Australian Government
Department of Health
Therapeutic Goods Administration

Better medicine labels

New requirements under TGOs 91 and 92

Jenny Burnett
Director, Scientific Operations Management Section
Scientific Evaluation Branch
Therapeutic Goods Administration

Royal Australian Chemical Institute (RACI) Pharmaceutical Science Group Seminar

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TGA Health Safety Regulation

Overview

- Why update the TGO 69?
- History and consultation
- Labelling Orders – changes and features
- Latest developments …

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

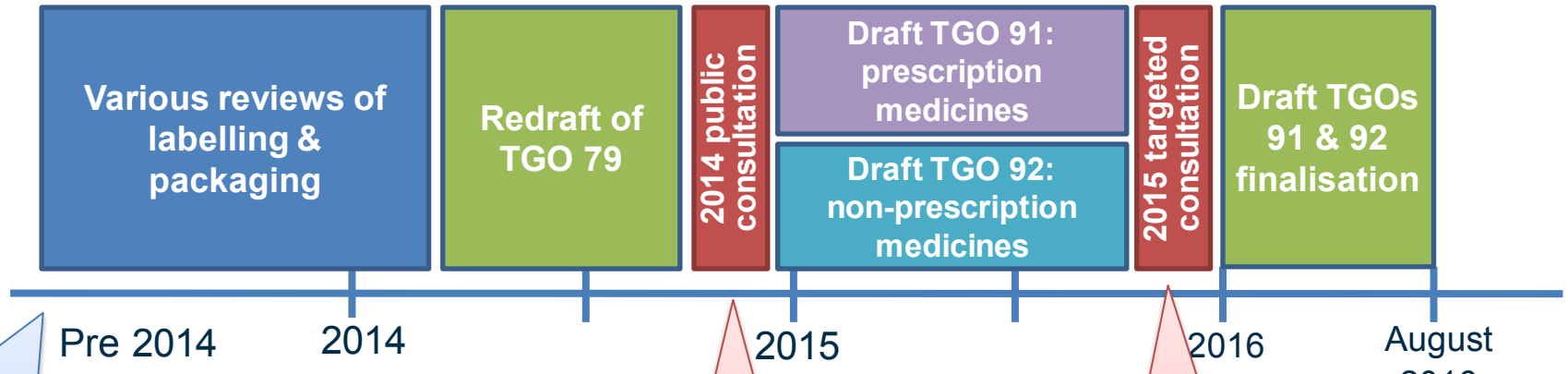
Reform outcomes

Consistent location of important health information

Ensure important information is not obscured

Improve safety and quality use of medicines for consumers

History and consultation



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

