EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (System for Australian Recall Actions) (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, as well as certain organisations, bodies or authorities. Therapeutic goods information in this context is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. The *Therapeutic Goods (System for Australian Recall Actions) (Information) Specification 2023* ("the Specification") is a legislative instrument made under subsection 61(5D) of the Act and specifies kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The Specification authorises the release of specified kinds of therapeutic goods information about recall actions in relation to therapeutic goods, which is held by the TGA in the database known as the System for Australian Recall Actions ("SARA"). The SARA is maintained by the TGA and is publicly accessible. The maintenance of the SARA, and the public release of relevant information from the SARA, provides a number of benefits for a broad range of key external stakeholders including therapeutic goods sponsors and manufacturers, consumers, patients, health care professionals and other regulatory agencies by providing access to information about recall actions relating to therapeutic goods in Australia.

The Specification repeals and replaces the *Therapeutic Goods Information (System for Australian Recall Actions) Specification 2013* ("the former Specification"), which would otherwise sunset on 1 April 2023, to ensure the continuation of the SARA beyond that date. The Specification replaces the former Specification without substantive change.

Background

The former Specification came into force in 2013 and specified, under subsection 61(5D) of the Act, kinds of information relating to recall actions involving therapeutic goods contained in the SARA, that the Secretary could release to the public under subsection 61(5C) of the Act. The former Specification enabled the TGA to publicly display information that the TGA received about recall actions in relation to therapeutic goods in Australia.

Before the former Specification was made, only Australian recall actions that were undertaken by the TGA at the consumer level were published on the TGA's website. Information about other Australian recall actions (such as recalls involving and impacting upon wholesalers, retailers or hospitals) was provided by the TGA to a limited group of external stakeholders such as state and territory recall coordinators (with the sponsor of the goods providing information to others affected by the recall). The creation of the SARA, and the release of information from the SARA authorised by the former Specification, allowed access by the public to information about Australian recall actions more generally for the first time.

The TGA is actively involved throughout the process of recalling therapeutic goods in Australia, including the identification of safety or quality concerns with therapeutic goods, the monitoring of therapeutic goods through product vigilance activities, working with sponsors in relation to the voluntary recall of some therapeutic goods and, in some instances, mandating the recall of therapeutic goods under provisions of the Act (sections 30EA, 32HA and 41KA of the Act refer).

The TGA independently and objectively assesses the risk posed by therapeutic goods in relation to which there are safety or quality concerns, to verify the potential risks to users and patients. The TGA also assesses and verifies the effectiveness of proposed recall actions to mitigate those risks, ensures an appropriate recall and communication strategy is in place and coordinates the recall action with the sponsor, state and territory recall coordinators and other affected parties including wholesalers, retailers, health practitioners, patients, patient support groups and consumers in relation to relevant recalls.

The SARA contains information about recall actions for therapeutic goods supplied in Australia including prescription medicines, over the counter medicines, complementary medicines, medical devices (including in-vitro diagnostic medical devices) and biologicals. The SARA was developed following feedback received from external stakeholders that the TGA should increase its transparency by releasing additional information about therapeutic goods.

The publicly available information in the SARA can be easily accessed using a simplified search function on the TGA website to obtain summary information about recall actions that may be of interest. In addition to wholesalers, retailers, health practitioners, patients and consumers, the SARA has also provided benefits to a wider range of stakeholders including Commonwealth, state and territory government agencies, academics, students, legal professionals and members of the general public.

Recent enhancements to the SARA have resulted in greater functionality, including:

- the ability to download search results of summary recall data into editable MS Excel spreadsheets, in addition to the existing PDF reports;
- convenient access to current and historical recall action data which assists with the identification and removal of therapeutic goods from the supply chain, through the conduct of hospital-based or state/territory health department initiated stock and audit reconciliation processes;
- sponsors, as the prime users of the TGA's recall process and SARA, will be able to review historic recalls data relating to their products, with a view to conducting an internal reconciliation to ensure all the actions for their products have in-fact been actioned appropriately;
- enhanced access and transparency with users having ready access to large volumes of recall action data; and
- further recognition of stakeholder expectations that critical TGA data sets are readily accessible.

Purpose

The Specification authorises the release of information about recall actions in relation to therapeutic goods and, like the former Specification, provides a legal basis under the Act to support release to the public of information in the SARA.

As with the former Specification, "recall action" is defined in the Specification as action taken by the responsible entity (which includes the person in relation to whom therapeutic goods are included in the Australian Register of Therapeutic Goods) to resolve a problem with therapeutic goods which have been supplied that have, or may potentially have, deficiencies relating to safety, quality, efficacy or performance, or presentation.

Schedule 1 to the Specification sets out in detail the kinds of therapeutic goods information about recall actions that the Secretary may release through the SARA. This includes, for example, the name and a description of the therapeutic goods that are the subject of the recall action, the responsible entity for the recall action, the date the recall action commenced, the nature of the recall action (e.g. permanent removal of the goods from the Australian market), recall instructions and relevant contact information for obtaining more information about the affected goods.

Consultation

In January 2023, the TGA contacted all peak industry organisations representing the sponsors and manufacturers of medicines, medical devices and biologicals advising of the need to remake the Specification. The TGA advised that it proposed to re-make the Specification without any significant amendments or changes to the type and amount of information which is currently released.

The organisations consulted included Assistive Technology Suppliers Australia, Accord Australasia, Medical Technology Association of Australia, Pathology Technology Australia and Consumer Healthcare Products Australia. Each of these organisations provided a response and all feedback was either supportive of, or did not object to, the remaking of the Specification as proposed. As part of their feedback, industry representatives advised that:

- they are pleased with the recent feature which provides for extraction of search data into an MS Excel spreadsheet;
- the SARA is useful for companies, in both Australia and overseas, as it provides good evidence of manufacturer and sponsor compliance on post-market issues; and
- the SARA provides an efficient source of such information and the current accessibility must be maintained.

The Office of Impact Analysis advised that the preparation of an Impact Analysis or certification letter is not required in relation to the making of the Specification (OBPR23-04191).

The Specification is a legislative instrument for the purposes of the *Legislation Act 2003*. 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 31 March 2023.

Attachment A

Details of the *Therapeutic Goods (System for Australian Recall Actions) (Information) Specification 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (System for Australian Recall Actions) (Information) Specification 2023* ("the Specification").

Section 2 – Commencement

This section provides that the Specification commences on 31 March 2023.

Section 3 – Authority

This section provides that the legislative authority for making the Specification is subsection 61(5D) of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 – Definitions

This section provides the definitions of key terms used in the Specification, including 'recall action' and 'responsible entity'. This section also notes that a number of terms used in the Specification have the meaning given in subsection 3(1) of the Act, including 'device number', 'listing number' and 'registration number'.

Section 5 – Therapeutic goods information

This section provides that the specified kinds of therapeutic goods information set out in the table in Schedule 1 are specified for the purpose of subsection 61(5C) of the Act. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in Schedule 1 to the Specification.

Section 6 – Repeals

This section provides that each instrument that is specified in Schedule 2 to the Specification is repealed as set out in the applicable items in that Schedule.

Schedule 1 – Specified kinds of therapeutic goods information

This Schedule specifies, for the purposes of section 5 of the Specification, the kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The kinds of therapeutic goods information specified in the table in this Schedule is information about recall actions in relation to therapeutic goods, that is held by the TGA in its System for Australian Recall Actions database ("the SARA"). The information in the SARA that may be released includes the type of goods that are the subject of the recall action (such as whether it is a medicine, biological or medical device), the registration, listing or device number of the goods, the subject of the recall action, and a product description of the goods the subject of the recall action, including all trade names for the goods, the active ingredients (where relevant) and other information to identify the goods (such as, potentially the strength of a medicine or the model number of a medical device). This information is released so the goods that are the subject of the recall action can be identified.

The information that may be released also includes the date the recall action was agreed to by the TGA (i.e. the recall commencement date), details of the recall action taken or being taken, recall

instructions, the responsibility entity (defined in section 4 as the sponsor or supplier in Australia) and contact information of the responsible entity for obtaining additional information about the goods the subject of the recall action. The purpose of releasing this information is so the public are aware of the nature of the recall action being taken to address a deficiency with the therapeutic goods that are the subject of the recall action and who they can contact for further information.

The information that may be disclosed may, in some limited circumstances, include information from which it may be possible to identify a particular individual. The name of the responsible entity and the contact details of the responsible entity may contain personal information identifying an individual. This information is usually company information or general contact information (for an information line or shared email inbox). However, in some cases a responsible entity may be an individual, and a responsible entity may choose to provide the details of an individual for the contact information. If the responsible entity is an individual, it would be reasonable and necessary to release this information, so the public (including medical practitioners and patients/users) are aware of the entity supplying the goods that are the subject of recall action in Australia and are able to contact that entity. The contact details of the responsible entity are chosen and provided by the responsible entity, so they may nominate for an individual's contact details to be released to the public in the SARA. Such use and disclosure would be consistent with the *Privacy Act 1988*.

The kinds of therapeutic goods information specified in the table in this Schedule also includes the class of recall action, level of recall action and TGA recall reference (all defined in section 4 of the Specification).

