I, <<name of delegate>>, delegate of the Minister for Health and Ageing for the purposes of section 10 of the Therapeutic Goods Act 1989 and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

(1) REVOKE, on and from 1 July 2010, Therapeutic Goods Order No. 69 “General requirements for labels for medicines” made on 27th August 2001; and

(2) DETERMINE that the matters specified in this Order constitute a standard for medicines.

Dated 2008

<<name of delegate>>
Delegate of the Minister for Health and Ageing
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Name of Order

This Order is Therapeutic Goods Order No. 79 General Requirements for the Labelling of Medicines.

Commencement

This Order commences on the day after the day it is registered on the Federal Register of Legislative Instruments.

Transition

(1) Until 30 June 2010, each medicine that is a listed good or a registered good, or that is exempted by the regulations from the operation of Part 3-2 of the Act, must comply with either this Order or Therapeutic Goods Order No. 69 “General requirements for labels for medicines”.

(2) On and from 1 July 2010, each medicine that is a listed good or a registered good, or that is exempted by the regulations from the operation of Part 3-2 of the Act, must comply with this Order.

Introduction

(1) 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, sponsor details and registration/listing status. 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.

(2) 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.

(3) 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 on the Therapeutic Goods Administration website (http://www.tga.gov.au) to assist sponsors in the design of labels for prescription medicines.

(4) 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.

(5) 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. (http://www.communication.org.au) should achieve this aim.

(6) However all medicine labels must comply with this 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 on Prescription Medicine Labelling.

5 Interpretation

(1) In this Order:

Act means the Therapeutic Goods Act 1989, as amended from time to time.

active ingredient means a therapeutically active substance included in a medicine.

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

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

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.

Note 1 Examples of acceptable batch number prefixes include ‘BATCH NUMBER’, ‘BATCH NO.’, ‘BATCH’, ‘B’, ‘B(N)’, ‘LOT NUMBER’, ‘LOT NO.’, or ‘LOT’, or words or symbols to this effect.

Note 2 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.

Note A calendar pack differs from a compliance pack which displays day/date markings solely to aid compliance.

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

compliance pack means a pack containing individual dosage units, and which is labelled with day/date markings solely as an aid to compliance. The order in which the individual dosage units are used has no effect on the therapeutic activity of the medicine.

concentrated solution for injection means a sterile liquid which must be diluted with another sterile liquid in order to prepare an injection.
**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.

*Note* For a medicine 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.

(b) powders for inhalation - the dose delivered from the inhaler in a single delivery.

*Note 1* This may not equate to a therapeutic dose.

*Note 2* 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.

**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; or

(b) atmospheric humidity or dryness; or

(c) normal atmospheric temperatures; or

(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 to become detached, during the shelf-life of the medicine.

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

**expiry date** 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.

*Note 1* 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.

*Note 2* A mixture of lower and upper case letters is acceptable.

**external** in relation to the use of a medicine means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice.
**health professional** includes the following:
(a) a medical practitioner, dental practitioner or pharmacist;
(b) a health care worker of any kind registered under a law of a State or Territory that provides for the registration of health care workers of that kind; or
(c) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

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

**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** means a medicine that:
(a) contains one or more homoeopathic preparations; and
(b) may contain excipients necessary for presentation of the medicine in the final dosage form.

**homoeopathic potency** means the dilution factor of a homoeopathic preparation, expressed as:
(a) ‘nX’ where each dilution is a decimal or ten fold dilution and ‘n’ is the number of dilutions such that the total dilution is $10^n$; or
(b) ‘nC’ where each dilution is a centesimal or hundred fold dilution and ‘n’ is the number of dilutions such that the total dilution is $100^n$; or
(c) ‘nM’ where each dilution is 1000 centesimal dilutions; or
(d) ‘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.

*Note*  Intermediate packaging is generally used to provide additional protection, or to permit consolidation of containers 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 name of the medicine is more or most conspicuously shown; or

(c) where the name of the medicine 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 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.

**name and address** in respect of the sponsor or supplier means the name of the Australian sponsor or supplier of the medicine and sufficient information to allow the sponsor or supplier 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/supplier’s registered place of business in Australia, not being a post office address.

*Note* The Australian telephone number may also be included.

**name of an active ingredient** means:

(a) the name of the active ingredient that is approved for inclusion in the Australian Approved Names List; or

(b) where the ingredient is a homoeopathic preparation:
   (i) either the name of the active ingredient or the substance from which the dilution was prepared, that is approved for inclusion in the Australian Approved Names List, together with a statement of the homoeopathic potency; or
   (ii) until such time as a name appears in the Australian Approved Names List, a traditional homoeopathic name in full or as traditionally abbreviated with a statement of the homoeopathic potency;

**name of an excipient** means the name of the excipient that is approved for inclusion in the Australian Approved Names List.

**name of the dosage form** means a word or words denoting the usual name of the pharmaceutical form of the medicine.

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

**native extract** means the 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 medicine which the container is deemed to contain, as stated on the label.

