NSW tag New South Wales Therapeutic Advisory Group Inc.

ABN 82 707 308 091

2nd May 2012

Office of Product Review
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Dear Sir/Madam,

Re: Safety concerns regarding packaging and labelling of injectable drug products

NSW Therapeutic Advisory Group (NSW TAG) is an independent, not-for-profit organisation comprised of clinical pharmacologists, pharmacists, nurses and clinicians committed to promoting the quality use of medicines in NSW public hospitals and the wider community. We write to alert the TGA to recent packaging issues of prescription medications that have caused safety concerns amongst our member hospitals. These issues appear to be increasing in frequency and we believe they are placing patients at risk of serious adverse events.

Below is a list of recent issues to illustrate the types of problems frontline health care professionals and consumers are facing with inadequate or look alike packaging.

1) **Packaging of Clexane® injections**: Sanofi, makers of Clexane®, have recently changed the internal packaging of a number of Clexane® syringes. The manufacturers report that the change in packaging of Clexane® has been accepted by the TGA. A picture of the new packaging (with clear plastic backing) and the old packaging (printed paper backing) is attached. The new packaging has no name or strength on the pack. The strength is written on the syringe in tiny font. The change was made because there had been complaints of the paper backing tearing and the syringe being picked up incorrectly resulting in the plunger falling out. This may be better for patients using Clexane® in their homes where they will only have one strength available, but it is potentially unsafe for hospital practice, where multiple strengths are available for use. Selecting the correct drug AND the correct strength by reading the product label is an essential component of safe dispensing and administration.

The lack of clear product identification on the packaging makes the potential for product selection errors extremely high.

NSW TAG has raised concerns with the company regarding this packaging change. They report that they will look into it but are possibly favouring increasing the font size of the printing on the syringe. Our members do not believe this change would allay their concerns as the syringes are very small. Enlarging the font on the strengths of 60mg and above will not work as it will cover the graduations. The previous packaging had assisted Sanofi in expanding the hospital share of the market with most hospitals using enoxaparin as their preferred low molecular weight heparin. The use of Clexane in the hospital setting is therefore widespread and the new packaging presents an urgent medication safety concern.

2) **Look alike labelling of Astra Zeneca pancuronium and suxamethonium injections:** Concern regarding the look alike labelling of the above injections (photo attached) has been raised. Pancuronium ampoules have red coloured print and suxamethonium ampoules have pink print. The font and layout of the labelling of both products is the same. This is particularly of concern in operating theatres where these drugs are most likely to be used and where ampoules need to be removed from their external packaging some time prior to use. Astra Zeneca is the only manufacturer of these products in Australia. In the last 12 months NSW Health has had two documented near miss incidents where pancuronium and suxamethonium were mistaken for each other. NSW Health requested that AstraZeneca review the labelling & packaging of pancuronium injection in 2005 and has repeated this request in 2012.

3) **Similar packaging and labelling of Pfizer injections:** A number of Pfizer injections packaged in plastic ampoules (including lignocaine 50mg /5mL, heparin 5000unit 5mL, heparinised saline 50units/5mL and midazolam 5mg/5mL) have look alike concerns. Boxes of the products are very similar, the ampoules are identical in size and shape and the print format on the ampoules is the same or very similar. There have also been reports of the print rubbing off in operating theatres. The potential for product selection errors is very high. Pfizer has been alerted to this problem, has notified hospital pharmacies as a result and will address the issue over the next few months. These look-alike products could be used by consumers as well as health care professionals.

4) **Look alike Astra Zeneca injections**: Members have identified issues with the labelling of sodium chloride 20% 10mL ampoules and lignocaine 1% (Xylocaine®) 5ml ampoules, which are both packaged in rectangular plastic ampoules with purple labelling and are very similar in appearance. A photo is attached.

