EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. It also provides for the establishment and maintenance of a national system of controls for the importation, manufacture, supply, commercial possession, advertising and export of vaping goods. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health, Disability and Ageing.

Section 41BD of the Act provides the meaning of 'medical device' for the purposes of the Act. Relevantly paragraph 41BD(1)(a) provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is, or is to be, supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i) to (v) and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. Those purposes include, for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

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 subsection 41BD(3) does not prevent articles from being therapeutic goods. That is, if an article is declared not to be a medical device, but otherwise meets the definition of 'therapeutic goods' in subsection 3(1) of the Act, the article will be regulated as such under Chapter 3 of the Act, rather than as a medical device under Chapter 4 of the Act.

The *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* (the Principal 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 *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025* (the Amendment Declaration) amends the Principal Declaration to declare four additional classes of goods not to be medical devices for the purposes of the Act. It also repeals and replaces Note 1 of section 4 to update the list of expressions used in the instrument that are defined in subsection 3(1) of the Act.

The Amendment Declaration provides for a 5-year transitional period for existing medical devices that are included in the Australian Register of Therapeutic Goods (the Register) to allow sponsors sufficient time to transition their products to the appropriate new regulatory category for their products.

Background

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.

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Products that meet the legislative definition of a therapeutic good under the Act are regulated by the TGA and, unless exempt, are required to be included in the Australian Register of Therapeutic Goods (the ARTG).

The main categories of therapeutic goods are medicines, medical devices, biologicals and a category known as 'other therapeutic goods' which principally comprises tampons, menstrual cups and certain kinds of disinfectants. Some goods, known as boundary products, have attributes of two or more of these regulatory categories, and as a result the appropriate regulatory pathway for such products is not immediately clear. Similarly, combination products contain two or more type of therapeutic goods with multiple therapeutic actions or effects.

Purpose

The purpose of the Amendment Declaration is to clarify the regulatory status of four classes of such boundary products. It is made under subsection 41BD(3) of the Act and adds four new items to the table in Schedule 1 to the Principal Declaration, with the effect that products covered by these items will not be medical devices for the purposes of the Act:

- New table item 8 declares that toothpastes (and other dentifrices) that achieve their principal intended action through having an effect by chemical or pharmacological means.
- New table item 9 declares that head or body lice treatments that achieve their principal intended action through having an effect by chemical or pharmacological means. This includes, for example, products causing neurotoxicity to the lice or that shut down their respiratory systems via a mothering/suffocating action.
- New table item 10 declares moisturisers and emollients that achieve their principal intended action through having an effect by chemical, metabolic or pharmacological means.
- New table item 11 declares that weight loss treatment products that are ingested into the body, which affect absorption of calories in the gastrointestinal system by metabolic means.

Specifying that these boundary products are not medical devices is designed to clarify the regulatory requirements for these products, assisting manufacturers to meet necessary requirements. The changes to the regulatory status of these products are also made in order to better align with comparable international jurisdictions and will also provide clarity for new products entering the market.

The 5-year transitional period for these changes allows sufficient time for manufacturers of the affected products to make the necessary adjustments to meet applicable regulatory requirements.

Consultation

Two public consultations were undertaken in relation to the changes reflected in the Amendment Declaration – one in 2022, and one in 2024.

The consultation undertaken in 2022 sought feedback on draft guidance prepared by the TGA for the regulation of boundary and combination products. Feedback on that consultation suggested that further clarity was needed in relation to certain boundary and combination products.

A second consultation was undertaken in 2024 in relation to the most appropriate regulatory pathway for a number of boundary and combination products, including the products affected by the Amendment Declaration. The TGA received 34 responses to the consultation, with overall support for legislating regulatory categories for the relevant products in the manner effected by the Amendment Instrument. A proposed 5-year transitional period was also supported.

Other details

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

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The Amendment 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 Amendment Declaration is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 1 January 2026.

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Attachment A

Details of the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration (No. 2) 2025* (the Amendment Declaration).

Section 2 – Commencement

This section provides that the Amendment Declaration commences on 1 January 2026.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Declaration is subsection 41BD(3) of the *Therapeutic Goods Act 1989* (the Act).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The Amendment Declaration is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Declaration is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Declaration has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023* (the Principal Declaration).

Item 1 – Section 4 (note)

This item repeals the existing Note 1 in section 4, which provides a list of expressions used in the instrument that are defined in subsection 3(1) of the Act, and replaces it with a new Note 1 that reflects a number of new expressions added to the instrument by the Amendment Declaration.

Item 2 – After section 5

This item inserts new section 6 to the Principal Declaration, which provides for application, saving and transitional provisions relating to the amendments made by the Amendment Declaration. The effect of this section is to provide for a 5-year transitional period for existing therapeutic goods whose regulatory category is changed by the Amendment Declaration. Medical devices that were included in the Register immediately prior to the commencement of the Amendment Declaration will not be subject to the declaration that they are not medical devices for a period of 5 years, ending 1 January 2031. During this period, they will continue to be regulated as medical devices until such time as their sponsors complete the necessary process for the goods to be regulated according to their appropriate new regulatory category. To assist this process, new section 6 provides for the affected goods to be subject to the new regulatory category for the purposes of the application process and the associated provisions of the Act.

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Item 3 – Schedule 1 (at the end of the table)

This item inserts new items 8 to 11 in Schedule 1 to the Principal Declaration.

New item 8 declares that toothpastes (and other dentifrices) that achieve their principal intended action through having an effect by chemical or pharmacological means are not medical devices for the purposes of the Act.

New item 9 declares that head or body lice treatments that achieve their principal intended action through having an effect by chemical or pharmacological means are not medical devices for the purposes of the Act. This includes, for example, products causing neurotoxicity to the lice.

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Attachment B

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) Amendment Declaration (No. 2) 2025

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 Act. Relevantly paragraph 41BD(1)(a) provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is, or is to be, supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i) to (v) and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. Those purposes include, for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

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Human rights implications

The Amendment 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 and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

The Amendment Declaration supports the right to health by clarifying the regulatory status of the goods it inserts into the Principal Declaration. This reduces the risk of confusion and provides greater certainty, for both industry and consumers, of the regulatory status of such products.

The amendments made by the Amendment Declaration also assist industry in understanding their regulatory requirements and responsibilities, including where relevant, the minimum standards that such goods are required to meet. The application of minimum regulatory requirements to these goods provides consumers with a degree of assurance as to the quality, safety and performance of such goods.

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Conclusion

The Amendment Declaration 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.

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