EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines Advisory Statements) Specification 2019

The *Therapeutic Goods Act 1989* ("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.

The *Therapeutic Goods* (*Medicines Advisory Statements) Specification 2019* ("the Specification") is made by the Minister under subsection 3(5A) of the Act to specify, for the purposes of paragraph 3(5)(ca) of the Act, advisory statements that are required to be set out on the label of medicines that are included in a class of medicine prescribed by the regulations. The Specification repeals and replaces the *Medicines Advisory Statements Specification 2017* ("the former Specification").

Regulation 3AA of the *Therapeutic Goods Regulations 1990* ("the Regulations") prescribes the classes of medicine for the purposes of paragraph 3(5)(ca) of the Act. These are, principally, over the counter ("OTC") medicines and registered complementary medicines. Regulation 3AA has the effect that the Specification will not apply to:

- medicines of a kind mentioned in Part 1 of Schedule 10 to the Regulations, which are principally prescription medicines, radiopharmaceuticals and medical gases; and

- listed complementary medicines that comply with the permissible ingredients determination for such medicines made by the Minister under section 26BB of the Act.

The exclusion of prescription medicines reflects that access to prescription medicines is controlled by medical practitioners, and that information about the potential benefits and risks of a medicine is part of the consultation between prescriber and patient. The exclusion of radiopharmaceuticals and medical gases reflects that these products are not usually supplied directly to consumers. The exclusion of listed complementary medicines that comply with the permissible ingredients determination made under section 26BB of the Act reflects that relevant requirements for such products form part of that determination, and so avoids duplication.

Background

Subsection 3(5) of the Act sets out a number of circumstances in which the presentation of therapeutic goods is considered to be unacceptable for the purposes of the Act. These include, for example, where the presentation of therapeutic goods states or suggests that the goods have ingredients, components or characteristics that they do not have, or where the label of the goods does not declare the presence of a therapeutically active ingredient.

Under paragraph 3(5)(ca) of the Act, the presentation of therapeutic goods is unacceptable where the goods are medicine that are included in a class of medicine prescribed by the

Regulations for the purposes of that paragraph, and where the medicine's label does not contain the advisory statements specified under subsection 3(5A) of the Act in relation to that medicine.

Subsection 3(5A) of the Act authorises the Minister to make a legislative instrument specifying advisory statements in relation to such medicines for the purposes of paragraph 3(5)(ca) of the Act.

The main kinds of medicines required to comply with the Specification are OTC and registered complementary medicines. Prescription medicines, and medicines such as radiopharmaceuticals and medical gases that are not usually supplied directly to consumers, are not within the scope of the instrument. Listed complementary medicines (i.e. medicines that are listed in the Register under section 26A of the Act) are also not subject to the Specification, provided that those medicines comply with the requirements of the permissible ingredients determination made by the Minister in respect of such products under section 26BB of the Act.

The advisory statements set out in the Specification are designed to address specific risks related to the use of OTC and registered complementary medicines that have been identified by means of pharmacovigilance activities, testing, adverse event reports or other scientific or clinical information. Having advisory statements on medicine labels is designed to ensure that consumers are informed about these risks.

The need for new advisory statements to be included on the labels of these medicines may arise for a number of reasons, including the entry of new medicines into the market, the identification of new risks associated with particular medicines and "down-scheduling" of medicines in the Poisons Standard.

"Down-scheduling" refers to where the Secretary amends the Poisons Standard to move a medicine from a higher risk schedule to a lower risk schedule, meaning an affected product may then be more widely available for self-selection by consumers. Consequently, there may be a need in such circumstances for advisory statements to help consumers to self-select in an informed manner and to use such medicines safely and effectively.

The Schedule to the Specification is principally based on the most recent version of the TGA document the '*Required Advisory Statements for Medicine Labels*' ("the RASML").

The Specification repeals and replaces the former Specification, which commenced on 1 July 2017. Under the former Specification, medicine sponsors were required to comply with Schedule 1 to that specification for the first 18 months after it commenced on 1 July 2017 (which was based on the edition of the RASML known as RASML 3), but could instead elect to comply with Schedule 2 to the former Specification during that period (which was based on the edition of the RASML known as RASML 4). After that initial 18 month period, sponsors were required under the former Specification to comply with Schedule 2 to that Specification.

