Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Order No. 69 - General Requirements for Labels for Medicines 2017

Therapeutic Goods Act 1989

I, Larry Kelly, delegate of the Minister for Health for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, determine that the matters specified in this Order constitute a standard for therapeutic goods of the kind described in section 5 of this Order.

Dated 30th June 2017.

(signed by)
Dr Larry Kelly
Delegate of the Minister for Health

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Introduction

The purpose of a medicine label is to provide information about the product such as its identity, potency, content, storage, expiry date, registration status and sponsor. Medicine labels also include other information not required by the Order, but which may be required by other legislative instruments or for commercial purposes. These include items such as signal headings (e.g. Prescription only, pharmacist only), bar codes and sponsor's logos.

For non-prescription medicines, the aim is that the information on the label is presented in such a way that consumers can:

(a) choose an appropriate medicine on their own;

(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, products 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 the Communications Research Institute of Australia Inc. should achieve this aim.

Guidelines to assist in the design of medicine labels are also available on the Therapeutic Goods Administration website (http://www.tga.gov.au).

The mandatory aspects of the Order for all medicines are contained in sections 1 - 11 inclusive and the Schedules to the Order. All medicine labels must comply with sections 1 - 11 and the Schedules to the Order, regardless of whether they have been designed in accordance with the industry Code of Practice or with guidelines.

1 Name of Order

This Order is the *Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines 2017*.

2 Commencement

This Order commences on 1 July 2017 and ceases to be in force on 1 September 2020.

3 Repeal

This Order repeals Therapeutic Goods Order No. 69, entitled 'General requirements for labels for medicines', made on 27 August 2001, as amended (Register ID: F2014C00926).

4 Transition arrangements

4(1) From the commencement of this Order up to and including 31 August 2020, each medicine to which this Order applies must comply with either:

(a) the requirements specified in this Order; or

(b) if also applicable to the medicine, the requirements specified in either:

(i) the *Therapeutic Goods Order No. 91- Standard for labels of prescription and related medicines* (TGO 91); or

(ii) the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* (TGO 92),

depending on which of those Orders is applicable to the medicine.

4(2) On and from 1 September 2020, each medicine to which this Order applies must comply with the requirements specified in either:

(i) TGO 91, if that Order is applicable to the medicine; or

(ii) TGO 92, if that Order is applicable to the medicine,

instead of the requirements in this Order.

4(3) Notwithstanding (1) and (2), medicines imported into or manufactured in Australia before 1 September 2020, but supplied by a person other than the sponsor after that date, must comply with this Order if, at the time of their release for supply, they complied with this Order.

5 Application and exemptions

5(1) This Order applies to those therapeutic goods that are medicines except goods:

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

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

(c) intended for use in the treatment of humans in accordance with rules specified for the purposes of subsection 19(7A) of the Act;

(d) that fall within the description of Item 9(a) of Schedule 5 to the Regulations;

(e) that have not reached their final stage of manufacture;

(f) that are personal imports as described under Item 1 of Schedule 5 to the Regulations;

(g) that are medicinal gases;

(h) that are solely for export;

(i) made up or compounded in accordance with the individual prescription of a medical practitioner or dentist by a pharmacist or by a person in the course of his or her employment by a pharmacist and under the actual personal supervision of that pharmacist;

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

(k) supplied in the course of treating a patient by a medical practitioner or dentist in the lawful practice of his or her profession, other than professional starter packs;

(l) made up or compounded extemporaneously for a specific and individual case, in that person's presence, by a complementary healthcare practitioner in the lawful practice of his or her profession.

5(2) Where transparent covering encloses or wraps a container or primary pack containing goods and the particulars which are required to be set out on the label of the container or on the primary pack are clearly visible through that transparent covering, the requirements of this Order do not apply to that transparent covering.

5(3) To avoid doubt, this Order will apply to medicines exempt from the listing and registration requirements, other than those specified in subsection 5(1) above.

6 Interpretation

6(1) In this Order -

'**Act**' means the *Therapeutic Goods Act 1989*;

'**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;

‘**Australian Approved Names List**’ has the same meaning as in regulation 2 of the Regulations;

‘**batch number**’ means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, 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 NUMBER’, ‘Batch No.’, ‘BATCH NO.’, ‘Batch’, ‘BATCH’, Ⓑ, ‘B’, ‘(B)’, ‘B/N’, ‘Lot Number’, ‘LOT NUMBER’, ‘Lot No.’, ‘LOT NO.’, ‘Lot’ or ‘LOT’; or words or symbols to this effect;

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

‘**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 the goods, and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include an article intended for ingestion;

