EXPLANATORY STATEMENT

Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018

Subsection 26BB(1), Therapeutic Goods Act 1989

OUTLINE

The *Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018* (the Determination) is a determination made by the Minister under subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act) and has the effect of specifying ingredients that may be contained in a medicine listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act, and requirements in relation to the inclusion of those ingredients in such medicines.

The Determination is intended to succeed (i.e. repeal and replace) the previous Determination which specified ingredients and related requirements for such medicines – the *Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2018*, which commenced on 16 March 2018 and was subsequently amended by the *Therapeutic Goods (Permissible Ingredients) Amendment Determination 2018* on 11 April 2018 (together referred to as the Previous Determination).

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

The Determination makes a number of changes to the Previous Determination. These include, for example, correcting a number of unintended errors, making a number of requirements relating to the use of particular ingredients clearer, and introducing 9 new ingredients for use in listed medicines for the first time and the removal of 4 ingredients due to duplication in names.

The Determination includes references to a number of external documents. In each case, the intention is for the references to relate to those documents ‘as in force or existing from time to time’, unless a specific version of the relevant document is identified. The words ‘as in force or existing from time to time’ are included, as appropriate, throughout the Determination to make it clearer that this is the intention in relation to references to other documents.

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Subsection 26BB(8) of the Act provides a contrary intention for subsection 14(2) of the *Legislation Act 2003* (the Legislation Act), by allowing a determination under section 26BB to make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

In accordance with paragraph 15J(2)(c) of the *Legislation Act 2003*, the documents referenced in this Determination are described below, together with information relating to how they may be accessed.

The Determination refers to the following New Zealand legislation:

> the *Animal Products Act 1999* (New Zealand), available free on-line at http://www.legislation.govt.nz/act/public/1999/0093/latest/DLM33502.html
>
> the *Animal Welfare Act 1999* (New Zealand), available free on-line at http://www.legislation.govt.nz/act/public/1999/0142/latest/DLM49664.html

The Determination also refers to the following documents that provide international standards for the safety and quality of ingredients for medicines (a fee is required for access to these documents):

> *British Pharmacopoeia* (BP) (as defined in the Act) available online at: https://www.pharmacopoeia.com;
>
> *European Pharmacopoeia* (EP) (as defined in the Act) available on-line at: http://online.pheur.org;
>
> *United States Pharmacopeia – National Formulary* (USP-NF) (as defined in the Act) available on-line at: http://www.usp.org/usp-nf;
>
> Food Chemicals Codex (FCC) published by the United States Pharmacopeial Convention available on-line at http://online.foodchemicalscodex.org.

It is anticipated that a sponsor of a medicine included in the Australian Register of Therapeutic Goods and other interested persons in the medicines industry using this instrument would be in possession of these standards in order to manufacture the medicine or use the ingredients. Further, versions of these documents are available through a number of libraries allowing public access.

The Determination commenced on the day after it was registered on the Federal Register of Legislation.

BACKGROUND

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

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exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

One of the controls established by the Act is to require that medicines that are listed in the Register under section 26A of the Act (listed medicines) only include ingredients which have been evaluated for safety and quality, and that consideration has been given to whether any conditions should be attached to the use of the ingredient, so that safety and quality can be maintained. The Determination supports the achievement of this control, by providing for a list of ingredients which have been assessed or determined previously to be safe and providing for the requirements applying to particular ingredients when contained in a relevant medicine.

Prior to the making of the first determination under subsection 26BB(1) of the Act, the *Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2015* (the original Determination), ingredients were authorised for use in listed medicines generally through the list of ingredients in Schedule 4 to the Therapeutic Goods Regulations 1990, or through notices made by the Minister under subsection 9A(5) of the Act (Listing Notices).

The Determination, however, provides for a single, comprehensive list of ingredients permitted for use in listed medicines, along with requirements applying to the use of particular ingredients included in listed medicines.

The requirements imposed under the Determination principally relate to ensuring the quality and safety of the ingredient when used. Requirements may relate, for example, to:

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

The purpose of the Determination is to repeal and replace the Previous Determination with this Determination that includes new ingredients that will be available for use in listed medicines, and that also incorporates a number of other changes to the Previous Determination.

These changes include:

- the addition of 9 new ingredients that have been determined to be suitable for inclusion in listed medicines, along with associated requirements relating to their use in these products;

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- changes to 75 existing ingredient entries, including for example:
  - making requirements for ingredients less restrictive, such as by removing route of administration restrictions or requirements for unnecessary warning statements;
  - making requirements for ingredients more restrictive, such as requiring warning statements with transitional provisions for existing listed medicines;
  - reflecting existing requirements from the Poisons Standard (SUSMP); and
  - making minor changes to make a number of entries clearer;
- the removal of 4 ingredients that have been determined not to be suitable for inclusion in listed medicines or were synonymous with other existing ingredients to avoid duplication.

The Determination provides transitional arrangements for medicines that are currently listed in the Register to comply with new requirements for ingredients included in the previous Determination, such as new concentration limits or safety information required on product labels. The transitional provisions do not apply to new products that are entered into the Register after the introduction of the new requirements.

Updated section 26BB Determinations are made on a regular basis. This updated is needed to ensure that new ingredients requested by industry are made available for use in listed medicines as soon as possible after they have been assessed or determined to be safe. Updating the Determination is necessary to provide industry with accurate and current information on restrictions for certain ingredients that reflect recent safety data, scientific naming conventions, changes to the Poisons Standard (SUSMP), legislative developments for therapeutic goods, and to correct minor errors. As listed medicines are available without a prescription from a registered medical doctor, there is an imperative to ensure that section 26BB Determinations are accurate and routinely maintained, so as to provide clear requirements for industry about what ingredients can be safely used in listed medicines and, about what safety information needs to be provided to consumers on product labels to ensure the safe use of those products by the public.

CONSULTATION

Consultation on the policy of making a determination under section 26BB has occurred since late-2014 with key industry bodies, the Australian Self Medication Industry, Complementary Medicines Australia and Accord. This included consultations on the inclusions of permitted ingredients when the first section 26BB Determination commenced on 1 January 2016. Engagement with industry on changes required in previous section 26BB Determinations and this new Determination occurred in 2016 and 2017.

A regulatory impact statement is not required for updates to the Determination as these are considered minor or machinery in nature. This exemption applies to the addition of new ingredients, correction of errors, clarification of requirements, reflection of existing Poisons Standard requirements against the relevant ingredients, or the outcomes of TGA safety evaluations where the regulatory impacts are minor or machinery in nature (Office of Best Practice Regulation References. 14416, 20999, and 21645).

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

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.

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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 Ingredients) Determination No. 2 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 Ingredients) Determination No. 2 of* 2018 (the Determination) is made by the Minister under subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act). The Determination has the effect of specifying ingredients that may be contained in a medicine listed in the Australian Register of Therapeutic Goods (the Register) under section 26A of the Act, and requirements in relation to the inclusion of those ingredients in such medicines. A person seeking to list a medicine in the Register under section 26A of the Act must certify, when doing so, that the medicine does not contain an ingredient that is not specified in the section 26BB Determination, and that none of the requirements specified in the section 26BB Determination in relation to the ingredients contained in the medicine have been contravened – paragraphs 26A(2)(ca) and (cb) of the Act refer.

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 ingredients and related requirements).

The Determination repeals and replaces the *Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2018* (which commenced on 16 March 2018, and was amended on 11 April 2018), and incorporates a number of changes to the previous Determination.

Human rights implications

This legislative instrument does not 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.

Cheryl McRae, delegate of the Minister for Health

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