TGA Medicine Labelling and Packaging Review

Consultation Paper

Response – 23rd August 2012

Nestle appreciate the opportunity to respond to the consultation paper on the TGA Medicine Labelling and Packaging Review and support efforts to improve labelling to make it easier for consumers to understand product labels and to help consumers to be able to use medicines correctly.

A well-designed label, which is easy to read, and enables consumers to readily find essential information, forms an important part in the quality use of medicines.

The proposals in this consultation document are to apply to all medicines, from prescription medicines to complementary medicines. Some of the objectives are to help address issues for higher risk medicines and while the proposed regulatory changes may be suitable for prescription medicines, in some cases they are unworkable for lower risk medicines. The proposed regulations may need to set different requirements for different risk medicines rather than trying to have a 'one size fits all' approach.

Nestlé sells ranges of complementary medicines and lower risk OTC medicines. Our ranges include herbal products, nutritional supplements, throat lozenges and chewable antacid tablets. The Nestlé comments to this submission are largely based on the effect of the proposed new regulations on these types of products.

Nestlé wishes to make the following comments on the proposed regulations outlined in the Medicine Labelling and Packaging Review.

1. Prominence of Active ingredients

1.1 This guideline is unclear on some points, which makes it very difficult to comment. The guideline states that the actives must be listed directly below the first letter of the brand name with the first letter of the active directly below the first letter of the brand name. However in the illustrations throughout the consultation document the first letter of the actives is directly below the first letter of the company name and not the brand name. Also it appears that in the illustrations the company name is bigger than the brand name which is slightly bigger than the actives.

For many OTC and complementary medicines the brand name is incorporated in a logo and does not always read left to right. Brand names can be in circles or at angles or running up and down. Some brand names and logos are in the middle of the label and cannot be easily moved to the left hand side of the label to accommodate the first letter of the active ingredients being below the first letter of the brand name. Sponsors of OTC and complementary medicines have developed logos to allow consumers to easily identify their brands and need to be able to keep their existing brand and logos. The active ingredients should be listed so as to be clearly visible and not mandated in every case to be directly below the first letter of the brand name.

1.2 The requirement to have active ingredients in equal prominence to the brand is unworkable in many cases. It seems excessive for listed medicines and lower risk OTC medicines where there is very minimal risk to the consumer from accidental overdose if they happened to consume multiple medicines containing the same active ingredients. Where there is a risk, this is already covered by mandatory warning statements and these will be on the back of the pack in the

medicine information box. Consumers of medicines will not know which ingredients carry a warning statement just by reading the active ingredient name on the front of the pack. The warning statements are equally as important as the active names for consumers to be able to use the medicine correctly. If consumers are going to be educated to look in the medicine information box for important product information then having the active ingredient names in large size on the front of the pack is unnecessary.

For many packs the brand and product names will need to be greatly reduced in size to allow the actives to be given equal prominence and for everything to fit on the pack.

Front of packs will become are covered in text that is all the same height. Bigger text for the active ingredients does not make it easier to find or read at all, especially when all text on the main label is of similar size. Labels will become cluttered and confusing, with reduced legibility and loss of product / brand recognition.

For products that consumers select themselves, first they look for the category of medicine they want to buy, then the brand, then the product name and / or the indications for use. These need to be given more prominence on the main panel of the medicine label than the active ingredients to help consumers find what they are looking for.

With equal prominence of active ingredients, brand names / product names and indications become difficult to find on the pack as they are lost in a block of text that is all the same size. The first thing that people are usually looking for when trying to find a medicine on a shelf or wall of products is the name. This proposal will make it much more difficult for consumers to find the OTC or complementary medicine product that they are looking for and it will make it more difficult for pharmacists to find the product that they are looking for. This proposal seems more likely to increase the chances of product mix up as product names would become smaller, get lost in the text on the label, and be more difficult to find and read. TGA should carefully risk assess the consequences before implementing a regulation that has the effect of making product names on packs smaller.