‘**date of manufacture**’ means:

(a) for a biological product, the date (month and year) of the latest quality control analysis performed on the product and which may be preceded by a period during which the product is stored under conditions which have been shown to preserve the potency of the product; or

(b) for a product other than a biological product, the date (month and year) during which the processing of the bulk product, from which the goods are to be packaged, is completed;

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

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

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

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

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

(a) where the goods are intended for ingestion or are intended for parenteral use, the method, dose and frequency of administration of the goods except where:

(i) the goods, other than vaccines, are specified in Schedule 4 or Schedule 8 of the Poisons Standard; or

(ii) the dose of the goods is usually determined for each individual patient by a medical practitioner, dentist, complementary healthcare practitioner, or by any other person authorised under relevant State/ Territory legislation to determine the dose; and

(b) where the goods are not intended for ingestion or are not intended for parenteral use, the method and frequency of administration, unless the goods are specified in Schedule 4 or Schedule 8 of the Poisons Standard; and

(c) in any case where the goods require some preparation, such as dissolving, suspending, diluting or reconstituting before use, instructions for preparation and statement of the conditions of storage and the maximum period of storage between preparation and use;

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

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

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

‘**expiry date prefix**’ means the prefix which precedes the expiry date, and clearly indicates that the following information is the expiry date. Examples of acceptable prefixes include ‘Expiry Date’, ‘EXPIRY DATE’, ‘Expiry’, ‘EXPIRY’, ‘Expires’, ‘EXPIRES’, ‘Exp. Date’, ‘EXP. DATE’, ‘Use before’, ‘USE BEFORE’, ‘Use By’, ‘USE BY’, ‘Exp’, or ‘EXP’ but terms such as ‘Best by’ or words to this effect are not acceptable;

‘**goods**’ means a medicine;

‘**herbal substance**’ has the same meaning as in regulation 2 of the Regulations;

‘**homoeopathic potency**’ means the dilution factor expressed as:

(a) ‘nX’, where each dilution is a decimal or ten-fold dilution and ‘n’ is the number of dilutions such that the total dilution is 10^n; or

(b) ‘nC’, where each dilution is a centesimal or hundred-fold dilution and ‘n’ is the number of dilutions such that the total dilution is 100^n;

‘**homoeopathic preparation**’ has the same meaning as in regulation 2 of the Regulations;

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

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

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

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

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

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

‘**main label**’ means:

(a) 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

(b) where the product name is equally conspicuous on two or more labels or portions of a label - each such label or portion;

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

‘**medicine**’ has the same meaning as defined in subsection 3(1) of the Act;

‘**name and address**’ in respect of a sponsor or supplier, means the name of the sponsor or supplier and sufficient information to allow the Australian 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 principal place of business in Australia, (not being a post office, cable, telegraphic or code address). 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;

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

'**Poisons Standard**' means the current Poisons Standard as defined in section 52A of the Act;

'**primary pack**' has the same meaning as in subsection 3(1) of the Act;

'**product name**' means the proprietary name of the goods, or if there is no proprietary name, the non-proprietary name of the goods;

'**proprietary name**' means the registered trademark of the therapeutic goods or the unique name assigned to the goods by the sponsor and appearing on a label;

'**quantity of the goods**' means:

(a) where the goods consist of discrete units, such as tablets or capsules - the stated number of units in the container; or

(b) where the goods are -

(i) a solid or semi-solid, other than a biological product or a medicine for injection - the stated weight of the solid or semi-solid in the container;

(ii) a liquid, other than a biological product - the stated volume of the liquid in the container;

(iii) a pressurised metered-dose preparation or dry powder inhaler - the stated number of doses in the container;

(iv) a non-pressurised metered dose preparation - the minimum number of doses in the container;

(v) a solid biological product - the stated number of doses or potency units in the container;

(vi) a liquid biological product - the stated volume of liquid in the container and, in addition, either the total number of doses or potency units in the container or the number of doses or potency units per unit volume.

'**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*;

'**small volume injection**' means an injection having a volume of less than or equal to 100 millilitres;

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

'**Sponsor**' has the same meaning as in subsection 3(1) of the Act;

'**standard**' has the same meaning as in subsection 3(1) of the Act;

'**warning statements**' means:

(a) any advisory statements that are required to be included in a medicine's label as specified in the legislative instrument made by the Minister under subsection 3(5A) of the Act, as in force from time to time;

(b) any warning statements specified in the standard that applies to the medicine;

(c) a warning statement indicating that incorrect route or method of administration may be hazardous;

(d) any warning required by the Secretary of the Department of Health to be included as a condition of registration or listing in relation to the medicine;

(e) any warning statement specified in the Regulations that applies to the medicine;

(f) any warning statements specified in the Poisons Standard that applies to the medicine.

6(2) In this Order, unless indicated to the contrary, a reference to:

(a) a section or a subsection, or a paragraph or subparagraph, is a reference to a provision in the Act or a reference to a provision of this Order, as applicable; and

(b) a regulation or subregulation is a reference to a provision in the Regulations.

7 Label requirements

Subject to regulation 15 of the Regulations, the requirements set out under this section apply to therapeutic goods to which this Order applies. Containers, and the primary packs (if any) in which therapeutic goods are packed, must each bear a label or labels which comply with the following requirements:

7(1) General

The particulars required by this Order to be included on a label or labels must be clearly visible and must be written:

(a) in the English language;

(b) in durable and legible characters; and

(i) in the case of the registration or listing number, not less than 1 millimetre height as required by paragraphs 15(1)(b) and (c) of the Regulations; and

(ii) in all other cases in letter height of not less than 1.5 millimetres;

(c) in a metric unit of measurement. For active ingredient(s), where a particular is a statement of quantity for which there is a metric unit of measurement, such that:

(i) a statement of quantity for 1 microgram up to 999 micrograms, both inclusive, must be expressed in terms of micrograms;

(ii) a statement of quantity for 1000 micrograms must be expressed as 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 must be expressed as 1000 milligrams or 1 gram;

(v) a statement of quantity for more than 1 gram up to 999 grams inclusive must be expressed in terms of grams;

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

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

7(2) Particulars to be included on a label

Subject to the qualifications contained in subsections 7(6), 7(11), 7(12), 7(13), 7(14) or 7(17), the label or labels must include:

(a) the product name;

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

(c) the quantity or proportion of all active ingredients in the goods in accordance with section 8;

(d) where the medicine contains any ingredient referred to in column 1 of the First Schedule as an excipient, 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 4 of the First Schedule in relation to such an ingredient; and

(iii) the medicine is not included in Schedule 4 or Schedule 8 of the Poisons Standard; then

a statement must be included on the primary pack indicating the goods contain these ingredients. The statement must be expressed using the name(s) of the excipient(s) appearing in column 1, or where two or more of the same ingredient group are included in the goods, the statement must include the approved Label-AAN stated in Column 5 of the First Schedule. Where any special labelling 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.

Where the goods are goods included in Schedule 4 or Schedule 8 of the Poisons Standard then it shall be sufficient compliance with this paragraph if the names of the excipient ingredients listed in Column 1 of the First Schedule are stated in any of the publications of product literature named in the Second Schedule to this Order;

(e) the name of the dosage form;

(f) the quantity of the goods (except for medicines for injection);

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

(h) the batch number of the goods preceded by the batch number prefix;

(i) the expiry date of the goods preceded by the expiry date prefix;

(j) the storage conditions applicable to the goods in accordance with section 11;

(k) directions for use of the goods;

(l) the name and address of the sponsor or supplier of the goods;

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

(i) where the goods are specified in Schedule 4 or Schedule 8 of the Poisons Standard; or

(ii) where the goods are a dispensing pack supplied solely to a complementary healthcare practitioner, and include on the label the words 'For Practitioner Dispensing Only'; and

(n) where the goods are included in the Australian Register of Therapeutic Goods, the registration or listing number is to be:

(i) on the label; or

(ii) on a securely affixed label adjacent to the main label; or

(iii) if the container is enclosed in a primary pack, on the primary pack label.

7(3) Particulars to be included on a main label

Subject to subsections 7(6), 7(11), 7(12), 7(13) and 7(17), the particulars required under paragraphs 7(2)(a), (b), (c), (e), (f) and (n) must appear on the main label of the goods except:

(a) where there are four or more active ingredients in the goods - in which case it shall be sufficient compliance with this subsection if the names together with the quantities or proportions of every active ingredient are included on a side panel or side label or on a rear panel or rear label of the container and primary pack for the goods;

(b) where there are two or more active ingredients that are vitamins or minerals or that are required to be quantified as the equivalent fresh or dry weight or volume under paragraphs 7(11)(b) or 7(11)(c) - it shall be sufficient compliance with this subsection if the names and quantities or proportions of these active ingredients

together with the names and quantities of every other active ingredient in the goods are included on a side panel or side label or on a rear panel or rear label; or

(c) where the goods are a sunscreen product - it shall be sufficient compliance with this subsection if the names together with the quantities or proportions of every active ingredient and the name of the dosage form are included on a side panel or side label or on a rear panel or rear label of the container and primary pack.

