CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
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I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☐ Prescription Medicines ☐ OTC Medicines

☐ Complementary Medicines ☐ Medical Devices

☐ Blood/Tissues ☐ Other

☐ Sole trader ☐ Business with employee(s)

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☒ Professional body

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☐ Reg. Affairs Consultant ☐ Laboratory Professional

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Pharmaceutical Society of Australia

Submission to the TGA Medicine Labelling and Packaging Review

AUG
2012

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission in response to the consultation paper (the 'Paper') released in May 2012 on the *TGA medicine labelling and packaging review* (the 'Review'). PSA has also contributed to this Review through other forums such as the external reference group.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are approximately 26,500 registered pharmacists (based on Pharmacy Board of Australia data released in May 2012). PSA's core functions include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and representing pharmacists' role as frontline health professionals.

Recommendations

PSA provides the following recommendations to this Review:

1. PSA seeks information on the process or expertise that will be used to determine the impact that "improved differentiation" between the brand name and active ingredient names may have on the requirement for 'equal prominence'.

2. While supportive of the concept of the proposed warnings on paracetamol- and ibuprofen-containing products, PSA seeks information on how warnings about other active ingredients are proposed to be prioritised for inclusion in the future.

3. PSA believes the inclusion of pharmacists in the risk assessment process for proposed labelling and packaging of new medicines should be a mandatory requirement.

4. PSA supports the removal of look-alike medicine branding (umbrella branding).

5. PSA recommends a clear list of inclusions or exclusions for the criterion that "active ingredients are closely related" in assessing the use of the same brand name for different products.

6. PSA welcomes the proposal to include a designated space requirement to accommodate dispensing labels.

7. PSA believes the minimum designated space for a dispensing label should be 80 x 40 mm.

8. PSA believes the use of clear flag labels which accommodate dispensing labels should be included as a recommendation.

9. PSA suggests investigating the possibility of obtaining an exemption for therapeutic goods from deceptive packaging legislation. This would provide the opportunity for further improvements to the labelling and packaging of small container medicines.

10. PSA welcomes the proposal to establish a panel or advisory committee to assist and provide advice to the TGA on the acceptability of proposed names, labels and packaging of medicines prior to registration approval.

11. PSA queries the prominence of the TGA web site address on the primary pack of medicines and suggests there may be more appropriate alternatives.

12. PSA seeks information on the timelines and scope of a review of requirements of pharmacists' dispensing labels.

Comments on specific issues in the Paper

Prominence of active ingredients on medicine labels

PSA is aware that the issue of 'equal prominence' of active ingredient names and brand name of a medicine has been considered at many opportunities and while the majority of stakeholders support the concept, it remains a complex topic in terms of implementation. We note the Paper states that 'equal prominence' is intended to capture the ease of location and identification of the names of active ingredients and the brand name. Generally we believe the illustrative example label on p. 18 of the Paper does enhance ease of identification of the active ingredient names. We note however that "improved differentiation" between the brand name and active ingredient names will be permitted through the use of different font style, letter spacing or font colour. This may seem counter-intuitive in some instances as, for example, different font style or letter spacing can affect font size and appearance thereby impacting on the prominence of names. PSA is interested in understanding what process or expertise will be used to determine the impact of "improved differentiation" on the criterion of equal prominence e.g. expert panel assessment, or consumer testing.

Improving consumer safety is a key focus of this Review and from this perspective PSA is supportive of the concept of the proposed warnings on paracetamol- and ibuprofen-containing products. However we query the feasibility of this proposal in terms of how warnings in the future for any other substance will be prioritised or selected.

Look-alike and sound-alike medicine brand names and look-alike packaging and branding

PSA welcomes the proposed requirement for submission of evidence of risk assessment of the proposed labelling and packaging of new medicines. Apart from the use of checklists and consumer testing, PSA strongly believes there should be a requirement for sponsors to consult with and obtain the views of

health practitioners including pharmacists. Practising pharmacists will be able to provide valuable feedback to sponsors on any new labelling or packaging in the context of the names, labelling and packaging of existing medicines and other matters arising from everyday professional practice, including consumer feedback and behaviour. We believe the inclusion of pharmacists in the risk assessment process should be a mandatory requirement.

PSA has strongly advocated for the removal of umbrella branding (look-alike medicine branding) based on feedback from member pharmacists of actual cases of consumer confusion. PSA therefore fully supports the proposed changes outlined in this section, in particular, recommendations 3.5 (which will no longer permit products to have a common parent brand name with a differentiation based on symptoms or use if they include the same active ingredient in the same quantity) and 3.6 (which will generally disallow the use of the same brand name for products with different active ingredients).

In relation to the proposed changes under 3.6, part a, we believe a definition may be required for the criterion that "active ingredients are closely related". Although one example ("different salts of the same pharmaceutical chemical") has been cited in the Paper, we believe a clearer list of what is considered to be "closely related" is necessary to avoid confusion or misunderstandings.

Dispensing label space

Provision of blank space. The recommendation for a dispensing label space for prescription medicine products has been in existence globally for many years. For example, the International Pharmaceutical Federation recommends "a clear blank space for the pharmacy label" in order to allow the addition of a dispensing label without obscuring important information for consumers.[1] The UK Medicines and Healthcare products Regulatory Agency also recommends "a blank white space in which there is no text of any kind, to aid legibility of the dispensing label".[2]

In Australia, a similar recommendation has been a part of a checklist of items for manufacturers to consider when designing labels and packaging for prescription medicines. The recommendation was also subsequently included in the *Best practice guideline on prescription medicine labelling*[3] which states "there should be a clear space for the pharmacist's dispensing label measuring a minimum of 80 x 40 mm". However, as the title suggests, this document provides best practice guidance to pharmaceutical sponsors and assessors of the Therapeutic Goods Administration in the design and review of the acceptability of prescription medicine labelling. It is not a mandatory requirement and therefore has not been uniformly implemented.

PSA regards this as a high priority issue from a patient safety perspective as it impacts on the ability of pharmacists to fulfil professional obligations and requirements when dispensing prescription medicines. We have consistently advocated for a mandatory requirement for a blank panel on the box of prescription medicine products to accommodate the pharmacist's dispensing label. We are aware that consumers have also requested "a blank white space" to allow for the "placement of the dispensing label".[4] One way

1 International Pharmaceutical Federation. FIP guidelines for the labels of prescribed medicines. Sep 2001.

2 Medicines and Healthcare products Regulatory Agency. Best practice guidance on labelling and packaging of medicines. MHRA guidance note, no. 25. Jun 2003.

3 Therapeutic Goods Administration. Best practice guideline on prescription medicine labelling. Nov 2005.

4 Consumers Health Forum of Australia. Achieving best practice in the packaging and labelling of medicines: report from the national consumer workshop. Jan 2011.

to achieve this is to include this element as a legislative requirement, for example, through the relevant Therapeutic Goods Order. However this suggestion has not been accepted to date.

We therefore welcome this proposed regulatory change to have a designated space for the dispensing label which is consistent with international best practice as stated in the Paper.

PSA is aware that modifications to labelling and packaging can have a regulatory and cost impact and that industry will require adequate transition arrangements. However, we do not support the view that the status quo should prevail in the absence of data or evidence to demonstrate a reduction in risk of adverse outcomes or events. We believe proposed changes are acceptable and warranted given they are based on international trends and best practice guidance over a considerable period of time.

Dimensions of proposed space. PSA notes that the proposed change (recommendation 5.1) suggests a designated space of 70 x 30 mm which is smaller than the standard Australian label size of 80 x 40 mm. This is of concern to PSA as it may lead to circumstances when the dispensing label will overlap with any text surrounding the smaller designated space.

