Bayer HealthCare

TGA Labelling and Packaging Review
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Bayer Consumer Care submission on the consultation document "TGA Medicine Labelling and Packaging Review" Version 1.0 May 2012

Dear Sir/Madam

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Bayer Consumer Care welcomes the opportunity to provide comment on the above consultation document.

Our major objections and concerns follows:

1 Issues with the consultation process

The principal deficiencies with the consultation process are:

- There has not been compliance with the COAG Principles of Best Practice Regulation.
- Critical views of an External Reference Group specifically set up to advise the TGA on this consultation were not taken into account.
- Insufficient time has been allocated to prepare a comprehensive industry response with tested alternative proposals.

2 Issues with the Consultation paper

The principal deficiencies with the Consultation paper are:

- The paper contains errors and inconsistencies which resulted in a lack of clarity and which made interpretation difficult.
- The figures include material which is not explained in the text, which do not comply with current labelling requirements, demonstrate a lack of internal consistency within the paper and imply additional proposals.
- No attempt was made to appropriately segregate the evidence of risk in relation to prescription and non-prescription medicines.
- No evidence was provided that the proposed reforms will achieve the stated objectives of the review.
- The Consultation paper does not indicate that the labelling requirements for prescription and non-prescription products are currently different, nor does it explain the reasons for the different requirements.
- The Consultation paper fails to clearly articulate how (or if) the proposed changes will apply differently to Prescription medicines, OTC medicines and Complementary medicines. This is inconsistent with the TGA's risk-based approach.

- Section 3 includes the erroneous amalgamation of four separate issues (look-alike sound-alike products, different strengths within a prescription medicine brand, umbrella branding and indication specific branding) into a single topic applicable to both prescription and non-prescription products. These four topics ought to be addressed separately because they each represent different sets of risks and they each have varying relevance for prescription and non-prescription products.
- Confusingly, the Consultation paper introduces a new term “Look-alike medicine branding” in place of the internationally recognised term “umbrella branding”.
- The Consultation paper does not define the term “look-alike/sound-alike” which is generally linked to confusion between prescription medicine brand names.
- The term “complementary medicines” is defined differently on pages 6 and 12. The Consultation paper does not properly indicate that complementary medicines can be prescription or non-prescription (as well as being listed or registered).
- Material is included in the figures which is not explained in the text. Because these inclusions are not discussed, respondents will be unable to assess and comment on the reasoning for their inclusion. Similarly, respondents will be unable to develop and propose suitable alternatives. Also, respondents are unable to determine whether or not the apparent changes are intentional or an oversight. This absence of commentary makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

3 Impact of proposals on pack size

The proposed changes involve both increased font sizes and increased levels of content. The inevitable consequence of this will be an increase in the physical dimensions of the product packaging. There will be numerous and significant flow-on implications should the physical dimensions of the product packaging increase to accommodate the reforms, some of these implications include:

- Increased costs associated with capital equipment and facilities.
- Increased costs of packaging (both primary and secondary).
- For imported goods, increased costs of unique Australian packaging and overhead recovery for down time and line changeovers (which could impact on the viability of Australian specific production).
- Decreased freight efficiencies.
- Storage space implications at the manufacturer, wholesaler and retailer levels.
- Shelf-space implications at retail level (with impacts on planograms and line fees to stock product).
- The extra packaging materials will result in increased wastage and possible incompatibilities with the Australian Packaging Covenant.

4 Risk-based approach

In relation to the TGA’s stated “risk-based approach to regulation”, the TGA states that:

"One of the roles of the TGA is to regulate therapeutic products based on an assessment of the evidence of the risks compared to the benefits of the therapeutic products. The TGA does this by applying scientific and clinical expertise."[1]
Despite this, the Consultation paper proposes uniform solutions across medicines categories. We do not support such a blanket approach. Furthermore, no evidence was provided that the proposed reforms will achieve the stated objectives of the review.
Bayer is unaware of any evidence suggesting that the current labelling requirements for non-prescription products are inadequate or represent a risk to consumers.

5 Prominence of active ingredients on medicine labels
Bayer's comments on active ingredients on medicine labels are:

- We acknowledge the importance of consumers being able to readily identify product ingredients on the label and the risks associated with taking more than one product containing the same ingredient(s).
- We believe that this could be achieved by giving due prominence to ingredient names.
- Only one option was put forward, that of "equal prominence". We do not support this proposal as there are alternative options possible which could effectively address the issue, ranging between "equal size" and the current situation. Our main concern is the potential detrimental impact on brand recognition, which is a vital element in consumer product selection.
- We do not support the proposal that active ingredients be displayed on 3 non-opposing panels. Ingredient identification could be enhanced through alternative mechanisms.
- We do not support the singling out of specific ingredients – instead a universal QUM message to address the issue of "doubling up" should be examined.
- Consistent with a risk-based approach a distinction should be drawn between the different non-prescription medicines categories. We do not support a blanket approach to be applied to all non-prescription medicines.
- The proposal that in the case of multi-ingredient products the 3 most abundant ingredients should be displayed on the front-of-pack would be nonsensical and potentially misleading for the vast majority of complementary medicines, e.g. multivitamins. We suggest instead that a 'referral' statement, e.g. "See back of pack for the active ingredients", could be considered.
  By way of example we enclose as Appendices 1,2 and 3 artwork mock-ups of two Bayer multivitamin products, Berocca and Elevit with Iodine where the outer cartons have incorporated the 3 most abundant active ingredients. In both cases the most abundant ingredients are minerals with lengthy Australian Approved Names (AANs). In Appendix 2 and 3 the AANs have been added to the labels in full according to our interpretation of the requirements outlined in the Consultation paper. As can be seen the labels are a nonsense and will

