

CONSULTATION DOCUMENT – APRIL 2005

DRAFT BEST PRACTICE GUIDELINE ON PRESCRIPTION MEDICINE LABELLING

Background

The Therapeutic Goods Order 69 *General requirements for labels for medicines* (TGO 69) sets out the legislative general requirements for labels for medicines. However, there is recognition that there are other prescription medicine specific principles of medicine labelling that would enhance the ability of health care professionals and consumers to select the correct medicine, use it safely, and therefore aid in reducing medication errors.

The Drug Safety and Evaluation Branch (DSEB) of the Therapeutic Goods Administration (TGA) and stakeholders have prepared this best practice guideline to guide pharmaceutical sponsors and TGA assessors in the design and review of the acceptability of prescription medicine labelling. The stakeholder group consisted of representatives of:

- Consumer’s Health Forum (CHF)
- Generic Medicines Industry Association (GMiA)
- National Medicines Policy Strategies Section, DHOA (APAC & PHARM)
- The Pharmacy Guild of Australia (The Guild)
- Pharmaceutical Defence Limited (PDL)
- Pharmaceutical Society of Australia (PSA)
- Australian Self-Medication Industry (ASMI)
- The Society of Hospital Pharmacists of Australia (SHPA)
- Medicines Australia (MA)
- The Royal Australasian College of Physicians (RACP)
- Council of Pharmacy Registering Authorities (COPRA)
- Medsafe

The UK Medicines and HealthCare Products Regulatory Agency’s (MHRA) Guidance Note No 25, *Best practice guidance on labelling and packaging of medicines*, was used as a reference source in developing this best practice guideline. The group also used as a basis *A Checklist of Items to Consider when Designing Labels and Packaging for Prescription Pharmaceutical Products* provided by Medicines Australia.

It is recognised that it may not always be possible to comply with the practices described in this guideline, however, every attempt should be made to do so. Some of the recommendations are particularly relevant to medicines likely to be dispensed to a patient for use at home; others, especially that surrounding potassium product labelling, apply mainly to hospital used products. Where there are space limitations, consideration needs to be given to innovative solutions to ensure that all relevant information is provided and legible.

Some of the recommendations are also subject to consideration as part of draft or impending Therapeutic Goods Labelling Orders. This guideline will be amended from time to time, and where appropriate, the recommendations that deal with matters covered under a mandatory order would be removed once that Order comes into force.

This document should be read with the mandatory labelling Order in force at the time and is complementary to the mandatory standards set out in that document.

Best Practice Labelling Suggestions

1. Space for the Pharmacist's Label

There should be a clear space for the pharmacist's dispensing label measuring a minimum of 80 x 40 mm. This is the size of the most commonly used computer-printed dispensing label. This means that after the pharmacist has labelled the package the following essential information will still be visible and that they should remain visible after the pharmacist has attached the dispensing label:

- Batch number
- Expiry date
- Storage instructions
- Brand name
- Strength
- Name of the active ingredient(s)
- Dose form
- Barcode (EAN barcode)
- Signal headings
- Warning statements
- AUSTR number

If the product is packaged in a small container, such as eye drops, consideration should be given to use of a cardboard backboard that would allow space for a pharmacist label. This should be on the primary container.

Words to the effect 'Place label here' should be placed in the designated Pharmacy Label space.

2. Batch Number and Expiry Date

The batch number and expiry date should be positioned together and situated preferably the end or side panel of the package.

The batch number and expiry date should be easily legible; for example ink is preferred over embossing. For eye preparations, and other topicals, the words "*after opening use within [xx] days*" should be on the label. See TGO for mandatory requirements.

3. Storage Conditions

Ideally, the storage conditions should be located close to the batch number and expiry date, and preferably on the front or side panels as end panels are already filled with brand / active ingredient names and / or batch expiry information.

4. Barcode

An EAN barcode can be used to facilitate electronic aids in dispensing and as a means of double-checking that this is the correct product to be dispensed. To be effective, it must be located so that it will not be covered by the pharmacist's dispensing label and can still be scanned after the pharmacist has affixed the dispensing label.

5. *Product Name and Strength*

Both the trade name and the active ingredient names and strength should be prominently and equally displayed on the packet on at least three sides, including the two end panels. Strength and quantity should also be displayed. To assist in easy storage and reference both trade and active ingredient names and strength/quantity should be displayed on end panels, with the first name alternating between the two end panels. To distinguish between the trade name and the active ingredient name, the first letter of the trade name should be in upper case and of the active ingredient name in lower case with a different colour for each.

There should be consistency in terminology to describe strength. All products in one product line should follow the same convention.

The use of 5mg/5ml and 10mg/ml for two products in a product line is strongly discouraged. Expressions of strength should be consistent throughout all labelling, including PI and CMI. See TGO for mandatory requirements.

6. *Dose Form*

Terminology concerning the long acting-dose forms should be consistent, relate to the product and be clearly specified on the label. For example, extended release, sustained release, controlled release or modified release are sometimes used.

7. *Packaging Colour and Design*

The use of colour and design should not unnecessarily clutter or obscure the message of the labels but make them clear and distinguishable.

