**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 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, 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 kinds of therapeutic goods information to the public, and to certain organisations, bodies, and 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(5C) relevantly provides that the Secretary may release to the public therapeutic goods information of a kind specified under subsection 61(5D). Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection 61(5C).

The *Therapeutic Goods Information (Laboratory Testing) Specification 2017* (“the Principal Specification”) is a legislative instrument made under subsection 61(5D) of the Act. It specifies kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act (“the specified information”). Broadly, the specified information relates to the laboratory testing activities of the TGA.

The *Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 2023* (“the Amendment Instrument”) is also made under subsection 61(5D) of the Act. It amends the Principal Specification, to provide, for the avoidance of doubt, the meaning and scope of the terms ‘*sample*’ and ‘*test*’ in the Principal Specification. In particular, the purpose of these amendments is to put it beyond doubt that the information specified by the Principal Specification encompasses information relating not only to samples of goods that are tested in accordance with Part 5 of the *Therapeutic Goods Regulations 1990* (“the Regulations”), but also information relating to samples tested outside the framework in Part 5 of the Regulations.

**Background**

*TGA’s laboratory testing program*

The TGA’s testing program plays a critical role in the regulation of therapeutic goods in Australia. It informs, and is a key component of, regulatory activities relating to product recalls, the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”), the cancellation of therapeutic goods from the Register, and the post-market monitoring, compliance testing, safety investigation and compliance review of therapeutic goods. In so doing, the TGA’s laboratory testing activities support the safety, quality, and efficacy or performance of therapeutic goods supplied in (or exported from) Australia, and are a critical component of efforts to ensure that therapeutic goods meet minimum acceptable standards.

The TGA’s testing program comprises several testing categories. These include, relevantly:

* programmed (or proactive) testing — to verify that goods that are registered, listed, or included in the Register, or that are exempt from, or approved or authorised in relation to, the requirement to be included in the Register, are of acceptable quality or performance as defined by official standards or agreed specifications; and
* responsive testing — to investigate quality and safety signals or other emerging issues in relation to therapeutic goods (including in relation to therapeutic goods that are not entered in the Register or the subject of an approval, authority, or exemption — i.e., unapproved goods) that are identified through a range of mechanisms including by, among other things, complaints, seizure of goods or adverse event investigations.

Part 5 of the Regulations sets out procedures relating to certain sampling and testing activities. Part 5 does not apply to all the TGA’s sampling and testing activities. Specifically, Part 5 applies only in relation to samples that are:

* delivered by the person in relation to whom the goods are registered, listed, or included in the Register (i.e., the sponsor), at the Secretary’s request, in compliance with a condition of the entry of those goods in the Register or pursuant to paragraph 28(5)(h) or subsection 41FN(2) of the Act; or
* taken by an authorised officer, pursuant to paragraph 24(1)(c) of the Regulations, from the premises of:
	+ a licence holder;
	+ a wholesaler;
	+ a manufacturer in respect of whom a conformity assessment certificate has been issued; or
	+ a sponsor in relation to whom the entry of goods in the Register is subject to a condition that they comply with regulation 24 of the Regulations.

However, the TGA also samples and tests goods that are not obtained in one of those ways. For example, the TGA may test samples that have been purchased from a retailer, or that have been provided to the TGA by another regulator, or a health or law enforcement agency. The TGA’s capacity to test such samples is critical to the effectiveness of its testing program, and its role in the regulation of therapeutic goods in Australia generally.

*The specified information*

The Principal Specification specifies kinds of information relating to laboratory testing that the Secretary may release to the public under subsection 61(5C) of the Act. Among other things, the specified information includes information relating to:

* the description of a sample of a therapeutic good tested by the TGA;
* the TGA’s reason(s) for testing the sample;
* the name and description of the tests performed, including information relating to the scope of the tests and any applicable standards relevant to the testing;
* the results of the testing, including whether the sample was found to comply with relevant standards and requirements;
* the outcomes of the testing, including subsequent action taken by the TGA or by the sponsor or manufacturer of the therapeutic good;
* related quality, safety and efficacy information, including information about the supply of the therapeutic good.

