Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026

I, Nicholas Henderson, as delegate of the Minister for Health and Ageing, make the following order.

Dated 25 September 2026

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health, Disability and Ageing

Authorised Version F2026L01311 registered 28/09/2026

Contents

Part 1—Preliminary 1

1 Name 1
2 Commencement....1
3 Authority 1
4 Definitions....1
5 Standard....8
6 Application 8
7 Repeals 9

Part 2—General labelling provisions 10

8 General requirements 10
9 Machine readable codes 10

Part 3—Labelling requirements for containers, primary packs and intermediate packaging 12

Division 1—Labels on containers and primary packs 12

10 Application 12

Subdivision 1.1—Main labels 12

11 Information to be included on the main label of a medicine....12

Subdivision 1.2—Labels 15

12 Information to be included on the label of a medicine....15

Division 2—Labels on intermediate packaging 16

13 Information to be included on the label on intermediate packaging 16

Division 3—Labelling requirements for certain containers and packaging 16

Subdivision 3.1—Injections 16

14 Injections in a container that is a small container (more than 3 mL and up to 25 mL).....16
15 Injections in a container that is a very small container (3 mL or less)....17

Subdivision 3.2—Other containers 18

16 Small container of a medicine that is not an injection (more than3 mL and up to 25 mL) 18
17 Very small container of a medicine that is not an injection (3 mL or less)....19
18 Individually wrapped dosage units....20
19 Strip, blister or dial dispenser pack 20
20 Plastic ampoule with a capacity of 8 mL or less 21

Subdivision 3.3—Composite packs 23

21 Medicines in a composite pack 23
22 Information to be included on the main label of a composite pack 23
23 Information to be included on the label of a composite pack 25

Part 4—Additional labelling requirements for certain medicines 26

24 Application of this Part....26

Division 1—Injections 26

25 Injections in a container with a capacity more than 100 mL....26
26 Injections in a container with a capacity 100 mL or less 27
27 Injections in a container with a stated volume of fill of 100 mL or more....27
28 Haemofiltration or haemodiafiltration solutions 28
29 Peritoneal dialysis solutions 28

Authorised Version F2026L01311 registered 28/09/2026

30 Potassium for injection or infusion 29
31 Neuromuscular blocking agents 29
32 Vaccines 29
Division 2—Specialty routes of administration or dosage forms 30
33 Medicines for use on skin or mucous membranes or by inhalation, or that is a metered nasal spray....30
34 Medicines for ophthalmic use 30
35 Modified release oral dosage forms 30
Division 3—Starter packs 31
36 Starter packs 31
Part 5—How information is to be expressed on the label 32
37 Use of metric units 32
38 Expression of quantity or proportion of active ingredients for medicines 33
39 Expression of quantity or proportion of active ingredients for medicines that are an injection 34
40 Expression of potency in biological medicines 36
41 Expression of activity of radionuclides in radiopharmaceutical preparations 36
42 Permitted statements of storage temperature conditions 36
43 Including common names of vitamins 37
Part 6—Application, saving and transitional provisions 38
44 Listing active ingredients on certain medicines 38
45 TGO 91 38
Schedule 1—Substances that are required to be declared on the label 40
Schedule 2—Specified ingredient names 48
Part 1—Dual labelling name 48
Part 2—Dual labelling name permitted until 30 April 2028 48
Schedule 3—Specified neuromuscular blocking agents (including their salts) 49
Schedule 4—Repeals 50
Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines 50

Authorised Version F2026L01311 registered 28/09/2026

Part 1—Preliminary

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026*.

(2) This instrument may also be cited as TGO 115.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	30 September 2026.	30 September 2026

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) batch;
(b) composite pack;
(c) container;
(d) current Poisons Standard;
(e) default standard;
(f) directions for use;
(g) label;
(h) medicine;
(i) primary pack;
(j) Register;
(k) registered goods;
(l) registration number;
(m) Secretary;
(n) sponsor;

Authorised Version F2026L01311 registered 28/09/2026

(o) standard;
(p) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

antimicrobial preservative means an ingredient added to a medicine to inhibit the growth of microorganisms in the medicine.

Australian Approved Names List has the same meaning as in the Regulations**.**

batch number means a number, or a combination of letters, numerals, or symbols, which is given by a manufacturer to a batch of medicine to uniquely identify the batch.

Note: The batch number may be used to trace the batch through all stages of manufacture and distribution.

batch number identifier means any words or symbols that clearly indicate that the information accompanying those words or symbols is the batch number.

Note: Common forms of the batch number identifier include the following (either in capital letters, lower case letters or a combination of capital and lower case letters):
(a) Batch number;
(b) Batch no.;
(c) Batch;
(d) B;
(e) (B);
(f) B/N;
(g) Lot number;
(h) Lot No.;
(i) Lot.

biological medicine means a therapeutic good that is a medicine, and not a biological, that is:

(a) a vaccine, a peptide, a protein or polysaccharide-based, and is not an antibiotic; and
(b) derived from humans, animals or other organisms or produced through recombinant technology or biotechnology; and
(c) required to be included in the Register as registered goods: and
(d) of a kind specified in Part 1 of Schedule 10 to the Regulations.

capacity, in relation to a container, means the volume of the container when empty.

capsule means a solid preparation with a hard or soft shell of various shapes and capacities, containing one or more active ingredients.

cohesive unit has the meaning given by subsection 11(5).

concentrated injection means a medicine in the form of a sterile liquid, to which a sterile diluent is added to prepare the medicine for administration by injection.

Authorised Version F2026L01311 registered 28/09/2026

deliverable dose means:

(a) in relation to a metered dose preparation—the dose delivered to a patient in a single actuation or delivery;

(b) in relation to a dry powder inhaler—the dose delivered from the inhaler in a single delivery.

dial dispenser pack means a circular rigid tray that has:

(a) single dosage units contained in individual spaces in the tray; and

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

(c) predefined portions on the lid or tray that can be detached to dispense individual dosage units.

diluent means a liquid used for reconstitution or dilution.

excipient means an ingredient in a medicine other than an active ingredient.

expiry date has the same meaning as in the Regulations.

expiry date identifier means any words or symbols that clearly indicate that the information accompanying those words or symbols is the expiry date, other than words indicating that the goods may be used after the date, including 'Best by' and 'Best before'.

Note: Common forms of the expiry date identifier include the following (either in capital letters, lower case letters or a combination of capital and lower case letters):

(a) Expiry date;

(b) Expiry;

(c) Expires;

(d) Exp. Date;

(e) Exp;

(f) Use by;

(g) Use before.

Global Trade Item Number, or ***GTIN***, means the GS1 identification key used to identify trade items as defined in the GS1 General Specifications.

Note: A GTIN comprises a GS1 company prefix, an item reference and check digit.

GS1 means the not-for-profit standards organisation known as GS1 that has its headquarters in Belgium.

GS1 General Specifications means the standard titled '*GS1 General Specifications*' published by GS1, as in force from time to time.

Note: This standard is available on the internet at www.gs1.org.

haemofiltration or haemodiafiltration solution means a replacement solution used in renal replacement therapy, where the movement of solutes is by convection rather than diffusion in haemofiltration or by a combination of convection and diffusion in haemodiafiltration.

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.

Authorised Version F2026L01311 registered 28/09/2026

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, and does not contain any added antimicrobial preservative.

intermediate packaging means packaging which:

(a) encloses one or more containers; and

(b) is enclosed in its primary pack.

label on intermediate packaging means the label on the intermediate packaging of a medicine.

isotonic, in relation to the tonicity of large volume injections, means an injection with an osmolality of 250 milliosmoles or more and 350 milliosmoles or less per kilogram of solvent, as determined by the osmotic pressure.

machine readable code means one of the following that provides access to information about a medicine:

(a) a code that encodes the Global Trade Item Number and is formatted in accordance with the GS1 General Specifications;

(b) a QR code.

main label means:

(a) the label, or part of the label, that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and

(b) if there are 2 or more labels:

(i) the label, or part of the label, where the name of the good is more or most conspicuously displayed; or

(ii) if the name of the good is equally more or most conspicuously displayed on more than one of those labels—each of the labels on which the name of the good is equally more or most conspicuously displayed.

medical gas means a gas or a combination of gases presented for use in humans for:

(a) treating or preventing disease; or

(b) administration to make a medical diagnosis; or

(c) the purpose of restoring, correcting or modifying physiological functions.

modified-release means:

(a) in relation to a tablet—a coated or uncoated tablet which contains special excipients or which is prepared by special procedures, or both, designed to modify the rate, the place or the time at which the active ingredient is, or active ingredients are, released; or

(b) in relation to a capsule—a hard or soft capsule in which the contents or shell, or both, contain special excipients or are prepared by special

Authorised Version F2026L01311 registered 28/09/2026

procedures designed to modify the rate, the place or the time at which the active ingredient is, or active ingredients are, released.

name means:

(a) in relation to an active ingredient or an excipient—the name that is included in the Australian Approved Names List;

(b) in relation to a dosage form—the name of:

(i) for a medicine that is intended to be, or is, a registered medicine—the name of the dosage form as entered, or proposed to be entered, in the Register in relation to the medicine or a pharmaceutical form consistent with that dosage form; or

(ii) for medicine that is not in the Register—the name of the pharmaceutical form of the medicine;

(c) in relation to a medicine—one of the following:

(i) for a medicine that is intended to be, or is, a registered medicine—the commercial name under which the medicine is, or is to be, supplied as entered, or proposed to be entered, in the Register;

(ii) for a medicine that is intended to be, or is, a registered medicine that does not have a commercial name under which the medicine is, or is to be, supplied—the name of the medicine in an application for registration, or the name of the medicine in the Register, excluding any of the following information:

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

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

(C) the dosage form, except where this is needed to differentiate medicines from other medicines;

(D) container details;

(E) the pack size;

(F) the statement ‘new formulation’ or representations to this effect;

(G) flavour descriptors, except where this is needed to differentiate medicines from other medicines;

(H) the name of the sponsor or person representing the sponsor, except where the name is intended by the sponsor, or intended because of the way it is represented, to form part of the name of the medicine; or

(iii) for a medicine that is not in the Register—the registered trade mark for the medicine or, if the name of the goods has not been registered under the *Trade Marks Act 1995*, a unique, invented, common or scientific name assigned to the medicine that appears on one or more labels of the goods.

