

REPLACEMENT 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 Amendment (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).

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 *Therapeutic Goods Act 1989* (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.

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 product standards. A principal purpose of these amendments is to uphold the integrity of the therapeutic goods scheme established by the Act by creating powers to support the efficient regulation of therapeutic vaping goods.

Details of the Amendment Regulations are set out in [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 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 (IA) was prepared in relation to the Government's reforms to the regulation of vapes, taking into account the feedback received from stakeholders throughout the consultation (OBPR23-03933). The IA is 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 were 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.

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

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 to the Amendment Regulations on the commencement of Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (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, which 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 2024* (the Amendment Regulations) are made under the *Therapeutic Goods Act 1989* (the Act).

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 CPI Regulations), 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 of 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 to 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 and authorised persons 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 to the effect that those goods 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 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, 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.

This provision, together with item 33, is intended to apply on and from 1 July 2024, not before that date. The intended effect of this amendment is to bring certain therapeutic vaping devices and device accessories imported or manufactured before 1 March 2024, that were previously exempt from regulation under the Act, within the regulatory scheme on and from

1 July 2024. It is not intended to 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.

Arrangements under the *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (the Possession and Supply Determination) are intended to mitigate any retrospective effect of item 3 together with item 33. If previously excluded devices are possessed by individuals, retailers and other entities, the Possession and Supply Determination permits possession of those goods by those persons for certain periods of time to facilitate:

- the use, disposal or exportation of the goods by the persons;
- return to wholesalers and sponsors through the pharmaceutical supply chain; or
- surrender of the goods to the Department of Health and Aged Care.

The relevant items are items 1 of Schedule 1 and items 1, 4, 5, 6 of Schedule 2 to the Possession and Supply Determination.

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 amends the wording in paragraph (g) in table item 2.17 of Part 2 of Schedule 4 to the MD Regulations.

Medical devices listed in an item in Part 2 of Schedule 4 are exempt from the requirement to be included in the Australian Register of Therapeutic Goods (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.

Paragraphs (fa), (fb), (fc), (fd) and (fe)

The conditions of exemption contained in paragraphs (fa), (fb), (fc), (fd) and (fe) are based on the statutory conditions under subsection 28(5) and section 41FN of the Act with respect to sponsors importing or supplying other medicines and medical devices in Australia.

The notification system established under the regulations for unapproved vaping goods (including therapeutic vaping devices and devices accessories) is analogous to registration and inclusion frameworks under the Act. The public interest and confidence in the regulatory scheme is served by ensuring sponsors of therapeutic vaping goods are subject to many of the same conditions that the Act automatically applies to sponsors of other medicines and medical devices with general marketing approval in Australia.

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 officer 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.

Authorised officers

Paragraphs (fb), (fc), (fd) and (fe) of table item 2.17 in Part 2 of Schedule 4 to the MD Regulations require a sponsor to do certain things in relation to an ‘authorised officer’.

The term ‘authorised officer’ is not defined in the Act or the MD Regulations, but is defined in, and used throughout, the TG Regulations. An ‘authorised officer’ is defined in regulation 2 of the TG Regulations as ‘in relation to a provision of these Regulations, means an officer authorised by the Secretary to exercise powers under that provision’.

Instead of ‘authorised officer’, the term ‘authorised person’ is used throughout the Act and the MD Regulations. ‘Authorised person’ is relevantly defined in section 3 of the Act as persons authorised by the Secretary to exercise powers under certain provisions.

For the avoidance of doubt, a reference to an ‘authorised officer’ in paragraphs (fb), (fc), (fd) and (fe) of table item 2.17 in Part 2 of Schedule 4 to the MD Regulations is intended to be a reference to an ‘authorised person’ within the meaning of the Act, and the use of the former term is an inadvertent drafting error. That error has since been corrected following the making of the Amendment Regulations (see item 5 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024*).

Under regulation 10.1 of the MD Regulations, the Secretary may authorise certain persons to exercise powers under paragraphs (fb) to (fd), including certain persons employed by a Commonwealth department or authority, and as part of the vaping goods reforms, certain persons employed by state or territory departments, administrative units or authorities with functions relating to health or law enforcement matters. In practice, the classes of persons

exercising powers under these provisions have the relevant training, skills and experience to carry out regulatory compliance action.

In accordance with the Act, authorised persons must be issued with an identity card. It is expected that, consistent with analogous powers concerning other medicines and medical devices in the Act and its regulations, authorised persons will carry and present identity cards to persons prior to entry into any premises pursuant to these discretionary powers. Further, authorised persons must comply with applicable Commonwealth, state and territory codes of conduct.

Purpose of powers

The conditions in paragraphs (fa) to (fe) are necessary to ensure that the Therapeutic Goods Administration (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.

These powers allow the TGA to effectively monitor the quality, safety and performance of therapeutic vaping devices and device accessories that are permitted to be supplied in Australia in accordance with the exemption. The powers are therefore intended to be used to ensure compliance with regulatory requirements under the Act and MD Regulations.

There are currently no therapeutic vaping devices or device accessories that have been evaluated by the TGA for inclusion on the Register for smoking cessation or the management of nicotine dependence. Accordingly, the TGA relies on sponsors to provide a notice under table item 2.17 of Part 2 of Schedule 4 to the MD Regulations, stating that the device or device accessory complies with the essential principles (or is imported or supplied with the consent of the Secretary) and that the device or device accessory is intended only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence.

Following notification, the Secretary may determine that the supply of the device or device accessory notified to the TGA be stopped or should cease because:

- the supply of the device or device accessory compromises public health and safety; or
- the device or device accessory does not comply with the essential principles.

Without the regulatory powers in paragraphs (fa) to (fe), there is a risk that the Secretary will have insufficient information to monitor the quality, safety and performance of therapeutic vaping devices and device accessories and make the determinations where necessary. The ability to make determinations to protect public health and safety is compromised without powers to require the production of documents and samples from sponsors of notified devices and device accessories, and to allow entry and access to relevant premises.

