CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	[redacted]
Company/organisation name and address:	[redacted]
Contact phone number:	[redacted]
☐ Yes ☒ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*
☒ Yes ☐ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☒ Prescription Medicines ☐ OTC Medicines

☐ Complementary Medicines ☐ Medical Devices

☐ Blood/Tissues ☐ Other

☐ Sole trader ☒ Business with 140 employee(s)

☐ Importer ☒ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer Organisation ☐ Institution *(eg. University, hospital)*

☐ Reg. Affairs Consultant ☐ Laboratory Professional

☐ Healthcare Practitioner - please indicate type of practice

☐ Other (please specify):

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[redacted]

21st August 2012

TGA Medicine Labelling and Packaging Review
Consultation Paper Version 1.0, May 2012

[redacted] hereby provides comment on the above-mentioned consultation paper. While we are in favour of the review overall, there are a few points which cause some concern.

Glossary of terms (p12)
"Blister strip: a sheet of plastic with pockets that contain tablets or capsules, sealed with a thin sheet of aluminium."

Comment: We believe this definition is too narrow, in that it does not include the situation where the blister is formed from two sheets of aluminium (ie. Alu/Alu), nor does it allow for a paper or laminated paper backing to the plastic sheet. [redacted] products are packaged into Alu / Alu blisters.

Prominence of active ingredients on medicine labels (p15-19)
"1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name."

Comment: We are concerned that giving the active ingredient equal prominence without also including the dosage form and route of administration may lead to problems.

[redacted] has two products which contain mannitol. While both are encapsulated powders for inhalation, one is a diagnostic aid for asthma and the other is a chronic therapy for cystic fibrosis. Also, there are other mannitol preparations on the Australian market with different uses (eg. IV infusion and intraocular irrigation).

While it is unlikely that a pharmacist would confuse an IV bag with a carton of capsules or a glass vial, the active ingredient may not necessarily distinguish a product. The brand name acts as a key identifier of any given product and a ruling to increase relative prominence of the active ingredient without discussing dosage form and route of administration has the potential in itself to create error.

Blister strip labelling (p32-34)
"6.1 The brand name of the medicine, the active ingredient and amount of active ingredient, batch number and expiry date must be repeated at least once every two units."

Comment: This requirement presents considerable difficulty from a practical point of view. [redacted] orders pre-printed foil packaging material in bulk. This bulk foil may be used for a number of batches and thus the batch number and expiry date cannot be pre-printed on the foil.

During the packaging process the batch number and expiry are embossed onto the edges of the blister strip. It is not possible to emboss anywhere in the middle of the blister strip, without risking the blister seal integrity. Thus the batch and expiry date cannot be added across every two units on a ten unit blister strip. A considerable investment in new machinery

and change to the current primary packaging process would be required to enable imprinting across the middle of a blister strip.

Additionally, the approved dose for one of our products is 10 capsules taken twice daily. The capsules are deliberately packaged into blister strips of 10 capsules to assist the patient in taking the correct number of capsules (ie. one blister strip = one dose). There is no reason for the patient to divide the blister strip into smaller pieces and thus no need to repeat the information on the blister strip more than once.

[redacted] acknowledges the proposed exemption for race-track style blister strips, and would like to propose that this same exemption be extended to products where the patient takes the contents of the entire blister strip in one dose.

We trust our comments are useful to the TGA in completing the Medicine Labelling & Packaging review.

Yours sincerely,

[redacted]