

# Undermining Australian controls on electronic nicotine delivery systems: illicit imports and illegal sales

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The proliferation of electronic nicotine delivery systems (ENDS) has created public health regulatory challenges the world over.<sup>1</sup> Driven by an industry that claims to be a partner in tobacco control, ENDS use has spread well beyond adults trying to quit smoking. Some countries have chosen to ban ENDS; others have sought to apply established tobacco control demand reduction measures—such as on-pack warnings and advertising restrictions—and other nations continue to wrestle with what legislative and policy framework is best for public health.<sup>2</sup> The diverse and continuously changing range of ENDS manufactured, marketed and sold further slows effective policy action.<sup>3</sup>

Australia has a unique medical model whereby ENDS and liquid nicotine are regulated as unapproved therapeutic products. As of October 2021, the Australian Therapeutic Goods Administration (TGA) requires a valid medical prescription to access ENDS or liquid nicotine from either a domestic pharmacy or an overseas supplier via the personal importation Scheme.<sup>4</sup> This scheme allows an individual to import up to a 3-month supply of liquid nicotine and/or ENDS at one time. This allows current cigarette users to access ENDS but is intended to prevent product uptake by those not already addicted to tobacco products, particularly young people.

It is illegal everywhere in Australia to sell ENDS or liquid nicotine to anyone who does not have a prescription. Even though ENDS may be prescribed for smoking cessation by a doctor and accessed through a pharmacy, they have not been approved by the TGA for any therapeutic purpose. The TGA has not assessed the safety, quality or efficacy of ENDS as a medicine for smoking cessation

as no manufacturer has submitted an ENDS for TGA assessment. The TGA has, however, released a product standard that sets out some minimum safety and quality requirements. The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* prohibits some substances with known health risks if inhaled, bans active ingredients other than nicotine and specifies a maximum nicotine concentration level (100 mg/mL).<sup>5</sup> The Standard also requires child-resistant packaging, an ingredient list and warning statements. Flavours are permitted if they are not otherwise prohibited ingredients. However, ENDS brought into Australia under the personal importation scheme are subject only to very basic requirements (eg, the nicotine concentration of the product must be the same as stated on the prescription).

On the surface, the aforementioned description of Australian ENDS control appears to ensure that only current smoked tobacco users, under the care of health professionals, could readily access ENDS. However, Australia is experiencing a rapid increase in vaping among adolescents and young adults. Data from New South Wales (NSW), Australia's most populous state, indicated that 32.7% of persons aged 16–24 had ever used an e-cigarette in 2021—the highest rate of all population age groups.<sup>6</sup> ENDS are being imported and then illegally sold at Australian retail outlets, including both bricks and mortar and online shops, and by individual suppliers who exploit social media channels.<sup>7</sup> While ENDS are tightly regulated by national laws, there are no restrictions on the importation, sale or possession of electronic non-nicotine delivery systems (ENNDS).<sup>7</sup>

ENNDS may also be sold by non-pharmacy retailers in all Australian states and territories, except Western Australia (WA), where they are captured by state laws that prohibit the sale of any products that are designed to resemble tobacco products or packages. Selling ENNDS to minors is banned in all states, but the illegal sale of both ENDS and ENNDS to underage

people is rampant.<sup>8</sup> Nicotine-containing devices can readily pass as non-nicotine-containing devices, since it is impossible to determine whether an e-cigarette contains nicotine, short of conducting laboratory analyses. The pairing of this regulatory loophole with the arrival of inexpensive, flavoured, disposable vaping devices that contain high-concentration nicotine salts has led to the swift upswing in adolescent and youth uptake and addiction.<sup>9</sup> Add aggressive online marketing<sup>10</sup> and misinformation about product safety and poor enforcement of ENNDS sales to minors laws, and it is unsurprising that use has skyrocketed.

Importers are not required to prove that their so called ENNDS are nicotine-free, nor are they required to label or package ENNDS in any standard way. Currently, ENDS/ENNDS devices are not manufactured in Australia, although there are a number of vaping liquid producers. Consignments of ENNDS that are not declared as containing nicotine may only be subjected to random laboratory testing by the TGA. Consequently, importers have flooded Australia with ENDS simply by not declaring the nicotine content present in the products.

Once products are imported and being sold on the retail market, state-level enforcement officers are again hamstrung by the need for laboratory testing of products. Despite these enforcement challenges, in the state of NSW alone, health authorities seized more than \$(AU)1 million worth of illegal ENDS and nicotine liquids in the first 5 months of 2022. The total value of illegal products seized in NSW between 1 July 2020 and May 2022 was valued at more than \$(AU)3 million.<sup>11</sup>

State-level health authorities, such as NSW Health and the WA Department of Health, have responded by increasing routine compliance and enforcement efforts and launching public education campaigns about the harmful ingredients in ENDS/ENNDS.<sup>12</sup> NSW Health can prosecute non-pharmacy retailers for illegally selling ENDS, with a maximum penalty of \$A1650, or 6 months in prison or both. Nationally, the TGA has announced that it has worked with state and territory government departments to issue 88 fines in the first 10 months since the October 2021 law change, from a total of 680 investigations.

Reluctant political ownership of this rapidly unfolding public health emergency is hampering efforts towards more effective public health policy approaches. In April 2022, the federal Minister for Health and Ageing wrote to state and territory

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health ministers urging them to stop illicit sales of ENDS. Meanwhile, state and territory health ministers have responded by criticising federal authorities for not stopping supply at the border and stated that nationally coordinated action is needed. An ideal solution would see the elimination of all ENDS/ENNDS sales that fall outside of the TGA prescription pathway. This would not only prevent the easy access to products by children and young people but also enhance the prescription-only model to ensure all smokers access smoking cessation support from health professionals when using ENDS.

This could be achieved by dissolving the unhelpful distinction between ENDS and ENNDS that has contributed to weak enforcement of existing laws. The Australian Customs (Prohibited Imports) Regulation should be amended to declare all ENDS/ENNDS, components and liquids prohibited imports, with an exemption only for those obtained by pharmacy wholesalers and individuals with a prescription.<sup>13</sup> Such an amendment would authorise Australian Border Force officers to intercept and seize non-prescription products at the border. Import controls alone, however, will not be enough. Australian state and territory governments must enforce established rules on prescription-only access to ENDS and liquid nicotine and apply these same rules to ENNDS.

Outside of the pharmacy model, neither ENDS nor ENNDS should have a long-term place in the retail market and should not be sold as common consumer goods. The existing TGA pathway for accessing ENDS with a prescription is in line with the highly limited evidence supporting their use for smoking cessation for some individuals.<sup>14–16</sup> Education campaigns alone will not protect young people from an industry that so freely disregards laws meant to protect health. All Australian governments must take concerted and immediate action to eliminate ENDS/

ENNDS retail sales outside of pharmacies. Failure to act will see a whole new generation of Australians addicted to dangerous products, a mistake we cannot tolerate repeating.

In 2012, Australia was heralded as a world leader in tobacco control for enacting ground-breaking plain packaging laws. While adequately controlling access to ENDS/ENNDS products is crucial, it is also time to reinvigorate action on smoked tobacco use. Deadly cigarettes remain readily available in every community across Australia. Selling overwhelmingly harmful and addictive products alongside household groceries has never made any sense. A visionary plan to end tobacco use and sales is long past due.

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