Document Review Form	
Document ID, Version & Name	**Notes**
TGA Medicine Labelling and Packaging Review, Consultation Paper Version 1.0, May 2012	Each comment within this document was made by one of the listed reviewers, but may not necessarily be supported by all reviewers.

Review Information			
Reviewer's Name and Designation			
Review start	6 July, 2012	**Review finish**	10 July, 2012

Section Heading or question	Reviewer Comment
Introduction	
General	All medicines should have a GTIN and a globally standardised barcode to represent the required information. When considering the appropriate bar code to apply to a medicine product, the organisation applying the bar code (generally the brand owner or manufacturer) has a number of considerations, including: • Available label space for application of the bar code. • Type of substrate onto which the bar code is being applied. • The need to include information additional to the GTIN (e.g., batch or expiry date) in the bar code. • Manufacturer printing abilities (e.g., is a linear bar code more appropriate than a 2 dimensional – GS1 DataMatrix – bar code). • Bar code reading capabilities of supply chain partners, e.g. wholesalers, hospitals, pharmacies.
General	The text in Figure 1 is lighter and slightly blurred; I found it hard to read after the darker text within the document.
Definition of non-prescription medicines	Suggest adding convenience stores also
About this review	
Page 7/8 "The aim of this aspect of the medicines regulatory framework is to reduce the risk of errors by health care professionals and facilitate consumer access to the information they need to: • make informed choices where they are self-managing minor conditions, such as a headache or a cold • safely use a medicine that they have been prescribed by a health care practitioner for the treatment of a more serious condition."	Should this reflect ability to safely identify and choose medication both via software applications for prescribing and dispensing and physical selection? (Maybe I'm expanding scope!) Believe the Product and Licence name should possibly be included or a better explanation of what the terms on the eBS are about should be included somewhere in the document. Also an explanation about why these names could differ to the actual Brand name would be good.

Have your say	
(no comments received on this section)	
Glossary of terms	
Active ingredient	Active ingredient-not sure that the explanation is sufficient here especially as the strength may be based on the BoSS (Basis of Strength Substance) e.g. calcium containing products may have their strength represented as calcium 500 mg but the product ingredient may be calcium carbonate. Maybe the glossary needs to include product ingredient as well to allow a differentiation. Amlodipine is another example of this where the intended active ingredient is amlodipine but the actual ingredient can be maleate or besylate. Perindopril erbumine and arginine are further examples where the perindopril content is the same but the actual salt strengths differ. Only allow Australian approved ingredient names and not synonyms. If synonyms can be used then ensure both approved and synonym should appear on the label.
Figure 2 (2)	Noted the Brand name makes no reference to dosage form. Believe the Brand name should make reference to it and it should not simply be added to the pack size. What happens to products such as modified release or enteric coated-is this information added with the Brand name.
Figure 2 (6)	Not sure adding TGA website adds anything for consumers. What if website changes then labels are out of date for every medicine registered for use in Australia resulting in massive cost for manufacturers.
Page 14	Figure 2 – presumably shows OTC item (as Medication Information Box). If these are to be dispensed there is no room for a dispensing label. (Note – I may still come to a consideration of this point.)
General	From a consumer point of view, I feel that the Expiry Date and Medicine Information Boxes (e.g. containing directions) on products in general could be printed in more visible text and expiry dates given higher visibility to prevent consumers taking old medication.

Prominence of active ingredients on medicine labels	
1.3 "most abundant"	I am assuming that by most abundant it means the ingredient present in the highest weight or volume. This may not necessarily be the most significant ingredient/s.
1.3	If a product has more than three ingredients, there must be some way of immediately identifying that there are more ingredients, otherwise it would be unwittingly assumed that the three ingredients shown are the only ingredients.
1.4	What if there are more than three ingredients in a single day or night preparation?
1.6	Would prescription medicines carry the same warning? There is no mention of them but I believe it is just as important for them to carry the same warning.
1.3	What is meant by 'most abundant' ingredients, and what is the limit of those listed on the front 4, 5, 6? I think this change introduces further confusion, and potentially highlights to the consumer somewhat insignificant ingredients on the package only due to their 'weight' contribution. What prompts someone to look at the full list on the side/back panel? If they have to do that anyway, why include anything other than 'multiple actives' on the front?
When overseas bullet point	Not sure that clear labelling helps when overseas as many ingredients are known by different names overseas e.g. paracetamol is known quite differently outside Australia
Identification of non-prescription medicines	I'm not convinced that adding warnings to labels helps alert consumers.
Figure 3	All the other places on the label should read codeine phosphate as well Brand name should contain dosage form e.g. modified release or enteric coated Ingredient order-should be alphabetical and not based on abundance. This will ensure there is no marketing pressure applied to ingredient order and everyone from consumers through to health professionals will know ingredient order is always alphabetical.