The *class of recall action* is the classification of the recall, determined by the TGA, based on the seriousness of the problem and degree of the safety risk associated with the deficient goods. There are three recall classifications:

- Class I - most serious safety-related action – a situation in which there is a reasonable probability that the use of, or exposure to, the deficient goods will cause serious adverse health consequences or death;
- Class II – urgent safety-related action – a situation in which use of, or exposure to, the deficient goods may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote; and
- Class III – lowest risk action – a situation in which use of, or exposure to, the deficient goods is not likely to cause adverse health consequences.

The *level of recall action* is also determined by the TGA and reflects the extent of supply of the deficient goods (e.g. whether the goods have only been supplied to wholesalers and no further, or whether the goods have travelled through the supply chain and have been purchased by consumers) and the persons or bodies notified of the recall action. There are four levels of recall action:

- Wholesale level – includes medicine and medical device wholesalers and state and territory purchasing authorities;
- Hospital level – includes wholesale level plus hospitals, nursing homes, respite facilities, hospital pharmacies, blood banks, pathology laboratories, human tissue banks and ambulance services;
- Retail level – includes hospital and wholesale levels plus health practitioners including retail pharmacists and dentists, and all other retail outlets such as supermarkets, health food stores and online stores; and
- Consumer level – includes retail, hospital and wholesale levels plus patients, patient support and consumer organisations and all other consumers.

The *class of recall action* and *level of recall action* are defined, with examples, in the *Uniform Recall Procedure for Therapeutic Goods (URPTG)* (Version 2.3, June 2022), published by the Therapeutic Goods Administration.

The *TGA recall reference* is the reference number the TGA assigns to recall action.

Schedule 2 – Repeals

This Schedule provides that the *Therapeutic Goods Information (System for Australian Recall Actions) Specification 2013* is repealed.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (System for Australian Recall Actions) (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 legislative instrument

Section 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, as well as certain organisations, bodies or authorities. Therapeutic goods information in this context is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions.

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Schedule 1 to the Specification sets out in detail the kinds of therapeutic goods information about recall actions that the Secretary may release through the SARA. This includes, for example, the name and a description of the therapeutic goods that are the subject of the recall action, the responsible entity for the recall action, the date the recall action commenced, the nature of the recall action (e.g. permanent removal of the goods from the Australian market), recall instructions and relevant contact information for obtaining more information about the affected goods.

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") and the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights ("the 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 facilitating the facilitating the public release of therapeutic goods information in relation to recall actions in Australia. As a consequence of the instrument, a person is able to access information including the name and a description of the recalled goods, the person undertaking the recall and its date of commencement, the nature of the recall action (e.g., permanent removal of the goods from the Australian market), recall instructions and relevant contact information for obtaining more information about the goods.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person's privacy, family, home and correspondence. It also prohibits unlawful attacks on a person's reputation. Limitations on the right to privacy must be according to law and not arbitrary, i.e. limitations must be reasonable and necessary in the particular circumstances, as well as proportionate to the objectives the limitations seek to achieve.

The information that may be disclosed in the SARA that may contain personal information is the name of the responsible entity, which is the person in relation to whom the goods are included in the Australian Register of Therapeutic Goods or the supplier of the goods in Australia, and the contact information of the responsible entity.

Although the responsible entity is most often a company, it may be possible to identify an individual from that information released in the SARA where the responsible entity is an individual. Further, while the contact information for the responsible entity is often general contact information (e.g. an information line phone number or shared email inbox), a responsible entity may nominate an individual to be the contact person.

The TGA, as part of the Australian Government Department of Health and Aged Care, is an APP entity for the purposes of the *Privacy Act 1988* ("the Privacy Act"). Such use and disclosure would be consistent with the *Privacy Act 1988*. The collection and use of the information for this purpose by the TGA, and its disclosure is critically important to ensure the safety of patients, users and the public. It is important that the public know the responsible entity that supplied the goods in Australia, even if it is an individual, and are able to contact the responsible entity.

Contact information would only be published in the SARA because the responsible entity provided particular contact information. If an individual's information is published as the contact information, this would be because the responsible entity chose to provide that individual's details as the contact information for the responsible entity, with the responsible entity effectively giving consent to the release of that information.

As such, the disclosure of the information would not be an arbitrary or unlawful interference with a person's privacy under Article 17 of the ICCPR, as the disclosure would be reasonable given it is appropriate and justified for the public to know who the responsible entity is (even if it is an individual) and the responsible entity would have nominated their appropriate contact details (which may be an individual's contact details), and the disclosure would be necessary and proportionate to the objective of ensuring the safety of therapeutic goods in Australia.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and any engagement with the right to privacy in Article 17 of ICCPR is reasonable, necessary and proportionate.