



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



GENERAL REQUIREMENTS FOR THE LABELLING OF MEDICINES AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY

Draft – May 2006

Notes:

- 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>>.*
- 2. A number of definitions appearing under 'Interpretation' will replicate definitions appearing elsewhere in the legislation, for example in the Ministerial Council Rules. As such, these definitions have not yet been finalised. Where a definition is shown as having the same meaning as in the Rules, an indicative definition has been included wherever possible. For the same reason, some terms used throughout this Order may be subject to later amendment for consistency with terms used in higher legislation.*

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DRAFT

<<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 of the Australian New Zealand Therapeutic Products Authority 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>>.

DRAFT

1 Introduction

The purpose of a medicine label is to provide information about the medicine such as its identity, potency, content, storage, expiry date, dose, directions for use, licensing status and sponsor details. Medicine labels may 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 bar codes and the sponsor's logo.

Labelling should contribute to the quality use of medicines. Quality use of medicines means selecting management options wisely, choosing suitable medicines if a medicine is considered necessary, and using medicines safely and effectively.

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 and to enhance patient safety. To help achieve this, the best practice guideline <<Best Practice Guideline on Prescription Medicine Labelling>> is available at <<web address for the Authority>> to assist sponsors in the design of labels for prescription medicines.

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*, published by Communications Research Institute of Australia Inc. and accessible from the <<web address for the Authority>> should achieve this aim.

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

All medicine labels must comply with clauses 2-10 and the First 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.

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 (General Exemptions) or unless an exemption from compliance with this Order has been granted by the Managing Director of the Australia New Zealand Therapeutic Products Authority in accordance with <<reference to the provisions in the Rules allowing exemption from standards>>.
- 2(2) Containers, intermediate packaging (if any) and primary packs 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 Rules>> from appearing on a label.

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 experimental purposes included in <<reference to relevant sections of the Medicines Rule>> or which are intended for other special access purposes specified in <<reference to relevant sections of the Medicines Rule>>;
- (b) are intended for use solely as investigational medicines;
- (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 to Item, Part and Schedule of the Medicine Rule>>;
- (f) are medicinal gases;
- (g) are export-only medicines;
- (h) are made up or compounded by a pharmacist, or a person in the course of his or her employment by a pharmacist and under the direct personal supervision of that pharmacist, in accordance with the individual prescription of a health professional authorised under relevant local 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 health professional 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, by a complementary healthcare practitioner in the lawful practice of his or her profession.

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

5 Interpretation

5(1) In this Order:

‘Act’ has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

Act means:

- (a) for Australia — the *Therapeutic Products Act 2006*; and
- (b) for New Zealand — the *Therapeutic Products and Medicines Act 2006*.]

‘active ingredient’, in relation to a medicine, has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

active ingredient means:

- (a) in relation to a medicine, a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the product as a medicine;]

‘adjuvant’ means an ingredient which, when administered with an antigen, modifies the immune response to that antigen.

‘Administration Rule’ means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Administration) Rule 2006*.

‘Agreement’ has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

Agreement:

- (a) means the Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products, done at Wellington on 10 December 2003; and
- (b) includes that Agreement as amended from time to time.]

‘anthroposophic medicine’ has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

anthroposophic medicine means a medicine that:

- (a) contains one or more anthroposophic preparations; and
- (b) may contain excipients necessary for presentation of the medicine in the final dosage form.]

‘anthroposophic preparation’ has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

anthroposophic preparation means a preparation prepared:

- (a) from one or more mother substances specified, for the purpose of this definition, in an Order; and
- (b) in accordance with:
 - (i) an anthroposophic manufacturing procedure described by an approved anthroposophic reference; or
 - (ii) a homoeopathic manufacturing procedure described in an approved homoeopathic pharmacopoeia.]

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

'Authority' has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

Authority means the Australia New Zealand Therapeutic Products Authority established by section [] of the *Therapeutic Products Act 2006* of Australia.]

'Authority Gazette' has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

Authority Gazette means the publication of that name on the Authority website.]

'<<name of Authority's approved names list>>' has the same meaning as in <<reference to location of definition>>.

[NOTE: the definition as at the date of this Order is as follows: <<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.

'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', **(B)**

'LOT NUMBER', 'LOT NO.', or 'LOT', or words or symbols to this effect. A mixture of lower and upper case letters is acceptable.

'calendar pack' means a 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 a compliance pack which displays day/date markings solely to aid compliance.

'Class 1 medicine' has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: indicative meaning is as follows:

A medicine is a **Class 1 medicine** if it:

- (a) contains only Class 1 permitted ingredients; and
- (b) is any of the following:
 - (i) a medicine that complies with the criteria specified in <<reference to relevant section and Schedule of the Medicines Rule>>; or
 - (ii) a homoeopathic medicine or anthroposophic medicine that complies with the criteria specified in <<reference to relevant section and Schedule of the Medicines Rule>>; or
 - (iii) a sunscreen preparation that complies with the criteria specified in <<reference to section and Schedule of the Medicines Rule>>; or
 - (iv) a medicine of a kind mentioned in <<reference to section and Schedule of the Medicines Rule>> that complies with the criteria specified for that medicine; or
 - (v) a medicine kit that complies with the criterion specified in <<reference to section and Schedule of the Medicines Rule>>; and
- (c) is not an export-only medicine.]

'Class 2 medicine' has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: Indicative meaning is as follows:

- A medicine is a **Class 2 medicine** if it is not:
- (a) a Class 1 medicine; or
 - (b) an export-only medicine; or
 - (c) a medicine in respect of which an exemption or approval under <<reference to section of Medicine Rule relating to exemptions from the requirements of product licensing.>>]

'complementary healthcare practitioner' has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

complementary healthcare practitioner means a herbalist, nutritionist, naturopath, practitioner of traditional medicine, or homoeopathic practitioner.]

'complementary medicine' has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: indicative meaning is as follows:

a **complementary medicine** is:

- (a) a medicine that:
 - (i) does not contain an active ingredient other than a substance:
 - (A) specified in <<reference to Schedule of the Medicines Rule specifying complementary medicine substances>>; or
 - (B) declared in writing by the Authority to be a complementary medicine substance for the purposes of this definition; and
 - (ii) does not contain a substance:
 - (A) specified in <<reference to Schedule of the Medicines Rule specifying substances ineligible for regulation as complementary medicines>>; or
 - (B) declared in writing by the Authority not to be a complementary medicine substance for the purposes of this definition; or
- (b) a homoeopathic medicine; or
- (c) an anthroposophic medicine; or
- (d) an essence.]

