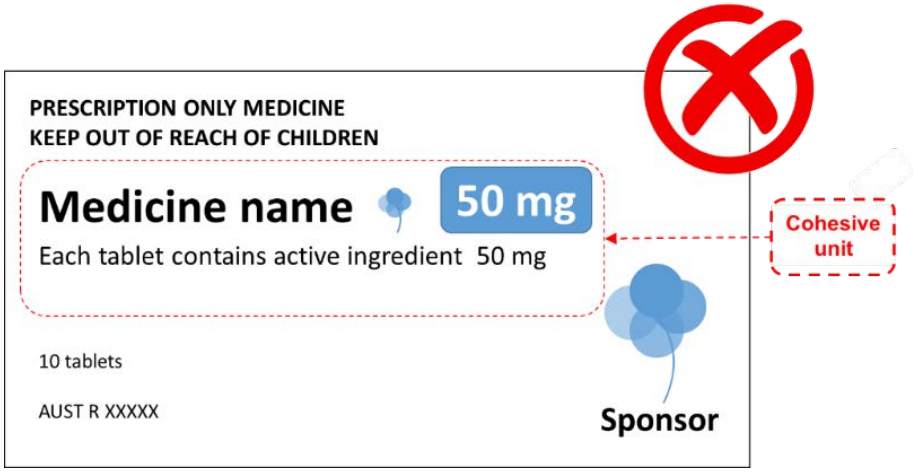
The name of the medicine and the name of active ingredient(s) on the main label must appear as a 'cohesive unit' (Subsection 9(3) of TGO 91).

The name and quantity of an active ingredient must be together and each active ingredient must be on a separate line of text. Active ingredient information must be immediately under the name of the medicine, without being separated by any text or graphics (except in certain circumstances).

Further details are outlined in Guidance on TGO 91 and TGO 92 (see Section 1.7.1).

Question

What is wrong with the following example?

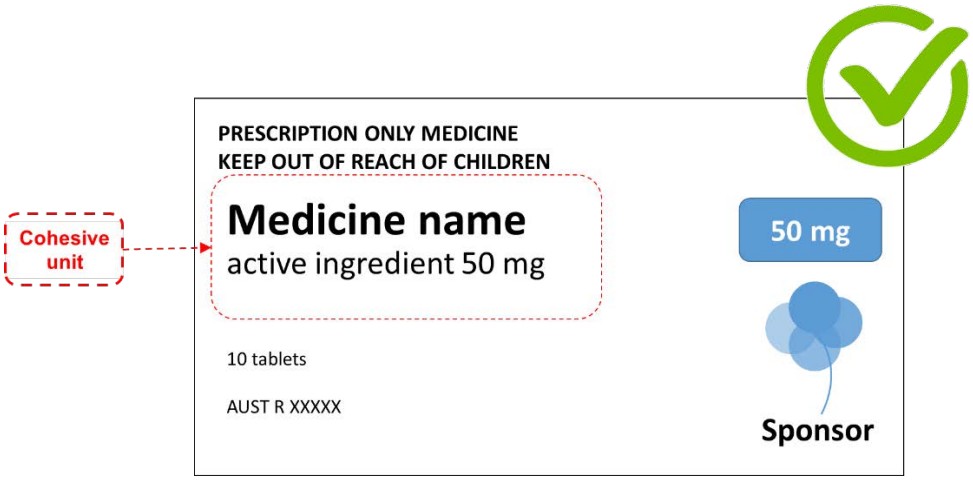


Answer

The logo of the sponsor and 'Each tablet contains' interrupt the cohesive unit (highlighted in red dashed box).

Solution

Unclutter your cohesive unit. Move logo, strength and 'each tablet contains' out of the cohesive unit.



You can place certain information on the same line as the cohesive unit as long as it is spaced far enough away. For example, justified to the right when the cohesive unit is justified to the left. In this example, the '50 mg' blue square graphic should be moved to the right of the label.

Useful tip!

Only certain information should be present in the cohesive unit. All other text and graphics need to be moved or removed.

Medicine name on three non-opposing sides – TGO 91 help card

Requirements

Where the medicine is packaged in a primary package that is a carton, the name of the medicine must appear on at least three non-opposing sides of the carton (Paragraph 8(1)(o) of TGO 91). This allows pharmacists to identify medicines easily regardless of how they are stacked on shelves.

Further details are outlined in Guidance on TGO 91 and TGO 92 (see Section 1.5.1).

Question

What is wrong with the following example?



Answer

The name of the medicine is displayed only on the front and back panels (that is, on two opposing sides).

Solution

Include the name of the medicine on additional non-opposing carton panels.



