



# **Therapeutic Goods (International Agreements—Notice of Prohibition) (Minamata Convention on Mercury) Instrument 2021**

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

Dated 9 August 2021

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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 (International Agreements—Notice of Prohibition) (Minamata Convention on Mercury) Instrument 2021*.

## 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 this instrument is published on the Department's website	

Note: This table relates only to the provisions of this instrument as originally made.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 section 9K 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) manufacture;
- (b) therapeutic goods.

In this instrument:

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

**mercury** means elemental mercury (Hg(0), CAS No. 7439-97-6), and includes mixtures of mercury (including alloys of mercury) with a mercury concentration of at least 95% by weight, but does not include non-Minamata mercury.

**mercury-added products** means the products listed in Part 1 of Annex A to the Minamata Convention, but does not include:

- (a) products essential for civil protection and military uses; or
- (b) products for research, calibration of instrumentation, or for use as reference standards; or
- (c) if no feasible mercury-free alternative for replacement is available—the following:

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- (i) switches and relays;
- (ii) cold cathode fluorescent lamps and external electrode fluorescent lamps for electronic displays;
- (iii) measuring devices; or
- (d) products used in traditional or religious practices; or
- (e) vaccines containing thiomersal as preservatives.

**Minamata Convention** means the Minamata Convention on Mercury done at Minamata on 10 October 2013, as in force or existing at the commencement of this instrument.

Note: The Minamata Convention can be accessed at <http://www.austlii.edu.au>.

**non-Minamata mercury** means any of the following:

- (a) mercury to be used for laboratory-scale research or as a reference standard;
- (b) naturally occurring trace quantities of mercury present in:
  - (i) products such as non-mercury metals, ores or mineral products (including coal); or
  - (ii) products derived from the products mentioned in subparagraph (i);
- (c) unintentional trace quantities of mercury in chemical products.

## 5 Proposed prohibition on therapeutic goods themselves

For subsection 9K(6) of the Act, in relation to each item in the table in Part 1 of Schedule 1, notice of the following details is given in relation to regulations containing a prohibition referred to in subsection 9K(1) of the Act:

- (a) the international agreement as set out in column 2 of the item; and
- (b) the satisfaction of the matters mentioned in subsection 9K(2) of the Act as set out in column 3 of the item; and
- (c) the proposed prohibition as set out in column 4 of the item.

## 6 Proposed prohibition on therapeutic goods containing an ingredient or component

For subsection 9K(6) of the Act, in relation to each item in the table in Part 2 of Schedule 1, notice of the following details is given in relation to regulations containing a prohibition referred to in subsection 9K(3) of the Act:

- (a) the international agreement as set out in column 2 of the item; and
- (b) the satisfaction of the matters mentioned in subsection 9K(4) of the Act as set out in column 3 of the item; and
- (c) the proposed prohibition as set out in column 4 of the item.

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## Schedule 1—Therapeutic goods subject of an international agreement: proposed prohibition

### Part 1—Prohibition on therapeutic goods themselves

Note: See section 5.

<b>Prohibition under subsection 9K(1)</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>International agreement</b>	<b>Subsection 9K(2) matters</b>	<b>Proposed prohibition</b>
1	Minamata Convention	the Minamata Convention requires parties to that Convention to take steps to prohibit or restrict the import of therapeutic goods that are mercury	the importation into Australia of a therapeutic good that is mercury from a non-party (the <i>exporting party</i> ) to the Minamata Convention, unless the Secretary has approved in writing, before the mercury is imported, an application to import the good from the exporting party after being satisfied that:  (a) either:  (i) Australia has provided the exporting party with written consent to the import; or  (ii) a general notification of consent is in force for Australia in accordance with paragraph 7 of Article 3 of the Minamata Convention; and  (b) the exporting party has provided written certification that the mercury is neither sourced from primary mercury mining nor excess mercury from the decommissioning of chlor-alkali facilities
2	Minamata Convention	the Minamata Convention requires parties to that Convention to take steps to prohibit or restrict the export of therapeutic goods that are mercury	the export from Australia of a therapeutic good that is mercury to a Party (the <i>importing Party</i> ) to the Minamata Convention, unless the Secretary has approved in writing, before the mercury is exported, an application to export the good to the importing Party after being satisfied that:  (a) the importing Party has provided its written consent to the export; and

<b>Prohibition under subsection 9K(1)</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>International agreement</b>	<b>Subsection 9K(2) matters</b>	<b>Proposed prohibition</b>
			<p>(b) the mercury is to be exported:</p> <ul style="list-style-type: none"> <li>(i) for a use allowed to the importing Party under the Minamata Convention; or</li> <li>(ii) for environmentally sound interim storage as set out in Article 10 of the Minamata Convention</li> </ul>
3	Minamata Convention	the Minamata Convention requires parties to that Convention to take steps to prohibit or restrict the export of therapeutic goods that are mercury	<p>the export from Australia of a therapeutic good that is mercury to a non-Party (the <i>importing party</i>) to the Minamata Convention, unless the Secretary has approved in writing, before the mercury is exported, an application to export the good to the importing party after being satisfied that:</p> <ul style="list-style-type: none"> <li>(a) the importing party has provided its written consent to the export; and</li> <li>(b) the importing party has provided written certification demonstrating that: <ul style="list-style-type: none"> <li>(i) it has measures in place to ensure the protection of human health and the environment, and to ensure compliance with Articles 10 and 11 of the Minamata Convention; and</li> <li>(ii) the mercury will be used only for a use allowed under the Minamata Convention to a Party to that Convention, or for environmentally sound interim storage as set out in Article 10 of the Minamata Convention</li> </ul> </li> </ul>
4	Minamata Convention	the Minamata Convention requires parties to that Convention to take steps to prohibit or restrict the import, export and manufacture of therapeutic goods that are mercury-added products	the importation into, export from and manufacture in, Australia of therapeutic goods that are mercury-added products

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## Part 2—Prohibition on therapeutic goods containing an ingredient or component

Note: See section 6.

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<b>Prohibition under subsection 9K(3)</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>International agreement</b>	<b>Subsection 9K(4) matters</b>	<b>Proposed prohibition</b>
1	Minamata Convention	the Minamata Convention requires parties to that Convention to take steps to prohibit or restrict the manufacture of therapeutic goods that contain mercury-added products	the manufacture in Australia of therapeutic goods that contain mercury-added products

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