ASCEPT RESPONSE TO TGA LABELLING PROPOSALS

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) is the professional and independent Society in Australia and New Zealand with expertise in the use and toxicity of medicines and chemicals. ASCEPT welcomes the opportunity to comment on the proposed options in the Regulation Impact Statement on the general labelling requirements for medicines. This submission will address ASCEPT’s views about some key issues, noting that individual members may make their own more detailed submissions to the proposal.

• The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) strongly support the initiative of the TGA to introduce new legislation to upgrade labelling of ALL Australian Medicines.
• We are extremely encouraged that many of the new proposals are very close to those that ASCEPT and its six Consortium members recommended in response to the TGA’s original consultation. (Attachment)
• In the current consultation, we consider that Option 3: Introduction of a new Therapeutic Goods Order (TGO 79) together with the Revised Practice Guidelines would most closely fulfil necessary improvements to Medicine Labelling. We support the proposed 2 year transition period (Option 3a) as we believe that changes are required as soon as possible for Consumer safety and optimal outcomes.

We particularly support
• The mandated font type and size for all medicines and packages
• The rules about the use of colour on packaging
• The Medicine Information Panel for non-prescription medicines

Our reasons for this are that ALL these new requirements in TGO 79 will greatly improve the legibility and clarity of the Active Ingredient names without unduly introducing new obstacles for industry and thus facilitating a quick transition. These changes can only enhance patient safety.
They will also increase the safety and decrease the risk of all medicines and will be of particular value for Consumers who purchase Over-the-Counter and Supermarket items in situations where no professional advice is available. For example, this will reduce the risk of overdoses of substances such as paracetamol and ibuprofen.

The suggested changes answer many of the concerns we expressed in our original submission eg:

‘We strongly support a change which would make it easier for consumers and health professionals to identify the active ingredient without searching all sides of the package with a magnifying glass which is currently sometimes the case.’

Overall we are greatly encouraged by the many improvements which are evident in the comparison of TGO 69 and TGO 79

One new issue of concern arises in the proposed Best Practice Guidelines

We are concerned that the QR codes (10.3.1), which can be read from mobile phones, can take consumers straight to Company marketing sites. We consider that they should ONLY take consumers to the Official CMI. We recommend that this QR code could only be used to provide a link to TGA eBS website.

There are, of course, a number of our original requests and suggestions that are not addressed by TGO 79 but we recognise that not everything can be done at once.

We consider the outstanding issues in our original submission (Appendix) that have not been altered are the following and could be implemented in the future:

Active ingredient Name above the Brand Name. We would still recommend the name of the active ingredient(s) to be directly ABOVE rather than below the trade name. This would greatly assist the active ingredient name becoming the primary identifier for all medications. This would help to prevent many medication misadventures, such as doubling up on the same medication, and misidentification of multiple versions of products. We would also recommend the name of the active ingredient(s) be in larger font and in bolder font than the trade name.

We also recommend that the distinguishing names for multiple products off-patent medicines should be limited to the active ingredient(s) name/sponsor (manufacturer) name. The use of invented brand names should be discouraged. Any permitted suffix should be standardised and convey meaningful information— for example, about the pharmacokinetic properties of the product.

In Summary

We are Extremely Encouraged by the proposed changes in TGO 79 and offer our full support for them to be implemented as rapidly as possible.

31 October 2014
attach
Response to TGA Medicine Labeling and Packaging
Review Consultation Paper

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) is strongly supportive of the TGA initiative to improve labeling on medicine packs and containers. We consider that any proposed changes should apply in all respects to ALL categories of medicines including prescription medicines, non-prescription medicines and complementary medicines.

Our specific comments on the issues that we consider of greatest concern (numbered as per the consultation document) are below.

1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name.

We strongly recommend that the active ingredient (preferably the INN) is the primary identifier of the medicine and that the brand name follows or is below the drug name. We support this recommendation and would add to it that the ingredient(s) should be in bold and stand out more than the trade name, as in Fig 3.

We also suggest that consideration should be given to avoiding colours that are inappropriate such as red-green for the relatively large percentage of males with this problem.

There is an issue with spelling out the full salt name - eg hydrochloride; a) it could be a lower font size or b) use the chemical name HCL. This unclutters the long active ingredient names(s). Abbreviation to chemical name could problematic for salts such as maleate however.

1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.

We strongly support all the suggestions in this section and consider them all absolutely essential. We have always taught our students that they must prescribe using generic names and consider that medicines should be known to all who prescribe, dispense and use them by generic names whenever possible. That this does not happen is a major patient safety problem. Some of the
medication safety issues with naming and labelling have been highlighted in a recent publication, citing relevant research, by some ASCEPT members (publication attached as Appendix One).  

Ideally we would prefer the active ingredient to be LARGER than the Trade Name ie the reverse of the present situation. ‘Equal Prominence’ is the minimum we would consider acceptable.

