TGA Medicine Labelling and Packaging Review

Consultation Paper Response

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?

- We support standardisation of the location of the active ingredient on the medicine label as standardisation has been shown to reduce errors and improve outcomes.
- We support increasing the prominence of the Generic name and this should be given more prominence than brand name, as this will reduce confusion, by patients and health professionals.
- Although not within the scope of this review, we support the introduction of tall man lettering on medicine packaging.
- We do not support the use of brand names for generic formulations e.g. Nifehexal, captopril-sandoz (no bias intended), as this causes confusion for patients and health professionals.
- We propose that only the innovator product be permitted to use a brand name on packaging.
- Consider use of other strategies to improve medication use for visually impaired persons e.g. Braille on blisters

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

- Support warnings, but advocate the inclusion of warnings for all non-steroidal anti-inflammatory medicines available without a prescription e.g. diclofenac, naproxen, mefenamic acid.
- Consider using a term that includes all health professionals who are able to prescribe rather than “doctor”.
- We advocate for a similar warning on combination products available over-the-counter that contain codeine.
- Support the position of the warning on the packaging.

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

- We advocate increasing the minimum font size from 1.5mm to a larger font size, to assist identification.

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?

- No, this is confusing.

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?

- Strongly support the proposed changes to address LASA names.
- We support the inclusion of generic names in the proposed recommendations (eg. rifampicin/rifabutin, penicillin/penicillamine). These drugs with LASA generic names should be required to conform to packaging recommendations in the same way as brand names.
- Packages containing different strengths of the same active ingredient should use colours and designs that contrast to avoid selection errors. e.g. atorvastatin-pfizer 40mg and 80mg have identical packaging. Avapro range uses different colours to distinguish between strengths.
- Corporate branding of generics can cause confusion and selection errors, even for drugs with different sounding names. eg. Sandoz-clarithromycin and Sandoz-ciprofloxacin can be confused as they have similar packaging and are the same strength (e.g. 250mg).

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?

- They will address the issues identified in the previous question.

Do you understand the proposed changes?

- Yes

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?

- We support the proposed standardised format and content of the medicine information box on over-the-counter and complementary medicines as this will improve access to information to assist in decision making by consumers.

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

- Investigate the use of technology – eg. Use of Quick Response (QR) codes on packaging to scan with smart phones that brings up the minimum information in a larger font size, and links to more detailed information.
- Community pharmacies should have computer terminals that consumers can use to search for information on medicines.

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.

- We disagree with the recommendation that products with more than three active ingredients should be exempt from the labelling requirements in place for other products. We feel that information such as uses and storage are important for selection of products by patients.

General question on the proposed regulatory changes for dispensing label space

Do you support a designated space for the dispensing label on prescription medicines?

- We support the inclusion of a designated space for dispensing labels on prescription medicines
- We propose that the size of the space should be increased to accommodate standard Australian dispensing labels (80x40mm).

General question on the proposed regulatory changes for blister strip labelling

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

- We support the proposed information, noting that the preferred option would be for the information be listed on each tablet.
- We support the use of "segments" over standard blister packing (e.g. Zyprexa, Zofran).
- The use of crimping the batch and expiry on the edge of blister strips should be discontinued.

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

- We propose different coloured blisters for different strengths of the same product (e.g. Dilatrend, Efexor-XR).
- We propose that the "race-track" format be limited to a those drugs that need to be taken in a sequential order (e.g. Oral contraceptives). Other drugs (e.g. digoxin 250mcg) should not use the race-track format so that necessary information can be included on the blister.
- Where the generic and trade name are both printed on the blister, the generic name should be more prominent than the brand name (similar to requirement for packaging).
- Name of manufacturer should not be more prominent than the generic names.

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.

- Generic name should be larger than 1.5mm and larger and more prominent than the brand name.
- We support all the other recommendations.

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

- Light coloured print (e.g. white/yellow) should not be used on clear plastic containers (e.g. Minims, ampoules).
- Avoid the use of red or green print as may not be able to be read by people who are colour blind.
- The use of uncoloured embossed lettering on plastic containers should not be used (eg.. Cellufresh).
- Consider standardised lid colour for eye drops within therapeutic groups to assist identification by patients (e.g. antibiotics, anti-inflammatories).

General question on the proposed regulatory changes for pack insert requirements

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

- We strongly support the proposed changes.

Do you have any further suggestions regarding pack inserts?

- Consumer Medicines Information should be included as a pack insert in all scheduled products. (e.g. Provided by manufacturer rather than pharmacist)
- The content of Consumer Medicines Information and Product Information should be regularly reviewed and updated to ensure currency of information (minimum 3 years or with each significant change).

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?

- We support the establishment of a committee with multidisciplinary input with a strong consumer focus.

Manager Medicines & Poisons Control - 23 August 2012