Schedule 1 substances – TGO 91 help card

Requirements

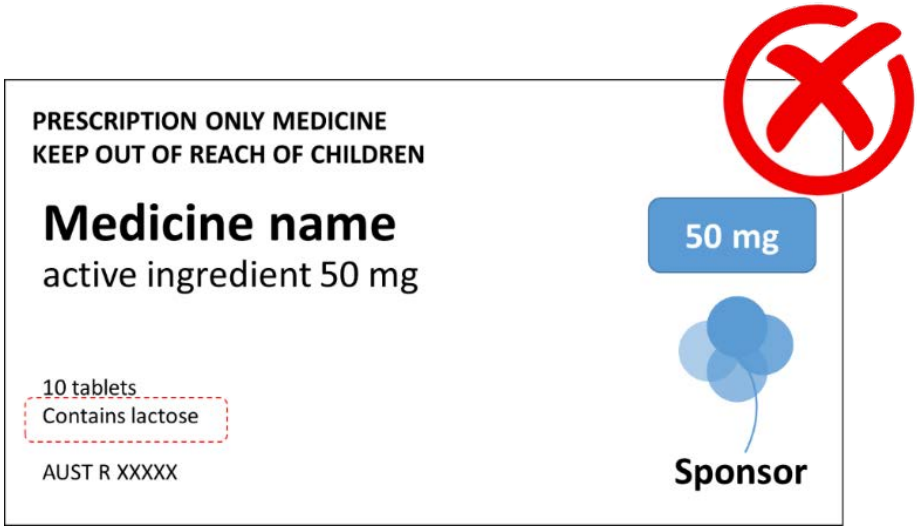
Where a substance referred to in Schedule 1 of TGO 91 is present in the medicine, under the conditions outlined in Schedule 1 the name of the substance must be present on the labels (Paragraph 8(1)(j) of TGO 91).

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

Further details are outlined in Guidance on TGO 91 and TGO 92 (see Section 1.5.9).

Question

What is wrong with the following example? For this example: the maximum daily dose of the product is 100 mg, which may be administered as two 50 mg tablets. Each tablet contains 60mg lactose.



Answers

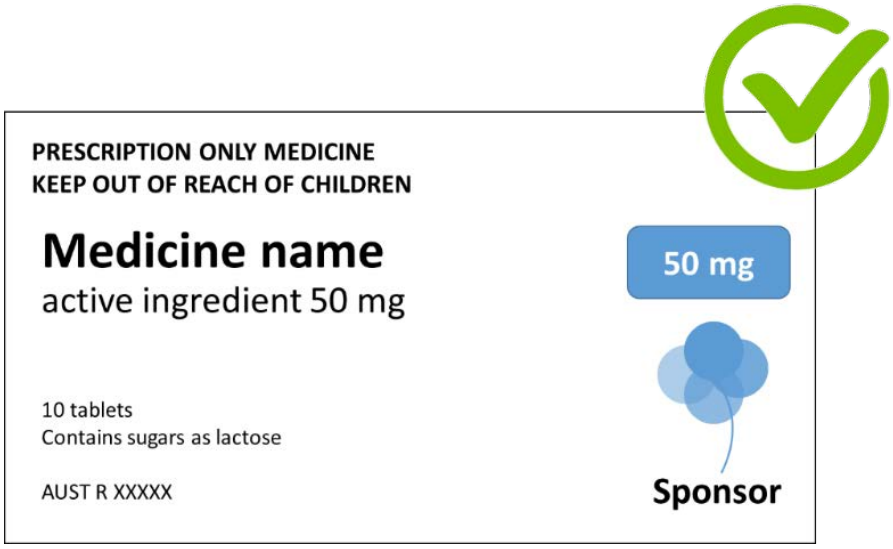
'Sugars' is not declared on the label.

Lactose is listed in Schedule 1of TGO 91. In this example, the dosage form is for oral administration therefore column 3 is applicable and 'lactose' must be declared on the label (column 4).

Also, lactose is a sugar that has a glycaemic effect so the entry 'sugars – monosaccharides and disaccharides' in Schedule 1 also applies. Because the maximum recommended daily dose of the medicine will contain more than 100 mg of lactose (that is, 2 × 50 mg tablets = 2 × 60 mg lactose per tablet = 120 mg lactose in maximum daily dose), column 2 and 3 are satisfied and 'sugars' must also be declared on the label.

Solution

Declare on the label that the medicine 'Contains sugars as lactose.'



Useful tips!

You should check all excipients in the formulation to determine if multiple substances need to be declared. This includes checking components of proprietary ingredient mixtures (such as flavours or colours).

You do not need to include Schedule 1 substances on the main label, but they must be present somewhere on the labels.

Location of batch and expiry details – TGO 91 help card

Requirements

TGO 91 requires that labels include both the:

- batch number of the medicine, preceded by the batch number prefix, and
- expiry date of the medicine, preceded by the expiry date prefix.

This information is required for all dosage forms on the container (for example, on a blister pack or vial label) and, if present, any other packaging (for example, the outer carton).

Options for how to present the batch and expiry prefixes are defined in Section 6 of TGO 91.