1.3	Not sure that where there are more than 3 ingredients that the most abundant ingredients must appear on the main label. This could result in a label which contains say all the ascorbic acid type ingredients and then pseudoephedrine could be the fifth most abundant ingredient and this would be left off the main label.
1.6	Does the paracetamol warning get attached to all medicines containing paracetamol and not just non-prescription as previous label has it attached
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.)	Will this always work? Situation where > 3 ingredients and key "potent" ingredient is less abundant than other less significant ingredients. This is likely to affect vaccines, cough and cold preps (but not day and night), multivitamins. What about mixed units? For example a mixture of mg and micrograms is OK, but what if one of the ingredients is measured in units? How would precedence of order be decided? (e.g. Kenacomb® products)
Page 17 'Mandatory warning on the label'	This is particularly important for medicines sold in supermarkets as the pharmacist is not present to discuss 'other medications' and to determine if it is appropriate or not. I believe it is a very important safety requirement for some medications to include a warning label. Paracetamol is great example as consumers consider it a relatively 'safe' drug and it is found in many different products which can be used together. Cold and flu medications taken with 'Lemsip MAX' (1000mg paracetamol per sachet) for the sore throat is a classic example of potential overdose. I think the warning label is best for S2 and S3 and unscheduled medications where consumers consider these products safe.
Page 17 'Designated space for dispensing sticker	I also strongly believe this is important and should be controlled. Too many times I see other pharmacists sticking the dispensing label over the 'expiry date' or the details of the medicine ingredients which are essential for 'quality checking' before handing out to the customer. I do think the sticker 'space' should be on the front of the medication and not on the back of the box which is how it is displayed on page 17.

Page 19 'contains Ibuprofen…."	Again I believe the TGA need to make it very clear on why they have chosen some medicines for 'warning labels' and others have not. Where will the TGA draw the line for warnings, does Pseudoephedrine require a warning about blood pressure etc?
… Paracetamol and ibuprofen are well known … p16	This is a scheduling issue – no amount of labelling will remove the need for counselling for these products due to the level of health literacy in this country. Instead of spending time designing the label it should be dealt with by NCCTG
1.3 … 3 active ingredients the most abundant ingredients … p18	Is this by weight or toxicity or some other process for multi-ingredient medicines e.g. polypills with 4 ingredients
1.3 Where there are more than 3 active ingredients…"	How would this work with multivitamins that are registered? Perhaps this recommendation should be reserved for Prescription Only Medicines and Pharmacist Only medicines, where there are more clear risks/benefits regarding medicine use.
Proposed regulatory changes 1.3	When there are more than 3 ingredients, the most abundant ingredient will appear first below the label name. What if that ingredient is potentially harmless whereas another ingredient with lesser amount, yet more potent and likely to cause side effects is listed somewhere below. The consumer may mistake the importance of the ingredient with this listing order.
General	There is no mention regarding the listing of dual ingredients on the label. The example provided on page 17 showed Paracetamol listed first followed by Codeine so I assume the listing follows the abundant ingredient rule also. Will this lead to confusion for products such as Coveram 5/10 and Coveram 10/5?
General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels	
What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?	Hopefully this will make consumers more aware of the actual ingredient/s of the medicines they are taking. I would expect this to have a knock-on effect to improve patient understanding and potentially reduce confusion resulting in improved compliance and reduced duplication of medicines.
	Agree-consistency in placement of active ingredient is important