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5) **Inadequate and look alike packaging of Phebra injections**: We have also been alerted us to similar packaging of Phebra Potassium Chloride 22.3% Concentrated Injection 10 mL ampoules and Magnesium Sulphate Heprahydrate 50% Concentrated Injection 10mL ampoules. One end of the box is labelled with product identification details, the other is simply labelled "10 x 10mL vials", identical for both products. A photo is attached. If the products are stacked with the unlabelled end of the box showing there is huge potential for the wrong product to be selected, which could lead to serious outcomes. Moreover neither product is labelled in accordance with the TGA's Best Practice Guideline on Prescription Medicine Labelling*

As can be seen, a number of different manufacturers are involved. Many of the pharmaceutical companies have been responsive to the safety concerns raised with them. However, many of the necessary changes require technical consultation before changes can be made and are likely to take some months to implement. During this time, hospitalised patients remain at risk of serious medication errors. We believe a pre-release review of proposed labelling changes by consumers and practitioners in all health care settings is necessary to ensure safety is optimised. Consideration must be given to the way in which products are used, including consideration of the complex processes surrounding medication use occurs in the hospital setting.

Yours sincerely,

A. A. Bennett

Dr Sasha Bennett
Executive Officer, NSW Therapeutic Advisory Group

[redacted]

*http://www.tga.gov.au/industry/labelling-pm-best-practice.htm

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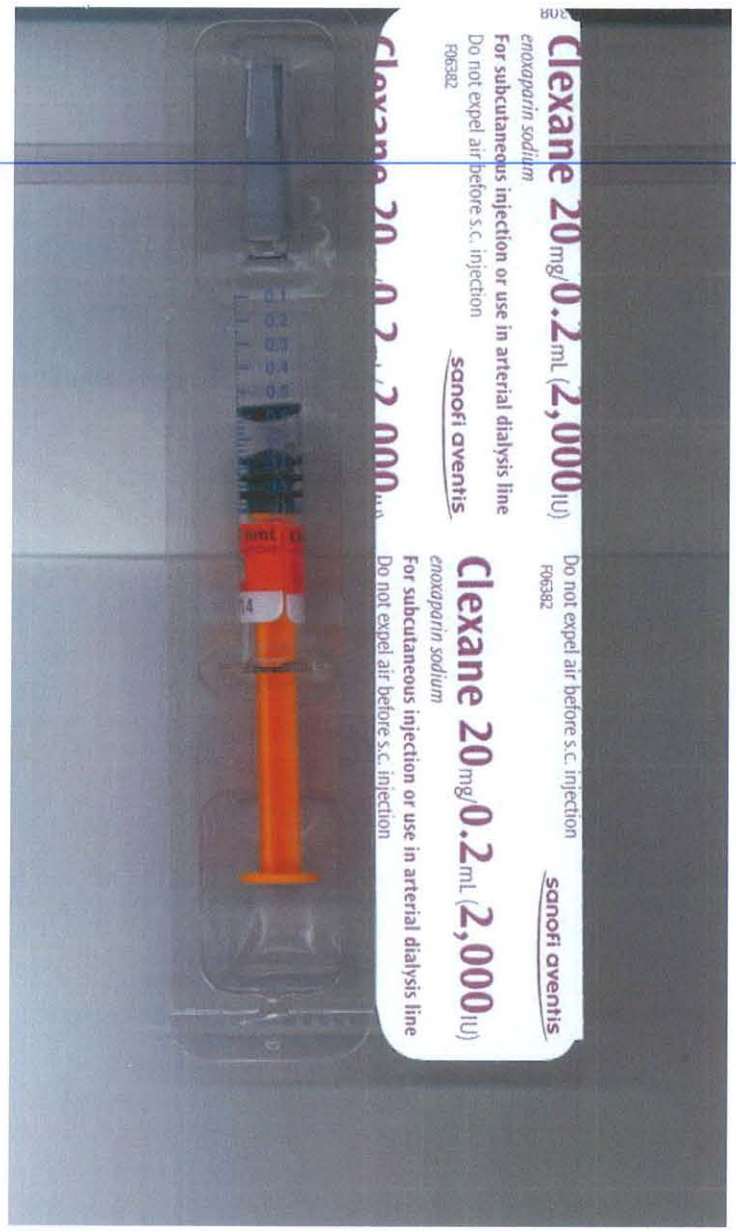
Sanofi Products: Clexane® Syringes

New and old packaging



Astra Zeneca Products:

