EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

The *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations) amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to support the *Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024* (the Amendment Act). The Amendment Act implements the national vaping reforms to restrict the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods (particularly non-therapeutic and disposable vaping goods).

In particular, the Amendment Regulations support the Amendment Act by specifying commercial quantities and units of vaping goods for the purposes of new offences and civil penalty provisions introduced by the Amendment Act for possessing vaping goods as part of a suite of measures designed to address and deter illicit trade.

The Amendment Regulations also provide transitional arrangements under which certain therapeutic vaping goods that would otherwise be unlawful upon commencement of the Amendment Act can be dealt with, and make a small number of minor consequential amendments. The Amendment Regulations also allow for the supply or export of compliant vaping goods that were imported or manufactured prior to 1 March 2024, as part of transitional arrangements to assist sponsors to comply with the reforms.

The Amendment Regulations also make a small number of related amendments, including to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law for the purpose of the Act, and to update a small number of definitions and exemptions to ensure consistency between the Act and the TG Regulations and MD Regulations in relation to key terms.

Details of the Amendment Regulations are set out in the Attachment.

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 Therapeutic Goods Administration (TGA) conducted two significant consultations in relation to these reforms largely implemented by the Amendment Act. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on proposed amendments 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 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 the 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.

In recent months, the TGA has undertaken extensive consultation with the states and territories on the commercial quantities of vaping goods prescribed in the Amendment Regulations, principally through the National E-Cigarette Working Group. The TGA also engaged with key stakeholders concerning the commercial quantities of vaping goods through the TGA Consultative Committee and TGA Industry Forum held on 17 May 2024. An impact analysis has been published on website of the Office of Impact Analysis at: oia.pmc.gov.au.

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The Amendment Regulations are made between enactment and commencement of the Amendment Act. Section 4 of the *Acts Interpretation Act 1901* confers upon the Governor-General the power to make regulations prior to the commencement of the Amendment Act. The Amendment Act received Royal Assent on 28 June 2024, prior to consideration of the Amendment Regulations.

Details of the Amendment Regulations are set out in the Attachment.

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

ATTACHMENT A

Details of the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations).

Section 2 – Commencement

This section provides for the commencement of the main amendments in Schedule 1 of the Amendment Regulations on the commencement of Parts 1 to 3 of Schedule 1 to the Amendment Act.

Schedule 2 repeals and replaces the commercial quantities specified in Schedule 1, and commences on the day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the Amendment Act commence. The delayed commencement of Schedule 2 is intended to provide a 3-month transition period to allow quantities of vaping goods that are below the commercial quantities specified in Schedule 1 to be depleted or disposed of as appropriate by persons who are not excepted from the offence and civil penalty provisions in the Act that apply to the possession of vaping goods in an amount equal to or exceeding the commercial quantity.

Schedule 3 commences on the later of the date that is immediately after the commencement of Parts 1 to 3 of Schedule 1 to the Amendment Act, or immediately after the commencement of Part 2 of the *Therapeutic Goods Law Application Act 2024* (WA). However, Schedule 3 does not commence at all if Part 2 of the *Therapeutic Goods Law Application Act 2024* (WA) does not commence.

Section 3 – Authority

This section provides that the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 202*4 (the Amendment Regulations) are be 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 – Main Amendments

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 still emerging.

The Government's vaping reforms are being implemented in stages over 2024. The Amendment Act is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms included amendments to the *Customs (Prohibited Imports) Regulations 1956*, the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.
- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an

import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.
- since 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standards.

The Amendment Regulations support the Amendment Act to implement measures that are necessary to give effect to the second stage of reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. The primary intent is to prohibit the importation, domestic manufacture and supply vapes in Australia unless certain requirements under 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 principally amends the TG Regulations and the MD Regulations (collectively, the Principal Regulations) to refine the exemptions that facilitate the importation, domestic manufacture and supply in Australia of legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence; to prescribe commercial quantities that apply for a 3 month transitional period following the commencement of the Amendment Regulations; and to extend the definition of 'protected persons' for the purpose of subsection 62(3) of the Act to state and territory officials in certain circumstances.

Specifically, Schedule 1 amends the TG Regulations and MD Regulations by:
- repealing the definitions of 'medical practitioner' and 'vaping device' and amending references to these terms throughout the Principal Regulations to reflect the application of the definitions of these terms inserted into the Act by the Amendment Act;
- extending the exemptions for notified therapeutic vaping goods, which are currently limited to therapeutic vaping goods that were imported or manufactured or after 1 March 2024, to therapeutic vaping goods that were imported or manufactured before 1 March 2024 where they meet current quality requirements;
- imposing new conditions on the exemptions for notified therapeutic vaping goods to require sponsors to provide a reasonable number of samples on request and to allow authorised officers to enter and inspect premises where sponsors or any other persons deal with therapeutic vaping goods;
- limiting persons that may supply therapeutic vaping goods to ultimate consumers under the exemptions for notified therapeutic vaping goods to pharmacists, medical practitioners and nurse practitioners that are authorised under state or territory law to supply prescription medicines;
- extending the list of persons in the exemptions that may supply and receive therapeutic vaping goods to include persons in relation to whom a consent is granted under section 41RC of the Act and persons specified in a determination under section 41R of the Act;
- extending the notice provisions for articles or components of therapeutic vaping devices and therapeutic vaping device accessories to therapeutic cannabis vaping goods;
- amending the definitions of therapeutic vaping device accessory and therapeutic cannabis vaping device accessory so they are not required to be refillable;

- clarifying that a ‘therapeutic vaping pack’ must include at least one therapeutic vaping substance or therapeutic vaping substance accessory;
- prescribing matters to facilitate the granting of authorities under subsection 19(5) of the Act without ethics committee approval in relation to therapeutic vaping substances that do not contain nicotine or any other active ingredient;
- clarifying that supply to the ultimate consumer under the special access scheme or the authorised prescriber scheme is not required in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack;
- prescribing things that may be required in an enforceable direction;
- prescribing commercial quantities, units and permitted quantities of vaping devices, vaping accessories, and vaping substances that are liquids;
- extending the definition of ‘protected persons’ under subsection 62(3) of the Act to state and territory officials to whom certain powers and functions are delegated under the Act;
- creating a time-limited exemption (for a period of 6 months following commencement of Schedule 1) to permit the export the therapeutic vaping goods and therapeutic cannabis vaping goods that comply with all Commonwealth and state or territory laws before commencement of Parts 1-3 of Schedule 1 to the Amendment Act; and
- including relevant transitional provisions.

