TGO 92 compliance workshop

Vanessa Caig, Assistant Director, Scientific Operations Management Section
Julie Varghese, Senior Evaluator, OTC Medicines Evaluation Section
Leila Shourabi, Scientific Compliance Evaluator, Listing Compliance Section

Department of Health and Aged Care, TGA

General update

Vanessa Caig
Assistant Director
Scientific Evaluation Branch
Department of Health and Aged Care, TGA

General update

Consultation on safety-related updates

Sunsetting of labelling orders

Safety updates to TGO 91 & TGO 92 in 2024

‘Updates to Australian medicine labelling rules to support medicine safety’ consultation is now open for comment about 3 safety issues:

- Making sure that quantities of active ingredients in injectable medicines intended for electrolyte replacement are clearly expressed in units important to health professionals.

- For medicines for injection administered by healthcare professionals that need some preparation before use, making sure that clear instructions on how to prepare and store these products is available in an appropriate format.

- Improving information on listed medicine labels about large solid oral dosage forms intended to be swallowed whole.

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

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

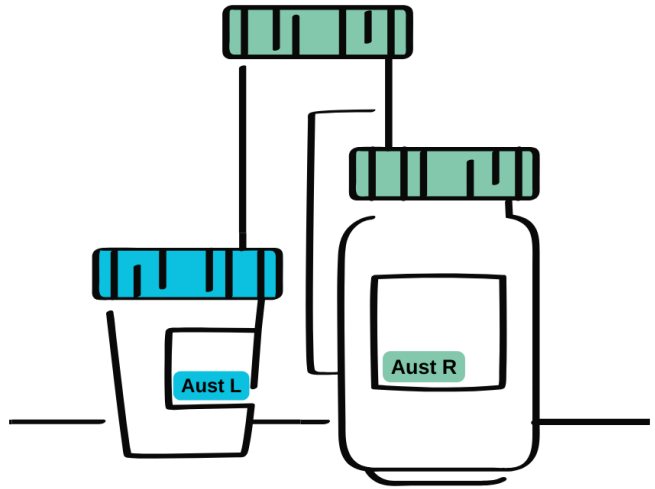
Purpose of medicine labels

- The design and content of labels on medicines can have a significant impact on the quality and safety of medicines use. Labels must clearly identify a particular product and provide sufficient information to allow people to make safe and informed decisions about its use.
- The primary role of a label is to ensure that the medicine is clearly and easily identifiable by health professionals and consumers
- Medicine labels are there to display what you are selecting, what the medicine can do for you, and how to use it
- Labels on medicines that are self-administered should provide information in a way that allows consumers to easily locate and understand the information about how to take their medicine safely and effectively. Standardised and consistent presentation of medicine-related information has the potential to improve health outcomes and reduce medication errors

International harmonisation

TGA aims for harmonisation as much as possible with international regulators however some requirements will always be Australian specific, such as:

- The AUST R or AUST L number
- Requirements from the Poisons Standard



Allergens - Schedule 1 Declarable substances

Schedule 1 is a high priority item to be addressed in sunsetting review.

Known challenges:

- declaration of wheat (not just gluten)
- sulfites cutoff
- gluten cutoff compared to MedSafe

Phenylalanine/aspartame

TGO 91/92:

Aspartame

Must include the name ‘aspartame’ on the label if in a product using oral route of administration

Phenylalanine

Must include the name ‘phenylalanine’ on the label if in a product using a route of administration other than skin and mucous membrane applications

*__Note 5: Phenylalanine -__ In the context of complementary medicines that contain phenylalanine, the Schedule 1 requirements apply in the following instances:

- Where phenylalanine is an ingredient in a medicine formulation.
- For medicines containing ingredients such as *Spirulina*, legumes, nuts or soy products that are naturally high in phenylalanine.
- Where processing of an ingredient, prior to inclusion in a pharmaceutical dosage form, results in enrichment of the phenylalanine content.

RASML (applicable to all registered non-prescription medicines):

Medicines containing aspartame or phenylalanine as an active or excipient ingredient should include the following warning statement when for oral ingestion

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

Labelling requirements & common deficiencies for registered non-prescription medicine labels

Julie Varghese
Senior Evaluator
Complementary and OTC Medicines Branch
Department of Health and Aged Care, TGA

Carton label – Registered non-prescription medicine

Main Label

TGO 92 requirements:

- Name of the medicine
- Name of the active ingredient(s)
- Quantity of the active ingredient(s)
- Name of the dosage form
- Quantity of the medicine

Critical Health Information (CHI) panel

Medicine Information

Active ingredients (in each tablet)

Paracetamol 500 mg
Phenylephrine hydrochloride 5 mg

Uses

For the temporary relief of symptoms of cold and flu including

- ✓ headache
- ✓ body aches & pain
- ✓ sore throat
- ✓ blocked or runny nose

Reduces fever.

Warnings

Do not use

- if you are taking other products containing paracetamol unless advised to do so by a doctor or pharmacist
- in children under 12 years of age

See your doctor or pharmacist before use if

- you have high blood pressure or heart problems or are taking antidepressant medication
- you are pregnant or likely to become pregnant

Unless advised by a doctor

- do not take this medicine for longer than a few days at a time if you are an adult
- do not give this medicine to children and adolescents for longer than 48 hours at a time

While using this product

- Keep to the recommended dose
- This product may cause sleeplessness
- If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26) or go to Hospital straight away even if you feel well because of the risk of delayed, serious liver damage.

Contains sugars (lactose).

Directions for use

Adults and children 12 years of age and over:
Take 2 tablets every 4-6 hours as necessary with water
Do not exceed 8 tablets in 24 hours.

Other information

Store below 25°C away from light.
Do not use if tamper evidence seal is broken.
Distributed by: Company X Pty Ltd, Woden, ACT 2606.

