EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025

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 Australia Government Department of Health and Aged Care (the Department).

Subsection 26BF(1) of the Act relevantly provides that the Minister may, by legislative instrument, make a determination relating to indications and requirements relating to those indications. In making a determination under subsection 26BF(1) of the Act, the Minister may have regard to whether the indication is a therapeutic use that relates to one or more of the following matters listed in subsection 26BF(2) of the Act:

- maintaining health;
- enhancing health;
- preventing a dietary deficiency;
- a disease, ailment, defect or injury, other than a serious form of the disease, ailment defect of injury.

Subsection 26BF(3) of the Act provides that the matters set out in subsection 26BF(2), listed above, do not limit the matters to which the Minister may have regard in deciding whether to make a determination under subsection 26BF(1) in relation to a particular indication.

The *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025* (the Determination) repeals and replaces the *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021* (the former Determination) and specifies indications (statements of therapeutic use) that are permitted to be made in relation to medicines listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act. These medicines are, principally, listed complementary medicines and a small number of listed over the counter medicines, such as sunscreens. The Determination also specifies requirements regarding the use of such indications in relation to these medicines.

Background

Medicines that are listed in the Register under section 26A of the Act (listed medicines) are considered to be 'low risk' and are not individually evaluated before those medicines are entered in the Register. The application process requires applicants to certify, under subsection 26A(2) of the Act, that the medicine to which the application relates is eligible for listing and compliant with a number of important regulatory requirements. For example, that the medicine is safe for the purpose for which it is to be used and complies with all applicable standards.

As these listed medicines are not evaluated by the TGA prior to obtaining market approval to the general public, the Act contains certain regulatory mechanisms to help ensure that those medicines are manufactured to appropriate quality standards and able to be used by consumers safely. In particular, the medicines may only contain ingredients from a specified list of ingredients made by the Minster under section 26BB of the Act (set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2025*), and any indications, or therapeutic claims, for those medicines must be covered by a list of permissible indications made by the Minister under section 26BF of the Act. These 'pre-approved' low-level indications are set out in the Determination for this purpose and are

designed to ensure that claims of therapeutic use for medicines listed under section 26A do not overstate their respective therapeutic benefits.

The requirement of listed medicines to use indications covered by the Determination is designed to ensure transparency, to provide greater protection for consumers from misleading or inappropriate claims in relation to such goods, and to otherwise assist industry to use appropriate low-level indications for listed medicines.

An applicant for the listing of a medicine must certify a range of matters specified in section 26A of the Act. In particular, paragraphs 26A(2)(fba), (fd) and (fe) require an applicant to certify that the indications included in the medicine's entry in the Register, and on the label, are covered by a determination made under subsection 26BF(1), and that any relevant requirements specified in the determination have not been contravened.

If a person making an application for the listing of a medicine incorrectly certifies the matters required under subsection 26A(2) in relation to indications, the Secretary may cancel or suspend the medicine from the Register (paragraphs 30(1)(e) and 29D(1)(b) of the Act refer). Criminal and civil penalty provisions may apply if a person makes a false or misleading statement in, or in connection with, a certification of a matter under subsection 26A(2) of the Act, including in relation to permissible indications and related requirements (sections 21A and 21B of the Act refer).

Purpose

Permissible indications

The Determination specifies indications, for the purposes of paragraphs 26BF(1)(a) of the Act, that may be used in relation to listed medicines These indications have been determined to be sufficiently low-level and appropriate for such medicines.

The Determination also permits the use of a small number of indications that relate to the following:

- the link between vitamin D and calcium (referring to osteoporosis);
- the link between folic acid and neural tube defects;
- the use of broad-spectrum sunscreens with a sun protection factor of 30 or higher in relation to the prevention of skin cancer.

The inclusion of such indications in the Determination principally reflects the importance of these indications in relation to public health and their history of use.

It should also be noted that paragraph 5(b) of the Determination has the effect of allowing persons in whose names the medicines are included in the Register to modify a permissible indication, to align with the supporting evidence that person holds in relation to the medicine, by using qualifying statements set out under one of the following headings in the code tables document published by the TGA:

- traditional context qualifiers—which specify the traditional paradigm for medicines supported by evidence of traditional use, for example, 'Traditionally used in Western herbal medicine'. The traditional context is a mandatory qualifier for indications where the sponsor holds evidence of traditional use;
- population qualifiers—which specify the target population for a medicine, for example, 'In healthy individuals', 'In adults' or 'In females';
- time of use qualifiers—which indicate the time of the intended therapeutic benefit for a medicine, for example 'Maintain/support energy levels during the day'. or the time of occurrence of a symptom of a disease, ailment defect or injury, for example, 'Decrease/reduce/relieve muscle stiffness after exercise';

- Traditional Chinese Medicine (TCM) patter qualifiers—which are only available for traditional Chinese medicines, and specify the underlying 'pattern' causing symptoms of a condition or illness in the TCM paradigm, for example 'Spleen Qi Deficiency pattern'.

Requirements for indications

In addition to specifying permissible indications for listed medicines, the Determination also specifies requirements, for the purposes of paragraph 26BF(1)(b) of the Act, which persons must comply with when using the permissible indications for their listed medicines. These requirements principally relate to ensuring the safe and appropriate use of listed medicines and may, for example:

- specify the type of evidence that a sponsor must hold to support the use of an indication, such as scientific evidence or evidence of traditional use;
- specify a vulnerable population for which the indication is not suitable, such as children; or
- require a statement to accompany the use of an indication on the label of a medicine, for example, 'If symptoms persist talk to your health professional'.

Schedule 1 to the Determination contains tables in 17 Parts that set out, for the purposes of sections 5 and 6 of the Determination, the indications that may be used in relation to listed medicines, requirements relating to the type of evidence required to support the use of an indication, and the requirements relating to the use of that indication.

Relevantly, subsections 6(3) to 6(7) of the Determination set out a number of overarching requirements that are not replicated in the tables in Schedule 1. These include, for example, a requirement that if the wording of a permissible indication is varied on the label of a medicine, or combined with another permissible indication to form a simple sentence, then the meaning or intent of the indication must not be changed, and the varied or combined indication must not infer or imply that the medicine is indicated for the treatment of a serious form of a disease, ailment, defect, or injury. 'Serious' in this context is defined in section 4 of the Determination as having the same meaning as serious, in relation to a form of a disease, condition, ailment or defect in section 28 of the Therapeutic Goods Advertising Code.

Amendments

The Determination repeals and replaces the former Determination, and incorporates a number of changes in comparison to the former Determination, including in particular:

- incorporating the code tables, and the listed medicines evidence guidelines (titled *Supporting claims and indications for listed medicines*), as in force or existing from time to time in accordance with subsection 26BF(6) of the Act;
- refining the definition of health professional;
- introducing a note in section 5 to clarify that the population qualifiers do not include a qualifier for pregnant individuals and that there is a separate table in Schedule 1 that sets out the indications that can be used for pregnancy or pregnant populations (i.e. Part 17 in Schedule 1);
- correcting an error in item 3 of Table 13 in Schedule 1 to the former Determination, to replace the reference to "reducing urinary PH" to "increasing urinary pH";
- introducing a new requirement in section 6 of the Determination that supports a longstanding policy position that the only indications that are permitted to be used in relation to medicines that are sunscreen products are the indications specified in Part 16 of Schedule 1;
- introducing a new table in Part 17 of Schedule 1 setting out indications relating to pregnancy – the indications contained in this new table are existing indications that were previously specified in the table of indication relating to the reproductive system in the former Determination;

- introducing a new table in Part 16 in Schedule 1 specifying sunscreen indications – the indications contained in this new table are existing indications that were previously specified in the table of indications relating to skin in the former Determination; and
- making other minor editorial and typographical amendments and corrections.

The new requirement that the only indications that may be used in relation to listed sunscreen products are those indications that relate to sun protection, give effect to longstanding TGA policy. While sunscreens can include non-therapeutic claims (e.g. cosmetic or insect-repellent claims) on their label, it has been a long-standing policy of the TGA that if a sunscreen makes therapeutic claims other than indications related to sun protection, then the sunscreen is required to be registered on the Register and undergo a pre-market evaluation for safety, quality and efficacy.

A requirement in column 4 of table 12 in Schedule 1 to the former Determination stating that sunscreen-specific indications are 'for use in sunscreen products only' or 'can only be used for sunscreen products (with certain SPF ratings)' clearly provided that sunscreen-specific indications cannot be used for non-sunscreen products. However, the former Determination did not explicitly indicate that sunscreen products cannot use other indications that are not sunscreen-specific. The Determination clarifies this in new subsection 6(3).

The reasons that listed sunscreens can only use sunscreen-specific indications, and sunscreens with other therapeutic claims should be assessed by the TGA for safety, quality and efficacy, are as follows:

- Sunscreens are an important health measure in Australia and can refer to prevention of skin cancer, unlike any other listed medicine. Having other non-sunscreen indications (e.g. 'Reduces symptoms of nappy rash' or 'Improves hair growth') associated with a sunscreen product may dilute the important health message that these products should be used for the prevention of skin cancer.
- It is important that sunscreens are used according to the directions on the label and are applied in a way that makes the sunscreen most effective. Many people may apply sunscreen too sparingly, and not frequently enough, and consequently do not receive the benefits that sunscreens are designed to deliver. Having multiple indications on a sunscreen label may require multiple different directions for use, which may be confusing and lead to inappropriate use of the product for sun protection.
- In addition, different directions for use depending on the therapeutic purpose may have safety implications. An example may be a formulation that reduces the occurrence of eczema and is directed for localised topical use on broken skin, which directly conflicts with required label statements for sunscreens whereby they should not be applied to broken skin.
- Sunscreen active ingredients in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2025* were assessed for safety in the context of use in sunscreens. There may be unintended consequences when these ingredients are used for other purposes and at frequencies and doses different to sunscreen use that have not been considered as part of a safety assessment. For example, sunscreens with UV filters provide protection from exposure to the sun's radiation. Having indications other than sun protection will potentially lead to people applying UV filters to their skin when there is no risk of sun exposure (e.g. when they are indoors or at night). There may be unintended consequences from increased and unnecessary use of UV filters which have not been assessed for use in that context.

Incorporation by reference

Subsection 26BF(6) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* (the Legislation Act), a determination under this provision 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 following identifies and explains the documents that are incorporated by reference in the Determination, the intended manner of incorporation and where they may be obtained.

Code tables

The Determination incorporates by reference the code tables, which are published by the TGA and provide terminology for use in product applications and on medicine labels, where relevant. The code tables are incorporated as in force or existing from time to time, in accordance with subsection 26BF(6) of the Act. The code tables are freely available on the TGA website via the *Public TGA Information* menu in the TGA eBusiness Services at www.ebs.tga.gov.au.

Evidence guidelines

The Determination incorporates by reference the document titled *Supporting claims and indications for listed medicines* (the evidence guidelines). The evidence guidelines provide information regarding the type of evidence that is required to support indications for listed complementary medicines, and obligations in relation to holding such evidence. The evidence guidelines are incorporated as in force or existing from time to time, in accordance with subsection 26BF(6) of the Act, and may be accessed for free from the TGA website at www.tga.gov.au.

Therapeutic Goods Advertising Code

The Determination incorporates by reference the Therapeutic Goods Advertising Code. The Determination incorporates the meaning of 'serious' as that term is defined in section 28 of the Therapeutic Goods Advertising Code. The Therapeutic Goods Advertising Code is defined in subsection 3(1) of the Act as meaning the code in force under section 42BAA of the Act, which is currently the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*.

The Therapeutic Goods Advertising Code sets out a range of requirements relating to the advertising of therapeutic goods in Australia. The Determination incorporates the Therapeutic Goods Advertising as in force or existing from time to time, in accordance with paragraph 14(1)(a) of the *Legislation Act 2003*, and is available for free from the Federal Register of Legislation website at www.legislation.gov.au.

Consultation

Between 24 April 2023 and 31 May 2023, the TGA consulted publicly on the proposal to clarify indications that may be used in relation to sunscreen products. Nineteen responses were received from various stakeholders, including sponsors, manufacturers, regulatory agents, industry organisations, government organisations, health professionals, consumer groups and a not-for-profit organisation.

The majority of respondents supported the proposal to clarify that the only indications that may be used in relation to listed sunscreens are those indications specified in the Determination as being for sunscreen products only. Many respondents stated that the continuation of the policy position was important for maintaining the integrity of these products and the important role they have in health care in Australia, due to the high rates of skin cancer in Australia.

