



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



## **CONSULTATION DOCUMENT**

### **DRAFT LABELLING REQUIREMENTS FOR MEDICINES**

#### **UNDER A JOINT AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY**

### **CALL FOR COMMENT**

April 2005



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**NOTES in reading this draft Order:**

1. *This draft Order makes reference in some parts to aspects of the proposed regulatory scheme that have still to be finalised. These areas are marked in the text in grey highlight. An example is reference to a 'unique identifier' being required on labels of medicines. At time of sending out this draft document for consultation, details such as the format of the 'unique identifier' have yet to be finalised. These gaps should, however, have no significant influence on the ability of stakeholders to provide comment.*

2. *Under the proposed joint regulatory arrangements, medicines will be classified as either Class I (overall low risk) or Class II (higher risk). However, in this draft labelling Order, it has been necessary to differentiate between Controlled Drugs, Prescription Medicines, OTC (non-prescription) Medicines and Complementary Medicines in terms of some proposed labelling requirements for each of these types of medicines and these alternate terms have been used. It is considered also that, for the purposes of this consultation, these alternate terms would be more familiar to many stakeholder groups.*

3. *Footnotes at the bottom of pages are used to provide explanatory material for consultation purposes only. They are not intended to remain in the final Order. In contrast, Supplementary Notes at the end of the Order, while not constituting part of the Order for legal purposes, are intended to remain.*

<<Name of Act/Rules>>

Managing Director's Order No. <<XX>>

## ***General Requirements for the Labelling of Medicines***

### **Commencement**

<<Appropriate legal statement regarding making of the Order by the Managing Director in accordance with provisions of the Act and/or Rules>>

This Order includes the First Schedule to this Order.

This Order commences from the day it is published in the Gazette <<or other date as specified>>.

# 1 Introduction

The purpose of a medicine label is to provide information about the medicine such as its identity, potency, content, storage, expiry date, <<licensing status>> and sponsor. Medicine labels also include other information not required by this Order, but which may be required by other legislation or for commercial purposes. These include items such as signal words (eg. Prescription Only Medicine, Pharmacist Only Medicine), bar codes and sponsor's logos. Labelling should contribute to the quality use of medicines.

For prescription medicines intended for dispensing in the manufacturer's original pack, and those for dispensing by qualified practitioners, labelling should be designed to minimise the risk of prescribing and dispensing errors. To help achieve this, the best practice guideline <<Best Practice Guideline on Prescription Medicine Labelling>> is available at <<web address for new joint agency>> to assist sponsors in the design of labels for prescription medicines<sup>1</sup>.

For non-prescription medicines, the aim is to present information on labels in such a way that consumers can:

- (a) choose an appropriate medicine;
- (b) use the medicine safely and effectively;
- (c) readily find the information they need, understand it and act on it appropriately; and
- (d) access further information, if they want to know more about the medicine.

Although there may be various means of achieving the aim stated above for non-prescription medicines, those with labels that have been designed in accordance with the industry code of practice entitled *Labelling Code of Practice: Designing usable non-prescription medicine labels for consumers*<sup>2</sup>, published by Communications Research Institute of Australia Inc. and accessible from the <<name and web address for new joint agency>> should achieve this aim.

The mandatory aspects of this Order for all medicines are contained in clauses 2-10 inclusive and the Schedule to the Order.

All medicine labels must comply with clauses 2-10 and the Schedule to the Order, regardless of whether they have been designed in accordance with the industry Code of Practice relating to non-prescription medicines or the best practice guideline for prescription medicine labelling.

<sup>1</sup> Consultation on a draft of this guideline document is being undertaken simultaneously with consultation on this draft Order.

<sup>2</sup> The Labelling Code of Practice was updated in December 2004 by the Communication Research Institute of Australia. This edition is available through the 'Publications' link on the CRIA website at (<http://www.communication.org.au>).

## 2 Application

- 2(1) The requirements set out in this Order apply to those therapeutic products that are medicines and that come within the operation of the <<name of the Act and Rules>>, unless specifically exempted under clause 4 or unless an exemption from compliance with this standard has been granted by the Managing Director of <<name of joint agency>> in accordance with <<reference to the provisions in the Rules allowing exemption from standards>>.
- 2(2) Containers and the primary packs (if any) in which medicines are packed must each bear a label or labels which comply with the requirements.

### 3 Prohibitions

The label must not contain anything that is prohibited by <<appropriate reference to prohibitions included in Act/Rules>> from appearing on a label.<sup>3</sup>

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<sup>3</sup> It is proposed that the Rules will reflect a number of prohibitions drawn from the Australia New Zealand Therapeutic Products Advertising Code that are relevant to medicine labels. In particular, this will stipulate that information on a medicine label must be truthful, balanced and not misleading, and claims must be valid and have been substantiated; and information on labels must not:

- encourage, or be likely to encourage, inappropriate or excessive use;
- directly or by implication, omission, ambiguity, exaggerated claim or comparison;
  - a. mislead or deceive, or be likely to mislead or deceive; or
  - b. abuse trust, or exploit lack of knowledge; or
  - c. exploit the superstitious, play on fear or, without justifiable reason, cause distress;
- unduly glamorise products or services, or prey on the vulnerability of particular audiences.
- contain any claim, statement or implication that the product is safe or that its use cannot cause harm or that it has no side effects or risks associated with its use;
- contain any claim, statement or implication that the product is effective in all cases of a condition;
- contain any claim, statement or implication that it is infallible, unailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- contain any matter which is likely to lead persons to believe that they are suffering from a serious ailment, or harmful consequences may result from the therapeutic product not being used.

Where comparative claims are made on a product label such claims must be balanced and must not be misleading, or likely to be misleading, either about the product that is the subject of the claim or any therapeutic product, or classes of therapeutic products, with which comparison is made. Comparative claims must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence. In comparing products, claims must not discourage consumers from taking medicines prescribed by a healthcare practitioner.

## 4 General Exemptions

4(1) The requirements of this Order do not apply to medicines that:

- (a) are intended for use in the treatment of another person in accordance with the exemptions for special and experimental uses included in <<appropriate reference to Act/Rules>> or which are intended for other special access purposes specified in Rules <<appropriate reference>>;
- (b) are intended for use solely as investigational medicinal products;
- (c) are starting materials used in the manufacture of medicines, except when:
  - (i) prepackaged for supply for other therapeutic purposes; or
  - (ii) formulated as a dosage form;
- (d) have not reached their final stage of manufacture;
- (e) are personal imports as described under <<appropriate reference>> of the Rules;
- (f) are medicinal gases;
- (g) are solely for export from Australia and/or New Zealand, excluding export from one of these countries to the other;
- (h) are made up or compounded by a pharmacist, or by a person in the course of his or her employment by a pharmacist and under the actual personal supervision of that pharmacist, in accordance with the individual prescription of a healthcare professional authorised under relevant New Zealand, or Australian State or Territory, legislation to prescribe;
- (i) are made up or compounded extemporaneously for a specific or individual case by a pharmacist in the lawful practice of his or her profession;
- (j) are supplied in the course of treating a patient by a healthcare professional, authorised under relevant New Zealand, or Australian State or Territory, legislation to prescribe, in the lawful practice of his or her profession, other than professional starter packs; or
- (k) are made up or compounded extemporaneously for a specific and individual case, in that person's presence, by a complementary healthcare practitioner in the lawful practice of his or her profession.

4(2) Where a transparent covering completely encloses or wraps a container or primary pack containing a medicine and the particulars which are required to be set out on the label of the container or on the primary pack are clearly visible through that transparent covering, the requirements of this Order do not apply to that transparent covering.

## 5 Interpretation<sup>4</sup>

5(1) In this Order:

**'Act'** means the <<name of Act>>, as amended from time to time;

**'active ingredient'** means a therapeutically active substance included in a medicine;


**'adjuvant'** means an ingredient which, when administered with an antigen, modifies the immune response to that antigen;

**'antimicrobial preservative'** means an ingredient added to a medicine to inhibit the growth of micro-organisms in the medicine;

<<name of agency's approved names list>><sup>5</sup> has the same meaning as in <<reference to Rules or other publication details>>

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

**'batch number'** means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of medicine, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution. There must be 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;

**'batch number prefix'** means the prefix which precedes the batch number and clearly indicates that the number is the batch number. Examples of acceptable batch number prefixes include 'BATCH NUMBER', 'BATCH NO.', 'BATCH', 'B', '(B)', 'B/N', 

'LOT NUMBER', 'LOT NO.', or 'LOT', or words or symbols to this effect. A mixture of lower and upper case letters is acceptable. Where a container is enclosed in a primary pack, the same batch number prefix should be used on both the container and primary pack;

**'calendar pack'** means a strip, blister or dial dispenser pack, containing individual dosage units, and which is labelled with day/date markings to specify the sequence in which the dosage units must be used in order to achieve the intended therapeutic activity. A calendar pack differs from strip, blister or dial dispenser packs which display day/date markings solely to aid compliance;

<sup>4</sup> Many definitions included in this clause will reflect definitions included in the Treaty, Act or Rules. Definitions to be included in the Act and Rules have not yet been finalised and there will be opportunity to comment on those during the consultation on the exposure drafts of that legislation. Where a definition is shown as being drawn from the Act or Rules, an indicative definition has been included in this draft Order wherever possible to assist stakeholders in understanding the intent of relevant clauses. It also should be noted that separate consultation has already been undertaken on the definitions of 'complementary medicine', 'homoeopathic medicine' and 'herbal substance'.

<sup>5</sup> The TGA and Medsafe are working towards harmonising the terminology used in Australia and New Zealand for ingredients in medicines, utilising International Non-Proprietary Names where possible. As part of this project, a proposed list of ingredient names (chemical, biological and herbal) will be released to stakeholders for comment.

**‘complementary healthcare practitioner’** means a person who is registered under a law of New Zealand, or an Australian State or Territory, as a herbalist, homoeopathic practitioner, chiropractor, naturopath, nutritionist, practitioner of traditional Chinese medicine, podiatrist or osteopath.

**‘complementary medicine’** has the same meaning as in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>;<sup>6</sup>

**‘compliance pack’** means a strip, blister or dial dispenser pack, containing individual dosage units, and which is labelled with day/date markings as an aid to compliance. The order in which the individual dosage units are used has no effect on the therapeutic activity of the product.

