A journey to better medicine labels
- an update on TGO 92

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Overview

- How did we get here?
- What do we have?
- How is it going?
  - 3 main issues
- Who is the label for?
Updating medicine labels

Responding to internal and external stakeholder needs:

- Medicine labels and QUM
- Addressing technical inadequacies
- Clearer labelling requirements
- Need for international alignment
Labelling Reform

- Consistent location of important health information
- Improved readability of important health information
- Improve safety and quality use of medicines for consumers
- Reduce medication errors
Two labelling Orders

When one

TGO 69

Becomes two

TGO 91

TGO 92

TGO 91 – Prescription and related medicines

TGO 92 – Non-prescription medicines
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
Reality of implementation
Nothing is perfect …

First round of amendments

- Multiple ‘declarable substance’ statements
- Clarity and consistency in Na and K statements
- New name for re-made TGO 69
- Oops!
Updates to legislative instruments

• Due process to follow
  – Assess regulatory impact
  – Legal drafting
  – Delegate’s approval and registration

• Amendment instruments
  – registered in early August
  – details in the Explanatory Statements

• Compilation due within 20 days

• Further amendments??
Updates to guidance

• Corrections:
  – Text wrapping for active ingredient
  – Examples for standardised herbal ingredients

• Further guidance on prominence of active ingredients

• More detail
Key changes – how are we faring?
"I admit this new bill is too complicated to understand..... We will just have to pass it to find out how it works!"

Grin and Bear It, George Lichty
Published in Los Angeles Times: March 12, 1947
Source – Language Log
Prominence of active ingredient

• Larger and clearer text
• Consistent location of information
• Easier identification of active ingredient name and quantity information
Questions from industry

- What exactly does ‘Name of the medicine’ mean?
- What is a cohesive unit?
- Does text alignment = cohesive unit?
- Where can the images and graphics be located?
- How close can other text be?
- Where can I write ‘each tablet contains’?
- My active ingredient doesn’t fit on one line!
Our advice …

• Prominence of active ingredients and medicine names table – pg. 18 of guidance
• Images permitted around the text or as a background image
• Overall presentation of the medicine – does it look like a cohesive unit?
• Correction to guidance – text can wrap onto next line
• Consider use of active moiety
Schedule 1 – Declarable substances

• Informing consumers!

• Substances, not excipients

• The list has grown
  – Crustacea  – Soya
  – Fish  – Milk
  – Eggs  – Tree nuts
What does this mean for sponsors?

• Some entries have been modified
  – gluten, 20 ppm cut-off

• Testing rationales
  – many entries have no detection limits
  – used during manufacturing process?
  – likely to be present in an ingredient?
  – what about contamination?
Tabulated CHI

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

Consistent order and grouping of information

Use of ‘active moiety’ on main label instead of full ingredient name
Questions from industry

- Can I include warning information under other headings?
- If I include a CHI table when it is not required, does it have to look the same?
- Can I include free-from statements in the ‘other information’ field?
- What can I include as the statement of purpose? How is this different from indications?
We all use medicine labels

Frequent enquiries from consumers and industry – interest level is high!

- New webpage for consumers
- New webpage for health professionals
- Input to newsletters
- Social media
- Specific guidance for industry?? – let us know
Questions?