NOTIFICATION

17 June 2016

Establishment of the PHARMAC labelling preferences for prescription pharmaceuticals

PHARMAC has established 'PHARMAC labelling preferences for prescription pharmaceuticals'. This was the subject of a consultation letter dated 30 June 2015. In summary, the decision is that:

- PHARMAC will have preferences for naming and labelling of pharmaceuticals it is considering for funding.
- These naming and labelling preferences are voluntary, and PHARMAC will use these preferences within the context of its wider decision-making framework when considering medicines for listing in the Pharmaceutical Schedule.
- PHARMAC will continue to consider naming and labelling alongside all other relevant considerations, for example costs and savings, health needs, health benefits, suitability, securing supply, and benefits associated with harmonisation with other jurisdictions.
- PHARMAC does not intend to apply these preferences retrospectively to products that are currently listed. However, should currently listed products be re-evaluated, for example following a new procurement process, the preferences will apply.

PHARMAC decided on establishing its labelling preference in June 2016. In doing so PHARMAC also decided that these preferences would undergo a review at such a time PHARMAC considers necessary. PHARMAC intends to keep its preferences aligned with the governing legislation. In the event that the governing legislation adopts or conflicts with the PHARMAC preferences, PHARMAC intends to make the appropriate changes.

These preferences are separate from requirements set out in legislation and regulations. We're confident they are consistent with regulatory requirements. But if inconsistencies arise, then regulatory and legislative requirements (including those that might occur in future) take precedence.

Details of the decision

As part of our Annual Tender evaluation process, PHARMAC seeks advice from the Tender Medical Evaluation Subcommittee (TMESC) of PTAC and other clinical advisers, who review samples and consider whether these pharmaceuticals would be suitable for Sole Subsidised Supply and Hospital Supply Status. During this process the TMESC frequently identifies the same or very similar issues with the suitability of pharmaceutical packaging, naming and labelling for different products every year. As a result of this, PHARMAC considers that the establishment of a labelling guidance document would provide suppliers with clarity on naming and labelling considerations and ensure a consistent approach to reviewing pharmaceuticals.

These preferences would be used in the review of Tender samples as well as other pharmaceuticals being considered for funding. The labelling preferences will be published on

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the PHARMAC website under the Tools & resources tab and linked in the Information for Pharmaceutical Suppliers section. Please follow this link.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by PHARMAC were considered in their entirety in making a decision on establishing the preferences. Most responses were supportive of the proposal. Issues raised and PHARMAC comment can be found below

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.

FEEDBACK RECEIVED

We appreciate all of the feedback that we received and acknowledge the time people took to respond

Clinical responses- refer to those responses submitted by health care professionals, District Health Boards and health care professional representative organisations.

Industry responses- refer to those responses submitted by pharmaceutical suppliers and pharmaceutical supplier representative organisations

Other responses- any responses which do not fall within the above two categories

Themes/Preference	Submission content	PHARMAC response
Support for the establishment of PHARMAC pharmaceutical labelling preferences.	The majority of supportive responses were from health care professionals and their representative organisations. Responses which supported the initiative: • Considered the preferences set out specific guidance in a detailed, clear, straight-forward manner. • Considered the preferences are an important step for patient safety and harm minimisation and would improve medication safety in the healthcare professionals' workplaces and at home. • Considered the preferences would help reduce confusion between health care professionals when discussing medications. • Considered PHARMAC is entitled to set its own requirements as a purchaser over and above the legislative requirements.	We consider the establishment of the PHARMAC labelling preferences for prescription pharmaceuticals would: • encourage the use of naming and labelling features that would support the Ministry of Health to reduce preventable harm from medication errors; • improve patient safety; • align with international best practice as outlined by our clinical advisers; and • increase transparency and consistency of our review processes.
Responses against the establishment of PHARMAC pharmaceutical labelling preferences.	The majority of responses that were not supportive were from pharmaceutical suppliers and their representative organisations. Responses which did not support the initiative: • Considered that the introduction of another set of guidelines would create confusion and impact on safe dispensing of medicines. There is therefore no need or place for a separate set of PHARMAC labelling preferences. • Considered evaluation of the safety, efficacy, and quality of medicines available in New Zealand is the responsibility of Medsafe. • Noted harmonisation of labelling requirements with overseas jurisdictions is particularly important for products supplied in New Zealand. Many products coming into New Zealand are supplied in packaging that is either harmonised with Australia, or is global packaging from the United States or United Kingdom. Requiring specific packaging for New Zealand is not viable given the small volumes of products distributed in New Zealand.	As part of our review processes PHARMAC seeks advice from the Tender Medical Evaluation Subcommittee (TMESC) and other clinical advisers on suitability of pharmaceuticals including naming and labelling. We consider it is important to identify known preferences so pharmaceutical suppliers developing labelling are making an informed decision about labelling of products intended for the New Zealand subsidised market. We will work alongside the Ministry of Health including Medsafe to ensure that our preferences are aligned with current and future legislation. Should there be any inconsistencies between PHARMAC's preferences and regulatory requirements, the latter will take precedence. The PHARMAC naming and labelling preferences are voluntary. The naming and labelling of pharmaceuticals will not be considered in isolation. We will always consider pharmaceuticals

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		for funding in the context of meeting our statutory objective and all other relevant considerations such as costs and savings, health needs, health benefits, suitability, securing supply, and benefits associated with harmonisation with other jurisdictions.
Clarification on use of the labelling preferences	Clarification was sought on • Whether the preferences would only apply to products that win tenders, ie Not requests for proposals (rfp) • Whether the preferences apply to both generic and innovator products • Whether PHARMAC would prefer products meeting these preferences, even if there is a greater cost associated • Which naming convention PHARMAC prefers for biologics/biosimilars that win tenders? • What are the labelling issues that these preferences are proposing to address • What the implication would be for pharmaceuticals already funded that may go through the tender process. Clarification suggestions • If and when final PHARMAC preferences are released, it should be clearly stated that these are guidelines only, and not mandatory requirements for suppliers. • PHARMAC should provide clarity on how these preferences would be used in funding decisions, and how they might relate when used with other criteria. For example, all things being equal would PHARMAC choose harmonised packaging over one that met additional labelling preferences?	We have added a preamble to the preferences document to outline how these preferences would fit into PHARMAC decision making. Preferences would apply to all labelling, innovator and generic. PHARMAC has not taken a position on naming conventions on biologics/biosimilars at this stage. The International Medication Safety Network (IMSN) 2013 Position Statement, that these preferences have largely been adopted from, outlines naming and labelling issues further in its background section. At this stage the preferences cover those factors which most frequently cause concern to us and our clinical advisers, some of which have been fed back from prescribers, dispensers and those administering pharmaceuticals.

Themes/Preference	Submission content	PHARMAC response
Preference 1- International non-proprietary names (INNs) ***1.1. PHARMAC prefers that proprietary (trade) names for pharmaceuticals are derived from INNs (generic names).*** ***1.2. Where the trade name is the INN name in combination with the company name as an identifier, PHARMAC prefers:*** ***1.2.1. The company name to be a suffix*** ***1.2.2. The company name to be written in full to avoid confusion with formulation type. For example, `ibuprofen-companyx' not 'ibuprofen-com'*** ***It is expected that with two exceptions (adrenaline and noradrenaline) the INN will be used on medicine labels in the New Zealand market. PHARMAC recommends the New Zealand Universal List of Medicines (NZULM) be consulted when designing a pharmaceutical name.***	Clinical responses • Endorsed PHARMAC's support of the WHO initiative to protect INN's and supported the use of INN names. • Did not support the use of suffixes and prefixes in brand names, outlining suffixes should only be used to convey meaningful information such as pharmacokinetic properties. • Suggested the order of ingredients for combination products needs to be consistent and, for combination products with two ingredients, the ingredients should define the product name. For combination products with three or more ingredients a standard name terminology is needed. • Noted that for biologics there are claims that the trade name should be used because of allegedly greater uncertainty as to generic substitution with biosimilars. However, considered PHARMAC should not make any naming exceptions for biologicals. Industry responses • Noted the practical implications such as where a difference between INN and the Australian Approved Name (AAN) exists for products harmonised in Australia, as well as when well-established international brand-names conflict with the preferences.	Preference outlined in 1.1 was the opposite of its intended meaning due to a typographical error that excluded the word 'not' in the sentence. This has been amended in the preferences. There is international movement away from country-specific terminology. It is expected that with two exceptions (adrenaline and noradrenaline), the INN will be used on medicine labels in the New Zealand market, this does not exclude the use of AAN but outlines the future direction of pharmaceutical naming. PHARMAC has not taken a particular position on naming conventions on biologics/biosimilars at this stage. We have decided to remove the preference for the company name to appear as suffix as a result of feedback. However, for products where the trade name is the INN name in combination with the company name as an identifier, PHARMAC prefers the company name to be written in full to avoid confusion with formulation type.

