CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	Celina Seeto PhD Senior Regulatory Affairs Associate
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Contact phone number:	02 8875 8647
☐ 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)*
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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

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23 August 2012

Our reference
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Dear Sir / Madam,

RE: TGA medicine labelling and packaging review consultation paper (24 May 2012)

Boehringer Ingelheim Pty Limited welcomes the opportunity to provide a response to the proposed recommendations put forward in the TGA Medicine Labelling and Packaging Review Consultation Paper (24 May 2012).

Boehringer Ingelheim as a manufacturer and supplier of both prescription and non-prescription medicines, shall be providing two responses.

1. The impact of the proposed recommendations on Prescription Medicines
2. The impact proposed recommendations on Non-prescription Medicines.

The attached response specifically focuses on Prescription Medicines. My colleague, Doug Anderson, shall be providing a response for Non-prescription Medicine.

Yours sincerely,
BOEHRINGER INGELHEIM PTY LIMITED

Celina Seeto PhD
Senior Regulatory Affairs Associate

Encl. Boehringer Ingelheim Prescription Medicine Response

Boehringer Ingelheim welcomes the opportunity to provide comments to the proposed recommendations discussed in the consultation paper by the TGA review. As a manufacturer and supplier of both prescription and non-prescription medicines, Boehringer Ingelheim will be providing two separate responses, one for prescription medicines and the other for non-prescription medicines.

This response shall focus specifically on **Prescription Medicines** and is structured in two parts:

1) General comments on the review
2) Specific comments addressing the individual recommendations

As discussed in the consultation paper, this review forms a part of the TGA's contribution to the National Medicines Policy, specifically the Quality Use of Medicine. The major issue for this review concerning appropriate labelling relate to **safety**. In particular, how appropriate labelling impacts:

- Side effects → increase of known side effects, unexpected side effects
- Efficacy → reduction in efficacy
- Dosing → taking too much, taking too little

Changes to the labelling and packaging **alone** will not eliminate these safety issues. These changes to the labelling and packaging will need to be done in conjunction with:

- Improving consumer medicine literacy (i.e. understanding what and why they are taking their medicines)
- Involving healthcare professionals to better educate and assist their patients

However, this has not been addressed in detail within the review.

PART 1: GENERAL COMMENTS ON THE REVIEW

1) "One-Size-Fits All" Approach

The recommendations proposed in this review, have been a "one-size-fits-all" approach to all medicines, regardless of whether they are registered (AUST R) or listed (AUST L) products. This approach to labelling and packaging is **not appropriate**. Medicines listed on the ARTG[1] are scheduled based upon a risk assessment. Products of lower risk are available to the consumer without having to consult with a healthcare professional. Conversely, products of higher risk are prescribed to the consumer after consultation with a healthcare professional.

- Prescription Only Medicine (S4) → the physician is responsible for the product selection for their patient

[1] Australian Register of Therapeutic Goods

- Pharmacist Only Medicine (S3) → the pharmacist assists the consumer with selection of the product. The consumer must interact with the pharmacist before they receive these products.
- Pharmacy Medicine (S2) → the consumer is responsible for selection of product and can ask a pharmacist or pharmacist assistant for advice (if required)
- General sale (unscheduled) → the consumer is solely responsible for selection of the product (e.g. supermarket setting) and there are no opportunities for discussion at point of sale with a health care professional

Under the current TGA guidelines[2] for labelling and packaging, specific guidance is given based upon the scheduling of the product. The labelling and packaging of medicines which can be selected by the consumer are required to provide more information to inform them of the product. Whereas products that are only available after consultation with a health care professional, do not include as much information on the labelling and packaging.

Therefore, the recommendations proposed in this review should be separated for:

- Prescription medicines
- Non-prescription medicines
    - Over the counter medicines
    - Complementary medicines

2) Other Overseas Health Agency Guidance(s) on Similar Labelling and Packaging Issues

Other overseas health agencies have guidances on labelling and packaging for many of the recommendations proposed by the TGA. It is surprising that none of these guidances have been quoted or discussed within the TGA consulation paper. Furthermore, other overseas agencies provide guidances that are specific to over-the-counter medicines.

3) Testing of any finalised test methodology

Before the adoption of any proposed changes, the impact of the changes will need to be objectively tested using scientifically rigorous test protocols. Once finalised, the final testing protocols shouldbe available to all companies to ensure transparency of the process.