**‘concentrated solution for injection’** means a liquid which must be diluted with another liquid in order to prepare an injection;

**‘container’** means an article that immediately covers a medicine, and includes an ampoule, blister pack, bottle, box, sachet, dial dispenser pack, jar, packet, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include an article intended for ingestion;

**‘Controlled Drug’**<sup>7</sup> means a medicine for human use that is classified in the <<scheduling standard>> as a ‘Controlled Drug’;

**‘date of manufacture’** means:

- (a) for a biological product, the date (month and year) of the latest quality control analysis performed on the product and which may be preceded by a period during which the product is stored under conditions which have been shown to preserve the potency of the product; or
- (b) for a medicine other than a biological product, the date (month and year) during which the processing of the bulk product, from which the medicine is to be packaged, is completed;

**‘delivered dose’** means in relation to:

- (a) pressurised metered dose preparations for inhalation, the dose delivered from the inhaler to the patient. For those preparations established as a metered dose, the metered dose is determined by adding the amount deposited within the device to the delivered dose. It may be determined directly; and

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<sup>6</sup> Consultation on the definition of ‘complementary medicine’ has been undertaken as part of the consultation on the document *Proposed regulatory definitions for complementary medicines and homoeopathic medicines in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at: <http://www.jtaproject.com/hot.htm#CMConsult>.

<sup>7</sup> In this Order, the term ‘Controlled Drug’ is used in a limited sense to refer to those medicines that are classified as such (Schedule 8 medicines) in the scheduling standard (*Standard for the Uniform Scheduling of Medicines and Poisons*). The term therefore does not encompass all drugs classified as Controlled Drugs under the New Zealand *Misuse of Drugs Act 1975* and Regulations, which include additional labelling requirements that apply in New Zealand to the various classes of Controlled Drugs listed in that legislation.

- (b) powders for inhalation, the dose delivered from the inhaler. For those preparations established as a metered dose, the dose is determined by adding the amount deposited within the device to the delivered dose. It may be determined directly;

**‘diluent’** means a liquid which is used to dilute a medicament for injection in order to prepare a dosage form;

**‘directions for use’** means directions that include:

- (a) where the medicine is intended for ingestion or is intended for parenteral use, the method, dose and frequency of administration of the medicine, except where:
  - (i) the medicine, other than a vaccine, is a Prescription Medicine or a Controlled Drug<sup>8</sup>; or
  - (ii) the dose of the medicine is usually determined for each individual patient by a healthcare professional authorised under relevant New Zealand, or Australian State or Territory, legislation to determine the dose; and
- (b) where the medicine is not intended for ingestion or is not intended for parenteral use, the method and frequency of administration, unless the medicine can only be supplied on the order of a person authorised under relevant New Zealand, or Australian State or Territory, legislation to prescribe; and
- (c) in any case where the medicine requires some preparation, such as dissolving, suspending, diluting or reconstituting before use, instructions for preparation and statement of the conditions of storage and the maximum period of storage between preparation and use;

**‘dispensing pack’**, in relation to complementary healthcare, means a pack which is to be supplied solely to complementary healthcare practitioners for supply to a person after affixing an instruction label following a consultation with that person;

**‘durable’** means of such nature and material that the influence of:

- (a) light;
- (b) atmospheric humidity or dryness;
- (c) normal atmospheric temperatures;
- (d) recommended storage temperatures; and
- (e) the contents of the container

will not, under normal storage conditions, cause the label to fade to the extent of becoming illegible, or become detached;

**‘excipient’** means an ingredient of a medicine other than an active ingredient;

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<sup>8</sup> Subject to resolution of overlap in labelling requirements between New Zealand *Misuse of Drugs Act 1975* and Regulations, and therapeutic products legislation.

**‘expiry date’** means the date (month and year) after which the medicine should not be used, being a date not more than five years after the date of manufacture;

**‘expiry date prefix’** means the prefix which precedes the expiry date, and clearly indicates that the information following the prefix is the expiry date. Examples of acceptable prefixes include 'EXPIRY DATE', 'EXPIRY', 'EXPIRES', 'EXP. DATE', 'USE BEFORE', 'USE BY', or 'EXP' but terms such as 'Best by' or words to this effect are not acceptable. A mixture of lower and upper case letters is acceptable. Where a container is enclosed in a primary pack, the same expiry date prefix should be used on both the container and primary pack;

**‘Gazette’** has the same meaning as in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>;

**Gazette** means<sup>9</sup>:

- (a) for New Zealand – the New Zealand Gazette published or purporting to be published under the authority of the New Zealand Government, and includes a supplement; and
- (b) for Australia – the *Commonwealth of Australia Gazette*.]

**‘herbal substance’** has the same meaning as in <<reference to Rules>>;<sup>10</sup>

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>;

**‘homoeopathic medicine’** has the same meaning as in <<reference to Rules>>;<sup>11</sup>

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>;

**‘homoeopathic potency’**<sup>12</sup> means the dilution factor expressed as:

- (a) 'nX', where each dilution is a decimal or ten fold dilution and 'n' is the number of dilutions such that the total dilution is  $10^n$ ; or
- (b) 'nC', where each dilution is a centesimal or hundred fold dilution and 'n' is the number of dilutions such that the total dilution is  $100^n$ ;

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<sup>9</sup> Indicative definition only.

<sup>10</sup> Consultation on the definition of 'herbal substance' has been undertaken as part of the consultation on the document *Regulation of herbal substances in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at: <http://www.jtaproject.com/hot.htm#CMConsult>.

<sup>11</sup> Consultation on the definition of 'homoeopathic medicine' has been undertaken as part of the consultation on the document *Proposed regulatory definitions for complementary medicines and homoeopathic medicines in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at: <http://www.jtaproject.com/hot.htm#CMConsult>.

<sup>12</sup> Consultation on the expression of potency for homoeopathic medicines has been undertaken as part of the consultation on the document *Regulation of homoeopathic and related medicines in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at <http://www.jtaproject.com/hot.htm#CMConsult>.

**'hypertonic'**, in relation to the tonicity of large volume injections, means an injection with an osmolality of more than 350 milliosmoles per kilogram of solvent;

**'hypotonic'**, in relation to the tonicity of large volume injections, means an injection with an osmolality of less than 250 milliosmoles per kilogram of solvent;

**'isotonic'**, in relation to the tonicity of large volume injections, means an injection with an osmolality within the range 250 milliosmoles to 350 milliosmoles per kilogram of solvent;

**'label'** means a display of printed information upon, or securely affixed to, the container and any primary pack containing the medicine;

**'large volume injection'** means an injection having a volume of greater than 100 millilitres;

**'letter height'** means the height of upper case (capital) letters or lower case letters having an ascender or descender, unless otherwise stated;

**'main label'** means:

- (a) the part of a label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and
- (b) where there are two or more labels or two or more portions of a single label – that label or portion of the label where the medicine name is more or most conspicuously shown; or
- (c) where the medicine name is equally conspicuous on two or more labels or portions of a label – each such label or portion;

**'medicament for injection'** means a sterile substance in a container to which a sterile diluent is added to prepare an injection;

**'medicine'** has the same meaning as in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

**Medicine** means<sup>13</sup>:

Any substance or combination of substances presented as having properties for treating or preventing a disease ailment, defect or injury in human beings, or any substance or combination of substances which may be used in human beings with a view to making a medical diagnosis or to restoring, correcting, maintaining or modifying physiological functions];

**'medicine kit'** means a kit in which the only therapeutic products present are medicines;

**'name and address'** in respect of a sponsor, means the name of the Australian and/or New Zealand sponsor and sufficient information to allow the sponsor to be uniquely identified so as to facilitate public contact on matters of complaint, use or general enquiry. The address must include information such as the city or suburb of the sponsor's principal place of business in

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<sup>13</sup> Indicative definition only.

Australia or New Zealand, not being a post office, cable, telegraphic or code address. The Australian or New Zealand telephone number, as appropriate, may also be included;

**‘name of an active ingredient’** means:

- (a) the name of the active ingredient that is approved for inclusion in the <<name of the agency’s approved names list>>; or
- (b) where the ingredient is a homoeopathic preparation<sup>14</sup>:
  - (i) either the name of the active ingredient, or the substance from which the dilution was prepared, that is approved for inclusion in the <<name of agency’s approved names list>>, together with a statement of the homoeopathic potency; or
  - (ii) until such time as a name appears in the <<name of agency’s approved names list>>, a traditional homoeopathic name in full or as traditionally abbreviated with a statement of the homoeopathic potency;

**‘name of an excipient’** means the name of the excipient that is approved for inclusion in the <<name of the agency’s approved names list>>;

**‘name of the dosage form’** means a word or words denoting the usual name of the pharmaceutical form of the medicine that is approved for inclusion in the <<name of the agency’s approved names list>>;

**‘non-proprietary name’** means the name used to describe the medicine in a specific standard. It includes the name of the dosage form. If no specific standard exists, it is a name comprising the name(s) of the active ingredient(s) and the name of the dosage form;

**‘osmolality’** means the number of osmoles (usually expressed as milliosmoles or mOsm) of the solute in a kilogram of water. The method usually used to determine osmolality is the depression of freezing point;

**‘OTC Medicine’** has the same meaning as in <<reference to Rules>>.

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

**‘Prescription Medicine’** means a medicine for human use that is classified in the <<scheduling standard>> as a ‘Prescription Only Medicine’;

**‘primary pack’** has the same meaning as in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

**Primary pack**, in relation to a therapeutic product, means<sup>15</sup> the complete pack in which the product is, or the product and its container are, to be supplied to consumers];

<sup>14</sup> The consultation document *Regulation of homoeopathic and related medicines in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at <http://www.jtaproject.com/hot.htm#CMConsult> also addresses the issue of naming of homoeopathic ingredients.

<sup>15</sup> Indicative definition only.

**‘product’** means a medicine;

**‘product name’** means the proprietary name of the medicine, or if there is no proprietary name, the non-proprietary name of the medicine;

**‘proprietary name’** means the registered trademark of the medicine or the unique name assigned to the medicine by the sponsor and appearing on a label;

**‘quantity of the medicine’** means:

- (a) where the medicine consists of discrete dosage units, such as tablets or capsules – the stated number of units in the container; or
- (b) where the medicine is:
  - (i) a solid or semi-solid, other than a biological product or a medicine for injection - the stated weight of the solid or semi-solid in the container;
  - (ii) a liquid, other than a biological product - the stated volume of the liquid in the container;
  - (iii) a pressurised metered-dose preparation or dry powder inhaler - the stated number of doses in the container;
  - (iv) a non-pressurised metered dose preparation - the minimum number of doses in the container;
  - (v) a solid biological product - the stated number of doses or potency units in the container;
  - (vi) a liquid biological product - the stated volume of liquid in the container and, in addition, either the total number of doses or potency units in the container or the number of doses or potency units per unit volume;

**‘Rules’** means the <<title of the Rules>>, as amended from time to time;

**‘<<required advisory statements for medicine labels’ or other title as agreed >><sup>16</sup>** means the document of that name, published by the <<name of joint agency>> on <<publication details>>;

**‘sample pack’** means a starter pack;

**‘scheduled’** means a medicine classified as a ‘Pharmacy Medicine’, a ‘Pharmacist Only Medicine’, a ‘Prescription Only Medicine’ or a ‘Controlled Drug’ in the <<scheduling standard>>.

