Australian Government

Department of Health
Therapeutic Goods Administration

# Therapeutic Goods Order No. 91 -

# Standard for labels of prescription and related medicines

made under section 10 of the *Therapeutic Goods Act 1989*

## Compilation No. 2

**Compilation date:** **2 July 2018**

**Includes amendments up to:** Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018

Prepared by the Department of Health

# About this compilation

### This compilation

This is a compilation of the *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* that show the text of the law as amended and in force on 02/07/2018 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

### Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

### Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

### Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## Introduction

(1) This Order sets out what kinds of information are required to be included on the label of prescription and other related medicines of the kind described in section 3, and in what circumstances.

(2) The purpose of the label on a medicine is to provide information about the medicine such as its identity, potency, content, storage, expiry date, dose, directions for use, sponsor details and registration status. Labels on medicines can also include other information not required by this Order but which may be required by other legislation or for commercial purposes, such as the sponsor's logo.

(3) The information included on a label contributes 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 those medicines safely and effectively.

(4) The requirements set out in this Order are consistent with the National Medicines Policy which aims to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The four central objectives of the policy are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

(5) This Order also sets out general requirements for the labels of prescription and related medicines. The purpose of the Order is to facilitate the quality use of those medicines by consumers and health professionals by ensuring appropriate labelling. Consideration of the following objectives in designing labels, and assessing and determining compliance with the requirements of this Order, will assist in achieving that purpose:

- minimising the risk of prescribing and dispensing errors;
- enhancing consumer safety;
- avoiding consumer confusion and the inappropriate use of medicines (including misuse, over-use, and under-use);
- assisting the appropriate selection of those medicines;
- assisting the safe and effective use of those medicines;

- optimising identification and usability of necessary information;
- improving consumers' ability to solve problems related to those medicines, such as managing multiple medicines; and
- where relevant, ensuring consumers are aware of where to go for further information about their medicine.

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

(7) Under the Act:

- whether a medicine conforms to a standard applicable to the medicine is a matter the Secretary must take into account in deciding whether to include the medicine in the part of the Register for registered goods
- failure to conform to a standard applicable to a medicine is grounds for the Secretary to suspend or cancel the registration of the medicine
- failure to conform to a standard applicable to a medicine is grounds for the Secretary to require public notification and recovery of the medicine
- it is an offence to supply medicines in Australia that do not comply with a standard applicable to the medicine relating to labelling or packaging and civil penalties may be payable in relation to such supply
- whether the presentation of a medicine is acceptable is a matter the Secretary must take into account in deciding whether a medicine can be registered – 'presentation' means the way in which the medicine is presented for supply and includes matters relating to the labelling and packaging of the medicine. Subject to specified notice requirements, the Secretary may decide to suspend or cancel the registration of a medicine, if it appears to the Secretary that the presentation of the medicine is not acceptable
- the presentation of a supplied medicine which appears to the Secretary to be not acceptable is also grounds for the Secretary to require public notification and recovery of the medicine.

(8) To avoid doubt, this section is not part of the Order.

## 1 Name of Order

This Order is to be known as the *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines.*

## 2 Commencement

This Order commences on 31 August 2016.

## 3 Application - Therapeutic goods to which this Order applies

(1) Subject to sections 4 and 5, this Order applies to the following medicines supplied or for supply in Australia:

(a) Medicines of a kind specified in Part 1 of Schedule 10 to the Regulations, except for the following:

(i) goods that contain a substance mentioned in Schedule 9 to the Poisons Standard or a substance that is not mentioned in Schedule 9 but which meets the criteria for mention in that Schedule when making a decision to amend the Poisons Standard under section 52D(2) of the Act;

(ii) a medical gas;

(iii) osmotic pumps;

(iv) blood products under Item 13 that are described under paragraphs (a) and (b) under the heading 'HUMAN BLOOD PRODUCTS' in Appendix A to the Poisons Standard;

(b) composite packs containing a prescription medicine.

## 4 Transition arrangements

(1) On and from 31 August 2016 and before 1 September 2020, each medicine to which this Order applies must comply with either:

(a) the requirements specified in this Order; or

(b) the requirements specified in:

(i) *Therapeutic Goods Order No. 69 General requirements for labels for medicines* (TGO 69), up until 30 June 2017 (inclusive); or

(ii) *Therapeutic Goods Order No. 69 - General Requirements for Labels for Medicines 2017* (TGO 69 (2017)), on or after 1 July 2017.

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

(3) Notwithstanding subsections (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 TGO 69 (2017) if at the time of their release for supply they complied with TGO 69 (2017).

## 5 Exemptions – Medicines to which this Order does not apply

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

(a) intended for use in the treatment of another person in accordance with an approval set out in paragraph 19(1)(a) of the Act; or

(b) intended to be supplied to a Category A person under the exemption provided for in regulation 12A of the Regulations; or

(c) the subject of an authorisation granted under subsection 19(5) of the Act and its use is consistent with the requirements set out in regulation 12B of the Regulations; or

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

(d) exempted from the operation of Division 2 of Part 3-2 of the Act because of an exemption made by the Minister under section 18A of the Act in relation to that medicine; or

(e) the subject of an approval under section 19A of the Act; or

(f) intended for use solely for experimental purposes in humans in accordance with an approval set out in paragraph 19(1)(b) of the Act or in accordance with the requirements set out in Item 3 of Schedule 5A to the Regulations; or

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

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

(i) imported for use in the treatment of the importer or the importer's immediate family as set out in Item 1 of Schedule 5 to the Regulations; or

(j) an export only medicine as defined in the Act; or

(k) made up or compounded extemporaneously 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

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

(m) supplied, in the course of treating a patient, by a health professional in the lawful practice of his or her profession, unless it is a medicine described in section 3 of this Order in a starter pack.

(2) The requirements of this Order do not apply to a transparent covering that encloses or wraps the container or primary pack containing a medicine and where the information that is required to be set out on the label of the container or the primary pack is clearly visible through that transparent covering.

