

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021*

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 TGA within the Department of Health.

Section 7AA of the Act relevantly provides that the Minister may, by legislative instrument, determine that specified goods are excluded goods for the purposes of the Act. The effect of a determination under section 7AA is to exclude the specified goods from regulation as therapeutic goods under the Act.

#### **Purpose and operation of the instrument**

The *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021* (“the Amendment Determination”) is made under section 7AA of the Act. The Amendment Determination gives effect to existing regulatory arrangements for vaping devices, by clarifying that the only vaping devices regulated as therapeutic goods in Australia are those devices intended by their supplier to be used exclusively for the vaporisation and administration of a medicine, including vapouriser nicotine. The Amendment Determination excludes all other vaping devices from regulation as therapeutic goods, including those devices that are intended to vaporise and administer a medicine in addition to other substances.

Vaping devices can broadly be described as devices that include a cartridge, capsule or other container that hold a substance (such as vapouriser nicotine). The devices produce a vapour or aerosol that is delivered into a person’s body when the person inhales through the device. Examples of vaping devices include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens. Vapouriser nicotine is a medicine that contains nicotine in salt or base form and may also be described as nicotine vape liquid, nicotine e-liquid or simply e-liquid.

Most vaping devices (except those that are intended to be used exclusively for the vaporisation and administration of a medicine) are not regulated as therapeutic goods in Australia. The Amendment Determination confirms this position, and so provides greater clarity about the regulatory status of these devices. The need for clarity has arisen in light of recent measures which affect the regulation of vapouriser nicotine in Australia. The Amendment Determination is intended to provide industry, health practitioners and members of the public with certainty that, despite those measures, the regulation of vaping devices remains unchanged.

#### **Legislative authority**

The *Therapeutic Goods (Excluded Goods) Determination 2018* (“the Principal Determination”) is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act.

The Amendment Determination amends the Principal Determination by adding new item 16 in Schedule 1. New item 16 specifies that vaping devices are excluded goods for the purposes of the Act, other than those vaping devices that are intended by their supplier to be used exclusively for the vaporisation and administration of a medicine. Vaping devices intended to vaporise and administer a medicine are therapeutic goods, as defined in section 3 of the Act.

The effect of the Amendment Determination is to clarify that the only vaping devices regulated as therapeutic goods are those devices intended by their supplier to vaporise and administer a medicine and not intended to be used for any other purpose. The Amendment Determination excludes all other vaping devices from regulation as therapeutic goods. In particular, new item 16 identifies vaporiser nicotine as an example of a medicine. This makes it clear that a vaping device intended by its supplier to exclusively vaporise and administer a medicine, such as vaporiser nicotine, is regulated as a therapeutic good, and that the following devices are not regulated as therapeutic goods:

- vaping devices intended to vaporise and administer a substance that is not a medicine; and
- vaping devices intended to vaporise and administer a medicine in conjunction with another substance, such as a flavour that is not an ingredient of the medicine.

In accordance with subsection 7AA(3) of the Act, before making a determination to exclude specified goods from the operation of the Act, the Minister must have regard to whether it is likely that the goods might harm the health of the members of the public if not regulated as therapeutic goods, whether it is appropriate in all of the circumstances to apply the national system of controls established by the Act, and whether the goods could be more appropriately dealt with under other regulatory schemes. The Minister may also have regard to any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

The most significant health risks posed by vaping principally relate to the harms of nicotine exposure and addiction. Such risks will be appropriately managed in Australia by ensuring that vaporiser nicotine is only accessible with the prescription of a medical practitioner and that the therapeutic goods regulatory framework applies to vaporiser nicotine medicines and the vaping devices designed (exclusively) to deliver such medicines. The regulation of these vaping devices as therapeutic goods is appropriate to ensure the devices are safe and perform as intended when administering a medicine. Further, the kinds of risks associated with the vaping devices that are excluded from the framework by the Amendment Determination will continue to be appropriately dealt with by Australian Consumer Law, as they have been to date. In the event of any safety issues or false or misleading statements in advertising for the excluded devices, provisions of the Australian Consumer Law would continue to afford protection to the public.

## **Background**

Within Australia and internationally there is widespread concern, including among public health policy makers and practitioners, about the increased use of vaporiser nicotine, particularly by youth. The Australian Government is taking a precautionary approach to the regulation of nicotine with a view to preventing the uptake of nicotine containing e-cigarettes, particularly among adolescents and young adults, providing efficacious smoking cessation support to patients, and reducing the likelihood of child poisoning by accidental consumption of nicotine. Recent measures affecting the regulation of nicotine-based products were informed by these concerns.