On 1 January 2019, the initial 18 month period from the commencement of the former Specification ended, with the effect that since that date sponsors of OTC and registered

complementary medicines have only had the option under the former Specification of complying with Schedule 2 to that instrument (RASML 4) in relation to their medicine labels.

This Specification repeals the former Specification and specifies a new edition of the RASML known as RASML 5. RASML 5 incorporates a number of new changes as compared with RASML 4. These changes consist of the introduction of new advisory statements for the following substances:

- alimemazine (trimeprazine), brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine and triprolidine for oral use, which are sedating antihistamines (e.g. "Do not give to children under 2 years of age");
- benzocaine, an anaesthetic for topical oral use;
- fennel oil; and
- oral fluconazole and topical miconazole, which are antifungal agents.

In addition, this Specification provides that the former Specification continues to apply for the first 18 months following the Specification's commencement notwithstanding the repeal of the former Specification. In effect, this means that sponsors will have the option of using the statements specified in either Schedule 1 to the Specification (RASML 5) or Schedule 2 to the former Specification (RASML 4) for the duration of the transition period.

On 1 September 2020, the 18 month transition period will end, with the effect that from that date, sponsors will only have the option of complying with Schedule 1 to the Specification (RASML 5) in relation to their medicine labels.

Consultation

Public comment was invited on the proposed amendments in RASML 5, as follows:

- sedating antihistamines: proposed additional advisory statements for medicines alimemazine (trimeprazine), brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine and triprolidine for oral use—the invitation to comment in relation to these changes was advertised on the TGA website (www.tga.gov.au) from 24 May 2018, and closed on 21 June 2018. Submissions and the TGA's response were published on the TGA website on 25 September 2018;
- miconazole and fluconazole: proposed advisory statements for medicines—the invitation to comment in relation to this change was advertised on the TGA website (www.tga.gov.au) from 24 May 2018, and closed on 21 June 2018. Submissions and the TGA's response were published on the TGA website on 14 September 2018; and
- benzocaine: proposed advisory statements for medicines—the invitation to comment in relation to this change was advertised on the TGA website (www.tga.gov.au) from 18 September 2018, and closed on 16 October 2018. Submissions and the TGA's response were published on the TGA website on 14 January 2019.

Submissions were received in relation to each of the above main changes, with the submissions supporting the proposals and setting out some suggestions for rewording of

proposed advisory statements in some cases. Several of the suggestions were incorporated into the final advisory statements.

Public consultation was not held in regard to the inclusion of the new advisory statement ("Keep out of reach of children") for fennel oil in Schedule 2 to the Specification. This advisory statement is included in accordance with requirements for fennel oil that were included, following public consultation, in the Poisons Standard on 1 June 2017.

The Office of Best Practice Regulation ("OBPR") advised that a regulation impact statement was not required in relation to the Specification (OBPR reference: 24796).

Incorporation by reference

The Specification specifies advisory statements by reference to certain matters contained in the "Poisons Standard", which is defined in the instrument as the current Poisons Standard as in force on the commencement of the instrument.

The current Poisons Standard is relevantly defined in the Act as the document last prepared by the Secretary under paragraph 52D(2)(b) of the Act. It reflects decisions regarding the classification of medicines and poisons into different schedules, signifying the degree of risk and the control recommended to be exercised over their availability to the public.

While the current Poisons Standard is a legislative instrument, it is not subject to disallowance under section 42 of the *Legislation Act 2003* ("the Legislation Act").

In accordance with section 14 of the Legislation Act, the Poisons Standard is incorporated as in force at the time of the Specification's commencement - that being, 1 March 2019. The current Poisons Standard commenced on 1 February 2019 and is freely available from the Federal Register of Legislation at www.legislation.gov.au.

Details of the Specification are set out in **Attachment A**.

The Specification 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**.

The Specification is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 1 March 2019.