'compliance pack' means a 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.

'composite pack' means a pack containing two or more medicines of different kinds which are for administration as a single treatment or as a single course of treatment. It is necessary for the medicines to be combined before administration or be administered in a particular sequence. The pack does not contain any medical devices.

'concentrated solution for injection' means a sterile liquid which must be diluted with another sterile 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.

‘date of production’ 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) that the first step is performed involving combining the active ingredient with other ingredients. For medicinal products consisting of a single active ingredient filled into a container, the initial date of the filling operation is taken as the date of production.

‘delivered dose’ means in relation to:

- (a) pressurised metered dose preparations for inhalation, the dose delivered from the inhaler to the patient in a single actuation or delivery. This may not equate to a therapeutic dose. For those preparations established as a metered dose, the metered amount is determined by adding the amount deposited within the device to the delivered dose. It may be determined directly; and
- (b) powders for inhalation, the dose delivered from the inhaler in a single delivery. This may not equate to a therapeutic dose. For those preparations established as a metered dose, the metered amount is determined by adding the amount deposited within the device to the delivered dose. It may be determined directly.

‘directions for use’ has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

directions for use, in relation to a therapeutic product, includes information on:

- (a) appropriate doses of the product; and
- (b) the method of administration or use of the product; and
- (c) the frequency and duration of treatment for each indication of the product; and
- (d) the use of the product by persons of a particular age or by persons having a particular medical condition.]

‘dispensing pack’, in relation to complementary medicines, means a pack which is to be supplied solely to a complementary healthcare practitioner 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; or
- (e) the contents of the container,

will not, under normal storage conditions, cause the label to deteriorate to the extent of becoming illegible, or become detached during the shelf-life of the medicine.

‘essence’ has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

essence means a preparation that:

- (a) is prepared in accordance with an approved essence manufacturing procedure; and
- (b) is derived from:
 - (i) plant material; or
 - (ii) a mineral; or
 - (iii) non-human animal material; and
- (c) is not derived from a substance that:
 - (i) is included in the Scheduling Standard; or
 - (ii) has the characteristics of a substance that could be included in the Scheduling Standard; and
- (d) may contain excipients necessary for presentation of the preparation in the final dosage form.]

‘excipient’ has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

excipient, in relation to a medicine, means an ingredient of the medicine other than the active ingredient.]

‘expiry date’ has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

expiry date, for a therapeutic product, means the date (expressed as a month and year, or as a day, month and year) after which the product should not be used, being a date that is not more than 5 years after:

- (a) if the particular batch of the product is released less than 30 days after the date of production — the date of release of the batch; or
- (b) if the particular batch of the product is released 30 days or more after the date of production — the date of production of the batch.]

‘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.

‘export-only medicine’ has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: indicative meaning is as follows:

- (1) A medicine is an **export-only medicine** if it is intended to be exported to a country that is not Australia or New Zealand, and will not be supplied in Australia or New Zealand.]

‘health professional’ has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

health professional includes the following:

- (a) a medical practitioner, dental practitioner or pharmacist;
- (b) a health care worker of any kind registered under:
 - (i) for Australia — a law of a State or Territory that provides for the registration of health care workers of that kind; or
 - (ii) for New Zealand — a law of New Zealand that provides for the registration of health care workers of that kind;

- (c) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.]

'herbal material' has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: indicative meaning is as follows:

herbal material means a plant or part of a plant (defined by its botanical scientific name according to the binomial nomenclature system and by the plant part), whether whole, fragmented, cut or ground, and in an unprocessed state (whether fresh or dried).]

'herbal preparation' has the same meaning as in <<reference to Herbal MDO>>.

[NOTE: indicative meaning is as follows:

herbal preparation means any preparation of a herbal material that involves any further processing of the raw herb other than drying, fragmenting, cutting or grinding.]

'homoeopathic medicine' has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

homoeopathic medicine means a medicine that:

- contains one or more homoeopathic preparations; and
- may contain excipients necessary for presentation of the medicine in the final dosage form.]

'homoeopathic preparation' has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

homoeopathic preparation means a preparation prepared:

- from one or more mother substances specified, for the purpose of this definition, in an Order; and
- in accordance with a homoeopathic manufacturing procedure described in an approved homoeopathic pharmacopoeia.]

'homoeopathic potency' has the same meaning as in <<reference to Homoeopathic MDO>>.

[NOTE: indicative meaning is as follows:

homoeopathic potency means the dilution factor of a homoeopathic preparation, expressed as:

- '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
- '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 ; or
- 'nM' where each dilution is 1000 centesimal dilutions; or
- 'nLM' or 'LMn', where each dilution of a 3C dilution is a fifty millesimal or fifty thousand fold dilution and 'n' is the number of dilutions such that the total dilution is $50,000^n$.]

'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.

'intermediate packaging' means a level of packaging which, if it exists, encloses one or more containers and is itself enclosed in a primary pack. Intermediate packaging is generally used to provide additional product protection, or to permit consolidation of products for ease of handling.

Examples of intermediate packaging include foil satchels enclosing aerosol inhalers and lidded trays holding injection ampoules or vials.

'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, any intermediate packaging and any primary pack containing the medicine.

'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 product name is more or most conspicuously shown; or
- (c) where the product name is equally conspicuous on two or more labels or portions of a label – that label or portion of the label designated as the main label.

'medicine' has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: indicative meaning is as follows:

- (1) For the purposes of this Rule, a therapeutic product is a **medicine** if it is a substance or combination of substances that:
 - (a) is presented as having properties for treating or preventing a disease, ailment, defect or injury in human beings; or
 - (b) may be used in human beings with a view to making a medical diagnosis or to restoring, correcting, maintaining or modifying physiological functions; or
 - (c) is declared to be a medicine by an order under paragraph (3) (a).
- (2) However, a therapeutic product is not a medicine for the purposes of this Rule if it is so declared by an Order under paragraph (3) (b).
- (3) The Authority may by Order declare that, for the purposes of the Rules, a therapeutic product:
 - (a) is a medicine; or
 - (b) is not a medicine.]

'medicine kit' means a pack containing two or more medicines that are for use as a unit but the pack and medicines contained in it do not constitute a composite pack. The pack does not contain any medical devices.

'Medicines Rule' means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*.

'mother substance' has the same meaning as in the Medicines Rule.