**nominal volume** means the volume of medicine 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.

Poisons Standard means the current Poisons Standard as defined in section 52A of the Act.

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.

registration or listing number means the combination of numbers, symbols and letters assigned to the goods under section 27 of the Act.

Regulations means the Therapeutic Goods Regulations 1990, as amended from time to time.


scheduled, in relation to a medicine, means a medicine included in Schedule 2, Schedule 3, Schedule 4 or Schedule 8 of the Poisons Standard.

signal words means the words relating to the schedule of the Poisons 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 State or Territory law.

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.

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 preparation.

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.

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 the Required Advisory Statements for Medicine Labels;
(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 Secretary to be included on the label as a condition of registration or listing of the medicine;
(e) any warning statement specified in the Regulations that applies 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.

(2) Terms and expressions used in this Order and defined in the Act have the same meaning in this Order as they have in the Act.

Note Terms and expressions defined in the Act include:
- listed goods
- complementary medicines
- composite pack
- container
- directions for use
- export only medicine
- medicine
- primary pack
- Register
- registered goods
- Secretary
- sponsor

(3) Terms and expressions used in this Order and defined in the Regulations have the same meaning in this Order as they have in the Regulations.

Note Terms and expressions defined in the Regulations include:
- Australian Approved Names List
- herbal substance
- homoeopathic preparation

6 Application
(1) This Order applies to those medicines that come within the operation of the Act.

(2) However, this Order does not apply to a medicine that is exempted under section 7, or in relation to which an exemption from compliance with the standard set out in this Order has been granted by the Secretary in accordance with section 14 or 14A of the Act.
7 Exemptions

(1) This Order does not apply to a medicine that is:

(a) intended for use in the treatment of another person in accordance with the paragraph 19(1)(a) of the Act or which is intended for other special access purposes specified in regulations 12A and 12B;

(b) intended for use solely for experimental purposes in humans; or

(c) a starting material used in the manufacture of a medicine, except when prepackaged for supply for other therapeutic purposes or formulated as a dosage form; or

(d) not at its final stage of manufacture; or

(e) a personal import as described under Item 1 of Schedule 5 of the Regulations; or

(f) a medicinal gas; or

(g) an export-only medicine; or

(h) 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 a law of a State or Territory to prescribe; or

(i) made up or compounded extemporaneously, for a specific or individual case, by a pharmacist in the lawful practice of his or her profession; or

(j) 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) 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; or

(l) intended solely for use in animals.

(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.

8 General requirements including label presentation

(1) The container, intermediate packaging (if any) and primary pack in which a medicine is packed must each bear a label or labels which comply with the requirements of this Order.

(2) The particulars required by this Order to be included on a label or labels must be:

(a) clearly visible and not be obscured; and

(b) in the English language; and

(c) in durable and legible characters; and

(d) unless otherwise specified, in letter height of not less than 1.5 millimetres; and
(e) in a colour or colours contrasting strongly with the statement's background, other than characters that are embossed or debossed; and

(f) unless otherwise specified, in a metric unit of measurement.

(3) 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, unless it is a container such as a blister or strip pack or sachet which individually encloses or seals dosage units in such a way that the container must be cut or torn to access the dosage units, and the container is enclosed in a primary pack that fully complies with the requirements of this Order.

9 Particulars to be included on the label

(1) Subject to the qualifications and special requirements specified in sections 10 and 11 of this Order, the label or labels on a container and primary pack must include:

(a) the name of the medicine; and

(b) the name(s) of all active ingredients in the medicine; and

(c) the quantity or proportion of all active ingredients in the medicine; and

(d) a statement indicating that the medicine contains any ingredient referred to in Column 1 of Schedule 1 if:

(i) this ingredient is present as an excipient in the medicine; and

(ii) any condition stated in Column 2 of Schedule 1 applies in relation to such an ingredient, or no condition is stated in Column 2; and

(iii) the medicine is intended to be administered via any one or more of the route(s) of administration referred to in Column 3 of Schedule 1.

The statement must be expressed using the Label Name stated in Column 4 of Schedule 1, and where any additional requirement is stated in Column 2 of Schedule 1 in relation to such an ingredient, a statement complying with that requirement must also be included.