Further, it would suggest that consideration has not been given to any additional space that may be required for the pharmacist to affix other ancillary warning or advisory labels to supplement the dispensing label information. The ancillary labels are important to highlight or reinforce issues which, for example, relate to dosage timing, guidance on administration of the medicine, storage conditions, safe and appropriate handling of the medicine, advice relevant to minimising possible adverse effects and expiry of the product.

PSA suggests that a minimum designated space of 80 x 40 mm is more appropriate as it is consistent with the standard size of Australian labels and mirrors the current TGA's best practice guideline.

Small containers

The issues outlined in the previous section are clearly relevant here but can present additional challenges for small containers.

Although PSA supports the general intent of recommendation 7.3, the reference to a requirement of "a clear space" is ambiguous and requires further specification. The proposed recommendation states that the clear space "need not be the size of a standard dispensing sticker" but "should allow a folded sticker to be attached like a flag without obscuring information". PSA would suggest that this option offers marginal improvement at best, but more likely very little improvement from a patient safety perspective since the folding/flagging of dispensing labels is what pharmacists already implement with difficulty.

PSA is disappointed that the option of using a clear flagged label (as suggested by the UK National Patient Safety Agency[5]) to provide space for a dispensing label has not been included in the recommendations and would ask that this be considered.

Another option which PSA believes warrants consideration is to increase the size of medicine containers. PSA understands that there has previously been some discussion around the possibility of seeking an exemption from legislation relating to deceptive packaging for therapeutic goods. PSA suggests this may

[5] National Patient Safety Agency. Design for patient safety: a guide to the design of dispensed medicines. Edn. 1. 2007.

provide some flexibility and further improvements for the labelling and packaging of small container medicines such as eye drops. PSA recommends that the TGA should explore this option.

Labels and packaging advisory committee

PSA welcomes the proposal to establish a panel or advisory committee to assist and provide advice to the TGA on the acceptability of proposed names, labels and packaging of medicines. PSA has previously called for consistency in this process. It has come to our attention that, while some companies engage with pharmacists and other health professionals to seek views and advice on proposed labelling and packaging, many do not. In some instances we understand companies have revised product labelling or packaging after registration of the product based on reports received from pharmacists where patient safety has been affected. This is clearly not an ideal situation as companies are more often not in a position to easily rectify any negative aspects of labelling and packaging in terms of logistics and associated cost.

While the Paper indicates this process is particularly important for products involving potential umbrella branding or look-alike / sound-alike issues, we firmly believe that practising pharmacists will provide valuable feedback to the TGA and sponsors on all aspects of names, labels and packaging by utilising their broad knowledge base of existing therapeutic goods as well as other factors relevant to professional practice. In addition, we re-iterate that this process must be undertaken prior to approval of registration of the product.

Other matters

Reference to TGA web site. PSA notes the proposal to include the web site address of the TGA on the primary pack of medicines (e.g. on the front panel near the AUST R or AUST L number) and while we understand the intent, we query the prominence (it appears to be in boldface in Figure 2 on p. 14). Our concern is that without an explanation of the type of information made available on the TGA web site, consumers may not find this useful or it may generate confusion. A possible addition or alternative might be to guide consumers to the NPS web site (www.nps.org.au) or to advise them to contact a health professional.

Requirements for pharmacists' dispensing labels. PSA understands that the requirements relating to dispensing labels for prescription (and other) medicines attached by pharmacist's are outside the scope of this Review. However, we wish to indicate that the outcomes of some issues being canvassed through this Review are likely to have flow-on effects on pharmacists' dispensing labels. For example, the way in which storage information is presented on a medicine pack or the availability of clear space on small containers may impact on the provisions of pharmacists' dispensing labels. We are therefore keen to receive any information on the timelines or scope of future reviews on matters relating to labelling and packaging.

Summary

PSA is happy to provide any additional information or clarification and would welcome the opportunity to work with the TGA and other organisations and stakeholders regarding our recommendations which we believe will help improve clarity and outcomes for Australian consumers.

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