

Dr Diana Sarfati
Director-General of Health

FROM **Tania Goatley / Sarah Brougham**
DDI +64 9 916 8766
MOBILE +64 21326731
EMAIL tania.goatley@bellgully.com
EMAIL sarah.brougham@bellgully.com
MATTER NO 404-2264
DATE 25 November 2022

Dear Dr Sarfati

Letter to Director-General of Health on behalf of BAT New Zealand regarding Vaping Regulatory Authority action against Nicotine Salt content in Vaping Products

We are instructed to write to you on behalf of BAT New Zealand (**BATNZ**).

You are likely already aware of communications between the Vaping Regulatory Authority (**VRA**) and participants in New Zealand's vaping industry in relation to its interpretation of the maximum nicotine salt strength permitted in a vaping substance, as prescribed in Sch 5, Pt 1, r 15 of the Smokefree Environments and Regulated Products Regulations 2021 (the **Nicotine Salt Regulation**).

As far as BATNZ is aware, this is the first time interpretative guidance regarding the Nicotine Salt Regulation has been issued since the Nicotine Salt Regulation first came into force on 11 August 2021.

The Nicotine Salt Regulation is part of the suite of product safety regulations passed under the Smokefree Environments and Regulated Products Act 1990 (**SERPA**) and the Smokefree Environments and Regulated Products Regulations 2021 (**Regulations**). To promote compliance with the product safety regulations, the product notification regime set out in Part 4 of the SERPA was introduced. The purpose of the notification regime is to "regulate the safety of notifiable products." This specific purpose sits alongside the overall purposes of the SERPA, which includes "supporting smokers to switch to regulated products that are significantly less harmful than smoking." Vaping products play a vital role in working towards this Government's Smokefree Aotearoa 2025 goal.

The product notification regime requires notifiers (manufacturers and importers of notifiable products) to notify products on the database maintained by the Director-General of Health before those products can be lawfully sold in New Zealand. At all times, all of BATNZ's nicotine salt containing vaping products have been notified on the Director-General's database.

We are instructed there is a material difference between the interpretative guidance recently issued by the VRA and the way many market participants have interpreted the Nicotine Salt Regulation since the draft regulation was first proposed for public consultation in January 2021. Had BATNZ understood at the time that the proposed Nicotine Salt Regulation was intended to have the interpretation now advanced by the VRA, it would have firmly submitted that the proposed regulation required amendment to specifically address the interpretation issue which is now apparent, and to properly accommodate for the substantial volume of nicotine salt vaping products in the market. If the VRA's recent interpretative guidance is enforced, it will have a significant

impact on New Zealand's vaping market and smokers attempting to "switch to regulated products that are significantly less harmful than smoking."

We are instructed to contact you to ensure the Director-General's office is aware of BATNZ's concerns regarding due process and procedural fairness at this stage. Despite several requests, the VRA has refused to meet with sector representatives to discuss its recent interpretation of the Nicotine Salt Regulation. To date, BATNZ believes it has not been given a fair opportunity to be heard on this matter, particularly in a context where it appears the VRA may ultimately move to suspend or cancel BATNZ's product notifications for products containing nicotine salts. BATNZ is also concerned as to the reasonableness of the VRA's interpretation of the Nicotine Salt Regulation, its procedural approach, and its refusal to engage with industry participants who (and whose customers) are directly and materially impacted by the VRA's interpretative guidance.

On 2 November BATNZ requested an opportunity to discuss this matter with the VRA. That request included an offer to make its global scientific representatives available to the VRA and the Ministry of Health. The VRA has not responded to that request, including to acknowledge receipt. Instead, on 21 November the VRA issued a s 71 request for information to BATNZ requiring a response within a period of only 9 working days (despite the broad and technical nature of the s 71 request and the existence of a statutory offence if BATNZ fails to meet the VRA's deadline).

On 23 November BATNZ was one of 10 signatories to a letter sent to the Associate Minister of Health, which has similarly not been acknowledged. Most recently, and perhaps most importantly for present purposes, BATNZ wrote to the VRA on 23 November requesting an extension to the VRA's 21 November request.

For the reasons set out in its 23 November letter, BATNZ does not believe 9 working days is a reasonable time period for collating the large volume of technical information the VRA has requested. It formally requested that the VRA grant an extension, and sought confirmation of whether the extension was acceptable by no later than **12 noon today, 25 November**.

Unfortunately, the VRA has failed to respond to, or acknowledge, BATNZ's 23 November letter, prompting this letter to you (out of some urgency).

We are instructed to advise the Director-General that we will appear on behalf of BATNZ in the event judicial review or declaratory judgment proceedings become appropriate or necessary.

However, BATNZ remains hopeful formal legal proceedings and other appeal processes should not be necessary, and that this matter can be resolved by appropriate consultation and open dialogue between the regulator and affected industry participants.

To that end, we are instructed to firmly reiterate BATNZ's request for an urgent meeting with the VRA or the Director-General to discuss the recent interpretative guidance issued regarding the Nicotine Salt Regulation, and to better understand how this might impact New Zealand's vaping industry moving forwards, and how vaping industry participants can work collaboratively with the regulatory bodies to ensure minimal disruption and confusion to customers, particularly those who rely on vaping products containing nicotine salts as less harmful alternatives to smoking.

We also request an urgent response, and by no later than **12pm Monday 28 November**, to BATNZ's 23 November letter and its reasonable request for an extension to enable it to meet the VRA's 21 November request for information.

We look forward to hearing from you.

Yours faithfully
Bell Gully

A handwritten signature in blue ink, appearing to read 'Tania Goatley' or 'Sarah Brougham', written in a cursive style.

Tania Goatley / Sarah Brougham
Partner / Associate