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TGA Medicine Labelling and Packaging Review

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Opening comments

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,200 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a core base of members practising in public and private hospitals and other health service facilities.

SHPA strongly supports the proposals detailed in the consultation paper and believes that the proposed changes will substantially improve the presentation of medicines to consumers.

In addition to the questions posed by TGA SHPA notes the following.

1. SHPA believes that if there is no consensus position following the consultation process **TGA should give priority to consumer wants and needs as the ability for consumers to read and understand the labelling of medicines is crucial to the safe and appropriate use of medicines.**

2. SHPA believes that in principle, the pack size for all medicines should be chosen to ensure that the new labelling requirements can be met rather than the labelling requirements being tailored to meet current packaging practices. This may require that the packaging for some medicines be changed to meet the new requirements. **TGA should take a lead position on this issue and adopt a best practice approach for Australia to assist with the safe and appropriate use of medicines.**

3. SHPA believes that consumer usability testing should be built into the design process for the packaging and labelling of medicines. Feedback should also be sought during any pre-marketing clinical trials undertaken in Australia.

4. Whilst the focus of the proposals is how labelling can be improved to assist consumers, they also offer an opportunity to assist pharmacists and other health workers to reduce 'picking errors'. In pharmacies and areas within hospitals boxes of medicines are often stacked on top of each other or placed in drawers rather than stored in 'stockflow' shelves or within automated storage devices. Figure 2 illustrates how the brand name and active ingredient name would be presented on the side of the box but specifications are not listed in the consultation paper. SHPA believes that the presentation of these names should mirror the requirements of the names on the front of the box; that is equal prominence of the active ingredient and brand name and listing of the same active ingredients.

5. SHPA believes that guidance on the name of the active ingredient requires inclusion of the need for standardised expressions of strength i.e. quantity / 1 mL (rather than quantity / 5 mL) and quantity per single ampoule or vial or prefilled syringe.

6. The requirements are silent on the size of the company name but the illustrations suggest that the company name can be in the largest font size or have the greatest prominence on the label. SHPA believes the company name should, at the most, have equal prominence with the brand name.

7. SHPA supports the designation of a specific space for the dispensing label but the area proposed (70 x 30 mm) is smaller than the standard label size of 80 x 40 mm.

SHPA believes the proposals should include a 80 x 40 mm space for the dispensing label.

8. The consultation paper is silent on the consumer confusion linked to medicines with different salts of the same active ingredients. Consumers may perceive that two medicines that are practically and / or clinically the same are different medicines as the actual active ingredient name is different e.g. oral potassium products. Also SHPA is aware of at least one report of a consumer discontinuing their calcium supplements as they were taking already taking another medicine with calcium – atovorstatin calcium. It may be appropriate that prominence is given to the 'practical' active ingredient name rather than the 'technical' active ingredient name.

9. The consultation paper is silent on the labelling of medicines presented 'ready-for-use' such as the packaging for prefilled syringe platforms and medicines in pre-filled dose administration devices. SHPA believes the TGA should provide guidance on these products.

10. SHPA believes the issue of mandatory, standardised barcoding on original packs and the dose administration device also needs to be considered. In 2003 SHPA called for the introduction of a standardised barcoding system for medicines in Australia, including the development of barcodes which also contain the expiry date and batch number information. This would facilitate the uptake of automated storage / dispensing systems and at the point of care safety systems as individual syringes, ampoules, capsules / tablets blister packs, foil strips or bottles of medicines etc. could be automatically, electronically checked to ensure that the correct medicine is being dispensed or administered to a patient.

11. All of the sample illustrations need to highlight all of the labelling requirements. Some of the illustrations in the consultation paper are not consistent with the proposed requirements, for example the active ingredient name does not have equal prominence with the brand name in Figure 9.

12. SHPA believes that images of the final labelling of the medicine device and its container should be considered as part of this review. Many products are now listed on websites using an image of the box / container without full details on the content of the product. This makes it impossible for consumers to distinguish between medicines that have common branding or look-alike names. As an example with Beconase® being used as a brand name for two products with different active ingredients: fluticasone and beclomethasone. It is impossible to identify which of these medicines you would be ordering from the information on this website, the consumer must know the brand name and the 'image' to identify if this is the product they require:
http://cincottachemist.com.au/product/116398-buy-beconase-12hr-hayfever-nasal-spray-200-online

SHPA notes that many relevant issues are listed as outside the scope of the review however we believe that most of these issues are pertinent to this review and should be considered in finalising labelling requirements for medicines in Australia.

SHPA would be pleased to participate as a member of the external reference group if required, please contact us through shpa@shpa.org.au.

