EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Minamata Convention) (Information) Specification 2022

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 ("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 (Minamata Convention) (Information) Specification 2022* ("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 bodies, and the purposes for which that information may be released to those bodies, under subsection 61(5AA) of the Act. The relevant bodies are the Department of Home Affairs ("Home Affairs") (including its operational arm, the Australian Border Force), the Department of Agriculture, Water and the Environment ("DAWE") and the Office of Chemical Safety ("OCS") (being the part of the Department of Health responsible for administering the Australian Industrial Chemicals Introduction Scheme ("AICIS")).

The Specification authorises the release of therapeutic goods information relating to the importation or exportation of therapeutic goods that are mercury, for the purpose of supporting cooperation between the TGA, Home Affairs, DAWE and OCS to monitor and support compliance with, and enforcement of border controls relating to, mercury, in connection with Australia's international obligations under the Minamata Convention on Mercury ("the Minamata Convention").

Background

The Minamata Convention aims to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. Mercury is a highly toxic heavy metal that poses a global threat to human health and the environment that can produce significant neurological and other defects in humans.

The Minamata Convention entered into force globally on 16 August 2017. The Australian Government ratified the Minamata Convention on 7 December 2021 and the convention entered into force for Australia on 7 March 2022. Amendments to the *Therapeutic Goods Regulations 1990* ("the Regulations") to implement Australia's obligations under the Minamata Convention, by prohibiting the import, export and manufacture of elemental mercury and specified kinds of mercury-added products, commenced upon ratification (on 7 March 2022).

The Minamata Convention provides a range of obligations on parties, including measures to control the supply and trade of mercury, prohibiting specific sources of mercury such as primary mining, and setting limitations and controls on specific mercury-added products and manufacturing processes in which mercury or mercury compounds are used.

The TGA has responsibilities under the Regulations concerning the importation into Australia of therapeutic goods that are mercury or mercury-added products. The Regulations prohibit the importation into Australia of therapeutic goods that are mercury from a non-party to the Minamata Convention and the exportation from Australia of such goods, except as approved under the Regulations. The Secretary is responsible for approving applications for such imports and exports. The Regulations also prohibit the importation into, exportation from and manufacture in Australia of therapeutic goods that are mercury-added products, and prohibit the manufacture in Australia of therapeutic goods that contain mercury-added products. The TGA will administer the provisions of the Regulations, including those concerning the processing of applications for approval of the imports and exports of therapeutic goods that are mercury.

Mercury is defined in the Regulations in a manner consistent with the Minamata Convention, as meaning elemental mercury (Hg(0), CAS No. 7439-97-6), and including mixtures of mercury (including alloys of mercury) with a mercury concentration of at least 95% by weight, but does not include non-Minamata mercury (this is a separately defined term and covers, principally, mercury used for laboratory-scale research or as a reference standard, certain naturally occurring trace quantities of mercury and unintentional trace quantities of mercury in chemical products.

The Memorandum of Understanding ("MOU") between the TGA, OCS, DAWE and Home Affairs, is designed to reflect cooperative arrangements between the parties to manage suspected unlawful imports and unlawful attempted exports of mercury, and to share information to support compliance and inform the analysis of trends in mercury trade over time.

Where approvals are provided in accordance with the Regulations for the import or export of therapeutic goods that are mercury, the TGA is responsible under the MOU for providing details of these approvals to the Australian Border Force in a timely manner. This information sharing is intended to assist Home Affairs in facilitating lawful trade and identifying unlawful trade.

Where Home Affairs suspects that an attempted importation or exportation of mercury is unlawful and the importer or exporter is unable to produce a valid permit, Home Affairs will either detain the suspected mercury (in the case of an attempted importation) or not clear the goods for export (in the case of an attempted export). It will then notify the Chemicals Management Branch in DAWE, who will identify the responsible participant for further action. If the responsible participant in a particular case happens to be the TGA, the TGA will determine whether the mercury is in breach of the therapeutic goods legislation. Following this, the TGA will advise Home Affairs whether the mercury should be further examined, released or seized.

The kinds of information specified in the Specification principally relate to the importation or exportation of therapeutic goods that are mercury, including information relating to importations and exportations of therapeutic goods that are mercury that have been approved under the Regulations; the investigation of importations and exportations of therapeutic goods that are mercury that may not have been approved under the regulations; relevant import or export data and analysis; and the examination and testing of samples of suspected mercury.

