EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023

The *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (the Amendment Regulations) address the risks posed by vaping to children and adolescents in Australia, while preserving legitimate patient access to therapeutic vapes for smoking cessation and the management of nicotine dependence under medical supervision. The Amendment Regulations implement heightened regulatory controls for the importation, manufacture, and supply of therapeutic vapes and complement prohibitions under the *Customs Act 1901*.

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 used in, whether produced in Australia or elsewhere, or exported from, Australia. Subsection 63(1) of the Act provides for the making of regulations not inconsistent with the Act, prescribing matters required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Amendment Regulations amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) (collectively, the Principal Regulations), to implement the first stage of the Government's vaping reform measures.

The Amendment Regulations are intended to address the risks posed by vaping to children and young people in Australia, the possible long term adverse health effects of vaping to Australians who use vapes, and the adverse health effects of toxic chemicals and other ingredients found in vapes. At the same time, the amendments preserve access to therapeutic vapes for smoking cessation and the management of nicotine dependence under medical supervision. All therapeutic vaping goods, including non-nicotine vapes, are to be supplied in Australia, only by registered pharmacists or other persons authorised to do so under state or territory law.

The Amendment Regulations appropriately and reasonably specify circumstances in which legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence may be lawfully imported, manufactured, and supplied in Australia. These circumstances are prescribed in the Principal Regulations as exemptions to the requirement for inclusion in the Australian Register of Therapeutic Goods (the Register).

The Amendment Regulations implement measures that are necessary to give effect to proposed reforms announced by the Minister for Health and Aged Care in May 2023. The broad intent is to impose heightened regulatory requirements on the importation, manufacture, and supply of vapes in Australia. The reforms support the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Principally, the Amendment Regulations appropriately and reasonably specify the circumstances in which legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence may be lawfully imported, manufactured and supplied in Australia by prescribing exemptions in the Principal Regulations, subject to certain conditions. This includes a pre-market notification requirement for therapeutic vapes prior to lawful importation, manufacture, or supply in Australia. The notification must be provided to the Secretary in relation to the goods' compliance with the relevant quality standards; and compliance will subject to post-notification surveillance by the Therapeutic Goods Administration (TGA) to ensure that the matters notified to the Secretary are correct.

The Amendment Regulations complement regulatory changes in the *Customs Legislation Amendment (Vaping Goods) Regulations 2023*. The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The Amendment Regulations commence on 1 January 2024. Details of the Amendment Regulations are set out in the Attachment A.

The Amendment Regulations are 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.

Consultation

The TGA conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on reforms to the regulation of nicotine vaping products in Australia. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA has engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique of 1 September 2023, which conveyed Ministers' collective commitment to enhancing regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding several webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for the Department of Health and Aged Care on regulatory measures to be implemented, including those that are implemented in these Amendment Regulations.

An impact analysis was prepared on the proposed reforms to the regulation of vapes, based on the feedback received from stakeholders and the Australian public. The Office of Impact Analysis assessed the impact analysis and determined that it was consistent with good practice and met Australian Government best practice regulation requirements (OBPR23-03933).

The impact analysis is supporting material to this explanatory statement (Attachment C) and has also been published on the Office of Impact Analysis website at: oia.pmc.gov.au/.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT A

Details of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 January 2024.

Section 3 – Authority

This section provides that the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (the Amendment Regulations) are made under the *Therapeutic Goods Act 1989.*

Section 4 – Schedules

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

Schedule 1 – Amendment of the *Therapeutic Goods Regulations 1990*

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are not yet known.

The Amendment Regulations implement measures that are necessary to give effect to the first of proposed reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. The broad intent is to prohibit the importation, manufacture and supply vapes in Australia unless certain requirements under the Therapeutic Goods Act 1989 (the Act) are met. The reforms implemented in the Amendment Regulations align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Summary

Schedule 1 of the Amendment Regulations amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) to appropriately and reasonably specify the circumstances in which legitimate therapeutic vapes that are medicines or other therapeutic goods for smoking cessation and the management of nicotine dependence may be lawfully imported, manufactured and supplied in Australia. These circumstances are prescribed in the TG Regulations as exemptions to the requirement for inclusion in the Australian Register of Therapeutic Goods (the Register). Specifically, the Amendment Regulations amend the TG Regulations by:

- expanding the regulation of therapeutic vaping substances under the TG Regulations to include non-nicotine vaping substances, accessories used with vaping substances, ingredients or components used in the manufacture of those items, kits containing one or more therapeutic vaping goods, and therapeutic vaping packs;
- prescribing an exemption setting out the circumstances in which these goods may be lawfully imported, manufactured, and supplied in Australia, without being included in the Register, including the following:
  - the only indications for the vaping goods are for use in smoking cessation or the management of nicotine dependence;
  - the sponsor of the goods, and any other person involved in the wholesale or retail supply of the goods, intend the goods to be supplied to the ultimate consumer of the goods in accordance with an approval or authority under section 19 of the *Therapeutic Goods Act 1989* (the Act) (namely, the Special Access and Authorised Prescribers Schemes);
  - the goods are not, or do not, include any medicinal cannabis products;
- introducing a pre-market notification requirement for these goods prior to lawful importation, manufacture or supply in Australia; the notification must be provided to the Secretary and will be subject to post-notification surveillance by the Therapeutic Goods Administration (TGA) to ensure that the matters that are notified to the Secretary are correct, including:
  - for therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack (collectively, therapeutic vaping goods)—the goods conform with any standard applicable to the goods, or are imported or supplied (as the case may be) with the consent of the Secretary under section 14 or 14A of the Act; and the only indications of the goods are for smoking cessation or the management of nicotine dependence;
  - for therapeutic goods that are nicotine in solution as a starting material for use in the manufacture of a therapeutic vaping substance, therapeutic vaping substance accessory or other therapeutic good, or any other starting materials that are ingredients or components for use in the manufacture of a therapeutic vaping substance or therapeutic vaping substance accessory—the goods are for use in therapeutic goods manufacture by a manufacturer who holds all relevant licences or approvals required under the Act, or the state or territory law in which further manufacture is to occur;
- requiring the notices mentioned above to be given for goods imported into Australia, before their importation, and for goods manufactured in Australia, other than vapes or vape accessories containing cannabis—before the goods are released for supply in Australia;
- specifying that the exemptions are subject to conditions, including that the required notification has been made and the goods are supplied to the ultimate consumer as a finished product by a registered pharmacist or other person authorised to supply prescription medicines;
- enabling determinations to be made by the Secretary that therapeutic vaping goods are not to be covered by the relevant exemptions if the Secretary is satisfied that their supply compromises public health and safety or the goods no longer comply, or did not comply, with applicable standards;
- prohibiting the importation of unregistered therapeutic vaping goods, under the personal importation scheme, apart from specified allowable quantities for travellers who arrive on board a ship or aircraft;

- removing the ability for the direct control exemption to apply to specified therapeutic goods. This exemption normally allows goods imported into Australia to be held under the control of the sponsor of the goods until specified circumstances occur, such as approvals, notifications or authorisations;
- creating a time-limited exemption from the requirement to obtain a manufacturing licence to manufacture a therapeutic vaping substance, therapeutic vaping substance accessory, therapeutic vaping kits and goods in a therapeutic vaping pack in Australia; the transition period applies in relation to persons who carried out equivalent steps in the manufacture of goods that were not therapeutic goods as at 2 May 2023; and
- including transitional provisions and consequential amendments, such as the repeal of provisions referencing nicotine vaping products.

