CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	[redacted]
Company/organisation name and address:	Bayer Australia Limited (HealthCare Pharma), 875 Pacific Highway, Pymble NSW 2073
Contact phone number:	[redacted]
☐ Yes ☒ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*
☒ Yes ☐ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☒ Prescription Medicines	☐ OTC Medicines
☐ Complementary Medicines	☐ Medical Devices
☐ Blood/Tissues	☐ Other

☐ Sole trader ☐ Business with employee(s)

☒ Importer	☐ Manufacturer	☒ Supplier	☐ Industry organisation
☐ Government		☐ Researcher	☐ Professional body
☐ Consumer Organisation		☐ Institution *(eg. University, hospital)*	
☒ Reg. Affairs Consultant		☐ Laboratory Professional	

☐ Healthcare Practitioner - please indicate type of practice

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Bayer HealthCare

TGA Labelling and Packaging Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

24 August 2012

Ref: RA 11424

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RE: BAYER HEALTHCARE PHARMA FEEDBACK ON PROPOSED CHANGES IN THE TGA MEDICINE LABELLING AND PACKAGING REVIEW CONSULTATION PAPER

Dear Sir/Madam,

Bayer Australia Ltd, HealthCare Pharma (Bayer), thanks the Therapeutic Goods Administration (TGA) for this opportunity to provide comments in response to the Consultation paper on *TGA Medicine Labelling and Packaging Review (version 1.0, May 2012)*.

Please find enclosed our comments with regards to the list of proposals.

We look forward to positive consid eration of these comme nts and would be interested in participating in future consultations on this issue.

Please do not hesitate to contact me by telephone (+61 2 9391 6133), fax (+61 2 9391 6061) or preferably via email (elaine.blair@bayer.com) should you require clarification on any of our comments.

Yours sincerely,

[redacted]

General Comments

Changes to labelling have a significant impact on resources and cost. This is especially the case for products that are manufactured overseas and controlled by a global system. Careful consideration must be exercised prior to implementation of mandatory changes to current labelling requirements.

Issues related to medicinal labelling are complex. What may be seen as an effective solution to one problem can increase regulatory burden without adding benefit in other areas.

Highly prescriptive mandatory requirements can be counter-productive in designing effective product labelling. Additionally, change in itself can create confusion for existing users of products already in the market and needs to be well justified.

The TGA should provide evidence of the need to make changes to mandatory labelling requirements.

The majority of issues discussed in the consultation document pertain to non-prescription medicines and it is already proposed that some of the changed requirements only be implemented for non-prescription medicines. Requirements should be reviewed separately for different categories of medicinal products - prescription/non-prescription/complementary medicines - as the scope and implications vary widely based on patient access, decision process and treatment pathway for the medicines based on scheduling and other factors.

In general, Bayer recommends separating requirements for prescription and non-prescription products. Further, special consideration should be given to listed medicines. Unlike registered medicines for which brand names and label artwork are evaluated and approved by the TGA, names and labels of complementary medicines are self-assessed by the Sponsor and may not undergo secondary review.

Finally, the timing and role of ANTZPA should be borne in mind when considering the public submissions in response to the Consultation paper.

Prominence of active ingredients on medicine labels

We welcome the initiative to increase the prominence of the active ingredient; however, we do not see major benefits by making it the same size as the brand name for prescription medicines, especially medicines that do not have generic equivalents.

In particular, this may cause confusion to consumers who are not familiar with chemical names. Some chemicals have very long names and the problem is exacerbated in the case of multiple ingredients, e.g. UROGRAFIN® containing meglumine diatrizoate and sodium diatrizoate.

Medicines produced by recombinant technology have particularly complex drug substance nomenclature (e.g. alglucosidase alfa-rch, imiglucerase-rch). The vast majority of consumers find these names difficult to pronounce and impossible to remember. It is much more realistic

that consumers of these products will refer to their medicine by brand name and recall the brand name when asked by a doctor or a pharmacist.