7(4) Preparations for ophthalmic use

Where the goods are a preparation for ophthalmic use, the label on the container and on the primary pack or, where subsection 7(11) applies, on the primary pack, must include, in addition to the requirements of subsections 7(2) and 7(3):

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

(b) where the goods, other than an ophthalmic ointment, do 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 goods consist of eye drops for multidose use - a statement to the effect that the eye drops should not be used later than four weeks after the container of the goods is first opened; and

(d) where the goods consist of a solid ophthalmic medicine for preparing eye drops for multidose use - a statement to the effect that the goods when prepared should not be used later than four weeks after the container is first opened, or where the shelf life of the prepared goods is less than four weeks, this lesser period shall be stated; and

(e) where the goods consist 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 goods consist of a solution or a suspension in an oil - the word 'oily' in or adjacent to the product name.

7(5) Injections other than large volume injections

In addition to the requirements referred to in subsections 7(2) and 7(3), where the goods are an injection or a medicament for injection other than a large volume injection:

(a) the main label on the container and on the primary pack of the goods must include:

(i) the approved route(s) of administration, such as 'intravenous', 'intramuscular', or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration; and

(ii) where the goods are a medicament for injection, the words 'for injection' must appear in or adjacent to the product name; and

(iii) where the goods are an injection which consists of a solution or a suspension in an oil, the label must include the word 'oily' in or adjacent to the product name;

(b) the label(s) on the container and primary pack or, where subsection 7(11) applies, on the primary pack of the goods must include:

(i) the name and quantity of each excipient in the goods, expressed:

- for single dose injections - as the quantity of that excipient in the stated volume of injection in the container; or
- for a medicament for injection - as the quantity of that excipient in the container; and
- where the injection is intended for multidose use - as the quantity of that excipient in one millilitre of the injection or as the quantity in a suitable dose volume where the stated volume is less than one millilitre; and

(ii) where the goods are 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 goods, the words 'Use in one patient on one occasion only. Contains no antimicrobial preservative.' or a statement to that effect;

(c) the label on the container and on the primary pack of goods which consist of a concentrated solution for injection, or, where subsection 7(11) applies, the label on the primary pack of such goods, must include:

(i) a direction not to administer the solution undiluted; and

(ii) a direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use;

(d) the label on the container and on the primary pack of goods which are an injection containing a radio-contrast agent, must include a statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre.

7(6) Large volume injections

Large volume injections are required to comply with subsections 7(2) and 7(3) subject to the following qualifications:

(a) in cases where there is no proprietary name of the goods, 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;

(b) in cases where the goods are intended for electrolyte replacement or nutritional therapy or are 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 ingredient in the goods in terms of percentages;

(c) in cases where the goods contain an active ingredient which is not intended for electrolyte replacement or nutritional therapy and is not intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportion of that active ingredient expressed in terms of weight (or potency, if appropriate) in the stated volume of injection in the container; and

in addition to these requirements, the label on the container and on the primary pack of goods which are large volume injections must include:

(d) the names and quantities of all excipients in the stated volume of injection in the container;

(e) where one or more active ingredients are amino acids and/or protein, a statement in grams of the total amount of nitrogen in the stated volume of injection in the container;

(f) where the goods are intended for use as an energy source, a statement in kilojoules of the energy equivalent of the stated volume of injection in the container;

(g) where the goods are intended for use as a radio-contrast agent, a statement of the equivalent amount of iodine in terms of milligrams of iodine per millilitre;

(h) the osmolality;

(i) a statement specifying whether the injection is 'hypotonic' or 'hypertonic' or 'isotonic';

(j) the pH range of the injection;

(k) the words 'single use' or 'single dose'.

7(7) Dialysis concentrates

In addition to the requirements referred to in subsections 7(2) and 7(3), the label on the container and on the primary pack of goods which are a concentrated solution for use in dialysis must include:

(a) the formulation of the solution expressed in terms of millimoles per litre of the concentrate;

(b) the names and quantities of all ingredients in terms of millimoles per litre of solution following dilution in accordance with directions;

(c) a direction not to use the solution undiluted;

(d) a direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use; and

(e) a statement 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or a statement to that effect.

7(8) Peritoneal dialysis solutions

In addition to the requirements referred to in subsections 7(2) and 7(3), the label on the container and on the primary pack of goods that are 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.

7(9) Preparations for use on skin or mucous membranes

In addition to the requirements referred to in subsections 7(2) and 7(3), the label of goods which are preparations for use on skin and mucous membranes, but not intended for ophthalmic use, must include the name of any antimicrobial preservative in the goods.