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2. Umbrella naming ***An umbrella segment is a section of a proprietary (trade) name that is used in the name of more than one pharmaceutical to create a brand for a range of products. Current best practice discourages the use of umbrella naming.*** ***2.1. PHARMAC prefers that suppliers develop new proprietary (trade) names or use the full INN name. PHARMAC recommends suppliers familiarise themselves with the approach taken by Medsafe outlined in its guideline.***	Clinical responses • Noted the potential for selection error when pharmaceuticals are named in a similar fashion. Industry responses • Outlined that umbrella branding is seen to be extremely important to sponsor companies marketing over the counter (OTC) pharmaceuticals. • Agreed with PHARMAC's recommendation for suppliers to familiarise themselves with the approach taken by Medsafe.	Our preference is that suppliers develop new trade names or use the full INN name. Suppliers who wish to use umbrella names should follow the Medsafe guideline for these.
3.1. Pharmaceutical name. ***The name of the pharmaceutical should include both the generic name and the propriety (trade) name (where applicable).*** ***3.1.1. PHARMAC prefers that the generic name appears prominently alongside the proprietary (trade) name (if any).*** ***3.1.2. PHARMAC prefers that the generic name appears prominently on at least three non-opposing faces of the outer packaging.***	Clinical responses • Supported giving the generic name equal or greater prominence and the generic name appearing on three non-opposing faces of the outer packaging. • (Some) supported the generic name appearing as the most prominent name, particularly for generic products. • (Some) noted that the trade name should also be prominent, as this also aids in reducing prescribing, dispensing and administration errors. • Noted that the generic name being the most prominent name could reduce confusion between patients and health care professionals when discussing the pharmaceuticals and reduce the risk of patients inadvertently taking two products with the same active ingredients. • Noted the sample illustration was a good example. • Provided suggestions in their responses for additional preferences PHARMAC should consider. These were: o preference to have the generic name and trade name appear spatially close together on all areas of the container and packaging, with the generic name appearing above the trade	We consider that generic names should appear prominently but being too descriptive, such as having a specified font size or a generic name being 'larger', does not allow for flexibility where a product could have its overall readability compromised. Examples of this include pharmaceutical products with multiple active pharmaceuticals or products with small containers. Feedback also suggests the importance of the trade name in distinguishing between products. We have decided not to elaborate this preference to the generic name having equal or greater prominence than the trade name as a result of feedback. We consider the addition of a preference for the generic name and trade to be spatially close and not be separated by intervening matter to be appropriate. This has been added to the PHARMAC preferences. We consider that there are numerous design elements that help distinguish between different products. A link to the Health Quality and Safety Commission (HQSC) report on Tall Man lettering has been added.

Themes/Preference	Submission content	PHARMAC response
	name, o preference for Tall Man lettering, o preferences for font sizes. Industry responses • (Some) were not supportive of having the generic name with equal or greater prominence to the trade name. • Considered that the trade names go through more vigorous review than generic names, generic names could sound similar and could look visually similar to one another increasing dispensing or administrating error risk. • Noted practical implications with regards to space availability were also raised. • Noted overall readability needed to be considered on a case by case basis and there may be instances where having the generic name/s in a larger or bolder font my negatively impact readability such as combination products. • Suggested aligning with the United States Food and Drug Administration (FDA) regulations. • Considered giving the generic name more prominence would only assist with interchangeability and substitution of medicines. In New Zealand the vast majority are covered by sole supply products so this is not applicable in many situations. • Considered increasing the prominence of the generic names would not be helpful and would not improve patient safety. Other responses: • Noted that there would be difficulties for multicomponent products given the amount of information to be displayed.	We consider that selection error can occur between different pharmaceutical products, and this can occur regardless of whether there are one or more brands of a particular pharmaceutical in the market.
3.2.1. PHARMAC prefers that dose strength and pharmaceutical form be given due prominence and be included in all labelling and packaging components where the generic name appears.	Industry response • Suggested when requesting the inclusion of the dose, strength and pharmaceutical form on all packaging components where the generic name appears that the packaging leaflet be excluded from this requirement. • Noted that there are significant size limitations on blister packaging and small containers, so flexibility in applying this standard is requested.	We note that there may be instances where including strength and dose form on all labelling and packaging components where the generic name appears may not always be possible due to space constraints. However, this is still a preference.

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3.2.2 PHARMAC prefers that the pharmacopoeia standard terms be used for pharmaceutical form. These should include standard expression for long acting dose forms.	Clinical responses • Outlined that there are inconsistencies in definitions of formulation types and these should be standardised. • Outlined that 'pharmacopeia standard terms' are not well understood and wanted further clarification on the intent of the preferences. Industry response • Noted that this preference was acceptable in principle however there needs to be latitude to align the pharmaceutical form as registered with Medsafe, for example in long-acting formulations "sustained release", "controlled release."	This preference was originally adapted from the International Medication Safety Network (IMSN) 2013 Position Statement. However, what constitutes a "standard term" in New Zealand will require further investigation. As such we have removed this preference.
3.2.3 PHARMAC prefers that the formulation type be written in full on labelling	Industry response • Disagreed with this preference for products other than small volume injection as this would result in confidential disclosure to commercial third parties. It should be sufficient to disclose certain excipients on labels, for example as outlined under "Excipients required to be declared on the label of medicines" in TGA's Therapeutic Goods Order 69 General requirements for labels for pharmaceuticals.	The intended purpose of this preference was to encourage suppliers to not use abbreviations for formulation type such as "PR" but instead write this out in full "prolonged-release". An example has been added to the preferences for clarity.

