Comments in relation to the TGA Medicine and Labelling Packaging Review August 2012:

Proposed Change	Comments
1.1	Support
1.2.1	Support
1.2.2	The font size of the active ingredient should be greater than 100% of the medicine brand name on the main/front label.
1.2.3	Support
1.2.4	Support
1.3	All active ingredients should appear on the main label with equal prominence. If only the most abundant is listed on the main label there is potential for active ingredients to be overlooked resulting in avoidable adverse effects or unintentional overdose for the consumer.
1.4	Support
1.5	Support
1.6	Support
1.7	Support

We think that increasing the prominence and standardising the location of the active ingredient on the medicine label will increase the consumer familiarity with the active ingredient. This will result in less confusion between brands of the same medication and reduce the risk of duplication of a medication.

The proposed warnings for paracetamol and ibuprofen will increase patient awareness of what products contain these medications.

By making the active ingtredient name larger than the brand name, this becomes the name that the consumers are more familiar with. This follows all good prescribing guidelines as all medications should be prescribed by the active or generic name.

12pt font size is the smallest that we consider reasonable.

The strength of the medication should always be listed next to the active ingredient in the same size and font.

The active ingredient in all liquid and IV medication should be printed as a standardised strength, ie Xmg/m for the product when reconstituted according to the manufacturer's directions. Currently medications can be listed as Xmg/mL, Xmg/5ml and Xmg/10ml. This increases the risk of confusion for consumers and medical professionals.

For medications that come in a salt formulation the strength should be listed for the active ingredient. E.g. Iron Liquid should be labelled as mg/ml of elemental iron, not as mg/ml of ferrous sulphate as doses are calculated on the element iron.

Proposed Change	Comments
3.1	Support
3.2	Support
3.3	Support
3.4	Support
3.5	Support
3.6	Support

The proposed changes should improve medication safety. Currently pharmacists take precautionary measures such as separating LASA names and LA packaging to try and reduce selection errors. By reducing the number of LASA products it reduces the potential for such selection errors and so reduces potential harm to patients.

As most consumers are only familiar with brand names, rather than active ingredients, the changes to look-alike medicine branding are of upmost importance. Many consumers do not realise that there is the same active ingredient in each version of the look-alike brands and may unintentionally take the same medication, marketed for different indications.

The brand name should not be able to include the active ingredient of the product (eg APO – gliclazide™). The products made by companies that follow this branding format all have LASA brand names and LA packaging, increasing the potential for selection error and decreasing the patient awareness of the active ingredient in their medication.

Proposed Change	Comments
4.1	Support
4.2	Support
4.3	Support
4.4	Support
4.5	Support
4.6	Support

By standardising the information required on the box or primary packaging and the format that this is presented in, consumers' awareness of this information will be increased. It will help to highlight to consumers that all medications, including those purchased at the supermarket, have the potential to cause harm if used incorrectly. It will also allow consumers to choose the most appropriate medication for their condition by making this information easily available and comparable.

For products with more than three active ingredients the use should also be printed on the primary packaging along with the dose and warnings. This will help consumers select the most appropriate product for their condition.

Proposed Change	Comments
5.1	The designated space should be consistent with the standard Australian label size so important information is not covered by the dispensary label.
5.2	Support
5.3	Support

As the Australian Standard label size is 80 x 40mm this should be the size of the space left to accommodate the dispensing label. Another option is to encourage pharmacies and dispensing programs to follow the international standard size labels.

If there is not enough space for the dispensing label then the pharmacist is required to either cover important information or to flag the label. Flagged labels should be avoided where possible as they make it harder for the patient to read the instructions and increase the chances of the label coming off the medication, leaving the patient without any instructions.

Proposed Change	Comments
6.1	This information should be printed on every unit.
6.2	Support
6.3	Support
6.4	Support the alternative option of printing the brand name, batch number and expiry date repeated on the foil.
6.5	Support

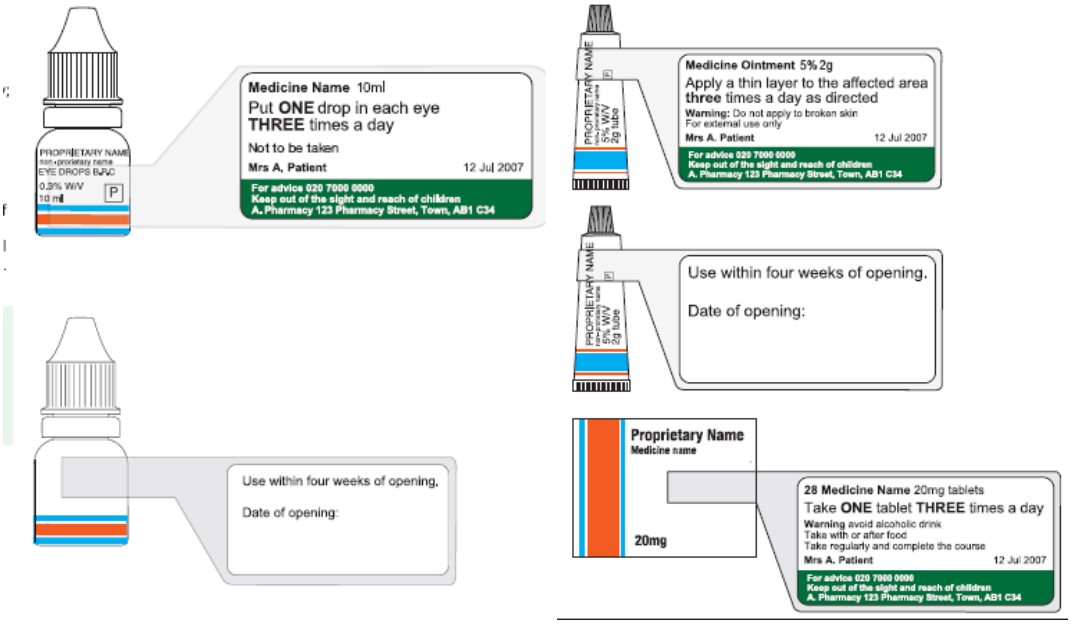
As many patients will cut the blister strips to take one or two doses with them, this information should be printed on every unit. This is also advantageous in the hospital setting where a patient may not be dispensed a whole blister strip on discharge.

If medication is not light sensitive it should be in clear plastic strips with foil cover to allow for easy tablet recognition without removing them from their packaging. This is also useful for pharmacists checking dose administration aids as it allows them to visually identify tablets they are unfamiliar with.

Medication should not be presented in a “race-track” format unless there is a clear indication due to changes in medication active ingredient throughout the blister, eg oral contraceptives. If companies wish to use “race-track” formatting on other medications, eg oral hypoglycaemics, they still must comply with the changes proposed in 6.1.

Proposed Change	Comments
7.1	Support
7.2	Support these recommendations plus the inclusion of storage conditions one opened.
7.3	Small containers, such as eye drops, should be manufactured with a plastic 'flag' which the pharmacist can then secularly attach the dispensing label to without obscuring any of the information on the bottle.

Example of comments for 7.3



Proposed Change	Comments
8.1	Support
8.2	Support

Where provided package inserts should have a minimum font size of 1.5mm with headings no less than 2mm.

If a full CMI is not provided as a package insert, then information should be provided to direct the consumer as to where one can be obtained.

Other comments:

To help ensure the potency and efficacy of vaccines all vaccines should be produced with a Vaccine Vial Monitor (VVM) as incorporated in their label.

This is the recommendation of the WHO and all vaccines supplied by UNICEF currently follow this standard.

VVMs complement the Cold Chain system by tracking the heat exposure for each individual vial from manufacture to administration to the patient.

Currently the cold chain track heat exposure for each transport step, however this information is not carried with the individual vial. This is particularly pertinent for remote areas where the vaccines have to travel long distances in extreme temperatures or where patients are collecting the vaccine from the pharmacy and taking it to the GP and they may not always store appropriately.

For further details see the WHO publication Getting Started with Vaccine Vial Monitors

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23/08/2012