On behalf of the members of the Australian Skeptics, Victorian Branch, thankyou for the oportunity to comment on the **TGA medicine labelling and packaging review**. Broadly we are in favour of the suggested changes.

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?

A. We agree, it's a significant improvement. Perhaps the active ingredients list should be above the product name and in larger font.

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

A. Agreed

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

A. Feedback from our members indicates that homeopathic descriptions of active ingredients are considered the most misleading of all labelling practices. The names used and the quantities shown need to be explained at length before they are understood.

"Oscillococcinum 30C" would appear to be allowable under the proposed changes. However, the ingredient name is really only of significance to other homeopaths, not consumers. "Duck liver" is a far clearer, understandable and plain English description of the listed ingredient. It's important that preference always be given to plain English terms so that consumers and health professionals are properly informed and not misled.

Also, the quantity shown in the active ingredients list should be of metric ISO standard i.e. use grams (g) or milligrams (mg), for liquids use millilitres (ml) - not smaller amounts such as pictograms or femtograms. Dilution ratios should not be used and homeopathic abbreviations for dilutions should not be used as they are misleading and confusing. If very small quantities of an active ingredient are present they should be expressed as a decimal of an amount. Typical consumers may be able to understand and visualise grams, i.e. 4.0mg, 0.001mg or 0.000001mg. If calculations show that there is less than 49% chance of a single molecule of the active ingredient listed exists in the product, rather than writing a long string of zeros it would be more honest to say, "This product is unlikely to contain any of the active ingredient listed".

It's also important that product names, logos and graphics on the packet don't make any implied claims that can't be properly/rigorously substantiated. Sensaslim and Fat Blaster are two examples of misleading product names. All health related terms, including derivations, abbreviations, and adjectives to health terms should not be permitted in product names and product logos. I.e. Healthy, lite, soothing, slim, cleanse, detox etc.

The TGA investigation into the confusing "Aust L" and "Aust R" scheme also closely relates to this packaging review. We await the outcome with interest.

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?

A. Consumers will be better informed. It will allow for realistic comparison of gerneric and brand name products.

What is the smallest size font that you consider readable?

A. It could be reasonably assumed that people with eyesight that does not allow them to read a character size typical of larger font books, 3-4mm, would carry or wear glasses. Existing research should be consulted on this question. The Canadian National Institute for the Blind (CNIB) has carried out such research. Guidelines derived from (CNIB) research are available here:

http://www.cnib.ca/en/services/resources/Clearprint/Pages/default.aspx

We would request that packaging standards in relation to font size and readability follow the CNIB guidelines.

We support the recommendations on:

- Look-alike sound-alike names and look-alike packaging
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- Standardised Information Format: the Medicine Information Box
- Dispensing label space
- Blister strip labelling
- Small containers
- Pack inserts
- Labels and packaging advisory committee

From the TGA web site:

The TGA will draft a Therapeutic Goods Order that reflects the outcomes of this consultation and, in accordance with the Best practice regulation handbook, will conduct a consultation to determine the economic impact of the proposed changes on the medicines industry.

We would like to highlight that the TGA also repesents the interests of Australian consumers. The economic impact of changes on the medicines industry shouldn't be the only consideration. Improving safety and helping consumers to be more informed should also be a consideration whilst making decisions on this review.

Edited by [redacted] committee member, on behalf of the Australian Skeptics, Victorian Branch.

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