However if the medicine is included in Schedule 4 or Schedule 8 of the Poisons Standard 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 Schedule 1 together with any additional statement as required by Column 2 of Schedule 1, 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; and

(f) the quantity of the medicine; and

(g) warning statements, where these apply to the medicine; and

(h) the batch number of the medicine preceded by the batch number prefix; and

(i) the expiry date of the medicine preceded by the expiry date prefix; and
(j) the storage conditions applicable to the medicine in accordance with subsection 12(5); and

(k) directions for use of the medicine except where:

(i) the medicine is included in Schedule 4 or Schedule 8 of the Poisons Standard; or

(ii) the dose of the medicine is usually determined for each individual patient by a health professional authorised under a law of a State or Territory 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, and those directions for use are set out in 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 in the enclosed leaflet; and

(l) if the medicine requires some preparation, such as dissolving, suspending, diluting or reconstituting before use - instructions for preparation and a statement of the conditions of storage and the maximum period of storage between preparation and use, except where:

(i) there is insufficient space on the label of the container or the primary pack to include this information; and

(ii) this information is set out in a leaflet inserted in the primary pack of the medicine; and

(iii) a statement is included on the label on the container or the primary pack, as the case may be, that those instructions are set out in the enclosed leaflet; and

(m) the name and address of the sponsor or supplier of the medicine; and

(n) a statement of the purpose or purposes for which it is intended that the medicine be used, except where:

(i) the medicine is included in Schedule 4 or Schedule 8 of the Poisons Standard; 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’; and

(o) if 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; or

(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; and

(p) if the medicine is scheduled - the applicable signal words set out as specified in the Poisons Standard; and
(q) if the medicine is included in the Register - the registration or listing number set out as specified in the Regulations.

Note: Unless otherwise approved by the Secretary, the Regulations require the number to be included:
• on the container label or, if the container is enclosed in a primary pack, on the label on that primary pack; and
• on the main label, or on a securely affixed sticker adjacent to the main label, immediately preceded by ‘AUST R’ in the case of registered goods or ‘AUST L’ in the case of listed goods; and
• the numbers and letters in each case to be not less than 1 millimetre in height.

(2) If a primary pack encloses more than one container of the same medicine then, in addition to the requirements of subsection 9(1), the label on the primary pack must include a statement of the number of containers within that primary pack.

(3) If intermediate packaging (if any) is opaque, then the label on the intermediate packaging must include:

(a) the name of the medicine; and
(b) the name(s) of all active ingredients in the medicine; and
(c) the quantity or proportion of all active ingredients in the medicine; and
(d) the batch number of the medicine preceded by the batch number prefix; and
(e) the expiry date of the medicine preceded by the expiry date prefix; and
(f) the name or registered trademark of the sponsor or supplier of the medicine.

10 Particulars to be included on the main label

(1) Subject to the qualifications and special requirements specified in subsections 10(2), 10(3), and 10(4), and section 11 of this Order, the particulars required under paragraphs 9(1)(a), (b), (c), (e), (f), (o), (p) and (q) must appear on the main label of the medicine.

(2) If the medicine is included in the Part of the Register for goods known as listed goods and:

(a) the medicine is a sunscreen preparation - the name of every active ingredient, together with the quantity or proportion of every active ingredient, and the name of the dosage form, may appear on a side panel or side label or on a rear panel or rear label; or
(b) there are two or more active ingredients in the medicine - the name of every active ingredient, together with the quantity or proportion of every active ingredient, may appear on a side panel or side label or on a rear panel or rear label.

(3) If the medicine is included in the Part of the Register for goods known as registered goods and:

(a) the medicine is included in Schedule 4 or Schedule 8 of the Poisons Standard, or is a medicine for injection - 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 name of the medicine on the main label in a letter height that is not less than 2 millimetres; or

(b) the medicine is not included in Schedule 4 or Schedule 8 of the Poisons Standard - the name of every active ingredient, together with the quantity or proportion of every active ingredient,
ingredient, must be prominently displayed on the main label in a letter height that is not less 2 millimetres.

(4) However if the medicine is included in the Part of the Register for goods known as registered goods and there are five or more active ingredients in the medicine, the names of every active ingredient, together with the quantity or proportion of every active ingredient, may be 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.

(5) Nothing in this Order prevents the inclusion on the main label of any other matters required by this Order to appear on the label of the medicine.

11 Qualifications and Special Requirements

(1) Preparations for ophthalmic use

In addition to the requirements of sections 9 and 10, if a medicine is a preparation for ophthalmic use, the label on the container and on the primary pack or, where subsection 11(14) or 11(15) applies, on the primary pack, must include:

(a) the name of any antimicrobial preservative in the medicine; or

(b) if 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) if 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) if 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; and

(e) if the medicine consists of a solid ophthalmic medicine - the words ‘for eye drops’ or ‘for eye lotion’ (as the case may be) in or adjacent to the name of the medicine; and

(f) if the medicine consists of a solution or a suspension in an oil – the word ‘oily’ in or adjacent to the name of the medicine.

(2) Injections with nominal volume greater than 100 millilitres

(a) If a medicine is an injection having a nominal volume greater than 100 millilitres, the label on the container and on the primary pack must comply with sections 9 and 10, and subsection 11(8) if applicable, subject to the following qualifications:

(i) where there is no trade name for the medicine - the name of the medicine 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 name of the medicine 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 name of the medicine 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, 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 name and quantity of each excipient in the nominal volume of injection in the container; and

(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; and

(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; and

(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; and

(v) the osmolality; and

(vi) a statement specifying whether the injection is hypotonic or hypertonic or isotonic; and

(vii) the pH range of the injection; and

(viii) the statement ‘Use in one patient on one occasion only. Contains no antimicrobial preservative’ or words to that effect.

