Executive Summary

Consultation

- The timeframe for consultation was insufficient given the far reaching proposals. The Industry peak body ASMI requested an extension and this was refused.
- The consultation paper was very poorly written and this goes against the principles of consultation and transparency. The paper contained errors and inconsistencies throughout making the limited time for review even more unrealistic. In some cases the proposals were ambiguous.

The objective of the review of the requirements for medicines labels and packaging is to develop appropriate regulatory solutions that effectively address the consumer safety risks.

- The TGA provides no evidence to support their concerns of risks to consumers with the current labelling and packaging.
- RB is very concerned that no differentiation has been made between non prescription and prescription medicines; and with non prescription medicines again no differentiation in approach across registered, listed or complimentary, in either their consideration of risk, nor in their proposal to reduce risk.
- This one size fits all approach fails to apply a risk based approach to regulation. No evidence has been provided that the proposed reforms would achieve the stated objectives of the review. The TGA should take a risk-based approach to the proposed changes. Changes must be evidence based, both in terms of the risk posed by the current requirements and the benefits to be obtained by the proposed change.
- It is RB's view that the proposals to increase font sizes and increase the content of label will in fact have the opposite effect to that desired by the TGA. The labels will become more complicated and prove more difficult for consumers to understand.
- Undoubtedly the pack sizes would have to increase and there has been no acknowledgment of this in the paper. A further consequence of these over crowded labels will be loss of brand identity and this will generate greater confusion and potentially increase the risk.

- No consideration has been given to the commercial impact to complexity and cost of overseas manufacture, viability of products packs in Australia that cannot be harmonised with the rest of the world. The net result may be a reduction in consumer choice and access to effective medicines.

- At no stage did TGA appear to consider the role they have in educating the consumer and how this could support any initiative to reduce any perceived confusion with medicines labelling.

- In RB's view it is premature to make such vast sweeping changes without conducting a RIS

RB provides below a more detailed response below to specific proposals and our comments focus on registered non prescription, over-the counter (OTC) medicines.

1. Pack size implications

The proposed changes require increased font size and additional information to that currently required. RB is very concerned that this will lead to an increase in the size of packaging. This will have a significant cost impact across the supply chain and in the trade. The TGA have failed to acknowledge this.

2. Prominence of active ingredients on medicine labels

The objective of the Review in relation to this issue:

> To develop appropriate regulatory solutions that effectively address the consumer safety risks posed by information about the active ingredient(s) contained in the medicine which is not always easy to find.

RB's position on the proposals

The TGA have not provided any evidence of the perceived risk of accidental overdose with non prescription medicines posed by the current packs already on the market.

There are no data provided to demonstrate that consumers do not know the actives in their medicine or indeed that they use this information in their purchase decision. The issue as presented in the review appears to be in relation to prescribing and dispensing prescription medicines, yet the solution to the problem is applied across prescription and non prescription medicines. There has been no risk based approach to the proposed regulation. Nor have the TGA provided any evidence that their proposal will resolve this perceived problem.

RB acknowledges the importance of consumers being able to readily identify product ingredients on the label. However, RB does not support the only proposal put forward, that of "equal prominence". Our main concern is the potential detrimental impact on brand recognition, which is a key element in consumer product selection of safe and effective medicines. RB provides evidence to support this in Appendix 1 – Confidential Section

RB does not support the proposal that active ingredients be displayed on 3 non-opposing panels. When packs already provide a significant amount of information for the consumer there is no evidence to suggest repeating details of the active ingredient a third time will solve the perceived problem.

The TGA have not differentiated between prescription and non prescription medicines and within the non prescription they have not differentiated between listed and registered. The review suggests "one size fits all". However, medicines containing paracetamol and ibuprofen have been singled out for additional presumed risk management measures. That is, "non prescription medicines that include paracetamol/ibuprofen must include the following information on the front of the packaging: Contains paracetamol/ibuprofen Xmg. Consult your doctor or pharmacist before taking other paracetamol/ibuprofen products. RB also question if the TGA has a broader list of ingredients where they believe further risk measures are needed and would again seek evidence for this.

