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:	GlaxoSmithKline Consumer Healthcare 82 Hughes Ave, Ermington, NSW 2115, Australia
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)* Due to its nature and content, certain sections of the document contain commercially sensitive information. These sections have been marked within bold square parentheses [] for emphasis and ease of reference and identification for redaction.
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☐ Prescription Medicines	☒ OTC Medicines
☐ Complementary Medicines	☒ Medical Devices
☐ Blood/Tissues	☐ Other

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24 August 2012

TGA Labelling and Packaging Review

PO Box 100

Woden ACT 2606

Email: labellingreview@tga.gov.au

Dear Sir/Madam,

Re: TGA Medicine Labelling and Packaging Review Consultation Paper (Version 1.0, May 2012)

GlaxoSmithKline Consumer Healthcare (GSK) makes the following submissions in relation to the **TGA Medicine Labelling and Packaging Review Consultation Paper** (Version 1.0, May 2012).

Although the comments herein are restricted to the perspective of over-the-counter (OTC) medicines, GSK hopes that the data and discussion provided in this submission will provide decisive information on the impact of the proposed regulatory changes to the labelling and packaging of medicines in Australia. Where our analysis differs from the views presented in the TGA Consultation Paper we have proposed recommendations for consideration.

Due to its nature and content, certain sections of the document contain commercially sensitive information. These sections have been marked within bold square parentheses **[]** for emphasis and ease of reference and identification for redaction.

Should you require any additional information please do not hesitate to contact me.

GlaxoSmithKline Australia Pty Ltd
ABN 47 100 162 481

TGA: MEDICINE LABELLING AND PACKAGING REVIEW CONSULTATION PAPER

CONSULTATION RESPONSE SUBMISSION PREPARED BY GLAXOSMITHKLINE CONSUMER HEALTHCARE

CONTENTS

EXECUTIVE SUMMARY

GlaxoSmithKline (GSK) is a global research-based pharmaceutical and healthcare company with a mission to improve the quality of human life by enabling people to do more, feel better and live longer.

GSK is sub-divided into a prescription division and a consumer healthcare division. GSK Consumer Healthcare manufactures and markets a wide range of over-the-counter (OTC) medicines that are sold in pharmacies and supermarkets.

OTC medicines are an essential, effective and convenient component of Australia's healthcare system. The on-pack labeling is a critical element of an OTC medicine because it provides all of the information a consumer needs for self-selection of a medicine and for its safe and effective use.

GSK Consumer Healthcare welcomes viable initiatives to further support the safe and effective use of OTC medicines and agrees with the principles behind the proposed regulatory changes to labelling and packaging. However, the specifics of some of the proposed changes when applied to OTC medicines have unintended consequences and so warrant further discussion and clarification.

This submission highlights these unintended consequences and proposes alternatives whilst still meeting the intention of better facilitating the safe use of OTC medicines by consumers.

Prominence of active ingredients on medicine labels

Size and position of active ingredients on front of label (primary display label)

- GSK believes that standardizing the location of the active ingredients on the front of pack may aid consumers in locating this information.
- Whilst there is some merit in having both pieces of information (brand name and active ingredients) in a familiar location, having them of equal size and immediately below the brand name creates clutter and obscures readability in an OTC environment.
- GSK proposes that having the active ingredient in a block in a standardized position along the baseline of the front of pack would retain a consistent approach irrespective of where the brand name appears on the pack. This provides design flexibility whilst allowing the consumer to find the active ingredient information in the same place irrespective of the brand position or the brand purchased.
- GSK proposes that the font size of the active ingredients in this block position be at least one-quarter as large as the size of the most prominent matter on the primary display label or, if space does not permit, that the current minimum font height of 1.5 mm be retained.
- How differentiation between the brand name and the active ingredients is achieved should be open to the label designer and should include such possibilities as typefaces, colour and use of upper and lowercase text.
- In order not to prevent the use of tallman lettering on labels, no mandatory restrictions should be put in place regarding the use of capital and small lettering.

Number of active ingredients on front of label (primary display label)

- Listing only the three most abundant active ingredients may be misleading to consumers. Such products could be more effectively labeled with a simple statement saying "See Medicines Information Box for a complete list of active ingredients in this product", or words to that effect.

Minimum font heights

- Other jurisdictions, such as the EU, suggest in their guidelines that a minimum font height of 1.4 mm is desirable to achieve an appropriate balance between readability and comprehension of information on the labels of medicines.
- Per TG069, the current minimum in Australia is set at 1.5mm and remains appropriate.

Active ingredient(s) to be included on at least 3 non-opposing faces of a carton

- GSK believes that standardizing the location of the active ingredients next to the brand does not aid consumers in locating this information.
- GSK proposes that flexibility be allowed as proposed by the use of the blocked area at the base of the front panel and by repeating the information as often as space allows, with a mandated minimum of it appearing on the front label and one additional face of the packaging.

Proposed front of pack warning statements

- The Australian pack labels for all paracetamol and ibuprofen products already include specific warning statements (as specified under RASML 148 and 149, respectively). As is the case with related legislation in Ireland, the UK and the USA, this warning is contained on the back of pack.
- This current position of these warning statements reflects a consumer practice of using the front of pack to make a correct choice (self-selection) of an OTC medicine and using the back of pack to inform correct usage of the product.
- The proposed regulatory change (1.6) goes beyond the current provisions by requiring an additional warning statement, with different wording, to that specified in RASML.
- There is no justification for the TGA taking a different and unilateral position to have the statement on the front panel. Particularly when the examples provided by TGA in the Consultation Paper do not meet labelling guidelines, only reinforcing the difficulty in meeting such a unique requirement were it to be imposed.
- Evidence, published from research undertaken at Michigan State University, demonstrates that consumers neither see nor recall required warnings on the front of the pack.[1] Only 8.2% of participants were able to recall a child-resistant warning on the front of pack. In contrast, 70% of participants spent time looking at the "Drug Facts" box on the back of the pack.

- GSK recommends against an additional front of pack warning. The published evidence suggests that this information be better placed, as it currently is, on the back of pack.
- Enhanced recall of this important safety message can be achieved through the adoption of a modified "Drug Facts" box (as has been suggested) and via public health initiatives providing information to consumers on how to read the label.

Wording of proposed front of pack warning statements

- The wording of the current warning statements "*do not take*" and "*do not use*" is more explicit and less permissive than those which have been proposed in the Consultation Paper and should be retained.
- Revising the warning to be similar to that used in other markets; e.g. "*Contains paracetamol. Do not take any other paracetamol-containing products*" is appropriate provided the statement is placed on the back of pack in a familiar position where it can be located and recalled.

Look-alike and sound-alike medicine brand names

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

- The proposals for LASA names and LA packaging provide a reasonable framework for initiating further discussion regarding its role in the naming of new medicines, but place an unnecessary burden of expense on the sponsor. It is of note that in other countries extensive review of proposed drug names is undertaken by the regulator and not the sponsor.
- Colour and design changes to the label of existing identified LASA products is only part of the solution. Other strategies recently proposed in the Australian literature (e.g. physical alerts to healthcare professionals, automated alerts in dispensing software, barcode scanning and improved methods of reporting errors)[2] warrant consideration.
- A clear system would need to be put in place to aid in determining whether the degree of similarity in names is problematic. Particular focus should be placed on developing a system to adequately assess the consequences of the patient missing the pharmacological action of the intended drug and the pharmacological actions and toxicities of the unintended drug.
- Further consideration as to how the TGA may adopt the use of algorithms that enable both orthographic and phonologic evaluation of proposed drug names is warranted.
- GSK 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 rather than increase complexity and add to the cost of medicine to the patient.

Look-alike medicine branding (umbrella branding)

- GSK is disappointed that the phrase "look-alike medicine branding" has been adopted in the Consultation Paper instead of the widely recognized phrase "umbrella branding". This change in terminology creates an unnecessarily negative and derogatory impression of this practice.
- The phrase umbrella branding has been used in Australia for many years and continues to be used in many other jurisdictions. GSK requests that this term be used in all future consultations and in any regulatory guidance produced as an outcome of the current consultation process.
- The proposals for look-alike medicine branding seek to improve consumer safety. However, there are no safety data to substantiate that confusion is enhanced by the use of umbrella brand names provided the products are appropriately labelled and sufficient consumer information is made available.
- The current proposals may each have a place with some therapeutic categories but should not be applied across all therapeutic categories.
- GSK proposes consideration of the proposal that a process and guidelines be put in place to put forward arguments for retention of look-alike medicine branding on a case-by-case basis.
- Such a proposal may best be stratified by risk, with all brands within low risk categories (e.g. medicated toothpastes, sunscreens etc) being exempted. In determining the suitability and risk-benefit of umbrella branding for other categories due consideration of the negative impact must also be assessed.
- In order for this to be achieved clear guidelines and protocols developed in collaboration with Industry would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.

Standardised information format: the Medicine Information Box

Order, content and design elements

- The inclusion of a standardized Medicine Information Box has the potential to improve consumer usage of OTC medicines by providing a familiar format and location for important information.
- In order to prove the value of the many and varied TGA proposed changes (aspects of which are drawn from numerous jurisdictions), it would be prudent for the TGA themselves to validate the specific combination and order of the proposed wording to ensure that the desired outcomes are achieved. This will be of particular importance to ensure comprehension of the proposed headings.
- Improvements can be made to the current proposals by allowing some level of flexibility to accommodate sub-headings (particularly where the content of the warning and allergy information section is lengthy) and/or other means of differentiating important information (such as the use of hairlines, bullets and colour contrasts) as and where the label space permits.

- Limitations, both in terms of cost and practicality for the end-user, need to be factored into any decision to require a printed insert of the Medicine Information Box.
- A risk-assessment approach should be undertaken with regards to the requirement to have a complete 'Medicines Box', with exclusions being applied to low risk medicines (such as sensitivity toothpastes) given the limited space and the low-risk nature of the product.

Blister strip labelling

Impracticalities of proposed changes to blister pack manufacture

- The proposed changes to the blister strip have not taken into account the specifics of the manufacturing process. Such changes place a considerable financial burden on the manufacturer.
- It is unfair to impose such a requirement on the manufacturer where the product is not perforated for the purpose of separating the blisters simply to reward consumers who decide to cut the package up for their own convenience with no consideration of the consequences. Industry has already produced innovative packs (such as handipacks) to avoid the need for this behavior.
- The investment required is disproportionate with the perceived consumer safety benefits.
- More importantly, they are likely to have multiple negative implications for the end users, in terms of increased costs of goods, deceptively increased package sizes and the potential of reverting to back to bottle packaging of loose pills.
- GSK proposes that the existing arrangements for labeling of blister strips be retained in line with TG069.
- Non-regulatory approaches, such as consumer education, are preferable to mitigate the risks of consumers cutting up blisters for their own convenience.

Incongruities of proposed changes to blister pack manufacture

- The proposed changes with respect to how to manage blister pack labeling for products that contain more than 3 active ingredients do not account for OTC medicines that contain day/night formulations whereby the day formulation contains 3 actives and the night formulation contains 4 actives.
- This incongruity makes it difficult to understand how any of the proposed changes will be applied in practice given the rationale underpinning them is to enhance consumer safety.

Small containers

Clarity is needed over conflicting proposals (7.1) and (4.6)

- The proposed changes at 7.1 are in conflict with those at 4.6. Clarity as to the specific proposed regulatory changes is therefore needed before an informed comment can be made.
- GSK is supportive of the proposed changes at 4.6 but does not support the need for inclusion of a detailed package insert, particularly if the outer package label meets the revised regulatory requirements.

Impact on "small containers" that are outside the current nominal capacity of 20mL

- The TGA proposals for prominence of actives and 2.0mm headlines in the Medicines Information Box would force an unnecessary increase in the size of the label of OTC medicines in small containers above the 20mL nominal capacity.
- The TGA should consider extending exemptions beyond the proposed limit to allow important products in therapeutically relevant pack sizes to remain available to the consumer.

Pack inserts

Package inserts provide a valuable route of consumer education

- Pack inserts represent a valuable means of providing much needed education to consumers at a point when they are most receptive to such information.
- They provide an avenue for consumers to enroll into patient support programs (such as tailored smoking cessation support) that can enhance their treatment and aid in crucial issues such as medication compliance.
- The WHO supports the use of package inserts as a viable means of educating consumers[3] and the FDA has recently announced its intentions to harness this avenue of communication to better educate consumers about the safe use of opioid analgesics.[4]
- Any restrictions to the provision of this information must be carefully balanced against any unintended impact on public health.

Labels and packaging advisory committee

- It is paramount that clear guidelines and protocols be established that are particular to the selection and use of OTC medicines to act as terms of reference to aid the Committee's deliberations and to aid industry in complying with any revised regulations relating to packaging and labeling.
- Given the inherent complexities of package design and product manufacture it is clearly evident that the composition of the proposed advisory committee should be

balanced such that views of tertiary-qualified packaging and manufacturing specialists (who not only bring a wealth of academic learning but also many years of experience in these areas) can be tabled and considered at the earliest stages of deliberation.

- Such a committee should serve in an advisory capacity only and should not overrule these guidance materials.

1. INTRODUCTION

GlaxoSmithKline (GSK) is a global research-based pharmaceutical and healthcare company with a mission to improve the quality of human life by enabling people to do more, feel better and live longer.

In Australia, GSK has improved people's wellbeing by delivering the highest quality medicines, vaccines and over-the-counter (OTC) healthcare products since 1886. The company currently provides over 1600 skilled jobs across the country, working with researchers and doctors to discover new ways of treating and preventing disease. In 2011 GSK invested $58 million in local research and development, and made significant contributions to Australia's $4.2 billion pharmaceutical and medicinal exports.

GSK is sub-divided into a prescription division and a consumer healthcare division. The entire company concurs on the overall merits and issues of the proposals raised within the Consultation Paper. However, given the differences in how prescription and OTC medicines are regulated, labelled and supplied to consumers each division has put in its own response to this consultation. This submission, therefore, focuses on the proposals and their implications as they relate to the OTC sector of the market only.

GSK Consumer Healthcare manufactures and markets a wide range of consumer products that are sold in pharmacies and supermarkets. The company's most well-known product, Panadol®, is manufactured at the Sydney facility. Each year the plant produces more than 50 million packs of solid dose format and 10 million bottles of paediatric liquids. In addition, many of these products are exported to over 15 different countries.

OTC medicines are an essential, effective and convenient component of Australia's healthcare system. It has been more than two decades since "self health care" was demonstrated to be a viable economic model for reducing the pressures of total health expenditure in Australia.[5] The use of OTC medicines has evolved a great deal since this time and has brought with it important benefits. It has created more self-reliant consumers and significant cost savings to the health care system. In addition, industry-driven innovation in collaboration with Government, has meant that the use of OTC medicines has expanded beyond their traditional role in the symptomatic relief of common conditions such as minor pain, cough and colds, to one that now encompasses disease prevention (e.g. tooth decay, smoking cessation), cure (e.g. fungal infection) and the management of common recurrent conditions (e.g. heartburn, allergy).

GSK Consumer Healthcare welcomes viable initiatives to further support the safe and effective use of OTC medicines and agrees with the intent behind the proposed regulatory changes to labelling and packaging. It is, however, of great concern that the views of the External Reference Group, which was specifically set up to advise the TGA on the Review, have not been fully taken into account. In particular that separate requirements for different classes of medicines should be considered. This has required GSK to go back and review previous concerns and then present new arguments and proposals. In doing so, considerable time, manpower and financial costs have been incurred to engage internal (regulatory, legal, manufacturing, marketing) and external personnel and specialists to develop packaging samples and conduct manufacturing and supply chain feasibility analyses.

GSK Consumer Healthcare has no issue with the Review itself. However, the proposals as they are currently presented need to be tempered with the potential for unintended consequences and knock-on effects in other areas of the National Medicines Policy, such as the cost/affordability of medicines and the viability of the industry *per se*. There are also

questions as to whether some of the proposed changes will actually achieve their intended benefit. This submission highlights these unintended consequences and proposes alternatives whilst still meeting the intention of better facilitating the safe use of OTC medicines by consumers.

The comments within this document represent the specific views of GSK Consumer Healthcare. They are intended to provide further insight over and above the general industry view that has been outlined in the ASMI submission.

2. PROMINENCE OF ACTIVE INGREDIENTS ON MEDICINE LABELS

Unlike prescription drugs, the on-pack labeling is a critical element of an OTC medicine because it provides all of the information a consumer needs for self-selection of a medicine and for its safe and effective use. Consumers use this information in two ways. In general terms, front of pack labeling is used predominantly at the point of purchase, to determine if a particular product is the right one for their particular symptoms or condition whilst the back of pack labeling is used at the point when they are ready to use the product.

The proposed regulatory changes are aimed at clarifying the label of medicines to better improve consumer safety and quality use of medicines. GSK concurs with the overarching intent of these proposals. However, the specifics of some of the proposed changes when applied to OTC medicines have unintended consequences and so warrant further discussion and clarification.

In considering the proposed regulatory changes it is therefore important to consider where the main problems occur – if it is in 'product selection' then the front of label issues are more critical; whereas if it is 'use' the back of label issues may be of more relevance. In addition, any proposed amendments should consider the need for stratification by level of risk, with all brands within a low risk categories (e.g. sensitivity toothpastes) being exempted.

Size and position of active ingredients on front of label (primary display label)

The majority of the proposed changes address the inclusion of the active ingredients on the front of label. Educating consumers on the active ingredients in the medicines they take is an important exercise. This information is imperative to aid accurate identification of the medicinal product they are using. Standardizing the location of this information (per the intent of proposal 1.1) may therefore aid consumers to some extent by building familiarization.

The current proposal does not take into account the fact that the location of brand name may move depending on the pack. This challenge may be avoided by creating an active ingredient in a block in a standardized position along the baseline of the front of pack. The benefits of this approach would be that it retains a consistent approach irrespective of where the brand name appears on the pack.

The proposal (1.2) further specifies that the brand name and the names of the active ingredients must be of equal font size, but that font style, letter spacing and colour may be used for differentiation. However, this emphasis on "equal prominence" along with the prescriptive nature of font size, limits the ability of manufacturers to adequately display the required information without causing unintended confusion. Such prescriptive templates, as have been proposed, stifle innovation and prohibit the future development of alternative options that take account of recognized models of information processing.

To illustrate some of the inherent issues involved, we provide below two case examples of commonly purchased OTC consumer brands.

CASE EXAMPLE 1:

Equal prominence does not always equate to improved consumer comprehension

The example below, of Eno®, shows that having both the brand name and active ingredients of equal size creates clutter and obscures readability. The consumer actively seeks out a brand name to reassure them that this is the product that they are familiar with.

CURRENT **REVISED**

As can be seen on the revised label, the brand name is barely legible whereas the active ingredients dominate the label. The revised label is tantamount to shouting information at the consumer that they do not understand. The net effect will be that the consumer is left confused and unsure about a once familiar product, inadvertently undermining the principles of self-care. Importantly, to accommodate the information, creates additional problems because it vastly increases the required size of the packaging, such that it increases from 200g to 1kg, bringing the economic viability of the product and the ability of the consumer to justify a 3-to4-fold increase in price into question.

REVISED

CURRENT

CASE EXAMPLE 2:

Keeping the brand name of sufficient size for consumer recognition results in a need for grossly oversize packs

The Sensodyne® example below shows that even with a reduction in the size of the brand name, having both the brand name and active ingredients of equal size would require a substantially larger pack size.

This is further complicated by the proposed introduction of the Medicine Information Box for what are very low risk medicines. The combination of circumstances creates larger containers and primary packaging. This has further impact on the supply chain in terms of space requirements, warehousing costs and transportation costs and on the consumer in terms of storage space in the home.

So as not to be misconstrued as deceptive, a larger package requires a larger volume of product inside. Thus resulting in a toothpaste tube that is 4 times greater in volume than the current minimum pack size (50g versus 200g) This increase in size would ultimately translate into a 3-to 4-fold increase in the costs to the consumer who will no longer be able to purchase a smaller pack size.

An additional consideration in this particular case is the fact that not all toothpastes in the Sensodyne brand are registered medicines. Some Sensodyne toothpastes, which utilize physical occlusion to convey relief from sensitivity are registered as devices and are therefore outside of the scope of this consultation. This creates an obvious issue of incongruity on the shelf where products with the same brand name are not labeled in the same way.

CURRENT

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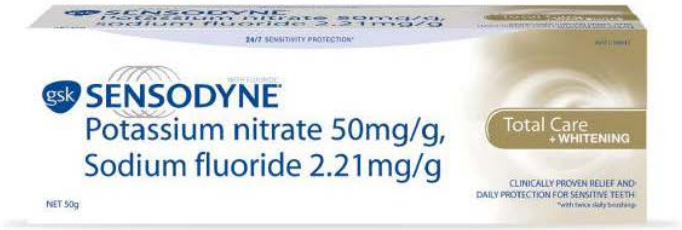

CURRENT

REVISED

Given that the intent is to ensure the consumer becomes aware of and takes note of this information then additional factors need to be considered to ensure that the information is legible. Research shows that to improve message legibility due consideration should be

given to font height (in preference to point size), font type, sans serif typefaces, letter spacing (compression), line spacing, use of "white space", use of bold text and judicious use of colour (both of the text and the background).[6]

The European Commission guidelines on the readability of labeling and package leaflets of medicinal products suggest a minimum usability level of 81%. This means that any user should be able to find 90% of what they are looking for and then understand 90% of what they find (90x90=81%).[7] Research undertaken in Europe has shown that consumers could find over 90% of answers in a package insert irrespective of the font size (fonts ranged from 7pt to 16pt).[8] In this study, other factors were found to influence readability — use of simple language, avoiding abbreviations, long sentences and repetition, and the use of different font colours.

Recent revisions have been made to labeling regulations in both the EU and the USA, neither of these explicitly recommend that the active ingredients should be the same size font as the brand name. Although the US legislation does not require the ingredient name to be adjacent to the brand name, it specifies that the ingredient name be:[9]

- At least one-quarter as large as the size of the most prominent matter on the primary display label; or
- At least as large as the size of the "Drugs facts" title (which should be no smaller than 8 pt type size).

Recommendations
GSK believes that standardizing the location of the active ingredients on the front of pack may aid consumers in locating this information. Whilst there is some merit in having both pieces of information (brand name and active ingredients) in a familiar location, having them of equal size creates clutter and obscures readability. GSK proposes that having the active ingredient in a block in a standardized position along the baseline of the front of pack would retain a consistent approach irrespective of where the brand name appears on the pack. GSK proposes that having the active ingredient in this standardized position and in a font size at least one-quarter as large as the size of the most prominent matter on the primary display label or a minimum height of 1.5mm be adopted. How differentiation between the brand name and the active ingredients is achieved should be open to the label designer and should include such possibilities as typefaces, colour and use of upper and lowercase text. Tallman lettering should be permissible.

Number of active ingredients on front of label (primary display label)

The proposal (1.3) regarding how to include the active ingredients in preparations containing more than 3 active ingredients may cause unnecessary confusion in that consumers may

believe that the product contains only 3 ingredients when it might contain many more than that. Equally, determining those that appear on the front using an arbitrary measure of abundance may not equate to the clinical usefulness of the product.

Recommendations
GSK believes that listing only the three most abundant active ingredients may be misleading to consumers. Such products could be more effectively labeled with a simple statement saying "See Medicines Information Box for a complete list of active ingredients in this product", or words to that effect.

Inclusion of the manufacturer's logo on front of label (primary display label)

Clarification is particularly sought as to whether the intention of the TGA is to mandate that the name/logo of the manufacturer also be placed prominently on the front of pack, as it has been in the labeling illustrations provided in the consultation paper. To do so would take up valuable space on an already crowded front panel (as shown below).

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Minimum font heights

The proposal specifies a font size of no less than 2mm for headlines (at 1.4) and 1.5mm for body text (at 1.6 and 1.7). The TGA has also asked for input as to the smallest size font that is considered readable.

In terms of the smallest size that is readable, this will of course vary considerably depending on the age of the person as well as their visual acuity.[8] As has already been demonstrated, research has shown that when consumers could find over 90% of answers in a package insert even when the font size was set at 7 point.[8] This research has helped to inform the EU readability guidelines, which now state that the minimum height for medicines labels should be 1.4mm (7 point Times New Roman).

The current Panadol® pack available in Australia contains a combination of heights, the smallest is 1.5mm. This height has been used on the back of the pack to enable the mandatory required information to be displayed whist providing sufficient line leading and white space for readability and clarity. This TGA approved label has been subject to usability

performance testing, consistent with the EU guideline, which has shown that 97% of people were able to find the information they needed and 96% were able to use that information.[10] This the current package label performs better than the minimum usability level of 81% that has been set by the EU for package labelling.[7]

One of the primary conclusions from this testing was that improvement in labelling performance can be brought about by applying professional labeling design methods without needing to change regulations.[10]

Recommendations
Other jurisdictions, such as the EU, suggest in their guidelines that a minimum font height of 1.4 mm is desirable to achieve an appropriate balance between readability and comprehension of information on the labels of medicines. However, per TG069, the current minimum in Australia is set at 1.5mm. GSK sees no justification provided by the TGA for the changes proposed and therefore we recommend that the TG069 requirements be maintained.

Active ingredients on at least 3 non-opposing faces of a carton

The proposal (1.5) states that the active ingredients and the brand name should be imprinted on 3 non-opposing faces of the carton and should be of equal proportion. We have discussed our concerns with the issue of equal proportion above and have proposed the use of a standardized blocked area at the baseline of the front of pack for the active ingredients. Having both pieces of information in the same size will not necessarily improve legibility of this information. Where this information is to be provided, a disparity in the proportion of the font size used should be provided for. Furthermore, in the case of small labels this requirement could force critical information onto a leaflet making it harder for the consumer to make appropriate selections of OTC medicines at the point of purchase.

Recommendations
GSK believes that standardizing the location of the active ingredients next to the brand does not aid consumers in locating this information. GSK proposes that flexibility be allowed as proposed by the use of the blocked area at the base of the front panel and by repeating the information as often as space allows, with a mandated minimum of it appearing on the front label and one additional face of the packaging.

Proposed front of pack warning statements

Proposed changes 1.6 and 1.7 recommend the inclusion of a specific warning statement on the front of the pack of paracetamol- and ibuprofen-containing products respectively.

The consultation document suggests that such warnings are already mandated on paracetamol packs in Ireland, the UK and the USA. However, this information is misleading. Although these packs do contain such a warning statement, it is not on the front of the pack (see summary table, below).

Current paracetamol warning statements in different markets around the world

Market	CURRENT paracetamol warning statement and location
UK	BACK OF PACK Contains paracetamol. Do not take with any other paracetamol-containing products.
Ireland	BACK OF PACK Contains paracetamol. Do not take any other paracetamol-containing products.
EU	BACK OF PACK Contains paracetamol. Do not take any other paracetamol-containing products.
USA[9]	BACK OF PACK (NOTE: MUST BE IN THE "WARNINGS" SECTIONS OF THE DRUG FACTS BOX) Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist."
Australia[11]	**BACK OF PACK** **Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.**

The body of the Consultation Paper states "*… it is proposed that a similar warning should be used in Australia to improve the quality use of medicines that contain these active ingredients by Australian consumers.*" The Australian pack label for all paracetamol products already includes exactly this type of warning (as specified under RASML 148). Importantly, as is the case with the legislation in Ireland, the UK and the USA, this warning is contained on the back of pack. The proposed regulatory change (1.6) goes beyond the current provisions by requiring an additional warning statement with different wording to that specified in RASML (clause 148).

Evidence, published from research undertaken at Michigan State University and partially funded by the Centre for Food and Pharmaceutical Packaging Research, has demonstrated that consumers neither see nor recall required warnings on the front of the pack.[1]

These researchers looked at two warnings (i) warnings that alert consumers to the fact that the package is not child-resistant and (ii) warnings that alert consumers to potential product tampering. US law mandates that these warnings be "conspicuous" and "prominent" so that it is likely that consumers will read them before leaving the store. The researchers looked at five different packs of paracetamol products available in the US, all of which have the child-resistant warning on the front of the pack. They found that:

- Participants spent significantly less time looking at the child-resistant warning than any other area of the pack;

- Participants found it significantly harder to read the child-resistant warning than any of the other information on the pack; and
- Only 8.2% of participants were able to recall the child-resistant warning.

Importantly, this research showed that 80% of participants spent time looking at the brand name and 70% spent time looking at the “Drug Facts” box. The rate of recall from these was significantly higher (ranging from 33-66%).

The authors challenge whether these results are simply down to the design elements of the label. It is possible that consumers believe these pieces of information to be a low priority (compared to the information found within the drug facts box) and therefore tend not to fixate on them when reading the label. They conclude that changing the graphic elements of the warning is not enough – a more comprehensive approach centered around consumer education is needed.

This research reflects a consumer practice of using the front of pack to make a correct choice (self-selection) of an OTC medicine and using the back of pack to inform correct usage of the product.

Recommendations
Given the above data and considerations, GSK recommends against an additional front of pack warning and the published evidence suggests that this information be better placed, as it currently is, on the back of pack. Enhanced recall of this important safety message can be achieved through the adoption of a modified drug facts box (as has been suggested) and via public health initiatives providing information to consumers on how to read the label.

Wording of proposed front of pack warning statements

Proposed changes 1.6 and 1.7 recommend specific wording for warning statements for paracetamol- and ibuprofen-containing products. As shown in the table below, these statements are different to those already mandated in the RASML (2008).

Current and proposed warning statements are different in their content and tonality

	Paracetamol	Ibuprofen
Current	Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.	Unless a doctor has told you to, do not use [this product/insert name of product] with other medicines containing [insert name of substance] or other anti-inflammatory medicines.
Proposed by TGA in Consulation Paper	"Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products."	"Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."

Recommendations
The wording of the current warning statements “do not take” and “do not use” is more explicit and less permissive than those which have been proposed and should be retained. Revising the warning to be similar to that used in other markets; e.g. *“Contains paracetamol. Do not take any other paracetamol-containing products”* is appropriate provided the statement is placed on the back of pack in a familiar position where it can be located and recalled.

3. LOOK-ALIKE AND SOUND-ALIKE MEDICINE BRAND NAMES

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

The existence of confusing drug names is considered one of the leading causes of medication errors. Although recent evidence suggests that such errors are more likely with branded prescription medicines, they do also occur with LASA active ingredient names and are most likely to cause problems when the medications are from different therapeutic classes (e.g. ketoprofen/ketotifen).[12]

The proposed changes (3.1, 3.2 and 3.3) provide a sensible starting point from which LASA names and LA packaging can be monitored and improved moving forward. These proposals focus primarily on applications for new medicines. There is a potential to automate screening to identify proposed names that are orthographically and/or phonetically similar to existing medicines, as implemented by US FDA.[2]

The assessment criteria to be applied are not clear. With a view to transparency and providing Industry with a means of anticipating the risk levels of proposed names, the TGA should seek to ensure scientific validation and reproducibility of the proposed assessment methods for predicting the risks of confusion between different brand names.

Other risk reduction strategies may also be required to address this issue. Several healthcare professional workflow practices and technological solutions have been recently proposed in the Australian literature and include font variation (including Tallman lettering), physical alerts, automated alerts in dispensing software, barcode scanning and improved methods of reporting errors.[2]

Criteria for defining LASA names

Within the Consultation Paper, existing medicines an arbitrary cut-off point for LASA brand names has been defined as brand names that differ by less than three letters. No rationale has been provided for this definition. Importantly it focuses only on string similarity (orthographics) while dismissing the importance of phonological coding, when both of these have been shown to increase the probability that experts and novices will make false recognition errors when trying to remember drug names.[13]

The Institute for Safe Medication Practices (ISMP) has compiled an eight-page list of look-alike, sound-alike pairs involved in errors reported to its National Medication Errors Reporting Program. Not all of these medicines would be identified if the proposed “less than 3 letters difference” criteria come into play. Indeed, amongst the medicines in a list of examples of LASA drug names identified in a recent Australian review, some (e.g. Diflucan and Diprvan) did not meet this criterion.[2] A better definition might be “Products that have a similar written name or similar phonetics to those of another health product”.

It has been suggested that checklist be determined to guide industry for assessment of LASA names. A clear system would need to be put in place to aid in determining whether the degree of similarity in names is problematic. Contributory factors could include the marketing status (Rx or OTC), therapeutic category, indication(s) and directions for use, the clinical setting for dispensing or use, the packaging and labelling, posolgy, the proposed dose and dosing interval. With particular reference to OTC products, the marketing status, the therapeutic category, the indications, packaging and labelling, the location on the shelf and

similar patient populations should be taken into account. When comparing the proposed name with another, the potential for harm must also be assessed. For instance, the consequences of the patient missing the pharmacological action of the intended drug and the pharmacological actions and toxicities of the unintended drug should also be taken into account considered.

Recommendations
The proposals for LASA names and LA packaging provide a reasonable framework for new medicines, but it places an unnecessary burden of expense on the sponsor. It is of note that in other countries extensive review of proposed drug names is undertaken by the regulator and not the sponsor. Colour and design changes to the label of existing identified LASA products is only part of the solution. Other strategies recently proposed in the literature (e.g. physical alerts, automated alerts in dispensing software, barcode scanning and improved methods of reporting errors)[2] warrant consideration. A clear system would need to be put in place to aid in determining whether the degree of similarity in names is problematic. Particular focus should be placed on developing a system to adequately assess the consequences of the patient missing the pharmacological action of the intended drug and the pharmacological actions and toxicities of the unintended drug. GSK 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.

Look-alike medicine branding (Umbrella branding)

Brands are a principal asset for the development and promotion of self-care. The value of brands is well recognized and their use results in a strong interest from the manufacturers' side in preserving the goodwill adhering to a product and, consequently, maintaining a high level of quality.

Given the enormous cost and the extreme high failure rate of new product developments, brand extension strategies have been developed to better implement new products into the market. These enable manufacturers to leverage the existing goodwill toward their brand (brand loyalty) whilst reducing the risk of putting a new product to market. This is of particular importance in the OTC medicines setting as, unlike prescription medicines, OTC products are generally not afforded patent or other protections to reward the cost and effort of product innovation.

GSK is disappointed that the phrase "look-alike medicine branding" has been adopted in the Consultation Paper instead of the widely recognized phrase "umbrella branding". This change in terminology creates an unnecessarily negative and derogatory impression of this practice. The phrase umbrella branding has been used in Australia for many years and

continues to be used in many other jurisdictions. GSK requests that this term be used in all future consultations and in any regulatory guidance produced as an outcome of the current consultation process.

Brands act as an internal beacon to consumers. Umbrella brands are used to allow consumers to easily navigate categories, recognize product families and then select individual products. Experience shows that umbrella brands are valuable asset for companies.[14] Confidence in OTC products is enhanced and, within an umbrella range, all products are endowed with a quality seal that is recognized as a critical attribute by consumers.

With specific regard to OTC medicines, there are no safety data to substantiate that confusion is enhanced by the use of umbrella brand names provided the products are appropriately labelled and sufficient consumer information is made available.

Equally, there is no evidence to date that the manufacturers' freedom to choose a particular brand name jeopardises the safety of the patient in the correct use of medicines. As such, the benefits of the proposed changes are likely to have minimal if any impact on consumer safety. Further, within the OTC setting in particular, confusion and risk are mitigated or diminished by number of features, including the form of the product, basic pack design, pack colour, use of prefixes, suffixes, sub-brands and adequate labelling.

It is not clear from the information provided how these proposed changes will be implemented and how currently available products will be reviewed, identified or amended. Whilst we see no justification for the proposed changes, any changes should first be reviewed in a collaborative manner and specific categories stratified by risk, with all brands within a low risk categories (e.g. sensitivity toothpastes) being exempted. In determining the suitability and risk-benefit of umbrella branding for other categories due consideration of the negative impact must also be given.

As it is currently presented, proposal 3.5 places a blanket exclusion on look-alike medicine branding across all product categories with no regard for their intended use or their safety profiles. GSK urges consideration the proposal that a process and guidelines be put in place that allows Companies to put forward arguments for retention of look-alike medicine branding on a case-by-case basis.

One of the underpinning principles behind umbrella branding is the ability to focus specific products based on particular attributes of interest to specific consumers. If proposal 3.5 were to go ahead with no further change then this would place unnecessary restriction on a number of different therapeutic categories, e.g. medicated toothpastes for use by people with tooth sensitivity symptoms.

A large number of sensitive toothpaste brands comprise essentially the same active ingredients (e.g. potassium salts for sensitivity relief) but with the inclusion of brand name extensions or qualifiers that aid in consumer selection. In this therapeutic category consumers look first for the brand name they value then select an appropriate product based on secondary preferences and needs (e.g. flavor, whitening, breath-freshening etc). All sensitive toothpaste products are designed to be used in the same manner, whilst it seems highly unlikely that a consumer would select more than one sensitive toothpaste product to tackle different aspects of their oral healthcare (e.g. one for whitening and another for breath freshening).

Whilst the proposal (3.6) that the same brand name cannot be applied to products that have different active ingredients is designed to protect the consumer from medication errors this

may not always be the case. GSK agrees in principle with the proposed regulatory changes but again urges an amendment to enable case-by-case consideration.

Paracetamol as a single active ingredient is indicated for the temporary relief of aches and pains associated with colds and flu. The current regulations permit the situation where a primary brand name contains paracetamol and an umbrella brand has been developed to incorporate a range of products with paracetamol plus additional ingredients to treat other cold and flu symptoms (such as nasal congestion). The consumer, seeking a cold and flu product would recognize the primary brand name and be inherently aware that is contains the same medicine (in this case paracetamol) as the primary brand with additional ingredients to target other cold and flu symptoms. This type of heuristic brand recognition likely circumvents the need to consider purchasing a second paracetamol-containing product. In this instance, removal of the umbrella branding may create more consumer confusion and lead to an inadvertent promotion of doubling up.

Recommendations
GSK is disappointed that the phrase "look-alike medicine branding" has been adopted in the Consultation Paper instead of the widely recognized phrase "umbrella branding". This change in terminology creates an unnecessarily negative and derogatory impression of this practice. The phrase umbrella branding has been used in Australia for many years and continues to be used in many other jurisdictions. GSK requests that this term be used in all future consultations and in any regulatory guidance produced as an outcome of the current consultation process. The proposals for look-alike medicine branding seek to improve consumer safety. However, there are no safety data to substantiate that confusion is enhanced by the use of umbrella brand names provided the products are appropriately labelled and sufficient consumer information is made available. The current proposals may each have a place with some therapeutic categories but should not be applied across all therapeutic categories. GSK proposes consideration of the proposal that processes and guidelines be put in place that allow Companies to put forward arguments for retention of look-alike medicine branding on a case-by-case basis. Such a proposal may best be stratified by risk, with all brands within a low risk categories (e.g. medicated toothpastes, sunscreens etc) being exempted. In determining the suitability and risk-benefit of umbrella branding for other categories due consideration of the negative impact must also be assessed. In order for this to be achieved clear guidelines and protocols would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.

4. STANDARDISED INFORMATION FORMAT: THE MEDICINE INFORMATION BOX

The proposal to standardize the back of the pack to contain a "Medicine Information Box" represents a reasonable strategy that will greatly aid consumers when locating information on the label. Such standardization presents the information in a uniform manner, uses simple to read language and an easy to use format that enables consumers to compare and select OTC medicines and follow the required dosage instructions.

Research conducted to assess the US "Drugs Facts" box suggests that formatting can improve the ease of acquiring important information from a drug label.[15] One of the main reasons is that the standardized label format allows consumers to learn where each of the sections are located which in turn reduces the time needed to find specific information. Other advantages include the use of horizontal lines to separate information under each major heading and use of a bullet point format to list chunks of information.

Notwithstanding this, recent data from the US demonstrates that individuals with low health literacy continue to struggle to read labels; in a recent study nationally representative study of more than 6100 parents 59.2% reported difficulty with understanding OTC medication labels and subjects with below-basic health literacy were 3.4 times more likely to struggle.[16] In addition, US data presented by the TGA in support of specific warning labels for paracetamol products shows that despite the "drugs facts" box having been mandated for almost 15 years only 6% of participants were able to correctly identify the active ingredients in 5 common OTC pain relievers.[17]

GSK agrees in principle with the proposed "Medicine Information Box" standardization and recognizes that some change will be necessary to convert medicines to this new system. However some refinements and caveats need to be accounted for in order to ensure that this system works equally well across all OTC medicines.

A risk-assessment approach should be undertaken with regards to the requirement to have a complete 'Medicines Box', with exclusions being applied to low risk medicines (such a sensitivity toothpastes) given the limited space and the nature of the product.

Title of the box

The visuals provided in the consultation document suggest that a heading "Medicine Information Box" should appear at the top of the label. However, the proposed regulatory changes don't make this explicit. Is it the intention of the TGA that these exact words be used? If so, it might be better to amend this to read "Medicine Information" as the addition of the word "box" is superfluous and takes up white space potentially detracting from the readability of the label.

Order and content of mandatory headings

Proposal 4.1 sets out the mandatory headings that must be included on the label. The rationale for the choice of these specific headings has not been explained in the Consultation Paper. There is some need to test that these headings are useful to consumers.

The current proposed “Warnings and Allergy Information” heading creates a large bulk of text that makes it difficult for the consumer to navigate and find the specific information they require. This issue was addressed by the FDA in designing the Drug Facts box, with the guidelines stating that this section of the label should be further sub-divided (as needed) with the use of sub- headings. Further chunking of the required information in this manner facilitates comprehension by creating shorter sections and breaking up the text.

Following the highly successful comprehension testing of the revised Panadol pack in 2002,[10] such headings as have already been incorporated into the existing labels of many of GSK OTC products. The sub headings currently in use on these packs are short and direct, to reduce ambiguity and provide easy to understand information for the consumer. This work won a National Prescribing Service QUM award.

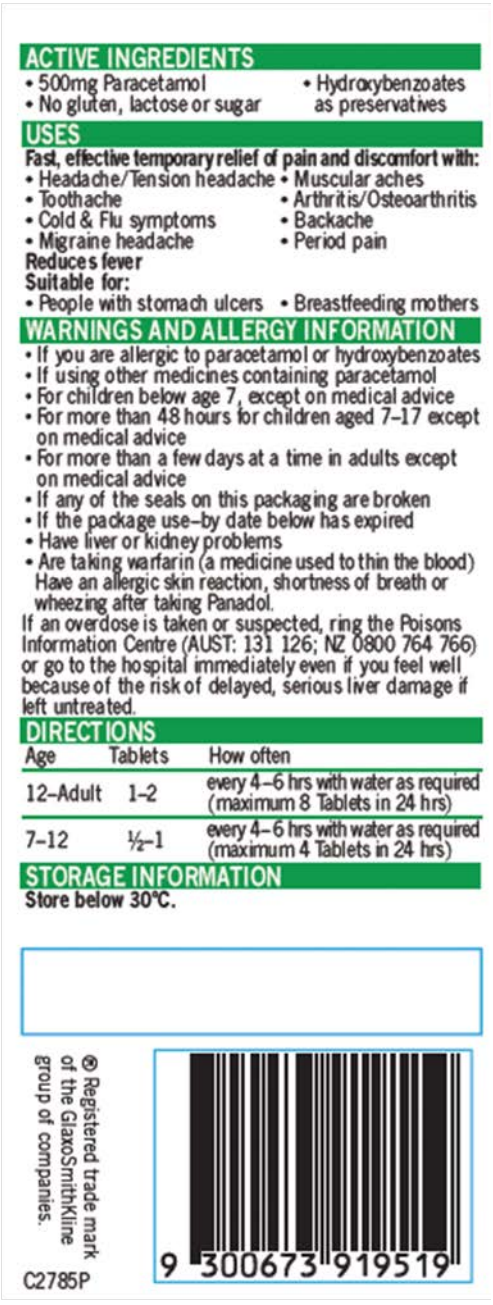
GSK suggests that the proposed regulatory changes may be improved by allowing sufficient flexibility to enable the use of sub-headings or other means of differentiating important information (such as the use of hairlines, bullets and colour contrasts) as and where the label space permits.

A side-by-side comparison of the current and revised back panels of a Panadol® pack, as is presented on the next page, demonstrates that the proposed “warnings and allergy information” heading diminishes the readability of the current label.

The proposed Medicine Information Box obscures important information as it ignores the value of chunking into useful subcategories and the temporal flow of information.

Current

Revised



Design elements

Proposals 4.2 and 4.3 provide stipulate the minimum required font sizes and the formatting of the text permissible in the medicines information box.

High contrast is imperative for readability. However, the use of colour can also enhance the usability of labels; it adds appeal and emphasis, assists in scanning and navigating and

increases identification. GSK asks that some flexibility be permitted, as it is in the US, to enable the title and headings of the Medicine Information Box to be presented in a single, alternative, contrasting color.

Small containers and products with more than 3 active ingredients

Recognizing the limited space availability of the label of some products, proposal 4.6 makes a provision for small packs and products that contain more than 3 active ingredients. Whilst it should be possible, given the suggestion (on page 29) that the font size may be reduced under some circumstances to accommodate the required information, in such instances where this is not feasible the additional requirement of a pack insert will have substantial cost implications.

It is also worth noting that if the intent of the Medicine Information Box is to inform the consumer at the point of purchase having this information contained inside the box where it is inaccessible undermines this goal.

Recommendations
The inclusion of a standardized Medicine Information Box has the potential to improve consumer usage of OTC medicines by providing a familiar format and location for important information. In order to prove the value of the many and varied TGA proposed changes (aspects of which are drawn from numerous jurisdictions), it would be prudent for the TGA themselves to validate the specific combination and order of the proposed wording to ensure that the desired outcomes are achieved. This will be of particular importance to ensure comprehension of the proposed headings. Improvements can be made to the current proposals by allowing some level of flexibility to accommodate sub-headings (particularly where the content of the warning and allergy information section is lengthy) and/or other means of differentiating important information (such as the use of hairlines, bullets and colour contrasts) as and where the label space permits. Limitations, both in terms of cost and practicality for the end-user, need to be factored into any decision to require a printed insert of the Medicine Information Box.

5. BLISTER STRIP LABELLING

The discussion around blister strip labeling has been presented without any data to support that current blister packaging standards pose a risk to public health. The proposed reforms offer some solutions that are unlikely to be practicable (due to font size) and do not take account of the impact of these measures on the manufacturing processes and the entire supply chain.

If implemented as proposed, these regulatory changes could threaten the viability of industry and may result in some medicines being lost to the Australian marketplace, a reduction of the numbers of manufacturers and manufacturers closing down with many jobs going overseas.

There is a danger that the implementation of the proposed changes would result in reverting to cheaper modes of packaging (such loose pills in bottles) to achieve compliance rather than maintain the blister pack requirements. This could ultimately have a negative impact on public health, with data demonstrating the use of blister packs to be associated with reduced mortality from suicide attempts.[18]

Impracticalities of proposed changes to blister pack manufacture

GSK agrees that it is important that the printed blister strip contains the brand name, active ingredients and quantity as well as the batch and expiry date of the medicine. However, proposal 6.1 stipulates that this information must appear at least once every two units.

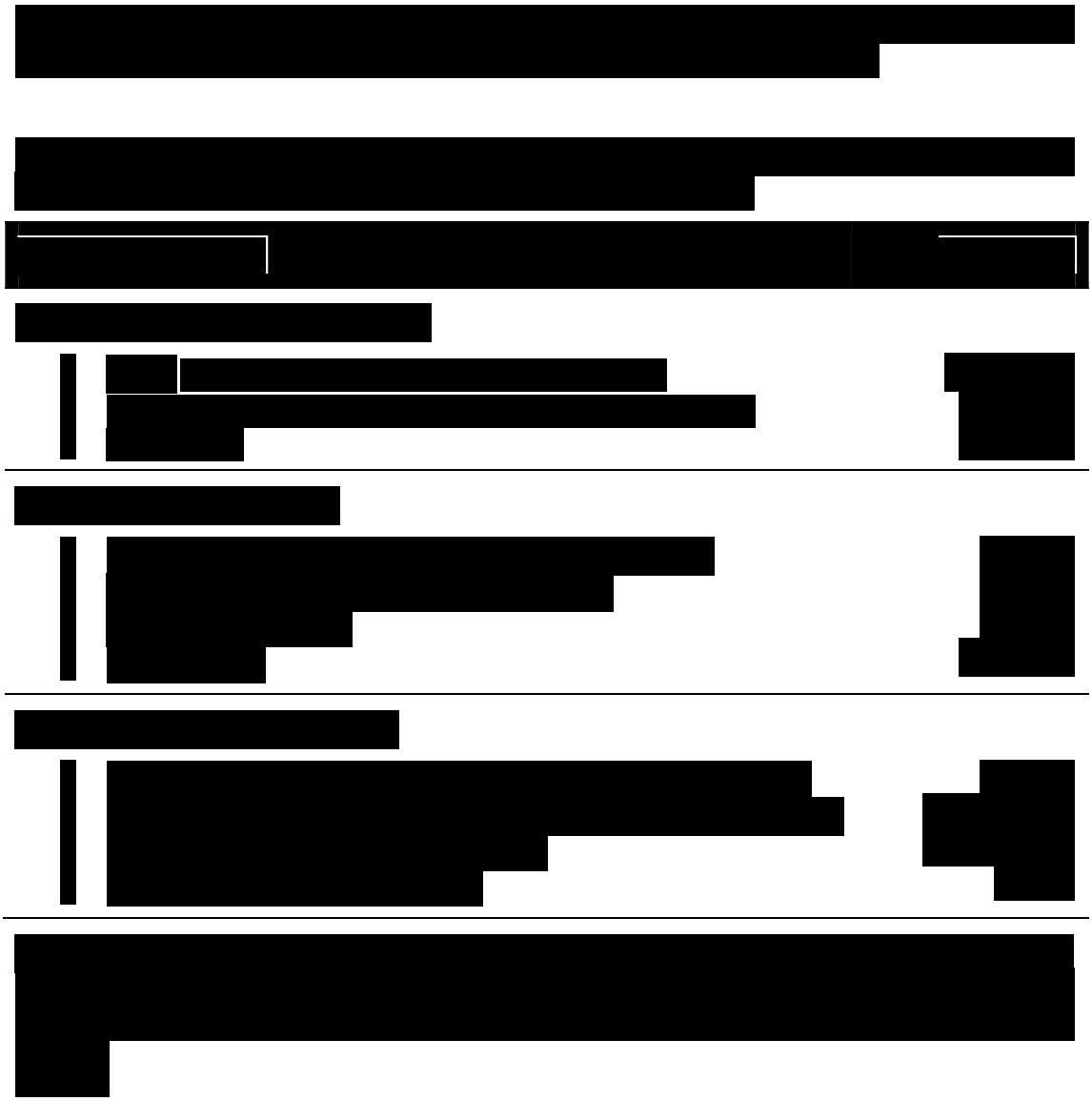
It is already usual GSK practice for the foil covering used in the manufacture of blister packs to be pre-printed in bulk with the brand and active ingredient details at least once every two dosage units. The batch and expiry date information are then printed (or in some cases embossed) onto the blister packs after the doses have been inserted. The current practice is to include this information once per blister strip.

Whilst sourcing a manufacturing plant capable of printing multiple batch and expiry information on a single blister strip is not an impossible task, it presents many practical barriers that would considerably challenge existing manufacturing capacity, slow production and increase costs. Some manufacturers may have access to such equipment, however it may not be practical to use for all lines.

The requirement (at proposal 6.3) to include at least 3 active ingredients on each segment of the blister strip has practical limitations. In order to accommodate this proposal and keep the height of the font to a legible size it will require that the blister package itself is increased in dimensions. This has knock-on effects through the entire supply chain, requiring an increase in the size of the outer packing, larger warehousing space, shipping more pallets and ultimately affecting shelf space and consumer convenience. On the latter point, increasing the dimension of the outer packaging to accommodate a larger blister back could be construed by consumer advocates as representing deceptive packaging.

[redacted]

[*] **Commercial-in-Confidence: Proprietary information pertaining to the manufacture of goods.**



Where the overly burdensome blister labeling proposals in the Consultation Paper to be put in place, it is estimated that a 5 year transition period would need to be applied to accommodate the need for extensive capital works to the plant and its machinery and to make the necessary artwork changes to meet these new requirements.

The Ermington site also manufactures products for different export markets. None of these other markets would need their foils printed in this manner. Thus, there is the potential that these markets might move their sourcing offshore to the detriment of the local economy. Such a reduction in manufacturing volumes would cascade to cost increases as economies of scale are eroded by the loss of export sales.

Additionally, these impacts have a consequential impact throughout the entire supply chain all the way from the wholesaler to the retailer as larger packs mean:

- Fewer packs per pallet
- More pallets shipped (with related increases in transport costs)
- Larger or greater numbers of warehouses to accommodate more stock
- Less product on shelf due to the need to fit larger packs on shelving in Pharmacies and supermarkets (with a related decrease in consumer convenience)

- More frequent ordering (with related administration and transport time costs)

Hence the eventual cost borne by the consumer will likely be considerably more than the increases to the cost of manufacture alone.

Recommendations
The proposed changes to the blister strip have not taken into account the specifics of manufacturing process. Such changes place a considerable financial burden on the manufacturer. The investment required is disproportionate with the costs involved and the perceived consumer safety benefits. More importantly, they are likely to have multiple negative implications for the end users, in terms of increased costs of goods, deceptively increased package sizes and reverting to back to bottle packaging of loose pills. It is unfair to impose such a requirement on the manufacturer where the product is not perforated for the purpose of separating the blisters simply to reward consumers who decide to cut the package up for their own convenience with no consideration of the consequences. Industry has already produced innovative packs (such as handipacks, small bottles etc) to reduce the need for this behavior. GSK proposes that the existing arrangements for labeling of blister strips be retained in line with TG069. Consumers should not be encouraged to separate products. Non-regulatory approaches, such as consumer education, are preferable to mitigate the risks of removing blisters from the primary packaging.

Incongruities of proposed changes to blister pack manufacture

Proposal 6.4 makes a special provision for medicines that contain more than 3 active ingredients. While the example cited is that of a multi vitamin, other medicines exist that would meet this criterion.

The proposal as it currently stands permits such medicines to be in blister packs that contain the brand name, batch and expiry but not the active ingredients. Given the premise for the revised blister strip labeling is to enhance consumer safety, this suggests that products containing more than 3 active ingredients pose less of a consumer safety risk than do those that contain fewer active ingredients.

This apparent disparity gains even more prominence when one considers the packaging of multi-symptom cold and flu preparations with specific day and night time tablets. In such a scenario, the day time product may contain 3 active ingredients (requiring all three ingredients and their quantities to be listed on each segment/each two dosage units of the blister strip) whilst the night time product may contain more than 3 active ingredients and therefore require only the brand name to be printed.

These considerations warrant further consideration to ensure and equitable outcome. The obvious solution would be to maintain the current status quo with respect to blister pack labeling.

Recommendations
The proposed changes with respect to how to manage blister pack labeling for products that contain more than 3 active ingredients do not account for OTC medicines that contain day/night formulations whereby the day formulation contains 3 actives and the night formulation contains 4 actives. This incongruity makes it difficult to understand how any of the proposed changes will be applied.

6. SMALL CONTAINERS

Special provisions have been put in place in an attempt to accommodate the restricted space for information on the labels of small contains (defined as containers that have a nominal capacity of 20 mL or less). There has been no discrimination between the requirements for small packs used in the OTC setting versus those supplied on prescription only.

Clarity is needed over conflicting proposals (7.1) and (4.6)

The proposal (at 7.1) specifies that containers must be enclosed in a primary pack that complies with all the labeling requirements and that also includes a pack insert for detailed instructions. This creates a direct conflict with the earlier proposals relating to the inclusion of the Medicine Information Box on the label of OTC medicines; wherein (at 4.6) there is no such additional requirement for a pack insert other than to accommodate information required on the Medicine information Box that does not fit on the outer packaging.

Clarity is therefore needed as to whether the proposed regulatory changes to small containers applies to all small contains or only to those for prescription medicines that are excluded from the requirements of the Medicine Information Box.

Recommendations
The proposed changes at 7.1 are in conflict with those at 4.6. Clarity as to the specific proposed regulatory changes is therefore needed before an informed comment can be made. GSK is supportive of the proposed changes at 4.6 but does not support the need for inclusion of a detailed package insert, particularly if the outer package label meets the revised regulatory requirements.

Impact on "small containers" that are outside the current nominal capacity of 20mL

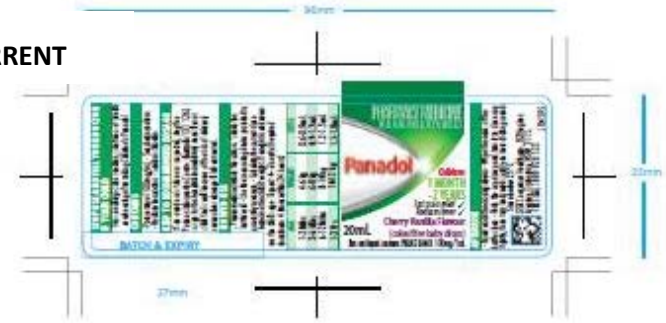
As has previously been addressed, the proposed requirement for the brand name and the active ingredients to be of equal prominence and of the same height obscures the clarity of this required information. This is highlighted even more so on a small container where the label space is already limited. This is especially of concern for those small containers of greater than 20mL nominal capacity.

In the case of Children's Panadol Baby Drops (nominal capacity 25mL), in order to meet the proposed label requirements, using the font heights stipulated, it is necessary to increase the size of the actual label. The current label is 96mm in length, whereas the revised label would need to be 137mm. This is illustrated in the figure below.

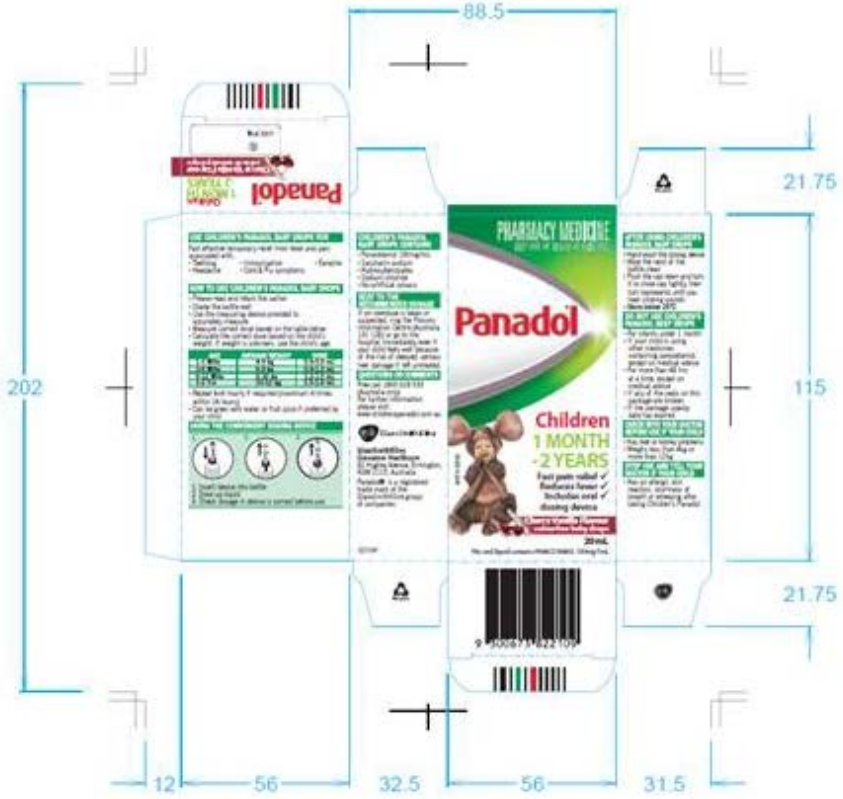
This increase in label size has a substantial knock on impact which is detrimental to public health. A larger label requires a larger bottle. In this particular case the increase in the diameter of the bottle needed to hold the larger label equates to a five-fold increase in bottle size, from 20mL to 100mL. Setting aside a 4-5 fold cost increase, a larger bottle requires either a larger volume of product, which in-turn increases the chances of accidental overdose. If the same volume of product were to be retained then packaging it in a larger bottle presents issues such as deceptive marketing and or stability problems due to too large a head space.

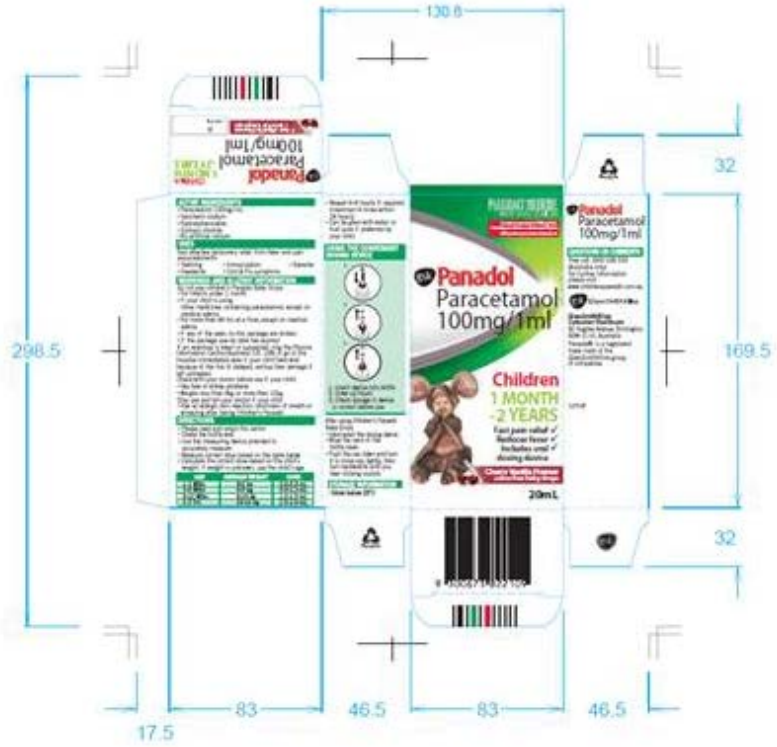
Current bottle label of Children's Panadol Baby Drops drawn to scale to show the large increase in label size required to accommodate the proposed regulatory changes.

CURRENT



REVISED





REVISED

CURRENT

Recommendations
The TGA proposals for prominence of actives and 2.0mm headlines in the Medicines Information Box would force an unnecessary increase in the size of the label of OTC medicines in small containers above the 20mL nominal capacity. The TGA should consider extending exemptions beyond the proposed limit to allow important products in therapeutically relevant pack sizes to remain available to the consumer.

7. PACK INSERTS

GSK agrees in principle that advertising material per se should not be permitted to be included in packs as separate inserts and that the pack insert must be in a form separate to the packaging. However, further guidance is required as to what constitutes “advertising material” in this context.

Package inserts provide a valuable route of consumer education

Additional information is currently included in a number of medicines packs for the purposes of consumer health education. Such purposes include, but are not limited to:

- Materials to enable consumers to register for patient support programs which are an invaluable adjunct to enhancing medication efficacy and compliance. A particular example is that of smoking cessation. Published data shows that consumers who are provided with self-help programs tailored to their specific needs have a higher chance of quitting, enhancing quit rates over and above nicotine replacement therapy alone.[19, 20] Instructions on how to enroll into such self-help programs is provided via package inserts so it is readily accessible to the consumer when they start to use this medicine.
- Materials to educate consumers about the condition for which they have purchased the medicines are an important means of helping consumers to understand their symptoms and adopt self-help strategies to circumvent future episodes. For example it may be helpful to describe other measures the patient should take to control symptoms (e.g. for a histamine H2-receptor antagonist, other ways to reduce heartburn). Such an approach is supported by the World Health Organization in its published **Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication**: "I*n addition to approved package inserts and leaflets wherever available, the preparation and distribution of booklets and other informational material for patients and consumers should be encouraged as appropriate*."[3]
- Materials to educate patients about the safe use of their medication. The FDA has recently announced new measures to help educate patients about the safe use of narcotic analgesics.[4] As part of this risk management plan, the FDA wants companies to give patients education materials, including a medication guide that uses consumer friendly language to explain safe use and disposal.

A total exclusion of any material (other than the CMI or Medicines Information Box) may be to the detriment of public health as it would prohibit the use of the pack as a means of conveying useful educational material to the consumer.

Recommendations
Pack inserts represent a valuable means of providing much needed education to consumers at a point when they are most receptive to such information. They provide an avenue for consumers to enroll into patient support programs that can enhance their treatment and aid in crucial issues such as medication compliance. The WHO supports the use of package inserts as a viable means of educating consumers[3] and the FDA has recently announced its intentions to harness this avenue of communicate to better educate consumers about the safe use of opioid analgesics.[4] Any restrictions to the provision of this information must be carefully balanced against any unintended impact on public health.

8. LABELS AND PACKAGING ADVISORY COMMITTEE

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. GSK is not opposed to this concept, in principle, provided that there is adequate guidance on the scope and conduct of such a committee. The composition of the committee should be such that it ensures an appropriate balance between regulators, external experts and industry thereby aiding to maintain a viable and responsible medicines industry.

Recommendations
It is paramount that clear guidelines and protocols be established that are particular to OTC medicine selection and use to act as terms of reference to aid the Committee's deliberations and to aid industry in complying with any revised regulations relating to packaging and labeling. Given the inherent complexities of package design and product manufacture it is clearly evident that the composition of the proposed advisory committee should be balanced such that views of tertiary-qualified packaging and manufacturing specialists who not only bring a wealth of academic learning but also many years of experience in these areas can be tabled and considered at the earliest stages of deliberation. Such a committee should serve in an advisory capacity only and should not overrule these guidance materials.

9. SUMMARY AND OVERVIEW OF OPINION ON RECOMMENDATIONS

The following table has been developed to provide an at-a-glance summary of the opinions and recommendations of GSK Consumer Healthcare relating to each proposed regulatory change. For ease of reference, the numbering system used in the consultation document has been replicated here.

Proposed regulatory change	General opinion	Recommendations
Prominence of active ingredients on medicine labels		
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	Agree that standardized location may be of some benefit.	GSK proposes that having the active ingredient in a block in a standardized position along the baseline of the front of pack, thus retaining a consistent approach irrespective of where the brand name appears on the pack.
1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name. 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. 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. 1.2.3 For improved differentiation between the brand name and the active ingredient	Disagree, equal font size does not equate to improved comprehension. More flexibility is required.	GSK proposes that a font size at least one-quarter as large as the size of the most prominent matter on the primary display label or a minimum of 1.5 mm be retained. GSK proposes that flexibility of label design should be enabled to allow optimal use of typefaces, colour and upper/lowercase text. GSK proposes that no mandatory restrictions should be put in place regarding the use of capital and small lettering in order not to prevent the use of tallman lettering on labels.

there should be a difference in font style or letter spacing or font colour. 1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.		
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.)	Disagree, may cause consumer confusion. Abundance may not equate to the clinical usefulness of the product.	GSK proposes that multi-ingredient products could be more effectively labeled with a simple statement saying "*See Medicines Information Box for a complete list of active ingredients in this product*", or words to that effect.
1.4 For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be no less than 2mm in height on the main/front panel.	Agree that this information is important but the font size is too big	GSK proposes that a minimum height of 1.5 mm, per TG069, be retained to accommodate this information on the front of pack.
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.	Disagree, equal font size does not equate to improved comprehension. More flexibility is required.	GSK proposes that some flexibility be allowed repeating the information as often as space allows, with a mandated minimum of it appearing on the front label and one additional face of the packaging.