Patients, pharmacists, and practitioners rely on monitoring activities conducted by the TGA to provide confidence in the quality, safety and performance of therapeutic goods supplied in Australia, including those on the notified vape list. Therapeutic vaping devices and device accessories are subject to the therapeutic goods framework. Without powers to support the TGA to test the accuracy of statements made by sponsors in notifications for such devices and device accessories, these vaping goods may continue to be supplied in the pharmaceutical supply chain without appropriate checks or balances.

The nature and volume of information, and the level of access to premises, that may be required by an authorised person is intended to be directly related to the risk associated with relevant therapeutic vaping goods. The provisions are necessary therefore to support efficient regulatory action and to provide confidence and assurance to the Australian public in the role of the TGA as a regulator of quality, safety and performance.

Scope of powers

The discretionary powers in paragraphs (fa) to (fe) of table item 2.17 in Part 2 of Schedule 4 to the MD Regulations will be exercised:

- when the TGA has received information, which suggests that a notified therapeutic vaping device or device accessory may not comply with the essential principles (or, where relevant, a medical device standard) or which otherwise relates to general concerns regarding the safety of the goods. This includes information – such as adverse event reports connected with the use of specific notified goods – received from sponsors or third parties, such as state and territory health authorities, pharmacists, medical practitioners, nurse practitioners or patients. The TGA routinely receives this type of information in relation to other therapeutic goods;
- when the TGA undertakes post-notification compliance monitoring and assessment to verify that the notified goods comply with the essential principles. Such monitoring and assessment is routinely carried out in relation to other therapeutic goods. The TGA’s laboratory testing is governed by a risk management framework based on ISO 31000, which is an international standard that provides principles and guidelines for risk management; and
- when the TGA has carried out regulatory compliance action, such as the testing of samples of the notified goods and the results have indicated concerns regarding the quality, safety or performance of the goods, which may warrant further investigation by way of an audit or inspection of the manufacturing site and/or the production of documents relating to the goods. An example includes testing of notified therapeutic vaping devices across different production batches having considerable variation in battery performance. Issues may be identified that affect the quality or safety of the goods, which may be resolved by remedial action recommended by TGA auditors, or warrant further regulatory action.

The following methodology will apply to the post-notification compliance monitoring of notified therapeutic vaping devices and device accessories:

- having regard to intelligence or signals received from third parties, as well as information received from sponsors and gathered by the TGA, the TGA will select

goods suspected of non-compliance with applicable regulatory requirements for targeted review according to a risk-based approach. Certain goods will be prioritised, such as those which may result in an immediate or potential health and safety risk to consumers, including:

- i. notified goods that are the subject of an adverse event report where safety concerns have been raised about a manufacturer who manufacturers notified goods on behalf of multiple sponsors; and
 - ii. notified goods with faulty batteries which have a high risk of explosion;
- the TGA will also select notified therapeutic vaping devices and device accessories for programmed reviews, including through random selection based on agreed parameters, for the purpose of determining whether there are compliance issues. Programmed reviews are a common, appropriate tool for ensuring that sponsors maintain compliance with regulatory requirements, as sponsors are aware that their goods may at any time be the subject of a random audit or request for documents demonstrating compliance with the essential principles. Reviews can also provide information which may demonstrate that certain goods, a sponsor or a manufacturer should be the focus of a future targeted review.

The factors that are anticipated to be taken into account by authorised persons (or, where relevant, the Secretary and their delegates) when considering whether to exercise the powers in paragraphs (fa) to (fe) include:

- the reliability and extent of information in the possession of the TGA with respect to the relevant notified goods, including information from the sponsor of the goods and third parties;
- the amount of relevant notified goods in the hands of patients, or the retail or wholesale supply chains, or intended to be imported or exported, along with the impact on patient access should compliance and/or enforcement action be undertaken;
- the seriousness or otherwise triviality, of any potential non-compliance with the essential principles (if known), including whether, and to what degree, the non-compliance may pose a risk to the health or safety of patients, their families or the broader Australian public;
- the sponsor's reputation and any history of non-compliance with the Act, the TG Regulations and the MD Regulations, or corresponding state or territory laws;
- whether the TGA has previously exercised these powers in relation to the sponsor of the relevant notified goods, and if so, the outcomes in relation to the exercise of those powers;
- the impact of the exercise of these powers on sponsors, including the time and costs of compliance;
- the availability, appropriateness and efficacy of any alternative regulatory compliance and/or enforcement action, such as obtaining a warrant if there are legal grounds to do

so, as well as alternative options to the use of such powers (including engaging with a sponsor on an informal basis);

- the significance and implications of any anticipated regulatory outcomes (if known), such as:
 - i. the impact to patients and the wider Australian community, including whether an urgent recall or similar action is needed to protect health and safety, or if patients need to be transitioned to alternative goods;
 - ii. the identification of non-compliance with the essential principles or other regulatory requirements, which could prompt further compliance and/or enforcement action, including criminal prosecution in the most serious of cases;
 - iii. whether the information could be used as part of an analysis of a class of goods to inform amendments to regulatory requirements, which will further protect patients and increase community safety;
- the time and expense involved for the TGA to exercise these powers, such as the cost of travel to a manufacturing site.

The discretionary powers in paragraphs (fa) to (fe) will only be exercised relevantly by authorised persons or the Secretary and their delegates who are responsible for monitoring and investigating compliance of notified vaping goods with regulatory requirements. This includes investigators responsible for compliance and enforcement action regarding medicines and medical devices, including the manufacturing quality of devices, and TGA laboratory staff who are responsible for testing samples of therapeutic goods.

