The Royal Australasian
College of Physicians

From the President

27 August 2012

Dr Rebecca Doolan
Project Manager
Labelling and Packaging Review
Therapeutic Goods Administration (TGA)
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Via Email: rebecca.doolan@tga.gov.au

Dear Dr Doolan

TGA Medicine Labelling and Packaging Review

The Royal Australasian College of Physicians (RACP) welcomes the invitation from the Therapeutic Goods Administration (TGA) to provide a submission to the Review of the Labelling and Packaging of Medicines (the Review). The Review is an excellent initiative for the quality use of medicines (QUM) as it will work towards reducing consumer confusion with medicine labels.

In responding to the general questions raised in the Review, the RACP's key recommendations include:

1. That all drugs are primarily identified by the active ingredient(s).
2. That the active ingredient (generic) name is written above the brand name and that the generic name is written in a larger font size (at least 50%) than the brand name.
3. That companies and regulatory bodies be required to check for similarities in the 'sound' and 'look' of names and that approved 'methodologies' to do this are used.

The RACP has further recommendations that address the TGA general questions to ensure the Review underpins the quality use of medicines and they are listed in the attached submission.

The RACP looks forward to the outcomes of the Review and would welcome the opportunity to work further with the TGA on the project's next steps.

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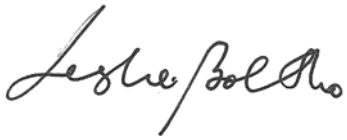
Yours sincerely



Dr Leslie E Bolitho AM

The Royal Australasian College of Physicians

TGA Medicine Labelling and Packaging Review

Submission by The Royal Australasian College of Physicians

The Royal Australasian College of Physicians (RACP) strongly supports the intent of the Therapeutic Goods Administration (TGA) regulatory changes for medication labels as proposed in the TGA Medicine Labelling and Packaging Review.

The Review will improve quality and safety of patient care by reducing consumer confusion that currently occurs because of inadequate medicine labelling practices. Patients/consumers and prescribers as well as other health professionals will benefit from a heightened awareness of the active ingredient name of medicines. Importantly, measures introduced to enhance patient and health professional understanding about the labelling of medicines will reduce the incidence of adverse events.

The RACP recommendations for the TGA Medicine Labelling and Packaging Review are as follows:

Prominence of active ingredient on medicine labels

The following measures aim to reduce consumer confusion with medicines labels:

1. That all drugs are primarily identified by the active ingredient(s).
2. That the active ingredient (generic) name is written above the brand name and that the generic name is written in a larger font size (at least 50%) compared to the brand name[1]. To determine the most appropriate font size, expert ophthalmological opinion should be sought to accommodate the requirements of those with impaired vision.
3. That the active ingredient name has a distinctive type face and, if possible, is printed in a different colour. This measure would be particularly helpful in situations where brands are changed but the active ingredient remains unchanged.
4. That the product strength should follow the name of the active ingredient.

Look-alike sound-alike names (LASA) and look-alike packaging

5. That the nomenclature of the product should not include or allude to the symptoms for which it is marketed to prevent consumers from taking more than the recommended unit dose of the drug. This is because many products that have this type of naming have the same active ingredient. Many consumers do not realise there is no difference between "BRAND for inflammation" and "BRAND for period pain".

[1] Shane L Carney, Madlen Gazarian, Justin T Denholm, David M Reith, Robert K Penhall, Christine R Jenkins, Kay A Wilhelm, Paul A Komesaroff, Mary M Osborn and Richard O Day What's in a name. Brand name confusion and generic medicines. Med J Aust 2011; 195 (11): 650-651

6. That similar sounding or looking medication names not be used because their use can lead to more consumer confusion and potential medication errors[1].

7. That companies and regulatory bodies be required to check for similarities in the 'sound' and 'look' of names and that approved 'methodologies' to do this are used.

Standardised Information Format: The medicine information box

8. That the mandatory headings are implemented as regulated by the US Food and Drug Association drug facts box and include headings such as active ingredient, indication, contraindications, warnings, dose and storage information.

Pack Inserts

9. That advertising information should not be included on the pack/box of the medicine to prevent dilute or distract the consumer from key information.

Labelling and Packaging Advisory Committee

10. That an expert panel working group is established to provide the TGA with ongoing advice relating to labels and packaging of medicines.

Blister Strip Labelling

11. That the brand name of the medicine, the active ingredient(name and amount), batch number and expiry date must be repeated at least once every two units on a blister pack to ensure that these details are still apparent to the consumer should they fragment the blister pack.

Dispensing label space

12. That a designated blank space to accommodate the dispensing label and special requirements for small containers is present on the medicine container. This measure would prevent obscuring the active ingredient name and other pertinent information.