Publication of this information complements other information that is published on the TGA’s website, including safety information such as early warnings, safety alerts, product recalls, adverse event notifications and general educational material about the safety of therapeutic goods. By facilitating the release of the specified information to the public, the Principal Specification is designed to increase the transparency and understanding of the regulation of therapeutic goods in Australia, as well as to promote consumer confidence in the quality, safety and efficacy or performance of therapeutic goods, and encourage industry compliance with legislative requirements.

**Purpose**

The Amendment Instrument is made in response to the decision of the Federal Court of Australia in *M House Pty Ltd v Secretary, Department of Health and Aged Care* [2023] FCA 768 (“*M House*”). In *M House*, the Court found that references to ‘*sample*’ and ‘*test*’ in the Principal Specification referred only to sampling and testing undertaken under Part 5 of the Regulations, and did not include sampling and testing undertaken outside of Part 5. The decision in *M House* is under appeal.

The Secretary’s position is that the references to ‘*sample*’ and ‘*test*’ in the Principal Specification encompass sampling and testing performed both under, and outside, Part 5 of the Regulations. That position reflects the TGA’s longstanding policy intention and practice concerning the release to the public of information relating to the testing of therapeutic goods.

Notwithstanding the Secretary’s position on the appeal, the Amendment Instrument is made to provide certainty in relation to the scope of the specified information.

Specifically, the Amendment Instrument provides that, for the avoidance of doubt, in the Principal Specification, ‘*sample*’ includes a sample (or part of a sample) taken, collected, or otherwise obtained, and ‘*test*’ includes a test, analysis, or examination conducted or otherwise carried out:

* under the Act;
* under regulations made pursuant to the Act (including the Regulations); or
* by, or at the request or on the instruction of, a Commonwealth officer, including in the exercise of the executive power of the Commonwealth.

In that way, the Amendment Instrument is intended to put beyond doubt that the Secretary may release information of a kind specified in the Principal Specification, regardless of whether the sampling and testing was conducted under Part 5 of the Regulations.

**Consultation**

No consultation was undertaken in relation to the Amendment Instrument. This is because the amendments align with the TGA’s existing policy and practices concerning the release of laboratory testing information under subsection 61(5C) of the Act.

An Impact Analysis was not required in relation to the development of the Amendment Instrument. 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 Amendment Instrument are set out in **Attachment A**.

The Amendment Instrument 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 Amendment Instrument is a disallowable legislative instrumentfor the purposes of the *Legislation Act 2003*.

The Amendment Instrumentcommences on the day after it is registered on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 2023***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 2023* (“the Amendment Instrument”).

**Section 2 – Commencement**

This section provides that the Amendment Instrument commences 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 Instrument is subsection 61(5D) 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. The Amendment Instrument is made in accordance with that provision.

**Section 4 – Schedules**

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

**Schedule 1—Amendments**

Schedule 1 amends the *Therapeutic Goods Information (Laboratory Testing) Specification 2017* (“the Principal Specification”).

**Item [1] – Section 4**

This item makes a minor editorial amendment to include a reference to subsection (1) before the existing text in section 4 of the Principal Specification. This item complements item [4] of this Schedule, which introduces new subsections 4(2) and (3) in the Principal Specification.

**Item [2] – Section 4 (at the end of the definition of *sample*)**

This item adds a note at the end of the definition of ‘*sample*’ in section 4 of the Principal Specification. This item complements item [4] of this Schedule, which, relevantly, introduces new subsection 4(2) in the Principal Specification.

**Item [3] – Section 4 (after paragraph (a) of the note)**

This item inserts a reference to ‘*Commonwealth officer*’ in the note at the end of section 4 of the Principal Specification, with the effect of identifying that the term ‘*Commonwealth officer*’ has the same meaning as in the Act.

