LIPA PHARMACEUTICALS
Contract manufacturers of non-sterile, over the counter and prescription drugs

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Lipa Pharmaceuticals Ltd appreciates the opportunity to comment on the TGA Medicine Labelling and Packaging Review Consultation paper Version 1.0, May 2012.

Lipa Pharmaceuticals is Australia's leading contract manufacturer of Complementary healthcare medicines and supplies the Asia Pacific region with a wide range of nutraceuticals, non-sterile prescription and OTC medicines. Operating in Sydney's south west, Lipa's 15,000 square meter facility is world class and TGA licensed. With a reputation in the Australasian market as an industry leader and innovator, Lipa has a proven track record of providing full turn-key solutions for leading marketers across the Asia Pacific Region.

As an organisation within the medicine industry, Lipa has been requested to include comment as to our support of these changes and also to assess the potential costs to our organisation. It appears that the review is heavily focussed on prescription and over-the-counter medicines and does not properly consider the impact that the suggested changes will have on complementary medicines. Due to the changes mentioned in the document it is most likely that quite a number of complementary medicines, especially those with smaller pack sizes, will need to add additional packaging components to fit the additional requirements, especially the prominence of active ingredient and the medicine box. This could be in the form of either a carton or a pack insert or both. Another option would be to increase the size of packaging to incorporate a larger label. This is not ideal as packaging should be chosen to accommodate the pack size and not the size of the label.

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Prominence of active ingredients on medicine labels

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

This may be possible for prescription medicine where the number of actives is generally low. Unfortunately this is not the case with a listed medicine where the number of actives does not allow for this to be practical. As such Lipa does not agree to this proposal. We consider the current requirements as listed in TGO69 3(3) to be sufficient.

1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.
1.2.1 The intention of 'equal prominence' is for the active ingredient to be as easy to locate and identify on the label as the brand name.
1.2.2. The font size of the active ingredient must be at least 100% of the font size of the medicine brand name of the main/front label.

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1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour.
1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.

Similar to 1.1 the above requirement is possibly practical for a prescription medicine where the active ingredient is possibly more important to the consumer or the pharmacist/physician. For listed medicines, such as complementary medicines, this is not as practical as they are typically for self selection by the consumer, the product claims and benefits would be far more beneficial for consumers to appear on the front / main panel. The use of the product is normally signified more by the product name and thus the product name should be considered the more prominent than the actives. It is more important for consumers to recognise the benefits they may require from the medicine rather than being familiar with the AAN for the active ingredient.

Where space on the label is limited, the requirement of equal prominence may in fact lead to a reduction in prominence of the product name rather than an increased prominence of the active ingredient.

1.2.4 should suggest that the actives be in the same format as the AAN.

We consider that TGO69 is considered acceptable for listed medicines rather than the above requirements.

1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the label immediately below the brand name and the names, together with the quantities of every active ingredient, are to be included on a side panel/label or on a rear panel/label for the product. (This does not apply to day and night preparations.)

Lipa does not support this proposal. The requirement for more than three active to have the three most abundant ingredients is not practical nor does it necessarily cover the highest risk profile of the medicine, especially listable medicines. The three most abundant ingredients in a multivitamin and mineral formula for example may ascorbic acid, Calcium and Magnesium yet from a risk profile the content of Selenium, Chromium or Retinyl Acetate would be considered a more appropriate list if overdose is a concern. It may also seem to be a little misleading to a consumer when a product of a name for example of Chromium Plus lists the three most abundant ingredients as Pyridoxine Hydrochloride, Nicotinamide and Thiamine Hydrochloride.

This will also create the requirement for more space to be applied on a label. This will lead to larger packaging or more components (leaflets etc.) to be added. If this leads to a situation whereby a bottle must be selected to accommodate a label then the optimal bottle size will not be chosen to accommodate the number of tablets in terms of head space. Alternatively, if this required information does not fit on the label and so the addition of an insert is required, the product will also require the addition of a carton, which adds cost for the consumer. Again the requirements of TGO69 are considered acceptable to cover requirements for active ingredients.

1.4 For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be no less than 2mm in height on the main/front panel.

Lipa does not agree with this proposal. The additional information would not be of any additional benefit and with the requirements of 1.3 means that 6 ingredients would be required on the front/main panel. This again is not practical as per the reasons provided for response for 1.3. This will only lead to a requirement for larger packaging components to fit the additional required information or the requirement for a pack insert. Both of these options will

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lead to additional cost to the product which would be considered unacceptable as cost to the consumer would outweigh any advantage to the consumer.

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

Lipa does not believe that this is necessary. The requirements of TGO69 are sufficient. Further requirements regarding medicine information boxes would require a significant amount of space and should be left for this and other mandatory requirements as per TGO69. Again, this will only lead to a requirement for larger packaging or pack inserts.

1.6 Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging:
"Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products."

1.7 Non-prescription medicines that contain ibuprofen must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging:
"Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."

If it is deemed necessary for the warning statements for Paracetamol and Ibuprofen then this should go through normal channels and be included in the RASML.

