

## **EXPLANATORY STATEMENT**

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

*Section 26BC, Therapeutic Goods Act 1989*

#### **OUTLINE**

This instrument, the Therapeutic Goods (Permissible Ingredients) Amendment Determination No. 2 of 2018 (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 2018*, which commenced on 19 June 2018 (the Principal Determination).

Section 26BC of the Act enables the Minister to, on his or her own initiative and by legislative instrument, vary a determination under section 26BB of the Act. 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 change to the Principal Determination, to vary requirements for a number of ingredients known to contain arbutin to reflect specific limits contained in the Poisons Standard.

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 listed 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.

## DETAILS OF THE AMENDMENT

The changes made by the Amendment Determination are to update the limits for arbutin which is a mandatory component of a number of ingredients included in the Principal Determination. Arbutin is a derivative of hydroquinone and at certain concentrations is subject to the requirements of the Poisons Standard. For a medicine to be listed in the Register it must not contain an ingredient that is included in a Schedule to the Poisons Standard. The changes clarify that if a listed medicine contains an ingredient known to contain the mandatory component arbutin, then there should not be a Scheduled amount of arbutin in the listed medicine.

The changes made by the Amendment Determination reflect the current Poisons Standards requirements for arbutin and applies to the *ingredients Achillea millefolium, Arctostaphylos uva-ursi, Chimaphila umbellata, Kalmia latifolia, Ledum palustre, Origanum majorana, Pyrus communis, Pyrus pyrifolia, Rhododendron ferrugineum, Turnera diffusa and Vaccinium vitis-idaea.*

## CONSULTATION

Engagement with industry on changes required to the previous section 26BB Determinations 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 Principal Determination is comprehensive and accurate.

In February 2018, the TGA published an outline of the changes proposed to be included in the Principal Determination to give industry an opportunity to raise potential concerns. This included the proposal to reflect existing Poison Standard requirements for herbal ingredients known to contain arbutin as a component. The TGA continued to consult with industry stakeholders after the commencement of the Principal Determination which identified the need to make the Amendment Determination.

A regulatory impact statement is not required for updates to section 26BB Determinations that are minor or machinery in nature. This exemption applies to the addition of permitted ingredients, correction of errors, clarification of requirements and ingredient names, changes to ingredient requirements or availability in order to reflect scheduling decisions contained in the Poisons Standard, 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). This amendment reflects scheduling decisions contained in the Poisons Standard and a regulatory impact statement is not required for the Amendment Determination.

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 Ingredients) Amendment Determination No. 2 of 2018 (the Amendment Determination)**

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 Determination No. 2 of 2018 (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 2018*, which commenced on 19 June 2018, (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 makes a change to the Principal Determination, to a number of ingredients known to contain arbutin to align with specific limits contained in the Poisons Standard.

### **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**