EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Permissible Indications) Determination (No. 2) 2019

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 Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health.

The *Therapeutic Goods (Permissible Indications) Determination (No. 2) 2019* ("the Determination") is a determination made by a delegate of the Minister for Health under section 26BF of the Act. The purpose of the Determination is to specify 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.

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.

The Determination also repeals and replaces the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2019* ("the Former Determination").

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 marketing 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 (currently set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2019*)), and any indications (or therapeutic claims) for those medicines are covered by a list of permissible indications made under section 26BF of the Act. These "pre-approved" low-level indications are set out in the Determination and are designed to ensure that medicines listed under section 26A do not overstate their respective therapeutic benefits.

The Determination 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. As mentioned above, the Determination enumerates permissible indications, which have been determined to be sufficiently 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 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).

The requirement for 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.

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: (a) maintaining health; (b) enhancing health; (c) preventing a dietary deficiency; and (d) 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 and their history of sfe use.

In relation to the authority for including these 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 paragraph 5(b) of the Determination has the effect of allowing persons in whose names 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 contained in the code tables document published by the TGA (as at the commencement of the Determination). Paragraph 5(b) 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 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’); and
- 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’.

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 a medicine's label (for example, 'If symptoms persist consult your healthcare practitioner').

Schedule 1 to the Determination sets out Tables 1 to 15, 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 (sections 5 and 6 of the Determination refer).

Subsections 6(3) to 6(6) of the Determination also set out a number of overarching requirements 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, then the meaning or intent of the indication must not be changed, and the varied or combined indications 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 ("the Code"). The note in section 4 of the Determination makes it clear that 'Therapeutic Goods Advertising Code' has the same meaning as in subsection 3(1) of the Act, which defines that term as the code in force under section 42BAA of the Act. Currently, this is the *Therapeutic Goods Advertising Code (No.2) 2018*.

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

- the addition of the following eight new indications with associated requirements relating to the use of those indications:
  - decrease/reduce/relieve urinary urgency associated with medically diagnosed overactive bladder;
  - decrease/reduce/relieve urinary incontinence associated with medically diagnosed overactive bladder;
  - decrease/reduce duration of symptoms of haemorrhoids;
  - maintains/supports refreshing sleep;
  - helps reduce occurrence of mild migraines;
  - helps reduce the occurrence of sore throat;
  - helps reduce carbohydrate metabolism; and
  - helps reduce the occurrence of symptoms of medically-diagnosed gluten-sensitivity caused by inadvertent gluten ingestion.
- expansion of the evidence requirement from 'traditional' to 'traditional or scientific evidence' for the following indication:
  - hepatoprotectant/protect the liver;
- the addition of the word 'helps' to the following indications to ensure consistency with other similar indications:
  - helps maintain/support joint cartilage health;
  - helps maintain/support good/beneficial/friendly gut flora during antibiotic use;

- helps maintain/support foetal CNS/brain development;

- the correction to the wording of the indication 'shukrala/aphrodisiac/enhance sexual vitality' to 'shukrala/spermatogenic/increases semen' as 'spermatogenic/increases semen' is not synonymous with 'aphrodisiac' and/or 'enhancing sexual vitality';

- the addition of the words 'If directed for women' to the requirement 'Advise your doctor of any medicine you take during pregnancy, particularly in the first trimester' to the following indications to clarify that the label statement is only required for products directed towards women:

  - maintain/support preconception health;
  - helps enhance/promote preconception health;

- the addition of the note: 'This requirement is not intended to apply when indications referring to osteoporosis (specified in column 2 of Table 2 of this instrument) are also made for the relevant medicine' to the requirement 'Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis' for the following indications referring to bone strength. The note clarifies that these indications can be used concurrently with specific permitted indications referring to osteoporosis:

  - aids/assists healthy bone development/growth/building;
  - help maintain/support bone mineralisation;
  - helps enhance/promote bone healing/repair;
  - helps enhance/promote bone health;
  - helps enhance/promote bone mass/density;
  - helps enhance/promote bone mineralisation;
  - helps enhance/promote bone strength;
  - helps enhance/promote/increase metabolism of (state mineral) in bones;
  - maintain/support (state mineral) absorption in bones;
  - maintain/support bone healing/repair;
  - maintain/support bone health;
  - maintain/support bone mass/density/integrity;
  - maintain/support bone strength;

- the addition of a required label statement 'If symptoms persist or worsen talk to your medical practitioner' and the requirement 'Product presentation must not imply or refer to severe morning sickness such as hyperemesis gravidarum' to the indication 'Decrease/reduce/relieve morning sickness' which were inadvertently omitted from the Former Determination;

- the addition of a required label statement 'Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect)' to 12 indications relating to coughs and colds that was inadvertently omitted from the Former Determination:

  - decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections;
  - relieve symptoms of mild upper respiratory tract infections;
  - helps reduce occurrence of symptoms of upper respiratory tract infections;
  - decongestant/relieve nasal congestion;
  - decrease/reduce/relieve bronchial mucous congestion;
  - decrease/reduce/relieve mild upper respiratory tract congestion;
  - kasa hara/relieve cough;
  - antitussive/cough suppressant;
  - decrease/reduce/relieve mild bronchial cough;
  - decrease/reduce/relieve cough;
  - relieve dry unproductive cough;
  - enhance/improve/promote/increase cough productivity.

Consultation

Between March and June 2019, the TGA engaged in ongoing communication with stakeholders who raised issues encountered when selecting indications for listed medicines. These communications involved telephone and written correspondence with individual sponsors and industry consultants.

