# Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) 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

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# Part 1—Preliminary

## 1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) Order 2026*.

(2) This instrument may also be cited as TGO 116.

## 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Note: This table relates only to the provisions of this instrument as originally made.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) health practitioner;
(h) homoeopathic preparation;
(i) label;
(j) listed goods;
(k) listing number;
(l) medicine;
(m) primary pack;
(n) Register;



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(o) registered goods;
(p) registration number;
(q) Secretary;
(r) sponsor;
(s) standard;
(t) 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.

***AS/NZS 2604:2021*** means the document Australian/New Zealand Standard AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force from time to time.

***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 that 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.

***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.

***critical health information***, in relation to a medicine, means the following information:

(a) the name of each active ingredient in the medicine;
(b) the quantity or proportion of each active ingredient in the medicine;



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(c) the information required to be included on the label of the medicine under paragraph 12(1)(e) as specified in Schedule 1;
(d) the information required to be included on the label of the medicine under paragraph 12(1)(f);
(e) the directions for use for the medicine required to be included on the label of the medicine under paragraph 12(1)(g);
(f) the indication of the medicine that is required to be on the label of the medicine under paragraph 12(1)(i).

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

***complementary healthcare practitioner*** means a person mentioned in paragraph 42AA(1)(c) of the Act.

***deliverable dose*** means:
(a) in relation to a metered dose inhaler or 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) singe 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.

***distinguishing mark*** means
(a) for listed medicines—any text or graphic related to the medicine to distinguish the medicine, sponsor or product range by a unique feature, logo, trade mark, slogan, tagline or other design element;
(b) for registered medicines—any text or graphic related to the house brand, store brand, own-name brand, private label brand or other similar branding of the medicine to distinguish the medicine.

***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;



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(g) Use before.

***health professional*** means any of the following:

(a) a health practitioner;

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

***herbal material*** means dried or fresh material from a plant, or part of a plant, that is whole, fragmented, cut or ground, where the plant is defined by its botanical name according to the binomial nomenclature system.

***herbal preparation*** means herbal material that has undergone processing other than fragmentation, cutting or grinding.

***homoeopathic medicine*** means a medicine that:

(a) contains one or more homoeopathic preparations; and

(b) may contain excipients necessary for the medicine to be presented in the final dosage form.

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

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

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

(c) "nLM" or "LMn" where, from a 3C starting dilution, each subsequent dilution is a fifty millesimal or fifty thousand-fold dilution and "n" is the number of dilutions such that the total dilution is $50{,}000^n$.

Note: Where 1000 centesimal dilutions are performed, the potency is expressed as nM, for example, 1M potency represents a 1000C dilution and 2M potency represents a 2,000C dilution.

***homoeopathic preparation*** has the same meaning as in the Regulations.

***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.

***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.



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***medicine kits*** has the same meaning as in item 12 in Schedule 4 to the Regulations.

***medium container*** means a container that:

(a) has a capacity of 60 mL or less; and

(b) is not a small container.

***modified-release*** means:

(a) in relation to a pill or tablet—a pill or tablet that may be coated or uncoated and 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 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—the following:

(i) for an ingredient that is not a homoeopathic preparation—the name that is included in the Australian Approved Names List;

(ii) for an ingredient that is a homoeopathic preparation— the name that is included in the Australian Approved Names List for the ingredient, or the substance from which the dilution was prepared, and a statement of the homoeopathic potency or, if the name is not included in the Australian Approved Names List, a traditional homoeopathic name in full, or as traditionally abbreviated, and a statement of the homoeopathic potency;

(b) in relation to an excipient—the name that is included in the Australian Approved Names List;

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

(i) for a medicine that is intended to be, or is, listed goods or registered goods—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 and not intended to be in the Register—the pharmaceutical form of the medicine;

(d) in relation to a medicine—either:

(i) the name of the medicine proposed in an application for listing or registration in the Register, or the name of the medicine in the Register, but does not include 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;



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(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, 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

(ii) where the medicine 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.

***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.

***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.

***pill*** means a solid preparation in a spherical or ovoid shape, with or without a coating, which is formed from a pliable mass that retains its shape during storage, containing one or more active ingredients, and is one of the following:

(a) a honeyed pill;

(b) a water-honeyed pill;

(c) a watered pill;



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(d) a pasted pill;
(e) a waxed pill;
(f) a concentrated pill;
(g) a dripping pill;
(h) a sugar pill.

***primary sunscreen*** has the same meaning as in AS/NZS 2604:2021.

***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***, in relation to a medicine, means:

(a) 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—the stated weight of the medicine in the container;
  (iii) for a medicine that is a liquid—the stated volume of fill in the container;
  (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; or
(b) 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.

Note: In relation to paragraph (b), an example of the quantity of medicine in a primary pack is 5 x 10 mL vials or 2 bottles of 10 tablets.

***Regulations*** means the *Therapeutic Goods Regulations 1990.*

***secondary sunscreen*** has the same meaning as in AS/NZS 2604:2021.

***small container*** means a container that has a capacity of 25 mL or less.

***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.

***standardisation*** means the process by which the content of a specific chemical constituent in herbal material or herbal preparation has been determined.

