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Therapeutic Goods Administration  
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*Sent via the TGA Consultation Hub*

### **ACCC submission to the Therapeutic Goods Administration on nicotine scheduling**

The Australian Competition and Consumer Commission (ACCC) welcomes the opportunity to make a submission to the Therapeutic Goods Administration (TGA) interim decision to amend the Poisons Standard in relation to nicotine, dated 23 September 2020. We have also made a submission on the same terms to the Senate Select Committee on Tobacco Harm Reduction inquiry into tobacco reduction strategies.

The ACCC continues to hold the views expressed in our previous submissions to the Department of Health's review of tobacco control legislation,<sup>1</sup> and the Parliamentary inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia.<sup>2</sup>

We consider the overall system of tobacco and nicotine control is an important public health issue that will be improved if the administration and enforcement of all legislative interventions that concern tobacco related products are centralised within the health portfolio. This includes e-cigarettes, electronic nicotine delivery systems, personal vaporisers, and novel and emerging tobacco products (including smokeless tobacco such as chewing tobacco and snuff).

The safety risks and harms posed by e-cigarettes and related products, such as e-liquid, primarily relate to their use, possession, storage, and availability. These matters can only be successfully addressed by a specialist health regulator or agency, such as the Department of Health or the TGA.

Other potential risks presenting from e-cigarettes, such as the electronic heating element, battery, and charging components, are ideally best addressed by specialist state and territory electrical safety regulators. Unfortunately not all regulators have appropriate jurisdiction, and given this and for the reasons outlined below, regulation by a specialist health regulator or agency will ensure an integrated regulatory framework and minimisation of compliance costs.

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<sup>1</sup> 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 <https://www.accc.gov.au/system/files/Tobacco%20-%20ACCC%20submission%20to%20the%20Review%20of%20Tobacco%20Control%20Legislation%20-%20signed%20by%20COO%208%20April%202019.PDF>

<sup>2</sup> ACCC submission to the review of tobacco control legislation 8 April 2019 <https://www.accc.gov.au/system/files/ACCC%20submission%20to%20the%20inquiry%20into%20electronic%20cigarettes%20and%20personal%20vaporisers%20-%203%20July%202017.pdf>

It is important to note that the ACCC's consumer product safety role does not extend to the development of health policy for e-cigarettes or novel tobacco products. The ACCC has responsibility for administering three specific instruments related to tobacco products:

- Consumer Protection Notice No.10 of 1991 (Smokeless Tobacco)
- Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008 No.195
- Competition and Consumer (Tobacco) Information Standard 2011

The first two instruments listed remain in the ACCC's remit as they were grandfathered during the transformation of the *Trade Practices Act 1968* into the *Competition and Consumer Act 2010*. The third instrument relates to health warnings on tobacco packaging, which was developed by the Department of Health in parallel with the development of the tobacco plain packaging legislation. The two were separated in apprehension of a legal challenge to the plain packaging legislation. All three instruments no longer align with the ACCC's general consumer product safety role.

### **TGA interim decision to amend the Poisons Standard in relation to nicotine**

The ACCC supports the efforts of the TGA to regulate e-cigarettes and novel nicotine delivery systems. This includes the TGA's interim decision on the proposed amendment to re-schedule nicotine for human use from Schedule 7 to Schedule 4 of the Poisons Standard (other than nicotine in tobacco prepared and packed for smoking or smoking cessation aids), so that nicotine in products such as e-cigarettes, e-liquid, chewing tobacco, heat-not-burn tobacco products, and snuff, can only be supplied with a doctor's prescription.

#### *Child resistant closures*

The ACCC also supports the introduction by the TGA of child resistant closures and packaging for liquid nicotine products, to mitigate the exposure risk of ingestion by children.

Children are vulnerable and may be attracted to e-liquids marketed, scented, and flavoured as novelty scents and flavours, such as chocolate or bubble-gum. If these liquids contain high levels of nicotine and are ingested by a child, they could cause serious illness or death. Several deaths overseas have been linked to children ingesting nicotine e-liquid, as well as one death in Australia in 2018 of an 18-month old child.

In addition to supporting child resistant closures for liquid nicotine products, the ACCC recommends that the TGA also consider regulating e-cigarette devices to child resistant standards.

E-cigarette devices are easy for users to operate for their intended purpose (heating e-liquid to create a vapour) and equally easy for children to operate and potentially inhale vapour containing nicotine or other chemicals. Some e-cigarette devices also have a removable and refillable cartridge that contains e-liquid. If a child were to access e-liquid containing nicotine from an e-cigarette device in either of the aforementioned ways, it could lead to serious illness or death.

