CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
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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

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Regulatory

24 August 2012

RE: TGA Labelling and Packaging Review

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Dear Sir/Madam,

On behalf of **Boehringer Ingelheim, Consumer Health Care (CHC)** this is to provide input to the TGA's Consultation Paper *"TGA Medicine Labelling and Packaging Review dated May 2012"* .

Boehringer Ingelheim's CHC product range covers a broad range including over-the-counter medicines and medical devices. The focus of my comments will be on OTC products.

In considering the changes proposed by the TGA we have given careful thought to the intentions of the various proposals put forward to address the **consumer safety risks.** The following issues were mentioned as objectives of this review, namely;

- information about the active ingredient(s) contained in the medicine is not always easy to find
- use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)
- medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine
- medicine containers and packaging that looks like that of another medicine
- lack of a standardised format for information included on medicines labels and packaging
- dispensing stickers that cover up important information
- information provided on blister strips
- information included on small containers
- information provided in pack inserts

The proposals and the intentions put forward can be summarised as follows:

Prominence of actives
The intention is to reduce the risk of overdosage/ double-dosing of medications. The consultation paper highlights the potential for accidental overdose of paracetamol and ibuprofen and suggests additional warning statements to be included on front of pack in addition to making the active ingredient more prominent.

Look alike (LA) and sound-alike (SA) medicine brand names and look-alike packaging and branding
Look-alike and sound-alike medicine names and Look-alike medicine packaging: The intention is to reduce the risk of consumer's accidentally being given the wrong medicine by a pharmacist or health care professional, or that they select the wrong medicine themselves due to the similarity of the name or packaging of a medicine.

Look-alike medicine branding, also known as brand extension or trade name extension: The intention is to reduce consumer confusion where a medicine is taken based on the brand name without checking the name of the active ingredient(s).

Standardised Information Format: the Medicine Information Box
The intention is to have a single recognisable format for the information required on the labels of non-prescription medicines for ease of consumer navigation of the label.

Dispensing label space
The intention is to avoid covering important label information already provided by the product manufacturer..

Blister strip labelling
The intention is to reduce risk of separated doses from losing information such as batch and expiry date.

Small containers
The intention is to ensure that the small container label contains the most important information that consumer or health care professional needs.

Pack inserts
The intention is to ensure that all relevant information is available to the consumer.

Labels and packaging advisory committee
The intention is to establish a panel to provide access to independent expert advice relating to labelling and packaging of medicines, particularly LA/SA and umbrella branding.

GENERAL COMMENTS ON THE REVIEW:

- In addressing TGA's proposed solutions we do not believe that one uniform solution across all therapeutic categories is appropriate. Prescription medicines and OTC medicines are different and have varying levels of risk. The TGA have a risk-based approach to the regulation of medicines and this should follow through to labelling and packaging.
- No evidence has been provided that current OTC-medicine labels have placed consumers at risk. In general then the current labelling requirements (TGO-69) provide sufficient regulatory controls for the safe use of medicines.

Taking each of the proposals in turn we have the following comments and/or alternative proposals which we believe will meet the intended purpose of ensuring consumer safety.

1. **Prominence of active ingredients on medicine labels**

General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels

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

TGA's consultation paper proposes two things in regard to active ingredient declaration on the medicine label:

1. Increase the font size of the active ingredient name to be equal to that of the brand name, and
2. Place the active ingredient name directly below the brand name.

We believe consumer confusion will result from the increased clutter on the label reducing legibility and comprehension. Further, for OTC medicines consumer selection is done on the basis of category and symptom (not active ingredient). Providing the consumer with the right information for them to make an informed purchase decision is important and active ingredient name is but one of many pieces of relevant information. If the active ingredient were to be placed in a consistent location on the label e.g a band at the bottom of the main label on a contrasting background and in distinctive font, this would meet the intention of TGA's proposal. In addition to this, adoption of a "Medicine Information Box" (discussed later) where the active ingredient is listed again is recommended.

The following comments are provided in relation to the proposals in the consultation paper:

(i) We do not support (Proposed regulatory change 1.1). Increasing the prominence of the active ingredient by mandating that the active ingredient appear immediately below the brand name is viewed as being overly prescriptive especially for OTC products which are usually self-selected by consumers by category/symptom, then brand (not active ingredient).