There are also limitations in the text as to the scope of the discretionary powers. For example:

- paragraph (fa) provides that only a ‘reasonable’ number of samples may be obtained;
- paragraph (fb) provides that authorised persons may only enter a premises at a ‘reasonable’ time; and
- paragraph (fc) provides that documents required to be produced must relate to the notified therapeutic vaping goods.

Further, the exercise of discretionary powers must be legally reasonable, and as a matter of policy, have a clear regulatory purpose.

Finally, in relation to paragraphs (fb) and (fd), most therapeutic vaping devices and device accessories are manufactured overseas and imported into Australia. In practice, it is anticipated that the production of information and samples will obviate the need for authorised persons to enter and inspect premises outside Australia. However, the power is available in paragraphs (fb) and (fd) to authorised persons if needed.

[Consideration of the Attorney-General’s Department’s Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers](#)

The Attorney-General's Department's Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers (the AGD Guide) was considered when drafting these provisions, in particular, paragraph 8.6 which provides that the Commonwealth Parliament has accepted powers to enter premises without express consent or a warrant in certain limited circumstances. Such circumstances apply in relation to the discretionary powers in paragraphs (fa) to (fe), as the circumstances in which these powers are enlivened is analogous to circumstances relating to licensed premises discussed in paragraph 8.6 of the AGD Guide.

Sponsors are analogous to persons who hold licences or obtain registration of their goods under the Act in relation to which the power to enter non-residential premises managed by those persons is justified for the purpose of ensuring compliance with licence or registration conditions.

Licence or registration holders who are subject to conditions of entry into non-residential premises are not dissimilar to sponsors of notified therapeutic vaping devices and device accessories. In this regard, both the licence or registration holder and the sponsor of the notified goods have chosen to voluntarily subject themselves to conditions and/or regulatory requirements under the Act and its regulations. By complying with conditions and/or regulatory requirements, these persons are permitted to lawfully supply therapeutic goods in Australia.

Put another way, each sponsor of notified therapeutic vaping devices and device accessories has freely decided to participate in a regulated market whereby participation is contingent on the sponsor reasonably and appropriately needing to comply with conditions. These conditions include those aimed at monitoring compliance for the purpose of verifying compliance of the sponsor's goods with the essential principles. The essential principles are put in place principally to protect patient and community safety and form the basis of any notification. The relevant powers are limited in nature and do not confer broad powers to seize documents and other evidential material, in contrast to ordinary search and seizure powers.

The AGD Guide also states that senior executive authorisation should be required for entry without consent or a warrant, together with reporting requirements, and such powers should also be exercised if avenues for obtaining a warrant by remote means have proven absolutely impractical in the particular circumstances.

As described above, one of the factors to be considered when determining whether to exercise these discretionary powers is the availability, appropriateness and efficacy of any alternative compliance or enforcement action, which includes the obtaining of a warrant.

As a matter of practice, site inspections without a warrant are a means to facilitate a more cooperative and informal exchange of information between the TGA and sponsors of notified therapeutic vaping devices and device accessories. For example, sponsors are provided with advance notice of an inspection on a date that is convenient for both parties. For these reasons, obtaining a warrant may not be appropriate or effective in all circumstances. The transparency of the TGA's compliance activities – where appropriate – builds rapport and trust between the TGA and regulated entities.

Site inspections conducted using the discretionary power will have the oversight of senior executive officers and will be undertaken in accordance with established processes.

Inclusion of powers in the MD Regulations

It is necessary and appropriate for the TGA to possess these discretionary powers because:

- the scheme places trust in regulated entities to make truthful and accurate statements as to the quality, safety and performance of notified therapeutic vaping devices and device accessories. There is no statutory process for the TGA to assess, approve or reject notifications when those notifications are made. Therefore, in order to ensure ongoing patient and community safety – and patient, regulator and industry confidence in the veracity of those statements – the TGA needs mechanisms to test and verify the accuracy of such information in a timely manner, and take action if necessary;
- the power to obtain samples of notified goods and conduct laboratory testing of such goods is critical to protect patient and community safety, by identifying whether goods pose risks (such as in response to reports that a notified therapeutic vaping device has an exploding battery) and, if emerging or systemic issues are identified, amending applicable regulatory requirements to improve safeguards across classes of notified goods;
- the TGA may be unable to request documents through alternative mechanisms, such as statutory notices issued under section 45AB of the Act if:
 - i. there is insufficient information regarding possible contraventions of the Act, TG Regulations or MD Regulations (this may not be readily apparent at all times); or
 - ii. documents are held by overseas manufacturers rather than domestic sponsors (where, for example, such information may be obtained via the sponsor under paragraph (fe) of item 4);
- in certain circumstances, programmed compliance monitoring may facilitate a more cooperative exchange of information between sponsors of notified goods and the TGA rather than more formal means;
- the power to require the sponsor to facilitate inspection of a manufacturing site ensures that the TGA can appropriately monitor compliance with applicable regulatory requirements, including by examining and taking samples of notified goods. Additionally, inspection is an efficient way for the TGA to monitor compliance, rather than requiring rounds of statutory notices for examples issues under section 45AB of the Act;
- gathering information in a timely and complete manner in response to a safety signal or other issue with specific notified goods is critical to protecting public health and safety; and

- as explained above, site inspections without a warrant are a means to facilitate a more cooperative and informal exchange of information between the TGA and sponsors of notified therapeutic vaping devices and device accessories.

It is appropriate that the paragraph (fa) to (fe) conditions are contained in delegated legislation, rather than primary legislation, because:

- the items amend the conditions to the exemption specified in table item 2.17 in Part 2 of Schedule 4 to the MD Regulations. This exemption is made under subsection 41HA(1) of the Act, which relevantly provides that the regulations may specify certain medical devices to be exempt from relevant regulatory requirements subject to conditions;
- the Act therefore anticipates that the exemption may be prescribed in the regulations subject to conditions. These conditions are intended to be specified in the regulations. It is not desirable to fragment conditions attaching to an exemption across the Act and the regulations. Rather, it is preferable for conditions to remain attached to the relevant exemption;
- the inclusion of these powers as conditions of exemption are appropriately limited to notified therapeutic vaping devices and device accessories. These powers are more confined than, for example, the general power to request information or documents under section 45AB of the Act.

As the regulation of vaping goods is complex, and the lawful and black-market supply of these goods is dynamic, it is necessary and appropriate for the exemption of therapeutic vaping devices and device accessories to be contained in regulations in accordance with the relevant head of power in section 41HA of the Act. The use of regulations in this manner facilitates more timely regulatory change as the situation requires.

Availability of merits review

Independent merits review is not available with respect to a decision made by the Secretary or an authorised person under paragraphs (fa) to (fe). Judicial review will still be available to a person affected by such a decision with standing to seek such review.

This reflects a balanced compromise between the needs to effectively monitor the quality, safety and performance of relevant unregistered therapeutic vaping goods and a person's right of review, noting that analogous powers ordinarily apply to other medical devices regulated under the Act, not just vaping devices and device accessories.

The Administrative Review Council has recognised that preliminary or procedural decisions, which facilitate or lead to the making of a substantive decision, are unsuitable for review. This is because preliminary decisions generally do not have substantive consequences.¹

Decisions under paragraphs (fa) to (fe) are unsuitable for merits review because decisions involving the exercise of those powers:

¹ Administrative Review Council, *What Decisions Should Be Subject To Merits Review?*, Canberra 1999, paragraphs 4.2 to 4.7 <[What decisions should be subject to merit review? 1999 | Attorney-General's Department \(ag.gov.au\)](#)>.

- are preliminary in nature – decisions, such as those requiring the sponsor to provide the Secretary a reasonable number of samples of a therapeutic vaping device, have no substantive effect but could assist the Department of Health and Aged Care in making determinations or taking further compliance and enforcement action;
- protect public health and safety – the Department of Health and Aged Care is responsible for protecting the public from the supply of therapeutic goods that are non-compliant with applicable product standards. In circumstances where the department holds significant concerns about the quality, safety or performance of relevant therapeutic vaping goods, the exercise of merits review rights could delay timely regulatory, compliance or enforcement action, particularly where the goods pose a grave or imminent risk to public health and safety.

The exclusion of decisions under paragraphs (fa) to (fe) from merits review is also consistent with the exclusion of merits review in relation to information gathering powers under the Act, as made by items 1 and 2 to Schedule 3 to the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*.

Amendment to paragraph (g)

Paragraph (g) of table item 2.17 in Part 2 of Schedule 4 to the MD Regulations 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.

Items [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 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 Act, 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 CPI Regulations 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 to 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) is 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) prescribes 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 46A, insertion of new section 46B – 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.

Under subsection 62(1) of the Act, a ‘protected person’ is immune from criminal responsibility in the following limited circumstances:

- when undertaking an activity (such as compliance and enforcement action) for the purpose of finding out whether the Act, TG Regulations or MD Regulations have been complied with; and
- in circumstances where the person obtains, possesses, conveys, or facilitates the conveyance of, goods contrary to an offence relating to the obtaining, possession, conveyance or facilitation of the conveyance of the goods.

A ‘protected person’ is defined in subsection 62(3) of the Act as meaning:

- an APS employee in the Department of Health and Aged Care; or
- a person of a kind prescribed by regulation, namely, a person prescribed under regulation 46B of the TG Regulations, which is presently limited to persons to whom powers or functions have been delegated under subsection 57(1A) of the Act.

Under subsection 57(1A) of the Act, the Secretary may only delegate certain enforcement and forfeiture powers in Chapter 5A, section 52AAA and/or section 52AAB of the Act to officers (being employees or sworn officials, not contractors or similar) of:

- a department of state of an Australian state, such as the New South Wales Ministry of Health; or
- a department or administrative unit of the public service of a territory, such as the Northern Territory Government’s Department of Health; or
- an authority of a state or a territory, such as the Queensland Police Service;

with functions relating to therapeutic goods, health or law enforcement.

These powers are intended to only be delegated to officers of state or territory institutions who are actively involved in conducting compliance and enforcement activities under the Act.

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.

The immunity is not a complete immunity from criminal responsibility. Rather, it only applies to offences against a law of the Commonwealth, a state or a territory relating to the obtaining, possession, conveyance or facilitation of the conveyance of the relevant goods.

In this regard, retaining goods condemned as forfeited to the Commonwealth under subparagraph 52AAA(6)(e)(i) of the Act for the purpose of proceedings in respect of which the goods may afford evidence is a primary example in which the Secretary and delegates of

the Secretary, including state or territory officers, may require immunity from criminal liability.

Some other circumstances in which immunity from liability may be required are as follows:

- where the Secretary or delegate takes possession of goods for the purpose of inspecting the goods to determine whether to exercise relevant powers (such as determining whether goods meet the requirements to be forfeited);
- where the Secretary or delegate issues a direction under subsection 42YT(2) of the Act that the goods are delivered to the Secretary to be destroyed or otherwise disposed of in an appropriate manner; and
- where a compliance officer possesses goods for the purpose of preparing a witness statement in a civil or criminal proceeding.

The Amendment Act amended the Act to implement a federal cooperative scheme between the Commonwealth, states and territories with respect to the regulation of vaping goods. The new framework authorises state and territory officials to undertake regulatory, compliance and enforcement action with respect to vaping goods. In practice, compliance may be undertaken by a range of state and territory agencies and by officers at a range of levels. In these circumstances, it is considered necessary that the immunity extend to all classes of persons specified in subsection 57(1A) of the Act.

The collaboration of state and territory officers is critical to the effective implementation of the reforms relating to the regulation of vaping goods, and so investigation and enforcement powers in relation to vaping goods have been delegated to certain officers within relevant parts of state and territory health departments, police services and similar institutions responsible in each jurisdiction for monitoring the lawful therapeutic vaping goods supply chain, and investigating and halting the black market.

Providing immunity to these officers in the course of exercising relevant powers under the Act is also consistent with the immunity afforded to APS employees in the Department of Health and Aged Care who have, for example, been delegated power under subsection 57(1) of the Act, and fall within the definition of ‘protected person’ in paragraph (a) of that term as defined in subsection 62(3) of the Act.

The states and territories have enacted corresponding laws that apply the Act, and associated instruments of a legislative or administrative character made under it, as laws of the relevant state or territory. As a result, effective regulation, compliance and enforcement is shared between the Commonwealth, states and territories to ensure comprehensive coverage.

Consequently, item 22 prescribes relevant state and territory officers as immune from criminal responsibility when properly undertaking compliance and enforcement activities under the Act. This is to ensure that the Commonwealth, States and Territories can effectively carry out compliance and enforcement action, including the exercise of investigatory powers, in relation to vaping goods.

This amendment will ensure that state and territory officers can undertake compliance and enforcement activities without such activities amounting to offences under the Act, other Commonwealth laws or state or territory laws.

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 permits 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 (b)(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 28 repeals paragraphs (g) and (h) of item 15 and inserts new paragraphs (fa), (fb), (fc), (fd), (fe), (g) and (h) in table item 15 of Schedule 5A to the TG Regulations.

Paragraphs (fa), (fb), (fc), (fd) and (fe)

The conditions of exemption contained in paragraphs (fa), (fb), (fc), (fd) and (fe) are based on the statutory conditions under subsection 28(5) and section 41FN of the Act with respect to sponsors importing or supplying other medicines and medical devices in Australia.

The notification system established under the regulations for unapproved vaping goods (including therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and therapeutic goods in a therapeutic vaping pack) is analogous to registration and inclusion frameworks under the Act. The public interest and confidence in the regulatory scheme is served by ensuring sponsors of therapeutic vaping goods are subject to many of the same conditions that the Act automatically applies to sponsors of other medicines and medical devices with general marketing approval in Australia.

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 officer such documents relating to the goods as the authorised officer requires and 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 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 goods, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the goods as the authorised officer requires and allow the authorised officer to copy the documents.

Authorised officers

Paragraphs (fb), (fc), (fd) and (fe) of table item 15 in Schedule 5A to the TG Regulations require a sponsor to do certain things in relation to an authorised officer.

The term ‘authorised officer’ is relevantly defined in the TG Regulations as persons authorised by the Secretary to exercise powers under certain provisions.

Under regulation 2A of the TG Regulations, the Secretary may authorise certain persons to exercise powers under paragraphs (fb) to (fe), including certain persons employed by a Commonwealth department or authority, and as part of the vaping goods reforms, certain persons employed by state or territory departments, administrative units or authorities with functions relating to health matters. In practice, the classes of persons exercising powers under these provisions have the relevant training, skills and experience to carry out regulatory compliance action.

In accordance with the TG Regulations, authorised officers must be issued with an identity card. It is expected that, consistent with analogous powers concerning other medicines and medical devices in the Act and its regulations, authorised officers will carry and present identity cards to persons prior to entry into any premises pursuant to these discretionary powers. Further, authorised officers must comply with applicable Commonwealth, state and territory codes of conduct.

Purpose of powers

The conditions in paragraphs (fa) 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.

These powers allow the TGA to effectively monitor the quality and safety of relevant therapeutic vaping goods that are permitted to be supplied in Australia in accordance with the exemption. The powers are therefore intended to be used to ensure compliance with regulatory requirements under the Act and TG Regulations.

There are currently no therapeutic vaping goods that have been evaluated by the TGA for registration, listing or inclusion in the Register for smoking cessation or the management of nicotine dependence. Accordingly, the TGA relies on sponsors to provide a notice under table item 15 of Schedule 5A to the TG Regulations, stating that the goods comply with applicable standards (or are imported or supplied with the consent of the Secretary) and the only indications of the goods are use for smoking cessation or the management of nicotine dependence.

Following notification, the Secretary may determine that the supply of the goods notified to the TGA be stopped or should cease because:

- the supply of the goods compromises public health and safety; or
- the goods do not conform with a standard applicable to the goods.

Without the regulatory powers in paragraphs (fa) to (fe), there is a risk that the Secretary will have insufficient information to monitor the quality and safety of relevant therapeutic goods and make the determinations where necessary. The ability to make determinations to protect public health and safety is compromised without powers to require the production of documents and samples from sponsors of such goods, and to allow entry and access to relevant premises.

Patients, pharmacists, and prescribers rely on monitoring activities conducted by the TGA to provide confidence in the quality and safety of therapeutic goods supplied in Australia, including relevant therapeutic vaping goods on the notified vape list. These goods are subject to the therapeutic goods framework. Without powers to support the TGA to test the accuracy of statements made by sponsors in notifications for such goods, these goods may continue to be supplied in the pharmaceutical supply chain without appropriate checks or balances.

The nature and volume of information, and the level of access to premises, that may be required by an authorised officer is intended to be directly related to the risk associated with relevant therapeutic vaping goods. The provisions are necessary therefore to support efficient regulatory action and to provide confidence and assurance to the Australian public in the role of the TGA as a regulator of quality, safety and performance.

