

## **EXPLANATORY STATEMENT**

### ***Therapeutic Goods Act 1989***

#### ***Therapeutic Goods (Permissible Indications) Determination (No.1) 2019***

### **OUTLINE**

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

The *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2019* (the Determination) is a determination made by a delegate of the Minister for Health under subsection 26BF(1) of the Act. The purpose of the Determination is to specify indications (these are statements of therapeutic use) that sponsors of medicines that are listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act (principally, these are listed complementary medicines and a small number of listed over the counter medicines, such as sunscreens) may use in relation to their products, and requirements regarding the use of such indications for such products. When applying to list their products in the Register, sponsors of these medicines may select an indication that is specified in the Determination, and may not use an indication which the Determination does not cover.

The Determination also repeals the *Therapeutic Goods (Permissible Indications) Determination No. 1 2018* (the First Determination).

The Determination commences the day after registration.

### **BACKGROUND**

#### **Listed medicines**

Medicines that are listed in the Register under section 26A of the Act (listed medicines) are considered ‘low risk’ and are not individually evaluated before they are entered in the Register. The application process requires sponsors of listed medicines to certify, under subsection 26A(2) of the Act, that their medicine is eligible for listing and is compliant with a number of important regulatory requirements (e.g. 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 before they are given marketing approval, the Act contains mechanisms to help ensure that they are of high quality and able to be used safely by consumers. In particular, they may only contain ingredients from an approved list (set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No.4) 2018*), and sponsors may only use indications for (and make claims in relation to) these medicines that are selected from a list of pre-approved low level indications to ensure that the products do not overstate their respective therapeutic benefits. These pre-approved

indications are set out in the *Therapeutic Goods (Permissible Indications) Determination No.1 2018*.

### **The Determination**

The Determination is made by the Minister and specifies both indications and requirements relating to the use of those indications, for the purposes of paragraphs 26BF(1)(a) and (b) of the Act. The Determination sets out a list of pre-approved indications which have been assessed and determined to be low level and appropriate for listed medicines. The related requirements are designed to support the safe use of medicines for which these indications are to be used.

If a person incorrectly certifies these matters, the Secretary may cancel or suspend their 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).

The requirement for listed medicines to only use indications included in the Determination is designed to ensure transparency and to provide greater protection for consumers from misleading or inappropriate claims in relation to these products, and to assist the industry to avoid the inadvertent use of non-compliant indications.

### **Permissible 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; and
- a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury.

The Determination also authorises the use of a small number of indications that extend beyond the principal matters identified above. These indications relate to the following:

- the link between vitamin D and calcium (referring to osteoporosis);
- the link between folic acid and neural tube defects; and
- 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, their safe history of use and the existence of a well-established evidence base in support of such messages.

In relation to the authority for including such indications in the Determination, subsection 26BF(3) of the Act makes it clear that the list of matters set out in subsection 26BF(2) (outlined above) does 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.

It should also be noted that subsection 5(2) of the Determination has the effect of allowing sponsors to modify a selected permissible indication, to align with the supporting evidence they hold for their medicine, by using qualifying statements contained in the TGA Code Tables document (as at the commencement of the Determination). Subsection 5(2) of the Determination has this effect by specifying as permissible indications – for the purposes of paragraph 26BF(1)(a) of the Act - indications set out in the tables in Schedule 1 to the Determination as modified by a selected qualifying statement from the Code Tables. Four types of qualifying statements are available for selection in this regard:

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

### **Requirements in relation to permissible indications**

In addition to specifying permissible indications for listed medicines, the Determination also specifies requirements that sponsors must comply with when using the permissible indications for their 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 evidence of traditional use or scientific evidence;
- specify a vulnerable population for which the indication is not suitable, such as children; or
- require an advisory statement to accompany the use of an indication on a medicine’s label, e.g. ‘*If symptoms persist consult your healthcare practitioner*’ (or words to that effect).

The Determination includes Tables 1 to 15 at Schedule 1 which list the following:

- indications that can be used in relation to listed medicines;
- requirements relating to the type of evidence required to support the use of an indication; and
- a range of other requirements relating to the use of a permissible indication.

