EXPLANATORY STATEMENT

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2018

Subsection 26BB(1), Therapeutic Goods Act 1989

OUTLINE

The *Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2018* (the Determination) is a legislative instrument made by a delegate of the Minister for Health under subsection 26BB(1) of the Act. The purpose of the Determination is to specify the ingredients that may be contained in a medicine that is listed in the Australian Register of Therapeutic Goods (the Register) under section 26A or 26AE of the Act, and requirements in relation to the inclusion of those ingredients in such medicines.

The Determination repeals and replaces the previous Determination which specified ingredients and related requirements for such medicines – the *Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018*, which was registered on the Federal Register of Legislation on 25 September 2018 and commenced on 28 September 2018 (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 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 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 Australian Register of Therapeutic Goods under section 26A or 26AE of the Act (respectively, AUST L listed medicines and AUST L(A) assessed listed medicines and, together, "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 in order to ensure the safety and quality of AUST L or AUST L(A) medicines containing that ingredient.

Under paragraphs 26A(2)(ca) and (cb) of the Act, for example, persons applying to list a medicine in the Register under section 26A of the Act must certify that their medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a) of the Act, and does not contravene a requirement in relation to such an ingredient that is set out in such a determination (paragraphs 26AB(2)(d) and (e) set out equivalent certifications for applicants seeking marketing approval for AUST L(A) medicines).

As such, the Determination is designed to provide a list of ingredients which have been assessed or determined previously to be safe for use in AUST L and AUST L(A) medicines, and to also provide for necessary requirements applying to the use of particular ingredients when contained in such products.

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 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, and in so doing to incorporate a number of changes in comparison to the Previous Determination.

These changes include:

- changes to 5 existing ingredient entries to:
    - make requirements for some ingredients less restrictive, for example by allowing an ingredient to be used as an excipient as well as an active

ingredient, and by allowing an ingredient to be used in an AUST L or AUST L(A) medicine that is for dermal application (i.e. as well as in such medicines when they are for oral administration);
    - correct an inadvertent error in a requirement relating to the use of the ingredient *Larix arabinogalactan*, that dates from the original Determination. Currently the requirement states that the concentration of polysaccharides in the medicine must be equal to or more than 85 per cent. However, the intention was to require that the concentration of polysaccharides must be equal to or more than 85 per cent of the amount of the ingredient *Larix arabinogalactan* in the medicine; and
    - make minor changes to a number of entries in order to make them clearer.

- remove one ingredient that was incorrectly classified as being appropriate for use in AUST L medicines during the drafting of the original Determination. The removed ingredient is not currently used in any listed medicines in Australia.

Updated section 26BB Determinations are made on a regular basis. These updates are needed to ensure that new ingredients, and new ingredient uses, requested by industry are made available for AUST L and AUST L(A) medicines as soon as possible after they have been assessed or determined to be safe. Updating the Determination is necessary to provide accurate and current information on restrictions for ingredients that reflects recent safety data, scientific naming conventions, changes to the Poisons Standard, legislative developments for therapeutic goods, and to correct minor errors.

As listed medicines are available without a prescription from a registered medical doctor, it is particularly important for public health and safety 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 medicine, 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.

INCORPORATION

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 Pharmacopeial Convention, available on-line at http://online.foodchemicalscodex.org:
- *Animal Products Act 1999*, of New Zealand, available online at http://www.legislation.govt.nz/;
- *Animal Welfare Act 1999*, of New Zealand, available online 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 Register and other interested persons in the medicines industry using the Determination - would be in possession of these documents in order to manufacture the medicine or use the ingredients. As these documents are 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 also 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 editions (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), 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.

CONSULTATION

Engagement with industry on changes required to previous determinations has occurred since early 2016, and remains the subject of ongoing consultation, principally with industry. Such consultation has occurred through face-to-face briefings, teleconferences and written correspondence. Key industry associations have provided comments that have been used to improve the formatting, readability and clarity of wording in previous determinations.

However, no consultation was undertaken for this Determination, principally because the changes reflected in the Determination in comparison with the Previous Determination are quite minor and machinery in nature – as outlined above, these consisted mainly of making a small number of ingredient requirements less restrictive, correcting an inadvertent error in one entry, making minor changes to clarify some entries and removing an ingredient that is not in use in Australia. Taking the nature of these changes into consideration, it would appear appropriate in this instance to have not consulted specifically on these measures.

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).

Details of the Determination are set out in Attachment A.

The Determination is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

This Determination is a disallowable legislative instrument, and commences on the day after it is registered on the Federal Register of Legislation.

ATTACHMENT A

Details of *Therapeutic Goods (Permissible Ingredients) Determination (No.4) 2018*

Section 1 Name

This section provides that the name of the Determination is the Therapeutic Goods (Permissible Ingredients) Determination (No.4) 2018.

Section Commencement

This section provides that the Determination commences on the day after it is registered on the Federal Register of Legislation.

Section 3 Authority

This section provides that the legislative authority for making the Determination is subsection 26BB(1) of the Act.

Section 4 Definitions

This section provides definitions for certain terms used in the Determination. The section notes that a number of terms have the same meaning as in the Act, including each of the British Pharmacopoeia, European Pharmacopoeia and the United States Pharmacopeia-National Formulary, as well as other terms including 'medicine' and 'Register'.

Section 5 Permissible ingredients and requirements applying to those ingredients

This section provides that the ingredients specified in column 2 of Table 1 in Schedule 1 to the Determination are specified for the purposes of paragraph 26BB(1)(a) of the Act.

This section also provides that, for the purposes of paragraph 26BB(1)(b) of the Act, the ingredients specified in column 2 of Table 1 in Schedule 1 to the Determination are, principally, subject to the following requirements:

- they may only be used in a medicine for a purpose or purposes specified in column 3 of Table 1 in Schedule 1; and
- they must comply with the requirements set out in column 4 of Table 1 in Schedule 1.

This section also specifies additional requirements in relation to specified ingredients in Table 1 in Schedule 1 that are derived from animal origins.

Section 6 Repeals

This section provides that each instrument that is specified in Schedule 2 to the Determination is repealed as set out in that Schedule.

Schedule 1 – Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

Schedule 1 sets out ingredients and related requirements for the purposes of section 5 of the Determination.

Schedule 2 – Repeals

Schedule 2 provides that the Determination repeals the whole of the legislative instrument *Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2018*.

ATTACHMENT B

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. 4) 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. 4) 2018* (the Determination) is made by the Minister under subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act).

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 Australian Register of Therapeutic Goods under section 26A or 26AE of the Act (respectively, AUST L listed medicines and AUST L(A) assessed listed medicines and, together, "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 in order to ensure the safety and quality of AUST L or AUST L(A) medicines containing that ingredient).

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 or 26AE of the Act, and specifying requirements in relation to the use 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. 3 of 2018* which was registered on the Federal Register of Legislation on 25 September 2018 and commenced on 28 September 2018 (the Previous Determination), and incorporates a number of changes in comparison to the Previous Determination.

These changes include:

- changes to 5 existing ingredient entries to:
    - make requirements for some ingredients less restrictive, for example by allowing an ingredient to be used as an excipient as well as an active ingredient, and by allowing an ingredient to be used in an AUST L or AUST L(A) medicine that is for dermal application (i.e. as well as in such medicines when they are for oral administration);
    - correct an inadvertent error in a requirement relating to the use of the ingredient *Larix arabinogalactan*, that dates from the original Determination. Currently the requirement states that the concentration of polysaccharides in the medicine must be equal to or more than 85 per cent. However, the intention was to require that the concentration of polysaccharides must be equal to or more than 85 per cent of the amount of the ingredient *Larix arabinogalactan* in the medicine; and
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Human rights implications

The Determination takes positive steps to promote the right to health in article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). This right is understood as the right of everyone to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In *General Comment No.*

14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

By prescribing those ingredients that are considered to be safe for use in listed medicines, and by setting out important requirements relating to the use of those ingredients in such medicines (such requirements may relate, for example, to maximum concentrations of such ingredients in listed medicines, or to the inclusion of warning statements on medicine labels such as 'Keep out of reach of children' for relevant ingredients), the safety of Australian consumers will be better protected, and they will be better able to make informed decisions about such medicines.

This is particularly important for listed medicines, as they are usually available for self-selection by consumers without a requirement to first obtain the advice or prescription of a registered medical doctor, or the advice of a pharmacist.

Conclusion

The Determination is compatible with human rights because it promotes the right to health in article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.

Cheryl McRae, delegate of the Minister for Health