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

Becomes two

TGO 91 – For prescription and related medicines

TGO 92 – For non-prescription medicines

Key features and changes to labelling requirements

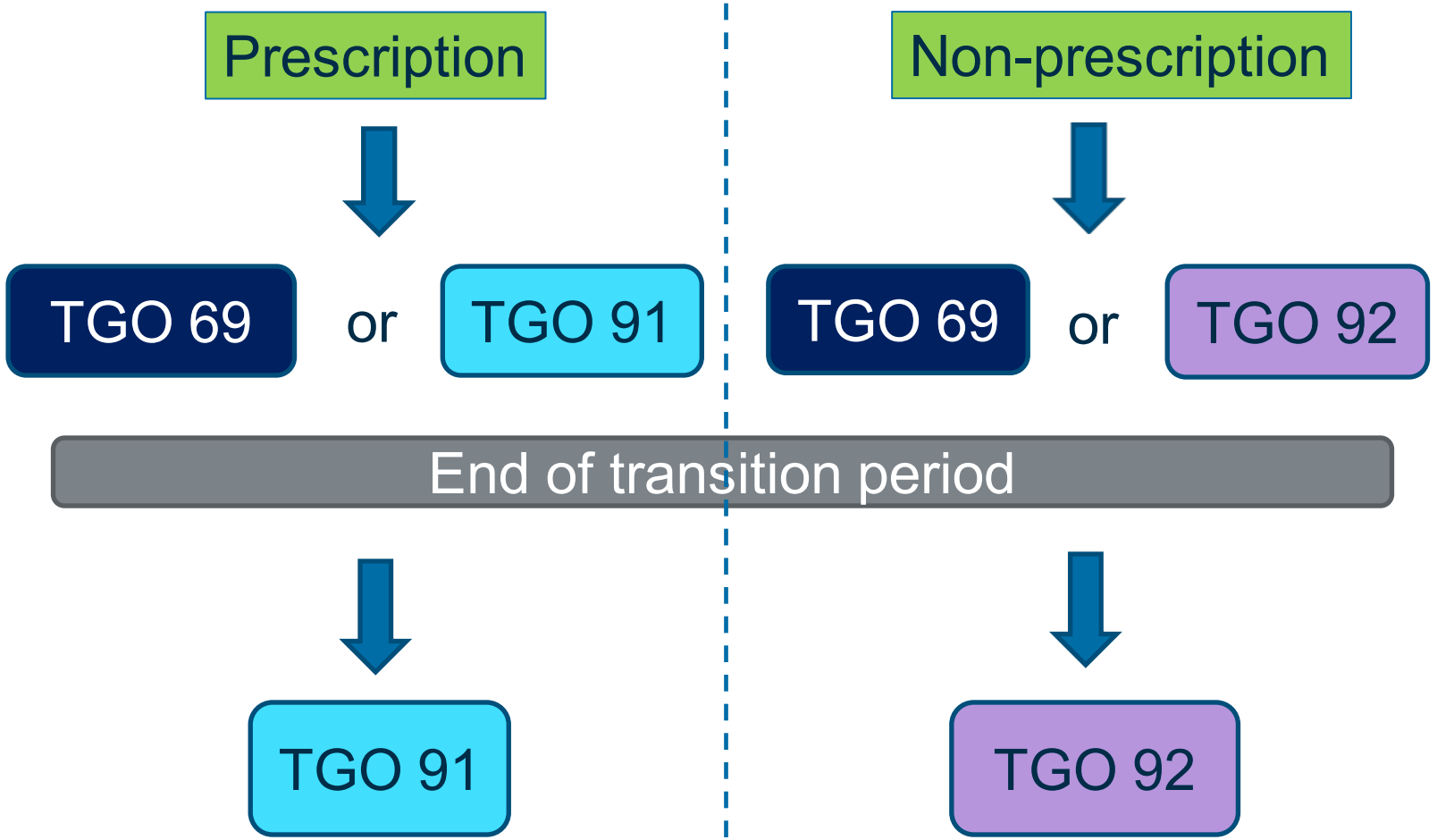
Implementation of the new requirements

TGO 91 and 92 are registered on the Federal Register of Legislation (FRL)

- Commencement date → 31 August 2016
- Transition period → ends 31 August 2020

TGO 69 has no effect from 1 September 2020

4 year transition period



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

- Informing consumers!
- The list has grown
  - Crustacea
  - Fish
  - Eggs
  - Soya
  - Milk
  - Tree nuts

- Prescription Medicines can use a label statement referring consumers to the CMI for declarable substances

Declarable substances - testing implications

- ‘Substances’ NOT excipients
- Testing rationales
- Some entries have been modified
  - Gluten now has a 20ppm cut off

Key prescription medicine changes

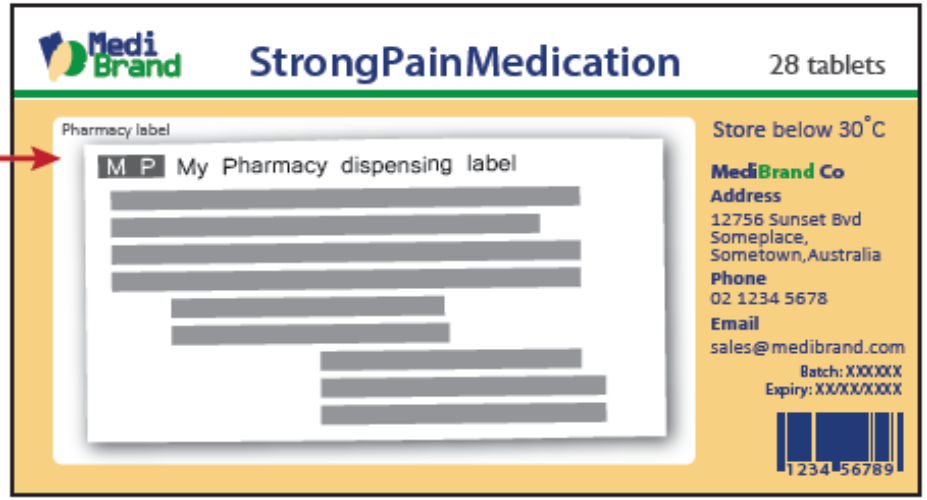
- Medicine name to be on at least 3 sides of the carton
- Mandatory 70x30mm space for dispensing labels
- Small containers now 25mL capacity
- Microgram and microlitre must be spelled out in full (no µ allowed except small and very small containers)

Prescription medicine label

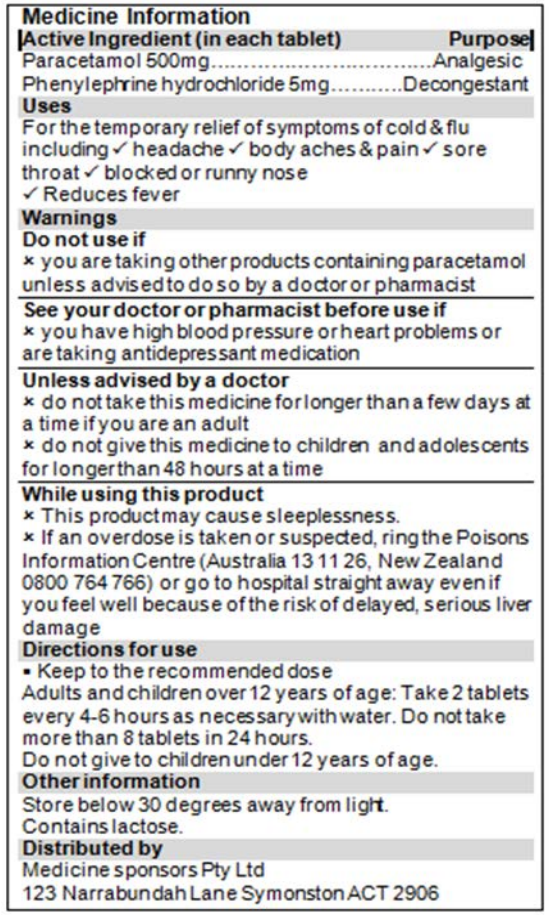
Statement identify substance from Schedule 1

Active ingredients immediately below medicine name
AND
larger text size

Dedicated space for pharmacy label



Key non-prescription medicine changes



Medicine Information

Active Ingredient (in each tablet)	Purpose
Paracetamol 500mg	Analgesic
Phenylephrine hydrochloride 5mg	Decongestant

Uses

For the temporary relief of symptoms of cold & 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

See your doctor or pharmacist before use if

× you have high blood pressure or heart problems or are taking antidepressant medication

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

× This product may cause sleeplessness.
× If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage

Directions for use

• Keep to the recommended dose
Adults and children over 12 years of age: Take 2 tablets every 4-6 hours as necessary with water. Do not take more than 8 tablets in 24 hours.
Do not give to children under 12 years of age.

Other information

Store below 30 degrees away from light.
Contains lactose.

Distributed by

Medicine sponsors Pty Ltd
123 Narrabundah Lane Symonston ACT 2906

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

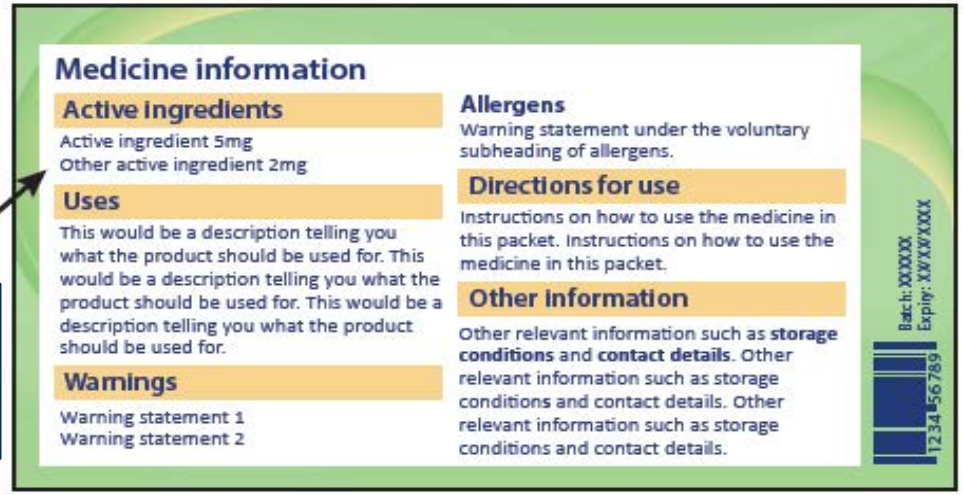
- Small containers now 25mL capacity
- New medium container size up to 60mL

Non-prescription OTC medicine label

Active ingredients immediately below medicine name
AND
larger text size

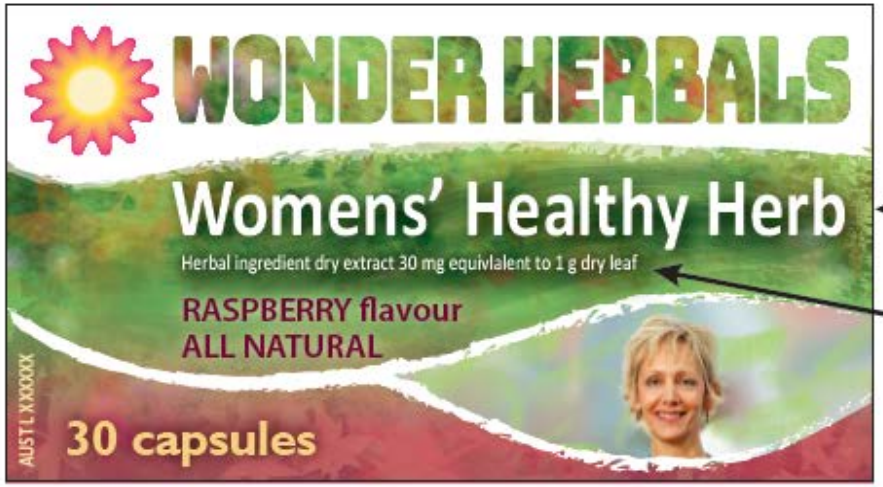
No additional information between medicine name and active ingredient

Improved contrast between required information and background



Critical Health Information in tabulated format with headings in specified order

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

Country of origin

- No requirement under therapeutic goods legislation
- Commerce (Imports) Regulations 1940
- Australian Consumer Law
  - ‘substantial transformation’

Now that it is out in the world…

Further amendments

- Multiple ‘declarable substance’ statements
- Clarity and consistency in Na and K statements
- New name for re-made TGO 69
- More guidance

Questions?

Australian Government

Department of Health

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