The Determination addresses a number of issues raised from stakeholder feedback, including the clarification and correction of a number of indication requirements and provides consistency with requirements for other indications included in the Determination. A number of sponsor applications to amend the Determination resulted in the inclusion of new indications.

The pending changes to the Determination (with the exception of four new indications recently considered for inclusion) were published on the TGA website on 14 August 2019 and stakeholders were advised to contact the TGA with any concerns. No objections to the proposed changes were raised by industry.

Incorporation by reference

The Determination adopts the document titled *Evidence guidelines: Guidelines on the evidence required to support indications for listed complementary medicines*, published by the TGA. This document provides information regarding the type of evidence that is required to support indications for listed complementary medicines; and obligations in relation to holding such evidence. In accordance with paragraph 14(1)(b) of the *Legislation Act 2003* ("Legislation Act"), the Determination incorporates that document as it is in force or existing at the commencement of the Determination. This document is available for free from the TGA's website, www.tga.gov.au/publication/evidence-guidelines.

The Determination also refers to 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 may be accessed for free on the TGA website via the *Public TGA Information* menu in TGA eBusiness Services at www.ebs.tga.gov.au. Once again, the Determination incorporates the code tables as in force or existing at the commencement of the Determination in accordance with paragraph 14(1)(b) of the Legislation Act.

As discussed above, the Determination incorporates the meaning of 'serious' as that term is defined in section 28 of the Therapeutic Goods Advertising Code. '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 Advertising Code (No.2) 2019*. The Code sets out a range of requirements relating to the advertising of therapeutic goods in Australia. In accordance with paragraph 14(1)(a) of the Legislation Act, the Determination incorporates the Code as in force from time to time. The Code is on the Federal Register of Legislation and is freely available at www.legislation.gov.au.

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 on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of *Therapeutic Goods (Permissible Indications) Determination (No. 2) 2019*

Section 1 Name

This section provides that the name of the Determination is the *Therapeutic Goods (Permissible Indications) Determination (No. 2) 2019.*

Section 2 Commencement

This section provides that this 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*.

Section 4 Definitions

This section sets out definitions for a number of terms used in the Determination. In particular, these include 'code tables', 'health professional', 'medical practitioner' and 'traditional Chinese medicine'(in relation to the type of evidence for an 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, for example, 'health practitioner', 'indications', 'label' and 'medicine'.

Section 5 Permissible indications

Paragraph 5(a) of the Determination provides that each indication specified in column 2 of a table in Schedule 1 is covered by the Determination for the purposes of paragraph 26BF(1)(a) of the Act.

Paragraph 5(b) of the Determination provides that each indication specified in column 2 of a table in Schedule 1 is also covered by the Determination when modified using one or more qualifying statements in the code tables under the headings referred to in subparagraphs 5(b)(i) to (iv).

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 Schedule 1 may only be used for a medicine if the indication is supported by evidence of the type specified in column 3, and the requirements set out in column 4 are met, in relation to the relevant indication.

Subsections 6(3) to (6) of the Determination contain a number of overarching requirements. These include, for example, that where an indication for a medicine is supported by traditional evidence, then the indication must be qualified with an appropriate 'Traditional context qualifier' from the code tables, and that this qualifier must be set out 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

Schedule 1 specifies indications and related requirements for the purposes of sections 5 and 6 of the Determination.

Schedule 2

Schedule 2 provides that the Determination repeals the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2019*.

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. 2) 2019

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

The *Therapeutic Goods (Permissible Indications) Determination (No. 2) 2019* ("the instrument") is made by the Minister under section 26BF of the *Therapeutic Goods Act 1989* ("the Act"). The purpose of the instrument is to specify indications (statements of therapeutic use) that are permitted to be made in relation to medicines that are listed in the Australian Register of Therapeutic Goods ("the Register") under section 26A of the Act. The instrument also specifies requirements in relation to the use of such indications.

Medicines that are listed in the Register under section 26A (principally, listed complementary medicines and listed over the counter medicines, such as sunscreens) are considered to be 'low risk' and are not individually evaluated prior to being entered in the Register. As these listed medicines are not evaluated by the TGA prior to obtaining marketing 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 (currently set out in the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2019*)), and any indications for those medicines are covered by a list of permissible indications made under section 26BF of the Act. These "pre-approved" low-level indications are set out in the Determination and are designed to ensure that medicines listed under section 26A do not overstate their respective therapeutic benefits.

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 instrument have not been contravened.

If a person incorrectly certifies these matters, 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).

The requirement for 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.

In addition to specifying permissible indications for listed medicines, the Determination also specifies requirements that 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 a medicine's label (for example, 'If symptoms persist consult your healthcare practitioner').

The instrument also repeals and replaces the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2019* ("the former instrument"). The instrument includes a number of changes compared to the former instrument, including in particular:

- the addition of eight new indications with associated requirements relating to their use in listed medicines;
- the addition of the word 'helps' to several indications to ensure consistency with other similar indications;
- the correction to the wording of an indication;
- the addition of words, label statement or note to a number of indications.

Human rights implications

The instrument 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.

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.

For example, some of the requirements in the instrument relate to the inclusion of statements on the label of a listed medicine to highlight important information about the medicine for consumers. These include, in relation to twelve indications that relate to coughs and colds, the addition of a required label statement to the effect that the medicine is intended for adults only or should not otherwise be used in children under two years of age without medical advice.

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 a prescription, or to seek the advice of a registered medical practitioner or pharmacist.

Conclusion

The instrument 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