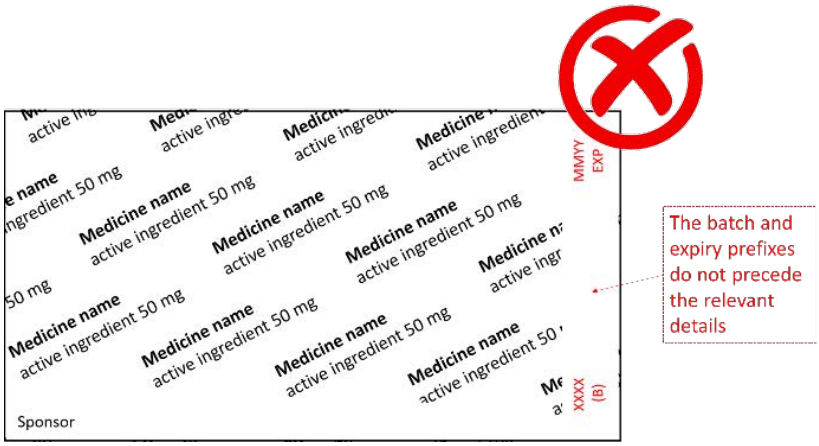
The batch number and expiry date must be preceded by the relevant prefixes, that is, the prefixes must be above or to the left of the related information.

Further details are outlined in Guidance on TGO 91 and TGO 92 (see Section 1.5.5).

Question

What is wrong with the following blister foil examples?



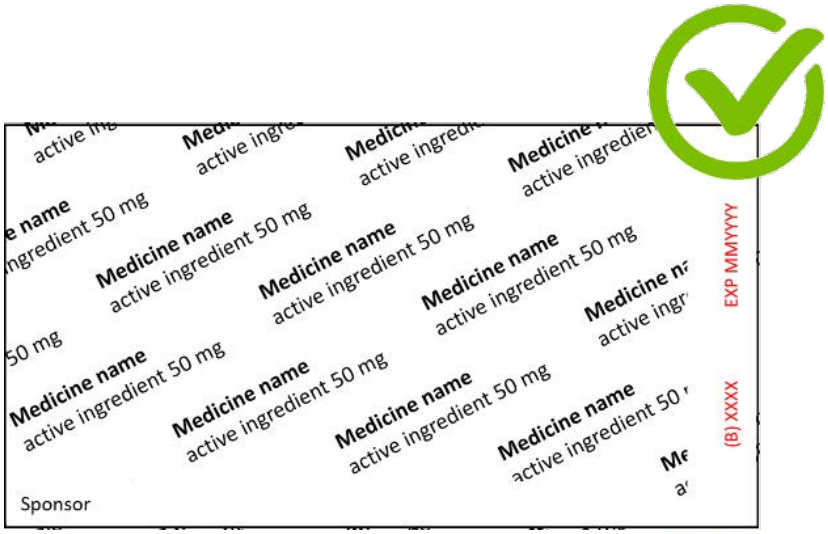


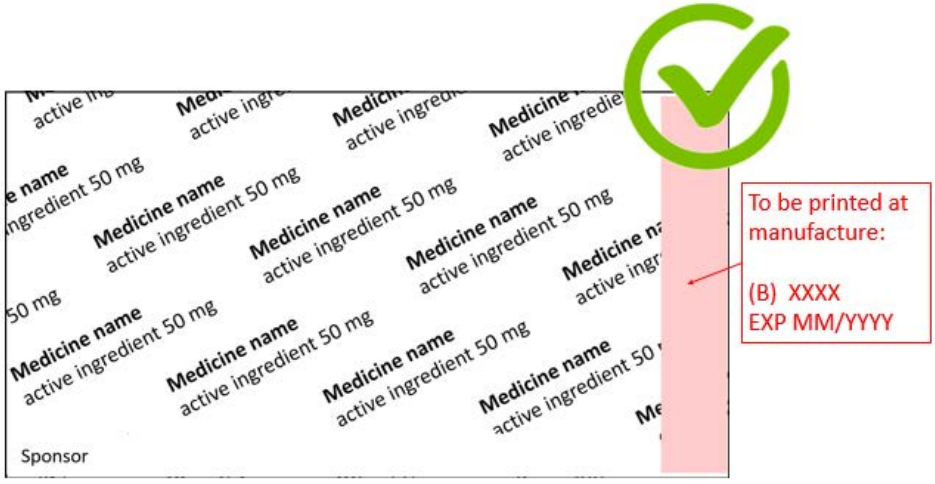
Answers

1. In the first example, the location of the batch and expiry details and their prefixes are not shown.
2. In the second example, the batch and expiry prefixes do not precede the batch and expiry details.

Solution

Show how and where the prefixes and details will appear on the printed labels. Make sure that the batch and expiry prefixes <u>precede</u> (i.e. are to the left or immediately above) the batch and expiry details.





Useful tip!

You can annotate the blister by:

1. including wording of batch and expiry details, or
2. identifying where the details will be located (highlighted in pink in the second example)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Scientific Evaluation Branch	March 2021

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Reference/Publication #