In particular, a delegate of the Secretary made a decision under regulation 42ZCZR of the *Therapeutic Goods Regulations 1990* to amend the Poisons Standard to reschedule nicotine so that certain nicotine containing products are only available (including when imported) with a prescription from an Australian medical practitioner. In practice, this means legal access to vaporiser nicotine in Australia will only be by prescription and via a therapeutic goods regulatory pathway. The decision balanced consumer demand for nicotine e-cigarettes to support smoking cessation and the public health need to reduce and prevent the initiation of nicotine addiction among non-smokers, in particular, adolescents. The decision is to be implemented from 1 October 2021.

In addition, the *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020* amended the *Therapeutic Goods (Medical Devices) Regulations 2002* to exempt medical devices intended by their supplier to be used for the vaporisation and administration of certain registered medicines containing nicotine for the purposes of smoking cessation, from the

requirement to be included in the Australian Register of Therapeutic Goods (“the Register”). While devices that are subject to the exemption would not require an application for inclusion in the Register, the devices would still fall within the regulatory ambit of the Act and require compliance with essential principles and relevant conformity assessment procedures. These amendments were designed to avoid unnecessary duplication in relation to applications for marketing approval, and commenced on 19 December 2020.

## **Consultation**

The TGA conducted extensive consultation in relation to the decision to reschedule nicotine under the Poisons Standard. Consultation was conducted in the form of a public invitation for submissions, targeted meetings and discussions with key stakeholders. As part of that process, the TGA received submissions concerning the regulation of vaping devices, including from the Australian Competition and Consumer Commission.

The TGA has also considered written submissions to the Senate Select Committee on Tobacco Harm Reduction and the public hearings of the Committee conducted on 13 and 19 November 2020. That consultation included consideration of the performance and reliability of vaping devices that are used to administer nicotine prescribed by medical practitioners for smoking cessation.

In January 2021 the TGA conducted roundtable discussions with relevant peak bodies and experts, including the Royal Australian College of General Practitioners (RACGP) and the Australian Medical Association. These discussions involved consideration of minimum quality and safety standards for vaporiser nicotine, as well as the performance of vaping devices used to vaporise and administer those medicines.

The preparation of a regulation impact statement for the Amendment Determination is not considered necessary given the Amendment Determination does not alter existing regulatory arrangements for vaping devices.

## **Other details**

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

The Amendment Determination 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 Determination 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.

**Details of the *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021* (“the Amendment Determination”).

**Section 2 – Commencement**

This section provides that the Amendment Determination 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 Determination is section 7AA 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. This Amendment Determination 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 Determination 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 Determination has effect according to its terms.

**Schedule 1 – Amendments**

This Schedule amends the *Therapeutic Goods (Excluded Goods) Determination 2018* (“the Principal Determination”).

Item 1 of this Schedule substitutes the note at the beginning of section 4 of the Principal Determination to also include a reference to ‘medicine’.

Item 2 of this Schedule adds a new item 16 at the end of the table in Schedule 1 to the Principal Determination. New item 16 specifies that vaping devices are excluded goods for the purposes of the Act, other than those vaping devices that are intended, by the person under whose name the device is or is to be supplied, to be used exclusively for the vaporisation and administration of a medicine, including vaporiser nicotine.

## Statement of Compatibility with Human Rights

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

### *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021*

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 (Excluded Goods) Determination 2018* (“the principal instrument”) is made under section 7AA of the Act and determines specified goods to be excluded goods for the purposes of the *Therapeutic Goods Act 1989* (“the Act”). The *Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021* (“the amendment instrument”) is also made under section 7AA of the Act and amends the principal instrument to specify that vaping devices are excluded goods for the purposes of the Act, other than vaping devices that are intended by their supplier to be used exclusively for the vaporisation and administration of a medicine.

The amendment instrument has the effect of clarifying that the only vaping devices that are subject to regulation as therapeutic goods are those devices intended by their supplier to vaporise and administer a medicine and not intended to be used for any other purpose. All other vaping devices are excluded from regulation as therapeutic goods.

The need for greater clarity around the regulatory status of vaping devices has arisen in light of recent measures which affect the regulation of vapouriser nicotine in Australia. The amendment instrument is intended to provide industry, health practitioners and members of the public with certainty that, despite those measures, the regulation of vaping devices in Australia remains unchanged.

#### Human rights implications

The instrument 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.

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 amendment instrument takes positive steps to promote the right to health by providing industry, health practitioners and members of the public with certainty in relation to the regulatory status of vaping devices. Further, the instrument enables the Department of Health and industry to appropriately focus valuable resources on regulating higher risk aspects of vaping, such as ensuring the quality, safety and efficacy of vapouriser nicotine and devices used exclusively to administer such medicines. As the instrument does not introduce any changes to existing regulatory arrangements, it does not otherwise engage any of the applicable rights or freedoms.

## **Conclusion**

This legislative 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.