Main Label

Common deficiencies

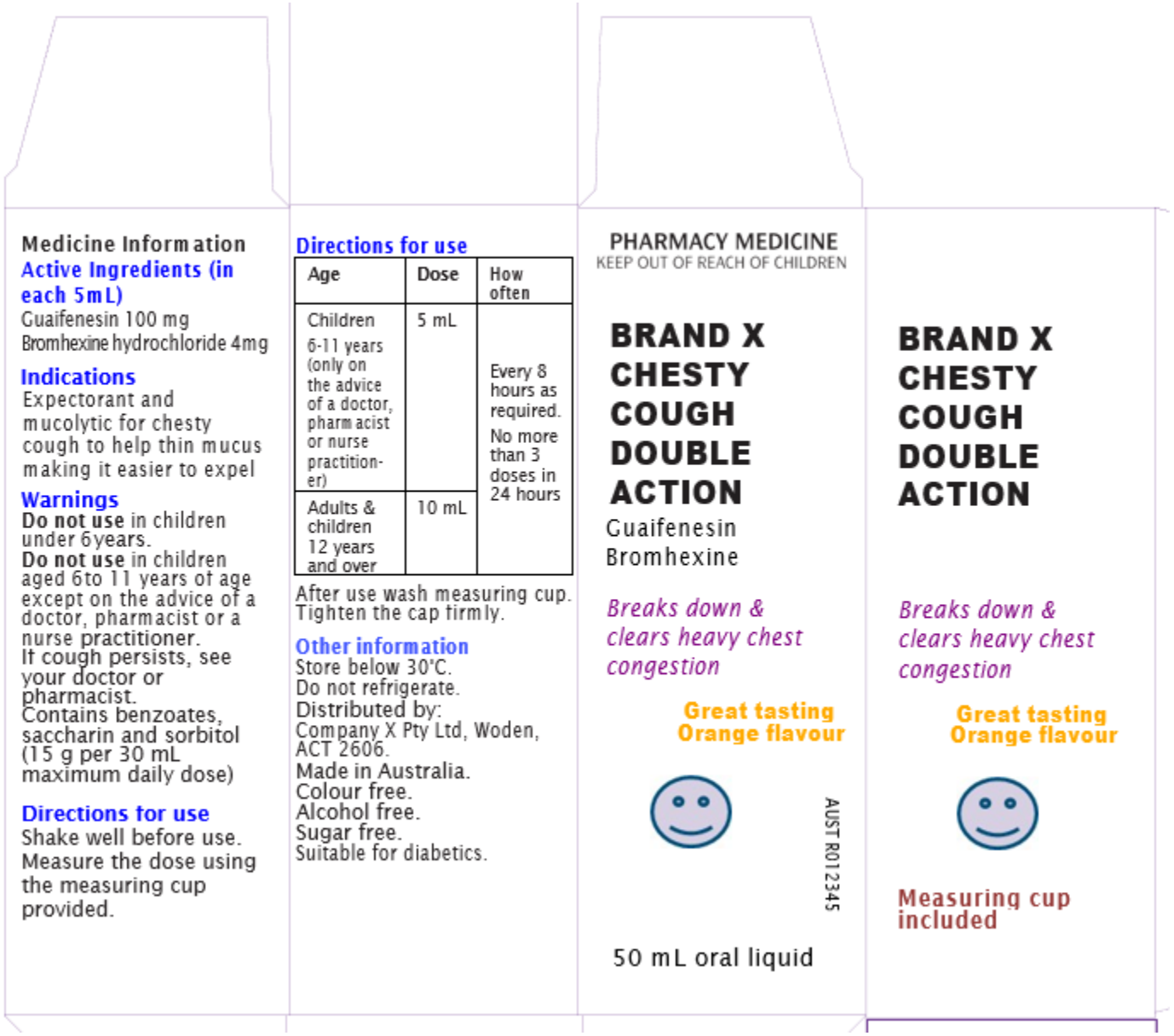
- Background graphics/designs that result in poor readability of text on the main label
- Background colours that result in poor contrast and poor readability of text on the main label
- Text size of the name & quantity of active ingredient(s) on the main label that are non-compliant with the text height requirements outlined in TGO 92
- The name of the medicine is equally prominent on more than one panel on the primary pack but not all the information required to be included on a main label are included on each panel that meets the definition of ‘main label’ in TGO 92
- Other text written on the same line as the signal heading at the top of the main label

Critical Health Information (CHI) panel

Common deficiencies

- Information presented in white text on a dark coloured background
- Information spans across multiple panels but missing ‘Continued -->’ at the bottom of the first panel and the title ‘Medicine Information (Continued)’ at the top of the second and any subsequent panel
- Selective capitalisation of text where it is not a requirement specified elsewhere (e.g. in other legislative instruments) for that text to be capitalised or bolded
- Inclusion of information under the ‘Other Information’ heading that are not specifically permitted to be included under this heading
- Inclusion of promotional claims and ‘Free from…’ claims in the CHI panel

Example



Medicine Information

Active Ingredients (in each 5mL)

Guaifenesin 100 mg
Bromhexine hydrochloride 4mg

Indications

Expectorant and mucolytic for chesty cough to help thin mucus making it easier to expel

Warnings

Do not use in children under 6 years.
Do not use in children aged 6 to 11 years of age except on the advice of a doctor, pharmacist or a nurse practitioner.
If cough persists, see your doctor or pharmacist.
Contains benzoates, saccharin and sorbitol (15 g per 30 mL maximum daily dose)

Directions for use

Shake well before use.
Measure the dose using the measuring cup provided.

Directions for use

Age	Dose	How often
Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)	5 mL	Every 8 hours as required. No more than 3 doses in 24 hours
Adults & children 12 years and over	10 mL	

After use wash measuring cup. Tighten the cap firmly.

Other information

Store below 30°C.
Do not refrigerate.
Distributed by:
Company X Pty Ltd, Woden, ACT 2606.
Made in Australia.
Colour free.
Alcohol free.
Sugar free.
Suitable for diabetics.

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

BRAND X CHESTY COUGH DOUBLE ACTION

Guaifenesin
Bromhexine

Breaks down & clears heavy chest congestion

Great tasting Orange flavour

AUST R012345

50 mL oral liquid

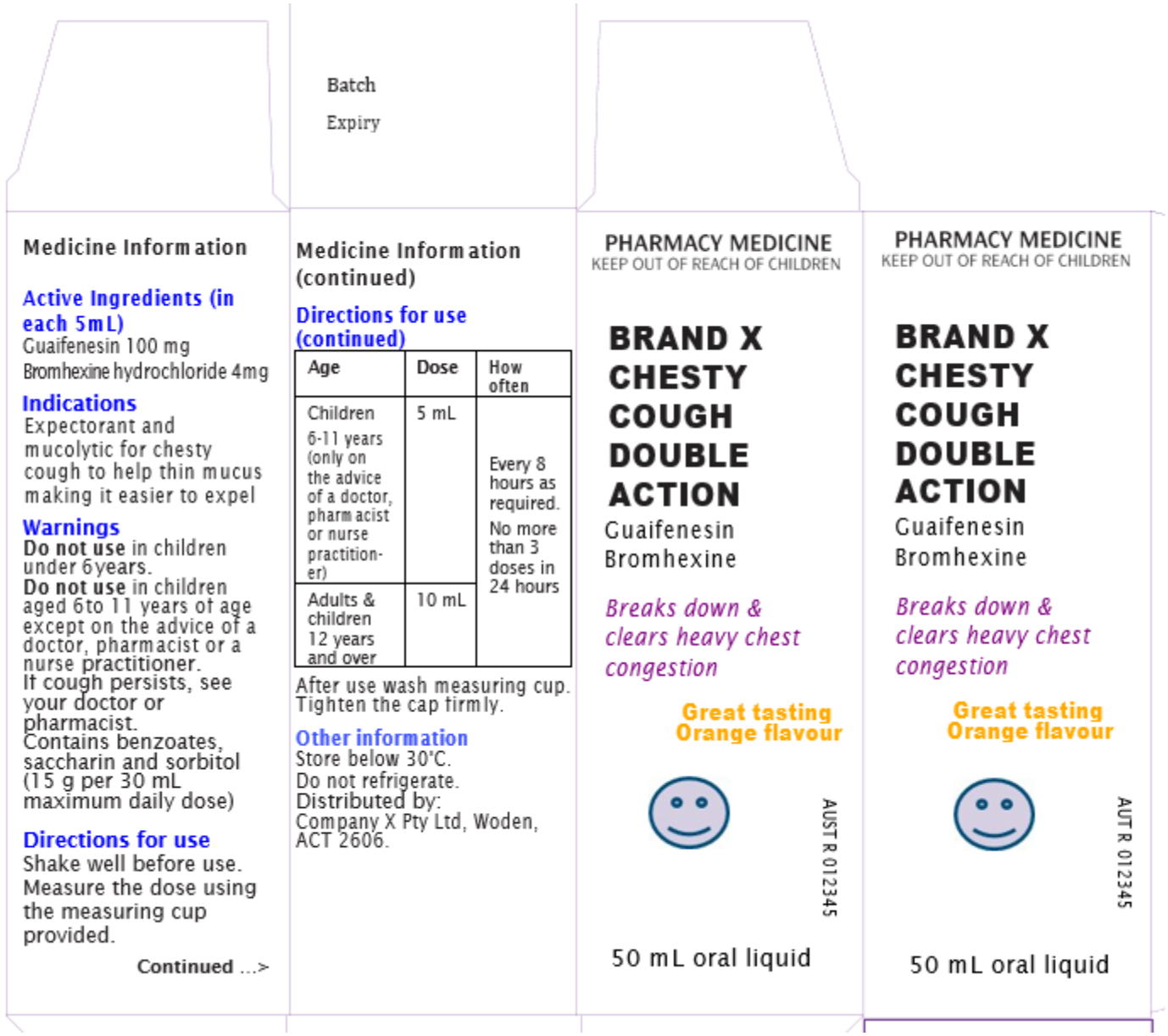
BRAND X CHESTY COUGH DOUBLE ACTION

Breaks down & clears heavy chest congestion

Great tasting Orange flavour

Measuring cup included

Example



Batch

Expiry

Medicine Information

Active Ingredients (in each 5mL)
Guaifenesin 100 mg
Bromhexine hydrochloride 4mg

Indications
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If cough persists, see your doctor or pharmacist.
Contains benzoates, saccharin and sorbitol (15 g per 30 mL maximum daily dose)

Directions for use
Shake well before use.
Measure the dose using the measuring cup provided.

Continued ...>

Medicine Information (continued)

Directions for use (continued)

Age	Dose	How often
Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)	5 mL	Every 8 hours as required. No more than 3 doses in 24 hours
Adults & children 12 years and over	10 mL	

After use wash measuring cup. Tighten the cap firmly.