#### *Customs regulations*

The Australian Border Force is responsible for regulating tobacco importation to Australia. Currently, under the Customs (Prohibited Imports) Regulations 1956 (Customs Regulations) individuals are permitted to import small quantities (less than 1.5 kg) of smokeless tobacco for personal use without the need for a permit.

To import more than 1.5 kilograms of smokeless tobacco for personal use, Regulation 4U of the Customs Regulations requires the individual to obtain a permit from the Commonwealth Minister prior to importation. The ACCC has a role in advising the Commonwealth Minister on import applications for smokeless tobacco.

The ACCC supports the TGA's interim decision in recognising that a nationally consistent approach to possession and importation of nicotine products is necessary. The ACCC welcomes further consideration from the TGA as to whether the Customs Regulations will need to be amended to reflect this.

### **The role of the ACCC in relation to tobacco, e-cigarettes and nicotine**

As Australia's competition and consumer protection agency, the ACCC administers the *Competition and Consumer Act 2010* (Cth) (CCA) which includes the Australian Consumer Law (ACL).

#### *Consumer goods under the ACL*

The ACCC has a role in ensuring products are marketed in a way that is truthful and to seek to ensure that consumer goods sold in Australia are safe. The ACCC does this by using a risk-based and intelligence-led approach to identify potentially unsafe consumer goods and to prevent or stop their supply or remove them from the market. The ACL defines 'consumer goods' as those goods that are intended to be used, or of a kind likely to be used, for 'personal, domestic or household use and consumption'.<sup>3</sup>

The ACCC is responsible for administering a range of permanent bans and mandatory standards concerning tobacco related products, including graphic health warnings and information required on tobacco packaging, reduced fire risk requirements for cigarettes, and a ban on the sale of chewing tobacco and snuffs intended for oral use.

Tobacco-related complaints received by the ACCC are assessed and responded to according to the ACCC's tobacco strategy and decision-making framework. The ACCC also has regard to its Compliance and Enforcement policy,<sup>4</sup> and Product Safety Priorities,<sup>5</sup> when considering tobacco related complaints.

In line with our tobacco strategy, we allocate resources to the issues posing the greatest risk to consumers and prioritise action according to an annually published list of priority factors. We are selective in the matters we investigate, including the product safety matters we address, and we cannot pursue all matters that come to our attention.

The ACCC took enforcement action in 2017 against three online e-cigarette retailers, Elusion Australia Limited (Elusion), The Joystick Company Pty Ltd (Joystick) and Social-Lites Pty Ltd (Social-Lites), for making false and misleading representations that their products did not contain toxins and carcinogens contained in cigarettes when this was not the case.

The ACCC's action focused on the false and misleading representations made by each of the suppliers and did not focus on any potential health effects of e-cigarettes. However, the Federal Court of Australia did highlight that the ACCC's enforcement action related to serious matters of public health. The Federal Court of Australia also recognised that the representations made by Elusion, Joystick and Social-Lites had the potential to mislead consumers about the health effects of non-nicotine e-cigarettes.<sup>6</sup>

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<sup>3</sup> Australian Consumer Law s 2(1).

<sup>4</sup> Australian Competition and Consumer Commission 2020 Compliance and Enforcement Policy and Priorities <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy-priorities>

<sup>5</sup> Australian Competition and Consumer Commission 2020 Product Safety Priorities <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/product-safety-priorities-2020>

<sup>6</sup> The Federal Court of Australia's judgments can be found at <http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2017/2017fca0398>, <http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2017/2017fca0397>, and <http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2017/2017fca0399>.

The ACCC does not have a role in developing health policy for e-cigarettes, nor does it have a role in regulating the use, marketing or safety of e-cigarette products in Australia. The ACCC also has no jurisdiction over:

- user behaviour (how e-cigarettes are used, or restricted to a certain quantity)
- storage (how e-cigarettes and related products such as e-liquids are packaged or contained)
- availability (who is able to sell them and how), or
- possession (for example, restricting e-cigarettes to a mandatory minimum age).

Where nicotine is present, the regulation of e-cigarettes is shared between Commonwealth, and state and territory governments, with the Department of Health playing a leadership role in tobacco control measures and the TGA regulating all such goods that make a therapeutic claim, including e-cigarettes that claim to help people cease smoking tobacco. However, despite many industry stakeholders claiming that the e-cigarettes are used as a smoking cessation aid, none are registered as such with the TGA.

#### *Serious injury or illness under the ACL*

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).<sup>7</sup>

This definition focuses the ACCC to acute physical injuries, 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 injuries 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.

#### *Government's Statement of Expectations*

Consistent with the Government's Statement of Expectations,<sup>8</sup> the ACCC seeks to avoid regulatory duplication. Where a matter relates to a specialist regime, such as 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, nor does it have jurisdiction over the availability, possession, storage or use of nicotine e-liquids.