The Determination also sets out a number of overarching requirements between subsections 5(3)(c) and 5(3) (e) that are not replicated in the Tables.

These include, for example, an overarching 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, the meaning of the indication must not be changed and the varied or combined indications must not infer or imply that the medicine is for the treatment of a serious disease, ailment, defect or injury.

‘Serious’ in this context is defined in section 4 of the Determination as having the same meaning as in the Therapeutic Goods Advertising Code (the Code). Section 4 of the Determination makes it clear that the Code has the same meaning as in subsection 3(1) of the Act, which defines the Code as the code in force under section 42BAA of the Act. Currently this is the *Therapeutic Goods Advertising Code (No.2) 2018*, and subsection 28(1) of that Code explains when a form of a disease, ailment or defect is a serious form.

The Determination also repeals and replaces the First Determination. The Determination includes a number of changes compared to the First Determination – including in particular:

- the addition of 15 new indications determined to be suitable for use by listed medicines along with the associated requirements relating to their use for these products;
- the removal of 7 indications:
  - three traditional Ayurvedic indications for ‘Medohara’, ‘Meha hara’ and ‘Pandu hara’ that are not appropriate to be supported by evidence of traditional use as they refer to biomarkers (lipids, blood sugar and iron) which require validation with scientific data;
  - two TCM indications referring to ‘stabilise mind’ and ‘open body orifices’ that could be used to refer to the treatment of a serious disease in the TCM paradigm and as such are not appropriate for use in listed medicines; and
  - two TCM indications that are duplicates of other indications that are already included in the Determination;
- changes in the wording to a number of requirements relating to labelling that refer to seeking the advice of a health professional. The change in wording is designed to better align those requirements with the terminology used in the Code, for clarity and greater consistency (without amending the overall intent or meaning of the original requirements);
- changes to a number of requirements relating to labelling for listed medicines with TCM and Ayurvedic indications, to recommend that consumers seek professional advice from a TCM or Ayurvedic medicine practitioner if they don’t understand the specific terminology used in these paradigms. The amended requirements do not change the intent or meaning of the requirements for these products in the First Determination, but are designed to provide greater flexibility for sponsors when these indications are used in a multi-paradigm medicine, such as when a TCM indication is used with a Western herbal medicine indication;
- a change to the wording of the indication ‘*Helps reduce occurrence of symptoms of food intolerance/allergies*’ to remove reference to ‘*food allergies*’, to reflect that food allergies may present as a serious disease or condition and are inappropriate for listed

medicines. This indication can still be used in listed medicines to refer to food intolerance;

- addition of a required label statement ‘Adults only’ OR ‘Not to be used in children under 2 years of age without medical advice’ to indications referring to cold and flu. Following a TGA safety review of these types of products in 2012, listed medicines making cold and flu indications (and products containing certain ingredients) were required to include a warning statement for children on their product labels. Consistent with many of the requirements for listing at that time (e.g. restrictions on the use of ingredients), this requirement was imposed administratively through the Electronic Listing Facility. The required label statement will provide clarity for sponsors and support the safe use of medicines for which these indications are to be used;
- a number of minor corrections and clarifications, e.g. to better reflect international nomenclature in TCM indications, set out a number of indications more clearly, and to explain when requirements relating to labelling will apply for indications relating to weight loss.

## CONSULTATION

Between March and December 2018 the TGA has engaged in ongoing communication with stakeholders who have raised issues that sponsors have encountered when selecting indications for their listed medicines. These communications were conducted via face-to-face meetings, teleconferences and written correspondence with individual sponsors and key industry associations Complementary Medicines Australia (CMA), Australian Self Medication Industry (ASMI) and Accord.

Separately, the TGA also engaged a member of the Advisory Committee on Complementary Medicines who is a TCM expert to review the TCM indications included in the First Determination to ensure that they were appropriate for use in relation to listed medicines.