Other information
Store below 30°C.
Do not refrigerate.
Distributed by:
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PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

BRAND X CHESTY COUGH DOUBLE ACTION
Guaifenesin
Bromhexine

Breaks down & clears heavy chest congestion

Great tasting Orange flavour

AUST R 012345

50 mL oral liquid

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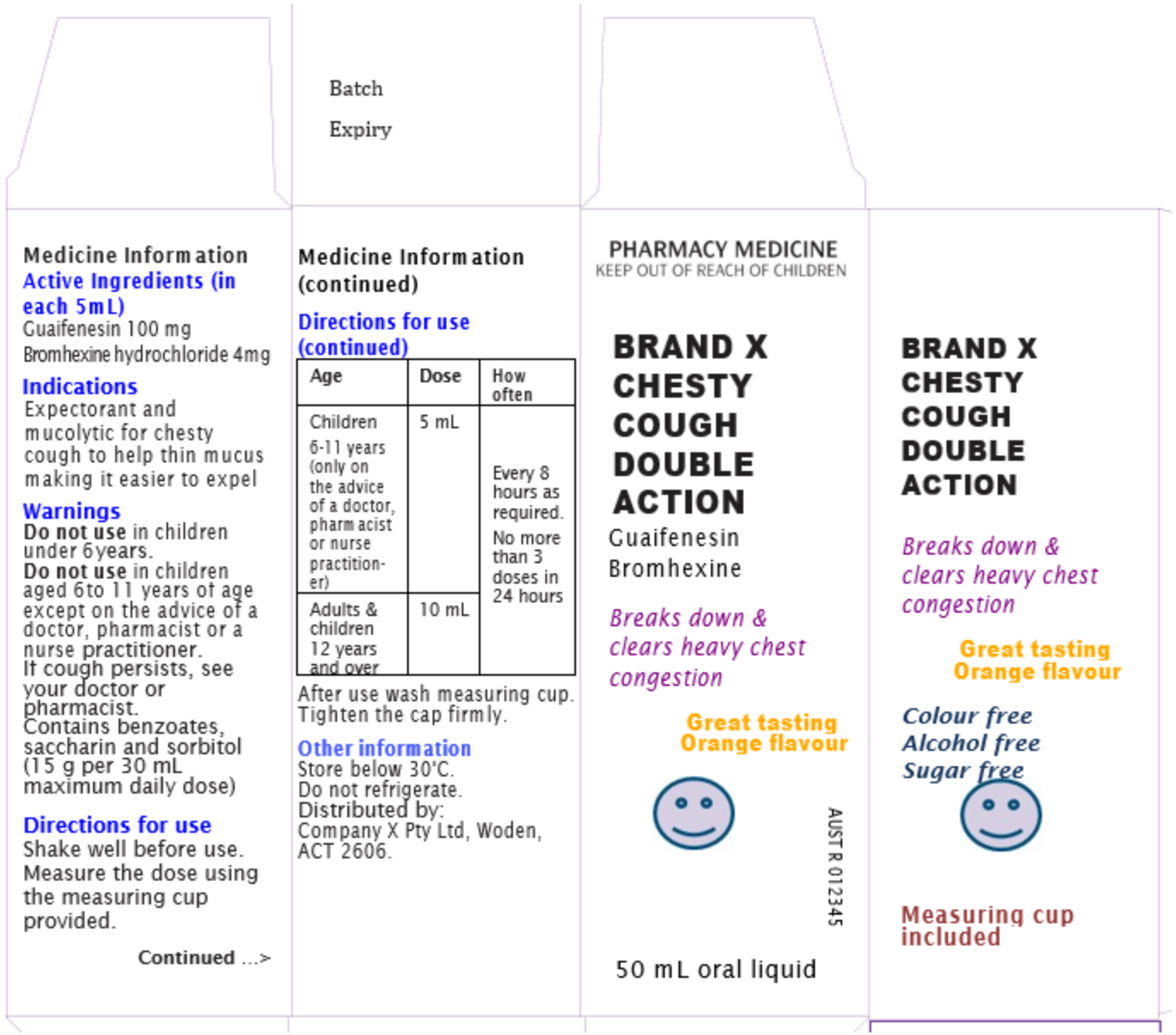
50 mL oral liquid

Example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If cough persists, see your doctor or pharmacist.
Contains benzoates, saccharin and sorbitol (15 g per 30 mL maximum daily dose)
Directions for use
Shake well before use.
Measure the dose using the measuring cup provided.
Continued ...>
Medicine Information (continued)
Directions for use (continued)
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50 mL oral liquid
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Breaks down & clears heavy chest congestion
Great tasting Orange flavour
Colour free
Alcohol free
Sugar free
Measuring cup included

Common compliance deficiencies for listed medicine labels

Leila Shourabi
Scientific Compliance Evaluator
Complementary and OTC Medicines Branch
Department of Health and Aged Care, TGA

Please note that:

- the TGA is unable to provide regulatory advice or interpretation of legislation for specific products;
- legislative provisions included in this presentation may be subject to certain caveats and exceptions. These provisions have been simplified for ease of reference during the workshop;
- examples show what a TGA delegate considers when assessing listed medicine labels. These are only examples of approaches that may be taken to achieve compliance. They should not be used to assess whether a medicine label is compliant; and
- all information in this presentation (and any guidance material) should be read in conjunction with TGO 92. Sponsors and manufacturers should refer to relevant legislation to assess the compliance of their medicine.

Introduction section of TGO 92

Purpose and objectives

- Information included on a label contributes to the **quality use of medicines**. Quality use of medicines means selecting management options wisely, choosing suitable medicines if a medicine is considered necessary, and using those medicines safely and effectively.

- Does the label of your medicine:
  - minimise self-selection errors?
  - enhance consumer safety?
  - avoid consumer confusion and the inappropriate use of your medicine?
  - assist the safe and effective use of your medicine?
  - optimise identification and usability of necessary information?
  - improve consumers' ability to solve problems such as managing multiple medicines or identifying symptoms that may be associated with an adverse reaction? …

TGO 92 does not specify all labelling requirements

- Other legislative instruments may require inclusion of information (that is not required by TGO 92) on the label of medicines for example:
  - the Therapeutic Goods (Permissible Ingredients) Determination;
  - the Therapeutic Goods (Permissible Indications) Determination; and
  - any applicable standards (including the Australian/New Zealand Sunscreen Standard for sunscreens, amongst others).