(ii) The vast majority of OTC-medicine purchasers are not pharmacist or scientists and are not familiar with complicated difficult to pronounce chemical names. Research we have conducted on OTC medicine purchases in pharmacy reveals that over 40% of products purchased in pharmacy are either doctor or pharmacist recommended. Having chosen the product the consumer needs to treat their condition, it is important that other information be available including information on ingredients (actives and excipients, warning statements etc.) and for this we support the adoption of a 'Medicine Information Box' alluded to later.

(iii) We support regulatory proposal 1.2.1 in so far as the 'active ingredient' information being easy to locate on a defined part of the label and we also support regulatory proposal 1.2.3 that this be in a distinctive font style and/or font colour.

(iv) We do not support proposal 1.2.2 that the font size of the active be at least 100% of the font size of the medicine brand name on the main/front label. To do so would result in consumer confusion through inability to distinguish brand name from active ingredient name. The overall look of the label will be very cluttered, reducing legibility.

The SUSMP (Standard for the Uniform Scheduling of Medicines & Poisons) sets out what needs to be on a medicine label, where it should be placed and the font size. The signal heading e.g PHARMACY MEDICINE must be in a font size at least 50% that of the largest letter on the label (i.e the brand name). Further, the warning statement KEEP OUT OF REACH OF CHILDREN must be at least 4/10th the size of the signal heading. If, the ingredient name had to be the same size as the brand name, then to fit all text on the label the height of all statements would need to be reduced including signal headings and warning statements.

Overseas regulatory authorities have not recommended "equal prominence" of brand name and active ingredient name. The European Guidance document (Guideline on the readability of the labelling and packaging leaflet and medicinal products for human use) notes that *…"generic names should be given due prominence through the choice of point size, font or embolding"* and *"use of a large type size will be appropriate, although other factors may also be important in making the information legible. Consideration should be given to the line spacing and use of white space to enhance the legibility of the information provided."* Alternatively, in USA and Canada the active ingredient text height recommended is 50% relative to the brand name.

(v) We do not support regulatory proposal 1.2.4 that the active ingredient should begin with an upper case letter but the remainder should be in lower case. There should be consistency with 'labelling prescription medicine best practice' which advocates that the active ingredient all appear in lower case.

(vi) We do not support proposal 1.3 regarding listing of the most abundant ingredients immediately below the brand name in the case of when there are more than 3 active ingredients in the product. Similar to our opposition to proposed regulatory change 1.1 mentioned above, we contend that increasing the font size does not necessarily make the label easier to read or understand. Consumers need to understand the link between active ingredient, dosage and usage. Merely increasing the font size of the active or shouting the ingredient name at a consumer who doesn't have the background knowledge to be able to interpret the relevance of the ingredient name is a futile exercise. The consumer needs to know what he/she need to do/ or not do , i.e 'Do not use other products containing paracetamol'. We are not opposed to declaration of ingredient name on the label. It can be placed in a consistent place on the label e.g bottom line of front main label (refer point 'iv' above) and in the 'Medicine Information Box'.

(vii) We do not support proposal 1.4 that requires listing of ingredients in 'day and night preparations' immediately below the brand name. As in the above point, we are not opposed to listing of ingredient names per se but it needs to be done in such a manner so as to avoid consumer confusion and increase label readability and understanding.

(viii) We do not support proposal 1.5 where the brand name and active ingredient must be repeated on 3 non-opposing faces of a carton. This requirement would appear to be more relevant to prescription products stored in the dispensary section of the pharmacy and under the direct supervision of the pharmacist. OTC-medicines, on the other hand are often displayed front of shop within categories for consumer selection by brand.

(ix) We do not support proposal 1.6 which states that "Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging in bold letters of at least 1.5mm in height 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.*—We believe that it is more appropriate for this statement to be included in the "Medicine Information Box" alongside other warnings which the consumer should be aware of for safe use of the product. A general warning statement or icon directing the patient/ consumer to "Read Medicine Information Box" on rear panel should be included on the front panel. Any warning statement printed on the front label needs to be placed in a position that does not contravene the SUSMP (Standard for the Uniform Scheduling of Medicines & Poisons) requirements e.g Figures 3, 4 on pages 17 and 18 of the consultation paper have the warning statement alongside the signal heading which contravenes the current requirements.

(x) We do not support regulatory proposal 1.7, namely; the inclusion of the statement --*Contains ibuprofen x mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation.*-- on the front label. The current labelling requirements detailed in the SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) and RASML (Required Advisory Statements for Medicine Labels) should remain unless TGA can provide evidence why this is no longer appropriate. Isolating this warning statement on the front of pack is inconsistent with the grouping of information in the "Medicine Information Box".

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

Answer: Please refer to our comments above, items (x) and (xi).

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

Answer: The positioning of the active ingredient name and quantity in a standardised location on the label (not necessarily directly below the brand name) on the front panel will help consumers find the information they need, HOWEVER the requirement for equal prominance with the brand name is not considered necessary.

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? What is the smallest size font that you consider readable?
Answer: 1.5mm font is readable. If consumers are educated about where to find information on the active ingredient name and quantity, there is no benefit in having this information in large lettering. The generic ingredient name is important information to be able to access but it is difficult for many consumers to understand. A specific warning is of more use to the average consumer than a complicated chemical name.

2. Look alike (LA) and sound-alike (SA) medicine brand names and look-alike packaging and branding

General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?
Answer: Provided a clear distinction is made between BRAND NAME and pre-fixes/ suffixes and colours are used where appropriate to distinguish between products, then medicine safety will not be compromised.

Proposal 3.1: Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names.
Answer: It is noted that the TGA will work with industry to develop guidelines to provide clarity about the proposed requirements. We welcome the proposal to have robust workable guidelines to aid label development, however they need to be clear and simple and not financially onerous to test.

Proposals 3.2: In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicine industry to develop guidelines to provide clarity about these proposed requirements.
Answer: From our experience we have successfully differentiated different strengths of product based on colour and use of sub-names. A review of our pharmacovigilance data base for cough products over a 6 year period (over 800 consumer enquiries) has shown no incident of consumer confusion related to LA/SA brand names for our OTC-medicines.

Whilst it is easy for a company to distinguish products within their own product range, the challenge will be distinguishing between products from other companies. Access to a computer base within the TGA may be necessary to do this. We are not aware of any incidents of consumer confusion in relation to OTC medicines. Before any changes are made the TGA should provide evidence that current labelling requirements for non-prescription medicines pose a risk to consumers.

Proposal 3.3: In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine.

Answer: The use of different colours and designs to distinguish between products in the ARTG is already common practice. As for proposal 3.2 above, before any changes are made the TGA should provide evidence that current labelling requirements for non-prescription medicines pose a risk to consumers.

Proposal 3.4: Products that are 'listed' on the ARTG cannot be marketed under the same brand name as a registered medicine.

Answer: We do not agree with this proposal and question the TGA on the rationale for this restriction. If a medicine can be adequately distinguished by way of suffix, prefix, colour or design then it should be permitted to be registered.

It is unclear as to what is meant by "brand name". Does this include the corporate name e.g Chemists Own, Terry White Chemists, Herron, Swisse ? Does it include different formats of the same products e.g slow-release, different flavours etc ?

If a company name is used as a brand name, then an uneven playing field is created. TGA clarification on this point is needed.

Proposal 3.5: Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.
For example: Products cannot be marketed as "BRAND headache", "BRAND backache", "BRAND jointpain" if they include the same active ingredients in the same quantity.

Answer: We do not support prohibiting the use of linking a brand name with a sub set of symptoms e.g BRAND-headache and BRAND-backache. There has been no evidence provided by the TGA supporting the increase of potential overdosing due to inapproriate labelling. The appropriate use of warning statement on the pack in the "Medicine Information Box" – refer point 1 (ix) such as *'Contains ibuprofen x-mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation.'* is an effective means of managing consumer risk.

For OTC-medicines that are self-selected by consumers there can be a justifiable reason for indication-specific branding. Having the indication on the front of the pack as part of the brand name assists the consumer in selecting the right product. For example the use of miconazole 2% for tinea, jock itch and thrush. Sub-branding by indication is justified as men do not want to use a female hygiene product or a tinea product for jock itch. These are embarassing conditions and consumers would prefer to be able to find a suitable product without having to read through all the possible indications.

Proposal 3.6: The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met:

(a) The active ingredients are closely related (e.g different salts of the same pharmaceutical chemical), and

(b) The safety profile, efficacy and dosage regimen are similar.

Answer: We do not agree with this proposal. Brand names in addition to sub names have been used successfully for many years without consumer confusion e.g Bisolvon **Chesty** Oral Liquid (containing bromhexine hydrochloride 4mg/5mL) and Bisolvon **Dry** Oral Liquid (containing dextromethorphan hydrobromide 10mg/5mL). Provided adequate distinction is made to differentiate between products, consumer safety can be managed. A review of our pharmacovigilance data base over a 6 year period (over 800 consumer enquiries) has shown no incident of consumer confusion related to LA/SA brand names for our OTC-cough/ cold medicines.

The TGA should acknowledge that there is no benefit for manufacturers to create confusion around their product range. Use of distinguishing features such as colours, suffixes and prefixes ensure product differentiation.

3. Standardised Information Format: the Medicine Information Box

General question on the proposed regulatory changes for Standardised Information Format: Medicine Information Box

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

Answer: The inclusion of a "Medicine Information Box" has merit because it provides in a standarised format all the information a consumer needs to safely use and store the medicine.

Are there other ways that the presentation of information could be improved ?

Answer: Label design should aim towards reduction of clutter and minimise repetition. Other improvements include:

i. Removal of the title "Medicine Information Box". On a small label where space is at a premium the grouping of the information appears to be self-explanatory.
ii. Consideration should be given to use of bullet points and cues for warnings and precautions (e.g ticks, crosses and question marks).
iii. Consumer friendly headings should be considered e.g 'When not to use'
iv. Not all products require the same level of information, e.g toothpastes, sunscreens, complementary medicines and OTC medicines are very different and allowance for this should be made.
v. A cue on front of pack directing consumer to check rear panel for 'Medicine Information' could be considered.

4. Dispensing label space

The requirement to leave space on a label for a dispensing label only applies to prescription products. (Refer Boehringer Ingelheim prescription product response).

5. Blister strip labelling

General question on the proposed regulatory changes for blister strip labelling

Do you think the proposed information detailed in points 6.1 – 6.5 for blister strips is sufficient?

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.

6.2 Where strips can be segmented, the brand name, the active ingredient and amount of active ingredient, batch number and expiry date is to appear on each segment.

6.3 A maximum of 3 active ingredients should be listed on each segment / each 2 units of a blister strip for registered medicines.
6.4 Where there are more than 3 ingredients, for example multi-vitamins packaged this way, it may be sufficient to include a single list of active ingredients printed on the foil of each blister strip. Alternatively, the brand name, together with batch number and expiry date, should be repeated on the foil.
For oral contraceptives and other medicines that have a "race track" format to support their safe use, the TGA proposes the following requirement:
6.5 Blister strips that have a "race track format" must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location.

Answer: We do not support the proposed changes to labelling of blister strips.

The current labelling requirements for blister strips enclosed in a primary pack (carton) recommends that the following information must appear at least once every two dosage units: the product name, the name of each active ingredient and the quantity/proportion of each ingredient. The container (blister strip) should also include the name or registered trade mark of the sponsor or supplier and the batch number and expiry date.

For OTC medicines sold in primary packaging the current labelling requirements as described in the preceeding paragraph provide the consumer with all the necessary information to use the product safely. Repeating the batch number and expiry date so as to appear on each dosage unit would require a huge investment cost and add complexity to the manufacturing process as foils would need to be pre-printed with the batch number and expiry date, leading to short runs and increased wastage. On-line printing capability would involve substantial set-up costs.

The cutting up of blisters into individual units appears to be an issue related to dispensing of prescription products in the hospital setting. Better educate consumers on the risks of removing blisters from their packaging or tablets from their primary packs which contain all the necessary information for their safe use.

The proposal to include additional labelling of blister foils is impractical from a global sourcing perspective. Many suppliers of medicines sold in Australia are overseas manufacturers and they would be unlikely to adopt such expensive and complicated arrangements for Australian only product. The consequence of this will be increased prices or product discontinuation which will ultimately lead to Australian consumers loosing access to quality medicines.