During these discussions, ASMI and CMA requested clarification on the status of required label advisory statements for children in relation to cold and flu indications. The industry associations requested that this issue be clarified as soon as possible, as sponsors are in the process of transitioning their products to select specific indications from the Determination and updating their product labels to comply with Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.

Based on this stakeholder and subject matter expert feedback, the Determination was developed to introduce the changes outlined above, including to correct a number of errors identified in the First Determination, provide greater clarity for a number of entries and to ensure that the list of permissible indications and related requirements is as comprehensive as possible and consistent with the low risk nature of the listed medicines to which it applies under the Act.

The Determination reflects this stakeholder and subject matter expert feedback, including for example the introduction of 15 new indications for use in relation to listed medicines, the removal of duplicate requirements for sunscreens and the correction and clarification of wording number of indications and related requirements. Stakeholders were generally supportive of the changes represented in the Determination.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

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, and commences the day after registration.

**Details of *Therapeutic Goods (Permissible Indications) Determination (No.1) 2019***

**Section 1 Name**

This section provides that the name of the Determination is the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2019*

**Section 2 Commencement**

This section provides that this Determination commences the day after registration.

**Section 3 Authority**

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

**Section 4 Definitions**

This section provides definitions for a number of terms used in the Determination including for example Code Tables, medical practitioner and a traditional Chinese medicine indication. This section also highlights that a number of terms used in the Determination have the meaning given to them in subsection 3(1) of the Act, e.g. ‘indications’, ‘label’ and ‘medicine’.

**Section 5 Permissible indications and requirements applying in relation to those indications**

This section provides that the indications set out in column 2 of Tables 1 to 15 of Schedule 1 to the Determination are specified for the purposes of paragraph 26BF(1)(a) of the Act. This section also specifies for that purpose the indications in column 2 of Tables 1 to 15 in Schedule 1 to the Determination when modified using the qualifying statements in the Code Tables under the headings referred to in paragraphs 5(2)(a) – (d).

Subsection 5(3) provides that, for the purposes of paragraph 26BF(1)(b) of the Act, the indications specified under subsections 5(1) and (2) are subject to the requirements set out in paragraphs 5(3)(a) – (e) of the Determination including, for example, that where traditional indications are used for a medicine the traditional indication must be qualified with an appropriate “Traditional context qualifier” from the Code Tables, and that this qualifier must be included on the label of the medicine.

**Section 6 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**

Schedule 1 sets out indications and related requirements for the purposes of section 5 of the Determination.

**Schedule 2**

Schedule 2 provides that the Determination repeals the whole of the legislative instrument *Therapeutic Goods (Permissible Indications) Determination No.1 of 2018*.



**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) 2019**

This 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**

The *Therapeutic Goods (Permissible Indications) Determination (No.1) 2019* is a determination made by the Minister under subsection 26BF (1) of the Act. The effect of the Determination is to specify indications that sponsors of medicines that are listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act (listed medicines) (these are principally listed complementary medicines and listed over the counter medicines such as sunscreens) may use in relation to their products, and requirements in relation to the use of such indications. When applying to list their products in the Register, sponsors of these medicines may select an indication that is specified in the Determination, and may not use an indication which the Determination does not cover.

Medicines that are listed in the Register under section 26A of the Act (listed medicines) are considered ‘low risk’ and are not individually evaluated before they are entered in the Register. The application process requires sponsors of listed medicines to certify, under subsection 26A(2) of the Act, that their medicine is eligible for listing and is compliant with a number of important regulatory requirements (e.g. 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 before they are given marketing approval, the Act contains mechanisms to help ensure that they are of high quality and able to be used safely by consumers. In particular, they may only contain ingredients from an approved list (set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No.4) 2018*), and sponsors may only use indications for (and make claims in relation to) these medicines that are selected from a list of pre-approved low level indications to ensure that the products do not overstate their respective therapeutic benefits. These pre-approved indications are set out in the Determination.

**The Determination**

The Determination is made by the Minister and specifies both indications and requirements relating to the use of those indications, for the purposes of paragraphs 26BF(1)(a) and (b) of the Act. The Determination sets out a list of pre-approved indications which have been assessed and determined to be low level and appropriate for listed medicines. The related requirements are designed to support the safe use of medicines for which these indications are to be used.