Schedule 2 amends the TG Regulations by repealing the commercial quantities prescribed in Schedule 1 and replacing them with lower commercial quantities. Schedule 2 commences on the day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the Amendment Act commence.

Schedule 3 amends the TG Regulations to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law.

Part 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Paragraph 10.6(2)(a)

Item 1 amends the reference to a ‘medical practitioner registered in a State or internal Territory’ in paragraph 10.6(2)(a) to omit the words ‘registered in a State or internal Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that already refers to registration in a State or Territory. Consequently, the words that are omitted are redundant when referring to a medical practitioner in the Principal Regulations and therefore not required.

Item [2] – Table item 1.1 of Part 1 of Schedule 4, column headed “Kinds of medical devices”, paragraph (d))

Item 2 similarly amends the reference to a ‘medical practitioner registered under a law of a State or Territory’ in table item 1.1 of Part 1 of Schedule 4 to omit the words ‘registered under a law of a State of internal Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that already refers to registration in a State or Territory, and consequently these words are redundant when referring to a medical practitioner in the Principal Regulations.

Item [3] – Table item 2.17 of Part 2 of Schedule 4, column headed 'Conditions', paragraph (b)

Item 3 repeals paragraph (b) of the column headed 'Conditions' in table item 2.17 of Part 2 of Schedule 4 and insert a new paragraph that includes the existing reference to goods imported or manufactured on or after 1 March 2024, and a new reference to goods that were imported or manufactured before 1 March 2024. A sponsor notice in relation to the latter category of goods must be provided before the device is supplied to the ultimate consumer and no later than 2 months after Schedule 1 to the Amendments Regulations commences.

The effect of this amendment, together with item 33, is to extend the operation of the exemption in item 2.17 so that goods that were imported or manufactured before 1 March 2024 and comply with the essential principles are eligible to be supplied to the ultimate consumer, provided that a sponsor notice is given by the sponsor to the Secretary within 2 months of the commencement of Schedule 1 to the Amendment Regulations. This will create a pathway for the supply of compliant stock that existed prior to the commencement of the application of the exemption on 1 March 2024.

The 2-month timeframe for the giving of a sponsor notice is intended to provide a sufficient period during which compliant stock may be identified and sponsors may make the necessary notification. A time limited period is required so that, at the conclusion of the period, there is certainty as to the goods that can be supplied under the exemption.

Item [4] – Table item 2.17 of Part 2 of Schedule 4, column headed 'Conditions', paragraph (g)

Item 4 inserts new conditions of exemption in paragraphs (fa), (fb), (fc), (fd) and (fe), and amend the wording in paragraph (g) in item 2.17.

Medical devices listed in an item in Part 2 of Schedule 4 are exempt from the need to be included in the Register, subject to the specified conditions in the relevant item. Item 2.17 in Part 2 of Schedule 4 provides for the exemption of specific devices subject to compliance with specified conditions. Item 2.17 allows for the lawful importation, manufacture and supply of unregistered therapeutic vaping devices and therapeutic vaping device accessories subject to conditions.

Paragraph (fa) requires the sponsor to provide a reasonable number of samples of a device to the Secretary on request, and to do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the essential principles may be undertaken efficiently.

Paragraph (fb) requires the sponsor to allow an authorised officer to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the device. While on those premises, the sponsor must allow the authorised officer to inspect the premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on the premises that relate to the device. The authorised officer must also be allowed to make any still or moving image or any recording of the premises or any thing on the premises.

Paragraph (fc) requires the sponsor, if requested to do so by an authorised officer, to produce to the authorised officer such documents relating to the device as the authorised person requires and to allow the authorised officer to copy the documents.

Paragraph (fd) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device allows an authorised officer to do the things referred to in paragraph (fb).

Paragraph (fe) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the device as the authorised officer requires and to allow the authorised officer to copy the documents.

The conditions in paragraphs (fb) to (fe) are necessary to ensure that the TGA can obtain information to determine whether therapeutic vaping devices and therapeutic vaping device accessories that have been notified as complying with the essential principles do in fact comply. This may be particularly useful in relation to therapeutic vaping devices and therapeutic vaping device accessories to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* applies, as that standard includes a range of requirements that apply to manufacturing processes, and the ability to enter manufacturing premises will assist in this regard.

Paragraph (g) specifies the persons to whom goods may be supplied by wholesale (persons who are not the ultimate consumer).

Subparagraph (g)(i) refers to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods. This amendment is made to align the language with that used in section 41QB(8)(a) of the Act, as inserted by the Amendment Act, when referring to the same person. The meaning of this provision is not changed.

Subparagraph (g)(ii) specifies a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

Subparagraph (g)(ii) is amended to align with the description of persons to whom vaping goods may be lawfully supplied by wholesale in section 41QB(8)(b), as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in the analogous subparagraph (g)(iv), which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice could extend to health professionals, such as dentists and optometrists. This amendment ensures that the exemption applies only in relation to goods supplied by wholesale to a wholesaler, pharmacist, medical practitioner or nurse practitioner that is authorised under the law of a State or Territory, and is consistent with the exception in section 41QB(10) of the Amendment Act, which applies only to the supply of vaping goods by wholesale to these persons.

Subparagraph (g)(iii) specifies a recipient to whom a consent under subsection 41RC(1) of the Act to supply the device has been given. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient to whom a consent is granted under section 41RC(1) of the Act.

Subparagraph (g)(iv) specifies, in relation to a device that is covered by a determination made by the Minister under section 41R of the Act, a recipient who is not the ultimate consumer specified in the determination, or included in a class of persons specified in the determination. This amendment is necessary to ensure consistency with the amendments under the Amendment Act that allow for goods to be supplied by wholesale to a recipient specified in a determination made by the Minister under section 41R of the Act.

Item [5] – Table item 2.17 of Part 2 of Schedule 4, column headed 'Conditions', paragraph (h)(ii)

Item 5 repeals paragraph (h)(ii) and inserts a new paragraph specifying supply to the ultimate consumer may only be by a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

This subparagraph is amended to align with the description of persons who may supply vaping goods to ultimate consumers in section 41QB(10) of the Act, as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in subparagraph (h)(ii) of item 2.17, which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice could extend to health professionals, such as dentists and optometrists.

