Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

31 October 2014

TGA Medicine Labelling Consultation
Management and Coordination Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

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 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.

Website: www.ascept.org
jen.coulls@ascept.org
ABN:78 008 461 354

Secretariat: Suite 25, Level 1, 213 Greenhill Road, Eastwood 5063
Telephone: 61 08 8274 3741
Facsimile: 61 08 8271 2884

- 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