## 6 Interpretation

In this Order:

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

***active ingredient*** means a therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action;

***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;

***approved product details***, in relation to a medicine, means details in relation to the medicine as approved under section 25 of the Act for the registration of the medicine;

***Australian Approved Names List*** has the same meaning as in 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 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 has the following characteristics:

(a) clearly indicates that the information following the prefix is the batch number; and

(b) is in the following form: 'BATCH NUMBER', 'BATCH NO.', 'BATCH', 'B', '(B)', 'B/N', 'LOT NUMBER', 'LOT NO.', or 'LOT', or words or symbols to this effect, including a mixture of lower and upper case letters;

***biological medicine*** means a medicine:

(a) that is a vaccine; or

(b) that is a peptide, protein or polysaccharide-based, but is not an antibiotic; and

(c) that is derived from humans, animals or other organisms or produced through recombinant technology or biotechnology; and

(d) that is required to be included in the Register as registered goods: and

(e) is of a kind specified in Part 1 of Schedule 10 to the Regulations,

but does not include a 'biological' within the meaning of section 32A of the Act;

***calendar pack*** means a pack containing individual dosage units that is labelled with day/date markings to specify the sequence in which the dosage units in the pack must be used in order to achieve the intended therapeutic activity;

***capacity*** means the volume of the empty container;

***Certificate of Registration***, in relation to a medicine, means the certificate given to the applicant for registration of a medicine under subsection 25AB(4) of the Act in relation to that medicine;

***composite pack*** has the same meaning as in the Act;

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

***container*** has the same meaning as in the Act;

***default standard*** has the same meaning as in the Act;

***delivered dose*** means, in relation to:

(a) metered dose preparations - the dose delivered to the patient in a single actuation or delivery; and

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

***dial dispenser pack*** means a container that has the following characteristics:

(a) each of the dosage units is located in individual pockets preformed in a circular rigid tray;

(b) a close-fitting, rotatable, transparent lid which can only be rotated in one direction is located over the tray; and

(c) the individual dosage units can be dispensed by detaching a predefined portion of the lid or tray, and rotating the lid to the appropriate position;

***diluent*** means a liquid used for reconstitution or dilution;

***distributor*** means a company or corporate entity, which is not the sponsor, that the sponsor has agreed should be identified on a medicine's label;

***excipient***, in relation to a medicine, means an ingredient of the medicine other than the active ingredient and includes adjuvants;

***expiry date***, in relation to a product, means the date (month and year) after which the medicine should not be used;

***expiry date prefix*** means a prefix which precedes the expiry date which has the following characteristics:

(a) clearly indicates that the information following the prefix is the expiry date;

(b) is in the following form: 'EXPIRY DATE', 'EXPIRY', 'EXPIRES', 'EXP. DATE', 'EXP', ‘Use by’ or ‘Use before’ or words to this effect, including a mixture of lower and upper case letters;

(c) is not in the following form: ‘Best by' or ‘Best before’ or words to this effect.

***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;

***haemofiltration or haemodiafiltration solution*** means a replacement/substitution solution used in renal replacement therapy where the movement of solutes is by convection rather than diffusion (haemofiltration) or by a combination of convection and diffusion (haemodiafiltration);

***health professional*** includes the following:

(a) a health practitioner of any kind registered under a law of a State or Territory that provides for the registration of health practitioners of that kind; and

(b) a biomedical engineer, prosthetist or rehabilitation engineer;

***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, as determined by the osmotic pressure;

***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, as determined by the osmotic pressure;

***infusion*****,** in relation to injections, means a sterile, pyrogen-free, aqueous solution or emulsion with water as the continuous phase that is intended for slow administration, usually in large volume (>100mL), and does not contain any added antimicrobial preservative;

***intermediate packaging*** means a level of packaging which, if it exists, encloses one or more containers and is itself enclosed in a primary pack;

***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, as determined by the osmotic pressure;

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

***machine readable code*** means a code that:

(a) encodes the Global Trade Item Number (GTIN) for the medicine as allocated under the GS1 System; and

(b) identifies different product variants and differentiates between different strengths, pack sizes and dose forms;

(c) is formatted as one of the GS1 Bar Codes specified within the GS1 General Specification, which includes 2D / Matrix bar codes such as GS1 DataMatrix;

*Note: The machine readable code may also include additional information such as batch number and expiry date details.*

***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 name of the medicine is more or most conspicuously shown; or

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

***medical gas*** means a gas or a combination of gases presented for treating or preventing disease or administered to humans with a view to making a medical diagnosis or for the purpose of restoring, correcting or modifying physiological functions in humans;

***medicine*** has the same meaning as in the Act;

***name and contact details*** in respect of a sponsor or distributor, means

(a) the name of the sponsor or distributor and sufficient information to allow the sponsor or distributor to be uniquely identified so as to facilitate public contact on matters of complaint, use or general enquiry. The contact details must include information such as the city or suburb of the sponsor's/distributor's principal place of business in Australia (not being a post office, cable, telegraphic or code address). The Australian telephone number, website or email address may also be included; or

(b) where there has been a change in the sponsor's or distributor's name or contact details in the previous twelve months, the name and contact details of the previous sponsor or distributor;

***name of an active ingredient*** means the name of the active ingredient that is accepted for inclusion in the Australian Approved Names List;

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

***name of the dosage form*** means:

(a) in relation to a medicine that is intended to be, or is, registered goods, the name of the dosage form as entered, or proposed to be entered, in the Register in relation to the medicine; and

(b) in relation to a medicine that is not entered in the Register, the name of the pharmaceutical form of the medicine;

***name of the medicine*** means the following:

(a) where the medicine is intended to be, or is, entered in the Register - the name of the medicine intended to appear or appearing on the Certificate of Registration in relation to the medicine, not including the following information:

  (i) the name of the active ingredient (except where the name of the active ingredient is intended by the sponsor to be, or because of the way it is represented, to form part of the name of the medicine);

  (ii) the strength (except where numbers or words denoting strength are included in that name to differentiate medicines, by strength);

  (iii) the dosage form (except where this is integral to differentiate medicines from other medicines);

  (iv) container details;

  (v) the pack size;

  (vi) 'new formulation' or representations to the same effect;

(vii) flavour descriptors (except where this is integral to differentiate medicines from other medicines);

(viii) the name of the sponsor or distributor (or part thereof) (except where the name is intended by the sponsor to be, or because of the way it is represented, to form part of the name of the medicine); and

(b) where the medicine is neither intended to be, nor is, entered in the Register:

(i) the registered trade mark for the medicine; or

(ii) a unique, invented, common or scientific name

assigned to the medicine by the sponsor and appearing on the label;

***neuromuscular blocking agent*** means, for the purposes of this Order, any of the ingredients (or salts thereof) specified in Schedule 3 to this Order;

***osmolality*** means the number of osmoles (usually expressed as milliosmoles or mOsm) of the solute in a kilogram of water;

***pharmaceutical benefit*** has the same meaning as in the Regulations;

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

***primary pack*** has the same meaning as in 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 medicine or a medicine for injection - the stated weight in the container;

(ii) a liquid, other than a biological medicine - the stated volume of fill 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 medicine - the stated weight, number of doses or potency units in the container;

(vi) a liquid biological medicine - the stated volume of fill in the container and

(A) the stated weight, total number of doses or potency units in the container, or

(B) the stated weight, number of doses or potency units per unit volume, and

(c) subject to paragraph (d), where the medicine is a medicine of any of the kinds referred to in paragraph (b) and the medicine consists of a number of identical containers within the primary pack – the number of containers (e.g. 5 x 10 mL vials);

(d) for each of the individual containers within the primary pack, the quantity of the medicine to be included on the individual container label would be as described in paragraph (b) (e.g. for a liquid that is not a biological medicine, the stated volume of fill in the container);

***Register*** has the same meaning as in the Act;

***registered goods*** has the same meaning as in the Act;

***registration number*** means the combination of numbers and letters that is required to be included on the label of medicines in a manner described in regulation 15 of the Regulations

***Regulations*** means the *Therapeutic Goods Regulations 1990;*

***Secretary*** has the same meaning as in the Act;

***small container*** means a container having a capacity less than or equal to 25 millilitres that is not a very small container;

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

***sponsor*** has the same meaning as in the Act;

***standard*** has the same meaning as in the Act;

***stated volume of fill*** means the volume of medicine that the container is specified by the sponsor to contain;

***stated weight*** means the mass of medicine that the container is specified by the sponsor to contain;

***starter pack*** means:

(a) for medicines for which a pharmaceutical benefit is payable - a pack that does not exceed one-third of the most commonly prescribed pharmaceutical benefits quantity (the pharmaceutical benefits primary quantity); and

(b) for other medicines - a pack that does not exceed one-third of the smallest trade pack; and

(c) where it is not practical to produce a pack for a medicine that is one-third of the most commonly prescribed pharmaceutical benefits quantity or of the smallest trade pack, whichever is relevant, the smallest trade pack for the medicine;

***supply*** has the same meaning as in the Act;

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

***very small container*** means a container having a capacity less than or equal to 3.0 millilitres;

***warning statements*** means:

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

(b) any warning statements required by the Secretary to be included on the label as a condition of registration in relation to the medicine; and

(c) any warning statements specified in the Poisons Standard.

## 7 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 that comply with the requirements of this Order that are applicable in relation to that medicine.

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

(a) be clearly visible and not be obscured; and

(b) be in English; and

(c) be in durable and legible characters; and

(d) unless otherwise specified elsewhere in this Order, be displayed in text size of not less than 1.5 millimetres, except

(i) in the case of the registration number, which must be in a text size of not less than 1.0 millimetre height as required by subparagraph 15(1)(c)(i) of the Regulations; and

(e) be in a colour or colours contrasting strongly with the background, except for:

(i) the expiry date and expiry date prefix; and

(ii) the batch number and batch number prefix

when that information is embossed or debossed and not printed; and

(f) unless otherwise specified elsewhere in this Order, be in metric units of measurement.

## 8 Information to be included on the label

(1) Subject to the qualifications and requirements specified in sections 9 and 10 below, the labels of a medicine 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 name of the dosage form; and

(e) the quantity of the medicine; and

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

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

(h) the storage conditions applicable to the medicine; and

(i) the name and contact details of the sponsor or distributor of the medicine**;** and

(j) where:

(i) a substance or substance within the group of substances referred to in Column 1 of Schedule 1 to this Order is present in the medicine; and

(ii) the circumstances as set out in Column 2 of Schedule 1 exist in relation to such a substance or no circumstances are set out 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,

then:

(iv) a statement:

(A) indicating that the medicine contains the substance expressed using the Name stated in Column 4 of Schedule 1; and

(B) where any of the circumstances and requirements set out in Column 2 of Schedule 1 exist in relation to the substance – a statement of the kind referred to as a 'requirement' in that Column (if any)

except where a statement is included on the label advising consumers to refer to the Consumer Medicine Information for information about other ingredient(s) present in the medicine that are referred to in Column 1 of Schedule 1 to this Order and where any of the circumstances and requirements in column 2 of Schedule 1 exist in relation to the ingredient (s); and

(k) relevant warning statements, where these are required in relation to a particular medicine**;** and

(l) if the medicine requires some preparation, such as dissolving, suspending, diluting or reconstituting before use - instructions for its preparation and, where relevant, 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 either the label of the container or the primary pack, or both, to include this information; and

(ii) this information is set out in a package insert provided in the primary pack of the medicine; and

(iii) a statement is included on whichever label on the container, or the primary pack, or both, that does not set out the information itself, that those instructions are set out in the package insert; and

(m) if the medicine is:

(i) an injection or infusion - 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

(n) a machine readable code, except where the medicine is a starter pack; and

(o) where the medicine is packaged in a primary pack that is a carton, the name of the medicine on at least three non-opposing sides of the carton.

(2) The label on a container for a medicine must include a minimum space of 70 x 30 millimetres for the dispensing label, except where:

(a) the medicine and its container are supplied in a primary pack, in which case the space must be included on the label of the primary pack ; or

(b) this is precluded by the dimensions of either the container or the primary pack; or

(c) the medicine is intended only for use in a clinical setting where self-administration will not occur; or

(d) the medicine is a starter pack.

(3) If the information required on the label on the container is obscured by intermediate packaging, 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 of the sponsor or distributor, or a registered trademark if it readily identifies the sponsor or distributor of the medicine.

(4) If the container is enclosed in a delivery device such that it cannot be removed, the information required on its label under subsection 8(1) must be applied on the delivery device and not the container.

(5) In addition to the requirements under this section, if the medicine comprises both a medicine in a container and an article that is not a device under the provisions of the Act but is included in the primary pack for such purposes as delivery of and/or measuring the medicine, the label on the primary pack must include a description of any such articles.

## 9 Information to be included on the main label

(1) Subject to the qualifications and special requirements specified in this section and section 10 of this Order, the information on the main label of the medicine 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 name of the dosage form; and

(e) the quantity of the medicine; and

(f) if the medicine is:

(i) an injection or infusion - 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

(g) if the medicine is a solution for injection, powder for injection or concentrated solution for injection and the route of administration is only for infusion – then in addition to the requirement set out in paragraph (f), the words ‘for infusion’ must be displayed adjacent to the name of the dosage form

(2) The name of the medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information or background text.

