



## Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

[REDACTED]  
HWANGBO SS PTY LTD  
ACN 674 088 325  
[REDACTED]

**By Email:** [REDACTED]

**Date given:** 22/10/2025

**Enquiries:**

Contact officer: [REDACTED]

Telephone: [REDACTED]

**Email:** [REDACTED]

**ENFORCEABLE DIRECTION GIVEN TO [REDACTED] AND HWANGBO SS PTY LTD**  
**Under section 42YT of the *Therapeutic Goods Act 1989*****PART A: Notice of Enforceable Direction**

I, [REDACTED], am a delegate of the Secretary of the Australian Department of Health, Disability and Ageing in the Therapeutic Goods Administration (**TGA**) under section 57(1) of the *Therapeutic Goods Act 1989* (the **Act**) and the Therapeutic Goods (Secretary) Delegation 2025.

I believe, on reasonable grounds, that there has been a contravention under sections 41QB and 41QC of the Act in relation to the supply and possession of at least a commercial quantity of vaping goods by Hwangbo SS Pty Ltd and [REDACTED], as follows:

- Hwangbo SS Pty Ltd supplied vaping goods in Australia, in contravention of section 41QB of the Act and possessed at least a commercial quantity of vaping goods, in contravention of section 41QC of the Act.
- [REDACTED], an executive officer of Hwangbo SS Pty Ltd, supplied vaping goods, in contravention of section 41QB of the Act and possessed at least a commercial quantity of vaping goods, in contravention of section 41QC of the Act.

I believe, on reasonable grounds, that it is in the interests of public health or safety to give Hwangbo SS Pty Ltd and [REDACTED] directions under section 42YT, listed in **Part D: Direction** below.

**PART B: Goods**

I make this direction in relation to the supply and possession of the vaping goods specified at **Attachment A** (the **Goods**).

**PART C: Reasons**

1. Hwangbo SS Pty Ltd (ACN 674 088 325) is an Australian Private Company.

2. According to the current ASIC business extract, [REDACTED] is the sole director and secretary of Hwangbo SS Pty Ltd.
3. The registered business address for Hwangbo SS Pty Ltd is Unit 7/335 Swanston Street, Melbourne VIC 3000. The Candy Store is located in Unit 7 on the ground floor within a contiguous block spanning 335-347 Swanston Street Melbourne VIC 3000, according to the corresponding subdivision plan. It may be reasonably inferred that the registered business address refers to the same physical location as the Candy Store, which operates at Unit 7/339 Swanston Street Melbourne VIC 3000.
4. Further, the account for the Square Pay terminal in the Candy Store is owned by Hwangbo SS Pty Ltd with the business address listed as 339 Swanston Street Melbourne VIC 3000. This matches the business address of the Candy Store.

#### Relevant legislation

5. Section 42YT enables the Secretary (or a delegate) to, by written notice, issue certain directions to a person if the Secretary (or delegate) believes, on reasonable grounds, that the person is not complying with the Act or an instrument made under this Act in relation to particular goods and it is in the interest of public health and safety to give the person directions under this section. A person must comply with the directions within a specified period in the notice. Under subsection 42YT(3), this period must be reasonable having regard to the circumstances.
6. A person commits an offence under subsections 41QB(1) or (2) of the Act, or contravenes subsection 41QB(3), if that person supplies vaping goods in Australia and no relevant exception under subsections 41QB(6) to (8) or 41QB(9) to (11) applies. 'Vaping goods' is defined in section 41P of the Act. Among other things, 'vaping goods' means a 'vaping substance', a 'vaping accessory' and a 'vaping device' which are each defined terms in section 41P.
7. A person commits an offence under subsection 41QC(1) or (3) of the Act if that person possesses a quantity of a kind of vaping goods in Australia that is at least the commercial quantity of this kind of vaping goods but less than 100 times that amount. A person contravenes subsection 41QC(10) if the person possesses at least the commercial quantity of a kind of vaping goods. Certain exceptions may apply – these are addressed in subsections 41QC(11A) and 41QC(12) to (14). The 'commercial quantity' of a kind of vaping goods is explained in reg 10N of the *Therapeutic Goods Regulations 1990 (Regulations)*. Relevantly, under reg 10N, the commercial quantity of vaping devices and vaping accessories is 9 vaping devices and 60 vaping accessories respectively.
8. Under section 54B of the Act, an 'executive officer' may be personally liable for the conduct of a body corporate. An executive officer of a body corporate means a person, by whatever name called and whether or not a director of the body, who is concerned in, or takes part in, the management of the body.

