EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Department of Health, Disability and Ageing.

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides, relevantly, that the matters in relation to which an order under subsection 10(1) may be specified include requiring that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order. Subsection 10(3) provides that the Minister may set out the particulars required on a label of therapeutic goods. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Under sections 14 and 14A of the Act, criminal offences and civil penalties may apply in relation to the import, supply or export of therapeutic goods that do not comply with an applicable standard. Registered or listed therapeutic goods that do not comply with an applicable standard may also be subject to suspension or cancellation from the Australian Register of Therapeutic Goods.

The *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026* ("the Order") is made under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for the labelling of prescription medicines in Australia. The Order is designed to specify the minimum requirements for the safe labelling of such medicines. The Order repeals and replaces the *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicine* ("the Former Order"), which would otherwise sunset on 1 October 2026.

Background

The Former Order was the previous standard that specified minimum requirements for the safe labelling of prescription medicines in Australia, mandating the information required to be included on the labels of such goods and the format and placement in which such information must be presented.

Labelling requirements are critical to the safe use of medicines and to assist health practitioners to safely recommend their use to Australians. Examples of information required by the Former Order include the name of the medicine, the name of the active ingredient and its strength or quantity, storage requirements, expiry date and the declaration of certain inert or inactive ingredients ("excipient" ingredients).

The Order principally replicates the requirements of the Former Order, with appropriate updates made to the structure and order in which the requirements are set out. There are a number of provisions in the Order which aim to reduce regulatory burden in comparison to the Former Order. These include, for example:

- where a medicine is for use on skin or mucous membranes or by inhalation, or is a metered nasal spray, only requiring the name of any antimicrobial preservative to be included on the label of the primary pack and container where it has not already been declared on the label in accordance with other requirements relating to substances in Schedule 1.

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- allowing the label of the primary pack and container to include active ingredients expressed without the salt, hydrate or solvate where:
    - in relation to the main label of a primary pack—the name of the active ingredient as expressed in the Australian Approved Names List is included elsewhere on the label of the medicine; and
    - in all cases—the strength of the active ingredient is based on the free base or acid and the salt is not important to the safety and efficacy of the medicine.
- Clarifying that batch number and expiry date do not need a prefix, and may be accompanied by the batch number identifier or expiry date identifier.

There are also some provisions in the Order that strengthen requirements in comparison to the Former Order. These include, for example:

- requiring injectable solutions intended for single use with a total stated volume of 1 mL to express the volume of fill in numbers, unless there is sufficient space to do so. For example, the active ingredient must be stated as '50 mg in 1 mL' or 50 mg/1 mL, not '50 mg/mL'.
- requiring that where potassium is the principal active ingredient in an injectable prescription medicine, for example, 10 mmol potassium chloride and 0.29% sodium chloride 100 mL, at a minimum, the name of the medicine, active ingredient and quantity or proportion of the active ingredient must be displayed on the label on the container in red text.
- Requiring medicines in a modified release dosage form to clearly state that they must not be crushed or chewed.

The Order also contains transitional arrangements under which medicines may comply with the Order or continue to comply with the Former Order, or comply with the Former Order except in relation to a small number of requirements in the Order that reduce regulatory burden, for a period of 5 years (that is, until 1 October 2031).

Purpose

The Order replaces the Former Order ahead of the date on which the Former Order would otherwise sunset, and improves clarity in relation to the requirements for labelling and packaging of prescription medicines. The Order reduces regulatory burden in appropriate areas and introduces a small number of new requirements that strengthen safeguards for these certain medicines.

The Order also reflects significant drafting changes to modernise the way the instrument is set out and requirements are described, without changing the operation or effect of the requirements, most of which are consistent with the Former Order.

The purpose of the Order is to support the safe and quality use of prescription medicines for Australian consumers through ensuring a clear, safety-based set of requirements for the labelling and packaging of such medicines.

