phebra

TGA Labelling and Packaging Review
Office of Prescription Medicines
Therapeutic Goods Administration
PO Box 100
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23rd August 2012

Dear Labelling and Packaging Review Team

Comments Concerning the Consultation Paper – TGA Labelling and Packaging Review

Phebra Pty Ltd (Phebra) would like to take this opportunity to provide comments and suggestions concerning the Therapeutic Goods Administration's (TGA's) consultation paper, 'TGA Medicine Labelling and Packaging Review – Consultation Paper'.

Background

Firstly, Phebra would like to thank the TGA for the opportunity to comment on this consultation document before the contents become introduced formally into guidance documentation and legislation. Given the critical nature of pharmaceutical labelling to the use of medicines by physicians and patients, and the potential impact of major changes in current procedure to the pharmaceutical industry, Phebra feel that it is important to use the opportunity given to review the document and respond.

Review of the Consultation Paper

Following release of the consultation paper Phebra have reviewed the information available and would like to take this opportunity to provide comment on the following points, listed below;

General Comments on the Consultation Document

Phebra would like to reiterate that, although the pharmaceutical industry clearly acknowledges and understands that it is the responsibility of the product Sponsor to ensure that product labelling is as clear as possible, there is an equal responsibility on both consumers and healthcare professionals to ensure they make best efforts to read and understand the information provided prior to use and ensure that they are familiar with the products being used.

Following review of the consultation document, there is also some concern that this guidance, which seems to have a strong Over-The-Counter (OTC) medicines focus, will be applied, possibly inappropriately, to prescription medicines which are restricted by their nature to hospital use (e.g. injectable vials).

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Consideration should be given to targeting the proposals to different environments where products are being administered, and by whom.

It is possible that to incorporate all of the changes proposed throughout the consultation document for products which currently have small packs, a larger pack size may be required – potentially resulting in a dramatic increase on storage and freight costs of products. For products with a small sales volume, where the market is limited but the requirement is critical, such potential increases in costing may render the product financially unviable resulting in their withdrawal from the marketplace.

There will also be instances (e.g. when product is provided within very small vials, where it will not be possible to amend the size or shape of the container/label to incorporate additional requirements) where the only option available to Sponsors will be to apply to the TGA for an exemption from the labelling requirements. Thus, these proposals may directly result in an increased workload for the TGA, as more Sponsors, due to packaging size constraints or other issues, will find it necessary to request exemptions from the TGA's proposed packaging amendments.

Phebra would like to request that, before any of the proposals are formally implemented in guidance and legislation, formal user-testing on mocked-up examples (such as those provided in the consultation document versus optimal examples of current product labelling) is conducted by the TGA to a defined protocol, to test and clearly demonstrate whether the proposed changes actually make the labelling clearer for the end user or not.

Prominence of Active Ingredients on Medicine Labels

Phebra understands the rationale behind ensuring that the font size of the the active ingredient name is 100% of the tradename, particularly in the OTC environment. However, as is clearly illustrated by the examples provided in the TGA's consultation document, this proposal has the potential to make labelling for products far more cluttered than at the present time, especially on small packs of product (e.g. packs of small vials/tablets) – hence reducing the clarity of labelling for the end-user rather than increasing it.

The current Best Practice Guidelines for Prescription Medicines state "To distinguish between the product name and the active ingredient name, the first letter of the product name should be in upper case and of the active ingredient name in lower case with a different colour for each. Fonts may be used to differentiate, but all fonts should be clearly legible.' If the active ingredient name also begins with an uppercase letter it may actually reduce the ability of consumers to distinguish between the active ingredient and the tradename of the product.

The consultation document also proposes that the active ingredient name be shown on 3 non-opposing sides of the carton – it would be helpful if some additional clarification could be provided concerning what is intended by this request and why application on non-opposing sides is required. It is also notable that, for small companies who make low-volume, but necessary products, for which there are often few therapeutic alternatives, the costs of the application of additional labels could result in products becoming financially unviable and being withdrawn from the market.