**Item [4] – At the end of section 4**

This item inserts new subsections 4(2) and (3) in the Principal Specification.

*New subsection 4(2)*

New subsection 4(2) concerns the scope of the term ‘*sample*’ in the Principal Specification. Specifically, it provides that, for the avoidance of doubt, this term includes a sample (or part of a sample) taken, collected, or otherwise obtained:

* under the Act; or
* under regulations made under the Act (including the Regulations); or
* by, or at the request or on the instruction of, a Commonwealth officer (including in the exercise of the executive power of the Commonwealth).

Paragraphs 4(2)(a) and (b) provide, for the avoidance of doubt, that ‘*sample*’ includes any sample taken, collected, or otherwise obtained under the Act or regulations made under the Act. This includes, for example, samples that are:

* obtained in a manner that enlivens the testing provisions in Part 5 of the Regulations — that is:
	+ taken by an authorised officer under paragraph 24(1)(c) of the Regulations; or
	+ delivered by a person (“the sponsor”) in relation to whom the goods are entered in the Australian Register of Therapeutic Goods (“the Register”), in compliance with paragraph 28(5)(h) or subsection 41FN(2) of the Act.
* taken by an authorised person from the premises of:
	+ a manufacturer who holds a licence issued under Part 3-3 of the Act, in accordance with the condition mentioned in paragraph 40(4)(b)(ii) of the Act;
	+ a manufacturer of a medical device in respect of whom a conformity assessment certificate has been issued — which the manufacturer must allow, in compliance with a condition imposed by the Act in respect of that certificate;
	+ a sponsor of a therapeutic good — which the sponsor must allow, in compliance with a condition imposed by the Act in respect of the registration, listing, or inclusion of the therapeutic good in the Register; and
* delivered by a person seeking the registration, listing, or inclusion of a therapeutic good in the Register, as required by the Act, and in a manner approved by the Secretary.

Samples covered by paragraphs 4(2)(a) and (b) also include those that are taken, collected, or otherwise obtained, by persons other than TGA officers who may be required to exercise powers or functions under the Act or regulations made under the Act (including, for example, Australian Border Force officers).

Paragraph 4(2)(c) provides, for the avoidance of doubt, that ‘*sample*’ includes a sample taken, collected, or otherwise obtained by, or at the request or on the instruction of, a Commonwealth officer. This includes, for example, samples that have been obtained in a way that does not enliven the testing provisions in Part 5 of the Regulations, such as a sample:

* taken or obtained by another entity (e.g., a regulator, health or law enforcement agency, or other authority) through the exercise of powers under their own legislation, which are then provided to the TGA for testing;
* purchased from an online or physical retailer;
* collected from the National Medical Stockpile;
* obtained from a State or Territory health authority, where the authority requests that the TGA test the sample;
* obtained from a user or consumer of a therapeutic good, where the user or consumer complains to the TGA about the safety or quality of a good and voluntarily sends a sample of the good the subject of their complaint to the TGA for testing.

*New subsection 4(3)*

New subsection 4(3) concerns the scope of the term ‘*test*’ in the Principal Specification. Specifically, it provides, for the avoidance of doubt, that this term includes a test, analysis, or examination conducted or otherwise carried out:

* under the Act; or
* under regulations made under the Act (including the Regulations); or
* by, at the request or on the instruction of, a Commonwealth officer (including in the exercise of the executive power of the Commonwealth).

New subsection 4(3) is drafted in substantially the same language as new subsection 4(2).