Incorporation by reference

Section 10(4) provides that, despite subsection 14(2) of the *Legislation Act 2003*, an order under subsection 10(1) may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

The Order adopts the standard titled "GS1 General Specifications" published by the not-for-profit standards organisation known as GS1 that has its headquarters in Belgium. This standard is available on the internet at www.gs1.org for free. The intended manner of the adoption of the GS1 General Specifications is as it is in force from time to time.

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Consultation

Between 16 December 2025 and 23 March 2026, the TGA undertook a public consultation on the proposal to replace the sunsetting Former Order with the requirements set out in the Order. The TGA received 110 online responses and another 8 responses by email. This consultation included a broad range of stakeholder groups, including consumers, academics, healthcare professionals and industry.

Feedback received from stakeholders has been incorporated into the drafting of the Order, where possible and appropriate, for instance in relation to how dosage forms are expressed, how warning statements are to be prominently displayed, and increased flexibility in displaying batch and expiry information.

Extracts of the draft proposed Order focussing on key changes to the wording of the active ingredient naming changes and transition arrangements were sent to Medicines Australia and Generics and Biosimilar Medicines Australia. These bodies represent innovator prescription medicine and generic prescription medicine sectors respectively. These bodies were required to review the intention and wording of the extracts. Their feedback was considered for further improvements to the Order and items to address in the associated guidance.

Details of the Order are set out in **Attachment A**.

The Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Order is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 30 September 2026.

Attachment A

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

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026* ("the Order"), and that the Order may also be cited as TGO 115.

Section 2 – Commencement

This section provides that the Order commences on 30 September 2026.

Section 3 – Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Section 4 – Definitions

This section provides the definitions of key terms used in the Order, for instance 'active ingredient' and 'batch number'.

This section also notes that some expressions used in the Order have the same meaning as in the Act, for instance 'medicine'.

Section 5 – Standard

This section provides that matters specified in the Order constitute a standard for the labelling of prescription medicines.

Section 6 – Application

This section provides that the Order applies to all medicines specified in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* (the Regulations) (Part 1 of Schedule 10 to the Regulations principally lists prescription medicines and a small number of medicines that are used in a hospital setting, such as dialysis solution), and composite packs containing only medicines and at least one such medicine. This section also makes it clear that the Order does not apply to a medicine listed in subsection 6(2) of the Order, including for instance medical gases and blood products that are whole blood or blood components including red cells, white cells, platelets and plasma.

Section 7 – Repeals

This section provides that each instrument in Schedule 4 to the Order is repealed as set out in the applicable items in that Schedule.

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Part 2 – General labelling provisions

Section 8 – General requirements

This section sets out general requirements for the labels of prescription medicines, including for instance that the primary pack, any intermediate packaging and the container of such a medicine must be labelled in accordance with the requirements specified in the Order, and that information required to be included on the label of such a medicine must be in English, clearly legible and printed in a manner that is durable.

Section 9 – Machine readable codes

Where a label of a prescription medicine contains a machine readable code that is a QR code, this section provides new mandatory requirements for information that is accessible via such a QR code, including for instance that the information must be in the control of the sponsor, or link to information about the medicine on the Therapeutic Goods Administration's website.

This section also sets out requirements relating to machine readable code generally (encompassing a machine readable code that is a QR code, and other kinds of machine readable codes), including for instance that the code must not replace information that is required to be included on the label unless permitted in the Order.

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

Division 1 – Labels on primary packs and containers

Section 10 – Application

This section provides that, with some exemptions where containers are enclosed in a primary pack and for composite packs, Division 1 applies to the label on a primary pack, intermediate packaging (if any) and a container.

Subdivision 1.1 – Main labels

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

This section provides the labelling requirements for the main label on the primary pack and container of a medicine, including for instance that such main labels must include the name of the medicine, the quantity or proportion of each active ingredient in the medicine and the name of the dosage form of the medicine.

Subdivision 1.2 – Labels

Section 12 – Information to be included on the label of a medicine

This section provides the labelling requirements for the label on the container and the primary pack of a medicine, including for instance that such labels must include the batch number and expiry date of the medicine.

