EXPLANATORY STATEMENT

Therapeutic Goods (Permissible Ingredients) Amendment (2016 Measures No. 1) Determination 2016

Section 26BC, Therapeutic Goods Act 1989

OUTLINE

This instrument, the Therapeutic Goods (Permissible Ingredients) Amendment (2016 Measures No.1) Determination 2016 (the Amendment Determination), is made under section 26BC of the *Therapeutic Goods Act 1989* (the Act). The purpose is to amend the *Therapeutic Goods (Permissible Ingredients) Determination No.2 of 2016*, which commenced on 28 July 2016 (the Principal Determination).

Section 26BC of the Act authorises the Minister to, on his or her own initiative and by legislative instrument, vary a determination under section 26BB. Determinations under section 26BB of the Act (section 26BB Determinations) have 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 Amendment Determination makes a number of changes to the Principal Determination, including introducing 12 new ingredients for use in listed medicines and making a number of requirements relating to the use of particular ingredients clearer.

The Amendment Determination includes references to a number of documents, as in force or existing from time to time. Subsection 26BB(8) of the Act provides a contrary intention for subsection 14(2) of the *Legislation Act 2003* (Legislation Act) by allowing a determination under section 26BB to incorporate 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, the documents referenced in this Amendment Determination are described below, together with information relating to how they may be accessed.

The Amendment 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 Amendment Determination also refers to the following documents that provide international standards for the safety and quality for ingredients for medicines. A fee is required for access to these documents, but it is expected that a sponsor of a medicine included in the Register would already have access to these documents.

> *British Pharmacopoeia* (BP) available online at: https://www.pharmacopoeia.com

United States Pharmacopeia – National Formulary (USP-NF): 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

The Amendment Determination will commence on the day after it is 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 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. Section 26BB Determinations support 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).

Section 26BB Determinations, however, provide 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 section 26BB Determinations 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 changes made by the Amendment Determination to the Principal Determination include:

- the addition of 12 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;
- changes to 47 ingredient entries that do not introduce new requirements for ingredients, including:
    - clarification of information for 13 ingredients;
    - making requirements for 6 ingredients less restrictive;
    - alignment of 17 ingredients with requirements for these substances included in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP));
    - correcting 11 typographical errors;
- removal of 1 (one) ingredient name that is a synonym of another ingredient. This change is the removal of a synonym name only, without removing availability of the ingredient to be used in listed medicines.

It is expected that updated section 26BB Determinations will be made on a quarterly basis - the need to make timely updates to such Determinations available arises for a number of reasons, including 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. In addition, as listed medicines are not prescribed by a doctor and are freely available, there is an imperative to ensure that section 26BB Determinations are accurate, and are 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

Engagement with industry on changes required in previous Section 26BB Determinations and the Amendment Determination has occurred since early 2016 and remains ongoing. Consultation has occurred through face-to-face briefings, teleconferences and written correspondence. Key industry associations have provided comments that have been used to improve: formatting; readability; and clarity of wording to help ensure that the Amendment Determination is comprehensive and accurate.

The Office of Best Practice Regulation (OBPR) has advised that a regulatory impact statement (RIS) is not required in relation to addition of permitted ingredients (OBPR Ref. 14416), or in relation to changes to the section 26BB Determination to correct errors, clarify requirements and ingredient names, or remove an ingredient to be in line with medicines scheduling decisions contained in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) (OBPR Ref. 20999). OBPR has advised that changes in the Amendment Determination appear to be minor in nature and given that the matter will not be considered by Cabinet, a RIS is not required (OBPR Ref. 21308).

The Amendment 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 Amendment 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 Ingredients) Amendment (2016 Measures No.1) Determination 2016

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) Amendment (2016 Measures No.1) Determination 2016* (the Amendment Determination) is made by the Minister under section 26BC of the *Therapeutic Goods Act 1989* (the Act). The Amendment Determination has the effect of amending the *Therapeutic Goods (Permissible Ingredients) Determination No.2 of 2016*, which commenced on 28 July 2016, (the Principal Determination).

Section 26BB Determinations have 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) of the Act and 29D(1)(b) 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 Amendment Determination incorporates a number of changes to the Principal Determination. These include, for example, introducing 12 new ingredients for use in listed medicines and making a number of changes to ingredient entries that do not introduce new requirements but make the requirements relating to the use of particular ingredients clearer.

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.

Mayada Kayali, delegate of the Minister for Health and Aged Care