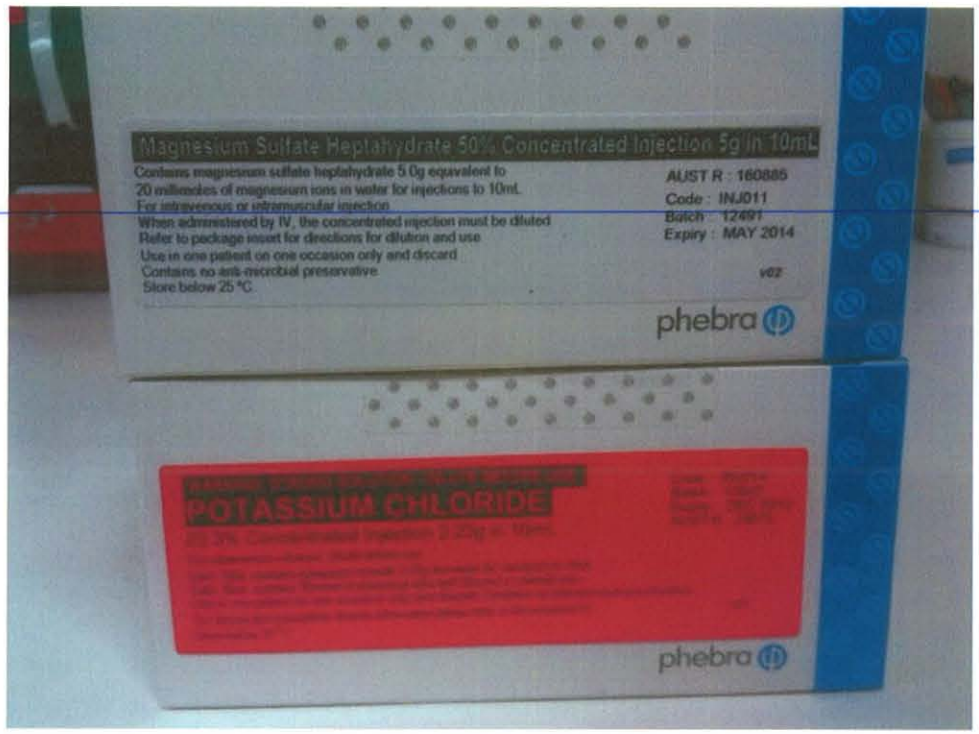
Pancuronium and Suxamethonium Injections

Pfizer Products

AstraZeneca Products:

Lignocaine 1% injection & Sodium Chloride 20% injection

Phebra Products



TGA Medicine Labelling and Packaging Review

23rd August 2012

Contact for further information:
Dr Sasha Bennett
Executive Officer
NSW Therapeutic Advisory Group

Email: nswtag@stvincents.com.au

The NSW Therapeutic Advisory Group (NSW TAG) is an independent not for profit association that promotes the Quality Use of Medicines (QUM) within and across the continuum of acute care. Our members are clinical pharmacologists, pharmacists, and other clinicians from each of the Drug and Therapeutics Committees in NSW public hospital and Local Health Districts. Our goal is to promote QUM by sharing unbiased, evidence based information about drug therapy and its use. Our objectives include supporting Drug and Therapeutics Committees to achieve safe, rational, high quality, cost-effective use of medicines in public hospitals and the wider community and hence the relevance of our position in putting forward this submission.

The objective of the TGA review of the requirements for medicines labels and packaging is to develop appropriate regulatory solutions that effectively address consumer safety risks. NSW TAG would like to emphasise that these consumer risks may be both direct and indirect. Changes to the regulation of medicines labels and packaging must consider the risks to consumers that may occur through medication handling by health care professionals in settings such as hospitals and extended care facilities, as well as those that may be encountered by consumers living in the community. Hospital settings represent quite different risks relative to the consumer's home use of medicines because of the vast range of medicines, the nature of those medicines, the numerous health care professionals handling medicines and the various complex hospital areas where medicines are handled.

NSW TAG acknowledges the difficulties that may be faced in reaching consensus opinion on the labelling and packaging of medicines, given the conflicting interests of the numerous stakeholders. We recommend that the best interests of the consumer be considered first and foremost in consideration of responses to the consultation, as this review provides a rare opportunity to significantly improve the safe and quality use of medicines for all Australians.

Prominence of active ingredients on medicine labels (1.1 – 1.5)
NSW TAG supports the concept of increasing the prominence and standardising the location of the active ingredient(s) on the medicine label. However, to achieve the goal of improving consumer knowledge of the active ingredient and also to reduce errors associated with product selection by health care professionals, NSW TAG strongly believes that the active ingredient name and its strength must be the **most** prominent feature on the medicine label. It is strongly recommended that the active ingredient(s) must be listed immediately below "Keep Out of Reach of Children" and **above** the brand name. This will ensure that consumers and health care professionals can readily locate the active ingredient name and strength.

Requirements of different letter spacing, font colour and style as proposed, will enable manufacturer's to make the brand name more prominent. The proposed regulatory changes would also allow manufacturer's to use upper case lettering, different colour backgrounds, bolding and/or italics to make the brand name appear more prominent than the active ingredient name. It is therefore recommended that greater specification is given to the attributes (and location) of the active ingredient and brand name. NSW TAG understands that differentiation between the brand name and active ingredient name is important and we therefore propose the following:

- the active ingredient name should be appear in a consistent format so as to be instantly recognizable. We suggest that the active ingredient name(s) should be white emboldened lettering on a black background. The brand name may use a different font colour to achieve prominence and differentiation but must be on white/off-white background.
- the font size of the active ingredient name(s) must be greater than that of the brand name on the main/front label,
- the active ingredient name(s) must be the largest font size of any writing on the label and
- the brand name must be directly under the active ingredient name.

It may be also prudent to specify minimum (and maximum) heights of lettering in millimetres rather than font size only.

Difficulties arise when there are more than three active ingredients in a product. The current recommendations suggest that the most abundant active ingredients should be listed (not including cough and cold products). However, abundance does not always reflect potency or predilection to adverse reactions. Further consideration is required regarding the description of active ingredients where there are more than three active ingredients in the product. Strategies may be identified from international regulators.

We also believe that the drug strength should have equal prominence to the active ingredient name, should appear directly next to the active ingredient name in the same font so that the exact product can be read and identified in one step. This will assist consumers to identify the strength they are taking and minimize selection of the wrong strength by health care professionals.

Bearing in mind that products are usually stored in pharmacy and clinical areas with the ends of the box displayed, to avoid product selection errors we believe that the active ingredient name and strength should appear on all faces of the box with greater prominence than the brand name

Standardising expression of product strength (concentration)

For all liquid medicines, including oral liquids and injections, a standard expression of strength (concentration) should be recommended. We suggest that the strength should be stated as quantity **per mL**. At present manufacturers can state the strength of the liquid in any way, resulting in significant variation (e.g. per mL, per 5mL, per 10mL, as a percentage or as a ratio). Misreading or misinterpretation of the strength leads to miscalculation of the volume required to administer a dose and serious adverse outcomes, often in high risk populations such as children.

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Use of symbols and abbreviations on packaging
The Australian Commission on Safety and Quality in Health Care's **Recommendations for Terminology, Abbreviations and Symbols used in the Prescribing and Administration of Medicines** (http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/32060v2.pdf) should be taken into consideration in the labelling pharmaceutical products. Whilst this document is primarily intended for use by healthcare professionals when prescribing and administering medicines, compliance with its use would be supported if pharmaceutical companies also adhered to its recommendations. For example, the use of "u" for units has been the cause of many medication errors, mainly because it can be misread as a zero resulting in a 10 times overdose. The use of "iu" for international units has resulted in the i being read as a 1 (e.g. 14 iu read as 141 u). These abbreviations are discouraged from use in prescribing, however are frequently seen on product packaging which acts to support their use.

Anti-inflammatory warning (1.7)
In relation to the warning regarding the use of ibuprofen: a similar warning should be on all over-the-counter non-steroidal anti-inflammatory medications such as diclofenac and naproxen.

Look-alike and sound-alike (LASA) medicine brand names and look-alike (LA) packaging and branding (3.1 - 3.3)
NSW TAG supports the process of risk assessment of LA packaging prior to the release of the product on the Australian market. NSW TAG is alerted to at least one incident involving LA packaging on a monthly basis. NSW TAG strongly supports 'purchasing for safety' initiatives of procuring organisations.