- Medicine labels must also comply with other Australian legislation requirements. For example:
  - State or Territory legislation for medicines and poisons; and
  - Commonwealth advertising requirements for therapeutic goods specified under the Act and the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument.

Inclusion of additional information on the label

Listed medicine labels may include additional information other than what is required by TGO 92 and other relevant legislative instruments (e.g. information for commercial purposes or claims about the medicine), however:

- it must not prevent compliance with relevant regulatory requirements and must align with certifications made by the sponsor under section 26A of the Act.
- sponsors should assess and justify how the inclusion of the additional information does not make the presentation of the medicine unacceptable (refer to subsection 3(5) of the Act).

Categories of common labelling deficiencies

Bean's Immune Defence is an oral liquid contained in a bottle that is packed in a cardboard box

Medicine name, active ingredient name(s) and quantity

Directions for use, storage conditions, batch number, expiry date and contact details

Warning statements

Schedule 1 substance declarations

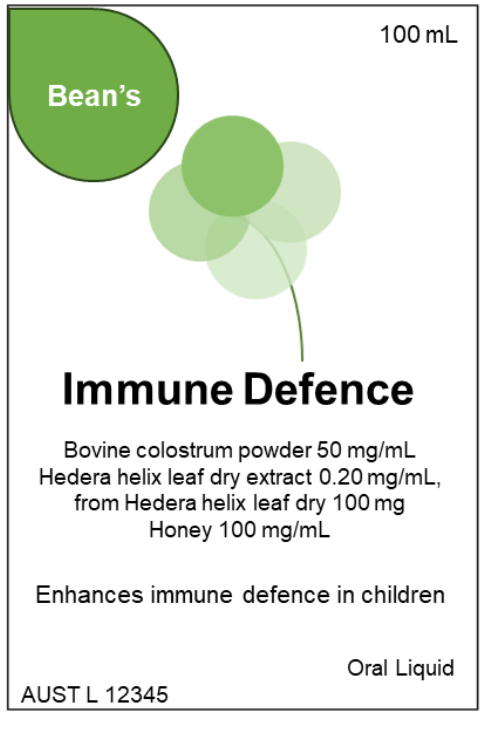
Warning statements

TGO 92 subsection 8(1)

- Paragraph 8(1)(k): **the labels** of a medicine must include relevant *warning statements* (also specifies certain warning statements under subparagraphs (i) and (ii) relating to all medicines).
- Section 6: ***warning statements*** are specified in or required by:
  (a) the Required Advisory Statements for Medicine Labels (RASML), under subsection 3(5A) of the Act;
  (b) any standard that applies to the medicine;
  (c) a condition of registration or listing in relation to the medicine;
  (d) the Permissible Ingredients Determination; and
  (e) the Poisons Standard.

Objective: assisting the safe and effective use of the medicine

Warning statements



ACTIVE INGREDIENTS:

- Bovine colostrum powder 50 mg/mL
- Hedera helix leaf dry extract 0.20 mg/mL, from Hedera helix leaf dry 100 mg
- Honey 100 mg/mL

DIRECTIONS:

Take separately or with food as instructed below and for 30 days:

6 months – 5 years: 2.5 mL, once a day

6 – 10 years: 5 mL, once a day

WARNINGS:

Contains sugars, benzoates, milk products and alcohol. The quantity of alcohol is 4% v/v.

STORAGE:

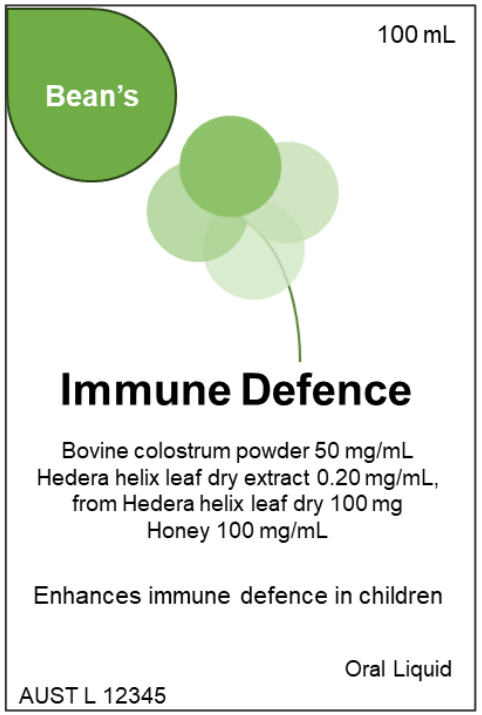
Store below 30°C away from sunlight.

Distributed by: Bean's Pty Ltd; 123 Bean's Ave, Bean's Town, Australia; www.bean'sown.com.au

The Therapeutic Goods (Permissible Ingredients) Determination:

Item	Ingredient Name	Purpose	Specific requirements
936	BOVINE COLOSTRUM POWDER	A	The following warning statement is required on the medicine label: **- (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect).**
2568	HONEY	A, E	When the route of administration is oral, the following warning statement is required on the medicine label: **- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).**