Attachment A

Details of the *Therapeutic Goods* (*Medicines Advisory Statements) Specification 2019*

Section 1 Name

This section provides that the name of the Specification is the *Therapeutic Goods (Medicines Advisory Statements) Specification 2019* ("the Specification").

Section 2 Commencement

This section provides that the Specification commences on 1 March 2019.

Section 3 Authority

This section provides that the legislative authority for making the Specification is subsection 3(5A) of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 Definitions

This section sets out definitions for a number of terms used in the Specification, for example "dermal use", "essential oils" and "signal heading".

This section also notes that a number of terms used in the Specification have the meaning given to them in subsection 3(1) of the Act, including "label" and "medicine".

Section 5 Interpretation

This section sets out provisions to assist in the interpretation of the Specification.
In particular, subsection 5(1) provides that unless the contrary intention appears, a reference to a substance in the Specification includes the items identified in paragraphs 5(1)(a) – (f) (such as the substance as prepared from natural sources or artificially), but does not include the items identified in paragraphs 5(1)(g) – (i) (including a preparation or product included in Appendix A of the Poisons Standard).

This section also clarifies the intended meaning in the Specification of references to a concentration, strength or quantity, the intended meaning of the expression "one per cent" and the meaning of a small number of symbols used in Schedules 1 and 2 to the Specification.

Section 6 Application

This section makes it clear that the Specification applies to a medicine that is a medicine in a prescribed class. The term "medicine in a prescribed class" is defined in section 4 of the Specification to mean a medicine that is included in a class of medicine prescribed by the *Therapeutic Goods Regulations 1990* ("the Regulations") for the purposes of paragraph 3(5)(ca) of the Act. Under regulation 3AA of the Regulations, such medicines are, principally, over the counter ("OTC") medicines and registered complementary medicines.

Section 7 Medicines advisory statements

This section provides that, subject to this section and section 8, the advisory statements mentioned in column 3 of the table in Schedule 1 are specified for the purposes of paragraph 3(5)(ca) of the Act in relation to a medicine that includes a substance described in column 1 of the corresponding row and meets the conditions described in column 2. Subject to subsection 7(2) and section 8, this has the effect that the advisory statements in column 3 of the table must be contained on the label of such a medicine.

Subsection (2) further provides that the advisory statements mentioned in Schedule 1, if varied or (where more than one such statement applies) combined to form a simple sentence on the label of a medicine in a prescribed class in a manner that does not change the intent of the advisory statement, are also specified for the purposes of paragraph 3(5)(ca) of the Act.

Section 8 Transitional arrangements

This section provides that between the commencement of the Specification on 1 March 2019 and 31 August 2020 ("the transition period"), a sponsor of a medicine to which the Specification applies may comply with the requirements in Schedule 2 to the *Medicines Advisory Statements Specification 2017* ("the former Specification"), instead of those in Schedule 1 to this instrument, in relation to the inclusion of advisory statements on their medicine labels. In effect, this means that sponsors will have the option of relying on either Schedule 1 to the Specification or Schedule 2 to the former Specification during this period.

This section also notes that from 1 September 2020, a sponsor of a medicine to which the Specification applies must comply with the requirements in Schedule 1 to this instrument, in relation to the inclusion of applicable advisory statements on their medicine labels specified in that Schedule.

Section 9 Repeals

This section provides that each instrument that is specified in Schedule 3 to the Specification is repealed as set out in the applicable items in that Schedule.

Schedule 1 Required Advisory Statements for Medicine Labels No.4

This Schedule specifies advisory statements for applicable medicines, based on the edition of the TGA document *Required Advisory Statements for Medicine Labels* ("RASML") known as RASML 5.

Schedule 2 Repeals

This Schedule repeals the whole of the *Medicines Advisory Statements Specification 2017*.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Therapeutic Goods (Medicines Advisory Statements) Specification 2019

This disallowable 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* (*Medicines Advisory Statements) Specification 2019* ("the instrument") is made by the Minister under subsection 3(5A) of the Act to specify for the purposes of paragraph 3(5)(ca) of the Act, advisory statements that are required to be set out on the label of medicines that are included in a class of medicines prescribed by the regulations. This has the effect that if the label of such a medicine does not contain an advisory statement identified in the Specification in relation to it, the medicine's presentation will be unacceptable.