For our smaller packs to comply with this guideline, the brand name has to be made so small that the product would be hard to find on a shelf amongst all the other products. A possible outcome of this is that sponsors will increasingly use on shelf advertising or try to make their packs and labels larger if possible so that the product name can stand out.

The examples given in the guidance document are for actives with short names. Products containing active ingredients that are vitamins, minerals or herbal ingredients can have active names can be very long. For example herbal actives for complementary medicines require a description of the herb species, plant part, preparation, what it is equivalent to or standardised to, and the common name so that consumers know what it is. Text will have to be minimal size on the label in order to have any hope of fitting it in. For complementary medicines, active names would not get bigger, but all the other text on the main label would just get smaller.

For example if the active ingredient is freeze dried garlic powder the label may state something like:

"**Allium sativum (garlic) root freeze dried powder equivalent to fresh bulb 1000mg (standardised to contain allin 10mg)"**

To have 3 herbal ingredients like this in equal prominence to the brand name will mean that the brand name will just have to be extremely small to fit everything on the label. Far from helping consumers, this will only make it more difficult for consumers to find the product that they are looking for as the main label will be cluttered with words as sponsors try and keep the brand name as large as possible but small enough to just fit all required information on the label.

1.3 We do not at all agree with the proposal 1.3 as it will be confusing and deceptive.

Consumers seeing a list of active ingredients on the front of the pack would be likely to assume that it is a complete list of the active ingredients.

For multi active products, putting the 3 most abundant active ingredients on the front of the pack and the names and quantities of all ingredients on another panel does not help consumers and is only likely to confuse. Looking at only the three most abundant actives only in some cases implies a completely different product purpose to the indication for use.

It also implies that the active ingredients in the greatest quantity, as listed on the front of the pack, are the most important or carry the greatest risk, when this is not always going to be the case.

All active ingredients must be listed together to avoid deception or confusion and selective declaration of only some active ingredients on the front of the pack should not be permitted.

Many complementary medicines have more than three active ingredients and consumers of complementary medicines should already be used to looking at the back or side of a pack to find the actives. For low risk complementary medicines, the active ingredients can be put in an active ingredient section of the medicines information box. If this is standardised across all complementary medicines, and consumers know where to look for the actives, then there should not be a need to have the active ingredients (or some of the active ingredients) and quantities also on the front of the pack.

1.4 For OTC day and night products, the requirement to have the active ingredients on the main panel of a primary pack in 2mm font height is an improvement on the current minimum of 1.5mm and should be achievable. This may not be achievable for complementary medicine day and night products that may have more than 3 active ingredients in each formulation and the actives have very long names. For complementary medicine day and night products, where it is not possible to list all the actives on the main panel there needs to be an allowance for them to be listed on the side or rear panel of the primary pack, such as in the medicine information box only.

1.5 This point will not be possible to comply with in many cases especially for products with many active ingredients or ingredients with long names. Medicine cartons are often quite thin on the side panels and the only way to comply with a requirement to have the brand name and

active ingredients on 3 non-opposing faces will be to make the cartons wider. This could require retooling of packing equipment and considerable expense, which would be passed on to consumers with no benefit to the consumer. For OTC products, it is excessive for all the active ingredients to be required to be listed on the front, back and 2 sides of a medicine carton.

1.6 and 1.7 This is a good idea but should not be limited to non-prescription medicines. Any prescription medicine containing paracetamol or ibuprofen should also require the same information. Consideration should be given to either having a single statement that applies to all active ingredients or trying to differentiate the information statements for paracetamol and ibuprofen as they are quite similar to each other in wording.

Limiting this statement to paracetamol and ibuprofen only may suggest to consumers that these are the only two ingredients that this applies to and that it is Ok to take multiple medicines containing the same active ingredient if the actives are not paracetamol or ibuprofen.

In future if the number of ingredients that are required to have this type of warning is increased it will lose impact.

