



## **Therapeutic Goods (Minamata Convention) (Information) Specification 2022**

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I, John Skerritt, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 9 May 2022

Adjunct Professor John Skerritt  
Deputy Secretary  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Minamata Convention) (Information) Specification 2022*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) Secretary;
- (b) therapeutic goods.

In this instrument:

**Act** means the *Therapeutic Goods Act 1989*.

**Agriculture Department** means the Department responsible for agriculture policy, including agricultural and veterinary chemicals.

**Australian Border Force** has the same meaning as in the *Australian Border Force Act 2015*.

**Australian Industrial Chemicals Introduction Scheme** means the scheme established under section 140 of the *Industrial Chemicals Act 2019*.

**Environment Department** means the Department responsible for environment policy, including environment protection.

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**Home Affairs Department** means the Department administered by the Minister administering the *Australian Border Force Act 2015*.

**mercury** has the same meaning as in the Regulations.

**Minamata Convention** has the same meaning as in the Regulations.

**Regulations** means the *Therapeutic Goods Regulations 1990*.

**therapeutic goods information** has the meaning given by subsection 61(1) of the Act.

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

For subsection 61(5AA) of the Act, in relation to each item, the kinds of therapeutic goods information specified in column 2 of the table in Schedule 1 may be released to a body specified in column 3, for the purposes specified in column 4 of that table.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a body that is specified under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

# Schedule 1—Therapeutic goods information

Note: See section 5.

<b>Therapeutic goods information that may be released</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Kinds of information</b>	<b>Bodies</b>	<b>Purpose</b>
1	<p>information about the importation or exportation of therapeutic goods that are mercury including, but not limited to, information that relates to:</p> <p>(a) importations and exportations of therapeutic goods that are mercury that have been approved under the Regulations;</p> <p>(b) the investigation of importations and exportations of therapeutic goods that are mercury and that may not have been approved under the Regulations;</p> <p>(c) relevant import or export data and analysis;</p> <p>(d) the examination and testing of samples of suspected mercury</p>	<p>the following bodies:</p> <p>(a) the Home Affairs Department (incorporating the Australian Border Force);</p> <p>(b) the Environment Department;</p> <p>(c) the Agriculture Department;</p> <p>(d) the part of the Department responsible for administering the Australian Industrial Chemicals Introduction Scheme</p>	<p>to support cooperation with the bodies mentioned in column 3 in relation to monitoring and supporting compliance with, and enforcement of, border controls relating to mercury (including therapeutic goods that are mercury), to satisfy Australia's international obligations under the Minamata Convention, and inform and support policy development in relation to mercury</p>