CONSULTATION

PHARMAC
Pharmaceutical Management Agency

30 June 2015

Establishment of PHARMAC labelling preferences

Purpose

PHARMAC is seeking feedback on the development of pharmaceutical labelling preferences (PHARMAC labelling preferences).

By establishing PHARMAC labelling preferences, we aim to:

- support the Ministry of Health to reduce preventable harm from medication errors and improve patient safety;
- provide guidance and therefore transparency to suppliers on PHARMAC's labelling preferences when considering a pharmaceutical for funding;
- ensure a consistent approach to the assessment of pharmaceutical labelling when reviewing samples, particularly during our tender processes; and
- align with international best practice.

PHARMAC would work alongside the Ministry of Health, including Medsafe, to ensure its labelling preferences align with any new regulatory requirements. The Ministry is currently developing a new regulatory regime for therapeutic products, following the decision to cease efforts on the Australia New Zealand Therapeutic Products Agency (ANZTPA). This new regime could result in changes to labelling requirements.

PHARMAC considers that labelling developed in accordance to these preferences would be of particular benefit to dispensers and prescribers, who are frequently exposed to the original packaging. The PHARMAC labelling preference would be considered alongside PHARMAC's other Operating Policies and Procedures and matters for evaluation.

The preferences proposed cover those factors which most frequently cause concern to PHARMAC and its clinical advisors. Additional labelling concerns and preferences would be addressed on a case by case basis.

Providing Feedback

We are interested in your views on what should be included in the PHARMAC labelling preferences. Please use the following questions to help guide your feedback.

- Are there any aspects of the proposed preferences which are unclear or could lead to confusion?

- PHARMAC is considering whether to elaborate on its labelling preference 3.1.1, and state that it would prefer the generic name to have equal or greater prominence than the trade name, for example, by having the generic name appear in a larger and/or bolder font. This would need to be considered with overall readability on a case-by-case basis. Are there any concerns with this elaborated preference?

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- PHARMAC is considering whether to include a preference for the primary strength representation for other liquid formulations. Are there any concerns or exceptions to this being the total quantity of the active pharmaceutical substance per total volume and per ml?

- Are there other safety warnings not outlined in the Act or Regulations that PHARMAC should consider stating a preference for?

- Are there other preferences which PHARMAC should consider in developing its labelling preferences for pharmaceuticals?

- Are there any concerns in this approach or particular situations that should be exceptions to these preferences?

How to give feedback

Please provide feedback by answering the questions that follow, or by providing any other views or information to us. We would prefer this feedback to be in writing, and provided to us through this survey or alternatively provided to us at:

Chloe Dimock
Tender Analyst
PHARMAC
PO Box 10 254
Wellington 6143

Email: consult@pharmac.govt.nz

Fax: 04 460 4995

Your feedback should be provided to PHARMAC by **4 August 2015**

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Background

PHARMAC runs competitive processes whereby one single brand becomes the Sole Subsidised Supply (SSS) brand and/or Hospital Supply Status (HSS) brand.

One of the largest procurement activities PHARMAC runs is the annual Invitation to Tender (Tender). The Tender is released in November every year and pharmaceutical suppliers bid for SSS and/or HSS of around 400-600 pharmaceutical presentations.

As part of its evaluation of the bids received, PHARMAC seeks advice from its Tender Medical Evaluation Subcommittee of The Pharmacology and Therapeutics Advisory Committee (TMESC) and other clinical advisors. TMESC and other clinical advisors review samples and consider whether these pharmaceuticals would be suitable for SSS and HSS. Suitability of a pharmaceutical is the practicality and appropriateness of a pharmaceutical given its use/s in the New Zealand community and/or hospital markets as advised by PHARMAC's clinical advisors. This includes whether the packaging and presentation is appropriate and whether there are any presentation issues with the pharmaceutical.

Every year, the TMESC identifies similar concerns with the suitability of pharmaceutical packaging and labelling. The most common concerns are:

- Visibility of the international non-proprietary (generic) name being poor.
- Expression of formulation type being confusing.
- Expression of concentration being confusing.
- Use of error-prone abbreviations, symbols and dose designations in packaging and labelling.
- Visibility of routes of administration and use of negative statements instead of positive statements to describe these.
- Poor use of colour to differentiate between strengths of pharmaceuticals due to the use of a similar tone or hue.
- Visibility and use of warning labels.

PHARMAC considers that the establishment of PHARMAC labelling preferences would provide suppliers with clarity on labelling considerations and ensure a consistent approach to reviewing pharmaceuticals. This would also enable suppliers to pre-empt these particular issues when designing labelling and packaging.

These preferences would be used in the review of tender samples as well as other pharmaceuticals being considered for funding.

Context

The primary purpose of pharmaceutical labelling and packaging is to provide clear unambiguous identification of the pharmaceutical and the conditions for its safe use. Safe use of pharmaceuticals depends on end users interpreting labelling and packaging accurately and being able to assimilate and act on the information presented.

PHARMAC considers the guidelines described in the International Medication Safety Network (IMSN) 2013 Position Statement should largely be adopted. This document has collated published documents on guidance for safe design of pharmaceutical labels and packaging from around the world, including guidelines developed by the Medicines and Healthcare products Regulatory Agency (MHRA-UK), National Patient Safety Agency (NHS) and the United States Food and Drug Administration (FDA).

PHARMAC appreciates the New Zealand market is small on a global scale and considers the use of harmonised packaging with other global markets is desirable. PHARMAC would continue to take a pragmatic approach when considering products for funding.

The proposed preferences have not adopted the IMSN document in its entirety as not all of the guidelines can/should be applied to all pharmaceuticals all of the time.

These preferences have been primarily developed for medicines. At this stage these preferences do not extend to medical devices being considered by PHARMAC for funding.

Resources used in the development of these preferences

The following resources have been used in the development of the PHARMAC labelling preferences and go into further detail on best practice:

1. International Medication Safety Network. Position Statement Making Medicine Naming, Labelling and Packaging Safer. Available at: http://english.prescrire.org/Docu/Images/IMSN/IMSN_MakingMedicinesNamingLabelingAndPackagingSafer2013.pdf

2. Medsafe New Zealand Medicines and Medical Devices Safety Authority. Guideline on the Regulation of Therapeutic Products in New Zealand Part 5 Labelling of medicines and related products. Edition 1.4 February 2015. Available at http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part5.doc

3. World Health Organisation. Essential medicines and health products, Guidance on INN. Available at http://www.who.int/medicines/services/inn/innguidance/en/

4. World Health Organisation. Essential medicines and health products, Publications: Publishing INN Lists. Available at http://www.who.int/medicines/services/inn/innguidance/en/

5. New Zealand Universal List of Medicines. Available at http://www.nzulm.org.nz/

6. Medicines and Healthcare Products Regulatory Agency (UK). Best Practice Guidance On The Labelling and Packaging Of Medicines. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328404/Best_practice_guidance_on_the_labelling_and_packaging_of_medicines.pdf

7. National Patient Safety Agency (England and Wales) Helen Hamlyn Research Centre. Design for patient safety: A guide to the graphic design of medication packaging. London (2007). Available at: www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=63053

8. National Patient Safety Agency (England and Wales) Helen Hamlyn Research Centre. Design for patient safety: A guide to the labelling and packaging of injectable medicines. London. 2008. Available at: http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59831

9. Health Quality and Safety Commission New Zealand. Error-prone abbreviations, symbols and dose designations, May 2012. Available at: http://www.hqsc.govt.nz/assets/Medication-Safety/Alerts-PR/Poster-error-prone-abbreviations-not-to-use.pdf

10. Best practice guideline on prescription medicine labelling (published by the Australian Therapeutic Goods Administration November 2005) http://www.tga.gov.au/industry/labelling-pm-best-practice.htm

11. Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1 published by the European Commission 12 January 2009) http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf