EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 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.

Subsection 26BB(1) of the Act relevantly provides that the Minister may, by legislative instrument, make a determination specifying ingredients and, for some or all of those ingredients, requirements in relation to those ingredients being contained in a medicine. Under subsections 26BB(2), (2A) and (3) of the Act, such requirements may relate to particular ingredients not being contained in particular medicines or being contained in particular medicines only in specified circumstances or within permitted concentrations or total amounts of an ingredient in a medicine.

The purpose of a legislative instrument made under section 26BB of the Act is to specify those ingredients that may be contained in a medicine that is listed in the Australian Register of Therapeutic Goods (the Register) under section 26A or 26AE of the Act, and specify requirements in relation to the inclusion of those ingredients in such medicines. Listed medicines can only contain ingredients specified in an instrument under section 26BB of the Act.

The *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026* (the Determination) repeals and replaces the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2026* (the former Determination). The Determination specifies those ingredients that may be contained in a medicine that is listed in the Register under section 26A or 26AE of the Act, and requirements in relation to the inclusion of those ingredients in such medicines.

Background

Medicines that are listed in the Register under section 26A of the Act are considered to be low risk and are not individually evaluated before those medicines are listed. Medicines that are listed in the Register under section 26AE of the Act are also considered to be low risk, but are evaluated in relation to whether the efficacy of the medicine for the purposes for which it is to be used has been satisfactorily established (these purposes are specific efficacy claims for which the sponsor of the medicine holds supporting evidence). When listed under section 26AE, these listed medicines are commonly referred to as ‘assessed listed medicines’.

As the safety and quality of medicines listed under sections 26A and 26AE are not evaluated by the TGA before being listed in the Register, the Act contains mechanisms to help ensure that those medicines are of appropriate quality and able to be used safely by consumers. In particular, medicines listed under sections 26A and 26AE may only contain ingredients from an approved list of ingredients that have been evaluated in relation to their quality, safety and suitability for use in such medicines. Sponsors of such medicines may also only use indications (statements of therapeutic use) from a list of pre-approved, low-level indications to ensure that these medicines do not overstate their therapeutic benefits.

Under paragraphs 26A(2)(ca) and (cb) of the Act, persons applying to list a medicine in the Register under section 26A of the Act must certify that the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a) of the Act; and does not contravene a requirement in relation to such an ingredient that is specified in such a determination. Paragraphs 26AB(2)(d) and (e) contain equivalent certification requirements for applicants seeking

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marketing approval in relation to assessed listed medicines. A listed medicine or assessed listed medicine may be cancelled from the Register if it appears to the Secretary that such a certification is incorrect.

Separately, items 3, 4A, 5, 7 and 8 of Schedule 4 to the *Therapeutic Goods Regulations 1990* (the Regulations), which identifies those therapeutic goods that are eligible for listing in the Register, require that, in order for the goods mentioned in each of those items to be eligible for listing, the goods must only contain ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act, and must not contravene a requirement in such a determination.

Purpose

The Determination, made under section 26BB of the Act, provides a comprehensive list of ingredients which have been assessed or otherwise considered to be safe for use in listed medicines and assessed listed medicines, and associated requirements to be met when using particular ingredients in such medicines.

The requirements imposed by the Determination are principally designed to ensure or support the quality and safety of listed medicines that contain permitted ingredients. The requirements may relate, for example, to:

- how a permitted ingredient is to be used in the medicine, that is, as an active, homoeopathic or excipient ingredient;
- the intended method of ingestion or application of the medicine, for example, oral or topical use;
- the source of the ingredient, or procedures to be followed in its manufacture;
- appropriate limits on the volume or concentration of an ingredient; and
- the inclusion of relevant safety information on product labels, for example, allergen advice or advice about the use of medicine containing the ingredient for susceptible members of the population such as children and pregnant women.

The Determination incorporates the following changes to the former Determination:

Addition of new ingredients

- the addition of the following new ingredients for use in listed and assessed listed medicines, and specific requirements for the use of the ingredient in medicines:
    - *oxaceprol;* and
    - *Lactococcus lactis subsp. lactis.*

Changes to existing ingredients

- minor amendments to the following ingredient to reflect expiry of the transition period for requirements relating to that ingredient, as well as minor formatting changes for the purpose of improving the internal consistency of the Determination:
    - *Theanine.*

- correction of minor typographical errors and minor formatting changes for the following two ingredients for the purpose of improving the internal consistency of the Determination:
    - *Xanthium sibiricum;* and
    - *Xanthium strumarium.*

Consultation

Between February 2025 and March 2026, the TGA engaged directly with the applicant who applied for the approval of the ingredient *oxaceprol*, in connection with the application.

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Between February 2025 and May 2026 the TGA engaged directly with the applicant who applied for the approval of the ingredient *Lactococcus lactis subsp. lactis*, in connection with the application.

The remaining changes in the Determination, in comparison with the former Determination, are minor changes to reflect the expiry of transition periods, minor formatting changes or correction of typographical errors to improve internal consistency. As these changes do not result in regulatory impact to any existing medicines, these changes were not included in consultation.

Incorporation by reference

Pharmacopoeia and FCC

The Determination references the British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopeia-National Formulary, and the note in section 4 of the Determination makes it clear that each is defined in subsection 3(1) of the Act.

The definitions of the pharmacopoeia in subsection 3(1) of the Act refer to the publications of each as in force from time to time. The intention in this Determination is therefore to adopt the defined meaning of the pharmacopoeia as set out in subsection 3(1) of the Act (an approach permitted by subsection 26BB(8) of the Act). These pharmacopoeia are incorporated in the Determination as in force or existing from time to time, in accordance with these provisions, and may be accessed from www.pharmacopoeia.com/, https://pheur.edqm.eu/home and www.uspnf.com/.

The Determination also adopts specified applicable monographs in the Food Chemicals Codex (the FCC) published by the United States Pharmacopeial Convention (available at www.foodchemicalscodex.org/) in relation to the following ingredients:

- *Glycerol Ester of Partially Hydrogenated Gum Rosin*;
- *Glyceryl Rosinate*; and
- *Polyisobutylene*.

The intended manner of adoption of the FCC is also as it is in force or existing from time to time, as permitted by subsection 26BB(8) of the Act.

However, these documents are not publicly available for free. Rather, where possible, by prior written agreement and without charge, the pharmacopoeia and the FCC may be viewed by members of the public at the TGA office in Fairbairn, ACT. While these documents are not available for free, it is anticipated that the persons most affected by their adoption in the Determination would likely be in possession of these documents. As important benchmarks for the safety of therapeutic goods and other consumer goods, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

It should also be noted, in relation to the pharmacopoeia, that the National Library's Trove online system (www.trove.nla.gov.au/) allows users to identify libraries in Australia that are open to the public where editions (in most cases, earlier editions) of the pharmacopoeia may be viewed (for example, the University of Tasmania or the University of Western Australia in relation to the British Pharmacopoeia).

Members of the public may also approach any library that participates in inter-library loans with those university libraries to request an inter-library loan, or to obtain a photocopy of a particular part or monograph for personal study or research (but not for commercial purposes). Fees apply in relation to the making of such a request. Enquiries should be made with local libraries, State libraries and the National Library.

Other documents incorporated by reference

The Determination also incorporates the following documents:

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- the *Animal Products Act 1999* and the *Animal Welfare Act 1999* of New Zealand, and regulations made under these Acts, in relation to two ingredients (Deer Velvet Antler Powder and Deer Velvet Antler Slice), which are incorporated as in force or existing from time to time (as permitted by subsection 26BB(8) of the Act) and are available for free from www.legislation.govt.nz/;
- the World Health Organization publication '*Expert consultation on oral rehydration salts formulation*', which is incorporated as at 18 July 2001 and which is available for free from www.rehydrate.org/ors/expert-consultation.html;
- the 'code tables' in 'TGA eBusiness Services', which are incorporated by reference as in force or existing from time to time (as permitted by subsection 26BB(8) of the Act) and may be accessed for free at www.ebs.tga.gov.au.

Other details

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

The Determination 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**.

This Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 12 June 2026.

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Attachment A

Details of the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026* (the Determination).

Section 2 – Commencement

This section provides that the Determination commences on 12 June 2026.

Section 3 – Authority

This section provides that the legislative authority for making the Determination is subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Interpretation

Subsection 4(1) provides definitions for a number of terms used in the Determination. These include 'code tables', 'excipient', 'homoeopathic preparation ingredient' and 'TGA eBusiness Services'.

The note to this section also makes it clear that a number of expressions used in the Determination have the same meaning as in the Act, including 'British Pharmacopoeia', 'European Pharmacopoeia' and 'United States Pharmacopeia-National Formulary'.

Subsection 4(2) provides that the terms set out in closed brackets in column 4 of the table in Schedule 1 to the Determination that are associated with warning statements in relation to particular ingredients, are terms from the code tables under the heading 'Product Warning', and are not required to be included on the label of the medicine.

Section 5 – Permissible ingredients

This section provides that the ingredients specified in column 2 of the table in Schedule 1 to the Determination are specified for the purposes of paragraph 26BB(1)(a) of the Act.

Section 6 – Requirements in relation to permissible ingredients being contained in medicine

This section provides that for an ingredient mentioned in column 2 of an item in the table in Schedule 1 to the Determination, the requirements in paragraphs 6(a) to (c) are specified for the purposes of paragraph 26BB(1)(b) of the Act. These include, for example, that the ingredient must only be used in a medicine for a purpose specified in relation to the ingredient in column 3 of that item and the ingredient must comply with the requirements specified in column 4.

Section 6A – Requirements relating to warning statements on labels

This section provides that where more than one ingredient in a medicine must comply with a requirement, specified in column 4 of the table in Schedule 1 in relation to the ingredient, for a liver toxicity-related warning statement on the medicine label in the form prescribed in paragraphs 6A(a) or (b), the warning statement may be stated only once on the label of the medicine provided that the requirements specified in paragraphs 6A(c) to (e) have been complied with.

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Section 7 – Repeals

This section provides that the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2026* is repealed.

Schedule 1 – Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine.

This Schedule specifies ingredients and related requirements for the purposes of sections 5, 6 and 6A of the Determination.

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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 (Permissible Ingredients) Determination (No. 2) 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 26BB(1) of the Act relevantly provides that the Minister may, by legislative instrument, make a determination specifying ingredients and, for some or all of those ingredients, requirements in relation to those ingredients being contained in a medicine. Under subsections 26BB(2), (2A) and (3) of the Act, such requirements may relate to particular ingredients not being contained in particular medicines or being contained in particular medicines only in specified circumstances or within permitted concentrations or total amounts of an ingredient in a medicine.

The purpose of a legislative instrument made under section 26BB of the Act is to specify those ingredients that may be contained in a medicine that is listed in the Australian Register of Therapeutic Goods (the Register) under section 26A or 26AE of the Act, and specify requirements in relation to the inclusion of those ingredients in such medicines. Listed medicines can only contain ingredients specified in an instrument under section 26BB of the Act.

The *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026* (the Determination) repeals and replaces the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2026* (the former Determination). The Determination specifies those ingredients that may be contained in a medicine that is listed in the Register under section 26A or 26AE of the Act, and requirements in relation to the inclusion of those ingredients in such medicines.

Background

Medicines that are listed in the Register under section 26A of the Act are considered to be low risk and are not individually evaluated before those medicines are listed. Medicines that are listed in the Register under section 26AE of the Act are also considered to be low risk, but are evaluated in relation to whether the efficacy of the medicine for the purposes for which it is to be used has been satisfactorily established (these purposes are specific efficacy claims for which the sponsor of the medicine holds supporting evidence). When listed under section 26AE, these listed medicines are commonly referred to as ‘assessed listed medicines’.

