

OFFICIAL



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

[REDACTED]
VEGANIC SKN LIMITED (ACN 142 515 437)
[REDACTED]
C/O [REDACTED]

Date given: 22/04/2026

Enquiries:

Email: [REDACTED]

Telephone: [REDACTED]

By Email: [REDACTED]

ENFORCEABLE DIRECTION
GIVEN TO VEGANIC SKN LIMITED (ACN 142 515 437)
Under section 42YT of the *Therapeutic Goods Act 1989* (Cth)

PART A: Notice of Enforceable Direction

I am a delegate of the Secretary of the Australian Department of Health, Disability and Ageing for the purposes of s 42YT of the *Therapeutic Goods Act 1989* (Cth) (**Act**) under subsection 57(1) of the Act and the *Therapeutic Goods (Secretary) Delegation 2025*.

I have decided to give Veganic SKN Limited (ACN 142 515 437) (**Veganic**) this direction under section 42YT of the Act on the basis that I believe, on reasonable grounds, that there has been a contravention of ss 19B and 19D of the Act by Veganic in relation to the goods that are specified in Table 1 in Part D below. Specifically, I believe, on reasonable grounds, that those goods are being manufactured in a manner that makes them separate and distinct (within the meaning of s 16 of the Act) from the therapeutic goods listed in relation to Veganic, and therefore that their manufacture and supply contravene ss 19B and 19D of the Act.

I believe, on reasonable grounds, that it is in the interests of public health or safety to give Veganic directions under section 42YT, listed in **Part D: Direction** below, in relation to those goods where they are not, in fact, entered in the Australian Register of Therapeutic Goods (**Register**) within the meaning of Direction 1(a) – (c) in Part D.

OFFICIAL

PART B: Goods

I make this direction in relation to the goods that are specified in Table 1 in Part D and that are not entered in the Register within the meaning of Direction 1(a) – (c) in Part D (**Goods**).

PART C: Reasons**Material considered**

1. I have considered the following material in coming to my decision to make this direction:
 - a. the notice dated 9 December 2025 requiring information and documents from Veganic under s 31 of the Act (**Section 31 Notice**);
 - b. Veganic's response to the Section 31 Notice, which it confirmed via email dated 17 December 2025 that it had been dispatched;
 - c. correspondence between the TGA and Veganic regarding this matter, namely:
 - i. a letter dated 22 January 2026 from the TGA to Veganic which outlined the TGA's concerns regarding Veganic's unlawful manufacture, advertising and supply of therapeutic goods that are not entered in the Register;
 - ii. a letter dated 30 January 2026 from Veganic's legal representatives, McLachlan Thorpe Partners, in response to the TGA's 22 January 2026 letter;
 - iii. a further letter dated 20 February 2026 from McLachlan Thorpe Partners in response to the TGA's 22 January 2026 letter, and its enclosed 5 February 2026 email from the TGA to [REDACTED] (a third party that was advertising and supplying sunscreens purchased from Veganic);
 - iv. a letter dated 24 February 2026 from the TGA to McLachlan Thorpe Partners in response to their correspondence of 30 January and 20 February 2026;
 - v. a letter dated 27 February 2026 from McLachlan Thorpe Partners to the TGA in response to the TGA's 24 February 2026 correspondence;
 - vi. an email dated 2 March 2026 from McLachlan Thorpe Partners and the TGA's response of the same date consenting to the requested extension of time within which to respond to the matters raised in the TGA's 24 February 2026 correspondence;
 - vii. emails dated 5 and 6 March 2026 from McLachlan Thorpe Partners to the associated TGA responses dated 6 March 2026;

- viii. a letter dated 10 March 2026 from the TGA to McLachlan Thorpe Partners in response to their 27 February 2026 correspondence;
 - ix. a letter dated 11 March 2026 from McLachlan Thorpe Partners to the TGA in response to the TGA's 10 March 2026 correspondence and requesting an extension and my response dated 12 March 2026;
 - x. a letter dated 19 March 2026 from McLachlan Thorpe Partners to the TGA requesting an extension and my response dated 20 March 2026; and
 - xi. letters dated 24 March 2026 from McLachlan Thorpe Partners to the TGA in response to the TGA's 10 March 2026 correspondence.
- d. Publicly available web and media content expressly referred to in the abovementioned correspondence, including:
- i. information in the ARTG Public Summary for each of the AUST L numbers referred to in that correspondence;
 - ii. the article dated 8 December 2025 published by the Australian Broadcasting Corporation (**ABC**) titled 'More than 30 zinc sunscreen brands using formula that failed preliminary SPF testing' (**ABC Article**);
 - iii. content available on Veganic's website, including the downloadable customised label ordering form referred to at paragraph 37 below; and
 - iv. screenshots of advertising for goods labelled with Veganic AUST L numbers, as set out in Attachment C to the TGA's 10 March 2026 letter (and attached to this decision as **Attachment B**).

Relevant legislation

2. Section 4 of the Act provides that its objects include the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods that are used in Australia. An important component of that national system of controls is the requirement that therapeutic goods that are supplied in Australia are entered in the Register, unless there is a special exemption, approval or authority under the Act that allows those goods to be supplied without an entry in the Register.
3. Sections 19B and 19D of the Act (among other provisions) have the effect that, in order to be lawfully manufactured and supplied in Australia, sunscreens that are therapeutic goods must be entered in the Register unless they are otherwise subject to an exemption, approval or authority under the Act.
4. Sunscreens that are for application to the skin and meet the criteria in item 7 of Schedule 4 to the *Therapeutic Goods Regulations 1990 (Cth)* (**Regulations**) are required to be included in the part of the Register for listed goods, and are therefore listable goods as defined at s 3(1) of the Act.

5. The therapeutic goods framework is designed to make sure that things that are in the Register are the same as the goods that are being manufactured, advertised and supplied in the Australian market. This is critical to the proper functioning of the system of controls established under the Act, as it ensures that:
 - a. appropriate pre-market procedures have been followed in relation to all of the key characteristics of the goods (including that appropriate certifications have been made, for listed medicines) before they are supplied;
 - b. the Therapeutic Goods Administration (**TGA**) as the regulator is able to readily identify the key characteristics of the goods once entered in the Register, which facilitates post-market monitoring of safety, quality, efficacy and other matters such as advertising requirements;
 - c. suppliers of therapeutic goods can easily identify the regulatory status of therapeutic goods by reviewing the Register as made publicly available by the Secretary from time to time; and
 - d. it is possible for health professionals, consumers and other members of the public to identify the entry in the Register relating to goods that they are using, including for the purposes of reporting adverse events or determining whether the goods they are using have been recalled, and have confidence that the matters set out in that entry are complete and accurate.
6. Section 16 of the Act sets out the circumstances in which a therapeutic good will be '*separate and distinct*' from another for the purposes of the Act. Where a therapeutic good is separate and distinct from the goods as described in the relevant entry in the Register, that has the legal effect that they are not entered in the Register under that entry. This supports the achievement of the important regulatory objectives referred to at paragraph 5 above.
7. For listable goods other than export only medicines, s 16(1A)(d) of the Act when read with r 11(1)(a) and (b) of the Regulations provides that a therapeutic good will be '*separate and distinct*' from another if it has '*a different name*' or '*different indications*'. This means that therapeutic goods being manufactured and supplied must have (among other things) the same name and indications as the goods listed in the Register.
8. If the goods being manufactured and supplied do not have the same name and indications as the goods listed in the Register, they are '*separate and distinct*' from the goods listed in the Register. This has the legal effect that the goods, as manufactured and/or supplied, are not entered in the Register at all.
9. 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 s 42YT(3), this period must be reasonable having regard to the circumstances.

Findings of fact and reasons

10. I believe, on reasonable grounds, that Veganic is not complying with s 19B and 19D of the Act because, for the reasons set out below, the evidence before me shows that the Goods are being manufactured in a manner that makes those sunscreens separate and distinct (within the meaning of s 16 of the Act) from the therapeutic goods listed in relation to Veganic, and therefore that their manufacture and supply contravenes ss 19B and 19D of the Act in circumstances where they are not otherwise subject to any exemption, approval or authority under the Act.

Circumstances where a therapeutic good has 'a different name' to the entry in the Register

11. The central issue in dispute in this matter is whether a therapeutic good as manufactured and supplied will be separate and distinct from a therapeutic good described in an entry in the Register (the AUST L number for which is included on the label of the therapeutic good as manufactured and supplied) in circumstances where:
- a. the therapeutic goods as manufactured and supplied bear a label containing a name for the goods that does not correspond to that of the relevant entry in the Register (**Market Name**); and
 - b. the label of the goods *also* contains the name identified in the relevant entry in the Register (**Register Name**) (generally in small print, near the AUST L number).
12. The above can sometimes occur where a company provides a 'white labelling' service, in which they manufacture and supply a range of therapeutic goods, each with different labels bearing different Market Names, under one entry in the Register. I refer to this practice in my decision as **white labelling**.
13. In Veganic's 24 March 2026 letter, it submitted (in effect) that the examples of sunscreens provided by the TGA, namely those in **Attachment A and B**, do not have a 'different name' for the purposes of s 16(1A) and r 11(1)(a) if the label of the goods contains both the Register Name and the Market Name.
14. In making these submissions, Veganic sought to support its construction by referring to various instances where the concept of 'name' or 'separate and distinct' has been used in different contexts in the Act, Regulations and in *Therapeutic Goods Order No. 92 (TGO 92)*. Veganic submits that its construction is consistent with:

... the overarching purpose of s 16, in particular, ... to ensure that it is possible to match a therapeutic good in the Australian market to its corresponding entry on the Register and thereby confirm that it is labelled

and marketed appropriately in accordance with its assessed therapeutic uses. This suggests that so long as the name of the good is included on the packaging, and that name matches the corresponding entry for the good on the register, the good is not “a separate and distinct” good under s 16’.

15. Veganic further submits that its construction of the Act is preferable and is *‘consistent with’ ‘the critical public purpose that is served by the Register and the need for the public to be able to identify the entry in the Register associated with a particular sunscreen’.*
16. For the following reasons, I do not agree with Veganic’s construction and find that if the label of goods contains both a Register Name and a Market Name, those goods have a ‘different name’ for the purposes of s 16(1A) and r 11(1)(a).
17. First, the Market Name is a name for the goods in question. Veganic has not contested this. If goods have a Market Name that is a different name to the therapeutic goods entered in the Register, I find the goods are separate and distinct from other therapeutic goods that do not have that name, including the goods as entered in the Register. This is the case even if the goods also have another name that is not a different name, such as the Register Name.
18. Second, in accordance with s 13(1)(b) of the *Legislation Act 2003* (Cth), I find that the reference to a ‘different name’ in r 11(1)(a) of the Regulations (which is prescribed for the purposes of s 16(1A)(d) of the Act) has the same meaning as ‘a different name’ in s 16(1)(d) of the Act. Section 16, including s 16(1), provides for various other instances where ‘a different’ characteristic has the effect that a good is taken to be separate and distinct from another. Veganic’s construction, when applied across s 16 of the Act, would have the effect that if a therapeutic good had an additional characteristic listed in s 16, it would not be a different characteristic for the purpose of that section.
19. This would mean that therapeutic goods would not be separate and distinct from those in the Register if they had two different formulations, strengths or dosage forms in one packet, as long as one of those formulations, strengths or dosage forms were the same as that which was in the Register. Similarly, Veganic’s construction would have the effect that goods would not be separate and distinct from those in the Register if they had an additional indication, as long as the goods also had one or more of the indications that were in the Register.
20. The correctness and completeness of the Register is critical to the achievement of the objects of the Act. It ensures that the TGA is able to properly scrutinise the safety, efficacy, quality and other characteristics of therapeutic goods through pre- and post-market processes. It also ensures that what is supplied into the market, and ultimately to consumers, is consistent with the outcomes of those processes.
21. Noting those implications, I do not agree that Veganic’s construction is consistent with the objects set out in s 4 of the Act, which are to provide for, among other things, the maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods.

22. Third, I disagree with Veganic’s interpretation of the overarching purpose of s 16 of the Act. I find that the overarching purpose of s 16, as evident from the language of the provision, is to identify where therapeutic goods are sufficiently different from each other as to require them to be dealt with separately under the Act, including where goods available in the market are meaningfully different from goods entered in the Register.
23. Fourth, I do not agree that the references to the concept of ‘name’ or ‘separate and distinct’ in different contexts in the Act, Regulations and TGO 92 supports Veganic’s construction. It is inevitable that the Act will express concepts slightly differently in different places, particularly where the Act is dealing with different things. For example, it makes sense that the provisions of the Act concerning the presentation of therapeutic goods refer to the name applied to the goods in the market.
24. In some cases, the matters raised by Veganic do not appear to materially support its construction of the Act. The submissions refer, for example, to provisions of the Regulations that relate to applications to include an additional trade name for goods in the Register. Contrary to Veganic’s submissions, the fact that the Regulations provide for such applications suggests that any Market Name for listed or registered goods is required to be entered in the Register – otherwise, there would be no need for applications of that kind.
25. I am therefore not persuaded that these matters materially support Veganic’s construction of section 16 of the Act or r 11 of the Regulations, particularly given my findings concerning the purpose of s 16 of the Act above and noting that many of the matters raised by Veganic are not in parts of the legislative framework that relate to the situation being dealt with here.
26. The matter in issue here is solely whether goods of the kind described in paragraph 11 above have a different name to the goods as entered in the Register, such that they are taken to be separate and distinct for the purposes of s 16(1A) of the Act. I have found that they are. I will now apply that finding to the various therapeutic goods in issue in this matter.

Evidence – Goods labelled with AUST L 407959

27. In December 2025, concerns were raised with the TGA that Veganic was manufacturing ‘white label’ sunscreens purportedly under AUST L 407959. To investigate this issue, the TGA issued Veganic the Section 31 Notice. That notice required Veganic to produce a range of information about the goods it was purporting to manufacture and supply under AUST L 407959.
28. Veganic’s response showed that it was manufacturing 94 therapeutic sunscreens bearing AUST L 407959 on the label. The label of each of those products contained both a Market Name, being a name for the goods that was different to the name entered in the Register, and the Register Name. Having regard to my above findings on the application of s 16 of the Act, it follows that none of those 94 therapeutic sunscreens were entered in the Register under AUST L 407959.

29. None of those therapeutic sunscreens were otherwise entered in the Register, nor were they subject to an exemption, approval or authority under the Act which would otherwise permit their manufacture or supply.
30. I therefore believe, having regard to the evidence supplied by Veganic under s 31 of the Act, that the manufacture and supply of those therapeutic sunscreens contravenes s 19B and 19D of the Act in circumstances where they were (and are) not listed or registered in the name of Veganic nor otherwise subject to an exemption, approval or authority under the Act.
31. In Veganic's 24 March 2026 letter, it requested a copy of the '*external referral*' referred to in the Section 31 Notice. While I have had regard to the Section 31 Notice and Veganic's response to that notice for the purpose of making my decision, I confirm that I have not reviewed or considered any material that could be characterised as an external referral, nor do I consider any external referral to be relevant to my decision to issue this direction.

Evidence – Goods labelled with AUST L 482407, 468425, 445961, 444962, 444961 and 444957 as identified in Attachments A and B

32. The TGA subsequently sought to identify the extent of Veganic's white labelling practices, including by reviewing online advertising of therapeutic goods bearing AUST L numbers associated with entries in the Register in Veganic's name.
33. In doing so, the TGA identified that the labels of each of the therapeutic sunscreens identified in **Attachment A and B** (previously provided to Veganic under cover of my letter dated 10 March 2026) bear AUST L numbers which correspond to entries in the Register in Veganic's name (specifically, AUST L 482407, 468425, 445961, 444962, 444961, 444957) and are being manufactured and supplied with a label that contains a Market Name that differs from the Register Name (in at least some instances, the label also contains the Register Name in small print).
34. None of the therapeutic sunscreens referred to in paragraph 33 above were otherwise entered in the Register, nor subject to an exemption, approval or authority under the Act.
35. In light of my findings above, I therefore believe, having regard to the publicly available advertising of the sunscreens included in **Attachment A and B**, that the manufacture and supply of those therapeutic sunscreens contravenes s 19B and 19D of the Act in circumstances where they were not listed or registered in the name of Veganic nor otherwise subject to an exemption, approval or authority under the Act.

Evidence – Veganic website, including product ordering forms

36. I have also reviewed Veganic’s website. That website clearly indicates that Veganic is engaged in white labelling, and that its business principally involves the manufacture of white label sunscreens for persons who order them.
37. Among the documents available on Veganic’s website is a downloadable customised label ordering form.¹ On that form, Veganic’s customers are invited to specify a product name (as referred to in Item 1 of that form) which is different to the name in the Register (as referred to in Item 7 of that form). The form specifies (by way of examples in Item 4) that it may be used for AUST L 511725, 515725, 515726, 515727, 515728, 515729, 515730 and 519485.
38. The way Veganic describes its business operations on its website therefore supports a conclusion that it is engaged in white labelling across the various AUST L numbers in issue. It also, specifically, provides evidence that Veganic offers to manufacture therapeutic sunscreens with labels that contain:
 - a. one of the AUST L numbers listed on the ordering form, being AUST L 511725, 515725, 515726, 515727, 515728, 515729, 515730 and 519485; and
 - b. a product name that differs from the name in the Register.
39. There is further a clear pattern in the form of the product names on the relevant entries in the Register. In most cases, the entries in the Register associated with Veganic are in the form of a product code (for example, ZinCLEAR A02, ZinCLEAR S06, ZinCLEAR M01). This is consistently the case across the entries in the Register corresponding with the AUST Ls that the TGA has identified on white labelled products being publicly advertised with a different Market Name (as discussed at paragraphs 27 to 35 above), as well as the list of AUST Ls in the Veganic customised label ordering form.
40. This pattern provides further support for a conclusion that any goods manufactured and supplied under entries of that kind would be manufactured and supplied with product names that differ from the product code name entered in the Register.
41. The evidence before me therefore indicates that Veganic is engaging in white labelling with respect to each of the AUST Ls identified in Table 1, and that in each case this involves manufacturing and supplying therapeutic sunscreens bearing a label with a Market Name which differs from the Register Name, even if the label also contains the Register Name.
42. I note that I put the above matters to Veganic for comment in my letter of 10 March 2026. In doing so, I noted that I was aware of the theoretical possibility that some goods were being lawfully supplied under those entries. I therefore

¹ URL <https://525b28ed-8056-4b03-9b3f-ddc3848a4217.filesusr.com/ugd/0daf5b_fc3391cca4fd4c5987528828f6bb59bf.pdf>.

invited Veganic to tell me if my understanding of how the goods were being manufactured and supplied was incorrect.

