

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Declared Goods) Order 2019

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 Commonwealth Department of Health.

Subsection 7(1) of the Act confers on the Secretary of the Department a power to declare, by order published in the *Gazette* or on the Department’s website, that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods for the purposes of the Act. In making a declaration that goods are or are not therapeutic goods, the Secretary must be satisfied that the goods are or are not in fact therapeutic goods as defined in the Act. In short, subsection 7(1) provides a mechanism for clarifying whether particular goods or classes of goods are or are not therapeutic goods, and therefore whether or not those goods are subject to the regulatory scheme established by the Act.

In making a decision that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are therapeutic goods, subsection 7(1A) of the Act provides that the Secretary must disregard paragraphs (e) and (f) of the definition of ‘therapeutic goods’ in subsection 3(1) of the Act. Paragraph (e) of that definition refers to goods for which there is a standard under subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*. Paragraph (f) refers to goods which have a tradition of use as foods for humans in the form in which they are presented. Accordingly, subsection 7(1A) ensures that an order declaring goods to be therapeutic goods under subsection 7(1) of the Act has the effect of bringing those goods within the ambit of the Act, notwithstanding any food standard that would otherwise apply to those goods, or whether those goods could be characterised as having a tradition of use as foods.

There are presently seven orders in force under section 7 of the Act declaring particular goods or classes of goods to be or not to be therapeutic goods (“the former Orders”). These orders are published on the TGA website in accordance with subsection 7(1) of the Act and may be identified as follows:

- (a) Order that Goods are Therapeutic Goods No. 1 of 1998 made on 28 November 1998;
- (b) Order that Goods are Therapeutic Goods No. 1 of 1999 made on 8 February 1999;
- (c) Order that Goods are Therapeutic Goods No. 2 of 1999 made on 23 February 1999;
- (d) Order that Goods are Therapeutic Goods No. 3 of 1999 made on 30 March 1999;
- (e) Order that Goods are Therapeutic Goods No. 4 of 1999 made on 6 April 1999;
- (f) Order that Goods are Therapeutic Goods No. 1 of 2009 made on 14 October 2009;
- (g) Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 made on 30 May 2011 (as amended) (“the EGO”).

The *Therapeutic Goods (Declared Goods) Order 2019* (“the Order”) is a new order made under subsection 7(1) of the Act. This order replaces and consolidates the former Orders and will enable all goods that have been declared to be or not to be therapeutic goods under section 7 to be housed in the one instrument.

Specifically, Schedule 1 of the Order declares the following goods to be therapeutic goods:

- certain goods or classes of goods which are presently declared to be therapeutic goods in the former Orders identified in paragraphs (a), (b), (d) and (e) above; and

- certain goods or classes of goods, when used, advertised, or presented for supply in a particular way, which are presently declared to be therapeutic goods in the former Orders identified in paragraphs (c) and (f) above.

Schedule 2 of the Order declares nine goods that were specified in the EGO not to be therapeutic goods when used, advertised or presented for supply in a particular way. The remainder of the goods specified in the EGO have previously been excluded from the operation of the Act under section 7AA of the Act by the *Therapeutic (Excluded Goods) Determination 2018* (“the Determination”).

The Order is concerned only with the goods specified in the former Orders, including the balance of goods within the EGO. On commencement of the Order, each of the goods declared to be or not to be therapeutic goods by the former Orders will be specified within either the Order made under section 7, or the Determination made under section 7AA of the Act, rendering the former Orders redundant. Accordingly, all of the former Orders will be repealed on commencement of the Order, by separate instrument.

In addition to providing one consolidated instrument for all goods subject to a declaration under section 7, the drafting of the Order reflects contemporary drafting standards and practices on matters relating to style and form, such as the use of plain English and compliance with the Office of Parliamentary Counsel’s Drafting Directions. Accordingly, the Order will result in improved readability, accessibility and presentation for stakeholders, without any substantive changes being made to the characterisation of the goods which are the subject of the Order.

The Order will be registered as a legislative instrument on the Federal Register of Legislation, consistent with requirements under the *Legislation Act 2003* (“the Legislation Act”). It is considered that an order made under section 7 of the Act is properly characterised as a legislative instrument (as defined in section 8(4) of the Legislation Act) as it:

- determines the law or alters the content of the law by declaring that particular goods or classes of goods are or are not therapeutic goods for the purposes of the Act; and
- in so doing, affects a privilege or interest, imposes an obligation, creates a right, or varies or removes an obligation or right by bringing those goods within, or removing those goods from, the purview of the regulatory system established by the Act.

The majority of the former Orders under section 7 of the Act were made prior to the advent of the comprehensive regime for the management of legislation established by the Legislation Act, and as such, were not registered.

Consultation

The TGA considers that consultation is not necessary or appropriate in the circumstances because the Order has no measurable impact on businesses, community organisations, individuals or any combination of them. The effect of the Order is limited to consolidating the existing declarations made by the former Orders within a single instrument. It does not alter the existing regulatory arrangements in relation to the goods declared either to be or not to be therapeutic goods.

Details of the Order are set out in **Attachment A**.

The Order 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 Order is disallowable for the purposes of the *Legislation Act 2003* and commences on the day following registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Declared Goods) Order 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Declared Goods) Order 2019* (“the Order”).

Section 2 – Commencement

This section provides that the Order commences on the day following registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Order is section 7 of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 – Definitions

This section provides the definitions of terms used in the Order. Some terms are defined in the Act and therefore, as explained in the note, have the same meaning as given in the Act.

Section 5 – Declared goods—therapeutic goods

This section is made under subsection 7(1) of the Act, and provides that the goods specified in Schedule 1 to the Order are declared to be therapeutic goods for the purposes of the Act.

Specifically, subsection 5(1) of the Order provides that goods or classes of goods specified in Part 1 of Schedule 1 are therapeutic goods, and subsection 5(2) provides that goods or classes of goods when used, advertised, or presented for supply as specified in Part 2 of Schedule 1 are therapeutic goods.

Section 6 – Declared goods—not therapeutic goods

This section is made under subsection 7(1) of the Act, and provides that the goods specified in Schedule 2 to the Order are declared not to be therapeutic goods for the purposes of the Act.

Specifically, subsection 6(1) of the Order provides that goods or classes of goods specified in Part 1 of Schedule 2 are not therapeutic goods, and subsection 6(2) provides that goods or classes of goods when used, advertised, or presented for supply as specified in Part 2 of Schedule 2 are not therapeutic goods.

Schedule 1

This Schedule specifies therapeutic goods in two parts:

- Part 1 specifies goods or classes of goods that are therapeutic goods; and
- Part 2 specifies goods or classes of goods that are therapeutic goods when used, advertised, or presented for supply in a particular way.

Schedule 2

This Schedule specifies goods that are not therapeutic goods in two parts:

- Part 1 is reserved for use in future to specify goods or classes of goods that are not therapeutic goods; and
- Part 2 specifies goods or classes of goods that are not therapeutic goods when used, advertised, or presented for supply in a particular way.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Declared Goods) Order 2019

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 (Declared Goods) Order 2019* (“the instrument”) is made under section 7 of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 7(1) of the Act confers on the Secretary of the Department a power to declare, by order published in the *Gazette* or on the Department’s website, that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods for the purposes of the Act. In making a declaration, the Secretary must be satisfied that the goods are or are not in fact therapeutic goods as defined in the Act. In short, subsection 7(1) provides a mechanism for clarifying whether particular goods or classes of goods are or are not therapeutic goods, and therefore whether those goods are subject to the regulatory scheme established by the Act.

There are presently seven orders in force under section 7 of the Act declaring particular goods or classes of goods to be or not to be therapeutic goods (“the former instruments”). The instrument is a new order made under section 7 and replaces and consolidates the former instruments, thereby enabling all goods that have been declared to be or not to be therapeutic goods under section 7 to be housed in the one instrument.

In addition to providing one consolidated instrument for all goods subject to a declaration under section 7, the drafting of the instrument reflects contemporary drafting standards and practices on matters relating to style and form, such as the use of plain English and compliance with the Office of Parliamentary Counsel’s Drafting Directions. Accordingly, the instrument will result in improved readability, accessibility and presentation for stakeholders, without any substantive changes being made to the regulation of the goods which are the subject of the instrument.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“ICESCR”). 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 improving the readability and clarity of, and facilitating access by the public, industry and other stakeholders to, declarations made under section 7 of the Act that goods are or are not therapeutic goods.

As the instrument does not introduce any substantive changes to existing regulatory arrangements, it does not otherwise engage any of the applicable rights or freedoms.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.

Dr Jane Cook, delegate of the Secretary of the Department of Health