EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020

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.

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) 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.

The *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020* ("the Specification") is a legislative instrument made under subsection 61(5AB) of the Act. The Specification repeals and replaces the *Therapeutic Goods (Clinical Trial Inspections) Specification 2020* ("the former Specification"), with the principal purpose of clarifying that the *National Statement on Ethical Conduct in Human Research* published by the National Health and Medical Research Council ("the National Statement"), and the *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)* published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) ("the Practice Guideline"), are incorporated as in force or existing at the time the Specification commences, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003* ("the Legislation Act"). The National Statement and the Practice Guideline are defined accordingly in section 4 of the Specification.

The Specification does not otherwise introduce any substantive changes to the former Specification with respect to the release of specified kinds of therapeutic goods information to specified persons, bodies or authorities, for specified purposes. As such, consistent with the former Specification, the 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 ("the approving authority") and the ethics committee responsible for approving the procedural protocol and monitoring the conduct of the trial ("the responsible ethics committee") 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.

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 provided that conditions specified in item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* ("the Regulations") are complied with in relation to the trial.

Schedule 1 to the 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.

In practice, the information intended for release under the 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.

A number of ethical and legal obligations and guidelines also apply to clinical trials to protect personal information of trial participants, including ethical principles founded in the Declaration of Helsinki first adopted by the 18th World Medical Association General Assembly in 1964. These principles are reflected in the National Statement and the Practice Guideline.

For example, the National Statement provides that researchers should adopt methods to reduce the risk of identification of participants during collection, analysis, and storage of data and information, and by further ensuring that the identity of participants cannot be reasonably ascertained in any publication, unless the participant has agreed to the identification. The Practice Guideline also provides, for example, that the confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements. The National Statement and the Practice Guideline also provide a number of requirements for consent agreements with clinical trial participants including in relation to the use and handling of personal information.

However, while the personal or sensitive information of clinical trial participants would not be released under the Specification, the names of the research staff involved in the clinical trial and the name of the authorised officer who conducted the inspection may be included in the information released. The release of this information is reasonable, necessary and proportionate in the circumstances because, in accordance with the provisions of the Specification, the names of the research staff and authorised officer could only be released to the approving authority and the responsible ethics committee of the clinical trial, both of which already have this information in their possession, and further, it could only be released 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.

Incorporation by reference

The Specification incorporates by reference the National Statement (*National Statement on Ethical Conduct in Human Research)* and the Practice Guideline (*Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*).

The purpose of the National Statement is to promote ethically good human research. The National Statement clarifies the responsibilities of the institutions and researchers for the ethical design, conduct and dissemination of results of human research, and review bodies in the ethical review of research. The National Statement sets national standards for use by any individual, institution or

organisation conducting human research. The National Statement is published by the National Health and Medical Research Council and is available for free on the internet at www.nhmrc.gov.au.

The Practice Guideline is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials. The Practice Guideline is published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The Practice Guideline is available for free on the internet at www.ich.org, and may also be accessed through the TGA website at www.tga.gov.au.

Both documents are incorporated as in force or existing at the time the Specification commences in accordance with paragraph 14(1)(b) of the Legislation Act.

Consultation

Extensive consultation was conducted in relation to the preparation of the former Specification. The TGA published a consultation paper, *Good Clinical Practice (GCP) Inspections Program* in January 2019 seeking submissions on a proposal to introduce a domestic good clinical practice ("GCP") inspection program for clinical trials conducted in Australia. The paper included consideration of a proposal to release therapeutic goods information obtained by authorised officers, in the course of inspecting clinical trials, to approving authorities and responsible ethics committees.

In response to the consultation, the TGA received a number of submissions from a diverse range of stakeholders. The majority of submissions indicated support and agreement for the introduction of a pilot GCP inspections program and the proposed establishment of a routine GCP inspections program. In addition, the majority of submissions supported the release of therapeutic goods information obtained by authorised officers in the course of clinical trial inspections to approving authorities and responsible ethics committees.

Given the Specification merely clarifies the incorporation of documents by reference and does not otherwise make any substantive changes, the rule-maker considered, in accordance with section 17 of the Legislation Act, that further consultation was not necessary or appropriate in the circumstances.

A regulation impact statement 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 regulation impact statement process (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 and commences on the day after registration on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020* ("the Specification").

Section 2 – Commencement

This section provides that the 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 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 – Definitions

This section provides the definitions of certain terms used in the Specification. In particular, this section defines the 'National Statement' as the *National Statement on Ethical Conduct in Human Research* published by the National Health and Medical Research Council, as in force or existing at the commencement of the Specification, and 'Practice Guideline' as the *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)* published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), as in force or existing at the commencement of the Specification.

This section also defines 'approving authority' as a person or body at whose site a clinical trial is being conducted (or conducted in part, for a clinical trial that is being conducted at more than one site), and that is responsible for the governance of the clinical trial (other than in relation to those matters within the remit of the responsible ethics committee), at that site.

Section 5 – Release of therapeutic goods information

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

Section 6 – Repeals

This section provides that the instruments specified in Schedule 2 are 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 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.

Specifically, 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 *Therapeutic Goods Regulations 1990* in relation to the clinical trial, including information that relates to the compliance of the relevant trial with the National Statement, the procedural protocol approved for the trial by the responsible ethics committee and the Practice Guideline.

Schedule 2 - Repeals

This Schedule repeals the *Therapeutic Goods (Clinical Trial Inspections) Specification 2020*.

Attachment B

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) Specification (No. 2) 2020

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 (Clinical Trial Inspections) Specification (No. 2) 2020* ("the instrument") is a legislative instrument made under subsection 61(5AB) of the Act. The instrument repeals and replaces the *Therapeutic Goods (Clinical Trial Inspections) Specification 2020* ("the former instrument"), with the principal purpose of clarifying that the *National Statement on Ethical Conduct in Human Research* published by the National Health and Medical Research Council ("the National Statement"), and the *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)* published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) ("the Practice Guideline"), are incorporated as in force or existing at the time the instrument commences, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003*. The National Statement and the Practice Guideline are defined accordingly in section 4 of the instrument.

The instrument does not otherwise introduce any substantive changes to the former instrument with respect to the release of specified kinds of therapeutic goods information to specified persons, bodies or authorities, for specified purposes. As such, consistent with the former instrument, the instrument 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 ("the approving authority") and the ethics committee responsible for approving the procedural protocol and monitoring the conduct of the trial ("the responsible ethics committee") 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 *Therapeutic Goods Regulations 1990* ("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.

In practice, the information intended for release under the instrument 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. However, while the personal or sensitive information of clinical trial participants would not be released under the instrument, the names of the research staff involved in the clinical trial and the name of the authorised officer who conducted the inspection may be included in the information released.

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 trial. This will enable safety concerns that arise in the course of a clinical trial 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 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.

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.