

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024* (the Regulations) further support the Australian Government's vaping reforms by clarifying the circumstances in which notified vaping goods are exempt from inclusion in the Australian Register of Therapeutic Goods (the Register) but able to be lawfully imported into or manufactured, possessed or supplied in Australia.

The *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods used in, or exported from, Australia. Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters that are required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 18(1) of the Act provides that the regulations may exempt, subject to conditions (if any) specified in the regulations, specified therapeutic goods, or a specified class of therapeutic goods from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F). Similarly, in relation to medical devices, section 41HA of the Act provides that the regulations may exempt, subject to conditions (if any) specified in the regulations, specified kinds of medical devices from the operation of Division 3 of Part 4-11 of the Act.

The *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* implemented the first stage of the Government's vaping reforms by introducing new exemptions in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and the *Therapeutic Goods Regulations 1990* (the TG Regulations) for certain therapeutic vaping goods. This will help ensure that the Therapeutic Goods Administration (TGA) is better able to regulate goods within the lawful supply chain and provide greater clarity to industry participants.

The exemptions operate to exempt certain therapeutic vaping goods for smoking cessation or the management of nicotine dependence from the requirement to be included in the Register, subject to specified conditions. This includes the requirement for the sponsor to provide a notice to the TGA prior to the lawful importation, manufacture or supply of the goods in Australia. The exemptions are relevantly contained in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations and item 15 of the table in Schedule 5A to the TG Regulations. In practice, these exemptions are referred to as the 'notified vaping goods' exemptions.

The Regulations amend the MD Regulations and the TG Regulations, principally to clarify the circumstances in which notified vaping goods are exempt.

Specifically, the Regulations make minor amendments to the description of exempt notified vaping goods to specify that an exemption is only applicable where:

- the sponsor has provided a relevant notice to the TGA;
- the sponsor has not withdrawn the notice; and
- the Secretary has not declared that supply of the vaping goods should cease on certain grounds, principally relating to the quality and safety of the vaping goods (which is known as a 'cease supply determination').

The Regulations also implement a small number of other, minor measures, including to:

- support the safety, quality and performance of notified vaping goods by updating existing conditions to clarify that notified vaping goods must comply with current versions of the applicable product standards, as updated and in force from time to time;
- support the TGA in monitoring the lawful supply of notified vaping goods, by enabling the Secretary to require a sponsor to provide information in a specified form about the supply of notified vaping goods; and
- make a small number of other minor or ancillary amendments, including amendments to correct unintended errors.

Details of the Regulations are set out in [Attachment A](#).

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised. The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after registration on the Federal Register of Legislation.

Consultation

Specific consultation was not undertaken in relation to the Regulations as the measures are minor, machinery, technical in nature, or consequential to the broader reforms. Significant consultation was separately undertaken by the TGA in relation to the Government's vaping reform measures, which included the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*, the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*, and related legislative instruments.

The Office of Impact Analysis has advised that the preparation of an impact analysis in relation to the Regulations is not required (OIA24-08080).

Authority: Subsections 3(1) (definition of 'commercial quantity'),
18(1), 41HA(1) and 63(1)
of the *Therapeutic Goods Act 1989*

Details of the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024* (the Regulations).

Section 2 – Commencement

This section provides for the Regulations to commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024* 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 the Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations would have effect according to its terms.

Schedule 1—Amendments

Part 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – Paragraph 10.7(1A)(c)

A decision to make a medical device the subject of a determination as referenced in paragraph (e) of the column headed “Conditions” in item 2.17 of the table in Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) is merits reviewable by operation of paragraph 10.7(1A)(c) of the MD Regulations.

This item makes a minor amendment to paragraph 10.7(1A)(c) of the MD Regulations to remove the words ‘paragraph (e) of the column headed “Conditions”’ and replace with ‘paragraph (d) of the column headed “Kinds of medical devices”’.

This amendment is consequential to the amendments made below to, among other things, transfer the relevant paragraph in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations from the column headed “Conditions” to the column headed “Kinds of medical devices”. This amendment ensures a sponsor continues to have rights to seek merits review.

Item 2 – Part 2 of Schedule 4 (cell at table item 2.17, column headed “Kinds of medical devices”)

Paragraph 41HA(1)(b) of the *Therapeutic Goods Act 1989* (the Act) provides that the regulations may exempt specified kinds of medical devices from the operation of Division 3 of Part 4-11 of the Act, and thereby exempt certain medical devices from the requirement to be included in the Australian Register of Therapeutic Goods (the Register). Subsection 41HA(2) provides that an exemption may be subject to conditions that are prescribed in the regulations.

Subregulation 7.1(2) of the MD Regulations exempts medical devices mentioned in the column headed “Kinds of medical devices” of an item in Part 2 of Schedule 4 to the MD Regulations from the operation of Division 3 of Part 4-11 of the Act, subject to compliance with the conditions mentioned in the column headed “Conditions”.

Relevantly, item 2.17 of the table in Part 2 of Schedule 4 exempts medical devices that are therapeutic vaping devices or therapeutic vaping device accessories, subject to the conditions mentioned in the column headed “Conditions” of that item. In practice, this exemption is referred to as one of the ‘notified vaping goods’ exemptions.

The conditions include requirements for the sponsor to, among other things, provide a pre-market notice to the Secretary prior to the importation, manufacture or supply of the device in Australia (paragraph (a) of the column headed “Conditions” refers). The notice must include a statement that:

- the device complies with the essential principles, or is imported or supplied (as the case may be) with the consent of the Secretary; and
- the device is intended by the sponsor only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence.

Moving aspects of these requirements from the column headed “Conditions” to the column headed “Kinds of medical devices” better reflects the regulatory intent of this notified vaping goods exemption. That intention is that a therapeutic vaping device or therapeutic vaping device accessory is only an exempt device where the sponsor has given a pre-market notice to the Secretary, maintains

that notice (and ongoing obligations related to that notice), and the device has not been the subject of a cease supply determination.

Further, the item incorporates a new paragraph in the column headed “Kinds of medical devices” to provide an express mechanism for a sponsor to withdraw its sponsor notice. The mechanism provides greater regulatory certainty to sponsors, as the conditions of exemption would cease to apply when the sponsor notice is withdrawn. Certainty as to when the obligations contained in the conditions of exemption cease to apply to sponsors is particularly important as an act or omission by a sponsor, which results in a breach of a condition of exemption may be a criminal offence (subsections 41MN(9), 41MN(9A) and 41MN(9B) of the Act refer) or contravene civil penalty provisions (subsection 41MNA(2A) of the Act refers).

Specifically, this item replaces the whole cell in the column headed “Kinds of medical devices” in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations, and substitute with a new cell comprising paragraphs (a) to (d). Essentially, this amendment makes it clear that the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations only applies to a medical device that is a therapeutic vaping device or a therapeutic vaping device accessory if:

- the sponsor has given a sponsor notice to the Secretary; and
- the sponsor has not withdrawn the sponsor notice; and
- the device is not the subject of a cease supply determination.

New paragraph (d) also has the effect of expanding the circumstances in which a therapeutic vaping device or therapeutic vaping device accessory may be the subject of a cease supply determination to include failure to comply with the condition in new paragraph (e) that would be added below. Relevantly, new paragraph (e) provides that a sponsor must, when requested by the Secretary, give a notice to the Secretary that the device complies with the essential principles, or is imported or supplied (as the case may be), with the consent of the Secretary under section 41MA or 41MAA of the Act.

In relation to therapeutic vaping devices and therapeutic vaping device accessories, compliance with the essential principles may be achieved by a device complying with:

- the essential principles as set out in Schedule 1 to the MD Regulations; or
- the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (the MDSO) (paragraph 41CB(1)(b) and subsection 41BH(2) of the Act refer) where applicable.

As the essential principles are contained in Schedule 1 to the MD Regulations, and noting there is no express contrary intention, any reference to the essential principles would be a reference to the essential principles as in force from time to time.

The MDSO is a disallowable legislative instrument made under section 41CB of the Act that is freely available on the Federal Register of Legislation (www.legislation.gov.au). It sets out minimum safety and performance requirements for certain therapeutic vaping devices and therapeutic vaping device accessories. The MDSO is a discretionary order that provides sponsors with an alternative standard for demonstrating compliance with the essential principles. The MDSO has limited operation, as specified in the application provision of that order.

The incorporation by reference of a disallowable legislative instrument, made under section 41CB of the Act, in the MD Regulations is consistent with subsection 14(1) of the *Legislation Act 2003* (the Legislation Act).

Item 3 – Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraph (a))

This item amends item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations to replace existing paragraph (a) in the column headed “Conditions” with a new paragraph (a). The amendment is consequential to the amendment made above to remove content that would otherwise be duplicative as a result of that amendment.

New paragraph (a) requires the sponsor to give the sponsor notice (i.e. the notice mentioned in new paragraph (b) of the “Kinds of medical devices” column and including the statement to be set out in that paragraph) to the Secretary in an approved form.

It is intended that new paragraph (a)—that is, the giving of a sponsor notice to the Secretary in the approved form—continues to satisfy the description of the paragraph contained in subparagraph 5A(13)(b)(i) of the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations).

Vaping goods may only be lawfully imported to Australia by a person with a licence and written permission granted by a prescribed authority under regulation 5A of the CPI Regulations. A prescribed authority may only grant a permission to a person who is a licence holder and one or more of the circumstances contained in paragraph 5A(12)(b) of the CPI Regulations apply. One of those circumstances is that the vaping goods meet the ‘notification requirements’ prescribed in subregulation 5A(13) of the CPI Regulations (subparagraph 5A(12)(b)(ii) refers). Subparagraph 5A(13)(b)(i) of the CPI Regulations is one of these ‘notification requirements’, and provides that “a notice in relation to the vaping goods has been given in accordance with paragraph (a) of the column headed “Conditions” of item 2.17 of Part 2 of Schedule 4 to the [MD Regulations]”.

Item 4 – Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraphs (c) to (e))

This item amends item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations to replace existing paragraphs (c) to (e) in the column headed “Conditions” with new paragraphs (c) to (e).

At a high level, this amendment clarifies that goods must comply with the essential principles as in force at all times while a device is notified (which may change from time to time). It also provides a mechanism by which the Secretary may require a sponsor to confirm that their device continues to comply with the essential principles (for example, in circumstances where the essential principles have been amended since a sponsor provided an original sponsor notice).

