Submission to the Therapeutic Goods Administration

Consultation on medicine labelling

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) in relation to the consultation on Medicine labelling.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia’s 28,000 pharmacists\(^1\) working in all sectors and locations.

PSA’s core functions relevant to pharmacists 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.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

Recommendations

1. PSA strongly supports Option 3 of the TGA’s proposed reforms which involves making a new legislative instrument (currently proposed as Therapeutic Goods Order 79).

2. PSA recommends the adoption of sub-option 3a in order to deliver benefits of this reform in a timely manner.

3. PSA suggests the TGA could re-assess the general minimum font size requirement to help further improve legibility of information on medicine labels particularly for consumers with low, deteriorating or impaired vision.

4. In the interest of clarity for consumers, PSA strongly recommends that active ingredient names should be placed first on medicine labels, immediately above the name of the medicine.

5. PSA recommends the inclusion of font size specifications for medicine names to ensure the principle of equal prominence of active ingredient names and medicine name is maintained.

6. In the interests of maximising consumer understanding and patient safety, PSA recommends inclusion of a requirement to use sentence case for the name of the medicine on the label.

7. PSA recommends that the space for pharmacist dispensing labels should be a minimum size of 80 x 40 mm to ensure consistency with the standard size of Australian dispensing labels and to also mirror the requirement in the TGA’s current best practice guideline.

8. PSA recommends the inclusion of expiry date and batch number information in the machine readable code of a medicine.

9. PSA does not support QR codes linking directly through to company websites irrespective of any requirement to comply with advertising restrictions. PSA supports the option to link through to Consumer Medicine Information documents which are held on the TGA’s website.

10. PSA recommends the inclusion of the establishment of a labelling and packaging advisory committee as previously proposed by the TGA.

11. PSA believes consumer testing of new and modified medicine labels should be conducted by sponsors and results submitted to the TGA.
General comments

Background

As the professional organisation for pharmacists, PSA has made submissions previously on labelling issues and participated in forums and ongoing discussions with a view to improving the labelling and packaging of medicines registered in Australia. PSA supports a rigorous and transparent regulatory system which protects Australian consumers from harm that may arise particularly from confusion or misunderstanding of information on the labelling and packaging of therapeutic goods.

PSA also expressed support of the TGA’s medicine labelling reforms through a joint position statement issued in 2013 in partnership with Australasian Pharmaceutical Science Association, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, Australian Medical Association, Council of Australian Therapeutic Advisory Groups, Royal Australasian College of Physicians and Society of Hospital Pharmacists of Australia. The group expressed concerns in relation to internationally reported information that confusion of medicine names is responsible for 25% of medication errors. The group indicated it was willing to assist the TGA in progressing proposed reforms in the interests of improving medication safety in Australia.

As health professionals with medicines expertise, pharmacists have firsthand knowledge, experience and insight into labelling and packaging issues that consumers encounter and find confusing, or where such issues may have the potential to result in harm. Pharmacists assist consumers and carers on a daily basis to help prevent errors or confusion and resolve problems associated with specific medicines, for example, look-alike or sound-alike names and similar or near-identical packaging. Other health professionals including prescribers and nursing home staff also seek clarification and assistance on such issues with pharmacists.

PSA supports Australia’s National medicines policy and in particular, professional pharmacy practice is firmly underpinned by quality use of medicines principles. Pharmacists have a core understanding and appreciation of labelling- and packaging-related issues which can impact negatively on the use of medicines by consumers or act as a barrier for individuals to obtain the best outcomes from a medicine.

Proposed options

The current TGA consultation offers three options for the future requirements for medicines labelling. However, it is clear from the regulation impact statement that Option 3 is the only option that provides overall meaningful improvements and, from PSA’s view, has the potential to deliver better outcomes for Australian consumers.

