Submission to Therapeutic Goods Administration

on

Labelling and Packaging Review

Background

As part of their Blueprint for Reform process, the TGA initiated a review of the labelling and packaging regulatory framework for prescription medicines (Rx), over the counter medicines (OTCs) and complementary medicines on 4 July 2011 and published the consultation paper on 24 May 2012. TGA had conducted reviews on labelling and packaging, including the ANZTPA review (Apr 2005 and May 2006), TGO79 (draft Jan 2008) and TGC 34th Meeting May 2009.

The Australian system of regulating medicines includes labelling and packaging requirements for Rx, OTCs and complementary medicines. The current requirements include the TGO80 (Child Resistant Packaging) and TGO69 (General Labelling Requirements). Underpinning these are the Best Practice Labelling Guidelines.

All these reviews proposed variations of the following:

- Prominence of the active ingredient(s)
    - the consumer can find and is aware of the active ingredient in the medication to reduce double dosing
- Look-alike & sound-alike medicine brand names and packaging, including addressing umbrella branding and indication specific products
    - removal of accidental mix up in medicines during dispensing or in self selection or in use at home
- Standardised information format
    - all labels are similarly formatted so the consumer can find the information
- Dispensing label space
- important information is not covered

- Blister strip labelling
    - consumers can cut blisters and still have the product name, active pharmaceutical ingredient (API) name and strengths, batch and expiry dating
- Pack inserts
    - clarity of information on pack insert
- Introduction of an Expert Advisory Committee
    - availability of expert advice to TGA
- Small containers (smaller than 20mL)
    - little change to current requirements in TGO69

Apotex Pty Ltd is a generic pharmaceutical company selling predominantly prescription medicines. Apotex has been awarded the AJP Best Ethical Packaging Award for Prescription Medicines for the last 3 years in a row (2009 – 2011). When the draft TGO79 was first published in 2008, we reviewed our labelling and packaging and decided to incorporate the additional proposals in our labelling. Our current packaging design is a result of extensive market research carried out with pharmacists and consumers to determine the best design that incorporated the following elements so that our labelling was clear, concise and easy to read, did not confuse patients, complied with TGO69 and incorporated the additional elements of TGO79 and Best Practice Guidelines and was readily recognisable as an Apotex brand.

The below submission will focus on prescription medicines with comments on the other segments. It should be stated up-front that as a company we work closely with pharmacists to deliver high quality products and assist them in the provision of high quality services and information so they can deliver high quality care to their patients. There is a clear understanding that Pharmacists accurately dispense the medication to the patient, regardless of whether the doctor prescribes by brand or active ingredient name. As part of due diligence, the pharmacist understands substitution and their role as a primary information provider to assist the patient to safely take their medication as prescribed.

Prominence of the active ingredient(s)

Apotex brand naming convention for their labels utilise the active ingredient name, with a prefix. Our brand name is therefore "APO-active ingredient name".

We agree in principle to the listing of the active ingredient directly below the brand name; however, we do not agree with the proposal for it to be of equal prominience and left aligned with the brand name.

Our market research showed that both these elements as proposed (of equal prominence and left alignment) created more confusion than placing the active ingredient name (with the salt) directly below and right aligning it at 50% of the brand name. This allowed for ease of identification of the active ingredient without making the label too busy and the pharmacist was able to accurately and quickly find the active ingredient on the label.

Look alike and sound alike medicine brand names

In addition to utilising predictable branding nomenclature, each Apotex brand of medicine has been assigned a distinctive pattern categorised by therapeutic groups and subgroups. The groups and associated themes are designed to help patients easily recognise their medicine.

Apotex considers more thought need to be put to the proposal to conduct risk assessments to reduce the potential of an accidental mix-up in medicines during dispensing. Currently it is difficult to determine whether it would have any impact on improving patient safety.

Standardised information format

Apotex considers that as long as the information is on the labelling, there should be no requirement for it to be in a standardised medicine information box. Further, Apotex does not consider it necessary to have the information box in a white background with black text. By not having the information in a proscribed box, it will be possible to ensure the information is logically placed on the box.

Dispensing space

Depending on the size of the packaging, Apotex agrees with the proposal of the suggested space of 70 x 30mm be left clear on one panel of the carton.

Blister strip labelling

Apotex does not agree with the proposal for the batch and expiry to be repeated at least once for every two units. It is our opinion that blister foils should not be cut and educating the consumer would be more cost effective

The current requirement of batch and expiry at the end of each platform and on the outer carton should be adequate, even for perorated platforms. The requirement for additional text on the strip will lead to an increase in platform size and possible infringement of the Trade Practice Act.

Introduction of an Expert Advsiory Committee

Apotex is equivocal about the value that an Expert Advisory would provide for the TGA.

Comments

The consultation paper itself is poorly constructed and has led to confusion around what is required. There is no differentiation between the proposed requirements for the Rx, OTC and complementary medicines, even though they all reside in different market segments and therefore have different information requirements and address different consumers. We are concerned that there have been repeated regulatory changes flowing from sequential reviews, and expect that, as the ANZPTA review of packaging and labelling has yet to commence, there will be further rounds of changes.

The major concern with all these reviews is that there is an absence of consideration of the cost associated with every incremental change that is required to be made to the labelling and packaging. For example, the cost to the company for implementing a single change (update of suburb name) across our range of products is in the vicinity of $7 million. More extensive changes will accordingly increase the cost to the company. This means that for some very low margin products, the decision will be to discontinue, rather than update them.

Whilst we approve with some of the proposals in the Labelling and Packaging review