#### Reasons

9. I have reasonable grounds to believe that Hwangbo SS Pty Ltd and [REDACTED] are not complying with sections 41QB and 41QC of the Act because:

- a. I have been provided with several reports from external agencies, including the Australian Health Practitioner Regulation Agency, Victoria Department of Health and Victoria Police, observe that the supply, advertising and possession of vaping goods at the Candy Store has been occurring since at least 25 July 2024.
  - b. Following the execution of a search warrant at the Candy Store on 8 August 2025 (**TGA Warrant**), the TGA seized 749 vaping devices, 73 vaping accessories and one A-frame advertising board, which advertised the sale of vapes at the front of the Candy Store. Investigators also observed multiple vape flavour menus on the premises of the Candy Store.
  - c. The vaping devices and vaping accessories seized in accordance with the warrant are 'vaping goods' as defined in section 41P of the Act.
  - d. The number of vaping devices and vaping accessories seized from this warrant exceeds the commercial quantity of vaping devices and vaping accessories as defined in regulation 10N of Regulations, being 9 vaping devices and 60 vaping accessories.
  - e. Following the TGA Warrant, on 14 October 2025, TGA investigators observed the Candy Store open and supplying vaping goods to customers.
  - f. Hwangbo SS Pty Ltd and [REDACTED] are responsible for the unlawful supply and possession of vaping goods in the Candy Store because:
    - i. the account for the Square Pay terminal in the Candy Store is owned by Hwangbo SS Pty Ltd with the business address listed as 339 Swanston Street Melbourne VIC 3000. This matches the business address of the Candy Store.
    - ii. Further the TGA has been advised that the business and lease of the Candy Store currently belongs to [REDACTED] by way of a sublease.
10. I have reasonable grounds to believe that it is necessary in the interests of public health or safety to issue Hwangbo SS Pty Ltd and [REDACTED] with this Enforceable Direction. This is because the location of the Candy Store is on the ground floor of a student accommodation building in a visible and easily accessible area of the Melbourne CBD that experiences high pedestrian traffic, especially by young students. It is very likely that there is a higher demand for vaping goods sold at the Candy Store by young students as well as other passing customers. Further, media reports indicate that the Candy Store has a significant public profile and is well-known in the area. Given the substantial health risks of vaping, especially among young people, ceasing the sale of vaping goods at the Candy Store would be in the interests of maintaining public health or safety.
11. The timeframes for Hwangbo SS Pty Ltd and [REDACTED] to comply with this Enforceable Direction are reasonable having regard to the following circumstances:
- a. Imposing shorter compliance timeframes are reasonable and justified in the circumstances of this case because:
    - i. I consider that ceasing supply of vaping goods at the Candy Store may be achieved in the one-hour timeframe as this would only require the Candy Store to be closed.

- ii. I consider the surrender of the vaping goods possessed by Hwangbo SS Pty Ltd and [REDACTED] may be achieved in the timeframe specified.
  - iii. The location of the Candy Store is in a visible and easily accessible area of the Melbourne CBD that experiences high pedestrian traffic, especially by young students. This increases the demand for vaping goods sold at the Candy Store by young students as well as other passing customers.
  - iv. Media reports indicate that the Candy Store has a significant public profile and is well-known in the area and, as such, is likely to have a broader reach to potential customers beyond the surrounding area in the Melbourne CBD.
  - v. As at the date of this Enforceable Direction, the Candy Store continues to sell vaping goods despite being put on notice several times that doing so is unlawful. This includes the continued supply following the execution of the warrant on 8 August 2025 and the letter of intent to issue enforceable and advertising directions on 25 September 2025. This letter provided the opportunity to make submissions as to why an enforceable directions notice should not be issued and required the supply and possession to cease by 3 October 2025. The TGA has not received a response from the entity and the Candy Store was observed to still be active on 14 October 2025. This conduct demonstrates ongoing and deliberate non-compliance with the vaping provisions, summarised above.
- b. However, these timeframes are balanced against the following considerations to ensure that Hwangbo SS Pty Ltd and [REDACTED] are practically able to comply with the directions:
- i. The small size of the store and that it appears there is only a single entryway to and from the store which is partially barred.
  - ii. Based on the available information, I have considered that there may be few staff present to help comply with the directions. Further, it is possible there is more stock located outside the premises of the Candy Store. I consider the timeframes for the corresponding directions are adequate when balanced with the seriousness of the conduct and ongoing non-compliance as described above, the likely consequences if the directions are not complied with as outlined in subsections 42YT(4) and (5) and any possibility that the review rights available under section 60 of the Act are exercised by Hwangbo SS Pty Ltd and [REDACTED].