1.3 Where there are more than 3 active ingredients etc

We also strongly support these suggestions, in a difficult area, which represent a considerable improvement on the present situation and are clearly illustrated in Fig 4 which we recommend should be implemented.

1.4 Products containing day and night preparations etc.

Another difficult topic and again we strongly support the suggested solution as demonstrated in Fig 4.

1.5 The active ingredient must be included with, and with equal prominence as, the brand name on at least 3 opposing faces of a carton

We strongly support a change which would make it easier for consumers and health professionals to identify the active ingredient without searching all sides of the package with a magnifying glass which is currently sometimes the case.

1.6 Package information for non-prescription medicines containing paracetamol

Agree with and support proposal

1.7 Package information for non-prescription medicines containing ibuprofen

Agree and support

General Questions on the proposed changes

• What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?

1. This very important. Members of our Society have consistently held the position to increase the prominence of the active ingredient on medicine labels for many years. Patients, consumers and prescribers and other health professionals will all benefit from knowing what the active ingredient is.

2. This will help consumers and prescribers use and understand one name per medicine, rather than the potentially confusing plethora that currently exist (a generic name and several trade names from different companies).

3. It will support use of the generic name when health professionals discuss medicines with consumers, and enable use of consistent unbiased information in reference to that one medicine for which a common name will now be prominent.

4. It will improve safety by reducing duplication where patients inadvertently are prescribed and/or take two formulations with different trade names but that actually are the same
5. It will reduce medication safety issues for medications with trade names that sound and/or look alike eg. Cardizem/Cardiprin; Prozac/Losec. 2,3,4

6. It will improve prescribing by supporting identification of classes of medicine e.g. less likely to prescribe two of the same class of medicine e.g. two ACE inhibitors (...pril) or two statins (...statin) etc. 3 This is becoming increasingly important as more and more combination tablets for common diseases are coming on the market. There are major content overlaps for numerous antihypertensive and diabetes medications and analgesics 5.

- **What do you think about the proposed warnings for paracetamol and ibuprofen containing products?**

1. These are absolutely essential and we strongly support them. There are numerous over the counter preparations containing these analgesics and without a warning consumers are at high risk of unwittingly taking the same ingredient in a multiple doses.

2. As an example; several pharmaceutical companies market paracetamol products as Brand Name for headache, Brand name for backache, Brand name for joint pain etc. This could readily result in a consumer taking all three at the same time and suffering a paracetamol overdose.

- **Are there any other concerns you have with the size or position of brand names and active ingredient?**

1. For decades the size and position of the brand name has been the first word(s) to catch the eye. It takes effort, very good eyesight and some persistence to find the active ingredient. Few consumers know that they should do this and most only know the brand names. Teaching prescribers to prescribe generically has largely been nullified by marketing and labeling.

2. We consider it absolutely vital that the generic name is in print no smaller than, and has greater prominence than, the brand name. As mentioned earlier our preference would be for the active ingredient(s) to be in the present size of the brand name and vice versa.

- **If the active ingredient is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?**

1. We find the suggestion that the generic name might be smaller than that of the brand name totally unacceptable.

2. If smaller than the brand name it will be less noticeable, less legible and less likely to be read by consumers.

- **What is the smallest size font you consider reasonable?**

This is not our area of expertise. However the major users of medications are elderly people many whom have poor eyesight. The acceptable font size for drug labels should be appropriate to the population not to "normal" vision.

We suggest that expert ophthalmological opinion is essential with regard to those receiving medications.
In this context we note that a number of companies eg J&J, GSK, Sanofi etc have improved pack instructions by increasing font size and consulting communication experts. The result is not perfect but is a big improvement on its predecessors. By no means all companies have done this and we suggest that a similar approach should be mandatory for ALL products-- including complementary medicines.

**Look-alike sound-alike names and look-alike packaging**

**3.1 to 3.3**

1. The primary mechanism for addressing sound alike trade names should be use of the generic drug name.
2. We consider these topics of importance and support the principles proposed but accept that considerable negotiation will be necessary with industry to achieve these changes. There could also be a need for international cooperation.
3. If achieved they would undoubtedly improve safety by reducing the existing confusion caused by the problems such as those listed in the document.
4. The Australian Council for Safety & Quality in Healthcare, Queensland Health and many others have compiled a list of similar medicine names which contribute to medication errors (ACSQH list is included as Appendix Two).6,7

**Look-alike medicine branding**

**3.5** Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.

For example: Products cannot be marketed as “BRAND headache”, “BRAND backache”, “BRAND joint pain” if they include the same active ingredients in the same quantity.

1. This issue is one that causes us many concerns because of the confusion it causes to consumers who may think ‘I have a head and back ache so I'll take two of each! ’, without realising they are the same drug.
2. We consider the proposal to be an excellent idea which reduces waste, reduces confusion and reduces risk of overdose.