	Better readability, greater understanding of active ingredients in a given product, less confusion, improved safety.
	Impact is minimal unless utilised with an effective health literacy program and use of web sites like NPS. How many people know what the term "active ingredient" really means?
	Increased safety and quality of the healthcare we provide, through the dispensing and administration of medicines for Australian consumers.
	Better visibility, lower risk of human error. It is my belief that a standardised format for information on labels/accompanying leaflets for products will also help consumers to find the required information quickly and accurately.
	I think it would be good to have the ingredients listed under the brand name.
	This will lead to greater awareness of the 'generic' name of the medication and reduce the current confusion regarding multiple brands of the same generic drugs.
What do you think about the proposed warnings for paracetamol and ibuprofen containing products?	Warnings are inconsistent in the graphics. Ibuprofen (Figure 2) includes amount but paracetamol (Figure 3 and 4) does not. These warnings are possibly only useful if the consumer also has some idea/understanding of the maximum daily dose. If warnings are to be included they should be on all OTC as well as prescription items.
	Appropriate
	Yes I agree to paracetamol having a warning label – perhaps it should mention max of 4g in 24 hours.
	I think having them is a positive step. I agree that the proposed warnings for paracetamol and ibuprofen should be displayed in a prominent position over a contrasting background. I feel these warnings should also apply for gluten and lactose (if not already).

	I think it is a great idea, even though the Pharmacist may let the consumer know, however it will help those that tend to take a number of different painkillers.
	The warning is very similar to an ancillary label attached on by pharmacist, from experience, not many people read it unless verbally told. It will work well if there's a NPS campaign bringing about consumer's awareness about it and understand the risks of combining products containing the same ingredients.
Are there any other concerns you have with the size or position of brand names and active ingredient?	I agree that a consistent location for name/ingredient would assist in location I disagree that the name and ingredient needs to be the same size to be clear. Not sure a specified Font size for name/ingredient is realistic given the variety in package dimensions. More useful to specify a maximum difference in font size between brand name and active ingredient, with a lower limit on font size/style used for legibility. Choice of font and other graphic design elements are just as important in making something prominent or easy to locate. Example day/night product label is very 'busy' and 'distracting', not sure where to look first.
	Agree-both need to be prominent with active ingredients in a smaller font
	The active ingredient doesn't need to be 100% of the font side of the medicine brand. Yes I agree it needs to be bigger probably to match elderly poor eyesight.
	See attached NHS Design Authority Medication Labelling Recommendations-2004
	I consider font sizes of '10' or smaller to pose potential difficulties for members of the public with even mild vision impairment (e.g. those who require reading glasses, pensioners, etc.).
	No I think it will good to have the ingredients directly under the label name, it will be much easier to locate and compare.

	Suggest standardising the font of the active ingredients on all drug labels, whereas for the brand name, the manufacturer is free to choose the font style. This will increase recognition of the active ingredient as consumers will be able to associate the font to the ingredients and train their eyes to look for it on the label.
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?	For branded products I don't foresee any issues, but I am concerned that the apparent ingredient duplication may be confusing for generic products.
	Knowing the active ingredients is important so being able to read and understand them will help to improve knowledge around active ingredients. Ingredients should not be printed over backgrounds that make it hard to read as often the colour of the background can make it almost impossible to read the words. Believe ingredient could use a smaller font than brand name and this may allow more ingredients to be included on primary label.
	Better association between brand and ingredient with increased knowledge of active ingredient by prescriber, nurse, patient.
	It will prevent duplication of active ingredients and prevent potential overdose situations. It may also encourage consumers to understand what ingredients are in different brand names and take note on what active ingredients they are actually taking and what the benefit might be.
	See attached NHS Design Authority Medication Labelling Recommendations-2004
	It will draw the consumer's attention to the ingredients.
	Gives equal prominence to the importance of the trade and generic name.
What is the smallest size font that you consider readable?	Font size alone does not determine readability. Other factors which need to be considered are font style, colour, background colour and pattern. In general for a "clean" font of dark colour on a plain light background I would think 10 point is the minimum.

	The exact font size cannot be considered in isolation of other graphic design elements as what is readable in one font style and size is illegible in another. Things to consider include (but not limited to) Font style (including serif / sans serif) Weight Font Colour Background colour Other contributing factors obviously include characteristics of person doing the reading e.g. age, quality of eye sight etc.
	Noted that space may be an issue, but at least 2.5 - 3 mm letters may be preferable. Other factors also need to be taken into account – typeface, colour, background colour, lighting, etc. Reading a label with a small font in a hospital ward at night with subdued lighting may pose a risk.
	10 point
	See attached NHS Design Authority Medication Labelling Recommendations-2004
	I consider font sizes of '10' or smaller to pose potential difficulties for members of the public with even mild vision impairment (e.g. those who require reading glasses, pensioners, etc.).
	10 points, we have to consider the older consumers that would have trouble reading it.
	This depends on many factors; age, lighting, pack size (eye drops compared to large blister pack) etc. Personally, I think the current font size on the eye drop containers should be the minimum.
Look-alike and sound-alike medicine brand names and look-alike packaging and branding	
3.2 and 3.3 "colours"	Consideration should be given to the range of colours which are differentiated by the commonest form/s of colour blindness.