Whilst 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, there are situations where this can reduce the usability of the product label. Bayer agrees that the name of the active ingredient should be prominent but not to be mandated to be the same size as the brand name. If appropriate, the same size, and in other cases at least 50% of the size of the brand name would be sufficient.

Equivalent font sizes for actives and brand names may not be the most effective way to achieve prominence of active ingredients. It is also important to recognise that differentiation and prominence can be achieved in other ways, including using different fonts and colours, bolding, standardising the location of the active ingredient, and overall design of the label.

Bayer considers that the list of the three *most abundant* active ingredients on the main panel could potentially be confusing. For example, the names for multivitamins containing more than three active ingredients should be selected based on importance of the ingredients, rather than on quantities (e.g. pre-natal multivitamins contain smaller quantities of folic acid than, e.g. calcium or magnesium, however, folic acid is the important ingredient in this patient group).

Lack of consumer understanding of differences between brand names and active ingredients, and how to identify and interpret them, is a significant issue. Increasing the size of the active ingredient on the label does not address the underlying problem which is one of consumer understanding. Effective solutions must include consistent and on-going education in schools, healthcare facilities and the media.

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

Bayer acknowledges the intent of the proposals to improve safe use of medicines. However, more detail and specific guidelines are needed before such proposals could be considered for implementation. These proposals, if implemented, have significant implications for costs and resources related to registering and maintaining brand names related to trademark registration. It must also be considered that trademarks represent valuable intellectual property for a company and have global implications.

Clarification is sought about when Sponsors will be required to submit evidence of risk assessment for proposed packaging and labelling. As the proposed trade name will be assessed during evaluation, rather than at the time of submission, it is impractical to conduct consumer testing for proposed brand names which may be required to change during evaluation. Further assessment into cost-benefit ratio for such assessment prior to submission of the application is warranted.

Currently, it is not possible to search electronically on the Australian Register of Therapeutic Goods (ARTG) for names differing by three letters or fewer compared to a proposed new name. Specific software may need to be developed and provided to industry/sponsors for planning purposes. Even if such software were available, it would not reveal names of products still under TGA evaluation or close to being approved by another sponsor since such information is not made public.

One of the TGA proposals is that products with a brand name differing by three letters or fewer from another product must have labels with different colours and designs contrasting

with the other product. However, it is not explained how Sponsors will obtain art work for other companies' products in order to meet this requirement.

It is also stated that applications to change packaging and labelling for existing products will be subject to the same requirement, i.e. if the brand name of the medicine differs from another medicine by less than three letters, the proposed changes must use colours and designs that contrast with the labelling of the other product. Such a proposal needs careful consideration. Changing the appearance of a product label that is already in use, and quite possibly an effectively designed label, may create a problem where there wasn't one before. Possibly the two products may have completely different uses and scheduling and no potential for cross-over in the marketplace. Also, if the intent is for Sponsors to be proactive about improving labels, additional barriers that deter companies from making label changes need to be avoided.

Standardised Information Format: the Medicine Information Box

We acknowledge the intent of the proposal to have a single recognisable format for the information required on the labels of non-prescription and complementary medicines for ease of navigation of information by consumer.

However, we suggest that the proposed headings may not all be relevant for all non-prescription and complementary products and flexibility should be introduced.

Separate guidelines to incorporate a risk based approach might be more appropriate than a one size fits all for different categories of prescription, non-prescription and complementary products.

Dispensing label space

Whilst we agree that a clear space is useful for pharmacists to avoid covering important information with the dispensing label, Bayer does not support the mandatory inclusion of a space of 70 x 30 mm on the label. This can be a "suggested" dimension where possible.

Introducing a mandatory requirement for inclusion of a clear space of 70 x 30 mm may mean that critical information is rearranged to allow for such a space. This reduces the area for displaying essential labelling information and can create unnecessary clutter. Alternatively, the size of the primary pack would have to be increased, which increases costs and creates storage issues for hospitals and pharmacies.