43. Veganic's submissions did not contest those proposed findings of fact. It has not provided any evidence that the subject goods were, to any extent, manufactured and supplied bearing labels that solely contain the Register Name. This supports a finding that the goods manufactured by Veganic bearing the AUST L numbers set out in Table 1 of the Direction each had a label showing a Market Name which differed from the Register Name.
44. Having regard to the available evidence, I therefore believe that all of the therapeutic sunscreens manufactured and supplied by Veganic purportedly under the AUST L numbers in Table 1 of the Direction are separate and distinct from the goods entered in the Register under those AUST L numbers.
45. None of those therapeutic sunscreens were otherwise entered in the Register, nor otherwise subject to any relevant exemption, approval or authority under the Act. I therefore believe, having regard to the above, that the manufacture and supply of those therapeutic sunscreens contravenes s 19B and 19D of the Act in circumstances where they were not listed or registered in the name of Veganic nor otherwise subject to an exemption, approval or authority under the Act.

Allowance for possibility of lawful manufacture and supply in the framing of the direction

46. It follows that I believe, on reasonable grounds, that Veganic is not complying with the Act in relation to the goods manufactured and supplied by Veganic in relation to the AUST Ls set out in Table 1 of the Direction.
47. Nonetheless, I have framed the directions in such a way that they do not capture goods unless they are separate and distinct from goods entered in the Register. This means that, if Veganic is, in fact, lawfully dealing with goods labelled with the AUST Ls set out at Table 1 of the Direction, those dealings would not be affected by the directions.

Reasonable grounds to believe that it is in the interests of public health or safety to give directions

48. I further believe, on reasonable grounds, that it is in the interests of public health or safety to give Veganic directions under s 42YT of the Act for the following reasons.
49. The requirement that goods be supplied under the name that they are entered in the Register is an important one. It ensures that consumers and businesses can properly identify the entry in the Register associated with a product if needed. It further helps to facilitate adverse event reporting and post-market actions such as recalls.
50. This requirement also allows the TGA to have visibility over the names under which therapeutic goods are being supplied. This assists the TGA in identifying

instances where the name of a therapeutic good claims that it is suitable for an indication that is not accepted in relation to the good in the Register, or where the name otherwise makes the presentation of the good unacceptable. This can result in the cancellation of the entry in the Register for the goods.²

51. In Veganic's 24 March 2026 letter, it made submissions that the directions would introduce administrative requirements that create consumer confusion when goods are recalled, and introduce economic barriers for Veganic's smaller customers, thereby reducing the availability and affordability of sunscreen in the Australian market.
52. I do not agree that the requirements imposed under the Direction would result in consumer confusion. I accept that if an issue affects a base formulation used across multiple listings, this may give rise to a recall of therapeutic goods entered in the Register under multiple AUST L numbers. I also accept that, if consumers were minded to use the AUST L number for their goods as the primary or sole reference point to identify whether the goods have been recalled, consumers would need to identify whether the AUST L number for their goods is amongst the list of those recalled.
53. I do not, however, consider that it is likely that consumers will be readily able to recall the AUST L of each of the therapeutic goods they are using. It is more likely that they will recall and refer to the name and label of their goods in identifying whether the goods have been recalled. This is why TGA announcements regarding recalls generally include a photo of the goods and the name of the goods.
54. Under Veganic's current business practice, it would be difficult for the TGA to identify, in a timely way, the name and an image of all goods supplied under the same AUST L. The only source from which the TGA could obtain that information is Veganic, and Veganic's approach to responding to the Proposal to Direct has, at times, suggested Veganic would itself have difficulty readily identifying all such goods in a timely way. This has the potential to delay or impair the proper conduct of such recalls.
55. If a recall announcement referred to the goods being recalled by their Register Name/product code (for example, ZinCLEAR S01) and AUST L number, consumers may not easily recognise the AUST L or the Register Name and understand that the recall applied to their product. Both the AUST L and the Register Name are only included in very small print on the labels the TGA has identified so far. It is unlikely that a consumer would readily recall either piece of information.