Proposed changes and consultation questions

Prominence of active ingredients on medicine labels
Research supports the proposal of layout and larger print size for the active ingredient name; consumers prefer and can more easily read labels in the proposed format. SHPA believes that the proposed changes will improve the readability of labelling and reduce the likelihood of consumers inadvertently taking two of the same medicine.

As the actual measurement of a letter differs according to the **font style, not just the font size,** the recommendations should mandate a minimum size in millimetres rather than mandating a font size. SHPA believes that many consumers would struggle to read print smaller than 2 mm and that a minimum of 1.5 – 2 mm should be set. TGA should take a lead position on this issue and adopt a best practice approach for Australia to assist with the safe and appropriate use of medicines.

The proposals are silent on the visibility of information on batch number and expiry date, they should be printed in colour not just embossed as it is important that this information is both easy to identify and readable.

Proposed change 1.2
SHPA would prefer that the active ingredient name was given prominence over the brand name and the active ingredient name should be presented in the clearest and easiest-to-read font. At a minimum, the active ingredient name should be given equal prominence to the brand name.

Proposed change 1.6
SHPA suggests that warning for paracetamol products could be clearer, for example: "Contains paracetamol Xmg. Consult your doctor or pharmacist before taking other medicines containing paracetamol."

We also believe that the print size of the warning needs to be adequate to ensure all consumers can read the warning.

Look- alike and sound-alike medicine brand names and look-alike packaging and branding
SHPA strongly supports all of the proposed changes, particularly proposed changes 3.5 and 3.6. However the consultation paper is silent on the use of logos, colours and background or watermarked images that are often used to link products in the mind of the consumer. SHPA believes the recommendations should discourage the use of logos, colours and background or watermarked images that detract from the clear identification of the active ingredient.

Proposed change 3.2
SHPA notes that if TGA was using the proposed changes two of the five examples listed on page 21 would not require changes to packaging.

SHPA also notes that differences to colour of packaging would not assist with reducing medication order or dispensing errors made by prescribers or pharmacists.

Standardised information format: the medicine information box
SHPA supports the concept of the medicine information box but believes that a standardised set of headings and detailed content is needed similar to the system used for food labelling. The information should be presented in the same order e.g. active ingredient, uses, warnings and allergies, directions, storage information. The examples listed in the

consultation paper have different headings / sections included and they are presented in different orders.

Information on the use of medicines in pregnancy should always be listed under the same heading. Similarly warnings or precautions on the use of the medicine in children need to be listed under the same heading. The recommendations should also indicate that information such as the colour / flavour of the product and any preservatives and colouring agents should be listed and where this information should be listed e.g. under storage or active ingredient. The examples shown in the consultation paper show these data in different sections with different formats.

Dispensing label space
SHPA strongly supports the concept of a designated space for the dispensing label.

Blister strip labelling
SHPA supports the proposed changes but believes that the colour / visibility of the print needs to be detailed. In addition the proposals should not remove the requirement that information on the active ingredient, batch number and expiry is always visible until all of the doses have been removed from the strip labelling.

As noted earlier, SHPA believes that the labelling of dose administration devices / support packaging also needs to be considered. The same level of information needs to be available for individual syringes, ampoules, capsule / tablet blister packs, foil strips or bottles of medicines etc.

As an example, Sanofi recently removed the labelling on their Clexane® prefilled syringe platforms and users must now rely on the syringe label with a transparent cover when selecting the medicine for administration. This makes it very difficult to identify the strength of the syringe unless it is removed from the platform. Anecdotally we understand users need to open the outside wrapping to check the correct medicine has been chosen and then they cannot use the syringe if the wrong strength has been chosen as the syringe cannot be kept for future use once removed from the packaging. In this instance poor labelling is leading to wastage, however SHPA has no knowledge / evidence of the extent of actual administration errors.

Small containers
SHPA appreciates the need for separate guidelines for the labelling of packages that form part of the delivery system. SHPA supports the proposed changes but would also suggest that a designated area for the label to be partially attached / flagged be identified.

Pack inserts
SHPA supports the proposal but suggests that TGA should also set a minimum print size of 1.5 – 2 mm to ensure readability of the information.

Labels and packaging advisory committee
SHPA believes an advisory committee would assist with advising the TGA on these issues. The benefits of changes to labels and packaging **will only be realised if the voice of the consumer is 'front and centre'** and includes representatives from numerous representative bodies including the aged care sector.

As noted earlier, SHPA believes that TGA should take a lead position on the issue of the labelling of medicines and adopt a best practice approach for Australia to assist with their safe and appropriate use.