In the context of a highly specialised area such as the health impacts of e-cigarettes and nicotine, the ACCC submits that the Department of Health and the TGA is better placed to understand and respond to these issues, to ensure an integrated regulatory framework and to minimise compliance costs.

#### **Regulation of consumer goods under the ACL**

Regulation under the ACL requires the Commonwealth Minister to introduce a legislative instrument in the form of a mandatory safety standard or permanent ban. However, there is currently unclear evidence of acute physical injury or illness, as defined within the ACL,

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<sup>7</sup> Australian Consumer Law s 2(1).

<sup>8</sup> Australian Government Statement of Expectations – Australian Competition and Consumer Commission, [http://www.treasury.gov.au/~media/Treasury/Policy%20Topics/Public%20Policy%20and%20Government/Statements%20of%20Expectations/Downloads/PDF/ACCC\\_Statement\\_of\\_expectations.ashx](http://www.treasury.gov.au/~media/Treasury/Policy%20Topics/Public%20Policy%20and%20Government/Statements%20of%20Expectations/Downloads/PDF/ACCC_Statement_of_expectations.ashx)

resulting from the design and construction of e-cigarette devices or composition of e-liquids, nor are there widely accepted 'safe' product specifications for the Commonwealth Minister to be able to consider regulation under the ACL.

The ACCC is aware that some stakeholders regard the ACL as an appropriate mechanism to regulate e-cigarettes. However, the ACL's product safety provisions are limited in their application as they only provide for the restriction of supply in certain circumstances related to the physical safety of consumer goods, such as requirements regarding their design, construction or composition. They do not provide for health controls and cannot regulate user behaviour, nor provide for the enforcement of mandatory age restrictions to reduce uptake by children and young people.

### *Mandatory standards*

The available options to regulate e-cigarettes under the ACL are limited. While the ACL provides a legislative scheme for mandatory safety and information standards, the power to introduce such standards is limited to circumstances where the Commonwealth Minister considers the minimum requirements set by the standard as reasonably necessary to prevent or reduce the risk of injury to a person arising from the design, construction, or composition of a consumer good.

Research on e-cigarette related injuries and deaths, both in Australia and internationally, has shown that it is primarily user behaviour and not the design of an e-cigarette device that causes safety risks.

The ACCC is aware of recent research published by the University of California Irvine that shows lung injury caused by e-cigarette devices with nickel-chromium alloy heating elements.<sup>9</sup> We note that these are early results of a single study, which itself acknowledges that more research needs to be conducted for the findings to be conclusive.

The ACCC has received very few reports about the safety of e-cigarettes and other novel nicotine vaping devices since our 2017 submission to the Parliamentary inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia.

Of the 117 complaints or queries received from July 2017 to October 2020, none relate to nicotine poisoning, four relate to e-cigarette devices overheating or exploding, and five relate to general safety concerns regarding an e-cigarette device's construction, such as hot e-liquid tipping or leaking out of an e-cigarette device. The remaining complaints and queries relate to general consumer matters, such as a product not working or not being supplied after purchase.

In order to intervene in a market and recommend that the Commonwealth Minister implement a mandatory safety standard under the ACL, the ACCC must meet regulatory impact assessment requirements set by the Office of Best Practice Regulation. To do so, the ACCC requires clear evidence that any proposed intervention would adequately mitigate the safety risk. Under the current state of evidence it is unclear whether the ACCC would meet its regulatory impact assessment requirements in recommending a mandatory safety standard under the ACL.

Furthermore, where there is evidence that the design and construction of e-cigarettes could result in serious injury, illness or death, the issue remains one of public health policy and should be overseen by a nationally consistent regulatory framework that does not de-couple safety regulation of novel tobacco products and nicotine vaping devices from tobacco health related issues.

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<sup>9</sup> E-cigarette of Vaping Product Use-Associated Lung Injury Produced in an Animal Model from Electronic Cigarette Vapor Exposure Without Tetrahydrocannabinol or Vitamin E Oil <https://news.uci.edu/2020/09/29/early-study-results-point-to-heating-element-in-vaping-and-e-cig-devices-as-cause-for-serious-lung-injuries/>

## *Permanent bans*

The ACL provides the regulatory option of permanently banning consumer goods in certain circumstances. Banning a consumer good is considered by the Commonwealth Minister where there is a risk that the design and construction of a consumer good will or may cause a serious injury or illness, or death, and there are no minimum requirements that could be set within a mandatory standard to ameliorate the identified safety risks.