7(10) Biological products

In addition to the requirements referred to in subsections 7(2), 7(3) and 7(5), the label of goods which are biological products must include:

(a) the name and proportion of any antimicrobial preservative in the goods;

(b) the name of any adjuvants in the goods;

(c) for viral 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 Australian Approved Names - Biological Lists of the Australian Approved Names List and the name of the tissue used in the manufacture of the goods; and

(ii) the name of any residual antibiotic present in the goods;

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

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

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

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

(h) for live vaccines:

(i) a statement of the recommended route(s) of administration such as 'intravenous', 'intramuscular', 'subcutaneous', 'oral' or other phrase, word or abbreviation denoting the recommended route(s) of administration; and

(ii) where the contents of the container are intended to be used on one occasion only, the words 'single use' or 'single dose'.

7(11) Small containers

Where:

(a) the goods are enclosed in a container which has a capacity of 20 millilitres or less; and

(b) the container is enclosed in a primary pack; and

(c) there are included, in a label on the primary pack, the particulars referred to in subsections 7(2), 7(3), and where applicable, subsections 7(4) or 7(5):

then, in relation to the label on the container, it shall be sufficient compliance with subsections 7(2), 7(3), 7(4) and paragraphs 7(5)(b) and 7(5)(c), if there are set out, on the label on the container, the particulars referred to in paragraphs 7(2)(a), (b), (c), (e), (f) and (h) and the name or registered trade mark of the sponsor or supplier or the proprietary name;

except that:

(a) for viral vaccines only, the particulars referred to in paragraph 7(2)(i) must also be set out on the label of the container; and

(b) where it is not practicable to set out these particulars in full on a label on the container, the particulars referred to in paragraphs 7(2)(a), (b) and (c) may be abbreviated, provided the abbreviation is unambiguous.

7(12) Individually wrapped goods

(a) Where:

(i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder;

(ii) each such dosage unit is individually wrapped in an unsealed protective cover;

(iii) each such dosage unit is, after being so wrapped, enclosed in a primary pack; and

(iv) the primary pack is labelled with the particulars referred to in subsections 7(2) and 7(3) -

then, in relation to the label for each individual wrapper, it shall be sufficient compliance with this Order if there are set out, on the individual wrapper, the particulars referred to in paragraphs 7(2)(a), (b) and (c) and the name or registered trade mark of the sponsor or supplier; or

(b) where:

(i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, single doses of a powder or single doses of a liquid or a patch; and

(ii) each such single dose or patch is sealed into an individual sachet or individual blister; and

(iii) one or more than one sealed dosage unit is enclosed in a primary pack; and

(iv) the outside of the primary pack is labelled with the particulars specified in subsections 7(2) and 7(3) -

then, in relation to the label on each individual sachet or blister, it shall be sufficient compliance with this Order if there are set out, on the individual sachet or blister, the particulars specified in paragraphs 7(2)(a), (b), (c), (h) and (i) and the name or registered trademark of the sponsor or supplier of the goods; or

(c) where:

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

(ii) the bags are contained in a primary pack; and

(iii) the primary pack is labelled with the particulars referred to in subsections 7(2) and 7(3) -

then the individual bag need not include the particulars referred to in subsections 7(2) and 7(3).

7(13) Strip, blister and dial dispenser packs

(a) Where:

(i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder; and

(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; and

(iii) the container is enclosed in a primary pack; and

(iv) the primary pack is labelled with the particulars referred to in subsections 7(2) and 7(3) -

then, in relation to the label on the container, it shall be sufficient compliance with this Order if there are set out on that container, the particulars referred to in paragraphs 7(2)(a), (b), (c), (h) and (i) together with the name or registered trade mark of the sponsor or supplier; or

(b) in the case of a container described in subparagraph 7(13)(a)(ii) in which each dosage unit is enclosed in such a manner that an individual segment containing the dosage unit can be readily detached, the particulars referred to in paragraphs 7(2)(a), (b) and (c) must appear at least once in relation to every two dosage units enclosed in the container.

7(14) Directions for use

Where there is insufficient space on the label of the container or on the primary pack to include directions for use, it shall be sufficient compliance with paragraph 7(2)(k) if there is included in a label on that container or primary pack, as the case may be, a statement to the effect that those directions for use are set out on a leaflet inserted in the primary pack of the goods provided that such a leaflet is in fact so inserted.

