Division of Pharmacy
Flinders Medical Centre

Sub 3

Comments in relation to:

TGA Medicine Labelling and Packaging Review

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Thank you for the opportunity to comment on the TGA consultation paper of May 2012 relating to the "TGA medicine labelling and packaging review" which will be consolidated into a broader response from SA Health or SAMAC.

Glossary – page 12-13

- Blister strip – are not always sealed with aluminium (e.g. plastic, thickened paper); definition needs to be reviewed.

Active ingredients – page 16-19

- Non-prescription medicines containing paracetamol or ibuprofen – reference is made to the addition of warning statements used in the UK, Ireland and US for such products. It should be noted that the Australian Pharmaceutical Formulary 22nd Ed (APF 22) similarly has recommendations for the use of such labels in its 'cautionary and advisory labels' section and should be considered by the TGA for use with paracetamol and ibuprofen containing OTC products.
- Suggest that the active ingredients be listed before the brand name for the reasons detailed on page 16.
- Support other changes: prominence of active ingredient is a welcome change, warning of paracetamol and ibuprofen products is positive, education should be directed at patients to familiarise themselves with generic names so as to avoid medication misadventure.

Medicine Information Box – page 25-29

- Excellent initiative. Information in the box must be factual in relation to indications and not have unsubstantiated claims made on the label – i.e. Needs to be regulated.

Dispensing label space – page 30-31

- Not a high priority as pharmacists can flag labels if required and or use the clear plastic labels for labelling small containers and bottles. From a patient safety and quality use of medicines perspective it is more prudent to have the required information (generic name, strength, bar-code, etc) on the box rather than a space for the dispensing label.

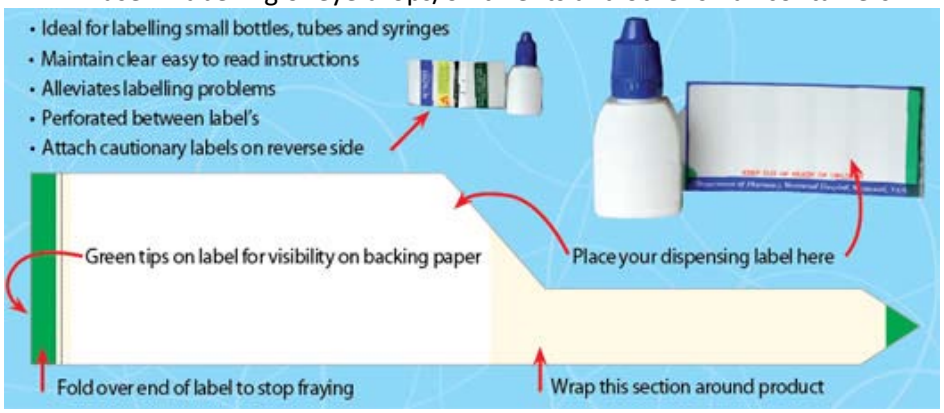
Blister strip labelling - page 32 - 34

- Not all backing is of aluminium foil, often paper/cardboard are used or plastic
- Review need for 'race-track' format for products other than oral contraceptives, as not needed for agents such as anti-hypertensives, etc.
- Welcome change and support the generic name, brand name, amount of active ingredient, batch and expiry to be on the blister strips, but strongly ask the review group to reconsider the requirement for this being repeated every two units (or have this as the minimum acceptable standard) but to be repeated for *every* unit. This will ensure medication mis-identification will not occur if the blisters were to be cut into individual doses. Many manufacturers already provide medicines in this format and are to be applauded – this should be a major consideration for the TGA to mandate.
- Other issues: the top of the blisters should be clear plastic to enable a second safety check of the correct medicine being dispensed, unless the product is to be protected from light in which case translucent packaging can be considered; backing of blister should preferably be

perforated between each unit; colour of printing on each unit should be different for each strength of product and compliment the colour used on the outer box.

Small containers – page 35-37

- 7.3 – expand to recommend that the use of clear eye drop label (as below) be standard for use in labelling of eye drops/ointments and other small containers



Pack inserts – page 38

- Pack inserts should refer to availability of full CMI

Labels and packaging committee – page 39

- Positive recommendation by the TGA which will embrace health care professionals to share in the ownership of this issue; many positives to be identified. I currently act as an advisor for a similar group for the FDA and have been able to provide much proactive advice and recommendations which have been beneficial for the regulator and rewarding to me as an individual.

Other comments:

- The TGA review group should familiarise themselves with the Australian Pharmaceutical Formulary 22nd Ed (http://www.psa.org.au/archives/8361)
- Reference group must include a representative from the Society of Hospital Pharmacists of Australia, as a leading authority in medication management, quality use of medicines and medication safety.
- Consider the inclusion of a paediatrics matter expert to advice on any special considerations for this population
- Discussion on standardisation of representing active ingredients (i.e. 5mg vs. 0.5% vs. 1:1000)
- Out of scope activities noted, although the code of practice for tamper evident packaging and review of child resistant packaging for medicines be identified as a priority.

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