In support of the specific focus on ibuprofen and paracetamol the TGA provide 5 references. RB question their relevance to accidental overdose with non prescription products containing ibuprofen and paracetamol in the Australian market. RB do not support this position. Proposals for additional warning statements for ibuprofen and paracetamol are duplicative when they already appear on the front and back of pack. Products containing ibuprofen and

paracetamol already have warning against concomitant use on the back of the pack. Again the TGA do not provide any evidence of increases of accidental overdose with products containing these active ingredients. RB have provided details of consumer complaints over a number of years in Appendix 1 – Confidential Section These labelling complaints do not show incidence of mis-use of the product.

The proposed changes will have a significant and detrimental impact on brand recognition, pack clutter and pack size for non prescription medicines. Examples of "mocked up" labels are provided in Appendix 2.

In the absence of evidence provided by the TGA, RB recommends the following measures to emphasis the active(s):

- a statement on the front of pack "see back of pack for the active ingredients". In addition,
- actives could be predominantly displayed or "called out to' consumers by means of specific font on agreed background to give prominence and readability
- use of colour, graphics, positioning in relation to brand name and different font types and sizes.
- a standard band at bottom of the front panel of the label for inclusion of the actives could facilitate recognition through consistent placement and presentation .
- 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 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.
- in line with the principles of QUM we recommend educational messaging to consumers that they should not "double-up" with products containing the same active without consulting their health care professional, irrespective of their designation from prescription to listed medicines.

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

The objective of the Review in relation to this issue is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by:

- Use of the same brand name for a range of products with different active ingredients resulting in look-alike medicines branding (also called brand extensions, umbrella branding or trade name extension);
- Use of the same brand name for a range of products with different active ingredients resulting in look-alike medicines branding (also called brand extensions, umbrella branding or trade name extension);

Stated alternatively:

- To reduce the risk of accidental overdose that could result from consumers being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines.

RB's position on the proposals

The Consultation paper is not clearly or logically presented. It groups related but distinct 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. Of particular note is the introduction of a new term "look-alike medicine branding "in place of the internationally recognised term "umbrella branding". RB provides some key points against each of the issues raised below.

- **Look -alike and -sound alike**

The proposals do not consider the different risk profiles of prescription medicines in comparison to non prescription. Dispensing errors relate to prescription medicines. Non prescription medicines have detailed information on labels today, prescription medicines do not. Consumers buy non prescription medicines by brand and indication, not by active.

RB and other global companies establish recognised brands to assist consumers find their product anywhere in the world. This builds consumer trust in effective treatments.

- **Look-alike medicines branding, brand extension or trade name extension (AUSTR/AUST L)**

The TGA propose that products that are listed on the ARTG cannot be marketed under the same name as a registered medicine. The TGA have not provided any rationale for this, there is no evidence that the current approach presents any risk to consumers.

- **Look-alike medicine branding, brand extension or trade name (different actives and indications)**

There is no clarity in the paper of what is meant by brand name. Branded Nurofen packs are shown but there is no reference to corporate names e.g. Chemists Own. There is no evidence in the paper to indicate consumer confusion.

Non prescription medicines include details on sub-brands, indication, levels of active, graphics and colours to help the consumer differentiate between products. No evidence has been provided by the TGA that accidental overdose is occurring because consumers are being given the wrong medicine or selecting the wrong medicine because of similarities in names or packaging of medicines with non prescription medicines.

Umbrella branding issues will depend on the category, brand, and heritage. Issues are associated with the perceived risk of the product and will be different across the range of medicines. Therefore a blanket restriction across all medicines without any transparency of decision will lead to greater consumer confusion and will impede innovation. .

Branding and brand recognition are key issues for non-prescription medicines, importantly from a consumer self-selection perspective and from an industry viability perspective. RB provides evidence to support this in Appendix 1 – Confidential Section. Companies have spent years building heritage and trust in their brands, these proposals will eliminate or at best reduce companies abilities to market these brands and this will ultimately lead to further confusion by consumers, given their current purchasing behaviours.

- **Look-alike medicines branding, brand extension or trade name extension (indication specific)**

The TGA has not provided any evidence to demonstrate that current labelling causes any risk to the consumer.

The stated intention of this proposal is to reduce the risk of accidental overdose. There is no evidence provided in the paper to show where there are issues of overdosing with the same active with non prescription medicines. RB have provided consumer data in Appendix 1 – Confidence Section. There were no trends in relation to mis-use and consumers contacts with indication specific products.

Providing the indication on pack is part of the sub-branding referred to above and RB have data to show that this assist consumers in selecting the appropriate product for their needs in Appendix 1 – Confidential Section.

