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29 March 2021

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ACCC submission to the Therapeutic Goods Administration consultation on vaporiser nicotine products

The Australian Competition and Consumer Commission (ACCC) welcomes the opportunity to make a submission in response to the Therapeutic Goods Administration (TGA) consultation paper on a proposed standard for vaporiser nicotine products (consultation paper).

The ACCC supports the TGA's efforts to regulate vaporiser nicotine products under the *Therapeutic Goods Act 1989* in the form of Therapeutic Goods Order 110 (TGO 110) and recommends expanding the scope of TGA 110 to include all personal vaporiser products, not just those containing nicotine. This will ensure regulatory gaps are not created in relation to non-nicotine flavoured liquids used in e-cigarettes or personal vaporisers (e-liquids), which consumers can mix with unflavoured nicotine liquid or salt concentrate to create a therapeutic good used as a smoking cessation aid.

The ACCC refers to its previous submissions to the Department of Health's review of tobacco control legislation,¹ the Parliamentary inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia,² and the TGA's interim decision to amend the Poisons Standard in relation to nicotine.³

We consider the overall system of e-cigarettes and related products to be an important public health issue. This health issue will only be successfully addressed if the administration and enforcement of all legislative interventions concerning e-cigarette products, including e-liquids, are enacted by a specialist health regulator or agency, such as the TGA or the Department of Health.

ACCC role in relation to e-cigarettes and e-liquids

As Australia's competition and consumer protection agency, the ACCC has a role in ensuring products are marketed in a way that is truthful and seeks to ensure that consumer goods sold in Australia are safe. The ACCC does this by administering and enforcing the *Competition and Consumer Act 2010* (Cth), which includes the Australian Consumer Law (ACL). The ACCC uses the product safety provisions of the ACL to address the safety of

¹ [ACCC submission to the Standing Committee on Health, Aged Care and Sport's inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia 3 July 2017](#)

² [ACCC submission to the review of tobacco control legislation 8 April 2019](#)

³ [ACCC submission to the Therapeutic Goods Administration on nicotine scheduling](#)

consumer goods. The ACL defines 'consumer goods' as goods intended to be used or likely to be used for personal, domestic or household use.⁴

The ACCC's consumer product safety role does not extend to specific regulatory responsibility for the safety of e-cigarettes or e-liquids. Consistent with the Government's Statement of Expectations,⁵ the ACCC seeks to avoid regulatory duplication. Where a matter relates to a specialist regime, such as nicotine scheduling by the TGA, the ACCC will refer it to the relevant agency for consideration. The ACCC does not hold the same level of technical expertise as the TGA in relation to the safety, quality or efficacy of e-cigarette devices or e-liquids.

Where an e-cigarette is a consumer good and is not captured by the regulatory framework of the TGA and the Department of Health, the ACCC's involvement may be formally triggered where a consumer good causes 'serious injury or illness' through 'use or foreseeable misuse'. Serious injury or illness is defined in the ACL as an acute physical injury or illness that requires medical or surgical treatment by, or under the supervision of, a medical practitioner or a nurse (whether or not in a hospital, clinic or similar place).⁶

This definition means the focus of the ACCC is on acute physical injuries or illnesses, which do not include an ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development) or the recurrence or aggravation of such an ailment, disorder, defect or morbid condition. Such acute physical injuries or illnesses are the traditional province of the ACCC and are distinguishable from public health issues such as potential illnesses that have a delayed onset (not acute) and may be associated with inhalation of, and exposure to, carcinogens.

Scope of TGO 110

TGO 110 has been proposed to specify safety and quality rules to mitigate the safety risks posed by vaporiser nicotine products identified by the TGA as medicines. It is proposed that TGO 110 will regulate these products through ingredient labelling, nicotine concentration labelling, warning statements, prohibiting certain ingredients, and child-resistant packaging.

Limiting the scope of TGO 110 to only nicotine liquid and salt products intended for use in e-cigarettes and personal vaporisers will create a regulatory gap for non-nicotine flavoured e-liquids that consumers purchase to mix with nicotine concentrates.

Concentrated nicotine products are readily available for purchase on numerous retail websites that sell to Australia. The same websites offering nicotine concentrate products also provide guidance to consumers on mixing the nicotine concentrate with non-nicotine flavoured e-liquid.

Consumers that choose to mix nicotine concentrates with non-nicotine flavoured e-liquid will have access to the same type of product intended to be regulated by TGO 110, but without the minimum safety and quality requirements that TGO 110 intends to provide because non-nicotine flavoured e-liquid is outside of the scope proposed to be regulated. Consumer mixed e-liquids (non-nicotine e-liquids mixed with nicotine concentrates) would remain unregulated under the proposed scope of TGO 110, and also would not be subject to child-resistant packaging requirements, which aim to address the risk of poisoning to young children.

