CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
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☐ 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 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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6 August 2012

TGA Labelling and Packaging Review
PO Box 100
Woden ACT 2606.

Dear Sir or Madam

Re: Recommendations to Change the Presentation of Information on the Labels and Packages of Medicines

Merck Serono Australia Pty Ltd completely supports the overall objectives of the TGA Medicine Labelling and Packaging Review of improving for consumers the safe use of medicines, either prescribed or self-selected in the retail setting. While the Company recognises that regulatory solutions can address safety risks, it is suggested that other measures introduced alongside those proposed in this review should be considered. One such example is the development of consumer educational programs encouraging consumers to seek sound reliable information on the medicines they are taking. Consumer Medicine Information (CMI) is available for all prescription medicines but few consumers would routinely seek it. Material that emphasises that all medicines carry risk, regardless of whether they are prescribed by a doctor or purchased from a supermarket or health food store should also be considered.

We note that TGA is considering the need for transition arrangements depending on the outcome of the review. The Company requests that TGA consults with the medicines industry to define those arrangements as many of the proposals included will have significant impact on the medicines industry from a regulatory and cost perspective.

Many of the concerns identified by the Company are related to space restrictions. Four of the six proposals will have a direct impact on the available space of a primary pack label, including increasing font size, adding additional information or dedicated space, e.g. for a pharmacy label.

Prominence of active ingredients on medicine labels.

The Company agrees that there is a risk of confusion to consumers who may inadvertently consume more than one a medicinal product with the same active ingredient. Increasing the prominence of the active ingredient on the product label by increasing font size, use of colour and standardised font type are helpful initiatives. However, these need to be weighed against the additional space requirements while still ensuring that the packaging size is proportionate to the quantity of product contained therein, thereby meeting the requirements of Trade Practices legislation.

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With regard to the question concerning the smallest legible font size, in general 1 mm, as per the current size requirement for the AUST R number on the primary pack, to 1.5 mm, is considered acceptable. However, larger font sizes for medicines for visually-impaired patients, including vitamins for improved eye health should be considered.

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

While the Company agrees in principle with the suggested measures, considerable improvement in the web interface for access to ARTG entries will be required to allow sponsors the opportunity to determine any similarities of proposed brand names with existing. Alternatively, if the TGA's investigations result in identification of appropriate software to assess such similarities, access via the TGA portal would be helpful for industry.

Standardised Information Format: the Medicine Information Box

The comments above regarding size restrictions apply in this case. Figure 8 provides an illustration of the intended presentation of the information. It appears to be consistent with the size of a label on a standard 200 mL bottle, for example, yet the information is too small to be legible. That said, the intent for the inclusion of a Medicine Information Box, especially for OTC products is a reasonable proposal as a means of standardising information and its location on a pack. However, this once more needs to be weighed against the pack size and the legibility of the information.

Provision for splitting information across panels for a carton or including some of the information as a package insert is noted. However, consideration is not given to any other packaging types, e.g. bottle.

Where CMI is available, patients might be instructed to request it from their pharmacist or download it from the TGA website.

Blister strip labelling

The Company supports including the brand name, active ingredient and quantity being repeated across 2 dosage units. The inclusion of batch number and expiry date with this information is not supported. Generally, batch number and expiry date is added to the packaging material during manufacture. The accommodation of this proposal will likely add to the costs of production.

Furthermore, consideration also needs to be given to promoting the practice of keeping the product in the original carton, thereby, ensuring the information contained on the carton is readily available for reference, and protects those dose units from damage caused by light, and depending on the storage of the individual units, heat and moisture.

Small containers

The proposal to have small containers enclosed in a primary pack that fully complies with all of the labelling requirements, including a pack insert that provides detailed instructions for use will

have little impact in improving patient safety when a pharmacist attaches the dispensing label to the small container, discarding the carton and pack insert. This practice should be considered in the context of this review.

An alternative proposal to the fold-out label, is a backing card containing the relevant information with a note advising the consumer to "keep the information with the medicine until you have finished using it". Referring the patient to their pharmacist or to the TGA website for the relevant CMI is also appropriate.

Pack Inserts

The inclusion of the pack "insert" printed on the inside of a carton provides benefits in that relevant information is available on each side of the one component. The issue of potential lost information from the carton could be easily addressed with the inclusion of a cutting line.

Merck Serono appreciates the opportunity to provide comments on the proposed changes, and looks forward to further consultation as the process continues, including transitional arrangements and additional detailed guidance documents.

Yours faithfully

Siân Stubbs
Regulatory Affairs Manager