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<sup>16</sup> This document will specify the advisory statements that must be included on the labels of medicines containing the specific ingredients listed and meeting the criteria given. Development of the new document will take into account current requirements in New Zealand for warning statements to be included on the labels of some medicines, and warning statements currently included in the document *Required Advisory Statements for Medicine Labels* (available at <http://www.tga.gov.au/meds/rasml.htm> ).

<<'scheduling standard' or other title as agreed>><sup>17</sup> has the same meaning as defined in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

'**signal words**'<sup>18</sup> means the word or words relating to the <<Schedule>> of the <<scheduling standard>> in which the medicine is included for the purpose for which it is to be used, and which must appear on the first line or lines of the main label in accordance with New Zealand, or Australian State or Territory, legislation. The format of signal words is specified in the <<scheduling standard>>;

'**small container**' means a container which has a capacity greater than 2 millilitres but not more than 20 millilitres;

'**small volume injection**' means an injection having a volume of greater than 2 millilitres but not more than 100 millilitres;

'**solid ophthalmic medicine**' means a substance in a container to which a sterile diluent is added to prepare eye drops or an eye lotion;

'**Sponsor**' has the same meaning as in <<reference to Rules>>.

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

**sponsor**, in relation to a therapeutic product, means<sup>19</sup> a person who:

- (a) exports, or arranges the export of, the product from Australia or New Zealand; or
- (b) imports, or arranges the import of, the product into Australia or New Zealand; or
- (c) in Australia or New Zealand - manufactures the product, or arranges for another person to manufacture the product, for supply (whether in Australia, New Zealand or elsewhere); but does not include a person who, on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia or New Zealand;
- (d) exports, imports or manufactures the product; or
- (e) arranges the exportation, importation or manufacture of the product];

'**standard**' has the same meaning as in <<<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<new definition to be inserted>>];

**standard** (other than a conformity assessment standard), in relation to a therapeutic product, means<sup>20</sup>:

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<sup>17</sup> This term will refer to the *Standard for the Uniform Scheduling of Medicines and Poisons*, the publication that will classify medicines and poisons into Schedules according to recommendations made on the appropriate controls to be applied over their availability to the public – for example, Pharmacy Medicines and Prescription Only Medicines.

<sup>18</sup> At this time, it is expected that signal words such as 'Pharmacist Only Medicine' and 'Prescription Only Medicine' and their required format will be specified in the scheduling standard.

<sup>19</sup> Indicative definition only.

<sup>20</sup> Indicative definition only.

- (a) for a product that is not a medical device – a standard specified in an order under section <<section number to be inserted>> of the Regulatory Rule that is applicable to the product; or
- (b) for a product that is a medical device – a standard specified in an order under section <<section number to be inserted>> of the Regulatory Rule that is applicable to the product; or
- (c) if no such order is applicable to the product but the product is the subject of a monograph in the <<insert title of reference pharmacopoeia(s)>><sup>21</sup>, the standard constituted by the statements in that monograph];

**‘starter pack’** means a presentation of a medicine containing a limited number of dosage units and intended for supply to a health professional for provision to patients for initiation of treatment. A starter pack may also be referred to as a sample pack;

**‘<<unique identifier>>’** means the combination of numbers, symbols and letters assigned to the medicine in accordance with <<reference to Act/Rules>><sup>22</sup>;

**‘very small container’** means a container having a capacity less than or equal to 2 millilitres;

**‘very small volume injection’** means an injection having a stated volume of less than or equal to 2 millilitres;

**‘warning statements’** means:

- (a) any labelling requirements specified in <<title of document specifying required advisory statements>>;
- (b) any warning statements specified in the standard that applies to the medicine;
- (c) a warning statement where incorrect route or method of administration may be hazardous;
- (d) any warnings required by the Managing Director of <<name of the joint agency>> to be included on the label as a condition of licensing in relation to the medicine;
- (e) any warning statement specified in the Rules that apply to the medicine;
- (f) any warning statements specified in the <<scheduling standard>> that apply to the medicine; and
- (g) where the medicine is for external use, the words ‘Caution: Not to be Taken’, or ‘For External Use Only’, or words of similar meaning.

5(2) In this Order, unless indicated to the contrary, a reference to:

- (a) a section or a subsection is a reference to a provision in the Act;
- (b) a rule is a reference to a provision in the Rules; and
- (c) a clause or a subclause is a reference to a provision of this Order.

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<sup>21</sup> Applicable pharmacopoeial standards are yet to be determined. This will be subject to separate consultation.

<sup>22</sup> This is the number assigned to a medicine when the medicine is included on the register of therapeutic goods. The format of this number has not yet been finalised.

## **6 Label Presentation**

- 6(1) The particulars required by this Order to be included on a label or labels must be:
- (a) clearly visible and not be obscured;
  - (b) written in the English language;
  - (c) in durable and legible characters;
  - (d) unless otherwise specified in this Order, in letter height of not less than 1.5 millimetres;
  - (e) in a colour or colours contrasting strongly with the statement's background; and
  - (f) unless otherwise specified in this Order, in a metric unit of measurement.
- 6(2) The lettering of the words required by this Order shall be clear, distinct, and legible, with no decoration, embellishment, or distortion that could interfere with the legibility of the words.
- 6(3) Where the medicine is presented in a plastic ampoule, the label on the container may be formed by way of embossing.
- 6(4) In all cases, the batch number, batch number prefix, expiry date and expiry date prefix may be embossed.
- 6(5) The label shall be durable, and
- (a) of such a nature and in such a position that it will not readily be defaced in the course of normal handling and use; and
  - (b) in such a position that it is not damaged, defaced, destroyed, or removed when the container is opened.

## 7 Particulars to be included on a label

7(1) Subject to the qualifications and special requirements specified in clause 9 of this Order, the label or labels must include:

- (a) the product name;
- (b) the name(s) of all active ingredients in the medicine;
- (c) the quantity or proportion of all active ingredients in the medicine;
- (d) where the medicine contains, as an excipient, any ingredient referred to in Column 1 of the First Schedule, and:
  - (i) a condition (if any) stated in Column 2 of the First Schedule applies in relation to such an ingredient; and
  - (ii) the medicine is intended to be administered via any one or more of the route(s) referred to in Column 3 of the First Schedule in relation to such an ingredient; then

a statement must be included on the label of both the container and primary pack (if any) indicating that the medicine contains these ingredients. The statement must be expressed using the <<Label-Name>> stated in Column 4 of the First Schedule. Where any additional requirement is stated in Column 2 of the First Schedule in relation to such an ingredient, a statement complying with those requirements must also appear on the label;

- (e) the name of the dosage form;
- (f) the quantity of the medicine;
- (g) warning statements, where these apply to the medicines;
- (h) the batch number of the medicine preceded by the batch number prefix;
- (i) the expiry date of the medicine preceded by the expiry date prefix;
- (j) the storage conditions applicable to the medicine in accordance with clause 10(5);
- (k) directions for use of the medicine except where there is insufficient space on the label of the container or on the primary pack to include directions for use, it shall be sufficient if there is included on a label on that container or primary pack, as the case may be, a statement to the effect that those directions for use are set out on a leaflet inserted in the primary pack of the medicine provided that such a leaflet is in fact so inserted;
- (l) the name and address of the sponsor of the medicine;

- (m) a statement of the purpose or purposes for which it is intended that the medicine be used, except:
  - (i) where the medicine is a Prescription Medicine or a Controlled Drug; or
  - (ii) where the medicine is a dispensing pack supplied solely to a complementary healthcare practitioner, and includes on the label the words 'For Practitioner Dispensing Only';
- (n) where the medicine is:
  - (i) an injection, the approved route(s) of administration, such as 'intravenous', 'intramuscular', or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration;
  - (ii) contained in an ampoule but is not an injection, a statement of the approved route of administration for the medicine, such as 'inhalation', 'For oral use only' or other phrase, word or abbreviation denoting the approved route(s) of administration;
- (o) where the medicine is scheduled under New Zealand, or Australian State or Territory, legislation, the applicable signal words written as specified in the <<scheduling standard>><sup>23</sup>; and
- (p) where the medicine is included in the <<name of new Register>>, the <<unique identifier>>.

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<sup>23</sup> Subject to resolution of overlap in labelling requirements between New Zealand *Misuse of Drugs Act 1975* and Regulations, and therapeutic products legislation.

## 8 Particulars to be included on a main label

8(1) Subject to the provisions specified in subclause 8(3) and clause 9 of this Order, the following particulars must appear on the main label of the medicine:

- (a) the product name;
- (b) the name(s) of all active ingredients in the medicine;
- (c) the quantity or proportion of all active ingredients in the medicine;
- (d) the name of the dosage form;
- (e) the quantity of the medicine;
- (f) the approved route(s) of administration of the medicine where the medicine is an injection, or is contained in an ampoule but is not an injection; and
- (g) where a medicine is scheduled under New Zealand, or Australian State or Territory, legislation, the applicable signal words, written as specified in the <<scheduling standard>>.

8(2) Where the medicine is included in the <<name of new Register>>, the <<unique identifier>> is to be included:

- (a) on the main label; or
- (b) on a securely affixed label adjacent to the main label.

8(3) Where the medicine is:

- (a) a Prescription Medicine, a Controlled Drug or a medicine for injection, then the names of all active ingredients must be prominently displayed adjacent to, or immediately under, the product name on the main label, and must be in a letter height at least half that used for the product name but, in any case, not be less than 2 millimetres;
- (b) an OTC Medicine, then the names of all active ingredients must be displayed in a prominent position on the main label and must be in a letter height that is not less than 2 millimetres; or
- (c) a Complementary Medicine, then the names of all active ingredients must be displayed on the main label in a letter height of not less than 1.5 millimetres,

except that:

- (d) where there are five or more active ingredients in a Prescription Medicine, a Controlled Drug, a medicine for injection or an OTC Medicine - in which case it shall be sufficient compliance with this subclause if the names together with the quantities or proportions of every active ingredient are included on a side panel or side label or on a rear panel or rear label of the container and primary pack for the medicine and are displayed in a letter height that is not less than 2 millimetres; or

- (e) where there are two or more active ingredients in a Complementary Medicine – in which case it shall be sufficient compliance with this subclause if the names and quantities or proportions of every active ingredient are included on a side panel or side label or on a rear panel or rear label; or
  - (f) where the medicine is a sunscreen product – in which case it shall be sufficient compliance with this subclause if the names together with the quantities or proportions of every active ingredient and the name of the dosage form are included on a side panel or side label or on a rear panel or rear label of the container and primary pack.
- 8(4) Nothing in this Order shall prevent the inclusion on the main label of any other matters required by this Order to appear on the label of any medicine.

## 9 Qualifications and Special Requirements

### 9(1) Preparations for ophthalmic use

In addition to the requirements of clauses 7 and 8, where the medicine is a preparation for ophthalmic use, the label on the container and on the primary pack or, where clause 9(13) applies, on the primary pack, must include:

- (a) the name of any antimicrobial preservative in the medicine; or
- (b) where the medicine, other than an ophthalmic ointment, does not contain an antimicrobial preservative, the words 'Contains no antimicrobial preservative. Use once only and discard residue' or a statement to that effect; and
- (c) where the medicine is for multidose use - a statement to the effect that the medicine should not be used later than four weeks after the container is first opened; and
- (d) where the medicine consists of a solid ophthalmic medicine for preparing eye drops for multidose use - a statement to the effect that the medicine when prepared should not be used later than four weeks after the container is first opened, or where the shelf life of the prepared medicine is less than four weeks, this lesser period shall be stated; and
- (e) where the medicine consists of a solid ophthalmic medicine - the label must include the words 'for eye drops' or 'for eye lotion' (as the case may be) in or adjacent to the product name; and
- (f) where the medicine consists of a solution or a suspension in an oil - the word 'oily' in or adjacent to the product name.

### 9(2) Large volume injections

- (a) Large volume injections are required to comply with clauses 7 and 8 subject to the following qualifications:
  - (i) in cases where there is no proprietary name of the medicine, the product name must include the name of the active ingredient(s) and the name of the dosage form, or where there are more than three active ingredients belonging to the same class of substances, such as amino acids, carbohydrates or electrolytes, the name of the class of substances and the name of the dosage form;
  - (ii) in cases where the medicine is intended for electrolyte replacement or nutritional therapy or is intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportions of dissolved, emulsified or suspended active ingredients in the medicine in terms of percentages; and
  - (iii) in cases where the medicine contains an active ingredient which is not intended for electrolyte replacement or nutritional therapy and is not intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportion of that active

ingredient expressed in terms of weight (or potency, if appropriate) in the stated volume of injection in the container.

- (b) In addition to the requirements of clauses 7 and 8 and subclause 9(2)(a), the label on the container and on the primary pack of a medicine which is a large volume injection must include:
- (i) the names and quantities of all excipients in the stated volume of injection in the container;
  - (ii) where one or more active ingredients are amino acids and/or protein, a statement in grams of the total amount of nitrogen in the stated volume of injection in the container;
  - (iii) where the medicine is intended for use as an energy source, a statement in kilojoules of the energy equivalent of the stated volume of injection in the container;
  - (iv) where the medicine is intended for use as a radio-contrast agent, a statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre;
  - (v) the osmolality;
  - (vi) a statement specifying whether the injection is 'hypotonic' or 'hypertonic' or 'isotonic';
  - (vii) the pH range of the injection; and
  - (viii) a statement 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or a statement to that effect.

### **9(3) Injections other than large volume injections**

In addition to the requirements referred to in clauses 7 and 8, where the medicine is a small volume injection, a very small volume injection or a medicament for injection:

- (a) the main label on the container and on the primary pack of the medicine must include:
  - (i) where the medicine is a medicament for injection, the words 'for injection' must appear in or adjacent to the product name; and
  - (ii) where the medicine is an injection which consists of a solution or a suspension in an oil, the label must include the word 'oily' in or adjacent to the product name;
- (b) the label on the container and on the primary pack or, where clause 9(13) applies, on the primary pack of the medicine must include:
  - (i) the name and quantity of each excipient in the medicine, expressed:
    - (A) for single dose injections - as the quantity of that excipient in the stated volume of injection in the container;

- (B) for a medicament for injection - as the quantity of that excipient in the container; or
  - (C) where the injection is intended for multidose use – as the quantity of that excipient in one millilitre of the injection or as the quantity in a suitable dose volume where the stated volume is less than one millilitre; and
- (ii) where the medicine is supplied in a container with potential for multidose use, such as a vial or pre-filled syringe, and an antimicrobial preservative is not included in the medicine, the words 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or a statement to that effect;
- (c) the label on the container and on the primary pack of medicine which consists of a concentrated solution for injection must include:
    - (i) a direction not to administer the solution undiluted; and
    - (ii) a direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use; and
  - (d) the label on the container and on the primary pack of a medicine which is an injection containing a radio-contrast agent, must include a statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre.

## **9(4) Dialysis concentrates**

In addition to the requirements referred to in clauses 7 and 8, the label on the container and on the primary pack of a medicine which is a concentrated solution for use in dialysis must include:

- (a) the formulation of the solution expressed in terms of millimoles per litre of the concentrate;
- (b) the names and quantities of all ingredients in terms of millimoles per litre of solution following dilution in accordance with directions;
- (c) a direction not to use the solution undiluted;
- (d) a direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use; and
- (e) a statement 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or a statement to that effect.

## **9(5) Peritoneal dialysis solutions**

In addition to the requirements referred to in clauses 7 and 8, the label on the container and on the primary pack of a medicine which is a solution for use in peritoneal dialysis must include:

- (a) the formulation of the solution expressed in grams per litre and in millimoles per litre;
- (b) the calculated osmolarity expressed in milliosmoles per litre;

- (c) the nominal volume of the solution in the container;
- (d) a statement that the solution is free from bacterial endotoxins, or where applicable, that it is apyrogenic;
- (e) a statement that the solution is not to be used for intravenous infusion; and
- (f) a statement 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or a statement to that effect.

## 9(6) Preparations for use on skin or mucous membranes

In addition to the requirements referred to in clauses 7 and 8, the label on a medicine which is a preparation for use on skin and/or mucous membranes, but is not intended for ophthalmic use, must include the name of any antimicrobial preservative in the medicine.

## 9(7) Biological products

In addition to the requirements referred to in clauses 7 and 8 and subclause 9(3), the label of a medicine which is a biological product must include:

- (a) the name and proportion of any antimicrobial preservative in the medicine;
- (b) the name of any adjuvants in the medicine;
- (c) for vaccines produced in animal cells or cell cultures:
  - (i) the name of the cell culture substrate or the name of the source animal, as specified in the **<<name of the agency's Biologicals approved names list'>>** and the name of the tissue used in the manufacture of the medicine; and
  - (ii) the name of any residual antibiotic that may be present in the medicine;
- (d) for antisera, the name of the animal in which the medicine has been prepared, as specified in the **<<name of the agency's Biologicals approved names list'>>**;
- (e) for monoclonal antibodies, the name of the origin of the hybridoma cell line, as specified in the **<<name of the agency's Biologicals approved names list'>>**, used in the preparation of the medicine;
- (f) for recombinant products, the name of the biological source as defined by the appropriate Biotechnology Product Descriptors as specified in the **<<name of the agency's Biologicals approved names list'>>** must be placed immediately after the active ingredient name; and
- (g) for other biological products, the name of the animal or organism, as specified in the **<<name of the agency's Biologicals approved names list'>>**, from which the medicine has been prepared.

## 9(8) Homoeopathic medicines<sup>24</sup>

In addition to the requirements referred to in clauses 7 and 8, where all the active ingredients in a medicine are homoeopathic ingredients:

- (a) the label on the container and the label on the primary pack (if any) must include a statement indicating that the product is a homoeopathic medicine; and
- (b) where the indications for use are of a kind permitted to be advertised only to persons described in <<reference to the Rules relating to advertisements to members of professional associations>>, the label on the container and the label on the primary pack (if any) must include a statement that the therapeutic indications have not been approved, such as 'Homoeopathic medicine without approved therapeutic indications'.

## 9(9) Formulations containing both homoeopathic and non-homoeopathic ingredients

In addition to the requirements referred to in clauses 7 and 8, where a medicine contains active ingredients that are homoeopathic ingredients and other active ingredients that are not homoeopathic ingredients:

- (a) the label on the container and the label on the primary pack (if any) must include a statement that the medicine includes ingredients that are homoeopathic ingredients, such as 'contains homoeopathic ingredients'; and
- (b) where the indications for use are of a kind permitted to be advertised only to persons described in <<reference to the Rules relating to advertisements to members of professional associations>>, the label on the container and the label on the primary pack (if any) must include a statement that the therapeutic indications of the homoeopathic ingredients have not been approved, such as 'Contains homoeopathic ingredients without approved therapeutic indications'.

## 9(10) Sunscreen preparations

Where the medicine is a sunscreen product and the goods are enclosed in a container which has a capacity of not more than 25 millilitres or 25 grams of product, the required labelling other than the label protection factor and the <<unique identifier>> may be reduced to a letter height of not less than 1 mm.

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<sup>24</sup> The labelling of homoeopathic medicines was one issue addressed in the consultation document *Regulation of homoeopathic and related medicines in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at <http://www.jtaproject.com/hot.htm#CMConsult>. Responses to that consultation will be considered also in relation to this draft labelling Order.

## 9(11) Medicine Kits

Where:

- (a) a medicine is contained in a kit;
- (b) the kit comprises only medicines; and
- (c) the label on each medicine in the kit fully complies with the requirements of this Order,

then in relation to the label on the primary pack of the kit, it shall be sufficient compliance with clauses 7 and 8 if there are set out on the label of the kit, the following particulars:

- (d) the product name given to the kit;
- (e) the name and address of the sponsor of the kit;
- (f) the product name of all medicines within the kit and their dosage form;
- (g) the name, and quantity or proportion, of all active ingredients in each of the medicines within the kit;
- (h) the quantity of the goods for each medicine within the kit;
- (i) a statement of purpose for each medicine within the kit;
- (j) directions for use for each medicine within the kit or a statement directing consumers to the directions for use presented on the label of each individual medicine within the kit;
- (k) the <<unique identifier>> given to the kit;
- (l) the batch number of the kit preceded by the batch number prefix;
- (m) an expiry date for the kit, being the earliest expiry date of the medicines within the kit, preceded by the expiry date prefix;
- (n) any warning statements that relate to the medicines within the kit;
- (o) the <<Label-Name>> for any ingredients referred to in Column 1 of the First Schedule if present as an excipient in any of the medicines within the kit and required to be displayed on the labels of the medicines within the kit and, if any additional requirement is stated in Column 2 of the First Schedule in relation to such an ingredient, a statement complying with those requirements must also appear on the label of the kit;
- (p) storage conditions applicable to the kit; and
- (q) the applicable signal words, written as specified in the <<scheduling standard>>, if any of the medicines within the kit are scheduled medicines. If the kit includes medicines that are scheduled differently from each other, then the signal words shall be the signal words indicating the most restrictive classification.

## **9(12) Starter Packs**

Where the medicine is a Prescription Medicine and is presented in a starter pack, then, in addition to the requirements referred to in clauses 7 and 8, the label on the primary pack must include:

- (a) a space to allow addition of at least the following dispensing details: patient's name, prescriber's name, directions for use, and date of supply;
- (b) an indicative dosage range; and
- (c) all warnings required under New Zealand, or Australian State or Territory, legislation to be applied at time of dispensing,

except where there is insufficient space on the label of the primary pack, it shall be sufficient if the indicative dosage range and warnings are set out in a leaflet inserted in the primary pack of the medicine provided that such a leaflet is in fact so inserted.

## **9(13) Small containers and very small containers including very small volume injections**

- (a) Where:
  - (i) the medicine is enclosed in a container which has a capacity of 20 millilitres or less;
  - (ii) the container is enclosed in a primary pack; and
  - (iii) the primary pack fully complies with the requirements of this Order,

then, in relation to the label on the container, it shall be sufficient compliance with clauses 7 and 8(1) and subclauses 9(1) and 9(3), if there are set out, on the label on the container, the following particulars:

- (iv) the product name;
- (v) the name(s) of all active ingredients in the medicine;
- (vi) the quantity or proportion of all active ingredients in the medicine;
- (vii) the name of the dosage form;
- (viii) the quantity of the medicine;
- (ix) where the medicine is:
  - (A) a medicine for injection, the approved route(s) of administration, such as 'intravenous', 'intramuscular', or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration and a warning statement where the incorrect route of administration may be hazardous; or

- (B) contained in an ampoule but is not a medicine for injection, a statement of the approved route of administration for the medicine, such as 'inhalation', 'For oral use only' or other phrase, word or abbreviation denoting the approved route(s) of administration of the medicine, and a warning statement where the incorrect route of administration may be hazardous;
- (x) the batch number of the medicine preceded by the batch number prefix;
- (xi) the expiry date of the medicine preceded by the expiry date prefix;
- (xii) the name or registered trade mark of the sponsor or the proprietary name of the medicine;
- (xiii) where the medicine is included in the <<name of new Register>>, the <<unique identifier>>; and
- (xiv) where the medicine is scheduled under New Zealand, or Australian State or Territory, legislation, the applicable signal words, written as specified in the <<scheduling standard>>,

except that:

(b) where:

- (i) the medicine is enclosed in a container which has a capacity of 2 millilitres or less;
- (ii) the container is enclosed in a primary pack;
- (iii) the primary pack fully complies with the requirements of this Order;
- (iv) the medicine has two or more active ingredients;
- (v) the product name is unique and unequivocally identifies the product;
- (vi) the product name appears on the label of the container in a letter height of not less than 2 millimetres,

then in relation to the label on the container, it shall be sufficient compliance with clauses 7 and 8 and subclauses 9(1) and 9(3), if there are set out, on the label on the container, the following particulars in a letter height of not less than 1 millimetre:

(vii) if the medicine is:

- (A) a medicine for injection, the approved route(s) of administration, such as 'intravenous', 'intramuscular', or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration and a warning statement where the incorrect route of administration may be hazardous; or

- (B) contained in an ampoule but is not a medicine for injection, a statement of the approved route of administration for the medicine, such as 'inhalation', 'For oral use only' or other phrase, word or abbreviation denoting the approved route(s) of administration of the medicine, and a warning statement where the incorrect route of administration may be hazardous;
- (viii) the batch number of the medicine preceded by the batch number prefix;
- (ix) the expiry date of the medicine preceded by the expiry date prefix; and
- (x) the quantity of the medicine.

## **9(14) Individually wrapped products**

(a) Where:

- (i) the medicine consists of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder;
- (ii) each such dosage unit is individually wrapped in an unsealed protective cover;
- (iii) each such dosage unit is, after being so wrapped, enclosed in a primary pack; and
- (iv) the primary pack fully complies with the requirements of this Order,

then, in relation to the label for each individual wrapper, it shall be sufficient compliance with this Order if there is set out, on the individual wrapper, the product name.

(b) Where:

- (i) the medicine consists of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, single doses of a powder or single doses of a liquid or a patch;
- (ii) each such single dose or patch is sealed into an individual sachet or individual blister;
- (iii) one or more than one sealed dosage unit is enclosed in a primary pack; and
- (iv) the primary pack fully complies with the requirements of this Order,

then, in relation to the label on each individual sachet or blister, it shall be sufficient compliance with this Order if there are set out, on the individual sachet or blister, the following particulars:

- (v) the product name;
- (vi) the name(s) of all active ingredients in the medicine;
- (vii) the quantity or proportion of all active ingredients in the medicine;

- (viii) the batch number of the medicine preceded by the batch number prefix;
- (ix) the expiry date of the medicine preceded by the expiry date prefix; and
- (x) the name or registered trademark of the sponsor of the medicine.

(c) Where:

- (i) the product consists of dry loose herbs contained in individual bags for infusion and the bag is retained around the herbs during infusion;
- (ii) the bags are contained in a primary pack; and
- (iii) the primary pack fully complies with the requirements of this Order,

then the individual bag need not include the particulars referred to in clauses 7 and 8.

## **9(15) Strip, blister and dial dispenser packs**

(a) Where:

- (i) the medicine consists of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder;
- (ii) two or more of the dosage units are individually enclosed in a strip, blister or dial dispenser pack such that the dosage units can only be extracted individually;
- (iii) the container is enclosed in a primary pack; and
- (iv) the primary pack fully complies with the requirements of this Order,

then, in relation to the label on the container, it shall be sufficient compliance with this Order if there are set out on that container, the following particulars:

- (v) the product name;
- (vi) the name(s) of all active ingredients in the medicine;
- (vii) the quantity or proportion of all active ingredients in the medicine;
- (viii) the batch number of the medicine preceded by the batch number prefix;
- (ix) the expiry date of the medicine preceded by the expiry date prefix; and
- (x) the name or registered trade mark of the sponsor,

except that:

- (b) where there are:
- (i) five or more active ingredients in the medicine; or
  - (ii) two or more active ingredients and the medicine is a Complementary Medicine,
- then in relation to the label on the container, it shall be sufficient if there are set out on that container, the following particulars:
- (iii) the product name;
  - (iv) the batch number of the medicine preceded by the batch number prefix; and
  - (v) the expiry date of the medicine preceded by the expiry date prefix.
- (c) Where two or more of the dosage units are individually enclosed in a strip, blister or dial dispenser pack such that the dosage units can only be extracted individually, and the container is not a calendar pack, then the product name, the name(s) of all active ingredients in the medicine, if required, and the quantity or proportion of all active ingredients in the medicine, if required, must appear at least once in relation to every two dosage units enclosed in the container.

## **9(16) Plastic ampoules**

- (a) Where the nominal volume of the medicine in a plastic ampoule is greater than 20 millilitres, the label on the container must meet the requirements of clauses 7 and 8 and any other subclause relevant to the route(s) of administration of the medicine, including a warning statement where the incorrect route of administration may be hazardous;
- (b) Where the nominal volume of the medicine in a plastic ampoule is less than or equal to 20 millilitres, it will be sufficient compliance with clause 7 and subclause 8(1) if the label on the container is in accordance with subclause 9(13), relating to small containers and very small containers including very small volume injections, and any other subclause relevant to the route(s) of administration of the medicine,

except that:

- (c) where the nominal volume of the medicine in a plastic ampoule is less than 5 millilitres and two or more ampoules are attached to a connecting strip, irrespective of whether or not the seal is broken when an ampoule is detached, it will be sufficient compliance with clause 7 and subclause 8(1) if there are set out on:
- (i) the label on each ampoule:
    - (A) the product name;
    - (B) the quantity or proportion of all active ingredients in the medicine expressed as the amount of active in the nominal volume of the ampoule;

- (C) the batch number of the goods preceded by the batch number prefix;
  - (D) the expiry date of the goods preceded by the expiry date prefix; and
  - (E) the approved route of administration; and
- (ii) the label on the connecting strip:
- (A) the name of the active ingredient;
  - (B) the name or registered trade mark of the sponsor; and
  - (C) a warning statement where the incorrect route of administration may be hazardous.

## **9(17) Composite packs**

Where a primary pack contains more than one kind of item, such as a vial containing a powder for reconstitution and an ampoule containing a diluent, which have different expiry dates, the expiry date included on the label on the primary pack shall be the expiry date of the medicine with the shorter shelf life.

## **10 Expression of Particulars**

### **10(1) Use of appropriate metric units**

For active ingredient(s), where a particular is a statement of quantity for which there is a metric unit of measurement, the appropriate metric units shall be as follows:

- (a) a statement of quantity for 1 microgram up to 999 micrograms, both inclusive, must be expressed in terms of micrograms;
- (b) a statement of quantity for 1000 micrograms must be expressed as either 1000 micrograms or 1 milligram;
- (c) a statement of quantity for more than 1 milligram up to 999 milligrams inclusive must be expressed in terms of milligrams;
- (d) a statement of quantity for 1000 milligrams must be expressed as either 1000 milligrams or 1 gram; and
- (e) a statement of quantity for more than 1 gram up to 999 grams inclusive must be expressed as grams,

except that where the medicine is one of a series of strengths containing the same active ingredient in the same dosage form, the labels must state the quantity of active ingredient in terms of either the highest or lowest metric unit of measurement in the series of strengths.

For example, a range of expressions of the active ingredient must be stated as 0.5 milligram, 1 milligram and 5 milligrams rather than 500 micrograms, 1 milligram and 5 milligrams.

### **10(2) Expression of quantity or proportion of active ingredients**

Except as provided in clause 10(4) (Expression of activity of radionuclides in radiopharmaceutical preparations) and clause 9(4) (Dialysis concentrates), the quantity or proportion of an active ingredient to be included on a label must be expressed:

- (a) for a discrete dosage unit - as the quantity of the active ingredient in the dosage unit;
- (b) for a liquid for ingestion - as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid;
- (c) for a solid for ingestion, where there is no discrete dosage unit - as the quantity of the active ingredient contained in the stated weight of a suitable dose of the solid;
- (d) for a transdermal patch - as the total quantity of the active ingredient in each patch and the quantity of the active ingredient released in a stated time;
- (e) for a homoeopathic medicine, where all the active ingredients are homoeopathic ingredients:
  - (i) notwithstanding subclauses (a), (b) and (c), as the quantity of the ingredient in one millilitre or in one gram of the medicine; or

- (ii) where each active ingredient is included in the medicine in the same proportion as every other active ingredient, expressed as 'Contains equal parts of' followed by the name of each homoeopathic ingredient;
- (f) for medicines which are required to be prepared before use and which after preparation are a liquid for ingestion - as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid, after preparation in accordance with the instructions set out on the label of the medicine;
- (g) for a medicine for injection:
  - (i) where the product is a medicament for injection – as the nominal quantity of the active ingredient in the container; or
  - (ii) for other medicines for injection, whether intended for multi- or single dose use, and
    - (A) the volume in the container is greater than 1 millilitre - as the total quantity of active ingredient in the total volume of the injection, followed by the quantity of the active ingredient in one millilitre of the injection; or
    - (B) the volume in the container is less than or equal to 1 millilitre, as the quantity of the active ingredient in the stated volume of the injection;

**Note:** In justified cases the strength may also be incorporated in the product name as a percentage (w/v or v/v) or another concentration term, but not including the quantity of active ingredient per millilitre;

  - (iii) where the preparation is a large volume injection intended for electrolyte replacement or nutritional therapy or is intended as a plasma volume expander or is intended as an additive to any of these types of large volume injection:
    - (A) as the number of millimoles in the stated volume of the injection in the container for each active ingredient or ion of precisely known molecular weight; or
    - (B) as the weight contained in the stated volume of the injection in the container for each active ingredient for which the molecular weight is not precisely known;
  - (iv) where the preparation is a large volume injection containing an active ingredient which is not intended for electrolyte replacement or nutritional therapy or as a plasma volume expander - as the weight of the active ingredient in the stated volume of injection in the container;- (h) for antibiotic preparations, where potency units are used as a measure of activity - as the number of such units expressed as International Units (IU) established by the World Health Organization;
- (i) for any other medicines which are required to be prepared before use - as the weight or volume of active ingredient in a stated weight or volume of the medicine, after preparation in accordance with the instructions included in the label of the medicine;

- (j) for preparations applied to the skin and mucous membranes, other than those covered by subclause (h) above - as a percentage expressed in terms of w/w, w/v, v/v or v/w, as appropriate, or as the weight or volume in a stated weight or volume of the medicine, as appropriate;
- (k) for preparations including a herbal substance<sup>25</sup>:
  - (A) where a herbal substance is a dry herb, fresh herb, powder, oil, fresh juice or dry juice preparation - as the quantity of the herbal substance in the preparation;
  - (B) where a herbal substance is an extract, tincture, decoction, infusion or spagyric - as the quantity of the raw material herb used to make the ingredient expressed as the equivalent dry or fresh weight; or
  - (C) where a herbal substance is a concentrated or diluted juice - as the quantity of the raw material juice used to make the concentrate or dilution expressed as the equivalent dry weight, fresh volume or fresh weight;
- (l) for preparations containing trace elements as salts intended as mineral supplements - as the quantity of the element with the name of the salt being indicated;
- (m) for preparations containing Vitamin A - as the quantity or proportion of Vitamin A expressed in terms of International Units (IU);
- (n) for pressurised metered dose inhalers and dry powder inhalers – as the delivered dose, except where the medicine is the subject of a monograph of the British Pharmacopoeia (BP) and the dose has been established as a metered dose. Where the powder for inhalation is supplied as a single dose in a capsule, or as a well in a blister tray or other suitable pharmaceutical form - as the quantity of active ingredient in each dosage unit;
- (o) for a preparation containing biological organisms - as the number of organisms present per metric unit for liquids and powders and as the number per dosage unit for other dosage forms;
- (p) for any other medicines:
  - (i) where the medicine is a liquid and includes an active ingredient which is a liquid - as the appropriate amount of the active ingredient, either by weight or volume, in a stated volume of the medicine;
  - (ii) where the medicine is a liquid and includes an active ingredient which is a solid - as the weight of active ingredient in a stated volume of the medicine;
  - (iii) where the medicine is a liquid and includes an active ingredient which is a gas - as the weight of the active ingredient in a stated volume of the medicine;

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<sup>25</sup> The expression of dry/fresh weight equivalence was addressed in the consultation document *Regulation of herbal substances in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at: <http://www.jtaproject.com/hot.htm#CMConsult>. Responses to that consultation will be considered also in relation to this draft labelling Order.

- (iv) where the medicine is a solid and includes an active ingredient which is a liquid - as the appropriate amount of the active ingredient, either by weight or volume, in a stated weight of the medicine;
- (v) where the medicine is a solid and includes an active ingredient which is a solid - as the weight of the active ingredient in a stated weight of the medicine; or
- (vi) where the medicine is a solid and includes an active ingredient which is a gas - as the weight of the active ingredient in a stated weight of the medicine.

### **10(3) Expression of potency in biological products**

- (a) The potency of liquid biological products or biological products which are required to be prepared before use must be included on labels and must be expressed as potency units, or weight of active ingredient per dose or per unit volume, or as the volume which contains the recommended dose.
- (b) The potency unit to be used must be the International Unit (IU) established by the World Health Organisation.
- (c) The potency of probiotic biological products must be included on labels and must be expressed as the number of each probiotic organism per dose unit.

### **10(4) Expression of activity of radionuclides in radiopharmaceutical preparations**

The quantity or proportion of an active ingredient, which is a radionuclide, included in a radiopharmaceutical preparation must be included on labels and must be expressed in terms of the total activity of the radionuclide in the container, in becquerels, at a specified date and hour.

### **10(5) Permitted statements of storage conditions**

- (a) For the purposes of clause 7, the following statements of storage conditions are permitted:
  - (i) 'Store below  $-18^{\circ}\text{C}$  (Deep freeze)';
  - (ii) 'Store below  $-5^{\circ}\text{C}$  (Freeze)';
  - (iii) 'Store below  $8^{\circ}\text{C}$  (Refrigerate)';
  - (iv) 'Store at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  (Refrigerate. Do not freeze)';
  - (v) 'Store below  $25^{\circ}\text{C}$ '; and
  - (vi) 'Store below  $30^{\circ}\text{C}$ ';
- (b) If none of the statements of storage conditions included in subclauses (i) to (vi) inclusive are applicable, the sponsor must apply to the Managing Director of <<name of the joint agency>> for permission to use an alternative statement.

## First Schedule

### Excipients required to be declared on the label of medicines

Reference to an excipient in this Schedule includes all salts and derivatives of the excipient.

Column 1 includes a general descriptor for the group of excipients requiring to be declared, and a number of indicative approved ingredient names for excipients that fall within that group. These do not constitute a complete or formal list of affected excipients. The term 'and their products' refers to all products derived from the named ingredient.

Column 2 includes any conditions that may further define when the declaration is required, and describes any requirements supplemental to the label declaration.

Column 3 identifies those routes of administration, where for the purposes of the First Schedule, the ingredients must be declared.

Column 4 identifies the <<Label-Name>>, which is the name to be used on the label of the medicine for the purposes of declaration of excipients included in Column 1. The <<Label-Name>> provides for grouping of excipients that have similar characteristics and is to be used irrespective of whether one or more of the ingredients in the group are present in the formulation. Presentation on the label should be in the form 'Contains <<Label-Name>>'.

Column 1 Ingredient Name or Group	Column 2 Condition (if any) and additional requirements (if any)	Column 3 Declaration Required for Routes of Administration	Column 4 <<Label-Name>>
<b>Aspartame</b>		Oral	Aspartame
<b>Benzoates</b> , including but not limited to: Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate		All	Benzoates
<b>Crustacea and Crustacean products</b> (see Note 1), including but not limited to: Crab		All	Crustacean products

<b>Column 1 Ingredient Name or Group</b>	<b>Column 2 Condition (if any) and additional requirements (if any)</b>	<b>Column 3 Declaration Required for Routes of Administration</b>	<b>Column 4 &lt;&lt;Label-Name&gt;&gt;</b>
Lobster Shrimp - white			
<b>Egg and egg products</b> , including but not limited to: Egg – whole Egg yolk – dried Lecithin - egg		All	Egg products
<b>Ethanol</b> , including but not limited to: Ethanol Absolute ethanol	<b>Condition:</b> Where present in a concentration of greater than 3% v/v.	All	Alcohol
<b>Fish and fish products</b> (see Note 2), including but not limited to: Cod Cod – liver oil Halibut Tuna		All	Fish products
<b>Galactose</b>		Oral	Galactose
<b>Gluten</b> or excipients derived from gluten-containing grains (see Note 3)	<b>Condition:</b> Where gluten or an excipient derived from gluten-containing grains is present. <b>Requirement:</b> To declare the source of the gluten ie the gluten-containing excipient eg wheat starch, on the label.	All, other than skin and mucous membrane applications	Gluten
<b>Hydroxybenzoic acid esters</b> , including but not limited to: Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate		All	Hydroxybenzoates

Column 1 Ingredient Name or Group	Column 2 Condition (if any) and additional requirements (if any)	Column 3 Declaration Required for Routes of Administration	Column 4 <<Label-Name>>
Sodium propyl hydroxybenzoate			
<b>Lactose</b> (see Note 4)	<b>Condition:</b> Where present, notwithstanding the entry for lactose under 'Sugars – Monosaccharides and disaccharides'.	Oral	Lactose
<b>Milk and milk products</b> , including but not limited to: Milk – nonfat dry Milk – whole dry Milk protein – hydrolysed		All	Milk product
<b>Peanuts and peanut products</b> , including but not limited to: Arachis hypogaea Arachis (peanut) oil		All	Peanut products
<b>Phenylalanine</b>		All, other than skin and mucous membrane applications	Phenylalanine
<b>Pollen – Bee</b>	<b>Requirement:</b> To include a statement to the effect that the product contains bee pollen, which may cause severe allergic reactions.	Oral	Pollen
<b>Potassium salts</b> , including but not limited to Potassium chloride Potassium bicarbonate Potassium clavulanate	<b>Condition:</b> Where the total potassium content of the maximum recommended daily dose of the formulation is greater than 156 mg (4 mmol). <b>Requirement:</b> To declare on the label (in mmol and mg) the quantity of potassium per maximum recommended daily dose.	Oral	Potassium salts

<b>Propolis</b>	<b>Requirement:</b> To include a statement to the effect that the product contains bee pollen, which may cause severe allergic reactions.	Oral	Propolis
<b>Royal Jelly</b>	<b>Requirement:</b> To include a statement to indicate explicitly that the product should not be taken by asthma or allergy sufferers, and that products containing royal jelly have been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers.	Oral	Royal Jelly
<b>Saccharin</b> , including but not limited to Saccharin calcium Saccharin sodium		Oral	Saccharin
<b>Sesame seeds and sesame seed products</b> , including but not limited to: Sesame seed Sesame oil Sesamum indicum		All	Sesame seed products
<b>Sodium salts</b> , including but not limited to: Sodium bicarbonate Sodium chloride	<b>Condition:</b> Where the total sodium content of the maximum recommended daily dose of the formulation is greater than 120 mg (5.2 mmol). <b>Requirement:</b> To declare on the label (in mmol and mg) the quantity of sodium per maximum recommended daily dose.	Oral	Sodium salts
<b>Soya beans and soya bean products</b> , including but not limited to: Glycine max Soya bean Soya oil Soyabean oil		All	Soya bean products