The ACCC submits that regulation of non-nicotine e-liquid should not be de-coupled from nicotine e-liquid regulation. We recommend expanding the scope of TGO 110 to include

⁴ Australian Consumer Law s 2(1).

⁵ [Australian Government Statement of Expectations – Australian Competition and Consumer Commission](#)

⁶ Australian Consumer Law s 2(1).

non-nicotine e-liquid products to prevent regulatory gaps. Expanding the scope will also ensure that the risks and harms associated with consumer mixed e-liquids are mitigated, and consumer-mixed products are afforded the same minimum safety and quality requirements as nicotine e-liquids.

If non-nicotine e-liquid products cannot be specified within TGO 110 or a Therapeutic Goods Order more broadly, we recommend the TGA consider a complimentary standard for these products using an appropriate regulatory function under the *Therapeutic Goods Act 1989*.

E-liquid ingredient safety

The consultation paper identifies several flavouring and diluent ingredients in e-liquids that may have a harmful effect on human health. As such, the TGA's preferred option identified within the consultation paper is for TGO 110 to prohibit these ingredients in all nicotine e-liquids.

In addition to the unsafe ingredients identified by the TGA, e-liquid safety risks have been identified in a recent Curtin University study⁷ that investigated the ingredients and toxicity of 52 e-liquids in their original and heated (vaped) form that were available for purchase in Australia. According to the authors, the study is the most comprehensive examination of the composition and toxicity of e-liquids available in Australia. The results of the study were presented to a group of public health experts on 3 December 2020, finding that:

- 100 per cent of e-liquids had between 1 to 18 chemicals which have unknown effects on respiratory health
- None of the brands had a complete accurate ingredient list
- 21 per cent of e-liquids contained nicotine
- 62 per cent of new e-liquids and 65 per cent of vaped e-liquids contained chemicals likely to be toxic if vaped repeatedly.

Prior to the TGA and Curtin University's findings, in 2015, the ACCC commissioned independent testing that identified the presence of known carcinogens and toxic chemicals in commercially available e-liquid products sold by 3 online e-cigarette retailers. The testing was part of enforcement action against these online retailers in which the Federal Court found the retailers contravened the ACL by making representations that their products did not contain harmful carcinogens and toxins, when this was not the case.⁸ The testing identified the presence of known carcinogens and toxic chemicals, such as formaldehyde, acetaldehyde and acrolein in the products tested, as well as acetone in another product.

The above research and testing findings demonstrate there is a real and urgent need to consistently regulate both nicotine and non-nicotine e-liquid to mitigate preventable injuries and illnesses to e-cigarette users.

The issue of e-liquid safety and regulation, both nicotine and non-nicotine, remains one of public health policy and should be overseen by a nationally consistent regulatory framework. Expanding the scope of TGA 110 to include non-nicotine e-liquid will ensure that the safety and regulation of nicotine e-liquid is not de-coupled from non-nicotine e-liquid products. It will also ensure the same level of regulation for harms and risks associated with e-liquid ingredients that the TGA and other studies have identified as posing a risk to human health.

⁷ <https://lungfoundation.com.au/news/ground-breaking-australian-study-confirms-major-concerns-over-e-cigarette-safety/>

⁸ <https://www.accc.gov.au/media-release/e-cigarette-companies-to-pay-penalties>

Nicotine e-liquids

The consultation paper identifies nicotine e-liquids and other vaporiser products as medicines, and also identifies that they are used in vaping devices such as e-cigarettes and other electronic nicotine delivery systems. However, we understand that there are no e-cigarette or vaping devices currently registered with the TGA on the Australian Register of Therapeutic Goods. Additionally, the recently published Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021 excludes all vaping devices from regulation as therapeutic goods, except those used exclusively to administer a medicine (including vaporiser nicotine). This includes excluding devices used to administer vaporiser nicotine mixed with other substances, such as non-nicotine flavoured e-juice.

Although the proposed TGO 110 seeks to provide quality and safety requirements for nicotine e-liquids, consumers of the nicotine products have no way of administering the vaporiser nicotine medicine except via an unassessed and unapproved e-cigarette or personal vaporiser device. The ACCC is concerned about the unknown safety risks that this situation may present to consumers and recommends the TGA consider the safety risks of a regulated medicine being administered through unregulated devices, in order to address any potential safety risks.

If you would like to discuss this submission, please contact Neville Matthew, General Manager, Risk Management and Policy, Consumer Product Safety Branch on 02 6243 1066 or at neville.matthew@accc.gov.au.

Yours sincerely

A handwritten signature in black ink that reads "Delia Rickard". The signature is written in a cursive, flowing style.

Delia Rickard
Deputy Chair