Authorised Version F2026L01311 registered 28/09/2026

name and contact details of the sponsor means information that would enable a person to contact the sponsor, or a person representing the sponsor, and that:

(a) includes:

(i) the name of the sponsor, or person representing the sponsor; or

(ii) where there has been a change in the sponsor or person representing the sponsor in the previous 12 months—the name of a previous sponsor or person previously representing the sponsor; and

(b) includes:

(i) an Australian phone number for the person described in paragraph (a); or

(ii) a current email address of the person described in paragraph (a); or

(iii) a website of the person described in paragraph (a) that states the Australian phone number or current email address for that person; and

(c) may include the address of the principal place of business of the person described in paragraph (a) in Australia, but does not include a post office, cable, telegraphic or code address of that person.

Note: References to a person include a company and an individual. See section 2C of the *Acts Interpretation Act 1901*.

name of the sponsor means information that would enable a person to identify the sponsor, or a person representing the sponsor, and that includes:

(a) the name of the sponsor, or person representing the sponsor; or

(b) where there has been a change in the sponsor or person representing the sponsor in the previous 12 months—the name of a previous sponsor or person previously representing the sponsor.

Note: References to a person include a company and an individual. See section 2C of the *Acts Interpretation Act 1901*.

osmolality means the number of osmoles, usually expressed as milliosmoles or mOsm, of a solute in a kilogram of water.

pharmaceutical benefit has the same meaning as in the Regulations.

product details, in relation to a registered medicine, means details about the medicine that reflects the basis on which the Secretary decided under subsection 25(3) of the Act to register the medicine.

product information document means a document approved under section 25AA of the Act.

quantity means:

(a) in relation to a medicine, where the medicine is in a single container that is a primary pack or is enclosed in a primary pack—the following:

(i) for a medicine consisting of discrete dosage units, such as tablets or capsules—the stated number of units in the container;

(ii) for a medicine that is a solid or semi-solid, other than a biological medicine or a medicine for injection—the stated weight of the medicine in the container;

(iii) for a medicine that is a liquid, other than a biological medicine—the stated volume of fill in the container;

Authorised Version F2026L01311 registered 28/09/2026

(iv) for a medicine that is a pressurised metered dose preparation or dry powder inhaler—the stated number of deliverable doses of the medicine in the container;

(v) for a medicine that is a non-pressurised metered dose preparation—the minimum number of deliverable doses of the medicine in the container;

(vi) for a medicine that is a solid biological medicine—the stated weight, number of doses or potency units of the medicine in the container;

(vii) for a medicine that is a liquid biological medicine—the stated volume of fill in the container and the:

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

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

(b) in relation to a medicine, where the medicine in a primary pack consists of more than one identical container, other than a strip or blister pack, within the primary pack—the number of containers in the primary pack and the quantity of the medicine in each individual container, or

(c) in relation to an ingredient—means the nominal quantity not including any overage.

Note: In relation to paragraph (b), an example of the quantity of medicine in a primary pack is 5 x 10 mL vials.

registered medicine means a medicine that is a registered good.

Regulations means the *Therapeutic Goods Regulations 1990.*

small container means a container that:

(a) has a capacity of 25 mL or less; and

(b) is not a very small container.

solid ophthalmic medicine means a medicine in the form of a solid, to which a sterile diluent is added to prepare the medicine for administration as eye drops.

starter pack means:

(a) for medicines for which a pharmaceutical benefit is payable—either:

(i) a primary pack that does not exceed one third of the most commonly prescribed pharmaceutical benefits quantity; or

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

(b) for medicines for which a pharmaceutical benefit is not payable—either:

(i) a pack that does not exceed one third of the smallest trade pack; or

(ii) the smallest trade pack for the medicine, if it is not practical to produce a pack that is one-third of the smallest trade pack

stated volume of fill means the nominal volume of medicine that a container is specified by the sponsor to contain.

stated weight means the nominal mass of medicine that a container is specified by the sponsor to contain.

Authorised Version F2026L01311 registered 28/09/2026

tablet means a solid preparation containing one or more active ingredients and obtained by compressing uniform volumes of particles or by another suitable manufacturing technique, such as extrusion, moulding or freeze-drying (lyophilisation).

text size means the height of the following:

(a) capital letters or lower case letters, including an ascender or descender;

(b) numbers or numerals;

(c) symbols.

Therapeutic Goods Administration has the same meaning as in the Regulations.

tree nut means the seeds of a variety of trees and shrubs that are characterised by a hard inedible shell enclosing an oily seed.

Note: For the avoidance of doubt, coconut is the fruit of the palm *Cocos nucifera* and is not a tree nut.

very small container means a container that has a capacity of 3.0 mL or less.

warning statements means all of the following:

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

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

(c) warning statements specified in the current Poisons Standard that apply to the medicine.

5 Standard

The matters specified in this instrument constitute a standard for the labelling of prescription medicines.

6 Application

(1) Subject to subsection (2), this instrument applies to all of the following therapeutic goods:

(a) medicines specified in Part 1 of Schedule 10 to the Regulations;

(b) composite packs that contain only medicines and at least one medicine mentioned in paragraph (a).

Note: For the avoidance of doubt, this instrument does not apply to a good that is a medical device that contains a substance included in Schedule 4 or 8 to the current Poison Standard.

(2) This instrument does not apply to a medicine mentioned in subsection (1) that is any of the following:

(a) a medicine that contains a substance mentioned in Schedule 9 to the current Poisons Standard, or meets the criteria for mention in that Schedule when making a decision to amend the Poisons Standard under section 52D(2) of the Act;

(b) a medical gas;

(c) blood products that are:

(i) whole blood; or

Authorised Version F2026L01311 registered 28/09/2026

(ii) blood components including red cells, white cells, platelets and plasma (including cryoprecipitate);

(d) a medicine intended for use in the treatment of another person in accordance with an approval under paragraph 19(1)(a) of the Act;

(e) a medicine intended to be supplied to a Category A patient under the exemption in regulation 12A of the Regulations;

(f) a medicine the subject of an authorisation granted under subsection 19(5) of the Act, where its use is consistent with the requirements in regulation 12B of the Regulations;

(g) a medicine intended for use in the treatment of humans in accordance with rules made for the purposes of subsection 19(7A) of the Act;

(h) a medicine 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 the medicine;

(i) a medicine the subject of an approval under section 19A of the Act;

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

(k) a starting material exempt under item 9 in Schedule 5 to the Regulations;

(l) a medicine that is not a finished product;

(m) a medicine imported for use in the treatment of the importer or the importer's immediate family under item 1 in Schedule 5 to the Regulations;

(n) an export only medicine;

(o) a medicine dispensed or extemporaneously compounded as mentioned in item 6 in Schedule 5 to the Regulations;

(p) a medicine administered or supplied by a health professional to a patient in the course of the treatment of that patient.

7 Repeals

Each instrument that is specified in Schedule 4 is repealed as set out in the applicable items in that Schedule.

Authorised Version F2026L01311 registered 28/09/2026

Part 2—General labelling provisions

8 General requirements

(1) The primary pack, any intermediate packaging and the container of a medicine must be labelled in accordance with the requirements specified in this instrument.

(2) The label on the primary pack, any intermediate packaging and the container of a medicine must be securely affixed to the primary pack, intermediate packaging and container.

(3) Despite subsection (1), a label is not required on any transparent covering that encloses or covers the primary pack, intermediate packaging or container of a medicine if the information required to be set out on the primary pack, intermediate packaging or container is clearly visible through that transparent covering.

(4) The information required to be included on the label on a primary pack, intermediate packaging (if any) and container must be:

(a) in English; and

(b) clearly legible; and

(c) printed in a manner that is durable; and

(d) unless otherwise specified in this instrument or the Regulations, displayed in text size of not less than 1.5 millimetres; and

(e) in a colour that contrasts strongly with the background, except for the expiry date, expiry date identifier, batch number or batch number identifier, when that information is embossed or debossed and not printed; and

(f) for units of measurement—unless otherwise specified in this instrument, stated in metric units of measurement.

Note: In relation to paragraph (d), paragraph 15(1)(c) of the Regulations requires the registration number of a medicine to be on the main label, or on a securely affixed sticker adjacent to the main label, and the numbers and letters must not be less than 1 mm in height.

9 Machine readable codes

(1) If a label includes a machine readable code that is a QR code, the information that is accessible via this code must:

(a) be in the control of the sponsor or, where permitted by this instrument, link to information about the medicine on the Therapeutic Goods Administration website; and

(b) not be inconsistent with information on the label of the medicine or the product details for the medicine; and

(c) be accessible by scanning the code only, and not require a person to log in, provide any personal information or make a payment to access the information.

Authorised Version F2026L01311 registered 28/09/2026

(2) If a label includes a machine readable code, unless permitted by this instrument, the code must not replace information that is required to be included on the label.

Authorised Version F2026L01311 registered 28/09/2026

Part 3—Labelling requirements for primary packs, intermediate packaging and containers

Division 1—Labels on primary packs and containers

10 Application

This Division applies to the label on a primary pack, intermediate packaging (if any) and a container, other than the following:

(a) where a container is enclosed in a primary pack—the label on a:
  (i) small container; or
  (ii) very small container; or
  (iii) medicine consisting of individually wrapped dosage units; or
  (iv) strip, blister or dial dispenser pack; or
  (v) plastic ampoule with a capacity less than 8 mL;

(b) the label on the primary pack of a composite pack.

Note 1: In relation to paragraph (a), requirements for the labels listed in that paragraph, where the containers are enclosed in a primary pack, are in Division 3. For the avoidance of doubt, additional requirements in Part 4 are also applicable to the labels listed in paragraph (a) and this Division applies to a primary pack enclosing a small container, very small container, individually wrapped medicine, strip, blister or dial dispenser pack, or plastic ampoule with a capacity less than 8 mL.

Note 2: In relation to paragraph (b), requirements for the label on the primary pack of a composite pack are in Division 3. For the avoidance of doubt, the label on the primary pack, intermediate packaging (if any) or container of each medicine in the pack must comply with any applicable requirements in this Division.

Subdivision 1.1—Main labels

11 Information to be included on the main label of a medicine

(1) The main label on the primary pack and container of a medicine must include the following information:
  (a) the name of the medicine;
  (b) the name of each active ingredient in the medicine;
  (c) the quantity or proportion of each active ingredient in the medicine;
  (d) the name of the dosage form of the medicine and, if the route of administration of the medicine is only for infusion, the words “for infusion” after the dosage form;
  (e) the quantity of the medicine in the container or primary pack;
  (f) if the medicine is for injection or infusion or enclosed in an ampoule that is not intended for injection—the route of administration of the medicine, or other phrase, word or abbreviation denoting the route of administration of the medicine.

(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 words or images.

Authorised Version F2026L01311 registered 28/09/2026

(3) The information required to be on the main label must be in text that is oriented in the same direction.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a primary pack or container without the salt, hydrate or solvate if:
  (a) the name of the active ingredient in the Australian Approved Names List appears elsewhere on the label of that primary pack or container; and
  (b) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
  (c) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

(5) The name of the medicine, the name of each active ingredient and the quantity or proportion of each active ingredient must appear as a cohesive unit (the ***cohesive unit***) on the main label of a medicine in the following manner:
  (a) the name and quantity or proportion of the active ingredients must appear together on separate lines of text:
    (i) immediately below the name of the medicine; or
    (ii) where the trade mark of the medicine might be disrupted or obscured—immediately after the name of the medicine; and
  (b) the name of the medicine, the name of the active ingredients and the quantity or proportion of the active ingredients must not be separated by any text or graphics, except when including:
    (i) additional information required by paragraph 38(2)(j) (element intended for mineral supplementation) or section 43 (Common name of vitamins); or
    (ii) if the medicine is a vaccine—a description of the vaccine, that appears between the name of the medicine and the name and quantity or proportion of each active ingredient, in accordance with subsection (6).

(6) The description of the vaccine:
  (a) must accurately describe the vaccine; and
  (b) may include the following information:
    (i) the disease for which the vaccine is indicated (for example, ‘pneumococcal’);
    (ii) the type of vaccine (for example, ‘conjugate’, ‘polysaccharide’, or ‘inactivated’);
    (iii) the number of strains, serotypes or variants (for example, monovalent, quadrivalent, or 13-valent).

(7) If signal words or cautionary statements are required to be included on the label under sections 16 to 25 of the current Poisons Standard, the cohesive unit must appear immediately below the signal words and cautionary statements and must not be separated from the signal words and cautionary statements by any text or graphics.

Authorised Version F2026L01311 registered 28/09/2026

(8) Despite subsections (3) and (5), where a medicine is supplied in a container that is a flexible bag and the medicine is for intravenous infusion or is a haemofiltration or haemodiafiltration solution, the name of the medicine and the name and quantity or proportion of each active ingredient do not need to appear as a cohesive unit or be oriented in the same direction.

(9) Despite paragraph (1)(b) and (c), if a medicine is a vaccine that has 3 or more active ingredients and is enclosed in a very small container, the active ingredients are not required to be included on the label if:

(a) there is insufficient space on the label to include this information; and

(b) the label includes either:

(i) a statement that the active ingredients are listed in the product information document for the medicine; or

(ii) a QR code that links to the product information document for the medicine.

(10) Subsection (11) does not apply where the medicine is:

(a) supplied in a small container or a very small container; or

(b) supplied in a container that is a flexible bag which encloses a medicine that:

(i) is for use as an intravenous infusion or is a haemofiltration or haemodiafiltration solution; and

(ii) has 8 or more active ingredients in the medicine.

Note: For the purposes of paragraph (10)(a) the minimum text sizes for active ingredients on labels of small containers and very small containers is specified in Division 3.

(11) The name of each active ingredient and the quantity or proportion of each active ingredient on the main label of a medicine must:

(a) if there are less than 4 active ingredients in the medicine—be displayed on the main label in a text size of not less than 3 mm; and

(b) if there are 4 or more active ingredients in the medicine—be displayed on the main label or, despite subsection (1) and (5), be included on a side label or rear label or a side or rear panel on a single label, in a text size of not less than 2.5 mm; and

(c) if any active ingredient in the medicine is an ingredient specified in Part 1 of Schedule 2—be displayed on the main label in a text size of not less than 2.5 mm.

(12) Paragraph (11)(c) does not apply to a medicine that is labelled in accordance with subsection (13).

(13) For medicine released for supply before 1 May 2028, an active ingredient specified in Part 2 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in Part 2 of Schedule 2.

(14) To avoid doubt, for medicine released for supply on or after 1 May 2028, an active ingredient specified in Part 2 of Schedule 2 must be included on the main

Authorised Version F2026L01311 registered 28/09/2026

label of a medicine containing that ingredient in accordance with the Australian Approved Names List.

Subdivision 1.2—Labels

12 Information to be included on the label of a medicine

(1) The label on the primary pack and container of a medicine must include all of the following information:

(a) the batch number, accompanied by the batch number identifier;

(b) the expiry date, accompanied by the expiry date identifier;

(c) storage conditions for the medicine;

(d) the name and contact details of the sponsor of the medicine;

(e) where:

(i) a medicine contains a substance, or substance within the group of substances, as described in column 2 of the table in Schedule 1; and

(ii) the route of administration of the medicine is mentioned in column 3 of the table in Schedule 1;

then either:

(iii) a statement indicating that the medicine contains the substance, expressed using the name stated in column 5 of the table in Schedule 1 and a statement of the kind required in column 4 of the table in Schedule 1 (if any); or

(iv) a statement advising consumers to refer to the Consumer Medicine Information for information about the substance referred to in column 2 of the table in Schedule 1 that is present in the medicine in accordance with the relevant item;

(f) warning statements;

(g) if the medicine requires preparation before use—instructions for preparation, the storage conditions for the medicine once prepared, and the maximum period of storage between preparation and use, except where:

(i) there is insufficient space on the label of the primary pack or the container 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 the primary pack and container that this information is set out in the package insert;

(h) on the primary pack only—a machine readable code that encodes the Global Trade Item Number and is formatted in accordance with the GS1 General Specifications, except where the medicine is a starter pack.

(2) If the primary pack of a medicine is a carton, the name of the medicine must be stated on at least 3 non-opposing sides of the carton.

(3) The label on the primary pack of a medicine, other than medicines in a composite pack, must include a minimum space of 70 x 30 millimetres for the dispensing label, except where:

Authorised Version F2026L01311 registered 28/09/2026

(a) the dimensions of the primary pack are insufficient; or
(b) the medicine is intended for use only in a clinical setting where self-administration will not occur; or
(c) the medicine is intended to be supplied as a starter pack.

(4) If a 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 administering the medicine, the label on the primary pack must include a description of any such articles.

(5) If a medicine is enclosed in a delivery device to form a single integral product which is intended exclusively for use in the given combination and the delivery device is not reusable or removable, the information required on the label of a container under this section must be on the delivery device.

Division 2—Labels on intermediate packaging

13 Information to be included on the label on intermediate packaging

If the information required to be on the label on a container is obscured by intermediate packaging, the intermediate packaging must be labelled with all of the following information:
(a) the name of the medicine;
(b) the name of each active ingredient in the medicine;
(c) the quantity or proportion of each active ingredients in the medicine;
(d) the batch number, accompanied by the batch number identifier;
(e) the expiry date, accompanied by the expiry date identifier;
(f) the name of the sponsor, or a registered trade mark if it readily identifies the name of the sponsor of the medicine.

Division 3—Labelling requirements for certain containers and packaging

Subdivision 3.1—Injections

14 Injections in a container that is a small container (more than 3.0 mL and up to 25 mL)

Note: Additional requirements also apply to injections as set out in Part 4—Division 1 as follows:
(a) injections in a container with a capacity less than or equal to 100 mL—section 26;
(b) injections in a container with a stated volume of fill of 100 mL or more—section 27;
(c) haemofiltration or haemodiafiltration solutions—section 28;
(d) peritoneal dialysis solutions—section 29;
(e) potassium for injection or infusion—section 30;
(f) neuromuscular blocking agents—section 31;
(g) vaccines—section 32.

Authorised Version F2026L01311 registered 28/09/2026

(1) This section applies to a medicine that is an injection and is contained in a small container that is enclosed in a primary pack.

(2) The label on the small container must include the following information in a text size of not less than 2 mm:
  (a) the name of the medicine;
  (b) the name of each active ingredient in the medicine.

(3) The label on the small container must include the following information in a text size of not less than 1.5 mm:
  (a) the quantity or proportion of each active ingredient in the medicine;
  (b) the name of the dosage form;
  (c) the quantity of the medicine;
  (d) the batch number, accompanied by the batch number identifier;
  (e) the expiry date, accompanied by the expiry date identifier;
  (f) either:
    (i) the name of the sponsor as it appears on the primary pack; or
    (ii) the registered trade mark, if it readily identifies the name of the sponsor of the medicine;
  (g) the route of administration of the medicine, or other word, phrase or abbreviation denoting the route of administration;
  (h) if the medicine is an injection which contains iodine and is intended for use as a radio-contrast agent—the equivalent amount of iodine in terms of milligrams of iodine per millilitre;
  (i) if the medicine is intended for electrolyte replacement and unless precluded by the container size—immediately below the name of the medicine, the name of the active ingredients and the quantity or proportion of the active ingredients in the medicine, the:
    (i) for potassium chloride—equivalent quantity of potassium chloride in weight in relation to the stated volume of fill of the injection; and
    (ii) for all other active ingredients—equivalent quantity or proportion of each active ingredient in millimoles in relation to the stated volume of fill of the injection.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
  (a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
  (b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

15 Injections in a container that is a very small container (3.0 mL or less)

Note: Additional requirements also apply to injections as set out in Part 4 -Division 1 as follows:
  (a) injections in a container with a capacity less than or equal to 100 mL—section 26;
  (b) injections in a container with a stated volume of fill of 100 mL or more—section 27;

Authorised Version F2026L01311 registered 28/09/2026

(c) haemofiltration or haemodiafiltration solutions—section 28;
(d) peritoneal dialysis solutions—section 29;
(e) potassium for injection or infusion—section 30;
(f) neuromuscular blocking agents—section 31;
(g) vaccines—section 32.

(1) This section applies to a medicine that is an injection and is contained in a very small container that is enclosed in a primary pack.

(2) The label on the very small container must include the name of the medicine in a text size of not less than 1.5 mm.

(3) The label on the very small container must include the following information in a text size of not less than 1 mm:
(a) the quantity of the medicine;
(b) the batch number, accompanied by the batch number identifier;
(c) the expiry date, accompanied by the expiry date identifier;
(d) the route of administration of the medicine, or other word, phrase or abbreviation denoting the route of administration;
(e) if the medicine contains only one active ingredient—unless the name of the medicine includes this information, the name of the active ingredient and the quantity or proportion of the active ingredient in the medicine, or an unambiguous abbreviation of the name and quantity;
(f) if the medicine is available in more than one strength—unless the name of the medicine includes this information, the quantity or proportion of each active ingredient.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
(a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
(b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

Subdivision 3.2—Other containers

16 Small container of a medicine that is not an injection (more than 3.0 mL and up to 25 mL)

(1) This section applies to a medicine that is not an injection and is contained in a small container that is enclosed in a primary pack.

(2) The label on the small container must include the following information displayed in a text size of not less than 2 mm:
(a) the name of the medicine;
(b) if the medicine has no more than 3 active ingredients—the name of each active ingredient in the medicine.

Authorised Version F2026L01311 registered 28/09/2026

(3) The label on the small container must include the following information displayed in a text size of not less than 1.5 millimetres:
  (a) if the medicine has 4 or more active ingredients—the name of each active ingredient in the medicine;
  (b) the quantity or proportion of each active ingredient in the medicine;
  (c) the name of the dosage form;
  (d) the quantity of the medicine in the container;
  (e) the batch number, accompanied by the batch number identifier;
  (f) the expiry date, accompanied by the expiry date identifier;
  (g) either:
    (i) the name of the sponsor as it appears on the primary pack; or
    (ii) the registered trade mark, if it readily identifies the name of the sponsor of the medicine;
  (h) if the medicine is contained in an ampoule—the route of administration of the medicine or other word, phrase or abbreviation denoting the route of administration;
  (i) if the medicine is an ophthalmic preparation for multidose use or a solid ophthalmic medicine for preparing eye drops for multidose use—a statement that the medicine should not be used later than four weeks, or another shorter period in accordance with the product details for the medicine, after the container is first opened.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
  (a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
  (b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

17 Very small container of a medicine that is not an injection (3.0 mL or less)

(1) This section applies to a medicine that is not an injection and is contained in a very small container that is enclosed in a primary pack.

(2) The label on the very small container must include the name of the medicine displayed in a text size of not less than 1.5 mm.

(3) The label on the very small container must include the following information displayed in a text size of not less than 1 mm:
  (a) the quantity of the medicine in the container;
  (b) the batch number, accompanied by the batch number identifier;
  (c) the expiry date, accompanied by the expiry date identifier;
  (d) if the medicine is contained in an ampoule—a statement of the route of administration of the medicine or other word, phrase or abbreviation denoting the route of administration;
  (e) 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

Authorised Version F2026L01311 registered 28/09/2026

medicine, or a suitable unambiguous abbreviation of the name and quantity.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
  (a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
  (b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

18 Individually wrapped dosage units

(1) This section applies to a medicine that consists of individual dosage units, where:
  (a) each dosage unit of the medicine is enclosed in an individual wrapper or blister, whether sealed or unsealed (***individually wrapped dosage unit***); and
  (b) one or more individually wrapped dosage units are enclosed in a primary pack.

(2) Subject to subsection (3), the label on the individual wrapper or blister must include the following information:
  (a) the name of the medicine;
  (b) the name of each active ingredient in the medicine;
  (c) the quantity or proportion of each active ingredient in the medicine;
  (d) the batch number, accompanied by the batch number identifier;
  (e) the expiry date, accompanied by the expiry date identifier;
  (f) either:
    (i) the name of the sponsor; or
    (ii) the registered trade mark, if it readily identifies the name of the sponsor of the medicine.

(3) The label on the container may include only the name of the medicine if:
  (a) the medicine consists only of pastilles or lozenges; and
  (b) each dosage unit is enclosed in an unsealed individual wrapper; and
  (c) each dosage unit is, after being wrapped, enclosed in a primary pack.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
  (a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
  (b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

19 Strip, blister or dial dispenser pack

(1) This section applies to a medicine that consists of individual dosage units; where:

Authorised Version F2026L01311 registered 28/09/2026

(a) two or more dosage units are individually enclosed in a strip, blister or dial dispenser pack such that each dosage unit is extracted individually; and
(b) the individual dose units are enclosed in a primary pack.

(2) Subject to subsection (3), the label on the strip, blister or dial dispenser pack must include the following information:
(a) the name of the medicine;
(b) the name of each active ingredient in the medicine;
(c) the quantity or proportion of each active ingredient in the medicine;
(d) the batch number, accompanied by the batch number identifier;
(e) the expiry date, accompanied by the expiry date identifier;
(f) either:
(i) the name of the sponsor; or
(ii) the registered trade mark, if it readily identifies the name of the sponsor of the medicine.

(3) If there are 4 or more active ingredients in the medicine, the label on the strip, blister or dial dispenser pack does not need to include the information in paragraphs (2)(b) or (c).

(4) If each dosage unit of the medicine is enclosed in the strip or blister pack in a way that allows for individual segments containing a single dosage unit to be readily detached from the pack, then at least every 2 segments of the pack must be labelled with the following information:
(a) if the medicine has less than 4 active ingredients—the name of the medicine, the name of each active ingredient in the medicine and the quantity or proportion of each active ingredient in the medicine;
(b) if the medicine has 4 or more active ingredients—the name of the medicine.

(5) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
(a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
(b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

20 Plastic ampoule with a capacity of 8 mL or less

(1) This section applies to a medicine contained in a plastic ampoule, where:
(a) each plastic ampoule has a capacity of 8 mL or less; and
(b) a connecting strip attaches 2 or more plastic ampoules; and
(c) the ampoules are enclosed in a primary pack.

(2) The following information must be included on the plastic ampoule, whether or not it is also included on the connecting strip:
(a) the name of the medicine;

Authorised Version F2026L01311 registered 28/09/2026

(b) the name of each active ingredient in the medicine, if not included in the name of the medicine;
(c) the quantity or proportion of each active ingredient in the medicine, if not included in the name of the medicine;
(d) the batch number, accompanied by the batch number identifier;
(e) the expiry date, accompanied by the expiry date identifier;
(f) the route of administration, or other word, phrase or abbreviation denoting the route of administration, followed by the word "only" or any applicable warnings against use by other routes of administration.

(3) For an ampoule with a capacity more than 3.0 mL, the following information must be included on either the ampoule or the connecting strip:
(a) the name of the dosage form;
(b) the quantity of the medicine in the container;
(c) storage conditions for the medicine;
(d) either:
(i) the name of the sponsor; or
(ii) the registered trade mark, if it readily identifies the name of the sponsor of the medicine;
(e) if the medicine is an ophthalmic preparation for multidose use or a solid ophthalmic medicine for preparing eye drops for multidose use—a statement that the medicine should not be used later than four weeks, or another shorter period in accordance with the product details for the medicine, after the container is first opened;
(f) if the medicine is an injection which contains iodine and is intended for use as a radio-contrast agent—the equivalent amount of iodine in terms of milligrams of iodine per millilitre;
(g) if the medicine is intended for electrolyte replacement and unless precluded by the container size—immediately below the name of the medicine, the name of the active ingredients and the quantity or proportion of the active ingredients in the medicine, the:
(i) for potassium chloride—equivalent quantity of potassium chloride in weight in relation to the stated volume of fill of the injection; and
(ii) for all other active ingredients—the equivalent quantity or proportion of each active ingredient in millimoles in relation to the stated volume of fill of the injection.

(4) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of a container without the salt, hydrate or solvate if:
(a) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
(b) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

Authorised Version F2026L01311 registered 28/09/2026

Subdivision 3.3—Composite packs

21 Medicines in a composite pack

Each medicine in a composite pack must be labelled in accordance with this instrument.

22 Information to be included on the main label on a composite pack

(1) The main label on a composite pack must include the following information:
  (a) the name of the composite pack;
  (b) the name of each medicine in the pack;
  (c) the name of each active ingredient in each medicine in the pack, if not included in the name of the medicine;
  (d) the quantity or proportion of each active ingredient in each medicine in the pack, if not included in the name of the medicine;
  (e) the name of the dosage form of each medicine in the pack and, if the route of administration of the medicine is only for infusion, the words "for infusion" after the dosage form;
  (f) the quantity of each medicine in the pack;
  (g) if a medicine in the pack is for injection, infusion or enclosed in an ampoule and is not intended for injection—the route of administration or other phrase, word or abbreviation denoting the route of administration of the medicine.

(2) If the composite pack is a carton, the name of the pack must be stated on at least 3 non-opposing sides of the carton.

(3) The name of the composite pack, and the name of each medicine in the pack, must separately be presented in a continuous, uninterrupted manner and not broken up by additional words or images.

(4) The information required to be on the main label must be in text that is oriented in the same direction.

(5) Where the name of an active ingredient in the Australian Approved Names List includes the salt, hydrate or solvate, the name may appear on the main label of the composite pack without the salt, hydrate or solvate if:
  (a) the name of the active ingredient in the Australian Approved Names List appears elsewhere on the label of the pack; and
  (b) the strength of the active ingredient is not based on the salt, hydrate or solvate; and
  (c) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

(6) Subject to paragraph (8), the name of the composite pack, followed by the name of each medicine in the pack and the name and quantity or proportion of each active ingredient in the medicine, must appear together on the main label of the pack.

Authorised Version F2026L01311 registered 28/09/2026

(7) If signal words or cautionary statements are required to be included on the main label of the composite pack under sections 16 to 25 of the current Poisons Standard, the name of the composite pack must appear immediately below the signal words and cautionary statements and must not be separated from the signal words and cautionary statements by any text or graphics.

(8) Despite paragraphs (1)(b), (c) and (d), if a medicine in the composite pack is a vaccine that has 3 or more active ingredients and is enclosed in a very small container, the name of the medicines and the active ingredients in the medicines are not required to be included on the label of the pack if:

(a) there is insufficient space on the label of the pack to include this information; and

(b) the label includes either:

(i) a statement that the active ingredients are listed in the product information document for the medicine; or

(ii) a QR code that links to the product information document for the medicine.

(9) The name of each active ingredient and the quantity or proportion of each active ingredient on the main label of a composite pack other than a vaccine must:

(a) if there are less than 4 active ingredients in total in the composite pack (when adding the number of active ingredients in each medicine in the composite pack together)—be displayed on the main label in a text size of not less than 3 mm;

(b) if there are 4 or more active ingredients in total in the composite pack (when adding the number of active ingredient in each medicine in the composite pack together)—be displayed on the main label or, despite subsection (1) and (6), be included on a side label or rear label or a side or rear panel on a single label, in a text size of not less than 2.5 mm;

(c) if any active ingredient in a medicine in the composite pack is an ingredient specified in Part 1 of Schedule 2—be displayed on the main label in a text size of not less than 2.5 mm.

Note: In relation to paragraphs (a) to (c), as it applies to a composite pack, where the same active ingredient is contained in 2 or more medicines in the composite pack, the active ingredient is counted separately for each medicine when working out the total number of active ingredients of all of the medicines in the composite pack.

(10) Paragraph (9)(c) does not apply to a medicine that is labelled in accordance with subsection (11).

(11) For medicine released for supply before 1 May 2028, an active ingredient specified in Part 2 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of the composite pack containing that ingredient as specified in Part 2 of Schedule 2.

(12) To avoid doubt, for medicine released for supply on or after 1 May 2028, an active ingredient specified in Part 2 of Schedule 2 must be included on the main label of a composite pack containing that ingredient in accordance with the Australian Approved Names List.

Authorised Version F2026L01311 registered 28/09/2026

23 Information to be included on the label on a composite pack

(1) The label on a composite pack must include all of the following information:

(a) the batch number, accompanied by the batch number identifier;

(b) the earliest of the expiry dates of the medicines in the composite pack, accompanied by the expiry date identifier;

(c) the most restrictive storage conditions of the medicines in the composite pack;

(d) the name and contact details of the sponsor of the composite pack;

(e) where:

(i) a medicine in the composite pack contains a substance, or substance within the group of substances, as described in column 2 of the table in Schedule 1; and

(ii) the route of administration of the medicine is mentioned in column 3 of the table in Schedule 1;

then either:

(iii) a statement indicating that the medicine contains the substance, expressed using the name stated in column 5 of the table in Schedule 1 and a statement of the kind required in column 4 of the table in Schedule 1; or

(iv) a statement advising consumers to refer to the Consumer Medicine Information for information about the substance referred to in column 2 of the table in Schedule 1 that is present in the medicine in accordance with the relevant item;

(f) warning statements for each medicine in the composite pack;

(g) if a medicine in the composite pack requires preparation before use—instructions for preparation, the storage conditions for the medicine once prepared, and the maximum period of storage between preparation and use, except where:

(i) there is insufficient space on the label to include this information; and

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

(iii) a statement is included on the label that this information is set out in the package insert;

(h) a machine readable code that encodes the Global Trade Item Number and is formatted in accordance with the GS1 General Specifications.

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

(a) the dimensions of the pack are insufficient; or

(b) the pack is intended for use only in a clinical setting where self-administration will not occur.

(3) If the composite pack contains a medicine that encloses 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 medicine for such purposes as administering the medicine, the label on the pack must include a description of any such articles.

Authorised Version F2026L01311 registered 28/09/2026

Part 4—Additional labelling requirements for certain medicines

24 Application of this Part

For the avoidance of doubt, the requirements in this Part apply in addition to the applicable requirements in Parts 2 and 3.

Division 1—Injections

25 Injections in a container with a capacity more than 100 mL

(1) This section applies to a medicine for injection, other than a haemofiltration or haemodiafiltration solution, in a container with a capacity more than 100 mL.

(2) The label on the primary pack and container must include the following information:

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

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

(c) if the medicine is a concentrated injection—a direction not to administer the solution undiluted;

(d) if the medicine contains an active ingredient that is not intended for electrolyte replacement or nutritional therapy, and the medicine is not intended for use as a radio-contrast agent or as a plasma volume expander or replacement—a statement of the proportion of that active ingredient expressed in terms of weight or potency in the stated volume of fill of the injection in the container;

(e) if the medicine contains more than 3 active ingredients belonging to the same class of substances (such as amino acids, carbohydrates or electrolytes)—the class of substances and the name of the dosage form;

(f) if the medicine contains iodine and the medicine is intended for use as a radio-contrast agent—a statement of the equivalent amount of iodine in milligrams of iodine per millilitre;

(g) if the medicine is intended for use as a radio-contrast agent or as a plasma volume expander or replacement—the proportions of dissolved, emulsified or suspended active ingredients in the medicine, included in the name of the medicine;

(h) if the medicine is intended for electrolyte replacement and has a stated volume of 100 mL or less—stated immediately below the cohesive unit, the:

(i) if the medicine contains potassium chloride—equivalent quantity of potassium chloride in weight in relation to the stated volume of fill of the injection; and

Authorised Version F2026L01311 registered 28/09/2026

(ii) equivalent quantity or proportion of each active ingredient, other than potassium chloride, in millimoles in relation to the stated volume of fill of the injection.

26 Injections in a container with a capacity of 100 mL or less

(1) This section applies to a medicine for injection in a container that has a capacity of 100 mL or less.

(2) The label on the primary pack, and the label on a container with a capacity of more than 25 mL, must include the following information:

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

(i) if the injection is intended to be for single dose use and is not a powder for injection, including a concentrated injection—as the nominal mass of that excipient, not including any overage, in the stated volume of fill of the injection in the container; or

(ii) if the injection is intended to be a single dose that is a powder for injection—as the nominal mass of that excipient, not including any overage, in the container; or

(iii) if 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;

(b) if the medicine is supplied in a container that has the potential to be 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;

(c) if the medicine is a concentrated injection—a direction not to administer the solution undiluted;

(d) if the medicine is an injection containing iodine and it is intended for use as a radio-contrast agent—the equivalent amount of iodine in milligrams of iodine per millilitre;

(e) if the medicine is intended for electrolyte replacement—immediately below the cohesive unit, the:

(i) if the medicine contains potassium chloride—equivalent quantity of potassium chloride in weight in relation to the stated volume of fill of the injection; and

(ii) equivalent quantity or proportion of each active ingredient, other than potassium chloride, in millimoles in relation to the stated volume of fill of the injection.

27 Injections in a container with a stated volume of fill of 100 mL or more

(1) This section applies to a medicine for injection in a container with a stated volume of fill of 100 mL or more.

(2) For the avoidance of doubt, this section applies in addition to sections 25 and 26.

Authorised Version F2026L01311 registered 28/09/2026

(3) The label on the primary pack and container must include the following information:
  (a) a statement indicating whether the injection is hypotonic, hypertonic or isotonic;
  (b) the osmolality of the injection solution;
  (c) the pH range of the injection solution;
  (d) if the medicine contains one or more active ingredients that are amino acids or proteins—the total amount of nitrogen in grams in the stated volume of fill of the injection in the container;
  (e) if the medicine is intended for use as an energy source—the energy equivalent, in kilojoules, of the stated volume of fill of the injection in the container.

28 Haemofiltration or haemodiafiltration solutions

(1) This section applies to a medicine that is a haemofiltration or haemodiafiltration solution.

(2) The label on the primary pack and container must include the following information:
  (a) the name and quantity or proportion of each active ingredient per litre of solution following preparation as directed;
  (b) the name and quantity or proportion of each active ingredient in millimoles per litre of solution following preparation as directed;
  (c) a statement indicating whether the solution is hypotonic, hypertonic or isotonic;
  (d) the osmolality of the solution;
  (e) the pH range of the solution;
  (f) the statement "Use in one patient on one occasion only. Contains no antimicrobial preservative" or words to that effect.

29 Peritoneal dialysis solutions

(1) This section applies to medicine that is a solution for use in peritoneal dialysis.

(2) The label on the primary pack and container must state the following information:
  (a) the formulation of the solution expressed in grams per litre and in millimoles per litre;
  (b) if the medicine is a concentrate, the formulation of the solution before it is diluted and after dilution expressed in grams per litre and in millimoles per litre;
  (c) the osmolarity expressed in milliosmoles per litre;
  (d) the stated volume of fill in the container;
  (e) a statement indicating whether the solution is free from bacterial endotoxins or, where applicable, that the solution is apyrogenic;
  (f) a statement that the solution is not to be used for intravenous infusion;

Authorised Version F2026L01311 registered 28/09/2026

(g) the statement “Use in one patient on one occasion only. Contains no antimicrobial preservative” or words to that effect;
(h) if the solution is a concentrate—the statement “Dilute before use”.

30 Potassium for injection or infusion

(1) This section applies to a medicine that contains potassium as the principal active ingredient in a medicine intended for injection.

(2) The label on the primary pack, intermediate packaging (if any) and container must include the name of the medicine, the active ingredient and quantity or proportion of the active ingredient in red colour text.

31 Neuromuscular blocking agents

(1) This section applies to a medicine that contains a substance specified in Schedule 3 or a salt of a substance specified in Schedule 3.

(2) 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.

(3) If the medicine is enclosed in a container that is not a very small container or a plastic ampoule, the label on the container of the medicine must include the warning statement “Warning: Paralysing agent” in black text on a fluorescent red or warm red background.

(4) If the medicine is in a container that is a very small container that is not a plastic ampoule, the label on the container must include one of the following warning statements in black text on a fluorescent red or warm red background:
(a) “Warning: Paralysing agent”;
(b) “Warning: Paralyser”;
(c) “Paralyser”.

(5) If the medicine is in a container that is a plastic ampoule, the label on each ampoule must include one of the following warning statements in any colour text and without background colour:
(a) “Warning: Paralysing agent”;
(b) “Warning: Paralyser”;
(c) “Paralyser”.

32 Vaccines

(1) This section applies to a medicine that is a vaccine.

(2) Despite paragraphs 25(2)(a) and 26(2)(a), the label is not required to list each excipient if:
(a) the full list of excipients would not reasonably fit on the label; and
(b) the label on the primary pack includes either:
(i) a statement that the excipients are listed in the product information document for the medicine; or

Authorised Version F2026L01311 registered 28/09/2026

(ii) a QR code that links to the product information document for the medicine.

Division 2—Specialty routes of administration or dosage forms

33 Medicines for use on skin or mucous membranes or by inhalation, or that is a metered nasal spray

(1) This section applies to a medicine that is:
  (a) for use on skin or mucous membranes; or
  (b) for inhalation; or
  (c) a metered nasal spray.

(2) The label on the primary pack and container must include the name of any antimicrobial preservative in the medicine, unless the antimicrobial preservative is required to be included on the label in accordance with paragraph 12(1)(e).

34 Medicines for ophthalmic use

(1) This section applies to a medicine that is a preparation for ophthalmic use.

(2) The label on the container, other than a small container or very small container that is enclosed in a primary pack, and the label on the primary pack of the medicine must include the following information:
  (a) the name of any antimicrobial preservative in the medicine;
  (b) if the medicine is not an ophthalmic ointment and 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 that the medicine should not be used for more than four weeks, or a shorter period in accordance with the product details for 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—both of the following:
    (i) a statement that the medicine, when prepared, should not be used for more than four weeks, or a shorter period in accordance with the product details for the medicine, after the container is first opened;
    (ii) the words "for eye drops".

35 Modified release oral dosage forms

(1) This section applies to a medicine for oral administration that is in a modified release dosage form.

(2) The label on the primary pack, intermediate packaging (if any) that obscures information on the container, and container must include the statement "Do not crush or chew" or words to that effect.

Authorised Version F2026L01311 registered 28/09/2026

Division 3—Starter packs

36 Starter packs

(1) This section applies to a medicine that is presented in a starter pack.

(2) The label on the primary pack or container must include the following:

(a) sufficient space to accommodate the ability for the prescriber to add the following dispensing details on the label:

(i) the patient's name;

(ii) the prescriber's name and telephone number;

(iii) the directions for use, including dose;

(iv) date of supply;

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

Authorised Version F2026L01311 registered 28/09/2026

Part 5—How information is to be expressed on the label

37 Use of metric units

(1) If the quantity of an active ingredient is to be expressed as mass for which there is a metric unit of measurement, the metric units must be expressed as follows:

(a) for a quantity of 1 microgram or more and up to 999 micrograms—in micrograms;

(b) for a quantity of 1000 micrograms—as either 1000 micrograms or 1 mg;

(c) for a quantity of more than 1 mg and up to 999 mg—in milligrams;

(d) for a quantity of 1000 mg—as either 1000 mg or 1 g;

(e) for a quantity for more than 1 g and up to 999 g—in grams;

(f) for a quantity expressed in micrograms—the metric unit must not be abbreviated, unless the quantity of the active ingredients is to be displayed on the label of a small container or very small container, in which case the abbreviation "µg" may be used;

(g) for a quantity expressed in milligrams or grams—the metric unit may be abbreviated as "mg" or "g" respectively.

(2) If the quantity of an active ingredient is to be expressed in a volume for which there is a metric unit of measurement, the metric units must be expressed as follows:

(a) for a quantity equal to or more than 1 microlitre and up to 999 microlitres—in microlitres;

(b) for a quantity of 1000 microlitres—as either 1000 microlitres or 1 mL;

(c) for a quantity of more than 1 mL and up to 999 mL— in millilitres;

(d) for a quantity of 1000 mL—as either 1000 mL or 1 L;

(e) for a quantity more than 1 L and up to 999 L—in litres;

(f) for a quantity in microlitres—the metric unit must not be abbreviated, unless the quantity of the active ingredient is to be displayed on the label of a small container or very small container, in which case the abbreviation "µL" may be used;

(g) for a quantity in millilitres or litres—the metric unit may be abbreviated as "mL" or "L" respectively.

(3) Despite subsections (1) and (2), if there are a range of medicines that contain the same active ingredient in the same dosage form but in different strengths, the quantity of the active ingredient must be included on the label with the same metric unit of measurement for each strength of the active ingredient.

Example: The quantity of the same active ingredient in the same dosage form in a range of medicines may be expressed as 0.5 mg, 1 mg and 5 mg, and not 500 micrograms, 1 mg and 5 mg.

(4) Despite subsections (1) and (2), if the label of a medicine has a warning statement which includes a statement about the quantity of an ingredient in mass or volume, the unit of measurement displayed for the quantity of the active ingredient contained in the medicine must be displayed in the same unit of measurement as the warning statement.

Authorised Version F2026L01311 registered 28/09/2026

(5) If the label includes a quantity that is expressed as less than one unit, the quantity must include the leading zero.

38 Expression of quantity or proportion of active ingredients for medicines

(1) This section applies to the label on a container, intermediate packaging (if any) and primary pack that encloses a medicine, other than:

(a) an injection; or

(b) a biological medicine; or

(c) a radionuclide in a radiopharmaceutical preparation.

Note: The requirements for injections are in section 39, the requirements for biological medicines are in section 40 and the requirements for radionuclides in radiopharmaceutical preparations are in section 41.

(2) If the label includes the quantity or proportion of an active ingredient, the quantity or proportion must be expressed as follows:

(a) if the medicine consists of a discrete dosage unit—the quantity of the active ingredient in the dosage unit;

(b) if the medicine is a solid for ingestion and there is no discrete dosage unit—the quantity of the active ingredient contained in the stated weight of a suitable dose of the solid;

(c) if the medicine is a liquid for ingestion that is not required to be prepared before use—either:

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

(ii) for a series of medicines of different strengths containing the same active ingredient—the quantity or proportion of active ingredient expressed consistently across the series in terms of the same stated dose volume;

(d) if the medicine is required to be prepared before use, and the process results in a medicine that is a liquid for ingestion—either:

(i) 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 on the label of the medicine; or

(ii) for a medicine that is part of a series of strengths containing the same active ingredient—the quantity or proportion of active ingredient expressed consistently across the series;

(e) if the medicine is required to be prepared before use, and the process does not result in a liquid for ingestion—the weight or volume of active ingredient in a stated weight or volume of the medicine, after preparation in accordance with the instructions on the label of the medicine;

(f) if the medicine is a transdermal patch, intrauterine drug delivery system or implant—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;

(g) if the medicine is an antibiotic preparation and the potency units are used as a measure of activity—the number of such units expressed as International Units (IU) established by the World Health Organization;

Authorised Version F2026L01311 registered 28/09/2026

(h) if the medicine is a metered dose preparation (such as a pressurised metered dose inhaler or a nasal spray) or dry powder inhaler—either:
  (i) the quantity delivered per actuation; or
  (ii) if the dose of the medicine was clinically established as the metered dose—the quantity metered per actuation;
(i) if the medicine is to be applied to the skin and mucous membranes, other than medicines subject to paragraphs (g) and (h)— a percentage expressed in terms of w/w, w/v, v/v or v/w, or as the weight or volume in a stated weight or volume of the medicine, as appropriate;
(j) if the medicine is in the form of an oral preparation that contains an active ingredient intended for mineral supplementation—both:
  (i) the name of the active ingredient; and
  (ii) the name and quantity of the element intended for mineral supplementation;
(k) if the medicine contains Vitamin A or a derivative of Vitamin A—the equivalent quantity or proportion of Vitamin A expressed in terms of microgram retinol equivalents;
(l) if the medicine contains a biological organism—either:
  (i) for liquids and powders—the number of organisms present per metric unit; or
  (ii) for all other dosage forms—the number of organisms present per dosage unit;
(m) for any other medicines—either:
  (i) if the medicine is a liquid and includes an active ingredient which is also a liquid—as the amount of the active ingredient, either by weight or volume, in a stated volume of the medicine; or
  (ii) if the medicine is a liquid and includes an active ingredient which is a solid or gas—as the weight of active ingredient in a stated volume of the medicine; or
  (iii) if the medicine is a solid or semi-solid and includes an active ingredient which is a liquid—as the amount of the active ingredient, either by weight or volume, in a stated weight of the medicine; or
  (iv) if 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.

Example 1: For the purposes of paragraph (c), where the dose volume is 5 mL, and the active ingredient has strengths of 1 mg/mL and 5 mg/mL, the quantity must be expressed as 5 mg in 5 mL and 25 mg in 5 mL, respectively.

Example 2: For the purposes of paragraph (d), where the dose volume of a medicine is 5 mL after preparation, and the active ingredient has 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.

39 Expression of quantity or proportion of active ingredients for medicines that are an injection

(1) This section applies to the label on a primary pack, intermediate packaging (if any) and container of a medicine that is an injection.

Authorised Version F2026L01311 registered 28/09/2026

(2) Where a label must include the quantity or proportion of an active ingredient, the quantity or proportion must be expressed as follows:

(a) the stated weight of the active ingredient in the container, if:

(i) the medicine is a powder for injection; and

(ii) the medicine is not intended for electrolyte replacement;

(b) if the stated volume of the medicine is greater than 100 mL and the medicine is intended for electrolyte replacement, for nutritional therapy, as a plasma volume expander, or as an additive to any of these types of injection—either:

(i) 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) 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;

(c) if the stated volume of a medicine is greater than 100 mL and the medicine contains an active ingredient which is not intended for electrolyte replacement, nutritional therapy or as a plasma volume expander—the weight of the active ingredient in the stated volume of injection in the container;

(d) if the stated volume of the medicine for injection is 100 mL or less and the medicine is intended for electrolyte replacement—both:

(i) for potassium chloride—the number of millimoles of potassium chloride in the stated volume of fill of the injection in the container; and

(ii) for all other active ingredients—the stated weight of each active ingredient in the stated volume of fill of the injection in the container;

(e) if the medicine is intended for multidose use—either:

(i) if the stated volume in the container is greater than 1 mL—the quantity of the active ingredient in 1 mL of the injection; or

(ii) if the stated volume in the container is less than or equal to 1 mL—the quantity of the active ingredient in a suitable dose volume of that medicine;

(f) if the medicine is intended for use as a single dose, regardless of whether dilution is required, and is not intended for electrolyte replacement—either:

(i) the stated weight of the active ingredient in the stated volume of fill of the injection in the container; or

(ii) if measured in units in clinical practice—the number of units in the stated volume of fill, expressed as:

(A) International Units (the ***IU***); or

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

(C) where the IU or a default standard have not been established, as the unit in the product details for the medicine;

(g) if the medicine is intended for single dose use and has a stated volume of 1 mL—the volume of fill "in 1 mL" or, if there is insufficient space, the volume of fill "/1 mL";

Authorised Version F2026L01311 registered 28/09/2026

(h) if the medicine is for nutritional therapy but the active ingredient is not intended for electrolyte replacement—the stated weight of the active ingredient in the stated volume of fill of the injection in the container;

(i) if the medicine is an antibiotic preparation and the potency units are used as a measure of activity—the number of such units expressed as International Units (IU) established by the World Health Organization;

(j) if the medicine contains Vitamin A or a derivative of Vitamin A—the equivalent quantity or proportion of Vitamin A expressed in terms of microgram retinol equivalents.

40 Expression of potency in biological medicines

(1) This section applies to the label on a primary pack, intermediate packaging (if any) and container of a biological medicine.

(2) If the medicine is a liquid or is required to be prepared before use, the potency must be:

(a) included on the label of the medicine; and

(b) expressed as:

(i) potency units; or

(ii) weight of active ingredient per dose or per unit volume, or the volume which contains the recommended dose.

(3) If the potency of the medicine is expressed on the label in potency units, the potency unit to be used must be:

(a) the International Unit (the ***IU)*** established by the World Health Organization; or

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

(c) where IU or a default standard have not been established, the unit specified in the product details for the medicine.

41 Expression of activity of radionuclides in radiopharmaceutical preparations

(1) This section applies to the label on a primary pack, intermediate packaging (if any) and container of a medicine that contains an active ingredient that is a radionuclide and is included in a radiopharmaceutical preparation.

(2) The quantity or proportion of the active ingredient which is a radionuclide and is included in a radiopharmaceutical preparation must be:

(a) included on the label; and

(b) expressed in terms of the total activity of the radionuclide in the container, in becquerels, at a specified date and hour.

42 Permitted statements of storage temperature conditions

If storage temperature conditions are to be included on the label of a medicine, the following statements of storage temperature conditions are permitted:

(a) “Store below –18ºC (Deep freeze)”;

Authorised Version F2026L01311 registered 28/09/2026

(b) “Store below –5ºC (Freeze)”;
(c) “Store at 2ºC to 8ºC (Refrigerate. Do not freeze)”;
(d) “Store below 25ºC”;
(e) “Store below 30ºC”;
(f) any other storage temperature conditions as specified in the product details for the medicine.

43 Common names of vitamins

If a medicine contains an active ingredient that is a vitamin, the word ‘vitamin’, or any suitable unambiguous abbreviation of the word vitamin, together with the common name of that vitamin, may appear on the main label on the primary pack, intermediate packaging (if any) or container 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.

Authorised Version F2026L01311 registered 28/09/2026

Part 6—Application, saving and transitional provisions

44 Listing active ingredients on certain medicines

Paragraphs 14(3)(i), 20(3)(g), 25(2)(h), and 26(2)(e), subparagraph 38(2)(a)(ii), paragraph 38(2)(d) and subparagraph 38(2)(f)(ii) apply in relation to a medicine that is manufactured or imported on or after 1 December 2026.

45 TGO 91

(1) In this section:

commencement day means the day this instrument commences.

TGO 91 means the *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines*, as in force immediately before the commencement day.

(2) Despite the repeal of TGO 91 by this instrument, TGO 91 continues to apply as if the repeal had not occurred to medicines to which this instrument applies that are supplied on or after the commencement day and released for supply before 1 October 2031, in accordance with subsection (3).

(3) Medicines to which this instrument applies that are released for supply before 1 October 2031 may comply with one of the following instead of the provisions of this instrument:

(a) TGO 91;

(b) both:

(i) the provisions of this instrument that are specified in column 3 in one or more of the items in the following table; and

(ii) the provisions of TGO 91, other than the provisions of TGO 91 specified in column 2 of those items mentioned in subparagraph (i) in the following table.

Equivalent provisions in TGO 91 and TGO 115

Column 1	Column 2	Column 3
Item	**Provisions in TGO 91**	**Provisions in TGO 115**
1	Paragraph 8(1)(j)	Paragraphs 12(1)(e) and 23(1)(e)
2	Subsection 10(9)	Subsection 33(2)
3	Paragraphs 8(1)(b) and 9(1)(b)	paragraphs 11(1)(b) and 11(4), paragraph 22(1)(c) and subsection 22(5)
4	Paragraphs 10(11)(d) and (e)	Paragraphs 16(2)(b) and 16(3)(a), and subsection 16(4)
5	Paragraph 10(12)(g)	Paragraph 17(3)(e) and subsection 17(4)

Authorised Version F2026L01311 registered 28/09/2026

Equivalent provisions in TGO 91 and TGO 115		
Column 1	**Column 2**	**Column 3**
Item	**Provisions in TGO 91**	**Provisions in TGO 115**
6	Paragraph 10(4)(d)	Paragraph 14(2)(b) and subsection 14(4)
7	Paragraph 10(5)(h)	Paragraph 15(3)(e) and subsection 15(4)
8	subparagraph 10(13)(a)(vi)	paragraph 18(2)(b) and subsection 18(4)
9	subparagraph 10(14)(a)(v)	paragraph 19(2)(b) and subsection 19(5)
10	paragraphs 8(1)(d) and 9(1)(d)	paragraphs 11(1)(d) and 22(1)(e)
11	paragraph 10(2)(c)	paragraph 25(2)(e)
12	paragraph 10(4)(f)	paragraph 14(3)(b)
13	paragraph 10(11)(g)	paragraph 16(3)(c)
14	paragraphs 8(1)(f) and (g) and 8(3)(d) and (e)	paragraphs 12(1)(a) and (b), 13(1)(d) and (e) and 23(1)(a) and (b)
15	paragraphs 10(4)(h) and (i)	paragraphs 14(3)(d) and (e)
16	paragraphs 10(5)(e) and (f)	paragraphs 15(3)(b) and (c)
17	paragraphs 10(11)(i) and (j)	paragraphs 16(3)(e) and (f)
18	paragraphs 10(12)(d) and (e)	paragraphs 17(3)(b) and (c)
19	subparagraphs 10(13)(a)(viii) and (ix)	paragraphs 18(2)(d) and (e)
20	subparagraphs 10(14)(a)(vii) and (viii) and 10(14)(b)(iii) and (iv)	paragraphs 19(2)(d) and (e)
21	subparagraphs 10(15)(b)(iv) and (v)	paragraphs 20(2)(d) and (e)
22	subparagraph 10(15)(b)(ii)	paragraph 20(2)(b) and subsection 20(4)

(4) For the avoidance of doubt, this instrument applies to medicines that are released for supply on or after 1 October 2031.

Authorised Version F2026L01311 registered 28/09/2026

Schedule 1—Substances that are required to be declared on the label

Note: See paragraph 12(1)(e).

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
1	***antibiotics***, that are not an active ingredient and that are present only as a residual impurity	all		contains residual [antibiotic name]
2	***aspartame***	oral		aspartame (phenylalanine), or where phenylalanine is included as a separate substance: (a) aspartame and phenylalanine; or (b) aspartame, phenylalanine
3	***bee pollen***	all		bee pollen
4	***benzoates*** Note: This includes the following: (a) benzoic acid; (b) sodium benzoate.	all		benzoates
5	***crustacea*** and ***crustacean products*** Note: This includes various species of aquatic animals which have an inedible chitinous outer shell, such as: (a) crab; and (b) crayfish; and (c) lobster; and (d) prawn; and (e) shrimp.	all		crustacea, or crustacean products
6	***egg, egg products***, and ***products manufactured in eggs*** Note: This includes the following:	all		egg, or egg products, or manufactured in eggs

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
	(a) dried egg yolk; (b) egg lecithin; (c) influenza vaccine.			
7	***ethanol***, present in a concentration of 3% v/v, 3% v/w or 3% w/w or more	all	the label must declare the quantity of ethanol as % v/v, % v/w or % w/w	alcohol
8	***fish*** and ***fish products*** Note: This includes the following: (a) cod; (b) cod–liver oil; (c) diadromous fish; (d) freshwater fish; (e) halibut; (f) marine fish; (g) shark; (h) tuna.	all		fish, or fish products
9	***galactose***	oral		galactose
10	***gluten***, or an ***ingredient derived from gluten-containing grain***, present in a concentration of 20 ppm or more Note: This includes gluten present as a natural constituent of an ingredient such as wheat starch.	all, other than skin and mucous membrane applications		gluten
11	***hydroxybenzoic acid esters***, other than salicylates, that are parabens with "hydroxybenzoate" in the Australian Approved Names List Note: This includes the following: (a) ethyl hydroxybenzoate;	all		hydroxybenzoates (parabens)

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
	(b) methyl hydroxybenzoate; (c) propyl hydroxybenzoate; (d) sodium ethyl hydroxybenzoate; (e) sodium methyl hydroxybenzoate; (f) sodium propyl hydroxybenzoate.			
12	***lactose*** Note: See item 13 for lactose for inhalation, infusion or injection.	oral	the substance must also be included on the label in accordance with item 28, as applicable, in relation to sugars—monosaccharides and disaccharides	lactose
13	***lactose*** derived from milk Note: See item 12 for lactose for oral administration.	inhalation, infusion or injection	the substance must also be included on the label in accordance with item 28, as applicable, in relation to sugars—monosaccharides and disaccharides	milk products
14	***milk*** and ***milk products*** Note: This includes the following: (a) casein; (b) hydrolysed milk protein; (c) nonfat dry milk; (d) whey powder; (e) whole dry milk.	all		milk, or milk products

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
15	***mollusc*** and ***mollusc components*** Note: This includes the following: (a) cuttlefish; (b) mussel; (c) oyster; (d) squid; (e) components such as oil, shell and ink (sepia).	all		mollusc, or mollusc products
16	***peanuts*** and ***peanut products*** Note: This includes the following: (a) *Arachis hypogaea*; (b) arachis (peanut) oil.	all		peanuts, or peanut products
17	***phenylalanine***, where present: (a) as an ingredient; or (b) in an ingredient naturally high in phenylalanine such as spirulina, legumes, nuts or soy products; or (c) due to processing of an ingredient resulting in enrichment of phenylalanine content	all, other than skin or mucous membrane applications		phenylalanine
18	***potassium salts***, where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1 mmol) elemental potassium Note: This includes the following: (a) potassium bicarbonate;	oral	the label must declare (in milligrams) the quantity of elemental potassium per dosage unit or in a stated weight or volume of the medicine	potassium

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
	(b) potassium chloride.			
19	***propolis***	oral		propolis
20	***royal jelly***	oral		royal jelly
21	***saccharin*** Note: This includes the following: (a) saccharin calcium; (b) saccharin sodium.	oral		saccharin
22	***sesame seeds*** and ***sesame seed products*** Note: This includes the following: (a) sesame seed; (b) sesame oil; (c) *Sesamum indicum*.	all		sesame seeds, or sesame seed products
23	***sodium salts***, where the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium Note: This includes the following: (a) sodium bicarbonate; (b) sodium chloride.	oral	the label must declare (in milligrams) the quantity of elemental sodium per dosage unit or in a stated weight or volume of the medicine	sodium
24	***soya beans*** and ***soya bean products***, other than: (a) soya oil that is fully refined; and (b) 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	all		soya beans, or soya bean products, or soy, or soy products

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
	when derived from soybean sources; and (c) phytosterols derived from vegetable oils and phytosterol esters from soybean sources; and (d) plant stanol ester produced from vegetable oil sterols from soybean sources Note: This includes the following: (a) *Glycine max*; (b) soya bean; (c) soya oil.			
25	***sorbic acid*** and ***sorbic acid salts*** Note: This includes potassium sorbate.	all		sorbates
26	***sucralose***	oral		sucralose
27	***sugar alcohols***, where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose Note: This includes the following: (a) erythritol; (b) isomalt; (c) lactitol; (d) maltitol; (e) mannitol; (f) polydextrose; (g) sorbitol; (h) xylitol.	oral	the label must: (a) state the quantity of sugar alcohols present per recommended maximum daily dose; and (b) except where the sugar alcohol is glycerol, include the statement "Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea"	sugar alcohols, or the name of the sugar alcohol

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
28	***sugars—monosaccharides and disaccharides***, where the total sugar content (including lactose) exceeds 100 mg per maximum recommended daily dose Note: This includes the following: (a) fructose; (b) glucose; (c) honey (as a mixture of sugars); (d) invert sugar; (e) lactose; (f) maltose; (g) sucrose..	oral	if substance is lactose, lactose must also be included on the label in accordance with item 12 or 13, as applicable	sugars
29	***sulfites***, that are: (a) added to the final formulation; or (b) incidental or upstream sulfites present at a concentration of 10 ppm or more Note: This includes the following: (a) potassium metabisulfite; (b) sodium bisulfite; (c) sodium metabisulfite; (d) sodium sulfite; (e) sulfur dioxide.	all		sulfites
30	***tartrazine***	all		tartrazine

31	***tree nuts*** and ***tree nut products***, other than chestnuts or chestnut products
	Note: This includes the following:
		all		if the type of tree nuts is known:
				(a) [specific tree nuts]; or
				(b) [specific tree nuts] product; or
				if the type of tree nut is not known:

Authorised Version F2026L01311 registered 28/09/2026

Substances or groups of substances in medicines that are required to be declared on the label				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Substance or groups of substances**	**Route of administration**	**Additional requirements (if any)**	**Name to be included on the label**
	(a) *Prunus dulcis*, almond and almond oil; (b) Brazil nut; (c) cashew; (d) hazelnut; (e) *Macadamia ternifolia* , macadamia and macadamia nut oil; (f) pecan; (g) pine nut; (h) pistachio; (i) *Juglans nigra* and walnut.			(c) tree nuts; or (d) tree nuts products
32	***wheat***, including: (a) hybridised strains, other than ethanol distilled from a wheat base; and (b) wheat-derived ingredients irrespective of whether it contains gluten, including maltodextrin where derived from wheat	all		wheat, or wheat products

Authorised Version F2026L01311 registered 28/09/2026

Schedule 2—Specified ingredient names

Note: See paragraph 11(11)(c), subsections 11(12) to (14), paragraph 22(9)(c), and subsections 22(10) to (12).

Part 1—Dual labelling name

Dual labelling of active ingredients	
Column 1	**Column 2**
Item	**Ingredient name**
1	alimemazine (trimeprazine)
2	mercaptamine (cysteamine)
3	Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)

Part 2—Dual labelling name permitted until 30 April 2028

Dual labelling of active ingredients	
Column 1	**Column 2**
Item	**Ingredient name**
1	dosulepin (dothiepin)
2	hydroxycarbamide (hydroxyurea)
3	tetracaine (amethocaine)
4	trihexyphenidyl (benzhexol)

Authorised Version F2026L01311 registered 28/09/2026

Schedule 3—Specified neuromuscular blocking agents (including their salts)

Note: See subsection 31(1).

Specified neuromuscular blocking agents (including their salts)	
Column 1	**Column 2**
Item	**Ingredient name**
1	alcuronium
2	atracurium
3	cisatracurium
4	dimethyltubocurarine
5	doxacurium
6	fazadinium
7	gallamine
8	hexafluronium
9	mivacurium
10	pancuronium
11	pipecuronium
12	rocuronium
13	suxamethonium
14	tubocurarine
15	vecuronium

Authorised Version F2026L01311 registered 28/09/2026

Schedule 4—Repeals

Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines

1 The whole of the instrument

Repeal the instrument.

Authorised Version F2026L01311 registered 28/09/2026