EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Advertising Complaints and Investigations Information) Amendment Instrument 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 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(5C) relevantly provides that the Secretary may release to the public therapeutic goods information of a kind specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C).

The *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019* ("the Principal Instrument") is 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). The purpose of the Principal Instrument, broadly, is to facilitate and support the Secretary in publishing information relating to complaints and investigations by the TGA in respect of the advertising of therapeutic goods and dissemination of generic information ("advertising cases").

The *Therapeutic Goods (Advertising Complaints and Investigations Information) Amendment Instrument 2024* ("the Amendment Instrument") is also made under subsection 61(5D) of the Act. It amends the Principal Instrument to replace the reference to the Administrative Appeals Tribunal in item 8 of the table in Schedule 2 with a generic reference to a tribunal. This amendment is made in anticipation of the Administrative Review Tribunal ("the ART") replacing the Administrative Appeals Tribunal ("the AAT") on 14 October 2024.

Background

The Principal Instrument

The Principal Instrument supports the Secretary, or a delegate of the Secretary, to publish therapeutic goods information that is of a kind specified and described in Schedule 2. The specified information relates to advertising cases that are created by the TGA following receipt of a complaint or on the TGA's own initiative, and includes details such as the name of the person responsible for the advertisement or dissemination of generic information; details about the therapeutic goods that the advertisement or dissemination related to; and details about the case itself, such as the nature of the alleged breach of the advertising controls in the Act or its regulations.

Relevantly, item 8 of the table in Schedule 2 to the Principal Instrument specifies information relating to the 'outcomes' of an advertising case, including:

- the findings that led to the outcomes and a summary of, and reasons for, the outcomes;

- actions taken and decisions made in relation to the case, including a summary of a decision made by the Secretary under the Act or its regulations, and any notice or statement of reasons given for that decision; and
- a reference or website link to an AAT decision or Court decision in relation to an advertisement or dissemination of generic information that was the subject of the case.

The Administrative Review Tribunal

The *Administrative Review Tribunal Act 2024* ("the ART Act") establishes the ART as a replacement for the AAT and commences on proclamation. The *Administrative Review Tribunal (Consequential and Transitional Provisions No. 1) Act 2024* is consequential to the ART Act and has the effect of repealing the *Administrative Appeals Tribunal Act 1975*, abolishing the AAT, and making consequential amendments to other Commonwealth legislation. Similarly, the *Administrative Review Tribunal (Consequential and Transitional Provisions No. 2) Act 2024* is consequential to the ART Act and updates references in other Commonwealth legislation.

The ART is expected to replace the AAT as the new federal administrative review body on 14 October 2024. References to the AAT in the Act will be consequentially amended on that date, and applications for merits review of a decision under the Act will be made to the ART.

Purpose

The Amendment Instrument amends item 8 of the table in Schedule 2 to the Principal Instrument to replace the reference to the AAT with a generic reference to the tribunal. This is to accommodate the legislative reforms replacing the AAT with the ART.

The new reference to a tribunal decision is intended to encompass decisions that are made by the ART in relation to advertising cases from 14 October 2024, as well as decisions that were made by the AAT in relation to advertising cases prior to the AAT's abolishment. The generic reference to a tribunal decision would only include ART and AAT decisions as they are the only tribunals with authority to review decisions made under the Act.

This amendment supports the continued release to the public of therapeutic goods information in relation to outcomes of tribunal hearings concerning advertising cases, despite the replacement of the AAT with the ART.

Consultation

No consultation was undertaken in relation to the Amendment Instrument, as the amendments are minor and machinery, and consequential to legislative reforms made by Parliament giving effect to the replacement of the AAT with the ART.

An Impact Analysis was not required in relation to the development of the Amendment Instrument. This is because 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 instrument for the purposes of the *Legislation Act 2003*.

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

Attachment A

Details of the *Therapeutic Goods (Advertising Complaints and Investigations Information) Amendment Instrument 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Advertising Complaints and Investigations Information) Amendment Instrument 2024* ("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 will be amended or repealed as set out in the applicable items in the Schedules, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019

This Schedule amends the *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019 ("the Principal Instrument")*

Item 1 – Schedule 2 (table item 8, column 3, paragraph (c))
This item makes a minor amendment to item 8 of the table in Schedule 2 to the Principal Instrument consequential to the passage of the *Administrative Review Tribunal Act 2024* and other related legislation which replaces the AAT with the ART.

Specifically, the item omits the reference to "an Administrative Appeals Tribunal decision or Court decision" in column 3, paragraph (c), of item 8, and substitutes a reference to "a decision of a court or tribunal".

Attachment B

Statement of Compatibility with Human Rights

This statement is prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Advertising Complaints and Investigations Information) Amendment Instrument 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

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.

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This amendment supports the continued release to the public of therapeutic goods information in relation to outcomes of tribunal hearings concerning advertising cases, despite the replacement of the AAT with the ART.

Human rights implications

The Amendment Instrument amends the Principal Instrument simply as a consequence of the anticipated abolition of the AAT and commencement of the ART. The Amendment Instrument does not change the effect of the Principal Instrument.

As the Amendment Instrument does not introduce any changes to the Principal Instrument other than to implement the changes outlined above, the Amendment Instrument does not engage any applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights because it does not raise any human rights issues.