nehta

Level 25, 56 Pitt Street
Sydney NSW 2000
Telephone: (02) 8298 2600
Facsimile: (02) 8298 2666

22 August 2012

Ms Rebecca Doolan
Project Manager, TGA Labelling and Packaging Review
PO Box 100
WODEN ACT 2606

Dear Ms Doolan

Subject: TGA Medicine Labelling and Packaging Review

Thank you for providing NEHTA the opportunity to participate in the consultation on medicine labelling and packaging. NEHTA's CEO Mr Peter Fleming has asked me to respond to your Consultation Paper on his behalf.

NEHTA is heavily involved in a range of activities to deliver national eHealth capability, including the Personally Controlled Electronic Health Record (PCEHR) System, Australian Medicines Terminology (AMT), electronic medications management and the National Product Catalogue. Since receiving the TGA Consultation Paper in June, a number of people across these areas have provided feedback on the Paper, so our response includes comments from the perspective of medicines management processes, medicines naming standards and editorial guidelines, supply chain management, and clinical safety.

NEHTA welcomes the review being undertaken by the TGA. One of NEHTA's objectives is to promote consistency through a standards based approach in order to improve safety and quality in healthcare. We see the TGA review into medicine labelling and packaging as promoting this approach.

Overall, NEHTA supports the changes proposed in the Consultation Paper.

However, we believe that to fully meet the objective of reducing the risk of error by healthcare professionals and address consumer safety risks, there is value in considering this framework in a broader context. We feel that guidelines on the naming and identification of medicines labelling are an important component to consider in the scope of the review, which would assist with medications management from product selection through to administration.

In line with this point are some more detailed comments below, with further commentary in an attachment to this letter:

- The Paper considers only one aspect related to use of medicines, i.e. labelling/packaging. It does not address the current inconsistency in the naming of medicines as presented to healthcare professionals and consumers, which also has a significant impact in achieving the desired outcomes of the review. This includes the Australian Register of Therapeutic Goods (ARTG) Public Summary, Product Information (PI), Consumer Medicines Information (CMI), package inserts, labels and packaging as well as the AMT and the Pharmaceutical Benefits Scheme. This information is also used as a basis for use in electronic prescribing and dispensing systems, personally controlled electronic health records and for other providers of electronic or print medicine data.
- The report lacks guidelines on the representation of active ingredient name, strength unit, ingredient order, dosage formulation, expression of 'freeness' (e.g. sugar free),

and potentially confusing Trade names (other than through use of visual graphics). As a result inconsistency in medicines labelling may still occur.

- The allocation of physical bar coding and Global Trade Item Numbers (GTINs) at the various levels of packaging has not been taken into account, but is a key area of interest for suppliers and buyers of medicines.

We also note that the United Kingdom has done considerable work in developing labelling and packaging guidelines, which may be of use to the TGA in this review. Specifically, the following guidelines were developed:

- National Health Service (2007) *Design for patient safety: A guide to the graphic design of medication packaging*. www.nrls.npsa.nhs.uk/resources/?EntryId45=63053
- National Health Service (2007) *Design for patient safety: A guide to labelling and packaging of injectable medicines.* www.nrls.npsa.nhs.uk/resources/?EntryId45=59831
- The Department of Health and The design Council (2003) *Design for patient safety: A system-wide design-led approach to tackling patient safety in the NHS.* www.designcouncil.org.uk/publications/design-for-patient-safety/

NEHTA welcomes the initiative by the TGA to establish a Labels and Packaging Advisory Committee and we would welcome the opportunity to participate in this reference group and others related to the Review.

Please contact me on (02) 8298 2674 or bettina.mcmahon@nehta.gov.au, or NEHTA's Terminology Manager Elizabeth Donohoo at elizabeth.donohoo@nehta.gov.au if you have any questions about the submission or would like to discuss this further.

I look forward to participating further in your work and assisting the TGA achieve its aim to reduce a number of consumer safety risks.

Yours sincerely

Bettina McMahon
Head of Policy & Information Services
National E-Health Transition Authority

Attachment A - Detailed commentary

About this review p.8

- While the scope of this review is limited to the presentation of information on medicine containers or boxes in which they are supplied the outcome should be considered in a much broader context. To ensure safety in identification and use of medicines from product selection (either by the healthcare professional at point of prescribing / dispensing or a consumer self-medicating) through to administration, it is imperative that the naming/labelling of medicines should be consistent across all 'regulated' documentation used by healthcare professionals and/or consumers. This may include ARTG Public Summary, PI, CMI, package inserts, labels and packaging and the Pharmaceutical Benefits Scheme. This information also forms source documentation to assist NEHTA in creating standardised terminology (AMT) for use in electronic prescribing and dispensing systems, PCEHR and for other providers of electronic or print medicine data.
- Labelling and packaging of medicines is critical for consumer safety and the quality of healthcare delivered to all Australians. A focus should be placed on allocation of GTINs and physical bar coding at all levels of packaging. In the longer term, this focus should also include provision of attribute information that should be applied to each level packaging (such as batch number and expiry date). A longer term view is that the allocation of GTINs would also be available in regulatory documentation.

What is an active ingredient? p.15

- Further definition around what constitutes an active ingredient may be necessary. The active ingredient name should include expression of the salt where this is the ingredient that the actual product strength is based on (see codeine 30 mg versus codeine phosphate 30 mg in *General comments on the proposed regulatory changes for the prominence of the active ingredients on medicines labels p.15-19* below).
- It is necessary to define the active ingredient such that salts are represented where required to define the actual strength of the product. For example, perindopril arginine and perindopril erbumine. These two "active ingredients" are present in two separate products with two separate strengths. Perindopril arginine 2.5 mg and perindopril erbumine 2 mg both contain perindopril 1.7 mg.
- The active ingredient should be consistently stated across all sources of information as already mentioned above in *About this review p.8*.

Identifying any ingredients that may cause allergic reactions, or interactions with other medicines p.16

- Currently there is no guidance in the document around expression of "freeness" on a product label where the user would reasonably expect the product might contain a particular ingredient (e.g. sugar free on an oral liquid medication). Care needs to be taken that manufacturers do not include such detail just to gain an apparent market advantage.

1.2.4 Casing of ingredient name

- This should be consistent across the various sources of information available. AMT uses lower case for ingredient names with clearly documented exceptions. This includes specific consideration of different types of ingredients, such as: stereoisomers; radioisotopes; Roman numerals; hyphenation of integers which form part of an ingredient name; miscellaneous documented exceptions such as hepatitis A and amphotericin B. Further reference can be found in *Australian Medicines Terminology Editorial Rules (v2 model)*.
- Consideration should be given to any published articles which assess the safety benefits of particular casing types (with the exclusion of Tall Man).

1.3 When there are more than 3 active ingredients, the most abundant ingredients..

- The paper does not mention how to represent multiple ingredients in general, i.e. when there is 3 or less.

- Displaying the most abundant ingredient first may not necessarily be the best option. This may result in the placement of undue importance on an individual ingredient. Consumers may be misled into believing that the ingredient which is listed first is the most important ingredient in a product.
- Consideration should be given to products containing the same ingredient combination but in different strength ratios which results in a different ingredient order for each, e.g.

COVERAM 10MG/5MG
perindopril arginine 10mg
amlodipine 5mg

COVERAM 5MG/10MG
amlodipine 10mg
perindopril arginine 5mg

- Using most abundant ingredient first (or other non-standardised order) may result in a mismatch with the strength order suggested by the Trade name leading to confusion and incorrect product selection (already a known safety issue with the above example).
- Consideration should be given to the representation of multiple ingredients with unduly long names, particularly on small containers and packages (e.g. Infanrix Hexa ®).
- NEHTA and an external stakeholder reference group managed by NEHTA have had considerable discussions around preferred 'ingredient order' for products containing more than one active ingredient. This has become a higher priority following reports of clinical errors due to inconsistency between product label names and medication orders/prescriptions which are often based on other available information (e.g. ARTG, AMT, PI, CMI, MIMS, and Australian Medicines Handbook). Clear guidelines should exist for defining ingredient order on labels and related documents and NEHTA would be willing to work with TGA (and other parties) to develop these.