Information and evidence regarding e-cigarette safety is frequently changing, with new studies regularly published in Australia and internationally. The ACCC considers that currently there is unclear evidence of e-cigarette use or foreseeable misuse causing serious injuries or illnesses or death as defined in the ACL.

If the ACCC was to consider regulating e-cigarette devices, the current state of evidence would more likely support a ban rather than a mandatory standard. This is because minimum safety requirements to suitably ameliorate risks would likely not be established, based on the varying and often contradictory studies and reports on e-cigarette safety.

## **E-cigarette regulation in Canada**

E-cigarettes manufactured, labelled, advertised, imported or sold in Canada are subject to five federal Acts and their Regulations, with all Acts and Regulations falling within the Health Canada portfolio. This includes the:

- Tobacco and Vaping Products Act
- Canada Consumer Product Safety Act
- Food and Drugs Act
- Vaping Products Labelling and Packaging Regulations

With Canadian vaping regulation only being formalised since 2018, there is limited evidence to its impact. However, the ACCC considers that vaping-related Acts and Regulations in Canada likely benefit from holistic regulation being conducted by one federal Government department. This ensures that industry stakeholders have one contact point for all vaping relating enquiries to assist in compliance. We also expect that Health Canada, and the Canadian Government more generally, has likely benefited from improved synergies as a result of vaping being regulated within the one Government department.

## **Potential for e-cigarette regulation in Australia**

The ACCC recognises there are challenges in ensuring the regulation of e-cigarettes and nicotine e-liquids is consistent nationally and uniformly enforced. Currently, the regulatory scope for e-cigarettes is complex and narrowly defined, resulting in regulation of these products largely falling to the states and territories. This is the case for both chemical content and electrical safety issues.

In relation to chemical content, a number of these laws include controls on advertising, sales to minors and where individuals can use e-cigarettes, and draw upon the TGA-administered Poisons Standard. The TGA's proposed amendments regarding nicotine scheduling will begin to address the risks associated with the possession and availability of nicotine e-liquids, and provide a consistent national framework that is uniformly enforced.

However, the potential safety risks posed by e-liquids remain unaddressed as there are no regulations applicable to the concentration, potency, chemical makeup, or flavourings of e-liquids. The ACCC is aware that some stakeholders believe the ACL is suitable to regulate these products, but notes the consumer product safety provisions of the ACL are not designed to identify or manage chemical safety risks.

The Department of Health has more appropriate technical expertise to regulate e-liquids and assess their potential health effects, similar to its regulation of cigarette flavourings, such as menthols.

The safety risks and harms from e-cigarette fires and explosions also remain largely unaddressed. E-cigarettes contain interchangeable parts, often including extra-low voltage lithium batteries. Failure of these parts has been linked to ignition of e-cigarettes, with a number of incidences of burn injuries reported overseas. Many have been linked to overcharging and overheating of batteries, causing the device to ignite or explode in close proximity to the user.

Since July 2017 to October 2020, the ACCC has received four reports of injuries from e-cigarettes igniting or exploding in Australia. The ACCC has also received reports of fires and injuries from other extra-low voltage lithium batteries.

State and territory electrical safety regulators are generally responsible for the regulation and safety of electrical appliances in Australia, and the ACCC submits that this regulatory framework is best placed to improve lithium battery quality and other electrical-related risks and harms associated with e-cigarettes.

The ACCC acknowledges that the electrical safety regulatory framework, however, is not consistent nationally as only some state and territory electrical safety regimes capture extra low voltage products and batteries (which operate under 50 volts) and may often be used in the construction of e-cigarettes.

Where a safety hazard emerges with an extra low voltage product, the ACCC has historically been required to intervene to ensure a consistent and national response. An example is our recent work on button battery safety, but it is worth noting that this work is focused on preventing children's exposure to button batteries rather than the regulation of battery power or voltage.

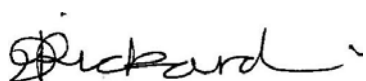
The ACCC submits that regulation of e-cigarette devices should not be de-coupled from tobacco and nicotine regulation. A device's electronic functions, the power of the heating element, and the rate of delivery of e-juice all collectively contribute to potential health risks of a user, even more so when a device contains nicotine.

The Department of Health (as the lead on tobacco control measures) and the TGA (as the regulator of therapeutic devices) appear the most appropriate agencies to regulate e-cigarette devices and nicotine e-liquids. This will ensure tobacco-related legislation and regulations are harmonised and consistent, and minimise confusion for those navigating the relatively new regulatory landscape of e-cigarettes.

### **Next steps**

If you would like to discuss the ACCC's submission, please contact Neville Matthew, General Manager, Risk Management and Policy, Consumer Product Safety Branch on [REDACTED] or at [REDACTED]

Yours sincerely



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