General questions

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

Quite a number of listed medicines have a substantial number of active ingredients (most multivitamin and minerals) and with the current packaging requirements have used almost all of the space on the existing labels. The requirement to add additional information on the front/main panel will then require for larger labels and thus changing components. The addition of a leaflet or equivalent may not be practical or will require the addition of a carton to existing packaging. This will unnecessarily increase the cost of medicines when existing requirements under TGO69 are considered acceptable.

What do you think about the proposed warnings for paracetamol and ibuprofen?

If it is deemed necessary for the warning statements for Paracetamol and Ibuprofen then this should go through normal channels and be included in the RASML.

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

Our concerns have been listed above.

If the active ingredient name 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?

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The addition of the active ingredient directly below and in similar font size may provide additional benefits and a reduction in possible risk to the consumer can only be found in a prescription medicine where the active may differentiate between similar brand names. It is not seen as an advantage for listed medicines due to the nature of multi active components and the actives and their uses may have multipurpose and the brand (or product) name will give a better indication of the use of the formulation. It also needs to be considered that non-prescription requires the use of marketing and this needs the brand (or product) name to be more prominent for the consumer. Prescription medicines do not require marketing to the consumer so the prominence of the active may be considered more useful.

What is the smallest size font that you consider readable?

The smallest size font that is readable will vary depending on the reader and also the type of font style and colouration applied on the packaging. Currently the TGA requires the AUST L to appear on the product at a minimum font size of 1mm so this must therefore be considered a readable font size or it would not be used as a minimum.

Look-alike and sound-alike medicine brand names and look-alike packaging and branding.

Lipa does not support these changes, especially for listed medicines. Lipa understands the concern for public safety for look-alike and sound-alike medicines especially with respect to prescription medicines where the risk to the consumer is high. It would be expected that the TGA work with industry to develop ways to reduce the potential for incorrect medicines to be provided to the consumer this could be included as part of the submission process for prescription medicines.

Listed medicines cannot be subjected to the same ruling as the product names are more generally targeting the action of the formula (e.g. Cold ease) or a type of formula (e.g. Multivitamin and mineral) or incorporating the active ingredient as part of the product name(e.g. Fish Oil, Glucosamine and Chondriotin).

The requirement for listed medicines not being able to be marketed as the same name as a registered medicine should also work that a registered medicine should not be marketed as the same name as a listed medicine.

Standardised Information Format: the Medicine Information box

To what extent do you think a standardised format for information on the labels of over-the-counter and complimentary medicines will improve access to information for these medicines?

Lipa does not support the need for a medicine box. The information currently required for a medicine box is already part of labelling requirements. The practical application of the medicine box and placement on labels or cartons may not have been fully considered, especially for those complementary medicines where there are a large number of active ingredients. This requirement along with the requirements of the prominence of active ingredients will most likely require the need for either larger packaging components, an addition of a leaflet or even the use of a carton. This is an additional cost burden for the product.

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The requirement for a white background with black text should not be considered mandatory. The box should be presented in such a way that is legible and in a sequential order. This will allow for greater flexibility in presentation yet allowing for some standardisation of information. Again the requirements needs to practical in application and should be based on a worse case scenario.

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products?

There are many products that contain more than three actives where, under the current requirements of TGO69, it does not require the use of additional packaging (cartons or pack inserts) to provide the information. If the new requirements lead to a need for additional packaging components for existing products that currently do not require this information then the changes specified would be considered unacceptable. The same can also be said for small containers although TGO69 already suggests that a small container if space is limited on the container then the container can be placed into a form of primary packaging where this information can be added. The TGA could move away from a standardised box requirement to a general set flow of mandatory information.
This would be considered more acceptable and most likely remove the need for additional components.

Dispensing label space

Do you support the designated space for the dispensing label on prescription medicines?

Lipa considers this proposal acceptable as this is preferable to covering over important information on a prescription medicine.

Blister strip labelling

Lipa do not support the proposed regulatory changes. The printing of batch number and expiry date every two blisters is not practical in that the current technology is not adequately set up to print in such a manner. We see the only tangible way to achieve this would be to pre-print the batch and expiry date on the foil. Pre-printed foil would involve a lot of waste of foil and high write off costs. This would be considered financially and environmentally irresponsible. In addition to this, pre-printed foil also presents difficulties in manufacturing with respect to registration. Lipa would suggest that the current requirements listed within TGO69 as acceptable and does not require any changes.

Small containers

Lipa considers the requirements under TGO69 to be sufficient for small containers.

Pack inserts

8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.

Lipa does not support this change. Advertising should be allowed to be included in a pack insert and if necessary to incorporate product information if space is limited on the label and this is compliant to the regulations. It is understood that advertising is prohibited for prescription medicine but this is not the case for listed medicines. As

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long as the advertising is compliant to the requirements of the Therapeutic Goods Advertising code (TGAC) this should be considered an acceptable practice.

8.2 A pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.

Lipa agrees with this requirement.

Labels and packaging advisory committee

Lipa would provide in principal support to the TGA setting up an expert advisory body to provide advice to the TGA on product specific and general matters relating to medicine labels and packaging. This would need to be in consultation with industry.

Jonathan Polis

Regulatory Affairs and Quality Assurance Manager
Lipa Pharmaceuticals Ltd

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