This amendment ensures that the exemption applies only in relation to goods supplied to the ultimate consumer by a pharmacist, medical practitioner or nurse practitioner, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amendment Act, which applies only to the supply of vaping goods to the ultimate consumer by these persons.

Item [6] and [7] – Table item 2.18 of Part 2 of Schedule 4, column headed "Kinds of medical devices", paragraphs (a) and (b) and column headed "Conditions", paragraph (a)

Item 6 inserts a reference to a component or article imported for use in the manufacture of a therapeutic cannabis vaping good in the column that specifies the goods to which the exemption in item 2.18 applies. Item 7 inserts a reference to a therapeutic cannabis vaping good in the description of the sponsor notice that must be provided as a condition of this exemption.

Current item 2.18 in Part 2 of Schedule 4 to the MD Regulations allows for the lawful importation of a component or article imported for use in the manufacture of a therapeutic vaping device and 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 conditions.

The effect of these amendments is that the notification requirements under subregulation 5A(13) of the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations) and under Part 2 of Schedule 4 to the MD Regulations will change for an article or component for use in the manufacture of a therapeutic cannabis vaping good. Specifically, an importer of such a good will be required to give a notice stating that the goods are for use in the manufacture, in accordance with the requirements of the *Therapeutic Goods Act 1989*, of a therapeutic cannabis vaping good by a manufacturer who holds all relevant licences and approvals required under the law of the relevant State or Territory. This notice requirement currently applies to importers of articles or components for use in the manufacture of therapeutic vaping devices and therapeutic vaping device accessories. These amendments will have the effect that the notification requirements for articles or components imported for use in manufacture, rather than as finished goods, will be the same whether those articles or components are for use in the manufacture of therapeutic vaping devices, therapeutic vaping device accessories, or therapeutic cannabis vaping goods.

A person seeking to import an article or component for use in the manufacture of a therapeutic cannabis vaping good must meet the notification requirements under subregulation 5A(13) of the CPI Regulations. Paragraph 5A(13)(a) of the CPI Regulations applies to a therapeutic cannabis vaping good, including an article or component to be imported for use in manufacture, and requires a statement that the goods comply with the essential principles or are imported with the consent of the Secretary. Paragraph 5A(13)(b) of CPI Regulations applies to goods that are not therapeutic cannabis vaping goods, and includes at subparagraph (ii) the option of giving a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations. By extending the application of item 2.18 of Part 2 of Schedule 4 to the MD Regulations to an article or component for use in the manufacture of a therapeutic cannabis vaping good, these amendments have the effect that a sponsor of these goods will meet the notification requirements under subregulation 5A(13) of the CPI Regulations by giving a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations, rather than needing to meet the more onerous notice requirement under paragraph 5A(13)(a) of CPI Regulations.

Item [8] – Part 2 of Schedule 4 (table item 2.18, column headed 'Conditions', after paragraph (b))

Item 8 inserts a new requirement as a condition of the exemption under item 2.18 that the sponsor must provide a reasonable number of samples of a device to the Secretary on request, and must do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the essential principles can be undertaken efficiently.

Items [9], [10] and [11] – Dictionary (paragraph (a) of the definition of 'health professional', definition of 'medical practitioner', and paragraphs (a) and (b) of 'serious')

Item 10 repeals the definition of 'medical practitioner' because the term is defined in the Act, as inserted by the Amendment Act. Items 9 and 11 amends the references to 'medical practitioner' in the definitions of 'health professional', and 'serious' to reflect the new definition of 'medical practitioner' in the Act, as inserted by the Amendment Act.

Item [12] – Dictionary (paragraphs (a) and (b) of the definition of therapeutic cannabis vaping device)

Item 12 amends the definition of 'therapeutic cannabis vaping device' to substitute the term 'vaping device' that is defined in the Act, as inserted by the Amendment Act, to ensure consistency with the definition under the Act.

Item 12 also adds subparagraph (a)(ii) to exclude from the definition of 'therapeutic cannabis vaping device' a component or article imported for use in the manufacture of a therapeutic cannabis vaping device. The exclusion of a component or article imported for use in the manufacture of a therapeutic cannabis vaping device from the definition of a 'therapeutic cannabis vaping device' has the effect that a component or article is not regarded as a 'therapeutic cannabis vaping device', and consequently a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations is required instead of a notice under paragraph 5A(13)(a) of the *Customs (Prohibited Imports) Regulations 1956* in order to meet the notification requirements under the subregulation 5A(13) of those regulations.

Item [13] – Dictionary (definition of therapeutic cannabis vaping device accessory)

Item 13 repeals the definition of therapeutic cannabis vaping device accessory and replaces it with a definition that changes the order of paragraphs (a) and (b) to align with the ordering of those requirements in the definition of 'vaping accessory' in the Amending Act. Item 13 also removes the requirement in paragraph (c) that the good must be designed or intended to be refillable. The only change to the meaning of this definition is that a good can be a 'therapeutic cannabis vaping device accessory' whether or not it is intended or designed to be refillable.

Item [14] – Dictionary (definition of therapeutic vaping device)

Item 14 repeals the definition of therapeutic vaping device and replaces it with a definition that references the term 'vaping device' as inserted into the Act by the Amendment Act. In effect, there is no change to the operation of this term.

Item [15] – Dictionary (definition of therapeutic vaping device accessory)

Item 15 repeals the definition of therapeutic vaping device accessory and replaces it with a definition that include the words 'designed or intended' in paragraphs of (a) and (b) rather than the chapeau of the definition, and removes the requirement in paragraph (c) that the good must be designed or intended to be refillable. The only change to the meaning of this definition is that a good can be a 'therapeutic vaping device accessory' whether or not it is intended or designed to be refillable.

Therapeutic Goods Regulations 1990

Item [16] – Regulation 2 (paragraph (a) of the definition of disposable therapeutic vape)

Item 16 amends paragraph (a) of the definition of disposable therapeutic vape in the TG Regulations to substitute the reference to 'vaping device' defined in the TG Regulations with

the defined term in the Act as inserted by the Amendment Act. In effect, there is no change to the operation of this term.

Item [17] – Regulation 2 (definition of therapeutic vaping pack)

Item 17 repeals the definition of therapeutic vaping pack and replaces it with a new definition that retains the elements of the current definition in the Act (that it must contain at least one therapeutic vaping device or therapeutic vaping device accessory and not contain any other therapeutic goods). Item 17 also supplements the definition with a new requirement that a therapeutic vaping pack must also contain at least one therapeutic vaping substance or therapeutic vaping substance accessory.

This amendment clarifies that a therapeutic vaping device or therapeutic vaping device accessory is only to be regulated as part of a therapeutic vaping pack, and consequently subject to the requirements of Chapter 3 of the Act, if the pack also contains a therapeutic vaping substance or therapeutic vaping substance, being goods that are regulated under Chapter 3 of the Act. This amendment ensures that a pack that contains only a therapeutic vaping device and/or a therapeutic vaping device accessory, being goods that are ordinarily subject to the requirements of Chapter 4 of the Act if not part of a therapeutic vaping pack, are not regulated under Chapter 3 of the Act unless the pack of which they are a part also contains goods that are regulated under Chapter 3 of the Act.

Item [18] – Regulation 2 (definition of therapeutic vaping substance accessory)

Item 18 repeals the definition of therapeutic vaping substance accessory to substitute the description of a vaping device with a reference to the defined term ‘vaping device’ inserted into the Act by the Amendment Act. It also changes the order of paragraphs (a) and (b) to align with the ordering of the definition of ‘vaping accessory’ in the Amendment Act. In effect, there is no operational change to the meaning of this term.

Item [19] – Regulation 2 (definition of vaping device)

Item 19 repeals the definition of ‘vaping device’, which is defined in the Act, as inserted by the Amendment Act, and accordingly a definition is no longer required in the Principal Regulations.

The definition in the Act, as inserted by the Amendment Act, is the same as that in the current TG Regulations, with the exception of the omission of note 2 in the definition in these Regulations. That note states that, to avoid doubt, therapeutic vaping substances accessories and therapeutic vaping device accessories are not devices to which paragraph (b) of the definition applies (being the paragraph that applies to temporarily inoperable, incomplete, damaged and unfinished devices). The note is not necessary because the definitions of ‘therapeutic vaping substance accessory’ and ‘therapeutic vaping device accessory’ refer to goods that are ‘designed or intended for use in, or with, a therapeutic vaping device’ and it is therefore clear that these items are for use *in or with* a therapeutic vaping device (being a therapeutic good that is a vaping device) rather than amounting to vaping devices in and of themselves.

Item [20] – After Part 2E, insertion of new Part 2F – Vaping goods - commercial quantities units and permitted quantities of vaping goods

Commercial quantity

Item 20 inserts Part 2F, titled 'Vaping goods' into the TG Regulations. New regulations 10N, 10P and 10Q form part of new Part 2F.

New regulation 10N prescribes commercial quantities of vaping goods for the purpose of the definition of 'commercial quantity' in subsection 3(1) of the Act, as inserted by the Amendment Act. Commercial quantities are required because the possession offences and civil penalty provision in section 41QC of the Act, as inserted by the Amendment Act, apply in relation to the possession of a commercial quantity of vaping goods other than in circumstances where the exceptions in sections 41QC applies. The exceptions provide for the possession of legitimate therapeutic vapes by specified persons in the supply chain, and by other persons specified in an instrument under section 41R or to whom consent is granted under section 41RC. Consequently, a contravention of section 41QC will only arise, and the commercial quantity is only relevant, in relation to vaping goods that are not legitimate therapeutic vapes and are not specified under section 41R or are goods in relation to which a consent has been granted under section 41RC.

The commercial quantities of vaping goods that are prescribed therefore seek to penalise the possession of illicit vaping goods for commercial purposes and to ensure that legitimate therapeutic use is not penalised.

Regulation 10N prescribes 14 vaping devices, 90 vaping accessories, and 600 ml of vaping substances that is a liquid. These quantities will apply for a period of 3 months after Schedule 1 to the Amendment Act commences, after which these quantities are repealed and replaced with the quantities prescribed in amending item 1 of Schedule 2 to the Amendment Regulations, being 9 vaping devices, 60 vaping accessories, and 400 ml of vaping substances that is a liquid.

The higher quantities that are prescribed for the first 3 months will effectively provide a transition period during which quantities of vaping goods that exceed the commercial quantities that will apply at the conclusion of that 3-month period can be depleted.

Units of vaping goods

New regulation 10P prescribes quantities of vaping goods for the purpose of the definition of 'unit' in subsection 3(1) of the Act, as inserted by the Amendment Act. The civil penalty provisions inserted into the Act by the Amendment Act relevantly provide that a person who contravenes the provisions commits a separate contravention in respect of each unit of vaping goods.

The quantities that are prescribed amount to one unit are 9 vaping devices, 60 vaping accessories and 400ml of vaping substance that is a liquid. These quantities are the same as the commercial quantities that will apply after 3 months.

Permitted quantities

New regulation 10Q prescribes quantities of vaping goods for the purpose of the definition of 'permitted quantity' in subsection 41QD(10) of the Act, as inserted by the Amendment Act. Section 41QD is an offence and civil penalty provision that applies to the possession, at retail premises by a person who is a retailer in relation to the premises, of less than a commercial quantity of vaping goods. An exception is provided in subsection 41QD(9) in relation to the possession of a quantity of a kind of vaping goods by a person if the vaping goods are for use by the person personally, and the quantity is no more than the 'permitted quantity' of that kind of vaping goods.

The purpose of the exception in subsection 41QD(9) is to ensure that the possession by a person who is a retailer within the meaning of section 41QD of a small quantity of vaping goods required for personal use (whether legitimate therapeutic use or otherwise) is not penalised simply because the possession occurs at retail premises. A separate exception in subsections 41QD(7) and (8) applies in relation to possession by authorised persons in the supply chain of vaping goods for legitimate therapeutic use.

The quantities prescribed are 2 vaping devices, 4 vaping accessories, and 60ml of vaping substance that is a liquid. The modest quantities that are prescribed are necessary to confine the exception to the possession of quantities that may be carried by an individual to support personal use over the course of a single day. It is necessary to limit the permitted quantities in this way, so that the exception does not apply to the possession of small quantities intended for commercial supply that could theoretically be for personal use over a longer period such as a month or three months.

Item [21] – After regulation 12B, insertion of new regulation 12BA – authorised prescriber authorities for therapeutic vaping substances that are not medicines

The Act provides a number of avenues that allow access to therapeutic goods that are not included in the Register. The authorised prescriber scheme under subsection 19(5) of the Act allows authorised medical practitioners to lawfully supply a specified 'unapproved' therapeutic good (or class of 'unapproved' therapeutic goods) to a class of patients with a particular medical condition. Ordinarily, there is requirement for ethics committee approval or specialist college endorsement for a medical practitioner to be given an authority to supply specified therapeutic goods (refer to subsection 19(6)(aa) of the Act). This requirement does not apply in the circumstances (if any) prescribed by the regulations for the purposes of this subsection. The current regulation 12B prescribes the medical practitioners, specified class of goods and circumstances where the requirement for approval by an ethics committee under paragraph 19(6)(aa) are not required.