What other changes would you like to see for this type of packaging ?
Answer: (i) An alternative solution especially for OTC labelling is to add a warning on the primary carton to 'Keep blister foil with pack'. (ii) Maintain the current blister pack labelling requirements as detailed in TGO-69. (iii) To make it easier for consumers to locate "Batch number" and "Expiry Date" on the blister platform, it is suggested that the words "Batch Number" and "Expiry Date" be printed on the foil and arrows be used to point towards where imprint/ embossing of this information is located.

6. Small containers

General question on the proposed regulatory changes detailed in items 7.1 – 7.3 for small container labelling:

7.1 These containers must be enclosed in a primary pack that fully complies with all labelling requirements and that includes a pack insert that provides detailed instructions for use.

7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres:

- *The brand name of the medicine*
- *The name(s) of all active ingredients in the medicine*
- *For ophthalmic preparations the name of any antimicrobial preservatives in the medicine*
- *Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert*
- *The batch number of the medicine*
- *The expiry date of the medicine*
- *If an injection, the approved route of administration*
- *If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened*
- *If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened*

7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. This space need not be the size of a standard dispensing sticker (80 x 40 mm), but should allow a folded sticker to be attached like a flag without obscuring information.

To what extent do you support the proposed changes for small container labels? Please provide details.

Answer: The proposed changes detailed in items 7.1 – 7.3 appear to be similar to the current requirement for the labelling of small containers.

We agree with the TGA that small labels provide unique challenges in regard to the provision of all necessary information for safe use. We support the continued use of the current TGO-69 labelling requirement for small labels .

Do you have any further suggestions for how labelling of small containers could be improved ?

Answer: No further comments provided.

7. Pack inserts

General question on the proposed regulatory changes for pack insert requirements detailed in points 8.1 and 8.2:

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

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.

Do you support the proposed changes for pack inserts? Why/why not?

Answer: The proposed changes detailed in items 8.1 – 8.2 appear to be similar to the current requirements. Current practice is that PI's and CMI's do not contain information related to advertising. Continuation of this current practise is supported.

Do you have any further suggestions regarding pack inserts?

Answer: Separate from PI's and CMI's which contain factual scientific content, we believe that non-prescription product manufacturer's should be permitted to include material of an advertorial nature within product packaging.

If a sponsor wishes to advertise the availability of other products which may be of benefit to the consumer, this should be permitted on the provision that this is clearly separate from the PI or CMI.

8. Labels and packaging advisory committee

General question on the proposed establishment of a labels and packaging advisory committee as follows:

The TGA proposes to establish a panel to provide advice on the acceptability of proposed names, labels and packaging, particularly for products involving potential umbrella branding or look-alike sound-alike issues.

It is important for the TGA to have access to independent expert advice on a range of matters relevant to the TGA's responsibilities as a regulator of therapeutic goods. Currently, the TGA has access to such expertise via its expert advisory committees that include subject matter experts who provide the TGA with advice on matters relating to applications for prescription medicines, non-prescription medicines, complementary medicines and medical devices, as well as post-market safety matters.

The TGA does not currently have access to specific expertise relating to the quality use of medicines for labelling and packaging. It is proposed that the panel will consist of persons who represent medicine users (including carers), community and hospital pharmacists, nurses, doctors and health care practitioners and the pharmaceutical industry.

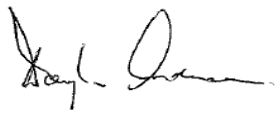
It is proposed that this expert advisory body will provide advice to the TGA on product-specific as well as general matters relating to medicine labels and packaging.

To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?

Answer: In the consultation paper it is stated that currently the TGA has access to independent expert advice on a range of matters relevant to the TGA's responsibilitities. This includes matters related to applications for prescription medicines, non-prescription medicines, complementary medicines and medical devices, as well as post-marketing safety matters. This group would undoubtedly be familiar with the issues related to labelling and packaging and hence the need to set-up a separate group would seem superfluous.

We have concerns that deferral of decisions to an expert group will lead to delays in registration timelines. What IS needed are clear guidelines on labels, brand names, umbrella branding etc. and label testing protocols with objective measures that can be consistently applied.

Yours faithfully
BOEHRINGER INGELHEIM PTY LIMITED



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