[2] TGO 69, A guide to labelling drugs and poisons

PART 2: COMMENTS ADDRESSING THE INDIVIDUAL RECOMMENDATIONS

a) Prominence of 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? (recommendations 1.1[3], 1.2[4], 1.3, 1.4, 1.5[5])

Boehringer Ingelheim (Prescription Medicines) Response

The impact of standardising the location of the active ingredient(s), would improve and increase the consumer's and healthcare professional's ability to locate the information on the product label. Standardisation would be useful to minimise the different interpretations of the guidelines, by both industry and the health authority. For prescription medicines, recommendations 1.1 and 1.2.4[6] are reasonable, and are in line with guidances from other overseas health authorities [EU[7], Canada[8]].

As discussed in Part 1 of this response, a "one-size-fits all" approach is not appropriate. Non-prescription medicines require more information on the label, compared to prescription medicines. For non-prescription medicines, an alternative proposal is placement of the active ingredient at the bottom of the main label. To increase prominence, the use of a band in a contrasting background and distinctive font would be incorporated.

The impact of increasing the prominence of the active ingredient(s) would also improve and increase the consumer's and healthcare professional's ability to locate the information on the product. The issue of prominence of the active ingredient(s) in relation to the brand name have been discussed by several overseas health authorities (EU[9], Canada[10]).

In this review, equal prominence of the active ingredient(s) is described by recommendations 1.2, 1.2.1[11], 1.2.2[12], 1.2.3[13] and 1.5. The intention of 'equal prominence' is, as described by recommendation 1.2.1, is for the active ingredient to be as easy to locate and identify on the label as the brand name. To ensure 'equal prominence,' the font size of the active ingredient(s) would need to be at least 100% of the font size of the medicine brand name and use different font style or letter spacing or font colour (recommendations 1.2.2 and 1.2.3).

[3] 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.
[4] 1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.
[5] 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.
[6] 1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.
[7] Article 54 of directive 2001/83/EC Labelling and Packaging Leaflet. a) the name of the medicinial product followed by its strength and pharmaceutical form; MHRA – guidance documents / best practice Section 4 General Considerations Subsection 4.2
Where the medicine contains a single active ingredient, the common name of this active ingredient should immediately follow the name of the medicine on the pack, unless it is part of the name. There should be no intervening text of any kind. The recommended International Non-proprietary Name should beused, or the usual common name where no rINN exists
[8] Section 3.4 Main Panel, subsection 3.4.2 Proper or Common Name
[9] EMEA Directive 2001/83/EC - Article 56 of; Code of Practice for Pack design for OTC Medicines "Layout & Typography advice"; Guideline on the readability of the labelling and packaging leaflet and medicinal products for human use"; MHRA – Best practice guidance - Section 4 General Considerations Subsection 4.3
[10] Health Canada – Draft guidance document Labelling of pharmaceutical drugs for human use – section 2.3 Legibility
[11] 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.
[12] 1.2.2 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 label
[13] 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.

Increasing the font height of the active ingredient(s) to that of the brand name would result in a reduction in legibility of the product label. This would increase the difficulty of differentiating the brand name from the active ingredient(s), which would be directly below the brand name (as per recommendation 1.1). Even with the use of different colours or font styles, this would not necessarily increase clarity. In addition, to ensure 'equal promience' of the active ingredient(s) on three non-opposing sides of the carton (as per recommendation 1.5), without increasing the carton dimensions, would significantly impact on legibility. This would further be reduced if more than one active ingredient is to be included (recommendation 1.3[14]).

Patients/consumers are not familar with chemical terminology. The inclusion of the active ingredient(s) may cause unnecessary alarm for a patient/consumer. For example if the active ingredient is a hydrochloride salt, the patient may think they are taking hydrochloric acid.

Though outside of the scope this review, the signal headers (e.g. PRESCRIPTION ONLY MEDICINE and KEEP OUT OF REACH OF CHILDREN) would also reduce in size as the heights are a proportion of the height of the brand name.

Overseas health authorities

None of the overseas health authorities have recommended "equal prominence" of the active ingredients relative to the brand name. The European guidance documents note that, "*The generic name(s) should be given due prominence through the choice of point size, font or emboldening.[...] Prominence is determined by factors other than size of text*" and that *"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."*[15]

Furthermore, both the FDA and Health Canada have recommended that the active ingredients be at least 50% of the height of the Brand name[16]. This is currently the recommendation of the height of the signal headers (e.g. PHARMACY ONLY MEDICINE, PRESCRIPTION ONLY MEDICINE) relative to the Brand name.