General comments on the proposed regulatory changes for the prominence of the active ingredients on medicines labels p.15-19

- Ingredient name *and strength* should be represented accurately and consistently across all documents and package labels including the Medicine Information Box. In particular it is noted that figure 3 does not show an accurate representation of the ingredient name and strength for the codeine portion of the product. The strength value of 30 mg actually refers to the amount of codeine phosphate present in the product.
- Where a group of products (e.g. topical preparations) shows more than one strength representation, consideration should be given to standardising the primary and alternate strength representations. Guidelines on this may be appropriate.
- Standardisation of strength unit representation may be appropriate, so that the units used are appropriate to the numeric value being represented. For example, should strengths > 999 be converted to the next strength (i.e. 1000 mg be displayed as 1 g); expression of larger units such as millions (e.g. 6 million compared with 6,000,000) or powers (e.g. 1 x 106) should also be considered.
- Standardisation in describing strength units is needed, either full words or abbreviations (as recommended by Institute for Safe Medication Practices or similar organisations). For example only one of these should be used - microgram, mcg, µ (Greek symbol mu).
- This document does not detail how products which contain more than one type of inner package are to be labelled (e.g. Nexium Hp7).
- There is also insufficient detail to explain how products with multiple tablets of various strengths would be labelled (e.g. Qlaira which has 5 different tablets in the one package).

3.1

- It would be useful for NEHTA to have access/input into the guidelines around submission of evidence of risk assessment of the proposed labelling and packaging.

3.2 & 3.3

- Packaging artwork, colour and design may be useful to differentiate LASA products, but these visual packaging details do not translate to an electronic system. Consideration should be given during the product registration process to avoid this need for differentiation.
- Refer to document *NHS Design Authority Medication Labelling Recommendations-2004*
- General consideration should be given to the Packaging design checklist section of the National Patient Safety Agency document, A guide to the graphic design of medication packaging.

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why / why not? p.23

- Although this document refers to medicine labelling and packaging, information describing the product in electronic information systems may pose risks if there are LASA issues, or where there is a general lack of clarity. Consideration of product labelling and packaging must also take into account how this information may be displayed electronically, in order to ensure that LASA and other clarity and consistency issues are not present.
- The physical changes with the contrasting on the product label may reduce selection errors related to handling of the physical product; however this will not reduce drug selection error during electronic prescribing and dispensing.

Look-alike medicine branding

Do you understand the proposed changes? p.24

- Further clarity is required around the definition of "active ingredient" when looking at products marketed with the same brand name for a subset of symptoms. (refer 3.5 and 3.6)
- For example, "BRAND headache (ibuprofen 200 mg)" and "BRAND backache (ibuprofen lysine 342 mg)". The active ingredients have a different salt and a different quantity but the amount of the base active ingredient (ibuprofen) is the same (200 mg). Would this be allowed under proposed rules?
- If the difference in ingredient amount is therapeutically negligible (consider the theoretical example of paracetamol 500 mg and paracetamol 510 mg) but presents as a different amount on the label, would this be permissible as "BRAND headache" and "BRAND back pain"?
- Where different salts of an active ingredient are used, is there a requirement that both the base amount and the salt amount are clearly visible on the label. For example, would a product containing ibuprofen lysine 342 mg also clearly display that it contains ibuprofen 200 mg?

Standardised Information Format: Medicine Information Box

Are there other ways that the presentation of information could be improved? p.29

- Consider standardisation of the display of active ingredient where both the salt strength and base strength are included. Consistency of base/salt order (i.e. "base strength (salt strength)" or "salt strength (base strength)"
- All ingredients should be expressed using a single Australian Approved Name.

General comments

- It is interesting to note that the example used on p.25 displays considerable information about the active ingredient, using different naming conventions and strength. Consider the use of guidelines for standardising the display of active ingredient and strength information on labels (and other documentation), taking into account how this would be translated into electronic systems via terminology.

Blister strip labelling

- There is a case for each level of product packaging to be allocated a GTIN and marked with a GS1 bar code, as each level of the product package needs to be uniquely and unambiguously identified at designated points in patient care and the supply chain. GTINs and bar codes are currently allocated to the outer levels of packaging, but for

patient care it is necessary for this level of identification to be available for individual doses which are administered to a patient at the bedside. The barcode information rendered at this granular level should include the dynamic attributes of Expiry Date and Batch Number.

General question on the proposed establishment of a labels and packaging advisory committee

To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?

- The introduction of a Labels and Packaging Advisory Committee would be seen as a positive step. Inclusion of NEHTA representation by both AMT and Supply Chain would be highly desirable. NEHTA would like to ensure that labelling and packaging descriptions are consistent with requirements of the Australian Medicines Terminology and are suitable for use in clinical information systems.

Appendix 3: Organisations represented on the external reference group

- We believe that NEHTA would provide valuable input to an external reference group, and would ideally be formally represented on any reference groups that are considering naming/labelling and packaging issues.