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3.2.4 PHARMAC prefers that strength is not represented in percentages, e.g. %w/w and %w/v	Clinical responses • Agreed in general percentages should not be used to indicate strength, they highlighted a number of exceptions where representation of strength as a percentage is considered appropriate: o local anaesthetics o eye drops o products for topical application, and o mix insulins. • Noted a change to widespread and longstanding experience with a certain format to represent strength (e.g. use of percentages to represent strength in local anaesthetics) could result in drug dosing error. • Recommended PHARMAC should consider this risk associated with changing long-standing format and seek more feedback. • Noted a particular risk exists where some agents in a therapeutic class are expressed in one style of strength representation and others in a different style. • Noted there is a preference for uniformity within agent classes rather than a blend of representations. • Considered that to reduce confusion the example should have the word "not" placed in front of the %w/w to make it clear these strength representations are not PHARMAC's preference. • Suggested if other units of concentration such as % w/w, % w/v or ratios (eg 1 in 1,000) are to be used on the label, the concentration should also be displayed as the total quantity of active pharmaceutical/total volume. Industry response • Noted that not having strength represented as a percentage would be difficult to implement as it conflicts with the TGA's guidelines.	We have amended this preference as a result of concerns raised during consultation. The preference now states: *3.2.4. PHARMAC prefers strength in total quantity of active pharmaceutical per total volume (in each container) or total quantity of active pharmaceutical per mL is displayed for injectable or single dose liquid preparations, even if other units of concentration such as percentages and ratios are displayed.* We consider that this provides an element of familiarity with well-established practice of using percentages or ratios to represent strength in some products whilst introducing a more consistent way to display strength in general.

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3.2.5 PHARMAC prefers that the strength of single dose injectable and liquid preparations should be stated as the total quantity of the active pharmaceutical substance per total volume and per mL. If the volume in the container exceeds 1mL, the concentration (quantity of active pharmaceutical substance per one mL) should be indicated immediately below the strength, either in brackets or in less prominent letters.	**Single-dose injectable and liquid products** Clinical responses • Considered strength as total quantity of the active pharmaceutical substance per total volume and per mL is preferable on external packaging. • Considered the total quantity of active pharmaceutical substance per volume in container should appear on container packaging. • suggested that amount per volume and amount within one unit of product are easily confused and therefore the two should appear using different terminology. For example 100 mg in 5 mL (20 mg/mL) or 'Each vial contains 100 mg (20 mg/mL)'. Other responses • Considered having strength of other liquid formulations expressed as total quantity of the active pharmaceuticals per total volume and per mL would be consistent with the way strength is listed in the NZULM.	The PHARMAC preferences are reflective of clinical responses received. We have added in a supplementary sentence: 'Where space allows use different terminologies for strength as total quantity of active pharmaceutical per total volume (in each container) or total quantity of active pharmaceutical per mL. For example each 5 mL ampoule contains 100 mg (20mg/mL) or 100 mg in 5mL (20 mg/mL).' to the preferences and has reflected this in the graphic examples.
	Multi-dose injectable products Clinical responses • Considered clarification was required for multi-dose injectable products. • Noted the graphic provided in the consultation document was sourced from The National Patient Safety Agency (England and Wales) design documents and was for multi-dose injectable products. • Noted a preference for multi-dose injectable preparations was not incorporated in the body of the text. • Agreed that there should be a preference for strength of multi-dose injectable products to appear as per unit volume only for example units/mL or mg/mL.	We have clarified the preferences for multi-dose injectable products included this in the preferences document We have removed the graphic for multi-dose injectable products from these preferences to reduce the document size. Suppliers can access it via the link to the National Patient Safety Agency (England and Wales) Design for patient safety: a guide to the labelling and packaging of injectable medicines document provided in the labelling preferences. We have included adapted graphics showing other preferences in its place.

Themes/Preference	Submission content	PHARMAC response
	Multi-dose oral liquids Clinical responses • Noted that multi-dose oral liquids often have the strength as amount of active pharmaceutical/s per 5 mL, which constitutes a standard dose, appearing most prominently. • Noted the exception to the above is controlled drugs which have strength appearing as the amount of active pharmaceutical per 1 mL. • Noted concerns about changing from current practice. • Noted potential for dosing errors particularly if there are differences between pharmaceuticals such as paracetamol or ibuprofen liquid that are both available on prescription or as OTC product • Considered multi-dose oral liquids should have strength most prominently expressed as quantity per 5 mL except for controlled drugs which should have strength most prominently expressed per mL. Other responses • Considered all oral liquid should be depicted per 5 mL with the per mL strength depicted less prominently. • Noted concern with oxycodone oral liquid which has its strength appear as 5mg/5mL as being misread as 5 mg/mL.	We have added the following preferences for multi-dose oral liquids: *3.2.6. PHARMAC prefers for multi-dose oral liquids (excluding controlled drugs) that the strength of liquid oral preparations should be stated as the total quantity of the active pharmaceutical substance per 5 mL volume (where appropriate). The concentration (quantity of the active pharmaceutical substance per one mL) should be indicated in less prominent letters.* *3.2.7. PHARMAC prefers for multi-dose controlled drug oral liquids, that the strength be expressed as the amount of the active pharmaceutical substance contained per mL.* These preferences are reflective of the majority of clinical responses received. However, any significant changes to labelling should be carefully managed
	Unit of measure Clinical responses • Noted that where the unit of measure prescribed differs from the unit of measure used on labelling calculation errors can occur, therefore the two should be aligned where possible. For example if standard prescribed dose is micrograms strength should be depicted on labelling as micrograms. The response noted that the issue is predominately for neonates, who are the most vulnerable group of patients. A small calculation error can be detrimental in these patients.	We agree that where possible strength should be depicted on labelling using the same unit of measure used when prescribed. This has been noted in the PHARMAC preferences.