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



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

***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.

***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 or listing in relation to the medicine; and

(c) warning statements specified in the current Poisons Standard that applies to the medicine;

(d) warning statements required in relation to an ingredient contained in the medicine as specified in an instrument made under subsection 26BB(1) of the Act;

(e) label statements required in relation to an indication of the medicine as specified in an instrument made under section 26BF of the Act, where that indication is included on the label of the medicine;

(f) advisory statements in relation to the medicine specified in an instrument made under subsection 3(5A) of the Act.

## 5 Standard

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

## 6 Application

(1) Subject to subsection (2), this instrument applies to all medicines, other than medicines to which the *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026* applies.

Note: For the avoidance of doubt, this instrument applies to medicines of a kind specified in Parts 2 and 3 of Schedule 10 to the Regulations, and any other medicines that the *Therapeutic Goods (Standards for Labelling Prescription Medicines) (TGO 115) Order 2026* does not apply to.



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(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

(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 mentioned in item 6 in Schedule 5 to the Regulations that is dispensed or extemporaneously compounded by a pharmacist or complementary healthcare practitioner;

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

## 7 Repeal

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



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# 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 a text size of not less than 1.5 mm; 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 and not printed; and

(f) for units of measurement 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 and listing 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 QR codes

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

(a) be in the control of the sponsor or 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.

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



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# 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 and a container, other than the following where the container is enclosed in a primary pack:

(a) the label on a small container (other than as mentioned in paragraph (d));

(b) the label on a medicine consisting of individually wrapped dosage units;

(c) the label on a strip, blister or dial dispenser pack;

(d) the label on a plastic ampoule with a capacity less than 8 mL.

Note: Requirements for the labels listed in this section where the containers are enclosed in a primary pack are in Division 3. For the avoidance of doubt, this Division applies to the primary pack enclosing a small container, individually wrapped medicine, strip, blister or dial dispense pack, or plastic ampoule with a capacity less than 8 mL.

## Subdivision 1.1—Main labels

### 11 Information to be included on the main label of a medicine or composite pack

(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) subject to subsection (6), 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;

(e) the quantity of the medicine in the container or primary pack;

(f) if the medicine is enclosed in an ampoule—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 except, where the name of the medicine includes a distinguishing mark, the distinguishing mark does not need to be presented in a continuous, uninterrupted manner.

(3) For listed medicines:

(a) where the name of the medicine on the label contains a distinguishing mark, the name of the medicine must still be clearly identifiable; and

(b) 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:

(i) the name of the active ingredient in the Australian Approved Names List appears elsewhere on the label of that primary pack or container; and



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(ii) the strength of the active ingredient is not based on the salt, hydrate or solvate; and

(iii) the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine.

(4) The information required to be on the main label of a medicine or composite pack must be in text that is oriented in the same direction.

(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 trademark of the medicine might be disrupted or obscured—adjacent to 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 or permitted by paragraphs 31(2)(i) to (l) (quantity or proportion of herbal material or herbal preparations), section 32 (Medicine for mineral supplementation) or section 35 (Common names of vitamins); or

(ii) where the medicine is in a composite pack or medicine kit—additional information to distinguish the medicines from other medicines in the pack; or

(iii) a distinguishing mark in or next to the name of the medicine; or

(iv) for listed medicines—any of the following:

(A) a description of the status of postbiotic microorganisms;

(B) a common name of a herbal active ingredient between the name of the active ingredient and the quantity or proportion of the active ingredient;

(C) an abbreviation or acronym of an active ingredient followed by the quantity or proportion of the active ingredient, which is followed by the name of the ingredient;

(D) a component of an active ingredient, and the quantity or proportion of the component, after the name and quantity of the active ingredient and in brackets.

(6) Where:

(a) critical health information is required to be on the primary pack under section 13; and

(b) the name of one or more active ingredients in the medicine includes a salt, hydrate or solvate which is not relevant to safety or efficacy;

then the name of the therapeutically active moiety of any of those active ingredients may be displayed on the main label of the primary pack instead of the names of those active ingredients if:



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(c) the main label does not display the quantity or proportion of all active ingredients in the medicine; and

(d) where the medicine has less than 4 active ingredients—the name of the therapeutically active moiety is displayed in a text size not less than 2 mm for a small container, 2.5 mm for a medium container or 3 mm for any other container; and

(e) the cohesive unit requirements specified in subsection (5) are met, except that the therapeutically active moiety is used instead of the name of the active ingredient and the quantity or proportion of all active ingredients is not included in the cohesive unit.

(7) Subject to subsection (6), where a medicine is intended to be, or is, a registered good, the name of each active ingredient and the quantity or proportion of each active ingredient on the main label of a medicine or composite pack must be:

(a) subject to paragraphs (b) to (d), if the medicine has less than 4 active ingredients (when adding the number of active ingredients in each medicine in the composite pack together)—displayed on the main label on the container and primary pack in a text size of not less than 3.0 mm; or

(b) if the medicine is in a medium container, and has less than 4 active ingredients (when adding the number of active ingredients in each medicine in the composite pack together)—displayed on the main label on the container in a text size of not less than 2.5 mm; or

(c) if the medicine is in a small container that is a primary pack, and has less than 4 active ingredients—displayed on the main label on the container in a text size of not less than 2.0 mm; or

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

Note 1: In relation to paragraphs (a) to (d), 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.

