

TGA Labelling and Packaging Review
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CATAG Submission re: TGA Labelling and Packaging Review

The Council of Australian Therapeutic Advisory Groups (CATAG) is a consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents. CATAG aims to standardise and improve medicines use primarily (but not exclusively) in the hospital sector across Australia through information sharing, advice and advocacy activities.

CATAG believes that the Labelling and Packaging Review is very valuable opportunity to improve the safe and effective use of medicines. In brief, CATAG supports those changes that will reduce patient harm from medication errors or misunderstanding in Australian hospitals, across transitions of care and in the community, and changes that will improve patient understanding and adherence to medicines.

CATAG supports the following changes to the requirements for labels and packaging of medicines in Australia:

Active ingredient name must be prominent (1.1-1.5)

CATAG strongly supports the need for prominent labelling of the active ingredient on the labels of all medicines, but believes that the changes proposed in the consultation paper do not go far enough to help consumers identify their medicines.

CATAG suggests that the active ingredient name:

- is the most prominent feature on the label
- appears above the brand name (not below) and in larger font than the brand name (equivalent font size of the brand name with the active ingredient name may increase confusion)
- is presented in a standardised format (same font type and size and colour, same location on the label) so that consumers can readily determine if different medicines contain the same active ingredient.
- has the strength of the active ingredient presented next to it in the same font
- is prominent on all faces of medicine cartons, so the medicine can be identified regardless of how it is placed on a shelf.

CATAG is aware of the educational programs and campaigns of the ACSQHC and the NPS in promoting the active ingredient name as the common language for health professionals and consumers when speaking about a medicine or identifying it. It is therefore essential that health professionals and consumers can readily locate the active ingredient name on the label of all medicines and differentiate it from the brand name.

The 'Keep out of reach from children' label should be separated from other text

CATAG supports the clear separation of 'Keep out of reach' from other text on the medicine label so that consumers can readily identify this as an important warning.

Look alike medicine branding and packaging (3.1-3.6)

CATAG supports the changes recommended in the consultation paper, but believes that these changes could be strengthened to reduce the risk of product selection error. CATAG supports 'purchasing for safety' initiatives of procuring organisations.

CATAG believes that generic brand names of prescription medicines should be discouraged. Multiple brand names increases the risk of prescription and transcription errors as healthcare practitioners cannot be expected to be familiar with them all (more than 10 for some medicines). Consideration should be given to the UK model for naming of generic medicines. See <http://www.mhra.gov.uk/Howweregulate/Medicines/Namingofmedicines/index.htm>.

Expiry date and batch on separate units (foils etc) (6.1-6.5)

CATAG does not believe that the proposed changes are sufficient. It is common practice in hospitals to dispense medicines in a small number of units. Having the active ingredient, strength, brand name, expiry date and batch number plus a bar code on every unit of the blister pack improves the safety of dispensing and administering medicines in hospitals and residential care facilities. CATAG also recommends that these same details are included on all levels of pack, whether or not they are part of the delivery system of the medicine. This includes the packaging for injectable solutions, inhalers, patches, nebuliser solutions, sprays, oral liquids etc. This would enable these products to be identified even if outer packaging is discarded.

Data matrix bar codes

CATAG supports the introduction of data matrix bar codes at the unit level (as suggested above). These should include the product's expiry date and batch number.

Standardised strengths on liquid formulations

CATAG recommend a standard expression of strength (concentration) for all liquid medicines to minimise dosage errors. CATAG suggest that the strength should be stated as quantity **per mL**.

Australian Medicines Terminology (AMT)

CATAG believes that consideration should be given to the potential impact of increased utilisation of Electronic Medicines Management Systems and dispensing automation. This is relevant in relation to the utilisation of AMT naming conventions in terms of providing clear, standard and unambiguous naming of medicines.

CATAG welcomes the opportunity to comment on the review and looks forward to an outcome which improves the safe and effective use of medicines