Pictures or graphics should be meaningful, appropriate, and represent the use of a drug, and not suggest an unapproved use.

If using “corporate livery”, companies should consider using other design elements (colour bands, positioning of text, boxes around text, reversed out printing) to assist distinguishing between products within their total product range and between different strengths and presentations.

Use of different colours or colour bars to distinguish between different strengths or presentations of the product is encouraged. A visual signal may be given if stronger colours are used for higher strength products and light shades for lower strength products.

If undertaking extensive changes to presentation, relevant user testing tailored to the needs of the particular user group is recommended.

8. *Tamper-evident Packaging*

The tamper-evident packaging should not interfere with the ability of the pharmacist to place the dispensing label.

9. *Specific Australian Issues*

Compliance with the following best practice recommendations will be taken by the TGA as acceptable:

Potassium labelling: It is imperative that all concentrated potassium products for injection or infusion should be packaged in a manner that uniquely identifies them.

The ampoules and vials should be clearly labelled as Potassium Chloride or the relevant salt; the end of the ampoules should contain “KCl”, or equivalent, in large lettering. The strength is to be prominently displayed as both millimoles and total content and strength in millimoles/litre; the instruction, “dilute before use” should be included; there should be a black block of colour on the “twist off” tab at the top of the ampoule. In relation to the vial, there should be a black “twist off” seal on the cap of the vial.

The premixed bags should only use red lettering for labelling. ‘Potassium’ should be in letters written vertically on the left hand side of the panel as well as horizontally, both in the largest font used on the label; concentration and content in millimoles should be displayed prominently and displayed next to the letters “Potassium”. The words “Potassium chloride” (or equivalent) should also displayed in large letters in the label. There should be a clear space at least equivalent to the maximum font size around main description and key information (such as diluent and volume).

Vinca alkaloids: All products should be prominently labelled firstly with, “*To be given intravenously only*” followed by, “*Fatal if given by any other routes*”.

Methotrexate: Confusion has arisen because this product can be prescribed once weekly or sometimes at more frequent intervals in either the community or hospital setting. There should be clear instructions, “*Check dose and frequency – methotrexate is usually taken once a week*”. Sponsors are encouraged to consider packaging methotrexate in indication-specific weekly or daily packs to assist to reduce errors.

10. *General issues*

Consideration should be given to including a diagram or other visual depiction of the product, such as individual tablets/capsules etc, with identification codes, and/or a description on the outer pack.

Avoid labels that easily detach from the container. See also TGO for mandatory requirements.

To avoid ambiguity of the message, only positive statements should appear on medicine labels. For example, “*For intravenous use only*” is preferred to a negative statement such as “*not for intravenous use*”.

Distinctive tablet markings may assist in identification of products and should be considered in product development.

To distinguish between the trade name and the active ingredient, the first letter of the trade name should be in upper case and the first letter of the active ingredient should be in lower case.

11. Blister packaging

Ideally for blister packaging, each blister cover should include both the active and the brand names, and the strength, batch number and expiry date of the medicine. However, this is not always possible. In cases where blisters are small, repetitive diagonal use of product names over the blister covers with expiry date and batch number on the side can assist with identification of partly used packs.

High-risk products, eg opioids & benzodiazepines, should be packed in blister packs where possible to facilitate accountability and reduce impulse ingestion. Consideration should be given to packaging high risk products in glass or otherwise take steps to reduce the risk of tampering.

12. Choice of brand names

Brand names for prescription medicines should clearly identify the product. They should be unique, but neither promotional nor offensive in relation to general community standards. Umbrella branding is strongly discouraged in prescription medicine labelling. The trade name could be based on the active ingredient name with the company identified.

Brand names can be confused with other product names if care is not taken in their selection. In choosing a brand name there should be comparative testing to existing brand names, for both prescription and non-prescription medicines. This should involve a review using the letters forming the name, the sound of the name and analysis of recognition by electronic databases, as well as handwriting. Ideally, consumer and/or health professionals will be used in focus user testing and results provided to the TGA.

13. Combination products

For combination products, the names of all active ingredients should be used in equal prominence to the brand name for the product itself. The brand name of the product must be clearly differentiated from the brand names for any of the ingredients. The quantities of the active ingredients should be clearly visible and may be incorporated in the trade name. For product ranges, the quantities of the actives should be incorporated into the trade name wherever possible, for example “XYZ 20/10”. Alternatively, or in addition, the words “*combination therapy*” should be added under the trade name.

14. New Line Products

If introducing new products to an existing range, consideration must be given to the potential for confusion with existing medicines. This may mean that not only will the new product have distinctive labelling, but revision of the existing product labelling may also be required.

15. Use of product names in other documents

Consumer Medicine Information

The Consumer Medicine Information (CMI) should contain both active and brand names at the beginning of the document. Use of brand name is only encouraged where information relates to that brand of the medicine. Use of active ingredient name for negative information only is not acceptable.

Product Information

The trade name should not be used only to present positive information in the product labelling, nor the generic name used to present only negative information associated with the product. The trade name should only be used where the information only applies to the characteristics of the branded product, for example, the description, form of presentation, strength, method of use and dosage.