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Consultation: Medicine labelling

22 August 2014

Closing date: 7 October 2014

Invitation to comment

The TGA is seeking comments from interested parties on any, or all, of the proposed options in the Regulation Impact Statement on the general labelling requirements for medicines.

The TGA is also seeking comments from interested parties on the following documents:

- Therapeutic Goods Order (TGO) No. 79 Standard for the labelling of medicines. If adopted, this will replace the current labelling order, TGO 69
- Comparison of TGO 79 with TGO 69
- Guideline on medicines labelling

Submissions are invited to include:

- suggested improvements or alternatives to proposed changes;
- whether or not you support the specific proposals or combinations of proposals. If you do not support the proposals you may make suggestions for an alternative acceptable to you;
- an assessment of how the proposed change will affect you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial?).

Consultation documents

How to access a pdf or Word document

Consultation: Regulation Impact Statement (RIS) - General requirements for labels for medicines

Consultation: Regulation Impact Statement (RIS) - General requirements for labels for medicines (pdf,345kb)

Consultation: Regulation Impact Statement (RIS) - General requirements for labels for medicines (Microsoft Word,126kb)

Consultation: Therapeutic Goods Order (TGO) No 79 - Standard for the labelling of medicines

Consultation: Therapeutic Goods Order (TGO) No 79 - Standard for the labelling of medicines (pdf,335kb)

Consultation: Therapeutic Goods Order (TGO) No 79 - Standard for the labelling of medicines (Microsoft Word,182kb)

Consultation: Comparison of TGO 79 with TGO 69

Consultation: Comparing TGO 79 with TGO 69 (pdf,297kb)

Consultation: Comparing TGO 79 with TGO 69 (Microsoft Word,117kb)

Consultation: Guideline on medicine labelling

Consultation: Guideline for the labelling of medicines (pdf,469kb)

Consultation: Guideline for the labelling of medicines (Microsoft Word,133kb)

Timetable

Documents released for consultation on **Friday 22 August 2014**.

Interested parties should respond by close of business **Tuesday 7 October 2014**.

Feedback will be released following consideration of submissions. (See 'What will happen').

About the consultation

The Regulation Impact Statement (RIS) will be presented along with the other documents (the TGO and associated Guidance documents) to the Assistant Minister for Health, Senator the Hon Fiona Nash, who is responsible for matters relating to the Therapeutic Goods Administration.

The documents are being released for comment, input and feedback from all parties affected by these reforms.

Background

A first consultation paper, Labelling & Packaging (closed consultations & reviews), was released by the TGA on 24 May 2012, with consultation closing on 24 August 2012.

The review was conducted to assess whether the requirements specified for medicine labels and packaging in the current Therapeutic Goods Order 69 (TGO 69) General requirements for labels for medicines, which has been in place since 2001, continue to be relevant to the objectives of the National Medicines Policy.

The objective of the review was to develop appropriate regulatory solutions that effectively addressed the consumer safety risks posed by the following issues:

- information about the active ingredient(s) contained in the medicine is not always easy to find
- use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)
- medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine
- medicine containers and packaging that looks like that of another medicine
- lack of a standardised format for information included on medicines labels and packaging
- dispensing stickers that cover up important information
- information provided on blister strips
- information included on small containers

The revised draft Therapeutic Goods Order (TGO 79) for labelling of medicines is a result of feedback from the first consultation process. The RIS will be used to assist Government decision making on whether the TGA can implement the revised Therapeutic Goods Order.

Content of submissions

Submissions may address, any, or all of the proposed amendments to Therapeutic Goods Order 79 and options identified in the RIS. In addition, submissions might include information on:

- suggested improvements or alternatives to proposed options;
- whether or not you support the specific options, If you do not support the options you may make suggestions for an alternative acceptable to you; and
- an assessment of how implementation of option 3 will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

The TGA is also seeking comments on improvements to the Guideline to Medicine Labelling and the document comparing TGO 79 to TGO 69.

How to respond

All submissions should be accompanied by a TGA submission cover sheet. Submissions must include full personal or organisational contact details (including address, telephone number and email).

Submission cover sheet: Consultation: Medicine labelling (Microsoft Word,36kb)

Electronic submissions are preferred and should be emailed to labellingreview@tga.gov.au. Please include '**Medicine Labelling Consultation**' in the subject line of the email.

Alternatively, hardcopy submissions may be mailed to:

TGA Medicine Labelling Consultation
Management and Coordination Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

What will happen

All submissions will be placed on the TGA Internet site unless marked confidential or indicated otherwise in the submission cover sheet (see Privacy information).

Submissions will be reviewed by the TGA and feedback on submissions will be provided through the TGA Internet site.

Consultation of the RIS will be used to inform the final RIS. The final RIS will be presented to Government as well as the finalised Order (TGO 79) and associated Guidance documents for consideration late 2014.

Privacy information

- The TGA collects your personal information in this submission in order to:
  - contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.
  - help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).
- The TGA will disclose your name and (if applicable) your designation/work title on the TGA Internet site (i.e. make this information publicly available) if you consent to the publication of your name on the TGA Internet site (please complete the cover sheet).
- Any text within the body of your submission that you want to remain confidential should be clearly marked 'IN CONFIDENCE'.
- Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Enquiries

Any questions relating to submissions should be directed to the Management and Coordination Section of the Office of Scientific Evaluation in the Market Authorisation Group by email to labellingreview@tga.gov.au or by telephone to 02 6232 8704.

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