

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines Advisory Statements) Specification 2021

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 Act is administered by the Therapeutic Goods Administration (“the TGA”), within the Australian Government Department of Health.

The *Therapeutic Goods (Medicines Advisory Statements) Specification 2021* (“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 *Therapeutic Goods (Medicines Advisory Statements) Specification 2019* (“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 medicines that comply with the permissible ingredients determination made by the Minister under section 26BB of the Act in relation to such medicines.

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 such 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 medicines that comply with the permissible ingredients determination made under section 26BB of the Act principally 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 therapeutic goods have ingredients, components or characteristics that they do not have, or where the label of such 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.

The acceptability of the presentation of a medicine is one of the criteria against which a medicine is evaluated for registration or (for certain medicines) listing in the Register (paragraphs 25(1)(e) and 26(1)(e) of the Act refer) and may be a basis for the cancellation of registration or listing (paragraph 30(2)(aa) of the Act refers).

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 medicines (in practice, medicines that are listed in the Register under section 26A or 26AE of the Act) are also not subject to the Specification, provided that they 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 Specification repeals and replaces the *Therapeutic Goods (Medicines Advisory Statements) Specification 2019* (“the former Specification”), which commenced on 1 March 2019.

The main changes reflected in the Schedule to the Specification (Required Advisory Statements for Medicine Labels 6) in comparison to the Schedule to the former Specification (Required Advisory Statements for Medicine Labels 5), include:

- the introduction of new advisory statements for the substances lidocaine (lignocaine), melatonin, menthol, methyl salicylate, mometasone and triptans (eletriptan, rizatriptan, sumatriptan, zolmitriptan);
- the removal of, or variations to, advisory statements for the substances sedating antihistamines (alimemazine, diphenhydramine, doxylamine and promethazine), chlorhexidine and codeine; and
- more minor corrections or clarifications in relation to the substances hydrocortisone, ibuprofen (Entry 3) and pyridoxine (Entry 2).

The Specification also includes transitional arrangements under which the former Specification, despite its repeal, continues to apply for the duration of the specified transition period, being the 18-month period from the commencement of the Specification on 1 January 2022 to 30 June 2023.

In effect, this means that medicine sponsors and manufacturers will have the option of using the statements specified in either the Specification or the former Specification for the duration of the transition period.

On 30 June 2023, the 18 month transition period will end, with the effect that from 1 July 2023, sponsors will only have the option of complying with the Specification in relation to their medicine labels.

Consultation

Public comment was invited on the following proposed amendments:

- lidocaine (lignocaine) - invitation to comment in relation to changes to RASML was advertised on the TGA website (www.tga.gov.au) from 6 April 2021 and closed on 18 May 2021. Submissions and the TGA's response were published on the TGA website on 16 November 2021;
- melatonin - invitation to comment in relation to new RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 August 2021 and closed on 17 September 2021. Submissions and the TGA's response were published on the TGA website on 16 November 2021;
- menthol - invitation to comment in relation to new RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 April 2021 and closed on 18 May 2021. Submissions and the TGA's response were published on the TGA website on 16 November 2021;
- methyl salicylate - invitation to comment in relation to new RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 April 2021 and closed on 18 May 2021. Submissions and the TGA's response were published on the TGA website on 16 November 2021;
- mometasone - invitation to comment in relation to new RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 August 2021 and closed on 17 September 2021. Submissions and the TGA's response were published on the TGA website on 16 November 2021;
- triptans (eletriptan, rizatriptan, sumatriptan, zolmitriptan) - invitation to comment in relation to new RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 August 2021 and closed on 17 September 2021. Submissions and the TGA's response were published on the TGA website on 17 November 2021;
- sedating antihistamines (alimemazine, diphenhydramine, doxylamine and promethazine - invitation to comment in relation to changes to RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 April 2021 and closed on 18 May 2021. Submissions and the TGA's response were published on the TGA website on 16 November 2021; and
- chlorhexidine, hydrocortisone, ibuprofen - invitation to comment in relation to changes to RASML warnings was advertised on the TGA website (www.tga.gov.au) from 6 August 2021 and closed on 17 September 2021. Submissions and the TGA's response were published on the TGA website on 17 November 2021.

Submissions were received in relation to each of the above proposed amendments, with most generally supportive and some suggestions for changes. Several of these suggestions were incorporated into the final advisory statements that are set out in Schedule 1 to the Specification.

The Office of Best Practice Regulation ("OBPR") advised that a regulation impact statement was not required in relation to the Specification (reference: OBPR21-01155).

Incorporation by reference

The Specification specifies certain advisory statements by reference to matters contained in the current Poisons Standard. 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. 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”). Subsection 52F(1) of the Act expressly allows for the dynamic incorporation of the current Poisons Standard by a legislative or notifiable instrument made under the Act, despite subsection 14(2) of the Legislation Act. The current Poisons Standard is incorporated as in force from time to time, in accordance with subsection 52F(1) of the Act. The current Poisons Standard is freely available 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 January 2022.

Details of the *Therapeutic Goods (Medicines Advisory Statements) Specification 2021*

Section 1 - Name

This section provides that the name of the Specification is the *Therapeutic Goods (Medicines Advisory Statements) Specification 2021* (“the Specification”).

Section 2 - Commencement

This section provides that the Specification commences on 1 January 2022.

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 words”.

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 “current Poisons Standard”, “label”, “medicine” and “supply”.

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) to (f) (such as the substance as prepared from natural sources or artificially), but does not include the items identified in paragraphs 5(1)(g) to (i) (such as a preparation or product included in Appendix A of the current Poisons Standard).

Subsection 5(2) clarifies, that unless a contrary intention appears, the intended meaning in the Specification of references to a concentration, strength or quantity, and the intended meaning of the expression “1%”.

Subsection 5(3) sets out the meaning of a small number of symbols used in Schedule 1 to the Specification.

Subsection 5(4) sets out a table of the signal word or words for substances included in a schedule to the current Poisons Standard for the definition of “signal words” in section 4.

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

Subsection 7(1) provides that, subject to subsection 7(2), the advisory statements mentioned in column 4 of an item in the table in Schedule 1 to the Specification are specified in relation to a medicine in a prescribed class that contains the substance described in column 2 of that item, in the circumstances set out in column 3 of that item, for the purposes of paragraph 3(5)(ca) of the Act. Subject to subsection 7(2), this has the effect that the advisory statements in column 4 of an item the table must be contained on the label of such a medicine.

Subsection 7(2) provides that the following advisory statements are specified in relation to a medicine in a prescribed class for the purposes of paragraph 3(5)(ca) of the Act, as an alternative to the advisory statements specified in relation to the medicine by subsection 7(1):

- the advisory statements specified by subsection 7(1) in relation to the medicine, as varied in a manner that does not change the intent of the advisory statements; or
- if more than one such statement is specified by subsection 7(1) 1 in relation to the medicine, the relevant statements combined to form a simple sentence in a manner that does not change the intent of each of the advisory statements.

This section also notes that the requirements only apply if the substance is included in the medicine as an active ingredient, unless specified otherwise in Schedule 1 to the Specification.

Section 8 - Transitional arrangements

This section has the effect that between the commencement of the Specification on 1 January 2022 and 30 June 2023 (“the transition period”) a sponsor of a medicine to which the Specification applies may comply with the requirements in Schedule 1 to the *Therapeutic Goods (Medicines Advisory Statements) Specification 2019* (“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 1 to the former Specification during the transition period.

This section also notes that once the transition period ceases (i.e. from 1 July 2023), the label of a medicine to which the Specification applies must comply with the requirements in Schedule 1 to this instrument.

Section 9 - Repeals

This section repeals the former Specification, the *Therapeutic Goods (Medicines Advisory Statements) Specification 2019*.

Schedule 1—Required Advisory Statements for Medicine Labels No. 6

This Schedule (Required Advisory Statements for Medicine Labels 6) specifies advisory statements for applicable medicines.

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 2021

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 2021* (“the instrument”) is made by the Minister under subsection 3(5A) of the *Therapeutic Goods Act 1989* (“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. The acceptability of the presentation of a medicine is one of the criteria against which a medicine is evaluated for registration or (for certain medicines) listing in the Register (paragraphs 25(1)(e) and 26(1)(e) of the Act refer) and may be a basis for the cancellation of registration or listing (paragraph 30(2)(aa) of the Act refers).

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 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.

The Specification repeals and replaces the *Therapeutic Goods (Medicines Advisory Statements) Specification 2019* (“the former Specification”), which commenced on 1 March 2019. The main changes reflected in the Schedule to the Specification (Required Advisory Statements for Medicine Labels 6) in comparison to the Schedule to the former Specification (Required Advisory Statements for Medicine Labels 5), include:

- the introduction of new advisory statements for the substances lidocaine (lignocaine), melatonin, menthol, methyl salicylate, mometasone and triptans ((eletriptan, rizatriptan, sumatriptan, zolmitriptan);

- the removal of, or variations to, advisory statements for the substances sedating antihistamines (alimemazine, diphenhydramine, doxylamine and promethazine), chlorhexadine and codeine; and
- more minor corrections or clarifications in relation to the substances hydrocortisone, ibuprofen (Entry 3) and pyridoxine (Entry 2).

The Specification also includes transitional arrangements under which the former Specification, despite its repeal, continues to apply for the duration of the specified transition period, being the 18 month period from the commencement of the Specification on 1 January 2022 to 30 June 2023. In effect, this means that medicine sponsors and manufacturers will have the option of using the statements specified in either the Specification or the former Specification for the duration of the transition period. On 30 June 2023, the 18 month transition period will end, with the effect that from 1 July 2023, sponsors will only have the option of complying with the Specification 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 ICESCR 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.