(3) The name of the medicine and the name(s) of active ingredient(s) on the main label must:

(a) appear as a cohesive unit by the placing of the name and quantity of each active ingredient together on separate lines of text either

(i) immediately below the name of the medicine; or

(ii) where the trademark of the medicine might be disrupted or obscured, adjacent to the name of the medicine; and

(b) not be separated by any text or graphics, except where additional information is:

(i) required or permitted by:

(A) paragraph 11(2)(j); or

(B) subsection 11(6); or

(ii) in relation to identifying the different formulations of the medicines contained in a composite pack.

(3A) Where medicines are supplied as part of a composite pack, the names of each active ingredient, together with its quantity or proportion, must be provided separately in relation to each medicine's formulation, on the main label of the composite pack.

(4) All text required by this Order to be on the main label must be oriented in the same direction.

(5) Subject to subsections 9(6), 9(7), 9(8) and 9(9), the name of the active ingredient(s) and the quantity or proportion of active ingredient(s) must be displayed in a text size of not less than 3.0 millimetres.

(6) Subject to subsections 9(7) and 9(8), if there are four or more active ingredients in the medicine**,** the names of each active ingredient**,** together with its quantity or proportion, may be included on a side panel or side label or on a rear panel or rear label, displayed in a text size of not less than 2.5 millimetres.

(7) If the medicine is

(a) either

(i) for use as an intravenous infusion; or

(ii) is a haemofiltration or haemodiafiltration solution; and

(b) is supplied in a flexible bag container,

then subsections 9(3) and 9(4) do not apply to the medicine and, where there are eight or more active ingredients in the medicine, subsections 9(5) and 9(6) also do not apply to the medicine.

(8) For subsection 9(6), where medicines are supplied as part of a composite pack:

(a) the total number of active ingredients in all of the medicines in the composite pack are to be counted; and

(b) if the same active ingredient is contained in two or more medicines in the composite pack, each of those active ingredients is to be counted separately;

for the purposes of determining if subsection 9(6) applies to the composite pack; and

(c) the required information under subsection 9(6) must be provided separately in relation to the formulation of each medicine in the composite pack.

(9) Where the name of an active ingredient included in the medicine comprises an ingredient name specified in Schedule 2 to this Order, either alone or in combination with any other descriptors, then the names of all active ingredients in the medicine**,** together with their quantity or proportion, must be displayed in a text size of not less than 2.5 millimetres.

(10) Subsection 9(9) does not apply:

(a) where the medicine is supplied in a small container or a very small container; or

(b) after 30 April 2023.

*Note: The minimum text sizes for active ingredients on labels of small containers and very small containers are less than 2.5 millimetres and specified elsewhere in this Order.*

# 10 Qualifications and special requirements

## (1) Preparations for ophthalmic use

In addition to the requirements of sections 8 and 9 above, if a medicine is a preparation for ophthalmic use, the label on the container and on the primary pack or, where subsections 10(11) or 10(12) applies, on the primary pack, must include:

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

(b) if the medicine, other than an ophthalmic ointment, does not contain an antimicrobial preservative - the statement ‘Contains no antimicrobial preservative. Use once only and discard residue’ or words to that effect;

(c) if the medicine is for multidose use - a statement to the effect that ‘the medicine should not be used more than four weeks’, or such shorter period as specified in the approved product details in relation to the medicine, after the container is first opened;

(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 more than four weeks or such shorter period as specified in the approved product details in relation to the medicine, after the container is first opened.

(e) if the medicine consists of a solid ophthalmic medicine for preparing eye drops for multidose use - the words 'for eye drops'.

### (2) Injections in a container with capacity greater than 100 millilitres

In addition to the requirements under sections 8 and 9 applying to the label on the container and on the primary pack, a medicine that is an injection in a container having a capacity of greater than 100 millilitres must, except where subsection 10 (7) applies, include the following information or statements on the label on the container and on the primary pack:

(a) the name and quantity of each excipient in the stated volume of fill of the injection in the container; and

(b) where the medicine contains an active ingredient that 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 information 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 fill of the injection in the container; and

(c) where the medicine contains more than three active ingredients belonging to the same class of substances, such as amino acids, carbohydrates or electrolytes in the medicine – the information must include the class of substances and the name of the dosage form; and

(d) where the medicine contains iodine and 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

(e) where the medicine is intended for use as a radio-contrast agent or as a plasma volume expander or replacement - the product name must include a statement of the proportions of dissolved, emulsified or suspended active ingredient(s) in the goods; and

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

### (3) Injections in a container with a capacity of 100 millilitres or less

Except where subsection 10(4) or 10(5) below applies in relation to the label on a container, if a medicine is an injection in a container with capacity of 100 millilitres or less, then in addition to the requirements of sections 8 and 9 above, the label on the container and on the primary pack must include:

(a) the name and quantity of each excipient in the medicine, expressed:

(i) for single dose injections (including concentrated solutions for injection) - as the nominal mass of that excipient (not including any overage) in the stated volume of fill of the injection in the container;

(ii) for a powder for injection - as the nominal mass of that excipient (not including any overage) in the container;

(iii) where the injection is intended for multidose use - as the quantity of that excipient in one millilitre of the injection or where the dose volume is less than one millilitre as the quantity in that dose volume; and

(b) 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 statement 'Use in one patient on one occasion only. Contains no antimicrobial preservative' or words to that effect; and

(c) where the medicine is a concentrated solution for injection, a direction not to administer the solution undiluted; and

(d) where the medicine is an injection containing iodine and 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.

### (4) Injections in a container with a capacity of 25 millilitres or less

Except where subsection 10(5) applies, if a medicine is an injection that:

(a)is in a container with capacity of 25 millilitres or less; and

(b) the container is enclosed in a primary pack, the label of which complies with sections 8 and 9 and subsection 10(3)

then, in relation to compliance of the label on the container with sections 8 and 9 and subsection 10(3), it shall be sufficient if the following information is displayed in a text size of not less than 2.0 millimetres:

(c) the name of the medicine; and

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

and the following information is displayed in a text size of not less than 1.5 millimetres:

(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 of the sponsor or distributor as it appears on the primary pack, or registered trademark if it readily identifies the sponsor or distributor 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) where the medicine is an injection containing iodine and 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.

