

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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 therapeutic goods information to the public, and 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) of the Act provides that the Secretary may release to a person, body or authority that is specified (or is of a kind specified), 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 (or kinds of persons, bodies or authorities), the kinds of therapeutic goods information and the purposes for which the information may be released under such arrangements.

The *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020* (“the Principal Specification”) is made under subsection 61(5AB) of the Act. The Principal Specification enables the Secretary to release certain therapeutic goods information about a clinical trial involving therapeutic goods, other than medical devices, to the approving authority for the trial and the ethics committee responsible for approving the procedural protocol and monitoring the conduct of the trial. The purpose of the Principal Specification is to better ensure that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations.

The *Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024* (“the Amendment Specification”) is a legislative instrument made under subsection 61(5AB) of the Act. It amends the Principal Specification to update the kinds of therapeutic goods information that may be released by the Secretary under the Specification to include information about clinical trials involving medical devices. The effect of the amendment is to enable the release of information about the conduct of clinical trials involving medical devices to the approving authority and the responsible ethics committee for the trial. This amendment gives effect to the extension of the Good Clinical Practice Inspection Program (“GCPIP”) to include clinical trials involving medical devices, and improves the TGA’s oversight of medical device clinical trials by ensuring information about the conduct of clinical trials involving medical devices, including any adverse events, is shared with the approving authority and responsible ethics committee.

Background

Clinical trials in relation to therapeutic goods that are medicines or biologicals may be approved by the Secretary under paragraph 19(1)(b) or 32CK(1)(e) of the Act (respectively), or conducted pursuant to a notification made in accordance with the conditions specified in item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (“the Regulations”) (provided other specified conditions are complied with in relation to the trial). Clinical trials in relation to therapeutic goods that are medical devices may be approved by the Secretary under section 41HB of the Act, or conducted pursuant to a notification made in accordance with the conditions specified in item 2.3 in Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”) (provided other specified conditions are complied with in relation to the trial).

Schedule 1 to the Principal Specification specifies the kinds of therapeutic goods information about the conduct of a clinical trial that may be released by the Secretary to the approving authority and the responsible ethics committee for the trial, for the purpose of better ensuring that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations.

In particular, the kinds of therapeutic goods information that may be released is information obtained by an authorised officer exercising powers in accordance with regulation 12AC of the Regulations in relation to a clinical trial, including information that relates to the compliance of the trial with the National Statement, the Practice Guideline, and the procedural protocol approved for the trial by the responsible ethics committee. Regulation 12AC empowers an authorised officer to enter, search and inspect the site of a clinical trial for the purpose of determining the compliance of the trial with requirements under the Act, the Regulations and other subordinate legislation.

The approving authority is the person or body at whose site a clinical trial is being conducted (or conducted in part, for a clinical trial conducted at more than one site) and that is responsible for the governance of the trial (other than in relation to those matters within the remit of the responsible ethics committee) at that site. The responsible ethics committee is the ethics committee that is responsible for approving the procedural protocol and monitoring the conduct of the trial at each trial site.

In practice, the information intended for release under the Principal Specification is principally the inspection report and associated documents prepared by an authorised officer following the exercise of powers under regulation 12AC of the Regulations. Importantly, this information does not include any personal or sensitive information in relation to participants of the clinical trial.

Purpose

Good Clinical Practice (“GCP”) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. Compliance with GCP is actively monitored and enforced by the TGA through the GCPIP. The GCPIP enables the TGA to conduct physical inspections of clinical trial sites to ensure that trials are being conducted in accordance with GCP standards. Compliance with GCP provides assurance that the rights, safety, and well-being of clinical trial participants are protected and that the trial data generated are credible.

Currently, the Principal Specification supports the sharing of information obtained during a GCP inspection about the conduct of a clinical trial involving therapeutic goods (other than medical devices) to the approving authority for the trial (“the approving authority”) and the ethics committee responsible for approving the procedural protocol and monitoring the conduct of the trial (“the responsible ethics committee”).

The TGA’s GCPIP was expanded in November 2023 to include the inspection of clinical trials involving medical devices (under regulation 7.4 of the MD Regulations). It is important for the TGA to be able to share information about the conduct of clinical trials involving medical devices with the approving authority and responsible ethics committee.

The purpose of the Amendment Specification is to amend the Principal Specification to support the release of information relating to clinical trials involving medical devices. The kind of information, kinds of persons or bodies and purpose remains unchanged. The effect of the amendments is principally to include clinical trials involving medical devices in the Principal Specification.

Consultation

Between August 2022 and September 2022, the TGA consulted publicly on the proposal to expand the GCPIP to medical device clinical trials. Sixty-six responses were received from various

stakeholders including, sponsors, manufacturers, research organisations, Human Research Ethics Committees (HRECs), consumers and state and territory governments. Subsequent, targeted consultations were also undertaken between November 2022 and May 2023 with HRECs, state and territory governments and other respondents to the public consultation, in relation to requiring sponsors to provide information to the Secretary of the Department about the safety or performance of the medical device used in the trial. No concerns were raised with the proposals.

An impact analysis was not required in relation to the development of the Amendment 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 impact analysis process (OPBR ID: 15070).

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

The Amendment 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 Amendment Specification is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024* (“the Amendment Specification”).

Section 2 – Commencement

This section provides that the Amendment Specification 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 Amendment Specification is subsection 61(5AB) 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 also made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument specified in a Schedule to the Amendment Specification is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule sets out amendments to the *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2024* (“the Principal Specification”).

Item 1 – Section 4

This item amends section 4 to introduce a definition referring to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”).

Item 2 – Section 4 (definition of *relevant authorised officer*)

This item replaces the definition of ‘relevant authorised officer’ in section 4, with the new definition including a reference to regulation 7.4 of the MD Regulations, which enables authorised persons to inspect a clinical trial involving medical devices.

Item 3 – Schedule 1 (table item 1, column 2)

This item amends item 1, column 2 of the table in Schedule 1 to the Principal Specification to remove the words “other than medical devices”. In effect, this amendment supports the Secretary in releasing information about the conduct of a clinical trial involving medical devices to the approving authority and the responsible ethics committee for the trial, for the purpose of better ensuring that clinical trials involving medical devices are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations.

The information that would be released under the instrument would not include any personal or sensitive information in relation to participants of the clinical trial. The information that may be released under the instrument may contain personal information in the form of the names of research staff involved in a clinical trial and the name of an authorised officer who conducted an

inspection of the site of the relevant clinical trial. The release of this information is considered to be reasonable, necessary and proportionate in the circumstances because, in accordance with the instrument, the information could only be released:

- to the approving authority and the responsible ethics committee of the clinical trial, both of which already have the information in their possession; and
- for the purpose of ensuring that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations.

The TGA, as part of the Department, is an APP entity for the purposes of the *Privacy Act 1988* (“the Privacy Act”). Any use and disclosure would be consistent with the Privacy Act. The collection and use of the information for this purpose by the TGA, and its disclosure, is critically important to ensuring that the approving authority and the responsible ethics committee for a clinical trial are informed about any compliance concerns or issues that may be identified in relation to a clinical trial involving medical devices. This will enable safety concerns that arise during a clinical trial involving medical devices to be addressed more promptly, and therefore better protect the health and safety of clinical trial participants and operators.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024

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

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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 (“ICESCR”); and
- the right to privacy in Article 17 of the International Covenant on Civil and Political Rights (“ICCPR”).

Right to health

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 takes positive steps to promote the right to health by ensuring that the approving authority and the responsible ethics committee for a clinical trial are better informed about any compliance concerns or issues that may be identified in relation to a clinical trial involving medical devices. This will enable safety concerns that arise during a clinical trial involving medical devices to be addressed more promptly, and therefore promote the right to health by better protecting the health and safety of clinical trial participants and operators.

Right to privacy

Article 17 of the ICCPR prohibits the arbitrary or unlawful interference with the privacy of a person and provides a right to protection of the law against such interference. In *CCPR General Comment No. 16: Article 17 (Right to Privacy), The Right to Respect of Privacy, Family, Home and Correspondence, and Protection of Honour and Reputation* (1988), the United Nations Human Rights Committee states that the terms “unlawful” and “arbitrary” mean that no interference can take place except in cases envisaged by the law, and even in those cases, the interference must be in accordance with the provisions, aims and objectives of the ICCPR and reasonable in the particular circumstances.

The information that would be released under the instrument would not include any personal or sensitive information in relation to participants of the clinical trial. The information that may be released under the instrument may contain personal information in the form of the names of research staff involved in a clinical trial and the name of an authorised officer who conducted an inspection of the site of the relevant clinical trial. The release of this information is considered to be reasonable, necessary and proportionate in the circumstances because, in accordance with the instrument, the information could only be released:

- to the approving authority and the responsible ethics committee of the clinical trial, both of which already have the information in their possession; and
- for the purpose of ensuring that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations.

As such, the disclosure of the information would not be an arbitrary or unlawful interference with a person's privacy under Article 17 of the ICCPR, as the disclosure would be reasonable given it is appropriate and justified. The disclosure would be necessary and proportionate to the objective of ensuring that clinical trials are conducted in a safe and lawful manner.

The TGA, as part of the Department, is an APP entity for the purposes of the *Privacy Act 1988* ("the Privacy Act"). Any use and disclosure would be consistent with the Privacy Act. The collection and use of the information for this purpose by the TGA, and its disclosure, is critically important to ensuring that the approving authority and the responsible ethics committee for a clinical trial are informed about any compliance concerns or issues that may be identified in relation to a clinical trial involving medical devices. This will enable safety concerns that arise during a clinical trial involving medical devices to be addressed more promptly, and therefore better protect the health and safety of clinical trial participants and operators.

Conclusion

This legislative instrument is compatible with human rights. The instrument promotes the right to health, and to the extent the instrument may limit human rights, those limitations are reasonable, necessary and proportionate.