

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (2024 Measures No 1) Regulations 2024

The Regulations restore the application of the ‘direct control exemption’ to medicinal cannabis vaping goods, to remove the unintended effect of excluding medicinal cannabis vaping goods from the ‘direct control exemption’.

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 provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024* (the Regulations) amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) to restore the application of the direct control exemption to therapeutic vaping goods that are, or include, a medicinal cannabis product. The exemption allows “unapproved” therapeutic goods to be imported and held by sponsors in secure conditions until specific circumstances apply, principally, the granting of approvals or authorities to supply the goods under the *Therapeutic goods Act 1989* in Australia.

Subsection 18(1) of the Act provides that the regulations may, subject to any conditions as are specified in the regulations, exempt specified therapeutic goods (or specified classes of therapeutic goods) from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F). The effect of this is to enable regulations to exempt specified therapeutic goods from the requirement to be included in the Australian Register of Therapeutic Goods (the Register) be lawfully imported into, supplied in, or exported from, Australia.

Subregulation 12(2) of the TG Regulations provides that, for the purposes of subsection 18(1) of the Act, therapeutic goods mentioned in column 2 of an item in Schedule 5A to the TG Regulations are exempt from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F). Such exemptions are subject to compliance with the conditions mentioned in column 3 of the relevant item in Schedule 5A (subregulation 12(3) refers).

Item 1 of Schedule 5A to the TG Regulations relevantly exempts, from the requirement to be included in the Register, goods that are imported into Australia by, and held under the direct control of, the sponsor of the goods until the goods are able to be principally supplied under one of the statutory pathways for the lawful supply of unapproved goods, such as supply by a medical practitioner under subsection 19(5) of the Act (otherwise, known as the Authorised Prescriber Scheme).

In practice, this exemption is known as the ‘direct control exemption’. It enables sponsors to import, and hold stock in secure conditions, unapproved therapeutic goods in anticipation of an approval or authority for the supply of the relevant therapeutic goods being granted by the Secretary, thereby supporting the timely availability of these goods in Australia as it ensures that such goods are on hand in Australia, rather than only being able to be imported when an approval or authority is granted.

As part of the reforms to the regulation of vapes in Australia, the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2024* (the Vaping Regulations) amended item 1 of Schedule 5A to the TG Regulations to, effectively, disapply the direct control exemption to therapeutic vaping goods, with effect from 1 March 2024. Excluding therapeutic vaping goods from this exemption was intended to ensure that the importation and supply of therapeutic vaping goods is undertaken in accordance with a new vaping-related exemption specifically designed to address the risks posed by such goods, namely item 15 of Schedule 5A to the TG Regulations.

However, the new definition of therapeutic vaping goods is broad enough to capture therapeutic vaping goods that are, or include, medicinal cannabis products. Consequently, the amendments made to item 1 of Schedule 5A by the Vaping Regulations would have the effect that therapeutic vaping goods that are, or include, medicinal cannabis products would no longer be able to be imported under the direct control exemption.

This outcome contrary to the policy intention, which was to minimise the impact on, and otherwise maintain the status quo for therapeutic vaping goods that are, or include, medicinal cannabis products.

The purpose of the Regulations is to remove this unintended effect for therapeutic goods that are, or include, medicinal cannabis products, from 1 March 2024. The Regulations commence on 1 March 2024, thereby ensuring that the amendment that was made to item 1 of Schedule 5A of the TG Regulations on 1 March 2024, as a consequence of the Vaping Regulations, would not take effect.

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

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 1 March 2024.

Consultation

No specific consultation was undertaken in relation to the proposed amendment as the Regulations are solely designed to correct an unintended effect of the Vaping Regulations and to avoid an unintended impact of those reforms on medicinal cannabis products, including the risk of interruptions to supply for patients who need to use such products, and their health practitioners.

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

Details of the *Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024*.

Section 2 – Commencement

This section provides for the Regulations to commence on 1 March 2024.

Section 3 – Authority

This section provides that the *Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024s* 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 – Amendments

Part 1—Main amendments

Therapeutic Goods Regulations 1990

Item 1 – Schedule 5A (table item 1)

This item replaces item 1 in Schedule 5A to the *Therapeutic Goods Regulations 1990* (the TG Regulations) to provide that the exclusion of therapeutic vaping goods from the direct control exemption in subparagraphs (a)(i) to (iv) does not apply to therapeutic vaping goods that are, or include, medicinal cannabis products.

Specifically, paragraph (a) in column 2 of item 1 in Schedule 5A is amended to exclude from the application of the direct control exemption:

- disposable therapeutic vapes, other than disposable therapeutic vapes that are, or include medicinal cannabis products;
- therapeutic vaping substances, other than therapeutic vaping substances that are medicinal cannabis products;
- therapeutic vaping substance accessories, other than therapeutic vaping accessories that are, or include medicinal cannabis products; and
- a therapeutic vaping kit, other than a therapeutic vaping kit where every good in the kit is, or includes, a medicinal cannabis product.