Warning statements



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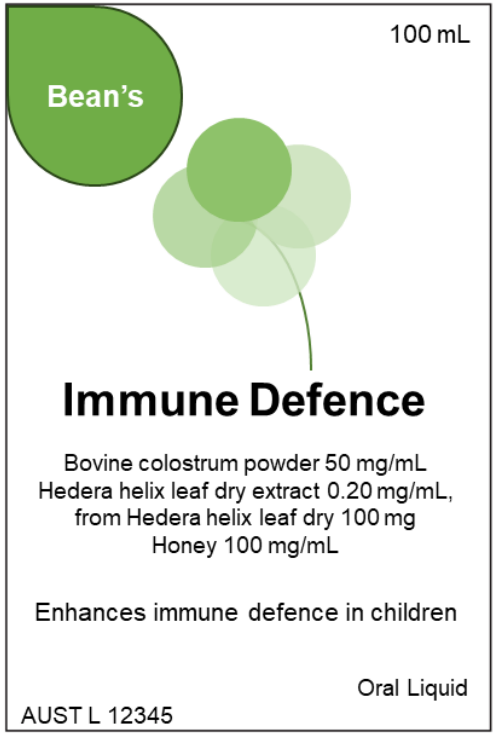

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- Hedera helix leaf dry extract 0.20 mg/mL, from Hedera helix leaf dry 100 mg
- Honey 100 mg/mL

DIRECTIONS:

Take separately or with food as instructed below and for 30 days:

12 months – 5 years: 2.5 mL, once a day

6 – 10 years: 5 mL, once a day

WARNINGS:

Not suitable for infants under the age of twelve months.

Contains sugars, benzoates, milk products and alcohol. The quantity of alcohol is 4% v/v.

STORAGE:

Store below 30°C away from sunlight.

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Schedule 1 substance declarations

TGO 92 subsection 8(1)

- Paragraph 8(1)(j): subject to certain circumstances, the presence of certain **substances** or groups of **substances** referred to in Schedule 1 must be declared on **the labels** of a medicine.
- 'Substances' may be included in a proprietary ingredient (PI) or they may not even be an ingredient (e.g. they may be present in a manufacturing aid or as a contaminant).
- **How to determine when a substance is present, especially when there are no circumstances specified for a substance? What detection limits are appropriate in such cases?**
    - assess the safety risk to consumers to determine whether a substance may be present in the medicine and should be declared.

Objective: assisting the safe and effective use of the medicine

Schedule 1 substance declarations

Column 1 Substance name or Group of substances name	Column 2 Circumstances (if any) and additional requirements (if any)	Column 3 Route of administration	Column 4 Name to be included on the label
aspartame		Oral	aspartame
antibiotics	When the antibiotics is not an active ingredient and is present only as a residual impurity	All	Contains residual 'antibiotic name'
benzoates, including: benzoic acid sodium benzoate		All	benzoates
crustacea and crustacean products (see Note 1), including: crab lobster white shrimp		All	crustacea; or crustacean products
egg, egg products, and products manufactured in eggs including: dried egg yolk egg lecithin influenza vaccine		All	egg; or egg products or manufactured in eggs
ethanol	**Circumstance:** Where present in a concentration of 3% v/v or more. **Requirement:** To declare on the label the quantity of ethanol as % v/v.	All	alcohol
fish and fish products (see Note 2), including:		All	fish; or fish products

Bean's Immune Defence contains benzoic acid in a PI.

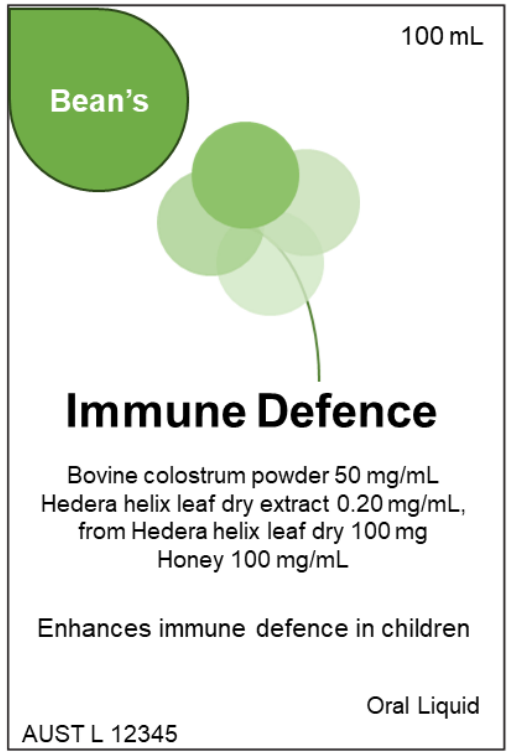
Contains benzoates.

Contains benzoates and alcohol. The quantity of alcohol is 4% v/v.

Bean's Immune Defence contains 4% v/v ethanol.

Contains alcohol. The quantity of alcohol is 4% v/v.

Schedule 1 substance declarations



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- Honey 100 mg/mL

DIRECTIONS:
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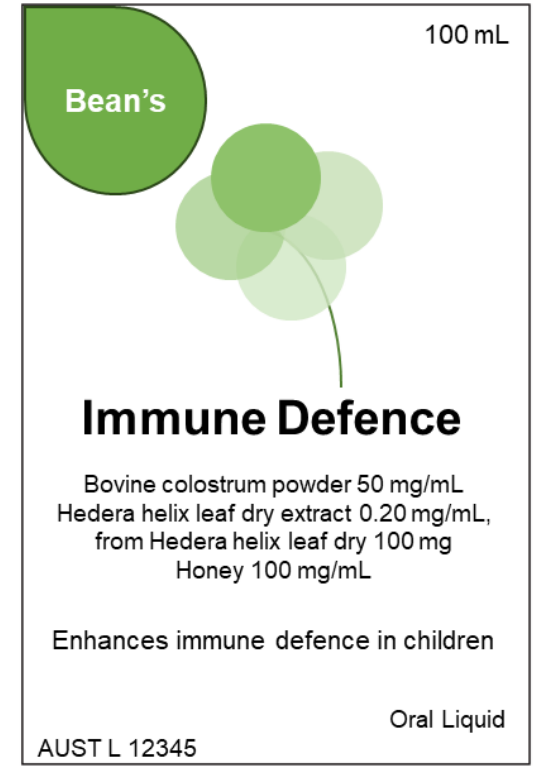
12 months – 5 years: 2.5 mL, once a day
6 – 10 years: 5 mL, once a day

WARNINGS:
Not suitable for infants under the age of twelve months.

