Changes to medicine labels

Jenny Burnett
Director, Scientific Operations Management Section
Scientific Evaluation Branch
Medicines Regulation Division, TGA
ARCS Scientific Congress Canberra 2016

10-11 August 2016
Overview

- Why update the TGO 69?
- History and consultation
- Labelling Orders – changes and features
- Questions
Updating the labelling Order

Responding to internal and external stakeholder needs:

• Medicine labels and QUM
• Addressing technical inadequacies
• Clearer labelling requirements
• Need for international alignment
Reform Outcomes

- Consistent location of important health information
- Ensure important information is not obscured
- Improve safety and quality use of medicines for consumers
- Reduce medication errors
History and consultation

Various reviews of labelling & packaging

Pre 2014

2001 – Re-drafting of TGO 69 commenced

2012- Public consultation on labelling and packaging

2013- Review of Evidence regarding key issues about labelling and packaging

Post ANZTPA- removal of ‘packaging’ requirements from scope of review

2014

Redraft of TGO 79

2014 public consultation

Draft TGO 91: prescription medicines

Draft TGO 92: non-prescription medicines

2015 targeted consultation

2015

Draft TGOs 91 & 92 finalisation

August 2016

Post 2014 public consultation, TGO 79 was split into two separate orders: TGO 91 and 92.

Stakeholders who provided submissions in 2014 public consultation were invited to comment.
Two labelling Orders

When one

TGO 69

Becomes two

TGO 91

TGO 92

TGO 91 – For prescription and related medicines

TGO 92 – For non-prescription medicines
Key features and changes to labelling requirements
4 year transition period

**Prescription**
- TGO 69
- or
- TGO 91

**Non-prescription**
- TGO 69
- or
- TGO 92

**End of transition period**
- TGO 91
- TGO 92
Prominence of Active Ingredient

- Larger and clearer text
- Consistent location of information
- Easier identification of active ingredient name and quantity information
Schedule 1 – Declarable substances

• The list has grown to address consumer needs
  – Crustacea
  – Fish
  – Eggs
  – Soya
  – Milk
  – Tree nuts

• Some entries have been modified
  – Gluten now has a 20ppm cut off

• Prescription Medicines can use a label statement referring consumers to CMI for declarable substances
Key prescription medicine changes

- Medicine name to be on at least 3 sides of the carton
- Mandatory 70x30mm space for dispensing labels
- Small containers now 25mL capacity
- Microgram and microlitre must be spelled out in full (no µ allowed except small and very small containers)
Prescription medicine label

- **MediBrand**
- **StrongPain Medication**
- Active ingredient 15 mg
- Other active ingredient 5 mg
- 28 tablets

**Dedicated space for pharmacy label**

**Statement identify substance from Schedule 1**

**Active ingredients immediately below medicine name AND larger text size**
Key non-prescription medicine changes

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 25mL capacity
- New medium container size up to 60mL
Non-prescription OTC medicine label

Active ingredients immediately below medicine name AND larger text size

No additional information between medicine name and active ingredient

Improved contrast between required information and background

Critical Health Information in tabulated format with headings in specified order

Changes to medicine labels
Non-prescription listed medicine label

- No logos or pictures that break up the medicine name
- Active ingredients immediately below medicine name (no new text size requirements)
- Improved contrast between required information and background

**Wonder Herbals Womens’ Healthy Herb**
will help provide you with relief for all your mild pain problems, including headache, toothache, period pain, back pain and other types of mild pain.
Take one tablet daily or as recommended by your health professional.

No artificial colours or flavours!

Contact Wonder Herbals
Add: 1275 The Main Northern Beaches, Sydney, Australia
Ph: 02 2234 5875
Email: wacaro@wonderherbals.com.au
Questions?