The rest of column 2 and the conditions in column 3 remain without change.

This amendment has the effect of restoring the availability of the direct control exemption for therapeutic vaping goods that are, or include, medicinal cannabis products. There will be no change to the application of item 1 in Schedule 5A to therapeutic vaping goods that are, or include, medicinal cannabis products, from 1 March 2024.

Part 2—Application provisions

Therapeutic Goods Regulations 1990

Item 2 – In the appropriate position in Part 9

This item amends the TG Regulations to introduce new Division 24 to set out the application provision relevant to the amendments made by item 1 of the Regulations.

New regulation 98 provides that the amendment to item 1 of the table in Schedule 5A to the TG Regulations applies in relation to therapeutic goods imported on or after 1 March 2024.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024

The *Therapeutic Goods Amendment (2024 Measures No 1) 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 subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act).

The *Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024* (the Regulations) amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) to restore the application of the direct control exemption to therapeutic vaping goods that are, or include, a medicinal cannabis product. The exemption allows “unapproved” therapeutic goods to be imported and held by sponsors in secure conditions until specific circumstances apply, principally, the granting of approvals or authorities to supply the goods under the *Therapeutic Goods Act 1989* in Australia.

Subsection 18(1) of the Act provides that the regulations may, subject to any conditions as are specified in the regulations, exempt specified therapeutic goods (or specified classes of therapeutic goods) from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F). The effect of this is to enable regulations to exempt specified therapeutic goods from the requirement to be included in the Australian Register of Therapeutic Goods (the Register) be lawfully imported into, supplied in, or exported from, Australia.

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Item 1 of Schedule 5A to the TG Regulations relevantly exempts, from the requirement to be included in the Register, goods that are imported into Australia by, and held under the direct control of, the sponsor of the goods until the goods are able to be principally supplied under one of the statutory pathways for the lawful supply of unapproved goods, such as supply by a medical practitioner under subsection 19(5) of the Act (otherwise, known as the Authorised Prescriber Scheme).

In practice, this exemption is known as the ‘direct control exemption’. It enables sponsors to import, and hold stock in secure conditions, unapproved therapeutic goods in anticipation of an approval or authority for the supply of the relevant therapeutic goods being granted by the Secretary, thereby supporting the timely availability of these goods in Australia as it ensures that such goods are on hand in Australia, rather than only being able to be imported when an approval or authority is granted.

As part of the reforms to the regulation of vapes in Australia, the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2024* (the Vaping Regulations) amended item 1 of Schedule 5A to the TG Regulations to, effectively, disapply the direct control exemption to therapeutic vaping goods, with effect from 1 March 2024. Excluding therapeutic vaping goods from this exemption was intended to ensure that the importation and supply of therapeutic vaping goods is undertaken in accordance with a new vaping-related exemption specifically designed to address the risks posed by such goods, namely item 15 of Schedule 5A to the TG Regulations.

However, the new definition of therapeutic vaping goods is broad enough to capture therapeutic vaping goods that are, or include, medicinal cannabis products. Consequently, the amendments made to item 1 of Schedule 5A by the Vaping Regulations would have the effect that therapeutic vaping goods that are, or include, medicinal cannabis products would no longer be able to be imported under the direct control exemption.

This outcome contrary to the policy intention, which was to minimise the impact on, and otherwise maintain the status quo for therapeutic vaping goods that are, or include, medicinal cannabis products.

The purposed of the Regulations is remove this unintended effect for therapeutic goods that are, or include, medicinal cannabis products, from 1 March 2024. The Regulations commence on 1 March 2024, thereby ensuring that the amendment that was made to item 1 of Schedule 5A of the TG Regulations on 1 March 2024, as a consequence of the Vaping Regulations, would not take effect.

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). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Regulations take positive steps to support the right to health by ensuring the continued availability of therapeutic vaping goods that are, or that include, medicinal cannabis products for Australian patients who need to take them. The purpose of the Regulations is to ensure that the Vaping Amendment Regulations do not have an unintended effect of impacting the importation and supply of such products.

The Regulations are solely designed to correct an unintended effect of the Vaping Regulations and to avoid an unintended impact of those reforms on medicinal cannabis products, including the risk of interruptions to supply for patients who need to use such products, and their health practitioners.

The Regulations, therefore, support the timely availability of these goods in Australia as it ensures that such goods are on hand in Australia, rather than only being able to be imported when an approval or authority is in place under one of the unapproved use pathways.

Conclusion

The Regulations are compatible with human rights, and do not raise any human rights issues.

Mark Butler, Minister for Health and Aged Care