Note 2: In relation to paragraphs (b) and (c), where the small or medium container is enclosed in a primary pack the main label on the primary pack must comply with the requirements in paragraph (a).

(8) For the avoidance of doubt, each medicine within a composite pack must be labelled in accordance with this instrument.

(9) Despite subsection (1), the name and quantity or proportion of the active ingredients in a medicine may instead appear on a label other than the main label if:

(a) the medicine is:

(i) intended to be, or is, a listed good that is not a sunscreen preparation and the medicine has 2 or more active ingredients; or

(ii) intended to be, or is, a registered good and the medicine has 4 or more active ingredients (when adding the number of active ingredients in each medicine in the composite pack together); and



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(b) the name and quantity or proportion of the active ingredients meet the requirements relating to the cohesive unit in subsection (5), other than the inclusion of the name of the medicine in the cohesive unit and its location on the main label.

(10) For listed goods to which subsection (9) applies, the name and quantity or proportion of the active ingredients do not need to appear together on separate lines of text if:
   (a) the medicine is enclosed in a small or medium container; or
   (b) the medicine has 10 or more active ingredients and there is insufficient space on the label.

(11) If subsection (10) applies and the name and quantity or proportion of the active ingredients do not appear together on separate lines of text:
   (a) the name and quantity or proportion of the active ingredients must appear together on a continuous line, or lines, of text; and
   (b) the name of the active ingredients must be displayed in bold text; and
   (c) information other than the names of the active ingredients must not be in bold text.

(12) Despite subsection (1), where the medicine is a sunscreen preparation, the name and quantity or proportion of an active ingredient, and the dosage form, may instead appear on a label other than the main label.

(13) Despite subsections (1) and (6), the name and quantity or proportion of an active ingredient in a medicine that is a registered good, other than a sunscreen, and has 4 or more active ingredients (when adding the number of active ingredients in each medicine in the composite pack together), may instead:
   (a) if the critical health information is not required to be displayed on the label of the primary pack under section 13—be displayed on a label other than the main label in a text size of not less than 2.5 millimetres; or
   (b) if the critical health information is required to be displayed on the label of the primary pack under section 13—not be included on the main label.

(14) Paragraph 11(7)(d) does not apply to a medicine that is labelled in accordance with subsection (15).

(15) 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.

(16) 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 medicine containing that ingredient in accordance with the Australian Approved Names List.



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## Subdivision 1.2—Labels

### 12 Information to be included on the label of a medicine or composite pack

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

(iii) a statement of the kind required in column 4 of the table in Schedule 1, if any; and

(iv) a statement indicating that the medicine contains the substance, expressed using the name as stated in column 5 of the table in Schedule 1;

(f) all of the following:

(i) warning statements;

(ii) if a medicine is for external use—the statement:

(A) "Not to be Swallowed" or "For External Use Only" or words to that effect; or

(B) for a nasal preparation—"Nasal use only" or words to that effect; or

(C) for an eye preparation—"For use in the eye only" or words to that effect;

(iii) if the medicine is for oral use, contains an active ingredient included in category B1, B2 or B3 or C in the document titled "*Prescribing medicines in pregnancy database*" as in force from time to time, published on the Therapeutic Goods Administration website, and is not subject to any other warning statements relating to pregnancy—the statement "If pregnant or likely to become pregnant, consult a pharmacist or a doctor before use" or words to that effect;

(iv) if the medicine is a registered good for oral use, contains an ingredient included in category D in the document titled "*Prescribing medicines in pregnancy database*" as in force from time to time, published on the Therapeutic Goods Administration website, and is not subject to any other warning statements relating to pregnancy—the statement "Do not use this medicine if pregnant or likely to become pregnant" or words to that effect;

(g) directions for use, except where:



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(i) the dose of the medicine is usually determined for each individual patient by a health professional authorised under a law of a State or Territory to determine the dose; or

(ii) if there is insufficient space on the label of either the container or the primary pack to include directions for use—the directions for use are set out on the package or in a package insert provided in the primary pack of the medicine, and the container or primary pack that does not have the directions for use states where the directions for use are set out;

(h) 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 container or the primary pack 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;

(i) the indications of the medicine.

Note: For the avoidance of doubt, the information required on the label under subsection (1) is required in addition to the information that is required to be included on the main label.

(2) For a listed medicine, the warning statements specified in paragraph (1)(f), must appear immediately below the heading "Warnings" or immediately following the prefix "Warnings", other than the warning statements specified in section 26 (Modified-release oral dosage forms) and section 27 (Large dosage forms).

(3) If the 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, the information required on the label of a container under this section must be on the delivery device.

## 13 Critical health information

(1) This section does not apply to the following:

(a) a medicine that is a medicated throat lozenge or an inorganic salt-based antacid that is in a solid dosage form and has a primary pack with less than 70 square centimetres of space available for a label;

(b) a medicine that is a skin antiseptic for hand hygiene or for use by a health professional as a patient pre-operative preparation;

(c) a medicine that is a paste or gel for cleaning teeth.

(1) If a medicine is, or is intended to be, a registered good, the critical health information must be displayed together on the label of the primary pack, in the following manner:

(a) the critical health information must be presented under appropriate headings and in the following order:

(i) active ingredients;



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(ii) indications;
(iii) warning statements (except a warning statement specified in subsection 27(2));
(iv) directions for use;
(v) other information (if any);

(b) the name of the active ingredients may also include words describing the purpose of the active ingredient by indicating the pharmacological category or the principal intended actions;

(c) the warning statements may include additional safety related information such as allergen advice, cautions, or additional warning or advisory statements;

(d) the following information may be included under the heading "other information", described in subparagraph (2)(a)(v), or under another separate appropriate heading that immediately follows the critical health information:
(i) requirements relating to storage conditions;
(ii) information about package features to prevent tampering;
(iii) the names of each excipient;
(iv) the name and contact details of the sponsor;
(v) the availability of the Consumer Medicine Information for the medicine;

(e) the text in paragraphs (a) to (d) is to be displayed in an uninterrupted manner.

(2) The critical health information referred to in subsection (2)(a) must be presented as follows:
(a) text, other than the headings, must be:
(i) in one colour only that is black or another dark coloured text; and
(ii) on a white or other contrasting background;
(b) all headings must be:
(i) in the same colour text; and
(ii) on the same colour background.

## Division 2—Labels on intermediate packaging

### 14 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;



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(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—Information to be included on the label of certain medicines

### 15 Medicines in a small container

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

(2) The label on the small container that encloses a registered medicine 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.

(3) The label on the small container must include the following information displayed in a text size of not less than 1.5 mm:
   (a) if the medicine is a listed medicine—the name of the medicine;
   (b) if the medicine is a registered medicine and has 4 or more active ingredients, or is a listed medicine—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;
   (e) the quantity of the medicine in the container;
   (f) the batch number, accompanied by the batch number identifier;
   (g) the expiry date, accompanied by the expiry date identifier;
   (h) 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;
   (i) if the medicine is contained in an ampoule—the route of administration of the medicine;
   (j) if the medicine is an ophthalmic preparation for multidose use—a statement that the medicine should not be used later than 4 weeks, or another shorter period in accordance with the product details for the medicine, after the container is first opened.

### 16 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.



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(2) Subject to subsections (3) and (4), 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 name of the sponsor of the medicine.

(3) The label on the individually wrapped dosage unit 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:
  (a) the individually wrapped dosage unit consists of dry herbs contained in a bag; and
  (b) the bag continues to enclose the herbs during infusion in hot water; and
  (c) the individual bag is enclosed in a primary pack;
the individual bag does not need to be labelled in accordance with subsection (2).

## 17 Strip, blister or dial dispenser pack

(1) This section applies to a medicine that consists of individual dosage units; where:
  (a) two or more dosage units are individually enclosed in a strip, blister or dial dispenser pack such that each dosage units is extracted separately; and
  (b) the strip, blister or dial dispenser pack is 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) The label on the strip, blister or dial dispenser pack does not need to include the information in paragraphs (2)(b) or (c), if



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(a) the medicine is intended to be, or is, is a registered good and has 4 or more active ingredients; or

(b) the medicine is intended to be, or is, a listed good and has 2 or more active ingredients.

(4) If each dosage unit of the medicine is enclosed in the strip or blister pack in a way that allows for individual segments of the pack 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 is intended to be, or is, a registered good and 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 is intended to be, or is, a registered good and has 4 or more active ingredients—the name of the medicine;

(c) if the medicine is intended to be, or is, a listed good and has less than 2 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;

(d) if the medicine is intended to be, or is, a listed good and has 2 or more active ingredients—the name of the medicine.

## 18 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 two or more plastic ampoules; and

(c) the ampules 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;

(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 followed by the word “only” or any applicable warnings against use by other routes of administration.

(3) 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:



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(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—a statement that the medicine should not be used later than 4 weeks, or another shorter period in accordance with the product details for the medicine, after the container is first opened.



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# Part 4—Additional information to be included on the label of certain medicines

## 19 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.

## 20 Medicine kits

(1) This section applies to a medicine kit.

(2) The following information must be included on the outermost layer of packaging of a medicine kit:

(a) the name of the kit;

(b) the name and contact details of the sponsor of the kit;

(c) the name of each medicine in the kit;

(d) the dosage form of each medicine in the kit;

(e) the name and quantity or proportion of each active ingredient in each medicine in the kit;

(f) the quantity of each medicine in the kit;

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

(h) the earliest of the expiry dates of the medicines in the kit, accompanied by the expiry date identifier;

(i) the warning statements that relate to the medicines in the kit;

(j) the most restrictive of the storage conditions of the medicines in the kit;

(k) the listing number given to the kit.

Note 1: For the purpose of paragraph (2)(k), the listing number must comply with any requirements specified in the Regulations.

Note 2: For the avoidance of doubt, the label on the container or primary pack of each medicine within a medicine kit must comply with any applicable requirements in this instrument.

## 21 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, 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 4 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:



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(i) a statement that the medicine, when prepared, should not be used for more than 4 weeks, or a shorter period in accordance with the product details for the medicine, after the container is first opened; and

(ii) the words “for eye drops”.

## 22 Medicines for use on skin or mucous membranes, for use by inhalation, or that are 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).