Themes/Preference	Submission content	PHARMAC response
	General points Industry responses • Noted consideration would need to be given to the current standard of practice, and changing this could lead to confusion and possible dispensing and administration errors. • Noted there may be a cost to of re-educating health care professionals should changes be made. • Noted having only one format in the presentation of the quantity of medicine would be clearer and reduce dosing errors. • Noted having two representations of strength (such as total quantity of the active pharmaceutical substance per total volume and per mL) may lead to confusion. It could also reduce readability where space is limited.	The preferences are intended for general guidance. Any changes to current practice would need to be considered on a case by case basis. The preferences outline that there may also be some instances where the stated preference is not appropriate for some pharmaceuticals.
Suggestion- PHARMAC should consider a preference for the expression of the salt and base strengths on the label	Clinical responses • Outlined a preference for the expression of the salt and base strengths on the label should be considered.	We have added a preference which outlines that the expression of salts, hydrates and solvents are represented on the label consistently with what is currently in the market for that pharmaceutical. PHARMAC has recommended the NZULM be consulted in the first instance.
3.3. Route(s) of administration ***3.3.1. PHARMAC prefers that positive messages be used to describe route of administration, such as "give by…"*** ***3.3.2. PHARMAC prefers that negative statements, such as "not for … use", be avoided.***	Clinical responses • Agreed with the preference to use positive messages. • Disagreed with the preference to avoid the use of negative statements. • Considered that a negative directive could provide a clear, strong and useful message that warns against inappropriate use of the pharmaceutical. Industry responses • Disagreed with avoidance of negative statements, particularly in reference to parenteral products. • Noted that the negative statement reinforces the correct use of the product, for example "For intramuscular use. This product is not suitable for use intravenously". • Noted that this was not consistent with the requirements in Australia and other countries. • Considered altering the tone of the route of administration	We have amended preferences for routes of administration as a result of feedback. Instead of avoiding the use of negative statements, PHARMAC prefers, where space allows, that a positive message precedes any negative statement.

Themes/Preference	Submission content	PHARMAC response
	instruction does not seem consistent with current and well established norms for such wording. • Noted the cost implications for non-harmonised production was also an issue. • Noted that a number of mandatory labelling requirements begin with "Do not use…" • Considered a compromise would be to include both positive and negative statements where space allows.	
3.4. Specific Warnings ***New Zealand legislative requirements for certain pharmaceuticals may require that specific warnings essential for safe use, are provided on the front face of the package.*** ***The Medsafe label statements database, which provides a list of warning and advisory statements that are required on pharmaceuticals and related products, should be adhered to as required by section 13(1)(i) of the regulations.*** ***3.4.1. In addition to these warning statements, PHARMAC prefers that*** ***3.4.1.1. cytotoxic drugs have "cytotoxic" clearly identifiable on packaging*** ***3.4.1.2. neuromuscular blocking agents have "warning: paralysing agent"*** ***3.4.1.3. penicillin products have "contains penicillin".*** ***3.4.1.4. Oral methotrexate products have "usually taken once a week".***	Clinical responses • Noted there are many pharmaceuticals available that have specific warnings and considered PHARMAC would need to provide guidance and rationale for inclusion criteria of specific warnings on packaging. The four included are only a few of many pharmaceuticals that can be considered high risk, or need specific instructions. • Noted care needs to be taken with the use of "cytotoxic" as currently there is no agreed list of pharmaceuticals that fall into this classification, and for some pharmaceuticals "hazardous" may be a more appropriate warning. • Considered it may not be appropriate for packaging that is intended to be dispensed to a patient to display some of these warnings and there could be a negative impact on the patient if they were to receive packaging with these. • Considered clarification was required on whether the preferences would apply to both packaging and container labelling. • [Some] agreed with the preferences outlined. Industry responses • Supported any specific warnings as outlined in the Medsafe label statement database. • Considered warnings and advisory statements are the domain of Medsafe and additional PHARMAC warnings would cause confusion and lack of standardisation. • Were not supportive of anything in addition to the Medsafe database. • Did not support anything relating to dosing instructions as outlined by the methotrexate preference as these can be misleading to patients. • Noted the Australian labelling and safety warning requirements	We have amended our preference relating to Specific Warnings as a result of feedback. Instead of outlining preferences for specific products PHARMAC has made this preference more general: *3.5.1. PHARMAC prefers specific warnings to be clearly identifiable from other information on labelling. For example the use of red font, or within a border to distinguish the warning from other information.* *3.5.2. PHARMAC prefers specific warning statements be included on both packaging and container labels (where space allows).*

Themes/Preference	Submission content	PHARMAC response
	should be considered by PHARMAC. Other response • Suggested that these align with the cautionary labelling system used in community pharmacy practice.	
4.1. PHARMAC prefers that mandatory information required on the packaging does not obscure the essential information as noted above. ***Medsafe has provided a comprehensive guideline on the minimum requirements for labelling.***	Industry response: • Considered Medsafe should determine whether its proposed labels are acceptable, not PHARMAC. If PHARMAC has preferences for what it considers to be 'essential information' then PHARMAC should take this matter up with Medsafe in order to arrive at one labelling standard.	The intention of this preference was to emphasise that essential information for the safe use of the pharmaceutical should not be obscured by other information, for example manufacturer's addresses.
5. Error-prone abbreviations, symbol and dose designations ***The use of abbreviations and acronyms may save time but can increase the potential for medication errors. The Health Quality and Safety Commission New Zealand (HQSC)'s error-prone abbreviations, symbols and dose designations should be considered when designing labelling.*** ***5.1. PHARMAC prefers that the HQSC-preferred term is used in labelling where space allows.***	Clinical response: • Outlined that preference 5 was unclear and could lead to confusion. • Considered that the HQSC document includes many abbreviations which are not relevant to the labelling of pharmaceuticals. • Considered four error-prone abbreviations, symbol and dose designations in the HQSC document deserved specific mention: o the abbreviation of micrograms as "mcg" has been reported internationally as being commonly misinterpreted as milligrams o abbreviations for international units, such as "U" have been misinterpreted as "0" leading to a tenfold overdose o the presence of a trailing zero (eg 4.0 mg instead of 4 mg) o the absence of a leading zero (eg 0.5mg instead of .5mg)	The HQSC document provides an appropriate reference and includes the error-prone abbreviations, symbol and dose designations specifically mentioned in feedback received a long with other less common error prone abbreviations, symbol and dose designations.

Themes/Preference	Submission content	PHARMAC response
6. Colour used in labelling ***Colour can help correctly identify, classify, and differentiate between pharmaceuticals. However, relying totally on colour to do this can lead to mistakes.*** ***6.1. PHARMAC prefers that when designating different colours between strengths there is no pattern in the colour scheme in the labelling.*** ***6.2. PHARMAC prefers that colour differences between strengths of a pharmaceutical are clearly distinguishable from one another. The same tone or hue should be avoided. This colour difference also needs to be clearly identifiable when the product is:*** ***6.2.1. in isolation*** ***6.2.2. in different lighting conditions*** ***6.2.3. alongside other pharmaceuticals.*** ***There are a number of sources of best practice guidelines for colouring on packaging. The National Patient Safety Agency (England and Wales) has provided a series of useful design examples in its graphic design guidelines.***	Clinical responses • Considered different strengths of a pharmaceutical need to be labelled in different colours, particularly those pharmaceuticals with a narrow therapeutic index. • Noted PHARMAC should be mindful of similar sounding drug names with the same coloured packaging remembering they will be placed on a dispensary shelf close to each other. • Noted that, in particular generic companies using the same colouring and packaging for multiple items increases the lookalike and sound alike issues. • Recommended strong contrast between background and text and avoidance of mono-chrome labelling should be considered. • Noted the American Society of Testing and Materials (ASTM) has divided drug used in anaesthesia into nine different classes with different colour coding described for each class by the ASTM international standards D4774 and this should be considered. • Noted the random use of colour on ampoules rings. • Noted the poor use of ink colour when printed directly onto plastic ampoules. • Recommended colouring on container packaging such as ampoules should be considered. • Considered there should be minimal use of colours to define dosage and agreed the use of distinctively different colours rather than hues of the same colour was appropriate. • Considered an additional statement should be included about people with impaired vision and colour blindness. Industry responses • noted having colour differences to clearly identify a product from another that may be ‘alongside‘ is almost impossible to control as package design is the responsibility of individual sponsors. • considered colours of labels can be seen as subjective. • considered colours should not be the only way to distinguish between product strengths.	We have the following preferences as a result of this feedback and clinical advice received: • PHARMAC prefers information to be written in colours that strongly contrast with its background. • PHARMAC prefers packaging colouring and primary container colouring of a pharmaceutical to be consistent. • PHARMAC prefers for tablet and capsule pharmaceuticals which are different colours between strengths within the manufacturer’s range (of that pharmaceutical form), that the colour of the physical tablet or capsule be reflected in the labelling of that strength. A supplementary sentence outlining colours look different in different lighting conditions; people have different perceptions of colour; and colour blindness means some people see colours differently has been added. An amendment has been made to preference 6.2.3 to outline that the colour difference needs to be clearly identifiable when the product is alongside other pharmaceuticals from the same manufacturer/supplier. We agree that colour difference should not be the only way to distinguish between products and have reflected this in the accompanying paragraphs. The ASTM international standards D4774 ‘Standard Specification for User Applied Drug Labels in Anesthesiology’ relates specifically to the labelling of unlabelled syringes filled by users or their agents to identify drug content. There are a number of organisations that have voiced concerns on the use of this coding system on commercial pharmaceutical products and over relying on colour-classification systems. Creating any shortcut for identifying a pharmaceutical without having to thoroughly read the label can lead to mistakes. The PHARMAC preferences should not reference the ASTM international standards D4774 as the preferences are intended for commercial products.