Scope of powers

The discretionary powers in paragraphs (fa) to (fe) of table item 15 of Schedule 5 To the TG Regulations will be exercised:

- when the TGA has received information which suggests that a relevant notified therapeutic vaping good may not conform with applicable standards or which otherwise relates to general concerns regarding the safety of the goods. This includes information – such as adverse event reports connected with the use of specific notified goods – received from sponsors or third parties, such as state and territory health authorities, pharmacists, medical practitioners, nurse practitioners or patients. The TGA routinely receives this type of information in relation to other therapeutic goods;
- when the TGA undertakes post-notification compliance monitoring and assessment to verify that the notified goods meet applicable standards. Such monitoring and assessment is routinely carried out in relation to other therapeutic goods. The TGA’s laboratory testing is governed by a risk management framework based on ISO 31000, which is an international standard that provides principles and guidelines for risk management; and
- when the TGA has carried out regulatory compliance action, such as the testing of samples of the notified goods and the results have indicated concerns regarding the quality or safety of the goods, which may warrant further investigation by way of an audit or inspection of the manufacturing site and/or the production of documents relating to the goods. An example includes testing of notified therapeutic vaping substances across different production batches having considerable variation in concentration of nicotine. Issues may be identified that affect the quality or safety of the goods, which may be resolved by remedial action recommended by TGA auditors, or warrant further regulatory action.

The following methodology will apply to the post-notification compliance monitoring of relevant notified therapeutic vaping goods:

- having regard to intelligence or signals received from third parties, as well as information received from sponsors and gathered by the TGA, the TGA will select goods suspected of non-compliance with applicable regulatory requirements for targeted review according to a risk-based approach. Certain goods will be prioritised, such as those which may result in an immediate or potential health and safety risk to consumers, including:
 - i. notified goods that are the subject of an adverse event report where safety concerns have been raised about a manufacturer who manufacturers notified goods on behalf of multiple sponsors; and
 - ii. notified goods with high concentrations of nicotine;
- the TGA will also select notified therapeutic vaping goods for programmed reviews, including through random selection based on agreed parameters, for the purpose of determining whether there are compliance issues. Programmed reviews are a common, appropriate tool for ensuring that sponsors maintain compliance with regulatory requirements, as sponsors are aware that their goods may at any time be the subject of a random audit or request for documents demonstrating compliance with the applicable standards. Reviews can also provide information which may

demonstrate that certain goods, a sponsor or a manufacturer should be the focus of a future targeted review.

The factors that are anticipated to be taken into account by authorised officers (or, where relevant, the Secretary and their delegates) when considering whether to exercise the powers in paragraphs (fa) to (fe) include:

- the reliability and extent of information in the possession of the TGA with respect to the relevant notified goods, including information from the sponsor of the goods and third parties;
- the amount of relevant notified goods in the hands of patients, or the retail or wholesale supply chains, or intended to be imported or exported, along with the impact on patient access should compliance and/or enforcement action be undertaken;
- the seriousness or otherwise triviality, of any potential non-compliance with applicable standards (if known), including whether, and to what degree, the non-compliance may pose a risk to the health or safety of patients, their families or the broader Australian public;
- the sponsor's reputation and any history of non-compliance with the Act, the TG Regulations and the MD Regulations, or corresponding state or territory laws;
- whether the TGA has previously exercised these powers in relation to the sponsor of the relevant notified goods, and if so, the outcomes in relation to the exercise of those powers;
- the impact of the exercise of these powers on sponsors, including the time and costs of compliance;
- the availability, appropriateness and efficacy of any alternative regulatory compliance and/or enforcement action, such as obtaining a warrant if there are legal grounds to do so, as well as alternative options to the use of such powers (including engaging with a sponsor on an informal basis);
- the significance and implications of any anticipated regulatory outcomes (if known), such as:
 - i. the impact to patients and the wider Australian community, including whether an urgent recall or similar action is needed to protect health and safety, or if patients need to be transitioned to alternative goods;
 - ii. the identification of non-compliance with applicable standards or other regulatory requirements, which could prompt further compliance and/or enforcement action, including criminal prosecution in the most serious of cases;
 - iii. whether the information could be used as part of analysis of a class of goods to inform amendments to applicable standards which will further protect patients and increase community safety;

- the time and expense involved for the TGA to exercise these powers, such as the cost of travel to a manufacturing site.

The discretionary powers in paragraphs (fa) to (fe) will only be exercised relevantly by authorised officers or the Secretary and their delegates who are responsible for monitoring and investigating compliance of relevant notified vaping goods with regulatory requirements. This includes investigators responsible for compliance and enforcement action regarding medicines and medical devices, including the manufacturing quality of medicines, and TGA laboratory staff who are responsible for testing samples of therapeutic goods.

There are also limitations in the text as to the scope of the discretionary powers. For example:

- paragraph (fa) provides that only a ‘reasonable’ number of samples may be obtained;
- paragraph (fb) provides that authorised officers may only enter a premises at a ‘reasonable’ time; and
- paragraph (fc) provides that documents required to be produced must relate to the notified goods.

Further, the exercise of discretionary powers must be legally reasonable, and as a matter of policy, have a clear regulatory purpose.

Finally, in relation to paragraphs (fb) and (fd), most relevant therapeutic vaping goods are manufactured overseas and imported into Australia. In practice, it is anticipated that the production of information and samples will obviate the need for authorised officers to enter and inspect premises outside Australia. However, the power is available in paragraphs (fb) and (fd) to authorised officers if needed.

Consideration of AGD Guide

The AGD Guide was considered when drafting these provisions, in particular, paragraph 8.6 which provides that the Commonwealth Parliament has accepted powers to enter premises without express consent or a warrant in certain limited circumstances. Such circumstances apply in relation to the discretionary powers in paragraphs (fa) to (fe), as the circumstances in which these powers are enlivened is analogous to circumstances relating to licensed premises discussed in paragraph 8.6 of the AGD Guide.

Sponsors are analogous to persons who hold licences or obtain registration of their goods under the Act in relation to which the power to enter non-residential premises managed by those persons is justified for the purpose of ensuring compliance with licence or registration conditions.

Licence or registration holders who are subject to conditions of entry into non-residential premises are not dissimilar to sponsors of relevant notified therapeutic vaping goods. In this regard, both the licence or registration holder and the sponsor of the notified goods have chosen to voluntarily subject themselves to conditions and/or regulatory requirements under the Act and its regulations. By complying with conditions and/or regulatory requirements, these persons are permitted to lawfully supply therapeutic goods in Australia.

Put another way, each sponsor of relevant notified therapeutic vaping goods has freely decided to participate in a regulated market whereby participation is contingent on the sponsor reasonably and appropriately needing to comply with conditions. These conditions include those aimed at monitoring compliance for the purpose of verifying conformity of the sponsor's goods with applicable standards. These standards are put in place principally to protect patient and community safety and form the basis of any notification. The relevant powers are limited in nature and do not confer broad powers to seize documents and other evidential material, in contrast to ordinary search and seizure powers.

The AGD Guide also states that senior executive authorisation should be required for entry without consent or a warrant, together with reporting requirements, and such powers should also be exercised if avenues for obtaining a warrant by remote means have proven absolutely impractical in the particular circumstances.

As described above, one of the factors to be considered when determining whether to exercise these discretionary powers is the availability, appropriateness and efficacy of any alternative compliance or enforcement action, which includes the obtaining of a warrant.

As a matter of practice, site inspections without a warrant are a means to facilitate a more cooperative and informal exchange of information between the TGA and sponsors of relevant notified therapeutic vaping goods. For example, sponsors are provided with advance notice of an inspection on a date that is convenient for both parties. For these reasons, obtaining a warrant may not be appropriate or effective in all circumstances. The transparency of the TGA's compliance activities – where appropriate – builds rapport and trust between the TGA and regulated entities.

Site inspections conducted using the discretionary power will have the oversight of senior executive officers and will be undertaken in accordance with established processes.

Inclusion of powers in the TG Regulations

It is necessary and appropriate for the TGA to possess these discretionary powers because:

- the scheme places trust in regulated entities to make truthful and accurate statements as to the quality and safety of relevant notified therapeutic vaping goods. There is no statutory process for the TGA to assess, approve or reject notifications when those notifications are made. Therefore, in order to ensure ongoing patient and community safety – and patient, regulator and industry confidence in the veracity of those statements – the TGA needs mechanisms to test and verify the accuracy of such information in a timely manner, and take action if necessary;
- the power to obtain samples of notified goods and conduct laboratory testing of such goods is critical to protect patient and community safety, by identifying whether goods pose risks (such as in response to reports that a notified therapeutic vaping substance contains unsafe chemicals, which may cause significant harm to users) and, if emerging or systemic issues are identified, amending applicable regulatory requirements to improve safeguards across classes of notified goods;
- the TGA may be unable to request documents through alternative mechanisms, such as statutory notices issued under section 45AB of the Act if:

- i. there is insufficient information regarding possible contraventions of the Act, TG Regulations or MD Regulations (this may not be readily apparent at all times); or
 - ii. documents are held by overseas manufacturers rather than domestic sponsors (where, for example, such information may be obtained via the sponsor under paragraph (fe) of item 28);
- in certain circumstances, programmed compliance monitoring may facilitate a more cooperative exchange of information between sponsors of notified goods and the TGA rather than more formal means;
- the power to require the sponsor to facilitate inspection of a manufacturing site ensures that the TGA can appropriately monitor compliance with applicable regulatory requirements, including by examining and taking samples of notified goods. Additionally, inspection is an efficient way for the TGA to monitor compliance, rather than requiring rounds of statutory notices for examples issues under section 45AB of the Act;
- gathering information in a timely and complete manner in response to a safety signal or other issue with specific notified goods is critical to protecting public health and safety; and
- as explained above, site inspections without a warrant are a means to facilitate a more cooperative and informal exchange of information between the TGA and sponsors of notified therapeutic vaping goods.

It is appropriate that the paragraph (fa) to (fe) conditions are contained in delegated legislation, rather than primary legislation, because:

- the items amend the conditions to the exemption specified in table item 15 of Schedule 5A to the TG Regulations. This exemption is made under subsection 18(1) of the Act, which relevantly provides that the regulations may specify certain medicines or other therapeutic goods to be exempt from relevant regulatory requirements subject to conditions;
- the Act therefore anticipates that the exemption may be prescribed in the regulations subject to conditions. These conditions are intended to be specified in the regulations. It is not desirable to fragment conditions attaching to an exemption across the Act and the regulations. Rather, it is preferable for conditions to remain attached to the relevant exemption;
- the inclusion of these powers as conditions of exemption are appropriately limited to certain notified therapeutic vaping goods. These powers are more confined than, for example, the general power to request information or documents under section 45AB of the Act.

As the regulation of vaping goods is complex, and the lawful and black-market supply of these goods is dynamic, it is necessary and appropriate for the exemption of relevant therapeutic

vaping goods to be contained in regulations in accordance with the relevant head of power in section 18 of the Act. The use of regulations in this manner facilitates more timely regulatory change as the situation requires.

Availability of merits review

Independent merits review is not available with respect to a decision made by the Secretary or an authorised officer under paragraphs (fa) to (fe). Judicial review will still be available to a person affected by such a decision with standing to seek such review.

This reflects a balanced compromise between the needs to effectively monitor the quality and safety of relevant unregistered therapeutic vaping goods and a person's right of review, noting that analogous powers ordinarily apply to other medicines and devices regulated under the Act, not just vaping goods.