[NOTE: indicative meaning is as follows:

mother substance means a homoeopathic, anthroposophic or essence starting material derived from a plant or a plant material, an alga, a fungus, a micro-organism, an animal material or a chemical, and includes a composition of such starting materials;]

'name and address' in respect of the sponsor means the name of the Australian or New Zealand sponsor of the product 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 registered place of business in Australia or New Zealand, not being a post office 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 Authority's approved names list>>; or
- (b) where the ingredient is a homoeopathic or anthroposophic preparation, or an essence, the name of the mother substance specified in <<reference to Homoeopathic MDO>>, together 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 Authority'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 Authority's approved names list>>.

'native extract' has the same meaning as in <<reference to Herbal MDO>>.

[NOTE: indicative definition is as follows:

native extract means material consisting only of components present in the original plant, or formed during the extraction process, excluding any excipients or other added substances. This term may refer to liquid extracts or semi-solid extracts from which the added solvent has been removed, or may refer to a dry extract, or that portion of a finished extract, that is comprised solely of plant components.]

'nominal capacity' means the quantity of product which the container is deemed to contain, as stated on the label.

'nominal volume' means the volume of product which the container is deemed to contain, as stated on the label.

'non-proprietary name' means 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.

'primary pack' has the same meaning as in the Administration Rule.

[NOTE: indicative meaning is as follows:

primary pack, in relation to a therapeutic product, means the complete pack in which the product is, or the product and its container are, to be supplied to consumers.]

'product' means a medicine.

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

‘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 nominal weight of the solid or semi-solid in the container;
 - (ii) a liquid, other than a biological product - the nominal volume of the liquid in the container;
 - (iii) a pressurised metered-dose preparation or dry powder inhaler - the stated number of deliverable doses in the container;
 - (iv) a non-pressurised metered dose preparation - the minimum number of deliverable 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 nominal 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 Rules made by the Ministerial Council under article 9 of the Agreement.

‘<<required advisory statements for medicine labels’ or other title as agreed >> means the document of that name, published by the Australia New Zealand Therapeutic Products Authority on <<publication details>>.

‘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.

‘Scheduling Standard’ means the register known as the Standard for the Uniform Scheduling of Medicines and Poisons established and maintained by the Authority under <<reference to relevant Part>> of the Administration Rule, as amended from time to time under that Part.

‘signal words’ 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 or relevant New Zealand legislation>>.

‘small container’ means a container which has a nominal capacity less than or equal to 20 millilitres or 20 grams.

‘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 the Administration Rule.

[NOTE: indicative meaning is as follows:

sponsor, in relation to a therapeutic product, means:

- (a) a person who imports, or arranges the import of, the product; or
- (b) a person who exports, or arranges the export of, the product; or
- (c) a person who, 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:

- (d) imports, exports or manufactures the product; or
- (e) arranges the importation, export or manufacture of the product; on behalf of another person who, at the time of the importation, export, manufacture or arrangements, is a resident of, or is carrying on business in, Australia or New Zealand.

‘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.

‘Sun protection factor’ (SPF) means the protection factor indicated on the container of a sunscreen product. Also called the ‘label protection factor’.

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

‘unique identifier’, in relation to a medicine, has the meaning given by <<reference to relevant section>> of the Medicines Rule.

[NOTE: indicative meaning is as follows:

unique identifier means a set of numbers, or letters and numbers, that is unique to a medicine, or to medicines of that kind.]

‘very small container’ means a container having a nominal capacity less than or equal to 2 millilitres or 2 grams.

‘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 the Australia New Zealand Therapeutic Products Authority 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) where the medicine is for external use, the words ‘Caution: Not to be Swallowed’, 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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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) 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, except for embossed or debossed characters; and
- (f) unless otherwise specified in this Order, in a metric unit of measurement.

6(2) The label must be:

- (a) durable, and
- (b) in such a position that it is not damaged, defaced, destroyed, or removed when the packaging is opened, except for containers such as blister or strip packs and sachets containing individual dosage units and which must be cut or torn to access the contents, provided that that container is enclosed in a primary pack that fully complies with the requirements of this Order.

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 on the container and primary pack 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 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 that requirement must also appear on the label.

Where the product is a Class 2 medicine that can only be supplied in accordance with the individual prescription of a health professional authorised under relevant local legislation to prescribe and there is insufficient space on the label of the container or the primary pack to include the <<Label-Name>> of any excipients listed in Column 1 of the First Schedule together with any additional statement as required by Column 2 of the First Schedule, then it shall be sufficient compliance with this paragraph if this information is set out in a leaflet inserted in the primary pack of the medicine.

- (e) the name of the dosage form;
- (f) the quantity of the medicine;
- (g) warning statements, where these apply to the medicine;
- (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:
- (i) the medicine can only be supplied in accordance with the individual prescription of a health professional authorised under relevant local legislation to prescribe; or
 - (ii) the dose of the medicine is usually determined for each individual patient by a health professional authorised under relevant local legislation to determine the dose; or
 - (iii) there is insufficient space on the label of the container or the primary pack to include directions for use, in which case it shall be sufficient if those directions for use are set out on a leaflet inserted in the primary pack of the medicine and a statement is included on the label on the container or the primary pack, as the case may be, that those directions are set out on the enclosed leaflet; or
 - (iv) the medicine is a homoeopathic or anthroposophic medicine that meets the requirements of <<reference to Schedule and Part of the Rules relating to homoeopathic and anthroposophic medicines and preparations exempt from product licensing>>;
- (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 where:
- (i) the medicine can only be supplied in accordance with the individual prescription of a health professional authorised under relevant local legislation to prescribe; or
 - (ii) the medicine is a dispensing pack supplied solely to a complementary healthcare practitioner, and includes on the label the words 'For Practitioner Dispensing Only';
 - (iii) the medicine is a homoeopathic or anthroposophic medicine that meets the requirements of <<reference to Schedule and Part of the Rules relating to homoeopathic and anthroposophic medicines and preparations exempt from product licensing >>;
- (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 or relevant New Zealand legislation>>;
 - (p) where the medicine is included in the <<name of new Register>>, the unique identifier; and
 - (q) 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.
- 7(2) Where a primary pack encloses more than one container of the same medicine then, in addition to the requirements of clause 7(1), the label on the primary pack must include a statement of the number of containers within that primary pack.
- 7(3) Where intermediate packaging (if any) is opaque, then the label on the intermediate packaging 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) the batch number of the medicine preceded by the batch number prefix;
 - (e) the expiry date of the medicine preceded by the expiry date prefix; and
 - (f) the name or registered trademark of the sponsor of the medicine.

8 Particulars to be included on a main label

- 8(1) Subject to the qualifications and special requirements specified in subclauses 8(2), 8(3), 8(4), 8(5) and 8(6) 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 or relevant New Zealand legislation >>.
- 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 product is a Class 1 medicine other than a sunscreen product:
- (a) the name of every active ingredient, together with the quantity or proportion of every active ingredient, must be displayed on the main label in a letter height of not less than 1.5 millimetres,
except that:
 - (b) where there are two or more active ingredients in the medicine, 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 in a letter height of not less than 1.5 millimetres.
- 8(4) Where the product is a Class 1 medicine that is a sunscreen product, the name of every active ingredient, together with the quantity or proportion of every active ingredient, and the name of the dosage form, may be included on a side panel or side label or on a rear panel or rear label of the container and any primary pack.
- 8(5) Where the product is a Class 2 medicine that can only be supplied in accordance with the individual prescription of a health professional authorised under relevant local legislation to prescribe, or is a medicine for injection:

- (a) the name of every active ingredient, together with the quantity or proportion of every active ingredient, must be prominently displayed adjacent to, or immediately under, the product name 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,

except that:

- (b) where there are five or more active ingredients in the medicine, it shall be sufficient compliance with this subclause if the names of every active ingredient, 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, in a letter height that is not less than 2 millimetres.

8(6) Where the product is a Class 2 medicine to which subclause 8(5) does not apply:

- (a) the name of every active ingredient, together with the quantity or proportion of every active ingredient, must be prominently displayed on the main label in a letter height that is not less than 2 millimetres,

except that:

- (b) where there are five or more active ingredients in the medicine, it shall be sufficient compliance with this subclause if the names of every active ingredient, 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, in a letter height that is not less than 2 millimetres.

8(7) 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 the 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 subclause 9(14) or 9(15) 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 unless otherwise justified and authorised; 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 unless otherwise justified and authorised, or where the shelf life of the prepared medicine is less than four weeks, this lesser period must 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 label must include the word 'oily' in or adjacent to the product name.

9(2) Injections with nominal volume greater than 100 millilitres

- (a) Where the medicine is an injection that has a nominal volume greater than 100 millilitres, the label on the container and on the primary pack must comply with clauses 7 and 8, and subclause 9(8) (Biological Products) if applicable, subject to the following qualifications:
 - (i) where there is no trade name for 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) 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) 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 nominal volume of injection in the container.
- (b) In addition to the requirements of clauses 7 and 8 and subclause 9(2)(a), and subclause 9(8) (Biological Products) if applicable, the label on the container and on the primary pack of an injection having a nominal volume greater than 100 millilitres must include:
 - (i) the names and quantities of all excipients in the nominal volume of injection in the container;
 - (ii) where one or more active ingredients are amino acids and/or protein, a statement giving the total amount of nitrogen, in grams, in the nominal volume of injection in the container;
 - (iii) where the medicine is intended for use as an energy source, a statement of the energy equivalent, in kilojoules, of the nominal 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 with nominal volume of 100 millilitres or less

Except where subclause 9(4) or 9(5) applies, where the medicine is an injection that has a nominal volume of 100 millilitres or less, or is a powder for injection or a concentrated solution for injection, in addition to the requirements of clauses 7 and 8, and subclause 9(8) (Biological Products) if applicable, the label on the container and on the primary pack must include:

- (a) where the medicine is a powder for injection or concentrated solution for injection, the words 'for injection' in or adjacent to the product name on the main label;
- (b) where the medicine is an injection which consists of a solution or a suspension in an oil, the word 'oily' in or adjacent to the product name on the main label;
- (c) the name and quantity of each excipient in the medicine, expressed:
 - (i) for single dose injections - as the quantity of that excipient in the nominal volume of injection in the container;

- (ii) for a powder for injection or a concentrated solution for injection - as the quantity of that excipient in the container; or
- (iii) 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 nominal volume is less than one millilitre;
- (d) 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;
- (e) where the medicine is a concentrated solution for injection:
 - (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
- (f) where the medicine is an injection containing a radio-contrast agent, a statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre.

9(4) Injections with nominal volume of 20 millilitres or less

Except where subclause 9(5) applies, where the medicine is an injection that:

- (a) has a nominal volume of 20 millilitres or less; and
- (b) the container is enclosed in a primary pack that fully complies with the requirements of this Order,

then,

- (c) in relation to the label on the container, it shall be sufficient compliance with clauses 7 and 8 and subclause 9(3), and subclause 9(8) (Biological Products) if applicable, if there are set out on the label on the container the following particulars in a letter height of not less than 1.5 millimetres:
 - (i) the product name;
 - (ii) the name(s) of all active ingredients in the medicine;
 - (iii) the quantity or proportion of all active ingredients in the medicine;
 - (iv) the name of the dosage form;
 - (v) the quantity of the medicine;
 - (vi) the batch number of the medicine preceded by the batch number prefix;
 - (vii) the expiry date of the medicine preceded by the expiry date prefix;

- (viii) the name or registered trade mark of the sponsor or the trade name of the medicine;
- (ix) the approved route of administration for the medicine, such as 'intravenous', 'intramuscular' or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration;
- (x) if the medicine is a concentrated solution for injection, a direction not to administer the solution undiluted; and
- (xi) if the injection is a biological product, the name of any adjuvants in the medicine.

9(5) Injections with nominal volume of 2 millilitres or less

Where:

- (a) the medicine is an injection that has a nominal volume of 2 millilitres or less;
- (b) the container is enclosed in a primary pack that fully complies with the requirements of this Order;
- (c) the medicine has two or more active ingredients; and
- (d) the product name is unique and unequivocally identifies the product,

then,

- (e) in relation to the label on the container, it shall be sufficient compliance with clauses 7 and 8 and subclause 9(3), and subclause 9(8) (Biological Products) if applicable, if there are set out on the label on the container the following particular in a letter height of not less than 1.5 millimetre:

- (i) the product name,

together with the following particulars in a letter height of not less than 1 millimetre:

- (ii) the quantity of the medicine;
- (iii) the batch number of the medicine preceded by the batch number prefix;
- (iv) the expiry date of the medicine preceded by the expiry date prefix; and
- (v) the approved route of administration for the medicine, such as 'intravenous', 'intramuscular' or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration; and
- (vi) if the medicine is a concentrated solution for injection, a direction not to administer the solution undiluted.

Where all conditions given in subclauses 9(5)(a), 9(5)(b), 9(5)(c) and 9(5)(d) above are not satisfied, then the requirements of subclause 9(4) (Injections with Nominal Volume of 20 Millilitres or Less) apply notwithstanding the nominal volume of the injection being 2 millilitres or less.

9(6) 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(7) 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(8) Biological products

In addition to the requirements referred to in clauses 7 and 8 and subclause 9(3) if applicable, 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 Authority's approved names list for biologicals>> 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 Authority's approved names list for biologicals>>;

- (e) for monoclonal antibodies, the name of the origin of the hybridoma cell line, as specified in the <<name of the Authority's approved names list for biologicals>>, 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 Authority's approved names list for biologicals>> 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 Authority's approved names list for biologicals >>, from which the medicine has been prepared.

9(9) Homoeopathic and anthroposophic medicines

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

- (a) the main label on the container and the main label on the primary pack (if any) must include a prominent statement indicating that the product is a homoeopathic medicine or an anthroposophic medicine (as appropriate);
- (b) where the medicine is a homoeopathic or an anthroposophic medicine that meets the requirements of <<reference to Schedule and Part of the Rules relating to homoeopathic and anthroposophic medicines and preparations exempt from product licensing>>, then the label should include:
 - (i) a statement to the effect that the medicine is only to be used in accordance with homoeopathic or anthroposophic principles (as the case requires); and
 - (ii) the Good Manufacturing Practice (GMP) licence number of the manufacturer.

9(10) Formulations containing both homoeopathic preparations 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 preparations, and other active ingredients that are not homoeopathic preparations:

- (a) the main label on the container and the main label on the primary pack (if any) must include a prominent statement indicating that the product contains homoeopathic preparations or anthroposophic preparations (as appropriate); and
- (b) the label on the container and the label on the primary pack (if any) must differentiate ingredients that are homoeopathic preparations, from those that are not, such as by including the statement 'contains homoeopathic preparations of' adjacent to the list of homoeopathic ingredients, or by prefacing the name of the homoeopathic active ingredient with the term 'homoeopathic'.

9(11) Sunscreen preparations

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

9(12) 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,

- (d) 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:
 - (i) the product name given to the kit;
 - (ii) the name and address of the sponsor of the kit;
 - (iii) the product name of all medicines within the kit and their dosage form;
 - (iv) the name, and quantity or proportion, of all active ingredients in each of the medicines within the kit;
 - (v) the quantity of the goods for each medicine within the kit;
 - (vi) a statement of purpose for each medicine within the kit;
 - (vii) 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;
 - (viii) the unique identifier given to the kit;
 - (ix) the batch number of the kit preceded by the batch number prefix;
 - (x) an expiry date for the kit, being the earliest expiry date of the medicines within the kit, preceded by the expiry date prefix;
 - (xi) any warning statements that relate to the medicines within the kit;
 - (xii) 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;

- (xiii) storage conditions applicable to the kit, being the most restrictive of the storage conditions for the medicines within the kit; and
- (xiv) the applicable signal words, written as specified in the <<Scheduling Standard or relevant New Zealand legislation>>, 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 must be the signal words indicating the most restrictive classification.

9(13) Starter Packs

Where the medicine can only be supplied in accordance with the individual prescription of a health professional authorised under relevant local legislation to prescribe 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 and contact details, 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.

9(14) Small containers (not including injections)

Except where subclause 9(15) applies, where:

- (a) the medicine is enclosed in a small container but is not an injection; and
- (b) the container is enclosed in a primary pack that fully complies with the requirements of this Order,

then,

- (c) in relation to the label on the container, it shall be sufficient compliance with clauses 7 and 8, and subclauses 9(1) (Preparations for Ophthalmic Use) and 9(8) (Biological Products) if applicable, if there are set out on the label on the container the following particulars in a letter height of not less than 1.5 millimetres:
 - (i) the product name;
 - (ii) the name(s) of all active ingredients in the medicine;
 - (iii) the quantity or proportion of all active ingredients in the medicine;

- (iv) the name of the dosage form;
- (v) the quantity of the medicine;
- (vi) the batch number of the medicine preceded by the batch number prefix;
- (vii) the expiry date of the medicine preceded by the expiry date prefix;
- (viii) the name or registered trade mark of the sponsor or the trade name of the medicine;
- (ix) if the medicine is contained in an ampoule, 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;
- (x) if the medicine is scheduled under New Zealand, or Australian State or Territory, legislation, the applicable signal words, written as specified in the <<Scheduling Standard or relevant New Zealand legislation>>;
- (xi) if the medicine:
 - (A) is an ophthalmic preparation 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 unless otherwise justified and authorised; or
 - (B) 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 unless otherwise justified and authorised, or where the shelf life of the prepared medicine is less than four weeks, this lesser period must be stated; and
- (xii) if the product is a biological product, the name of any adjuvants in the medicine,

9(15) Very small containers (not including injections)

Where:

- (a) the medicine is enclosed in a very small container but is not an injection;
- (b) the container is enclosed in a primary pack that fully complies with the requirements of this Order;
- (c) the medicine has two or more active ingredients; and
- (d) the product name is unique and unequivocally identifies the product,

then,

- (e) in relation to the label on the container, it shall be sufficient compliance with clauses 7 and 8, and subclauses 9(1) (Preparations for Ophthalmic Use) and 9(8) (Biological

Products) if applicable, if there are set out on the label on the container the following particular in a letter height of not less than 1.5 millimetres:

- (i) the product name,

together with the following particulars in a letter height of not less than 1 millimetre:

- (ii) the quantity of the medicine;
- (iii) the batch number of the medicine preceded by the batch number prefix;
- (iv) the expiry date of the medicine preceded by the expiry date prefix; and
- (v) if the medicine is contained in an ampoule, 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.

Where all conditions given in subclauses 9(15)(a), 9(15)(b), 9(15)(c) and 9(15)(d) above are not satisfied, then the requirements of subclause 9(14) (Small Containers) apply notwithstanding the nominal capacity of the container being less than or equal to 2 millilitres or 2 grams.

9(16) Individually wrapped products

- (a) Where:

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

then,

- (v) in relation to the label on each individual wrapper, sachet or blister, irrespective of whether these are sealed or unsealed, it shall be sufficient compliance with this Order if there are set out, on the individual wrapper, sachet or blister, the following particulars:
 - (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 batch number of the medicine preceded by the batch number prefix;
 - (E) the expiry date of the medicine preceded by the expiry date prefix; and

(F) the name or registered trademark of the sponsor of the medicine,

except that:

(b) where:

- (i) the medicine consists only of pastilles or lozenges;
- (ii) each dosage unit is individually wrapped in an unsealed protective cover; and
- (iii) each dosage unit is, after being so wrapped, enclosed in a primary pack that 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.