(3) **Injections with nominal volume of 100 millilitres or less**

Except where subsection 11(4) or (5) applies, if a 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 sections 9 and 10, and subsection 11(8) 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 name of the medicine on the main label; and

(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 name of the medicine on the main label; and

(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; or

(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; and

(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 statements ‘Use in one patient on one occasion only. Contains no antimicrobial preservative’ or words to that effect; and

(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.

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

Except where subsection 11(5) applies, if a 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 in relation to the label on the container, it shall be sufficient compliance with sections 9 and 10 and subsection 11(3), and subsection 11(8) if applicable, if there are set out on that label the following particulars in a letter height of not less than 1.5 millimetres:

(c) the name of the medicine; and

(d) the name(s) of all active ingredients in the medicine; and

(e) the quantity or proportion of all active ingredients in the medicine; and

(f) the name of the dosage form; and

(g) the quantity of the medicine; and

(h) the batch number of the medicine preceded by the batch number prefix; and

(i) the expiry date of the medicine preceded by the expiry date prefix; and

(j) the name or registered trademark of the sponsor or supplier of the medicine or the trade name of the medicine; and

(k) 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

(l) if the medicine is a concentrated solution for injection - a direction not to administer the solution undiluted; and

(m) if the injection is a biological product - the name of any adjuvants in the medicine.
(5) **Injections with nominal volume of 2 millilitres or less**

(a) Subject to paragraph (b), if a medicine is an injection that has a nominal volume of 2 millilitres or less and:

(i) the container is enclosed in a primary pack that fully complies with the requirements of this Order; and

(ii) the name of the medicine is unique and unequivocally identifies the medicine, then in relation to the label on the container, it shall be sufficient compliance with sections 9 and 10 and subsection 11(3), and subsection 11(8) if applicable, if there is set out on the label of the container:

(iii) the name of the medicine in a letter height of not less than 1.5 millimetres, together with the following particulars in a letter height of not less than 1 millimetre:

(iv) the quantity of the medicine; and

(v) the batch number of the medicine preceded by the batch number prefix; and

(vi) the expiry date of the medicine preceded by the expiry date prefix; and

(vii) 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

(viii) if the medicine is a concentrated solution for injection - a direction not to administer the solution undiluted.

(b) However:

(i) if the medicine contains only one active ingredient - the label on the container must also include the name of the active ingredient and the quantity or proportion of the active ingredient in the medicine in a letter height of not less than 1 millimetre; and

(ii) if the medicine is available in more than one strength, and the name of the medicine does not identify the strength - the quantity or proportion of the active ingredient(s) is/are to be included on the label on the container in accordance with subsection 12(2) in a letter height of not less than 1 millimetre.

(c) If all conditions given in paragraph (a) above are not satisfied, then the requirements of subsection 11(4) apply notwithstanding the nominal volume of the injection being 2 millilitres or less.

(6) **Peritoneal dialysis solutions**

In addition to the requirements referred to in sections 9 and 10, 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; and

(b) the calculated osmolarity expressed in milliosmoles per litre; and
(c) the nominal volume of the solution in the container; and

(d) a statement that the solution is free from bacterial endotoxins, or where applicable, that it is apyrogenic; and

(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 words to that effect.

(7) **Preparations for use on skin or mucous membranes**

In addition to the requirements referred to in sections 9 and 10, 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.

(8) **Biological products**

In addition to the requirements referred to in sections 9 and 10 and subsections 11(2) and 11(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; and

(b) the name of any adjuvants in the medicine; and

(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 Biological Lists of the Australian Approved Names List and the name of the tissue used in the manufacture of the medicine; and

   (ii) the name of any residual antibiotic that may be present in the medicine; and

(d) for antisera - the name of the animal in which the medicine has been prepared, as specified in the Biological Lists of the Australian Approved Names List; and

(e) for monoclonal antibodies - the name of the origin of the hybridoma cell line, as specified in the Biological Lists of the Australian Approved Names List, used in the preparation of the medicine; and

(f) for recombinant products - the name of the biological source, as defined by the appropriate Biotechnology Product Descriptors as specified in the Biological Lists of the Australian Approved Names List, placed immediately after the active ingredient name; and

(g) for other biological products - the name of the animal or organism, as specified in the Biological Lists of the Australian Approved Names List, from which the medicine has been prepared.

(9) **Homoeopathic medicines**

In addition to the requirements referred to in sections 9 and 10, where all the active ingredients in a medicine are homoeopathic preparations, the main label on the container and the main label on the primary pack (if any) must include a prominent statement to the effect that the medicine is a homoeopathic medicine.
(10) Formulations containing both homoeopathic preparations and non-homoeopathic ingredients

In addition to the requirements referred to in sections 9 and 10, 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 to the effect that the medicine contains homoeopathic preparations; 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’.