[14] 1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main 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.)
[15] EU – Guideline on the readability of the labelling and packaging leaflet and medicinal products for human use
[16] FDA - Code of Federal Regulations Title 21; Subchapter C – Drugs: general, Part 201 Labeling Subpart A – General labeling provisions, section 201.10 Drugs - subsection (g)(2)and Health Canada - Section 3.4 Main Panel, subsection 3.4.2

What do you think about the proposed warnings for paracetamol and ibuprofen containing products? (Recommendations 1.6 and 1.7)

Boehringer Ingelheim (Prescription Medicines) Response

No comments are provided as this is not applicable to prescription only medicines.

Are there any other concerns you have with the size or position of brand names and active ingredient? (Recommendations 1.1, 1.2, 1.3)

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? (Recommendations 1.1, 1.2, 1.3)

Boehringer Ingelheim (Prescription Medicines) Response

As previously discussed, if both the active ingredient(s) and the brand name are the same font height, this would reduce the clarity and legibility of the information provided on the label. As a result, the patient/consumer could find it difficult to visually differentiate between the brand name and the active ingredient(s), which may lead to more errors rather than reducing them.

Possible alternatives to the current proposed recommendations:

- Include a leading statement of “Each tablet contains:” before listing the active ingredient(s)
- For the font height of the active ingredient(s) to be similar to that proposed by overseas health authorities e.g. at least 50% of the brand name height

What is the smallest size font that you consider readable? (recommendation 1.4)

Boehringer Ingelheim (Prescription Medicine) response

The readability of a font size is dependent on the visual capability of the individual. A person’s capability may be impaired/reduced for several reasons (e.g. age, injury or medical condition). Currently, the TGO 69 has recommended that the minimum font height be 1.5 mm and for the purpose of this review, this should be retained.

b) Look-alike sound-alike (LASA) names and look-alike (LA) packaging

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not? (recommendations 3.1[17], 3.2[18] and 3.3[19])

Boehringer Ingelheim (Prescription Medicines) Response

The proposed changes relating to LASA names and LA packaging may help minimise some of the errors encountered, but are **not** the only changes that need to be considered to improve medicine safety. In the consulation paper the key risks to the consumer from LASA brand names and LA packaging raised were:

- accidentally being given the wrong medicine by a pharmacist or health care professional or
- selecting the wrong medicine themselves due to the similarity of the name or packaging of a medicine

a) Accidentally giving the wrong medicine by a pharmacist or health care professional

The proposed changes have not taken into consideration the involvement of either the pharmacist or physician. There are two points of contact where potential errors in the selection of medicines can occur:

1) when the physician is "writing" the prescription and
2) at the point of dispensing by the pharmacist.

i.e. patient → physician → prescription → pharmacist → dispensed medicine → patient

The duty of care for ensuring the patient/consumer receives the correct medicine is the responsibility of both the physician and pharmacist.

b) Selecting the wrong medicine themselves due to the similarity of the name or packaging of a medicine

This is not necessarily an issue for prescription only medicines. The selection of medicines is determined by the patients' healthcare professional. However, for patients/consumers with complex medicine regimens, an opportunity arises where the pharmacist may provide assistance to their patient/consumer to minimise potential errors in taking the wrong medicine, when they are at home.

[17] 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.

[18] 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 medicines industry to develop guidelines to provide clarity about these proposed requirements.

[19] 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.

In addition, it would also be useful to understand the learnings of other overseas health authorities' implementation of similar proposals (e.g. EU [20], Health Canada [21]).

c) Specific comments to the recommendations

Recommendation 3.1: It is appreciated that the TGA will work with industry to develop appropriate risk assessment guidance(s) for proposed labelling and packaging. With the development of test methodology, the testing should be done objectively, using scientifically rigorous methods. Caution should be taken if the method of screening proposed brand names to currently registered brand names relies solely on an electronic system. Such programs may have difficulties distinguishing the subtle nuances of how words are generally pronounced in Australia.

Recommendations 3.2 and 3.3: These recommendations state that "*if the brand name [either proposed or approved] of the medicine differs from another medicine included on the ARTG by less than three letters, then the presentation/proposed changes must use colours and designs that contrast with the medicine label and packaging of the existing product*".

The suggestion of using contrast colours and design would assist in creating a visual difference, but to ensure that the labelling and packaging is **different** to existing products would be difficult. Individual companies are aware of the labelling and packaging for their products. However, each company may not be fully aware of the labelling and packaging of other company products.

To the best of our knowledge, no central database of all approved Australian labelling and packaging that is accessible by different companies exists. Only the TGA has access to such information. It may be useful for the TGA to develope such a central database as part of this review.

d) Products with similar names but are of different scheduling

The recommendations are for the screening of similar brand names across all products in the ARTG. However the examples used in the consultation paper relating to errors are limited to products with similar names within the same scheduling class (e.g prescription only medicine vs pharmacy medicine).