Part 1—Main amendments

Item 1 – Regulation 2

Item 1 inserts a definition of a ***disposable therapeutic vape*** in regulation 2 of the TG Regulations. Regulation 2 provides for the definition or interpretation of terms used in these Regulations. The term disposable therapeutic vape is used in Schedules 5 and 5A to the TG Regulations to describe exemptions that apply, or do not apply, in relation to those goods.

Disposable therapeutic vape is defined as a therapeutic good that is a vaping device, that is fully assembled with all the constituent components fixed permanently in place and is not designed or intended to be disassembled, is prefilled with the therapeutic vaping substance or liquid and is not designed to be refilled.

Item 2 – Regulation 2 (definition of *nicotine vaping product*)

Item 2 repeals the definition of nicotine vaping product in regulation 2 of the TG Regulations. Unlike the current definition of nicotine vaping product, the regulation of therapeutic vaping goods under the TG Regulations is no longer predicated on the presence of nicotine.

Item 3 – Regulation 2

Item 3 inserts into regulation 2 of the TG Regulations additional defined terms to support the new provisions and amendments introduced by the Amendment Regulations. The following terms are inserted:

- ***therapeutic vaping device***, which has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). This is a new term included in the MD Regulations;
- ***therapeutic vaping device accessory***, which has the same meaning as in the MD Regulations. This is also a new term included in the MD Regulations;
- ***therapeutic vaping good***, which means, a therapeutic vaping device, a therapeutic vaping device accessory, a therapeutic vaping substance or a therapeutic vaping substance accessory;
- ***therapeutic vaping kit***, which means a kit, covered by subsection 7B(1) of the Act, that contains one or more therapeutic vaping substances or therapeutic vaping substance accessories and does not contain any other goods;
- ***therapeutic vaping pack***, which means a primary pack that contains two or more therapeutic vaping goods, including at least one therapeutic vaping device or therapeutic

vaping device accessory and does not contain any other goods. A therapeutic vaping pack differs from a therapeutic vaping kit in that it contains at least one therapeutic vaping device or therapeutic vaping device accessory;

- ***therapeutic vaping substance***, which means a therapeutic good that is a liquid or other substance designed or intended for vaporisation with a vaping device. In effect, a therapeutic vaping substance is the component of a vape that is commonly known as e-liquid;
- ***therapeutic vaping substance accessory***, which means a cartridge, capsule, pod or other vessel that contains a therapeutic vaping substance, whether or not the vessel is designed or intended to be refilled, and is used in or with a therapeutic vaping device;
- ***vaping device***, which means the device which generates or releases, using a heating element and by electronic means, an aerosol, vapour, or mist for direct inhalation by the user of the vape. Vaping device includes devices that are incomplete, damaged, temporarily or permanently inoperable or unfinished.

For the avoidance of doubt, the definition of vaping device includes a note providing examples of devices that are not vaping devices. Those being, humidifiers, diffusers, nebulisers and inhalers. Humidifiers, diffusers, and some steam inhalers do not meet the definition of a vaping device because the vapour or mist is not for direct inhalation by the user. Devices that release vapour or mist into the air, and direct that air towards the user through a mask, such as some inhalers and nebulisers also do not meet the definition of a vaping device.

Devices that do not produce vapour or mist using a heating element, such as nebulisers and most inhalers, do not meet the definition of a vaping device because those devices do not generate the vapour or mist using a heating element. A heat-not-burn device, which heats processed tobacco without combustion and produces a vapour for direct inhalation, does meet the definition of a vaping device. An e-hookah device that vaporises tobacco for direct inhalation does meet the definition of a vaping device, but a traditional non-electronic shisha device does not meet the definition of a vaping device because it does not use electronic means and does not create a vapour, mist, or aerosol.

Item 4 – Subregulations 12(5) to (7)

Item 4 repeals subregulations 12(5) to (7) of the TG Regulations which are no longer required. The types of goods to which the Amendment Regulations applies is broader than those described in subregulations 12(5) to (7), which are limited to vaping products that contain nicotine, and has the effect of regulating all therapeutic vapes regardless of whether those goods contain nicotine.

Item 5 – Subregulation 12B(1B) (table item 58, column 5)

Item 5 amends subregulation 12B(1B) of the TG Regulations. It, after the words ‘smoking cessation’ in column 5 of item 58, inserts the words ‘or management of nicotine dependence’. This facilitates prescribing unregistered vaping substances to manage nicotine dependence under the Authorised Prescriber Scheme.

Item 6 – At the end of subregulation 48(1AB)

Item 6 inserts a new paragraph (c) in subregulation 48(1AB). Regulation 48 of the TG Regulations provides for the list of initial decisions that are reviewable by the Minister and subsequently by the Administrative Appeals Tribunal; and the list of eligible persons who may seek review of initial decisions. The inclusion of the new paragraph (c) has the effect of allowing an eligible person to seek Ministerial review of a determination by the Secretary that the supply of the goods, which were the subject of a notification under item 15 of Schedule 5A to the TG Regulations, be stopped or ceased because the Secretary is satisfied that the supply compromises public health and safety or the Secretary is satisfied that the goods do not conform with a standard applicable to the goods. The decision of the Minister is reviewable by the Administrative Appeals Tribunal.

Item 7 – After Part 1 of Schedule 3

Item 7 inserts a new Part 2 in Schedule 3 to the TG Regulations. The new Part 2 includes a new item 1. New item 1 has the effect of requiring those therapeutic vaping substances and therapeutic vaping substance accessories that are not medicines to be included in the part of the Register for registered goods, if registered. Therapeutic vaping substances and therapeutic vaping substance accessories are not medicines if not represented to achieve, or likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human. This may be the case for therapeutic vaping substances and therapeutic vaping substance accessories that rely on psychological means for smoking cessation or the management of nicotine dependence, in the absence of an active ingredient.

Item 8 – Schedule 4 (at the end of the table)

Item 8 inserts a new item 17 in Schedule 4 to the TG Regulations. This enables a therapeutic vaping kit, if each of the goods in the kit are registered goods, to be included in the part of the Register for listed good. In effect, this prevents sponsors from attempting to include therapeutic vaping kits in the part of their Register for listed goods when the kits contain goods that are simply exempt goods. Kits may only be included in the Register as listed goods, provided each good contained in the kit is already registered.

Item 9 – Schedule 5 (table item 1, column 2, after paragraph (a))

Item 9 inserts a new paragraph (b) in column 2 of item 1 in Schedule 5 to the TG Regulations. Schedule 5 lists therapeutic goods and the circumstances in which the goods are not required to be included in the Register (exempt from the operation of Part 3-2 of the Act (with the exception of sections 30EA, 31A and 31C to 31F)). Item 1 allows for personal importation of therapeutic goods for use in the treatment of the importer or the importer's immediate family, subject to specified requirements being met. However, new paragraph (b) has the effect of excluding disposable therapeutic vapes, therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack from the operation of the personal importation exemption in item 1 of Schedule 5 to the TG Regulations.

