

## **EXPLANATORY STATEMENT**

### **Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018**

*Subsection 26BB(1), Therapeutic Goods Act 1989*

#### **OUTLINE**

This instrument, the Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018 (the Determination), is made 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. 2 of 2018*, which commenced on 19 June 2018 and was subsequently amended by the *Therapeutic Goods (Permissible Ingredients) Amendment Determination No. 2 of 2018* on 6 July 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, to include new ingredients and make requirements relating to the use of certain ingredients less restrictive; as well as amend the names of existing ingredients.

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.

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 documents that are intended to be adopted as in force from time to time. These documents provide important international standards for the safety and quality of ingredients for medicines (a fee is required for access to these documents, with the exception of the two New Zealand Acts, which are available for free from the website noted below):

*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 Pharmacopoeial Convention available on-line at <http://online.foodchemicalscodex.org>;

*Animal Products Act 1999*, of New Zealand (at <http://www.legislation.govt.nz/>);

*Animal Welfare Act 1999*, of New Zealand (at <http://www.legislation.govt.nz/>);

The Determination also includes a reference to a World Health Organization publication “Expert consultation on oral rehydration salts formulation”, dated 18 July 2001 – this document is available for free online at <http://rehydrate.org/ors/expert-consultation.html>.

While unfortunately the pharmacopoeia and the FCC are not available for free, it is anticipated that the persons most affected by their adoption - sponsors of medicines 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. As important international benchmarks for the safety and quality of therapeutic goods, it would not be feasible from a regulatory perspective to not adopt such benchmarks because they are not available for free.

It should be noted that the National Library’s Trove online system (<https://trove.nla.gov.au/>) allows users to identify libraries in Australia that are open to the public where (in most cases, earlier) editions of these pharmacopoeia may be viewed (for example, the University of Tasmania or the University of Western Australia in relation to the BP). Members of the public may also approach any library that participates in inter-library loans to request an inter-library loan with such university libraries, to obtain a photocopy of a particular part or monograph for personal study or research (but not for commercial purposes), at a usual cost of \$16.50 per request (enquiries should be made with local libraries, State libraries and the National Library).

For example, Trove indicates that free access to the EP’s 2004 version is available through Open University ([https://openlibrary.org/books/OL22071008M/European\\_pharmacopoeia](https://openlibrary.org/books/OL22071008M/European_pharmacopoeia)),

and that access to the 1996 edition of the FCC is available at the University of Melbourne Library and the Hawksbury Campus Library of the University of Western Sydney - both open to the public.

Separately, free access to the 1993 version of the BP is available at the State Library of Victoria, and access is available to the 2013 version of the USP at the University of Sydney Library, including for community borrowers (it appears that individual members of the public may join the University of Sydney Library to borrow on this basis, at a cost of \$40 for three months). Pre 2001 versions of both documents are also available for free at the National Library.

The Determination commenced on 28 September 2018.

## **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 and 26AE of the Act (listed and assessed 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.

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:

- include the following new ingredients following evaluations of their suitability for use in listed medicines; *Khaya sengalensis*, capryloyl glycerine/sebacic acid copolymer, *Saxifraga stolonifera*, sodium polyacrylate starch and *Syzygium jambos*; and
- amend the requirements for the following ingredients to make them less restrictive, following evaluation of their suitability for use in listed medicines; methyl methacrylate crosspolymer, polyglyceryl-2 triisostearate, and sodium metaphosphate.

In addition, the ingredient name *Astragalus mongholicus* will be amended to be *Astragalus membranaceus*. This is to reflect the current understanding of the taxonomy of the herb. Ortho-cymen-5-ol will be amended to 4-isopropyl-3-methylphenol to align with TGA naming conventions.

Updated section 26BB Determinations are made on a regular basis. This update 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

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 Previous Determination is comprehensive and accurate.

In February 2018, the TGA published an outline of the changes proposed to be included in the Previous Determination to give industry an opportunity to raise potential concerns. This included the proposal to update the name of the herb '*Astragalus membranaceus*'. Following

the commencement of the Previous Determination, the TGA continued to consult with industry stakeholders. The TGA received information that this change of name was not aligned with the taxonomical classification of *Astragalus* species in the Medicinal Plant Names Services (MPNS) database; namely that *Astragalus membranaceus* and *Astragalus mongholicus* are not synonymous. The TGA contacted sponsors of medicines listed following the commencement of the Determination, and advice was received that a change to the previous naming of *Astragalus membranaceus* would not introduce any issues associated for those sponsors. As such, the name is updated in the Determination to the original '*Astragalus membranaceus*', and will reflect the correct name.

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).

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) Determination No. 3 of 2018 (the 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) Determination No. 3 of 2018 (the Determination) is made by the Minister under subsection 26BB(1) of the *Therapeutic Goods Act 1989* (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 and 26AE 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 or 26AE 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.

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 30(1)(ea) 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) or 26AB(2) of the Act (including certification relating to permissible ingredients and relevant requirements).

The Determination repeals and replaces the *Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018* (which commenced on 19 June 2018, and was amended on 6 July 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.

**Michael Shum, delegate of the Minister for Health**