EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023

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 and Aged Care ("the Department").

Section 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, and to certain organisations, bodies, or authorities. Subsection 61(1) of the Act provides that 'therapeutic goods information' means, for the purposes of the section, information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department's functions.

Subsection 61(5AA) provides that the Secretary may release to a specified person, body or authority (or one that is of a specified kind), specified kinds of therapeutic goods information, for a specified purpose. Subsection 61(5AB) relevantly provides that, for the purposes of subsection 61(5AA), the Minister may, by legislative instrument, specify a person, body or authority, the kinds of therapeutic goods information and the purposes for which the information may be released under such arrangements.

The *Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023* ("the Specification") is a legislative instrument made under subsection 61(5AB) of the Act. It specifies the kinds of therapeutic goods information that the Secretary may release to specified persons, bodies or authorities, and the purposes for which that information may be released under subsection 61(5AA) of the Act.

The Specification provides for the release of certain therapeutic goods information to Therapeutic Guidelines Ltd ("TGL") for the purpose of facilitating the publication of the specified information in the journal *Australian Prescriber* which is now published by TGL. The information specified is information about a prescription medicine that is registered in the Australian Register of Therapeutic Goods ("the Register"), and is contained in the Australian Public Assessment Report (including the attached approved Product Information) for that medicine.

Consequentially, the Specification repeals and replaces the *Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015* ("the former Specification"), which supported the sharing of information with NPS MedicineWise as the former publisher of *Australian Prescriber*.

Background

For a prescription medicine to be lawfully imported into, supplied in, or exported from, Australia, it must be registered in the Register (unless it is the subject of an exemption, approval, or authority under the Act). The sponsor of the relevant medicine is responsible for applying to the TGA for registration of the medicine in the Register, and for providing the quality, clinical and nonclinical data that must accompany such an application. This data set is evaluated by the TGA before the Secretary (or a delegate) makes a decision as to whether the medicine should be registered in the Register.

To support transparency, the TGA publishes reports for prescription medicine submission where the significance to the public is considered to be high. This report is known as an Australian Public Assessment Report ("AusPAR"). The AusPAR provides information on the steps undertaken in the

submission evaluation, the outcomes of each step and the reasons for decisions. The TGA undertakes consultation with the sponsor of a medicine during preparation of an AusPAR, which is then published on the TGA website.

The Product Information ("PI") for the registered prescription medicine is also published as an attachment to the AusPAR. A medicine's PI document provides health professionals with a summary of the quality, safety, and effectiveness of the medicine. Product Information is approved by the Secretary (or a delegate) under section 25AA of the Act. The AusPAR may also include an attached extract from the Clinical Evaluation Report.

AusPARs are published on the TGA website at www.tga.gov.au/resources/auspar.

Australian Prescriber

The *Australian Prescriber* is an independent journal published for the benefit of Australian health professionals (principally prescribers), which contains articles, features and information about medicines and other therapeutic goods. The purpose of this journal is to help health professionals to make informed choices when prescribing by making available independent, reliable, and accessible information about medicines and other therapeutic goods.

Each edition of *Australian Prescriber* features information on prescription medicines that have recently been approved by the TGA and registered on the Register. The section usually contains a description of the medicine, its indications, pharmacology, the outcome of relevant clinical trials, contraindications and precautions, and a summary of its overall likely benefit for the intended patient group.

Where available, these features take into account the material published by the TGA in the AusPAR, PI document and Clinical Evaluation Report extract for the relevant prescription medicine.

Until 2022, *Australian Prescriber* was published by NPS MedicineWise. However, from 1 January 2023, TGL became the new publisher of *Australian Prescriber*. TGL is an independent non-profit organisation established to promote the quality use of medicines.

Purpose

The purpose of the Specification is to allow the Secretary to provide TGL with information that is set out in an AusPAR (including its attachments) for a registered prescription medicine ("the specified information"), before that information is published on the TGA website.

This information would be shared with TGL in advance of the AusPAR being published on the TGA website to avoid delay in TGL publishing a feature of the relevant medicine in *Australian Prescriber*. It would allow TGL to extract the relevant parts of the specified information and prepare the *Australian Prescriber* feature ready for publication soon after the AusPAR has been published on the TGA website. Importantly, however, an AusPAR for a medicine will not be provided to TGL until it is in the form in which it will be published on the TGA website. Sponsors will be informed that the AusPAR will be provided to TGL.

The Specification therefore supports TGL being in a position to publish the specified information (or extracts of the same) in *Australian Prescriber* soon after it has been published on the TGA website. This would reduce delay in prescribers having access to information, concerning the TGA's evaluation of the relevant medicine as published in *Australian Prescriber*, to inform prescribing of suitable treatments for patients.

Consultation

TGL and Medicines Australia were informed of the proposed specification. Broader consultation on the Specification was not undertaken as the Specification has the same effect as the former Specification, but simply reflects that the *Australian Prescriber* is now published by TGL. Further, the information in *Australian Prescriber* would only be published once the AusPAR has been published on the TGA website, and the Specification imposes no additional regulatory burden on industry.

An Impact Analysis was not required in relation to the development of the Specification, as the matter of specifying kinds of therapeutic goods information under section 61 of the Act is the subject of a standing exemption from the requirement to prepare an Impact Analysis (OBPR ID15070).

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

The Specification is compatible with 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 2003* and commences the day after registration on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023* ("the Specification").

Section 2 Commencement

This section provides that the Specification commences on the day after registration on the Federal Register of Legislation.

Section 3 Authority

This section provides that the legislative authority for making the Specification is subsection 61(5AB) of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 Definitions

Section 4 provides definitions for a number of terms used in the Specification. These include 'Australian Prescriber', 'AusPAR, 'approved Production Information', 'registered prescription medicine', 'therapeutic goods information', and 'Therapeutic Guidelines Ltd'.

The note to this section also makes it clear that a number of expressions used in the Specification have the same meaning as in the Act, including 'medicine', 'Register', and 'Secretary'.

Section 5 Release of therapeutic goods information

This section provides that, for the purpose of subsection 61(5AA) of the Act, the kinds of therapeutic goods information specified in column 2 of each item of the table in Schedule 1 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

Section 6 Repeals

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

Schedule 1 – Therapeutic goods information

This Schedule specifies the kinds of therapeutic goods information, the body, and the purpose for which the information may be released, for section 5 of the Specification.

Item 1 of the table in Schedule 1 permits the Secretary to release certain information about a prescription medicine that has been registered in the Australian Register of Therapeutic Goods ("registered prescription medicine"). It specifies:

- in column 2, as the information that may be released by the Secretary — information about a registered prescription medicine that is contained in the Australian Public Assessment Report for the medicine ("the specified information");
- in column 3, as the body to which the specified information may be released — Therapeutic Guidelines Ltd (ABN 45 074 766 224) ("TGL"); and

- in column 4, as the purpose for which the specified information may be released — the facilitation of TGL's publication of the specified information in the independent journal known as *Australian Prescriber* soon after the publication of that information on the TGA website.

AusPARs do not contain any personal information, so release of information under this Specification to TGL would not include personal information.

Schedule 2 – Repeals

This Schedule provides that the *Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015* is repealed.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023

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 (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023* ("the Specification") is a legislative instrument made under subsection 61(5AB) of the Act. It specifies the kinds of therapeutic goods information that the Secretary may release to specified persons, bodies or authorities, and the purposes for which that information may be released under subsection 61(5AA) of the Act.

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Subsection 61(5AA) provides that the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB) of the Act, therapeutic goods information of a kind specified under subsection 61(5AB), for a purpose specified under that subsection. Subsection 61(5AB) relevantly provides that, for the purposes of subsection 61(5AA), the Minister may, by legislative instrument, specify a person, body or authority, the kinds of therapeutic goods information and the purposes for which the information may be released under such arrangements.

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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 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 supports the right to health by facilitating the early release of information contained in an AusPAR to TGL so that *Australian Prescriber* can be published in a timely manner, soon after the AusPAR is published on the TGA website. This would support prescribers having access to information, concerning the TGA's evaluation of the relevant medicine as published in *Australian Prescriber*, to inform prescribing of suitable treatments for patients.

Conclusion

This legislative instrument is compatible with human rights because it supports the right to health in Article 12 of the ICESCR.