Item 10 – Schedule 5 (after table item 1)

Item 10 inserts a new item 1A in Schedule 5 to the TG Regulations. Item 1A allows for the importation of disposable therapeutic vapes, therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits or goods in a therapeutic vaping pack imported into Australia by a person (the ***first person***) on board a ship or aircraft, if those goods are for the medical treatment of the first person or one or more persons on board a ship or aircraft who are under the care of the first person. The exemption operates as a travellers' exemption and the amount of the goods permitted under the exemption are subject to specified limits. The importation of the therapeutic goods is obliged to meet the requirements of paragraph 5(2)(b) or subregulation 5A(2) of the *Customs (Prohibited Imports) Regulations 1956*. Thus, in these circumstances, the goods are exempt from the requirements in Part 3-2 of the Act, except sections 30EA, 31A and 31C to 31F).

Item 11 – Schedule 5 (table items 5 and 5A)

Item 11 repeals item 5 and 5A in Schedule 5 to the TG Regulations. Both items refer to nicotine vaping products. As the regulation of vapes no longer is limited to nicotine vaping products, these items are no longer required, and any exemption now included in Schedule 5 refers to vaping goods that are not limited to those containing nicotine. In addition, a new exemption, subject to different criteria and as well as conditions, is inserted as a new item 15 in Schedule 5A. This exemption applies to a broader range of goods than the old item 5 and 5A in Schedule 5 to the TG Regulations.

Item 12 – Schedule 5 (at the end of the cell at table item 9, column 2)

Item 12 adds paragraphs (c) and (d) to column 2 of item 9 in Schedule 5 to the TG Regulations. Item 9 provides for the exemption of starting materials that are ingredients or components for use in the manufacture of therapeutic goods from the requirement for those starting materials to be included in the Register as set out in Part 3-2 of the Act. However, this exemption does not apply to specified starting materials currently listed in paragraphs (a) and (b) of item 9.

Paragraphs (c) and (d) are added to item 9 to the effect that where the starting materials are nicotine in solution imported for use in the manufacture of a therapeutic good (referred to in paragraph (c)), or are ingredients or components imported for use in the manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory (referred to in paragraph (d)), those starting materials are not covered by the exemption in item 9. Note that new item 16 of Schedule 5A provides a separate exemption relating to starting materials for use in the manufacture of therapeutic vaping substances, therapeutic vaping substance accessories and other therapeutic goods, subject to certain conditions being met.

Item 13 – Schedule 5A (cell at table item 1, column 2)

Item 13 repeals and substitutes the cell at column 2 of item 1 in Schedule 5A to the TG Regulations. Therapeutic goods listed in an item in Schedule 5A are exempt from the operation of Part 3-2 of the Act, which is the requirement for the goods to be included in the Register, subject to the specified conditions applying to that particular item being met. Item 1 currently exempts from the operation of Part 3-2 therapeutic goods that are imported into

Australia, held under the direct control of the sponsor and are subject to the conditions under column 3, until specified circumstances occur such as the goods being authorised for supply under specified provisions of the Act. The amendment to item 1 excludes disposable therapeutic vapes, therapeutic vaping substances, therapeutic vaping substances accessories, therapeutic vaping kits and goods in a therapeutic vaping pack from the exemption detailed in item 1. A new exemption provided in item 14 is instead available.

Item 14 – Schedule 5A (at the end of the table)

Item 14 adds new items 15 and 16 in Schedule 5A to the TG Regulations. New item 15 of Schedule 5A provides the lawful basis for allowing unregistered therapeutic vaping goods to be imported, manufactured and supplied in Australia despite these goods not being included in the Register, and subject to specified conditions being met.

Importantly, products are only covered by this exemption where goods are intended to be supplied to the ultimate consumer in accordance with an approval or authority under section 19 of the Act, that being the Special Access or Authorised Prescriber Schemes. This ensures the relevant goods are prescribed by an appropriate health practitioner. State and territory laws also impose a requirement for vapes containing certain substances, such as nicotine, to be prescribed.

The goods that covered by this item are therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits or goods in a therapeutic vaping pack (that is, contains a therapeutic vaping device). The only indications that are allowed for these exempt goods are for smoking cessation or the management of nicotine dependence.

The new item 15 does not include goods that are, or include, medicinal cannabis products. Thus, unregistered therapeutic vaping substances and therapeutic vaping substance accessories, kits and packs containing medicinal cannabis as the vaping substance or where the medicinal cannabis is in the vaping accessories, are not covered by the new exemption, including the pre-market notification requirements for lawful importation, manufacture, and supply in Australia. Existing processes for the importation, manufacture and supply of medicinal cannabis products that are medicines continue to apply (although there are changes to the regulation of therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories that are designed or intended to be used with, but do not contain, cannabis).

However, unregistered therapeutic vaping goods such as those containing nicotine, vitamin D, melatonin, and other non-nicotine substances need to comply with the conditions prescribed as follows:

- the sponsor of the goods must give the Secretary a notice, in a form approved in writing by the Secretary, stating that the goods conform with any standard applicable to the goods, or are imported or supplied with the consent of the Secretary under section 14 or 14A of the Act, and the only indication of the goods are for smoking cessation or the management of nicotine dependence. In practice, the applicable standards are specified in orders made under section 10 of the Act. The approved form for the notification is available on the TGA website at www.tga.gov.au;
- the pre-market notification described in paragraph (a) must be given to the Secretary before importing the goods into in Australia, or for those goods manufactured in Australia, before the goods are released for supply in Australia;

- the sponsor must hold information or evidence to support the statements made in the notice;
- neither of the statements made in the notice are incorrect;
- the Secretary must not have made a determination that is published on the Department's website that the supply of the goods be stopped or should cease for the following reasons:
  - the Secretary is satisfied that the supply compromises public health and safety; or
  - the Secretary is satisfied that the goods do not conform with a standard applicable to the goods;
- the sponsor must be able to provide the Secretary information or evidence to substantiate compliance with standards when requested and do so within the period requested by the Secretary;
- in relation to goods manufactured in Australia, the goods are manufactured in Australia by the holder of the licence or the person who is exempt from the requirement to hold a licence under Part 3-3 of the Act;
- the goods may be supplied to a person who is not the ultimate consumer of the goods only if:
  - the supply is to the holder of a licence under Part 3-3 of the Act, that is a manufacturing licence; or
  - the supply is to a person who is exempt in accordance with subsection 34(2) of the Act from the operation of Part 3-3 of the Act in relation to the manufacture of the goods; or
  - the supply is to a person who is registered as a pharmacist under a law of a state or territory providing for the registration of pharmacists; or
  - the supply is to any other person who is authorised, under the law of the state or territory in which that person deals with goods, to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and the supply is in accordance with that authorisation;
- the goods may be supplied to the ultimate consumer of the goods only if:
  - the goods are supplied as a finished product; and
  - the supply is by a registered pharmacist or by another person who is authorised, under the law of a state or territory, to supply one or more substances included in Schedule 4 to the current Poisons Standard to an ultimate consumer and the supply is in accordance with that authorisation; and
  - the supply is in accordance with an approval or authority under section 19 of the Act;
- the sponsor of the goods must keep records relating to the source and supply of the goods and if requested by the Secretary, provide those records within the period requested by the Secretary; and
- the sponsor must provide information of a kind mentioned in subsections 29A(2) or 29AA(2) of the Act (generally relating to adverse events resulting from the use of the goods) within the specified periods.

New item 15 confers a discretionary power on the Secretary to determine that the supply of the goods be stopped or should cease because the supply compromises public health and safety or the goods do not conform with the standards applicable to the goods. This power is included to ensure that faulty or non-compliant goods can be prohibited from further supply.

The supply of unregistered goods under item 15 is dependent on the notification provided by the sponsor and is relied on by the Secretary to allow for the importation, manufacture and supply of the goods without pre-market assessment being undertaken by the Secretary. It is therefore important that there is an administrative decision-making process to stop or cease the supply of goods if post-notification surveillance shows that supply of the goods compromises the public health and safety, or that the goods do not conform with the applicable standards, which compromises their quality and/or the health and safety of individuals using them.

Without the availability of this determination the goods would be allowed to be supplied continuously to the public. A determination will only be made if the Secretary is satisfied that the supply compromises public health and safety, or that the goods do not conform with a standard applicable to the goods. The determination is reviewable by the Minister and subsequently by the Administrative Appeals Tribunal under new paragraph 48(1AB)(c).

New item 16 allows the importation of unregistered therapeutic goods that are (a) nicotine in solution as a starting material for use in the manufacture of a therapeutic vaping substance, a therapeutic vaping substance accessory or other therapeutic good, or (b) any other starting material that is an ingredient or component for use in the manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory. The exemption applies subject to the condition that the sponsor gives a written notice to the Secretary stating that the goods are to only be supplied for those purposes in accordance with the requirements of the Act and any law of the state or territory in which the manufacture is to occur.

The notice needs to be given before importing the goods. The goods identified in new item 16 are those starting materials used in the manufacture of goods under the Act, which have not been the subject of a notice given for the purposes of paragraph (a) of column 3 of the new item 15 to Schedule 5A. This is appropriate in the circumstances on the basis that it would be difficult for a sponsor to provide a notification as to compliance with applicable standards or be granted a consent by the Secretary for the importation of the goods under section 14 or 14A of the Act.

Part 2—Transitional provisions

Item 15 – Division 14 of Part 9

Item 15 repeals Division 14 of Part 9 of the TG Regulations as it is no longer required following the repeal of item 5 of Schedule 5 (refer to item 11), which relates to nicotine vaping products.

Item 16 – Regulation 80

Item 16 repeals regulation 80 of the TG Regulations as it is no longer required with the repeal of item 5A of Schedule 5A (refer to item 11). Item 5A in Schedule 5, as inserted by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to kits containing nicotine vaping products manufactured on or after the commencement of that Part. All references to nicotine vaping products are repealed by the Amendment Regulations.

Item 17 – In the appropriate position in Part 9

Item 17 inserts a new Division 23 into Part 9 of the TG Regulations. Division 23 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions. Whilst the Amendment Regulations commence on 1 January 2024, the introduction of certain provisions is, in effect, delayed by the application provisions.

Clause 93 – Definitions

Clause 93 provides a definition for the term "amending regulations" in the new Division 23. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023.*

Clause 94 – Approving supply under authorised prescriber scheme

Clause 94 provides that the amendment of subregulation 12B(1) of the TG Regulations made by Schedule 1 to the amending regulations applies in relation to an authority given under subsection 19(5) (the Authorised Prescriber Scheme) of the Act on or after 1 January 2024.

*Clause 95 – Good*s *to be included in parts of the Register*

Clause 95 provides that the amendments of Schedules 3 and 4 to the TG Regulations made by Schedule 1 to the amending regulations apply to therapeutic vaping substances, therapeutic vaping substance accessories and therapeutic vaping kits from 1 January 2024. These amendments relate to the requirement for registration or listing in the relevant Part of the Register. Kits, that contain only registered goods are required to be included in the part of the Register for listed goods, whereas therapeutic vaping substances and therapeutic vaping substance accessories are required to be included in the part of the Register for registered goods.

Clause 96 – Exempt goods

Clause 96 provides application provisions to the exemptions provided in the amending regulations, principally those that exempt specified therapeutic vaping goods from the application of Part 3-2 of the Act relating to inclusion in the Register.

Subclause (1) provides that paragraph (b) of item 1 of the table in Schedule 5, and new item 1A, as inserted by Schedule 1 to the amending regulations apply in relation to disposable therapeutic vapes imported on or after 1 January 2024 and any other therapeutic vaping goods imported on or after 1 March 2024. This means that, on or after 1 January 2024, the personal importation scheme as provided for in item 1 of Schedule 5 no longer allows the importation of disposable therapeutic vapes.

Other therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits, and goods in a therapeutic vaping pack are still be covered by the personal importation scheme until the end of February 2024.

However, note that new item 1A of Schedule 5 allows personal importation for travellers on board a ship or aircraft for their treatment or the treatment of persons under their care, subject to limitations in quantities and amounts. This new item applies to disposable therapeutic vapes from 1 January 2024 and to the other therapeutic vaping goods mentioned in that item from 1 March 2024.

Subclause (2) provides that the repeal of items 5 and 5A of Schedule 5 to the TG Regulations, and of the definition of nicotine vaping product in regulation 2 of the TG Regulations, by Schedule 1 to the amending regulations applies in relation to disposable therapeutic vapes imported, or manufactured, on or after 1 January 2024 and any other therapeutic goods imported, or manufactured, on or after 1 March 2024. In relation to other therapeutic vaping goods, the requirements set out in new item 15 of Schedule 5 apply on or after 1 March 2024. For nicotine vaping products, the exemptions that are repealed (items 5 and 5A of Schedule 5) are replaced by new items 15 and 16 of Schedule 5A on 1 March 2024.

Subclause (3) provides that the exemption applying to starting materials that are (a) nicotine in solution imported for use as an ingredient in a therapeutic vaping substance, therapeutic vaping substance accessory or other therapeutic good, or (b) other ingredients or components imported for use in the manufacture of a therapeutic vaping substance or of a therapeutic vaping substance accessory, apply in relation to starting materials imported on or after 1 March 2024.

Subclause (4) provides that the amendment of item 1 of Schedule 5A to the TG Regulations made by Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after 1 March 2024. This exemption relates to allowing the sponsor of therapeutic goods imported into Australia to hold or store goods under the sponsor's direct control, subject to certain conditions, until the goods become the subject of a lawful notification, approval or authority or other actions under the Act. However, on or after 1 March 2024, this exemption no longer applies to disposable therapeutic vapes, therapeutic vaping substance, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack. Item 15 of Schedule 5A now governs the importation and manufacture of relevant goods on or after 1 March 2024. Item 16 of Schedule 5A governs the importation of relevant starting materials on or after 1 March 2024.

Subclause (5) provides that item 15 of Schedule 5A to the TG Regulations, as inserted by Schedule 1 to the amending regulations, applies in relation to therapeutic goods imported or manufactured on or after 1 March 2024.

Item 15 introduces the pre-market notification requirements, which provide the basis for the lawful importation, manufacture and supply of the specified therapeutic vaping goods in Australia. Although the exemption commences on 1 March 2024, sponsors who intend to import or manufacture therapeutic vaping goods of a kind provided in the new item 15, on or after 1 March 2024, will need to make a pre-market notification prior to 1 March 2024 to avail themselves of the exemption by the time those goods are imported or released for supply.