Options 1 and 2

As stated in the consultation documents, Option 1 (maintaining the status quo) is not supported by published evidence and “fails to tackle the fundamental concerns that have been identified” with current labelling arrangements. Healthcare system costs will continue to rise under this option and “health outcomes will decrease”. This would not be a logical or sensible option to adopt.
Option 2 involves updating the best practice guidance on medicines labelling. For many years PSA has recognised that these guidelines contain useful recommendations for the pharmaceutical industry. However the voluntary nature of the guidance document has been its weakness and PSA has been disappointed to hear about incidents and anecdotes from member pharmacists that clearly suggest there is ample scope to improve on uptake and implementation of the full range of recommendations in the document. While a further update (as proposed in Option 2) may enhance or refresh the document, PSA strongly believes it will not contribute to meaningful improvements for health consumers.

**Support for Option 3**

Thus PSA expresses support for Option 3 and rejects Options 1 and 2. PSA notes the consultation paper states that Option 3 is likely to provide the greatest net benefit by taking “a balanced approach” between addressing potential risks to consumer safety related to the labelling of medicines with the regulatory cost to industry.

In relation to the three sub-options presented for different transition periods, PSA acknowledges these are primary considerations for industry. However, it would be PSA’s preference to see the implementation of a short transition period in order to maximise the benefits for Australian consumers, governments and health care professionals.

**Comments on specific issues**

In this section PSA provides feedback on specific issues and requests the TGA to give further consideration of these matters.

**General font size requirement**

Apart from a number of specific exceptions, required information on labels must be in text size not less than the equivalent of 6 point Arial. PSA understands this is not a strict system of measurement but rather, the aim is to provide a benchmark of a typically acceptable presentation which could be used as a comparator to judge the legibility of fonts. Nevertheless, there has been a level of concern expressed by PSA member pharmacists that, in practice, a large proportion of older Australians (the main group of users of medicines) with deteriorating vision struggle with the small size text of medicine information on labels. This is a common encounter for pharmacists.

PSA notes reference to a 2007 study in the consultation paper (Regulation Impact Statement, p. 13) which reports on consumer preference for “the label format with a larger font size over those currently available”. While in that report it is suggested that manufacturers “look beyond the mandatory minimum font size” and “develop strategies to improve comprehension of information on OTC medication labels”, PSA believes the TGA could re-assess the general minimum font size requirement with a view to further improve legibility of information on medicine labels.

**Location of active ingredient names**

Australian health consumers are being encouraged to check the ingredients of their medicines so that they are better informed about what medicines they are taking and to prevent duplication of
ingredients and consequential harm. To assist consumers and carers to focus on the active ingredients names, PSA believes it would be logical and helpful to have the active ingredient names listed first on the medicine pack.

While PSA recognises that the new requirements for the display of names will introduce consistency overall, we believe the placement of active ingredient names immediately below the (brand) name of the medicine will not provide maximum clarity for many consumers. Where multiple brands of the same product are registered in Australia, the active ingredient name is the common piece of information that consumers should be able to locate and recognise easily. For consumers taking many medicines, once again it is vital that they are able to easily compare active ingredient information in order to identify whether or not an ingredient is duplicated.

PSA strongly recommends that the TGA considers an amendment to the proposed requirements so that active ingredient names are required to be placed first, immediately above the name of the medicine.

Displaying the name of the medicine

Font size

The consultation documents in various places state/recommend that:

- names of active ingredients and the name of the medicine have to appear as a cohesive unit;
- unless otherwise specified (e.g. for medicines in very small containers), all required information needs to be displayed in text size of not less than the equivalent of 6 point Arial; and
- fonts used for all words in the medicine name should be of similar size and style.

In addition, there are specifications for minimum text size for names of active ingredients which are dependent on the number of active ingredients.

A query has been raised around the absence of guidance on specific font size requirements for medicine names. The requirement for active ingredient names and medicine name to “appear as a cohesive unit” would not preclude the use of a different style or size of font for the medicine name which may result in greater emphasis being displayed by the medicine name. PSA believes more explicit recommendations are needed for medicine name text size to ensure the principle of equal prominence of active ingredient names and medicine name is maintained.

Use of capital letters

The TGA guideline states that the use of upper or lower case for the name of the medicine on the label is at the sponsor’s discretion.

PSA understands that capital letters can impact on readability in a negative way for some consumers. PSA appreciates that medicine names are small blocks of text and not long sentences or paragraphs; therefore, it might be regarded that the negative effect that capital letters can have on the consumer’s ability to capture and understand the information is minimal.
Nevertheless PSA notes that the U.S. Food and Drug Administration has previously recommended capitalising only the first letter in the brand name because “words written in all-capital letters are less legible than words written in mixed case letters”. Therefore in the interests of maximising consumer understanding and patient safety, PSA recommends that the TGA considers including a requirement to use sentence case for the name of the medicine on the label.

**Space for dispensing label**

PSA welcomes the inclusion of a requirement for space to accommodate the pharmacist’s dispensing label on the primary pack of prescription medicines. PSA has previously noted that this best practice recommendation has been in existence globally for many years.

However, PSA notes that the specifications for the minimum space size have remained unaltered from a previous consultation proposal as 70 x 30 mm. We understand this is smaller than the standard Australian label size of 80 x 40 mm and therefore re-iterate our concerns that this may lead to circumstances when the dispensing label will overlap with text surrounding the smaller designated space.

In addition it is standard professional practice for the pharmacist to also affix ancillary warning or advisory labels to supplement the dispensing label information. The ancillary labels are important to highlight or reinforce issues such as dosage timing, storage conditions, or safe and appropriate handling or administration of the medicine.

PSA recommends that a minimum designated space of 80 x 40 mm should be included as it is consistent with the standard size of Australian dispensing labels and the requirement also mirrors the TGA’s current best practice guideline.

**Machine readable codes**

**Expiry date and batch number information**

Although the expiry date of the medicine is a labelling requirement, a suggestion has been made that expiry date information could also be integrated into the machine readable code (e.g. EAN barcode) on the medicine pack. PSA is aware that the inclusion of the product’s batch number information in the barcode has also been suggested previously.

Such pieces of information would be helpful for pharmacists and inclusion in machine readable code is believed to be feasible with recent advances in technology.

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Optional QR codes

PSA does not object to the optional inclusion of QR codes to facilitate consumer access to medicine information. However, we do have concerns with the option for the QR code to link directly through to a company website. While we understand that the website must comply with relevant advertising restrictions, we do not support this option as it is difficult to rigorously monitor website content.

PSA supports QR code links to Consumer Medicine Information documents which are held on the TGA’s website.

Labelling and packaging advisory committee

PSA previously welcomed the TGA’s 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.

While such a proposal is not evident in the consultation papers, PSA continues to support the establishment of such a group and suggests 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. We also re-iterate that this process must be undertaken prior to approval of registration of the product. Such an important initiative will contribute to consistency in processes and enhance patient safety and quality use of medicines.

Consumer testing

Mandatory requirements proposed through this consultation are expected to provide for ‘better’ medicine labels and therefore improve consumer understanding and safety. It is important, however, that any new or modified medicine labels are subjected to consumer testing for readability, comprehension and usability. Consultation and testing with target consumer groups should be conducted to assess medicine labels, for example around legibility of information, clarity of directions and ease of use. Results of consumer testing should be submitted to the TGA by sponsors.

Summary

PSA believes Option 3 is the only feasible option in terms of delivering improved outcomes for Australian consumers, supporting pharmacists and other health professionals to assist consumers and carers with their medicines on a daily basis, and reducing costs which flow on to governments from labelling- and packaging-related incidents.

As the professional organisation for pharmacists, PSA would be pleased to discuss future opportunities for collaboration to assist the TGA meet its objectives through improved medicines labelling and packaging.

We are happy to provide clarification or further assistance in relation to our submission.
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