TGA Medicine Labelling and Packaging Review

SA Health Consultation Response

August 2012

General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels

What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?

This is an important change which will have a strong positive impact on optimising Quality use of Medicines (QUM).

Ensuring that the active ingredient name is prominent would improve the likelihood that consumers as well as Health Professionals will recognise the medicine by its active ingredient, rather than only by the brand name. This would improve communication between health professionals and consumers regarding their medicines and increase prescribing by generic/active ingredient, rather than brand name. Understanding of the active ingredient would reduce consumer confusion regarding what medicine they are taking and thereby increase medication compliance and reduce likelihood of inadvertent ingestion of medicines for which a previous allergy or adverse drug reaction has occurred.

This would also reduce safety risks where consumers or health professionals may accidently double-up on a dose by taking two different brands of the same medicine. It would also reduce the likelihood of look-alike sound alike (LASA) errors.

A comprehensive education program to assist consumers understand what an 'active ingredient' is would inform consumers that the same medicine is available in different brands and thereby reduce confusion. An education program should also incorporate information regarding TGA processes for approving medicines for use in Australia, to allay misconceptions of some consumers regarding inferior quality of generic brands.

What do you think about the proposed warnings for paracetamol and ibuprofen containing products?

These warnings are sensible and provide a positive change which is welcomed by SA Health. The changes will improve patient safety by reducing the risk of accidental overdose by taking multiple paracetamol or NSAID-containing products, particularly for over-the-counter products marketed differently, but containing the same or similar ingredients. The font size will be an important consideration for elderly patients and the vision-impaired.

Are there any other concerns you have with the size or position of brand names and active ingredient?

SA Health recommends that the active ingredient is printed in large font, as the primary identifier of the drug, with the brand name in brackets, in smaller font, either following, or below the active ingredient name. A minimum would be that the active ingredient is printed in 20pt bold. This requirement is particularly important for consumers who may be vision impaired, or have difficultly reading English. This would further increase the probability that health professionals and consumers would recognise a medicine by its active ingredient, rather than brand name. This is particularly important when patients are transferring between healthcare settings (e.g. hospital to community/aged care or changing community pharmacies), as different brands of the same medicine may be provided in different settings.

A more prominent active ingredient name would also encourage prescribing by generic/active ingredient, rather than brand name, allowing better market competition and more competitive medicines prices and reducing consumer perception that one brand is superior over another.

SA Health recommends that consideration be given toward restricting the size of the company name on the packet, in a similar way to the brand name restriction, where the company name may not be in a larger font than the active ingredient name.

If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?

See above. SA Health recommends that the active ingredient name is more prominent than and before/above the brand name.

What is the smallest size font that you consider readable?

The smallest size font considered readable is 20pt for the active ingredient name. SA Health recommends that the font be plain and bold to accommodate vision-impaired consumers. Consideration to the use of braille is suggested.

For products with more than 3 active ingredients, it will be important to promote checking of the side or rear panel to ensure consumers are aware of any ingredients which may be associated with an allergy/adverse drug reaction.

General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?

Yes, the proposed changes will significantly reduce the risks of error due to LASA names and LA packaging and hence improve medication safety.

Questions raised:

- Will the proposed changes apply to similar generic names as well? This is also an area where medication errors occur?
- Has the concept of deleting trade names altogether been considered?
- under 3.6b suggest addition of same or similar indication.

General questions on the proposed regulatory changes for look-alike medicine branding

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?

These changes will confer considerable benefits to consumer safety by reducing the risk of confusion regarding medicines, their active ingredients and mechanisms of action.

In particular, prohibiting differential marketing of a product for particular subsets of symptoms (e.g. 'headache' and 'joint pain') would reduce the potential for consumers to perceive that the same medicine, marketed differently, contains different active ingredients, thereby reducing the risk of doubling up on dosages. It would also help to reduce misconceptions regarding the mechanism of action for the medicine (e.g. that 'headache' medicine targets the head, and 'joint pain' medicine targets joints).

A further consideration to support patient safety is to prohibit brand names - by only allowing the company name and drug/active ingredient, the potential for confusion of medicines may be further reduced. Many other consumable products do not have a product brand name, as well as a company brand name, especially if the product is not unique to a particular company. There is no need for medicines to have specific product brand names, other than to encourage use of a specific brand, which is against the principles of QUM.

In addition, SA Health recommends consideration is given towards standardisation of strengths on all liquid and transdermal formulations. It is envisaged this change would improve safety by preventing accidental dosing errors due to mixing up of the different strengths of the same product. It will also reduce confusion regarding drug concentration per ml and per dose unit, and rates of drug delivery versus total amount of drug per dose unit. (e.g. GTN patches).

Another major source of medication errors and patient morbidity is confusion with rapid and slow release preparations (e.g. with opioids). Suggest further consideration of how to reduce the likelihood of substitution of these products.

Do you understand the proposed changes?

Yes

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?

Yes, the potential for harm is reduced if information regarding the medicine, in particular, its active ingredient name, and any warnings are readable.

Question raised:

- Will the new labels be applied to existing products as well as new products? That is, will there be a set time before it is expected that all products will comply with the new labelling requirements?

General question on the proposed regulatory changes for Standardised Information Format: Medicine Information Box

To what extent do you think a standardised format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines?

This is an excellent idea. Standardisation will provide familiarity for consumers as to where and what to routinely look for in information provided. The information provided must be factual in relation to indications, not have unsubstantiated claims and it should be written in plain English and clearly structured.