However, a small group of respondents, including sponsors and regulatory agents, supported options allowing sunscreen to make non-sunscreen related indications and claims, as they believed these options would foster innovation and provide marketing advantages for sunscreen sponsors to differentiate their products. The views of these respondents was considered carefully in determining the appropriate option. However, the TGA considers that these benefits associated with allowing sunscreen products to make non-sunscreen related claims are outweighed by the safety concerns that

are addressed by clarifying that the only indications that may be used in relation to listed sunscreens are those indications specified in the Determination.

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**.

The OIA have advised that a detailed analysis is not required as the impacts of the proposed changes do not represent a significant difference from the status quo. Therefore, the preparation of an Impact Analysis is not required (OIA reference OIA25-09171).

The Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*,and commences on the day after it is registered on the Federal Register of Legislation.

ATTACHMENT A

Details of the *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025* (the Determination).

Section 2 – Commencement

This section provides that the Determination commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

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

Section 4 – Definitions

This section provides definitions for key terms used in the Determination, including for example, 'code tables', 'evidence guidelines', 'health professional' and 'medically diagnosed'.

This section also notes that a number of terms used in the Determination have the meaning given in subsection 3(1) of the Act, including for example, 'health practitioner', 'indications', 'label' and 'presentation'.

Section 5 – Permissible indications

Section 5 of the Determination provides for permitted indication for the purposes of paragraph 26BF(1)(a) of the Act.

In particular, paragraph 5(a) provides that each indication specified in column 2 of the tables in Parts 1 to 17 of Schedule 1 to the Determination is covered by the Determination for the purposes of paragraph 26BF(1)(a) of the Act.

Paragraph 5(b) provides that each indication specified in column 2 of the tables in Parts 1 to 17 of Schedule 1 to the Determination when modified using one or more qualifying statements set out in the code tables under the headings specified in subparagraphs 5(b)(i) to (iv).

The note to section 5 clarifies that the population qualifiers in the code tables do not include pregnant individuals and there is a separate table in Part 17 of Schedule 1 with indications relating to pregnancy or pregnant populations.

Section 6 – Requirements in relation to permissible indications

Section 6 specifies requirements in relation to an indication covered by the Determination for the purposes of paragraph 26BF(1)(b) of the Act.

Subsection 6(2) provides that each indication specified in column 2 of a table in Parts 1 to 17 of Schedule 1, may only be used for a medicine if the indication is supported by evidence of the type specified in column 3, and that the requirements specified in column 4 (if any) are met, in relation to the relevant indication.

Subsection 6(3) provides that in relation to a medicine that is a sunscreen product, the only indications that may be used in relation to the product are the indications specified in column 2 of an item in the table in Part 16 of Schedule 1, which relate to sunscreens.

The note to subsection 6(3) makes it clear that for medicines that are sunscreen products, the requirements specified in subsection 6(3) apply in addition to the requirements specified in subsection 6(2).

Subsection 6(4) of the Determination provides that if the wording of an indication is varied on the label of a medicine, then the indication as varied must not change the meaning or intent of the indication, infer or imply that the medicine is for the treatment of a serious form of a disease, ailment, defect or injury, or infer or imply that the medicines is for preventing or curing a disease, ailment, defect or injury.

Subsection 6(5) of the Determination provides that if 2 or more indications are combined on the label of the medicine to form simple sentences, then the indication as combined must not change the meaning or intent of each indication, infer or imply that the medicine is for the treatment of a serious form of a disease, ailment, defect or injury, or infer or imply that the medicines is for preventing or curing a disease, ailment, defect or injury.

Subsection 6(6) of the Determination provides that indications specified in column 2 of the table in Part 17 of Schedule 1, which relate to pregnancy, must not be combined on the label of the medicine to form a simple sentence with an indication specified in column 2 of the tables in Parts 1 to 16 of Schedule 1.

The note to subsection 6(6) makes it clear that while indications specified in column 2 of an item in a table in Part 17 of Schedule must not be combined on the label with an indication specified in column 2 of an item in a table in Parts 1 to 16 of Schedule 1 to form a simple sentence, these indications may be listed separately on the label of a medicine.

Subsection 6(7) of the Determination provides that if an indication is modified by one or more qualifying statements in accordance with paragraph 6(5)(b), whether or not the indication is varied or combined in accordance with subsection 6(4) or (5), then each qualifying statement must be set out on the label of the medicine, and the indication as modified or combined must not infer or imply that the medicine is for the treatment of a serious form of a disease, ailment, defect or injury.

Subsection 6(8) of the Determination provides that if an indication in relation to a medicine is supported by traditional evidence, the indication must be qualified with an appropriate traditional context qualifier, as set out in the code tables, and that qualifier must be included on the label of the medicine.

Section 7 – Repeals

This section provides that each instrument that is specified in Schedule 2 to the Determination is repealed as set out in the applicable items in that Schedule.

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

Schedule 1 specifies indications and related requirements for the purposes of sections 5 and 6 of the Determination, and consists of the following 17 Parts:

- Part 1 specifies indications relating to general health or body parts;
- Part 2 specifies indications relating to bone;
- Part 3 specifies indications relating to the cardiovascular system;

- Part 4 specifies indications relating to endocrine system;
- Part 5 specifies indications relating to the gastrointestinal system;
- Part 6 specifies indications relating to the immune system;
- Part 7 specifies indications relating to muscles;
- Part 8 specifies indications relating to the nervous system;
- Part 9 specifies indications relating to nutrition;
- Part 10 specifies indications relating to the reproductive system;
- Part 11 specifies indications relating to the respiratory system;
- Part 12 specifies indications relating to skin;
- Part 13 specifies indications relating to the urinary system;
- Part 14 specifies traditional Chinese medicine indications;
- Part 15 specifies traditional Ayurvedic medicine indications;
- Part 16 specifies sunscreen indications;
- Part 17 specifies indications relating to pregnancy;

Schedule 2 - Repeals

Schedule 2 provides that the Determination repeals the *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021*.

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 Indications) Determination (No. 1) 2025

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 26BF(1) of the Act relevantly provides that the Minister may, by legislative instrument, make a determination relating to indications and requirements relating to those indications. In making a determination under subsection 26BF(1) of the Act, the Minister may have regard to whether the indication is a therapeutic use that relates to one or more of the following matters listed in subsection 26BF(2) of the Act:

- maintaining health;
- enhancing health;
- preventing a dietary deficiency;
- a disease, ailment, defect or injury, other than a serious form of the disease, ailment defect of injury.

Subsection 26BF(3) of the Act provides that the matters set out in subsection 26BF(2), listed above, do not limit the matters to which the Minister may have regard in deciding whether to make a determination under subsection 26BF(1) in relation to a particular indication.

The *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025* (the Determination) repeals and replaces the *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021* (the former Determination) and specifies indications (statements of therapeutic use) that are permitted to be made in relation to medicines listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act. These medicines are, principally, listed complementary medicines and a small number of listed over the counter medicines, such as sunscreens. The Determination also specifies requirements regarding the use of such indications in relation to these medicines.

Medicines that are listed in the Register under section 26A of the Act (listed medicines) are considered to be 'low risk' and are not individually evaluated before those medicines are entered in the Register. The application process requires applicants to certify, under subsection 26A(2) of the Act, that the medicine to which the application relates is eligible for listing and compliant with a number of important regulatory requirements. For example, that the medicine is safe for the purpose for which it is to be used and complies with all applicable standards.

As these listed medicines are not evaluated by the TGA prior to obtaining market approval to the general public, the Act contains certain regulatory mechanisms to help ensure that those medicines are manufactured to appropriate quality standards and able to be used by consumers safely. In particular, the medicines may only contain ingredients from a specified list of ingredients made by the Minster under section 26BB of the Act (set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2025*), and any indications, or therapeutic claims, for those medicines must be covered by a list of permissible indications made by the Minister under section 26BF of the Act. These 'pre-approved' low-level indications are set out in the Determination for this purpose and are designed to ensure that claims of therapeutic use for medicines listed under section 26A do not overstate their respective therapeutic benefits.

The requirement of listed medicines to use indications covered by the Determination is designed to ensure transparency, to provide greater protection for consumers from misleading or inappropriate claims in relation to such goods, and to otherwise assist industry to use appropriate low-level indications for listed medicines.