[1] http://www.tga.gov.au/about/tga-regulatory-framework.htm

likely mislead and confuse. In Appendix 1 where abbreviated AAN's have been used the label is still potentially misleading and confusing.

- The impact on the labelling of small containers should be assessed and allowances considered.
- For non-prescription medicines, alternative options for achieving due prominence of ingredient names should be investigated. These include:
    - Use of colour, graphics, positioning in relation to brand name and different font types and sizes.
    - A standard band at the bottom of the front panel of the label for inclusion of the actives could facilitate recognition through consistent placement and presentation which is supported by available evidence.
    - A "scaling approach" to the size of the actives (e.g. similar to the approach taken for signal headings) and making these proportional to available label space (height/area) to make this practicable in the case of smaller packs.
    - It seems likely that a standardised back-of-pack format for information ("Medicine Information Box") will facilitate consumer's ability to locate and identify the active ingredient and this should be taken into account when considering any changes to the front-of-pack.
    - Consideration should be given to a standardised warning in relation to the risks associated with taking more than one medicine containing the same ingredient.
    - Non-regulatory approaches to mitigate risks must also be considered. Consumer education is a critical element in enhancing QUM. This would be consistent with Recommendation 14 in the Australian Commission on Safety and Quality in Health Care Report 2011: "*Educate consumers on medicines names and label content and where to locate further information"*[2]*.*

6 Look-alike and sound-alike medicine brand names and look-alike packaging and branding

Bayer's comments on LASA issues are as follows:

- While Bayer fully endorses the objective of avoiding possible harm which may result from confusing different medicines, we do not support the blanket and simplistic approach to both prescription and non-prescription medicines advocated in the consultation paper.
- Distinction should be drawn between proposals in relation to prescription and non-prescription medicines. The paper confusingly amalgamates four interrelated issues into a single topic applicable to both prescription and non-prescription products. The four issues (look-alike sound-alike products; different strengths within a prescription medicine brand; umbrella branding; indication specific branding) all apply differently to prescription and non-prescription medicines.

[2] Australian Commission on Safety and Quality in Health Care 2011, Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines, ACSQHC, Sydney.

- LASA is a complex and multi-faceted area for non-prescription medicines in particular. Branding and brand recognition through brand extensions ("umbrella branding") are key issues for non-prescription medicines, both from an industry viability perspective but equally importantly from the consumer self-selection perspective. The costs associated with establishing a novel non-prescription medicine brand (as well as developing consumer awareness and trust) are considerable. These costs will be a key determinant in the decision to launch a new product. Inappropriate restrictions on umbrella branding will have a detrimental impact on access to new products.
- Consistent with a risk-based approach, proposals should be reflective of the risks posed by the different categories of products. For example, the potential risks associated with ingesting a medicine are different from those associated with topical application of product.
- Given the complexity of these issues (and in view of the above) Bayer feels strongly that this area requires more in depth exploration and consultation with all stakeholders to generate confidence that reforms will achieve the stated objectives and not result in unintended consequences.
- The TGA in collaboration with consumers, industry and other stakeholders should pursue the development of guidelines for LASA and brand extensions ("umbrella branding"). Clear guidelines and protocols would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.
- Additionally, Bayer believes that evidence-based and objective decision-making would be greatly enhanced by the development of a broadly acceptable label testing methodology. The aim of such a methodology would be to generate test results that would provide confidence that any risks in relation to product identification and other issues impacting on safe use have been effectively addressed.
- Bayer proposes that the TGA commissions a paper on international best practices for label comprehension testing.

7 Standardised information format: the Medicine Information Box

Bayer's comments on the Medicine Information box are as follows:

- Bayer agrees that a standardised back-of-pack format for medicine information has merit.
- Any proposed back-of-pack format should be tested prior to adoption.
- Provision should be made for alternative formats and colour contrasting to accommodate different product categories or types, subject to consumer testing.
- The relevance/need for the title "Medicine Information Box" should be consumer tested – it may not be relevant to all product categories.
- The impact on the labelling of small containers should be assessed and allowances considered.
- A "matrix" approach to headings outlining which ones are required for which categories should be considered.
- Cues on the front-of-pack drawing attention to the panel should be explored and tested.

