NSW GOVERNMENT Health

Trim No.: H12/45869, h12/46667

Ms Rebecca Doolan
Project Manager
Labelling and Packaging Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Ms Doolan

I refer to your letter dated 18 June 2012 in which you sought submissions on the TGA's medicine labelling and packaging review.

All of the recommendations in *"Appendix 1: Consolidated list of recommendations"* (http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-13-appendix1.htm) are generally **supported**.

In addition the following comments are made about particular issues:

Prominence of active ingredients

Add after "brand name" wherever occurring: "if any".

Add to recommendation 1.2, "The active ingredient/s must be printed in at least the same boldness or intensity as the brand name."

Specific guidance may be needed about how to accommodate excessively long active ingredient names.

Look-alike sound-alike names and look-alike packaging

Add after recommendation 3.3 "New medicines or applications to change the labelling and packaging of existing medicines, must use colours and designs that contrast with those used in the medicine label and packaging of other strengths (if any) of the medicine, and with other medicines produced by the same sponsor."

Tall Man Lettering should be recommended or required for products with look-alike names.

Look-alike medicine branding

In recommendation 3.6.a, "closely related" should be more clearly defined, i.e. only different salts or compounds of the same chemical substance, where the differing components are inert.
Add to 3.6.b that the approved indications must be the same.

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Standardised information format: the Medicine Information Box

It needs to be clarified how this relates to the approved Consumer Medicine Information.

Dispensing label space

Add to recommendation 5.1 the space should be at least 80 x 40 mm (as noted in recommendation 7.3, this is the size of a standard dispensing label) and in a prominent position.

Blister strip labelling

Add to recommendation 6.1, the required information should, as far as possible, be printed in such a way that it remains legible after the medicine has been pushed out of the blisters.

Regarding recommendation 6.5, the required information (or at least the active ingredient/s and amount/s) should be repeated regularly on the blister platform, not appear only once, even for medicines packed in "racing track format".

Suggested additional recommendations:

All required information must be printed in a colour which strongly contrasts with the background colour.

The *AUST R* or *AUST L* number should appear immediately under the brand name and the name/s and strength/s of the active ingredient/s. "*R*" and "*L*" should be replaced with the full words "*Registered*" or "*Listed*". The "*AUST Listed*" number should be immediately followed by the words "*The effectiveness of this product has not been evaluated.*"

Should you require any further information or clarification, please contact Ms Judith Mackson or Mr Peter Gilfedder at Pharmaceutical Services, NSW Ministry of Health on (02) 9391-9944.

Yours sincerely

22/8/12

Deborah Hyland
A/Deputy Director-General
Governance, Workforce and Corporate Services

Attachment

CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	Judith Mackson, Chief Pharmacist
Company/organisation name and address:	Pharmaceutical Services, NSW Ministry of Health Locked Mail Bag 961, North Sydney NSW 2059
Contact phone number:	(02) 9391-9944

☐ Yes ☒ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*
☐ Yes ☒ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☐ Prescription Medicines ☐ OTC Medicines

☐ Complementary Medicines ☐ Medical Devices

☐ Blood/Tissues ☐ Other

☐ Sole trader ☐ Business with employee(s)

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Industry organisation

☒ Government ☐ Researcher ☐ Professional body

☐ Consumer Organisation ☐ Institution *(eg. University, hospital)*

☐ Reg. Affairs Consultant ☐ Laboratory Professional

☐ Healthcare Practitioner - please indicate type of practice

☐ Other (please specify):

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