(11) Sunscreen preparations

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

(12) Medicine kits

(a) If a medicine is contained in a medicine kit, the label on the container and the primary pack (if any) of each medicine in the kit must comply fully with the requirements of this Order.

(b) However, in relation to the label on the medicine kit, it shall be sufficient compliance with sections 9 and 10 if there are set out on the label of the kit the following particulars:

(i) the name given to the kit; and

(ii) the name and address of the sponsor of the kit; and

(iii) the names of all medicines within the kit and their dosage forms; and

(iv) the name, and quantity or proportion, of all active ingredients in each of the medicines within the kit; and

(v) the quantity of the goods for each medicine within the kit; and

(vi) a statement of purpose for each medicine within the kit; and

(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; and

(viii) the batch number of the kit preceded by the batch number prefix; and

(ix) an expiry date for the kit, being the earliest expiry date of the medicines within the kit, preceded by the expiry date prefix; and

(x) any warning statements that relate to the medicines within the kit; and

(xi) the Label Name for any ingredients referred to in Column 1 of Schedule 1 if present as an excipient in any of the medicines within the kit and, if any additional
requirement is stated in Column 2 of Schedule 1 in relation to such an ingredient, a statement complying with those requirements; and

(xii) storage conditions applicable to the kit, being the most restrictive of the storage conditions for the medicines within the kit; and

(xiii) if any of the medicines within the kit are scheduled - the applicable signal words, set out as specified in the Poisons Standard; and

Note: 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.

(xiv) the listing number given to the kit, set out as specified in the Regulations.

(13) **Starter packs**

(a) Where a medicine is included in Schedule 4 or Schedule 8 of the Poisons Standard and is presented in a starter pack, then, in addition to the requirements referred to in sections 9 and 10, the label on the container or primary pack (if any) must include:

(i) a space to accommodate the addition of at least the following dispensing details: patient’s name, prescriber’s name and contact details, directions for use including dose, and date of supply; and

(ii) all warnings required under State or Territory law to be applied at time of dispensing.

(b) However, where there is insufficient space on the label of the primary pack, it shall be sufficient if any warnings required by subparagraph (ii) are set out in a leaflet inserted in the primary pack of the medicine.

(14) **Small containers (nominal capacity less than or equal to 20 millilitres or 20 grams, not including injections)**

Except where subsection 11(15) applies, if:

(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 in relation to the label on the container, it shall be sufficient compliance with sections 9 and 10, and subsections 11(1) and 11(8) if applicable, if there are set out on that label the following particulars in a letter height of not less than 1.5 millimetres:

(c) the name of the medicine; and

(d) the name(s) of all active ingredients in the medicine; and

(e) the quantity or proportion of all active ingredients in the medicine; and

(f) the name of the dosage form; and

(g) the quantity of the medicine; and

(h) the batch number of the medicine preceded by the batch number prefix; and

(i) the expiry date of the medicine preceded by the expiry date prefix; and
(j) the name or registered trademark of the sponsor or supplier of the medicine or the trade name of the medicine; and

(k) 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; and

(l) if the medicine:

(i) 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

(ii) 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; and

(m) if the medicine is a biological product - the name of any adjuvants in the medicine; and

(n) if the medicine is scheduled - the applicable signal words, as required by, and set out in, the Poisons Standard.

(15) Very small containers (nominal capacity less than or equal to 2 millilitres or 2 grams, not including injections)

(a) Subject to paragraph (b), if the medicine is enclosed in a very small container but is not an injection, and:

(i) the container is enclosed in a primary pack that fully complies with the requirements of this Order; and

(ii) the name of the medicine is unique and unequivocally identifies the medicine, then in relation to the label on the container, it shall be sufficient compliance with sections 9 and 10, and subsections 11(1) and 11(8) if applicable, if there are set out on the label on the container:

(iii) the name of the medicine in a letter height of not less than 1.5 millimetres, together with the following particulars in a letter height of not less than 1 millimetre:

(iv) the quantity of the medicine; and

(v) the batch number of the medicine preceded by the batch number prefix; and

(vi) the expiry date of the medicine preceded by the expiry date prefix; and

(vii) 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.
(b) However:

(i) if the medicine contains only one active ingredient - the label on the container must also include the name of the active ingredient and the quantity or proportion of the active ingredient in the medicine in a letter height of not less than 1 millimetre; or

(ii) if the medicine is available in more than one strength, and the name of the medicine does not identify the strength - the quantity or proportion of the active ingredient(s) is/are to be included on the label in accordance with subsections 12(2) in a letter height of not less than 1 millimetre.

(c) If all conditions given in paragraph (a) above are not satisfied, then the requirements of subsection 11(14) apply notwithstanding the nominal capacity of the container being less than or equal to 2 millilitres or 2 grams.