## 23 Medicines containing homeopathic preparations

(1) This section applies to a medicine containing active ingredients that are all homeopathic preparations.

(2) The main label on the container and the primary pack must include the statement “homeopathic medicine” or words to that effect, displayed in a text size that is:

(a) at least 50% of the text size of the name of the medicine; and

(b) not less than 2 mm.

## 24 Medicines that contain both homeopathic and non-homeopathic preparations

(1) This section applies to a medicine that has at least one active ingredient that is a homeopathic preparation and at least one active ingredient that is not a homoeopathic preparation.

(2) The main label on the container and on the primary pack must include the statement “contains homeopathic preparations” or words to that effect, displayed in text size:

(a) at least 50% of the text size of the name of the medicine; and

(b) not less than 2 mm.

(3) The label on the container and on primary pack must clearly indicate which active ingredients in the medicine are homeopathic preparations.

## 25 Composite packs

(1) This section applies to a composite pack.

(2) The following information must be included on the outermost layer of packaging of a composite pack:

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



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(b) the most restrictive of the storage conditions of the medicines in the composite pack.

## 26 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 directions for use must include the statement "Swallow whole. Do not crush or chew" or words to that effect.

## 27 Large dosage forms

(1) This section applies to a medicine for oral administration that is:
  (a) a round tablet with a diameter of more than 13 mm; or
  (b) a pill or a tablet, other than a round tablet, with either:
    (i) a length or longest dimension of more than 22.4 mm; or
    (ii) a width or widest dimension of more than 10.5 mm; or
  (c) a capsule with either:
    (i) a length or longest dimension of more than 24.1 mm; or
    (ii) a width or widest dimension of more than 9.5 mm.

(2) The directions for use on the container and primary pack must include the following statements:
  (a) if the medicine is in transparent packaging, such that the size of the dosage form is clearly visible through the packaging, or in a medium container—"Warning: large [name of dosage form]. Swallow with water";
  (b) for all other medicines—"Swallow with water" or words to that effect.

(3) The main label or lid sticker on the primary pack of a medicine, other than a medicine with transparent packaging or in a medium container, must include the following:
  (a) an image of the actual size of the pill, tablet or capsule;
  (b) the words "actual size", and the statement "Warning: large [name of dosage form]", immediately adjacent to the image in paragraph (a).

(4) The label is not required to include the information specified in subsections (2) or (3) if:
  (a) the primary pack is a small container; or
  (b) the medicine is not intended to be swallowed whole and the directions for use on the label of the container and primary pack clearly states the manner in which the dosage form is to be consumed or that the medicine is not to be swallowed whole.

## 28 Medicines that have a vaginal route of administration

(1) This section applies to a medicine that is intended to be, or is, a listed good and the medicine is for vaginal administration.



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(2) The label on the container and the primary pack must include the warning statement "Do not use if pregnant or [trying/likely] to become pregnant unless directed by your health practitioner".

## 29 Sunscreen preparations

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

(2) If a sunscreen preparation is enclosed in a small container, the label of the sunscreen preparation must display:
  (a) the sun protection factor in a text size of not less than 1.5 mm; and
  (b) despite any text size requirements in Part 3, all other information in a text size not less than 1.0 mm.

(3) The label on the container and primary pack of a sunscreen preparation must:
  (a) comply with clause 5 of AS/NZS 2604:2021; and
  (b) comply with clause 6.1 of AS/NZS 2604:2021.

(4) The label on the container and primary pack that encloses a sunscreen preparation that is a primary sunscreen must:
  (a) include the following statements or words to the effect:
    (i) "avoid prolonged exposure in the sun";
    (ii) "wear protective clothing—hats and eyewear when exposed to the sun";
    (iii) "apply generously to the skin 20 minutes before sun exposure, then reapply every 2 hours, and after swimming, sweating or towelling";
  (b) comply with clauses 6.2.1(b), (c) and (d), clause 6.2.2.2 and clause 6.2.2.3 of the AS/NZS 2604:2021, as applicable.

(5) The label on the container and primary pack that encloses a sunscreen preparation that is a secondary sunscreen must comply with clause 6.3 of the AS/NZS 2604:2021, as applicable.

(6) The label on the container and primary pack of a sunscreen preparation must include the following statements in the directions for use:
  (a) if the sunscreen preparation is in the dosage form of a spray, foam, aerosol or any other dosage form that has a risk of inhalation of the sunscreen preparation—"Use in a well ventilated area and avoid inhalation" or words to that effect;
  (b) if the sunscreen preparation is in the dosage form of a spray, foam, aerosol or any other dosage form with a risk of the sunscreen preparation coming in contact with the eyes, nose or mouth—"Do not [spray/apply] directly onto the face. [Spray/apply] onto hands and then apply to face" or words to that effect;
  (c) if the sunscreen preparation is in the dosage form of a spray, aerosol or any other dosage form with a risk of the sunscreen preparation being dispersed into the environment—"Do not apply the product in windy conditions", "Apply product out of the wind" or words to that effect;
  (d) if the sunscreen preparation is in the dosage form of:



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(i) a spray or aerosol—"Apply liberally and evenly until the product looks and feels wet on the skin" or words to that effect; or

(ii) a roll on, stick or any other dosage form that has a risk of inadequate application—"Apply generously and evenly on all exposed skin" or words to that effect;

(e) if the sunscreen preparation is in the dosage form of a spray or aerosol—"Hold the container 10 to 15 cm away from the body" or words to that effect.



