

7 December 2022

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Director-General of Health  
Manatū Hauora | Ministry of Health

By email: diana.sarfati@health.govt.nz

Tēnā koe Dr Sarfati,

### Product safety requirements for vaping products

1. I have been instructed by Powle & Hodson Lawyers, which represents VEC Ltd and ALT New Zealand Ltd, New Zealand companies that manufacture, sell and distribute vaping products. VEC and ALT, which trade as “VAPO” and “alt.” respectively, are wholly independent of the tobacco industry.
2. Powle & Hodson Lawyers have asked me to write to you directly in response to the Vaping Regulatory Authority’s (**VRA**) recent correspondence with manufacturers, importers and retailers of vaping products. In particular, I raise matters of considerable concern about the VRA’s interpretation of the product safety requirements for vaping products and about the process the VRA has followed in grappling with this issue.
3. The VRA has misinterpreted in a material way the permissible nicotine strength levels in the relevant regulations. Its misinterpretation will have a profound effect on the ability of New Zealanders to stop smoking through the use of vaping products.

### *Legislative framework*

4. Under the Smokefree Environments and Regulated Products Act 1990 (**Act**) a manufacturer, importer or retailer of a vaping product must not sell a vaping product in New Zealand<sup>1</sup> unless the product:
  - a. has been notified (and that notification has not expired/been recalled, suspended or cancelled);<sup>2</sup> and
  - b. complies with all product safety requirements.

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<sup>1</sup> Smokefree Environments and Regulated Products Act 1990, ss 60 and 65.

<sup>2</sup> Smokefree Environments and Regulated Products Act 1990, ss 62 and 63; Smokefree Environments and Regulated Product Regulations 2021, reg 77.

5. The product safety requirements for vaping products are set out in Schedule 5 to the Smokefree Environments and Regulated Product Regulations 2021 (**Regulations**), the relevant component of which provides:

*Nicotine*

14 The strength of free-base nicotine in a vaping substance must not exceed 20mg/mL.

15 The strength of nicotine salt in a vaping substance must not exceed 50mg/mL.

16 The total nicotine content in a container of vaping substance sold at retail must not exceed 1,800 mg, whether it is present as free-base nicotine or nicotine salts.

6. The Regulations came into force on 11 August 2021.
7. Although notification did not become mandatory until 11 February 2022,<sup>3</sup> VEC has been notifying its vaping products since August 2021.
8. Clause 15 has, both within the Ministry and throughout the industry, always meant that the *nicotine strength* in a vaping substance made using nicotine salts could not exceed 50mg/mL. It does not mean that the amount/level/concentration of *nicotine salt* in a vaping substance must not exceed 50mg/mL. That would result in a significantly reduced nicotine strength in vaping products, which would be at odds with the measures put in place when the Regulations were drafted, and which would undermine the ability of vaping substances to act as a tool to stop people from smoking.
9. However, the VRA has concluded recently that clause 15 means that the *concentration of nicotine salt* (generally nicotine benzoate) must be no more than 50mg/mL. That, the VRA has concluded, means that the actual nicotine strength of a 50mg/mL nicotine salt vaping substance would be approximately 28mg/mL.
10. Accordingly, suddenly and erroneously, products with a previously acceptable concentration of nicotine salt of around 80mg/mL, with a corresponding *nicotine strength* of less than the 50 mg/mL limit, are being regarded as non-complying.
11. The fact that clause 15 in schedule 5 to the Regulations has been universally understood to refer to nicotine strength – and not to nicotine salt content – has its genesis in the consultation process undertaken by Manatū Hauora | Ministry of Health (**Ministry**) when the Regulations were proposed. Although the proposed language was the same - “The strength of nicotine salt in vaping substances must not exceed 50 mg/mL”,<sup>4</sup> the accompanying public consultation document explained:<sup>5</sup>

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<sup>3</sup> <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products/vaping-information-all-industry/product-notification-applications>

<sup>4</sup> <https://www.health.govt.nz/system/files/documents/publications/appendix-a-product-safety-requirements-21dec2020.pdf>

<sup>5</sup> [https://www.health.govt.nz/system/files/documents/publications/smokefree-environments-regulated-products-act-1990-proposals-regulations-public-consultation-document\\_21dec2020.pdf](https://www.health.govt.nz/system/files/documents/publications/smokefree-environments-regulated-products-act-1990-proposals-regulations-public-consultation-document_21dec2020.pdf)

**Nicotine strength.** We propose limiting the strength of nicotine allowed in vaping substances to not exceed 20mg/mL for free-base nicotine and 50mg/mL for nicotine salt.

12. It follows that public consultation was predicated on nicotine strength of 50mg/mL where the vaping substance was made with nicotine salt. The Ministry explained:<sup>6</sup>

Nicotine salts are less alkaline than free-base nicotine, allowing higher concentrations that provide nicotine absorption levels closer to those from smoking cigarettes. Nicotine salts may be an effective alternative for long-term smokers.

13. Additionally, the Ministry’s notification systems affirm VEC’s understanding of clause 15. The Ministry’s “Product Notification applications” webpage, which provides information on the notification process, hyperlinks to a sample Excel template.<sup>7</sup> Under the heading *Nicotine Strength*, two of the tabs on the template - “HARP VRA Notification Sample Data” and “Field Value Selection” - show a range of possible nicotine levels *up to and including 50mg/mL*:

| Product_Type                       | PG:VG_ratio | Nicotine_Strength  | Container_Size | CAS_Number    | Proprietary | Method_Of_Use                             | P_Quantity |
|------------------------------------|-------------|--|----------------|---------------|-------------|---|------------|
| Freebase Nicotine Vaping Substance | 0:100       | Freebase: (0mg,3mg,6mg,9mg,12mg,18mg)  | 10mL           | XXXXXXXX-YY-Z | N           | Dermal - absorption through the skin      | 20         |
| Kit                                | 10:90       | Salts: (3mg,5mg,6mg,9mg,10mg,12mg,15mg,20mg,24mg,25mg,30mg,35mg,36mg,40mg,48mg,50mg) | 15mL           |               | Y           | Nasal - sniffing                          | 25         |
| Nicotine Salt Vaping Substance     | 20:80       |  | 20mL           |               |             | Oral - absorption through the oral mucosa |            |
| Smokeless Tobacco Product          | 30:70       |  | 30mL           |               |             | Oral - chewing                            |            |
| Vaping Device                      | 40:60       |  | 40mL           |               |             | Oral - inhalation                         |            |
|                                    | 50:50       |  | 50mL           |               |             | Oral - sucking                            |            |
|                                    | 60:40       |  | 60mL           |               |             |   |            |
|                                    | 70:30       |  | 70mL           |               |             |   |            |
|                                    | 80:20       |  | 80mL           |               |             |   |            |
|                                    | 90:10       |  | 90mL           |               |             |   |            |
|                                    | 100:0       |  | 100mL          |               |             |   |            |
|                                    |             |  | 110mL          |               |             |   |            |
|                                    |             |  | 120mL          |               |             |   |            |

14. This is consistent with the Ministry’s online database, the Health Advisory and Regulatory Platform (HARP), which was established under s 77 of the Act for the purposes of notification. Under the heading *Nicotine Strength*, HARP provides a drop-down menu with a number of tick options, which allow a notifier to select nicotine strength levels *up to and including 50mg/mL*:

<sup>6</sup> Above n 4.

<sup>7</sup> Above n 3.

Nicotine Strength\*

42mg

44mg

45mg

46mg

47mg

48mg

50mg

\* Select all applicable nicotine strengths. Round up to the next higher strength if not listed.

\* Select all applicable container sizes.

Select to add another product to this notification.

### VRA's correspondence to notifiers

15. Notwithstanding that this has been the Ministry's position and the accepted industry practice from the outset, the VRA has recently departed materially and erroneously from that position. This occurred abruptly and without any consultation with the industry, technical experts and/or other stakeholders.
16. In an email of 27 October 2022, the VRA advised all manufacturers, importers and retailers of vaping products that, in terms of clause 15, the "50 mg/mL limit in vaping substances refers to the permitted concentration of **nicotine salt** in a substance, not the concentration of nicotine" (emphasis in original). The VRA noted that "a number of nicotine salt vaping substances are being sold in New Zealand that do not comply with [the] concentration limit for nicotine salts ... based on a misunderstanding" of clause 15.
17. The VRA then wrote to VEC (and other notifiers) on 21 November 2022, identifying a number of notified products which the VRA alleges may be non-compliant with the product safety requirements because the nicotine salt concentration exceeds 50mg/mL. In reliance on s 71 of the Act, the VRA has now required VEC to provide information about each of the identified products by 9 December 2022.

### Analysis

18. VEC is in the process of compiling that information.
19. However, I consider it to be clear that the VRA has itself misinterpreted clause 15 of Schedule 5 to the Regulations; as the Ministry has indicated from the outset, it is the *nicotine strength* of a vaping product made with nicotine salt that must not exceed 50mg/mL; not the *amount of nicotine salt* in the product.

