EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) 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 Non-Prescription Medicines) (TGO 116) 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 non-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. 92 - Standard for labels of non-prescription 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 non-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. This is particularly the case for non-prescription medicines which include medicines that consumers are able to self-select without the advice of a health practitioner, and medicines that consumers may select without a prescription but with the advice of a pharmacist. Examples of information required by the Former Order to be on labels of non-prescription medicines include the name of the medicine, the name of the active ingredient and its strength or quantity, indications, warnings, directions for use, storage requirements, expiry date and the declaration of certain substances that may cause adverse health reactions.

The Order principally replicates the requirements of the Former Order, with appropriate updates including to the structure and order in which the requirements are set out in the Order. There are a

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

number of provisions in the Order which aim to reduces regulatory burden of compliance with the Order in comparison to the Former Order. These include, for instance, allowing:

- for listed medicines, the main label of the container and primary pack to include the name of the active ingredient without the salt, hydrate or solvate, if the name of the active ingredient in the Australian Approved Names List appears elsewhere on the label of that container or primary pack, the strength of the active ingredient is not based on the salt, hydrate or solvate, and the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine;
- the name of the medicine on the main label to be interrupted by a distinguishing mark.

There are also some provisions in the Order that strengthen requirements for labelling of non-prescription medicines in comparison to the Former Order. These include, for example:

- in relation to medicines for oral administration that are a large tablet, pill or capsule intended to be swallowed whole, requiring the directions for use to include a warning statement alerting the consumer that the medicine is a large dosage form to be swallowed with water and, where the medicine is not visible through the container, to include an image of the actual size of the tablet;
- in relation to medicines that are a sunscreen preparation, detailing certain labelling standards as set out in the AS/NZS 2604:2021 and other relevant legislation.

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 the labelling and packaging of non-prescription medicines. The Order reduces regulatory burden in appropriate areas and introduces a small number of new requirements that strengthen safeguards for certain medicines, noting in particular that non-prescription medicines are in most instances accessed by consumers without consultation with a health practitioner.

The Order also reflects 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 non-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 incorporates by reference categories B1, B2, B3, C and D in the document titled "*Prescribing medicines in pregnancy database*" as in force from time to time. This document is publicly available for free on the Therapeutic Goods Administration website (www.tga.gov.au).

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

The Order also adopts the 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 ("the Sunscreen Standard"). The Sunscreen Standard is available - for a fee - from the website for Standards Australia (www.standards.org.au). The intended manner of the adoption of the Sunscreen Standard is as it is in force from time to time.

While the Sunscreen Standard is not available for free, it is anticipated that persons most affected by its adoption in the Order would likely be in possession of this document. As an important benchmark for sunscreen products, it would be infeasible from a regulatory perspective to not adopt such a benchmark on the basis that it is not available for free.

Further, by prior written arrangement with the TGA, members of the public may request to view a copy of the Sunscreen Standard without charge at the TGA office in Fairbairn, ACT.

Members of the public may also approach a library in Australia to borrow, view or photocopy a copy of the Sunscreen Standard, if possible. Fees may apply in some instances in relation to such requests. Enquiries should be made with local libraries, state libraries or the National Library.

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. Several stakeholders also augmented their online response with additional content provided 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, increased flexibility in displaying batch and expiry information, and the required warning statement for listed medicines with a vaginal route of administration.

Extracts of the draft proposed Order focussing on key changes to requirements and transition arrangements were sent to Consumer Healthcare Products Australia, Complementary Medicines Australia and Accord Australasia. These bodies represent the non-prescription medicine sector, the complementary medicine sector and (principally) the sunscreen sector respectively. These bodies were requested to review the intention and wording of the extracts (not their amenability of the changes themselves). 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.

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

Attachment A

Details of the *Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) Order 2026*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) Order 2026* ("the Order"), and that the Order may also be cited as TGO 116.

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 non-prescription medicines.

Section 6 – Application

This section provides that the Order applies to all medicines other than those listed in subsection 6(2) and medicines to which the *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026* applies.

Section 7 – Repeal

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

Part 2—General labelling provisions

Section 8 - General requirements

This section sets out general requirements for labels of non-prescription medicines, including for instance that the primary pack, any intermediate packaging and the container of such a medicine must

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

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 – QR codes

This section provides new mandatory requirements for information that is accessible via a QR code on a label. This information 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, Division 1 applies to the label on the container and the primary pack.