Division 2 – Labels on intermediate packaging

Section 13 – Information to be included on the label on intermediate packaging

This section provides the labelling requirements for the label on intermediate packaging, where the information required to be on the label on the container is obscured by the intermediate packaging.

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These include, for instance, that the label on the intermediate packaging must include the name of the medicine and the name of each active ingredient of the medicine.

Division 3 – Labelling requirements for certain containers and packaging

Subdivision 3.1 – Injections

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

This section applies to a medicine that is an injection and that is contained in a small container, where the small container is enclosed in a primary pack. This section sets out requirements for the label on the small container, including for instance that the quantity or proportion of all active ingredients in the medicine and the name of the dosage form must be displayed in a text size of not less than 1.5 mm.

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

This section applies to a medicine that is an injection and that is contained in a very small container, where the very small container is enclosed in a primary pack. This section sets out requirements for the label on the very small container, including for instance that the name of the medicine must be displayed in a text size of not less than 1.5 mm and (if the medicine contains only one active ingredient) that the name and quantity or proportion of the active ingredient in the medicine (or an unambiguous abbreviation of the name and quantity) must be displayed in a text size of not less than 1 mm.

Subdivision 3.2 – Other containers

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

This section applies to a medicine that is not an injection, where the medicine is contained in a small container that is enclosed in a primary pack. This section sets out requirements for the label on such small container, including for instance that the name of the medicine and (if the medicine has 3 active ingredients or less) the name of each active ingredient of the medicine, must be displayed in a text size of not less than 2 mm.

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

This section applies to a medicine that is not an injection, where the medicine is contained in a very small container that is enclosed in a primary pack. This section sets out requirements for the label on the very small container, including for instance that the name of the medicine must be displayed in a text size of not less than 1.5 mm and, if the medicine contains only one active ingredient, that the name and quantity or proportion of the active ingredient in the medicine or an unambiguous abbreviation of the name and quantity must be displayed in a text size of not less than 1 mm.

Section 18 – Individually wrapped dosage units

This provision applies to a medicine that consists of individual dosage units, where each dosage unit of the medicine is enclosed in an individual wrapper or blister (whether sealed or unsealed) and one or more individually wrapped dosage units are enclosed in a primary pack. The label on the individual wrapper or blister must include specified information, including for instance the name of the medicine and the name of each active ingredient of the medicine.

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Section 19 – Strip, blister or dial dispenser pack

This section applies to a medicine that consists of individual dosage units, where two or more dosage units are individually enclosed in a strip, blister or dial dispenser pack such that each dosage unit is extracted separately, and the individual dose units are enclosed in a primary pack. The label on the strip, blister or dial dispenser pack must include specified information, including for instance the name of the medicine and the name of each active ingredient of the medicine.

Section 20 – Plastic ampoule with a capacity of 8 mL or less

This section applies to a medicine contained in plastic ampoules, where each plastic ampoule has a capacity of 8 mL or less, a connecting strip attaching 2 or more plastic ampoules and the ampoules are enclosed in a primary pack. Certain information must be included on each plastic ampoule, whether or not the required information is also included on the connecting strip. This information includes, for instance, the name of the medicine and the name and quantity or proportion of each active ingredient of the medicine, if such details are not included in the name of the medicine. Other information can be included on the plastic ampoule or connecting strip.

Subdivision 3-3 – Composite packs

Section 21 – Medicines in a composite pack

This section requires that each medicine in a composite pack must be labelled in accordance with this Order.

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

This section provides the labelling requirements for the main label on the primary pack of a composite pack. This includes for instance that the main label must include the name of the composite pack, the name of each medicine in the pak, the name of each active ingredient in each medicine in the pack if not included in the name of the medicine, and the quantity or proportion of each active ingredient in each medicine in the pack.

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

Part 4 – Additional labelling requirements for certain medicines

Section 24 – Application of this Part

This section provides that, for the avoidance of doubt, the requirements in Part 4 of the Order apply in addition to the applicable requirements in Parts 2 and 3 of the Order.

Division 1—Injections

Section 25 – Injections in a container that has a capacity more than 100 mL

This section applies to a medicine for injection in a container with a capacity more than 100 mL, other than where the medicine is a haemofiltration or haemodiafiltration solution. The label on the primary pack and container of such a medicine must include certain information, including for instance the name and quantity of each excipient in the stated volume of fill of the injection in the container, and (if the medicine is a concentrated injection) a direction not to administer the injection undiluted.

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

This section applies to a medicine for injection that is in a container that has a capacity of 100 mL or less. This section requires that the label on the primary pack and container of such a medicine must include specified information, including for instance the name and quantity of each excipient in the medicine as expressed in a specified way, depending on the intended purpose of the injection.

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

This section applies to a medicine for injection that is in a container with stated volume of fill of 100 mL or more. This section requires that the label on the primary pack and container of such a medicine must include specified information, including for instance a statement of whether the injection is hypotonic, hypertonic or isotonic, and the osmolality of the injection solution.

Section 28 – Haemofiltration or haemodiafiltration solutions

This section applies to a medicine that is a haemofiltration or haemodiafiltration solution, and requires that the label on the primary pack and container of such a medicine must include specified information, including for instance the name and quantity or proportion of each active ingredient per litre of solution following preparation as directed, and the osmolality and pH range of the solution.

Section 29 – Peritoneal dialysis solutions

This section applies to a medicine that is a solution for use in peritoneal dialysis, and requires that the label on the primary pack and container of such a medicine must include specified information, including for instance the formulation of the solution expressed in grams per litre and in millimoles per litre, and whether the solution is free from bacterial endotoxins or, where applicable, that the solution is apyrogenic.

Section 30 – Potassium for injection or infusion

This section applies to a medicine for injection that contains potassium as the principal active ingredient. The label on the container, intermediate packaging and primary pack of such a medicine must be in red colour text.

Section 31 – Neuromuscular blocking agents

This section applies to a medicine that contains a substance, or a salt of a substance, specified in Schedule 3 to the Order. The label on the primary pack of such a medicine must include warning statements displayed using a particular text and background, including for instance “Warning: Paralysing agent” in black text on a fluorescent red or warm red background.

Section 32 – Vaccines

This section applies to a medicine that is a vaccine. It provides an exemption from the requirement to list each excipient on the label on the primary pack of a vaccine that is an injectable.

Division 2—Specialty routes of administration or dosage forms

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

This section applies to a medicine that is for use on skin or mucous membranes, or that is for inhalation or that is a metered nasal spray. This section requires that the label on the primary pack and container of a such medicine must include the name of any antimicrobial preservative in the medicine,

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unless the antimicrobial preservative is required to be included on the label in accordance with paragraph 12(1)(e).

Section 34 – Medicines for ophthalmic use

This section applies to a medicine that is a preparation for ophthalmic use. The label on the container (other than a small container or very small container) and the label on the primary pack must include specified information, including for instance the name of any antimicrobial preservative in the medicine.

Section 35 – Modified release oral dosage forms

This section applies to a medicine that is for oral administration and that is in a modified release dosage form. This section requires that the label on the container, any intermediate packaging that obscures information on the container, and the primary pack of such a medicine, must include the statement "Do not crush or chew" or words to that effect.

Division 3 – Starter packs

Section 36 - Starter packs

This section applies to a medicine that is presented in a starter pack. This section requires that the label on the primary pack or container must include sufficient space to accommodate the ability for the prescriber to add the dispensing details such as the patient's name, directions for use, the dose and date of supply, and include the statement "starter pack' or words to that effect.

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

Section 37 – Use of metric units

This section sets out requirements relating to the use of metric units on the label of a prescription medicine, including for instance in relation to how a quantity of micrograms of 1 microgram or more must be expressed.

Section 38 – Expression of quantity or proportion of active ingredients for medicines

This section applies to the label on a container, any intermediate packaging and a primary pack, that encloses a medicine other than an injection, biological medicine or radionuclide in radiopharmaceutical preparations. The quantity or proportion of an active ingredient must be expressed in a certain manner, including for instance as the quantity of the active ingredient in the dosage unit, if the medicine consists of a discrete dosage unit.

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

This section applies to the label on the container, any intermediate packaging and the primary pack of a medicine that is an injection. Where such a label must include the quantity or proportion of an active ingredient, the quantity or proportion must be expressed in a certain manner, including for instance as the stated weight of the active ingredient in the container, if the medicine is a powder for injection, and is not intended for electrolyte replacement.

Section 40 – Expression of potency in biological medicines

This section applies to the label on a container, any intermediate packaging and a primary pack that encloses a medicine that is a biological medicine. If the medicine is a liquid or is required to be

prepared before use, the potency must be included on the label of the medicine and expressed in a specified way. If the potency of the medicine is expressed on the label in potency units, the potency unit must meet specified requirements.

Section 41 – Expression of activity of radionuclides in radiopharmaceutical preparations

This section applies to the label on a container, any intermediate packaging and a primary pack that encloses a medicine that contains an active ingredient that is a radionuclide, and that is included in a radiopharmaceutical preparation. This section requires that the quantity or proportion of the active ingredient which is a radionuclide must be included on the label and expressed in terms of the total activity of the radionuclide in the container, in becquerels, at a specified date and hour.

Section 42 – Permitted statements of storage temperature conditions

This section permits specified statements of storage temperature conditions if storage temperature conditions are to be included on the label of a medicine to which the Order applies, including for instance "Store below –18ºC (Deep freeze)".

Section 43 – Common names of vitamins

This section requires that 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 of the container, any intermediate packaging or the primary pack that encloses the medicine, in the manner specified. To that end, this section specifies that such information may either be on the same line of text between the approved name of the active ingredient and the quantity of that active ingredient, or on a separate line of text immediately below the related name of the active ingredient and its quantity.

Part 6—Application, saving and transitional provisions

Section 44 – Listing active ingredients on certain medicines

This section provides that 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) only apply to a medicine that is manufactured or imported on or after 1 December 2026.

Section 45 – TGO 91

This section provides the transitional arrangements for transitioning form compliance with the Former Order to compliance with the Order.

For medicines released for supply before 1 October 2031, the Former Order continues to apply such that these medicines may, instead of complying with the Order in full, comply with the Former Order or certain provisions in the Order and certain provisions in the Former Order.

All medicines released for supply on or after 1 October 2031 must comply with the Order in full.

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

This Schedule lists substances or groups of substances present in medicines to which the Order applies that are required to be declared on the label in accordance with paragraph 12(1)(e) of the Order.

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Schedule 2 – Specified ingredient names

This Schedule lists permitted ingredient names for the dual labelling of active ingredients, for the purposes of paragraph 11(11)(c), 11(12) to (14), paragraph 22(9)(c) and subsections 22(10) to (12).

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

This Schedule lists specified units for neuromuscular blocking agents (including their salts), for the purposes of subsection 31(1) of the Order.

Schedule 4 – Repeals

This Schedule provides that the *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* is repealed. This instrument was, otherwise, due to sunset on 1 October 2026.

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Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instruments

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides, relevantly, that the matters in relation to which an order under subsection 10(1) may be specified include requiring that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order. Subsection 10(3) provides that the Minister may set out the particulars required on a label of therapeutic goods. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Under sections 14 and 14A of the Act, criminal offences and civil penalties may apply in relation to the import, supply or export of therapeutic goods that do not comply with an applicable standard. Registered or listed therapeutic goods that do not comply with an applicable standard may also be subject to suspension or cancellation from the Australian Register of Therapeutic Goods.

The *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026* ("the Order") is made under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for the labelling of prescription medicines in Australia. The Order is designed to specify the minimum requirements for the safe labelling of such medicines. The Order repeals and replaces the *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicine* ("the Former Order"), which would otherwise sunset on 1 October 2026.