We support electronic screening of proposed new brand names against existing brand names to identify potential LASA names. However, this proposal should be extended to include screening of all new generic drug names, which are frequently confused with each other (e.g. amlodipine/amitriptyline; glipizide/gliclazide/glibenclamide; fluoxetine/fluvoxamine). Confusion between brand and generic names also occurs (e.g. Clomid/clomipramine, duloxetine/Doloxene).

We also suggest that a more rigorous method of assessing the likelihood of drug selection errors should be considered when assessing new drug names for safety. International literature should be reviewed to identify and evaluate mechanisms currently in place for assessing potential new drug/brand names. One example that NSW TAG is aware of is the ERRS model, developed by the Institute for Safe Medication Practice (ISMP) in the USA, which uses a rigorous testing process to evaluate the potential for LASA errors with new drug names. The ERRS evaluation process involves testing the interpretation of the name when written in different handwritings and when spoken with different voices/accents. More information is available at http://www.med-errs.com/Contents/ErrsModel.aspx

NSW TAG does not believe the proposed threshold of two letters is sufficient to reduce LA names and packaging. This is exemplified by the 'Coversyl" and "Coumadin" controversy that occurred in 2010. This LASA issue would not be averted under the proposed changes. Other factors such as place in the alphabet, indication and visual shape or length of the name and strength(s) of the product must also be considered in the risk assessment of potential LASA names and LA packaging. Examples of other products that vary by more than three letters and are frequently confused by both patients and healthcare professionals include: Diamicron/Diaformin/Diabex; Avandia/Avapro/Avandamet; Topamax/Tofranil; Nexium/Lexapro. We could list many others.

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Computerised techniques may assist with identification of potential LASA names and LA packaging. Any new screening technique should be employed to identify potential issues with both existing and new products. Currently organisations are reactive to incidents that occur due to LASA medicines which results in significant cost to the manufacturer in changing its packaging and a period of time when a known risk still exists due to the time involved in rectifying it. A screening system would enable us to be proactive in preventing errors. For products identified as being at risk for confusion, NSW TAG supports the proposal to use contrasting colours and designs to differentiate the two products. Particular attention should be given to injectable drug products, which are frequently packaged in plain boxes (due to them not being marketed to consumers) and are the subject of many product selection errors in the acute care setting. Examples, including images, were provided to the TGA in a recent letter (dated 2nd May 2012) highlighting these issues (attached). In addition, major concern is currently being expressed in the hospital sector with regard to look-alike Pfizer polyamps.

Medicine Branding (3.4 - 3.6)

We strongly suggest that consideration be given as to whether generic brands of existing prescription medicines should be allowed to be given new brand names. This practice adds to the ever-increasing pool of product names and increases the risk of LASA errors. Healthcare practitioners cannot be expected to be aware of all brand names for every medicine, and as such the potential for medication errors is increased. Consideration should be given to the UK model for naming of generic medicines.

Use of the same prefix for multiple products, for example, APO, Sandoz, Hexal etc., should be discouraged. It is not uncommon in hospitals for a patient to report they take “Sandoz” thinking it is their medicine’s name. This practice also increases product selection errors and encourages unclear prescribing. These prefixes have also been involved in generic versus brand name confusion, for example APO brand of morphine has been interpreted as apomorphine.

Our members believe that suffixes used in product names should be standardised. For example, the consistency in naming and labelling of controlled release products needs to be improved. There are numerous different terms which may or may not imply that the product is controlled release. Controlled release preparations may use suffixes such as XL, XR, ER, CR, and CD amongst others. There can also be confusion in the meaning of these suffixes. For example, CD may stand for “controlled delivery” or “chewable/dispersible”; ED may mean “extended delivery” or “every day”. Some controlled release products do not use a suffix (e.g. Imdur (isosorbide mononitrate SR) and Kapanol (morphine sulfate SR)) and often the release characteristics of these products are only printed in small writing on the packaging. There can be variation between the terminology used for identical products from different manufacturers (e.g. controlled release nifedipine: Adefin XL, Adalat Oros, Addos XR; controlled release venlafaxine: Efexor XR, Elaxine SR, Altven). Consistent terminology would assist health professionals and patients to easily recognise and identify controlled release formulations and prevent the wrong product being dispensed or administered. Another consequence of the confusion is that medicines may be crushed or chewed inappropriately, which may result in adverse effects.