Therapeutic vaping goods imported or manufactured before 1 March 2024 are not covered by this exemption. Sponsors may continue to rely on the existing exemption applying in relation to such products (item 5 of Schedule 5 to the TG Regulations) to supply and run down stock, provided that stock was imported or manufactured before the relevant dates, being 1 January 2024 (for disposable vapes) and 1 March 2024 (for all other vapes) as applicable.

Subclause (6) provides that item 16 in Schedule 5A to the TG Regulations, as inserted by Schedule 1 to the amending regulations, applies in relation to certain starting materials imported on or after 1 March 2024. This means that the exemption from the requirements of Part 3-2 of the Act applying to imported nicotine in solution for use as a starting material, and any other ingredients or components imported for use in the manufacture of therapeutic vaping substances or therapeutic vaping substance accessories, applies to goods that were imported on or after 1 March 2024. Note however that, depending on the timing, a notification may need to be provided to the Secretary before 1 March 2024 if the goods are to be lawfully imported on or after 1 March 2024.

Clause 97 – Transitional vaping manufacturers—exemption from Part 3-3 of the Act

Clause 97 provides a transition provision for transitional vaping manufacturers in relation to the exemption from Part 3-3 of the Act.

Subclause (1) specifies the circumstances in which a person is a ***transitional vaping manufacturer***, namely if:

- the person carries out, on or after 1 January 2024, a step in the manufacture of therapeutic vaping goods that are a therapeutic vaping substance, a therapeutic vaping substance accessory, a therapeutic vaping kit, or goods in a therapeutic vaping pack; and
- the person was, as at 2 May 2023, carrying out an equivalent step in the manufacture of other goods that were the same kind of goods as the therapeutic goods referred to in paragraph (a) except that the other goods were not therapeutic goods; and
- before carrying out the step referred to in paragraph (a), the person had notified the Secretary, in a form approved under subregulation (2), in relation to the step referred to in paragraph (b).

In effect, subclause (1) allows a manufacturer who was carrying out steps to manufacture vaping goods not regulated under the Act, as at 2 May 2023, to carry out the equivalent steps of manufacture in relation to therapeutic vapes for a transitional period. This exemption

allows manufacturers of non-therapeutic vapes a period to transition their business to manufacture therapeutic vapes.

Subclause (2) provides that the Secretary may, in writing, approve a form that needs to be used by manufacturers for the purposes of paragraph (1)(c). The approved form is available on the TGA website at www.tga.gov.au.

Subclause (3) provides that, for the purposes of subsection 34(2) of the Act, the transitional vaping manufacturer is exempt from the operation of Part 3-3 of the Act in relation to the step of manufacture referred to in paragraph (1)(a) of the amending regulations. Subsection 34(2) provides that the regulations may exempt a person identified in the regulations from the operation of Part 3-3 of the Act in relation to the manufacture, or a step of manufacture, of therapeutic goods or a class of therapeutic goods identified in the regulations.

However, note pursuant to subclause (4), this exemption from the operation of Part 3-3 of the Act ceases to have effect on 1 December 2024 and these manufacturers are required to hold a manufacturing licence to carry out a step of manufacture of the therapeutic goods described in paragraph (1)(a) of the amending regulations.

Schedule 2 – Amendment of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Summary

Schedule 2 to the Amendment Regulations principally amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (MD Regulations) to appropriately and reasonably specify the circumstances in which legitimate therapeutic vapes that are medical devices for smoking cessation and the management of nicotine dependence may be lawfully imported, manufactured and supplied in Australia. These circumstances are prescribed in the MD Regulations as exemptions to the requirement for inclusion in the Register. Specifically, the Amendment Regulations amend the MD Regulations by:

- expanding the regulation of therapeutic vaping devices under the MD Regulations to include therapeutic vaping device accessories, and components or articles used in the manufacture of therapeutic vaping devices and therapeutic vaping device accessories;
- prescribing an exemption setting out the circumstances in which these goods may be lawfully imported, manufactured, and supplied in Australia, without being included on the Register, including that the only indications for the therapeutic vaping devices and therapeutic vaping device accessories are for use in smoking cessation or the management of nicotine dependence and introducing a pre-market notification requirement; requiring the notices for therapeutic vaping devices or therapeutic vaping device accessories imported into Australia, before their importation, and for those goods manufactured in Australia—before the goods are first supplied in Australia;
- specifying that the exemptions are subject to conditions, including that the required notification has been made, that no determination has been made that the supply of goods be ceased, and the goods are supplied as a finished product by a registered pharmacist or other person authorised to supply prescription medicines;
- enabling determinations to be made by the Secretary that certain therapeutic vaping goods will not be covered by the relevant exemptions if the Secretary becomes satisfied that their supply compromises public health and safety or the goods no longer comply, or did not comply, with the applicable standards;
- prohibiting the importation of unregistered therapeutic vaping goods, therapeutic vaping devices, and therapeutic vaping device accessories under the personal importation scheme, except minor exceptions for travellers who arrive on board a ship or aircraft and subject to specified allowable quantities; and
- removing the ability for the direct control exemption to apply to therapeutic vaping devices or therapeutic vaping device accessories. This exemption normally allows goods imported into Australia to be held under the control of the sponsor until specified circumstances occur, such as approvals, notifications or authorisations. However, note that this exemption, continues to apply to therapeutic cannabis vaping devices and therapeutic device accessories, which allows for their supply once the relevant approval or authorisation has been granted. The definitions of therapeutic vaping devices or therapeutic vaping device accessories do not include therapeutic cannabis vaping devices and therapeutic cannabis device accessories respectively.

Separately, the amendments in Schedule 2 to the Amendment Regulations introduces a pre-market notification requirement for therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories, which are imported into Australia in reliance of the existing exemption in item 2.1 of Schedule 4 to the MD Regulations. The effect of this amendment is to require the sponsor to provide a notice to the Secretary prior to the importation stating that: the device complies with the essential principles, or is imported or

supplied (as the case may be) with the consent of the Secretary under section 41MA or 41MAA of the Act and the sponsor holds information or evidence to support the statement made.

This largely preserves the existing regulatory requirements for therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories. The new notification requirement is introduced to facilitate the introduction of new import controls in regulations made under the *Customs Act 1901.* There is also change in how the personal importation scheme operates for therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories.

Part 1—Main amendments

Item 1 – Subregulations 7.1(4) to (7)

Item 1 repeals existing subregulations 7.1(4) to (7) of the MD Regulations. These subregulations presently apply conditions to the exemptions provided in item 1.6 in Part 1 of Schedule 4 to the MD Regulations. Item 1.6 presently applies to systems or procedure packs that contain nicotine vaping products. As repeal item 1.6 is repealed (please refer to item 5 of Schedule 2 to the Amendment Regulations), subregulations 7.1(4) to (7) similarly needs to be repealed.

Item 2 – At the end of subregulation 10.7(1A)

Item 2 adds a new paragraph (c) in subregulation 10.7(1A) of the MD Regulations. Regulation 10.7 provides the list of initial decisions by the Secretary, that on request by an eligible person within a specified period, may be reviewed by the Minister, and subsequently by the Administrative Appeals Tribunal. The addition of new paragraph (c) in subregulation 10.7(1A) means that the decision by the Secretary to make a determination referred to in paragraph (e) of the column headed "Conditions" in item 2.17 of the table in Part 2 of Schedule 4 is an initial decision for the purposes of the subregulation 10.7(1A).

Item 2.17 provides for the exemption of a medical device that is a therapeutic vaping device or a therapeutic vaping device accessory (which does not include therapeutic cannabis vaping goods), from the requirement to be included in the Register, subject to the applicable conditions being met.

Item 3 – Part 1 of Schedule 4 (table item 1.1 column headed "Kinds of medical devices", after paragraph (a))

Item 3 inserts a new paragraph (ab) in column 2 of item 1.1 of Schedule 4 to the MD Regulations. New paragraph (ab) has the effect of excluding a therapeutic vaping device, a therapeutic cannabis vaping device, a therapeutic vaping device accessory and a therapeutic cannabis vaping device accessory from the operation of the personal importation exemption provided under item 1.1. Item 1.1 provides that the specified medical devices in item 1.1, subject to the applicable conditions in that item, may be imported into Australia for use in the treatment of the importer, or a member of the importer's immediate family, without needing to be included in in the Register. This amendment has the effect of stopping the use of the personal importation scheme in relation to these goods.

Item 4 – Part 1 of Schedule 4 (after table item 1.1)

Item 4 inserts a new item 1.1A under Part 1 of Schedule 4 to the MD Regulations. New item 1.1A provides a travellers' exemption to enable a therapeutic vaping device, therapeutic cannabis vaping device, therapeutic vaping device accessories or therapeutic cannabis vaping device accessories, to be imported by a person on board a ship or aircraft for the medical treatment of that person or one or more other persons on board the ship or aircraft who are under the care of that person. The importation of the medical devices needs to meet the requirements of paragraph 5(2)(b) or the subregulation 5A(2) of the *Customs (Prohibited Imports) Regulations 1956*, which include quantity limitations.

Item 5 – Part 1 of Schedule 4 (table items 1.5 and 1.6)

Item 5 repeals items 1.5 and 1.6 under Part 1 of Schedule 4 to the MD Regulations. Current items 1.5 and 1.6 refer to nicotine vaping products, which are no longer to be used in either the TG Regulations or MD Regulations. Both regulations cover a wider range of therapeutic vaping goods and therapeutic vaping devices, no longer being limited to goods that contain nicotine.

Item 6 – Part 2 of Schedule 4 (cell at table item 2.1, column headed "Kinds of medical devices")

Item 6 repeals and substitutes the cell at the column headed "Kinds of medical devices" of item 2.1 in Part 2 of Schedule 4 to the MD Regulations. Medical devices listed in an item in Part 2 of Schedule 4, subject to the specified conditions in the relevant item, are exempt from the need to be included in the Register. Item 2.1 exempts from the offences associated with importing unregistered medical devices, that are imported into Australia, held under the direct control of the sponsor and are subject to the conditions outlined in column 3 to the item, until specified circumstances occur such as the goods being authorised for supply under s41HC of the Act. The amendment to item 2.1 excludes therapeutic vaping devices and therapeutic vaping device accessories, but not therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories, from the exemption.

Item 7 – Part 2 of Schedule 4 (table item 2.1, column headed "Conditions" after paragraph (b))

Item 7 inserts a new paragraph (c) in column 3 of item 2.1 of Part 2 of Schedule 4 to the MD Regulations. In effect, this requires sponsors of therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories to provide notice to the Secretary if those sponsors are to avail themselves of the exemption provided in item 2.1. This notice needs to be in a form approved in writing by the Secretary, and state the device complies with the essential principles, or is imported or supplied with the consent of the Secretary under section 41MA or 41MAA of the Act, and the sponsor holds information or evidence to support the goods compliance or the existence of the relevant consent. The approved form is available on the TGA website at www.tga.gov.au. This requirement is introduced to align with importation requirements being imposed in regulations made under the *Customs Act 1901.*

Item 8 – Part 2 of Schedule 4 (table item 2.11A)

Item 8 repeals item 2.11A in Part 2 of Schedule 4 to the MD Regulations. This item applies to a nicotine vaping device or system or procedure pack consisting of nicotine vaping device and a medicine. There is a new exemption applying to therapeutic vaping devices or therapeutic vaping device accessories, which is not limited to those containing nicotine (refer to item 2.17 in Part 2 of Schedule 4) and which are subject to new conditions such as pre-market notification requirements. Item 2.11A is repealed and effectively replaced by the exemption in new item 2.17 of the table in Part 2 of Schedule 4.

Item 9 – Part 2 of Schedule 4 (at the end of the table)

Item 9 adds new items 2.17 and 2.18 in Part 2 of Schedule 4 to the MD Regulations.

New item 2.17 allows for the lawful importation, manufacture and supply of unregistered therapeutic vaping devices and therapeutic vaping device accessories and mirrors the exemption provided for vaping medicines and other therapeutic goods by the new item 15 of the table in Schedule 5A of the TG Regulations. New item 2.17 applies to a medical device that is a therapeutic vaping device or a therapeutic vaping device accessory (which does not include therapeutic cannabis vaping goods). The exemption is subject to the following conditions:

- the sponsor must give the Secretary a notice (the sponsor notice), in a form approved in writing by the Secretary, stating that:
  - the device is intended, by the person under whose name the device is or is to be supplied, only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence; and
  - the device complies with the essential principles, or is imported or supplied (as the case may be) with the consent of the Secretary under section 41MA or 41MAA of the Act;
- the sponsor notice must be given:
  - for a device imported into Australia—before the device is imported; or
  - for a device manufactured in Australia—before the device is first supplied in Australia;
- the sponsor holds information or evidence to support the statements made in the sponsor notice;
- neither of the statements made in the sponsor notice is incorrect;
- the device is not the subject of a determination, by the Secretary and published on the Department's website, that the supply of the device be stopped or should cease because:
  - the Secretary is satisfied that the supply compromises public health and safety; or
  - the Secretary is satisfied that the device does not comply with the essential principles;
- the sponsor must:
  - if requested by the Secretary, give the Secretary the information or evidence referred to above; and
  - do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made);
- the sponsor of the device may supply the device to person who is not the ultimate consumer of the device only if that person is:

  - the holder of a licence; or
  - a person who is exempt under subsection 34(2) of the Act from the operation of Part 3-3 of the Act in relation to the manufacture of the device; or
  - a person who is registered as a pharmacist under a law of a state or territory providing for the registration of pharmacists; or
  - another person who is authorised, under a law of a state or territory in which that person deals with the goods, to supply goods that contain one or more substances included in Schedule 4 to the current Poisons Standard and the supply is in accordance with that authorisation; or
- the device may only be supplied to the ultimate consumer of the device only if supplied as a finished product by a registered pharmacist or other person who is authorised, under a law of a state or territory in which that person deals with the goods, to supply prescription medicines;
- the sponsor must:
  - keep records relating to the source and supply of the device; and
  - if requested by the Secretary, give the records to the Secretary within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made); and
- the sponsor must provide information of a kind mentioned in subsections 41MP(2) or 41MPA(2) of the Act relating to the device to the Secretary within the prescribed periods.

The exemption in item 2.17 is conditional on the device not being subject to a determination by the Secretary that its supply should be stopped or should cease because the Secretary is satisfied that the supply compromises public health and safety or the Secretary is satisfied that the device does not comply with the essential principles.

The exemption does not involve the Secretary making any pre-market assessment of the quality, safety, and efficacy of the medical device prior to its importation, manufacture or supply, and instead, is solely reliant on the statement provided by the sponsor in the notification described in paragraph (a) of the condition. If this discretionary decision to stop supply were not available, public health and safety would risk being compromised. All applicable good decision-making principles apply, and the decision is reviewable by the Minister and subsequently by the Administrative Appeals Tribunal. The approved form for the sponsor notice under the above item is available on the TGA website at www.tga.gov.au.

Item 9 also inserts a new item 2.18 in Part 2 of Schedule 4 to the MD Regulations that allows for the lawful importation of a component or article imported for use in the manufacture of a therapeutic vaping device a therapeutic vaping device accessory (which does not include a therapeutic cannabis vaping device or therapeutic cannabis vaping device accessory). The exemption is subject to the following conditions:

- the sponsor must give the Secretary a notice (the ***sponsor notice***), in a form approved in writing by the Secretary, stating that the device is for use in the manufacture, in accordance with the requirements of the Act, of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals (however described) required under the law of the state or territory in which the manufacture is to occur;
- the sponsor notice must be given before importing the device; and
- the device may be supplied only for use in manufacture as referred to in paragraph (a).

The approved form is available on the TGA website at www.tga.gov.au.

Item 10 – Dictionary

Item 10 inserts new definitions in the Dictionary of the MD Regulations. The following definitions are inserted:

- ***therapeutic cannabis vaping device*** means a medical device that:
  - is a vaping device (within the meaning of TG Regulations) other than a disposable therapeutic vape (within the meaning of that instrument); and
  - is intended, by the person under whose name the device is or is to be supplied, to be used only to administer medicinal cannabis products or medicines containing synthetic cannabis;
- ***therapeutic cannabis vaping device accessory*** means a therapeutic good that is an unfilled cartridge, capsule, pod or other vessel that is designed or intended:
  - to contain a therapeutic vaping substance; and
  - only for use in or with a therapeutic cannabis vaping device; and
  - to be refillable;
- ***therapeutic cannabis vaping good*** means a therapeutic cannabis vaping device or a therapeutic cannabis vaping device accessory;
- ***therapeutic vaping device*** means a therapeutic good that is a vaping device (within the meaning of the TG Regulations) other than:
  - a disposable therapeutic vape (within the meaning of that instrument); or
  - a therapeutic cannabis vaping device;
- ***therapeutic vaping device accessory*** means an unfilled cartridge, capsule, pod or other vessel that is designed or intended:
  - to contain a therapeutic vaping substance; and
  - to be refillable;

  but does not include a therapeutic cannabis vaping device accessory; and
- ***therapeutic vaping substance*** has the same meaning as in the TG Regulations.

The devices referred to in the definition of ***therapeutic cannabis vaping good***, which includes a therapeutic cannabis vaping device and therapeutic cannabis vaping device accessory, only refers to those devices that are intended to be used to administer medicinal cannabis products or medicines containing synthetic cannabis.

Vaping devices that already contain medicinal cannabis products or medicines containing synthetic cannabis, fall under the definition of medicinal cannabis products already present in the TG Regulations. Medicinal cannabis products are not captured by the new regulatory framework in the Amendment Regulations and continue to be regulated under the current medicinal cannabis framework. The Amendment Regulations only have limited application to therapeutic cannabis vaping devices and therapeutic cannabis vaping device accessories through the operation of amending items 4 and 7 of Schedule 2 to the Amendment Regulations.

Part 2—Transitional provisions

Items 11, 12 and 13 – repeal of provisions

Items 11, 12 and 13 repeals subregulation 11.51(1), subregulations 11.58(1) to (5), and regulation 11.65 respectively.

Subregulation 11.51(1) provides transitional provisions in relation to item 1.5 of Part 1 of Schedule 4 to the MD Regulations as applied to custom made medical devices. Subregulation 11.51(1) provides that the item continues to apply on and after 25 February 2021 in relation to a custom-made medical device that is manufactured before that day and a custom-made medical device that is manufactured on or after that day, where the request from the health professional was made before that day. As item 1.5 is repealed, subregulation 11.51(1) is no longer required.

Subregulations 11.58(1) to (5) relate to transitional provisions that apply to item 1.5 and 1.6 of Part 1 of Schedule 4 to the MD Regulations when these items were introduced. As these items are repealed, these transitional provisions are no longer required.

Regulation 11.65 provides transitional provisions applying to nicotine vaping products as referred to in item 1.6 of Part 1 of Schedule 4 to the MD Regulations. As item 1.6 repealed, regulation 11.65 is no longer required.

Item 14 – Application provision

Item 14 inserts a new Division 11.19 – Application provisions relating to the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* into Part 11 of the MD Regulations. This new Division contains a new regulation 11.73.

New regulation 11.73 provides that amendments to the MD Regulations made by Part 1 of Schedule 2 to the Amendment Regulations (except for the amendments to the Dictionary) apply in relation to therapeutic goods imported or manufactured on or after 1 March 2024.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023

The *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (the Amendment Regulations) are 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 the legislative instrument

The Amendment Regulations address the risks posed by vaping to children and adolescents in Australia, while preserving legitimate patient access to therapeutic vapes for smoking cessation and the management of nicotine dependence under medical supervision. The Amendment Regulations implement heightened regulatory controls for the importation, manufacture, and supply of therapeutic vapes and complement prohibitions under the *Customs Act 1901*.

The Amendment Regulations amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) (collectively, the Principal Regulations), to implement the first stage of the Government's vaping reform measures.

The Amendment Regulations are intended to address the risks posed by vaping to children and young people in Australia, the possible long term adverse health effects of vaping to Australians who use vapes, and the adverse health effects of toxic chemicals and other ingredients found in vapes. At the same time, the amendments preserve access to therapeutic vapes for smoking cessation and the management of nicotine dependence under medical supervision. All therapeutic vaping goods, including non-nicotine vapes, are to be supplied in Australia, only by registered pharmacists or other persons authorised to do so under state or territory law.

The Amendment Regulations appropriately and reasonably specify circumstances in which legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence may be lawfully imported, manufactured, and supplied in Australia. These circumstances are prescribed in the Principal Regulations as exemptions to the requirement for inclusion in the Australian Register of Therapeutic Goods (Register).

The Amendment Regulations implement measures that are necessary to give effect to proposed reforms announced by the Minister for Health and Aged Care in May 2023. The broad intent is to impose heightened regulatory requirements on the importation, manufacture, and supply of vapes in Australia. The reforms support the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Principally, the Amendment Regulations appropriately and reasonably specify the circumstances in which legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence may be lawfully imported, manufactured, and supplied in Australia by prescribing exemptions in the Principal Regulations, subject to certain conditions. This includes a pre-market notification requirement for therapeutic vapes prior to lawful importation, manufacture, or supply in Australia. The notification must be provided to the Secretary in relation to the goods' compliance with the relevant quality standards; and compliance will subject to post-notification surveillance by the Therapeutic Goods Administration (TGA) to ensure that the matters notified to the Secretary are correct.

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not and the long-term health risks of vaping are not yet known.