Existing paragraphs (c) and (d) require that a sponsor holds information or evidence to support the statements which the sponsor made in the sponsor notice, and neither of the statements made in the sponsor notice is incorrect. The statements in the sponsor notice are that:

- the device is intended by the sponsor only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence; and
- the device complies with the essential principles, or is imported or supplied (as the case may be) with the consent of the Secretary under section 41MA or 41MAA of the Act.

Existing paragraph (e) currently provides that a device must not be the subject of a cease supply determination. A proposed amendment above would move the substance of this provision, with

amendment, from the column headed “Conditions” to the column headed “Kinds of medical devices” in item 2.17.

New paragraph (e) introduces a new condition of exemption to require a sponsor to provide, on request by the Secretary, a notice restating one of the matters which the sponsor stated in its original sponsor notice—namely, that either the device complies with the essential principles or that the device is being imported or supplied (as the case may be) with the consent of the Secretary. The notice must be given by the sponsor in an approved form and within the period requested by the Secretary (which must be at least 5 working days). The approved form for such a notice would be published on the Therapeutic Goods Administration (TGA) website at www.tga.gov.au.

The principal purpose of paragraph (e) is to provide an efficient mechanism for the Secretary to confirm that:

- if the essential principles or the MDSO (or a future applicable medical device standard) is amended and the amendment applies to a sponsor’s device—the sponsor continues to warrant that the device complies with the essential principles that apply to the device (or the sponsor has the consent of the Secretary to import or supply the device, despite the non-compliance); and
- if the sponsor stated in its original sponsor notice that a device was being imported or supplied with the consent of the Secretary under section 41MA or 41MAA of the Act, and then that consent expires or is withdrawn—the sponsor warrants that the device complies with the essential principles.

Confirmation that sponsors consider that their devices comply with the essential principles, is critical to the maintenance of the notified vaping goods exemptions in the MD Regulations, and the health and safety of the Australian community. Devices that are the subject of this notified vaping exemption are not evaluated by the Secretary for quality, safety or performance.

New paragraph (e) provides the Secretary with a mechanism to require sponsors to make a representation about the compliance of their devices with changes to the essential principles, helping to reduce risks associated with the use of those devices.

This mechanism is also intended to reduce administrative and regulatory burden for sponsors by providing a straightforward mechanism to certify compliance with the essential principles, rather than undergoing a detailed evaluation by the Secretary under Chapter 4 of the Act as to whether the device complies with the essential principles. This new condition is not anticipated to materially change a sponsor’s regulatory requirements under the notified vaping goods exemption, as current conditions of exemption require a device to comply with the essential principles at all times (and as amended from time to time) while the device is exempt (paragraph (d) of the “Conditions” column for item 2.17 refers).

New paragraph (c) makes minor amendments to the existing condition of exemption requiring sponsors to hold information or evidence to support the statement made in the sponsor notice.

New paragraph (d) clarifies that those statements must be, and continue to be, correct.

The minor amendments to paragraphs (c) and (d) are intended to have two primary effects. First, the new conditions make a consequential amendment to new paragraph (e) to provide that obligations concerning the sponsor’s statement that the device complies with the essential principles (or is imported or supplied with the consent of the Secretary) applies only in relation to the most recent statement given by the sponsor to that effect, either in a statement provided under new paragraph (e) or the original sponsor notice.

Second, new paragraphs (c) and (d) are intended to put beyond doubt that the sponsor is required to hold information or evidence to support that a device complies with the essential principles, and that the statement made by the sponsor that the device does comply with the essential principles is correct, in relation to the essential principles both as in force at the time of making a sponsor notice (or a statement under new paragraph (e)), and at all times while the device continues to be the subject of the exemption. This is the understanding of the TGA in relation to the effect of current paragraphs (c) and (d). Notwithstanding this position, this amendment is made to provide certainty in relation to the scope of these obligations.

Item 5 – Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraphs (fb) to (fe))

This item makes a minor editorial amendment by removing the references to ‘authorised officer’ in paragraphs (fb) to (fe) in the column headed “Conditions” in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations and replacing with the term ‘authorised person’.

This amendment corrects a drafting error in some of the conditions, which inadvertently used the term ‘authorised officer’. The term ‘authorised officer’ is not otherwise used in the MD Regulations, rather, the MD Regulations refer to an ‘authorised person’ when providing for the vesting of a power in a person authorised to exercise it.

Item 6 – Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, subparagraph (i)(ii))

This item makes a minor amendment to replace the reference to ‘the records’ in subparagraph (i)(ii) in the column headed “Conditions” in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations, with ‘a copy of the records’, to clarify that sponsors are only required to provide a copy of relevant records to the Secretary (if requested), rather than the original records themselves.

Item 7 – Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, at the end of paragraph (i))

This item introduces new subparagraph (iii) at the end of paragraph (i) in the column headed “Conditions” in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations.

Under current paragraph (i), sponsors are already required to keep records relating to the source and supply of a device and provide those records to the Secretary on request.

This amendment introduces a more flexible and targeted way for the Secretary to obtain information about supply from sponsors by introducing a new condition of exemption that requires sponsors to, on request from the Secretary, provide information relating to the supply of a relevant device in a period specified by the Secretary (for example, between 1 January and 30 March or from the date the sponsor notice was provided to the date of the request under this provision) to the Secretary, in an approved form.

Information required to be provided to the Secretary could include, for example, identifying information about the devices, the date of supply, the quantity of devices supplied and the ultimate recipients of those devices. The approved form for providing information to the Secretary would be published on the TGA website at www.tga.gov.au.

The condition provides that the information must be provided within the period requested by the Secretary, which must be at least 5 working days starting on the day in which the request is made.

This amendment, by providing that a sponsor needs to provide supply information in an approved form, provides greater certainty for sponsors in relation the information that may be requested by the

Secretary (on a targeted or potentially periodic basis) and create efficiencies for sponsors and the TGA.

In particular, the provision of information in an approved form to the Secretary will support efficient information collection and analysis by the TGA. While in certain circumstances the TGA may wish to obtain and analyse specific supply records obtained under subparagraph (ii), it is anticipated that the TGA will more often wish to aggregate and then analyse supply figures to, for example, measure the effectiveness of the vaping reforms or detect diversion of vaping goods from the legitimate supply chain. In these kinds of circumstances, it is not administratively efficient for the TGA to review and extract data from the different forms of supply records kept by each sponsor.

Therapeutic Goods Regulations 1990

Items 8 and 9 – Regulation 10N (table heading and table, heading to column 2)

These items make minor editorial amendments to the table in regulation 10N of the *Therapeutic Goods Regulations 1990* (the TG Regulations).

The table in regulation 10N prescribes commercial quantities of vaping goods, for the purposes of the definition of ‘commercial quantity’ in subsection 3(1) of the Act. However, it has been identified that the table currently refers to ‘unit’ rather than ‘quantity’ of vaping goods.

These items correct drafting errors. In particular, item 8 amends the heading in the table in regulation 10N to correct the erroneous reference to ‘Unit’ by replacing it with ‘Commercial quantity’. Item 9 amends the heading to column 2 to correct the erroneous reference to ‘Unit of vaping goods’ by replacing it with ‘Quantity’.

Item 10 – Paragraph 48(1AB)(c)

A decision to make a therapeutic good the subject of a determination as referenced in paragraph (e) of column 3 of item 15 of the table in Schedule 5A to the TG Regulations is merits reviewable by operation of paragraph 48(1AB)(c) of the TG Regulations.

This item makes a minor amendment to paragraph 48(1AB)(c) of the TG Regulations to remove the words ‘paragraph (e) of column 3’ and replace with ‘paragraph (g) of column 2’.

This amendment is consequential to the amendments made below to, among other things, transfer the relevant paragraph in item 15 of the table in Schedule 5A to the TG Regulations from column 3 to column 2. It ensures that a sponsor continues to have rights to seek merits review.

Item 11 – Schedule 5A (at the end of the cell at table item 15, column 2)

Subsection 18(1) of the Act provides that the regulations may exempt specified therapeutic goods or classes of therapeutic goods from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F), and thereby exempt certain therapeutic goods from the requirement to be included in the Register. Subsection 18(1) further provides that an exemption may be subject to conditions that are prescribed in the regulations.

Subregulation 12(2) of the TG Regulations exempts therapeutic goods mentioned in column 2 of an item in Schedule 5A to the TG Regulations from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F), subject to compliance with the conditions mentioned in column 3.

Relevantly, item 15 of the table in Schedule 5A, exempts certain therapeutic goods that are therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits, or

goods in a therapeutic vaping pack, subject to several conditions. In practice, this exemption is referred to as one of the ‘notified vaping goods’ exemptions.

The conditions include requirements for the sponsor to, among other things, provide a pre-market notice to the Secretary prior to the importation, manufacture or supply of the goods in Australia (paragraph (a) of column 3 refers). The notice must include a statement that:

- the goods conform with any standard applicable to the goods, or are imported or supplied (as the case may be) with the consent of the Secretary; and
- the only indications of the goods are use for smoking cessation or the management of nicotine dependence.

Moving aspects of these requirements from column 3 to column 2 better reflects the regulatory intent of the notified vaping goods exemption. That intention is that the relevant vaping goods are only exempt goods where the sponsor has given a pre-market notice to the Secretary, maintains that notice (and the ongoing obligations related to that notice), and the goods have not been the subject of a cease supply determination.

Further, the item incorporates a new paragraph in column 2 to provide an express mechanism for a sponsor to withdraw its sponsor notice. The mechanism provides greater regulatory certainty to sponsors, as the conditions of exemption would cease to apply when the sponsor notice is withdrawn. Certainty as to when the obligations contained in the conditions of exemption cease to apply to sponsors is particularly important as an act or omission by a sponsor, which results in a breach of a condition of exemption may be a criminal offence (subsections 22(6) and 22(7AA) of the Act refer) or contravene civil penalty provisions (subsection 22AA(2) of the Act refers).

Specifically, this item amends column 2 in item 15 of the table in Schedule 5A to the TG Regulations by introducing new paragraphs (e) to (g). Essentially, this amendment makes it clear that the exemption in item 15 in Schedule 5A to the TG Regulations only applies to certain therapeutic vaping substances, therapeutic vaping substance accessories, therapeutic vaping kits and goods in a therapeutic vaping pack if:

- the sponsor has given a sponsor notice to the Secretary; and
- the sponsor has not withdrawn the sponsor notice; and
- the goods are not the subject of a cease supply determination.

New paragraph (g) also has the effect of expanding the circumstances in which the goods may be the subject of a cease supply determination to include failure to comply with the condition in new paragraph (e) of column 3 added below. Relevantly, new paragraph (e) provides that a sponsor must, when requested by the Secretary, give a notice to the Secretary that the goods conform with each standard that is applicable to the goods (as in force from time to time), or is imported or supplied (as the case may be), with the consent of the Secretary under section 14 or 14A of the Act.

Item 12 – Schedule 5A (table item 15, column 3, paragraph (a))

This item amends column 3 of item 15 of the table in Schedule 5A to the TG Regulations to replace existing paragraph (a) with a new paragraph (a). The amendment is consequential to the amendment made above to remove content that would otherwise be duplicative as a result of that amendment.

New paragraph (a) requires a sponsor to give the sponsor notice (i.e. the notice mentioned in new paragraph (e) in column 2 of that item, and including the statement to be set out in that paragraph) to the Secretary in an approved form.

It is intended that new paragraph (a)—that is, the giving of a sponsor notice to the Secretary in the approved form—continues to satisfy the description of the paragraph contained in subparagraph 5A(13)(b)(iii) of the CPI Regulations.

Vaping goods may only be lawfully imported to Australia by a person with a licence and written permission granted by a prescribed authority under regulation 5A of the CPI Regulations. A prescribed authority may only grant a permission to a person who is a licence holder and one or more of the circumstances contained in paragraph 5A(12)(b) of the CPI Regulations apply. One of those circumstances is that the vaping goods meet the ‘notification requirements’ prescribed in subregulation 5A(13) of the CPI Regulations (subparagraph 5A(12)(b)(ii) refers). Subparagraph 5A(13)(b)(iii) of the CPI Regulations is one of these ‘notification requirements’, and provides that “a notice in relation to the vaping goods has been given in accordance with paragraph (a) of column 3 of item 15 of Schedule 5A to the [TG Regulations]”.

Item 13 – Schedule 5A (table item 15, column 3, paragraphs (c) to (e))

This item amends item 15 of the table in Schedule 5A to the TG Regulations to replace existing paragraphs (c) to (e) in column 3 with new paragraphs (c) to (e).

At a high level, this amendment clarifies that goods must conform with the version of each applicable standard as in force at all times while a good is notified (which may change from time to time). It also provides a mechanism by which the Secretary may require a sponsor to confirm that their good continues to conform with the applicable standard (for example, in circumstances where an applicable standard has been amended since a sponsor provided an original sponsor notice).

Existing paragraphs (c) and (d) require that a sponsor holds information or evidence to support the statements which the sponsor made in the sponsor notice, and neither of the statements made in the sponsor notice is incorrect. The statements in the sponsor notice are that:

- the only indications of the goods are use for smoking cessation or the management of nicotine dependence; and
- the goods conform with any standard that applies to the goods, or is imported or supplied (as the case may be) with the consent of the Secretary under section 14 or 14A of the Act.

Existing paragraph (e) currently provides that the goods must not be the subject of a cease supply determination. A proposed amendment above would move the substance of this provision, with amendment, from column 3 to column 2 of item 15.

New paragraph (e) introduces a new condition of exemption to require a sponsor to provide, on request by the Secretary, a notice restating one of the matters which the sponsor stated in its original sponsor notice—namely, that either the goods conform with each standard that is applicable to the goods, or that the goods are being imported or supplied (as the case may be) with the consent of the Secretary. The notice must be given by the sponsor in an approved form and within the period requested by the Secretary (which must be at least 5 working days). The approved form for such a notice would be published on the TGA website at www.tga.gov.au.

The principal purpose of paragraph (e) is to provide an efficient mechanism for the Secretary to confirm that:

- if the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110) (or a future applicable standard) is amended and the amendment applies to a sponsor's goods—the sponsor continues to warrant that the goods conform with the standards that apply to the goods (or the sponsor has the consent of the Secretary to import or supply the goods, despite the non-compliance); and
- if the sponsor stated in its original sponsor notice that the goods were being imported or supplied with the consent of the Secretary under section 14 or 14A of the Act, and then that consent expires or is withdrawn—the sponsor warrants that the goods conform with each applicable standard.

Confirmation that sponsors consider that their goods conform with updated standards is critical to the maintenance of the notified vaping goods exemptions in the TG Regulations, and the health and safety of the Australian community. Goods that are the subject of this notified vaping exemption are not evaluated by the Secretary for quality, safety or efficacy.

New paragraph (e) provides the Secretary with a mechanism to require sponsors to make a representation about the conformity of their goods with changes to the applicable standards, helping to reduce risks associated with the use of those goods.

This mechanism is also intended to reduce administrative and regulatory burden for sponsors by providing a straightforward mechanism to certify conformity with applicable standards, rather than undergoing a detailed evaluation by the Secretary under Part 3-2 of the Act as to whether the goods conform with applicable standards. This new condition is not anticipated to materially change a sponsor's regulatory requirements under the notified vaping goods exemption, as current conditions of exemption require goods to conform with applicable standards at all times (and as amended from time to time) while the goods are exempt (paragraph (d) in column 3 of item 15 refers).

New paragraph (c) makes minor amendments to the existing condition of exemption requiring sponsors to hold information or evidence to support the statement made in the sponsor notice.

New paragraph (d) clarifies that those statements must be, and continue to be, correct.

The new paragraphs (c) and (d) incorporate by reference 'each standard (as in force from time to time) that is applicable to the goods'. In practice, the applicable standards are specified in orders made under section 10 of the Act. Currently the relevant standard applicable to the goods is TGO 110. As the applicable standards are specified in an instrument other than the TG Regulations, it is necessary for paragraphs (c) and (d) to expressly refer to those standards 'as in force from time to time', distinct from the provisions relating to medical devices, where the essential principles apply.

TGO 110 is a disallowable legislative instrument made under section 10 of the Act and sets out minimum safety, quality and efficacy standards for therapeutic vaping goods. TGO 110 is freely available on the Federal Register of Legislation (www.legislation.gov.au).

The incorporation by reference of a disallowable legislative instrument made under section 10 of the Act, as in force from time to time, in the TG Regulations is consistent with subsection 14(1) of the Legislation Act.

The minor amendments to paragraphs (c) and (d) are intended to have two primary effects. First, the new conditions make consequential amendments to new paragraph (e) to provide that obligations concerning the sponsor's statement that the goods conform with each applicable standard (or is imported or supplied with the consent of the Secretary) applies only in relation to the most recent statement given by the sponsor to that effect, either in a statement provided under new paragraph (e) or the original sponsor notice.

Second, new paragraphs (c) and (d) are intended to put beyond doubt that the sponsor is required to hold information or evidence to support that the goods conform with each applicable standard, and that the statement made by the sponsor that the goods conform with an applicable standard is correct, both as in force at the time of making a sponsor notice (or a statement under new paragraph (e)), and at all times while the goods continue to be the subject of the exemption. This is the understanding of the TGA in relation to the effect of current paragraphs (c) and (d). Notwithstanding this position, this amendment is made to provide certainty in relation to the scope of these obligations.

Item 14 – Schedule 5A (table item 15, column 3, subparagraph (j)(ii))

This item makes a minor amendment to replace the reference to ‘the records’ in subparagraph (j)(ii) in column 3 of item 15 of the table in Schedule 5A to the TG Regulations, with ‘a copy of the records’, to clarify that sponsors are only required to provide a copy of relevant records to the Secretary (if requested), rather than the original records themselves.

Item 15 – Schedule 5A (table item 15, column 3, at the end of paragraph (j))

This item adds new subparagraph (iii) at the end of paragraph (j) in column 3 of item 15 of the table in Schedule 5A to the TG Regulations.

Under current paragraph (j), sponsors are already required to keep records relating to the source and supply of the goods, and provide those records to the Secretary on request.

This amendment introduces a more flexible and targeted way for the Secretary to obtain information about supply from sponsors by introducing a new condition of exemption that requires sponsors to, on request from the Secretary, provide information relating to the supply of relevant vaping goods in a period specified by the Secretary (for example, between 1 January and 30 March or from the date the sponsor notice was provided to the date of the request under this provision) to the Secretary, in an approved form.

Information required to be provided to the Secretary could include, for example, identifying information about the goods, the date of supply, the quantity of goods supplied and the ultimate recipients of those goods. The approved form for providing information to the Secretary would be published on the TGA website at www.tga.gov.au.

The condition would provide that the information must be provided within the period requested by the Secretary, which must be at least 5 working days starting on the day in which the request is made.

This amendment, by providing that a sponsor needs to provide supply information in an approved form, provides greater certainty for sponsors in relation the information that may be requested by the Secretary (on a targeted or potentially periodic basis) and create efficiencies for sponsors and the TGA.

In particular, the provision of information in an approved form to the Secretary will support efficient information collection and analysis by the TGA. While in certain circumstances the TGA may wish to obtain and analyse specific supply records obtained under subparagraph (ii), it is anticipated that the TGA will more often wish to aggregate and then analyse supply figures to, for example, measure the effectiveness of the vaping reforms or detect diversion of vaping goods from the legitimate supply chain. In these kinds of circumstances, it is not administratively efficient for the TGA to review and extract data from the different forms of supply records kept by each sponsor.

Part 2—Transitional provisions

Part 2 of this Schedule provides for transitional arrangements in relation to the amendments made to the MD Regulations and TG Regulations by Part 1 of this Schedule.

Therapeutic Goods (Medical Devices) Regulations 2002

Item 16 – In the appropriate position in Part 11

This item introduces new Division 11.23 in the MD Regulations to provide the application, transitional and savings provisions relating to the amendments to the MD Regulations made by Part 1 of Schedule 1 to the Regulations.

New regulation 11.82 of the MD Regulations provides for the definitions that are used in new Division 11.23 of the MD Regulations. Relevantly, the definitions introduced by new regulation 11.82 include:

- amending regulations, which means the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024*;
- commencement day, which means the day Division 11.23 commences;
- conditions column which means the column headed “Conditions” in the table in Part 2 of Schedule 4; and
- devices column, which means the column headed “Kinds of medical devices” in the table in Part 2 of Schedule 4.

New subregulation 11.83(1) provides that, subject to this regulation, the amendments made by Part 1 of Schedule 1 to the Regulations, applies in relation to medical devices that are:

- imported or manufactured on or after the commencement day; or
- supplied on or after the commencement day, where the devices are owned by, or in the possession or control of, the sponsor immediately before the commencement day.

The second part of this transitional arrangement is intended to cover devices supplied in circumstances where a sponsor may, immediately before commencement, have ownership, possession, custody or control of the devices. This includes, for example, devices:

- owned and possessed by the sponsor;
- held by the sponsor, where ownership of those devices has passed to another person;
- held on consignment at a wholesaler on behalf of the sponsor; and
- in the possession of a transport operator who is delivering the devices from the place of importation to a warehouse owned by the sponsor.

New subregulation 11.83(2) provides that the substitution of paragraph (c) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, made by Part 1 of Schedule 1 to the Regulations, applies in relation to information or evidence held by the sponsor on or after the commencement day.

New subregulation 11.83(3) provides that paragraph (e) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, substituted by Part 1 of Schedule 1 to the Regulations, applies in relation to a request made by the Secretary under that paragraph on or after the commencement day.

New subregulation 11.83(4) provides that the amendment to subparagraph (i)(ii) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, made by Part 1 of Schedule 1 to the Regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.

New subregulation 11.83(5) provides that subparagraph (i)(iii) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, added by Part 1 of Schedule 1 to the Regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.

New subregulation 11.84(1) applies on relation to a notice:

- given before the commencement day, under paragraph (a) (the ‘old provision’) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4 as in force immediately before that day; and
- not withdrawn or otherwise ceased to have effect (however described) before the commencement day.

Subregulation 11.84 provides that such notice has effect on and after the commencement day as if it had been given under paragraph (b) (the ‘new provision’) of the devices column in that item, and a statement given in the notice under a subparagraph of the old provision has effect on and after the commencement day as if it had been given under the corresponding subparagraph of the new provision. This has the effect that a sponsor notice that was given to the Secretary before the amendments continues to be in effect, meaning a sponsor does not have to provide a new sponsor notice.

New subregulation 11.84(2) applies to a determination:

- made by the Secretary, as referred to in paragraph (e) of the conditions column in item 2.17 of Part 2 of Schedule 4 as in force immediately before that day; and
- in force immediately before the commencement day.

Subregulation 11.84(2) provides that such determination has effect on and after the commencement day as if it were a determination referred to in paragraph (d) of the devices column in that item. This has the effect that, if a determination by the Secretary that the supply of the device should be stopped or cease was given before the commencement of the proposed Regulations, the determination continues to have effect.

Therapeutic Goods Regulations 1990

Item 17 – In the appropriate position in Part 9

This item introduces new Division 27 in the TG Regulations to provide the application, transitional and savings provisions relating to the amendments to the TG Regulations made by Part 1 of Schedule 1 to the Regulations.

New regulation 109 of the TG Regulations provides definitions that are used in new Division 27 of the TG Regulations. Relevantly, the definitions introduced by new regulation 109 include:

- amending regulations, which means the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024*; and
- commencement day, which means the day Division 27 commences.

New subregulation 110(1) provides that subject to this regulation, the amendments of paragraph 48(1AB)(c) and item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the Regulations, applies in relation to therapeutic goods that are:

- imported or manufactured on or after the commencement day; or
- supplied on or after the commencement day, where the therapeutic goods are owned by, or in the possession or control of, the sponsor immediately before the commencement day.

The second part of this transitional arrangement is intended to cover goods supplied in circumstances where a sponsor may, immediately before commencement, have ownership, possession, custody or control of the goods. This includes, for example, goods:

- owned and possessed by the sponsor;
- held by the sponsor, where ownership of those goods has passed to another person;
- held on consignment at a wholesaler on behalf of the sponsor; and
- in the possession of a transport operator who is delivering the goods from the place of importation to a warehouse owned by the sponsor.

New subregulation 110(2) provides that the substitution of paragraph (c) of column 3 in item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the Regulations, applies in relation to information or evidence held by the sponsor on or after the commencement day.

New subregulation 110(3) provide that the substitution of paragraph (e) of column 3 in item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the Regulations, applies in relation to a request made by the Secretary under that paragraph on or after the commencement day.

New subregulation 110(4) provides that the amendment to subparagraph (j)(ii) of column 3 in item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the Regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.

New subregulation 110(5) provides that subparagraph (j)(iii) of column 3 in item 15 of the table in Schedule 5A, added by Part 1 of Schedule 1 to the Regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.

New subregulation 111(1) applies in relation to a notice:

- given before the commencement day, under paragraph (a) (the ‘old provision’) of column 3 in item 15 of the table in Schedule 5A as in force immediately before that day; and
- not withdrawn or otherwise ceased to have effect (however described) before the commencement day.

Subregulation 111(1) provides that such notice has effect on and after the commencement day as if it had been given under paragraph (e) (the ‘new provision’) of column 2 in that item, and a statement

given in the notice under a subparagraph of the old provision has effect on and after the commencement day as if it had been given under the corresponding subparagraph of the new provision. This has the effect that a sponsor notice that was given to the Secretary before the amendments continues to be in effect, meaning a sponsor does not have to provide a new sponsor notice.

New subregulation 111(2) applies to a determination:

- made by the Secretary as referred to in paragraph (e) of the of column 3 in item 15 of the table in Schedule 5A as in force immediately before that day; and
- in force immediately before the commencement day.

Subregulation 111(2) provides that such a determination has effect on and after the commencement day as if it were a determination referred to in paragraph (g) of column 2 in that item. This has the effect that, if a determination by the Secretary that the supply of the device should be stopped or cease was given before the commencement of the proposed Regulations, the determination continues to have effect.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024* (the 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 Regulations are made under subsections 3(1) (definition of ‘commercial quantity’), 18(1), 41HA(1) and 63(1) of the *Therapeutic Goods Act 1989* (the Act).

Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters that are required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 18(1) of the Act provides that the regulations may exempt, subject to conditions specified in the regulations, specified therapeutic goods, or a specified class of therapeutic goods from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F). Similarly, in relation to medical devices, section 41HA of the Act provides that the regulations may exempt, subject to conditions specified in the regulations, specified kinds of medical devices from the operation of Division 3 of Part 4-11 of the Act.

The Regulations further support the Australian Government’s vaping reforms by clarifying the circumstances in which notified vaping goods are exempt from inclusion in the Australian Register of Therapeutic Goods (the Register) but able to be lawfully imported into or manufactured, possessed or supplied in Australia. This will help ensure that the Therapeutic Goods Administration (TGA) is better able to regulate goods within the lawful supply chain and provide greater clarity to industry participants.

The *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* implemented the first stage of the Government’s vaping reforms by introducing new exemptions in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and the *Therapeutic Goods Regulations 1990* (the TG Regulations) for certain therapeutic vaping goods.

The exemptions operate to exempt certain therapeutic vaping goods for smoking cessation or the management of nicotine dependence from the requirement to be included in the Register, subject to specified conditions. This includes the requirement for the sponsor to provide a notice to the TGA prior to the lawful importation, manufacture or supply of the goods in Australia. The exemptions are relevantly contained in item 2.17 of the table in Part 2 of Schedule 4 to the MD Regulations and item 15 of the table in Schedule 5A to the TG Regulations. In practice, these exemptions are referred to as the ‘notified vaping goods’ exemptions.

The Regulations amend the MD Regulations and the TG Regulations, principally to clarify the circumstances in which notified vaping goods are exempt.

Specifically, the Regulations make minor amendments to the description of exempt notified vaping goods to specify that an exemption is only applicable where:

- the sponsor has provided a relevant notice to the TGA;
- the sponsor has not withdrawn the notice; and
- the Secretary has not declared that supply of the vaping goods should cease on certain grounds, principally relating to the quality and safety of the vaping goods (which is known as a ‘cease supply determination’).

The Regulations also implement a small number of other, minor measures, including to:

- support the safety, quality and performance of notified vaping goods by updating existing conditions to clarify that notified vaping goods must comply with current versions of the applicable product standards, as updated and in force from time to time;
- support the TGA in monitoring the lawful supply of notified vaping goods, by enabling the Secretary to require a sponsor to provide information in a specified form about the supply of notified vaping goods; and
- make a small number of other minor or ancillary amendments, including amendments to correct unintended errors.

Human rights implications

The 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).

Right to health

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 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 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 Regulations take positive steps to promote the right to health by supporting the Government’s vaping reforms to bolster and clarify the regulatory framework for the importation, domestic manufacture and supply of therapeutic vaping goods in Australia.

In particular, the Regulations promote the right to health by:

- supporting the safety, quality and efficacy of notified vaping goods by ensuring that goods supplied in Australia through the pharmaceutical supply chain, continue to comply with the applicable quality standards as amended from time to time; and

- supporting the effectiveness of the regulation of the lawful pharmaceutical supply chain by ensuring that sponsors can withdraw a notice given to the Secretary as part of ceasing supply of that good in Australia (resulting in its removal from the notified vape list), and supporting the TGA's disruption of the illicit supply of vaping goods in Australia by ensuring that goods that do not comply with the applicable standards may be removed from the legitimate supply chain.

The overarching reforms to the regulation of vaping goods, including these amendments, will arrest the increasing uptake of recreational vaping, especially amongst youth and young adults; effectively restricting the domestic supply of non-therapeutic vaping goods while still allowing for legitimate therapeutic use. This 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.

In supporting these reforms, the 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 Regulations require sponsors to, on request from the Secretary, provide information relating to the supply of notified vaping goods during a relevant period (for example, between 1 January and 30 March or from the date a sponsor notice is provided to the date of the request for information) to the Secretary. Most of the information required to be provided to the Secretary will be business related information, for example, identifying information about the goods, the date the goods were supplied and the quantity of goods supplied.

However, the Regulations engage the right to protection against arbitrary and unlawful interferences with privacy because information required to be provided to the Secretary may also include information relating to the recipients of notified vaping goods, namely, medical practitioners, nurse practitioners and pharmacies. While in most cases, these recipients will be corporate entities, some recipients of notified vaping goods will be small businesses that are non-corporate entities operating under individual names. This means that such information may necessarily involve disclosing personal information relating to those persons, being their individual trading names.

The TGA, as part of the Australian Government 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 requirement for sponsors to provide information about the supply of unregistered vaping goods 'during a relevant period in a form approved by the Secretary' is necessary, targeted and proportionate to the need for the Secretary to have oversight of sponsors' activities during that period for goods that have not been evaluated by the Secretary for safety, quality, efficacy and 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, in the form prescribed, on the supply of notified vaping goods,

even if that person is an individual, 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 Regulations are compatible with human rights because they support the right to health in Article 12 of the ICESCR, engages the right to privacy in Article 17 of the ICESCR in a measured and proportionate way, as outlined above and otherwise does not raise any other human rights issues.

Mark Butler, Minister for Health and Aged Care