



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**



***DRAFT LABELLING REQUIREMENTS FOR MEDICINES UNDER THE  
AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY***

**Report on stakeholder consultation  
and consideration by the Joint Expert Committee on Trans Tasman  
Labelling Requirements for Medicines of issues raised in stakeholder  
responses**

**May 2006**

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## Introduction

The consultation document *Draft Labelling Requirements for Medicines under a Joint Australia New Zealand Therapeutic Products Agency* was released for stakeholder comment on 14 April 2005.

The format of the document was a draft Managing Director's Order, containing ten sections and Supplementary Notes. The document had been developed by the Joint Expert Committee on Trans Tasman Labelling Requirements for Medicines (the Committee) over the period October 2004 to March 2005. Background to this development and information on the Committee membership can be found at <http://www.anztpa.org/label/labeldraft.htm>.

The consultation document was provided directly to stakeholders in Australia and New Zealand, including industry associations, consumer organisations, government departments, government advisory committees, professional organisations and retail organisations. The document was also placed on the joint agency (now named as the Australia New Zealand Therapeutic Products Authority) website, with links from both the Medsafe and Therapeutic Goods Administration (TGA) websites.

Medsafe and the TGA encouraged all stakeholders to review in detail the draft requirements and stakeholders were advised that it was intended that the requirements given in the draft Order form the basis of the legally binding standard for medicine labelling to become active from commencement of the joint agency. Stakeholders also were advised that the draft labelling requirements made reference in some parts to aspects of the joint regulatory scheme that were still to be finalised. These areas were highlighted in the text. However, it was considered that these gaps in the draft labelling Order would have no significant impact on the ability of stakeholders to provide comment on the content of the document.

The consultation on the draft labelling requirements was undertaken concurrently with consultation on the document *Draft best practice guideline on prescription medicine labelling*, a guideline document intended to complement mandatory standards for the labelling of prescription medicines.

Stakeholder consultation closed at the end of June 2005. In total 72 submissions were received, as follows:

	<b>Australia</b>	<b>New Zealand</b>
<b>Industry associations</b>	3	4
<b>Individual sponsors / manufacturers</b>	7	7
<b>Therapeutic goods consultants</b>	1	-
<b>Consumers</b>	3	-
<b>Government</b>	6	4
<b>Advisory committees</b>	5	-
<b>Professions</b>	9	13
<b>Pharmacy Guilds and retail organisations</b>	-	1
<b>Other</b>	1	2
<b>Comments only on best practice guidelines</b>	4	2

Some of the key themes emerging from the industry responses (including industry associations) were: necessary transition time to meet new requirements; the impact of the proposed requirements on small and very small containers with limited label space and multiple ingredients; the role of country-specific labels in protecting against parallel importation, and also for national supply of blood products; the need for exemptions for low-volume imported products; the proposed new requirement for label disclosure of excipients for prescription medicines; labelling of starter packs; and font size requirements for active ingredient names.

From the professional areas, responses focussed on the need for legibility, larger minimum letter heights and the avoidance of confusion between various strength products; labelling of generic medicines; a preference for printed, not debossed, batch and expiry information; adequate space for the pharmacist's label; and the role of barcodes in reducing medication errors.

Not all issues raised by stakeholders fell within the scope of the Committee's Terms of Reference, for example, issues relating to dispensing practices.

Review of stakeholder responses by the Committee occurred over the course of two meetings held on 15 August 2005 (in Sydney, Australia) and 4-5 October 2005 (in Auckland, New Zealand) respectively.

## **Major Issues Identified in Stakeholder Responses**

Preliminary review of the stakeholder responses by the TGA and Medsafe identified a number of significant issues for consideration by the Committee, particularly in view of the divergence between industry and the professions in the focus of responses.

These issues were:

1. Transition time - industry case for additional time beyond the joint licence being granted to make label changes;
2. Requirement for declaration of excipients listed in the First Schedule on the labels of prescription medicines;
3. Rationale for differentiation between OTC and complementary medicines in requirements – particularly font size and specified location for active ingredient details, dependent on type of medicine;
4. Labelling of sample / starter packs, including differentiation of sample and starter packs and overlap with Medicines Australia Code of Conduct;
5. Requirements for small and very small containers, including: definitions of small and very small containers and injections; and increased amount of information needed on small containers (ophthalmic, preparations, injections and biologicals);
6. Unique identifier - minimum font size and inclusion on both container (immediate packaging) and primary pack (outer packaging);

7. Problems with the legibility of embossing on plastic ampoules and expiry and batch details on cardboard;
8. Abbreviation of 'microgram';
9. Continuation of country specific labelling: plasma products, low volume products entering NZ, prevention of parallel importation;
10. Name and address requirements – proposed requirement for label to show name and address of product licence holder rather than allowing the option of a supplier's name and address;
11. Terminology:
  - Container and primary pack – inconsistency with international / current NZ terminology;
  - Tonicity – use of osmolality not osmolarity; definitions of isotonic, hypertonic and hypotonic;
  - Batch number and requirement for clear and obvious relationship between batch number on all levels of packaging;
  - Batch number prefix and expiry date prefix – requirement for consistency through same prefix being used on container and primary pack;
12. Bar coding.

The following sections summarise the Committee's consideration of these issues and the outcomes reached. These outcomes are reflected in the latest version of the Australia New Zealand Therapeutic Products Authority draft labelling Order, *General requirements for the labelling of medicines*, also available at <http://www.anztpa.org/consult/index.htm>.

## **Issue 1      Transition time**

### **Issue:**

The consultation responses from individual sponsors and industry associations provided numerous arguments for a transition period beyond the three year period proposed for obtaining a joint Australia New Zealand product licence under new regulatory arrangements.

### **Outcome:**

The Committee noted the comments but agreed that transition time for labelling was closely related to other transition time issues for the new Authority. It therefore was a policy matter to be dealt with by the joint Authority in conjunction with consideration of overall transition times.

## **Issue 2      *Declaration of excipients listed in the First Schedule on the labels of prescription medicines***

### **Issue:**

The proposed requirement is that the labels of all medicines show the names of those excipients that have the potential in sensitive individuals to cause severe allergic reactions or result in other serious adverse health consequences. In some cases there is also an associated warning. Currently in Australia, this type of disclosure is required for non-prescription medicines but is not required for prescription medicines and controlled drugs on condition that this excipient information is declared in a Consumer Medicines Information document (CMI) or the current edition of MIMS Annual or the Australia Prescription Products Guide. The prescription medicines industry strongly objected to the extension of this requirement for excipient disclosure on labels to prescription medicines.

### **Committee considerations:**

The Committee noted that the case presented by industry stakeholders was based largely on the argument that prescribers and other health professionals have access to information on excipients contained in prescription medicines at the time of prescribing, with consumers being informed via the CMI, and labels for prescription medicines and controlled drugs having limited space. A further concern expressed was that declaration of excipients may result in patient non-compliance because some patients may place concerns over the presence of an excipient ahead of the need for the medicine.

In considering stakeholder comments on the proposed requirement, the Committee took into account the following factors:

- Excipient information on a label may be covered by the dispensing label, whereas information in a CMI is always visible;
- There is no certainty that CMI is provided to consumers and recent evaluation of CMI delivery in Australia had shown that delivery remained patchy;
- Dispensing practice in NZ differed, with prescriptions often satisfied from bulk packs. Such bulk packs do not have pack inserts;
- The declaration of specified excipients is a safety issue and in practice, prescribers often are not aware of excipient information or of a patient's allergy to particular substances;
- Issues associated with the presence of particular excipients should be resolved through discussion between the patient and healthcare providers and this discussion may be facilitated by the label declaration;
- A pack insert could be regarded as an extension of the label. If there is insufficient room on the label for excipient information, this could be included in the pack insert. The pack insert could be a CMI document;
- Separate legislation will govern the availability of CMI, but the Agency's legislation will not extend to the dispensing process or the actual provision of CMI to consumers;
- Pack inserts are not possible with all pack types; and
- A similar requirement for excipient declaration exists in the UK/Europe (Directive 2001/83/EC Article 65, and guidelines made under this Article). This Directive requires that all excipients in parenteral, ophthalmic and topical medicinal products appear on the labelling of the immediate or outer packaging, and for all other medicinal products, those

excipients known to have a recognised action or effect (as included in the Commission's guideline) must be declared on the labelling.

**Outcome:**

On balance, the Committee concluded that there are compelling reasons to ensure that information on specified excipients is available to consumers of prescription medicines through labelling, notwithstanding that there may be practical difficulties in achieving this. It would be inappropriate to base mandatory labelling requirements on the assumption that all Australian and NZ consumers receive CMI.

The Committee confirmed the proposed requirement that, for prescription medicines, information on excipients specified in the First Schedule to the Order, must appear on the label of the medicine. However, where there is insufficient space on the label for this, the excipient information may be included in a package insert, provided such a package insert is in fact inserted into the primary pack of the product.

**Issue 3      *Rationale for differentiation between OTC and complementary medicines in requirements – particularly font size and specified location for active ingredient details***

**Issue:**

The draft Order differentiated between prescription, OTC and complementary medicines in requirements for presentation (font size and location) of active ingredient names, and in the circumstances under which active ingredient details may be shifted from the main label to a side or rear label.

A number of responses from industry stakeholders sought clarification of the reason for this differentiation, and the rationale for the new requirements. The industry submissions frequently objected to the proposed requirements as being too onerous, and for prescription medicines, as having a negative impact on the ability to brand products effectively. Label space issues particularly for small packs were identified.

Conversely, the generic medicines industry strongly supported giving active ingredient names greater label prominence and health professionals and consumers also supported this as a means to promote generic dispensing, make labels more readable and overcome some causes of medication errors.

**Committee considerations:**

The Committee gave consideration to the following:

- Whether the font size differentiation proposed was justifiable and rational;
- The conflicting views of stakeholder groups with respect to the minimum font size that is readable;
- Whether requirements for presentation of active ingredient information on labels could be expressed in terms of Class 1 and Class 2 medicines rather than as originally proposed;

- Advice given in the *Draft best practice guideline on prescription medicine labelling* on presentation of active ingredient names and the practical difficulties associated with mandating the best practice requirements;
- Whether there was a case for allowing active ingredient information for all Class 1 medicines and Class 2 complementary medicines to appear on a side or rear label irrespective of the number of active ingredients; and
- Whether the proposal for prescription medicines that active ingredient details appear in a font size at least half that used for the trade name should be extended to OTC medicines also.