Products with LASA names in the ARTG, depending on the product scheduling, may not be physically located next to each other in the pharmacy. A product that is scheduled as Pharmacy Only Medicine would not be located next to a Prescription Only Medicine product. Therefore, the recommendation to screen LASA should be restricted to within the same scheduling class.

[20] EMA - Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (CPMP/328/98, Revision 5)
[21] Health Canada – Draft Guidance Document Labelling of Pharmaceutical Drugs for human Use, Section 4.5 Look-alike, Sound-alike Drug Product Names

c) Look-alike medicine branding

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?

Do you understand the proposed changes?

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?

Boehringer Ingelheim (Prescription Medicines) Response

The proposed recommendations (3.4 to 3.6) are more applicable to non-prescription medicines. Therefore no response is provided for this section.

d) 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 complementary medicines will improve access to information for these medicines?

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

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? Please propose an alternative if you don't agree with current recommendation.

Boehringer Ingelheim (Prescription Medicines) Response

The proposed recommendations (4.1 to 4.6) are not applicable to prescription medicines. Therefore no response is provided for this section.

e) Dispensing label space

Do you support a designated space for the dispensing label on prescription medicines? Why/why not?

Boehringer Ingelheim (Prescription Medicines) Response

The recommendation of a desgnated space for the dispensing label would be appropriate for Prescription Only Medicines (recommendation 5.1[22]). The proposed space of 70 x 30 mm would need to be verified that it would be able to accommodate the majority of dispensing labels used by pharmacies.

For products where a clear designated space for the dispensing label is difficult (due to size and shape) recommendations 5.2[23] and 5.3[24] imply that it is the industry's the responsibility to ensure that the necessary information is not to be obsured when a pharmacy label is placed on the product. For these two recommendations, further discussions should be held with the pharmacy society bodies (e.g. Pharmacy Guild, Pharmaceutical Society of Australia, etc) to better understand what the needs of the pharmacist are to ensure that any dispensing label does not obsure important information that has already been included by the Sponsor. This may result in guidelines to ensure critical information is not inadvertently obscured by a pharmacy label.

[22] 5.1 A designated space of 70 x 30 mm, consistent with international best practice, must be provided to accommodate the dispensing label.
[23] 5.2 Where a clear space is not practical due to constraints from packaging size and shape, the information should be arranged so that information that is likely to be obscured is the same as the information repeated on the label. The area for placement of the sticker should be illustrated by corner placement marks on the packaging.
[24] 5.3 For small containers, for example eye drops and ointments, where a designated space of 70 x 30 mm is impractical, a clear space should be provided to affix the edges of a folded dispensing label.

f) Blister strip labelling

Do you think the proposed information for blister strips is sufficient?

What other changes would you like to see for this type of packaging?

(recommendations 6.1[25], 6.2[26], 6.3[27], 6.4[28], 6.5[29])

Boehringer Ingelheim (Prescription Medicines) Response

It is acknowledged that for some products, there is difficulty in reading some of the information on the blister strips (e.g. batch and expiry date). One proposal could be to improve the legibility of batch and expiry date information on current packaging.

Regarding the proposed recommendations, the comments in this section of the review have not been referenced to any published data and appear anecdotal. However, there appear to be three main concerns:

- not enough information for the consumer if the blister strip is not with the outer carton
- situations where a section of the blister strip is dispensed
- segmented blister strips where the information is not repeated on each segment

1) Not enough information for the consumer if the blister strip is not with the outer carton

The purpose of the blister strip is to be a suitable container for tablets or capsules. It is not designed to be the primary packaging. Blister strips are often in an outer carton to ensure that the contents are not damaged during day to day handling. The outer carton also provides a suitable amount of space to include the necessary information to be available for the consumer (i.e. dispensing label).

If the blister strip is to contain all the necessary information (which appears to be the main concern) then two things would have to occur: a) increase the size of the blister strip and b) increase the size of the outer carton.

To increase the size of the blister strip and outer carton would result in an increase to the inherent costs associated with manufacturing the product (e.g. new equipment, new resizing/tooling for the packaging, new validation of the new packaging and new stability data). These costs would lead to an increase in the cost of goods, which would flow onto the consumer.

[25] 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.
[26] 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.
[27] 6.3 A maximum of 3 active ingredients should be listed on each segment / each 2 units of a blister strip for registered medicines
[28] 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.
[29] 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.

The increase in packaging would also impact on the storage capabilities within the pharmacy dispensary. This may also raise the question of "deceptive packaging".

There must be a balance between providing enough information for the consumer on the blister, whilst ensuring the legibility of all information on the blister without increasing the current overall size of the packaging. Therefore, better education of the consumer to keep the blister strip with the outer carton should be encouraged. This may be accomplished by including a statement that the blister strips should be kept with the carton.

2) Situations where a section of the blister strip is dispensed [e.g. hospital]

Blister strips packaging are available either as: perforated or non-perforated. If the hospital pharmacist is required to dispense a section of a blister strip to a carer or patient, the perforated blister strips would be appropriate. However, not all products are packaged in perforated blister strips, and not all companies use perforated blister strips.

Therefore, for medicines that are available in non-perforated blister strips, the practice of sectioning part of the blister strip should be discouraged. The proposed recommendations for non-perforated blister strips, encourages such practices and does not support Quality Use of Medicines. Further discussions with the TGA and hospital pharmacists should occur to better develop work practice guidelines.

3) Segmented blister strips where the information is not repeated on each segment

The benefit of including the proposed information (brand name, active ingredient, batch and expiry, company name or logo) onto each segment would help the consumer especially if individual segments are separated from the complete blister strip. However, this would need to be incorporated without reducing the legibility of the information provided.

g) Small containers

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

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

Boehringer Ingelheim (Prescription Medicines) Response

It is unclear what the intent of the proposal actually is as what is proposed for the label is not significantly different to TGO 69 requirements. Recommendation 7.1 requires a primary pack that fully complies with all labelling requirements AND a pack insert with detailed instructions for use. Regarding recommendation 7.3[30], a designated space for dispensing label, as discussed previously in section e) Dispensing label space, further discussions with pharmacy body societies should occur to better understand their needs

h) Pack inserts

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

Do you have any further suggestions regarding pack inserts?

Boehringer Ingelheim (Prescription Medicines) Response

Agree to both recommendations 8.1[31] and 8.2[32]

[30] 7.5 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.
[31] 8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert
[32] 8.2 A pack insert must be in a form separate to the packaging; ie it cannot be printed on the inside of a carton.

i) Labels and packaging advisory committee

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? (recommendation 9[33])

Boehringer Ingelheim (Prescription Medicines) Response

Boehringer Ingelheim agrees in principle with this recommendation. However careful consideration needs to be given as to how and when the Label and Packaging Advisory committee will assist the TGA with their reviews.

The timing of when the labelling and packaging of the medicine is to be review would have an impact on the approval and subsequent launch to the market. Therefore further discussion is required on the following points:

- Would the packaging and labelling be reviewed by the committee as part of the evaluation of a medicine?
- Would this review process occur during the evaluation phase so that any recommendations/questions could be included with the consolidated S31 questions?
- If this review was later in the evaluation process then this could lead to delays in approval and launch because we wouldn't be able to finalise the artwork for production until after this process had been completed

In addition, it is important that equitable representation of all interested parties should be allowed to be part of the committee and the process is transparent.

[33] 9 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

References:

Australian guidance documents

- A guide to labelling drugs and poisons in accordance with the Standard for the uniform scheduling of drugs and poisons – October 2007 - http://www.tga.gov.au/pdf/labelling-drugs-poisons-guide.pdf (accessed 27 July 2012)
- Therapeutic Goods Order No. 69 – General requirements for labels for medicines – F2009C00264 - http://www.comlaw.gov.au/Details/F2009C00264 (accessed 27 July 2012)

Canadian guidance document

- Draft guidance document Labelling of pharmaceutical drugs for human use - http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/consultation/drug-medic/draft_ebauche_label_guide-eng.pdf (accessed 02 Aug 2012)

European guidance documents

- Code of practice for pack design for OTC medicine – http://www.pagbpackaingcode.com (accessed 24 July 2012)
- Committee For Human Medicinal Products (CHMP) - Guideline On The Acceptability Of Names For Human Medicinal Products Processed Through The Centralised Procedure - 11 December 2007 CPMP/328/98, Revision 5 - http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004142.pdf (accessed 02 Aug 2012)
- Directive 2001/83/EC of the European parliament and the council of 6 November 2001 on the community code relating to medicinal products for human use - http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf (accessed 27 Jul 2012)
- European commission enterprise and industy directorate-general - Guideline on the readability of the labelling and package leaflet of medicinal products for human use – Revision 1, 12 January 2009 ENTR/F/2/SF/jr (2009)D/869 - http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf (accessed 02 Aug 2012)
- MHRA Guidance Note No 25 - Best practice guidance on labelling and packaging of medicines (June 2003) - http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007554.pdf (accessed 02 Aug 2012)

USA guidance document

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