

Updates to the Notification of therapeutic vaping goods



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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today

Welcome

Housekeeping



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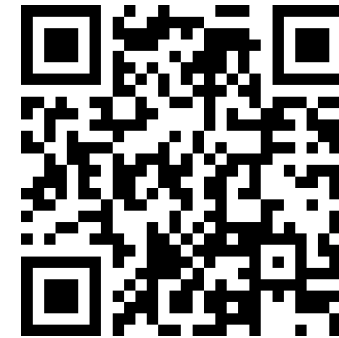
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What we'll cover

1

Sponsor notice – Therapeutic vaping goods

2

Transition provisions for product standards

3

Therapeutic vaping good categories



Notified therapeutic vaping goods

Therapeutic goods, if:

(a) the goods are:

- (i) therapeutic vaping substances; or
- (ii) therapeutic vaping substance accessories; or
- (iii) a therapeutic vaping kit; or
- (iv) goods in a therapeutic vaping pack; and

(b) the goods are not, or do not include, any medicinal cannabis products; and

(c) the only indications of the goods are use for smoking cessation or the management of nicotine dependence...

(item 15 of Schedule 5A to the *Therapeutic Goods Regulations 1990*)

Medical device, if:

(a) the device is:

- (i) a therapeutic vaping device; or
- (ii) a therapeutic vaping device accessory; and

(b) the.... device 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...

(item 2.17 of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*)

Certain starting materials: item 16 of Schedule 5A to the *Therapeutic Goods Regulations 1990*

Certain components or articles: item 2.18 of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*

Therapeutic vaping goods categories

therapeutic vaping device means a therapeutic good that is a vaping device, other than:

- (a) a disposable therapeutic vape; or
- (b) a therapeutic cannabis vaping device.

therapeutic vaping device accessory means a therapeutic good that is an unfilled cartridge, capsule, pod or other vessel:

- (a) that is designed or intended for use in, or with, a therapeutic vaping device; and
 - (b) that is designed or intended to contain a therapeutic vaping substance; and
 - (c) whether or not the cartridge, capsule, pod or other vessel is designed or intended to be refilled;
- but does not include a therapeutic cannabis vaping device accessory.

therapeutic vaping substance means a therapeutic good that is a liquid or other substance designed or intended for use in or with a vaping device.

therapeutic vaping substance accessory means a vaping accessory that:

- (a) is designed or intended for use in, or with, a therapeutic vaping device; and
- (b) contains a therapeutic vaping substance.

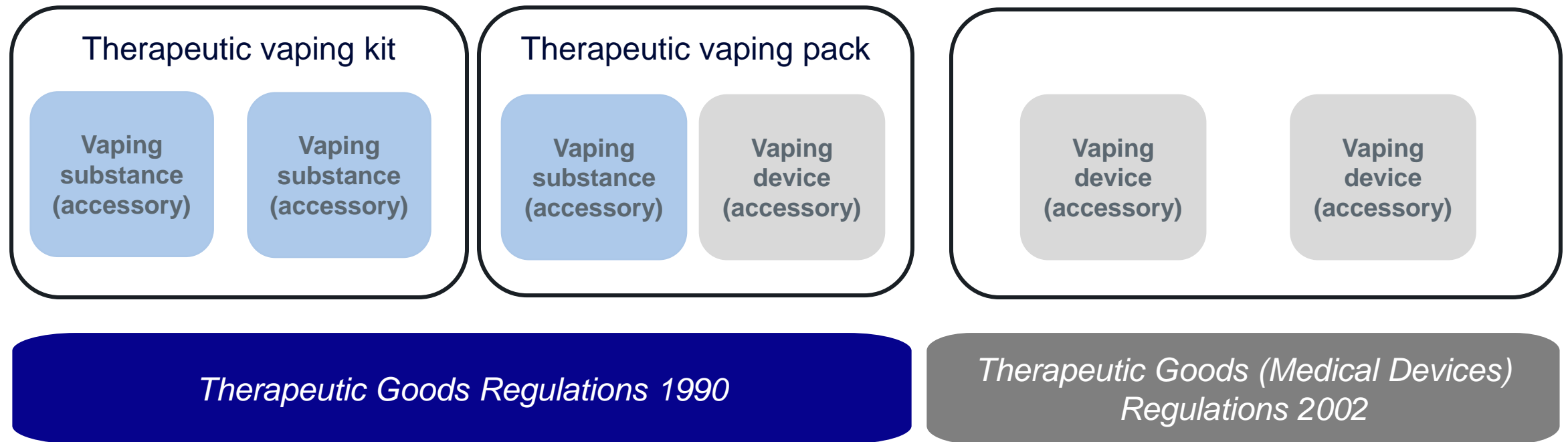
therapeutic vaping kit means a kit, covered by subsection 7B(1) of the Act, that:

- (a) contains one or more therapeutic vaping substances or therapeutic vaping substance accessories; and
- (b) does not contain any other goods.

therapeutic vaping pack means a primary pack that:

- (a) contains at least one therapeutic vaping substance or therapeutic vaping substance accessory; and
- (b) contains at least one therapeutic vaping device or therapeutic vaping device accessory; and
- (c) does not contain any other therapeutic goods.

Products containing multiple therapeutic vaping goods



Product standards – 1 October 2024

Enhanced product standards with application in stages:

- 1 March 2025 – products imported or manufactured
- 1 July 2025 – products supplied

Re-statement

- Sponsors may be asked to re-state compliance at any time.
- Products not re-stated may be:
 - withdrawn by the sponsor, or
 - determination that supply should cease by TGA.

Example scenario – Generic Pharmaceuticals

TGA requested re-statement of compliance of all my currently notified goods:

1. 3mL 5mg/mL unflavoured pod, not compliant with updated TGO110, importation ceased 25 February 2025, but wish to run down current stock by May 2025
2. 25mL zero nicotine cartridge, compliant with updated TGO110, continue to import and supply
3. vape, complies with Essential Principles by the MDSO, complies with updated MDSO, continue to import and supply
4. proprietary thread battery, historical entry which the sponsor no longer import or supply, and is not in the supply chain
5. kit, domestically manufactured, which contains 1 and 2. Wish to continue to domestically manufacture after 1 March 2025 and supply

Example scenario – Generic Pharmaceuticals

TGA requested re-statement of compliance of all my currently notified goods:

- | | |
|---|--|
| 1. 3mL 5mg/mL unflavoured pod, not compliant with updated TGO110, importation ceased 25 February 2025, but wish to run down current stock by May 2025 | 1. Restate compliance (including with <u>previous</u> TGO 110) and withdraw notice after no more stock. Withdraw ODC permit. |
| 2. 25mL zero nicotine cartridge, compliant with updated TGO110, continue to import and supply | 2. Restate compliance (including with <u>updated</u> TGO 110) |
| 3. vape, complies with Essential Principles by the MDSO, complies with updated MDSO, continue to import and supply | 3. Restate compliance (including with <u>updated</u> MDSO) |
| 4. proprietary thread battery, historical entry which the sponsor no longer import or supply, and is not in the supply chain | 4. Withdraw notice now. If current ODC permit, withdraw permit now as well |
| 5. kit, domestically manufactured, which contains 1 and 2. Wish to continue to domestically manufacture after 1 March 2025 and supply | 5. Cannot continue to be notified or supplied as non-compliant with TGO 110. Must withdraw notice now |

Example scenario – Generic Pharmaceuticals

TGA requested re-statement of compliance of all my currently notified goods:

- | | |
|---|---|
| <ol style="list-style-type: none">1. 3mL 5mg/mL unflavoured pod, not compliant with updated TGO110, importation ceased 25 February 2025, but wish to run down current stock by May 20252. 25mL zero nicotine cartridge, compliant with updated TGO110, continue to import and supply3. vape, complies with Essential Principles by the MDSO, complies with updated MDSO, continue to import and supply4. proprietary thread battery, historical entry which the sponsor no longer import or supply, and is not in the supply chain5. kit, domestically manufactured, which contains 1 and 2. Wish to continue to domestically manufacture after 1 March 2025 and supply6. New 3mL 5mg/mL unflavoured pod, compliant with TGO110, to be imported and supplied7. New kit, domestically manufactured which contains 2 and 6.8. New vape, complies with the Essential Principles by the updated MDSO, importation to commence after 1 March 2025 | <ol style="list-style-type: none">1. Restate compliance (including with <u>previous</u> TGO 110) and withdraw notice after no more stock. Withdraw ODC permit.2. Restate compliance (including with <u>updated</u> TGO 110)3. Restate compliance (including with <u>updated</u> MDSO)4. Withdraw notice now. If current ODC permit, withdraw permit now as well5. Cannot continue to be notified or supplied as non-compliant with TGO 110. Must withdraw notice now6. New notice. New permit.7. Each good in kit must be notified, then must notify of kit.8. New notice. New permit. |
|---|---|