(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(17) 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,

(v) 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:

(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 batch number of the medicine preceded by the batch number prefix;
- (E) the expiry date of the medicine preceded by the expiry date prefix; and
- (F) 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 Class 1 medicine,

then,

(iii) in relation to the label on the container, it shall be sufficient if there are set out on that container, the following particulars:

- (A) the product name;
- (B) the batch number of the medicine preceded by the batch number prefix; and
- (C) the expiry date of the medicine preceded by the expiry date prefix.

(c) In addition to the requirements referred to in subclauses 9(17)(a) or 9(17)(b) as applicable, where 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(18) Plastic ampoules

(a) Where:

- (i) a medicine is contained in a plastic ampoule, irrespective of whether it is a medicine for injection or not;
- (ii) the nominal volume of the medicine in the plastic ampoule is less than 5 millilitres;
- (iii) two or more ampoules are attached to a connecting strip; and
- (iv) the ampoules and their connecting strip are enclosed in a primary pack that fully complies with the requirements of this Order,

then the information required by this Order to appear on the label of the container of the medicine may be divided between the ampoule and the connecting strip, subject to the following provisions.

- (b) As a minimum requirement, and irrespective of whether or not the seal is broken when an ampoule is detached, the following information must appear on the label of each ampoule:
- (i) the product name;
 - (ii) the quantity or proportion of all active ingredients in the medicine expressed as the amount of active in the nominal volume of the ampoule;
 - (iii) the batch number of the goods preceded by the batch number prefix;
 - (iv) the expiry date of the goods preceded by the expiry date prefix; and
 - (v) the approved route of administration.
- (c) All other information required by this Order to appear on the label of the container of the medicine may appear on either each ampoule or the connecting strip.

9(19) Composite packs

- (a) Where a medicine is contained in a composite pack, the label of each medicine in the composite pack, and the label on the primary pack of the composite pack, must comply fully with the requirements of this Order.
- (b) Where the 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 must be the expiry date of the component with the shorter shelf life.
- (c) Where the primary pack contains more than one kind of item which have different storage conditions, the storage conditions included on the label on the primary pack must be the most restrictive of the storage conditions for the medicines within the composite pack.

10 Expression of Particulars

10(1) Use of appropriate metric units

- (a) For active ingredient(s), where a particular is a statement of mass for which there is a metric unit of measurement, the appropriate metric units must be as follows:
- (i) a statement of quantity for 1 microgram up to 999 micrograms inclusive must be expressed in terms of micrograms;
 - (ii) a statement of quantity for 1000 micrograms may be expressed as either 1000 micrograms or 1 milligram;
 - (iii) a statement of quantity for more than 1 milligram up to 999 milligrams inclusive must be expressed in terms of milligrams;
 - (iv) a statement of quantity for 1000 milligrams may be expressed as either 1000 milligrams or 1 gram; and
 - (v) a statement of quantity for more than 1 gram up to 999 grams inclusive must be expressed as grams,
- except that:
- (vi) where a range of medicines contain the same active ingredient or ingredients in the same dosage form in a series of strengths, the labels must state the quantity of each active ingredient in terms of either the highest or lowest metric unit of measurement in the series of strengths for each active ingredient. For example, a range of expressions of the active ingredient would be stated as 0.5 milligram, 1 milligram and 5 milligrams, or 500 micrograms, 1000 micrograms and 5000 micrograms, rather than 500 micrograms, 1 milligram and 5 milligrams.
- (b) Where the active ingredient is in liquid form, the equivalent metric units of volume should be used. For example, a statement of volume for more than 1 millilitre up to 999 millilitres inclusive must be expressed in terms of millilitres, but a statement of volume for 1000 millilitres may be expressed as either 1000 millilitres or 1 litre.
- (c) Where a statement of quantity is expressed as less than unity, the statement of quantity must include the leading zero.

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), 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, except that where the liquid for ingestion is one of a series of strengths containing the same active ingredient, the quantity or proportion of active ingredient must be expressed consistently across the series in terms of the same stated dose volume. For example, a range of liquids for

ingestion containing the same active ingredient in different strengths would be stated as 1 milligram per millilitre and 5 milligrams per millilitre rather than 1 milligram per millilitre and 25 milligrams per 5 millilitres;

- (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 or an anthroposophic preparation:
 - (i) notwithstanding subclauses (a), (b) and (c), as the quantity of the preparation in one millilitre or in one gram of the medicine, or
 - (ii) where the product is a fully potentised, single ingredient, homoeopathic or anthroposophic medicine, it is sufficient to state the ingredient name and potency, providing it is clear that the ingredient comprises 100% of the product; or
 - (iii) where all ingredients are homoeopathic or anthroposophic preparations, which are all included in the medicine in the same proportion, expressed as 'Contains equal parts of..' followed by the name and potency of each homoeopathic or anthroposophic 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, except that where the medicine is one of a series of strengths containing the same active ingredient, the quantity or proportion of active ingredient must be expressed consistently across the series in terms of the same stated dose volume;
- (g) for a medicine for injection:
 - (i) where the product is a powder for injection or a concentrated solution for injection – as the nominal quantity of the active ingredient in the container; or
 - (ii) where the nominal volume of the injection is greater than 100 millilitres, and the product is 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 injection:
 - (A) as the number of millimoles in the nominal 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 nominal volume of the injection in the container for each active ingredient for which the molecular weight is not precisely known; or
 - (iii) where the nominal volume of the injection is greater than 100 millilitres and the product contains 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 nominal volume of injection in the container; or

(iv) for other medicines for injection, whether intended for multi- or single dose use:

(A) where the nominal 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) where the nominal volume in the container is less than or equal to 1 millilitre, as the quantity of the active ingredient in the nominal 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 the product name may not state the quantity of active ingredient per millilitre;

(h) for antibiotic preparations, where there is no accepted unit of mass and 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 medicines containing an ingredient which is a herbal material, such as a dry, fresh, milled or powdered herb - as the weight of the herbal material;

(l) for medicines containing an ingredient derived from a herbal material:

(A) where a herbal preparation is an oil, fresh juice or dry juice - as the quantity of the herbal preparation; or

