EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (Standards for Labelling Consequential Amendments) Instrument 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 Australian Government Department of Health, Disability and Ageing ("the Department").

Section 42BAA of the Act provides that the Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods, known as the Therapeutic Goods Advertising Code.

The *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* ("the Advertising Code Instrument") is made under section 42BAA and specifies a range of requirements relating to the advertising of therapeutic goods in Australia.

The *Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (Standards for Labelling Consequential Amendments) Instrument 2026* ("the Amendment Instrument") is also made under section 42BAA of the Act, in accordance with subsection 33(3) of the *Acts Interpretation Act 1901*, which relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

The purpose of the Amendment Instrument is to make a small number of minor, consequential amendments to the Advertising Code Instrument to reflect the making of new medicine labelling standards under section 10 of the Act, by updating the following in the Advertising Code Instrument:

- references to the *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines* ("TGO 91") with the new *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order* 2026 ("TGO 115"); and
- references to the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* ("TGO 92") with the new *Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) Order* 2026 ("TGO 116").

Background

The Advertising Code Instrument refers to the standards for labelling prescription and non-prescription medicines in the following ways:

- section 19 of Schedule 1 provides that an advertisement about a medicine may be required to contain specified information about the medicine, such as the name of the medicine, the name of the dosage form of the medicine and the quantity of the medicine within the meaning of the standard for labelling non-prescription medicines. Additionally, this section provides that advertisements about a medicine may, in certain circumstances, need to include health warnings about a medicine that are required under a relevant instrument, which is defined to include the standard for labelling of non-prescription medicines;
- subsection 34(1) of Schedule 1 requires that a medicine in a price information list must be specified with reference to the name of the medicine within the meaning of the standards for labelling of prescription and non-prescription medicines, as applicable.

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The standards for labelling of medicines were formerly TGO 91 for prescription medicines and TGO 92 for non-prescription medicines ("the former labelling standards") which have since been repealed by TGO 115 and TGO 116 respectively. The former labelling standards were repealed and replaced as these instruments would have otherwise sunsetted on 1 October 2026, in accordance with section 50 of the *Legislation Act 2003* ("the Legislation Act").

Therefore, minor consequential amendments are required to be made to the Advertising Code Instrument to replace all references to TGO 91 and TGO 92 with TGO 115 and TGO 116 respectively.

Incorporation by reference

The Amendment Instrument amends the Advertising Code Instrument to incorporate by reference TGO 115 and TGO 116.

TGO 115 is a disallowable legislative instrument which constitutes a standard for the purposes of section 10 of the Act and sets out requirements for the labelling of prescription medicines.

TGO 116 is a disallowable legislative instrument which constitutes a standard for the purposes of section 10 of the Act and sets out the requirements for the labelling of non-prescription medicines.

For the avoidance of doubt, in accordance with section 14 of the *Legislation Act 2003*, TGO 115 and TGO 116 are incorporated as in force or existing from time to time. TGO 115 and TGO 116 are freely available on the Federal Register of Legislation at www.legislation.gov.au.

Consultation

Due to the administrative nature of the changes made by the Amendment Instrument, the Department did not consult industry stakeholders in relation to these consequential amendments to the Advertising Code Instrument.

Other details

Details of the Amendment Instrument are set out in **Attachment A**.

The Amendment Instrument is compatible with 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 Amendment Instrument is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 30 September 2026.

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Attachment A

Details of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (Standards for Labelling Consequential Amendments) Instrument 2026*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (Standards for Labelling Consequential Amendments) Instrument 2026* ("the Amendment Instrument").

Section 2 – Commencement

This section provides that the Amendment Instrument commences on 30 September 2026.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument is section 42BAA of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that subsection.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1—Amendments

Schedule 1 amends the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* ("the Advertising Code").

Item 1 repeals the definitions for TGO 91 and TGO 92 in section 4 of Schedule 1 to the Advertising Code Instrument.

Item 2 inserts two new definitions into section 4 of Schedule 1 to the Advertising Code Instrument:

- TGO 115, which means the *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order* 2026 ("TGO 115") which is the legislative instrument that repeals and replaces TGO 91; and
- TGO 116, which means the *Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) Order* 2026 ("TGO 116") which is the legislative instrument that repeals and replaces TGO 92.

Items 3 to 5 provides for amendments to be made to sections in the Advertising Code Instrument that refer to the standards for labelling medicines. The items repeal existing references to TGO 91 and TGO 92, and replace these references with the new instruments, TGO 115 and TGO 116 respectively.

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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 (Therapeutic Goods Advertising Code) Amendment (Standards for Labelling Consequential Amendments) Instrument 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 legislative instrument

Section 42BAA of the *Therapeutic Goods Act 1989* ("the Act") provides that the Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods, known as the Therapeutic Goods Advertising Code.

The *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* ("the Advertising Code Instrument") is made under section 42BAA and specifies a range of requirements relating to the advertising of therapeutic goods in Australia.

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The purpose of the Amendment Instrument is to make a small number of minor, consequential amendments to the Advertising Code Instrument to reflect the making of new medicine labelling standards under section 10 of the Act, by updating the following in the Advertising Code Instrument:

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- subsection 34(1) of Schedule 1 requires that a medicine in a price information list must be specified with reference to the name of the medicine within the meaning of the standards for labelling of prescription and non-prescription medicines, as applicable.

The standards for labelling of medicines were formerly TGO 91 for prescription medicines and TGO 92 for non-prescription medicines ("the former labelling standards") which have since been repealed by TGO 115 and TGO 116 respectively. The former labelling standards were repealed and replaced as these instruments would have otherwise sunsetted on 1 October 2026, in accordance with section 50 of the *Legislation Act 2003* ("the Legislation Act").

Therefore, minor consequential amendments are required to be made to the Advertising Code Instrument to replace all references to TGO 91 and TGO 92 with TGO 115 and TGO 116 respectively.

Human rights implications

The Amendment Instrument 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 standards of physical and mental health. 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 Amendment Instrument engages the right to health by ensuring the Advertising Code remains current and up to date, which in turn requires advertisements for therapeutic goods to include important information relating to the safe and proper use of therapeutic goods and otherwise to not include information that is false or misleading. The Amendment Instrument aligns the Advertising Code with the latest standards for the labelling of medicines, ensuring that the general public receives accurate and balanced information about the quality, safety and efficacy of therapeutic goods in accordance with the Advertising Code.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.

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