# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration 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 and Aged Care.

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 2025* (the Amendment Declaration) makes a minor amendment to the Principal Declaration to correct an unintended consequence arising from amendments made by the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* (the Vaping Amendment Declaration).

## Background

The Principal Declaration, made under subsection 41BD(3) of the Act, declares particular instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or particular classes of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, not to be medical devices for the purposes of the Act.

As part of the reforms to the regulation of vapes in Australia, on 1 January 2024, the Vaping Amendment Declaration amended item 3 of Schedule 1 to the Principal Declaration to provide that non-reusable articles that are for use in combination with a therapeutic good, whether or not the therapeutic good is a medicine, as a single integral unit intended to administer that therapeutic good, are not medical devices for the purposes of the Act.

As explained in the Explanatory Statement to the Vaping Amendment Declaration, this amendment was intended to ensure that non-reusable vaping devices that contain a vaping substance that is intended to be for therapeutic use, but did not meet the definition of 'medicine' in subsection 3(1) of the Act, were declared not to be medical devices, and therefore regulated under Chapter 3, rather than Chapter 4 of the Act.

However, concerns have arisen that the use of the expression 'therapeutic good' in item 3 of Schedule 1 to the Principal Declaration (as amended by the Vaping Amendment Declaration), inadvertently captures a broader range of therapeutic goods that should continue to be regulated as medical devices under Chapter 4 of the Act. For example, nasal sprays, dermal fillers, surgical markers and blood storage anticoagulants.

This outcome is contrary to the policy intention, which was to clarify, and ensure uniformity of regulation of, non-reusable vaping devices that contain a therapeutic vaping substance, whether that substance is a medicine or another therapeutic good.

**Purpose**

The purpose of the Amendment Declaration therefore is to rectify an unintended effect of the amendments made by the Vaping Amendment Declaration, while still giving effect to the original policy objective.

Specifically, the Amendment Declaration amends the Principal Declaration to:

- remove references to 'therapeutic good' in item 3 of Schedule 1, and revert to the original expression 'medicine'; and

- introduce a new item in Schedule 1 that declares vaping devices that are pre-filled with a therapeutic vaping substance that form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are not medical devices for the purposes of the Act.

**Consultation**

Consultation was not undertaken in relation to the making of the Amendment Declaration as the purpose of the Amendment Declaration is simply to correct an unintended consequence of the Vaping Amendment Declaration.

Significant consultation was separately undertaken in relation to the Government's vaping reform measures, which included the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*, related regulations and other legislative instruments, including the Vaping Amendment Declaration.

**Other details**

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

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 Office of Impact Analysis (OIA) has advised that an impact analysis is not required in relation to the amendments to the Principal Declaration on the basis that the amendments do not significantly differ from the status quo as it would give effect to the original policy intent (OIA25-08830).

The Amendment Declaration is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment Declaration 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 2025* (the Amendment Declaration).

**Section 2 – Commencement**

This section provides that the Amendment 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 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

This item amends section 4 of the Principal Declaration to introduce definitions of ‘therapeutic vaping substance’ and ‘vaping device’, consequential to the amendments made below.

## Item 2 – Schedule 1 (table item 3)

This item amends item 3 of Schedule 1 to the Principal Declaration to replace ‘therapeutic good’, wherever occurring, with the expression ‘medicine’. This amendment has the effect of removing the unintended effect of the amendments made to that item by the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* (the Vaping Amendment Declaration).

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

This item introduces new item 12 in Schedule 1 to the Principal Declaration to declare that vaping devices that are pre-filled with a therapeutic vaping substance that form a single integral product which is intended exclusively for use in the given combination and that are not reusable (but may be multi-dose) are not medical devices for the purposes of the Act. This item would include, for example, a disposable therapeutic vape.

The effect of this amendment is that non-reusable vaping devices that contain a therapeutic vaping substance that is intended to be for therapeutic use, whether the substance is a medicine or another therapeutic good, are declared not to be medical devices, and therefore are regulated as therapeutic goods under Chapter 3 of the Act, instead of Chapter 4.

Collectively items 2 and 3 are intended to rectify an unintended effect of the amendments made by the Vaping Amendment Declaration, and to give effect to the original policy intention.

**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 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.

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 2025* (the Amendment Declaration) makes a minor amendment to the Principal Declaration to correct an unintended consequence arising from amendments made by the *Therapeutic Goods (Articles that are Not Medical Devices) Amendment (Vaping) Declaration 2023* (the Vaping Amendment Declaration).

### Background

The Principal Declaration, made under subsection 41BD(3) of the Act, declares particular instruments, apparatus, appliances, software, implants, reagents, materials or other articles, or particular classes of instruments, apparatus, appliances, software, implants, reagents, materials or other articles, not to be medical devices for the purposes of the Act.

As part of the reforms to the regulation of vapes in Australia, on 1 January 2024, the Vaping Amendment Declaration amended item 3 of Schedule 1 to the Principal Declaration to provide that non-reusable articles that are for use in combination with a therapeutic good, whether or not the therapeutic good is a medicine, as a single integral unit intended to administer that therapeutic good, are not medical devices for the purposes of the Act.

As explained in the Explanatory Statement to the Vaping Amendment Declaration, this amendment was intended to ensure that non-reusable vaping devices that contain a vaping substance that is intended to be for therapeutic use, but did not meet the definition of 'medicine' in subsection 3(1) of the Act, were declared not to be medical devices, and therefore regulated under Chapter 3, rather than Chapter 4 of the Act.

However, concerns have arisen that the use of the expression 'therapeutic good' in item 3 of Schedule 1 to the Principal Declaration (as amended by the Vaping Amendment Declaration), inadvertently captures a broader range of therapeutic goods that should continue to be regulated as medical devices under Chapter 4 of the Act. For example, nasal sprays, dermal fillers, surgical markers and blood storage anticoagulants.

This outcome is contrary to the policy intention, which was to clarify, and ensure uniformity of regulation of, non-reusable vaping devices that contain a therapeutic vaping substance, whether that substance is a medicine or another therapeutic good.

**Purpose**

The purpose of the Amendment Declaration therefore is to rectify an unintended effect of the amendments made by the Vaping Amendment Declaration, while still giving effect to the original policy objective.

Specifically, the Amendment Declaration amends the Principal Declaration to:

- remove references to 'therapeutic good' in item 3 of Schedule 1, and revert to the original expression 'medicine'; and

- introduce a new item in Schedule 1 that declares vaping devices that are pre-filled with a therapeutic vaping substance that form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are not medical devices for the purposes of the Act.

**Human rights implications**

As the purpose of the Amendment Declaration is simply to rectify an unintended effect of the Vaping Amendment Declaration, it does not engage any applicable rights or freedoms.

**Conclusion**

The Amendment Declaration is compatible with human rights because it does not raise any human rights issues.