**Outcome:**

In reaching its recommendation, the Committee concluded that:

- From a safety perspective, it is desirable that the active ingredient name be as large as, or larger than, the trade name;
- The differentiation proposed for labelling is based on an increase in font size for higher risk medicines, not a decrease in font size for lower risk medicines;
- The labelling Order will give the minimum standard for letter height, but there will be nothing to prevent the active ingredient name appearing larger than the minimum specified;
- If the requirements of the Order are too onerous, many exemptions from its requirements will be sought and some companies may choose to reduce the size of the brand name rather than increase the size of the active ingredient names;
- Although the Rules will refer only to Class 1 and Class 2 medicines, for purposes of labelling there is a need for Class 2 medicines to be sub-divided into prescription medicines and other Class 2 medicines, as specific requirements or concessions will need to apply to one group and not the other. Furthermore, there will be different guideline documents for each group; and
- For prescription medicines, linking the size and prominence of the active ingredient name to that of the trade name, as well as mandating an increase in font size for the active ingredient name, provided an acceptable compromise to the competing requirements of stakeholders. This was seen as the option most likely to be achievable for all presentations and pack sizes of prescription medicines and therefore able to be mandated.

The Committee therefore agreed that:

- Its original proposal regarding the minimum font size for active ingredient details for:
  - prescription medicines (half the size of the trade name but in any case no less than 2 mm);
  - OTC medicines (2 mm); and
  - complementary medicines (1.5 mm),be retained but expressed in terms of Class 1 / Class 2 medicines;
- The requirements for Class 2 medicines be sub-divided into those for self-select medicines and those for medicines only available on prescription; and
- Class 1 sunscreens would remain a special case.

## **Issue 4      *Labelling of sample / starter packs and overlap with Medicines Australia Code of Conduct***

### **Issue:**

While several comments were received in relation to differences between sample and starter packs (which the draft Order had defined as being the same), Medicines Australia also drew attention to an apparent overlap between the proposed requirements of the labelling Order and provisions being incorporated in the Medicines Australia Code of Conduct relating to the supply of starter packs to health professionals.

Specifically, there was an objection to the proposed requirement that starter packs must be labelled with an indicative dosage range. It was the view of Medicines Australia that, as doctors may prescribe a different dose to that given in the indicative range, it may be confusing for the patient to be presented with two different sets of dosage instructions. It was considered by Medicines Australia that inclusion in the Code of Conduct of the requirements that the primary pack label should allow sufficient space for a dispensing label and the representative should supply adhesive labels, pre-printed with the fields ‘Name and telephone number of Medical Practitioner’, ‘Name of Patient’, ‘Dosage Instructions’ and ‘Date’, or alternatively these same fields be pre-printed on the label, should be adequate to achieve appropriate labelling of starter packs.

### **Committee considerations:**

In relation to the labelling of starter packs, the Committee considered:

- Its previous agreement that inclusion on starter packs of prescription medicines of a panel on which dispensing details could be written would be consistent with the quality use of medicines and the absence of a dedicated panel could potentially result in patient name or dosage instructions obliterating other important label information;
- The perceived advantages and disadvantages of including indicative dosages on the label of starter packs;
- The small size of starter packs and limited area for label information, although the proposed requirement in the draft Order allowed the indicative dosage range and warnings to be included in a leaflet inserted in the pack;
- The extent of application of the Medicines Australia Code of Conduct, with it only applying in Australia and not New Zealand;
- The use of an additional statement such as “your doctor may prescribe a different dose” to allay concerns when the prescribed dose and indicative dose differ; and
- The precedent of the usual dose range being required in CMI documents.

### **Outcome:**

The Committee accepted the distinction between sample pack and starter pack, with a starter pack being a physician’s sample used to initiate treatment, whereas a sample pack is provided as a free sample (trial pack).

In relation to dosage instructions, it was agreed that information for patients on the indicative dosage range is part of a safety and quality approach to medicines and availability of this

information provides a checking mechanism for patients and doctors, when no pharmacist is involved in the dispensing process.

It also was agreed that, in addition to the prescriber's name, the label should include contact details for the prescriber as this was normally required under legislation governing dispensing. Space must be allowed for this also.

The Committee therefore agreed that:

- The proposed definition and references to 'sample pack' should be removed from the labelling Order, on the understanding that sample packs must comply with standard requirements for those medicines;
- The proposed requirement for inclusion of the indicative dosage range should be retained; and
- Allowance must be made for inclusion also of the prescriber's contact details.

## ***Issue 5            Requirements for small and very small containers, and small volume injections***

### **Issue:**

A number of the consultation responses from industry anticipated difficulties in meeting the proposed requirements for labelling of small, and very small, containers and injections with small nominal volumes.

### **Committee considerations:**

In relation to this issue, the Committee considered the following matters:

- The need for consistency in the terminology used in the Order to describe different size containers, with 'Volume', 'Capacity', 'Stated volume', and 'Nominal volume' being used variably in the draft Order;
- Cut-off limits between the different sizes of containers or injections, noting that some confusion may have arisen from the different size ranges proposed in the draft Order for small containers (not more than 20 mL) and small volume injections (not more than 100 mL);
- The need for improvement in clarity between requirements for small containers and injections, particularly where other provisions also may apply (eg for ophthalmic or biological products); and
- The requirements proposed for the label on small, and very small containers, and equivalent volume injections in terms of a progression of pack size, taking into account practicality and strategies to enhance identification of products and reduce administration errors.

In relation to terminology the Committee confirmed that the intention was to refer to nominal volume, which is taken to be the volume the container is intended to hold. This is the volume stated on the label. It is different to the actual volume of the container. Similarly, for semi-solid preparations such as creams or ointments, the nominal weight is the weight stated on the container.

In relation to the concessions proposed for injections with volumes less than or equal to 2 mL (and very small containers), the Committee acknowledged that the aim of these was to remove the routine need for exemptions from labelling requirements, such as those often necessary for multi-ingredient vaccines. Although the proposed concessions, which included omission of the active ingredient names from the label on the container, could be justified when there are multiple active ingredients in a product of very small nominal volume, the product name would need to be sufficiently unique to unequivocally identify it. Hence the conditions proposed. It was confirmed that, if all stated conditions are not met, then requirements would default to those for injections with nominal volumes of 20 mL or less.

For concentrated solutions, the Committee considered that inclusion of a direction on labels advising not to administer the solution undiluted was a safety matter, and therefore this direction should be required on the label of all concentrated injections irrespective of size. Inclusion only on the primary pack label would not be adequate, although the specific directions for dilution could be placed on the primary pack label only.

The Committee considered it to be important that positive statements, rather than negative statements, are consistently used on labels to avoid confusion and as an aid in preventing medication errors. With this in mind, the Committee reconsidered the proposed requirement for small and very small volume injections and other ampoules that not only must the route of administration be shown, but there also be a warning statement where the incorrect route of administration may be hazardous. This latter warning would probably require a negative statement. The Committee concluded that use of the word 'only' to describe the correct route of administration should generally be sufficient to indicate that the medicine is not to be administered by any other routes.

The Committee also considered requirements for signal headings on small containers, and noted that the labelling Order must be consistent with the Poisons Standard and relevant New Zealand legislation in this matter. However it was agreed that for injections and small containers with nominal volumes up to 20 mL, it would be more sensible to devote the limited label space to product-specific safety-related information rather than signal headings. Therefore the Agencies were requested to refer any inconsistency in this requirement to the attention of the scheduling committee, with a view to amendment of the Poisons Standard and/or relevant New Zealand legislation.

### **Outcomes:**

The Committee agreed that:

- The terms 'nominal volume' and 'nominal weight' should be defined under 'Interpretation' and the small, and very small, volume concessions should also apply to small nominal weights;
- In order to more clearly specify requirements, the requirements for injections should be separated from all small container and very small container requirements and cross-referencing to other parts of the Order should be reduced as far as possible;
- In relation to the nominal volumes upon which classifications of small and very small containers were based, 2 mL was confirmed as the cut-off between these on the basis of experience with exemption requests, with the upper volume limit for small containers remaining 20 mL, notwithstanding requests from stakeholders that this be increased;

- Different sizes of injections should not be defined by name - rather, provisions in the Order relating to injections should be specified by injection volume with the appropriate volume cut-offs being 2 mL, 20 mL, and 100 mL;
- In relation to concessions and requirements, some of the original proposals were modified (see **Attachment 1 and 2** for a summary of the revised requirements) although all concessions remained contingent on the primary pack being fully labelled in accordance with the Order, and certain concessions were contingent on other conditions being met also. Some of the agreed variations to requirements for the label on the container included:
  - Reduction in the minimum letter height for product name on very small containers from 2 mm originally proposed to 1.5 mm for consistency with minimum size required on small containers;
  - Reduction in the minimum letter height for active ingredient names on small containers of Class 2 medicines from 2 mm to 1.5 mm (1.5 mm already applying to Class 1 medicines);
  - Removal of the need for inclusion of the additional requirements relating to biological products (if applicable) on the label of small or very small containers or equivalent size injections, other than the name of any adjuvants on small containers, equivalent size injections and very small containers;
  - Removal of the requirement for the unique identifier to appear on the label on the container of injections of 20 mL or less that are supplied in fully-labelled primary pack; and
  - Addition of a requirement for the label on the container of concentrated solutions for injection, notwithstanding their volume, to include a direction not to administer the solution undiluted.

### **Additional consideration - Plastic ampoules**

In relation to plastic ampoules joined with a connecting strip, the Committee noted that it could not be assumed that medicines presented in this way were always injections, as this presentation could also be used also for products such as inhalations. While any product presented in a plastic ampoule would need to meet the standard labelling requirements for the relevant product type, the intent of the clause relating to plastic ampoules was to stipulate the location of specific label information when such ampoules are joined with a connecting strip.

As drafted, the stated provisions for plastic ampoules applied only to ampoules with a volume of 5 mL or less that are attached to a connecting strip from which the ampoules are detached for use and which carries part of the mandatory labelling. The Committee discussed the practice of hospitals detaching these ampoules from the strip and questioned whether continuation of arrangements which allow part of the essential information to appear on the strip remains justified. The Committee considered difficulties associated with embossing on plastic ampoules, and noted that printing on the connecting strip is technically easier. This also facilitates visual checking of the solution in the ampoule for clarity prior to use as it does not obscure the view. As significant re-configuration of packaging/labelling equipment would be needed if relocation of label information from the connecting strip to the ampoule was now to be required, the Committee agreed that this arrangement for plastic ampoules should be retained. The Committee agreed that it was an oversight however that the draft Order did not mention that the arrangements for splitting of information between the ampoule and the connecting strip were dependent on there being a fully labelled primary pack. The

Committee agreed that the applicable clause should be re-drafted to more clearly specify the permitted arrangements and to clarify the basis for these.

## **Issue 6      *Unique identifier - minimum font size and inclusion on both container and primary pack***

### **Issue:**

Consultation responses from industry associations and individual sponsors supported a minimum font size for the unique identifier (currently in Australia this is the Aust L/R number) of 1 mm rather than 1.5 mm as proposed, stating that there was a lack of evidence to support the increase in font size (for Australia) and that the increase in size would lead to crowding of the label. Conversely, responses from other groups such as consumers and professionals argued more generally that even font sizes of 1.5 mm were not legible for some parts of the population.

