EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Restricted Medicines) 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.

Subsections 3(2A) and (2B) of the Act provide that the Minister may specify, by legislative instrument, medicines and classes of medicine for the purposes of paragraphs (a) and (b), respectively, of the definition of 'restricted medicine' in subsection 3(1) of the Act. Restricted medicine is defined as meaning a medicine specified in an instrument under subsection 3(2A) or a medicine included in a class of medicine specified in an instrument under subsection 3(2B) of the Act.

The purpose of this instrument is to specify medicines or classes of medicine under these provisions for the purposes of the definition of 'restricted medicine' in subsection 3(1) of the Act.

The *Therapeutic Goods (Restricted Medicines) Specification 2021* ("the Specification") is made under subsections 3(2A) and (2B) of the Act and specifies medicines and classes of medicine that fall within the meaning of 'restricted medicine', so that applications for the registration of the specified medicines in the Australian Register of Therapeutic Goods ("the Register") are accompanied by product information for the medicine in the form approved by the Secretary. The practical effect of the Specification is that higher-risk medicines (predominantly those containing a substance in Schedules 3, 4, 8 or 9 to the current Poisons Standard) are registered with product information approved by the Secretary, which is then made accessible to prescribers to ensure safe prescribing practice.

The Specification repeals and replaces the *Restricted Medicine Specification 2011* ("the Former Specification"), which is due to sunset on 1 October 2021 under the sunsetting provisions of the *Legislation Act 2003*. The Specification replaces the Former Specification without substantive changes and continues to specify the same medicines and classes of medicine for the purposes of the definition of 'restricted medicine' in subsection 3(1) of the Act.

Background

The Specification identifies medicines and classes of medicine that are restricted medicines for the purposes of the definition of 'restricted medicine' in subsection 3(1) of the Act.

Paragraph 23B(2)(e) of the Act requires an application under section 23 for the registration of a medicine in the Register to be accompanied by product information for the medicine in the form approved by the Secretary under section 7D of the Act. An application for the registration of a restricted medicine that is not accompanied by product information would not pass preliminary assessment under section 23B of the Act and would therefore not be evaluated.

Product information in relation to therapeutic goods means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations

of the goods (subsection 3(1) of the Act refers). Under subparagraph 25(1)(da)(i) of the Act, the product information provided by an applicant for registration is one of the matters that the Secretary must evaluate for the purpose of determining whether the medicine should be included in the Register.

Under subsections 25AA(1) and (1A) of the Act, the Secretary must approve an applicant's product information if a decision is made to register a restricted medicine under subsection 25(3) of the Act and the product information reflects the basis on which that decision was made.

The medicines or classes of medicine that are specified as restricted medicines are set out in Schedule 1 to the Specification. The effect of the inclusion of medicines or classes of medicine in Schedule 1 is that an application for registration of one of those medicines must be accompanied by product information.

Consultation

The Office of Best Practice Regulation advised that a regulation impact statement was not required in relation to the making of the Specification (OBPR ID 43510 and 44512).

In July 2021, the TGA wrote to a number of stakeholders, including Medicines Australia, Generic and Biosimilar Medicines Association, Consumer Health Products Australia and Complementary Medicines Australia to seek feedback on the suitability of the medicines specified as restricted medicines. Two (2) responses were received which supported the proposal to remake the Former Specification without altering existing arrangements.

The Specification is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*. 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 commences on 30 September 2021.

Attachment A

Details of the *Therapeutic Goods (Restricted Medicines) Specification 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Restricted Medicines) Specification 2021*.

Section 2 – Commencement

This section provides that the instrument commences on 30 September 2021.

Section 3 – Authority

This section provides that the legislative authorities for making the instrument are subsections 3(2A) and 3(2B) of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, 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. This instrument is made in accordance with that provision.

Section 4 – Definitions

This section provides the definition of terms used in the instrument. 'Act' means the *Therapeutic Goods Act 1989* and 'Regulations' means the *Therapeutic Goods Regulations 1990*.

This section also notes that some expressions used in the instrument, for example, 'current Poisons Standard' and 'restricted medicine', are defined in the Act and therefore have the same meaning as in the Act.

Section 5 – Restricted medicines

Subsection 5(1) is made for the purposes of subsection 3(2A) of the Act. It provides that a medicine mentioned in an item in the table in Schedule 1 is specified for the purposes of paragraph (a) of the definition of 'restricted medicine' in subsection 3(1) of the Act.