Themes/Preference	Submission content	PHARMAC response
7. Braille ***7.1. PHARMAC prefers the use of braille on packaging***	Clinical responses • Outlined that New Zealand patients do not often receive the original packaging. • Did not support this preference. Industry responses • Noted that there would be an additional cost associated with braille, both in producing the material but also having to move away from bulk packaging to packaging of smaller quantities that would actually reach patients. • Noted it could favour innovator products as it would reduce the advantage low-margin generics have in reducing price. • Considered this should not be mandatory, and outlined there are alternative means, for example audio consumer pharmaceutical information that can be used to assist those who have limited or no sight. • Considered there was evidence that the use of braille is declining worldwide.	This preference has been removed as a result of feedback.
8. Expiry date ***8.1. PHARMAC prefers expression of the expiry date as an exact date or otherwise add the words "use before".***	Clinical responses • Supported the clarification of expiry, and considered that 'Expiry 00/00/00' was the most clear terminology. • Considered readability was particularly important. • Noted difficulties with readability of indented expiry dates. • Considered expiry should be printed in indelible ink. Other responses • Noted the requirements for expiry dates are open to confusion and would benefit from simple examples to explain what is intended by the precise date or use before formula. Industry responses • Considered that greater flexibility is required for expressions of expiry date. • That expiry date labelling is dictated by the capability of the manufacturing plant's printing line including where the expiry could be placed on packaging and labelling. • "Use before" or "best before" should not be used as this can lead to confusion.	As a result of feedback we have removed the preference for the expression of the expiry date. We note there are multiple acceptable ways to express expiry date. Where the expression of expiry date is deemed unacceptable this could be addressed on a case by case basis. We have added a preference for the expiry date to be clearly visible and where printed to be printed in indelible ink.

Themes/Preference	Submission content	PHARMAC response
	• Noted expiry date is set down in many global directives and/or guidelines and under systems such as PIC/S, and movement away from recognised formats would cause confusion and unnecessary production expense to manufacturers, as well as impacting harmonised products. • Considered an exact date would not add additional value since there is enough flexibility in stability data to support a few weeks variability. • Considered there was no added safety benefit.	
9. Space for a dispensing label and machine readable codes ***9.1. For packaging designed to be used by the patient, PHARMAC prefers a clearly designated space for affixing a patient label.*** ***9.2. PHARMAC prefers that there are space allowances for machine readable codes and that the information contained within the machine readable code includes:*** ***9.2.1. batch number*** ***9.2.2. expiry date*** ***9.2.3. Global Trade Item Number (GTIN).***	Clinical responses • Supported this preference, in particular the use of barcodes on labelling noting it was an added safety feature when included on primary container labelling. • Noted that labelling space was rarely sufficient (normal pharmacy label is 40 mm x 70 mm). • Recommended that barcodes be a mandatory requirement. Industry responders • Noted most pharmaceuticals are repackaged in pharmacies, making this unnecessary. • Considered that the space for pharmacy labels would only be effective if there were mandatory requirements for pharmacies to use these as intended. • Noted there is often limited space on labels that would make this feasible. Other responses • Suggested PHARMAC recommend a preference for machine readable codes to be formatted in compliance with GS1 General Specifications for barcodes and barcoding which includes two dimensional (2D)/ Matrix bar codes such as GS1 DataMatrix as well as GS1 linear barcode symbologies. • Considered that without the above level of specificity, pharmaceutical labellers may choose to use any symbology to encode GTINs and any additional attribute data (e.g. batch, lot, serial number etc). • Noted the use of non-standardised symbologies will lead to confusion, supply chain inefficiencies and unnecessary additional cost throughout the sector.	These preferences are voluntary Space to put the pharmaceutical label is desirable but not always practical so we have added 'where space allows' to this preference. This preference is for packaging designed to be used by the patient. We have added a link to the Health Information Standards Authority (HISO) endorsement for GS1 Standards.

Themes/Preference	Submission content	PHARMAC response
10. Blister containers ***10.1. PHARMAC prefers that each blister pocket include both the generic name, proprietary (trade) name (where applicable), and the strength of the pharmaceutical.*** ***10.2. Where blisters are small, PHARMAC prefers repetitive diagonal use of generic name and strength over the blister covers with expiry date and batch number on the side to assist with identification of partly used packs.***	Clinical responses • Supported PHARMAC's preferences for blister packaging. • Considered small font size is a problem and readability particularly for patients that have reading difficulties is a concern. • Noted expiry should appear on blister strips, there are some instance where this is not the case. Industry responses • Noted from a manufacturing perspective having the generic name, proprietary name and strength of the pharmaceutical on each blister pocket may not be feasible every two blister pockets would be more appropriate and is a requirement in other jurisdictions • Noted a company's ability to comply with these preferences is dependent on manufacturing capabilities, changing manufacturing in any way could come at an increased cost. • Preferred the use of repetitive diagonal use of generic name and strength over the blister covers.	As a result of feedback we have amended this preference, to have the information outlined over every two blister pockets rather than every pocket. We have also outlined a preference for the expiry date and batch number to appear at both ends or on the side of each blister.
11. Other considerations ***PHARMAC takes a pragmatic approach when considering a pharmaceutical for funding. PHARMAC and its clinical advisers may have additional preferences not covered in this document, however these would be advised on a case by case basis.***	Industry response • Noted that PHARMAC has not committed to funding products that meet the proposed preference, and retains the right to add preferences in the future without consultation. This lack of clarity would impact on the ability of suppliers to make decisions relating to supply.	A preamble has been included in the preferences which outlines where these preferences sit in PHARMAC decision making. The naming and labelling preferences are voluntary, and we will use these preferences within the context of our wider decision making framework when considering medicines for listing in the Pharmaceutical Schedule. The preferences aim to provide guidance and transparency on PHARMAC's naming and labelling preferences. Some preferences are only identified on a case by case basis and there are also instances where the preference may not be suitable for some pharmaceuticals. The preferences address the most common naming and labelling issues that PHARMAC encounters, and PHARMAC's preferred approach.