Industry responses also opposed the proposed requirement for the unique identifier to appear on both the container and primary pack (if used) as this differed from the current arrangement in Australia where the unique identifier need only appear on the primary pack, if the container is enclosed in a primary pack.

### **Committee considerations:**

The Committee considered the following:

- The role of the unique identifier in communicating recall information, for example, in distinguishing between products with similar names;
- Other functions of the unique identifier, for example, as an indicator that a product has been approved by the Authority;
- Whether there are some container types that are not likely to be separated from their primary pack, or on which it would be impractical to include the unique identifier, which could be excluded from the requirement for the unique identifier to appear on both levels of packaging; and
- The totality of label information and specifically the inclusion of other numbers on the label, including batch numbers and bar codes.

The Committee noted that the Therapeutic Goods Committee (TGC) had recently undertaken extensive consultation in Australia on the presentation of the AUST R / AUST L number (among other issues) and the proposals in the new labelling Order which sought to give the unique identifier more prominence were based closely on the outcomes of the TGC consultation. There was a marked difference in the stakeholder comments received in response to the TGC's consultation and the current consultation.

The Committee agreed that, as consumers and health professionals are more likely to separate some container types (for example, bottles) from their primary pack than others (for example, blister strips), it may be possible to exempt some container types from the requirement to have the unique identifier on both levels of packaging.

**Outcome:**

The Committee confirmed that:

- The minimum font size for the unique identifier should be 1.5 mm; and
- The unique identifier should be required on the labels of both the container and the primary pack as originally proposed, but noting that the unique identifier had not been included among the proposed requirements for inclusion on the labels of very small containers, very small volume injections, individually wrapped products, or strip, blister and dial dispenser packs, packed inside a fully labelled primary pack.

Further to this, and taking into consideration stakeholder comments, the Committee agreed that the unique identifier need not be required on the labels of small containers or equivalent sized injections packed inside a fully labelled primary pack.

**Issue 7      *Legibility of embossing on plastic ampoules and for expiry and batch details on cardboard***

**Issue:**

The Committee received a number of comments from the professions and government agencies or their advisory committees relating to the use of embossing or debossing on labels. These comments concerned the poor quality of some embossing or debossing, difficulty in reading embossed or debossed information, lack of colour contrast, inconsistency with the requirement for labels to be clear, legible and distinct, and easy confusion between some characters and letters when embossed or debossed.

**Committee considerations:**

The Committee considered:

- Whether the practices of embossing and debossing should be prohibited or discouraged;
- Whether removing the specific permissions in the draft labelling Order for embossing would assist in focussing on the requirement for all label details to be legible and durable; and
- The potential for broader use of embossing or debossing of label information and whether limitations on what elements of label information may be embossed should be stated explicitly.

The Committee noted:

- Lack of legibility of some embossing or debossing was a significant issue;
- That the TGC had recently consulted also on a proposal to disallow the use of embossing for batch and expiry information. The TGC received numerous responses from industry opposing the proposal. Reasons given included the common use of embossing by manufacturers world-wide and its acceptance by health authorities world-wide, the capital expenditure needed to move from embossing to printing, technical limitations to printing on some types of packaging, and advantages of embossing or debossing as a deterrent to counterfeiting and tampering with expiry details;
- Advice from industry members that as equipment is being replaced by industry, less use will be made of embossing batch and expiry date information as ink printing technologies

are improving. The exception to this would be plastic ampoules, as printing on these on a per batch basis remains difficult;

- The draft *Best Practice Guideline on Prescription Medicine Labelling* which states that, with respect to batch number and expiry date, ink is preferred over embossing; and
- Embossing or debossing of batch and expiry details, and embossing labels on plastic ampoules may be acceptable, but other label information should not be embossed.

**Outcome:**

The Committee agreed that:

- It is not feasible to prohibit embossing or debossing of batch and expiry details or the labels of plastic ampoules;
- However, the specific clauses in the draft Order referring to embossing should be deleted allowing the test of legibility and durability to more clearly apply to embossed or debossed information; and
- A Supplementary Note would be useful to expand on the requirement for legibility of embossed or debossed label information and the preference for inked embossing wherever technically feasible.

## **Issue 8      Abbreviation of ‘microgram’**

**Issue:**

Consultation responses from many stakeholders, but particularly professional bodies, argued in favour of the use of ‘mcg’ as the abbreviation for microgram rather than ‘µg’ as stated in the Supplementary Notes to the draft Order. However, the abbreviation ‘µg’ complies with the Australian *National Measurement Act*, and is the correct SI abbreviation as used in both the British Pharmacopoeia (BP) and the United States Pharmacopeia (USP).

**Committee considerations:**

The Committee took the following into consideration:

- The need for microgram to be written in full wherever possible;
- Consumer and health professional understanding of the two abbreviations ‘µg’ and ‘mcg’;
- Potential for misreading of either abbreviation by consumers or health professionals, particularly when hand-written;
- Current legislation relating to metric terminology and abbreviations;
- Pharmacopoeial standards for abbreviations;
- Advice in the *National In-Patient Medication Chart* that the abbreviation ‘µg’ should be avoided as it may be mistaken for milligram when hand written, and instead ‘mcg’ should be clearly written, or preferably microgram should be written in full; and
- The possibility of different abbreviations being permitted for non-prescription medicines and prescription medicines (as currently permitted in Australia).

**Outcome:**

This was a difficult issue for the Committee to resolve. Although there was unanimous support for microgram to be written in full wherever space permitted, a unanimous position

could not be reached on the appropriate abbreviation to be used for microgram when there are space limitations. The majority view of the Committee however was that the legally and scientifically accepted abbreviation 'µg' must be used if any abbreviation is used. The Committee agreed that, for reasons of consistency and education, the same abbreviation should be used for both Class 1 and Class 2 medicines. It was accepted that, if space permitted, whenever microgram is written in full, it should be followed by 'µg' in brackets. A Supplementary Note should provide guidance on the abbreviation for 'microgram'.

**Further discussion:**

Having reached this outcome for microgram, the Committee considered whether it was possible to similarly determine a single abbreviation to denote volume, particularly millilitres. Currently both 'mL' and 'ml' were in use, the former largely in Australia and the latter often in NZ. The Committee noted however that the SI abbreviations and the *National Measurement Act* permitted use of either abbreviation. The Committee therefore accepted that either abbreviation could be used on labels.

**Issue 9      *Continuation of country specific labelling: plasma products, low volume products entering NZ, prevention of parallel importation***

**Issue:**

A number of comments were made in the consultation responses in relation to the need for continuation of country specific labelling, including as an aid in prevention of parallel importation, and for low volume imported products.

**Outcome:**

The Committee noted that these issues were largely related to policy governing the joint regulatory arrangements and as such were outside the scope of its Terms of Reference.

**Issue 10**      ***Name and address requirements – proposed requirement for label to show name and address of product licence holder<sup>1</sup> rather than allowing the option of a supplier's name and address***

**Issue:**

Consultation responses from industry argued for retention of the option to include on the label a supplier's name and address instead of the name and address of the product licence holder. Supporting arguments were based on variable licensing and distribution agreements, appropriateness in some circumstances of the supplier being the point of contact for enquiries, product licence holders sometimes being contract regulatory companies, difficulties with imported products, and issues over disclosure of commercial arrangements.

**Committee considerations:**

The Committee gave consideration to the following:

- The entity legally responsible for the product, including the fact that some suppliers may have no legal connection to the product licence holder;
- The advantages and disadvantages of labels having country-specific contact details;
- The legal acceptability (or otherwise) of a single product having multiple versions of a label (different contact details for different locations);
- Implications for consumers of the point of contact for enquiries or complaints possibly being overseas;
- The consultation undertaken by the TGC in 2004, specifically the proposal to remove the option of allowing supplier details to appear on labels instead of sponsor details (allowing the inclusion of supplier details as additional information), and the variable industry support for this proposal at the time which appeared to depend on distribution arrangements currently in place; and
- The practicality (or otherwise) of a single label showing multiple supplier details.

**Outcome:**

The Committee confirmed that labels must show the name and contact details of the legal entity responsible for the product. This is the product licence holder and inclusion of their name and contact details should be the minimum requirement. There would be no objection to the product licence holder also including details of any distributor as additional information on the label although this would be optional.

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<sup>1</sup> The May 2006 revised draft Labelling Order uses the term 'sponsor' in place of the term 'product licence holder' appearing in the earlier version. This is because the labelling requirements of this standard are intended to apply to both licensed medicines and certain medicines that are exempted by the Medicines Rule from the need for a product licence. Where it is intended that medicines exempt from product licensing also be exempt from compliance with labelling requirements, a specific exemption for the particular circumstances has been included in the draft Order.

## **Issue 11      Terminology**

### **Issues:**

A number of issues relating to terminology and the implications of various proposed definitions were raised in the consultation responses. These included the following:

- ‘container’ and ‘primary pack’ – inconsistency of these names with international (European Union - EU), and also current NZ, terminology;
- tonicity, specifically definition of the milliosmolar range that could be considered isotonic, and reference to osmolality rather than osmolarity;
- batch numbering and the proposed requirement for a clear and obvious relationship between the batch number on all levels of packaging; and
- batch number prefixes and expiry date prefixes and the proposed requirement for consistency through use of the same prefix on both container and primary pack of any one medicine.

### **Committee considerations:**

#### *Container and primary pack*

The Committee noted that the equivalent terms used in the EU (Directive 2001/83/EC) were *immediate packaging* (the container or other form of packaging immediately in contact with the medicinal product) and *outer packaging* (the packaging into which is placed the immediate packaging). Other suggestions made by stakeholders included primary pack or primary package (for what was currently termed the container) and secondary pack or product pack (for what was currently termed the primary pack). Inner pack and outer pack were suggested also.

On balance, the Committee supported the adoption of the European terminology (immediate packaging and outer packaging) as this would give clarity and be least ambiguous. However adoption of these terms would be dependent on adoption of the same terms in any superior legislation. There would necessarily be a flow-on effect to other instruments (for example, other Orders) and documents (for example, guidelines).

#### *Tonicity – osmolality versus osmolarity*

The stakeholder consultation had elicited several comments on the milliosmolar range that could be considered isotonic clinically, and also on whether labelling should refer to osmolarity rather than osmolality, with osmolarity stated to be more relevant to pharmacy practice.

In relation to tonicity, some stakeholders had commented that the range 250-350 milliosmoles per kilogram of solvent was too wide, and suggestions for revised ranges were given although no scientifically justified argument for these ranges was presented. Although the Committee considered that there was some justification for narrowing the range based on the osmolality of blood, the selection of an alternate range was somewhat arbitrary. The Committee did not consider there was sufficient reason to do this.

In relation to osmolality versus osmolarity, the Committee noted the following:

- Osmolality is a measure of the osmotically active solute within the solvent. In terms of physiological function, and determining if something would be osmotically compatible with blood, osmolality is the most precise measure and therefore most important;
- Osmolarity is widely used in pharmacy practice because it expressed osmoles as a function of volume. It is however a derived calculation based on which osmotically active solutes are included in the calculation. If there is an osmotically active solute that is not included in the calculation, there would be a gap between osmolality (the measured tonicity) and osmolarity (the calculated or 'true' tonicity); and
- Osmolality is approximately equal to osmolarity when considering dilute solutions but in concentrated solutions the solute mass may be of significance and the gap between osmolality and osmolarity could have an important physiological effect.

The Committee therefore concluded that:

- There was no information available to support a change to the definitions of isotonic, hypotonic and hypertonic, and any revised figures would be arbitrary; and
- Use of the term osmolality was technically correct and therefore should be retained. Furthermore a subtle labelling change from reference to osmolality to reference to osmolarity may go unnoticed, and result in problems in practice.

### *Batch numbering*

The Committee discussed the proposal that the definition of batch number be expanded to include a requirement for 'a clear and obvious relationship between the batch number shown on the labels of all components of a medicine that are separately labelled with this information', as stated in the draft Order released for stakeholder consultation. The rationale for this had related to problem reports received by the TGA concerning different batch numbers on blister strips and their primary pack and concerns of consumers that such products may have been tampered with.

A number of industry responses received by the Committee stated that the intention of this requirement was unclear, that it was a manufacturing issue and not a labelling issue, and/or that because manufacturers have different practices, coordination of batch numbers on different levels of packaging is not always practical or possible.

The Committee accepted comments that:

- The ultimate product licence holder may not have the ability to influence the batch number used on all levels of packaging;
- Many medicines are not manufactured in Australia or New Zealand and overseas manufacturers may not be willing to change batch numbering systems;
- If achievable, it may be costly; and
- Traceability of the product through all batch numbers must be possible, but correct manufacturing processes permit this.

As the majority view of Members was that a clear and obvious relationship between batch numbers should not be specified, the Committee agreed that the definition of batch number should be amended accordingly. Nevertheless, the Committee supported the inclusion of a Supplementary Note stating that it was preferred for there to be a clear and obvious relationship between batch numbers on all different levels of packaging if the batch number could not be identical. Retention of the Good Manufacturing Practice requirement for

stringent traceability of product batches and cross-correlation between batch numbers used for all levels of packaging was assumed.

#### *Batch number prefixes and expiry date prefixes*

The Committee considered the proposed requirement that, when a container is enclosed in a primary pack, the same batch number prefix or expiry date prefix should be used on both the container and primary pack. The rationale for this proposed requirement was to assist consumer identification of batch numbers and expiry dates.

In response to the consultation, a number of industry stakeholders had advised that a requirement for uniformity of prefix across packaging is impractical as different equipment and production lines may not be identical in the choice of batch or expiry prefixes, and use of different manufacturers and equipment for different stages of manufacturing may mean that the prefix varies with packaging level or between batches. Furthermore, clarity was more important than consistency and space limitations may mean that although abbreviations are necessary on the container, primary packs may be able to accommodate the full term.

In view of the comments received, and the practical difficulties envisaged, the Committee concluded that use of the same prefixes on all levels of packaging should not be mandated.

The Committee was concerned however that the terms ‘expiry’ and ‘use before’ may be interpreted differently and therefore a Supplementary Note should advise that it was preferred that there not be a mix of ‘expires’ or its variants with ‘use before’ or its variants on a single product.

#### **Outcomes:**

The Committee agreed that:

- The term ‘immediate packaging’ would be preferable to the term ‘container’ and the term ‘outer packaging’ would be preferable to the term ‘primary pack’;
- The definition of ‘batch number’ should be amended to remove the proposed requirement for a clear and obvious relationship between the batch numbers shown on different levels of packaging;
- The definitions of ‘batch number prefix’ and ‘expiry date prefix’ should be amended to remove the proposed requirement for the same prefix to be used on both the container and its primary pack; and
- A Supplementary Note should be included to advise that, because of possible misunderstanding, different levels of packaging on a single product should not mix the expiry date prefixes ‘expires’ (or its variants) with ‘use before’ (or its variants).

## **Issue 12      Bar coding**

#### **Issue:**

A number of stakeholders proposed that bar coding become mandatory, while others mistakenly assumed that the term ‘unique identifier’ referred to a bar code.

### **Committee considerations:**

The Committee noted that although bar codes are increasingly being used for checking, at present they are largely used for supply/logistic purposes. Bar codes are of little use to consumers, or in recall circumstances, and it was concluded that bar coding is not sufficiently advanced in Australia and New Zealand to legislatively require this at the present time. However, although the draft labelling Order did not mandate bar-coding, it did not prohibit it. In fact, the introduction to the Order mentioned bar codes as one of a number of possible, non-mandatory label inclusions and product licence holders should be encouraged by this to consider bar-coding when developing labels.

### **Outcome:**

In view of correspondence received and recognition of action in the UK and USA towards bar coding, the Committee recommended to the new Authority that bar coding requirements be given thorough consideration in due course under a separate process. This was considered to be too complex an issue to incorporate into the current labelling review and its timelines.

## **Other Stakeholder Comments Received**

The Committee also discussed a number of other matters raised in the stakeholder responses. **Attachment 3** outlines the main clauses/subclauses discussed (other than those relating to major issues identified above). Some consequential changes to the draft labelling Order, as indicated, were supported by the Committee.

## **Other Matters Considered by the Committee**

### ***Intermediate packaging***

In relation to products with more than two levels of packaging, the Committee noted that currently no particular requirements had been proposed for the labelling of the intermediate packaging. The Committee considered that standardised requirements for this may be useful particularly if the intermediate packaging is opaque.

In considering this proposal, the Committee noted that:

- Although such products are not supplied without fully labelled primary packs, in the hospital scenario, products are frequently removed from the primary pack, potentially making identification and batch checking difficult;
- Appropriate labelling on intermediate packaging therefore is a safety issue; and
- Practically, comprehensive labelling of intermediate packaging such as foil pouches may be difficult for industry to achieve but the intermediate packaging of many products may already be labelled with adequate information.

The Committee concluded that the labelling Order should recognise that there may be intermediate packaging, and specify minimum labelling requirements for opaque intermediate packaging. The Committee recommended therefore that the draft labelling Order should be

amended to specify requirements for labelling of opaque intermediate packaging, these requirements being the same as those for sealed individually wrapped products.

The Committee agreed that the labelling Order should include a definition of ‘intermediate packaging’ and specify requirements for the labelling of opaque intermediate packaging.

However, in recognition of this new proposal representing a potentially major change for industry, the Committee agreed there was a need for industry consultation on the issue and information to be sought on what the current practices for labelling of intermediate packaging were.

## Issues Relating to Labelling of Complementary Medicines

The Committee noted that issues relating to the labelling of complementary medicines, in particular those relating to herbal, homoeopathic and anthroposophic medicines, were being reviewed in line with recommendations made by both the Complementary Medicines Evaluation Committee (CMEC) and the OCM Industry Consultation Group (OICG)<sup>2</sup> following consideration of stakeholder responses to the consultation papers *Regulation of Herbal Substances in a Joint Australia New Zealand Therapeutic Products Agency*, and *Regulation of Homoeopathic and Related Medicines in a Joint Australia New Zealand Therapeutic Products*.

The Committee was in agreement that relevant outcomes from this separate consultation process could be incorporated into the final draft labelling Order.

**Attachment 4** outlines this consultation process, and summarises the consideration of the major issues identified, and the outcomes reached

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<sup>2</sup> The OCM / Industry Consultation Group (OICG) consists of Australian and New Zealand industry representatives who have been nominated by the Complementary Healthcare Council of Australia (CHC), the Australian Self-Medication Industry Inc. (ASMI) and Natural Products New Zealand (NPNZ). The OICG provides a forum for considering technical issues affecting the regulation of complementary medicines.

## Attachment 1

**Summary of amended requirements and concessions for small and very small containers**

	<b>Small container</b>	<b>Very small container</b>
Applicable definitions	Nominal capacity less than or equal to 20 millilitres or 20 grams (does not include small volume injections)	Nominal capacity less than or equal to 2 millilitres or 2 grams (does not include very small volume injections)
Conditions (other than capacity), if any	Concessions apply to label on the container only and label on the primary pack must fully comply with standard labelling requirements	Concessions apply to label on the container only and label on the primary pack must fully comply with standard labelling requirements; concessions only apply if there are two or more active ingredients; and product name is unique and unequivocally identifies product.
<b>Label is to include:</b>		
Product name	Yes (no abbreviation)	Yes (no abbreviation)
Name(s) of all active ingredients	Yes (font size for active ingredient names may be reduced to 1.5 mm; no abbreviation)	Not required
Quantity or proportion of all active ingredients	Yes (no abbreviation)	Not required
Declaration of any excipients referred to the First Schedule	Not required	Not required
Name of dosage form	Yes	Not required
Quantity of the medicine	Yes	Yes (minimum font size 1 mm)
Warning statements	Not required	Not required
Batch number & batch number prefix	Yes	Yes (minimum font size 1 mm)
Expiry date & expiry date prefix	Yes	Yes (minimum font size 1 mm)
Storage conditions	Not required	Not required
Directions for use	Not required	Not required
Name and address of product licence holder	Only name or registered trademark of product licence holder or proprietary name of medicine	Not required

	<b>Small container</b>	<b>Very small container</b>
Statement of the purpose	Not required	Not required
Route(s) of administration	Yes (only where the medicine is in an ampoule)	Yes (only where the medicine is in an ampoule – minimum font size 1 mm)
Signal words	Yes if applicable	Not required
Unique identifier	Not required	Not required
<b>Plus, if an ophthalmic preparation:</b>		
Name of any antimicrobial preservative or 'Contains no antimicrobial preservative. Use once only and discard residue' or a statement to that effect	Not required	Not required
A statement to the effect that the medicine should not be used later than four weeks after the container is first opened	Yes (only where the medicine is for multi-dose use or is a solid ophthalmic medicine for preparing eye drops)	Not required
For solid ophthalmic medicines for preparing eye drops or eye lotion, the words 'for eye drops' or 'for eye lotion' in or adjacent to the product name	Not required	Not required
For ophthalmic preparations consisting of solution or suspension in oil, the word 'oily' in or adjacent to the product name	Not required	Not required
<b>Plus, if a biological product:</b>		
Name and proportion of any antimicrobial preservative	Not required	Not required
Name of any adjuvants	Yes (if a biological product)	Yes (if a biological product)
For vaccines produced in animal cells or cell cultures, approved name for the cell culture substrate or source animal, as specified in the <<authority's biologicals approved names list'>> and name of the tissue used in the manufacture of the medicine	Not required	Not required
For vaccines produced in animal cells or cell cultures, name of any residual antibiotic that may be present in the medicine	Not required	Not required
For antisera, approved name for the animal in which the medicine has been prepared, as specified in the <<authority's biologicals approved names list'	Not required	Not required