² See, for example, the decision of the Administrative Appeals Tribunal in *Cat Media Pty Limited and Minister for Health and Aged Care* [2023] AATA 2792 (31 August 2023).

56. This issue would have implications not only for recalls, but also for other matters such as whether consumers would clearly identify the goods in issue when reporting adverse events to the TGA.
57. I accept that complying with the requirements of the Act, as reflected in this direction, would give rise to costs for Veganic and possibly, by extension, Veganic's customers. Listing goods in the Register is associated with certain costs (e.g., an application to list fee of \$1,014 per item 3(b) of clause 3 in schedule 9 to the Regulations and an annual charge of \$1,473 per items 7(1)(c)(i) and 7(2)(c)(i) of the *Therapeutic Goods (Charges) Regulations 2018*).
58. These costs may reduce the affordability of some sunscreens placed on the Australian market by persons who have previously been dealing with the goods without complying with their regulatory obligations and paying associated fees and charges. I consider it unlikely, however, that these costs would materially reduce the overall availability of sunscreen in the Australian market. Given the relatively small amount of those charges, it is likely that they would only be a material obstacle to putting a sunscreen on the market if the amount of sunscreen intended to be manufactured was small. I am also aware that there are a large number of other therapeutic sunscreens on the Australian market. I therefore consider issuing the Direction will have a negligible effect on the timely availability of sunscreens to consumers overall.
59. In Veganic's 24 March 2026 letter, it also made submissions that, even if I do not agree with its construction of the Act regarding the implications of the name of the goods, it is not open to me to find that I believe, on reasonable grounds, that it is in the interests of public health or safety to issue the Direction in circumstances where Veganic is willing to cooperate with the TGA in its consideration of these matters and there is no allegation that the goods pose any threat to public health.
60. Veganic's assertion that it is willing to cooperate with the TGA in its consideration of these issues does not address the compliance issues or amount to an undertaking to address the issues. As of the date of this decision, the compliance issues identified in this decision concerning the use of Market Names that differ from the Register Name of the goods have not been addressed.
61. I therefore believe that it is in the interests of public health or safety to issue the direction as it appears to be necessary to bring Veganic into compliance with the requirements of the Act which are imposed to achieve public health and safety objectives. As explained in further detail above, the requirement that goods be supplied under the name that they are entered in the Register is an important one for the proper operation of the national system of controls on safety, quality and efficacy of therapeutic goods established by the Act.
62. Veganic also made submissions that there is no basis on which the Secretary could form a view, on reasonable grounds, that it is in the interests of public health or safety to direct Veganic to destroy certain goods where the issues appear to relate to labelling and registration requirements and not to product safety. These submissions were, in part, made concerning the proposed direction

with respect to goods where there was no SPF indication entered in the Register in respect of the AUST L number on the label of the goods. As discussed at paragraphs 75 to 80 below, that direction is no longer going to be imposed as that issue has been addressed.

63. To the extent that the Directions, in their final form, could still require that goods be destroyed, I note that the Directions are framed in a way that only requires Veganic to destroy goods where it has not rectified the white labelling issues in accordance with Direction 1 and 2(a). Where this is the case, I find that it is in the interests of public health or safety to direct Veganic to destroy the goods in light of the factors discussed above, and given there would be no other mechanism to lawfully deal with the goods unless they are otherwise subject to an exemption, approval or authority under the Act.
64. I note, for completeness, that Veganic's 24 March 2026 letter made submissions to the effect that the directions would be inconsistent with a decision of a delegate made 16 January 2026 not to recommend that the Minister vary the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2026*. I have not considered information relating to the 16 January 2026 decision for the purpose of making this decision, nor do I consider that a decision made by another delegate of the Secretary in relation to a different statutory test is relevant to whether I believe, on reasonable grounds, that it is in the interests of public health or safety to give Veganic directions under s 42YT of the Act.

Exercise of discretion

65. I consider that it is appropriate in all of the circumstances to exercise my discretion to issue the Direction in the form set out in Part D. In coming to that view, I have placed considerable weight both on the need to ensure Veganic's business practices are brought into compliance with the Act, as well as the extent to which the continuation of the white labelling practice would damage the interests of public health and safety and undermine the operation of the regulatory framework established by the Act more generally.
66. I have also considered, as a factor weighing against the exercise of my discretion to issue the Direction, the cost to Veganic and its customers of making that decision. I have ultimately decided that consideration should be given limited weight, and certainly much less weight than the need to secure compliance with the Act and the public health and safety considerations discussed above.
67. In coming to that view, I have taken into account both the cost to Veganic and its customers of ceasing the white labelling practice (including as noted in its submissions) and the costs that would be incurred in either re-labelling or destroying the goods subject to the Direction.
68. As to the costs of ceasing the white labelling practice (including listing fees and annual charges), I consider they are costs that Veganic and its customers should already have been incurring under the framework established under the Act. Other sunscreen manufacturers and suppliers are already bearing those costs.