7(15) Homoeopathic preparations

Where all the active ingredients in the goods are homoeopathic preparations then:

(a) the label on the container and the label on the outside of the primary pack if any, must include, in addition to the relevant requirements in subsections 7(2) and 7(3), a statement indicating that the active ingredients in the goods are homoeopathic preparations, such as, 'homoeopathic product' or 'homoeopathic preparation'; and

(b) where the indications for use are of a kind permitted to be advertised only to complementary health care practitioners who are members of any of the bodies mentioned in Schedule 1 to the Regulations, the label on the container and the label on the outside of the primary pack if any, must include a statement that the therapeutic indications have not been approved, such as 'Homoeopathic product without approved therapeutic indications'.

7(16) Formulations containing both homoeopathic and non-homoeopathic ingredients

Where goods contain active ingredients that are homoeopathic preparations and other active ingredients that are not homoeopathic preparations -

(a) the label on the container and the label on the outside of the primary pack, if any, must include, in addition to the relevant requirements in subsections 7(2) and 7(3), a statement that the goods include ingredients that are homoeopathic preparations, such as 'Contains homoeopathic ingredients'; and

(b) where the indications for use are of a kind permitted to be advertised only to complementary health care practitioners who are members of any of the bodies mentioned in Schedule 1 to the Regulations, the label on the container and the label on the outside of the primary pack, if any, must include a statement that the therapeutic indications of the homoeopathic ingredients have not been approved, such as, 'Contains homoeopathic ingredients without approved therapeutic indications'.

7(17) Plastic ampoules

Where:

(a) the medicine is presented in a plastic ampoule, the label on the container may be formed by way of embossing;

(b) the nominal volume of the medicine in the plastic ampoule is between 5 millilitres and 20 millilitres inclusive, the label on the container must be in accordance with subsection 7(11), relating to small containers and must include a statement of the approved route(s) of administration such as 'intravenous', 'intramuscular', 'subcutaneous', 'inhalation' or other phrase, word or abbreviation denoting the approved route(s) of administration and a warning statement where the incorrect route of administration may be hazardous;

(c) the nominal volume of the medicine in the plastic ampoule is greater than 20 millilitres, the label on the container must meet the requirements of subsections 7(2), 7(3) and any other subsections relevant to the route of administration of the medicine, including a warning statement where the incorrect route of administration may be hazardous;

(d) the nominal volume of the medicine in the plastic ampoule is less than 5 millilitres and two or more ampoules are attached to a connecting strip in such a

way **that the seal is broken** when an ampoule is detached, it will be sufficient for compliance with subsections 7(2) and 7(3) if there are set out on the label on each ampoule the product name, the strength expressed as the amount of active in the nominal volume of the ampoule and the approved route of administration. The label on the connecting strip must include the name of the active ingredient, the batch number and the name or registered trade mark of the sponsor or supplier and a warning statement where the incorrect route of administration may be hazardous;

(e) the nominal volume of the medicine in the plastic ampoule is less than 5 millilitres and two or more ampoules are attached to a connecting strip in such a way that individual ampoules can be detached **without breaking the seal**, it will be sufficient for compliance with subsections 7(2) and 7(3), if there are set out on the label on each container the product name, the strength expressed as the amount of active in the nominal volume of the ampoule, the batch number and the route of administration. The label on the connecting strip must include the name of the active ingredient, and the name or registered trade mark of the sponsor or supplier and a warning statement where the incorrect route of administration could be hazardous.

7(18) Composite packs

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

8 Expression of quantity or proportion of active ingredient in medicines

Except as provided in section 10 (Expression of activity of radionuclides in radiopharmaceutical preparations) and subsection 7(7) (Dialysis concentrates), the quantity or proportion of an active ingredient to be included on a label as required by paragraph 7(2)(c) must be expressed:

8(1) for a discrete dosage unit - as the quantity of the active ingredient in the dosage unit;

8(2) for a liquid for ingestion - as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid;

8(3) 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;

8(4) for a transdermal patch - as the quantity of the active ingredient released in a stated time;

8(5) for a homoeopathic preparation, where all the active ingredients are homoeopathic preparations: -

(a) notwithstanding subsections 8(1), 8(2) and 8(3), as the quantity of the ingredient in one millilitre or in one gram of the preparation; or

(b) where each active ingredient is included in the preparation in the same proportion as every other active ingredient - expressed as 'Contains equal parts of' followed by the name of each homoeopathic ingredient;

8(6) for goods 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 goods;

8(7) for a preparation for injection:

(a) where the preparation is a medicament for injection - as the nominal quantity of the active ingredient in the container;

(b) where the injection is intended for multidose use and

(i) the volume in the container is 1 millilitre or greater - as the quantity of the active ingredient in one millilitre of the injection; or

(ii) the volume in the container is less than 1 millilitre - as the quantity of the active ingredient in a suitable dose volume of the injection;

(c) where the injection is a small volume injection and is usually intended for administration as a single dose - as the quantity of active ingredient in the stated volume of the injection in the container.

