

Sub 6

Labelling Review

To the Review:

Thank you for the opportunity to comment. Broadly, the proposals are sensible and will enhance safety.

I have specific comments:

In the interests of safety through reduction of confusion due to multiple brand names of identical generic medicines, I am supportive of all registered medicines being identified most prominently by the generic name of the medicine. The generic name should be bigger (50% greater would be impactful) and more prominent by way of font, bolding and colour. The generic name should be above the brand name.

In order to increase the uptake of generic medicines, that is at too low a level in Australia, I **recommend that the PBS purchase generic drugs only when the patent on the originator drug expires. As part of this initiative, PBS would only purchase generic brands that have labels as noted in my first point.**

Therefore I support proposal 1.1 but proposals 1.2 (1.2.1., 1.2.2) are not strong enough. Generic name should be MORE prominent than the Trade name. I support 1.2.3 that increases the differentiation.

I support the proposals associated with the following topics

- additional requirements for non-prescription medicines containing paracetamol and ibuprofen (page 16, 17 and 19)
- measures to eliminate or reduce the risks of 'look-alike' medicine branding such as:
 - products listed on the ARTG cannot be marketed under the same name as a registered name
 - medicines containing the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses
 - the same brand name cannot be applied to products that have different active ingredients (pages 20-24)
- mandated standard information and format on labels and packaging (pages 25-29)
- mandated designated space to accommodate the dispensing label (pages 30-31)
- additional requirements for blister strip labelling (pages 32-34)
- special requirements for small containers (pages 35-37)
- special requirements for pack inserts (pages 38-39)
- the establishment of an expert panel to provide the TGA with ongoing advice about product-specific as well as general matters relating to labels and packaging (page 39).

Sincerely

Ric Day

Richard DAY, AM MD FRACP

Professor of Clinical Pharmacology, St Vincent's Hospital Clinical School and Pharmacology, School of Medical Sciences, Faculty of Medicine, UNSW

Director Clinical Pharmacology & Toxicology, St Vincent's Hospital, Sydney

Immediate Past President DIA 2011-2012

Mail Address: Clinical Pharmacology & Toxicology, Therapeutics Centre, St Vincent's Hospital, Darlinghurst, NSW, Australia, 2010

Tel: 61-(0)2-8382-2331 **Fax:** 61-(0)2-8382-2724 **Mobile:** 0414-772-459

Web: <http://www.med.unsw.edu.au/medweb.nsf/page/resinterestsshowperson?OpenDocument&StaffID=8400044>

Admin Officer: Ms Thuy Huynh

Tel: 61-(0)2-8382-2304

Email: cpt@unsw.edu.au

Convenor Masters Medical Science Drug Development: <http://drugdev.med.unsw.edu.au/>

Better Use of Medicines means Better Health Outcomes