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24 August 2012

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

Dear Sir/Madam

Re: TGA Medicine Labelling and Packaging Review: Consultation Paper

Pfizer Australia would like to thank the TGA for the opportunity to comment on the proposed packaging and labelling reforms presented in the TGA Medicine Labelling and Packaging Review Consultation Paper (May 2012).

Pfizer Australia is a member of Medicines Australia (MA), the peak industry body for innovative medicines in Australia. Pfizer supports the position held by MA on the Medicine Labelling and Packaging Consultation Paper.

In addition to the comment enclosed, Pfizer raises the following key points for consideration:

- The Consultation Paper combined prescription and non-prescription medicine packaging and labelling recommendations. However, this generalised approach does not reflect the complexity of the labelling requirements for these two groups. Pfizer has therefore addressed the recommendations relating to prescription medicine in this response. The Pfizer Consumer Healthcare (PCH) division intend to respond separately to this consultation.

- Pfizer suggests the TGA further consider how the packaging and labelling recommendations in the Consultation will be developed with the framework of, and transition to, the ANZTPA joint agency.

- Mandatory requirements for packaging and labelling of medicines need to assess the evidence that demonstrate to what extent a manufacturer's package or label may contribute to medication error, and whether packaging and labelling reforms will reduce the incidence of such errors.

The following comments address the consolidated list of recommendations provided in Appendix 1 of the Consultation Paper:

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.

Pfizer has no objection to evidence-based changes that improve readability of a medicine label. However, for products with limited space, multiple active ingredients, or differentiating fonts, it may not be possible to align the first letter of the active ingredient with the first letter of the brand name.

Therefore, Pfizer does not agree with the recommendation that the first letter of the active ingredient must be aligned immediately below the first letter of the brand name.

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.

Further clarification should be provided for the definition of "equal prominence" as it could be confused with equal size, even if this is not the intent.

TGA Best Practice Guideline on Prescription Medicine Labelling currently addresses this item appropriately by requiring that the active ingredient and brand name should be prominently and equally displayed.

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.

The intent of this recommendation is to improve visibility of the active ingredient by increasing the size of the active ingredient to 100% of the brand name. Pfizer agrees the prominence of the active ingredient name is important for product identification; however the following need to be considered in relation to the space available:

- the length of AANs, for example, pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed and meningococcal serogroup C conjugated vaccine, will dictate the size of the brand on the pack.
- the requirement to include up to three actives in the front panel for multi ingredient preparations
- the fact that SUSMP legislation regulates on the position, lay out, font type and size of the signal heading and addition of the statement KEEP OUT OF REACH OF CHILDREN.

Increasing the font size of the active ingredient name to 100% of the brand name would frequently require a reduction in the brand name size due to space constraints, rather than a proportional increase to the size of the active ingredient name. Accordingly, the SUSMP signal heading size would also be affected. Pfizer believes it is not the intent of this recommendation to impact the size of the SUSMP signal headings, as this is clearly not in the best interest of public health.

It is essential that such changes be subject to independent readability testing. Undoubtedly, for small containers ($\leq$20 mL), and products with more than one active ingredient, this recommendation will reduce label clarity and ease of identification.

Possible alternatives to the proposed 100% font size should also be evidence-based, and might include:

- The font size of the active be no less than 25% of the height of the brand
- Using a similar approach to that taken for determination of signal headings (SUSMP) – the active ingredient to be 50% of the height of the brand name to a maximum of 6 mm.
- Text size proportional to the available letter height.
- Use of other techniques such as colour, font style and letter spacing to differentiate between brand name and active ingredient (as per Recommendation 1.2.3)

Pfizer believes TGA Best Practice Guideline on Prescription Medicine Labelling currently addresses the font size of the active ingredient name appropriately by requiring that the active ingredient and brand name should be prominently and equally displayed.

1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour.

Pfizer has no objection in principle, however further detail on the risk benefit profile of this proposal is needed.

1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.

Brand names usually start with an upper case letter, therefore it is unclear how introducing an upper case letter for the active ingredient improves differentiation between the active ingredient and the brand name.

Pfizer believes Recommendation 1.2.3 already addresses differentiation between brand name and active ingredient, by introducing a difference in font style, colour or letter spacing.

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.)

Further clarification needs to be provided on the definition of "most abundant ingredient" as an ingredient may not have the most quantitative amount in the product, but due to its potency, may be the "most abundant". Furthermore, how would a Sponsor reconcile the relative abundance of ingredients whose contents are listed as IU as opposed to mg amounts?

This requirement would result in the remaining text on the main label being compromised for space and will cause congestion and cluttering of the main panel. In addition, patients may be inclined to rely solely on the ingredients list on the front panel and neglect to check the full list elsewhere on the label.

Pfizer believes the existing TGO 69 requirements appropriately address this point.

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 2 mm in height on the main/front panel.

The Pfizer Consumer Healthcare (PCH) division have responded separately to this recommendation on behalf of Pfizer Australia Pty Ltd.

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.

Further clarification is sought on the definition of "equal prominence" and "non-opposing", as a carton design implies all faces are opposing.

This recommendation also does not consider products without a carton such as medicines supplied in bottles, tubes, sticks, canisters, sachets, etc, and will also pose an issue for small containers in small cartons where space is already limited.

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 1.5 mm 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."

The Pfizer Consumer Healthcare (PCH) division have responded separately to this recommendation on behalf of Pfizer Australia Pty Ltd.

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 1.5 mm 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."

The Pfizer Consumer Healthcare (PCH) division have responded separately to this recommendation on behalf of Pfizer Australia Pty Ltd.

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 methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names.

The requirement to submit the risk assessment will cause an onerous additional expense to the Sponsors of new medicines and should be taken into account. Pfizer has no objection in principle, however further detail on the benefit risk profile of this proposal is needed.

If this recommendation does proceed, then robust guidance should be provided by the TGA. Pfizer is keen to continue working with the TGA in the development of such guidance as packaging and labelling reforms progress.

3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements.

Sponsors currently do not have access to an electronic screening tool that would enable detection of proposed brand names with such letter similarity, and would not be able to detect brand names for new medicines currently under evaluation and not yet approved by TGA. Clarification is also needed regarding the above definition of LASA names as being those that differ by three letters or fewer. For example, there is no difference between the letters in "Advil" and "Livda", or "Viagra" and "Avigra", however they do not look alike or sound alike.

Pfizer does not object to Recommendation 3.2 that a new medicine brand, which differs from another product on the ARTG by three letters or fewer, would use contrasting colour and design to differentiate from the existing product. This measure may to help reduce the risk of dispensing and medication errors.

In practice, how will the TGA facilitate the requirement for Sponsors to differentiate impacted new medicine label and packaging? For S2 and S3 medicine, Sponsors could access existing product packaging through community pharmacy, however packaging for existing S4 and S8 prescription medicines are not generally accessible.

Will the TGA provide a copy of the packaging and container label of the existing look-alike/sound-alike product/s to the Sponsor of the new medicine to enable differentiation?

Does the TGA intend for registered product packaging and labelling to be accessible on eBS, similar to that for veterinary medicines online via APVMA/Infopest, to assist Sponsors to differentiate packaging for impacted new medicines?

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.

As discussed for Recommendation 3.2, the accessibility of packaging for existing products on the ARTG will need to be addressed for this measure to be effective. For two or more existing products whose brand names differ by three letters of fewer and whose packaging does not contrast, how would the TGA determine which existing product should change its packaging colour and design?

In the future this matter would no longer be an issue as the TGA would reject proposed LASAs based on electronic screening, as Sponsors would not have the ability to do this.

Look-alike medicine branding

To reduce the risk of consumer confusion and medication errors caused by look-alike medicine branding, the TGA proposes the following regulatory options:

3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.

This recommendation would require an export only medicine, as an AUST L product, to have a different trade name to registered medicines marketed locally.

In addition, this recommendation will also impact medicine kits. A medicine kit is an AUST L, however these kits may contain AUST R products. Further information is needed as to whether kits that include AUST R products will be impacted by being listed under the same brand name.

Pfizer would appreciate further clarification on this recommendation and how it is intended to apply to export only medicines and medicine kits.

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.

The Pfizer Consumer Healthcare (PCH) division have responded separately to this recommendation on behalf of Pfizer Australia Pty Ltd.

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.

The Pfizer Consumer Healthcare (PCH) division have responded separately to this recommendation on behalf of Pfizer Australia Pty Ltd.

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.)**
- **Directions/Dosage instructions**
- **Storage information.**

4.2 The font height for information must be no smaller than 1.5 mm, with heading height at least 2 mm.

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.

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.

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 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.

The Pfizer Consumer Healthcare (PCH) division have responded separately to Recommendations 4.1, 4.2, 4.3, 4.4, 4.5 and 4.6. on behalf of Pfizer Australia Pty Ltd.

Dispensing label space

5.1 A designated space of 70 x 30 mm, consistent with international best practice, must be provided to accommodate the dispensing label.

Pfizer does not object in principle to this recommendation, however, Pharmacists should be educated in the practice of applying these labels to the space provided.

For products administered in a hospital setting directly to the patient, such as specialist IV medicines, the requirement for a dispensing label box has no benefit with respect to Quality Use of Medicine and medicine safety. This recommendation should only apply to those products that will be dispensed to a patient, for example via community pharmacy.

5.2 Where a clear space is not practical due to constraints from packaging size and shape, the information should be arranged so that information that is likely to be obscured is the same as the information repeated on the label. The area for placement of the sticker should be illustrated by corner placement marks on the packaging.

Pfizer does not object in principle to this recommendation, however, Pharmacists should be educated in the practice of applying these labels to the space provided.

For medicine labelling where the main and back panels are identical, corner placement marks should not be necessary as it does not matter on which panel the dispensing label is placed.

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.

Pfizer does not object in principle to this recommendation, however, Pharmacists should be educated in the practice of applying these labels to the space provided.

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.

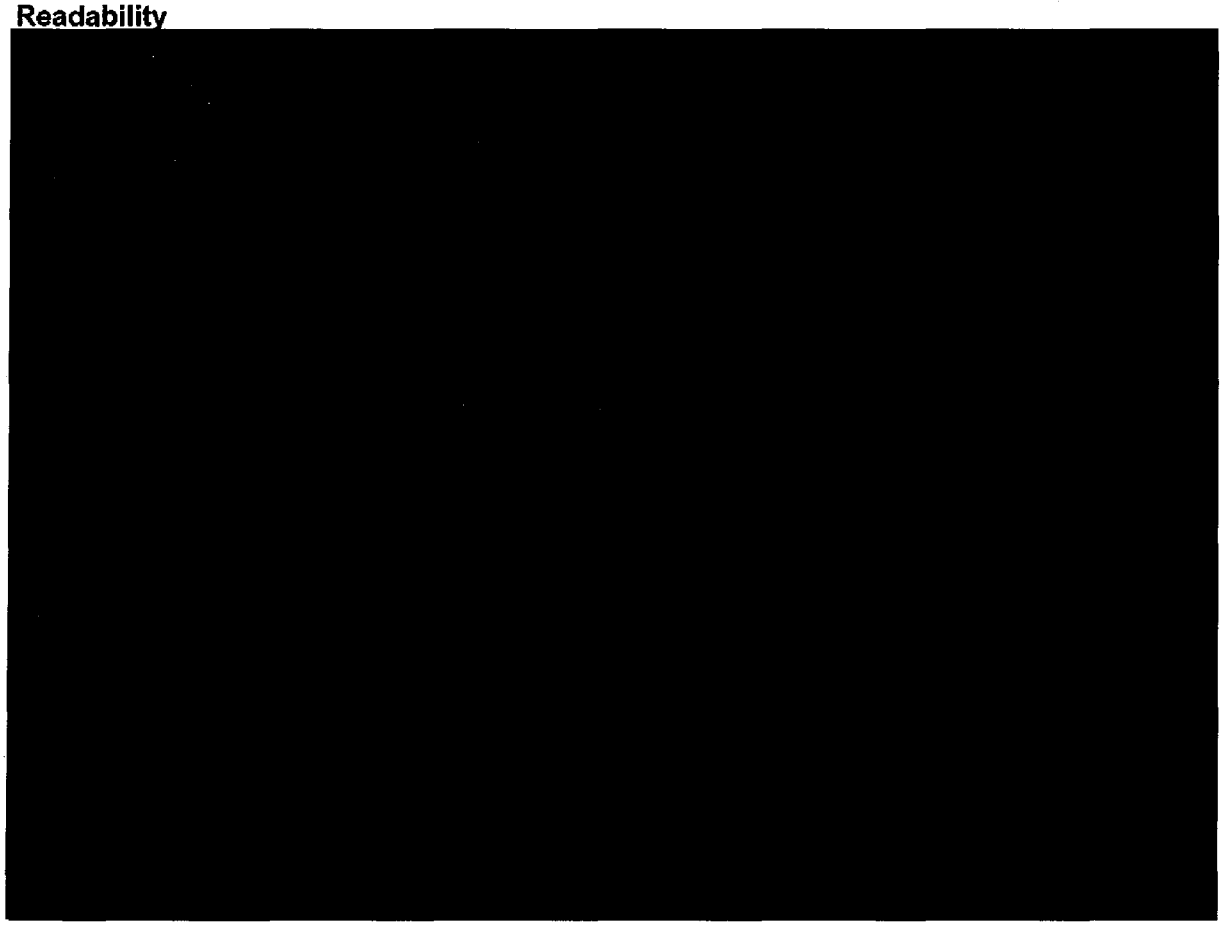
6.2 Where strips can be segmented, the brand name, the active ingredient and amount of active ingredient, batch number and expiry date is to appear on each segment.

Pfizer does not agree with Recommendations 6.1 and 6.2. The issues are common to both proposals, and have thus been addressed as a single response.

Sponsors go to considerable effort to ensure product packaging presents all relevant medicine information in a manner that is clear and useful for the safety of the patient. Repetition of the brand name, active ingredient name and quantity, batch number and expiry date every segment/every two blister units is not reasonable and will serve only to support the storage of blisters away from the carton. Such a practice should be discouraged, not encouraged, as it may compromise safe use of medicines. The recommendations have also not considered that the foils include additional information such as Sponsor logo, component number and trademark information.

In addition to the detrimental impact on Quality Use of Medicine, Pfizer has identified several concerns regarding the proposed changes to the printing of foil blister strips in accordance with Recommendations 6.1 and 6.2.

Readability



[redacted]

Implementation

[redacted]

[redacted]

Inconsistency with requirements for different packaging presentations
Pfizer does not believe Recommendations 6.1 and 6.2 consistently address container labelling for dosage forms that utilise blister packs. For example, the creation of a calendar or Webster pack by a Pharmacist requires equal diligence when dispensing drug product, however the patient has no way of checking the batch or expiry information provided in the primary pack from the manufacturer.

The TGA Consultation document states "*Often blister strips are stored away from their outer wrapping or packaging that contains the information about how to use the medicine safely. For example, it is not uncommon for people to carry a blister strip in their handbag, purse or travel bags without the primary container.*"

While blister labelling is emphasised, the recommendations do not consider the same potential issue for bottle packs. The medicine information is not provided per unit dose; however the dose form can just as easily be removed from the outer pack/primary container and separated from identifying details and instructions for use.

Packaging Covenant
Pfizer is a signatory to the Packaging Covenant. A key element in this document is the commitment to 'avoid or minimise the use of materials and other resources' (Table 1, page 6). The proposed printing of batch specific information would make adhering to this extremely difficult for the following reasons:

- Excess foil would need to be printed if off line printing was used. If this foil was not used in the packaging process it would then become waste as it has batch detail printed on it.
- The set up of on-line foil printing will create additional waste at the line set-up stage when the printing and blister pockets are lined up on the machine.
- The effects of foil 'wander' would create increased waste, because if the blister details are not fully printed over the blister pocket the blister is then rejected.
- Any changes to blister size would use excess foil and plastic film. This would increase the amount of non-recyclable waste and not meet the requirements of 'Minimise materials' (Table 3, page 22)

Pfizer does not support Recommendations 6.1 and 6.2. As shown in Appendix 1, the necessary compression of text across every segment/every two blisters creates readability difficulties due to the knurl. Increasing the information on the blister also encourages separation of the blister from the outer packaging, which has no benefit to patient safety.

These recommendations have significant and long term capital investment implications, as well as production, logistics and compliance impacts for Sponsors. The requirement for repetition of the brand name, active ingredient name and quantity, batch number and expiry date every segment/every two blister units is not supported by evidence of reduced medication error and improved patient safety, and is therefore not reasonable. Pfizer remains committed to evidence-based regulatory reforms to medicines labelling and packaging that will improve patient safety and reduce medication errors.

6.3 A maximum of 3 active ingredients should be listed on each segment/each 2 units of a blister strip for registered medicines.

Pfizer does not object in principle to this recommendation, however as described in the response to Recommendations 6.1 and 6.1 consideration must be given to the significant space constraints on blister strips. Further detail from TGA on the benefit risk profile of this proposal is needed.

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.

Pfizer has no objection in principle, however further detail on the benefit risk profile of this proposal is needed.

For oral contraceptives and other medicines that have a "race track" format to support their safe use, the TGA proposes the following requirement:

6.5 Blister strips that have a "race track format" must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location.

Pfizer has no objection in principle, however further detail on the benefit risk profile of this proposal is needed.

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.

The recommendation that all small containers include a pack insert should be further clarified. What content would the pack insert include? Does the TGA suggest the CMI be provided as the pack insert? Under the existing arrangement the CMI should already be provided to patients by the Pharmacist when the medicine is dispensed.

In many cases the outer carton of a small container would necessitate an increase in size to accommodate a pack insert. The consequences of this change would include an impact on the production line to adjust for a non-standard outer carton, and a related increase in cost of goods.

Furthermore, many medicines in small containers supplied to Australia are produced for the global market, of which Australia is a very small portion. Australian-specific pack dimensions, particularly for specialist low-volume medicines, are likely to introduce challenges for production scheduling, consequently impacting supply flexibility and a manufacturer's ability to respond to situational need.

Finally, if there is a dispensing label attached with instructions on dosage and directions for use and the expiry period upon opening, then a pack insert containing detailed directions for use should not be required.

An assessment of the benefit risk profile of this proposal should be conducted once the purpose and content of the pack insert is further defined. Pfizer remains committed to evidence-based regulatory reforms to medicines labelling and packaging that will improve patient safety and reduce medication errors.

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**
- **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.**

The recommendation that the above information must be included on the primary label for a small container is not reasonable, particularly for very small containers such as eye drops or ampoules, where the container volume is frequently less than 5 mL.

Generally, the volume of information proposed would make it very difficult, if not impossible to include on a primary label for a small container label at a minimum 1.5 mm letter height. Please provide evidence to Industry that such a label has been tested for patient readability and comprehension.

Reference is also made to the previous comment for Recommendation 1.3 regarding the definition of the "most abundant" ingredient and how this would be addressed for this recommendation.

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.

Pfizer has no objection to this recommendation. The Company notes the standard dispensing sticker was previously defined as 70 x 30 mm under Recommendation 5.1 of this Consultation, which is inconsistent with the dimensions 80 x 40 mm cited here.

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.

Pfizer notes the existing agreement between Medicines Australia members and the TGA which permits the inclusion of a Patient Support Program (PSP) enrolment form as a pack insert. The existing agreement stipulates the PSP pack insert must not be promotional and must state the PSP is not approved or authorised by the TGA.

Recommendation 8.1 pertains to the inclusion of advertising material as a pack insert. The Company understands that it would therefore not impact PSP pack insert enrolment forms which are not promotional, and so does not object to this recommendation.

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.

Pfizer has no objection in principle to the recommendation that a pack insert should be separate to the packaging, however this should be further considered with respect to Recommendation 7.1, which proposes the inclusion of a pack insert for all small containers. If both Recommendations are implemented by the TGA, Sponsors are left with no alternative for impacted small container medicines other than to increase the pack dimensions to fit in a separate pack insert.

Pfizer therefore does not support the recommendation for inclusion of a pack insert for all small containers.

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.

Pfizer does not object to this recommendation, provided the expert advisory body ensures consistency, and publishes their minutes and findings. The expert advisory body must also have a balanced representation of experts, including a communications representative.

Further Comment

Any reform to packaging and labelling should further consider medicines used in hospital, institutional, and inpatient health care settings where medicine packaging is not seen by the patient. Many recommendations contained within this Consultation would have a profound impact on product packaging in this setting, with no relevance to the improvement of medicine safety and Quality Use of Medicines.

There are a number of discrepancies in the consultation document which may alter the intent, therefore are raised below:

Figure 2 p14
This labelling review has made no reference to a Country of Origin requirement. This is related to the Customs Act and should arguably be outside the scope of this consultation document.

The Batch, Expiry & Barcode features may not be able to be placed in the suggested position. The placement of these features is dependent upon the available packaging lines associated with the respective global manufacturing plants that generally cater for many different markets. Given the size of the Australian market in terms of global supply (estimate 1%) it would not be feasible to introduce dedicated packaging lines for Australia into global manufacturing plants due to both cost and space constraints. These features should be present on the labelling however the placement should be at the Sponsor's discretion.

There are no signal headings. Whilst it is appreciated that the SUSMP is outside the scope of this review it is incorrect to represent that a quantity of information will fit a standard size carton without inclusion of the required signal headings.

The TGA website is stated under the AUST R number. This labelling review has made no reference to this being a formal requirement. Furthermore, the inclusion of the TGA website address would contravene Medsafe's guidelines, and does not consider Trans-Tasman labelling harmonisation.

Figure 3 p17
The TGA's recommendation for the placement of the warning on Paracetamol is not aligned with the requirements of the SUSMP, in that no text can be placed on same lines as the required signal headings.

The active ingredients and quantities are repeated twice on the front panel.

The active ingredients are not 100% of the largest font of the brand name.

The barcode information is on the same line as the signal headings.

Figure 4 p18
The TGA's recommendation for the placement of the warning on Ibuprofen is not aligned with the requirements of the SUSMP, in that no text can be placed on same lines as the required signal headings.

Figure 10 p33
The perforation shown in this figure splits the blister platform into 2 equal sections. This would result in the batch and expiry date across the 2 dosage units being split, which defeats the purpose of recommendation.

Considering the number of SKUs on the Australian market and the significant regulatory and financial burden involved in updating labels, Pfizer proposes changes arising from this consultation should be prospective and apply to new and existing products that subsequently undergo label changes.

Pfizer Australia is committed to Quality Use of Medicines and supports appropriate, evidence-based regulatory reform that aligns the objectives of the Australian National Medicines Policy. Consultation is the first step, however further collaboration is necessary to better understand the concerns of all stakeholders. Certainly, much work in partnership with TGA, industry, and other stakeholders is still needed to develop a single, comprehensive guidance document for packaging and labelling of prescription medicines in Australia.

Pfizer supports evidence-based regulatory reform to medicines labelling and packaging that will improve patient safety and reduce medication errors, and looks forward to working with the TGA on this review.

Should you require further information, please do not hesitate to contact Brian Hewitt in the first instance.

Yours sincerely

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