Consistent with a risk-based approach, proposals should be reflective of the risks posed by the different categories of products (for example, the risks of confusing two prescription products are different to the risks posed by confusing two sunscreens).

While the objective of avoiding possible harm which may result from confusing different medicines is very important, RB do not support the broad-brush and over simplistic approach to both prescription and non-prescription medicines advocated in the consultation paper. Prescription and non-prescription issues and proposals need to be separated.

Given the complexity of these issues and the points raised above RB feels strongly that this area requires:

a) clear understanding of incidence of overdosing with products in the above mentioned groups.
b) incidence by different labelling issue e.g. look alike, sound alike and direct causality to labelling
c) evidence to show this occurred because the consumer didn't realise the products they took contained the same active
d) confidence that reforms will achieve the stated objectives and not result in unintended consequences.

<u>Alternative options</u>

- RB believes that evidence-based decision making would be further enhanced by the development of a broadly acceptable label testing methodology. The aim would be to generate tests results that would provide confidence that any risks in relation to product identification have been effectively addressed.
- 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. These guidelines are essential and should be tested rigorously prior to implementation.

- RB proposes that the TGA commissions a paper on best practices for label comprehension testing.
- These programs should be supported with consumer education programs led by TGA and other relevant government departments.

4. Standardised information format: the Medicine Information Box

The objective of the review in relation to this issue:

To develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:

- 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 medicines branding (also called brand extensions, umbrella branding 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 standardised format for information included on medicines labels and packaging

RB's position on the proposals

- RB agrees that a standardised back-of-pack format for medicine information has merit. However, we note that only 1 paper is provided in evidence to suggest incorrect placement of information on pack increases the risk of inappropriate use or storage of a medicine. Once again we question the relevance of this paper as it is related to prescription medicines.
- RB note and recognise that a significant amount of work has already been done by ASMI and industry generally on developing labels based on consumer testing. This is not referred to in the paper.
- The proposal as it stands is cumbersome and takes up a significant amount of space on the label. It will reduce legibility and this is in conflict with the stated aims of the review. RB have provided "mocked up" labels in Appendix 2.
- Colour contrast rather than mandated black and white should be permitted as this assists readability and allows for differentiation.
- The bar code needs to be at 100% magnification and cannot be truncated. This would cause significant problem in the trade. Current proposal is not viable on the side panel of cartons. This has not been addressed in the paper and RB question if the key trade e.g. Woolworths and Coles have been consulted on this matter, This is not something that should be imposed on industry who then have to solve the problem for their key stakeholder or bear the likely cost.

Alternative options and considerations

- Any proposed back-of-pack format should be rigorously tested prior to adoption.
- Provision should be made for alternative formats 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.
- 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 back (MIB) should be explored and tested

5. Dispensing label space

This item has been identified as applying to prescription medicines only.

RB offers no comment in relation to this part of the Consultation paper.

6. Blister strip labelling

Objective of the Review in relation to this issue;

In the consultation paper it is asserted that:

> *“Often blister strips are stored away from their outer wrapping or packaging that contains the information how to use the medicine safely”.*
>
> *“There is a risk that the medicines may not be taken in accordance with the dosage instructions or it may be taken with another medicine that contains the same active ingredients”.*

We conclude from these statements that the objective of the Review would be:

> To develop appropriate regulatory solutions to effectively address the consumer safety risks posed by the following issue:
>
> - Information about the active ingredient(s) contained in the medicine and instructions for usage are not available on the blister strip.

Summary of RB Position

- RB rejects the proposal to include the batch and expiry data more frequently on the blister strip than currently required.
- 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.
- Any wording that suggest separation of blisters from packaging will potentially only serve to encourage this practice.

Alternative proposals

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

7. Small containers

RB position on this issue

- 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.
- RB agrees with the comments about the practical considerations and challenges in relation to small containers.

Options proposed by RB

- 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).

8. Pack Inserts

RB Position

- 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.

Options proposed by RB

- That pack inserts should only be required if all the necessary information cannot be included on the product's label.
- RB suggests that the current practices in relation to cross-referencing remain in place (as outlined in ARGOM).

9. Labels and packaging advisory committee

RB's position in relation to this proposal

- RB does not support the establishment of such a committee
- RB would like clear guidelines and protocols developed as a starting point. The guidelines and protocols should allow objective assessment of the risks, benefits and merits of labelling and packaging