TGA MEDICINE LABELLING AND PACKAGING REVIEW
NPS SUBMISSION

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Independent, not-for-profit and evidence based, NPS MedicineWise enables better decisions about medicines and medical tests. We are funded by the Australian Government Department of Health and Ageing.

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Executive summary

NPS appreciates the opportunity to review the TGA Medicine Labelling and Packaging consultation paper. We applaud the TGA on taking a lead role in addressing this significant issue and we are keen to see that the problems associated with packaging and labelling are not understated and the final recommendations embrace international best practice standards.

The packaging, labelling and the naming of medicines is a significant issue that impacts on quality use of medicines in health care, particularly in respect to safety. Concerns regarding packaging and labelling have been longstanding and we support the priority areas identified, noting these align with priorities previously recognised by NPS *(Naming, packaging and labelling of medicines: Briefing prepared for the Department of Health and Ageing, November 2010).* Moreover our *brand choices* campaign is strongly focused on consumers knowing the active ingredient of medicines and being able to locate it on medication packaging, further improving consumer medication safety.

In reviewing the consultation paper we would like to highlight the following:

1. Prominence of active ingredients on medicine labels
- The need for the active ingredient to take prominence to improve consumer awareness and safety
- Improved visibility of all active ingredients contained in the medicine
- Strengthening the proposed paracetamol and ibuprofen warnings by motivating consumers to consult their doctor or pharmacist.

2. Look-alike and sound-alike medicines and look-alike packaging and branding
- The provision to utilise the barcode on the packaging of the medication to verify medication selection at point of dispensing
- Overseas approaches to risk assessment should be considered further, such as consumer and health professional testing of medicine names prior to registration
- Consideration should be given to an agreed methodology for consumer testing of labels.

3. Blister strip labelling
- Each segment of the blister strips should be self contained with the medicines information to improve medication safety, particularly on admission into acute care settings
- Medicines information contained on race track format blister strips needs to be provided in a single location which will not be affected by the removal of medication from the blister.

4. Other issues
- The use of dose administration aids is associated with additional issues related to packaging and labelling.
- Expiry dates should be printed to ensure legibility, not embossed.

We are strongly of the view that the TGA should apply best practice international standards where these exist and make it very clear that these have informed the development of the proposed regulations. It may be appropriate to expand the consultation to include adopting the NHS National Patient Safety Agency design guides for medication packaging and labelling of injectable medicines as best practice for medicines labelling in Australia.

We are happy to expand on any of the issues raised in this paper. Thank you again for the opportunity to contribute.

NPS provides the following responses to the proposed regulatory changes by the TGA.

a. Prominence of active ingredients on medicine labels

NPS has long advocated people learn the active ingredients in their medicines or at least know where to find it on the label to avoid adverse events. Therefore we strongly support increasing the prominence and standardising the location of the active ingredient on the medicine label. It is important for building consumer awareness and literacy to have this presented clearly, consistently and in an easily identifiable format. However, the illustrated label within the consultation document (p18) highlights that no reference is made to 'active ingredient' and this could be addressed with a heading or similar.

It is particularly critical these changes are made to reduce the confusion for consumers using OTC medicines arising from umbrella branding.

1.2 Consumer medication safety may be improved by listing the active ingredient directly above the brand name rather than beneath it. This is the most prominent position and would enhance the importance of the active ingredient, further improving consumer awareness and medication safety. Equal prominence of the active ingredient with the brand name with the first letter of the active ingredient being listed directly below the brand name will only go some way to alleviating the present confusion amongst brands and active ingredients. Some additional consumer testing may be needed to inform this decision.

1.3 The proposed system of where there are more than three active ingredients only listing the most abundant on the main label may be improved by including a statement of where all the active ingredients of the medicine can be found. For example 'all active ingredients are listed on the side panel of this box'.

1.6/1.7 The suggested warnings for products containing paracetamol and ibuprofen would potentially be made more meaningful to consumers by motivating them to consult their doctor or pharmacist before taking other products containing paracetamol or ibuprofen. A statement such as 'Contains paracetamol Xmg. *For your medication safety* consult your doctor or pharmacist before taking or paracetamol containing products' is one way to motivate consumers to seek medical advice on these medicines.

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

Naming, packaging and labelling of medicines should be designed to minimise the risk of errors made by health professionals and consumers for both prescription and over the counter medicines and to enhance health outcomes and patient safety.

Safety concerns which can be contributed to by the packaging, labelling and naming of medicines include sub-therapeutic dosing, overdosing or administration of the incorrect medicine. This can result from various stages of the medication process, including prescribing and supply where 'look-alike' and 'sound-alike' names and packaging can result in wrong medication selection, and administration where unclear directions can result in inaccurate dosing. These safety concerns have significant implications for consumers, resulting in adverse drug events which can affect quality of life.

We have some concerns that the proposed labelling and packaging regulations do not go far enough in addressing these broader safety issues. In particular, the omission of the use of Tall Man lettering from the scope of the review is concerning as this should be a mandated requirement for industry to reduce the risks associated with look-alike, sound-alike medicines. We note the TGA's explanation that it is not, in general, a consumer solution, however, there have been cases (e.g. the repacked

Coversyl and Coumadin) in which this may have been useful for health professionals and consumers alike. NPS recommends Tall Man lettering be investigated for use in selected settings, such as prescribing software standards where drop-down pick lists are used and Tall Man lettering may reduce selection errors.

NPS is of the view that while the changes may improve medicine safety, there are some additional considerations that need to be taken into account to ensure the regulatory changes address all issues. Extensive testing with consumers and health professionals should be undertaken to ensure the proposed regulations are adequate and address the full range of information needs.

In the United States, the Food and Drug Administration undertakes formal testing of brand names before products are registered. The program involves doctors, pharmacists and nurses who work within the Food and Drug Administration reviewing and interpreting simulated outpatient and inpatient prescriptions with the proposed names.

NPS recommends the TGA considers mirroring the FDA approach to testing branding through simulation of real life prescribing and dispensing scenarios involving health professionals. The current proposal outlines the TGA working with industry to ensure sponsors submit evidence of risk assessment. We believe this risk assessment should be undertaken independently and according to a methodology previously agreed by TGA and industry bodies to ensure consistency.

The implementation of bar coding when using a standardised system may improve errors associated with already existing LASA medicine brand names and packaging. This has been suggested by the National Coordinating Council for Medication Error Reporting and Prevention. NPS suggests the TGA considers any implications of bar code technology carefully in setting regulations for packaging to ensure sustainability into the future.

c. Blister strip labelling

6.4 Each unit of a blister strip should contain medicines information which allows easy identification of the medicine if one unit of the blister was removed from the outer packaging. This becomes of particular significance with acute care admissions. Although we are reducing the importance of brand names, in this instance it would be more practical to repeat the brand name of the medication on the foil rather than a single list of active ingredients which can easily become obstructed. This would allow the medication's active ingredients to be identified on admission to an acute care facility.

6.5 'Race track format' blister strips must contain the active ingredients, their amounts, batch number and expiry date in a single location. A practical place would be after the last tablet.

d. Other issues

Our increasing ageing population gives rise to the importance of dose administration aids. The use of dose administration aids is associated with additional issues related to packaging and labelling. For improved medication safety, particularly in residential care settings, we urge that a review of packaging and labelling issues related to dose administration aids be undertaken.

We also iterate the importance of making expiry dates legible. This could be achieved by printing rather than embossing the dates on the packaging.