Themes/Preference	Submission content	PHARMAC response
Suggestion - PHARMAC should consider a preference for Storage Conditions	Clinical response • Suggested a preference for storage conditions should be considered. Storage conditions are often difficult to visualise on the label and if not followed the pharmaceutical may become unusable. • Considered a preference for storage conditions to be highlighted, especially if the drug requires refrigeration.	Preferences have been added relating to storage conditions as a result of feedback.
Suggestion - PHARMAC should clarify which of the labelling preferences apply to external packaging and which apply to containers such as ampoules or vials	Responses noted that: • It was not clear which of the preferences would apply to containers. • There needed to be considerations for small ampoules and vials where there was limited space. • Ampoules can be hard to identify when labels are wrapped around the ampoule or printed directly onto the ampoule. • A preference for the pharmaceutical name to be printed longitudinally along the length of the ampoule and for paper labelling rather than printing straight onto glass would result in better visibility and hence easier identification of pharmaceuticals. • Stating the concentration below the strength of a product is not advisable as they considered the additional text which would reduce readability on the primary pack/label and could lead to confusion. • An example of appropriate labelling should be provided.	We have added preferences for ampoules and vials along with a graphic example adapted from the National Patient Safety Agency (England and Wales) Helen Hamlyn Research Centre. Design for patient safety: A guide to the labelling and packaging of injectable medicines (2008).
Suggestion - Packaging should have a tick box to use when a pack has been opened	Clinical response • Suggested the addition of a tick box would be helpful to identify part-packs.	This may be useful, however this has not be raised by the TMESC or other clinical advisers. We consider the focus should remain on the things that would most improve patient safety.
Suggestion - Preference for accurate labelling of products which contain common allergens	Clinical response • Noted the challenge allergy suffers have to go through to figure out whether a product contains common allergens such as lactose or starch when it is not on the labelling.	Patients with severe allergies to any excipient should be consulting their healthcare professional prior to using any medication and should not be relying solely on the labelling of products, particularly as a number of products are not dispensed in original packaging.

Themes/Preference	Submission content	PHARMAC response
Suggestion - Further thought should be given to ensuring a balance between plain language for consumers/public and clinical language for clinicians.	Clinical responses • Noted that local research shows the majority of New Zealanders have limited ability to obtain, process and understand basic health information (Ministry of Health, 2010). Many who take medications may not have sufficient levels of health literacy to understand even simple instructions making it even more important for labelling to cater to consumer needs. • Māori are at particular risk given their lower levels of health literacy when compared with non-Māori (Ministry of Health, 2010) • Plain language is essential to ensure good understanding, for example, the use of mouth instead of oral may be helpful.	There is always a balance between providing the information which enable health care professionals to prescribe, dispense and administer to patients accurately and safety and what a patient would want to see on labelling. We consider that a lot of the issues raised regarding consumer information is much broader than the scope intended for these preferences and while important, does not consider these should or can be addressed through these PHARMAC preferences.
Suggestion - Addition of more consistent information on the packaging regarding the condition/s a particular drug is indicated for.	Clinical response • Noted concerned about the high number of patients who are unaware of what the medicines they have been prescribed are for.	Healthcare professionals who prescribe and administer pharmaceuticals are best placed to inform patients about the pharmaceuticals' therapeutic purpose for them personally. A number of products have multiple indications and often patients do not receive their medicines in the commercial pack. We consider that the labelling of pharmaceuticals should not be the primary source of this information for patients.

Feedback received outside of the Scope of this consultation

Themes/Preference	Submission content	PHARMAC staff consideration and view
Pack sizes	Clinical response • Noted that dispensing would be a lot safer and more efficient if medications were purchased in pack sizes appropriate for New Zealand. That includes: o not coming in bulk sizes; and/or o not coming in sizes such as 28 tablets, where a 30 tablet pack size is more appropriate.	Pack size is one of a number of important factors that are considered when assessing the suitability of pharmaceuticals. For the purpose of these preferences we do not consider pack size to be within the scope.
The preferences should be added to the requirements for vendors of pharmacy IT programmes (Lots & Toniq) to have this built into the IT system	Clinical responses • Considered preference should be added to healthcare IT systems.	This sits outside of the scope of this consultation.
Product specific feedback	Clinical responses • A number of specific examples were provided for particular products where naming and labelling is considered unacceptable.	The preferences are intended as a more general guide. PHARMAC has noted the feedback.