**3.6** The same brand name cannot be applied to products which have different active ingredients or combinations of active ingredients etc

1. We strongly agree with and support this suggestion. We consider it particularly confusing to have the same brand name refer to products containing different active ingredients (common examples include cold ‘flu and sinusitis and pain products) We would favour having the active ingredients listed for the individual product.
2. The proposals would go a long way towards reducing confusion for consumers and improving the accuracy of communications between consumers and health professionals.
General Questions

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?

1. Considerable benefits will ensue to consumers, giving them the opportunity to understand that, unlike the current situation, the same brand name should always imply that it contains the same ingredients.
2. It will encourage consumers to find and read ingredients thus increasing safety.
3. The change would hugely improve the accuracy of communications between consumers and health professionals. At present, unless the bottle is in front of them, a brand name for such products gives a prescriber no idea what their patient is taking and formulary or internet searches for recalled names are highly susceptible to error.

Do you understand the proposed changes?

The changes proposed would help to decrease confusion, and would lead to improved medication safety for Australians. We understand and support the proposed changes, and would like to see further prominence to the active ingredients of all medicines (prescription, non-prescription, complementary).

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?

Yes. Further, if the primary identifier of the drug is the active ingredient name this will have substantial benefit. There have been many studies on medication safety now which demonstrate the importance of clarity of labeling and naming of medications in reducing harm to consumers.

Medicine Information Box

We support the introduction of a clear, standardised Medicine Information Box, as proposed. This would be a clear way to include unbiased information about the active ingredient(s). It should, however, also point to the Consumer Medicines Information that is available in full (either printed from their health professional or from a website). This would provide a good way for consumers to access information about their medicine, and would point the way to more complete information sources. The suggestion for 3 or more active ingredients is a compromise, and companies should be required to make strong arguments before being permitted to pursue this compromise.

Dispensing Label

The mandatory space proposed for the dispensing label is strongly supported. Currently it is often very difficult to attach a label without covering some essential material. Various ways of folding sticky labels to try and display the required information are often resorted to. This often leads then to tearing or other loss of information when the consumer accesses the doses over the ensuing month or so. The mandatory space would go a long way towards helping to ensure all vital information can be seen by the consumer and their health professionals, and would lead to improved storage and use of medicines.

Blister Strip Packaging

The proposed changes for blister strip labeling are supported. Ideally every dose should be labeled with this information (rather than just every segment). The ‘race track’ packaging suggestions do
make sense, as the strips are not perforated – however they can (and are) often cut up into individual doses and therefore at least the active ingredient name would ideally be printed for each dose.

**Small Containers**

The compromises suggested for small containers are supported. However, the issue of the dispensing label attachment will still be problematic. Attaching like a flag can lead to damage with use.

**Pack Insert**

The package insert should definitely not include advertising material, and should not be printed on the inside of the box. The package insert should be the Consumer Medicines Information if one is available for that product, and should be based on the active ingredient(s), not on a branded product.

**Labels and Packaging Advisory Committee**

The proposed committee is an excellent idea, and should have strong consumer representation. The committee should have sufficient resources to be able to benchmark internationally, as more global integration of solutions and evaluation of improved labeling and packaging is essential. Such a committee would be a very good resource for the TGA. ASCEPT looks forward to making a contribution to the initiative and the Advisory Committee.
Position Statement on Labelling for Joint Society Meeting with TGA

We represent doctors, including general practitioners and specialist physicians, clinical and academic pharmacologists and pharmacists. We have broad agreement on the following:

1. We strongly endorse the TGA initiative on the Medicine Labelling and Packaging Review, which will benefit Health Professionals and Consumers and greatly improve Medication Safety. Confusion of Medicine names is reported to be responsible for 25% of medication errors in the USA and elsewhere.1-5

2. For clarity and safety the **Australian Approved Name(s)** of the **active ingredient(s)** should be the **primary** identifier for all medications

3. The **active ingredient name** should be as close as possible spatially to any brand name on all areas of the container and packaging

4. When multiple versions of products (commonly referred to as “generic versions”) are introduced, in order to differentiate between various manufacturers’ versions of the same off-patent medicine, the **active ingredient** name should be:
   - Above any brand or sponsor name (see below) and
   - In a larger font than any brand or sponsor name and
   - In a bolder font than any brand or sponsor name

5. The distinguishing names for multiple products of off-patent medicines should be limited to the active ingredient(s) name / sponsor (manufacturer) name. The use of invented brand names for generic products and use of suffixes and prefixes in brand names should be discouraged. Any permitted suffix should be standardised and convey meaningful information-for example, about the pharmacokinetic properties of the product.

6. These reforms would greatly reduce the current risks of:
   - Confusion between Health Professionals and Consumers when discussing medications
   - Taking two different brand names of the same generic substance
- Unawareness that a combination product contains an active ingredient already prescribed in a different form
- Adverse Drug Reactions to medications, such as paracetamol, available without Health Professional advice

7. We are all willing to assist the TGA in progressing the proposed reforms

11 February 2013

1 Barmann A. Reducing medication mrrors through naming, labelling and packaging. JMed Systems 2004; 28; 9-29.