Item 21 inserts new regulation 12BA into the Principal Regulations relating to authority that may be granted under subsection 19(5) of the Act (the authorised prescriber scheme) to a medical practitioner for the supply of unapproved therapeutic vaping substances that are not medicines. In addition, new regulation 12BA allows for a specified medical practitioner to be granted authorisation to prescribe and supply unapproved therapeutic vaping substances that do not contain nicotine without having to apply for ethics committee approval. The effect of regulation 12BA is to ensure that therapeutic vaping substances that do not contain nicotine are treated the same way under the authorised prescriber scheme as therapeutic vaping substances that contain nicotine or any other active ingredient under regulation 12B.

Regulation 12B currently prescribes matters necessary for an authority to be granted under the authorised prescriber scheme in relation to medicines that are therapeutic vaping substances and that contain nicotine. Regulation 12B does not apply to therapeutic vaping substances that do not contain nicotine or any other active ingredient because regulation 12B is limited to medicines and these goods do not meet the definition of 'medicine'. This amendment prescribes matters necessary for an authority to be granted under the authorised prescriber scheme in relation to therapeutic vaping substances that are not medicines.

The class of persons that is prescribed in subregulation 12BA(2) for the purposes of paragraph 19(6)(a) of the Act is the same class as that prescribed under regulation 12B, being medical practitioners engaged in clinical practice in or outside a hospital are a prescribed class of medical practitioners.

Subregulation 12BA(2) prescribes therapeutic vaping substances that are not medicines where they are to be administered by inhalation and the supply is for the treatment of smoking cessation or the management of nicotine dependence for the purpose of subsection 19(6) of the Act. The effect of this is that an authorised prescriber authority can be granted for these goods without requiring approval from an ethics committee, as is the case under regulation 12B for therapeutic vaping substances that contain nicotine where the supply is for the treatment of smoking cessation or the management of nicotine dependence.

Subregulation 12BA(3) prescribes the class of recipients for the purposes of paragraph 19(6)(b) of the Act as the class of persons each of whom is seeking treatment for smoking cessation or the management of nicotine dependence.

Subregulation 12BA(4) prescribe the circumstances in which therapeutic vaping substances may be authorised for supply under the authorised prescriber scheme as being that the supplier of the authorised vaping substance or class of authorised vaping substances complies with the treatment directions (if any) mentioned in the authority for the authorised vaping substance or class of authorised vaping substances. These are the same circumstances prescribed under regulation 12B for therapeutic vaping substances that contain nicotine.

Item [22] – After regulation 47B, insertion of new section 47C - Protected persons

Item 22 inserts new regulation 46B into the TG Regulations to prescribe a person for the purpose of the definition of 'protected person' in the new subsection 62(3) of the Act, as inserted by the Amendment Act. The person prescribed is a person to whom powers or functions are delegated under the new subsection 57(1A) of the Act, as inserted by the Amendment Act, which provides for the Secretary to delegate all or any of the powers and functions under Chapter 5A (enforcement), section 52AAA (forfeiture of things seized under search warrant), or section 52AAB (return or retention of thing declared not to be forfeited) to an officer of a Department of State, a Department or administrative unit of the Public Service of a Territory, or an authority of a State or of a Territory, being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement.

The effect of this amendment is that state and territory officers that are delegated powers or functions under subsection 57(1A) of the Act will be 'protected persons' for the purpose of section 62 of the Act and accordingly will be protected from criminal responsibility in accordance with section 62. That section protects certain persons from criminal responsibility

for offences under a law of the Commonwealth or a State law, in circumstances relating to obtaining, possessing, or conveying goods in connection with finding out whether the Act or Principal Regulations have been complied with. This amendment will ensure that state and territory officers can undertake compliance and enforcement activities without such activities amounting to contraventions of the Act.

Item [23] – paragraph 47A(2)(a)

Item 23 amends the reference to a 'medical practitioner registered in a State or Territory' in paragraph 47A(2)(a) to omit the words 'registered in a State or Territory'. The Amendment Act inserts a definition of 'medical practitioner' into the Act that incorporates registration in a State or Territory, and consequently these words are redundant when referring to a medical practitioner in the Principal Regulations.

Item [24] – After regulation 47B, insertion of new regulation 47C - Enforceable directions

This item inserts a new regulation 47C that prescribes, for the purpose of paragraph 42YT(2)(e) of the Act, a requirement to quarantine goods, store goods in a secure manner, and not supply goods, as things that may be the subject of an enforceable direction under section 42YT of the Act. The power to require these things to be done is necessary to ensure the supply of therapeutic goods can be prevented where the Secretary believes, on reasonable grounds, that therapeutic goods do not comply with the Act and the direction is necessary to protect the health and safety of humans.

Item [25] – Schedule 5 (table item 1, column 2, paragraph (d))

Item 25 amends the reference to a 'medical practitioner registered under a law of a State or Territory' in item 1 of Schedule 5 to omit the words 'registered under a law of a State or Territory'. The Amendment Act defines a 'medical practitioner' by reference to registration in a State or Territory and therefore these words are redundant when describing a medical practitioner in the Principal Regulations.

Item [26] – Schedule 5A (table item 15, column 2, paragraph d))

Item 26 amends item 15 to clarify that the requirement that a wholesaler must 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 Act (being the special access and authorised prescriber schemes) does not apply in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack.

Unlike therapeutic vaping substances and therapeutic vaping substance accessories, which may only be supplied to the ultimate consumer pursuant to the special access scheme or the authorised prescriber scheme, therapeutic vaping devices or therapeutic vaping device accessories that are regulated under Chapter 4 of the Act are not presently required to be supplied to the ultimate consumer pursuant to the special access or authorised prescriber schemes. This amendment clarifies that therapeutic vaping devices and therapeutic vaping device accessories are to be treated in the same way when part of a therapeutic vaping pack.

