

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Adverse Event Management System—Sponsors) (Information) Specification 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, 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(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 for which the information may be released under such arrangements.

The *Therapeutic Goods (Adverse Event Management System—Sponsors) (Information) Specification 2023* (“the Specification”) is a legislative instrument made under subsection 61(5AB) of the Act. It specifies the kinds of therapeutic goods information that the Secretary may release to specified persons, bodies or authorities, and the purposes for which that information may be released under subsection 61(5AA) of the Act.

The Specification provides that the therapeutic goods information that may be released is de-identified information contained in an adverse event report recorded in the Adverse Event Management System (“the AEMS”) where the adverse event report includes:

- the product name of a medicine or biological; or
- the active ingredient of the medicine or biological, and does not include the product name of the medicine or biological.

The specified persons to whom the information may be released are sponsors of the goods to which the specified therapeutic goods information relates. Further, the Specification provides that the purpose of the release is to assist the sponsor in satisfying pharmacovigilance obligations under the Act, to ensure the safe use of the goods.

### **Background**

The TGA monitors the safety of therapeutic goods approved for use in Australia. As part of its surveillance system, the TGA collects reports of possible adverse events associated with medicines and biologicals in the AEMS — the TGA’s internal database for adverse events —

from sponsors, medical practitioners, States and Territories, and members of the public. Adverse events are principally unintended and sometimes harmful occurrences associated with the use of a therapeutic good. An adverse event may range from mild to severe and may or may not be causally related to the use of the therapeutic good.

Adverse events reports will typically include the tradename or active ingredient of the medicine or biological associated with the adverse event, and the circumstances of the adverse event (including reactions, symptoms, and tests or procedures taken). It may also include personal information and sensitive personal information, such as a person's medical history.

Providing adverse event information to sponsors in a timely manner supports sponsors to meet their pharmacovigilance obligations under the Act. These obligations require sponsors to implement their own surveillance systems for monitoring, detecting, assessing, understanding and preventing adverse events, and other related problems, including reporting adverse events to the TGA and retaining records relating to the safety of therapeutic goods (for example, in relation to medicines, in sections 28, 29A and 29AA of the Act). Adverse event information is critical in detecting new safety signals and quality issues, and to ensuring that therapeutic goods available in Australia remain safe, effective and of appropriate quality.

A subset of the information recorded in the AEMS' adverse event reports in relation to medicines and biologicals is de-identified and made publicly available in the Database of Adverse Event Notifications – medicines ("the DAEN"), including the kind of adverse event, whether the medicine or biological is the only medicine or biological suspected to be related to the kind of adverse event, and, as summary information, how many reports identify death as a reported outcome.

However, in order to better fulfill their pharmacovigilance obligations, sponsors currently request de-identified data directly from the TGA to gain access to adverse event report information that is not available publicly through the DAEN. This process is inefficient for both sponsors and the TGA.

## **Purpose**

The Specification authorises the release of de-identified adverse event reports in the AEMS portal to sponsors, allowing them timely access to more detailed information regarding adverse events associated with their medicines and biologicals.

This is intended to support sponsors in monitoring, detecting, assessing, understanding and preventing adverse events, as part of their pharmacovigilance surveillance system. This would support the early detection of safety signals and, potentially, issues with a therapeutic good, allowing for appropriate action to be taken in relation to a safety signal if detected, providing better outcomes for Australians using medicines and biologicals.

## **Consultation**

Between 19 January 2022 and 18 February 2022, the TGA publicly consulted on a proposal to implement electronic functionality that would allow sponsors to view and export relevant de-identified medicine adverse event data relating to their goods from TGA systems, reducing the need to rely on manual email processes.

A total of 44 responses were received, with submissions broadly supporting the proposed initiative. Respondents included sponsors of prescription, non-prescription, and complementary medicines, and medicinal cannabis products, as well as research organisations (such as PharSafer).

Almost all respondents stated that they rely on both the DAEN and direct contact with the TGA to obtain information on medicine adverse events, and in relation to the proposed functionality, respondents stated that they wished to retain access to the same data they currently access via these means. Such data includes the kind, frequency and seriousness of the adverse event experienced by the patient, as well as information concerning the patient's underlying medical conditions and concomitant use of medicine(s).

However, to the extent it is captured in the AEMS, respondents also requested access to additional information to assist them in identifying duplicate adverse event reports, including, for example, information about the patient's ethnicity, and the Worldwide Unique Case Identification Number for the adverse event report. This feedback was taken into account, with the TGA proposing to release this information only where it does not potentially identify the individual patient.

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 12 May 2023.

## **Attachment A**

### **Details of the *Therapeutic Goods (Adverse Event Management System—Sponsors) (Information) Specification 2023***

#### **Section 1 Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Adverse Event Management System—Sponsors) (Information) Specification 2023* (“the Specification”).

#### **Section 2 Commencement**

This section provides that the Specification commences on 12 May 2023.

#### **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 Interpretation**

Subsection 4(1) provides definitions for a number of terms used in the Specification. These include ‘adverse event’, ‘AEMS’, ‘product name’ and ‘therapeutic goods information’.

The note to this section also makes it clear that a number of expressions used in the Specification have the same meaning as in the Act, including ‘biological’, ‘medicine’, ‘Secretary’ and ‘sponsor’.

#### **Section 5 Release of therapeutic goods information**

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

#### **Schedule 1 – Therapeutic goods information**

This Schedule specifies the kinds of therapeutic goods information, the persons, bodies or authorities (or kinds of persons, bodies or authorities), and the purposes for which the information may be released, for section 5 of the Specification.

Item 1 of the table in Schedule 1 permits the release of de-identified information contained in an adverse event report in relation to a medicine or biological (“the relevant goods”) that is recorded in the Adverse Event Management System (“AEMS”), where the adverse event report includes the product name of the relevant goods, to the sponsor (and persons authorised to act on behalf of the sponsor) of the relevant goods, for the purposes of assisting the sponsor in satisfying their pharmacovigilance obligations under the Act.

Item 2 of the table in Schedule 1 permits the release of de-identified information contained in an adverse event report in relation to a medicine or biological that is recorded in the AEMS, where the adverse event report includes the active ingredients of the medicine or biological (“the relevant active ingredient”) and does not include the product name of the medicine or biological, to a sponsor (and persons authorised to act on behalf of a sponsor) of a medicine or biological that contains the relevant active ingredient, for the purposes of assisting the sponsor to satisfy their pharmacovigilance obligations under the Act.

The information that the TGA records in the AEMS may, in some circumstances, include information from which it may be possible to identify a particular individual. However, in accordance with the Specification, the information released will only be information that is de-identified. The information will only be released where it does not potentially identify the individual patient. Use and disclosure of information in accordance with the Specification would be consistent with the Department’s obligations under the *Privacy Act 1988*.

## Statement of Compatibility with Human Rights

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

### *Therapeutic Goods (Adverse Event Management System—Sponsors) (Information) Specification 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 (Adverse Event Management System—Sponsors) (Information) Specification 2023* (“the Specification”) is a legislative instrument made under subsection 61(5AB) of the Act. It specifies the kinds of therapeutic goods information that the Secretary may release to specified persons, bodies or authorities, and the purposes for which that information may be released under subsection 61(5AA) of the Act.

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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 (“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 improving the safe use of medicines and biologicals. The instrument improves the expedient release of vital adverse event information to sponsors, which supports their obligations to monitor and detect new risks, and changes in the nature of known risks, associated with medicines and biologicals that are supplied in Australia. The timely identification of changes in a medicine or biological’s risk-benefit profile ensures that risks to consumers can be appropriately managed and mitigated.

## **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.