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POTENTIAL REFORMS TO THE REGULATION OF NICOTINE VAPING PRODUCTS: CONSULTATION PAPER

The Collaboration for Evidence, Research and Impact in Public Health (CERIPH), is a multi-disciplinary research centre within the School of Population Health at Curtin University in Western Austalia. CERIPH aims to seek solutions that promote health, prevent disease and protect populations from harm.

We welcome the opportunity to comment on the Therapeutic Goods Administration's (TGA's) review of potential reforms to the regulation of nicotine vaping products (NVPs). We acknowledge that reforms are urgently needed to address the large-scale illegal importation and illegal supply of these products. We applaud this initiative and Australia's precautionary approach to vaping products.

The emergence of NVPs and their accessibility and uptake, particularly by young people, has been overwhelming, adversely impacting the public health gains made in tobacco control. The tobacco industry's diversification into NVPs aims to reach new markets, and because of this, our Government is tasked with developing appropriate policies and regulations [1] to protect the health of Australians, youth in particular. We need to remember that the tobacco industry has a well-documented history of opposing effective public health regulations to restrict availability and access to their products, such as those proposed by the TGA [2,3].

The tobacco industry is currently promoting its NVPs as a harm reduction approach while we know they are ultimately recruiting new customers [4] as the industry is driven by the need to secure business and profit [5,6]. Therefore, the tobacco industry should be excluded from any NVP policy or regulation formulation. Excluding the tobacco industry supports Article 5.3 of the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) (to which Australia is a Party), which aims to protect public health policies with respect to tobacco control from 'commercial and other vested interests of the tobacco industry' [7].

The review is organised into four sections:

1. Border controls
2. Pre-market assessment of NVPs
3. Minimum quality and safety standards for NVPs
4. Clarifying the status of NVPs as therapeutic goods

With respect to each of the above sections, CERIPH recommends the following:

Section 1 – Option 4

Section 2 – Option 3 (but if option 3 is not considered feasible Option 1)

Section 3 – Option 7

Section 4 – Yes

What follows is CERIPH's nominated reform option and a brief rationale for the selected option.

1. Border controls and regulations

CERIPH supports Option 4 *- Introduce controls on the importation of all vaping products through the Customs Regulations to assist with the enforcement of the controls on NVPs*

The Federal Government to introduce an amendment to the Customs (Prohibited Imports) Regulations 1956 declaring all vaping products as prohibited imports. This amendment should include both nicotine and non-nicotine vaping products.

An integrated approach to NVPs and non-nicoting vaping products is needed, as distinguishing between nicotine and non-nicotine vaping products impedes enforcement management, complicating the identification of non-compliant vaping products, while necessitating costly and time-consuming laboratory analysis to determine the presence of nicotine in products. Recent Telethon Kids Institute (WA) [8-9] research clearly showed the presence of nicotine in e-liquids labelled as non-nicotine, as well as a range of harmful chemicals, showing non-nicotine vapes are not a harmless product.

Australia's National Industrial Chemical Notification and Assessment scheme [10] reported that the aerosol in non-nicotine vaping products produces 369 chemicals and contaminants, many of which are harmful. Many flavouring compounds present in these products have been deemed safe for ingestion, however, none have been assessed as safe for inhalation via vapourisation [11]. In addition, all vaping products (nicotine and non-nicotine) can cause injuries (e.g., burns, fractures, teeth displacement, lodgement of foreign bodies after explosion) and contribute to electronic and plastic waste [12].

However, there should be an exemption for the access to NVPs through TGA's approved channels, so that individuals can access the NVP for smoking cessation under medical supervision. Medical supervision provides optimal outcomes, with research showing that smokers who discuss their quit goals and progress with a health professional's guidance are more likely to successfully quit [13].

Option 2 is not supported as a standalone strategy. Considering the current supply/access to vaping products, it has been ineffectual in stopping the illegal supply of vaping products. In addition, consideration should be given to reducing the annual allowance of NVP supply (< 15 months); and access only to NVPs via local pharmacies (ensuring patient receive health professional advice).

2. Pre-market TGA assessment of NVPs

CERIPH supports Option 3 *– Establish a regulated source of quality NVPs by requiring registration in the ARTG, following successful evaluation of quality, safety, and efficacy (for smoking cessation). However, in the event that option 3 is not considered feasible, CERIPH supports option 1 (make no changes).*

To date, no NVP had been approved by the TGA for use as a therapeutic good for smoking cessation. Option 3 would provide an opportunity to establish a registry of known NVPs assessed for quality, safety, and efficacy for smoking cessation. Adopting an approach whereby vaping products in the Australian Register of Therapeutic Goods (ARTG) are of a specific standard will instil confidence in health professionals when prescribing and individuals when using these products.

In the event that **Option 3** is not considered feasible, we support Option 1 (make no changes), until Option 3 can be implemented. We certainly do not want to disadvantage individuals wanting access to smoking cessation products due to time delays resulting from the introduction of Option 3.

We do not support Option 2 - *Establish a regulated source of quality NVPs by requiring pre-market assessment of NVPs by the TGA against a quality and safety standard (rather than requiring all the*

requirements for registration in the ARTG to be met), with or without an assessment fee. Option 2 will reduce standardisation of assessments and potentially assessment standards; give the false impression that the products are endorsed by the TGA, which may result in confusion, less clarity and less confidence in these smoking cessation products; and potentially undermine the role and stature of the TGA.

3. Minimum quality and safety standards for NVPs

CERIPH supports Option 7 *– Includes options 2, 3, 4, 5 and 6 together (Except for the option to require additional warning statements).*

We support the proposed amendments to the TGO 110 but also encourage complementary actions to address the limitations of the current regulatory framework. Decreasing the availability and overall access to vaping products should be a priority to reduce harm to young people. Therefore, the illegal importation of these products must be stopped through increased border control. Option 7 will completment Option 4 listed under the section 'Border Controls and regulations'.

Specific Comments

Prohibit all flavours (except tobacco) and additional ingredients: Vaping products are designed to increase their attractiveness and stimulate use among young people, with sweet flavours, such as chocolate milk and tutti fruitti, along with brightly coloured packaging. Flavours, of which there are about 15,000, trigger increased interest in purchasing and the use of vaping products [12]. As flavoured vaping products are attractive to the young and vulnerable there is a need for regulation. The US Food and Drug Administration has announced plans to ban all flavours other than tobacco [14]. All flavours (except tobacco) should be prohibited.

Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements: The packaging of vaping products is often eye-catching, with the intent of generating interest and is thereby a promotional tool. Branded packaging has been found to increase interest among young people while plain packaging decreases interest [15]. In Israel, the Netherlands and the Canadian province of British Columbia, plain packaging is required for vaping products and e-liquids [16].

Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL: Liquid nicotine is highly toxic. Vape-related calls to the Poisons Information Centre have increased over the last five years. Most poisonings occur in children and toddlers. Ingestion of just 1–2 mL of nicotine within pre-mixed e-liquid can kill a child [17]. It has been documented that there is limited evidence as to the 'ideal' nicotine concentration in e-liquids; however, 18 mg/ml has been shown to reduce nicotine cravings and promote tobacco cessation [17], which is in line with those concentrations proposed. In addition, a prescription scheme enables follow-up support by a medical professional so nicotine dosages can be adjusted as required [18].

Remove access to disposable NVPs: Disposable vaping products pose a serious environmental hazard, introducing heavy metals, lead, mercury, and flammable lithium batteries to the environment. This waste will not biodegrade. Furthermore, recent evidence suggests that children who use vaping products usually use disposable products [19] and restricting access to disposable NVPs will reduce children's use.

4. Clarifying the status of NVPs as ‘therapeutic goods’

Yes, we support the clarification of the status of NVPs as therapeutic goods. Currently, NVPs are regulated as unapproved *therapeutic goods*. However, it seems unclear as to whether those not labelled as containing nicotine can be considered *therapeutic goods.* This, therefore, requires clarification.

Faithfully,

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