If consumers are being educated to look for important information in a medicine information box is there any benefit in selecting one warning and also putting it on the front of pack. Consumers seeing the warning on the front of pack may think that this is the only warning that they need to take notice of and ignore other important warning statements included on the back of the pack in the medicine information box.

Other: On figure 2: "The components of a label". Number 6 is listed as the website address of the TGA. There is no other mention of the TGA website address in the proposed regulatory changes. This seems to imply that the TGA website address will need to be on the main panel of each medicine label, if that is the intention then there could be some issues.

Many products are sold in both Australia and New Zealand in the same packaging. The TGA website address could cause confusion for New Zealand consumers and Medsafe could potentially not approve the labels or require an addition of a Medsafe website address as well. If the TGA website address is to added to packs then Australian and New Zealand regulators need to be in agreement as to the format so that it acceptable in both countries.

The landing page of the TGA would need to be made friendlier so that consumers arriving there can find useful information or post comments.

There would need to be consumer education that this is the TGA website and not a company website and what sort of information might be found at the TGA website.

The website address just sitting by itself may be confused by some consumers as the company contact details. Consumers may go to the TGA website seeking further information about the product and possibly call TGA or email their enquiry to TGA, if this happens TGA would need to have a way of responding to the questions and helping consumers to make contact with the correct sponsor.

The TGA website address with no other qualifying statement may be seen as implying that the product is somehow endorsed by the TGA.

3. Look alike sound alike names and packaging

3.1– 3.2 Sponsors of new medicines will be required to submit evidence of a risk assessment of the proposed labelling and packaging. How will sponsors be able to identify all medicines on the market that may need to be risk assessed against? For listed medicines will this require copies labels and a risk assessment to be submitted to TGA? This will add increased cost, and time for product listing and will require increased TGA resources with little or no increase to medicine safety for low risk listed medicines.

When developing new medicines, sponsors need a level of certainty that the proposed name will be acceptable. Sponsors cannot be expected to know that their brand name differs from all other brand names by more than 3 letters. TGA will need to provide some way for sponsors to check their proposed brand names electronically prior to listing or registration of new products.

The selection of "three letters or fewer" seems arbitrary for requiring contrasting design and colours.

The requirement of a risk assessment should not be applied to lower risk OTC medicines and listed medicines.

There are examples of brand families on the market where a sponsor has brand names with suffixes to differentiate the products. These different brands in sponsors 'brand family 'may differ from each other by three letters or less. For lower risk medicines this should be permitted without submission of a risk assessment. Sponsors of these brands already try to differentiate the different products and brands from each other to help consumers to select the right product.

For registered medicines, the TGA already reviews the label as part of the approval process and this process should be sufficient to identify any potential brand name similarity issues for registered OTC products.

At the time of listing a new medicine, if TGA find the brand name is similar to that of competitor's medicine brand then the sponsor should be contacted to provide more information for assessment rather than requiring a risk assessment for every new product listing.

Issues of look alike – sound alike need to also extend to foods and cosmetics. That is that food and cosmetic products and medicine products should not have the same or similar names and be capable of being confused where there is a risk to consumer health and safety.

3.3 We do not agree with this proposal. If there are two different medicines on the market where the brand name and colour design are not contrasting then a fair way of determining which product has to change needs to be developed. It is not fair to say that the first medicine to change the label must change their colours and designs to contrast with the other medicine.

Sponsors should be encouraged to update their labels to comply with the new guideline and not left concerned that they will be the ones who need to change product brand name or brand colours if they update their label before another sponsor.

For OTC and complementary medicines, sponsors try to make their brands and products differentiated so that consumers can find them. Brands and product appearance can have a lot of value, especially for OTC products where sponsors may have spent a lot of money advertising and promoting their product to consumers for many years in particular brand colours and design. Sponsors that are forced to change the product appearance may lose a lot of brand equity and be forced to do a lot of advertising to maintain the value of their brand. Any sponsors, particularly of OTC and complementary medicines, who are forced to change the appearance or brand of their product after many years of advertising and promotion, should be adequately compensated.

For products that consumers select, changes to medicine packs of products with similar sounding names should only be required if it is shown that there is a likelihood of consumers selecting the wrong product and there is a risk to the consumer. Over the counter products are usually placed in stores in therapeutic categories so it is very unlikely that a consumer would mistakenly select a medicine for a completely different category or indication. Sponsors of OTC products try to differentiate them from other products in the category and try to highlight the indications to help consumers select the correct medicine.

Look alike medicine branding

3.4 Product “name” needs to be defined. There are product ranges on the market where some products in the brand are listed products and other products in the brand are registered products and this should be allowed to continue.

3.5 Some active ingredients, at the same quantity of active ingredient per dose, may be suitable for totally unrelated indications. There would be problems in requiring all of the indications to be stated on the one product and advantages to the consumer in allowing selective marketing. Requiring a sponsor to put both unrelated indications on the label of a medicine may confuse consumers as to the purpose of the product, especially if a consumer sees the product advertised for only one of the indications for use.

For example Trifolium pratense 100mg may be used as the only active ingredient for products for relief of symptoms of menopause and relief of symptoms due to prostate enlargement. Requiring a sponsor to put both indications on the may confuse consumers as to the purpose of the product, especially if a consumer sees the product advertised for only one of the indications for use.

3.6 There are many medicines already on the market with different active ingredients sold under the one brand. A company's brand is its reputation and promise of a quality product to the consumer.

For lower risk complementary medicines, listed medicines and lower risk OTC medicines there is very low risk to consumers by having medicines containing different active ingredients under the same brand.

Consumers look to buy brands that they know from companies that they trust. Sponsors of OTC and complementary medicines may have many products, with various different actives under the one brand. Forcing companies to have a different brand name for every single product will lead to financial loss of brand equity and they should receive adequate compensation. There would also be an additional cost to amend the listing or registration of a multitude of complementary, listed and OTC products under new brands and have them re-ranged in stores with no benefit to consumer safety and the result would be utter confusion for consumers as they can't find the products that they have been buying and using for years.

Ranges of complementary medicines for example are often sold under the one brand name (or company name that is used like a brand name). There is no risk to the safety of consumers by this practice.

Retailers can have huge numbers of complementary medicines on the shelf and sponsors use brand names and brand colours for their product ranges to help consumers to navigate the category and find the brand and product that they are looking for. Requiring sponsors to invent new brand names for each individual complementary and OTC product that has different active ingredients will be of no benefit to consumers. It will cause problems for consumers as there will be many cases where they can no longer find the product brands that they regularly buy that have had to change brand name. Especially if each product that the sponsor owns has to be designed differently so that it does not look like the sponsors other products.

Sponsors are only able to advertise and support a limited number of brands. Companies that sell products under one brand internationally will not create a new brand for each product just for Australia as it would not be commercially viable. The outcome of introducing this regulation would be that Australians would not be able to buy many of the medicines that they buy today.

Products with different active ingredients must be allowed to continue to be marketed under the same brand. Though it is not unreasonable to expect that a brand that is strongly associated with a particular active ingredient by consumers should not be allowed to be used for a product that does not contain that ingredient and contains another ingredient of very different safety profile, if there is potential for consumers to mistakenly take the product thinking that it contains the active ingredient that the brand is well known for.

With the huge number of complementary medicine products, if each one is force to have a different brand name, it will hugely increase the number of brands and the likelihood of confusing the brand name of a product with that of another product on the market.

4. Medicine Information Box

4.1 We support the concept of the medicine information box on the primary packaging and suggest allowing some more flexibility in the design.

The barcode in figure 2 is also too small and would not be acceptable for retailers. In this figure the bar code would need to be larger and only fit on the back of the pack. This means that for this example of a normal sized carton, when the barcode is at the correct size and is located on the back of the pack, the medicine information box would not fit on the back of the pack as shown.

For smaller primary packs it will be very difficult to get the medicine information box in this format on the pack as well as the actives prominently displayed on the main label as required and to get all the information onto the label. For smaller packs we suggest that the guideline be written to allow a less rigid application of the format of the medicine information box to allow the information to be included on the label in a way that still provides good access to consumers of the information required.

Standardised information on labels of over the counter medicines will help consumers to find the information. This guideline requires the active ingredients to be in a font as large as the brand name on the main panel of a medicine and also to be in the medicine information box. If consumers are now looking for the active ingredients in the medicine information box then it is perhaps not as necessary to have them so prominently displayed on the front of the pack. This duplication will make it difficult to get all the required information onto some smaller medicine packs.

The heading medicine information box may cause difficulties for complementary medicines that are sold in both Australia and New Zealand in the same packaging and are regulated as medicines in Australia but are not medicines in New Zealand. It may also be confusing for consumers on products that they do not regard as medicines such as toothpaste or sunscreens. The box should be permitted without any heading as it will be obvious to consumers that it contains the important information about the product.

For smaller packs, especially our stickpacks and roll packs which are about 4 times longer than they are high, it is difficult to get the medicine information box onto the pack. Due to the format of the box, the information needs to be rotated at 90 degrees to the rest of the text on the pack, running across the pack rather than running the length of the pack. This means that the text put into the information box needs to be made smaller than it is on our existing packs to accommodate the headings, the format of the medicine information box and the orientation of the box.

For smaller packs, the guideline should specifically allow for the text to be included in a less rigid format to enable it to be included on the label. For listed medicines, where the product label is not reviewed by TGA, the guideline should be written in such a way that sponsors with smaller packs can comply with the written requirements of the guideline and not have to apply to TGA for exemptions from the guideline for each product.

A suggestion is to not require the title “Medicine Information Box’ and for a minimum of 2 bolded headings that are the same text height as the rest of the text in the box. For example the minimum headings could be “Active ingredients” and “How to use”, with everything other than the active ingredients being in the how to use box.

4.2 For smaller packs the guideline should allow the headings to have the same height as the other text of 1.5mm if sufficiently bolded and that the headings not have to be on separate lines to the other text. The heading “medicine information box” should not be mandatory for smaller packs. This flexibility in formatting of the medicine information box would allow for better label design, greater ability to put all the required information on the label and for easier to read text.

4.3 We suggest that sponsors be able to have the medicine information box in the brand colours, or the dominant brand colour on a white background as long as they are clearly contrasting and legible. Bolding of allergens should be also be considered as is often done on food labels.

4.4 Where there is insufficient space on one face of a pack then the medicine information box should be able to be broken up. This will be required for many complementary medicines with a large number of active ingredients. Pack inserts should not be mandatory in this case.

A suggestion is to allow 2 boxes, one for “Active ingredients” and the other containing all the information which could be headed “How to use”. This would be a help for complementary medicine labels with lots of actives that may need to break up the box to get all the information in.

4.5 Allergens should be listed in the medicines information box. Some flexibility in the design of the box and the headings should be allowed especially for smaller packs. Allergen names should also be bolded to help consumers find them when making a purchase decision.

4.6 For medicines with more than 3 active ingredients or for small containers, we do not agree with the proposal to have only the minimum information of the directions and warnings and allergen information in the medicine information box on the primary pack label, especially for OTC products that consumers may self select.

As well as the directions and warning and allergy information, a medicine must also have the following information on the primary label:

- Storage information so that the consumer knows how to store the medicine before opening it.
- Uses / indications for use so that the consumer knows what the medicine is for before they purchase it.

- All the active ingredients, so that the consumer can know all of the active ingredients before they purchase a medicine. Where all the actives are already included elsewhere on the primary pack label they should not have to be repeated in the medicine information box on small primary packs or primary packs for products with a large number of active ingredients.

6. Blister Strip Labelling

6.1 The information proposed for the blister strip (brand name, active ingredients and quantities, batch number and expiry date) is not sufficient.