As the safety and quality of medicines listed under sections 26A and 26AE are not evaluated by the TGA before being listed in the Register, the Act contains mechanisms to help ensure that those medicines are of appropriate quality and able to be used safely by consumers. In particular, medicines listed under sections 26A and 26AE may only contain ingredients from an approved list of ingredients that have been evaluated in relation to their quality, safety and suitability for use in such medicines. Sponsors of such medicines may also only use indications (statements of therapeutic use) from a list of pre-approved, low-level indications to ensure that these medicines do not overstate their therapeutic benefits.

Under paragraphs 26A(2)(ca) and (cb) of the Act, persons applying to list a medicine in the Register under section 26A of the Act must certify that the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a) of the Act; and does not contravene a

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requirement in relation to such an ingredient that is specified in such a determination. Paragraphs 26AB(2)(d) and (e) contain equivalent certification requirements for applicants seeking marketing approval in relation to assessed listed medicines. A listed medicine or assessed listed medicine may be cancelled from the Register if it appears to the Secretary that such a certification is incorrect.

Separately, items 3, 4A, 5, 7 and 8 of Schedule 4 to the *Therapeutic Goods Regulations 1990* (the Regulations), which identifies those therapeutic goods that are eligible for listing in the Register, require that, in order for the goods mentioned in each of those items to be eligible for listing, the goods must only contain ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act, and must not contravene a requirement in such a determination.

Purpose

The Determination, made under section 26BB of the Act, provides a comprehensive list of ingredients which have been assessed or otherwise considered to be safe for use in listed medicines and assessed listed medicines, and associated requirements to be met when using particular ingredients in such medicines.

The requirements imposed by the Determination are principally designed to ensure or support the quality and safety of listed medicines that contain permitted ingredients. The requirements may relate, for example, to:

- how a permitted ingredient is to be used in the medicine, that is, as an active, homoeopathic or excipient ingredient;
- the intended method of ingestion or application of the medicine, for example, oral or topical use;
- the source of the ingredient, or procedures to be followed in its manufacture;
- appropriate limits on the volume or concentration of an ingredient; and
- the inclusion of relevant safety information on product labels, for example, allergen advice or advice about the use of medicine containing the ingredient for susceptible members of the population such as children and pregnant women.

The Determination incorporates the following changes to the former Determination:

Addition of new ingredients

- the addition of the following new ingredients for use in listed and assessed listed medicines, and specific requirements for the use of the ingredient in medicines:
    - *oxaceprol;* and
    - *Lactococcus lactis subsp. lactis.*

Changes to existing ingredients

- minor amendments to the following ingredient to reflect expiry of the transition period for requirements relating to that ingredient, as well as minor formatting changes for the purpose of improving the internal consistency of the Determination:
    - *Theanine.*

- correction of minor typographical errors and minor formatting changes for the following two ingredients for the purpose of improving the internal consistency of the Determination:
    - *Xanthium sibiricum;* and
    - *Xanthium strumarium.*

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Human rights implications

The Determination 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 instrument takes positive steps to promote the right to health by ensuring the safety and quality of therapeutic goods that are listed medicines. The Determination prescribes those ingredients that are considered to be safe for use in listed medicines. The Determination also sets out important requirements relating to the use of those ingredients in such medicines. Such requirements may relate, for example, to maximum concentrations of such ingredients in listed medicines, or to the inclusion of warning statements on medicine labels (such as 'Keep out of reach of children' for relevant ingredients).

Through the Determination, the safety of Australian consumers will be better protected, and they will be better able to make informed decisions about such medicines. This is particularly important for listed medicines, given that those medicines are not evaluated for safety and quality by the TGA prior to listing in the Register. Further, those medicines are usually available for self-selection by consumers without a requirement to first obtain the advice or prescription of a registered medical practitioner or the advice of a pharmacist.

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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