This proposal should not be mandatory for hospital-use products or for products not dispensed by a pharmacist.

Blister strip labelling

Bayer does not support a mandatory requirement that batch number and expiry date must be repeated at least once every two units. We consider that the proposal is impractical and expensive to implement.

Batch number and expiry date are variable information elements added "on-line" and there are manufacturing equipment restrictions on where this information appears on blister packs.

Many medicinal products supplied in Australia are globally sourced. Proposal 6.1 is not in line with international practice, and will create significant and unnecessary increases in costs of goods. Such a requirement would have significant impact on costs of production including new equipment and tooling, foil wastage, reduced batch size, and additional work required on checking of production runs. Overseas manufacturers are unlikely to adopt this packaging arrangement for Australia only. Possible consequences may include increased prices, product discontinuations or use of cheaper packaging options such as bottles for Australian products. This is not ultimately in the best interests of the consumer.

Whilst the intent to the proposals is to reduce risk of separated doses from losing information, this could possibly achieved in other ways such as educating consumers not to cut blister units, and to retain blister packs within the primary pack (carton) whenever possible.

Small containers

With regards to proposal 7.1, Bayer considers that either the container should be enclosed in a primary pack that complies fully with all labelling requirements or that includes a pack insert.

A proposal that requires inclusion of small containers in a primary pack AND with a pack insert has not been fully justified.

For proposal 7.2, in addition to the name of the active ingredient, we suggest to also include quantity of the active ingredient if possible. As suggested in response to proposal 1.3, in the case of products containing more than 3 active ingredients, clearer guidance is needed on the selection of three ingredients on the label of the container i.e. 'most abundant' may not necessarily be the best way of choosing ingredients.

For prescription medicines, a clear space on the container label for a dispensing label would be useful depending on the layout of individual label. However, this should not be a mandatory requirement.

Pack inserts

The intent of the proposals is to ensure that all relevant information is available to the consumer.

It is stated in the Consultation paper that *a pack insert is a document that provides consumers with more detailed information about the medicine, such as more detailed directions for use than those provided on the medicine container or primary packaging*.

For injectable medicines such as hospital products which are administered by healthcare professionals, inclusion of diagrams for directions for use on the inside of a carton may provide easy access of information by nurses/doctors. This may be viewed as a positive and convenient way of providing this information to healthcare professionals and does not cause any consumer health risks. Depending on the design and arrangement of the information, printing of information on the inside of a carton does not necessarily cause a loss of information that is presented on the outside of the carton.

Hence we wish to seek clarification and evidence for proposing that a pack insert must be in a form separate to the packaging i.e. it cannot be printed on the inside of a carton.

Labels and packaging advisory committee

Bayer supports, in principle, the concept of establishing a labels and packaging advisory committee. However, further detail must be provided, preferably via a consultation with stakeholders, to develop clear guidelines on representation of the committee (e.g. selection of members), and the roles and contributions of the committee, prior to its establishment.

In particular, processes and decision-making criteria to be used by the committee should be clearly defined to ensure objective and consistent assessment of the risks and benefits of the labelling and packaging of medicines. Industry should be well and in advance informed of these processes.

Further clarifications are needed on how the committee would assist with the current submission, evaluation and approval processes and timeframes.

When establishing the proposed committee, consideration must be given to ensuring that timely approval of medicine applications is not be impacted. Separate guidelines may be needed for prescription and non-prescription medicines.

We also wish to seek further clarification on the working relationship of the proposed committee in relation with existing committees such as the Advisory Committee on Medicines Scheduling (ACMS).

Conclusion

Bayer appreciates the opportunity to provide comments on the Consultation paper entitled *TGA Medicine Labelling and Packaging Review (version 1.0, May 2012)*. Bayer is supportive of the intent behind the proposals to improve the quality use of medicines by Australian consumers. Since changes to labelling have a significant impact on resources and cost in bringing products to market, careful consideration must be exercised prior to implementation of mandatory changes to current labelling requirements.