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

(d) where the preparation is a large volume injection intended for electrolyte replacement or nutritional therapy or is intended as a plasma volume expander or is intended as an additive to any of these types of large volume injection -

(i) as the number of millimoles in the stated volume of the injection in the container for each active ingredient or ion of precisely known molecular weight; or

(ii) as the weight contained in the stated volume of the injection in the container for each active ingredient for which the molecular weight is not precisely known;

(e) where the preparation is a large volume injection containing an active ingredient which is not intended for electrolyte replacement or nutritional therapy or as a plasma volume expander - as the weight of the active ingredient in the stated volume of injection in the container;

8(8) for antibiotic preparations, where potency units are used as a measure of activity - as the number of such units expressed as International Units (IU) established by the World Health Organization;

8(9) for any other goods which are required to be prepared before use - as the weight or volume of active ingredient in a stated weight or volume of the goods, after preparation in accordance with the instructions included in the label of the goods;

8(10) for preparations applied to the skin and mucous membranes (other than those covered by subsection 8(8) 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 goods, as appropriate;

8(11) for preparations including a herbal substance:

(a) where a herbal substance is a dry herb, fresh herb, powder, oil, fresh juice or dry juice preparation - as the quantity of the herbal substance in the preparation;

(b) where a herbal substance is an extract, tincture, decoction, infusion or spagyric - as the quantity of the raw material herb used to make the ingredient expressed as the equivalent dry or fresh weight; or

(c) where a herbal substance is a concentrated or diluted juice - as the quantity of the raw material juice used to make the concentrate or dilution expressed as the equivalent dry weight, fresh volume or fresh weight;

8(12) 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;

8(13) for preparations containing Vitamin A - as the quantity or proportion of Vitamin A expressed in terms of retinol equivalents (R.E.);8(14) for pressurised metered dose inhalers and dry powder inhalers - as the delivered dose, except where the medicine is the subject of a monograph of the British Pharmacopoeia (BP) and the dose has been established as a metered dose. Where the powder for inhalation is supplied as a single dose in a capsule, or as a well in a blister tray or other suitable pharmaceutical form - as the quantity of active ingredient in each dosage unit;

8(15) 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;

8(16) for any other goods:

(a) where the goods are a liquid and include 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 goods;

(b) where the goods are a liquid and include an active ingredient which is a solid - as the weight of active ingredient in a stated volume of the goods;

(c) where the goods are a liquid and include an active ingredient which is a gas - as the weight of the active ingredient in a stated volume of the goods;

(d) where the goods are a solid and include 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 goods;

(e) where the goods are a solid and include an active ingredient which is a solid - as the weight of the active ingredient in a stated weight of the goods; or

(f) where the goods are a solid and include an active ingredient which is a gas - as the weight of the active ingredient in a stated weight of the goods.

9 Expression of potency in biological products

9(1) (a) The potency of liquid biological products or biological products which are required to be prepared before use must be included on labels and must be expressed as potency units or weight of active ingredient per dose or per unit volume or as the volume which contains the recommended dose;

(b) The potency unit to be used must be the International Unit (IU) established by the World Health Organisation.

9(2) 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 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.

11 Permitted statements of storage conditions

11(1) For the purposes of subsection 7(2):

(a) the following statements of storage conditions are permitted -

(i) 'Store below -18^{o}C (Deep freeze)';

(ii) 'Store below -5^{o}C (Freeze)';

(iii) 'Store below 8^{o}C (Refrigerate)';

(iv) 'Store at 2^{o}C to 8^{o}C (Refrigerate. Do not freeze)';

(v) 'Store below 25^{o}C'; and

(vi) 'Store below 30^{o}C';

(b) if none of the statements of storage conditions included in subparagraphs 11(1)(a)(i) to (vi) inclusive are applicable, the sponsor must apply to the Secretary for permission to use an alternative statement; and

(c) a statement of storage conditions specifying a maximum temperature in excess of 30^{o}C may be permitted on application to the Secretary, subject to the review of data to establish the stability of the goods at the higher temperature.

First schedule

Excipients required to be declared on the label of medicines

Reference to an excipient in this Schedule includes all salts and derivatives of the excipient. Ingredient names listed in column three of the table are indicative and do not constitute a complete or formal list.

The table below identifies those routes of administration where, for the purposes of the First Schedule, the ingredients must be declared.