Contains sugars. Contains milk products.

STORAGE:
Store below 30°C away from sunlight.

Distributed by: Bean's Pty Ltd; 123 Bean's Ave, Bean's Town, Australia; www.bean'sown.com.au



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WARNINGS:
Not suitable for infants under the age of twelve months.

Contains sugars, benzoates, milk products and alcohol. The quantity of alcohol is 4% v/v.

STORAGE:
Store below 30°C away from sunlight.

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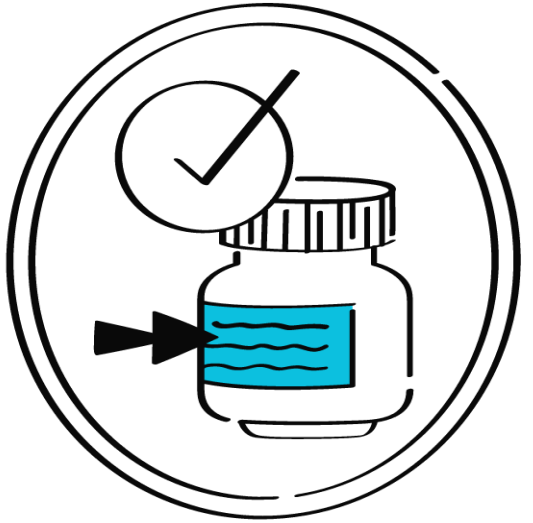
Medicine name, active ingredient name(s) and quantity on the main label

TGO 92 subsections 9(2) and 9(3)

- Subsection 8(1): the name of the medicine, the name(s) and quantity or proportion of all active ingredient(s) in the medicine must be included on **the labels** of the medicine.

- Subsection 9(2): the name of the medicine on the **main label:**
  - must be presented in a continuous, uninterrupted manner; and
  - not be broken up by additional information or background text.



Medicine name, active ingredient name(s) and quantity on the main label

TGO 92 subsections 9(2) and 9(3)

- Subsection 9(3): subject to certain criteria, **the name of the medicine and the name(s) of active ingredient(s) on the main label** must:
  - appear as a **cohesive unit** by the placing of the name and quantity of each active ingredient together **on separate lines of text** either:
    - **immediately below** the name of the medicine; or
    - **adjacent to** the name of the medicine (where the trademark might be disrupted or obscured); and
  - **not be separated** by any text or graphics, **except** where additional information is permitted by specified parts of the Order.

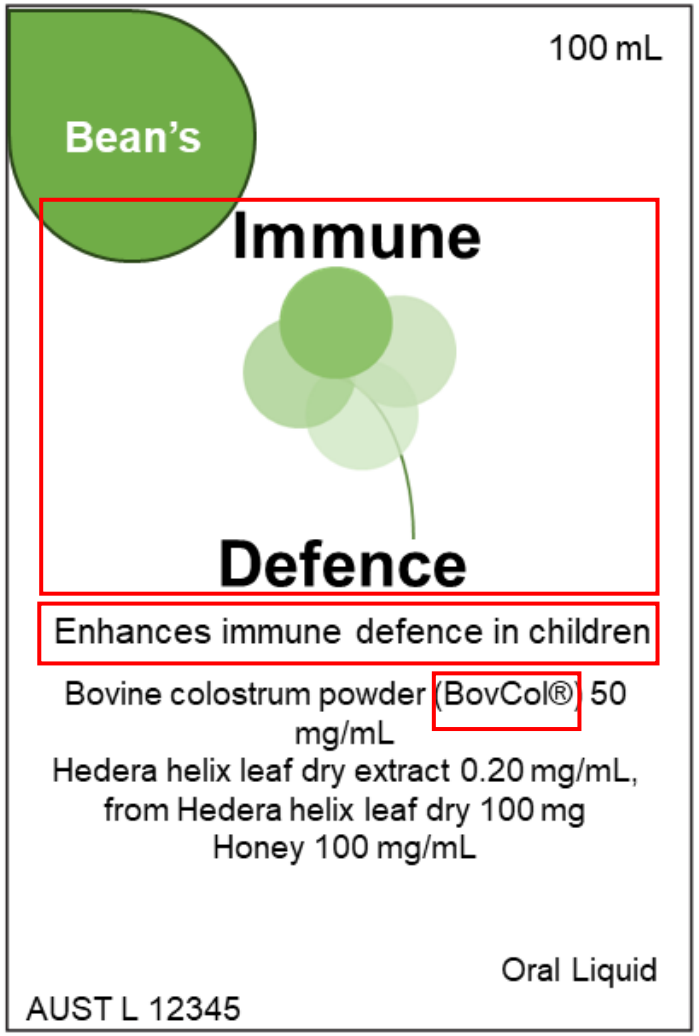
Objective: minimising self-selection errors, optimise identification and usability of necessary information