Subsection 5(2) is made for the purposes of subsection 3(2B) of the Act. It provides that a medicine included in a class of medicine mentioned in an item in the table in Schedule 1 is specified for the purposes of paragraph (b) of the definition of 'restricted medicine' in subsection 3(1) of the Act.

Section 6 – Repeals

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

SCHEDULE 1 – RESTRICTED MEDICINES

The table in Schedule 1 specifies the medicines or classes of medicine that are restricted medicines. Specifically, it provides that a medicine that is a product of a kind mentioned in an

item in the table in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* ("the Regulations"), other than a product mentioned in paragraph (b) in column 2 of item 1 or item 14, is a restricted medicine. In addition, it provides that a medicine containing a substance in Schedule 3 to the current Poisons Standard is a restricted medicine.

The medicines that are products of a kind mentioned in Part 1 of Schedule 10 to the Regulations include those that contain a substance mentioned in Schedule 4 (prescription only medicine), Schedule 8 (controlled drug) and Schedule 9 (prohibited substance) to the current Poisons Standard. Because these substances are considered high risk, there are restrictions on the way they can be supplied. The medicines that are products of a kind mentioned in Part 1 of Schedule 10 to the Regulations also include vaccines, allergens and immunoglobulins. Medicines containing a substance in Schedule 3 to the current Poisons Standard are those that can be supplied without a prescription but only by a pharmacist.

Medicines described in paragraph (b) in column 2 of item 1 of the table in Part 1 of Schedule 10 to the Regulations are excluded, as that paragraph refers to substances not mentioned in Schedules 4, 8 or 9 to the current Poisons Standard but which meet the criteria for mention in any of those Schedules. If an application for registration was to be made for such a substance and, either the substance is included in any of those Schedules at any time during the evaluation process or the Secretary otherwise comes to the view that it would be appropriate for product information to be approved as part of the registration process for that medicine, the Secretary may notify the applicant to supply product information in the approved form with the application. The same applies in relation to an application for a medicine that contains a substance which is not in Schedule 3 but meets the criteria for mention in Schedule 3.

Item 14 in Part 1 of Schedule 10 to the Regulations (which currently refers to therapeutic goods referred for evaluation to the Prescription Medicines Authorisation Branch of the Therapeutic Goods Administration) is excluded because therapeutic goods would only be referred once an application for registration has already been submitted. Item 14 could not apply to a medicine at the time an application for registration for the medicine was being made.

SCHEDULE 2 – REPEALS

This Schedule specifies that the *Restricted Medicine Specification 2011* is repealed. That instrument would otherwise sunset on 1 October 2021 pursuant to the *Legislation Act 2003*.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Restricted Medicines) 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 legislative instrument

The *Therapeutic Goods (Restricted Medicines) Specification 2021* ("the instrument") is made under subsections 3(2A) and (2B) of the *Therapeutic Goods Act 1989* ("the Act"). This instrument repeals and replaces the *Restricted Medicine Specification 2011* ("the former instrument"), which is due to sunset on 1 October 2021 pursuant to the *Legislation Act 2003*.

Subsections 3(2A) and (2B) of the Act provide that the Minister may specify, by legislative instrument, medicines and classes of medicine for the purposes of paragraphs (a) and (b), respectively, of the definition of 'restricted medicine' in subsection 3(1) of the Act. Restricted medicine means a medicine specified in an instrument under subsection 3(2A) or a medicine included in a class of medicine specified in an instrument under subsection 3(2B) of the Act.

The instrument replaces the former instrument without substantive changes and continues to specify the same medicines or classes of medicine for the purposes of the definition of 'restricted medicine' in subsection 3(1) of the Act.

The instrument specifies medicines and classes of medicine mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* (except for those specified in paragraph (b) in column 2 of item 1, or item 14) and medicines containing a substance in Schedule 3 to the current Poisons Standard. Those medicines or classes of medicine specified in Schedule 1 to the instrument are medicines for which, under the Act, applications for registration in the Australian Register of Therapeutic Goods must be accompanied by product information.

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 standards of physical and mental health.

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 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 support the right to health by supporting the statutory requirement under the Act that applications for the registration of a restricted medicine be accompanied by product information. Once approved, the product information is publicly

available and benefits health practitioners and patients using restricted medicines by providing information about the safe and effective use of the medicine, including information regarding its usefulness and limitations.

Conclusion

The instrument is compatible with human rights because it maintains and supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.