

E-cigarettes should be regulated

They pose many risks for tobacco control and health, and any possible benefits are few and uncertain

As reported in this issue of the *MJA*,¹ Australia, with the world's lowest rates of smoking among adults² and adolescents,³ is seeing nascent, modest growth in e-cigarette use, despite having some of the strongest restrictions on their marketing and sales. Manufacturers, now including all major tobacco corporations, have spent large sums publicising their brands, using tactics that have promoted cigarettes so successfully, but boosted by the added reach of the internet. They are ahead of the regulatory curve, adopting imagery, messages and tactics prohibited in cigarette promotions, such as the sponsorship of youth events.⁴ They have spiced their products with a bewildering array of flavourings that in many countries would be illegal in cigarettes, and have garnered vocal support from those who see any restriction on the use of e-cigarettes by governments as a threat to individual freedom. Some aspects of these developments are, however, surprising.

The first is that, despite intensive marketing, the use of e-cigarettes in some countries now seems to be plateauing,⁵ suggesting that their much vaunted appeal for smokers and the talk of mass migration to e-cigarettes has been exaggerated.

The second is the naive embrace of the e-cigarette and tobacco industries by some in tobacco control. Public Health England extensively promoted a message that e-cigarettes were "95% safer" than combustible cigarettes,⁶ a claim based not on empirical evidence but upon a single reference to a meeting⁷ that was attended by researchers who were mostly known supporters of e-cigarettes, and partially funded by an organisation with links to the tobacco industry.^{8,9}

This is despite hundreds of articles documenting the malfeasance of the tobacco industry, as recognised in the World Health Organization Framework Convention on Tobacco Control, which explicitly advises against engagement with the industry. Some of those investigating e-cigarettes are even receiving funding from tobacco manufacturers, now seeking to represent themselves as "part of the solution"¹⁰ while continuing their concerted opposition to measures effective in tobacco control.

In Australia, anyone considering importing or supplying e-cigarettes as a cessation aid must submit an application to the Therapeutic Goods Administration (TGA) with evidence of their safety and efficacy.¹¹ The TGA then considers the evidence before determining whether the product may be sold, and, if so, under what conditions. The TGA website notes that "no assessment of electronic cigarettes has been undertaken and, therefore, the quality



and safety of electronic cigarettes is not known". Further, nicotine is, appropriately, classified as a poison except when formulated in low doses in some smoking cessation products (or when supplied in tobacco, an historical anomaly common to all countries). Recent research has identified the role of nicotine in promoting angiogenesis and thus the spread of tumours,¹² and the risks it poses to adolescent brain development.¹³ Further, there have been several reports about the use of e-cigarette liquids in suicide attempts.^{14,15}

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These and other concerns about safety were reviewed in detail by Pisinger and Døssing¹⁶ in an article that, remarkably, was not cited in the Public Health England review of the evidence about e-cigarettes, despite being published in a leading international journal. The authors concluded that there was no such thing as a standard e-cigarette, so that studies on one brand could not be extrapolated to others. They reported that many studies have found evidence that the inhaled products contained harmful substances, some of which do not occur in tobacco smoke, while the levels of substances common to both were found to vary wildly, and in some cases were higher than in tobacco smoke.

For a product promoted by some as a game-changer in quitting smoking, it has been remarkably difficult to obtain evidence that e-cigarettes are any more effective than unassisted cessation or conventional nicotine replacement therapy.¹⁷ A Cochrane review reported the evidence as being of "low/very low quality",¹⁸ and a

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recent meta-analysis concluded that they, in fact, reduced the probability of quitting.¹⁹ In these circumstances, it seems prudent to adopt the precautionary principle and to carefully monitor emerging evidence on their safety and cessation efficacy, the uptake of vaping and smoking by young people, and any further relevant developments.²⁰

E-cigarettes have at least two distinct roles. The first is as products that may assist in smoking cessation, with possible but as yet unproven benefits that surpass those of existing methods. Second, they are a means for the tobacco industry to circumvent restrictions on promoting both their image and their tobacco products. This dual role implies the need for parallel regulatory tracks. The first involves the application of existing provisions for the authorisation, marketing (eg, claims regarding effectiveness as quitting aids) and sales of therapeutic goods.

The second involves applying existing controls on all promotions that may encourage smoking, including exposure of children and young people to advertising and other forms of promotion and to any other use of smoking or tobacco-related imagery.

This twin-track approach offers a means for evaluating and maximising any potential benefits while minimising risks of harm. In the meantime, Australian governments and health authorities should not be distracted from existing approaches to reducing smoking, which are bringing such encouraging results.

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