8 Dispensing label space
This item has been identified as applying to prescription medicines only. Bayer Consumer Care offers no comment in relation to this part of the Consultation paper.

9 Blister strip labelling
Bayer rejects the proposal to include the batch and expiry data more frequently on the blister strip than currently required for the following reasons:

- The identified risk is that blister strips stored away from the packaging will not contain information about how to use the medicine safely. However, the proposed repetition of the batch and expiry data will not provide this information and will therefore have no impact on the quality use of medicine.
- The proposed change does nothing to address the identified risk and therefore cannot be justified.
- More frequent inclusion of the batch and expiry data on the blister strips will have far-reaching consequences throughout the manufacturing and supply chain and will result in substantial increases in costs.

Non-regulatory approaches to mitigate risks must also be considered e.g. consumer education on the risks of removing blisters from their packaging.

10 Small containers
Bayer's comments on small containers are as follows:

- The consultation paper appears to re-state existing requirements for non-prescription medicines and it should be clarified how the "proposed changes" differ from the current arrangements.
- Bayer agrees with the comments about the practical considerations and challenges in relation to small containers.
- Given the practical limitations of small containers, the impact of the proposed changes in their entirety need to be examined in detail (for example the inclusion for the "Medicines Information Box" headings alone will have a significant impact).

11 Pack Inserts
Bayer's comments on pack inserts are as follows:

- It appears that the proposed changes simply re-state the current arrangements. It is not clear how the "proposed changes" differ from the current arrangements.
- Pack inserts should only be required if all the necessary information cannot be included on the product's label.
- Bayer suggests that the ARGOM already provides appropriate guidelines in relation to cross-referencing of other products and these should remain in place.

12 Labels and packaging advisory committee
There may be some value in an appropriately constituted Committee to objectively apply clear guidelines and protocols to expedite evidence-based decision making in relation to medicines labelling and packaging.

The Consultation paper lacks specific details on the role and authority of the committee so further consultation on the constitution of such a committee is required.

13 ANZTPA

Harmonisation implications for Australia and New Zealand under ANZTPA have not been considered. Bayer believes consultation must be considered a trans-tasman project and include both countries.

14 General questions posed in the Consultation paper

Bayer would like to register our disappointment at the questions included in the Consultation paper. The leading nature of the questions appears designed to provoke a pre-determined response. The questions presume that the proposed changes will achieve the stated objectives of the review. Some of the questions are misplaced and/or difficult to understand. It is unclear how these questions will reliably inform the review.

Bayer's response to the questions posed in the Consultation paper are as follows:

<u>General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels</u>

Q. What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?
A. If implemented as proposed, the impact will be significant (as discussed above).

Q. What do you think about the proposed warnings for paracetamol and ibuprofen containing products?
A. Bayer offers no comment on this.

Q. Are there any other concerns you have with the size or position of brand names and active ingredient?
A. Bayer's concerns with the proposed changes are discussed above.

Q. 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?
A. The "benefits" of the proposed changes have not been established. Bayer's concerns with the proposed changes are discussed above. Bayer contends that there are other ways of achieving due prominence apart from increasing the font size.

<u>General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging</u>

Q. Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?
A. Bayer's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current

requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General questions on the proposed regulatory changes for look-alike medicine branding

Q. What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?
A. Bayer's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you understand the proposed changes?
A. As discussed above, the Consultation Paper has confusingly amalgamated separate issues and has co-mingled prescription and non-prescription risks. This has resulted in a lack of clarity which made interpretation difficult. This lack of clarity has compromised the consultation process.

Q. If you can read the labels and warnings clearly, will these changes reduce the potential for harm?
A. [it is unclear why this question has been included in this section] Bayer's concerns with the proposed LASA changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

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

Q. 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?
A. Bayer's concern with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Are there other ways that the presentation of information could be improved?
A. Bayer has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

Q. 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.
A. Bayer's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the

effectiveness of the proposed changes. The alternatives put forward by Bayer all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General question on the proposed regulatory changes for dispensing label space

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

A. This item has been identified as applying to prescription medicines only. Bayer Consumer Care offers no comment in relation to this part of the Consultation paper.

General question on the proposed regulatory changes for blister strip labelling

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

A. Bayer's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

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

A. Bayer has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed regulatory changes for small container labelling

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

A. Bayer's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

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

A. Bayer's concerns with the proposed changes are discussed above.

General question on the proposed regulatory changes for pack insert requirements

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

A. Bayer's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you have any further suggestions regarding pack inserts?
A. Bayer has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed establishment of a labels and packaging advisory committee
Q. 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?
A. Bayer's position on this topic is discussed above.

Attachments
Attached to this submission are:

- Appendix 1 Example of Elevit AUST R 174543 artwork
- Appendix 2 Example of Elevit AUST R 174543 artwork
- Appendix 3 Example of Berocca AUST L 81974 artwork

We thank you for the opportunity to provide comments on this consultation document and we look forward to further consultation on a new draft in the near future.

Yours sincerely

Lynda McFarlane
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Bayer Limited