Please find below comments provided by Medication Services Queensland staff and other interested parties which have been collated by Medication Services Queensland.

TGA Medicine Labelling and Packaging Review

Feedback on proposed regulatory changes

Page 15	**Prominence of active ingredients on medicine labels**
General Question (GQ)1	What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?
Response	• Easier consumer recognition active ingredient, despite multiple trade names, with less likelihood of accidental overdose. • Clearly identifies active ingredient. Improves ability to compare products and identify products with the same active ingredients. • Increasing the prominence and consistently displaying the active ingredient should minimise risk and increase consumer safety • This is likely to increase awareness of the active ingredient. However, having the active ingredient in the same font size and alignment may increase confusion as to which is the brand name and which is the generic name amongst consumers. • The Queensland Health Medicines Advisory Committee recommended that MSQ advocate that generic names take precedence on medicine labels, and that the use of trade names for all versions of a generic medicine be reduced or prohibited.
GQ 2	What do you think about the proposed warning for paracetamol and ibuprofen containing products?
Response	• Pertinent, considering frequency of use and ready availability of both medications. • Good. Unsure of benefit of having X mg as part of the warning as it is a unit strength not dose and is already clearly identifiable next to the active ingredient on label, the text is sufficient. • I support the paracetamol/ibuprofen warning label. Pharmacists apply this label to dispensed items and this warning will ensure that OTC and supermarket lines are appropriately labelled. • The warning will be of great value for non-prescription medicines containing paracetamol and ibuprofen where a pharmacist may not be involved in the sale.
GQ 3	Are there any concerns you have with the size or position of brand names and active ingredient?
Response	• No concern with proposed regulatory changes.

	• Some active ingredients may have a very long name (Betamethasone Dipropionate) for the box size. Will making the active and trade names the same size result in a very small font for both? Proposed regulatory change 1.5 on page 19 = "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." This will be very small on the box ends of eye drops and tubes of cream. Displaying the 3 "most abundant" ingredients may be difficult if all ingredients are perceived to be equally active. Examples: Infanrix Hexa injection: Diptheria toxoid, Hepatitis B vaccine, Pertussis Vaccine, Poliomyelitis Vaccine, Tetanus toxoid and Haemophilus influenza vaccine Movicol: Macrogol, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride It will also be difficult for AUSTL items to determine the 3 "most abundant" ingredients to put on the main label. • While the TGA may not be able to pursue this, there is really no need for the brand name from a QUM perspective. Ideally the generic name would be the most prominent with perhaps the manufacturer's name or logo as the 'branding' (e.g. Ramipril Sandoz). • Focus of the proposed changes seems to be on oral medications, however major medication errors occur with injectable products – need to consider the impact for labelling of ampoules and vials, does the brand/ingredient format apply to these products as they are not mentioned in this section?
GQ 4	If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?
Response	• The eye will always be more readily drawn to a larger font as a priority. • Having it the same size implies that it has the same importance and is more likely to be remembered. • As per response to Question 1, there is a risk that having both names with equal prominence may confuse consumers as to which is the brand name and which is the active ingredient. Otherwise, the more prominent the active ingredient the better.
GQ 5	What is the smallest size font that you consider readable?
Response	• Not smaller than Arial size 11 point font
Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: **Rationale:** Ideally, although unlikely, the generic name should be the most prominent with perhaps the manufacturer's name

	or logo as the 'branding' (e.g. Ramipril Sandoz). There is no need for a brand name from a QUM perspective
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits: • If the result is larger boxes, this may impact on available shelf space and the amount of stock held AM
Page 20	**Look-alike and sound-alike medicine brand names and look-alike packaging and branding**
GQ 1	Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?
Response	• Yes – a major proportion of medication errors are associated with dispensing of LASA products. • Yes, it will reduce some errors of selection. New medicines will be less likely to have similar names which will reduce confusion. However, changing only colours and designs on existing products may reduce selection errors but not errors associated with confusing one for the other (prior to physical selection). • I think these changes might minimise the number of products consumers have to choose from. In supermarkets and other unassisted environments, I think that these changes will improve patient safety. • In addition to the proposed changes, it would be useful to incorporate a mechanism whereby post-marketing reports of LASA errors due to the name and packaging of the product requires the manufacturer to make changes to the name and/or packaging. Often times, the names and packaging do not appear to be an issue initially but then issues arise in practice. • Suggest there is further clarity in regards to how the proposed regulatory changes are to be monitored / governed. For example does the Labels and Packaging Advisory Committee review potential look alike and sound alike names and look alike packaging prior to registration on the Australian Register of Therapeutic Goods (ARTG).
GQ 2	What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?
Response	• Avoids patient confusion regarding different medicines marketed under same brand. • Reduce possibility of consumer mistaking a product for one they had previously taken effectively. Reduce the possibility of adverse effects from taking the mistaken product. • I think these changes might minimise the number of products consumers have to choose from. In supermarkets and other unassisted environments, I think that these changes will improve patient safety. • It reduces the risk of incorrect product selection and confusion amongst consumers.
GQ 3	Do you understand the proposed changes?

Response	• Yes • I found the changes quite confusing. 3.5 – Can Panadol Osteo and Panadol Extend still co-exist since they have different pack sizes? Is "…same active ingredient, same quantity" actually referring to "Same active ingredient in the same strength"? 3.6 – Can Nurofen tension headache still exist because it contains Ibuprofen lysine? AM
GQ 4	If you can read the labels and warnings clearly, will these changes reduce the potential for harm?
Response	• It will increase the likelihood of patients heeding the warnings if they are more readily legible. • As above, minimising the number of products should minimise confusion and improve patient safety. • Definitely.
Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale:
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits:
Page 25	**Standardised Information Format: the Medicine Information Box**
GQ 1	To what extent do you think a standardised format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines?
Response	• Patients may be more likely to access information on a box rather than that included in a package insert. • I support introducing a standardised Medicine Information Box for medications. Will pack inserts be required for complementary medications that have insufficient label space? • This will be very useful to consumers and helps them find the information they need conveniently.
GQ 2	Are there other ways that the presentation of information could be improved?
Response	• "Directions" section could be moved higher in the medicine information box. • There could be minimum specifications for packaging size – this would help ensure that all packaging contains the information box at the preferred font size.
GQ 3	Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and