Paragraphs 4(3)(a) and (b) provide, for the avoidance of doubt, that ‘*test*’ includes testing, analysis, or examination conducted or otherwise carried out under the Act or regulations made under the Act. This includes, for example, testing of samples:

* undertaken by the TGA’s laboratories (or a laboratory external to the Department) in accordance with Part 5 of the Regulations;
* performed by an authorised person while at the premises of:
	+ a manufacturer who holds a licence issued under Part 3-3 of the Act, in accordance with the condition mentioned in paragraph 40(4)(b)(ii) of the Act;
	+ a manufacturer in respect of whom a conformity assessment certificate has been issued — which the manufacturer must allow, in compliance with a condition imposed by the Act in respect of that certificate; and
	+ a sponsor of a therapeutic good — which the sponsor must allow, in compliance with a condition imposed by the Act in respect of the registration, listing, or inclusion of the therapeutic good in the Register.

Tests covered by paragraphs 4(3)(a) and (b) also include those that are conducted or otherwise carried out, by persons other than TGA officers who may be required to exercise powers or functions under the Act or regulations made under the Act (including, for example, Australian Border Force officers).

Paragraph 4(3)(c) also provides, for the avoidance of doubt, that ‘*test*’ includes tests conducted or otherwise carried out by, or at the request or on the instruction of, a Commonwealth officer. This includes, for example, testing:

* conducted or otherwise carried out in relation to samples that are obtained in a way that does not enliven the testing provisions in Part 5 of the Regulations; or
* by a laboratory external to the Department at the instruction of a TGA officer (e.g., where that laboratory has specialised equipment to test a particular therapeutic good).

New subsection 4(3) also ensures there is no doubt in relation to the scope of activities that are encompassed by references to ‘*test*’ in the Principal Specification. Specifically, it puts beyond doubt that a reference to this term in the Principal Specification also encompasses a reference to an analysis or examination. This is necessary as the TGA’s laboratory testing activities are not limited to tests as that term may ordinarily be interpreted (e.g., as the taking of a series of steps to induce a physical reaction in, or to generate data in relation to, a therapeutic good).

Rather, the TGA’s testing of a particular good also includes an examination of that good (e.g., to measure its physical properties, or inspect its labelling and packaging), and an analysis of the data that is produced through the testing process (including in relation to whether the goods comply with an applicable standard).

**Attachment B**

**Statement of Compatibility with Human Rights**

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

***Therapeutic Goods Information (Laboratory Testing) Amendment Instrument 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 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 *Therapeutic Goods Information (Laboratory Testing) Specification 2017* (“the Principal Specification”) is a legislative instrument made under subsection 61(5D) of the Act. It specifies kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act (“the specified information”). Broadly, the specified information relates to the laboratory testing activities of the TGA.

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*TGA’s laboratory testing program*

The TGA’s testing program plays a critical role in the regulation of therapeutic goods in Australia. It informs, and is a key component of, regulatory activities relating to product recalls, the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”), the cancellation of therapeutic goods from the Register, and post-market monitoring, compliance testing, safety investigation and compliance review of therapeutic goods. In doing so, the TGA’s laboratory testing activities support the safety, quality, and efficacy or performance of therapeutic goods supplied in (or exported from) Australia, and are a critical component of efforts to ensure that therapeutic goods meet minimum acceptable standards.

The TGA’s testing program comprises several testing categories. These include, relevantly:

* programmed (or proactive) testing — to verify that goods that are registered, listed, or included in the Register, or that are exempt from, or approved or authorised in relation to, the requirement to be included in the Register, are of acceptable quality or performance as defined by official standards or agreed specifications; and
* responsive testing — to investigate quality and safety signals or other emerging issues in relation to therapeutic goods (including in relation to therapeutic goods that are not entered in the Register or the subject of an approval, authority, or exemption — i.e., unapproved goods) that are identified through a range of mechanisms including by, among other things, complaints, seizure of goods or adverse event investigations.

Part 5 of the Regulations sets out procedures relating to certain sampling and testing activities. Part 5 does not apply to all the TGA’s sampling and testing activities. Specifically, Part 5 applies only in relation to samples that are:

* delivered by the person in relation to whom the goods are registered, listed, or included in the Register (i.e., the sponsor), at the Secretary’s request, in compliance with a condition of the entry of those goods in the Register, pursuant to paragraph 28(5)(h) or subsection 41FN(2) of the Act; or
* taken by an authorised officer, pursuant to paragraph 24(1)(c) of the Regulations, from the premises of:
	+ a licence holder;
	+ a wholesaler;
	+ a manufacturer in respect of whom a conformity assessment certificate has been issued; or
	+ a sponsor in relation to whom the entry of goods in the Register is subject to a condition that they comply with regulation 24 of the Regulations.

However, the TGA also samples and tests goods that are not obtained in one of those ways. For example, the TGA may test samples that have been purchased from a retailer, or that have been provided to the TGA by another regulator, or a health or law enforcement agency. The TGA’s capacity to test such samples is critical to the effectiveness of its testing program, and its role in the regulation of therapeutic goods in Australia generally.

*The specified information*

The Principal Specification specifies kinds of information relating to laboratory testing that the Secretary may release to the public under subsection 61(5C) of the Act. Among other things, the specified information includes information relating to:

* the description of a sample of a therapeutic good tested by the TGA;
* the TGA’s reason(s) for testing the sample;
* the name and description of the tests performed, including information relating to the scope of the tests and any applicable standards relevant to the testing;
* the results of the testing, including whether the sample was found to comply with relevant standards and requirements;
* the outcomes of the testing, including subsequent action taken by the TGA or the sponsor or manufacturer of the therapeutic good;
* related quality, safety, and efficacy information, including information about the supply of the therapeutic good.

Publication of this information complements other information that is published on the TGA’s website, including safety information like early warnings, safety alerts, product recalls, adverse event notifications, and general educational material about the safety of therapeutic goods. By facilitating the release of the specified information to the public, the Principal Specification is designed to increase the transparency and understanding of the regulation of therapeutic goods in Australia, and to promote consumer confidence in the quality, safety, and efficacy or performance of therapeutic goods, and encourage industry compliance with legislative requirements.

*Purpose*

The Amendment Instrument is made in response to the decision of the Federal Court of Australia in *M House Pty Ltd v Secretary, Department of Health and Aged Care* [2023] FCA 768 (“*M House*”). In *M House*, the Court found that references to ‘*sample*’ and ‘*test*’ in the Principal Specification referred only to sampling and testing undertaken under Part 5 of the Regulations, and did not include sampling and testing undertaken outside of Part 5 of the Regulations. The decision in *M House* is under appeal.

The Secretary’s position is that the references to ‘*sample*’ and ‘*test*’ in the Principal Specification encompass sampling and testing performed both under, and outside, Part 5 of the Regulations. That position reflects the TGA’s longstanding policy intention and practice concerning the release to the public of information relating to the testing of therapeutic goods.

Notwithstanding the Secretary’s position on the appeal, the Amendment Instrument is made to provide certainty in relation to the scope of the specified information.

Specifically, the Amendment Instrument provides that, for the avoidance of doubt, in the Principal Specification, ‘*sample*’ includes a sample (or part of a sample) taken, collected, or otherwise obtained, and ‘*test*’ includes a test, analysis, or examination conducted or otherwise carried out:

* under the Act;
* under regulations made pursuant to the Act (including the Regulations); or
* by, or at the request or on the instruction of, a Commonwealth officer, including in the exercise of the executive power of the Commonwealth.

In that way, the Amendment Instrument is intended to put beyond doubt that the Secretary may release information of a kind specified in the Principal Specification, regardless of whether the sampling and testing was conducted under Part 5 of the Regulations.

**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 standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 continuing to promote transparency and public awareness in relation to the laboratory testing activities conducted by the TGA. The publication of kinds of information specified by the Principal Specification complements the other safety-related information the TGA publishes on its website, including information relating to safety alerts, adverse event notifications, and product recalls. By putting beyond doubt the breadth of the specified information, the TGA can continue to release important laboratory testing information so that the Australian public are better informed about the safety of therapeutic goods that are imported into, exported from, or supplied in, Australia.

**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.