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To whom it may concern,

Thank you for the opportunity to comment on the TGA Medicine Labelling and Packaging Review Consultation Paper.

Prominence of active ingredients on medicine labels

- Support prominence of active ingredients. Suggest active ingredient(s) listed before trade name, not after.
- Support equal prominence of active and trade name in terms of font size, however suggest active ingredient(s) are bolded. (Bolded font may offer more emphasis rather than difference in font style).
- Support paracetamol and ibuprofen warnings. Suggest emphasising the amount contained in each unit dose of a product (e.g. 500mg in each tablet) along with the maximum total 24 hour dose (e.g. 4grams paracetamol every 24 hours) rather than maximum total number of unit doses.

Proposed regulatory changes - Look-alike sound-alike names and look-alike packaging

- Proposed changes appear to be effective
- Suggest (as stated earlier) that active ingredient(s) listed before trade name, not after. The examples listed are of LASA brand names. Of course, LASA errors may still occur if the generic name is listed first, however, the use of generic names may prompt the dispenser about the drug's identity more so than the brand name.

Proposed regulatory changes - Look-alike medicine branding

- Support *3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.*
- Support *3.6 The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients.* This is particularly relevant for combination products containing either paracetamol or ibuprofen along with other active ingredients (e.g. cold and flu preparations).

Standardised information format: the Medicine Information Box

- Definitely support this change for over-the-counter and particularly for complementary medicines. Support Information Box needing to be standardised in terms of the content and format.
- "Uses" section needs to be approved/monitored to ensure that the claims are evidenced-based, particularly for complimentary medicines.

- Agree that Information Box does not need to be on the front of the packaging but needs to be in on the largest other face of a box or in a prominent and easy-to read position on a bottle.
- Agree for a pack insert if there is insufficient space on the outer packaging (see below regarding Pack Inserts).

Dispensing label space

- Support change for a designated space on the packaging for a label.
- For boxes, a standard sized space for the label is an excellent idea. Packaging should already be labelled with generic name, trade name, strength, batch number, expiry, etc. The space for a label is in addition to the packaging and should not compromise or replace the details of the original packaging.
- For smaller boxes or bottles, a space may be left for a flagged label, however flagged labels are less ideal, in my opinion, than a clear label upon which the dispensing label is attached (such as that used for eyedrop bottles). Flagging may obscure the details included on the dispensing label, particularly near the area of the fold.
- Clear labels need to be of sufficient strength/adhesiveness so that the dispensing label is securely affixed to it and subsequently the original packaging of the medicine.

Blister strip labelling

- Blister strips should have the full details of the medicine on every single unit dose (including generic, trade names, strength, batch number and expiry). This is very important from a safety and identification perspective. Please consider this a mandatory requirement for all manufacturers.
- “Race-track” style labelling should be used minimally and only when appropriate (e.g. contraceptive pill). The benefit for a consumer (in terms of being able to identify if they have taken their medication that day) does not seem to outweigh the benefit of being able to identify each single dose of a blister strip.
- Details on each unit dose may have other benefits such as being able to separate single doses for packing into dosage administration aids (e.g. for medicines which need to be kept in the original packaging) or supply of part blister strips (such as in the case of emergency supplies in community pharmacy or when part strips are supplied to wards in the hospital setting).

Small containers

- Support use of clear labels for affixing dispensing label to original packaging (see above regarding Dispensing Label Space). This will mean that details on the original packaging (which is already limited by space) is not obscured by the dispensing label.

Pack inserts

- Agree with recommendations regarding advertising and printing on the inside of the packaging.
- Pack inserts should be the Consumer Medicines Information leaflet, where this exists for the product. Pack inserts may be small (with subsequently small font), thus the insert should explain that a standard or large font CMI is available from the pharmacist on request.
- Where a pack insert is used, reference to such insert should be included on the original packaging to inform the consumer that such an insert has been included with the product (either inside the box or attached to the bottle via removable adhesive.

Labels and packaging advisory committee

- Support the role of such a committee, particularly with consumer members and healthcare professionals working in various settings. Risks can be identified, expertise shared and strategies implemented to bring about positive safety changes.

Other comments

- Items outside of scope of this review noted. Clear identification of the generic drug name (as outlined in the above proposed changes) will likely improve safety more so than use of strategies such as tall-man lettering.
- Ampoules/vials - labels to ideally indicate the approved route of administration, particularly where more than one form exists for a product such as acetylcysteine for inhalation and for intravenous use. Additionally, standardisation of the presentation of the strength would be ideal, e.g. total amount per ampoule/vial (e.g. 500mg/5mL) instead of/in addition to amount per mL to avoid accidental administration of whole contents of ampoule/vial.

Regards,
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