

EXPLANATORY STATEMENT

Therapeutic Goods (Permissible Indications) Determination No.1 of 2018

Subsection 26BF(1), Therapeutic Goods Act 1989

OUTLINE

The *Therapeutic Goods (Permissible Indications) Determination No.1 of 2018* (the Determination) is a determination made by the Minister under subsection 26BF(1) of the *Therapeutic Goods Act 1989* (the Act) and has the effect of specifying indications (these are principally statements about a medicine's therapeutic uses) that sponsors of medicines listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act 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.

The Determination commences on the day after it is registered.

BACKGROUND

Listed medicines

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.

Medicines that are listed in the Register under section 26A of the Act are considered 'low risk', and are not individually evaluated before they are entered in the Register. When applying to list their medicines in the Register, sponsors must certify under subsection 26A(2) of the Act that their medicine is eligible for listing and complies with all applicable regulatory requirements (e.g. that the medicine is safe for the purpose for which it is to be used, and that it complies with all applicable standards).

As these medicines are not evaluated by the TGA before being listed in the Register, the Act establishes a number of mechanisms to help ensure that they are of high quality and able to be used safely by consumers. One of these controls, introduced by the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018*, is that only certain low-level indications that are suitable for listed medicines, and that reflect that these products are not assessed prior to marketing approval in Australia, are able to be used in connection with these medicines.

When applying to list their medicines in the Register, sponsors must certify that (among other things), each indication proposed to be accepted in relation to the inclusion of their medicine in the Register is covered by a determination made under paragraph 26BF(1)(a) of the Act, and that if such a determination specifies requirements in relation to the use of such an indication under paragraph 26BF(1)(b) of the Act, that they have not contravened any of those requirements (paragraphs 26A(2)(fd) and (fe) of the Act refer).

The Determination

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

If a person incorrectly certifies as to these matters, the Secretary may cancel, or suspend, their goods from the Register (paragraphs 30(1)(e) and 29D(1)(b) of the Act refer). Offences, and civil penalty provisions may also 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, and the introduction of the Determination itself, will benefit industry, health practitioners and consumers by providing a transparent, single source of information about what indications are able to be used for these medicines, assist industry to avoid inadvertent use of non-compliant indications and provide greater protection for consumers from misleading or inappropriate claims.

These measures also implement recommendation 38 of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review), agreed to by the Government as part of its response to the Review, which recommended the establishment of a list of permitted indications for listed medicines, from which sponsors must exclusively draw when applying to list their medicines in the Register.

Permissible indications

Most of the indications specified in the Determination have been assessed and considered to be compatible with one or more of the criteria set out in subsection 26BF(2) of the Act, which identify the principal matters that the Minister may have regard to when deciding to make a determination under subsection 26BF(1) - these are:

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

A small number of indications authorised under the Determination extend beyond these criteria – these are indications that relate to the link between vitamin D and calcium (referring to osteoporosis), the link between folic acid and neural tube defects, and to 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 these kinds of indications in the Determination principally reflects their public health importance, safe history of use and well-established evidence base.

Subsection 4(2) of the Determination has the effect of allowing sponsors to modify a selected 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 this instrument). Subsection 4(2) does this by specifying indications that are modified by a selected qualifying statement from the Code Tables as permissible indications. Four types of qualifying statements will be 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 TCM paradigm, for example: “*Spleen Qi Deficiency pattern*”;
- “Population qualifiers” - which specify the target population for a medicine, e.g. “*in healthy individuals*”, “*in women*” or “*in men*”; 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 such 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 the traditional use of a medicine, 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 to the Determination which provides for the list of indications that can be used in relation to listed medicines in column 2 of the Tables, requirements relating to the type of evidence required to support the use of an indication in column 3 and any other requirements relating to the use of an indication in column 4. The Determination also sets out a number of overarching requirements in paragraphs 4(3)(c) – (e) of the instrument that are not replicated in the Tables.

These include, for example, that if the wording of an indication is varied on the label of a medicine or combined with another 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. Section 3 of the Determination defines ‘serious’ in this context as having the same meaning as in the Therapeutic Goods Advertising Code 2015, which defines that term as meaning forms of those diseases, conditions, ailments or defects which are generally accepted either to not be appropriate to be diagnosed or treated without consulting a suitably qualified

healthcare professional or to be beyond the average consumer's ability to accurately evaluate and treat safely without regular supervision by a qualified healthcare professional (e.g. cardiovascular diseases, haematological diseases).

CONSULTATION

Following broad consultation undertaken as part of the Review, specific consultation on the proposed criteria and implementation options for permitted indications was conducted between February and March 2017. 60 submissions were received, with the majority of stakeholders supporting the option to implement this reform. In August 2017, the TGA released an exposure draft of the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 that became the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* and that provided for the introduction of the list of permitted indications, criteria that the Minister may have regard to when deciding to make a determination and the power to also specify requirements related to the use of permitted indications.

The TGA also undertook significant consultation throughout 2017 to develop the final list of permitted indications. A draft list of indications was developed based on industry submissions to previous consultations undertaken in 2012 and 2013, and these indications were then assessed against the proposed criteria in the Bill. The draft list was further refined following targeted workshops held in March and April 2017 with key industry associations (the Australian Self Medication Industry, Complementary Medicines Australia and Accord Australasia, consumer groups and healthcare professionals). The draft list of indications was then published on the TGA website for public comment between July and October 2017. 110 submissions were received during that period from consumers (12 submissions) and industry stakeholders (98 submissions). Industry submissions primarily proposed additional indications for inclusion in the instrument, while consumer submissions expressed concerns about the terminology and evidence base for 'traditional indications' and contended that the number of indications in the instrument should be reduced.

Stakeholder comments were considered and the instrument was further refined to incorporate some improvements for greater clarity and in order to ensure that the list of indications is comprehensive and commensurate with the low risk nature of listed medicines.

The permitted indications reform is being introduced in response to Recommendation 38 of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review). No further regulatory analysis is required as it is covered by the RIS-like process (OBPR reference 18884) that was undertaken for the Review. Deputy Secretary, Mark Cormack, of the Strategic Policy and Innovation Group of the Department wrote to the Office of Best Practice Regulation (OBPR) certifying that the Review undertook a process and analysis similar to that required for a RIS.

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

In relation to compatibility with human rights, it is considered that the Determination 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*, and a Statement of Compatibility setting that out in further detail is below.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

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 of 2018

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 of 2018* (the Determination) is made by the Minister under subsection 26BF(1) of the *Therapeutic Goods Act 1989* (the Act). It has the effect of specifying indications (these are principally statements about a medicine's therapeutic uses) that sponsors of medicines listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act 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.

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, and related requirements designed to support the safe use of medicines for which these indications are to be used. The Determination is designed to provide a transparent, single source of information about what indications are able to be used for these medicines, assist industry to avoid inadvertent use of non-compliant indications and better protection for consumers from misleading or inappropriate claims.

Most of the indications specified in the Determination have been assessed and considered to be compatible with one or more of the criteria set out in subsection 26BF(2) of the Act, which identify the principal matters that the Minister may have regard to when deciding to make a determination under subsection 26BF(1) - these are:

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

A small number of indications authorised under the Determination extend beyond these criteria – these are indications that relate to the link between vitamin D and calcium (referring to osteoporosis), the link between folic acid and neural tube defects, and to 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 these kinds of indications in the Determination principally reflects their public health importance, safe history of use and well-established evidence base.

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

listed medicines e.g. by specifying the type of evidence that a sponsor must hold to support the use of an indication in relation to their product, specifying a vulnerable population for which an indication is not suitable (e.g. children) or requiring an advisory statement to accompany the use of an indication on a medicine's label.

Human rights implications

As the Determination does not have any effect other than to specify the indications which sponsors of medicines listed under section 26A of the Act may use in relation to their products, and requirements relating to the use of such indications for such products (as outlined above), it would not appear to engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Larry Kelly, delegate of the Minister for Health