<p><b>Sorbates</b>, including but not limited to: Potassium sorbate Sorbic acid</p>		All	Sorbates
<p><b>Sugar alcohols</b>, including but not limited to: Isomalt Lactitol Maltitol Mannitol Sorbitol Xylitol</p>	<p><b>Condition:</b> Where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose. <b>Requirement:</b> To declare on the label the quantity of sugar alcohols present per recommended maximum daily dose; and a statement 'Products containing (name of sugar alcohol) may have a laxative effect or cause diarrhoea'.</p>	Oral	Sugar alcohols
<p><b>Sugars – Monosaccharides and disaccharides</b> (see Note 4), including but not limited to: Glucose Honey (as a mixture of sugars) Invert sugar Lactose Maltose Sucrose</p>	<p><b>Condition:</b> Where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose which requires a separate declaration) exceeds 100 mg per recommended daily dose.</p>	Oral	Sugars
<p><b>Sulfites</b>, including but not limited to: Sulfur dioxide Potassium metabisulfite Sodium bisulfite Sodium metabisulfite Sodium sulfite</p>		All	Sulfites
<p><b>Tartrazine</b></p>	See Note 5	All	Tartrazine CI 19140

<p><b>Tree nuts and tree nut products</b> (see Note 6), including but not limited to          Macadamia nut oil          Macadamia ternifolia          Almond oil          Prunus dulcis          Walnut          Juglans nigra</p>		All	Tree nut products
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**Note 1: Crustacea** include various species of aquatic animals which have an inedible chitinous outer shell. These include crab, crayfish, lobster, prawn and shrimp.

**Note 2: Fish** includes freshwater fish, diadromous fish and marine fish. This includes shark.

**Note 3: Gluten** – it is recognised that formulations of medicines do not usually include gluten as a separate excipient, although it may be present naturally as a constituent of some excipient ingredients, such as wheat starch. The <<insert name of agency>> agrees that medicines can be regarded as ‘gluten-free’ if the product contains no detectable gluten and contains no oats or malt.

**Note 4: Sugars – Monosaccharides and disaccharides** – some sugar derivatives may not have a significant impact on glycaemic control. Lactose forms part of total sugars for the purposes of determining if the sugars will have a significant glycaemic effect and for calculating the total daily dose.

**Note 5: Tartrazine** – <<Name of joint agency Guidelines for the Registration of Drugs (OTC medicines)>> permits tartrazine in products for ingestion if supplied before 15 February 1991. For products supplied after this date, tartrazine may only be used for topical products.

**Note 6: Tree nuts** are the seeds of a variety of trees and shrubs which are characterised by a hard inedible shell enclosing an oily seed. Tree nuts include almond, Brazil, cashew, chestnut, and walnut. Coconut is the fruit of the palm (*Cocos nucifera*) and is not considered to be a tree nut.

## Supplementary Notes

The following Supplementary Notes are intended to explain various parts of the Order and are not part of the Order.

### 1. Application - provision for exemption for specific products

Section <<reference to Act/Rule requiring compliance with standards>> requires therapeutic products including medicines to comply with standards. These standards include standards for labelling and packaging.

However a mechanism is included in <<Rule>> for seeking an exemption for individual products from compliance with standards such as any of the labelling requirements specified in this Order, except where the Order reproduces requirements from the Act or Rules.

Where exemption from any of the labelling requirements in this Order is sought for medicines intended for supply in Australia and/or New Zealand, the sponsor is required to apply in writing to the <<name of new agency>> for a formal exemption stating precisely the particular requirement from which exemption from compliance is being sought and providing a reason for seeking the exemption.

The ability of the Managing Director of the <<name of new agency>> to grant exemptions for particular products from specified provisions of this Order is reflected in subclause 2(1) of this Order.

### 2. General exemptions

Certain classes of medicine are exempt from compliance with the labelling requirements specified in this Order. These classes of medicine are referred to in clause 4 of this Order. The following paragraphs provide additional explanation of some of these general exemptions.

#### Special Access Scheme Medicines

Subclause 4(1)(a) of this Order exempts from compliance with this Order those medicines which are neither exempt products nor included in the <<name of register>> but are imported into Australia and/or New Zealand, or supplied in Australia and/or New Zealand, on the basis of being intended for Individual Patient Use or other special access purposes in accordance with provisions included in the Rules.

#### Investigational Medicinal Products

Subclause 4(1)(b) exempts medicines intended solely for use as investigational medicinal products (clinical trial medicines) from compliance with this Order.

The <<name of joint agency>> Code of Good Manufacturing Practice for Medicinal Products includes, as an Annex (<<insert Annex number>>), requirements pertaining to Investigational Medicinal Products. These requirements include labelling and packaging instructions. The labelling requirements are reproduced below for reference:

### **Labelling instructions**

17. Labels should include:

- a) name of the sponsor;
- b) pharmaceutical dosage form, route of administration, quantity of dosage units (and name/identifier of the product and strength/potency in case of open trial);
- c) the batch and/or code number to identify the contents and packaging operation;
- d) the trial subject identification number, where applicable;
- e) directions for use;
- f) “for clinical trial use only”;
- g) the name of the investigator (if not included as a code in the trial reference code);
- h) a trial reference code allowing identification of the trial site and investigator;
- i) the storage conditions;
- j) the period of use (use-by date, expiry date or re-test date as applicable), in month/year;
- k) “keep out of reach of children” except when the product is for use only in hospital.

*The outer packaging may include symbols or pictograms to clarify certain information mentioned above and the request ‘return empty packaging and unused products’.*

*Additional information, for example any warnings and handling instructions, where applicable, may be displayed according to the order. A copy of each type of label should be kept in the batch record.*

18. *On the immediate packaging when the outer packaging carries the particulars mentioned in paragraph 17 a-k, the particulars mentioned in paragraph 17 a-f, shall be given.*

19. *When the outer packaging carries the particulars mentioned in paragraph 17 a-k and the immediate packaging takes the form of blisterpacks or small immediate packaging units such as ampoules on which the particulars mentioned in paragraph 17 a-f cannot be displayed, the particulars mentioned in paragraph 17 a, c and d as well as route of administration in case of ampoules, shall at least appear on the immediate packaging.*

20. *In case of use date extension, an additional label should be affixed to the investigational medicinal product. This additional label should include the new use date and repeat the batch number. It may be superposed on the old use*

*date, but, for quality control reasons, not on the original batch number. This operation may be performed on site by the clinical trial monitor(s) or the clinical trial site pharmacist, in accordance with specific and standard operating procedures and under contract if applicable. The operation should be checked by a second person. Documented evidence of this additional labelling should be available in the trial documentation and in the batch records.*

### **Starting Materials and Medicines Not at Final Stage of Manufacture**

Subclause 4(1)(c) of this Order exempts starting materials, that is ingredients and materials used in the manufacture of medicines, except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form. This means that active ingredients and excipients intended for use in the manufacture of medicines are exempt. However, if the same ingredients are prepackaged ready for sale for therapeutic use, they are not exempt. For example, an ingredient such as liquid paraffin can be used in manufacture of drug products, in which case it is exempt from these requirements, or can be pre-packaged for sale to the public, in which case it is not exempt.

Similarly, in process materials such as bulk finished tablets, which are still to be packaged for supply, are exempt under subclause 4(1)(d) from the requirements in this Order.

### **Personal Imports**

Subclause 4(1)(e) of this Order exempts medicines which are Personal Imports for use in the treatment of the importer or his or her immediate family, subject to certain conditions as described in <<XX of the Rules>>.

### **Dispensing Labels**

It is recognised that the particulars required to be included on a dispensing label must comply with the relevant New Zealand, or Australian State or Territory, legislation applying to the dispensing of medicines. Under subclause 4(1)(h), this Order exempts the label of these dispensed medicines from the requirements of the Order. This subclause does not exempt the original sponsor's pack to which the dispensing label is attached, or from which the dispensed medicine is prepared, from compliance with this Order.

### **Practitioner Supplied Products**

Subclause 4(1)(j) is intended to apply to the situation where a doctor, dentist or other appropriately authorised health professional supplies an individual patient with a dose of a medicine to be taken immediately and/or repacks a small number of doses to be taken away. It is not intended to apply to starter packs supplied by a sponsor to a health professional and these starter packs are required to comply fully with the requirements of this Order.

## Transparent Coverings

Subclause 4(2) applies to transparent film wrappers, such as cellophane wrappers, that fully enclose a primary pack of a medicine and, because of their transparency, do not obscure any of the labelling information required by this Order.

Where such wrappers are used as a form of tamper-evident packaging, the distinctive design on the wrapper must not obscure any of the information required on the label of the medicine.

Subclause 4(2) does not apply to presentations that consist of a transparent bubble attached to a backing board, with the medicine enclosed between the transparent bubble and the backing board. The backing board of such presentations is expected to fully comply with the requirements of this Order and, because the container of the medicine may shift within the bubble, reliance cannot be placed on visibility of the labelling on the container through the bubble.

## 3. Interpretation

Many definitions included in clause 5 reflect definitions included in the Treaty under which the joint agency is being established to regulate therapeutic products, and the consequent <<name of Act>> and <<name of Rules>>. For reference purposes, and to provide a comprehensive document, these definitions have been reproduced in this Order. While such definitions are accurate at the time this Order is gazetted, readers should check the Act or Rules, as relevant, for the most current definition.

Explanatory comments on some of the definitions follow:

### Batch numbers and expiry dates

The definition of batch number requires that there be a clear and obvious relationship between the batch number shown on the labels of all components of a single batch of medicine that are separately labelled with this information – for example, a foil strip containing tablets and the primary pack containing a number of the foil strips. This clear relationship is important for consumer recognition of affected products in recalls, and to circumvent concerns over possible tampering. Where, for manufacturing reasons, the same batch number cannot be used on the different levels of packaging, one method of achieving an obvious relationship would be to utilise a variable prefix or suffix attached to common numbers or letters (for example, Batch 123A, 123B etc).

Also to assist consumer recognition of batch and expiry date details, the Order requires that the same batch number prefix, and expiry date prefix, be used on all levels of packaging showing the batch number and expiry date respectively. It is not acceptable, for example, to use 'B/N' on the container, and 'Batch' on the primary pack, or 'Expiry' on the container, and 'Use Before' on the primary pack.

It is recommended that batch number and expiry date details be co-located, preferably on the end or side panel of the package.

