EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Clinical Trial Inspections) Specification 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 relevantly 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 relevantly 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) relevantly 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 2020* ("the Specification") is a legislative instrument made by the delegate of the Minister under subsection 61(5AB) of the Act to specify kinds of therapeutic goods information that may be released to specified kinds of persons or bodies by the Secretary, for specified purposes, under subsection 61(5AA) of the Act.

The purpose of the Specification is to enable 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.

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.

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.

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

Regulations in relation to the clinical trial, including information that relates to compliance of the relevant trial with the National Statement on Ethical Conduct in Human Research (published by the National Health and Medical Research Council), the procedural protocol approved for the trial by the responsible ethics committee and the Guideline for Good Clinical Practice (published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Incorporation by reference

The Specification incorporates by reference the Guideline for Good Clinical Practice (published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and the National Statement on Ethical Conduct in Human Research (published by the National Health and Medical Research Council). These documents have the meaning given by paragraphs 12AB(2)(a) and 12AD(c) of the Regulations, respectively.

The documents relate to the conduct of clinical trials in relation to therapeutic goods, and are available for free at the following websites: www.ichcpg.net and www.nhmrc.gov.au.

Consultation

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 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.

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 2003* and commences on the day after registration on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Clinical Trial Inspections) Specification 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Clinical Trial Inspections) Specification 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").

Section 4 – Definitions

This section provides the definitions of certain terms used in the Specification. In particular, this section 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.

This section also defines the 'National Statement' as having the meaning given by paragraph 12AD(c) of the *Therapeutic Goods Regulations 1990* ("the Regulations") and the 'Practice Guideline' has the meaning given by paragraph 12AB(2)(a) of the Regulations.

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 this instrument, 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.

Schedule 1

This Schedule specifies the kinds of therapeutic goods information, the kinds of persons or bodies, and the purposes for the purposes of section 5 of the Specification.

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.

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 Regulations in relation to the clinical trial, including information that relates to compliance of the relevant trial with the National Statement on Ethical Conduct in Human Research (published by the National Health and Medical Research Council), the procedural protocol approved for the trial by the responsible ethics committee and the Guideline for Good Clinical Practice (published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

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 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 2020* ("the instrument") is made under subsection 61(5AB) of the *Therapeutic Goods Act 1989* ("the Act").

Section 61 of the Act relevantly 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 relevantly 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) relevantly 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 instrument is made by the delegate of the Minister under subsection 61(5AB) of the Act, and specifies the kinds of therapeutic goods information that may be released to specified kinds of persons or bodies by the Secretary for specified purposes under subsection 61(5AA) of the Act.

The purpose of the instrument is to enable the Secretary to release 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.

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 who 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.

Clinical trials for 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 instrument 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 Regulations in relation to the clinical trial, including information that relates to compliance of the relevant trial with the National Statement on Ethical Conduct in Human Research (published by the National Health and Medical Research Council), the procedural protocol approved for the trial by the responsible ethics committee and the Guideline for Good Clinical Practice (published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights ("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 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.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.