### (5) Injections in a container with a capacity of 3.0 millilitres or less

If a medicine is an injection that:

(a) is in a container with a capacity of 3.0 millilitres or less; and

(b) the container is enclosed in a primary pack, the label of which complies with the sections 8 and 9 and subsection 10(3)

then, in relation to compliance of the label on the container with sections 8 and 9 and subsection 10(3), it shall be sufficient if:

(c) the name of the medicine is displayed in a text size of not less than 1.5 millimetres; and

the following information is displayed in a text size of not less than 1.0 millimetre:

(d) the quantity of the medicine; and

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

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

(g) 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

(h) if the medicine contains only one active ingredient - the name of the active ingredient and the quantity or proportion of the active ingredient in the medicine, or suitable unambiguous abbreviation of the name and quantity, unless the name of the medicine includes this information; and

(i) if the medicine is available in more than one strength, the quantity or proportion of each active ingredient, unless the name of the medicine includes this information.

## (6) Injections with a stated volume of fill of 100 millilitres or more

In addition to the requirements under subsection 10(2) or 10(3), a medicine that is an injection with a stated volume of fill equal to or greater than 100 millilitres must also include the following information on the label on the container and the primary pack:

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

(b) where the medicine is intended for use as an energy source - a statement of the energy equivalent, in kilojoules, of the stated volume of fill of the injection in the container; and

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

(d) the osmolality of the injection solution; and

(e) the pH range of the injection solution.

## (7) Haemofiltration and haemodiafiltration solutions

The label on the container and on the primary pack of a medicine that is a haemofiltration or haemodiafiltration solution must, in addition to the requirements referred to in sections 8 and 9, include:

(a) the name and quantity of each active ingredient per litre of solution following preparation in accordance with directions; and

(b) the name and quantity of each active ingredient in terms of millimoles per litre of solution following preparation in accordance with directions; and

(c) a statement specifying whether the solution is hypotonic, hypertonic or isotonic; and

(d) the osmolality of the solution; and

(e) the pH range of the solution; and

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

## (8) Peritoneal dialysis solutions

The label on the container and on the primary pack of a medicine that is a solution for use in peritoneal dialysis must, in addition to the requirements referred to in sections 8 and 9, include:

(a) the formulation of the solution expressed in grams per litre and in millimoles per litre, including, if it is a concentrate for a peritoneal dialysis solution, the formulation both before and after dilution; 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; and

(g) if a concentrate, the statement 'Dilute before use.'

## (8A) Neuromuscular blocking agent-containing medicines

In addition to the requirements of sections 8 and 9, and the requirements in subsections 10(3), (4), (5) and (15) as applicable, if a medicine contains a neuromuscular blocking agent, then:

(a) the label on the primary pack must include the warning statement 'Warning: Paralysing agent' in black text on a fluorescent red or warm red background; and

(b) the label on the container must include the warning statement 'Warning: Paralysing agent' in black text on a fluorescent red or warm red background, except:

(i) where subsection 10(5) applies, in which case this warning statement may be shortened to 'Warning: Paralyser' or 'Paralyser'; or

(ii) where subsection 10(15) applies, in which case this warning statement must be on the label of each ampoule, and may be shortened to 'Warning: Paralyser' or 'Paralyser', and may be in any colour text with no background colour.

## (9) Preparations for use on skin and/or mucous membranes or by inhalation, and metered nasal sprays

The label on a container and on a primary pack (if any) of a medicine that is a preparation for use on skin and/or mucous membranes or is for inhalation or is a metered nasal spray, must, in addition to the requirements referred to in sections 8 and 9 above, include the name of any antimicrobial preservative in the medicine.

## (10) Starter packs

Where a medicine is presented in a starter pack, in addition to the requirements referred to in sections 8 and 9, the label on the container or primary pack (if any) must include:

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

(b) the statement 'starter pack' or words to that effect.

## (11) Small containers (not including injections)

If:

(a) the medicine is enclosed in a small container (but is not a very small container) and is not an injection; and

(b) the container is enclosed in a primary pack, the label of which complies with sections 8 and 9 and subsection 10(1) (if applicable),

then, in relation to compliance of the label on the container with sections 8 and 9 and subsection 10(1) (if applicable), it shall be sufficient if the following information is displayed in a text size of not less than 2.0 millimetres:

(c) the name of the medicine; and

(d) the name(s) of all active ingredients in the medicine, unless there are four or more active ingredients;

and the following information is displayed in a text size of not less than 1.5 millimetres:

(e) where there are four or more active ingredients, the name(s) of all active ingredients in the medicine; and

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

(g) the name of the dosage form; and

(h) the quantity of the medicine in the container; and

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

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

(k) the name of the sponsor or distributor as it appears on the primary pack, or registered trademark if it readily identifies the sponsor or distributor of the medicine; and

(l) 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

(m) 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, or another shorter period as specified in the approved product details in relation to the medicine, after the container is first opened ; 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, or another shorter period as specified in the approved product details in relation to the medicine, after the container is first opened;

## (12) Very small containers (not including injections)

If:

(a) the medicine is enclosed in a very small container but is not an injection; and

(b) the container is enclosed in a primary pack, the label of which complies with sections 8 and 9 and subsection 10(1) (if applicable),

then, in relation to compliance of the label on the container with sections 8 and 9, and subsection 10(1) (if applicable), it shall be sufficient if the name of the medicine is displayed in a text size of not less than 1.5 millimetres, together with the following information displayed in a text size of not less than 1.0 millimetre:

(c) the quantity of the medicine in the container; 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) 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

(g) if the medicine contains only one active ingredient - the name of the active ingredient and the quantity or proportion of the active ingredient in the medicine, or suitable unambiguous abbreviation of the name and quantity.

## (13) Individually wrapped medicines

(a) Subject to paragraph (b), if:

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

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

(iii) one or more dosage units are enclosed in a primary pack; and

(iv) the label on the primary pack complies with sections 8 and 9,

then, in relation to compliance of the label on each individual wrapper or blister with sections 8 and 9, it shall be sufficient if the following information is displayed:

(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 of the sponsor or distributor, or registered trademark if it readily identifies the sponsor or distributor of the medicine.

(b) If:

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

(ii) each dosage unit is enclosed in an unsealed individual wrapper; and

(iii) each dosage unit is, after being so wrapped, enclosed in a primary pack that complies with sections 8 and 9,

then, in relation to compliance of the label for each individual wrapper with sections 8 and 9, it shall be sufficient if the name of the medicine is displayed.

## (14) Strip, blister and dial dispenser packs

(a) Subject to paragraph (b), if:

(i) a medicine consists of individual dosage units such as tablets, capsules, pills, 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, the label of which complies with sections 8 and 9,

then, in relation to compliance of the label on the strip, blister or dial dispenser pack with sections 8 and 9, it shall be sufficient if the following information is displayed:

(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 of the sponsor or distributor, or registered trademark if it readily identifies the sponsor or distributor of the medicine.

(b) If, in relation to a medicine referred to in (a) there are:

(i) four or more active ingredients in the medicine,

then, in relation to compliance of the label on the strip, blister or dial dispenser pack with sections 8 and 9, it shall be sufficient if the following information is displayed:

(ii) the name of the medicine; and

(iii) the batch number of the medicine preceded by the batch number prefix;

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

(v) the name of the sponsor or distributor, or registered trademark if it readily identifies the sponsor or distributor of the medicine.

(c) In addition to the requirements referred to in paragraphs 10(14)(a) and (b) as relevant, if each dosage unit is enclosed in the strip or blister such that an individual segment containing the dosage unit can be readily detached, then the following information must appear on the label of the strip or blister at least once in relation to every two dosage units:

(i) for a medicine to which paragraph 10(14)(a) applies – the name of the medicine, the name(s) of all active ingredients in the medicine and the quantity or proportion of all active ingredients in the medicine; and

(ii) for a medicine to which paragraph 10(14)(b) applies – the name of the medicine.

## (15) Plastic ampoules

(a) Subject to paragraph (b), if:

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

(ii) the capacity of the plastic ampoule is 8 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 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) 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 name(s) of all the active ingredients in the medicine; and

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

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

(v) the expiry date of the goods preceded by the expiry date prefix; and

(vi) the approved route(s) of administration followed by the word 'only' and/or warnings against use by other routes of administration.

(c) If a medicine is contained in a plastic ampoule with a capacity of 25 millilitres or less, but greater than 8 millilitres, then the requirements of subsection 10(4), or subsection 10(11), as relevant, apply notwithstanding the container being a plastic ampoule.

(d) If a medicine is contained in a plastic ampoule with a capacity greater than 25 millilitres, then the requirements of subsection 10(2) or subsection 10(3), as relevant, apply notwithstanding the container being a plastic ampoule.

## (16) Composite packs

(a) The expiry date on the package that, together with medicines, constitutes a composite pack must be the earliest of the expiry dates of the medicines that constitute the composite pack.

(b) The storage conditions on the package that, together with medicines, constitutes a composite pack must be the most restrictive of the storage conditions of the medicines that constitute the composite pack.

*Note:* *The label on the container and primary pack (if any) of each medicine comprising a composite pack must comply with this Order.*

## 11 How information is to be expressed

### (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) Where a range of medicines contains the same active ingredient(s) in the same dosage form in a series of strengths then the label must state the quantity of each active ingredient in terms of either the highest or lowest metric unit of measurement in the series of strengths.

*Example:* *A range of expressions for active ingredient may be stated as 0.5 milligram, 1 milligram and 5 milligrams, or 500 micrograms, 1000 micrograms and 5000 micrograms, but not 500 micrograms, 1 milligram and 5 milligrams.*

*Note:* *The abbreviations 'mg' and 'g' can be used on all labels but 'microgram' should be used in full unless the medicine is in a small or very small container. Then the abbreviation 'μg' may be used.*

(c) Where the active ingredient is in liquid form, the equivalent metric units of volume must be expressed in the same manner.

*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.*

*Note: The abbreviations 'mL' and 'L' can be used on all labels, but 'microlitre' should be used in full unless the medicine is in a small or very small container. Then the abbreviation 'μL' may be used.*

(d) Where the information is a statement of mass or volume, the unit of measurement must be consistent with the unit of measurement used in any warning statement required for that ingredient.

(e) Where a statement of quantity is expressed as less than one (1) unit, the statement of quantity must include the leading zero.

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

Subject to subsections 11(3) or 11(4) below, 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 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;

(c) subject to paragraph (d) below, if the medicine is a liquid for ingestion:

(i) as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid; or

(ii) in the case where the liquid for ingestion is one of a series of strengths containing the same active ingredient – as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid with the quantity or proportion of active ingredient expressed consistently across the series in terms of the same stated dose volume.

*Example: Where the dose volume is 5 mL, and there are strengths of 1 mg/mL and 5 mg/mL, these must be labelled as 5 mg in 5 mL and 25 mg in 5 mL, respectively.*

(d) for a medicine required to be prepared before use, and:

(i) where the process results in a medicine that is a liquid for ingestion:

(A) 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; or

(B) in the case where the medicine is one of a series of strengths containing the same active ingredient - 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 with the quantity or proportion of active ingredient expressed consistently across the series in terms of the same stated dose volume; and

*Example: Where the dose volume is 5 mL after preparation, and there are strengths of 1 mg/mL and 5 mg/mL, these must be labelled as 5 mg in 5 mL and 25 mg in 5 mL, respectively.*

(ii) for any other medicines - 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;

(e) for a transdermal patch, intrauterine drug delivery system or implant - as the total quantity of the active ingredient in each patch, drug delivery system or implant and the quantity of the active ingredient released in a stated time;

(f) for a medicine for injection:

(i) where the medicine is a powder for injection or a concentrated solution for injection – as the stated weight of the active ingredient in the container;

(ii) where the stated volume of the medicine for injection is greater than 100 millilitres and the medicine is intended:

(A) for electrolyte replacement or nutritional therapy; or

(B) as a plasma volume expander; or

(C) as an additive to any of these types of injection,

then:

(D) 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

(E) 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;

(iii) where the stated volume of the medicine for 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 stated volume of injection in the container;

(iv) where the medicine for injection is intended for multidose use:

(A) where the stated volume in the container is greater than 1 millilitre - as the quantity of the active ingredient in one millilitre of the injection; and

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

(v) where the medicine for injection is intended for use as a single dose (whether dilution is required or not) - as the stated weight of the active ingredient in the stated volume of fill of the injection in the container.

(g) 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;

(h) for pressurised metered dose inhalers, dry powder inhalers and other metered dose products such as nasal sprays, the quantity of the active ingredient is:

(i) the quantity delivered per actuation; or

where the Secretary, when registering the medicine, has accepted that the dose of products containing those active ingredients was clinically established as the metered dose, then:

(ii) the quantity metered per actuation;

(i) for preparations applied to the skin and mucous membranes, other than those covered by paragraphs (g) and (h) - 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;

(j) for the purposes of paragraphs 11(2)(a) – 11(2)(d), for oral preparations that contain active ingredients intended for mineral supplementation, it is sufficient that the quantity or proportion of that active ingredient to be included on a label be expressed as:

(i) the name of the active ingredient; and

(ii) the name and quantity of the element intended for mineral supplementation.

