CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	Kimberly Belsky, Executive Director Policy & Communication
Company/organisation name and address:	Bausch + Lomb 7 Giralda Farms, Suite 1001, Madison NJ 07940 USA and locally Pty Ltd, Level 4, 207 Pacific Highway, St Leonards, NSW, 2065, AUSTRALIA
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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 10000 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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Therapeutic Goods Administration (TGA)
Labelling and Packaging Review, PO Box 100, Woden, ACT, 2606
E-mail: labellingreview@tga.gov.au

23 August 2012

Re: May 2012, Version 1.0: Public Consultation Paper on the TGA Medicine Labelling and Packaging Review

7 Giralda Farms, Suite 1001
Madison, NJ 07940
T 877-442-6925

Dear Sir or Madam:

On 24 May 2012, the TGA released a consultation paper that explores new ways of helping consumers better understand information on medicine labels and packaging. The consultation paper applies to all medicines whether they are purchased from a supermarket or a pharmacy without a prescription, or following a consultation with a doctor and the pharmacist at the point of dispensing.

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Our core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, our company is headquartered in Rochester, N.Y., and employs more than 10,000 people worldwide. Our products are available in more than 100 countries including Australia.

We appreciate the opportunity to provide comments on this consultation paper and offer the following comments:

Comment #1- Prominence of active ingredients on medicine labels

Page 19, Proposed regulatory change 1.5 states, "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.". While we agree with the proposed concept to aid in the accurate identification of the drug by the consumer and pharmacist, we note that this may present a particular challenge for small containers.

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Specifically, it will be challenging to maintaining a specific font size[1] for small containers, especially for products with longer brand names and multiple active ingredients. We believe prominence and clarity can also be achieved through the use of different colour/styles as noted in 1.2.3 (page 18 of the Consultation Paper).

With the above noted, reference is made to the following European documents:

1. The March 2011, European Medicines Agency (EMA) public consultation[2], "QRD recommendations on pack design and labelling for centrally authorised non-prescription human medicinal products". Section 4.1.1 (line 109-111) 'Name of the Medicine' states, "If possible, it should appear on at least three non-opposing sides of an outer carton (including one end panel), whenever space allows for the display. This will aid identification, whichever way the medicine is stored on the shelf." We note that this statement emphasizes the need for prominence while incorporating flexibility for package size.

2. Page 4 of the MHRA July 2012 document entitled, 'Best Practice Guidance on The Labelling And Packaging Of Medicines[3]' which states, "The full name of the medicine should appear on at least three non-opposing faces of the pack to aid accurate identification of the drug. This is particularly applicable to carton presentations for medicines available on prescription but can be relevant on all medicines. Where this is, employed the end-face of the pack, the side face and the front face should include the full name of the product. However, an abbreviated pharmaceutical form may be used on the label in the interests of clarity for the patient but must accord with abbreviations accepted by the member states and the Commission."

To maintain the importance of the recommendation and allow sufficient flexibility, we recommend the following revision for consistency to the documents noted above:

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[1] Section 1.2.2 states, "The font size of the active ingredient must be at least 100% of the font size of the medicine brand name on the main/front panel."

[2] Draft Quality Review of Documents recommendations on pack design and labelling for centrally authorised non-prescription human medicinal products available from http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500104662&murl=menus/document_library/document_library.jsp&mid=WC0b01ac058009a3dc&jsenabled=true

[3] http://www.mhra.gov.uk/home/groups/pl-a/documents/websiteresources/con157150.pdf

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"Whenever space allows, ~~T~~the active ingredient should ~~must~~ be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton. For small containers, prominence may also be achieved through the use of different font colour and/or font style."

Comment #2 – Look-alike and sound-alike (LASA) brand names and look-alike packaging and branding recommendation

Page 23 of the consultation document notes that the TGA will work with industry to develop guidance on risk assessment evidence to be submitted on the proposed labelling and packaging (Section 3.1) and guidelines to provide clarity about proposed requirements regarding brand names and use of colours and designs, etc. (Section 3.2). Towards that end, we recommend the TGA refer to existing Health Authority documents and related information make use of these learnings and experience as appropriate. For example,

1. United States FDA Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (Feb 2010)[4]
2. June 2010, United States FDA public workshop entitled: Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors[5]
3. Health Canada Guidance for Industry: Drug Name Review: Look-alike Sound-alike Health Product Names[6]
4. European Medicines Agency Guideline On The Acceptability Of Names For Human Medicinal Products Processed Through The Centralised Procedure[7]

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[4] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf

[5] http://www.fda.gov/Drugs/NewsEvents/ucm214703.htm

[6] http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/drugs-drogues/lasa_premkt-noms_semblables_precomm-eng.php and http://www.hc-sc.gc.ca/dhp-mps/brgtherap/proj/alike-semblable/lasa-pspcs_com_response-reponse-eng.php

[7] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004142.pdf and Overview Of Comments Received On Draft Guideline On The Acceptability Of Names For Human Products Processed Through The Centralised Procedure http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004145.pdf

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Comment #3– Small container recommendations

Page 37 of the consultation document poses the general question "Do you have any further suggestions on how labeling of small containers could be improved?" We offer the following recommendations:

- In addition to currently used abbreviations, the Agency consider additional abbreviations that may be used to conserve space when and where appropriate (e.g., POM for Prescription Only Medicine as used in the UK)[8]
- If there is a pack insert already included, allow flexibility to replace appropriate text with a reference to "Please see package insert for full prescribing information"
- Provide for additional flexibility to conserve space through the use of simplified graphics or a reduction of content or font size requirements

Furthermore, we wish to highlight that the recommendations may be particularly challenging to achieve for containers less than 10 mL. We recommend, for example, that Section 7.3[9] incorporate flexibility regarding the blank space and leave the use of the sticker (folded flag or otherwise) to the discretion of the pharmacist.

Comment #4– Pack inserts – Timing to implement changes

Page 38 of the consultation document states, "Pack inserts are provided where the medicine is contained in a small container." We agree that pack inserts can be a valuable document for consumers providing detailed information about the medicine (e.g., directions for use) however, we wish to highlight that the addition of a pack insert may require specification development for revisions to the container (e.g., increase to accommodate a pack insert). Medicine cartons are precisely designed for packaging the drug product. A change to accommodate a pack insert can effect a change in the carton specification (e.g., larger carton, new seal location). This change can require line trials to assess current equipment capabilities. Furthermore, these line trials must be scheduled into an already established production schedule. Scheduling a line trial must be balanced with limiting disruptions of product supply for other important medicines. The impact of including a pack insert can potentially result in a one to six month delay, depending on manufacturing requirements. We respectfully request the Agency consider the points in the context of timing for implementation of any new requirements.

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[8] We acknowledge that, to be beneficial, .abbreviations must be well understood by the consumer and pharmacist

[9] Section 7.3 states, "A clear space should also be provided to allow a pharmacist to affix a dispensing sticker…but should allow a folded sticker to be attached like a flag without obscuring information."

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We trust these comments and recommendations will enhance the guideline, when final, while maintaining the intent of the proposed changes.

Sincerely,

Kimberly Belsky
Executive Director, Policy and Communication
Global Regulatory Affairs – Pharmaceuticals