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

## 30 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 less than 1,000 micrograms—in micrograms;

(b) for a quantity of 1,000 micrograms—as either 1,000 micrograms or 1 milligram;

(c) for a quantity of a more than 1 mg and less than 1,000 mg—in milligrams;

(d) for a quantity of 1,000 mg—as either 1,000 mg or 1 g

(e) for a quantity for more than 1 g and less than 1,000 g—in grams;

(f) for a quantity expressed in micrograms—the following:

(i) other than on the label of a small or medium container—as "microgram";

(ii) on the label of a small container or medium container—the abbreviation "µg" or "mcg" 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 less than 1,000 microlitres—in microlitres;

(b) for a quantity of 1,000 microlitres—as either 1,000 microlitres or 1 mL;

(c) for a quantity of more than 1 mL and less than 1,000 mL—in millilitres;

(d) for a quantity of 1,000 mL—as either 1,000 mL or 1 L;

(e) for a quantity more than 1 L and less than 1,000 L—in litres;

(f) for a quantity expressed in microlitres—the following:

(i) other than on the label of a small container—as "microlitres";

(ii) on the label of a small container—the abbreviation "µL" may be used;

(g) for a quantity expressed 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 active ingredient in mass or volume, the unit of measurement displayed for the quantity of the active



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ingredient contained in the medicine must be displayed in the same unit of measurement as the warning statement.

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

## 31 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 medicine that contains an active ingredient for mineral supplementation that is an oral preparation.

Note: The requirements for a medicine that contains an active ingredient for mineral supplementation that is an oral preparation are set out in section 32.

(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 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 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—the total quantity of the active ingredient in each patch and the quantity of the active ingredient released in a stated time;

(g) if the medicine is a pressurised metered dose inhaler, dry powder inhaler or other metered dose preparation—either:

(i) the quantity delivered per actuation; or



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(ii) if the medicine is a registered medicine, and the dose of the medicine was clinically established as the metered dose —the quantity metered per actuation;

(h) if the medicine is to be applied to the skin and mucous membranes, other than medicines subject to paragraph (g)—a percentage 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;

(i) if the medicine contains an active ingredient that is herbal material, and the label does not claim standardisation—the weight of the herbal material;

(j) if the medicine contains an active ingredient that is herbal material, and standardisation is claimed on the label—the average amount of herbal material and the quantity of the standardised constituents in the herbal material;

(k) if the medicine contains an active ingredient that is an herbal preparation, other than an essential oil, and the label does not include standardisation—the dry or fresh weight of the herbal material from which the preparation was derived;

(l) if the medicine contains an active ingredient that is an herbal preparation, other than an essential oil, and standardisation is claimed on the label—the average amount of the herbal material from which the preparation is derived and the quantity of standardised constituents in the herbal material;

(m) if the medicine contains an active ingredient that is an enzyme—the activity unit specified in column 2 of the table in Schedule 3 in relation to the particular enzyme set out in column 4 of the table in that Schedule;

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

(o) 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;

(p) for any other medicines—either:

(i) if the medicine is a liquid and includes an active ingredient which is also a liquid—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—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—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—the weight of the active ingredient in a stated weight of the medicine.



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## 32 Medicine for mineral supplementation

(1) This section applies to a medicine in the form of an oral preparation that contains an active ingredient intended for mineral supplementation.

(2) Where a label must include the name of the active ingredient and quantity or proportion of the active ingredient, this may be expressed as:

(a) the name of the active ingredient and the quantity or proportion of the active ingredient; and

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

## 33 Active ingredients for homoeopathic preparations

The label on the container and on the primary pack of a medicine that contains a homoeopathic preparation must include:

(a) if the medicine is a fully potentised, single ingredient homoeopathic medicine—the name of the active ingredient and a clear statement that the medicine solely consists of this active ingredient; or

(b) if all of the active ingredients in a medicine are homoeopathic preparations of the same proportions—the statement "Contains equal parts of [the name of each active ingredient]"; or

(c) in all other medicines—the quantity of the preparation in one millilitre or one gram of the medicine.

## 34 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)";

(b) "Store below –5ºC (Freeze)";

(c) "Store at 2ºC to 8ºC (Refrigerate. Do not freeze)";

(d) "Store below 25ºC";

(e) "Store below 30ºC";

(f) where a medicine is, or intended to be, a registered good—any other storage temperature conditions as specified in the product details for the medicine.

## 35 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 a label of 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.



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# Part 6—Application, saving and transitional provisions

## 36 TGO 92

(1) In this section:

***commencement day*** means the day this instrument commences.

***TGO 92*** means the *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines*, as in force immediately before the commencement day.

(2) Despite the repeal of TGO 92 by this instrument, TGO 92 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 92;

(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 92, other than the provisions of TGO 92 specified in column 2 of those items mentioned in subparagraph (i) in the following table.