(k) In addition to the requirements of paragraphs 11(2)(a) –11(2)(i), the following requirements apply in the circumstances specified in the following subparagraphs:

(i) for preparations containing Vitamin A or a derivative of Vitamin A - as the equivalent quantity or proportion of Vitamin A expressed in terms of microgram retinol equivalents;

(ii) for a preparation containing biological organisms - as the number of organisms present per metric unit for liquids and powders and as the number of organisms present per dosage unit for other dosage forms;

(l) for any other medicines:

(i) where the medicine is a liquid and includes 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 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 or semi-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 or semi-solid and includes an active ingredient which is a solid - as the weight of the active ingredient in a stated weight of the medicine.

## (3) Expression of potency in biological medicines

(a) For a liquid biological medicine or a biological medicine required to be prepared before use, the potency:

(i) must be included on the label of the medicine; and

(ii) 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:

(i) the International Unit (IU) established by the World Health Organization;

(ii) a unit defined in an applicable default standard; or

(iii) where IU or pharmacopoeial monographs have not been established, then the potency unit to be used is that specified in the approved product details in relation to the medicine.

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

The quantity or proportion of an active ingredient which is a radionuclide and is included in a radiopharmaceutical preparation must be:

(a) included on labels; and

(b) 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 temperature conditions

For the purposes of this Order, the following statements of storage temperature conditions are permitted:

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

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

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

(iv) 'Store below 25$^{o}$C';

(v) 'Store below 30$^{o}$C'; and

(vi) any other storage temperature conditions as specified in the approved product details in relation to the medicine.

## (6) Inclusion of common names of vitamins

Where a medicine contains an active ingredient that is a vitamin, then the word 'vitamin', or any suitable unambiguous abbreviation of the word vitamin, together with the common name of that vitamin, may appear on a main label of the medicine either:

(a) on the same line of text - between the approved name of the active ingredient that is a vitamin and the quantity of that active ingredient; or

(b) on a separate line of text - immediately below the related name of the active ingredient that is a vitamin and the quantity of that active ingredient.

## Schedule 1

# Substances or Groups of substances present in medicines that are required to be declared on the label of medicines

**Column 1** includes a general descriptor for the substance or group of substances required to be declared on the label of medicines, and a number of indicative substances names for particular groups of substances.

**Column 2** specifies the circumstance, such as specified concentration of the substance when present in the medicine or specified amounts of substances contained in the medicine, where if it occurs require the particular declaration on the label identifying the particular substance or group of substances set out in column 1, and provides additional required statements that are supplemental to the required declaration on the label. Where there are no circumstances specified in column 2, then the presence of the substance or group of substances is required to be declared on the label irrespective of any circumstance, concentration or amount of the substance or group of substances present in the medicine.

**Column 3** identifies those routes of administration of the medicine containing the substance or group of substances, where for the purposes of this Schedule and taking into consideration any circumstance specified in column 2, the substance or group of substances must be declared on the label.

**Column 4** identifies the name of the substance, the group of substances or a general descriptor of the substance to be included on the label of the medicine where the particular substance or group of substances are present in the medicine. The name also describes a group of substances that have similar characteristics and is to be used irrespective of whether one or more of the substances in the group are present in the formulation. Presentation on the label must be in the form "Contains 'Name (as set out under Column 4)'". Where more than one name (as set out under Column 4) is required to be declared, they may be combined to form simple sentences where appropriate.

| Column 1<br>Substance name or Group of substances name | Column 2<br>Circumstances (if any) and additional requirements (if any) | Column 3<br>Route of administration | Column 4<br>Name to be included on the label |
|---|---|---|---|
| **aspartame** | | Oral | aspartame |
| **antibiotics** | When the antibiotic is not an active ingredient and is present only as a residual impurity | All | Contains residual 'antibiotic name' |
| **benzoates**, including:<br>benzoic acid<br>sodium benzoate | | All | benzoates |

| | | | |
|---|---|---|---|
| **crustacea and crustacean products** (see Note 1), including:<br>crab<br>lobster<br>white shrimp | | All | crustacea; or<br>crustacean products |
| **egg, egg products**, and products manufactured in eggs including:<br>dried egg yolk<br>egg lecithin<br>influenza vaccine | | All | egg; or<br>egg products or manufactured in eggs |
| **ethanol** | **Circumstance:** Where present in a concentration of 3% v/v or more.<br>**Requirement:** To declare on the label the quantity of ethanol as % v/v. | All | alcohol |
| **fish and fish products** (see Note 2), including:<br>cod<br>cod – liver oil<br>halibut<br>tuna | | All | fish; or<br>fish products |
| **galactose** | | Oral | galactose |
| **gluten** or ingredient derived from gluten-containing grain (see Note 3) | **Circumstance:** Where gluten is present in a concentration of 20 parts per million or more. | All, other than skin and mucous membrane applications | gluten |
| **hydroxybenzoic acid esters**, including:<br>ethyl hydroxybenzoate<br>methyl hydroxybenzoate<br>propyl hydroxybenzoate<br>sodium ethyl hydroxybenzoate<br>sodium methyl hydroxybenzoate<br>sodium propyl hydroxybenzoate | | All | hydroxybenzoates |
| **lactose** (see Note 4) | | Oral | lactose |
| **milk and milk products**, including (see Note 4):<br>casein<br>hydrolysed milk protein<br>nonfat dry milk<br>whey powder<br>whole dry milk | | All | milk; or<br>milk products |

| | | | |
|---|---|---|---|
| **peanuts and peanut products,** including:<br>*Arachis hypogaea*<br>arachis (peanut) oil | | All | peanuts; or<br>peanut products |
| **phenylalanine (see Note 5)** | | All, other than skin and mucous membrane applications | phenylalanine |
| **pollen** | | Oral | pollen |
| **potassium salts**, including:<br>potassium bicarbonate<br>potassium chloride | **Circumstance:** Where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1mmol) elemental potassium.<br>**Requirement:** To declare on the label (in mg) the quantity of elemental potassium per dosage unit or in a stated weight or volume of the medicine. | Oral | potassium |
| **propolis** | | Oral | propolis |
| **royal jelly** | | Oral | royal jelly |
| **saccharin**, including:<br>saccharin calcium<br>saccharin sodium | | Oral | saccharin |
| **sesame seeds and sesame seed products**, including:<br>sesame seed<br>sesame oil<br>*Sesamum indicum* | | All | sesame seeds; or<br>sesame seed products |
| **sodium salts**, including:<br>sodium bicarbonate<br>sodium chloride | **Circumstance:** Where the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium.<br>**Requirement:** To declare on the label (in mg) the quantity of elemental sodium per dosage unit or in a stated weight or volume of the medicine. | Oral | sodium |