20. Despite the awkward drafting of clause 15, I consider that the above meaning is the only available interpretation, having regard to the text and purpose of the provision, as well as the context.<sup>8</sup>

### Text

21. There are two textual indicators that it is the nicotine strength that is the focus of this provision. The first is the fact that clause 15 falls under the general heading “Nicotine”.<sup>9</sup> In other words, the product safety requirement is concerned with nicotine levels, not nicotine salt levels. This emphasis is also apparent in the text of the surrounding clauses, namely, clauses 14 and 16.
22. The second textual indicator is the use of the word “strength”. If the VRA’s interpretation is correct, one would expect the use of the word “amount” or “content”; “strength” is not a natural fit. The use of the word “strength” in clause 15 appears to be a shorthand for “nicotine strength”. “Nicotine strength” is the phrase used in regulation 77(2)(c), which prescribes the requirements for product notification, in Forms 3 and 4 of the Regulations, and in the Ministry’s notification mechanisms described at [13] and [14] above. This makes sense as it is the nicotine strength of a vaping product that is pertinent to the consumer.<sup>10</sup>
23. It follows that clause 15 proscribes a *nicotine strength* in excess of 50mg/mL where the vaping substance is made using nicotine salts.

### Purpose

24. This understanding of clause 15 is consistent with one of the principal purposes of the Act, which is “to support smokers to switch to regulated products that are significantly less harmful than smoking”.<sup>11</sup>
25. For the reasons that follow, this purpose simply cannot be achieved if the VRA’s interpretation of clause 15, which would cap nicotine content at 28.5mg/mL for vaping products made using nicotine salt,<sup>12</sup> is correct.
26. The Associate Minister of Health, in a Cabinet Paper entitled “Supporting smokers to switch to significantly less harmful alternatives”, made the following observations:<sup>13</sup>

New Zealand has a goal to be smokefree by 2025. This is generally agreed to mean that fewer than five percent of New Zealanders will smoke daily. Achieving this will be challenging.

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<sup>8</sup> Legislation Act 2019, s 10(1).

<sup>9</sup> Legislation Act 2019, s 10(3) and (4).

<sup>10</sup> Smokefree Environments and Regulated Product Regulations 2021, Schedule 5, clause 1(i).

<sup>11</sup> Smokefree Environments and Regulated Product Act 1990, s 3A(d).

<sup>12</sup> Email from Sam Horsefield to notifiers of 27 October 2022: “the maximum permitted nicotine concentration in a vaping substance containing fully dissolved nicotine benzoate would be 28.5 mg/mL”.

<sup>13</sup> Cabinet Paper “Supporting smokers to switch to significantly less harmful alternatives” at [14] - [22].

### *Supporting smokers to reduce their harm from tobacco*

While many people want to quit smoking, it can be very hard to do so, particularly for those who face complex challenges in life.

...

The emergence of vaping products ... provides smokers with more choice. Many smokers who find it hard to quit may be able to switch to less harmful and often much cheaper alternatives.

The benefits to a smoker of switching include reducing the direct risks to their health and to their children's health from second-hand smoke, reducing the likelihood that their children will become smokers, and increasing their disposable income.

...

#### *Harm reduction and support for smoking cessation*

The tar and toxins in tobacco smoke, rather than the nicotine, are responsible for most of the harm associated with tobacco use. Vaping and smokeless tobacco products do not combust and are, therefore, highly likely to be much less harmful than smoking.

There is scientific consensus that vaping is significantly less harmful than smoking (around 95%). It is likely that vaping can also help smokers to stop smoking, but the evidence for vaping as an effective tool is still emerging.

27. In order to support smokers to switch to vaping, the nicotine levels of vaping products need to be comparable to cigarettes. The smoker needs to experience a similar physiological reaction.
28. In that regard, the Technical Expert Advisory Group on Electronic Cigarette Product Safety (**TEAG**), appointed by the Ministry, agreed unanimously that:<sup>14</sup>
  - a. "low nicotine strength may affect acceptability and switching from smoking to vaping"; and
  - b. "20mg per mL (Europe standards) was too low".
29. The TEAG proceeded to advise the Ministry that it should adopt a "60 mg/mL limit *for nicotine* in vaping liquids made using nicotine salts" and a "36 mg limit *for nicotine* in vaping liquids made using free-base nicotine".<sup>15</sup>
30. The TEAG's final advice confirms two critical points. First, it confirms VEC's interpretation of clause 15, namely, that it is the *nicotine* strength in a vaping substance made using nicotine salts which must not exceed 50mg/mL; not the proportionate amount of nicotine salt. The TEAG was not at all concerned with the composition or the concentration of the nicotine salt.
31. Secondly, it confirms the expert view that 20mg/mL is too low, and that an upper limit of 36mg/mL (where free-base nicotine is used) or 60mg/mL (where nicotine salt is used) is appropriate for smoking cessation purposes. The VRA's proposed nicotine strength cap of 28.5mg/mL for vaping

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<sup>14</sup> TEAG minutes of 11 December 2017 at item 4.