In addition this requirement could, potentially, be difficult to implement for very small or oddly-shaped cartons (e.g. narrow) and might result, as noted previously, in the cartons needing to be made artificially large in order to accommodate the text requirements (see General Comments on the Consultation Document).

Look-Alike and Sound-Alike Medicine Brand Names and Look-Alike Packaging and Branding

Firstly, Phebra would like to comment that it is difficult to provide a detailed analysis of the potential impact of the TGA's plans in this regard, without having a much clearer understanding of what requirements will be made with regards to consumer testing and risk-assessment checklists. Certainly user-testing as conducted in the European Union can be extremely time-consuming and expensive for the Sponsor with results that can be difficult to interpret.

Phebra would also like to request additional clarification with regards to how the TGA intends to implement plans for products whose names differ by less than 3 letters – particularly for those products which are currently approved and on the marketplace. Under such circumstances, when there are 2 currently approved products with similar names, which product would be required to change labelling if they are deemed to be too similar and, furthermore, how could Sponsors easily have transparency over whether another product with a similar name and labelling exists? It would be far from ideal for a Sponsor to submit an application to update the registration for a product, only to discover after submission that changes to the labelling are being mandated due to a previously unidentified similarity. This could have an adverse effect upon the TGA's current workload, due to the possible requirement for resubmission of applications and greater numbers of S31 Requests for Additional Information.

Standardised Information Format: the Medicine Information Box

This requirement is going to be challenging to meet for those products which are packaged in very small cartons, particularly when combined with the additional proposed requirements for text sizing, inclusion of the active ingredient name on 3 sides of the carton and a possible requirement for dispensing label space.

Phebra does, however, note that in products where there is limited space on the carton that the Information Box can be provided as part of a pack insert – could this form part of the existing pack insert, or would a new, separate, pack insert document need to be provided?

Additionally, how relevant is this labelling requirement for those products which are classified as OTC, but whose use is restricted to hospitals e.g. Carbosorb, which is a charcoal product used orally in the treatment of overdose?

Dispensing Label Space

Based on feedback received from hospital pharmacists, Phebra would like to query the necessity of leaving a dispensing label space on products intended for use within hospitals e.g. injectable products. In practice, such products rarely having dispensing labels attached and are often of a very small size e.g. on occasion as small as 1 mL (see also comment on Small Containers). The imposition of such a requirement could result in additional cramping of necessary information on existing labels thus, as noted previously, rendering labels more difficult to read for nurses and doctors, particularly during emergency administration situations.

Blister Strip Labelling

Phebra is particularly concerned with regards to the TGA's proposal regarding the inclusion of repeating batch and expiry information on blister foils. Although Phebra understands the TGA's logic for doing so, the introduction of such a requirement would place huge constraints upon the manufacture of products packaged in this way – in some cases requiring extensive re-tooling of facilities (a major investment), or

placing extreme constraints upon when such products can be manufactured, in instances where foils must be pre-ordered (as the information on the foil generated will need to match up with the date of manufacture). Such a measure will also result in a dramatic increase in staff costs relating to the packaging of such products, if the additional information can only be accommodated via an additional labelling step. As noted previously, this may result in an increased workload for the TGA due to an increase in the number of applications requesting exemption from current labelling standards.

Small Containers

Phebra note that currently it is a requirement of TGO69 that the quantity of all active ingredients be stated on the labelling of small containers – has this requirement been removed from the current proposals, or has it merely not been explicitly stated in the consultation document? The removal of the quantity of active ingredients from the label of injectable products could result in medication errors and would not contribute to the safe use of medicines.

Phebra would also like to note that, the consultation document refers to small containers as being less than 20 mL, however, small containers may in some instances be as small as 1 mL for injectable products – which leaves little room for the provision of a dispensing label, even when folded. Is such a requirement for products intended for use within the hospital environment?

Phebra would like to conclude by reiterating that we feel it is important to play an active role in the review of such consultation documents and, as a consequence, we would be more than happy to answer further questions, provide additional feedback concerning our responses, or participate in additional discussions concerning the proposed labelling and packaging review.

Please do not hesitate to contact me should you require any additional information or clarification concerning this response document.

Yours sincerely

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