Allowing Veganic to avoid the costs of complying with the Act, while its competitors bear those costs and must factor those into the cost of their products, would not be fair or reasonable.

69. As to the costs of re-labelling or destruction, I consider that this Direction adopts a balanced and reasonable approach to bringing Veganic into compliance. It requires Veganic to immediately cease engaging in unlawful manufacture and supply, but then allows it an opportunity (through re-labelling) to bring its products into compliance with the requirements of the Act and release them into the market in a form that does not harm the public health and safety interests this Direction is intended to protect.
70. It is only if Veganic does not bring those goods into compliance, and those goods therefore remain incapable of being lawfully supplied under the Act, that Veganic is required to destroy them.
71. I note that Veganic has made submissions that it is disappointed that the TGA is prioritising investigation and compliance action on this issue rather than concerns going to public safety, and that the directions are not proportionate to the concerns raised in the correspondence.
72. I do not consider that it is correct to say that the TGA is prioritising this matter rather than concerns going to public safety. The TGA can and does do multiple things at once. Further, the directions prevent and address the unlawful manufacture and supply of goods that are not entered in the Register and do so in a way that would allow most of the goods to continue to be marketed if they were re-labelled or otherwise brought into compliance with the Act. As discussed earlier, I consider that this action is proportionate to the conduct identified.
73. Veganic has further made submissions that it is open and willing to discuss these matters with the TGA, or to address additional queries that the TGA may have in advance of any further decision being made. I consider that Veganic has had ample opportunity to provide written submissions on these matters, and consider it appropriate to proceed with issuing the Direction based on the material before me. In coming to that view, I have taken into account that I do not have any additional queries in relation to Veganic's submissions to date.
74. Finally, I consider the timeframes for Veganic to comply with the Direction are reasonable having regard to the content of the Direction. I note that the timeframes were included in the Proposal to Direct, and Veganic has not made any submissions in relation to those timeframes.

Entries in the Register that do not include SPF indications

75. For completeness, I note that previous correspondence indicated that the TGA had identified several entries in the Register (being AUST L 407959, 444957, 398843, and 398844) under which Veganic appeared to be purporting to manufacture and supply goods with labels bearing an SPF indication that was not (at the time of my 10 March 2026 letter) accepted in relation to the entry in the

Register corresponding with the labelled AUST L. While the TGA had not identified any advertising for AUST L 402729, there was also no SPF indication accepted in relation to that entry.

76. As outlined in that earlier correspondence, I consider that the legal effect of this was that the goods as manufactured and supplied were separate and distinct from the goods described in the entries in the Register.
77. I note, however, that a letter from Veganic's solicitors dated 24 March 2026 indicated that Veganic would, on a no admissions basis, take steps to rectify this issue by ensuring that the SPF indication was included in each of the relevant entries in the Register. Veganic then proceeded to take those steps. I find that each of those entries in the Register now have a permitted SPF indication entered in the Register.
78. The issue of therapeutic sunscreens purportedly supplied under entries in the Register that do not include an SPF indication has therefore fallen away, and no longer needs to be dealt with by the issue of a direction under s 42YT of the Act.
79. For that reason, I have made the following changes to the Direction as compared to the version sent to you in Attachment A to my letter of 10 March 2026:
 - a. the Direction will not apply to goods supplied bearing AUST L 398843, 398844 and 402729 (and those AUST L numbers and corresponding Register Names have been removed from Table 1 in the Direction), as the sole issue relating to goods purportedly supplied under those AUST Ls was the absence of an SPF indication on the relevant entry in the Register;
 - b. the direction otherwise no longer includes references to goods being separate and distinct by reason of their indications not corresponding to the entry in the Register under which they were purportedly supplied.
80. For completeness, I note that AUST L 407959 and 444957 continue to be listed in Table 1, and remain subject to the Direction. This is because I consider (for the reasons set out above) that the goods Veganic has manufactured and supplied and that are labelled with those AUST L numbers are separate and distinct from their respective entries by virtue of their name.

PART D: Direction

In my capacity as delegate of the Secretary for the purposes of s 42YT of the *Therapeutic Goods Act 1989* (Cth), I require Veganic SKN to do the following, within the specified time periods and at Veganic SKN's expense:

1. By **28 April 2026**, cease the supply of, and quarantine, all finished therapeutic goods that are sunscreens (**therapeutic sunscreens**) that remain in the possession or control of Veganic SKN and are not entered in the Australian Register of Therapeutic Goods (**Register**).