Furthermore suffixes such as ‘HCT’ and “Plus” to indicate an add-on drug to another medication are not acceptable. In our experience this is confusing to patients (for example, misinterpreted as being the “stronger” version of the drug) and is often missed in medication history taking. It

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also often results in the wrong preparation being dispensed or administered to the patient. It is unclear whether Point 3.6 applies to this practice, and perhaps this point should be expanded for clarity.

With regard to point 3.5, NSW TAG recommends that products cannot be marketed as "BRAND headache" etc., if they include the same active ingredients *no matter what the quantity*.

Standardised Information Format: the Medicine Information Box (4.1 – 4.6)
NSW TAG supports the consistent placement and presentation of key medicines information so that consumers are assisted in making informed choices and using medicines safely. These boxes represent an added safeguard for medicine use but are not a substitute for patient counselling or provision of CMIs. The way in which information is currently presented in Figures 6, 7 and 8 is hard to read and contains inconsistent content and headings. Rules regarding how information is presented including the language used and the layout are required.

It is paramount that these boxes contain evidence-based information and acknowledge that not all patients may derive benefit from a medicine. This is exemplified in Figure 6 where the information under "Uses of Chondroiton" is not evidence-based and suggests certainty of action. This figure also gives details of sodium content per daily dose rather than per tablet, which could cause confusion to consumers. The medicines information box should state facts only and should not feature any marketing messages, such as the use of "easy to swallow" tablet in Figure 6.

The messages in the "When using this medicine" panel require greater prominence and emboldening of "If pregnant or breastfeeding" and "Keep out of reach of children". We suggest this section be entitled "Precautions". The latter precaution applies to every medicine and should be given greater prominence at the top of the panel. For all oral liquids the packaging should feature a reminder to replace the child resistant cap after each dose. Incidents have occurred where a bung is inserted into the bottle and the cap not replaced and children have then been able to consume the medicine.

It is also noted that in Figure 6 there is information under "Storage Information" that is not storage information. If information about the product appearance is deemed a requirement in the Medicines Information Box, this may need its own section. Furthermore regarding potential side effects contained in the "Warnings and Allergy Information" section, it is unclear what threshold for listing of side effects will be used for inclusion in the panel. In Figure 7 the "Warnings and Allergy Information" contains 'floating' information regarding preservative content (as required by point 4.5 of the recommendations). This information should have a standardised placement in the Medicine Information Box and have an emboldened heading such as "**Potential allergen**: contains X% YYYYYY as a preservative".

An alternative suggestion could be to include this information in a section titled "Other ingredients". It would also be useful for consumers to be able to quickly and easily identify ingredients they may wish/need to avoid, such as gelatin, colours, flavours, sucrose, lactose etc. Some E-numbers may be of animal or vegetable origin and there are many who want to know the origin of a substance (bovine, porcine etc.) "Emulsifying agent" is not sufficiently informative. Equally if a product has been made adopting a religious practice e.g. halal gelatin, this should be made clear on the labelling.

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As the Medicines Information Box has been modeled on the FDA's Drug Facts Box, we suggest it may be useful to seek feedback from FDA regarding perceptions of the Drug Facts box and any proposed changes to their version. Moreover it is unclear whether the Medicines Information Box applies to prescription products as well as OTC products. If used for prescription products, confusion may be raised with the Indication listings when medicines are used 'off-label'.

The font size for the Medicine Information Box may be too small, and the cramped spacing (in order for it to fit on the package) may make it too hard for people with visual impairment to read. A potential solution is to make a printout of the Medicine Information Box with the text in large font and wrap this around the actual medication blister strips or bottles inside the packaging then hold it together with a small removable seal containing the words "Warning: Please read the following information carefully prior to using this medication."

The use of scannable QR codes on packaging has also been suggested by our members. These would link the consumer to full product information and may avoid consumers accessing less reputable information about their medicines on the internet.