1.6 Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging: "Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products."	Agree that warning statements are important, but the front of pack is not the most appropriate place. Wording too permissive and less explicit than current RASML statement.	Evidence, published from research undertaken at Michigan State University, demonstrates that consumers neither see nor recall required warnings on the front of the pack.[1] GSK proposes that revising the warning to be similar to that used in other markets; e.g. "*Contains paracetamol. Do not take any other paracetamol-containing products*" is appropriate provided the statement is placed on the back of pack in a familiar position where it can be located and recalled.
1.7 Non-prescription medicines that contain ibuprofen must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging: "Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."	Agree that warning statements are important, but the front of pack is not the most appropriate place. Wording too permissive and less explicit than current RASML statement.	GSK proposes that the current RASML wording is more appropriate and should be provided on the back of pack in a familiar position where it can be located and recalled.
Look-alike sound-alike names and look-alike packaging		
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	Agree that this provides a reasonable starting point, but places an unnecessary burden of expense on the sponsor.	GSK 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. It is of note that in other countries extensive review of proposed drug names is undertaken by the regulator and not the sponsor.

methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names.		
3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), i**f 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.	Disagree, assessment criteria do not take phonologic similarities into account.	GSK feels strongly that this area requires more in depth exploration, particularly with regard to how the TGA may adopt the use of algorithms that enable both orthographic and phonologic evaluation of proposed drug names.
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.	Disagree, assessment criteria do not take phonologic similarities into account.	GSK feels strongly that this area requires more in depth exploration, particularly with regard to how the TGA may adopt the use of algorithms that enable both orthographic and phonologic evaluation of proposed drug names.
Look-alike medicine branding (umbrella branding)		
To reduce the risk of consumer confusion and medication errors caused by look-alike medicine branding, the TGA proposes the following	Strongly disagree. There are no safety data to substantiate that	GSK proposes consideration of the proposal that a process and guidelines be put in place that allows Companies to put forward arguments for retention of look-alike medicine branding on a case-

regulatory options: 3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine. 3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom. For example: Products cannot be marketed as "BRAND headache", "BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity. 3.6 The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met: a. The active ingredients are closely related (e.g. different salts of the same pharmaceutical chemical), and b. The safety profile, efficacy and dosage regimen are similar. Examples of the application of the above requirements include: A brand name that has historically been strongly associated with a particular anti-histamine would	confusion is enhanced by the use of umbrella brand names provided the products are appropriately labelled and sufficient consumer information is made available. The current proposals may each have a place with some therapeutic categories but should not be applied across all therapeutic categories.	by-case basis. Such an amendment may best be stratified by risk, with all brands within a low risk categories (e.g. sensitivity toothpastes and sunscreens) being exempted. In determining the suitability and risk-benefit of umbrella branding for other categories due consideration of the negative impact must also be assessed. In order for this to be achieved clear guidelines and protocols developed in collaboration with industry would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.

not be permitted to be used for a new product with a different type of active ingredient, such as a corticosteroid or a different anti-histamine. A well known combination product that contains paracetamol under a particular umbrella brand name would not be able to use this same umbrella brand name for another combination product that also contains ibuprofen.		
Standardised Information Format: The Medicine Information Box		
4.1 Mandated information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardised Medicine Information box, based on the US FDA Drug Facts box. The mandatory headings are: • Active ingredient, including the amount in each dosage unit • Uses (indications) • Warnings and Allergy Information (including when the product should not be used and when to consult with a doctor of pharmacist. This section also includes information about possible side effects and substances or activities to avoid. The final lines of this section should include information about preservatives in the product.)	Agree, this concept has merit and has the potential to improve consumer usage of OTC medicines by providing a familiar format and location for important information.	In order to prove the value of the many and varied TGA proposed changes (aspects of which are drawn from numerous jurisdictions), it would be prudent for the TGA themselves to validate the specific combination and order of the proposed wording to ensure that the desired outcomes are achieved. This will be of particular importance to ensure comprehension of the proposed headings. GSK proposes that some improvements can be made to the current proposals by allowing some level of flexibility to accommodate sub-headings (particularly where the content of the warning and allergy information section is lengthy) and/or other means of differentiating important information (such as the use of hairlines, bullets and colour contrasts) as and where the label space permits. GSK proposes that a risk-assessment approach be undertaken with regards to the requirement to have a complete 'Medicines Box', with exclusions being applied to low risk medicines such a sensitivity toothpastes given the limited space and the low-risk nature of the product.

• Directions/Dosage instructions • Storage information.		
4.2 The font height for information must be no smaller than 1.5mm, with heading height at least 2mm.	Partially agree There is no TGA justification provided to apply the 2.0mm headline.	GSK partially agrees with the proposals made in for far as they are in line with the current guidance provided in TG069.
4.3 The Medicine Information Box must have a white background with black text. Headings must be highlighted or bolded so they are sufficiently emphasised.	Disagree, the use of colour can also enhance usability of labels; it adds appeal and emphasis, assists in scanning and navigating and increases identification.	GSK proposes that some flexibility be permitted, as it is in the US, to enable the title and headings of the Medicine Information Box to be presented in a single, alternative, contrasting color.
4.4 Where there is insufficient room on a single face of a package, the box may be split over more than one face. However, the overall format of the information is to remain the same. In these instances a pack insert may also be included containing the Medicine Information Box as a continuous table.	Disagree, pack insert undermines the intent of the Medicine Information Box, which is to inform the consumer at the point of purchase.	GSK proposes that where space is insufficient then the minimum information be included and a variation in the font size be permitted if necessary, as has been proposed by the TGA (at 4.6)
4.5 Information about the presence in the medicine of an allergen listed in Schedule 1 of TGO 69, which may be amended, must be included under the heading Warnings and Allergy	Partially agree	GSK agrees in principle with the proposals made. However, we note that when all information proposed under this heading is considered it creates a large bulk of text that might be better dealt with through the use of sub-headings.

Information.		
4.6 For products containing more than 3 active ingredients, or products in small containers, there may be insufficient space on the medicine container or primary packaging for a complete Medicine Information Box. In these cases a complete Medicine Information Box should be included as a pack insert. The minimum information to be included on the label will include information under the following headings: • Directions • Warnings and Allergy Information. Where space restrictions do not allow for the required information to be provided in the Medicine Information Box, an alternative arrangement or formatting of information should be provided to the TGA for assessment and approval, together with a justification for non-standardised presentation. This may include breaking the information over more than one panel, or reduction in font size.	Disagree, pack insert undermines the intent of the Medicine Information Box, which is to inform the consumer at the point of purchase.	GSK prefers the approach of a minimum information and a variation in the font size be permitted if necessary.
Dispensing label space		
5.1 A designated space of 70 x 30mm, consistent with international best practice, must be provided to accommodate the dispensing label. 5.2 Where a clear space is not practical due to	Agree	GSK agrees in principle with the proposals made. Please note that in proposal 7.3 this area is designated as being 80 x 40mm in area. **The two sizes need to be reconciled.**

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. 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.		
Blister strip labelling		
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.	Strongly disagree The proposed changes to the blister strip have not taken into account the specifics of manufacturing process. Such changes place a considerable financial burden on the manufacturer.	GSK proposes that the existing arrangements for labeling of blister strips be retained in line with TG069.
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	Strongly disagree It is unfair to impose such a requirement on the	Consumers should not be encouraged to separate products. Non-regulatory approaches, such as consumer education, are preferable to mitigate the risks of removing blisters from the

appear on each segment.	manufacturer where the product is not perforated for the purpose of separating the blisters simply to reward consumers who decide to cut the package up for their own convenience with no consideration of the consequences.	primary packaging.
6.3 A maximum of 3 active ingredients should be listed on each segment / each 2 units of a blister strip for registered medicines.	Strongly disagree	GSK proposes that the existing arrangements for labeling of blister strips be retained in line with TG069.
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.	Agree	GSK agrees in principle with the proposals made.
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	Agree	GSK agrees in principle with the proposals made.

and expiry date in a single location.		
Small containers		
The following requirements are proposed for medicine containers with a nominal capacity of 20 millilitres or less: 7.1 These containers must be enclosed in a primary pack that fully complies with all labelling requirements and that includes a pack insert that provides detailed instructions for use.	Strongly disagree	GSK is supportive of the proposed changes at 4.6 but does not support the need for inclusion of a detailed package insert, particularly where the outer package label meets the revised regulatory requirements.
7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres: • The brand name of the medicine • The name(s) of all active ingredients in the medicine • For ophthalmic preparations the name of any antimicrobial preservatives in the medicine • Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert	Disagree, in order to meet the proposed label requirements for small container it may be necessary to increase the size of the actual label. The TGA proposals for prominence of actives and 2.0mm headlines in the Medicines Information Box would force an unnecessary increase in the size of the label of OTC medicines in small containers above the 20mL nominal capacity.	GSK proposes that the TGA should consider extending exemptions beyond the proposed limit to allow important products in therapeutically relevance pack sizes to remain available to the consumer.

• The batch number of the medicine • The expiry date of the medicine • If an injection, the approved route of administration • If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened.		
7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. This space need not be the size of a standard dispensing sticker (80 x 40 mm), but should allow a folded sticker to be attached like a flag without obscuring information.	Agree	GSK agrees in principle with the proposals made, noting that they are applicable only to prescription medicines. Please note that in proposal 5.1 this area is designated as being 80 x 30mm in area. **The two sizes need to be reconciled.**
Pack inserts		
8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.	Disagree, pack inserts represent a valuable means of providing much needed education to consumers at a point when they are most	GSK proposes that package inserts with a valid educational intent, such as patient support programs, should continue to be allowed.

	receptive to such information.	
8.2 A pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.	Agree in principle, but flexibility should be allowed.	GSK agrees with the proposal to prohibit printing direct onto the inside of pack. However, clarification should be provided to ensure that this does not preclude use of innovative technological approaches such as pre-attaching printed information to the inside of the carton.
Labels and packaging advisory committee		
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.	Agree	GSK proposes that clear guidelines and protocols be established that are particular to OTC medicine selection and use to act as terms of reference to aid industry in complying with any revised regulations relating to packaging and labeling. Given the inherent complexities of package design and product manufacture the composition of the proposed advisory committee should include tertiary-qualified specialists who not only bring a wealth of academic learning but also many years of experience in these areas. Such a committee should serve in an advisory capacity only and should not overrule these guidance materials.

10. REFERENCE MATERIALS

Copies of reference materials can be made available upon request.

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