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The Former Order was the previous standard that specified minimum requirements for the safe labelling of prescription medicines in Australia, mandating the information required to be included on the labels of such goods and the format and placement in which such information must be presented.

Labelling requirements are critical to the safe use of medicines and to assist health practitioners to safely recommend their use to Australians. Examples of information required by the Former Order include the name of the medicine, the name of the active ingredient and its strength or quantity, storage requirements, expiry date and the declaration of certain inert or inactive ingredients ("excipient" ingredients).

The Order principally replicates the requirements of the Former Order, with appropriate updates made to the structure and order in which the requirements are set out. There are a number of provisions in the Order which aim to reduce regulatory burden in comparison to the Former Order. These include, for example:

- where a medicine is for use on skin or mucous membranes or by inhalation, or is a metered nasal spray, only requiring the name of any antimicrobial preservative to be included on the

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label of the primary pack and container where it has not already been declared on the label in accordance with other requirements relating to substances in Schedule 1.

- allowing the label of the primary pack and container to include active ingredients expressed without the salt, hydrate or solvate where:
    - in relation to the main label of a primary pack—the name of the active ingredient as expressed in the Australian Approved Names List is included elsewhere on the label of the medicine; and
    - in all cases—the strength of the active ingredient is based on the free base or acid and the salt is not important to the safety and efficacy of the medicine.
- Clarifying that batch number and expiry date do not need a prefix, and may be accompanied by the batch number identifier or expiry date identifier.

There are also some provisions in the Order that strengthen requirements in comparison to the Former Order. These include, for example:

- requiring injectable solutions intended for single use with a total stated volume of 1 mL to express the volume of fill in numbers, unless there is sufficient space to do so. For example, the active ingredient must be stated as '50 mg in 1 mL' or 50 mg/1 mL, not '50 mg/mL'.
- requiring that where potassium is the principal active ingredient in an injectable prescription medicine, for example, 10 mmol potassium chloride and 0.29% sodium chloride 100 mL, at a minimum, the name of the medicine, active ingredient and quantity or proportion of the active ingredient must be displayed on the label on the container in red text.

The Order also contains transitional arrangements under which medicines may comply with the Order or continue to comply with the Former Order, or comply with the Former Order except in relation to a small number of requirements in the Order that reduce regulatory burden, for a period of 5 years (that is, until 1 October 2031).

Purpose

The Order replaces the Former Order ahead of the date on which the Former Order would otherwise sunset, and improves clarity in relation to the requirements for labelling and packaging of prescription medicines. The Order reduces regulatory burden in appropriate areas and introduces a small number of new requirements that strengthen safeguards for these certain medicines.

The Order also reflects significant drafting changes to modernise the way the instrument is set out and requirements are described, without changing the operation or effect of the requirements, most of which are consistent with the Former Order.

The purpose of the Order is to support the safe and quality use of prescription medicines for Australian consumers through ensuring a clear, safety-based set of requirements for the labelling and packaging of such medicines.

Human rights implications

The order engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to

health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Order establishes a ministerial standard for the way prescription medicines are labelled for commercial supply in Australia. The Order specifies the minimum requirements for such medicines, principally by reference to their labelling and packaging. Establishing minimum standards for labelling promotes the right to health as labelling is critical to the safe and quality use of medicines. Information to be included on labels is important in ensuring that consumers know what they are consuming and that labels have appropriate warning statements and directions for use. The way in which the information is presented on a label is also important in supporting the safety and quality use of medicines, for instance, so important text is more prominent and all information is legible.

The Order implements important changes to the labelling of prescription medicines that promote the right to health, such as the introduction of labelling requirements for medicines in a modified dosage form. The label of such medicines are required to clearly state that they must not be crushed or chewed, which is important for the safe use of such medicines.

The Order also implements a 5 year transition period to ensure continuity of supply of medicines while labels are updated to comply with the new requirements. From 1 October 2031, all medicines must then comply with the Order.

Conclusion
The Order is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.