## Controlled drugs

In this Order, the term 'Controlled Drug' is used in a limited sense to refer to those medicines that are classified as such (<<Schedule 8 medicines>>) in the <<scheduling standard - *Standard for the Uniform Scheduling of Medicines and Poisons*>>. The term does not encompass all drugs classified as Controlled Drugs under the New Zealand *Misuse of Drugs Act 1975* and Regulations, which includes some substances/medicines classified in Australia as Prescription Only Medicines or Pharmacist Only Medicines for example.

Sponsors supplying, in New Zealand, drugs classified as Controlled Drugs under the New Zealand *Misuse of Drugs Act 1975* should be aware of additional labelling requirements applying to the various classes of Controlled Drugs listed in that legislation.

## Medicine kits and composite packs

Kits (also sometimes referred to as system or procedure packs) and composite packs are differentiated in the Rules <<reference to the Rules to be inserted>>.

A package and therapeutic products in the package together constitute a kit if the package and therapeutic products are for use as a unit, each therapeutic product within the package is included in the <<name of Register>> or is exempt from the requirement to be included in the <<name of Register>>, and the package and therapeutic goods do not constitute a composite pack or procedure pack.

In contrast to a kit, a composite pack contains therapeutic products that are for administration as a single treatment or a single course of treatment, and it is necessary for the therapeutic products to be combined before administration or administered in a particular sequence. Examples of composite packs would be a package containing a vial of powder for injection and an ampoule of diluent, and a combination pack containing two antibiotics and a proton pump inhibitor for the treatment of peptic ulcer disease due to *H. pylori* infection.

Kits may contain medicines only, medical devices only or both medicines and medical devices. When the kit contains only medicines, it is considered to be a medicine kit and the requirements of this Order apply. When the kit contains a mix of medicines and medical devices (for example a first aid kit containing medicines such as paracetamol and aspirin and medical devices such as surgical dressings), the kit itself is considered to be a medical device, and the essential principles relating to information to be provided with medical devices (as stated in the <<name of relevant Rule relating to medical devices to be inserted>>) apply, notwithstanding that each medicine within the kit would need to comply with this Order.

## <<Scheduling Standard>>

<<Note regarding content of the scheduling standard and relationship to other NZ, & Australian State & Territory legislation.>>

## 4. Unacceptable presentation

The <<Act/Rules>> state that the presentation of therapeutic products is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods. For example, the presentation of a medicine would be unacceptable if the label states or suggests that the medicine has ingredients, components or characteristics that it does not have, or the presentation of the medicine may lead to unsafe use.

In designing labels or selecting trade names, sponsors should be careful to ensure that similarity in the appearance of the package with that of other medicines, or similarity in the appearance or sound of trade names, does not result in an unacceptable presentation.

## 5. Use of the English language

Subclause 6(1)(b) requires the mandatory label information to be written in the English language. As far as possible 'Plain English' should be used in order to assist consumer understanding, particularly for non-prescription medicines (OTC and Complementary Medicines). 'Plain English' is language that the intended audience can understand and act upon from a single reading. It is concise and direct, and does not use complex terminology. The end result also should be visually appealing, making locating and understanding the information easy.

In some cases, non-English product names may be present – for example, many Chinese and other forms of traditional medicines may have the product name expressed in non-Anglicised characters such as Pinyin and Chinese characters. It is unlikely that many of these names can be translated into a meaningful English name. In such cases, it is sufficient if the sponsor provides a certified English translation of the non-English characters to the Agency to verify that the name does not include prohibited claims. It is preferable however for the non-Anglicised characters to be accompanied by Latin or botanical names.

## 6. Letter size

Subclause 6(1)(d) requires that, unless otherwise specified in this Order, the mandatory label information appear in a letter height of at least 1.5 millimetres.

The specified variations to this are as follows:

- for Prescription Medicines, Controlled Drugs and medicines for injection, the names of all active ingredients must appear on the main label in a letter height at least half that used for the product name but, in any case, not less than 2 millimetres [subclause 8(3)(a)]. In cases where there are five or more active ingredients in these medicines, and the names of the active ingredients are shifted to a side or rear panel of the label, then the letter height must not be less than 2 millimetres;

- for OTC medicines, the names of all active ingredients must appear on the main label in a letter height of at least 2 millimetres [subclause 8(3)(b)]. In cases where there are five or more active ingredients in these medicines, and the names of the active ingredients are shifted to a side or rear panel of the label, then the letter height must not be less than 2 millimetres;
- for medicines that have two or more active ingredients and that are either very small volume injections or are presented in very small containers (less than or equal to 2 millilitres), the minimum letter height for the mandatory information on the container label (other than the product name) is 1 millimetre. Use of this reduced font size is conditional however on the product name appearing on the container label in a letter height of at least 2 millimetres and there being a fully compliant primary pack [subclause 9(13)(b)];
- for sunscreen preparations presented in containers not exceeding 25 millilitres or 25 grams in capacity, the minimum letter height for the required labelling (other than the SPF factor and the <<unique identifier>>) is 1 millimetre [subclause 9(10)]; and
- signal words, as specified in the <<scheduling standard>>. These are required to be written in letters at least half the height of the largest letter or numeral on the label, but need not be larger than 6 millimetres provided the nominal capacity of the container is not greater than 2 litres [subclause 7(1)(o)].

Subclause 6(2) requires that the letters not be distorted in any way that could interfere with legibility. This means that where the Order requires use of a letter height greater than 1.5 millimetres, there must be a proportionate increase in letter width and spacing.

## 7. Reference to ‘name of the dosage form’

Appropriate names for the dosage form can be found in the <<name of new approved names publication >> and in the <<name of default pharmacopoeial standard(s)>>.

Synonyms or abbreviations for the names of dosage forms used in monographs of the <<name of default pharmacopoeial standard(s)>> may be used on labels.

It is recognised that the names of dosage forms for products such as sunscreens do not always conform with the usual names of dosage forms used for medicines and in such cases another name descriptive of the nature of the product can be used.

Subclause 7(1) could be interpreted to require the ‘name of the dosage form’ to appear up to four times on a label, as follows:

- under subclause 7(1)(a), as a part of the statement of the ‘non proprietary name’, such as ‘Aspirin Tablets BP’;

- under subclause 7(1)(c), as part of the statement of quantity or proportion of all active ingredients in the medicine, such as 'Each tablet contains Aspirin 300 mg';
- under subclause 7(1)(e), as the name of the dosage form, such as 'Tablets'; and
- under subclause 7(1)(f) as part of the quantity of the medicine, such as '25 Tablets'.

Where the product name includes the name of the dosage form, a separate statement of the name of the dosage form can be omitted. Similarly, the statement of quantity or proportion of active ingredients in the medicine could be combined with the statement of quantity of the medicine, such as '25 Tablets each containing Aspirin 300 mg'.

## 8. Expression of paediatric doses

Subclause 7(1)(k) requires that the label include directions for use and, where the medicine is intended for ingestion, these directions include dose and frequency of administration unless the medicine can only be supplied on prescription (in which the case the dose will be specified by the healthcare practitioner).

Paediatric doses of liquid preparations expressed *solely* in terms of either age or weight may not be appropriate for particular children and may result in parents or carers having difficulty in determining the correct dose (for example, where the weight is not known, or the child is outside the normal weight range for a particular age group). Paediatric doses of liquid preparations should therefore be presented with age, weight and millilitres unless otherwise justified.

## 9. Names of large volume injections

The naming of large volume injections is described at subclause 9(2) of this Order. This note provides further guidance to sponsors in the naming of large volume injections.

The 'non-proprietary name' should include the name or names of the active ingredient(s), together with a word(s) denoting the name of the dosage form. The majority of large volume injections contain one, two or three active ingredients and the use of the non-proprietary name which specifies the identity and amount of each active ingredient together with the usual name of the dosage form should not present any difficulty.

However, it would be impractical to include the name of each individual active ingredient in the non-proprietary name for the medicine containing, for example, multiple amino acids. For such products the non-proprietary name can be a general name which categorises the types of active ingredient present.

For example -

'Amino Acid and Electrolyte Intravenous Infusion'

'Triglyceride, Phospholipid and Glycerol x% Intravenous Infusion'

The use of a general term such as 'electrolyte', 'carbohydrate', 'amino acid', etc. will be permitted where the product contains more than three active ingredients in one category.

## 10. Homoeopathic preparations<sup>26</sup>

There are currently no names approved specifically for homoeopathic ingredients. However, sponsors are encouraged to use the equivalent Approved Name wherever possible to provide consumers with consistent terminology for chemical, herbal or biological names.

Similarly to other medicines, the expression of content of the active ingredient on the label should provide information on the final concentration of the active ingredient in the preparation. If the homoeopathic product contains more than one active ingredient, the relative quantities should be stated, for example:

Each 1 mL contains:

ingredient A    5X    300 microgram  
ingredient B    4X    500 microgram  
etc.

Or

Contains equal parts of

ingredient A    5x  
ingredient B    4x  
etc.

## 11. Expression of 'microgram'

The requirements for the expression of microgram are that wherever possible, 'microgram' should be stated in full to minimise the possibility of confusion with 'milligram'. When it is not practicable to use the word 'microgram' in full, the preferred abbreviation is 'µg'. However, the term 'mcg' is acceptable for use in other than prescription medicines.

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<sup>26</sup> This Supplementary Note will be revised following conclusion of the consultation on the document *Regulation of homoeopathic and related medicines in a joint Australia New Zealand therapeutic products agency* which was released in December 2004 and is available at <http://www.jtaproject.com/hot.htm#CMConsult>.

## **12. Expression of quantity or proportion of vitamins and minerals**

As a general principle, the quantity or proportions of vitamins have, in the past, been expressed in biological units of potency until such time as their purity and assay procedure allows quantitative expression in terms of mass.

Currently, only Vitamin A has an international standard expressed in biological units. Other vitamins are generally expressed in terms of mass.

Vitamin A can be expressed on the label solely in International Units. For all other vitamins, the expression of amount should be in terms of mass (such as milligrams or micrograms, as appropriate).

For Betacarotene, (a precursor of Vitamin A), the statement of strength of Betacarotene is required to be expressed in terms of mass (such as milligrams) rather than international units of Vitamin A activity. It is known that the amount of Betacarotene which is converted in the body to Vitamin A depends to some extent on reserves of Vitamin A in the body. It is therefore considered inaccurate to express the content of Betacarotene in International Units.

It is recognised that various optical isomers and salts of alpha tocopherol (Vitamin E) are in use, which have different activity depending on their source, i.e. synthetic or naturally occurring. To allow the consumer to compare the activity of these tocopherols from different sources in various products, sponsors may also include their activity in International Units.

For cholecalciferol and ergocalciferol (Vitamin D), the expression of strength on the label is required to be in terms of mass. Sponsors may also include a potency statement in International Units.

For preparations containing trace elements of salts intended as mineral supplements, the quantity or proportion of active ingredient should be expressed in terms of the quantity of the element with the name of the salt being indicated.