Dispensing label space (5.1 – 5.3)
NSW TAG supports a designated space for the dispensing label on prescription medicines. This will ensure important consumer information is not covered by a label. However there appears to be an inconsistency between the information provided: "The standard size of label used in Australia is 80 x 40 mm" (page 30) and the size of the designated space for a label of 70 x 30 mm (page 31). The allocated dispensing label area should be the same size or slightly larger than the standard dispensing label size.

Consideration should also be given to the findings from the 3D Labels Project, which can be accessed via
http://beta.guild.org.au/uploadedfiles/Research_and_Development_Grants_Program/Projects/2003-010_fr.pdf

We suggest that the recommendations are more prescriptive on exactly where the dispensing label space should be (i.e. internal or external packaging). The external box is often thrown away, so we would advise that dispensing label space be included on the direct medicine container wherever possible, for example with topical preparations, inhalers, oral liquids and tablets/capsules that come in a bottle within an external box.

Blister strip labelling (6.1 – 6.5)
NSW TAG does not believe the proposed changes for blister strip labelling are sufficient. As mentioned above, it should be borne in mind that in hospitals blister strips are often removed from the external packaging for supply to patients (in plain labelled boxes) or to clinical areas for administration to patients. The information on the blister strip is therefore relied upon for clear and accurate product identification. It is common practice to cut or divide blister strips to avoid wastage, so information needs to remain intact if this occurs.

With the current recommendations, vital information about the product may be obscured or lost if the blister strip is cut or divided. In addition we feel that the labelling may become obscured once the contents are removed from blisters. We recommend that active ingredient, strength, brand name, expiry date and batch number plus a *bar code* must be on **every unit** of the blister pack. It may sometimes be difficult to fit all information on one side of the blister unit and in these cases expiry dates and batch numbers could be placed on the other side of the

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packaging for each unit. Labelling of the individual dosage units would ensure that the product remains identifiable down to the last dose being removed from the blister, and if the blister were cut or split. It should also be noted that in the example shown in Figure 10, if the perforation down the middle of the blister pack is used, the information about the medicine would become inadequate on each half of the blister. Hence, it should be considered that any perforation that can be used to separate units must ensure each unit contains the recommended information when the units are separated.

Barcoding of unit doses

Barcoding at the point of care is a simple but effective way of significantly reducing medication administration errors in hospitals and care facilities. It works with electronic medication records, an area into which Australia is rapidly advancing at the current time. The professional administering the medication scans the patient's wristband which brings up the patient's medication chart. The professional then selects and scans the drug product and the system will alert the user if the wrong product has been selected. This system is in widespread use in the USA and has been shown to dramatically reduce administration errors (ref: ASHP Statement on Bar-Code-Enabled Medication Administration Technology, available at http://www.ashp.org/DocLibrary/BestPractices/AutoITStBCMA.aspx). The ASHP document states that each unit dose package should be labelled with both human-readable medication identification information and a machine-readable code that includes the medication's unique identifier and, when feasible, its lot number and expiration date. Reportedly, the driver behind implementation in the USA was a mandate from the FDA that all drug products must be barcoded at unit dose level. Australia needs to consider barcoding at the point of care alongside the implementation of electronic medication records. Pharmaceutical companies should be encouraged by the TGA to prepare for the implementation of barcoding systems. A mandate from the TGA to insist that medications are barcoded at the unit-dose level would mean that Australia would be ready to advance this important medication safety initiative. The TGA labelling and packaging review provides an excellent opportunity to explore this further with key stakeholders.

Small containers (7.1 – 7.3)

NSW TAG agrees with the recommendation that the label on the internal container for small containers should contain details in a letter height no less than 1.5mm. The active ingredient(s) and strength should be given prominence, as for external packaging. Unusual abbreviations and terminology, such as guttae, otic etc., should be avoided as per the ACSQHC recommendations, because these are not universally understood and can lead to errors.

The preservative content should be listed for injections, not just eye drops as currently proposed.

Patients with visual impairment often struggle to read the information on small packages. Health care professionals may select the wrong product from the shelf due to the product identification being too small. We would suggest that small containers have normal size packaging that complies with all of the TGA new recommendations. A cardboard insert or sleeve can be placed inside the packaging to hold the medication.

Labelling of Internal Packaging Other than Blister Strips and Small Containers

As stated previously, it is commonplace in hospitals for products to be removed from their external packaging (box) and the external packaging discarded. Indeed many patients do this in their homes. Although the recommendations consider the labelling of blister strips and small

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containers, we feel the recommendations are unclear on the labelling of other internal packaging. We believe that all internal packaging, whether or not this forms a part of the delivery system, should be subject to the same standards for labelling of drug name, brand name and strength, batch number and expiry date as the external packaging (including layout of information and allocation of dispensing label space). This includes the packaging for injectable solutions, inhalers, patches, nebuliser solutions, sprays, oral liquids etc.

A recent example highlights the heightened risk to consumers that inadequate internal packaging and labelling represents in the hospital setting. Clexane® (enoxaparin) syringe packaging was recently changed because of consumer complaints about syringe access. The paper backing, which was previously labelled with the proprietary name and strength of the product, was changed to a clear backing with no description of the product. The syringe is too small for adequate labelling containing the description of the product. Whilst the changes may have helped the consumer access a one-strength syringe in their home, the change represents major risks to hospital handling of Clexane® where multiple strengths are stocked. It is unclear whether the proposed packaging and labelling changes had been evaluated by hospital practitioners prior to introduction. The company informed NSW TAG that the TGA had accepted the packaging and labelling changes. Information from the company suggests that re-labelling of the packaging is unlikely to occur in the future as the changes have been made globally. It should also be noted that rectification would add expense to the current packaging. In response to our and others' concerns, Sanofi Aventis produced posters for use in hospitals to advertise the change but this is unlikely to adequately address the increased risk to consumers and health care practitioners that this packaging and labelling change represents. This incident further highlighted another issue regarding packaging and labelling: that companies were likely to be more responsive to our concerns when actual harm had occurred as opposed to preventing harm.

Package Inserts (8.1 - 8.2)
It would be an extremely valuable addition to include a removable sticker stating the active ingredient(s), brand name and strength inside the package for patients to remove and keep in their medication record. This will facilitate the transfer of this important information to all healthcare providers.

Labelling and Packaging of Schedule 8 and Schedule 4D Medicines
Pharmacist members have indicated that it would be useful if liquid Schedule 8 medicines were printed with accurate volume markings on the bottle, to enable the pharmacist to accurately record the remaining volume in the bottle to meet legislative requirements.

Schedule 8 and Schedule 4D medications should be sealed with a tamper evident seal (including liquid formulations).

Labelling of Batch number and Expiry Date
NSW TAG suggests that batch number and expiry date should be printed on the packaging, not embossed. Embossed details can be very difficult to read for both health care professionals and consumers.

Evaluation of changes
NSW TAG is unable to comment on the value of the recommendations to reduce the potential for harm as they currently stand, as no evidence has been presented that any of the

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interventions have an impact in practice. As such NSW TAG recommends evaluation of changes to the labelling and packaging of medicines.

Labels and packaging advisory committee

As outlined at the beginning of this submission, medication management in hospitals and similar settings can be hazardous to consumers given the vast range of medicines, the nature of these medicines and the numerous and diverse range of health care professionals that handle medicines. In particular, look alike and sound alike (LASA) medicines pose increased risks to consumers in hospitals. There have been numerous incidents and near-misses due to LASA medicines in recent months in NSW hospitals.

NSW TAG strongly supports the formation of a TGA labels and packaging advisory committee that includes independent multidisciplinary health care practitioners working in a variety of health care settings as well as consumers and regulators i) to screen any proposed changes to packaging and labelling of ALL medicines and ii) to assess labelling and packaging of ALL new medicines prior to their registration in Australia.

In summary, NSW TAG recommends that the TGA takes a strong and leading position on labelling and packaging of medicines that incorporates evidence where available, to ensure medicines are used with optimum safety by both consumers and health care professionals in all settings.

Promoting the quality use of medicines

P.O. Box 766 Darlinghurst NSW Australia 2010 • **Telephone +61 2 8382 2852** • Fax +61 2 8382 3529
Email: nswtag@stvincents.com.au • Web: www.nswtag.org.au
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