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In relation to the authority for including such indications in the Determination, subsection 26BF(3) of the Act makes it clear that the list of matters set out in subsection 26BF(2) (outlined above) does 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.

It should also be noted that subsection 5(2) of the Determination has the effect of allowing sponsors to modify a selected permissible indication, to align with the supporting evidence they hold for their medicine, by using qualifying statements contained in the TGA Code Tables document (as at the commencement of the Determination). Subsection 5(2) of the Determination has this effect by specifying as permissible indications – for the purposes of paragraph 26BF(1)(a) of the Act - indications set out in the tables in Schedule 1 to the Determination as modified by a selected qualifying statement from the Code Tables. Four types of qualifying statements are available for selection in this regard:

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- ‘Population qualifiers’ - which specify the target population for a medicine, e.g. ‘*in healthy individuals*’, ‘*in adults*’ or ‘*in females*’; and
- ‘Time of use qualifiers’ - which indicate the time of the intended therapeutic benefit for a medicine, e.g. ‘*Maintain/support energy levels during the day*’, or the time of occurrence of a symptom of a disease, ailment, defect or injury e.g. ‘*Decrease/reduce/relieve muscle stiffness after exercise*’.

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In addition to specifying permissible indications for listed medicines, the Determination also specifies requirements that sponsors must comply with when using the permissible indications for their medicines. These requirements principally relate to ensuring the safe and appropriate use of listed medicines and may for example:

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- require an advisory statement to accompany the use of an indication on a medicine’s label, e.g. ‘*If symptoms persist consult your healthcare practitioner*’ (or words to that effect).

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  - three traditional Ayurvedic indications for ‘Medohara’, ‘Meha hara’ and ‘Pandu hara’ that are not appropriate to be supported by evidence of traditional use as they refer to biomarkers (lipids, blood sugar and iron) which require validation with scientific data;
  - two TCM indications referring to ‘stabilise mind’ and ‘open body orifices’ that could be used to refer to the treatment of a serious disease in the TCM paradigm and as such are not appropriate for use in listed medicines; and
  - two TCM indications that are duplicates of other indications that are already included in the Determination.
- changes to a number of requirements relating to labelling that refer to seeking the advice of a health professional. The change in wording is designed to better align those requirements with the terminology used in the Code, for clarity and greater consistency (without amending the overall intent or meaning of the original requirements);
- changes to a number of requirements relating to labelling for listed medicines with TCM and Ayurvedic indications, to recommend that consumers seek professional advice from a TCM or Ayurvedic medicine practitioner if they don’t understand the specific terminology used in these paradigms. The amended requirements do not change the intent or meaning of the requirements for these products in the First Determination, but are designed to provide greater flexibility for sponsors when these indications are used in a multi-paradigm medicine, such as when a TCM indication is used with a Western herbal medicine indication;
- a change to the wording of the indication ‘*Helps reduce occurrence of symptoms of food intolerance/allergies*’ to remove reference to ‘*food allergies*’, to reflect that food allergies may present as a serious disease or condition and are inappropriate for listed medicines. This indication can still be used to refer to food intolerances.

### **Human rights implications**

The Determination takes positive steps to promote the right to health in article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). This right is understood as the right of everyone 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.

Identifying those indications that are considered to be safe for use in relation to listed medicines, and setting out 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 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.

For example, some of the requirements in the Determination relate to the inclusion of advisory statements on the label of a listed medicine to highlight important information about the medicine for consumers – e.g. for the indication “Aid/assist in the healing of minor body tissue injuries”, the label statement “If symptoms persist, seek the advice of a healthcare professional” is required.

These benefits are particularly important in relation to listed medicines, as these medicines are usually available for self-selection by consumers, without a requirement to first obtain the advice or prescription of a registered medical doctor, or the advice of a pharmacist.

### **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.

**Cheryl McRae, delegate of the Minister for Health**