Subdivision 1.1—Main labels

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

This section provides the labelling requirements for the main label on the container and on the primary pack 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 of 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 or composite pack

This section provides the labelling requirements for the label on the container and the primary pack of a medicine, specifying information that does not need to be included on the main label, including for instance that such labels must include indications and directions for use of the medicine.

Section 13 – Critical health information

This section provides the critical health information which must be displayed together on the label of the primary pack where a medicine is or is intended to be a registered good, and the manner in which such critical health information must be displayed, including for instance the name and quantity of the active ingredients, indications, warnings and directions for use.

Division 2—Labels on intermediate packaging

Section 14 – Intermediate packaging

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

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

Division 3—Information to be included on the label of certain medicines

Section 15 – Medicines in a small container

This section applies to a medicine that is contained in a small container that is enclosed in a primary pack, and sets out requirements for the label on the small container. This includes for instance, in relation to registered medicine, that the name of the medicine and (if the medicine has 3 active ingredients or less) the name of each active ingredient in the medicine must be displayed in a text size of not less than 2 mm. For listed medicines, and registered medicines with 4 or more active ingredients, this same information can be in a text size of not less than 1.5 mm.

Section 16 – Individually wrapped dosage units

This section 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 required information, including for instance the name of the medicine and the name of each active ingredient of the medicine.

Section 17 – 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 strip, blister or dial dispenser pack is enclosed in a primary pack. The label on the strip, blister or dial dispenser pack must include required information, including for instance the name of the medicine and the name of each active ingredient of the medicine.

Section 18 – 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 attaches two or more plastic ampoules and the ampoules are enclosed in a primary pack. Certain information must be included on the plastic ampoule, whether or not it is also included on the connecting strip, including for instance the name of the medicine and the quantity or proportion of each active ingredient in the medicine. Other information can be included on the plastic ampoule or connecting strip.

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

Section 19—Application of this Part

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

Section 20 – Medicine kits

This section applies to medicines that are contained in a medicine kit. This section requires that a medicine kit must have specified information on the outermost layer of the kit's packaging, including for instance the name of the kit and the name of each medicine in the kit.

Section 21 – 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) and the label on the primary pack must include specified information, including for instance the name of any antimicrobial preservative in the medicine.

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

Section 22 – Medicines for use on skin or mucous membranes, for use by inhalation, or that are a metered nasal spray

This section applies to a medicine that is for use on skin or mucous membranes, for inhalation or a metered nasal spray. 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) of the Order.

Section 23 – Medicines containing homeopathic preparations

This section applies to a medicine where all active ingredients in the medicine are homeopathic preparations. The main label on the container and the primary pack must include the statement "homeopathic medicine" or words to that effect, in a text size that is at least 50% of the text size of the name of the medicine and in a text size that is not less than 2 mm.

Section 24 – Medicines that contain both homeopathic and non-homeopathic preparations

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 homeopathic preparation. The main label on the container and on the primary pack must include the statement "contains homeopathic preparations" or words to that effect, in a text size that is at least 50% of the text size of the name of the medicine and in a text size that is not less than 2 mm.

Section 25 – Composite packs

This section applies to medicines that are contained in a composite pack. A composite pack must only be supplied with specified information on the outermost layer of packaging, including for instance the earliest of the expiry dates of the medicines in the composite pack.

Section 26 – 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. The directions for use for such a medicine must include the statement "Swallow whole. Do not crush or chew" or words to that effect.

Section 27 – Large dosage forms

This section applies to a medicine for oral administration that consists of a pill, tablet or capsule that is of certain dimensions that are designed to identify large dosage form medicines. The directions for use on the container and primary pack must include specified statements, and the main label or lid sticker on the primary pack must, in most instances, include specified information, including for instance an image of the actual size of the tablet, pill or capsule.

Section 28 – Medicines that have a vaginal route of administration

This section applies to a medicine that is intended to be, or that is, a listed good for vaginal administration. 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".

Section 29 – Sunscreen preparations

This section applies to a medicine that is a sunscreen preparation. The requirements for the labelling for such products include, for instance, that the label on the container and the primary pack of a sunscreen must comply with clauses 5 and 6.1 of AS/NZS 2604:2021. Specific requirements apply to

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

primary sunscreens and secondary sunscreens, and additional information is needed in the directions for use for certain dosage forms.

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

Section 30 – Use of metric units

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

Section 31 – Quantity or proportion of active ingredients for medicines

This section sets out requirements relating to the expression of the quantity or proportion of active ingredients on the label of a non-prescription medicine, including for instance by reference to the stated weight or volume of the active ingredient in certain medicines.

Section 32 – Medicine for mineral supplementation

This section applies to a medicine in the form of an oral preparation that contains an active ingredient intended for mineral supplementation. Where a label must include the name of the active ingredient and the quantity or proportion of the active ingredient, this may be expressed as the name of the active ingredient and the quantity or proportion of the active ingredient, and the name and quantity of the element intended for mineral supplementation.

Section 33 – Active ingredients for homoeopathic preparations

This section applies to a medicine that contains a homeopathic preparation, and sets out the requirements for the label on the container and primary pack. This includes for instance, in relation to a fully potentised, single ingredient homeopathic medicine, that the name of the active ingredient and a clear statement that the medicine consists solely of that active ingredient, must be included on the label.

Section 34 – 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 non-prescription medicine, including for instance "Store below –18ºC (Deep freeze)".

Section 35 – Including common names of vitamins

This section allows a medicine that contains an active ingredient that is a vitamin to include the word "vitamin" or any suitable unambiguous abbreviation for the word vitamin, together with the common name of that vitamin, on a label of the container, intermediate packaging (if any) or the primary pack that encloses the medicine, either 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 the quantity of the active ingredient.

Part 6—Application, saving and transitional provisions

Section 36 –TGO 92

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

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

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.

Schedule 2 – Specified ingredient names

This Schedule lists permitted ingredient names for the dual labelling of active ingredients, for the purposes of paragraph 11(7)(d) and subsections 11(14) to (16) of the Order.

Schedule 3 – Specified units for enzymes

This Schedule lists specified units for enzymes, for the purposes of paragraph 31(1)(m) of the Order.

Schedule 4 – Repeals

This Schedule provides that the *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* is repealed. This instrument was, otherwise, due to sunset on 1 October 2026.

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

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 Non-Prescription Medicines) (TGO 116) 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 instrument

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 Non-Prescription Medicines) (TGO 116) 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 non-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. 92 - Standard for labels of non-prescription 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 non-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. This is particularly the case for non-prescription medicines which include medicines that consumers are able to self-select without the advice of a health practitioner, and medicines that consumers may select without a prescription but with the advice of a pharmacist. Examples of information required by the Former Order to be on labels of non-prescription medicines include the name of the medicine, the name of the active ingredient and its strength or quantity, indications, warnings, directions for use, storage requirements, expiry date and the declaration of certain substances that may cause adverse health reactions.

The Order principally replicates the requirements of the Former Order, with appropriate updates including to the structure and order in which the requirements are set out in the Order. There are a

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

number of provisions in the Order which aim to reduces regulatory burden of compliance with the Order in comparison to the Former Order. These include, for instance, allowing:

- for listed medicines, the main label of the container and primary pack to include the name of the active ingredient without the salt, hydrate or solvate, if the name of the active ingredient in the Australian Approved Names List appears elsewhere on the label of that container or primary pack, the strength of the active ingredient is not based on the salt, hydrate or solvate, and the salt, hydrate or solvate is not relevant to the safety or efficacy of the medicine;
- the name of the medicine on the main label to be interrupted by a distinguishing mark.

There are also some provisions in the Order that strengthen requirements for labelling of non-prescription medicines in comparison to the Former Order. These include, for example:

- in relation to medicines for oral administration that are a large tablet, pill or capsule intended to be swallowed whole, requiring the directions for use to include a warning statement alerting the consumer that the medicine is a large dosage form to be swallowed with water and, where the medicine is not visible through the container, to include an image of the actual size of the tablet;
- in relation to medicines that are a sunscreen preparation, detailing certain labelling standards as set out in the AS/NZS 2604:2021 and other relevant legislation.

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 the labelling and packaging of non-prescription medicines. The Order reduces regulatory burden in appropriate areas and introduces a small number of new requirements that strengthen safeguards for certain products, noting in particular that non-prescription medicines are in most instances accessed by consumers without consultation with a health practitioner.

The Order also reflects 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 non-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

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312

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 non-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 non-prescription medicines that promote the right to health, such as the introduction of labelling requirements for large dosage units that are intended to be swallowed whole to ensure that consumers are aware of this prior to purchasing 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.

Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01312