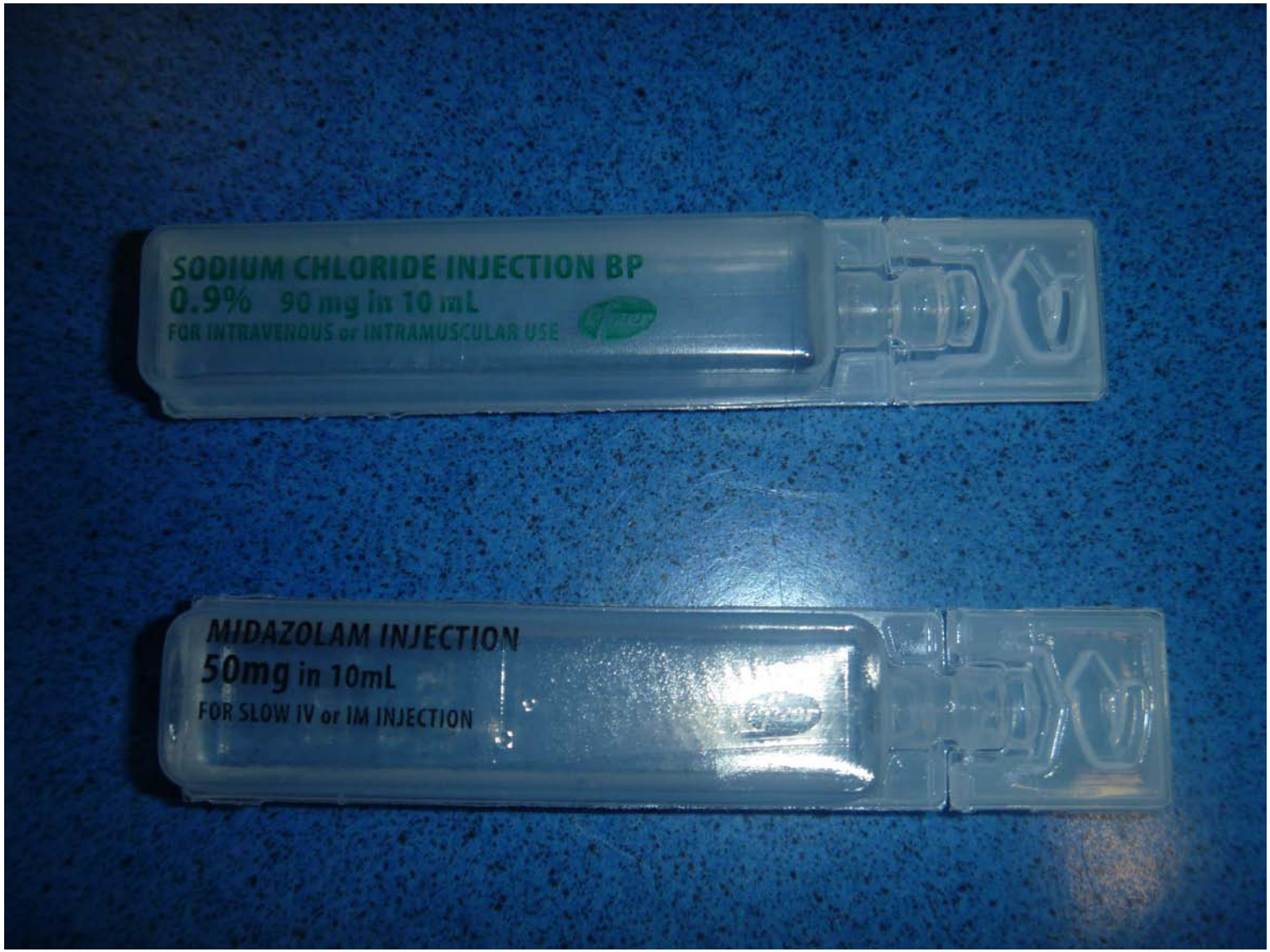
	allergy information), is sufficient for these products? Please propose an alternative if you don't agree with current recommendation.
Response	• I can't think of any instances where a product with > 3 active ingredients is packaged in a container too small to list the ingredients (many multivitamin packs are large enough to list all ingredients), but a pack insert would be a reasonable compromise should this circumstance arise. • May be insufficient space for warnings and allergy…suggest Use, Directions and Storage on product with a reference to read insert for warnings and allergy information before taking. • I think this is sufficient. Especially if the complete Medicines Information Box is included as pack inserts. • As per response above, there could be minimum specifications for packaging size to ensure that all the information can be included on the package
Industry/ stakeholder feedback	Proposed regulatory changes (check one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale:
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits:
Page 30	**Dispensing label space**
GQ 3	Do you support a designated space for the dispensing label on prescription medicines? Why/why not?
Response	• Yes – it means the dispenser doesn't have to cover any pertinent information on the packaging. • Yes, prevents possibility of obscuring important information and facilitates checking process i.e. correct product is labelled for the correct patient. • Yes. Ideally, the space should be the same as the standard size of labels used in Australia (i.e. 80 x 40 mm). There could be minimum specifications for packaging size so that there will always be space for a label. • Yes, so that important information is not obscured eg batch/expiry, and product name and strength is visible to enable checking procedures. A related, and equally important issue, is the font size/case and placement/alignment of information on dispensing labels- there have been studies on the readability of dispensing labels from a patient perspective, yet dispensing software has not incorporated recommendations to improve labelling to reduce risk of medication errors at the point of consumer self-administration of medicines. This may be outside the scope of this review, but could be flagged as an issue. • 5.3 - Suggest specifying 'without obscuring information' as specified at 7.3

Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale:
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits: • Important non-financial benefits – prevents covering storage instructions, barcodes, batch numbers and expiry dates.
Page 32	**Blister strip labelling**
GQ 1	Do you think the proposed information for blister strips is sufficient?
Response	• Yes • Barcoding of blister stip packaging should be incorporated
GQ 2	What other changes would you like to see for this type of packaging?
Response	• Current proposed regulatory changes are adequate. • There could be minimum specifications for blister strip size to ensure that the information can fit in legible font. • In terms of blister strips for products with more than 3 multiple ingredients, I think it should be the trade name, batch number and expiry repeated every segment or every 2 units (rather than the full list of ingredients once down the strip). After one or two tablets/capsules have been popped out of the blister pack it becomes it could be hard to read all the ingredients. The same if the strip is cut into sections like it is in hospital settings.
Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale:
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits:
Page 35	**Small containers**
GQ 1	To what extent do you support the proposed changes for small container labels? Please provide details.
Response	• Support all proposed regulatory changes, particularly provision of a clear space to allow fixation of a dispensing sticker.

	• I support the proposed changes for small container labels. Will very small packaging (e.g. Travatan eye drops) be required to change to comply with these new regulations?
GQ 2	Do you have any further suggestions for how labelling of small containers could be improved?
Response	• Perhaps manufacturer could consider “flag” style label to allow inclusion of further information. • Space reserved for the pharmacy label should be clearly marked as such with a suggestion to ‘flag’ the label. • Proposed changes don’t appear to address the issue of standardisation of labelling of concentration/total volume/total mg content of injectable products. The way that concentration and total mg content is presented on labels has been a source of significant medication administration errors (over and under dosing) due to misinterpretation of label information and should also be reviewed. Refer also to comments for GQ3.
Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale:
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits:
Page 38	**Pack inserts**
GQ 1	Do you support the proposed changes for pack inserts? Why/why not?
Response	• Yes - advertising material may distract patients from importation medication information and outer cartons are often discarded. • Yes. It ensures that consumers have convenient access to the information they need.
GQ 2	Do you have any further suggestions regarding pack inserts?
Response	
Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale

	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits:
Page 39	**Labels and packaging advisory committee**
GQ 1	To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?
Response	• The proposed panel members would all provide the TGA with an individual and relevant perspective on labelling and packaging, with a likely outcome of improved quality use of medicines. • This is a much-needed committee and one that will help escalate packaging issues in a more systematic manner than how it is currently done. • Note that the Society of Hospital Pharmacists (SHPA) was not represented on the external reference group, & recommend that this be considered for membership of the Labels and Packaging Advisory Committee. • Clarification is needed as to whether this is a committee or a panel.
Industry/ stakeholder feedback	Proposed regulatory changes (tick one) **Supported** ☒ **Not supported** ☐ If not supported, suggestions for acceptable alternative: Rationale
	Assessment of how the proposed change will affect you or your business (likely benefits or costs, financial or non-financial): If possible quantify costs and benefits:
	General Comments
	• Barcoding on packets and foils be introduced. Batch numbers and expiry dates should be captured everywhere Diminish corporate branding so ther is more space allocated for the above • Proposed changes look reasonable. • Medication Services Queensland also supports the submission made by the Australian Commission on Safety and Quality in Health Care.

Please see the attached photographs as examples of the confusability of injectable medicines in plastic ampoules which can lead to errors and should be considered by this or a similar process by the TGA


SODIUM CHLORIDE INJECTION BP
0.9% 90 mg in 10 mL
FOR INTRAVENOUS or INTRAMUSCULAR USE
MIDAZOLAM INJECTION
50mg in 10mL
FOR SLOW IV or IM INJECTION


LIGNOCAINE INJECTION 1%
lignocaine HCl
50mg in 5mL
(B) FJ18 EXP APR 14
LIGNOCAINE INJECTION 2%
lignocaine HCl
100 mg in 5 mL
HEPARIN INJECTION
heparin sodium
5 000 IU in 5mL
IV/SC USE
ATROPINE
INJECTION BP
atropine sulfate
1200 µg in 1 mL
IV/SC/IM USE
ATROPINE
INJECTION BP
atropine sulfate
600 µg in 1 mL
IV/SC/IM USE
Midazolam
Sandoz®
5mg/5mL
midazolam solution for
injection 5mg/5mL