Note in Fig 7 the brand name is larger than the active ingredient. Suggest the same principles should apply as for labels.

Are there other ways that the presentation of information could be improved?

Information relating to complementary medicines could be improved if it was accompanied by a hand-out, similar to a CMI included with prescription medicines. As with CMIs, this should be accompanied by counselling. In addition, the 'keep out of reach' warning should be separated from other text to improve prominence.

Font size will be an issue (1.5mm/2mm).

Suggest consideration of utility of bolding the sub-headings.

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products? Please propose an alternative if you don't agree with current recommendation.

Yes, this is sufficient; however it would be useful to make additional information available via information sheets &/or website.

Pack inserts should provide for all medicines not just injectables.

Suggest add active ingredient under 4.6

General question on the proposed regulatory changes for dispensing label space

Do you support a designated space for the dispensing label on prescription medicines? Why/why not?

Yes, this would prevent important information such as the expiry date being covered up by the dispensing label.

In addition, SA Health recommends mandatory barcoding for all products/formulations to facilitate efficiency and safety in dispensing and administration systems including electronic systems.

General question on the proposed regulatory changes for blister strip labelling

Do you think the proposed information for blister strips is sufficient?

No. SA Health recommends that at the very least, the active ingredient, expiry date and batch number is clearly written on every unit. If the blister strip is cut into individual doses, there is a possibility of unidentifiable contents if every second unit is labelled which presents as a safety risk for patients and healthcare professionals. This is presently a common occurrence. Many manufacturers already provide medicines in this manner, which is to be commended and this should be a major consideration for the TGA to mandate.

There is also a need for review of the 'race track' format for products other than oral contraceptives, to ensure the utility with other agents, e.g. anti-hypertensive medicines.

What other changes would you like to see for this type of packaging?

Consideration should also be given to the backing of blister strips – each unit should be perforated with the colour of printing on each unit different for each strength of product and it should complement the colour used on the outer box. Consideration should also be given to the actual colours used on the backing of the blister strip. Some colours are very difficult to read, such as orange, especially for the visually impaired consumer.

General question on the proposed regulatory changes for small container labelling

To what extent do you support the proposed changes for small container labels? Please provide details.

The proposed changes are a step in the right direction, however further improvements could be made. Consider change to the nominal capacity to 10ml.

Note: not only applicable to eye drops but also to ear and nose drops and potentially some oral preparations.

Do you have any further suggestions for how labelling of small containers could be improved?

The use of a flag label could allow sufficient information to be printed onto small medicine packs in readable font. 1.5mm height font would be too small for many consumers to read and although the provision of information on an insert in the medicine box is useful, this may easily be lost. If the inside of the flag label is left blank, the dispensing label could be affixed in this space.

Include space for the date opened where applicable.

Note: antimicrobial preservatives also relevant for other routes of administration e.g. nose, ear, oral, inhaled and some dermatological preparations.

An issue with a flag label is acknowledged as wear and tear and may fall off after some use. Other suggestions include:

- The use of a wrap-around flag label that is secured at one end so the flap does not become worn (such as the use of a magnetic strip to secure the ends)
- The use of a Quick Response (QR) code that enables, the consumer, with the use of their smartphone to access larger amounts of information. (Users with a camera phone equipped with the correct reader application can scan the image of the QR Code to display information, connect to a wireless network or open a web page in the telephone's browser).
- The insertion of a micro audio strip within the label that can be activated using an iPhone app to access further information for those visually impaired or unable to read.

General question on the proposed regulatory changes for pack insert requirements

Do you support the proposed changes for pack inserts? Why/why not?

Yes, the restriction of advertising materials would improve QUM. The information provided should be written in simple, plain English, contain factual, relevant information only and should refer to the availability of a full CMI.

Do you have any further suggestions regarding pack inserts?

Why is the mandatory requirement limited to injectable medicines?

General question on the proposed establishment of a labels and packaging advisory committee

To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?

This committee would provide good oversight of medicines labels and packaging and improved cognisance of consumer health risks associated with medicine labels and packaging. It will be important to ensure this committee is multi-disciplinary and includes consumer advocates.

Other Comments:

1. Concern for the similarity in appearance of plastic ampoules. These are safer/easier to open, more accessible and the labelling is often clearer than glass transparent ampoules.

   However, as more plastic ampoules come onto the market there is a risk of medication selection errors as they are looking more similar even with different colour printing. Different drugs often share the same colour printing, e.g. suxamethonium, heparin 25,000 units and metoclopramide all have purple printing. They look the same even though their uses are very different which can result in extreme harm to the patient if mixed up. One feature of glass ampoules was coloured rings on the neck of the ampoule – this is not a current feature of plastic ampoules. What can be done to make plastic ampoules more distinguishable?

2. Confusion with labelling when strength of product (e.g. in salt form) is different to the usual strength or dose administered. For example metronidazole benzoate 320mg in 5ml with metronidazole 400mg in 5ml. Another example is etoposide and etoposide phosphate. Suggest prominence given to base drug and/or the strength of the most commonly administered dose.
3. Review focus mainly on products in use in community setting. Consideration should be given to safety improvements and standardisations for a broader range of products including products used in hospitals e.g. intravenous fluids and medicines, electrolytes, anaesthetic agents and re-packaged items (e.g. chemotherapy).
4. Standardisation of labelling products which have both a strength and a release rate e.g. transdermal products to reduce confusion and errors with these agents.