(16) Individually wrapped medicines

(a) If:

(i) a 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; and

(ii) each dosage unit is enclosed in an individual wrapper, sachet or blister; and

(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 in relation to the label on each individual wrapper, sachet or blister, whether or not these are sealed or unsealed, it shall be sufficient compliance with sections 9 and 10 if the following particulars are set out on that label:

(v) the name of the medicine; and

(vi) the name(s) of all active ingredients in the medicine; and

(vii) the quantity or proportion of all active ingredients in the medicine; and

(viii) the batch number of the medicine preceded by the batch number prefix; and

(ix) the expiry date of the medicine preceded by the expiry date prefix; and

(x) the name or registered trademark of the sponsor or supplier of the medicine.

(b) However, if:

(i) the medicine consists only of pastilles or lozenges; and

(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 sections 9 and 10 if there is set out, on the individual wrapper, the name of the medicine.
(c) Where:

(i) the medicine consists of dry loose herbs contained in individual bags for infusion and the bag is retained around the herbs during infusion; and

(ii) the bags are contained in a primary pack that fully complies with the requirements of this Order,

then the individual bag need not be labelled with the particulars referred to in sections 9 and 10.

(17) Strip, blister and dial dispenser packs

(a) If:

(i) a medicine consists of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder; and

(ii) two or more dosage units are individually enclosed in a strip, blister or dial dispenser pack such that the dosage units can only be extracted individually; and

(iii) the strip, blister or dial dispenser pack is enclosed in a primary pack that fully complies with the requirements of this Order,

then in relation to the label on the strip, blister or dial dispenser pack, it shall be sufficient compliance with sections 9 and 10 if the following particulars are set out on that label:

(iv) the name of the medicine; and

(v) the name(s) of all active ingredients in the medicine; and

(vi) the quantity or proportion of all active ingredients in the medicine; and

(vii) the batch number of the medicine preceded by the batch number prefix; and

(viii) the expiry date of the medicine preceded by the expiry date prefix; and

(ix) the name or registered trademark of the sponsor or supplier of the medicine.

(b) However, if there are:

(i) five or more active ingredients in the medicine and the medicine is included in the Part of the Register for goods known as registered goods; or

(ii) two or more active ingredients in the medicine and the medicine is included in the Part of the Register for goods known as listed goods,

then in relation to the label on the strip, blister or dial dispenser pack, it shall be sufficient compliance with sections 9 and 10 if there are set out on that label, the following particulars:

(iii) the name of the medicine; and

(iv) the batch number of the medicine preceded by the batch number prefix; and

(v) the expiry date of the medicine preceded by the expiry date prefix.
c) In addition to the requirements referred to in paragraph (a) and (b) as relevant, if the strip, blister or dial dispenser pack is not a calendar pack, then the name of the medicine, 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 on the label at least once in relation to every two dosage units enclosed in the strip, blister or dial dispenser pack.

(18) Plastic ampoules

(a) If:

(i) a medicine is contained in a plastic ampoule, whether or not it is a medicine for injection; and

(ii) the nominal volume of the medicine in the plastic ampoule is 5 millilitres or less; and

(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.

(b) However, as a minimum requirement, whether or not the seal is broken when an ampoule is detached from the strip, the following information must appear on the label of each ampoule:

(i) the name of the medicine; and

(ii) the quantity or proportion of all active ingredients in the medicine expressed as the amount of active ingredient in the nominal volume of the ampoule; and

(iii) the batch number of the goods preceded by the batch number prefix; and

(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 either on each ampoule or the connecting strip.

(d) If a medicine is contained in a plastic ampoule which has a nominal volume of 20 millilitres or less, but greater then 5 millilitres, then the requirements of subsection 11(4) or subsection 11(14), as relevant, apply notwithstanding the container being a plastic ampoule.

(e) If a medicine is contained in a plastic ampoule which has a nominal volume greater than 20 millilitres, then the requirements of subsection 11(3) or subsection 11(2) or section 9, as relevant, apply notwithstanding the container being a plastic ampoule.
(19) Composite packs

(a) If a medicine is contained in a composite pack, the label of each medicine in the composite pack, and the label on the composite pack, must comply fully with the requirements of this Order.

(b) If the composite pack contains more than one kind of medicine, such as a vial containing a powder for reconstitution and an ampoule containing a diluent, and the medicines have different expiry dates, the expiry date included on the label of the composite pack must be the expiry date of the medicine with the shorter shelf life.

(c) If the composite pack contains more than one kind of medicine and the medicines have different storage conditions, the storage conditions included on the label of the composite pack must be the most restrictive of the storage conditions for the medicines within the composite pack.

(d) If the composite pack contains more than one kind of medicine and the medicines are scheduled differently from each other, the signal words included on the label of the composite pack must be the signal words indicating the most restrictive classification.

12 Expression of Particulars

(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 metric units must be expressed 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.

(b) However, where a range of medicines contains the same active ingredient(s) in the same dosage form in a series of strengths then, to minimise confusion between strengths, the label should 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 example, a range of expressions for 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.

(c) Where the active ingredient is in liquid form, the equivalent metric units of volume must be expressed in the same manner. 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.
(d) Where a particular is a statement of mass or volume, the unit of measurement should be consistent with that used in any advisory statement required by the Required Advisory Statements for Medicine Labels for that ingredient.

(c) Where a statement of quantity is expressed as less than unity, the statement of quantity must include the leading zero.

(2) Expression of quantity or proportion of active ingredients

Except as provided in subsection 12(4) 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. However where the liquid for ingestion is one of a series of strengths containing the same active ingredient, the quantity or proportion of active ingredient should 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 should 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 preparation:

(i) notwithstanding paragraphs (a), (b) and (c), as the quantity of the preparation in one millilitre or in one gram of the medicine; or

(ii) where the medicine is a fully potentised, single ingredient, homoeopathic medicine, it is sufficient to state the ingredient name and potency, providing it is clear that the ingredient comprises 100% of the medicine; or

(iii) where all ingredients are homoeopathic 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 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 should be expressed consistently across the series in terms of the same stated dose volume;

(g) for a medicine for injection:

(i) where the medicine 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 medicine 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 medicine 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;

(Not: In justified cases the strength may also be incorporated in the name of the medicine as a percentage (w/v or v/v) or another concentration term, but the name of the medicine 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 paragraph (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:

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

(iii) 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 retinol equivalents;

(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 British Pharmacopoeia and the dose has been established as a metered dose, in which case it should be expressed as the metered amount. Where a 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.

(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 Secretary.

(c) The nominal potency of probiotic biological products must be included on labels and must be expressed as the number of each probiotic organism per dose unit.

(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.

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

(a) For the purposes of section 9, 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’;

(vi) ‘Store below 25°C (Do not refrigerate)’;

(vii) ‘Store below 30°C’; and

(viii) ‘Store below 30°C (Do not refrigerate)’.

(b) If none of the statements of storage conditions included in paragraph (a) are applicable, the sponsor of the medicine must apply to the Secretary for permission to use an alternative statement.
Schedule 1

Excipients required to be declared on the label of medicines

Column 1 includes a general descriptor for the group of excipients required to be declared, and a number of indicative 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 Schedule 1, 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’”.

<table>
<thead>
<tr>
<th>Column 1 Ingredient Name or Group</th>
<th>Column 2 Condition (if any) and additional requirements (if any)</th>
<th>Column 3 Declaration Required for Routes of Administration</th>
<th>Column 4 Label-Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspartame</td>
<td></td>
<td>Oral</td>
<td>Aspartame</td>
</tr>
<tr>
<td>Benzoates, including: Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate</td>
<td></td>
<td>All</td>
<td>Benzoates</td>
</tr>
<tr>
<td>Crustacea and Crustacean products (see Note 1), including: Crab Lobster Shrimp - white</td>
<td></td>
<td>All</td>
<td>Crustacea; or Crustacean products</td>
</tr>
</tbody>
</table>

Note 1: This includes any derivatives of the named ingredient.