(B) where a herbal preparation is an extract, tincture, decoction, infusion or spagyric - as the quantity of the native extract, as well as the dry weight of the herbal material from which the preparation was derived, except:

a. where the herbal preparation is a traditional fresh herb preparation, in which case the fresh weight of the herbal material from which the preparation was derived may be quantified; or

b. where the herbal preparation is a fresh or dry plant tincture, with a native extract ratio of 1:1 or less (ie 1:2, 1:5, etc.), in which case the weight of the herbal material from which the preparation was derived need only be quantified; or

c. where the herbal preparation is a standardised extract, the amount of the standardised component(s) must also be quantified;

- (C) where a herbal preparation is a concentrated or diluted juice - as the quantity of the raw material juice used to make the concentrate or dilution as well as the dry weight, fresh volume or fresh weight of the herbal material from which the preparation was derived;
- (m) 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;
- (n) for preparations containing Vitamin A - as the quantity or proportion of Vitamin A expressed in terms of International Units (IU);
- (o) 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 <<insert name of default pharmacopoeia(s)>> and the dose has been established as a metered dose in which case it should be expressed as the metered amount. 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;
- (p) 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;
- (q) 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;
 - (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 and supported by the World Health Organisation. Where International Units have not

been established, then the potency unit used is to be as agreed by the Managing Director of the Authority.

- (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 (Particulars to be Included on a Label) , the following statements of storage conditions are permitted:
 - (i) 'Store below -18°C (Deep freeze)';
 - (ii) 'Store below -5°C (Freeze)';
 - (iii) 'Store below 8°C (Refrigerate)';
 - (iv) 'Store at 2°C to 8°C (Refrigerate. Do not freeze)';
 - (v) 'Store below 25°C '; and
 - (vi) 'Store below 30°C ';
- (b) If none of the statements of storage conditions included in subclauses (i) to (vi) inclusive are applicable, the sponsor of the medicine must apply to the Managing Director of the Australia New Zealand Therapeutic Products Authority for permission to use an alternative statement.

First Schedule

Excipients required to be declared on the label of medicines

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 ingredient names for excipients in that group. The term 'and their products' refers to all products derived from the named ingredient where the derived product can reasonably be expected to cause or be associated with the same clinical response in susceptible individuals.

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>>
Aspartame		Oral	Aspartame
Benzoates , including: Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate		All	Benzoates
Crustacea and Crustacean products (see Note 1), including: Crab Lobster Shrimp - white		All	Crustacea; or Crustacean products

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>>
Egg and egg products , including: Egg – whole Egg yolk – dried Lecithin - egg		All	Egg; or Egg products
Ethanol	Condition: Where present in a concentration of greater than 3% v/v.	All	Alcohol
Fish and fish products (see Note 2), including: Cod Cod – liver oil Halibut Tuna		All	Fish; or Fish products
Galactose		Oral	Galactose
Gluten or excipients derived from gluten-containing grains (see Note 3)	Condition: Where gluten or an excipient derived from gluten-containing grains is present.	All, other than skin and mucous membrane applications	Gluten
Hydroxybenzoic acid esters , including: Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate Sodium propyl hydroxybenzoate		All	Hydroxybenzoates
Lactose (see Note 4)	Condition: Where present, notwithstanding the entry for lactose under 'Sugars – Monosaccharides and disaccharides'.	Oral	Lactose

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>>
Milk and milk products , including: Milk – nonfat dry Milk – whole dry Milk protein – hydrolysed		All	Milk; or Milk products
Peanuts and peanut products , including: Arachis hypogaea Arachis (peanut) oil		All	Peanuts; or Peanut products
Phenylalanine		All, other than skin and mucous membrane applications	Phenylalanine
Pollen, including Bee Pollen	Requirement: To include a statement to the effect that the product contains pollen (or Bee Pollen as applicable), which may cause severe allergic reactions.	Oral	Pollen (or Bee Pollen as applicable)
Potassium salts , including: Potassium chloride Potassium bicarbonate Potassium clavulanate	Requirement: To declare on the label (in mg) the quantity of elemental potassium per maximum recommended daily dose.	Oral	Potassium
Propolis	Requirement: To include a statement to the effect that the product contains propolis which may cause severe allergic reactions.	Oral	Propolis
Royal Jelly	Requirement: 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

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>>
Saccharin , including: Saccharin calcium Saccharin sodium		Oral	Saccharin
Sesame seeds and sesame seed products , including: Sesame seed Sesame oil Sesamum indicum		All	Sesame seeds; or Sesame seed products
Sodium salts , including: Sodium bicarbonate Sodium chloride	Condition: Where the total sodium content of the maximum recommended daily dose of the formulation is greater than 120 mg. Requirement: To declare on the label (in mg) the quantity of elemental sodium per maximum recommended daily dose.	Oral	Sodium
Soya beans and soya bean products , including: Glycine max Soya bean Soya oil Soyabean oil		All	Soya beans; or Soya bean products
Sorbates , including: Potassium sorbate Sorbic acid		All	Sorbates

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>>
Sugar alcohols , including: Isomalt Lactitol Maltitol Mannitol Sorbitol Xylitol	Condition: Where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose. Requirement: 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'.	Oral	Sugar alcohols
Sugars – Monosaccharides and disaccharides (see Note 4), including: Glucose Honey (as a mixture of sugars) Invert sugar Lactose Maltose Sucrose	Condition: 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.	Oral	Sugars
Sulfites , including: Sulfur dioxide Potassium metabisulfite Sodium bisulfite Sodium metabisulfite Sodium sulfite		All	Sulfites
Tartrazine	See Note 5	All	Tartrazine CI 19140

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>>
Tree nuts and tree nut products (see Note 6), including: Macadamia nut oil Macadamia ternifolia Almond oil Prunus dulcis Walnut Juglans nigra		All	Tree nuts; or Tree nut products

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.

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 Authority's Guidelines for the Registration of 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 Orders>> requires therapeutic products including medicines to comply with standards. These standards include standards for labelling and packaging. However a mechanism is included in <<insert reference to the Rules>> 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 of the medicine is required to apply in writing to the Australia New Zealand Therapeutic Products Authority 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 Australia New Zealand Therapeutic Products Authority 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 Medicines

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

The Australia New Zealand Therapeutic Products Authority Code of Good Manufacturing Practice for Medicinal Products includes, as an Annex (<<insert Annex number>>), requirements pertaining to investigational medicines. These requirements include labelling and packaging instructions. The labelling requirements can be obtained at: <<insert relevant link to website>>.

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 <<appropriate reference to the Medicines Rule>>.

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 sponsor's original 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 the 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 Australia New Zealand Therapeutic Products Authority 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, expiry dates and prefixes

The definition of batch number requires the number, or combination of numbers, symbols or letters, given by a sponsor of a medicine to a batch of medicine, to uniquely identify that batch, such that it is possible to trace that batch through all stages of manufacture and distribution.

To assist consumer recognition of affected products in recalls, and to circumvent concerns over possible tampering, it is preferred that the same batch number be used on all levels of packaging for any single batch of product. Where, for manufacturing reasons, this is not possible, it is desirable that there be a clear and obvious relationship between the batch numbers shown on the labels of each component 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. One method of achieving a clear and obvious relationship would be to utilise a variable prefix or suffix attached to common numbers or letters (for example, Batch 123A, 123B etc).

It is considered that the expiry date may be misunderstood if different levels of packaging on a single product use a mix of the expiry date prefixes 'expires' (or its variants) with 'use before' (or its variants). Although the Order does not require use of the same expiry date prefix on all levels of packaging showing the expiry date, sponsors are encouraged to use consistent terminology for the expiry date prefix on all levels of packaging.

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

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.

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 of medicines 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. '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. To avoid ambiguity of the message, only positive statements should appear on medicine labels. For example, '*For intravenous use only*' is preferred to a negative statement such as '*not for intravenous use*'. The end result also should be that the label is visually appealing, making locating and understanding the information easy.

Text in languages or characters other than English may be included on labels, provided that mandatory information is in English in the first instance.

There is significant potential for misinterpretation of some non-Anglicised characters or PinYin names, due to phonetic similarities or the fact that they may not represent specific names or words, but represent descriptions of actions, uses or physical characteristics of the medicine, which may potentially lead to interchange of ingredients or uses. Therefore, where non-Anglicised characters or PinYin names are present on a label, a certified English translation of such characters or names must be provided to the Authority to verify that the interpretation of the terms is valid and appropriate.

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 Class 2 medicines that can only be supplied on prescription 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(5)(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 [subclause 8(5)(b)];

- for other Class 2 medicines, the names of all active ingredients must appear on the main label in a letter height of at least 2 millimetres [subclause 8(6)(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 [subclause 8(6)(b)];
- for medicines that have two or more active ingredients and are either injections with volume no greater than 2 millilitres or 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 which must be no less than 1.5 millimetres) is 1 millimetre. Use of this reduced font size is conditional however on the product name being unique and unequivocally identifying product and the primary pack being fully compliant [subclauses 9(5)(e) and 9(15)(e)]; and
- for sunscreen preparations presented in a container not exceeding 25 millilitres or 25 grams in nominal capacity, the minimum letter height for the required labelling (other than the SPF factor and the unique identifier) is 1 millimetre [subclause 9(11)].

Where the Order requires use of a letter height greater than 1.5 millimetres, there should be a proportionate increase in letter width and spacing.

7. Embossing or debossing

Embossing or debossing of label information can often be associated with problems of visibility and legibility. While this Order does not prohibit the use of embossing or debossing for the display of label information, it is expected that use of embossing or debossing would be limited to batch number and expiry details. The use of embossing (or debossing) for the product name and active ingredient details on plastic ampoules is likely to be unacceptable unless the embossing is of a different colour to enhance legibility.

Sponsors should note that where such labelling techniques are used, the requirements for legibility and durability given in clauses 6(1) and 6(2) are paramount. For this reason, inked embossing is encouraged for batch number and expiry date details on cardboard cartons.

8. Reference to 'name of the dosage form'

Appropriate names for the dosage form can be found in the <<name of Authority's approved names publication >>.

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'.

9. 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 health professional).

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.

10. Name and address of the sponsor

Subclause 7(1)(l) requires that the label include on it the name and address of the sponsor of the medicine, being the legal entity responsible for the product in accordance with the Rules.

Where a sponsor chooses to distribute a product to the market through a separate supplier, the sponsor may include on the label, in addition to their own name and address, the name and contact details for the supplier.

11. 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 of medicines 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.

12. Homoeopathic and anthroposophic preparations

Reference should be made to the <<Homoeopathic MDO >>, and to the <<name for the regulatory guidelines for complementary medicines>>, for further guidance in relation to the naming and expression of homoeopathic and anthroposophic preparations.

The <<name of Authority's approved names list >> sets out the approved name for all permitted mother substances. The full approved name for all homoeopathic or anthroposophic preparations will always comprise the name of the mother substance, directly followed by the homoeopathic potency, for example:

Kali Carbonicum 6X or Lachesis 30C

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 medicine contains more than one active ingredient, the relative quantities should be stated, for example:

Contains equal parts of:

Bryonia 30C

Rhus Toxicodendron 30C

or,

Each 1gram of product contains:

Ledum 30C	2mcL/g*
Berberis vulgaris-mahonia 12X	2mcL/g*

*Where quantity of the homoeopathic preparation is stated, it should be clear to the consumer that the quantity expressed relates to the amount of the potentised homoeopathic preparation included in the dosage form, and not to the amount of the mother substance. It is **not** acceptable to precede the approved name with the quantity "Contains 300mcg Crataegus 12X". It is also **not** acceptable to link the quantity of the preparation directly with the statement of potency (i.e. "Calcaria phosphorica 6X 200mcg/g"), as the consumer may interpret this as meaning that there is '6 times' the amount stated, or that the preparation is '6 times' stronger.

13. Herbal preparations

Reference should be made to the the <<name for the regulatory guidelines for complementary medicines>>, for further guidance relating to:

- the naming, expression and quantification of herbal preparations;
- definitions of herbal preparations, including 'extract' and 'tincture'; and
- abbreviations for names of preparations for use on labels where space is a limiting factor.

14. Expression of 'microgram'

The requirement for the expression of microgram on medicine labels is 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 on a medicine label, the abbreviation applicable to all classes of medicines is 'µg'. Where this abbreviation for microgram is used on the label of a container packed inside a primary pack, the primary pack label should, if space permits, state microgram in full followed by the abbreviation in brackets, that is 'microgram (µg)'.

15. 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 as 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.

16. Expression of quantity or proportion of sodium and potassium when present in excipients

In addition to requirements for quantification of active ingredients, the First Schedule requires potassium and sodium, when present in a medicine as components of excipient ingredients, to be declared on the label. This declaration is to advise of the quantity of potassium or sodium contained in the maximum recommended daily dose and should be expressed as milligrams of elemental potassium or sodium.

However as many health professionals prefer to consider the content of potassium and sodium in terms of millimoles rather than milligram amounts, sponsors are encouraged also to provide equivalent millimolar amounts on the label.