Under regulation 3AA of the *Therapeutic Goods Regulations 1990* ("the Regulations"), the main kinds of medicines required to comply with the Specification are over the counter ("OTC") medicines and registered complementary medicines.

Prescription medicines, and medicines such as radiopharmaceuticals and medical gases that are not usually supplied directly to consumers, are not within the scope of the instrument. Listed complementary medicines (i.e. medicines that are listed in the Register under section 26A of the Act) are also not subject to the Specification, provided that those medicines comply with the requirements of the permissible ingredients determination made by the Minister in respect of such products under section 26BB of the Act.

The advisory statements set out in the instrument are designed to address specific risks related to the use of OTC and registered complementary medicines that have been identified by means of pharmacovigilance activities, testing, adverse event reports or other scientific or clinical information. Having advisory statements on medicine labels is designed to ensure that consumers are informed about these risks.

The need for new advisory statements to be included on the labels of these medicines may arise for a number of reasons, including the entry of new medicines into the market, the identification of new risks associated with particular medicines and "down-scheduling" of medicines in the Poisons Standard.

"Down-scheduling" refers to where the Secretary amends the Poisons Standard to move a medicine from a higher risk schedule to a lower risk schedule, meaning an affected product may then be more widely available for self-selection by consumers. Consequently, there may be a need in such circumstances for advisory statements to help consumers to self-select in an informed manner and to use such medicines safely and effectively.

The instrument repeals and replaces the previous specification, the *Medicines Advisory Statements Specification 2017*, which commenced on 1 July 2017 ("the former Specification").

As with the former Specification, the Schedule to this instrument is principally based on the latest version of the Therapeutic Goods Administration document the '*Required Advisory Statements for Medicine Labels*' ("the RASML").

Under the former Specification, medicine sponsors were required to comply with Schedule 1 to that specification for the first 18 months after it commenced on 1 July 2017 (which was based on the edition of the RASML known as RASML 3), but could also elect to comply with Schedule 2 to the former Specification during that period (which was based on the edition of the RASML known as RASML 4). After that initial 18 month period, sponsors were required under the former Specification to comply with Schedule 2 to the former Specification.

On 1 January 2019, the initial 18 month period from the commencement of the former Specification ended, with the effect that since that date sponsors of OTC and registered complementary medicines have only had the option under the former Specification of complying with Schedule 2 to that specification (RASML 4) in relation to their medicine labels.

This instrument repeals the former Specification and specifies a new edition of the RASML known as RASML 5. RASML 5 incorporates a number of new changes as compared with RASML 4. These changes consist of the introduction of new advisory statements for the following substances:

- alimemazine (trimeprazine), brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine and triprolidine for oral use, which are sedating antihistamines (e.g. "Do not give to children under 2 years of age");
- benzocaine, an anaesthetic for topical oral use;
- fennel oil; and
- oral fluconazole and topical miconazole, which are antifungal agents.

In addition, this instrument provides that the former Specification continues to apply for the first 18 months following the instrument's commencement notwithstanding the repeal of the former Specification. In effect, this means that sponsors will have the option of using the statements specified in either Schedule 1 to the instrument (RASML 5) or Schedule 2 to the former Specification (RASML 4) for the duration of the transition period.

On 1 September 2020, the 18 month transition period will end, with the effect that from that date, sponsors will only have the option of complying with Schedule 1 to the instrument (RASML 5) in relation to their medicine labels.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR").

Article 12 of the IESCR promotes the right of all individuals 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.

The instrument takes positive steps to promote the right to health by ensuring the safe and proper use of OTC and registered complementary medicines. The instrument seeks to protect and promote the health of Australians by ensuring that these medicines carry advisory statements that highlight important safety information for consumers. The instrument particularly supports the right to health in relation to the quality of scientifically approved medicines that reflect up to date information about safe use (e.g. required advisory statements relating to medicines that should not be used by persons who are pregnant, or statements highlighting that consumers should consult their doctor or pharmacist before using a product if those persons are regularly taking other medicines as well).

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and does not raise any human rights issues.

Jane Cook, delegate of the Minister for Health