Therapeutic Goods Order No.79 - General Requirements for the Labelling of Medicines
CONSENTATION DRAFT – January 2008
<table>
<thead>
<tr>
<th>Column 1 Ingredient Name or Group</th>
<th>Column 2 Condition (if any) and additional requirements (if any)</th>
<th>Column 3 Declaration Required for Routes of Administration</th>
<th>Column 4 Label-Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg and egg products, including:</td>
<td>Egg – whole&lt;br&gt;Egg yolk – dried&lt;br&gt;Lecithin - egg</td>
<td>All</td>
<td>Egg; or Egg products</td>
</tr>
<tr>
<td>Ethanol</td>
<td>Condition: Where present in a concentration of 3% v/v or more.</td>
<td>All</td>
<td>Alcohol</td>
</tr>
<tr>
<td>Fish and fish products (see Note 2), including:</td>
<td>Cod&lt;br&gt;Cod – liver oil&lt;br&gt;Halibut&lt;br&gt;Tuna</td>
<td>All</td>
<td>Fish; or Fish products</td>
</tr>
<tr>
<td>Galactose</td>
<td></td>
<td>Oral</td>
<td>Galactose</td>
</tr>
<tr>
<td>Gluten or excipients derived from gluten-containing grains (see Note 3)</td>
<td>Condition: Where gluten or an excipient derived from gluten-containing grains is present.</td>
<td>All, other than skin and mucous membrane applications</td>
<td>Gluten</td>
</tr>
<tr>
<td>Hydroxybenzoic acid esters, including:</td>
<td>Ethyl hydroxybenzoate&lt;br&gt;Methyl hydroxybenzoate&lt;br&gt;Propyl hydroxybenzoate&lt;br&gt;Sodium ethyl hydroxybenzoate&lt;br&gt;Sodium methyl hydroxybenzoate&lt;br&gt;Sodium propyl hydroxybenzoate</td>
<td>All</td>
<td>Hydroxybenzoates</td>
</tr>
<tr>
<td>Lactose (see Note 4)</td>
<td>Condition: Where present, not withstanding the entry for lactose under 'Sugars –Monosaccharides and disaccharides’.</td>
<td>Oral</td>
<td>Lactose</td>
</tr>
<tr>
<td>Ingredient Name or Group</td>
<td>Condition (if any) and additional requirements (if any)</td>
<td>Declaration Required for Routes of Administration</td>
<td>Label-Name</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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<tr>
<td>Milk and milk products, including:</td>
<td></td>
<td>All</td>
<td>Milk; or Milk products</td>
</tr>
<tr>
<td>Milk – nonfat dry</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Milk – whole dry</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Milk protein – hydrolysed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peanuts and peanut products, including:</td>
<td></td>
<td>All</td>
<td>Peanuts; or Peanut products</td>
</tr>
<tr>
<td>Arachis hypogaea</td>
<td></td>
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<tr>
<td>Arachis (peanut) oil</td>
<td></td>
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</tr>
<tr>
<td>Phenylalanine</td>
<td></td>
<td>All, other than skin and mucous membrane applications</td>
<td>Phenylalanine</td>
</tr>
<tr>
<td>Pollen (including both pollen collected by bees and pollen collected by mechanical means)</td>
<td>Requirement: To include a statement to the effect that the product contains pollen which may cause severe allergic reactions.</td>
<td>Oral</td>
<td>Pollen (Pollen - Bee as applicable)</td>
</tr>
<tr>
<td>Potassium salts, including:</td>
<td>Requirement: To declare on the label (in mg) the quantity of elemental potassium per maximum recommended daily dose.</td>
<td>Oral</td>
<td>Potassium</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Potassium bicarbonate</td>
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<td></td>
<td></td>
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<tr>
<td>Potassium clavulanate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propolis</td>
<td>Requirement: To include a statement to the effect that the product contains propolis which may cause severe allergic reactions.</td>
<td>Oral</td>
<td>Propolis</td>
</tr>
<tr>
<td>Royal Jelly</td>
<td>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.</td>
<td>Oral</td>
<td>Royal Jelly</td>
</tr>
<tr>
<td>Saccharin, including:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Saccharin calcium</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Saccharin sodium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Ingredient Name or Group</td>
<td>Column 2</td>
<td>Condition (if any) and additional requirements (if any)</td>
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<tr>
<td></td>
<td><strong>Sesame seeds and sesame seed products</strong>, including:</td>
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<tr>
<td></td>
<td>Sesame seed</td>
<td></td>
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<td></td>
<td>Sesame oil</td>
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<td></td>
<td>Sesamum indicum</td>
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<td></td>
</tr>
<tr>
<td></td>
<td><strong>Sodium salts</strong>, including:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium bicarbonate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>Soya beans and soya bean products</strong>, including:</td>
<td></td>
<td></td>
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<td></td>
<td>Glycine max</td>
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<td></td>
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<tr>
<td></td>
<td>Soya bean</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Soya oil</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Soyabean oil</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>Sorbates</strong>, including:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Potassium sorbate</td>
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<tr>
<td></td>
<td>Sorbic acid</td>
<td></td>
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<tr>
<td></td>
<td><strong>Sugar alcohols</strong>, including:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Isomalt</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lactitol</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Maltitol</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Mannitol</td>
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<td></td>
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<td></td>
<td>Sorbitol</td>
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<td></td>
<td>Xylitol</td>
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</tbody>
</table>

**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.

**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'.
<table>
<thead>
<tr>
<th>Column 1 Ingredient Name or Group</th>
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<th>Column 3 Declaration Required for Routes of Administration</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Sugars – Monosaccharides and disaccharides</strong> (see Note 4), including: Glucose Honey (as a mixture of sugars) Invert sugar Lactose Maltose Sucrose <strong>Condition:</strong> 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.</td>
<td>Oral</td>
<td>Sugars</td>
<td></td>
</tr>
<tr>
<td><strong>Sulfites</strong>, including: Sulfur dioxide Potassium metabisulfite Sodium bisulfite Sodium metabisulfite Sodium sulfite</td>
<td>All</td>
<td>Sulfites</td>
<td></td>
</tr>
<tr>
<td><strong>Tree nuts and tree nut products</strong> (see Note 6), including: Macadamia nut oil Macadamia ternifolia Almond oil Prunus dulcis Walnut Juglans nigra</td>
<td>All</td>
<td>Tree nuts; or Tree nut products</td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2 Condition (if any) and additional requirements (if any)</td>
<td>Column 3 Declaration Required for Routes of Administration</td>
<td>Column 4 Label-Name</td>
</tr>
<tr>
<td>----------</td>
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<td>-----------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Ingredient Name or Group</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**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** – Tartrazine is permitted 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.