3.2 differing by three letters or fewer	Rather than allowing this to happen and then stipulating that the manufacturers use means of differentiation (label colour, packaging design, etc) which is a reactive step, wouldn't it be preferable to be pro-active and not approve such similarities in the first place.
3.5	Very strongly agree with this proposal. The current plethora of these types of products makes duplication of medicines a minefield for the unwitting consumer. Will this be made retrospective?
3.6	Strongly agree with this as it currently causes substantial confusion for consumers. I would suggest that this should never occur (i.e. remove the two exceptions)
Table-Lasix	If this is an Australian list then hope we would see frusemide
Page 20 – Look-alike medicine branding occurs when two or more products are marketed under the same brand name; this may also be known as brand extension.	Not sure what this means – two products with a different set of ingredients, salts, formulation? Maybe example?
Page 21 – Table of LASA issues In the case where the medicine container or primary packaging looks like a toy, as may be the case with some inhalers, or a food, there is a risk that children may be inadvertently exposed to the medicine.	Not sure what relevance this has to LASA.
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.	Appears appropriate – actual guidelines would be useful to review.

Pg 23 (3.5) Products cannot be marketed as "BRAND headache"	Strongly agree to this point. Firstly there is a risk of overdose as the customer takes Nurofen headache and Nurofen backache at the same time. It also takes away the 'active' involvement of the customer with understanding what they are taking and why… it also takes it out of the hands of the pharmacists. Customers need to be educated by the pharmaceutical companies and pharmacists/GP etc. that 'Ibuprofen' is an anti-inflammatory and can be used for a range of symptoms e.g. headache, period pain, back ache… creating these individual boxes for each different symptom confuses the patient and takes away the ability or necessity for the patient to be actively involved in understanding the medicines that they are taking.
General	See attached NHS Design Authority Medication Labelling Recommendations-2004
General	Real life example: In a public hospital setting, patients were routinely given intranasal surgery and sent home with a Flo kit (saline rinse), were advised to get more refills from their local pharmacy if they ran out of saline sachets from the kit. After a few years of this being the normal practice/advise, a new version of Flo was released with xylometazoline (sympathomimetic agent with vasoconstrictive activity) and many patients were purchasing this new version instead of the original saline version. Flo Post Op Nasal & Sinus Sachet Kit 70 (saline post-op rinse) Flo Rapid Relief Nasal Decongestant 15ml (xylometazoline) The result of this was that many patients were reversing the benefits of the surgery and returning to hospital with complications.
What would be the changes proposed for the packaging?	This is not very clear in the changes to be made.
General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging	

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?	It may assist consumers in correctly identifying their medicines when they have 2 or more LASA medicines, otherwise the differentiation is lost. However it is worth noting that some products may become 'known' to the consumer by the look, design and colour of the package (guaranteed to be used greatly by marketing divisions) which may in turn stop them actually carefully reading the name leading to an error in selection if other products with unrelated names had similar colour and design. This means both aspects – naming and design – would need to be monitored for degree of similarity.
	Agree-this will certainly help consumers with over the counter medicines.
	I agree that look-alike medicine branding from the prospective of the consumer can be quite confusing and misleading, so changing the way these brands are marketed to the consumer will help. Removing the ability to selectively market active ingredients as more suitable for treating specific symptoms will help limit confusion when purchasing general sale or across the counter products. E.g. if a product is marketed "BRAND migraine" and "BRAND period pain", a customer may in a supermarket setting buy two products and take them simultaneously not realising they contain the same active ingredient and have subsequently overdosed. It can also make it more difficult for consumers to compare different brands/products or cause confusion when discussing options or receiving advice from medical professionals.
	It should improve medicine safety. I think it will differentiate between the products that are out in the market already and will hopefully alert consumers that it is a new product.
	There is no mention of changing packaging that looks alike. For example, Coumadin 5mg and Coversyl 5mg have the same bottle shape, very similar label and located close to each other in the dispensary (alphabetical order) therefore led to various cases of selection errors as noted by the Pharmacy Board. This should be discussed also.
General questions on the proposed regulatory changes for look-alike medicine branding	