**Equivalent provisions in TGO 92 and TGO 116**

| Column 1 | Column 2 | Column 3 |
|---|---|---|
| **Item** | **Provisions in TGO 92** | **Provisions in TGO 116** |
| 1 | paragraph 8(1)(j) | paragraph 12(1)(e) |
| 2 | paragraph 8(1)(b) | paragraph 11(3)(b) |
| 3 | paragraph 9(1)(b) | subsection 11(6) |
| 4 | paragraph 11(1)(b) | paragraph 30(2)(f) |
| 5 | subparagraph 11(2)(i)(iii) | paragraph 31(2)(m) |
| 6 | paragraph 9(3)(a) | subsection 11(5) |
| 7 | subsection 9(2) | subsections 11(2) and 11(3), and subparagraph 11(5)(b)(iii) |
| 8 | paragraphs 8(1)(d) and 9(1)(d) | paragraph 11(1)(d) |
| 9 | paragraph 9(3)(a) | subsection 11(10) |
| 10 | paragraph 10(7)(g) | paragraph 15(3)(d) |
| 11 | paragraph 10(6)(c) | paragraph 20(2)(d) |
| 12 | paragraphs 8(1)(f) and (g) and 8(4)(d) and (e) | paragraph 12(1)(a) and (b) |
| 13 | paragraphs 10(6)(f) and (g) | paragraph 20(2)(g) and (h) |



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| Equivalent provisions in TGO 92 and TGO 116 | | |
|---|---|---|
| **Column 1** | **Column 2** | **Column 3** |
| **Item** | **Provisions in TGO 92** | **Provisions in TGO 116** |
| 14 | paragraphs 10(7)(i) and (j) | paragraphs 15(3)(f) and (g) |
| 15 | subparagraphs 10(8)(a)(viii) and (ix) | paragraph 16(2)(d) and (e) |
| 16 | subparagraphs 10(9)(a)(vii) and (viii) and 10(9)(b)(iv) and (v) | paragraph 17(2)(d) and (e) |
| 17 | subparagraphs 10(10)(b)(iv) and (v) | paragraph 18(2)(d) and (e) |
| 18 | subparagraphs 11(2)(i)(i) and 11(2)(i)(ii) | paragraphs 31(2)(j) and 31(2)(l) |
| 19 | subparagraph 10(10)(b)(ii) | subparagraph 18(2)(b) |
| 20 | paragraph 10(7)(b) | paragraphs 15(3)(a) and 15(3)(b) |
| 21 | subsection 10(2) | subsection 22(2) |

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



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# 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:<br>(a) aspartame and phenylalanine; or<br>(b) aspartame, phenylalanine |
| 3 | ***bee pollen*** | all | | bee pollen |
| 4 | ***benzoates***<br>Note: This includes the following:<br>(a) benzoic acid;<br>(b) sodium benzoate. | all | | benzoates |
| 5 | ***crustacea*** and ***crustacean products***<br>Note: This includes various species of aquatic animals which have an inedible chitinous outer shell, such as:<br>(a) crab; and<br>(b) crayfish; and<br>(c) lobster; and<br>(d) prawn; and<br>(e) shrimp. | all | | crustacea, or crustacean products |
| 6 | ***egg, egg products***, and ***products manufactured in eggs***<br>Note: This includes the following: | all | | egg, or egg products, or manufactured in eggs |



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| 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;<br>(b) egg lecithin;<br>(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***<br>Note: This includes the following:<br>(a) cod;<br>(b) cod–liver oil;<br>(c) diadromous fish;<br>(d) freshwater fish;<br>(e) halibut;<br>(f) marine fish;<br>(g) shark;<br>(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<br>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<br>Note: This includes the following:<br>(a) ethyl hydroxybenzoate; | all | | hydroxybenzoates (parabens) |



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| 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;<br>(c) propyl hydroxybenzoate;<br>(d) sodium ethyl hydroxybenzoate;<br>(e) sodium methyl hydroxybenzoate;<br>(f) sodium propyl hydroxybenzoate. | | | |
| 12 | ***lactose***<br>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***<br>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, or milk products |
| 14 | ***milk*** and ***milk products***<br>Note: This includes the following:<br>(a) casein;<br>(b) hydrolysed milk protein;<br>(c) nonfat dry milk;<br>(d) whey powder;<br>(e) whole dry milk. | all | | milk, or milk products |



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| 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***<br>Note: This includes the following:<br>(a) cuttlefish;<br>(b) mussel;<br>(c) oyster;<br>(d) squid;<br>(e) components such as oil, shell and ink (sepia). | all | | mollusc, or mollusc products |
| 16 | ***peanuts*** and ***peanut products***<br>Note: This includes the following:<br>(a) *Arachis hypogaea*;<br>(b) arachis (peanut) oil. | all | | peanuts, or peanut products |
| 17 | ***phenylalanine***, where present:<br>(a) as an ingredient; or<br>(b) in an ingredient naturally high in phenylalanine such as spirulina, legumes, nuts or soy products; or<br>(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<br>Note: This includes the following:<br>(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 |



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| 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***<br>Note: This includes the following:<br>(a) saccharin calcium;<br>(b) saccharin sodium. | oral | | saccharin |
| 22 | ***sesame seeds*** and ***sesame seed products***<br>Note: This includes the following:<br>(a) sesame seed;<br>(b) sesame oil;<br>(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<br>Note: This includes the following:<br>(a) sodium bicarbonate;<br>(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:<br>(a) soya oil that is fully refined; and<br>(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 |



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| 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<br>(c) phytosterols derived from vegetable oils and phytosterol esters from soybean sources; and<br>(d) plant stanol ester produced from vegetable oil sterols from soybean sources<br>Note: This includes the following:<br>(a) *Glycine max*;<br>(b) soya bean;<br>(c) soya oil. | | | |
| 25 | ***sorbic acid*** and ***sorbic acid salts***<br>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<br>Note: This includes the following:<br>(a) erythritol;<br>(b) isomalt;<br>(c) lactitol;<br>(d) maltitol;<br>(e) mannitol;<br>(f) polydextrose;<br>(g) sorbitol;<br>(h) xylitol. | oral | the label must:<br>(a) state the quantity of sugar alcohols present per recommended maximum daily dose; and<br>(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 |



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| 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<br>Note 1: This includes the following:<br>(a) fructose;<br>(b) glucose;<br>(c) honey (as a mixture of sugars);<br>(d) invert sugar;<br>(e) lactose;<br>(f) maltose;<br>(g) sucrose.<br>Note 2: Lactose forms part of total sugars for the purposes of determining if the sugars will have a significant glycaemic effect and for calculating the total daily dose. | 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:<br>(a) present in the finished product; or<br>(b) incidental or upstream sulfites present at a concentration of 10 ppm or more<br>Note: This includes the following:<br>(a) potassium metabisulfite;<br>(b) sodium bisulfite;<br>(c) sodium metabisulfite;<br>(d) sodium sulfite;<br>(e) sulfur dioxide. | all | | sulfites |
| 30 | ***tartrazine*** | all | | tartrazine |



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| 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** |
| 31 | ***tree nuts*** and ***tree nut products***, other than chestnuts or chestnut products<br>Note: This includes the following:<br>(a) *Prunus dulcis*, almond and almond oil;<br>(b) brazil nut;<br>(c) cashew;<br>(d) hazelnut;<br>(e) *Macadamia ternifolia* , macadamia and macadamia nut oil;<br>(f) pecan;<br>(g) pine nut;<br>(h) pistachio;<br>(i) *Juglans nigra* and walnut. | all | | if the type of tree nuts is known:<br>(a) [specific tree nuts]; or<br>(b) [specific tree nuts] product; or<br>if the type of tree nut is not known:<br>(c) tree nuts; or<br>(d) tree nuts products |
| 32 | ***wheat***, including:<br>(a) hybridised strains, other than ethanol distilled from a wheat base; and<br>(b) wheat-derived ingredients irrespective of whether it contains gluten, including maltodextrin where derived from wheat | all | | wheat, or wheat products |



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# Schedule 2—Specified ingredient names

Note: See paragarph 11(7)(d) and subsections 11(14) to (16).

## 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) |



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# Schedule 3—Specified units for enzymes

Note: See paragraph 31(1)(m).

| Specified units for enzymes | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Activity Unit** | **Unit Description** | **Permitted Ingredients** |
| 1 | actinidain units | Actinidain units | actinidain (of Actinidia deliciosa and chinensis) |
| 2 | ALU | Acid lactase units | Tilactase |
| 3 | ALU/g | Acid lactase unit per gram | Tilactase |
| 4 | CU | Cellulase unit | Cellulase |
| 5 | CU/g | Cellulase unit per gram | Cellulase |
| 6 | DUAA | Alpha-amylase dextrinising unit | Amylase |
| 7 | DU/g | Dextrinising unit per gram | Amylase |
| 8 | HUT | Haemoglobin units on the tyrosine basis | Protease |
| 9 | HUT/g | Haemoglobin unit on the tyrosine basis per gram | Protease |
| 10 | LipU | Lipase units | Lipase |
| 11 | LipU/g | Lipase unit per gram | Lipase |
| 12 | million PU | Million Papain units | any of the following:<br>(a) Bromelains;<br>(b) Papain |
| 13 | million PU/g | Million Papain units per gram | any of the following:<br>(a) Bromelains;<br>(b) Papain |
| 14 | thousand ALU | Thousand Acid lactase unit | Tilactase |
| 15 | thousand ALU/g | Thousand Acid lactase units per gram | Tilactase |
| 16 | thousand CU | Thousand cellulase unit | Cellulase |
| 17 | thousand CU/g | Thousand cellulase unit per gram | Cellulase |
| 18 | thousand DUAA | Thousand alpha-amylase dextrinising unit | Amylase |
| 19 | thousand DUAA/g | Thousand alpha-amylase dextrinising unit per gram | Amylase |
| 20 | Thousand HUT | Thousand haemoglobin units on the tyrosine basis | Protease |
| 21 | Thousand HUT/g | Thousand haemoglobin units on the tyrosine basis per gram | Protease |
| 22 | thousand LipU | Thousand lipase unit | Lipase |
| 23 | thousand LipU/g | Thousand lipase units per gram | Lipase |



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| | | | |
|---|---|---|---|
| 24 | USP Unit | United States Pharmacopoeial Unit | Caricain (of Carica papaya) |



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# Schedule 4—Repeals

## *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines*

### 1 The whole of the instrument

Repeal the instrument.



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