The Administrative Review Council has recognised that preliminary or procedural decisions, which facilitate or lead to the making of a substantive decision, are unsuitable for review. This is because preliminary decisions generally do not have substantive consequences.²

Decisions under paragraphs (fa) to (fe) are unsuitable for merits review because decisions involving the exercise of those powers:

- are preliminary in nature – decisions, such as those requiring the sponsor to provide the Secretary a reasonable number of samples of a relevant therapeutic vaping good, have no substantive effect but could assist the Department of Health and Aged Care in making determinations or taking further compliance and enforcement action;
- protect public health and safety – the Department of Health and Aged Care is responsible for protecting the public from the supply of therapeutic goods that are non-compliant with applicable standards. In circumstances where the department holds significant concerns about the quality or safety of relevant therapeutic vaping goods, the exercise of merits review rights could delay timely regulatory, compliance or enforcement action, particularly where the goods pose a grave or imminent risk to public health and safety.

The exclusion of decisions under paragraphs (fa) to (fe) from merits review is also consistent with the exclusion of merits review in relation to information gathering powers under the Act, as made by items 1 and 2 to Schedule 3 to the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*.

Amendments to paragraphs (g) and (h)

Paragraph (g) of table item 15 in Schedule 5A to the TG Regulations 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

² Administrative Review Council, *What Decisions Should Be Subject To Merits Review?*, Canberra 1999, paragraphs 4.2 to 4.7 <[What decisions should be subject to merit review? 1999 | Attorney-General's Department \(ag.gov.au\)](#)>.

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 goods. 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

Therapeutic Goods (Medical Devices) Regulations 2002

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.

The intended effect of this amendment is to bring certain therapeutic vaping devices imported or manufactured before 1 March 2024, that were previously exempt from regulation under the Act, within the regulatory scheme on and from 1 July 2024.

This provision, together with item 3, is intended to apply on and from 1 July 2024, not before that date. It is not intended to 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.

Arrangements under (the Possession and Supply Determination) are intended to mitigate any retrospective effect of item 33 together with item 3. If previously excluded devices are possessed by individuals, retailers and other entities, the Possession and Supply Determination permits possession of those goods by those persons for certain periods of time to facilitate:

- the use, disposal or exportation of the goods by the persons;

- return to wholesalers and sponsors through the pharmaceutical supply chain; or
- surrender of these goods to the Department of Health and Aged Care.

The relevant items are items 1 of Schedule 1 and items 1, 4, 5, 6 of Schedule 2 to the Possession and Supply Determination.

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 persons 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 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.

Therapeutic Goods Regulations 1990

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

Therapeutic Goods Regulations 1990

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.

For the avoidance of doubt, the reference to ‘Unit’ in the table heading is intended to be a reference to ‘Commercial quantity’, and the reference to ‘Unit of vaping goods’ in the heading to column 2 is intended to be a reference to ‘Quantity’. The use of the former terms is in inadvertent error. That error has since been corrected following the making of the

Amendment Regulations (see items 8 and 9 of Schedule 1 to the *Therapeutic Goods (2024 Measures No. 3) Regulations 2024*).

Schedule 3 – Other amendments

Therapeutic Goods Regulations 1990

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.

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 Amendment (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.

The Amendment Regulations support the Amendment Act by specifying commercial quantities and units of vaping goods for the purposes of new offence 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 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 *Therapeutic Goods Act 1989* (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 product standards. A principal purpose of these amendments is to uphold the integrity of the therapeutic goods scheme established by the Act by creating powers to support the efficient regulation of therapeutic vaping goods.

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 CPI Regulations), the TG Regulations and 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) and the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights (the ICCPR).

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.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person's privacy, family, home and correspondence. It also prohibits unlawful attacks on a person's reputation. Limitations on the right to privacy must be according to law and not arbitrary. Limitations must be reasonable and necessary in the circumstances, as well as proportionate to the objectives that the limitations seek to achieve.

The Amendment Regulations principally require sponsors to, on request from the Secretary (or an authorised officer or authorised person, as the case may be), provide documents or information relating to the sponsor's compliance with the relevant exemption.

By way of example, documents or information required to be produced or collected by the TGA may include certificates of analysis and product specifications, including formulation details and performance data. These documents will ordinarily relate to the activities of commercial entities.

However, the Amendment Regulations engage the right to protection against arbitrary and unlawful interferences with privacy because information required to be provided may also

include information relating to individuals associated with commercial entities. This means that compliance in certain circumstances may involve disclosing personal information.

The TGA, as part of the Department of Health and Aged Care, is an APP entity for the purposes of the *Privacy Act 1988* (the Privacy Act). Consequently, any collection or use of personal information must be consistent with the Privacy Act.

The Department of Health and Aged Care takes seriously its obligations and compliance with requirements applying to personal information under the Privacy Act. This includes adherence to the Australian Government Agencies Privacy Code and the Department's Privacy Policy.

The Privacy Policy includes procedures for:

- collecting personal information only where it is reasonably necessary for, or directly related to, a function or activity that the Department performs;
- using or disclosing information only for the purpose for which it was collected by the Department unless the Privacy Act permits otherwise; and
- storing and disposing of personal information in accordance with the *Archives Act 1983* and relevant authorities, which includes destroying or deidentifying information the Department no longer needs for the purpose it was collected, unless the law requires the information to be retained.

The requirement for sponsors to provide information relating to compliance with a relevant exemption is necessary, targeted and proportionate to the need for the Secretary, authorised officers and authorised persons to have oversight of sponsors' compliance activities for goods that have not been evaluated by the TGA for safety, quality, efficacy or performance and are not included in the Register.

As such, the collection or use of the information would not be an arbitrary or unlawful interference with a person's privacy under Article 17 of the ICCPR, as the collection would be reasonable to ensure the Secretary has information regarding a sponsor's compliance with an exemption and any use of the information would be necessary and proportionate to the objective of protecting the legitimate and lawful pharmaceutical supply chain and public health.

Conclusion

The Amendment Regulations are compatible with human rights because they promote the right to health in Article 12 of the ICESCR, engage the right to privacy in Article 17 of the ICESCR in a measured and proportionate way, as outlined above and otherwise do not raise any other human rights issues.