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?	Agree with 3.5 about not allowing the marketing the same product for a subset of symptoms or uses although also believe industry will work out how to get around this requirement.
	Should decrease risk.
	I believe any changes will reduce the potential for harm, but also help reduce the potential for confusion/frustration for consumers and medical staff alike.
	I think it will make it safer for consumers as they will be able to differentiate between the old and new products.
	This will reduce the incidents of consuming multiple doses of the same active ingredient.
Do you understand the proposed changes?	In reference to 3.5 (& 3.6), is a different 'salt' of an active ingredient considered the same or different for the purposes of determining the same quantity of active ingredient and restriction on **sub-branding**, e.g. Brand headache (ibuprofen 200 mg), Brand backache (ibuprofen lysine 342 mg) – the active ingredients have different quantity but base active ingredient is same quantity. Is this allowed under proposed rules? What if the difference is therapeutically negligible but presents as a different amount 'on label'? Where different 'salts' of an active ingredient are used, is there a requirement that both base and salt are clearly visible on the label (for both registered and listed medicines)?
	Yes
	Yes I believe there is more to distinguishing the products than letters and contrasting colours/patterns. Term length should be different (short vs long), completely different container types e.g. bottles only for some products would benefit. Different shaped boxes.
	The examples given in 3.5 & 3.6 do help to clarify the proposed changes.

	Yes, it will make it much easier for the consumer to choose a product as they wouldn't have to choose between targeted products.
	Yes. Is this for moving forward or will it apply to existing products?
If you can read the labels and warnings clearly, will these changes reduce the potential for harm?	Labels and warnings are frequently ignored or only read once at time of purchase. Many medicines end up outside of their 'outer packaging' once at home. Consumers interested in warnings/precautions will look for them, others won't and increasing their prominence for the purpose of reducing potential for harm I think is questionable.
	Not sure consumers actually will ready the warnings-needs verbal warnings as well.
	Possibly – but this also needs to address naming in general and selection an interpretation issues that may occur in clinical information systems and online reference systems.
	Yes, recognising that older Australians take more medications per capita and can often have associated presbyopia
	Yes. Consumers don't always know to look for warnings, having these stated clearly, with clear labels can help to draw attention to important information.
	Of course, it will make a big difference for a consumer to know if they can take the medicine or not. Yes these changes will reduce the potential for harm.
Standardised Information Format: the Medicine Information Box	
4.1	Does the 3 ingredient limit also apply to ingredients shown in the information box?
4.1	Are there any recommendations around when to show the total amount of certain ingredients, such as sodium, potassium, etc.
4.2	Suggest some guidelines on appropriate font styles (e.g. sans serif) for this very small font size. Seriffed fonts would be very difficult to read in this size.

4.6 "…a complete Medicine Information Box should be included as a pack insert"	I would suggest that rather than "should" contain the insert, they must contain the insert. I think this should also be applied to instances where the Medicine Information Box breaks over more than one panel.
Page 25 - General	The use of a Medicine Information Box may be an issue where an OTC (or complementary medicine) is prescribed and dispensed, i.e. where there is a dispensing label to be applied. This may be standard practice in public hospitals where all medication (prescription, OTC etc.) is dispensed to a patient with a dispensing label.
4.2 The font height for information must be no smaller than 1.5mm, with heading height at least 2mm.	Font height may be too small.
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.	May small containers, e.g. eye drops, may not be packaged in an outer container. The use an insert may be an issue.
General	See attached NHS Design Authority Medication Labelling Recommendations-2004
Location of Medicine Information Box	There is no mention as to whether this label must be external or can be on the inside of the carton.
Why is the amount of Sodium included on the information box?	It should be clearly outlined why the Sodium information is included.
General question on the proposed regulatory changes for Standardised Information Format: Medicine Information Box	
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?	Will only be useful if it contains information on all of the ingredients, not just the three most abundant.

	Needs to be done with an education campaign so consumers know what to look for and how to read and understand the information. Making medicines pharmacy or pharmacist only can help here as education can be done during the selling of the product.
	Concept is good. Needs to be readable and understandable by consumers.
	Yes I agree this the medicine info box should become mandatory for over the counter and complementary, however, it does take the responsibility away from the health professionals (pharmacists, naturopaths)… Consumers will be less likely to require advice/assistance from these health professionals. The directions are not always relevant and do differ for each individual following a consultation and history check…
	Greatly
	Presenting the product information in a standard, uniform way can help consumers look for the information they require, without skipping through or missing important points or directions/safety information (e.g. Storage, Allergies, and precautions when using the product/interactions with other medications).
	To a great extent it will improve the access of information. It will allow consumers to make an informed decision.
	As the information on the label is standardised, consumers will have direct access to the essential information each time they pick up with an OTC or complementary medicines thus allowing for more informed health decisions to be made.
Are there other ways that the presentation of information could be improved?	Remove any marketing information that may be included within the information Ensure information is reviewed regularly and kept up to date Use Australian approved ingredient names Only allow TGA approved uses to be included

	Consideration of other ways to present information in readable/printable format. Use of smartphone app based on scan of barcode, web access to Medicines Information Box via AUST L etc.
	See attached NHS Design Authority Medication Labelling Recommendations-2004
	Directions should be followed by the Users, it will make it easier to read.
	With the increased use of smart phones these days, a Quick Response (QR) code  can be included on the label for the consumer to scan. This can take them directly to a web page with all the relevant and standardised information about the medication.
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.	As well as package insert the information could be made available electronically via app or from TGA website. This way it could be kept up to date and consumer would always be provided with the most up to date information
	Appears reasonable.
	Yes sufficient
	I think the information will be sufficient as any more information might make it too difficult to read for the consumer.
Dispensing label space	
5.1	The introductory section states that the standard label size in Australia is 80 x 40 mm yet the designated space is only 70 x 30 mm. Shouldn't the designated space match the standard label size?
General	Allocate 70 x 35mm white space for dispensing label

Size of the default dispensing label space	Document does not acknowledge the wide variety of size of dispensing labels. Some labels are very long, almost 15cm long, and some labels have multiple layers to assist with re-ordering.
General	There are 2 sizes for the dispensing label, large one (80 * 40 mm) and a smaller (not sure of the size but longer and flatter) where pharmacist can use for smaller container and those requiring 'flagging'. Suggest including this information in as pharmacist are not restricted to one label size only.
General question on the proposed regulatory changes for dispensing label space	
Do you support a designated space for the dispensing label on prescription medicines? Why/why not?	Yes. Important information (ingredients, warnings, batch number, expiry date, etc.) is frequently hidden from the consumer due to the current lack of designated dispensing label space on many containers and poor placement of labels by the dispensing pharmacist or technician.
	Agree-this will ensure important information such as batch and expiry date is not covered by the label
	Yes. Placement of labels has always been an issue and not all pharmacists take enough care to ensure important information is not obscured.
	Yes I support this and agree with 5.3 for small containers
	Yes – standardising the location, size, content and format of a dispensing label will ensure consistency in labelling and be more readily recognised for consumers to read when it is consistently applied across all medicines.
	Yes, it will help assist pharmacists as well as limit clinical risk to patients and human error.
	Yes, I support it. As a Pharmacist I often found it difficult to label a product without covering useful information such as storage.
	In practice, I normally scan the medication after dispensing and then place the sticker over the bar code as it's now considered non-essential information. Suggest the barcode be included in this designated labelling space.

Blister strip labelling	
General	Batch number and expiry date should always be printed, never embossed. Font size of batch number and expiry date should also be considered, with a strong recommendation to never use pixelated or dotted printing.
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.	Suggest repeated use of brand name, batch number and expiry date. Once tablets or capsules have been pushed out it becomes difficult to read a detailed list of names.
General	There is a case for each level of packaging to be allocated a GTIN and marked with a GS1 bar code as each needs to be unique and unambiguously identified at some point in the patient care or supply chain – this should include the following typical hierarchy: • Individual tablet (dose) in a blister pack – administered at the patient bedside • Box of 24 tablets – issued at the dispensary of a retail or hospital pharmacy as well as used for handling and shipping at the wholesaler or manufacturer, and receiving at the hospital or retail pharmacy • Shrink wrap of 12 boxes – used for handling and shipping at the wholesaler or manufacturer, and receiving at the hospital or retail pharmacy • Carton of 12 shrink wraps - used for handling and shipping at the wholesaler or manufacturer
"Each 2 units of a blister strip"	How will this work with some medications such as 'Nexium' which comes in strips of 7 or if the strips are able to be torn down to individual tablets?
'race track'	What is a 'race track' blister pack format? Sequential dosing format? Suggest explaining.
General question on the proposed regulatory changes for blister strip labelling	

Do you think the proposed information for blister strips is sufficient?	Yes it is good to see that the batch and expiry number will be repeated on the back as at present they are in very tiny print on one side of the blister pack and it is very difficult to read. "max of 3 active ingredients" need to be more specific about how this will be determined… which products will be selected? What are the criteria? Who determines this – TGA or pharmaceutical company?
	No … it should be rendered as a barcode to allow for Bar Coding at Point of Care
	Yes, I think it will be good to have the information on the strip as often the information is not visible and makes it hard to know what it is.
What other changes would you like to see for this type of packaging?	Ensure batch and expiry date is not embossed into the foil as it's almost impossible to read especially if blisters have been removed from box.
	Requirements about colour of text and type of background to ensure readability.
	See attached NHS Design Authority Medication Labelling Recommendations-2004
	I think the proposed changes are sufficient. No more information as it will make it difficult to read.
	Font colour should be standardised as the printing on some current blister strips are very difficult to read. For example silver font on a foil strip.
Small containers	
7.2	Bullet point three states that preservatives must be included for ophthalmic preparations. Is this included in the three ingredients or is it in addition to the three most abundant ingredients?

7.3	Consider including label space dimensions for attaching the "flag" dispensing label.
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.	Good – if insert required. But may be lost/discarded.
7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres…	Letter size may be a readability issue. Many eye drop users may have vision issues.
General	See attached NHS Design Authority Medication Labelling Recommendations-2004
Proposed changes 7.2: Where there are more than 3 active ingredients	Similar to the point made about the proposed change 1.3 where the most potent or low therapeutic window active ingredient is only presence in the medication in a small amount, it won't be listed on the immediate bottle but only seen on the primary packaging or insert?
General question on the proposed regulatory changes for small container labelling	
To what extent do you support the proposed changes for small container labels? Please provide details.	Proposals appear reasonable but small containers are always going to have size and space limitations. Proposals need to balance what is essential for the label and what should be placed on inserts to ensure key information on label is readable.
	I support all except the 3 or more active ingredients are chosen as the 'more abundant' it should be rephrased to say the most clinically active/relevant medication.
	I fully support the proposed changes. I feel that the expiry date should be clearly communicated and fully visible (with full date, i.e.: "dd/mm/yyyy" rather than "mm yyyy" or similar)
	I think it is a great idea and support this proposal fully. It will help provide more information relevant to storage and expiry.

	All the changes sound reasonable however, I think where there 2 or more ingredients, the ingredient that will most likely more prone to cause side effects, have drug interactions or low therapeutic index should be included on the container label.
Do you have any further suggestions for how labelling of small containers could be improved?	I support the changes for the small containers. Coversyl is a small plastic bottle which is sold in a cardboard container – there is a place for the dispense label on the cardboard container, however, customers throw the cardboard container in the bin and just keep the plastic bottle inside which now doesn't have a dispense label on it. If you were to place the dispense label on the plastic bottle, it covers up ingredient type and the expiry date. The proposed space for the dispense label is ok or perhaps TGA should make these different containers have a 'tab' for the dispense labels.
	See attached NHS Design Authority Medication Labelling Recommendations-2004
Pack inserts	
General	Are there any recommendations around font size, etc. for package inserts?
General question on the proposed regulatory changes for pack insert requirements	
Do you support the proposed changes for pack inserts? Why/why not?	Yes. Advertising not relevant at this level. Information should be specific for safe use of medicine and not potentially distracting.
	Yes, agree. Having access to the information without compromising/interfering with the packaging and its own information is important.
	Yes, I somewhat support this change. Although, I wouldn't like to see a lot of advertisement information, it will be good to include information about the Sponsor such phone number.
	Agree, no advertisement information should be included in the insert and it should be physically separate from the container for easier access.