As there are often different products marketed under the one brand name, the product name must also be included on the blister strip to easily allow the consumer to differentiate which product it is. If the product name is not included on the blister then the consumer would have to try and work it out for themselves based on the active names and quantities and consumers could confuse the different products if they remove the blister strips from the cartons.

The name of the sponsor should also be included on the blister strip.

It will not be possible to have all of the required information repeated for every two units on the blister packs. Problems will occur for products with multiple active ingredients or active ingredients that have long names, especially for complementary medicines.

There will be real difficulties in having a batch number and expiry date for every 2 dosage units. For imported medicines it may prove to be impossible to get suppliers to make this change just for Australia as the comparatively small volume of products affected would not justify the cost involved.

Adding extra batch codes and expiry dates will make the text more cluttered and difficult to read and will not reduce the risk of a consumer taking the wrong medicine if the blister is removed from the primary pack.

There are 2 options and both of them would add significant costs and complexity to the manufacturing process and Australian consumers would have to pay more to buy products in blister packs. The options will be

1) To preprint the blister foil with a new batch number and expiry date for every production batch and change the print each time. This would require a different item number of foil for each print run and the batch number and expiry date to be printed on the foil each run, with extra costs to change it each time and left over foil write offs. It would be exceptionally difficult for manufacturers who produce a lot of batches and there would be a potential for errors on the artwork or to mix up the foils and put the wrong foil on the blister. The long lead times for foil will also cause problems if the foil arrives later than expected and the

expiry date is wrong then the foil will not be usable. Perhaps this will mean no production can be scheduled close to the end of each month causing higher costs due to line downtime.

2) To print the codes online, blister packers will need to be reconfigured, if it is possible at all. New blister packers may need to be purchased, to have 4 coders for an 8 tablet blister. For online printing of the code it will be difficult to precisely print so as not to go over other text on the label. There would be costs to convert blister packers to be able to print all the codes and blister lines would need to be dramatically slowed down to accommodate the printing of batch and expiry dates which would add additional ongoing production costs.

Printing multiple codes on blisters online may require bigger blister platforms or fewer tablets per blister. A logical solution would be to keep the blister platform the same size but change from 8 tablets per blister platforms to 4 tablets per blister and put twice as many platforms in each carton. This will increase product cost, carton width and also result in extra packaging material use for no real benefit to the consumer.

6.2 If blister strips can be segmented, having all the information on each segment and also for every 2 dosage units is even harder and will also not be possible. The illustration in figure 10 of the guideline does not have all the information on each section even for a simple 2 section blister. Some blisters can segment into individual units or for each two units.

6.3 On a blister strip all of the active ingredients should be listed together. In cases where they cannot all be repeatedly listed for every two dosage units then either there should be a single list of all the active ingredients or the complete list of active ingredients should be permitted to be repeated but fewer times than for every two dosage units.

6.4 A blister strip should list all of the active ingredients that are in the product. For medicines with more than 3 active ingredients (or for actives with very long names) it is a far better solution to print a single list of the active ingredients on the foil than to try and print lots of 3 active ingredients for every 2 dosage units which may potentially be confusing for consumers.

For lower risk OTC, listed and complementary medicines we propose that the following be on the blister pack once. Sponsor name, brand name, product name, Name and quantity of each active ingredient, batch number and expiry date.

Batch code and expiry date should only be required once on each blister strip. Other information could be repeated only if space allows.

Consumers should be educated not to separate blisters from the carton and perhaps a statement on the blister and / or carton could advise consumers to store the blister with the carton.

7. Small containers

The definition of small container is for medicines labelled as having a nominal capacity of 20mL or less. There needs to be recognition in the guideline for small containers of products that are not liquids. It is suggested to have a definition of a small container based on the surface area of the container, or the surface area of a container that can accommodate a label rather than the labelled volume of liquid product inside the container.

We currently have the following small containers for which it is not possible to fit all of required labelling information onto the container.

- **Individually wrapped lozenges and chewable tablets where an unsealed individual wrap (container) is placed around the product and the individually wrapped products are packed in a primary pack, which is usually a stickpack**. The purpose of this type of individual chewable tablet or lozenge wrap is to prevent the lozenges or tablets from sticking together inside the primary pack. It is not possible to include a pack insert into a stickpack.

  A chewable tablet or lozenge may be only a few centimetres in diameters or a few cm X a few cm. The individual wrap is folded on one side of the lozenge or tablet leaving only one face where printing is readable.

  For this type of individual chewable tablet or lozenge wrap that is unsealed it is not possible to align the wrap so that the same part of the wrap always appears on the product face to be readable.

  Due to the very small size, only a very limited amount of information can be printed on the container. This information needs to be repeated several times on the individual wrapper to ensure that it in the correct area to be readable before the wrap is removed from the product.

  The best that can be achieved on an unsealed individual lozenge or chewable tablet wrap is to have information such as the sponsor name printed repeatedly on the wrap. It is also not possible to print a batch number or expiry date on this type of individual product wrap.

  These types of products are usually not removed from the primary pack prior to consumption as the unsealed individual product wrap (container) would easily come off and then the product would pick up moisture and become sticky.

- **Individually wrapped lozenges and chewable tablets where a sealed individual wrap is placed around the product and the individually wrapped products are packed in a primary pack, which is usually a bag.** The purpose of this type of individual chewable tablet or lozenge wrap is to prevent the lozenges or tablets from sticking together inside the primary pack.

  The sealed individual wrap for a chewable tablet or lozenge may have a face of only a few cm X a few cm. The individual wrap is usually sealed at both ends and down one side. This leaves only one full side of the container and approximately half of the other side that can be printed.

It is possible to print a limited amount of information on a sealed individual lozenge or tablet wrap but not a batch code or expiry date.

The guideline needs to make an allowance for the labelling of low risk individually wrapped tablets and lozenges.

We agree that small containers should be packaged into a primary pack that fully complies with all the labelling requirements. But if the primary pack fully complies with the labelling requirement it is unnecessary, costly and wasteful to also require a pack insert.

For some types of products such as stickpacks of individually wrapped lozenges or chewable tablets, it is not possible to include a pack insert into the primary pack.

For low risk OTC products and all listed products, a packaging insert should not be required where small containers are included in a primary pack that fully complies with the labelling requirements. In these cases, the inclusion of a packaging insert will not improve consumer safety.

7.1 We agree that small containers should be enclosed in a primary pack that fully complies with all the labelling requirements unless the label on the small container is able to fully comply with the labelling requirements. If the small container has a label that fully complies with the labelling requirements, then it should not be mandatory to add another level of unnecessary packaging.

If the primary pack complies with the labelling requirements then a pack insert should not be required for every product. Low risk OTC medicines, listed and complementary medicines should not be required to have pack inserts for every product with a small container.

It is not possible for us to include a pack insert in a stickpack of individually wrapped lozenges or chewable tablets.

7.2 For small containers of products with more than three active ingredients, we do not support the allowance of including only the three most abundant active ingredients on the container and the complete list on the primary pack and on a pack insert. In this case if the primary pack and the pack insert are discarded, a consumer is likely to think that the active ingredient list on the container is a complete list of the active ingredients.

Either all of the active ingredients, or none of the active ingredients should be included on the label of a small container.

There needs to be a section in the guideline for individually wrapped lozenges and tablets that can reasonably be complied with.

7.3 We do not have any prescription products so has not made any comments on dispensing stickers.

8. Pack inserts

8.1 We agree with the principle that advertising material should not be permitted to be included as a separate insert in a medicine pack or incorporated into a pack insert.

In writing any regulation about including advertising material in product packs, the definition of an advertisement needs to be considered.

The definition of an advertisement in the Therapeutic Goods Act is very broad and all product labels and pack inserts would be likely to meet this definition of an advertisement.

8.2 We agree that a pack insert should be separate to the packaging and not printed on the inside of the pack.