For the purposes of Direction 1, a therapeutic sunscreen is not 'entered in the Register' unless, when released for supply, the label for that therapeutic sunscreen:

- a. contains an AUST L number that corresponds to an entry in the Register in relation to Veganic SKN and is set out in Table 1 below;
- b. contains the name identified in the entry in the Register that corresponds to the AUST L number on the label (**Register Name**); and
- c. does not contain any name for the therapeutic sunscreen other than the Register Name.

AUST L number	Register Name
519485	ZinCLEAR M01
515725	ZinCLEAR A02
515727	ZinCLEAR S06
515726	ZinCLEAR S05
515733	ZinCLEAR SA02
515728	ZinCLEAR S07
515730	ZinCLEAR SM05
515729	ZinCLEAR SM04
511725	ZinCLEAR ST01
482394	ZinCLEAR SA01
482407	ZinCLEAR SM03
468425	ZinCLEAR A01
445961	ZinCLEAR S04

444962	ZinCLEAR SM02
444957	ZinCLEAR S02
444961	ZinCLEAR S03
407959	zinclearS01

2. By **9 October 2026**, with respect to each therapeutic sunscreen that was required to be quarantined under Direction 1, either:
- a. relabel or repackage the therapeutic sunscreen in such a manner that the label for that sunscreen:
 - i. contains an AUST L number that corresponds to an entry in the Register in relation to Veganic SKN or the person on whose behalf Veganic SKN manufactures the therapeutic sunscreen;
 - ii. contains the name identified in the entry in the Register that corresponds to the AUST L number on the label; and
 - iii. does not contain any name for the therapeutic sunscreen other than the name corresponding to the AUST L number on the label; or
 - b. destroy the goods.

PART E: Demonstrating compliance with the Direction

To demonstrate that you have complied with the Direction set out above, we request that you email evidence of your compliance to nonprescriptionmedicines@health.gov.au within 5 business days of the date by which you are required to comply with each direction.

You are not legally required to provide that evidence, and this request does not form part of the things you are being required to do under this Direction as set out in Part D above. You are nonetheless encouraged to do so to assist the TGA in assessing whether the Direction has been complied with, and whether the compliance issues that have resulted in the Direction are resolved.

If the evidence is not voluntarily provided, the TGA may compel you to produce the relevant information and documents under a notice to produce issued under an appropriate provision of the Act.

Your evidence of compliance should identify what has been done in relation to the sunscreens manufactured by Veganic SKN which bear each of the AUST L numbers listed in Table 1.

Examples of evidence you can provide include:

In relation to Direction 1, by 5 May 2026, please provide:

- copies of internal correspondence directing staff to cease supply of goods and any responses confirming cessation of supply; and
- copies of correspondence to purchasers advising of the TGA's direction to quarantine the goods.

In relation to Direction 2, by 16 October 2026, please provide:

- copies of new labels or packaging for the goods;
- copies of the records kept in relation to the steps in manufacture involved in repackaging or relabelling the goods;
- copies of invoices or other records relating to the destruction of the goods; and
- batch manufacturing records showing the rectified labels have been used in the production and release for supply records.

PART F: 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. The relevant legislation is reproduced at **Attachment C** to this Notice.

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 the conduct in relation to which this Direction was issued.

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

Publication of enforceable direction

It is the TGA's usual practice to publish decisions to give an enforceable direction.³ This practice ensures regulatory transparency.

Consistent with that practice, a delegate of the Secretary is considering publishing this Direction and a web statement summarising the content of the Direction under s 61(5A) and s 61(7)(b) of the Act. If the delegate decides to publish this information, the publication will be available at [Media releases | Therapeutic Goods Administration \(TGA\)](#).

³ See, for example, the enforceable direction under s 42YT of the Act at URL <https://www.tga.gov.au/news/regulatory-decision-notice/enforceable-direction-hwangbo-ss-pty-ltd-and-redacted> and other regulatory decision notices at URL <https://www.tga.gov.au/news/regulatory-decision-notice>.

Review rights

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

Signed and authorised by

[REDACTED]

[REDACTED]

Listing Compliance Section
Complementary and OTC Medicines Branch
Telephone: [REDACTED]
Email: [REDACTED]

22 April 2026

Enclosures

Attachment A – List of advertisements depicting sunscreens bearing Veganic SKN Limited AUST L numbers

Attachment B – Screen captures of advertisements identified in Attachment A

Attachment C – Relevant legislation

Attachment D – Information about review rights

Attachment C – Relevant legislation

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 and 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) repackage 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 D – 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

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.

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 dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to: