24 August 2012

TGA Medicine Labelling and Packaging Review – GuildLink Response

Broadly, the proposals outlined in "TGA Medicine Labelling and Packaging Review" Consultation Paper are sensible and will enhance patient safety, particularly the 'look-alike and sound-alike' changes. However, changes proposed should be in line with global standards to enable the best possible rate of adoption/compliance.

Page 14, Figure 2: The Components of a Medicine Label

GuildLink seek clarification regarding point 6 – Website address of the TGA. Is the TGA website included as an example for the purposes of Figure 2? Our current understanding is that only a Sponsor controlled website can be included on the packaging. Can other websites be included on the packaging instead?

Small Containers

General Questions:
To what extent do you support the proposed changes for small container labels? Please provide details. Do you have any further suggestions for how labelling of small containers could be improved?

Key points:

- Section 7.1 – GuildLink seeks clarification on the following:
  - To understand the proposal in relation to Pharmaceutical companies that have adopted solely electronic distribution of Consumer Medicine Information instead of package inserts in line with Therapeutic Goods Regulations Regulation 9A (2)(b) "*in another manner that will enable the information to be given to a person to whom the goods are administered or otherwise dispensed.*"

  - Specifically, how will pharmaceutical companies who electronically distribute medicines information be affected where the medicine containers have a nominal capacity of 20 millilitres or less? Examples include eye drops. It is important to note that some of these medicines have Consumer Medicine Information available electronically in other formats such as Large Print, particularly where sight can be an issue from a patient safety point of view. At present, injectable products require the Product Information included as a package insert, which is designed for healthcare professionals most likely administering the medicine to the patient, not consumers. We believe the proposed changes may create inconsistency in the currency and availability of information where electronic versions are already in place should package inserts be required.

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- We suggest that information, particularly for consumers, be available in a consistent, electronic format that will enable the information to be provided in a format best suited to the individual patients – e.g. Large Print, Synthetic audio, etc. Furthermore, we suggest this will encourage the pharmacist-consumer interaction, when the item is dispensed for the first time.

As the aim of this review is for improved patient safety, we suggest that the points raised be considered in light of achieving this objective.

Thank you for the opportunity to comment.

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