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23rd 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 (Version 1.0; May 2012)

Alphapharm Pty Limited has completed a review of the TGA Labelling and Packaging Review Discussion Paper (Version 1.0; May 2012) and makes the following comments on the proposed changes in this letter and in the accompanying document.

Alphapharm places strong emphasis on ensuring that the labelling of our medicines is in line with the principles of quality use of medicines and concurs with the TGA's proposal to initiate an update to Therapeutic Goods Order 69 (TGO 69) in the interest of improving consumer safety and ensuring the quality use of medicines. However, in line with the principles of our National Medicines Policy, any change must be supported by a quantifiable and cost-effective gain in health outcomes. For many of the recommendations, we are unable to conclude that this is the case.

Alphapharm is Australia's leading supplier of prescription medicines to the Pharmaceutical Benefits Scheme (PBS) and has the widest portfolio of products. Therefore, the impact of the labelling requirement changes will be greater for Alphapharm than for any other pharmaceutical company. As the local manufacturer and distributor of more than 250 individual products to the Australian market, Alphapharm plays a significant role in the supply of high quality, safe and affordable medicines to patients nationwide. As highlighted in the attached document, the costs involved in implementing the proposed changes will have significant ramifications on operational and logistical expenditure, which will all certainly lead to an increase in the cost of manufacture and supply of goods.

Additionally, the pharmaceutical industry will continue to be impacted by Expanded and Accelerated Price Disclosure (EAPD), which results in a progressive reduction in the price of PBS listed medicines to reflect more closely the price at which the medicines are supplied. April 2012 saw an average 28.7% price reduction applied to 75 medicines, while August 2012 saw an average 27.47% price reduction applied to a further 13 medicines. In light of this pricing initiative, Alphapharm is of the view that many of the proposed packaging and labelling changes will add significant pressure to the challenge of maintaining low costs of manufacture in order to provide ongoing supply of medicines.

Consequently, any change to the current packaging and labelling requirements must consider both the cost implications to the industry and the expected benefits to the safe and effective use of medicines.

As highlighted in many of our specific responses to the proposed labelling and packaging initiatives, the costs to Alphapharm will in some instances be several millions of dollars.

We are not convinced that this expenditure will be offset by any significant safety or efficacy benefits to the consumer, as the TGA document provides very little evidence to clearly identify what specific problems are associated with existing labelling and packaging standards, and what additional benefits are expected if the recommended changes are implemented.

Without this necessary evidence, it is impossible for Alphapharm to justify the increase in costs of manufacture associated with some of the changes. Without such evidence or without the guarantee that medicine prices will be increased to offset the expected costs associated with the recommendations, we may need to discontinue supply of products made marginal by the implementation of some of the recommended changes. In our experience, applications to increase the price of PBS listed medicines have been problematic for Government.

The format of our response replicates the key points outlined in the TGA discussion paper with Alphapharm's response and position identified after each point. Other comments not specifically related to the points raised in the discussion paper have also been included at the end of this response document for the TGA's consideration.

Alphapharm respectfully requests that the TGA recognises the substantial costs and resources associated with the implementation of adopting the changed requirements, and takes Alphapharm's comments and concerns into consideration when moving forward to the next stage of the review process.

In summary, without objective evidence of benefit that is expected from the implementation of the recommendations, Alphapharm is unable to support some of the proposals. Significant increases in the cost associated with the implementation of many of the proposals may also affect Alphapharm's ability to continue to supply some products into an increasingly low price Australian market.

Yours faithfully,

Dr. Martin Cross
Managing Director of Alphapharm Pty Limited

Objectives of this review

The objective of this review of the requirements for medicine labels and packaging is to address the following issues:

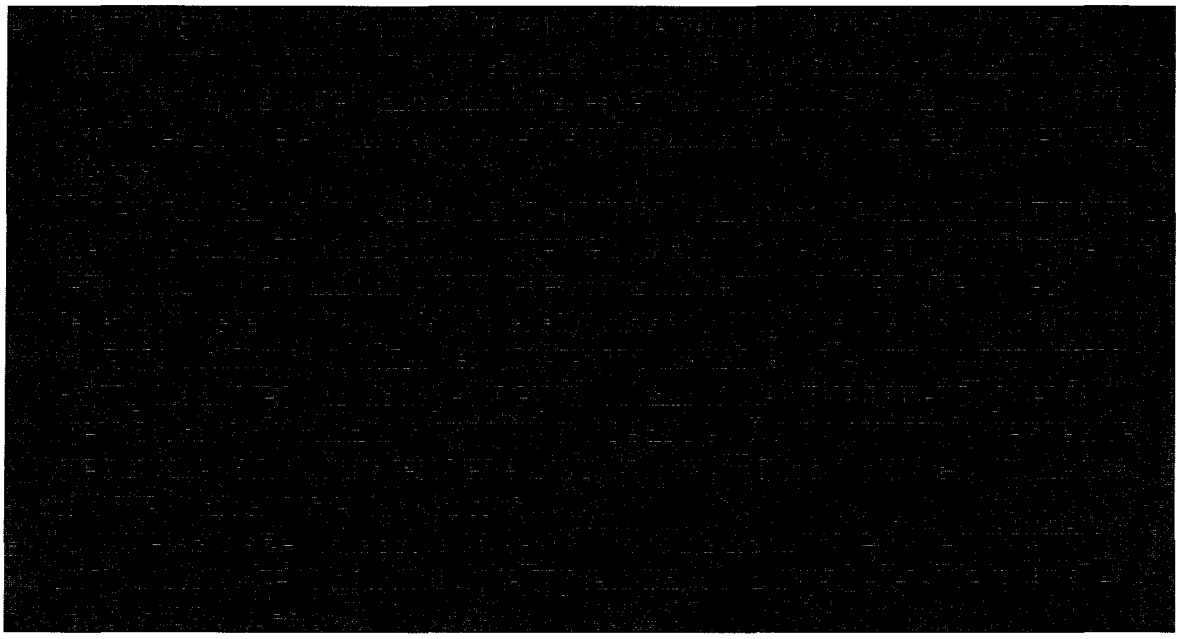
- information about the active ingredient(s) contained in the medicine is not always easy to find
- use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)
- medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine
- medicine containers and packaging that looks like that of another medicine
- lack of a standardised format for information included on medicine labels and packaging
- dispensing stickers that cover up important information
- information provided on blister strips
- information included on small containers
- information provided in pack inserts

Consolidated comments (as categorized by sub-heading):

Prominence of active ingredients of medicine labels

Summary of proposed changes:

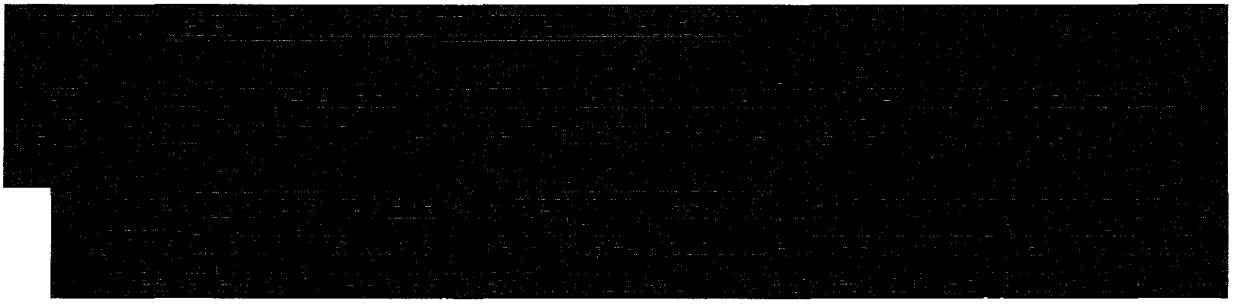
- active name must be listed immediately below the brand name, with the first letter of the active ingredient below the first letter of the brand name
- on the front/main panel, the active ingredient must have equal prominence with the brand name, i.e.
    - the active ingredient is to be as easy to locate and identify on the label as the brand name
    - 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
    - there should be a difference in font style, letter spacing or font colour between the brand name and the active ingredient
    - the active should begin with an uppercase letter but the remainder should be in lower case
- where there are more than 3 active ingredients, the most abundant ingredients must appear on the main/front label immediately below the brand name and the names, together with the quantities of every API, are to be included on a side or rear panel/label for the product (except for day and night preparations)
- 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 not less than 2mm in height on the main/front panel
- the API must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton
- OTC medicines that contain paracetamol/ibuprofen must include the following information on the front of the packaging (in bold text and with letters at least 1.5mm high and on a background that contrasts with the rest of the packaging): "Contains paracetamol/ibuprofen. X mg. Consult your doctor or pharmacist before taking other paracetamol products."



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

Summary of proposed changes:

- Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging (guidance will be developed between the TGA and industry on this assessment, which may include consumer testing or risk assessment checklists. The TGA is also investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names)
- If a proposed brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed label and packaging must use colours and designs that contrast with that of the existing product. TGA will work with industry to develop clear guidelines for this during implementation of the change.
- In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another existing medicine on 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
- Products 'listed' on the ARTG can't be marketed under the same name as a registered medicine
- Medicines containing the same quantity of APIs can't 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 (e.g. a product can't be marketed under the names "BRAND headache" and "BRAND backache" if they include the same APIs in the same quantity)
- The same brand name can't be applied to products that have different APIs or combination of APIs unless the APIs are closely related (e.g. different salts of the same chemical, the safety profile, efficacy and dosage regimen are similar)



would like to know how this would work with products that are only registered but not necessarily marketed. Sponsors need ready access to this artwork for comparative purposes. Will the TGA be able to provide this information to ensure that labelling/packaging is clearly differentiated?
- Further information from the TGA is required to assess the likely impact of the need for a risk assessment on industry in terms of costs, resources, etc. This will depend on what the TGA is expecting from the risk assessment
- Such a risk assessment process could take several hours of a regulatory associate's time to conduct external testing, if it's similar to the process designed to test consumer acceptability of CMIs. While there will be financial implications in conducting such surveys, especially if external input is required, time and resource allocation must also be taken into consideration.

Standardised Information Format: the Medicine Information Box

Summary of proposed changes:

- TGA is proposing to mandate information on labels and packaging of OTC medicines and complementary medicines and present them in a standardised Medicine Information box, based on the US FDA Drug Facts box. i.e.

PHARMACY ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN
TG Pharmacy Cream®

Medicine Information Box

Active ingredient

Hydrocortisone acetate 0.5% (w/w) 30g net

Uses

Temporary relief for itching and rashes arising from:
• eczema • dermatitis • soap • detergent
• cosmetics and jewellery • insect bites

Warnings and allergy information

CAUTION - Do not use for children under two years old unless a doctor has told you to.

Do not use for more than seven days unless a doctor has told you to.

Do not use in the eyes.

Do not use for acne.

Do not use under waterproof bandages unless a doctor has told you to

Tell your doctor or pharmacist before you use this product if:

• You have had an allergic reaction to any medicine that you have used previously to treat your current condition.

• You are pregnant, might become pregnant or are breast feeding.

Do not use the cream if you have:

• a viral skin infection (such as cold sores, shingles or chicken pox)

• a fungal skin infection (such as thrush, tinea or ringworm)

• a bacterial skin infection (such as impetigo or boils) unless your doctor or pharmacist tells you.

When using this product

If your condition does not improve after 3 weeks of treatment, consult your doctor or pharmacist

Contains 0.1% chlorocresol as a preservative.

Directions

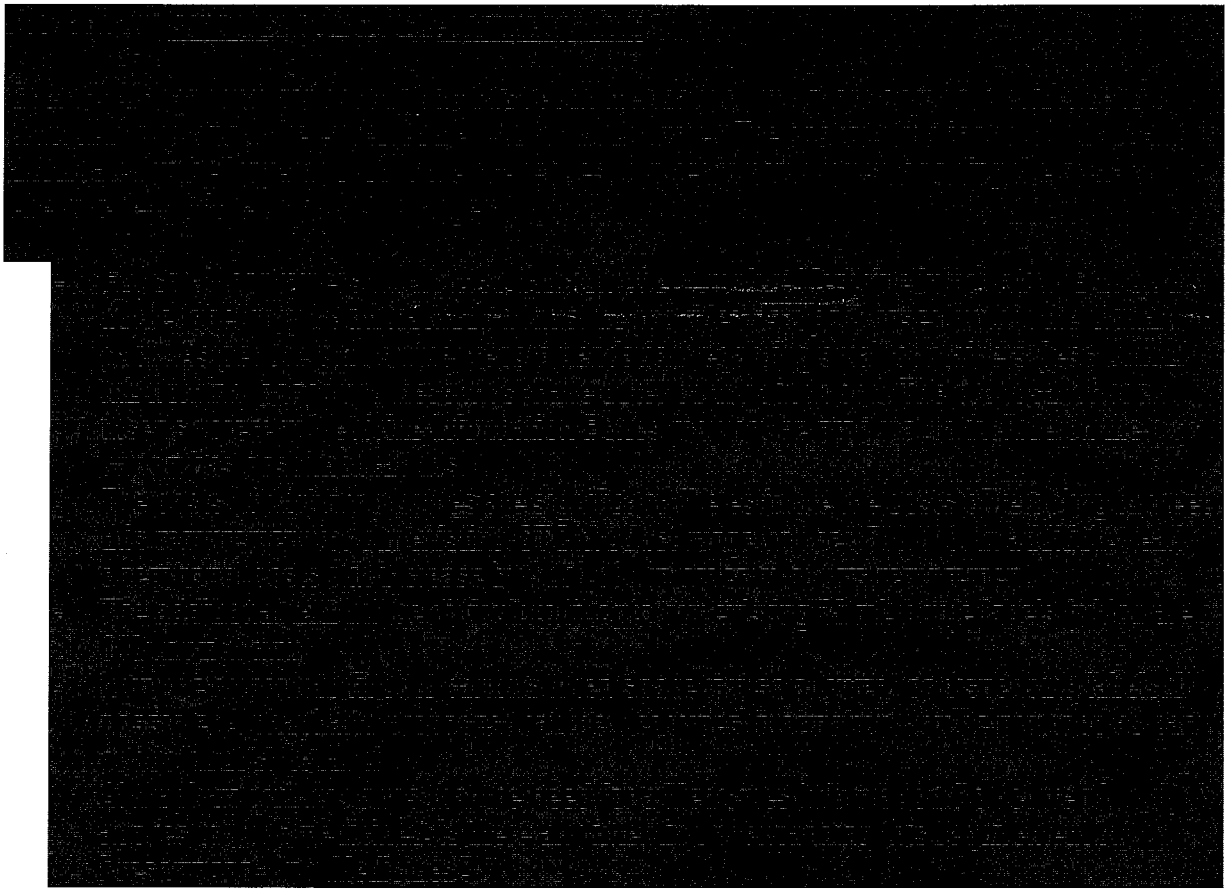
Apply sparingly one to two times daily to the affected area of your body.

Storage information

Store below 25°C. Protect from moisture.

- Font height is no smaller than 1.5mm, with heading height at least 2mm.
- The Medicine Information Box must have a white background with black text. Headings must be highlighted/bolded.

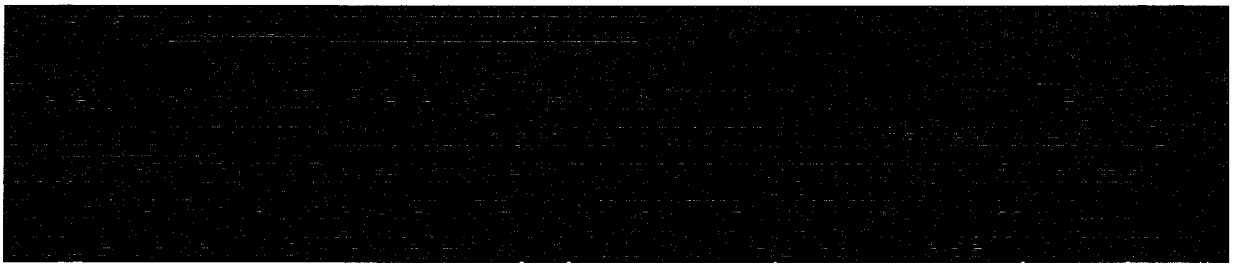
- The box may be split over more than one face if there is insufficient room on a single face. However, the overall format of the information is to remain the same. In these instances, a pack insert containing the Medicine Information Box may be included as an alternative.
- Information about the presence of an allergen listed in Schedule 1 of TGO 69 must be included under the heading Warnings and Allergy Information
- For products containing more than 3 active ingredients, or products in small containers, where there may be insufficient space on the container or primary packaging for a complete Medicine Information Box, the completed version should be included as a pack insert. The minimum information to be included on the label will include information under the headings 'Directions' and 'Warnings and Allergy Information'.

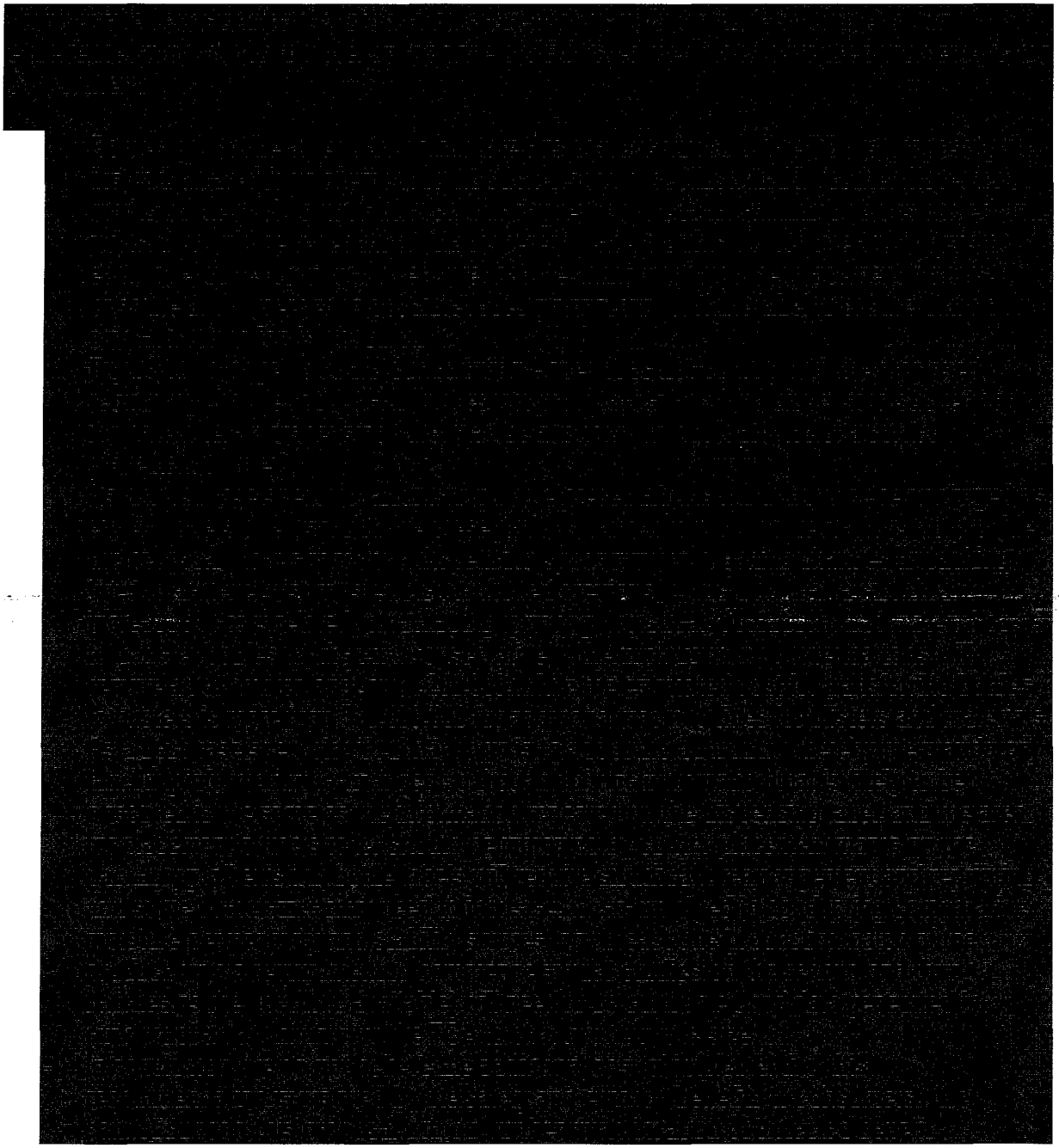


Dispensing label space

Summary of proposed changes:

- A designated space of 70 x 30mm must be provided to accommodate the dispensing label
- If a clear space is not practical due to constraints from packaging size and shape, the information on the back panel of the carton/label should be arranged so that if it were to be obscured, the information has already been repeated on the dispensing sticker. The area for placement of the sticker should be illustrated by corner placement marks on the packaging
- For small containers (for example eye drops and ointments), where a 70 x 30 mm clear space is impractical, a clear space should be provided to affix the edges of a folded dispensing label.





Blister strip labelling

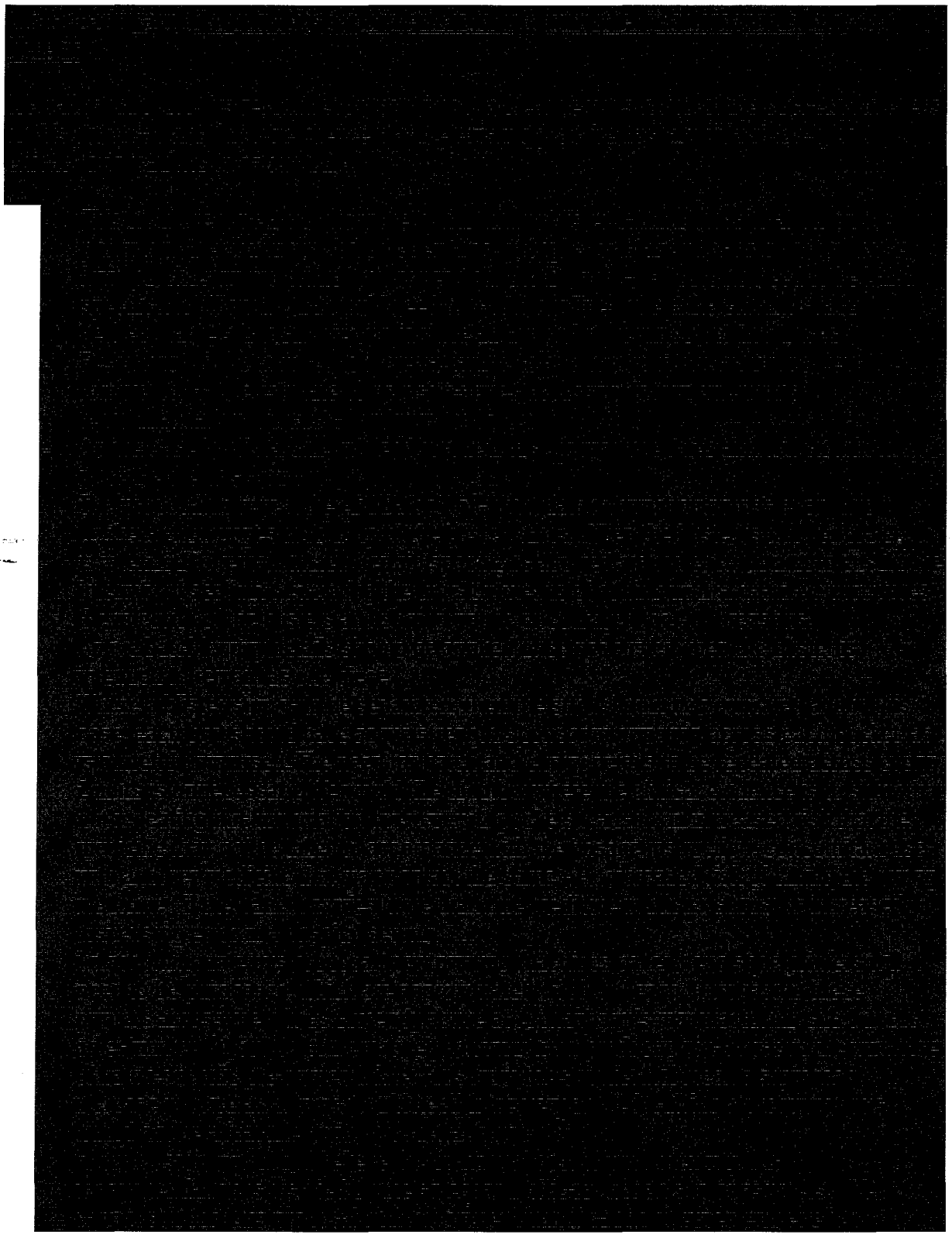
Summary of proposed changes:

For blister strips, other than those that have a calendar blister strip format, the following requirements are proposed:

- brand name, API name and amount of API, batch number and expiry must be repeated at least once every two units
- where strips can be segmented (i.e. are perforated), the brand name, API, amount of API, batch no. and expiry date is to appear on each segment
- a max of 3 APIs should be listed on each segment/each 2 units of a blister strip for registered medicines
- where there are more than 3 actives, it may be sufficient to include a single list of actives printed on the foil of each blister strip. Alternatively, the brand name, together with batch no. and expiry date, should be repeated on the foil.

For oral contraceptives and other medicines that have a calendar format:

- these blister strips must include the trade name, the API and their amount(s), batch no. and expiry date in a single location.



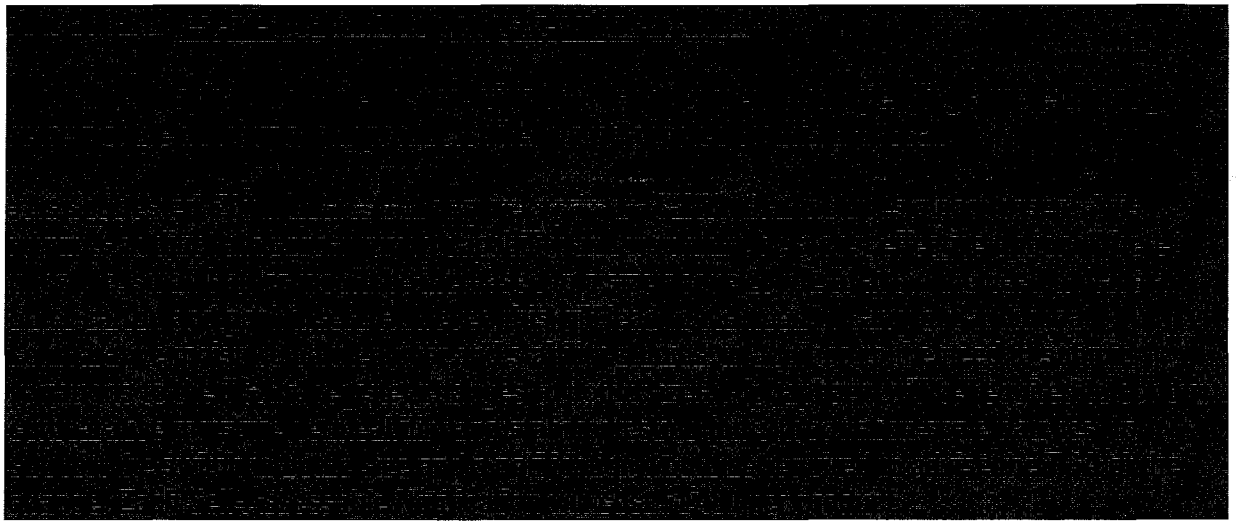
Small Containers

Summary of proposed changes:

The following requirements are proposed for medicine containers with a nominal capacity of 20mL or less:

- these containers must be enclosed in a primary pack that fully complies with all labelling requirements and includes a pack insert that provides detailed instructions for use
- the container label must include the following details in a letter height of at least 1.5 mm:
    - brand name
    - name(s) of all API's

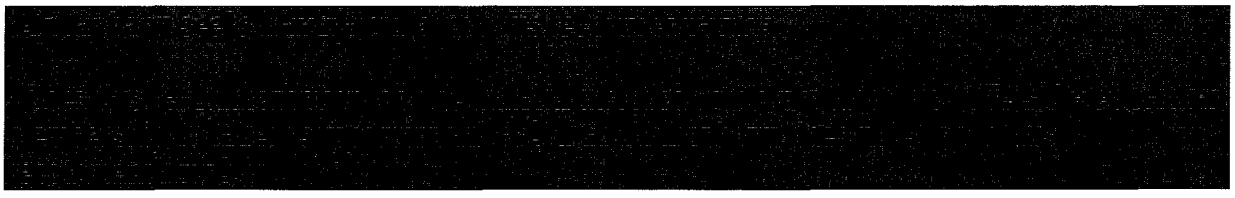
    - ophthalmic preparations → the name of any antimicrobial preservatives
    - where there are more than 3 API's, the 3 most abundant ingredients are to be included on the label of the container and the complete list included on the primary packaging and the package insert
    - batch no.
    - expiry date
    - if an injection, the route of administration
    - if an ophthalmic preparation/solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than 4 weeks after the container is first opened
- a clear space should be provided to allow the pharmacist to affix a dispensing sticker (doesn't need to be the standard size, but should allow a folded sticker to be attached without obscuring information)



Pack inserts

Summary of proposed changes:

- Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert
- A pack insert must be in a form separate to the packaging, i.e. it can't be printed on the inside of a carton



Labels and packaging advisory Committee

Summary of proposed changes:

- Proposal is to establish a panel to provide advice on the acceptability of proposed brand names, labels and packaging → particularly for products involving potential umbrella branding or LASA issues
- This panel will consist of persons who represent the patient, community and hospital pharmacists, nurses, doctors and HCP's and the pharmaceutical industry. This expert advisory body will provide advice to the TGA on product-specific as well as general matters relating to labels and packaging