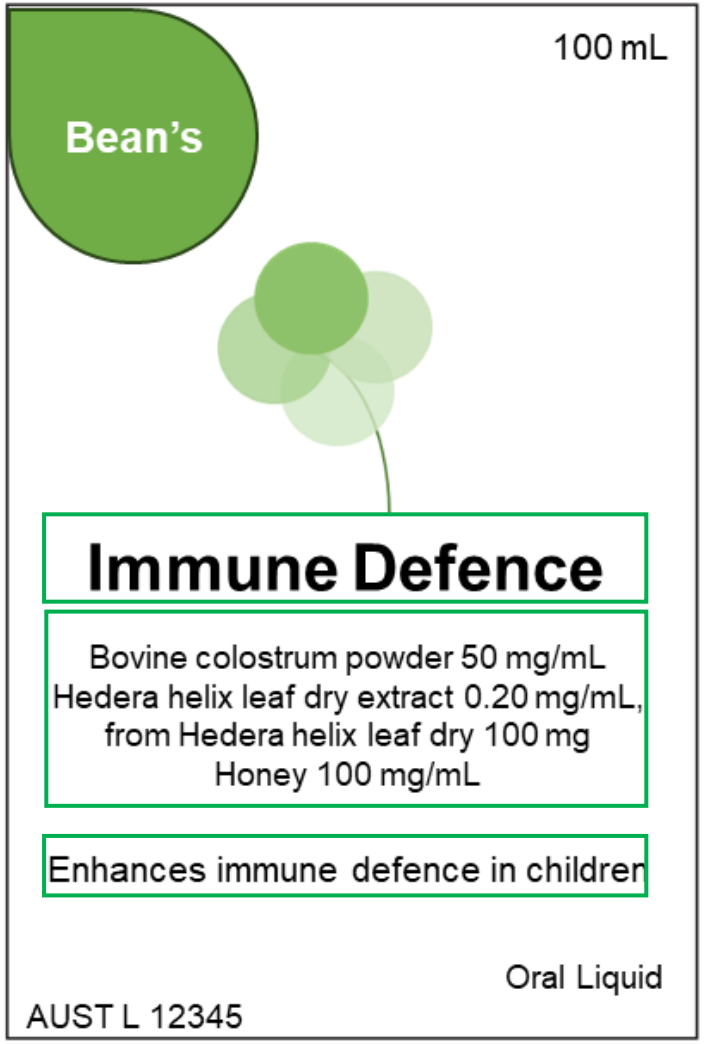
Medicine name, active ingredient name(s) and quantity on the main label

Medicine name is interrupted

Names and quantity of active ingredients are not immediately below the name of the medicine

Name and quantity of this active ingredient are separated by a trademark





Medicine name, active ingredient name(s) and quantity on the main label

Subsections 9(3), 9(5), 9(6), 9(8) and others

- Different requirements may apply for presentation of medicine name and ingredient name(s) on main labels for medicines that:
  - are supplied in a small or a medium container and contain multiple active ingredients;
  - contain two or more active ingredients from certain categories (vitamins, minerals, certain herbal preparations);
  - contain four or more active ingredients;
  - are sunscreen preparations; and
  - are medicine kits or composite packs.

Refer to section 9 in conjunction with relevant subsections in section 10 of TGO 92 for details.

Objective: minimising self-selection errors, optimise identification and usability of necessary information

Directions for use, storage conditions, batch number, expiry date and contact details

Directions for use

- Must be included on all labels, unless subject to exceptions specified in section 8 of TGO 92.
- Refer to subsection 3(1) of the Act for definition of this term, which includes information on appropriate dose, method of administration, frequency and duration of treatment and use by persons of particular ages.

Objective: avoiding consumer confusion and the inappropriate use of the medicine

Storage Conditions

- Must be included on all labels, unless subject to exceptions specified in section 8 of TGO 92.
- Permitted statements of storage temperature conditions are specified in section 11 of TGO 92.

Objective: assisting the safe and effective use of the medicine

Directions for use, storage conditions, batch number, expiry date and contact details

Batch number (and prefix), expiry date (and prefix)

- Must be included on all labels.
- Refer to section 6 of TGO 92 for definition and specified forms.
- Expiry date prefix must not be in the form of 'Best by' or ‘Best before’ or words to this effect.

Objective: assisting the safe and effective use of the medicine

Directions for use, storage conditions, batch number, expiry date and contact details

Name and contact details of a sponsor or distributor

- Refer to section 6 of TGO 92 for definition.
- Must include sufficient information to allow sponsor or distributor to be uniquely identified so as to facilitate public contact.
- If there is a change in sponsorship, receiving sponsor may choose to supply medicines bearing the relinquishing sponsor's name and contact details on the label for up to 12 months.
- Websites (and social media pages) included on the label form part of the presentation of the medicine and must comply with the relevant regulatory requirements (including advertising requirements).

Objective: ensuring consumers are aware of where to go for further information about the medicine

Website and link references

Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines	https://www.legislation.gov.au/F2016L01287/latest/versions
Medicine labels: Guidance on TGO 91 and TGO 92	https://www.tga.gov.au/resources/resource/guidance/medicine-labels-guidance-tgo-91-and-tgo-92
Listed medicines	https://www.tga.gov.au/products/medicines/non-prescription-medicines/listed-medicines
Compliance and education for listed medicines	https://www.tga.gov.au/products/medicines/non-prescription-medicines/listed-medicines/compliance-and-education-listed-medicines
Legislation and legislative instruments	https://www.tga.gov.au/about-tga/legislation/legislation-and-legislative-instruments
Therapeutic Goods determinations	https://www.tga.gov.au/about-tga/legislation/legislation-and-legislative-instruments/therapeutic-goods-determinations
Role of the sponsor	https://www.tga.gov.au/role-sponsor
Australian Register of Therapeutic Goods (ARTG)	https://www.tga.gov.au/australian-register-therapeutic-goods
How we regulate medicines	https://www.tga.gov.au/how-we-regulate-medicines
Compliance management	https://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management
TGA Business Services	https://www.tga.gov.au/tga-business-services

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Complementary and OTC Medicines Branch

Phone: 02 6289 4627

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