TGA Medicine Labelling and Packaging Review

23rd August 2012

Statewide Dispensary Managers Group

Statewide Hospital Pharmacy

Tasmania

TGA Labelling and Packaging submission

The Tasmanian Statewide Dispensary Managers Group fully supports the TGA's review of look-alike and sound-alike medicine brand names and look-alike packaging and branding.

Following our most recent pharmaceutical tender, look-alike products (in particular packaging) has resulted in numerous safety concerns, despite our tender items being reviewed for safety, some of these look-alike products were obscure and difficult to assess on a large-scale tender.

Please see below formal responses to proposed changes.

Proposed regulatory changes – Look-alike sound-alike names and look-alike packaging.

3.1 Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names. - **Support**

3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements. - **Support**

3.3 In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine. - **Support**

Proposed regulatory changes - Look-alike medicine branding

3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine. - **Support**

3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom. - **Support**

3.6 The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met:

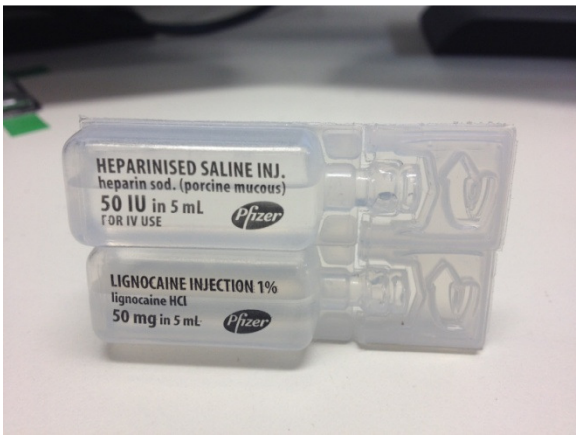
a) The active ingredients are closely related (e.g. different salts of the same pharmaceutical chemical), and
b) The safety profile, efficacy and dosage regimen are similar.

- Support

Other issues not covered by proposed changes

Whilst we remain supportive of the proposed changes outlined above, there is a significant issue around look-alike branding that is not fully addressed by these suggestions. LASA brand names are effectively covered in 3.1 to 3.3 and "umbrella" branding is effectively tackled by 3.4 to 3.6, the issue of look-alike packaging of unrelated medications has not been addressed.

Medications, which are not in the same therapeutic class, are being packaged by companies in identical packaging, assumedly to enhance their brand. This issue is further compounded when medications in a different class have the same strength. Although the brand names and drug names are very different, the packaging is so similar it poses a high risk of error. Please see examples below:



It is recognised that there is a possibility of look-alike packaging occurring between products from different companies, and there would be difficulties in assessing this. The primary concern here is companies deliberately producing a product range that looks identical. It is proposed that a regulatory change be implemented that requires pharmaceutical companies to package their products in a manner that allows each product to be readily distinguishable from other products marketed by that company.