Label Australian Approved Names (Label-AAN) have been created for certain excipients that have similar characteristics; grouping provides for the use of the 'Label-AAN' on the label where two or more of the ingredients in the group are present in the formulation. Presentation on the label should be in the form 'contains (label-AAN)'.

Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Ingredient Group or Name	**Conditions and Special Labelling Requirements**	**Ingredient Name(s)**	**Declaration Required for Routes of Administration**	**Grouping Name (Label-AAN)**
Aspartame		Aspartame	Oral	
Benzoic acid		Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate	All	Benzoates
Ethanol	**Condition:** Where present in a concentration of 3% v/v or more. **Requirement:** It shall be considered sufficient compliance with paragraph 7(2)(d) of this Order to use the statement 'Contains alcohol'.	Ethanol	All	Alcohol
Galactose		Galactose	Oral	
Gluten or excipients derived from gluten-containing grains (See also Note 1)*	**Condition:** Where gluten or an excipient derived from gluten-containing grains is present. **Requirement:** To declare the source of the gluten i.e. the gluten-containing excipient e.g. wheat starch, on the label.	Gluten	All; other than skin and mucous membrane applications	

Column 1	Column 2	Column 3	Column 4	Column 5
Ingredient Group or Name	**Conditions and Special Labelling Requirements**	**Ingredient Name(s)**	**Declaration Required for Routes of Administration**	**Grouping Name (Label-AAN)**
Hydroxybenzoic acid esters		Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate Sodium propyl hydroxybenzoate	All	Hydroxybenzoates
Lactose	**Condition:** Where present, notwithstanding the entry for lactose under 'Sugars - Monosaccharides and disaccharides'. **Requirement:** To declare the presence of lactose on the label; and **Condition:** 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.	Lactose Lactose monohydrate	Oral	
Peanuts and peanut products			All	
Phenylalanine		Phenylalanine	All; other than skin and mucous membrane applications	
Pollen -Bee		Pollen	Oral	
Propolis		Propolis	Oral	
Royal Jelly		Royal Jelly	Oral	
Saccharin		Saccharin	Oral	

Column 1	Column 2	Column 3	Column 4	Column 5
Ingredient Group or Name	**Conditions and Special Labelling Requirements**	**Ingredient Name(s)**	**Declaration Required for Routes of Administration**	**Grouping Name (Label-AAN)**
Sodium salts	**Condition:** Where the total sodium content of the formulation is greater than 120 mg of sodium per maximum recommended daily dose. **Requirement:** To declare the quantity of sodium per maximum recommended daily dose on the label.	Sodium bicarbonate Sodium chloride	Oral	Sodium salts
Sorbic acid		Potassium sorbate Sorbic acid	All	Sorbates
Sugar alcohols	**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'.	Isomalt Lactitol Maltitol Mannitol Sorbitol Xylitol	Oral	
Sugars - Monosaccharides and disaccharides (See also Note 2)	**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 100mg per recommended daily dose. **Requirement:** To declare the presence of certain sugars on the label.	Glucose Honey (as a mixture of sugars) Invert sugar Lactose Lactose monohydrate Maltose Sucrose	Oral	Sugars
Sulfite, metabisulfite and bisulfite salts and sulfur dioxide		Sulfur dioxide Potassium metabisulfite Sodium metabisulfite Sodium sulfite	All	Sulfites
Tartrazine	See Note 3	Tartrazine	All	

Note 1: Gluten - it is recognised that formulations of medicines do not usually include gluten as a separate excipient, although it may be present naturally as a constituent of some excipient ingredients, such as wheat starch. The Therapeutic Goods Administration agrees that medicines can be regarded as 'gluten-free' if the product contains no detectable gluten **and** contains no oats or malt.
Note 2: Sugars - Monosaccharides and disaccharides - some sugar derivatives may not have a significant impact on glycaemic control.

Column 1	Column 2	Column 3	Column 4	Column 5
Ingredient Group or Name	**Conditions and Special Labelling Requirements**	**Ingredient Name(s)**	**Declaration Required for Routes of Administration**	**Grouping Name (Label-AAN)**
Note 3: Tartrazine - The Australian Guidelines for the Registration of Drugs Volume 2 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.				

Second schedule

Alternative sources of product literature for disclosure of excipients - prescription medicines

Alternative sources of product literature for partial qualitative disclosure of excipients in medicines included in Schedules 4 and Schedule 8 of the Poisons Standard are:

1. The 'Product Information document (PI)' and 'Consumer Medicines Information (CMI)' available at PI/CMI search facility (https://www.tga.gov.au/picmi-search-facility)

2. The current edition of 'MIMS Annual' available at http://www.mims.com.au/index.php/products/product-overview.