

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Articles that are Not Medical Devices) Declaration 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 41BD of the Act provides the meaning of ‘medical device’ for the purposes of the Act. Subsection 41BD(1) provides a broad definition of ‘medical device’, which includes instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, specified under subsections 41BD(2A) and (2B) of the Act.

Subsection 41BD(3) of the Act provides that the Secretary may, by legislative instrument, declare that a particular instrument, apparatus, appliance, software, implant, reagent, material or other article, or a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, are not medical devices for the purposes of the Act. A declaration under this subsection does not prevent articles from being therapeutic goods and has the effect that therapeutic goods declared to not be medical devices are regulated as therapeutic goods under Chapter 3 of the Act (instead of being regulated under Chapter 4 of the Act as medical devices).

The *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* (“the Declaration”) is a legislative instrument made under subsection 41BD(3) of the Act and declares that a number of articles are not medical devices for the purposes of the Act. The Declaration replaces a number of instruments declaring particular articles to not be medical devices, without change to the content of those instruments. The Declaration therefore does not have any substantive change in effect and simply consolidates a number of instruments into one legislative instrument.

Background

Previously, subsection 41BD(3) of the Act conferred on the Secretary of the Department the power to declare that particular (or particular classes of) instruments, apparatus, appliances, software, implants, reagents, materials or other articles, are not, for the purposes of the Act, medical devices, by order published in the *Gazette* or on the Department’s website.

The effect of an instrument under subsection 41BD(3) of the Act is that therapeutic goods declared to not be a medical device are not regulated under Chapter 4 of the Act, and are instead regulated under Chapter 3 of the Act. Chapter 4 includes regulatory requirements that are appropriate for medical devices, including requirements for conformity assessment certification for quality management and compliance with Essential Principles for medical devices. However, the regulatory framework for medical devices may not be appropriate for certain therapeutic goods, or there may be uncertainty as to whether certain therapeutic goods are or are not medical devices for the purposes of the Act. An instrument under subsection 41BD(3) provides clarity on the regulatory arrangements applying to particular therapeutic goods.

A number of administrative instruments were made under subsection 41BD(3) of the Act and published on the Department’s website or registered as notifiable instruments on the Federal Register of Legislation.

However, the characterisation of instruments made under subsection 41BD(3) as administrative or notifiable instruments was inconsistent with subsection 8(4) of the *Legislation Act 2003* (“the Legislation Act”), as such instruments:

- determine the law or alter the content of the law that applies to such goods, by declaring that a particular (or a particular class of) instrument, apparatus, appliance, software, implant, reagent, material or other article, are not, for the purposes of the Act medical devices; and
- affect a privilege or interest, impose an obligation, create a right, or vary or remove an obligation or right by altering the regulatory status of such goods under the Act.

On 22 March 2023, Schedule 12 to the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023* (“the Amendment Act”) commenced. Schedule 12 included an amendment to subsection 41BD(3) of the Act to clarify that an instrument under subsection 41BD(3) (to declare that an article or class of articles is not a medical device) is a legislative instrument. Schedule 12 to the Amendment Act also contained a savings provision with the effect that any order that was in force under subsection 41BD(3) of the Act prior to the commencement of the Amendment Act continues to be in force.

Purpose

There are 4 instruments that were made under subsection 41BD(3) of the Act prior to the amendments made by the Amendment Act (“the former Instruments”). The former Instruments are as follows and are published on the TGA’s website (with one also registered on the Federal Register of Legislation as a notifiable instrument):

- Therapeutic Goods (Articles that are not Medical Devices) Order No.2 of 2004;
- Therapeutic Goods Information (Articles that are not Medical Devices) Order No.1 of 2010;
- Therapeutic Goods (Articles that are not Medical Devices) Order No.1 2017; and
- Therapeutic Goods (Materials or Articles that are Not Medical Devices) Order 2019.

The Declaration repeals and replaces the former Instruments for the principal purpose of consolidating the former Instruments into a single legislative instrument, without change to the substantive content or effect of the former Instruments. The Declaration sets out all of the articles that were previously declared to not be medical devices under subsection 41BD(3) of the Act. Any substantive changes to the former Instruments will be made by legislative instrument in future.

Consultation

Consultation on the proposed Declaration was not undertaken in the circumstances as the Declaration has the same effect as the former Instruments and does not alter the existing regulatory arrangements in relation to the articles declared to not be medical devices. Rather, the Declaration simply consolidates the existing declarations made by the former Instruments (without change) into a single legislative instrument.

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

The Declaration 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 Declaration is a disallowable legislative instrument for the purposes of the Legislation Act and commences on the day after it is registered on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023*

Section 1—Name

This section provides that the name of the instrument is the *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* (“the Declaration”).

Section 2—Commencement

This section provides that the Declaration 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 Declaration is subsection 41BD(3) of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4—Definitions

This section provides the definitions of terms used in the Declaration, including, for example, ‘fungicide’, ‘hospital grade disinfectant’, ‘household grade disinfectant’ and ‘sterilant’.

The note to this section provides that certain terms used in the Declaration have the meaning given in subsection 3(1) of the Act, including ‘medicine’ and ‘medical device’.

Section 5—Articles that are not medical devices

This section declares that, for the purposes of the Act, the particular (or particular classes of) instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified in Schedule 1 to the Declaration are not medical devices.

Section 6—Repeals

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

Schedule 1—Articles declared not to be medical devices

This Schedule declares the articles that are not medical devices for the purposes of section 5. The articles mentioned in the table in this Schedule are the same articles specified in the instruments in Schedule 2, that are repealed and replaced by the Declaration.

Schedule 2—Repeals

This Schedule specifies, for the purposes of section 6, the following instruments are repealed:

- Therapeutic Goods (Articles that are not Medical Devices) Order No.2 of 2004;
- Therapeutic Goods Information (Articles that are not Medical Devices) Order No.1 of 2010;
- *Therapeutic Goods (Articles that are not Medical Devices) Order No.1 2017*;
- *Therapeutic Goods (Materials or Articles that are Not Medical Devices) Order 2019*.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Articles that are Not Medical Devices) Declaration 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 41BD of the Act provides the meaning of ‘medical device’ for the purposes of the *Therapeutic Goods Act 1989* (“the Act”). Subsection 41BD(1) provides a broad definition of ‘medical device’, which includes instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, specified under subsections 41BD(2A) and (2B) of the Act.

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The *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* (“the Declaration”) is a legislative instrument made under subsection 41BD(3) of the Act, and declares that a number of articles are not medical devices for the purposes of the Act.

Background

Previously, subsection 41BD(3) of the Act conferred on the Secretary of the Department the power to declare that particular (or particular classes of) instruments, apparatus, appliances, software, implants, reagents, materials or other articles, are not, for the purposes of the Act, medical devices, by order published in the *Gazette* or on the Department’s website.

The effect of an instrument under subsection 41BD(3) of the Act is that therapeutic goods declared to not be a medical device are not regulated under Chapter 4 of the Act, and are instead regulated under Chapter 3 of the Act. Chapter 4 includes regulatory requirements that are appropriate for medical devices, including requirements for conformity assessment certification for quality management and compliance with Essential Principles for medical devices. However, the regulatory framework for medical devices may not be appropriate for certain therapeutic goods, or there may be uncertainty as to whether certain therapeutic goods are or are not medical devices for the purposes of the Act. An instrument under subsection 41BD(3) provides clarity on the regulatory arrangements applying to particular therapeutic goods.

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However, the characterisation of instruments made under subsection 41BD(3) as administrative or notifiable instruments was inconsistent with subsection 8(4) of the *Legislation Act 2003* (“the Legislation Act”), as such instruments:

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- affect a privilege or interest, impose an obligation, create a right, or vary or remove an obligation or right by altering the regulatory status of such goods under the Act.

On 21 March 2023, Schedule 12 to the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023* (“the Amendment Act”) commenced. Schedule 12 included an amendment to subsection 41BD(3) of the Act to clarify that an instrument under subsection 41BD(3) (to declare that an article or class of articles is not a medical device) is a legislative instrument. Schedule 12 to the Amendment Act also contained a savings provision with the effect that any order that was in force under subsection 41BD(3) of the Act prior to the commencement of the Amendment Act continues to be in force.

Purpose

There are 4 instruments that were made under subsection 41BD(3) of the Act prior to the amendments made by the Amendment Act (“the former Instruments”). The former Instruments are as follows and are published on the TGA’s website (with one also registered on the Federal Register of Legislation as a notifiable instrument):

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The Declaration repeals and replaces the former Instruments for the principal purpose of consolidating the former Instruments into a single legislative instrument, without change to the substantive content or effect of the former Instruments. The Declaration sets out all of the articles that were previously declared to not be medical devices under subsection 41BD(3) of the Act. Any substantive changes to the former Instruments will be made by legislative instrument in future.

Human rights implications

The Declaration engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“the 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 Declaration supports the right to health by, in effect, determining the regulatory arrangements that apply to particular therapeutic goods. The Declaration provides clarity for industry to facilitate compliance with appropriate regulatory requirements. This supports the availability of therapeutic goods in Australia. It also ensures the appropriate level, and kind, of regulation is applied to therapeutic goods.

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

Conclusion

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