Item [27] – Schedule 5A (table item 15, column 3, paragraph (b))

Item 27 repeals paragraph (b) of column 3 in table item 15 of Schedule 5A and inserts a new paragraph that extends the scope of the notification requirement in relation to vaping goods that have been imported into Australia or manufactured in Australia before 1 March 2024. The current notification requirements only apply where the goods are imported into Australia, or manufactured in Australia on or after 1 March 2024. This item permit sponsor notices to be given in relation to vaping goods that were imported into Australia before 1 March 2024 and manufactured in Australia before 1 March 2024 provided the notice is given no later than 2 months after Schedule 1 to the Amendment Regulations commences. Note however that despite allowing for the supply of these goods, supply of these goods is limited to pharmacists and other persons specified in subparagraph (i)(ii) (also refer to item 29).

Item 15 of Schedule 5A provides the lawful basis for allowing therapeutic vaping goods to be imported, manufactured and supplied in Australia, despite these goods not being included in the Register, subject to specified conditions being met.

The effect of this amendment, together with amending item 35, is to extend the operation of the exemption in item 15 so that goods that were imported or manufactured before 1 March 2024 and comply with applicable standards are eligible to be supplied to the ultimate consumer under item 15, provided that they are notified within two months of the commencement of Schedule 1 to the Amendment Regulations. This will create a pathway for the supply of compliant stock that existed prior to the commencement of the application of the exemption on 1 March 2024.

The imposition of the 2-month timeframe, beginning on the day these amendments come into force, for the giving of a sponsor notice is intended to provide a sufficient period during which compliant stock may be identified and sponsors may make the necessary notification.

Item [28] – Schedule 5A (table item 15, column 3, paragraphs (g) and (h))

Item 25 repeals paragraphs (g) and (h) of item 15 and inserts new paragraphs (fa), (fb), (fc), (fd), (fe), (g) and (h).

Paragraph (fa) requires the sponsor to provide a reasonable number of samples of the goods to the Secretary on request, and to do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the relevant standards can be undertaken efficiently.

Paragraph (fb) requires the sponsor to allow an authorised officer to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the goods. While on those premises, the authorised officer must be allowed to inspect the premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on the premises that relates to the goods. The authorised officer must also be allowed to make any still or moving image or any recording of the premises or any thing on the premises.

Paragraph (fc) requires the sponsor, if requested to do so by an authorised officer, to produce to the authorised person such documents relating to the goods as the authorised person requires and allow the authorised person to copy the documents.

Paragraph (fd) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the goods allows an authorised officer to do the things referred to in paragraph (fb).

Paragraph (fe) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the goods as the authorised person requires and allow the authorised person to copy the documents.

The conditions in paragraphs (fb) to (fe) are necessary to ensure that the TGA can obtain information to determine whether therapeutic vaping goods that have been notified as complying with standards do in fact comply with those standards.

Paragraph (g) specifies the persons who may lawfully manufacture the goods in Australia.

Subparagraph (g)(i) refers to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods. This amendment is made to align the language with that is used in section 41QA(5)(b)(i) of the Act, as inserted by the Amendment Act, when referring to the same person. The intent of this provision has not changed.

Subparagraph (g)(ii) refers to a person to whom the Secretary has given consent in accordance with subsection 41RC(1) of the Act, as inserted by the Amendment Act, to manufacture the goods and the manufacture of the goods is in accordance with that consent.

Paragraph (h) specifies the persons to whom goods may be supplied by wholesale (persons who are not the ultimate consumers of the goods).

Subparagraph (h)(i) refers to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the device. This amendment is made to align the subparagraph with language used in section 41QB(8)(a) of the Act, as inserted by the Amendment Act, when referring to the same person. The intent of this provision does not change.

Subparagraph (h)(ii) is amended to align with the description of persons to whom vaping goods may be lawfully supplied by wholesale in section 41QB(8)(b) of the Act, as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in the analogous subparagraph (h)(ii), which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice extends to health professionals such as dentists and optometrists. This amendment ensures that the exemption applies only in relation to goods supplied by wholesale to a wholesaler, pharmacist, medical practitioner or nurse practitioner that is authorised under the law of a State or Territory, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amendment Act, which applies only to the supply of vaping goods by wholesale to these persons.

Subparagraph (h)(iii) refers to a recipient to whom a consent under subsection 41RC(1) of the Act to supply the goods has been given. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient to whom a consent is granted under section 41RC(1) of the Act.

Subparagraph (h)(iv) specifies, in relation to a good that is covered by a determination made by the Minister under section 41R of the Act, a recipient specified in the determination, or included in a class of persons specified in the determination. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient specified in a determination made by the Minister under section 41R of the Act.

Item [29] – Schedule 5A (table item 15, column 3, subparagraph (i)(ii))

Item 29 amends the description of the persons in subparagraph (i)(ii) of item 15 who may supply goods to the ultimate consumer, to specify a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

This subparagraph is amended to align with the description of persons who may supply vaping goods to the ultimate consumer in section 41QB(10) of the Act, as inserted by the Amending Act. This class of persons is narrower than the class of persons currently specified in subparagraph (i)(ii) of item 15, which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the Poisons Standard, and in practice extends to health professionals such as dentists and optometrists.

This amendment ensures that the exemption applies only in relation to goods supplied to the ultimate consumer by a pharmacist, medical practitioner or nurse practitioner, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amending Act, which applies only to the supply of vaping goods to the ultimate consumer by these persons.

Item [30] – Schedule 5A (table item 15, column 3, subparagraph (i)(iii))

Item 30 amends item 15 to clarify that the requirement that the ultimate supply to a consumer must be in accordance with such an approval or authority under section 19 of the Act (being the special access scheme or the authorised prescriber scheme) does not apply in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack.

Unlike therapeutic vaping substances and therapeutic vaping substance accessories, which may only be supplied to the ultimate consumer pursuant to the special access scheme or the authorised prescriber scheme, therapeutic vaping devices or therapeutic vaping device accessories that are regulated under Chapter 4 of the Act are not required to be supplied to the ultimate consumer pursuant to the special access or authorised prescriber schemes. This amendment makes it clear that therapeutic vaping devices and therapeutic vaping device accessories are to be treated in the same way when part of a therapeutic vaping pack.

Item [31] – Schedule 5A (table item 16, column 3, after paragraph (b)

Item 31 inserts a new condition in item 16 of Schedule 5A that the sponsor must provide a reasonable number of samples of a good to the Secretary on request, and must do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post notification testing to assess compliance with the standards can be undertaken efficiently.