	<b>Small container</b>	<b>Very small container</b>
For monoclonal antibodies, approved name of the origin of the hybridoma cell line, as specified in the <<authority's biologicals approved names list'>>, used in the preparation of the medicine	Not required	Not required
For recombinant products, approved name for the biological source as defined by the appropriate Biotechnology Product Descriptors as specified in the <<authority's biologicals approved names list'>> placed immediately after the active ingredient name	Not required	Not required
For other biological products, approved name for the animal or organism, as specified in the <<authority's biologicals approved names list'>>, from which the medicine has been prepared	Not required	Not required

**Attachment 2**

**Summary of amended requirements and concessions for injections based on nominal volume**

	<b>Nominal volume greater than 100 mL</b>	<b>Nominal volume less than or equal to 100 mL</b>	<b>Nominal volume less than or equal to 20 mL</b>	<b>Nominal volume less than or equal to 2 mL</b>
Conditions (other than volume), if any	Nil - same labelling requirements apply to container and primary pack	Nil - same labelling requirements apply to container and primary pack	Concessions apply to label on container only; label on primary pack must fully comply with standard injection labelling requirements (i.e. requirements for ≤ 100 mL).	Concessions apply to label on container only; label on primary pack must fully comply with standard injection labelling requirements; there are two or more active ingredients; and product name is unique and unequivocally identifies product.
<b>Label is to include:</b>				
Product name	Yes (no abbreviation)	Yes (no abbreviation)	Yes (no abbreviation)	Yes (no abbreviation)
Name(s) of all active ingredients	Yes (no abbreviation)	Yes (no abbreviation)	Yes (font size may be reduced to 1.5 mm; no abbreviation)	Not required
Quantity or proportion of all active ingredients	Yes (see clause relating to expression of quantity or proportion of active ingredient for details of how to express this)	Yes (express as total quantity in total volume and as total quantity per mL)	Yes (if volume > 1 mL, express as total quantity in total volume and as quantity per mL; if volume ≤ 1 mL, express as total quantity in nominal volume)	Not required
Declaration of any excipients referred to the First Schedule	Yes - if applicable	Yes - if applicable	Not required	Not required
Name of dosage form	Yes	Yes	Yes	Not required
Quantity of the medicine	Yes	Yes	Yes	Yes (minimum font size 1 mm)
Warning statements	Yes - if applicable	Yes - if applicable	Not required	Not required
Batch number & batch number prefix	Yes	Yes	Yes	Yes (minimum font size 1 mm)
Expiry date & expiry date prefix	Yes	Yes	Yes	Yes (minimum font size 1 mm)

	<b>Nominal volume greater than 100 mL</b>	<b>Nominal volume less than or equal to 100 mL</b>	<b>Nominal volume less than or equal to 20 mL</b>	<b>Nominal volume less than or equal to 2 mL</b>
Storage conditions	Yes	Yes	Not required	Not required
Directions for use	Yes - but not required if the medicine can only be supplied on prescription or if dose is usually determined for an individual patient by a health professional authorised under relevant legislation (applicable to most injections)	Yes - but not required if the medicine can only be supplied on prescription or if dose is usually determined for an individual patient by a health professional authorised under relevant legislation (applicable to most injections)	Not required	Not required
Name and address of product licence holder	Yes	Yes	Yes - but only name or registered trademark of product licence holder or proprietary name of medicine	Not required
Statement of the purpose	Yes - except where the medicine is a Prescription Medicine or a Controlled Drug or a dispensing pack supplied solely to a complementary healthcare practitioner, and includes 'For Practitioner Dispensing Only'	Yes - except where the medicine is a Prescription Medicine or a Controlled Drug or a dispensing pack supplied solely to a complementary healthcare practitioner, and includes 'For Practitioner Dispensing Only'	Not required	Not required
Approved route(s) of administration or abbreviation denoting the approved route(s) of administration	Yes	Yes	Yes	Yes
Signal words	Yes - if applicable	Yes - if applicable	Not required	Not required
Unique identifier	Yes	Yes	Not required	Not required
The words 'for injection' in or adjacent to product name	n/a	Yes - where the medicine is a powder for injection or a concentrated solution for injection	Not required	Not required

	<b>Nominal volume greater than 100 mL</b>	<b>Nominal volume less than or equal to 100 mL</b>	<b>Nominal volume less than or equal to 20 mL</b>	<b>Nominal volume less than or equal to 2 mL</b>
The word 'oily' in or adjacent to the product name	n/a	Yes - where the medicine is an injection consisting of a solution or suspension in an oil	Not required	Not required
The name and quantity of each excipient in the medicine	Yes - name & quantity of each excipient in the stated volume of the injection in the container	Yes - name & quantity of each excipient stated as: - quantity of excipient in stated volume of the injection (single dose injections); - quantity of excipient in the container (powder for injection or concentrated solution for injection); or - quantity of excipient in 1mL or a suitable dose volume where stated volume is less than 1mL (multidose injections)	Not required	Not required
The words 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or a statement to that effect	Yes	Yes - if supplied in container with potential for multi-dose use (eg vial, or pre-filled syringe) & antimicrobial preservative is not present.	Not required	Not required
A direction not to administer the solution undiluted	n/a	Yes - if a concentrated solution for injection	Yes - if a concentrated solution for injection	Yes - if a concentrated solution for injection
A direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use	n/a	Yes - if a concentrated solution for injection	Not required	Not required
A statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre.	Yes - for medicines intended for use as a radio-contrast agent	Yes - for injections containing a radio-contrast agent	Not required	Not required
A statement in grams of the total amount of nitrogen in the stated volume of injection in the container	Yes - where one or more active ingredients are amino acids and/or protein	n/a	n/a	n/a

	<b>Nominal volume greater than 100 mL</b>	<b>Nominal volume less than or equal to 100 mL</b>	<b>Nominal volume less than or equal to 20 mL</b>	<b>Nominal volume less than or equal to 2 mL</b>
A statement in kilojoules of the energy equivalent of the stated volume of injection in the container	Yes - where the medicine is intended for use as an energy source	n/a	n/a	n/a
Osmolality	Yes	n/a	n/a	n/a
A statement specifying whether the injection is 'hypotonic' or 'hypertonic' or 'isotonic'	Yes	n/a	n/a	n/a
pH range of the injection	Yes	n/a	n/a	n/a
<b>Plus, if a biological product:</b>				
Name and proportion of any antimicrobial preservative	Yes - if a biological product (but all excipients must be stated anyway)	Yes - if a biological product (but all excipients must be stated anyway)	Not required	Not required
Name of any adjuvants	n/a	Yes - if a biological product	Yes - if a biological product	Not required
Approved name for the cell culture substrate or the source animal, as specified in the <<agency's biologicals approved names list>> and name of the tissue used in the manufacture of the medicine	n/a	Yes - for vaccines produced in animal cells or cell cultures	Not required	Not required
Name of any residual antibiotic that may be present in the medicine	n/a	Yes - for vaccines produced in animal cells or cell cultures	Not required	Not required
Approved name for the animal in which the medicine has been prepared, as specified in the <<agency's biologicals approved names list>	Yes - for antisera	Yes - for antisera	Not required	Not required
Approved name of the origin of the hybridoma cell line, as specified in the <<agency's biologicals approved names list>>, used in the preparation of the medicine	Yes - for monoclonal antibodies	Yes - for monoclonal antibodies	Not required	Not required

	<b>Nominal volume greater than 100 mL</b>	<b>Nominal volume less than or equal to 100 mL</b>	<b>Nominal volume less than or equal to 20 mL</b>	<b>Nominal volume less than or equal to 2 mL</b>
Approved name for the biological source as defined by the appropriate Biotechnology Product Descriptors as specified in the <<agency's biologicals approved names list'>> must be placed immediately after the active ingredient name	Yes - for recombinant products	Yes - for recombinant products	Not required	Not required
Approved name for the animal or organism, as specified in the <<agency's biologicals approved names list'>>, from which the medicine has been prepared	Yes - for other biological products	Yes - for other biological products	Not required	Not required

### Discussion of Other Stakeholder Comments Received

Note: Clause and subclause numbers quoted in the following table refer to the applicable clause or subclause number in the consultation document *Draft Labelling Requirements for Medicines under a Joint Australia New Zealand Therapeutic Products Agency* that was released to stakeholders in April 2005. Subsequent amendment and re-formatting of the draft Order may have resulted in different clause or subclause numbers now applying to the specific provisions.

Clause / subclause of draft Order	Issue/Discussion	Amendment
1 Introduction	Several suggestions were made to further expand the descriptive clause describing the purpose of a medicine label – including that labelling contributes to the quality use of medicines, labels include information on dosage and directions for use, and labels should be designed in order to minimise the risk of dispensing errors and to enhance patient safety.	The Committee agreed to amendment of clause 1 as suggested.
	Inclusion of reference to other specific (non-health) legislation that may apply to labels was suggested. The Committee noted that Australia and NZ did not have common legislation in many of these areas, and it would not be possible to comprehensively list all such legislation.	Nil
2 Application	A number of responses questioned the ability for exemptions from requirements to be granted. The Committee noted that exemption arrangements for labelling would be the same as those for exemption from any other standard in force under the new legislation i.e. the Managing Director of the Authority would have the ability to grant exemptions from standards, including labelling requirements. Such exemptions would be considered on a case by case basis.	Nil
4 General exemptions: Subclauses 4(1)(h), (i), (j) and (k)	The Committee noted a number of comments relating to the general exemptions for products supplied / dispensed / compounded etc by various health professionals in the course of treating a patient. These comments indicated clarification was needed to enhance the understanding of the practical difference between the different circumstances. The Committee confirmed the intent of each subclause and agreed that the wording should be clarified.	Revise wording of subclauses 4(1)(h), (i), (j) and (k).
5 Interpretation	The Committee noted the need to ensure consistency of definitions with those contained in the Rules and other relevant documents.	Amend as required.
	Definitions added: <b>anthroposophic medicine</b> <b>Class 1 medicine</b> <b>Class 2 medicine</b> <b>composite pack</b>	Add definitions.
	Definitions deleted: <b>complementary healthcare practitioner</b> (the Committee noted that issues of registration were a jurisdictional matter, and this was not relevant to the labelling Order) <b>Controlled Drug</b> (term no longer used in draft Order) <b>diluent</b> (definition not required – has common meaning) <b>large volume injection, small volume injection, very small volume injection</b> (different injection sizes no longer to be defined by name) <b>medicament for injection</b> (replaced in Order with 'powder for	Delete definitions.

Clause / subclause of draft Order	Issue/Discussion	Amendment
	injection or concentrated solution for injection') <b>OTC Medicine</b> (term no longer used in draft Order)	
	Definitions amended: <b>Calendar pack</b> (as these may not always be strip, blister or dial dispenser packs) <b>Date of manufacture</b> (for consistency with definition contained in European Guidance on start of shelf-life) <b>Delivered dose</b> (to make clear that the term refers to the amount delivered from a single actuation, spray or inhalation and it does not necessarily equate to a therapeutic dose which may be more than one actuation or spray) <b>Durable</b> (to limit the requirement for durability to the shelf-life of the product) <b>Expiry date</b> (to allow for products that require a day of expiry also) <b>Main label</b> (editorial, plus to allow for designation of one of two equally conspicuous labels or portions of the label as the main label) <b>Name and address</b> (editorial changes, noting that name/address of distributor and website address are optional) <b>Quantity of the medicine</b> (to replace the term 'dose' as there may be confusion between the delivered dose and what is a therapeutic dose) <b>Warning statements</b> (relating to clarification of proposed warning 'not to be taken' for external use medicines; and deletion of reference to warning statements in the scheduling standard as these are being transferred to the replacement document for RASML)	Amend definitions.
	Definitions already discussed and possibly amended under issues: <b>batch number</b> <b>batch number prefix</b> <b>container</b> <b>expiry date prefix</b> <b>hypertonic</b> <b>hypotonic</b> <b>isotonic</b> <b>primary pack</b> <b>sample pack</b> <b>small container</b> <b>starter pack</b>	As outlined under issues above.
6 Label presentation: Subclause 6(1)(b)	Comments concerning language requirements for consumers from culturally and linguistically diverse backgrounds were noted, including the need for a supply of information in a range of community languages. Although this could not be mandated through the labelling Order, the requirement for labels to be written in the English language would be supported by a Supplementary Note advising that labels should be written in 'plain English'.	Nil
6 Label presentation: Subclause 6(1)(d)	A large number of comments were received relating to the proposed minimum default font size of 1.5 mm – industry stakeholders arguing for smaller font sizes, and professional bodies and consumers seeking larger font sizes. The Committee noted that 1.5 mm had been the default font size for a number of years – this default font size was being retained but the draft Order also: proposed to increase the required font size for active ingredient names for Class 2 medicines; and allow a smaller font size (1 mm) for certain information on the labels of very	Nil to 6(1)(d) but amendments to related clauses as per Issue 3 and Issue 5 above

Clause / subclause of draft Order	Issue/Discussion	Amendment
	small containers and injections. The Committee considered the practicalities and consequences of both larger and smaller font sizes for labels. Although font size was an important issue affecting legibility, it was considered that the proposals put forward were the best possible compromise. Letter spacing, font and colour selection, and reducing clutter on labels were also noted to be important influencers of legibility.	
6 Label presentation: Subclause 6(1)(e)	Stakeholders from industry argued that colour contrast was a subjective requirement, open to interpretation and therefore should not be specified. Conversely, other responses drew attention to the needs of people in vulnerable population groups (eg colour blind, elderly). Although the <i>Best Practice Guideline on Prescription Medicine Labelling</i> included advice on contrasting colours and colour clarity, the Committee considered that this requirement should remain in the labelling Order (with the exception of certain embossed or debossed particulars).	Nil
6 Label presentation: Subclause 6(2)	In response to comments that reference to ‘no decoration, embellishment or distortion’ was subjective, and the remainder of the clause repeated requirements previously stated, the Committee accepted that this subclause should be deleted in entirety.	Delete clause 6(2)
6 Label presentation: Subclause 6(5)	This clause related to durability of the label and in particular being positioned in such a way that it is not damaged in the course of normal handling, or when the container is opened. Comments received drew attention to the fact that the label on some product presentations (sachets, blister packs, ampoules) is necessarily destroyed upon opening. Stakeholders also suggested that the requirements stated in this clause were implied by the definition of durable and therefore were unnecessary. Although the Committee agreed that subclause 6(5)(a) may be redundant, it was considered that the definition of durable did not address the issue of positioning to prevent damage upon opening of the container. This subclause therefore should be amended to accommodate those presentations where damage to the label in removing a dosage unit is usual.	Delete subclause 6(5)(a) and amend subclause 6(5)(b).
7 Particulars to be included on a label Subclause 7(1)(b)	In relation to active ingredient names, some submissions included suggestions aimed at increasing consumer awareness of generic names. The Committee noted that larger font size for active ingredient names for Class 2 medicines had already been agreed for this purpose and the <i>Best Practice Guideline on Prescription Medicine Labelling</i> included further recommendations on this matter. Also in relation to active ingredient names, the Committee noted requests for clarification of whether abbreviations could be used. The Committee considered that abbreviations should not be permitted (in view of the multitude of substance names potentially able to be abbreviated, potential for misreading of abbreviations and often a lack of awareness of chemical and other abbreviations by consumers), unless a specific exemption request was granted.	Nil
7 Particulars to be included on a label Subclause 7(1)(g)	The Committee noted the suggestion that all warning statements be removed from the labelling Order and transferred to RASML. The Meeting noted work on RASML was in progress but it was not sufficiently advanced to take this action at this stage.	Nil
8 Particulars to be included on a main	Industry suggestions that, for all complementary medicines, active ingredient names be permitted to appear on a side or rear	Nil

Clause / subclause of draft Order	Issue/Discussion	Amendment
label Subclause 8(3)(e)	panel of the label irrespective of the number of active ingredients were noted. However the Committee considered that it is desirable for all active ingredients to be declared on the main label of all medicines. The concession to allow active ingredient names to be moved to a side or rear panel when there were two or more active ingredients in a complementary medicine had been proposed in recognition of the names of some active ingredients in complementary medicines being long and complex. The Committee did not consider that there was justification for extending the concession to single ingredient products.	
9 Qualifications and special requirements Subclause 9(1) Preparations for ophthalmic use	Comments regarding the four weeks open shelf life for multidose ophthalmic preparations suggested that specifying this time limit precluded technological innovation in preservative technology. The Committee noted that although the basis for the four weeks time limit was historical and related to pharmacopoeial requirements, for this type of product there must be a clear statement on the label of how long the product may be used for once opened. There was no sound basis for any other standard length of time. However the Agency could determine that a different length of time would be appropriate in justified cases.	Amend subclauses 9(1)(c) and (d) to permit Agency to authorise a different open shelf life if appropriately justified but otherwise retain 4 weeks as the default period.
9 Qualifications and special requirements Subclause 9(11) Medicine kits	The Committee clarified that if the storage conditions of the medicines within the kit differ, then the label of the kit itself should show the most restrictive of those of the individual medicines contained in the kit.	Amend subclause 9(11)(p)
9 Qualifications and special requirements Subclause 9(14) Individually wrapped products	In relation to requirements for individual dosage units in unsealed protective covers, the Committee noted the comment that where there were multiple strengths in any particular product, the wrapper should include the strength in addition to the product name. The Committee discussed the types of products that might be presented in unsealed wrappers, and concluded that the only products which should not require active ingredient details should be lozenges and pastilles in unsealed wrappers. Other dosage forms presented in unsealed wrappers should be subject to the same requirements as when presented in sealed wrappers or other form of unit dose packaging.	Amend subclauses 9(14)(a) and (b)
9 Qualifications and special requirements Subclause 9(15) Strip, blister and dial dispenser packs	The Committee noted comment questioning the need for inclusion of the name or registered trade mark of the product licence holder on the container label for strip, blister or dial dispenser packs and also comment asking if the company logo could be used as the trade mark. In relation to the requirement for the name or registered trademark, the Committee noted that this was no different to current requirements in Australia and use of a trademark was intended to address space constraints on this type of packaging. The Committee considered there was no reason to remove this requirement. In relation to use of the company logo as the trademark, this would only be possible if the company logo is properly registered as the trademark.	Nil
9 Qualifications and special requirements Subclause 9(15)(c) Strip, blister and dial dispenser packs	This subclause related to repetition of product name and active ingredient details at least once over every two individual dosage units in a strip, blister or dial dispenser packs. Stakeholder comments indicated misunderstanding of the requirement as written. The Committee noted that the requirement differed little from current requirements in Australia and NZ, and was a reasonable compromise between requiring full identification of	Editorial only.

Clause / subclause of draft Order	Issue/Discussion	Amendment
	each dosage unit and practicality. In essence, the subclause required that where a medicine is presented in a strip, blister or dial dispenser pack, the product name and name and quantity of each active ingredient is repeated once over each two dosage units. This requirement would apply irrespective of whether or not the strip or blister foil is perforated but not if the strip, blister or dial dispenser pack meets the definition of a calendar pack.	
10 Expression of particulars Subclause 10(1) Use of appropriate metric units	The Committee noted comment that the difference in dose for some active ingredients can be greater than 1000-fold (eg 0.1µg and 100 mg). Therefore a requirement for products containing the same active ingredient in a series of strengths to use the same metric unit of measurement to state the quantity of the active ingredient in all strengths in the series may not be practical. The Committee considered however that it was important for the correct recognition of the relative strength of each medicine within a range that the same units of measurement be used. To overcome possible confusion or misreading of quantities expressed as less than unity, the Committee considered that the Order should require the leading zero always to be used in such cases. It was confirmed that, in relation to products containing multiple active ingredients, the draft Order did not require use of the same units for each active ingredient in a medicine, but only that across a series of medicines containing the same active ingredients in different strengths, the same units must be used for each individual active ingredient.	Editorial only
10 Expression of particulars Subclause 10(2) Expression of quantity or proportion of active ingredients	Subclause 10(2)(b) – liquids for ingestion. The Committee concurred with comment that it is important for liquids for ingestion that are presented in a series of strengths also to have the quantity of active ingredient expressed consistently across the range.	Amend subclause 10(2)(b)
	Subclause 10(2)(d) – transdermal patches. The Committee noted that this subclause required the label to show the total quantity of active ingredient in each patch in addition to the quantity of active ingredient released in a stated time. While recognising that the delivery rate was the important consideration in prescribing, the Committee did not agree with comment received that including the total quantity may cause confusion for the patient and result in misuse.	Nil
	Subclause 10(2)(g) – medicines for injection. Particularly for electrolytes, the Committee agreed with comment that the quantity of active ingredient in a medicine should be expressed in the units most commonly used by prescribers – eg sodium, potassium, calcium and magnesium in mmol. It was noted that subclause 10(2)(g)(iii) already required this for large volume injections intended for electrolyte replacement. This requirement to express amounts in molar terms did not however carry through to solid dose forms.	Nil
	Subclause 10(2)(g)(ii)(A) – for injections with a nominal volume greater than 1 millilitre, this subclause required the quantity of active ingredient to be expressed as both the total quantity in the total volume as well as the quantity in one millilitre. Industry stakeholders considered this would be cumbersome and clutter the label particularly for small injections with multiple ingredients and would be potentially	Nil

Clause / subclause of draft Order	Issue/Discussion	Amendment
	confusing for health professionals. The Committee noted that although this was an increase on TGO 69 requirements for some injections, it provided health professionals with better information. It also was noted that active ingredient details (names and quantities) would not be required at all where the injection has a nominal volume of 2 mL or less and has 2 or more active ingredients.	
10 Expression of particulars Subclause 10(5) Permitted statements of storage conditions	The Committee noted that the labelling Order did not preclude sponsors adding reference to protection from humidity and/or light if required for any particular product. However the need for this additional information would need to be decided on a case by case basis.	Nil
First Schedule Excipients required to be declared on the label of medicines Introductory remarks	The Committee accepted argument that not all derivatives or products of named excipients are problematic or associated with the same adverse responses in susceptible individuals (eg in some cases, this will depend on the degree of purification or extraction of components from the named excipient).	Amend explanation of Column 1 and delete from entries words 'but not limited to'
First Schedule Excipients  Ethanol	The Committee confirmed that the warning should be required for all routes of administration as adverse events were known to have occurred from ethanol contained in topical preparations.	Nil
First Schedule Excipients  Gluten (plus Note 3: Gluten)	The Committee noted industry comment that declaration of the source of the gluten was unnecessary and 'contains gluten' should be sufficient information. Industry stakeholders also requested clarification of the threshold for a product being considered as gluten-free, and specifically the level of testing required to establish this.  The Committee noted that the level at which gluten would be detectable would depend on the method of analysis and equipment. It would be expected that a reasonably sophisticated test method would be used. However this was not something that could be specified in the labelling Order. The Committee agreed that it would be adequate for the label declaration to state 'Contains gluten' and not declare the actual source of the gluten.	Amend entry
First Schedule Excipients  Pollen - Bee	The Committee noted that currently this entry stated 'Pollen – Bee', but attention had been drawn to the fact that not all pollen is harvested from bees.  The Committee agreed to amend the entry so that it referred to all pollen, whether or not it is harvested from bees.	
First Schedule Excipients  Potassium salts Sodium salts	Some industry stakeholders had requested harmonisation of the labelling Order with the TGA's OTC guidelines that currently required potassium and sodium content to be declared on labels as the amount per recommended dose.  The Committee concurred that the OTC guidelines and labelling Order should be harmonised, but the mandatory labelling requirements given in the labelling Order should be the basis for the harmonisation rather than vice versa.  Industry stakeholders also had commented that the use of mmol was not relevant to consumers and could be confusing – therefore the amounts should be expressed on labels in mg only. In relation to this, the Committee conceded that at the present time, label statements in terms of mg amounts are more meaningful for consumers and it would be confusing to have amounts of active ingredients expressed differently to excipients. The Committee also reconsidered proposed cut-off	Amend entries

Clause / subclause of draft Order	Issue/Discussion	Amendment
	limits, noting that as potassium may be ingested from many sources (including multiple medications) and the safety margin in people at risk is small, all potassium should be declared rather than there be a cut-off limit. However the cut-off limit for sodium should be retained as 120 mg per maximum recommended daily dose.	
Supplementary Notes	The Committee noted that a number of comments had been received on the Supplementary Notes included in the draft Order. These comments however were more closely related to the specific provisions of the Order and on which comment had also been provided, rather than the explanation of the provisions. It was anticipated that a number of the Supplementary Notes would be amended in conjunction with agreed amendments to the draft Order.	As required
Miscellaneous comments	<p>The Committee noted a number of other suggestions and comments relating to the draft Order. The Committee agreed that:</p> <ul style="list-style-type: none"> <li>• it would be impractical to include a sample label in the Order, as there were many different product types and the ideal label may vary with each;</li> <li>• for similar reason, a standard format or order for the required information would not be practical;</li> <li>• the labelling Order was not able to mandate that certain label items remain visible after the pharmacist's label is attached. Practically it may not be achievable in all cases, and related to a practice issue not within the Committee's scope. It should however be considered for inclusion in the <i>Best Practice Guideline on Prescription Medicine Labelling</i>; and</li> <li>• the labelling Order did not prohibit the inclusion on labels of country specific information if relevant.</li> </ul>	Nil

## Outcomes of Complementary Medicines Consultation Relevant to Labelling Requirements

### Consultation Process

In January 2005, the following consultation documents were released by Medsafe and the Therapeutic Goods Administration (TGA), for stakeholder comment:

- *Proposed Regulatory Definitions for Complementary Medicines and Homoeopathic Medicines in a Joint Australia New Zealand Therapeutic Products Agency,*
- *Regulation of Herbal Substances in a Joint Australia New Zealand Therapeutic Products Agency,* and
- *Regulation of Homoeopathic and Related Medicines in a Joint Australia New Zealand Therapeutic Products Agency.*

The Consultation Papers proposed new regulatory definitions for complementary medicines and homoeopathic medicines, and identified issues relating to the regulation of herbal substances, and the regulation of homoeopathic and other vibrational type medicines, under the joint Authority.

Stakeholders were requested to provide comment to help inform the development of a risk-based regulatory framework for complementary medicines (including herbal, homoeopathic and related medicines). Stakeholders were also invited to provide any other comment to assist the development of appropriate regulatory arrangements for these types of medicines, including matters relating to labelling.

The consultation period closed on 11 March 2005. Fifty-three submissions were received from a wide representation of stakeholder groups, including: individuals, consumer groups, peak complementary medicine industry associations, professional associations, sponsors and manufacturers of complementary medicine products, practitioners and practitioner associations (representing a range of herbal and homoeopathic philosophies).

The Office of Complementary Medicines convened a group of experts with experience in the regulation and manufacture of complementary medicines in Australia and New Zealand, to 'provide a forum for considering technical issues affecting the regulation of complementary medicines'. This group is called the Office of Complementary Medicines / Industry Consultation Group (OICG). The OICG is composed of Members nominated by the peak industry bodies: the Australian Self-Medication Industry Inc (ASMI), the Complementary Healthcare Council of Australia (CHC), Natural Products New Zealand (NPNZ) and the New Zealand Self-Medication Industry Inc (NZSMI).

Members of the OICG were asked to review the submissions and consider appropriate regulatory arrangements in the light of the stakeholder comments received, with a view to working closely with the TGA and Medsafe in developing the draft Rules relating to complementary medicines under the joint Agency. It was also intended that submissions received from stakeholders would be used to inform the development of other legislative instruments, such as Managing Director Orders (MDOs), for regulating complementary

medicines. The draft regulatory arrangements for complementary medicines were also considered by the Complementary Medicines Evaluation Committee (CMEC).

The OICG and the CMEC review of stakeholder responses relating to the labelling of complementary medicines occurred over the course of several meetings held between October 2005, and February 2006.

It should be acknowledged that further consultation will occur on a number of the proposed regulatory arrangements, particularly those relating to the regulation of homoeopathic and anthroposophic medicines. The labelling proposals put forward in this draft document relating to complementary medicines are based upon regulatory positions derived from stakeholder input, and further considered deliberation by the OICG and the CMEC. However, it is possible that the outcome of consultation on the draft Medicines Rule may result in a small number of these proposals being further amended or deleted.

### **Major Issues Identified in Stakeholder Responses Relevant to Labelling**

In some instances the advice received from the CMEC and that received from the OICG on labelling matters differed. The following situations are highlighted:

1. Placement of differentiation statements for homoeopathic and anthroposophic medicines;
2. Differentiation of formulations containing both homoeopathic and non-homoeopathic ingredients; and
3. Quantification of homoeopathic ingredients.

The following sections summarise the two committees' consideration of these issues and the outcomes reached. These outcomes are reflected in the revised version of the Australia New Zealand Therapeutic Products Authority draft labelling Order, *General requirements for the labelling of medicines* now being released.

#### **Issue 1: Placement of differentiation statements for homoeopathic medicines**

##### *Issue:*

The initial proposal was that where all active ingredients in a medicine are homoeopathic preparations, or anthroposophic preparations, respectively, the main labels for the product must include a prominent statement indicating that the product is a homoeopathic or an anthroposophic medicine (as appropriate). The CMEC and the OICG disagreed as to the required position for this statement.

##### *Committee consideration:*

Most stakeholders supported the position that "Homoeopathic remedies should be clearly differentiated from other medicines on the label of the product to ensure that consumers are aware of the different nature of these medicines."

The issue of differentiating other vibrational remedies from homoeopathic remedies was fairly straight-forward. Stakeholders generally agreed that Bach flowers, bush remedies, gem essence, radionically-produced remedies and medicines are not homoeopathic or anthroposophic medicines, and should not be labelled or classified as either ‘homoeopathic’ or ‘anthroposophic’.

The CMEC proposed that the term ‘homoeopathic’ (or ‘anthroposophic’ as appropriate) needed to appear prominently on the main label, preferably directly adjacent to the product name. They expressed concern that, as many consumers do not read further than the main label, it is important that a statement that the product is homoeopathic should be immediately apparent and visible.

The OICG recommended, however that label placement of the term “Homoeopathic Medicine”, or “Anthroposophic Medicine”, should be flexible, and at the discretion of the sponsor.

*Outcome:*

It was concluded that, consistent with the labelling code of practice, consumer advice relating to the unique nature of homoeopathic or anthroposophic medicines should be immediately evident on the main label of a product. However, the requirement that the statement be immediately adjacent to the product name was determined not to be necessary.

The final proposed wording states that where all active ingredients in a medicine are homoeopathic preparations, or anthroposophic preparations, respectively, the main labels for the product must include a prominent statement indicating that the product is a homoeopathic medicine or an anthroposophic medicine

**Issue 2: Formulations containing both homoeopathic preparations and non-homoeopathic ingredients<sup>3</sup>**

*Issue:*

It was initially proposed that where a medicine contains active ingredients that are a combination of homoeopathic and non-homoeopathic ingredients<sup>4</sup>, the labels must differentiate ingredients that are homoeopathic from those that are not. How this differentiation should occur was a matter for consideration by both committees.

*Committee consideration:*

Both the OICG and the CMEC agreed that where a product contains both homoeopathic and non-homoeopathic ingredients, the product should not be labelled as a homoeopathic medicine. However, it is important to appropriately differentiate the two types of ingredients

The CMEC proposed that the inclusion of the term ‘homoeopathic’ in ingredient names would be an essential component of appropriate consumer presentation of homoeopathic

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<sup>3</sup> Where the product is not labelled as an ‘Anthroposophic medicine’.

<sup>4</sup> The issue of whether or not it is appropriate to combine homoeopathic and non-homoeopathic ingredients is one that is most appropriately dealt with as part of the consultation on the draft Medicines Rule.

and anthroposophic medicines, particularly where the homoeopathic ingredient is part of a formulation that contains non-homoeopathic ingredients.

The OICG recommended that where there is a mix of homoeopathic and non-homoeopathic preparations, the label should include a statement along the lines of “contains homoeopathic preparations of...”. It was also suggested that it may be appropriate to link this statement to the ingredient list, possibly with some degree of separation for homoeopathic ingredients.

The CMEC once again expressed concern regarding the importance of a statement that the product contains homoeopathic preparations should be immediately apparent and visible, as many consumers do not read further than the main label.

*Outcome:*

On balance, it was concluded that where a medicine contains active ingredients that are a combination of homoeopathic and non-homoeopathic ingredients, sponsors should have a choice as to how to differentiate ingredients that are homoeopathic from those that are not (such as by including the statement ‘Contains homeopathic preparations of...’ adjacent to the list of homoeopathic ingredients, or by prefacing the name of the homoeopathic active ingredient with the term ‘homoeopathic’).

However, it was also concluded that where products contain both homoeopathic and non-homoeopathic ingredients, there should be a prominent statement “Contains homoeopathic preparations” on the main label of the product.

### **Issue 3: Quantification of homoeopathic ingredients**

*Issue:*

There was disagreement between the OICG and the CMEC with respect to the requirement to express the quantity of the homoeopathic ingredient, per millilitre or per gram of the medicine, on the label.

*Committee consideration:*

A number of stakeholders did not, in general, support the quantification of homoeopathic ingredients on the label, believing the information to be meaningless, although some conceded that in some situations, quantification of the homoeopathic ingredient may be warranted.

Industry stakeholders, however, did support the quantification of homoeopathic ingredients, although it was suggested that it must be made very clear that the potency is part of the ingredient name, so as to identify that it is the homoeopathic form of the substance.

The CMEC were not in accordance with the Industry position that quantification of homoeopathic ingredients continue to be expressed on product labels. They indicated that consumers could misconstrue the quantification of the homoeopathic ingredient to mean that the substance itself is included in the product. The CMEC did not consider the quantification

of a homoeopathic ingredient, in terms of weight/volume, appropriate for inclusion on the labels of homoeopathic and anthroposophic medicines.

The OICG considered that homoeopathic medicines should be labelled in the same way as all other medicines, and supported quantification of homoeopathic ingredients on labels. Industry also expressed concern that if quantification is not required on the label, it would not be readily apparent if a manufacturer does not fully potentise the whole amount of remedy added to the product (i.e. the homoeopathic component may be further ‘diluted’ with carrier or diluent).

The OICG also proposed that where a homoeopathic product contains 100% of the active homoeopathic ingredient (eg. fully potentised liquid), the ingredient need not be quantified. However this was suggested as a concession only to exempt homoeopathic products, and the OICG stated that it should still be necessary to state that the product contains 1g/g or 1mL/mL of the active ingredient”.

*Outcomes:*

It was agreed that, consistent with current European Union requirements, the amount of homoeopathic and anthroposophic preparations added to a formulation should be quantified on the label, either as the quantity of the preparation in one millilitre or in one gram of the medicine, or, where all ingredients are homoeopathic or anthroposophic preparations and are included in the medicine in the same proportion, expressed as ‘Contains equal parts of..’ followed by the name and potency of each homoeopathic ingredient.

It was also proposed that, where the product is a fully potentised, single ingredient, homoeopathic or anthroposophic medicine, it is sufficient to state the ingredient name and potency, providing it is clear that the ingredient comprises 100% of the product.

**Discussion of amendments to the draft labelling Order**

Note: Clause and subclause numbers quoted in the following table refer to the applicable clause or subclause number in the consultation document *Draft Labelling Requirements for Medicines under a Joint Australia New Zealand Therapeutic Products Agency* that was released to stakeholders in April 2005. Subsequent amendment and re-formatting of the draft Order may have resulted in different clause or subclause numbers now applying to the specific provisions.

Clause / subclause of draft Order	Amendment	Discussion/reasoning
5 Interpretation	New definitions (or indicative definitions) added: <b>anthroposophic medicine</b> <b>anthroposophic preparation</b> <b>complementary medicine</b> <b>herbal material</b> <b>herbal preparation</b> <b>homoeopathic medicine</b> <b>homoeopathic preparation</b> <b>mother substance</b> <b>native extract</b>	The Committees noted the need to ensure consistency of definitions with those proposed for inclusion in the Rules and other relevant documents.

Clause / subclause of draft Order	Amendment	Discussion/reasoning
	Definition amended: <b>Homoeopathic potency</b>	'Homoeopathic potency' was amended to include reference to 'M' and 'LM' dilutions. Some stakeholders recommended that the Labelling Order is not the appropriate place for the potency definition. However, as this term is referred to in the labelling Order text, it is appropriate that the definition be included as indicative of that now proposed for inclusion in the draft Medicines Rule.
	Definition amended: <b>Name of active ingredient</b>	Following stakeholder input, the draft Medicines Rule proposes the development of a list of approved homoeopathic names.
	Definitions retained: <b>Dispensing pack</b>	The issue of 'dispensing packs' is one still under consideration following a recommendation of the Expert Committee on Complementary Medicines in the Health System. Therefore this definition has been retained for the present time.
7 Particulars to be included on a label Subclause 7(1)(k)	Addition of an exemption from the requirement that directions for use be included on the label, where the medicine is a homoeopathic or anthroposophic medicine exempt from the requirement to obtain a product licence.	It is expected that the draft Medicines Rule will propose that certain single ingredient homoeopathic medicines will be exempt from the requirement to obtain a product licence, providing a number of conditions are met.
7 Particulars to be included on a label Subclause 7(1)(m)	Addition of an exemption from the requirement that a statement of purpose or purposes for which it is intended that the medicine be used, where the medicine is a homoeopathic or anthroposophic medicine exempt from the requirement to obtain a product licence.	It is expected that the draft Medicines Rule will propose that certain single ingredient homoeopathic medicines will be exempt from the requirement to obtain a product licence, providing a number of conditions are met.
9 Qualifications and special requirements Subclause 9(10)(a) Homoeopathic and anthroposophic medicines	Amend the wording such that the main label on the immediate packaging and the main label on the outer packaging (if any) must include a prominent statement indicating that the product is a homoeopathic medicine or an anthroposophic medicine (as appropriate).	See discussion on Issue 1, above
9 Qualifications and special requirements Subclause 9(10)(b) Homoeopathic and anthroposophic medicines	Delete previous wording that required a statement such as "homoeopathic medicine without approved therapeutic indications", where the indications for the product were of a kind permitted to be advertised only to persons described in Schedule 1 of the Therapeutic Goods Regulations.	It is expected that the draft Medicines Rule will no longer make reference to these advertising exemptions.
	Amend the wording such that where the medicine is a homoeopathic or anthroposophic medicine that is exempt from the requirement to obtain a product	It is expected that the draft Medicines Rule will propose that certain single ingredient

Clause / subclause of draft Order	Amendment	Discussion/reasoning
	license, then the label of that product should include: <ul style="list-style-type: none"> <li>a) a statement to the effect that the medicine is only to be used in accordance with homoeopathic or anthroposophic principles (as the case requires); and</li> <li>b) the Good Manufacturing Practice (GMP) license number of the 'Release for Supply' manufacturer.</li> </ul>	homoeopathic medicines will be exempt from the requirement to obtain a product licence, providing a number of conditions are met.
9 Qualifications and special requirements Subclause 9(11)(a) Formulations containing both homoeopathic preparations and non-homoeopathic ingredients	Amend the wording such that where the medicine contains active ingredients that are homoeopathic preparations, and other active ingredients that are not homoeopathic preparations, the main label on the immediate packaging and the main label on the outer packaging (if any) must include a prominent statement indicating that the product contains homoeopathic preparations or anthroposophic preparations (as appropriate).	See discussion on Issue 2, above
9 Qualifications and special requirements Subclause 9(11)(b) Formulations containing both homoeopathic preparations and non-homoeopathic ingredients	Delete previous wording that required a statement such as "homoeopathic medicine without approved therapeutic indications", where the indications for the product were of a kind permitted to be advertised only to persons described in Schedule 1 of the Therapeutic Goods Regulations.	It is expected that the draft Medicines Rule will no longer make reference to these advertising exemptions.
	Addition of a requirement that where the medicine contains active ingredients that are homoeopathic preparations, and other active ingredients that are not homoeopathic preparations, the label on the immediate packaing and the label on the outer packaging (if any) must differentiate ingredients that are homoeopathic preparations, from those that are not, such as by including the statement 'contains homoeopathic preparations of..' adjacent to the list of homoeopathic ingredients, or by prefacing the name of the homoeopathic active ingredient with the term 'homoeopathic'.	See discussion on Issue 2, above
10 Expression of particulars Subclause 10(2)(e) Expression of quantity or proportion of active ingredients	Amend the wording so that the quantity of proportion of an active ingredient to be included on the label must be expressed for a homoeopathic <i>or an anthroposophic</i> preparation (i.e. delete reference to 'medicine, where all the active ingredients are homoeopathic').	Quantification is required for all homoeopathic or anthroposophic preparations. See discussion on Issue 3, above.
	Amend Subclause 10(2)(e)(i) such that it is the quantity of the preparation that must be quantified.	See discussion on Issue 3, above.
	Addition of Subclause 10(2)(e)(ii), such that where the product is a fully potentised, single ingredient, homoeopathic or anthroposophic medicine, it is sufficient to state the ingredient name and potency, providing it is clear that the ingredient comprises 100% of the product.	See discussion on Issue 3, above.

Clause / subclause of draft Order	Amendment	Discussion/reasoning
	Amend Subclause 10(2)(e)(iii) such that where all ingredients (delete active) are homoeopathic or anthroposophic preparations, which are all included in the medicine in the same proportion, they may be expressed as ‘Contains equal parts of..’ followed by the name and potency of each homoeopathic ingredient.	See discussion on Issue 3, above.
10 Expression of particulars Subclause 10(2)(k) Expression of quantity or proportion of active ingredients	Amend Subclause 10(2)(k) such that it includes reference to the ‘herbal material’.	‘herbal material’, is a newly proposed term, defined in 5 Interpretation.
10 Expression of particulars Subclause 10(2)(l) Expression of quantity or proportion of active ingredients	Amend Subclause 10(2)(l) such that it replaces the term ‘substance’ with ‘ingredient’, and the term ‘herbal substance’ with ‘herbal preparation’.	Stakeholder consultation determined that the term ‘herbal substance’ could be confusing, given that the term is currently defined in Australian legislation in terms of what herbal preparations are permitted in Listed medicines, whilst general understanding of the term encompasses many ingredients of herbal origin.
10 Expression of particulars Subclause 10(2)(l) Expression of quantity or proportion of active ingredients	Amend subclause such that where a herbal preparation is an extract, tincture, decoction, infusion or spagyric, the quantity of the native extract, as well as the dry weight of the herbal material from which the preparation was derived, should be expressed, except: <ul style="list-style-type: none"> <li>a. where the herbal preparation is a traditional fresh herb preparation, in which case the fresh weight of the herbal material from which the preparation was derived may be quantified; or</li> <li>b. where the herbal preparation is a fresh or dry plant tincture, with a native extract ratio of 1:1 or less (i.e. 1:2, 1:5, etc.) in which case the weight of the herbal material from which the preparation was derived need only be quantified; or</li> <li>c. where the herbal preparation is a standardised extract, the amount of the standardised component(s) must also be quantified.</li> </ul>	These amendments were proposed following OICG consideration of stakeholder input.