VicTAG Inc.

Victorian Therapeutics Advisory Group
www.victag.org.au: ABN: 27224983348

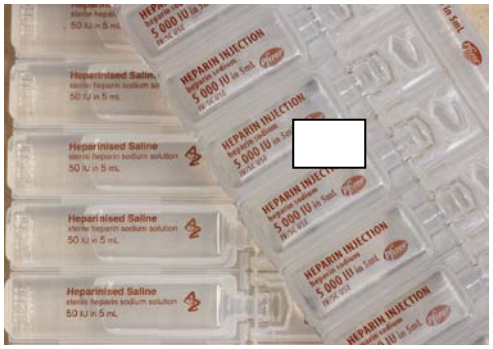
On behalf of the Victorian Therapeutic Advisory Group Quality Use of Medicines (Vic TAG QUM) group, we have the following comments on the TGA Labelling and Packaging review:

Item	Ref	Comment
Active ingredient prominence	1.1 -1.7	We support these proposed changes. We believe increasing the prominence and standardising the active ingredient will have a positive impact and will make it easier for consumers to be aware of the active ingredient. It will be safer as they will more easily be able to determine if they have two medicines with the same active name. At present there is a risk that consumers may take two medicines with the same active ingredient if they only go by the prominent brand name. We agree with the proposal to state the content of paracetamol and ibuprofen and the addition of the warning. The added advantage of making the active ingredient the same size as the brand is that the eye is not drawn towards the brand name. The smallest font size should be 3 mm.
LASA packaging	3.1-3.3	We support criteria to reduce the risk of confusion with LASA. We do not believe the criteria outlined here will solve the problem. There are issues of confusion with: • Products with similar packaging and names with more than 3 different letters, e.g. *Lycinate* and *Sigmaxin*[1], DBL gentamicin and DBL ephedrine[2] • Products that are different but the packaging is the same, e.g. *Minims*[3] • Same drug and different strengths, e.g. Cardizem 60mg and 360mg[4], heparin and heparinised saline[5] • Different drugs but same manufacturer and identical packaging, e.g. fluconazole, ciprofloxacin[6] (see illustrations at end of document) A better solution would be for the TGA not to approve any product that has less than 3 letters different from another generic. The sponsor should be required to change the name of the product. In addition, sponsors should be required to demonstrate that they have designs and colours that minimise the risk of confusion between their products and strengths. Overseas standard for colours relating to certain medications should be considered in the standards, e.g. red on the labelling for neuromuscular blocking agents, various colours for ophthalmic solutions (Table).
LASA branding	3.4-3.6	We strongly agree with these proposed changes.

		At present there are products with brand names that contain different ingredients to those when they were first marketed. This may be misleading to the consumer and should not be permitted.
Medicine information box-	4.1-4.6	A medicine information box will not add any value. It contains small font, is cluttered and makes updating the information difficult. It cannot contain all information needed, e.g. paediatric dosing information
Dispensing label _	5.1- 5.3	We strongly support the concept of a designated space for a dispensing label however we believe this should be 80 X 40 mm which is the standard dispensing label size
Blister strip labelling	6.1 -6.5	We strongly support improved labelling on blister strips. This is important for hospitals as blister strips rather than original packs are supplied to the wards. Wherever possible we recommend that all the specific requirements listed, e.g. brand name and generic name should be repeated for each unit (not every two units) on the proviso that the size of the font is large enough to be readable. We also recommend that the changes also include the requirement that the writing size, font, colour and contrast between colour of writing and foil is such to make the writing readable.
Small containers		We are supportive of these changes but consider that: • the brand name should be 2 mm (this is thought to be the minimum readable size, especially for the population who routinely use eye drops), • the strength should be required on the container label, • "*A folded sticke*r" to be attached like a flag should be reworded to say the "*dispensing label*" to be attached like a flag.
Pack insert		We support this recommendation.
Advisory Committee		We support this recommendation and emphasise that at least some members have current knowledge of practice at the coal face.
Additional Comments on labelling which are relevant for hospitals who are currently implementing electronic prescribing		We recommend that TGA develop a standard way of naming products on their register and not just take the name format submitted by the Sponsor. This is vital for electronic prescribing menus. Ideally they should have rules relating to naming that are consistent with NeHTA naming rules. Examples of where this naming has caused a problem are: - Combination products, e.g. Panadeine Forte – do not have the strength of the individual components in the TGA list name so this is how NehTA's synonym was named. This resulted in prescribers not being able to

		see the strengths contained within each product when searching for medications, - a product named by the sponsor using capital letters resulted in the NeHTA synonym being capitalised - this makes this product stand out when the prescriber is looking at a list of products, which is not appropriate.

Illustrations



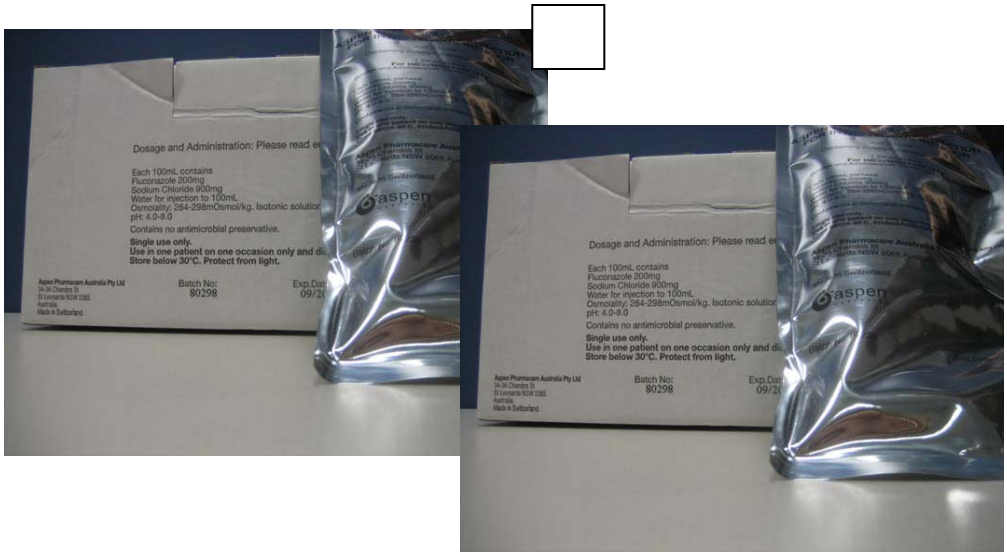


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Table: Colour Codes for Topical Ocular Medications

2010 American Academy of Ophthalmology

Class	Colour	Pantone Number
Anti-infectives	Tan	467
Anti-inflammatories/steroids	Pink	197
Mydriatics and cycloplegics	Red	1797
Nonsteroidal anti-inflammatories	Gray	4
Miotics	Dark Green	348
Beta-blockers	Yellow	Yellow C
Beta-blocker combinations	Dark Blue	281
Adrenergic agonists	Purple	2583
Carbonic anhydrase inhibitors	Orange	1585
Prostaglandin analogues	Turquoise	326