Do you have any further suggestions regarding pack inserts?	Presentation of any duplicated information (brand name, active ingredients, order of ingredients, form, strength etc.) in the package insert should be consistent with how it appears on inner/outer packaging
	See earlier comments re electronic availability.
	Having a sizing standard or limit to font size and number of sheets per pack might also be useful.
	Just that the information should be easy and simple to read.
	Currently the information provided by the pack inserts can range between basic to technical (for example, product information with clinical trials data). Suggest standardising the format so all members of the public could easily understand (CMI information maybe).
Labels and packaging advisory committee	
(no comments received on this section)	
General question on the proposed establishment of a labels and packaging advisory committee	
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?	Having a platform to manage consumer health risks would most likely assist, given the variety of stakeholders proposed from across the health sector.
	To a great extent as they will have more of an idea of what is the best practice.
	This committee will provide the TGA with a broader view of the impacts medicine labels and packaging have on them and their work as they are the ones directly affected by the changes. With the different parties involved; manufacturers, providers and users, the many improvement possibilities could be explored and decided at a faster rate.
Appendix 1: Consolidated list of recommendations	
(no comments received on this section)	

Appendix 2: Reference list	
(no comments received on this section)	
Appendix 3: Organisations represented on the external reference group	
(no comments received on this section)	
Appendix 4: Questions & answers about the labelling and packaging review	
(no comments received on this section)	

Packaging design checklist

Issue	Recommendation	Page
Secondary packaging		
Medicine name and strength obscured	*Allocate 70 x 35mm white space for dispensing label*	19
Dispensing label and medicine name mismatched	*Position the generic name and medicine strength above or next to the space for the dispensing label*	21
Critical information does not appear in the same field of vision	*Put critical information in the same field of vision on at least three non-opposing faces*	23
Some text can only be read by flipping the pack or reading upside down	*Orientate text in the same direction*	25
Difficult to recognise important information	*Use blank space to emphasise critical information*	27
Brand name confused with the generic name of a medicine	*Ensure the generic medicine name is suitably clear*	29
Medicines with similar names confused for one another	*Use Tallman lettering to emphasise the difference between look-alike or sound-alike medicine names*	31
Wrong strength of a medicine selected	*Differentiate between strengths of the same medicine*	33
Easy to miss the decimal point in numbers with a trailing zero	*Do not add trailing zeros to numbers*	35
Small type size is difficult to read	*Body text in a minimum of 12 point*	37
Sentences in capital letters or italic type are hard to read	*Use upper and lower case*	39
Simulated handwriting and ornate typefaces are hard to read	*Use sans serif typefaces*	41
Lightweight typeface is hard to read	*Use bold or semi-bold type*	43

Issue	Recommendation	Page
Secondary packaging		
Condensed typeface is hard to read	*Do not use condensed typefaces*	45
Squashing lines of text closer together or reducing the distance between individual letters makes text difficult to read	*Do not squash lines of text closer together or adjust the spaces between letters*	47
Irregular amount of space between words	*Align text to the left*	49
Text illegible over an image or logo	*Do not place text over images or logos*	51
Insufficient contrast between background and type	*Create a strong contrast between type and background colour*	53
Using colour		
Colour differentiation inadvertently associated with a particular feature	*Use colour differentiation to highlight information*	57
Colour does not help distinguish between products in a manufacturer's range	*Use opposing, meaningless colours*	59
Primary packaging		
Glare caused by light reflecting on the foil	*Use non-reflective foil*	63
Text damaged when blister strip is cut	*Put medicine name and strength clearly on each pocket*	65
Reduced legibility due to combined effect of foil material, small type size and background colour	*Create a strong contrast between type and background colour*	67
Reduced legibility due to combined effect of a small type size and lightweight font on a foil background	*Use bold or semi-bold type*	69
Blister strip with the wrong secondary packaging	*Match the styles of primary and secondary packaging*	71

Recommendations

- Create a front panel that features only the key information. Subsequent information can be shown on the back panel.
- Key information consists of:
  - Non-proprietary drug name
  - Strength of the medicine:
    - > total quantity in the container (larger font); and
    - > strength per unit volume (smaller font).
  - Administration route(s)
  - Warnings

Recommendations

- Hide the manufacturer's barcode on end flaps and ensure that a barcode that can be used in clinical practice is present on the exterior of the pack.

Discussion

As we move towards using auto-id technology, linear bar codes containing the Global Trading Index Numbers (GTIN) will be required on all medicine products within the NHS, with the eventual goal of using GS1 codes.[12]

GTINs and 2D data matrix codes both contain the product name, batch number, expiry and possibly a unique pack identifier. This information can be used by both the manufacturers and the end users.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has recommended the use of 2D data matrix codes, and the Council of Europe report recommends these be implemented on unit packaging, such as ampoules and vials.[7]