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Questions are now open



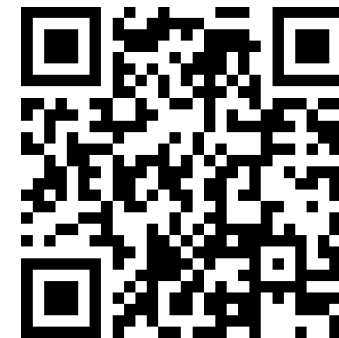
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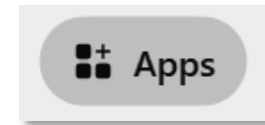


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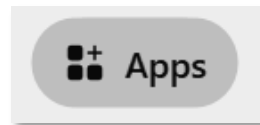
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Engagement and Policy Section

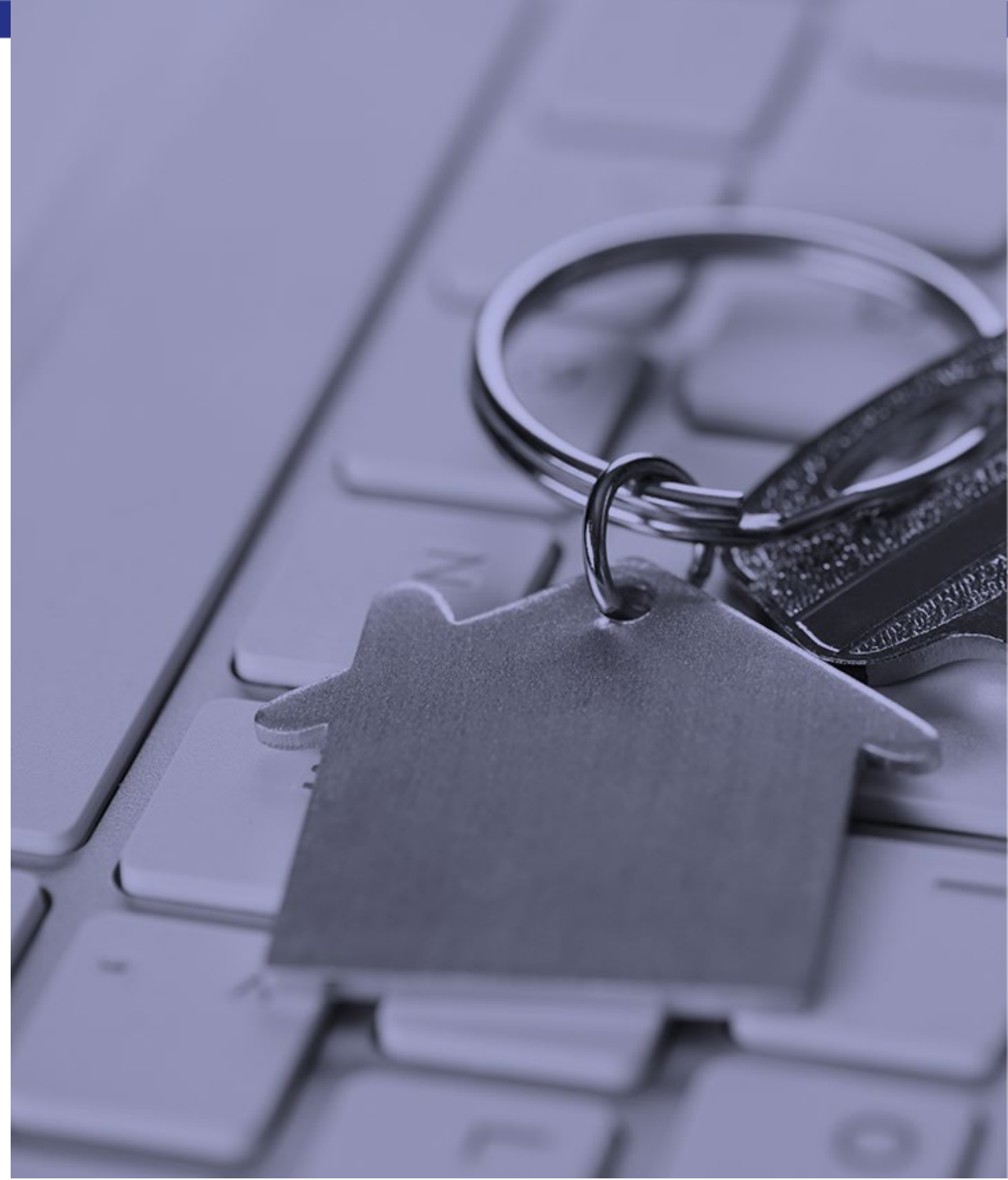
Vaping Implementation and Enforcement Branch

Department of Health and Aged Care, TGA

Contact us

Vaping Regulation and Reporting Section

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