<sup>15</sup> TEAG minutes of 25 June 2018 at item 3 under the heading "Limit on nicotine strength" (emphasis added).

products made using nicotine salt,<sup>16</sup> falls well short of these figures. That amount would be insufficient to enable a person to switch from smoking to vaping.

32. Incidentally, the use of vaping to support New Zealand's smokefree 2025 goal appears to have been effective. In November, the Associate Minister of Health announced that, in the last decade, New Zealand's smoking rates have halved and that, in the last 12 months, a quarter of Māori women have quit smoking.<sup>17</sup>
33. For completeness, I note that - when the issue was first raised by a reporter from Fair Go - the VRA manager expressed uncertainty to his colleagues as to the proper interpretation of clause 15. He suggested "look[ing] at Vaping TEAG notes from when they were discussing/recommending nicotine limits to see if that was how they intended it".<sup>18</sup> A VRA senior advisor responded "I've had a look through the TEAG minutes and haven't found any specific mention on whether the limit in the regs applies to the overall nicotine salt or simply the nicotine".<sup>19</sup>
34. As noted at [29] above, the TEAG did, in fact, address the issue squarely; it recommended a "60 mg/mL limit *for nicotine* in vaping liquids made using nicotine salts". Unfortunately, the TEAG's recommendation appears to have been overlooked, and the VRA manager was deprived of the opportunity to consider clause 15 with the TEAG's clear intent in mind.
35. The email exchanges between the VRA staff members disclosed under the Official Information Act 1982 show that the new and erroneous interpretation of the Regulations is based upon their own views and assumptions and without the benefit of considering information of the type that has been identified in this letter.<sup>20</sup>

### Context

36. The final factor which supports VEC's interpretation of clause 15 is the pharmaceutical context in which the Regulations sit. The pharmaceutical industry is focussed on identifying, measuring and recording the *active* ingredient in a product. The active ingredient in vaping products is nicotine, not the nicotine salt. This is the proper focus of clause 15.
37. Having regard to the text, purpose and context, and to the Ministry's own interpretation of clause 15 (as set out at [8] to [11] above), it is clear that it is the nicotine - rather than the nicotine salt - which must not exceed 50mg/mL.

### *Impact*

38. The VRA's interpretation of clause 15 would have a materially disruptive effect on the industry. By way of example, VEC would be prohibited from selling 18 of its 20 top-selling products. The impact

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<sup>16</sup> Email from Sam Horsefield to notifiers of 27 October 2022: "the maximum permitted nicotine concentration in a vaping substance containing fully dissolved nicotine benzoate would be 28.5 mg/mL".

<sup>17</sup> <https://www.beehive.govt.nz/release/new-zealand-records-lowest-smoking-rate-ever>.

<sup>18</sup> Email from Matthew Burgess to Sam Horsefield and Stephanie Parlane of 19 October 2022 at 10:42pm.

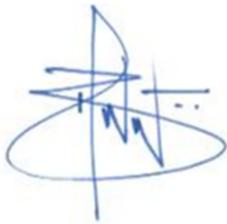
<sup>19</sup> Email from Sam Horsefield to Matthew Burgess and Stephanie Parlane of 20 October 2022 at 9:20am.

<sup>20</sup> Email exchanges between Matthew Burgess, Sam Horsefield and Stephanie Parlane from 19 - 25 October 2022.

is not only a significant financial one for VEC and other industry participants - there would also be adverse health outcomes for people who wish to stop smoking.

39. As Action for Smokefree 2025 (**ASH**) explained to the VRA, in its email of 28 October 2022, the 50mg/mL vaping products are widely-used in cessation programmes and by individuals who wish to stop smoking.
40. It follows that there are a number of people who depend on these vaping products to become and remain smoke-free and that the VRA's actions will force those people to revert to smoking cigarettes, in defiance of the objectives of the Act.
41. Because of these profound health and financial impacts, any shift away from the TEAG's expert advice to the Ministry, and from the settled understanding of the ambit of clause 15, would have to occur in a careful and considered way.
42. Unfortunately this is not what has occurred here; in the space of a single week following Fair Go's inquiry, the VRA has – through a misinterpretation – moved away from the proper interpretation of clause 15, to publicly criticising the industry on the basis of a mistaken view that it has failed to comply with the product safety requirement in clause 15. These are the most significant issues with the process that has been followed.
43. Over the last month, VEC has on a number of occasions expressed a desire to meet with the Ministry to engage in a constructive dialogue about the regulation of the vaping industry, including the nicotine strength in vaping products. That continues to be its position. VEC asks that its request be accommodated before any further action is taken by the VRA under the Act. VEC reserves its right to take further steps in the event that the VRA maintains its flawed interpretation of clause 15, and fails to confirm the correct legal position for the industry and to the public.

Nāku noa, nā



**Paul Radich KC**