Consultation

The TGA consulted Home Affairs, DAWE and OCS in April 2022 on the proposal to authorise the release of information to be specified in the Specification to them in connection with the cooperative arrangements outlined in the MOU. No concerns were raised in relation to the proposal.

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 ID 15070).

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 (Minamata Convention) (Information) Specification 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Minamata Convention) (Information) Specification 2022* ("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 notes that the meanings of certain terms used in the Specification, e.g. 'Secretary' and 'therapeutic goods', are defined in the Act. Other terms have been defined for the purposes of the Specification, including 'Agriculture Department', 'Environment Department' and 'Home Affairs Department'. The Agriculture Department and Environment Department are the Department of Agriculture, Water and the Environment under current administrative arrangements.

This section also provides that several expressions have the same meaning as in the *Therapeutic Goods Regulations 1989* ("the Regulations"), including 'mercury' and 'Minamata Convention'.

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 the Specification, the kinds of therapeutic goods information specified in column 2 may be released to a body specified in column 3, for the purposes specified in column 4 of that table.

Schedule 1 – Therapeutic goods information

This Schedule specifies that therapeutic goods information relating to the importation or exportation of therapeutic goods that are mercury can be released to the Department of Home Affairs (incorporating its operational arm, the Australian Border Force), the Department of Agriculture, Water and the Environment and the Australian Industrial Chemicals Introduction Scheme (within the Department of Health). This therapeutic goods information may be released to support cooperation between these bodies in relation to monitoring and supporting compliance with, and enforcement of, border controls relating to mercury to satisfy Australian's international obligations under the Minamata Convention and inform and support policy development in relation to mercury.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Minamata Convention) (Information) Specification 2022

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 (Minamata Convention) (Information) Specification 2022* ("the instrument") is a legislative instrument made under subsection 61(5AB) of the *Therapeutic Goods Act 1989* ("the Act").

The purpose of the instrument is to ensure the release of specified therapeutic goods information to the Department of Home Affairs ("Home Affairs") (including its operational arm, the Australian Border Force), the Department of Agriculture, Water and the Environment ("DAWE"), and the Office of Chemical Safety ("OCS") (being the part of the Department of Health responsible for administering the Australian Industrial Chemicals Introduction Scheme ("AICIS")) to support cooperation in relation to monitoring and supporting compliance with, and enforcement of, border controls relating to mercury. This cooperation is to satisfy Australia's international obligations under the Minamata Convention on Mercury ("the Minamata Convention"), and is to inform and support policy development in relation to mercury.

The Minamata Convention aims to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. Mercury is a highly toxic heavy metal that poses a global threat to human health and the environment that can produce significant neurological and other defects in humans.

The Minamata Convention entered into force globally on 16 August 2017. The Australian Government ratified the Minamata Convention on 7 December 2021 and the Convention entered into force for Australia on 7 March 2022. Amendments to the *Therapeutic Goods Regulations 1990* ("the Regulations") to implement Australia's obligations under the Minamata Convention by prohibiting the import, export and manufacture of elemental mercury and specified kinds of mercury-added products, commenced upon ratification.

The instrument reflects the need for cooperation between the TGA, Home Affairs, DAWE and OCS to investigate importations and exportations of therapeutic goods that are mercury that may not have been approved under the Regulations. It is critical to ensure that these persons and bodies are able to access information about importations and exportations of this sort to give effect to Australia's obligations under the Minamata Convention.

The kinds of information specified in this instrument are information about the importation or exportation of therapeutic goods that are mercury. The kinds of information that may be released to Home Affairs, DAWE and OCS include information relating to: importations and exportations of therapeutic goods that are mercury that have been approved under the Regulations; the investigation of importations and exportations of therapeutic goods that are mercury that may not have been approved under the regulations; relevant import or export data and analysis; and the examination and testing of samples of suspected mercury.

The instrument gives legislative effect to arrangements under a Memorandum of Understanding between Home Affairs, DAWE, OCS and the TGA ("the MOU") that clarifies and defines the roles

and responsibilities of each participant in implementing border controls for mercury. The instrument allows the TGA to share information with those bodies to meet its information-sharing obligations under the MOU.

Human rights implications

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

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.

By supporting the cooperation of the parties to the MOU, the instrument takes steps to promote the right to health by helping to ensure that there is an effective enforcement and compliance scheme in place to identify and prevent unlawful imports and exports of mercury. In so doing, the instrument forms part of measures taken in Australia to implement and reflect the Minamata Convention, which aims to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. Mercury is a highly toxic heavy metal that poses a global threat to human health and the environment that can produce significant neurological and other defects in humans.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR.