



National Poisons Register

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Dear Ms Doolan

Thank you for the opportunity to participate in the TGA Medicine Labelling and Packaging Review.

We approach this review from the perspective of the NSW Poisons Information Centre (PIC) and the National Poisons Register (NPR). For these national services, accurate and straightforward identification of product tradenames and active ingredients is essential. The scope of these services includes but is not limited to medicines. The principle of accurate product identification including active ingredients is applicable to many product groupings including medicines, and is an area of concern for both the PIC and the NPR.

Product information is gathered by the NPR and included on the NPR Database. This information is then accessed by the PIC when it is required for the management of poisoning incidents. In 2011, the nationwide network of PICs handled in excess of 210,000 poisoning exposures and enquiries. For the NSW PIC, the split of exposures involving medicinal and non-medicinal products was even.

The NPR seeks product information predominantly on non-medicinal items. However it does register pharmaceuticals when product sponsors specifically request this, and it seeks formulations of OTC medicines that are not listed in standard drug compendia such as MIMS.

The NPR approaches the product identification task in a proactive manner by listing products on the NPR Database when they are submitted by manufacturers. In

contrast, the PIC requires accurate product identification in emergency situations over the telephone. Often the PIC is called on to assist members of the public who may be agitated or distressed due to an accidental or intentional medicine overdose. It is the experience of the PIC that in these stressful circumstances people can have difficulty locating drug names on medicine packaging. The proposed standardised format for information on medicine packaging could prove to be very helpful in such situations.

Some of our comments are focussed on situations that fall into the categories of emergency or potential emergency. The urgency of such circumstances should however not be seen to overshadow the applicability of the comments to less urgent scenarios.

Please find attached our comments on certain specific recommendations. If you require clarification or additional comment on any of the points raised, please contact either of the undersigned for further information.

Yours sincerely

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The following comments are made with reference to the Consultation Paper (Version 1.0, May 2012) Appendix 1: Consolidated list of recommendations.

Recommendations 1.1, 1.2.1 and 1.2.2

Prominence of active ingredients on medicine labels

The clear identification of the active ingredient(s) in a medicine is essential as it is perhaps the most fundamental role of medicine packaging.

The unambiguous declaration of the active ingredient(s) aids in the correct identification of drugs involved in emergency situations. Successful identification is vital not only to members of the public but also to health professionals such as paramedics responding to both accidental and intentional drug overdoses. Callers to the PIC are often very distressed, and can have trouble locating ingredient information on medicine packaging. Any measure that assists the identification process will improve the health outcomes of emergency situations.

Recommendation 1.3

Medicines containing more than three active ingredients

Listing some, but not all, of the active ingredients on the main label could be misleading. It is a natural assumption that the ingredient list on the main label is comprehensive. Listing a subset of the ingredient list would necessitate a clear statement in that same area that there are further ingredients, and that those ingredients are listed elsewhere on the medicine packaging.

Further, for some medicines with extensive ingredient lists, it may be that the three most abundant ingredients on a weight basis are not necessarily the three that are of most concern in terms of potential toxicity or side effects. This approach could possibly misrepresent the nature of a given medicine to a consumer.

Recommendation 1.4

'Day and Night' medicines that have different formulations

Some form of description of the different tablets/capsules would be valuable in this area. This description would assist consumers to identify the different formulations in a single medicine package.

Some boxes of day and night preparations already include a pictorial representation of each of the two different tablets/capsules, which does help the consumer to identify the two different tablets/capsules accurately.

Alternatively, the two different tablets/capsules could be briefly described. For example:

Day capsules (green capsules)

Pseudoephedrine hydrochloride 30mg

Paracetamol 500mg

Codeine phosphate 10mg

Night capsules (red and white capsules)

Pseudoephedrine hydrochloride 30mg

Chlorpheniramine maleate 2mg

Paracetamol 500mg

Recommendation 4.1
Medicine information box

A standardised Medicine Information Box would assist greatly in emergency situations for the identification of the active ingredients by consumers and health professionals.

Recommendations 6.1 and 6.2
Blister strip labelling

In addition to the items suggested for inclusion on the blister strips/segments, the ARTG number for the medicine is a valuable identifier and should also be listed.

Recommendation 6.3
Blister strip labelling of medicines containing more than 3 active ingredients

As discussed in the above comment on Recommendation 1.3, listing some but not all of the active ingredients could be misleading.

Recommendation 6.4 is preferred over Recommendation 6.3.

Recommendation 7.2
Small containers of medicines containing more than 3 active ingredients

For medicines containing more than three active ingredients, listing some but not all of the active ingredients could be misleading. This consideration applies equally to medicines in small containers.

In addition to the items suggested for inclusion on the container label, the ARTG number for the medicine is a valuable identifier that should also be listed if possible on the label of small containers.

Recommendation 7.3
Small containers and positioning of dispensing labels

Some very small containers (e.g. 5mL eye drops) impose an inherent height limitation in addition to the container's small circumference when affixing dispensing labels. Thus even a folded dispensing label cannot be attached without it extending significantly above or below the body of the container. In these circumstances, dispensing labels may need to be cut as well as folded, making them difficult for consumers to read.

Further Comment

Whilst not specifically addressed in the Consolidated List of Recommendations, one feature of medicine packaging that requires some comment is the **standard display of ARTG numbers**.

For both listed and registered medicines, the ARTG numbers provide unique identifiers that can readily assist both consumers and health professionals to access information held on the ARTG. With the ready public availability of the ARTG via the TGA website, important information about a medicine can easily be obtained; the ARTG number is the most straightforward identifier to use when accessing this register.

On this basis, we suggest that where practical, the font size of the ARTG number be increased on medicine packaging to make it more easily recognised and identified.

An increase in the prominence of the ARTG number on medicine packaging could have the added advantage of emphasising to the general public the importance of the inclusion of medicines on the ARTG. The more that the public associates the listing or registration of medicines on the ARTG with an assurance of the appropriate level of TGA assessment, the more likely it becomes that they will heed warnings regarding the potential dangers of medicines purchased over the internet that are not listed or registered by the TGA.