The Amendment Regulations implement measures that are necessary to give effect to the first of proposed reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. The broad intent is to prohibit the importation, manufacture and supply vapes in Australia unless certain requirements under the Therapeutic Goods Act 1989 (the Act) are met. The reforms implemented in the Amendment Regulations align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Human rights implications

The Amendment Regulations engage the following human rights:

- the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR);
- the right to a fair hearing under Article 14(1) of the International Covenant on Civil and Political Rights (the ICCPR);
- Article 6(2) of the Convention of the Rights of the Child (CRC); and
- Article 33 of the CRC.

The right to health

The Amending Regulations engage the right to health in Article 12 of the ICESCR. Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health and includes an obligation on state parties 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.

Vaping has been associated with a range of short-term health risks and its long-term health effects use are still unknown. Vape marketing and use in the community has increased rapidly in recent years, particularly among young people and poses a major risk to population health and Australia's success in tobacco control.

The Amendment Regulations take positive steps to promote the right to health by supporting the Government's package of regulatory reforms concerning vapes. These reforms bolster and simplify the regulatory framework for the importation, manufacture and supply of therapeutic vapes in Australia, subject to compliance with relevant quality standards applying to these goods, for use in smoking cessation or the management of nicotine dependence. The reforms promote the right to health as the new requirements will limit access to therapeutic vapes from registered pharmacists and other authorised persons. In relation to therapeutic vapes containing nicotine, those goods will require a prescription to be given to the patient by a health practitioner in accordance with state and territory law to enable those vapes to be dispensed or supplied.

The benefits of this are twofold. Firstly, the reforms will arrest the increasing uptake of recreational vaping, especially amongst youth and young adults; effectively restricting domestic supply of non-therapeutic vapes while still allowing for therapeutic use strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to support Australians combating smoking addiction or nicotine dependence. Not permitting the supply of affordable and cheap disposable single use vapes

under the reforms also limits the availability of vapes to youth and young adults. Ensuring vapes are only accessed under medical supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

The reforms also take positive steps to promote the right to health by increasing the safety, quality, labelling and packaging requirements for unregistered therapeutic vapes. These new requirements will be found in revised applicable standards under a therapeutic goods order under section 10 of the Act, which will be introduced over the course of 2024. The increased safety and quality requirements minimise the risks associated with the supply of unregistered therapeutic goods, which have not been evaluated by the TGA for safety, quality and efficacy. The effectiveness of these requirements is further bolstered by the criminal, civil and regulatory sanctions that may apply under the Act for persons who import, manufacture or supply therapeutic vapes that do not comply with applicable standards and notification requirements.

In supporting these reforms, the Amendment Regulations promote and address aspects of the right to health under Article 12 of the ICESCR that relate to recognising the right of everyone to enjoy the highest attainable standard of physical and mental health.

The right to a fair hearing

The Amending Regulations engage the right to a fair hearing under Article 14(1) of the ICCPR. The right to a fair hearing is a fundamental part of the rule of law and the proper administration of justice. The essential right to a fair hearing provides that all persons are entitled to a fair and public hearing before an independent and impartial court or tribunal established by law.

The Amendment Regulations provide for the review of decisions made by the Secretary determining that the supply of unregistered therapeutic vaping goods, that have been the subject of a pre-market notification, must be stopped or ceased because the Secretary is satisfied that the supply compromises public health and safety, or the Secretary is satisfied that the goods do not conform with the relevant standards applying to the goods. The sponsor of the goods, being the person who is ultimately responsible for their importation or manufacture, is required to provide a notification under the new exemption that the goods comply with applicable standards or are imported, manufactured or supplied with the consent of the Secretary under the Act, and the goods are only indicated for use in smoking cessation or the management of nicotine dependence.

The decision of the Secretary is reviewable by the Minister for Health and Aged Care, and the Minister's decision is reviewable by the Administrative Appeals Tribunal. The relevant review provisions are included in regulation 48 of the TG Regulations and regulation 10.7 of the MD Regulations. A person adversely affected by that decision may seek a review initially by the Minister and subsequently by an independent Tribunal, which is the Administrative Appeals Tribunal.

Measures to ensure the survival and development of children

Article 6(2) of the CRC requires state parties to take measures to ensure the survival and development of children to the greatest extent possible.

Vaping goods pose a particular risk to children. The variability in concentration and toxicity of the active ingredients, particularly nicotine but also other toxic substances, increases the risk that children who consume these ingredients may ingest a fatal dose or suffer severe adverse effects. In addition, vapes contain flavours designed to entice children, and for which the adverse effects are unknown. Although these flavours may be safe when ingested, their safety profile when inhaled directly into the lungs is not well established.

Vaping goods are frequently designed to look like other ubiquitous objects such as pens, USB devices, lip gloss, toys and sippy cups. The designs use colours, illustrations and cartoons are deliberately attractive to children and may lead to misconceptions that vaping goods are harmless when this is not the case.

To the extent that restricting the importation, manufacture and supply of vaping goods may adversely affect the health of persons (including young persons) who are already addicted to nicotine, the prohibition in this amendment will not extend to those who are legitimately prescribed vaping substances that contain nicotine for the management of that dependence, in accordance with clinical guidelines, under appropriate medical supervision. In summary, the measure will promote the survival and development of children to the greatest extent possible and where the measure may limit a child's rights, the limitation is necessary in order to protect the Australian community from the risks to health that misuse can cause, and is reasonable and proportionate as access to vaping substances is still available where there is a legitimate medical need.

Measures to protect children from illicit use of narcotic drugs and psychotropic substances

Article 33 of the CRC specifically requires state parties to take appropriate measures to protect children (up to the age of 18) from the illicit use of narcotic drugs and psychotropic substances. Although prohibited psychoactive substances are not specifically listed in the relevant international treaties banning narcotic drugs and psychotropic substances, the Committee on the Rights of the Child has recognised that article 33 has a broad application and may impose obligations on state parties to protect children from the use of substances that are not listed in the Conventions, such as alcohol and tobacco. The Committee therefore urges state parties to regulate or prohibit information on and marketing of substances, such as alcohol and tobacco, particularly when the information or marketing targets children and adolescents.

The new controls on the importation, manufacture and supply on vaping goods will promote the protection of children from exposure and easy access to addictive and unsafe vaping goods. Under the reforms, vaping goods are only intended to be accessed by legitimate patients through limited supply channels involving a registered pharmacist or person authorised under state or territory law to supply prescription medicines. This will reduce the potential for vapes to be supplied unlawfully to children.

The import, manufacture and supply control on vaping goods is therefore an important tool for promoting children's rights to be protected from nicotine dependence and exposure to

other dangerous substances contained in vaping goods. Restricting the importation, manufacture and supply of untested and potentially dangerous substances contained in vaping goods by these measures will assist in preventing their supply to, and access by, children.

These measures seek to promote the requirement to protect children from exposure to, and use of, addictive substances contained in vaping goods to the greatest extent possible. The limitation is necessary to protect the Australian community from the risks to health that misuse can cause. The limitation is also reasonable and proportionate as access to vaping goods is still available where there is a legitimate therapeutic need under appropriate medical supervision.

Conclusion

The Amendment Regulations are compatible with human rights because they promote the right to health in Article 12 of the ICESCR, the right to a fair hearing in Article 14(1) of the ICCPR, Article 6(2) of the CRC, Article 33 of the CRC and otherwise do not raise any other human rights issues.