#### **PART D: Direction**

##### **I DIRECT HWANGBO SS PTY LTD AND [REDACTED] to:**

1. Cease supplying the Goods located at the Candy Store within **1 hour** of this direction being given;

2. Surrender the Goods located at the Candy Store within **2 hours** of this direction being given;
3. Surrender all other unlawful vaping goods within your possession to the TGA by **close of business (5pm AEDST) 1 day after** the day this direction is given.

To demonstrate that you have complied with the Directions set out above, we request that you email evidence of your compliance to the email address listed on the first page of this Direction. Examples of evidence you can send include:

- A reconciled stock list indicating items that have been surrendered to the TGA
- Photographs or video captures of any warehouse or offsite storage facilities controlled by Hwangbo SS Pty Ltd And [REDACTED] demonstrating compliance

#### **PART E: Other information**

This information is for **general guidance only**. We recommend that you obtain independent legal advice if you have specific concerns.

#### **Effect of not complying with this Direction**

If you fail to comply with this notice within the period specified, you will:

- a. commit an offence under subsection 42YT(4) of the Act; and
- b. contravene a civil penalty provision under subsection 42YT(5) of the Act

which could lead to court action against you. Section 42YT is reproduced at **Attachment B** to this Notice. Sections 41QB and 41QC of the Act are reproduced at **Attachments C and D**, respectively.

In conjunction with pursuing civil or criminal court action, the TGA may also seek an injunction from the Federal Court of Australia ordering you to immediately cease your advertising.

The TGA could also issue an infringement notice as an alternative to these actions.

#### **Review rights**

This decision is reviewable. Your review rights are set out in **Attachment E**.

[REDACTED]

*[electronically signed]*

[REDACTED]

Vaping Implementation and Enforcement Branch  
Therapeutic Goods Administration  
PO Box 100; WODEN ACT 2609

#### **Enclosures**

**Attachment A** – Goods

**Attachment B** – Relevant legislation

**Attachment C** – Information about review rights

**Attachment A – Goods**

	<b>Good</b>
1.	Alibarbar Ingot 9000
2.	Alibarbar Pandora 7000
3.	HQD Cuvie Slick 6000
4.	IGET Bar 3500
5.	IGET Bar Plus 6000
6.	IGET Bar Plus Pod 6000
7.	IGET Bar Pro 10000
8.	RELX Infinity 2 Plus
9.	RELX Pod Pro
10.	RELX Pod Pro 2
11.	IGET Bar Plus Pod (6000 Puffs)
12.	HDQ Cuvie Slick Mesh Coil
13.	IGET Disposable Cartridge Bar Plus

## **Attachment B – Relevant legislation**

### **41QB Offences and civil penalty provision--supplying vaping goods**

#### *Offences*

(1) A person commits an offence if the person supplies vaping goods in Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence of strict liability if the person supplies vaping goods in Australia.

Penalty: 200 penalty units.

#### *Civil penalty provision*

(3) A person contravenes this subsection if the person supplies vaping goods in Australia.

Maximum civil penalty:

- (a) for an individual--7,000 penalty units; and
- (b) for a body corporate--70,000 penalty units.

(4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods supplied by the person in Australia.

Note: For **unit** of vaping goods, see subsection 3(1).

#### *Exceptions--general*

(5) Subsections (1) to (4) do not apply if:

- (a) subsections (6), (7) and (8) apply in relation to the supply of the vaping goods by the person; or
- (b) subsections (9), (10) and (11) apply in relation to the supply of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (6), (7) and (8) or subsections (9), (10) and (11): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

#### *Exceptions--wholesale supply chain*

(6) This subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered on the Register; or
- (b) both of the following apply:
  - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device



under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;

(ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or

(c) the vaping goods are covered by a determination made by the Minister under section 41R.

(7) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the person:

(i) is the holder of a licence and a permission, granted under regulations made for the purposes of section 50 of the *Customs Act 1901*, to import the vaping goods; or

(ii) is otherwise approved under those regulations to import the vaping goods; or

(b) the person is the holder of a licence in force under Part 3 - 3 that authorises a step in the manufacture of the vaping goods; or

(c) the person is the holder of a conformity assessment document that applies to the vaping goods; or

(d) both of the following apply:

(i) the person is a wholesaler who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 3 to the current Poisons Standard under a law of the State or Territory in which the supply occurs;

(ii) the supply occurs in accordance with the licence or authority; or

(e) both of the following apply:

(i) the Secretary has given the person a consent under subsection 41RC(1) to supply the vaping goods;

(ii) the supply occurs in accordance with the consent; or

(f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:

(i) the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods; and

(ii) the supply occurs in accordance with the determination.

(8) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the person (the **recipient**) to whom the vaping goods are supplied is the holder of a licence in force under Part 3 - 3 of this Act that authorises a step in the manufacture of vaping goods; or

(b) the recipient is 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 3 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; or

(c) the Secretary has given the recipient a consent under subsection 41RC(1) to supply the vaping goods; or

(d) in the case of vaping goods that are covered by a determination made by the Minister under section 41R--the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods.

*Exceptions--retail supply chain*

(9) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the vaping goods are therapeutic goods that are entered on the Register; or

(b) both of the following apply:

(i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;

(ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or

(c) the vaping goods are covered by a determination made by the Minister under section 41R.

(10) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the person is a pharmacist; or

(b) the person is a 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 3 to the current Poisons Standard under a law of the State or Territory in which the supply occurs.

(11) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the supply is:

(i) to another person for use by that person for smoking cessation, management of nicotine dependence or another indication determined by the Minister under section 41RA; or

(ii) to another person, who is the carer of a third person, for use by the third person for smoking cessation, management of nicotine dependence or another indication determined by the Minister under section 41RA; and

(b) if the vaping goods are, or contain, a vaping substance--the vaping substance is in final dosage form; and

(c) the supply is:

- (i) in accordance with this Act (apart from this section); and
- (ii) consistent with the person's authority to supply the vaping goods under a law of the State or Territory in which the supply occurs.

***Meaning of final dosage form***

(12) For the purposes of paragraph (11)(b), a vaping substance is in ***final dosage form*** if the vaping substance is in a form that can be administered to a person without any change or modification (other than vaporisation).

**41QC Offences and civil penalty provision--possessing at least commercial quantity of vaping goods**

***Offences--possessing at least commercial quantity but less than 100 times commercial quantity***

(1) A person commits an offence if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods.

Penalty: Imprisonment for 2 years or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) Absolute liability applies to paragraph (1)(b).

(3) A person commits an offence of strict liability if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods.

Penalty: 120 penalty units.

***Offences--possessing at least 100 times commercial quantity but less than 1,000 times commercial quantity***

(4) A person commits an offence if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is at least 100 times the commercial quantity, but less than 1,000 times the commercial quantity, of that kind of vaping goods.

Penalty: Imprisonment for 4 years or 3,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(5) Absolute liability applies to paragraph (4)(b).

(6) A person commits an offence of strict liability if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is at least 100 times the commercial quantity, but less than 1,000 times the commercial quantity, of that kind of vaping goods.

Penalty: 240 penalty units.

*Offences--possessing 1,000 times commercial quantity or more*

(7) A person commits an offence if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(8) Absolute liability applies to paragraph (7)(b).

(9) A person commits an offence of strict liability if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods.

Penalty: 420 penalty units.

*Civil penalty provision*

(10) A person contravenes this subsection if:

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is at least the commercial quantity of that kind of vaping goods.

Maximum civil penalty:

- (a) for an individual--7,000 penalty units; and
- (b) for a body corporate--70,000 penalty units.

(11) A person who contravenes subsection (10) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia.

Note: For **unit** of vaping goods, see subsection 3(1).

*Exception--possession for personal use*

(11A) Subsections (1) to (3) and (10) and (11) do not apply in relation to the possession of a quantity of a kind of vaping goods by the person if:

- (a) the vaping goods have been lawfully supplied to the person; and

- (b) the vaping goods are for use by the person personally; and
- (c) the quantity is less than 5 times the commercial quantity of that kind of vaping goods.

Note: The person bears an evidential burden in relation to the matters in subsection (11A): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

*Exceptions--general*

(12) Subsections (1) to (11) do not apply if subsections (13) and (14) apply in relation to the possession of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (13) and (14): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

(13) This subsection applies in relation to the possession of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered on the Register; or
- (b) both of the following apply:
  - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;
  - (ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or
- (c) the vaping goods are covered by a determination made by the Minister under section 41R.

(14) This subsection applies in relation to the possession of the vaping goods by the person if:

- (a) the person:
  - (i) is the holder of a licence and a permission, granted under regulations made for the purposes of section 50 of the *Customs Act 1901*, to import the vaping goods; or
  - (ii) is otherwise approved under those regulations to import the vaping goods; or
- (b) the person is the holder of a licence in force under Part 3 - 3 of this Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
- (d) both of the following apply:
  - (i) the person is 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 3 to the current

Poisons Standard under a law of the State or Territory in which the person possesses the goods;

(ii) the possession of the goods is in accordance with the licence or authority; or

(e) both of the following apply:

(i) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods;

(ii) the possession is in accordance with the consent; or

(f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:

(i) the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods; and

(ii) the possession is in accordance with the determination.

**42YT Secretary may give directions if this Act or an instrument is not being complied with**

(1) This section applies if the Secretary believes, on reasonable grounds, that:

(a) a person is not complying with this Act or an instrument made under this Act in relation to particular goods; and

(b) it is in the interests of public health or safety to give the person directions under this section.

(2) The Secretary may, by written notice, give directions to the person requiring the person to do any of the following, within the period specified in the notice and at the person's own cost:

(a) relabel, or label, the goods;

(b) repack the goods;

(c) destroy or otherwise dispose of the goods;

(d) deliver the goods to a specified person to be destroyed or otherwise disposed of in an appropriate manner;

(e) any other thing prescribed by the regulations in relation to the goods.

Note: For variation and revocation of the directions, see subsection 33(3) of the *Acts Interpretation Act 1901*.

(2A) A notice given under subsection (2) must set out the Secretary's reasons for giving the notice.

(3) A period specified in a notice given under subsection (2) must be reasonable having regard to the circumstances.

**Offence**

(4) A person commits an offence if:

(a) the person is given a notice under subsection (2); and

(b) the person fails to comply with the notice within the period specified in the notice.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

*Civil penalty provision*

(5) A person contravenes this subsection if:

- (a) the person is given a notice under subsection (2); and
- (b) the person fails to comply with the notice within the period specified in the notice.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

## Attachment C – Information about review rights

### Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

### Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the [TGA website](#) for specific information and detailed guidance for making a request for reconsideration.

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

A list of all attachments in the submission, or a table of contents, would also be appreciated, particularly for requests involving a significant number of supporting materials sent in multiple emails.

All requests for reconsideration should be given to the Minister by email:

Email: '**Minister.Butler.DLO@health.gov.au**' and copied to  
'**decision.review@health.gov.au**'

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "... - Email 1 of 3", "... - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.



Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the *Administrative Review Tribunal Act 2024*, if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the [Administrative Review Tribunal \(ART\)](#) for a review of that decision upon reconsideration.

**NOTE:** This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the TG Act OR is set aside, varied or remitted by the ART or is otherwise overturned or stayed.