| | | | |
|---|---|---|---|
| **soya beans and soya bean products**, including:<br>*Glycine max*<br>soya bean<br>soya oil<br>excluding:<br>• soya oil that is fully refined;<br>• d-alpha tocopherol, d-alpha tocopheryl acetate, d-alpha tocopheryl acid succinate, mixed (high-alpha type) tocopherols concentrate, or mixed (low-alpha type) tocopherols concentrate when derived from soybean sources;<br>• vegetable oils derived phytosterols and phytosterol esters from soybean sources;<br>• plant stanol ester produced from vegetable oil sterols from soybean sources. | | All | soya beans; or<br>soya bean products |
| **sorbic acid and sorbic acid salts**, including:<br>potassium sorbate | | All | sorbates |
| **sucralose** | | Oral | sucralose |
| **sugar alcohols** (see Note 5A), including:<br>erythritol<br>isomalt<br>lactitol<br>maltitol<br>mannitol<br>polydextrose<br>sorbitol<br>xylitol | **Circumstance**: Where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose.<br><br>**Requirement:** To declare on the label the quantity of sugar alcohols present per recommended maximum daily dose; and a statement 'Products containing (name of sugar alcohol) may have a laxative effect or cause diarrhoea'. | Oral | sugar alcohols; or<br>name of sugar alcohol |
| **sugars – monosaccharides and disaccharides** (see Note 6), including:<br>fructose<br>glucose<br>honey (as a mixture of sugars)<br>invert sugar<br>lactose<br>maltose<br>sucrose | **Circumstance:** 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 maximum recommended daily dose. | Oral | sugars |

| | | | |
|---|---|---|---|
| **sulfites**, including: (see Note 7)<br>potassium metabisulfite<br>sodium bisulfite<br>sodium metabisulfite<br>sodium sulfite<br>sulfur dioxide | | All | sulfites |
| **tartrazine** | | All | tartrazine |
| **tree nuts and tree nut products** (see Note 8), including:<br>almond oil<br>*Juglans nigra*<br>macadamia nut oil<br>*Macadamia ternifolia*<br>*Prunus dulcis*<br>walnut | | All | tree nuts; or<br>tree nut products |

**Note 1**: **Crustacea** include various species of aquatic animals which have an inedible chitinous outer shell. These include but are not limited to crab, crayfish, lobster, prawn and shrimp.

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

**Note 3: Gluten –** some formulations of medicines may contain gluten that is present naturally as a constituent of an ingredient such as wheat starch.

**Note 4: Lactose,** where obtained from milk, does not require the 'contains milk product' statement.

**Note 5: Phenylalanine -** In the context of complementary medicines that contain phenylalanine, the Schedule 1 requirements apply in the following instances:

- Where phenylalanine is an ingredient in a medicine formulation.
- For medicines containing ingredients such as *Spirulina*, legumes, nuts or soy products that are naturally high in phenylalanine.
- Where processing of an ingredient, prior to inclusion in a pharmaceutical dosage form, results in enrichment of the phenylalanine content.

**Note 5A: Sugar alcohols** – It is generally accepted that while glycerol is a sugar alcohol, it does not have a laxative effect. Therefore, glycerol is not required to be declared in relation to sugar alcohols and their associated laxative effect.

**Note 6: 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. Where lactose is present in the medicine, the entries under 'lactose', 'sugars –monosaccharides and disaccharides' and 'milk and milk products' (if of dairy origin) each apply.

**Note 7: Sulfur dioxide** – some formulations of medicines may contain sulfur dioxide as a residue, for example, gelatin, but must be identified.

**Note 8**: **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.

## Schedule 2

# Specified medicine ingredient names

| Ingredient name |
|---|
| dactinomycin (actinomycin D) |
| tetracaine (amethocaine) |
| amphotericin B (amphotericin) |
| amobarbital (amylobarbitone) sodium |
| Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain) |
| trihexyphenidyl (benzhexol) |
| asparaginase (colaspase) |
| mecobalamin (co-methylcobalamin) |
| methylrosanilinium chloride (Crystal violet CI42555) |
| mercaptamine (cysteamine) |
| dosulepin (dothiepin) |
| doxycycline hyclate |
| formoterol (eformoterol) |
| furosemide (frusemide) |
| glycopyrronium bromide (glycopyrrolate) |
| hydroxycarbamide (hydroxyurea) |
| lidocaine (lignocaine) |
| pentoxifylline (oxpentifylline) |
| phenobarbital (phenobarbitone) |
| estropipate (piperazine oestrone) |
| procaine benzylpenicillin (procaine penicillin) |
| calcitonin salmon (salcatonin) |
| tetracosactide (tetracosactrin) |
| alimemazine (trimeprazine) |

## Schedule 3

# Specified neuromuscular blocking agents (or salts thereof)

| |
|---|
| alcuronium |
| atracurium |
| cisatracurium |
| dimethyltubocurarine |
| doxacurium |
| fazadinium |
| gallamine |
| hexafluronium |
| mivacurium |
| pancuronium |
| pipecuronium |
| rocuronium |
| suxamethonium |
| tubocurarine |
| vecuronium |

## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

**Abbreviation key—Endnote 2**
The abbreviation key sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

**Misdescribed amendments**
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

## Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

## Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
|---|---|---|---|
| Therapeutic Goods Order No.91- Standard for labels of prescription and related medicines | 16/08/2016 (see F2016L01285) | 31 August 2016 | |
| Therapeutic Goods Order No.91A- Therapeutic Goods Order No.91 (Standard for labels of prescription and related medicines) Amendment Order 2017 | 14/08/2017 (see F2017L01019) | 15 August 2017 | |
| Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018 | 18/06/2018 (see F2018L00790) | 2 July 2018 | |

## Endnote 4—Amendment history

| Provision affected | How affected |
|---|---|
| s4(1) | rsF2017L01019 |
| s4(3) | rsF2017L01019 |
| s5(1) | adF2017L01019 |
| s6 | amF2018L00790 |
| s9(3A) | adF2018L00790 |
| s9(8) | amF2018L00790 |
| s10(8A) | adF2018L00790 |
| s11(6) | amF2018L00790 |
| Sch1 | amF2017L01019 |
| Sch3 | adF2018L00790 |