Item [32] – Schedule 7 – (table items 22 and 23, column 2, subparagraph (a)(iii))

Item 32 amends references to a 'medical practitioner registered under a law of a State or Territory' to omit the words 'registered under a law of a State or Territory'. The Amendment Act defines a 'medical practitioner' by reference to registration in a State or Territory and these words are therefore redundant when describing a medical practitioner in the Principal Regulations.

Part 2—Transitional provisions

Item [33] – regulation 11.73

Regulation 11.73 currently states that the amendments made by Part 1 of Schedule 2 to the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (other than the amendments of the Dictionary) apply to therapeutic goods imported or manufactured on or after 1 March 2024.

Item 33 replaces the reference in regulation 11.73 to therapeutic goods imported or manufactured on or after 1 March 2024 with a reference to therapeutic goods imported or manufactured before, on or after 1 March 2024. This amendment is necessary because the Amendment Regulations amend item 2.17 of Part 2 of Schedule 4 to the MD Regulations so that it applies to therapeutic goods imported or manufactured before 1 March 2024.

This amendment, together with amending item 3, has the effect that therapeutic goods imported or manufactured before 1 March 2024 are eligible to meet the requirements of the exemption in item 2.17. It does not have retrospective effect because the exemption requires prospective meeting of those requirements, including the giving of a sponsor notice, in order for the exemption to apply.

This amendment has the effect that items 1.5 and 1.6 of Part 2 of Schedule 4 to the MD Regulations, which were repealed by the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* in relation to therapeutic goods imported or manufactured on or after 1 March 2024, are now also repealed in relation to therapeutic goods imported or manufactured before 1 March 2024. This is consistent with the amendments to the Act made by the Amendment Act, under which the new offence and civil penalty provisions relating to vaping goods in the Act apply to vaping goods unless an exemption applies under which 'the sponsor has given a notice in compliance with the exemption'. The exemptions in items 1.5 and 1.6 of Part 2 of Schedule 4 do not require a notice to be given and consequently goods that are exempt under those items cannot meet this requirement, and therefore are prohibited to be supplied.

Item [34] – Part 11, Application provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Item 34 insert a new Division 11.22 into Part 11 of the MD Regulations. Division 11.22 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions.

Clause 11.79 – Definitions

Clause 11.79 provides a definition for the term "amending regulations" in the new Division 11.22. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.*

Clause 11.80 – Application of amendments

Clause 11.80 provides that the amendment made by item 3 of Schedule 1 applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule. This has the effect that therapeutic goods imported or manufactured before, on or after the commencement of the Schedule will be eligible to provide a sponsor notice and meet the requirements of the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations.

Clause 11.80 also provides that the amendments made by items 4 and 5 of Schedule 1 apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule. This has the effect that the new conditions of the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations requiring the provision of a reasonable number of samples on request and allowing authorised officers to enter and inspect premises, and the description of the persons who may supply goods to the ultimate consumer, do not apply in relation to goods imported or manufactured before the commencement of that Schedule.

Clause 11.80 also provides that the amendments made by item 6, 7 and 12 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported on or after 1 October 2024. This has the effect that articles or components for use in the manufacture of therapeutic cannabis vaping goods that are imported on or after 1 October 2024 will be excluded from the definition of "therapeutic cannabis vaping device " and accordingly will be required to give a notice under section 2.18 of Part 2 of Schedule 4 to the MD Regulations.

Clause 11.80 also provides that item 8 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule. It also has the effect that the new condition requiring the provision, on request, of a reasonable number of samples of goods imported under item 2.18, does not apply to in relation to therapeutic goods imported before the commencement of that Schedule.

Clause 11.81 – Transitional vaping devices—exemption from Division 3 of Part 4-11 of the Act

Clause 11.81 provides a transition provision for transitional vaping devices in relation to the exemption from Division 3 of Part 4-11 of the Act.

Subclause (1) provides that medical devices that are exported from Australia are ***transitional vaping devices*** if the devices are therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods, and were imported, manufactured or supplied before the commencement of Schedule 1 to the Amendment Regulations, and as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

In effect, clause 11.81 allows a sponsor to export therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods that complied with all relevant laws that were applicable at the time the goods were imported, manufactured or supplied (as applicable), without requiring the goods to be included in the Register. The clause reduces regulatory burden associated with exporting such goods, allowing sponsors to potentially minimise the financial impact where such goods can no longer be lawfully supplied in Australia.

Pursuant to subclause (3), this exemption from the operation of Part Division 3 of Part 4-11 the Act ceases to have effect at the end of the period of 6 months starting on the day Schedule 1 to the Amendment Regulations commence. After this date, these goods will be required to be included in the Australian Register of Therapeutic Goods to be lawfully exported.

Item [35] – subregulation 96(5)

Subregulation 96(5) provides that item 15 of the table in 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 35 replaces the reference in subregulation 96(5) to therapeutic goods imported or manufactured on or after 1 March 2024 with a reference to therapeutic goods imported or manufactured before, on or after 1 March 2024. This amendment is necessary because amending item 3 amends item 15 in Schedule 5A to the TG Regulations so that it applies to therapeutic goods that were imported or manufactured before 1 March 2024.

This amendment, together with amending item 3, has the effect that therapeutic goods imported or manufactured before 1 March 2024 are eligible to meet the requirements of the exemption in item 15 of Schedule 5A to the TG Regulations. It does not have retrospective effect because the exemption requires prospective meeting of those requirements, including the giving of a sponsor notice, in order for the exemption to apply.

Item [36] – Part 9, Division 26 - Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Item 36 inserts a new Division 26 into Part 9 of the TG Regulations. Division 26 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions.

Clause 104 – Definitions

Clause 104 provides a definition for the term "amending regulations" in the new Division 26. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.*

Clause 105 – Authorities for therapeutic vaping substances that are not medicines

Clause 105 provides that the amendment to regulation 12BA applies in relation to an authority given under subsection 19(5) of the Act on or after the commencement of Schedule 1 to the amending regulations. This has the effect that authorities under the authorised prescriber scheme can be granted in the absence of ethics committee approval for therapeutic vaping substances that do not contain nicotine or any other active ingredient upon commencement of that Schedule.

Clause 106 – Therapeutic vaping packs

Clause 106 provides that the amendment made by item 17 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured on or after 1 October 2024.

This has the effect that a primary pack that is imported or manufactured before 1 October 2024 and consists only of therapeutic vaping devices and/or therapeutic vaping device accessories will continue to be regarded as a therapeutic vaping pack, whereas a primary pack that is imported or manufactured on or after 1 October 2024 will only be regarded as a therapeutic vaping pack if it also contains at least one therapeutic vaping substance and/or therapeutic vaping substance accessory.

Clause 107 – Exempt goods

Clause 107 provides that the amendment made by item 27 of Schedule 1 applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule. This has the effect that therapeutic goods imported or manufactured before, on or after the commencement of the Schedule will be eligible to provide a sponsor notice and meet the requirements of the exemption in item 15 of Schedule 5A to the TG Regulations.

Clause 107 also provides that the amendments made by items 26 and 28 to 30 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule. This has the effect that the new conditions of the exemption in item 15 of Schedule 5A to the TG Regulations requiring the provision of a reasonable number of samples upon request and allowing authorised officers to enter and inspect premises, and the description of the persons who may supply goods to the ultimate consumer, do not apply in relation to goods imported or manufactured before the commencement of that Schedule. It also has the effect that the amendment to clarify that a special access scheme or authorised prescriber approval is not required for devices that are a part of a therapeutic vaping pack applies from the commencement of Schedule 1.

Clause 107 provides that the amendments made by item 31 of Schedule 1 apply in relation to therapeutic goods imported on or after the commencement of that Schedule. This has the effect that the new condition requiring the provision, on request, of a reasonable number of

samples of goods imported under item 16 of Schedule 5A to the TG Regulations does not apply to in relation to therapeutic goods imported before the commencement of that Schedule.

Clause 108 – Transitional vaping goods—exemption from Part 3-2 of the Act

Clause 108 provides a transition provision for transitional vaping goods in relation to the exemption from Part 3-2 of the Act.

Subclause (1) defines ***transitional vaping goods*** as therapeutic vaping goods that are exported and that were imported, manufactured or supplied before the commencement of Schedule 1 to the Amendment Regulations, and as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

In effect, clause 108 allows a sponsor to export therapeutic vaping goods that complied with all relevant laws that were applicable at the time the goods were imported, manufactured or supplied (as applicable), without requiring the goods to be included in the Australian Register of Therapeutic Goods. The clause reduces regulatory burden associated with exporting such goods, allowing sponsors to potentially minimise the financial impact where such goods can no longer be lawfully supplied in Australia.

Pursuant to subclause (3), this exemption from the operation of Part 3-2 of the Act ceases to have effect at the end of the period of 6 months starting on the day Schedule 1 to the Amendment Regulations commence. After this date, these goods will be required to be included in the Australian Register of Therapeutic Goods to be lawfully exported.

Schedule 2 – Commercial quantities

Item [1] – Regulation 10N (table)

Schedule 2 commences on the day after the end of the period of 3 months beginning on the day Schedule 1 to the Amendment Regulations commences. Item 1 would repeal the table in regulation 10N and replaces it with lower commercial quantities of 9 vaping devices, 60 vaping accessories, and 400 ml of vaping substance that is a liquid.

Schedule 3 – Other matters

Item [1]– After paragraph 3(3)(bab)

Item 1 inserts a reference to the *Therapeutic Goods Law Application Act 2024* (WA) in subregulation 3(3), with the effect that the *Therapeutic Goods Law Application Act 2024* (WA) is declared to be a corresponding State law for the definition of 'corresponding State law' in subsection 3(1) of the Act. This item commences on the later of the commencement of Schedule 1 to the Amending Act and immediately after the commencement of Part 2 of *Therapeutic Goods Law Application Act 2024* (WA). However, it does not commence at all if Part 2 of *Therapeutic Goods Law Application Act 2024* (WA) does not commence.

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 Reforms) Regulations 2024

The *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (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 support the *Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024* (the Amendment Act), which implements reforms to the regulation of all vaping goods. The Amendment Act implements the national vaping reforms to restrict the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods, particularly non-therapeutic and disposable single use vapes.

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 prescribe matters and make other consequential amendments necessary to implement the measures in the Amendment Act.

In particular, the Amendment Regulations support the Amendment Act by prescribing commercial quantities, permitted quantities and units of vaping goods for the purposes of the new offence and civil penalty provisions introduced by the Amendment Act relating to the possession of vaping goods as part of a suite of measures designed to address and deter illicit trade in Australia.

The Amendment Regulations provide transitional arrangements under which certain therapeutic vaping goods that would otherwise be unlawful on commencement of the Amendment Act may be dealt with, and make a small number of minor consequential amendments. The Amendment Regulations also allow for the supply or export of compliant vaping goods that were imported or manufactured prior to 1 March 2024, as part of transitional arrangements to assist sponsors to comply with the reforms.

In addition, the Amendment Regulations make a small number of related amendments, including to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law for the purpose of the Act, and to update a small number of definitions and exemptions to ensure consistency between the Amendment Act and the TG Regulations and MD Regulations in relation to key terms.

The Amendment Regulations support the national vaping reform measures that are intended to address the risks posed by vaping to youth and young adults 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. The amendments provide for additional controls for the importation, manufacture and supply of therapeutic vaping goods, including new conditions for exemptions to ensure compliance with applicable standards.

Principally, the Amendment Regulations appropriately and reasonably support objectives to enable legitimate patient access to certain therapeutic vaping goods for smoking cessation and the management of nicotine dependence, where clinically appropriate.

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 still emerging.

The Government's vaping reforms are being implemented in stages over 2024. The Amendment Act is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms included amendments to the *Customs (Prohibited Imports) Regulations 1956*, the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD

Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply;
- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply;
- since 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standards.

The Amendment Regulations would support the Amendment Act to implement measures that are necessary to give effect to the second stage of reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. 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 right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR).

The right to health

The Amendment 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. Marketing and use of vapes in the community has increased rapidly in recent years, particularly among youth and young adults 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, domestic manufacture and supply of therapeutic vapes in Australia, subject to compliance with relevant quality standards applying to those goods, for use in smoking cessation or the management of nicotine dependence. The reforms promote the right to health as the new requirements limit patient access to therapeutic vapes from medical practitioners, nurse practitioners and registered pharmacists.

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 legitimate 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.

The reforms also take positive steps to promote the right to health by ensuring that access to therapeutic vapes are only those in appropriate setting and supervision by a health practitioner.

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.

Conclusion

The Amendment Regulations are compatible with human rights because they promote the right to health in Article 12 of the ICESCR.