An applicant for the listing of a medicine must certify a range of matters specified in section 26A of the Act. In particular, paragraphs 26A(2)(fba), (fd) and (fe) require an applicant to certify that the indications included in the medicine's entry in the Register, and on the label, are covered by a determination made under subsection 26BF(1), and that any relevant requirements specified in the determination have not been contravened.

If a person making an application for the listing of a medicine incorrectly certifies the matters required under subsection 26A(2) in relation to indications, the Secretary may cancel or suspend the medicine from the Register (paragraphs 30(1)(e) and 29D(1)(b) of the Act refer). Criminal and civil penalty provisions may apply if a person makes a false or misleading statement in, or in connection with, a certification of a matter under subsection 26A(2) of the Act, including in relation to permissible indications and related requirements (sections 21A and 21B of the Act refer).

Permissible indications

The Determination specifies indications, for the purposes of paragraphs 26BF(1)(a) of the Act, that may be used in relation to listed medicines These indications have been determined to be sufficiently low-level and appropriate for such medicines.

The Determination also permits the use of a small number of indications that relate to the following:

- the link between vitamin D and calcium (referring to osteoporosis);
- the link between folic acid and neural tube defects;
- the use of broad-spectrum sunscreens with a sun protection factor of 30 or higher in relation to the prevention of skin cancer.

The inclusion of such indications in the Determination principally reflects the importance of these indications in relation to public health and their history of use.

It should also be noted that paragraph 5(b) of the Determination has the effect of allowing persons in whose names the medicines are included in the Register to modify a permissible indication, to align with the supporting evidence that person holds in relation to the medicine, by using qualifying statements set out under one of the following headings in the code tables document published by the TGA:

- traditional context qualifiers—which specify the traditional paradigm for medicines supported by evidence of traditional use, for example, 'Traditionally used in Western herbal medicine'. The traditional context is a mandatory qualifier for indications where the sponsor holds evidence of traditional use;
- population qualifiers—which specify the target population for a medicine, for example, 'In healthy individuals', 'In adults' or 'In females';
- time of use qualifiers—which indicate the time of the intended therapeutic benefit for a medicine, for example 'Maintain/support energy levels during the day'. or the time of occurrence of a symptom of a disease, ailment defect or injury, for example, 'Decrease/reduce/relieve muscle stiffness after exercise';
- Traditional Chinese Medicine (TCM) patter qualifiers—which are only available for traditional Chinese medicines, and specify the underlying 'pattern' causing symptoms of a condition or illness in the TCM paradigm, for example 'Spleen Qi Deficiency pattern'.

Requirements for indications

In addition to specifying permissible indications for listed medicines, the Determination also specifies requirements, for the purposes of paragraph 26BF(1)(b) of the Act, which persons must comply with when using the permissible indications for their listed medicines. These requirements principally relate to ensuring the safe and appropriate use of listed medicines and may, for example:

- specify the type of evidence that a sponsor must hold to support the use of an indication, such as scientific evidence or evidence of traditional use;
- specify a vulnerable population for which the indication is not suitable, such as children; or
- require a statement to accompany the use of an indication on the label of a medicine, for example, 'If symptoms persist talk to your health professional'.

Schedule 1 to the Determination contains tables in 17 Parts that set out, for the purposes of sections 5 and 6 of the Determination, the indications that may be used in relation to listed medicines, requirements relating to the type of evidence required to support the use of an indication, and the requirements relating to the use of that indication.

Relevantly, subsections 6(3) to 6(7) of the Determination set out a number of overarching requirements that are not replicated in the tables in Schedule 1. These include, for example, a requirement that if the wording of a permissible indication is varied on the label of a medicine, or combined with another permissible indication to form a simple sentence, then the meaning or intent of the indication must not be changed, and the varied or combined indication must not infer or imply that the medicine is indicated for the treatment of a serious form of a disease, ailment, defect, or injury. 'Serious' in this context is defined in section 4 of the Determination as having the same meaning as serious, in relation to a form of a disease, condition, ailment or defect in section 28 of the Therapeutic Goods Advertising Code.

Amendments

The Determination repeals and replaces the former Determination, and incorporates a number of changes in comparison to the former Determination, including in particular:

- incorporating the code tables, and the listed medicines evidence guidelines (titled *Supporting claims and indications for listed medicines*), as in force or existing from time to time in accordance with subsection 26BF(6) of the Act;
- refining the definition of health professional;
- introducing a note in section 5 to clarify that the population qualifiers do not include a qualifier for pregnant individuals and that there is a separate table in Schedule 1 that sets out the indications that can be used for pregnancy or pregnant populations (i.e. Part 17 in Schedule 1);
- correcting an error in item 3 of Table 13 in Schedule 1 to the former Determination, to replace the reference to "reducing urinary PH" to "increasing urinary pH";
- introducing a new requirement in section 6 of the Determination that supports a longstanding policy position that the only indications that are permitted to be used in relation to medicines that are sunscreen products are the indications specified in Part 16 of Schedule 1;
- introducing a new table in Part 17 of Schedule 1 setting out indications relating to pregnancy – the indications contained in this new table are existing indications that were previously specified in the table of indication relating to the reproductive system in the former Determination;
- introducing a new table in Part 16 in Schedule 1 specifying sunscreen indications – the indications contained in this new table are existing indications that were previously specified in the table of indications relating to skin in the former Determination; and
- making other minor editorial and typographical amendments and corrections.

The new requirement that the only indications that may be used in relation to listed sunscreen products are those indications that relate to sun protection, give effect to longstanding TGA policy. While sunscreens can include non-therapeutic claims (e.g. cosmetic or insect-repellent claims) on their label, it has been a long-standing policy of the TGA that if a sunscreen makes therapeutic claims other than indications related to sun protection, then the sunscreen is required to be registered on the Register and undergo a pre-market evaluation for safety, quality and efficacy.

A requirement in column 4 of table 12 in Schedule 1 to the former Determination stating that sunscreen-specific indications are 'for use in sunscreen products only' or 'can only be used for sunscreen products (with certain SPF ratings)' clearly provided that sunscreen-specific indications cannot be used for non-sunscreen products. However, the former Determination did not explicitly indicate that sunscreen products cannot use other indications that are not sunscreen-specific. The Determination clarifies this in new subsection 6(3).

The reasons that listed sunscreens can only use sunscreen-specific indications, and sunscreens with other therapeutic claims should be assessed by the TGA for safety, quality and efficacy, are as follows:

- Sunscreens are an important health measure in Australia and can refer to prevention of skin cancer, unlike any other listed medicine. Having other non-sunscreen indications (e.g. 'Reduces symptoms of nappy rash' or 'Improves hair growth') associated with a sunscreen product may dilute the important health message that these products should be used for the prevention of skin cancer.
- It is important that sunscreens are used according to the directions on the label and are applied in a way that makes the sunscreen most effective. Many people may apply sunscreen too sparingly, and not frequently enough, and consequently do not receive the benefits that sunscreens are designed to deliver. Having multiple indications on a sunscreen label may require multiple different directions for use, which may be confusing and lead to inappropriate use of the product for sun protection.
- In addition, different directions for use depending on the therapeutic purpose may have safety implications. An example may be a formulation that reduces the occurrence of eczema and is directed for localised topical use on broken skin, which directly conflicts with required label statements for sunscreens whereby they should not be applied to broken skin.
- Sunscreen active ingredients in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2025* were assessed for safety in the context of use in sunscreens. There may be unintended consequences when these ingredients are used for other purposes and at frequencies and doses different to sunscreen use that have not been considered as part of a safety assessment. For example, sunscreens with UV filters provide protection from exposure to the sun's radiation. Having indications other than sun protection will potentially lead to people applying UV filters to their skin when there is no risk of sun exposure (e.g. when they are indoors or at night). There may be unintended consequences from increased and unnecessary use of UV filters which have not been assessed for use in that context.

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.

Specifying permissible indications that are considered to be safe for use in relation to listed medicines, together with important requirements relating to the use of those indications for such medicines, will enable Australian consumers to be better protected from the making of inappropriate claims about the benefits of listed medicines and also more aware of important safety information relating to the use of such products. Consumers will also be better able to make more informed decisions about such medicines as a result of these measures.

Additionally, introducing a requirement that the only indications that may be used in relation to listed sunscreen products are those indications that relate to sun protection, ensures that consumers clearly receive important health messaging about the use of such products for the prevention of skin cancer. Further, it minimises risks of consumer confusion about the appropriate way to use the product for sun protection.

Conclusion

The Determination is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.