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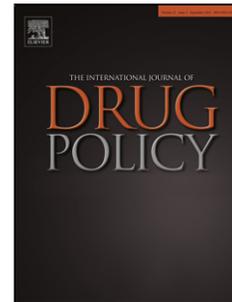
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## Highlights

We discuss the history of regulation of nicotine for vaping in Australia  
Current Australian laws provide two options for regulating nicotine for vaping  
No products have been approved for sale under option 1 (prescription medicine)  
We propose using option 2 (dangerous poison) to trial a nicotine licence scheme

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A Licence to vape: Is it time to trial a nicotine licensing scheme to allow Australian adults controlled access to personal vaporiser devices and refill solutions containing nicotine?

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A Licence to vape: Is it time to trial a nicotine licensing scheme to allow Australian adults controlled access to personal vaporiser devices and refill solutions containing nicotine?

### **Abstract**

Australia has some of the most restrictive laws concerning use of nicotine in e-cigarettes. The only current legal option for Australians to legally possess and use nicotine for vaping is with a medical prescription and domestic supply is limited to compounding pharmacies who prepare medicines for specific patients. An alternative regulatory option that could be implemented under current drugs and poisons regulations is a 'nicotine licensing' scheme utilising current provisions for 'dangerous poisons'. This commentary discusses how such a scheme could be used to trial access to nicotine solutions for vaping outside of a 'medicines framework' in Australia.

*Keywords:* nicotine; electronic cigarettes; nicotine licensing;

## Background

E-cigarettes (also known as personal vaporisers or electronic nicotine delivery systems) have been mass-marketed as a 'cleaner' form of recreational nicotine than tobacco cigarettes since around 2006 in the USA, UK and Europe. The use of these devices has grown substantially in recent years, suggesting they have wide appeal to smokers (Yong et al., 2014). These devices work by heating a mixture (or 'juice') of propylene glycol and/or vegetable glycerine, nicotine and flavourings to produce an aerosol that is inhaled by the user.

Unflavoured and nicotine-free solutions are also sold.

There is a wide variety of e-cigarettes available that include: single use disposable devices that resemble conventional cigarettes in appearance; rechargeable devices that use replaceable pre-filled cartridges; refillable tank style (or 'ego') devices; and bespoke devices produced by and for collectors. The refillable device styles allow greater user control, including the option to 'mix your own' juice, and in some cases, alter the heating temperature. Using an e-cigarette is known as 'vaping' and regular users often refer to themselves as 'vapers'.

A very substantial public health gain could be achieved if a substantial proportion of smokers switch to e-cigarettes, because the health risks of regular use of these products are likely to be much lower than those of cigarette smoking (Abrams, 2014; Hajek, Etter, Benowitz, Eissenberg, & McRobbie, 2014; Royal College of Physicians, 2007). Critics argue, on the other hand, that some of the hard fought for gains that have been achieved from tobacco control policies could be lost if increased use of e-cigarettes led to an increased uptake of smoking among non-smokers, or discouraged quitting among smokers if most e-cigarette users continued to smoke cigarettes while using e-cigarettes (dual use) instead of quitting smoking (Chapman, 2013, 2014).

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The population health impact of e-cigarettes will depend on patterns of e-cigarette uptake, the way in which these devices are used by smokers and whether their use increases or decreases smoking. Evidence from the UK suggests that widespread access to e-cigarettes has not had a detrimental effect on smoking prevalence which has declined in population surveys as e-cigarette use has increased, and e-cigarette use is very rare among non-smokers (Dockrell, Morrison, Bauld, & McNeill, 2013). An observational study of UK smokers that had made a quit attempt without formal cessation assistance in the past 12 months indicated that those who used an e-cigarette were more likely to be abstinent from smoking at follow-up than those who either used no aid or approved nicotine replacement therapies (NRT) purchased over the counter (Brown et al., 2014). While the emerging evidence indicates that quitting success rates are still relatively modest with e-cigarettes, they do appear to increase the success rate of quit attempts and may be superior to approved over the counter NRT products (McRobbie, Bullen, Hartmann-Boyce, & Hajek, 2014; Brown et al., 2014; Bullen et al., 2013).

The risks associated with short-term e-cigarette use appear to be very low and similar to approved NRT products (McRobbie et al., 2014; Bullen et al., 2013; Caponnetto et al., 2013). There is only limited information on the risks of long-term e-cigarette use (Hajek et al., 2014). It is also unclear what percentage of e-cigarette users will continue to use these products indefinitely and how many will use e-cigarettes as an interim step towards nicotine abstinence.

### **The Legal Status of E-cigarettes in Australia**

The legal status of e-cigarettes in Australia is complicated (Douglas, Hall, & Gartner, 2015). Australia's regulatory framework for medicines and poisons classifies substances into nine schedules. Nicotine falls under different schedules, depending upon its intended use. Nicotine in tobacco intended for smoking is exempt from scheduling and so are therapeutic

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cessation aids for oromucosal or transdermal use (e.g. gum, lozenges, mouth spray, patches etc). All other nicotine preparations for human therapeutic use are Schedule 4 (prescription only medicines), such as nicotine nasal spray. Nicotine in preparations of 3% nicotine or less packed and sold for the treatment of animals is in Schedule 6; for all other non-therapeutic applications, Schedule 7 (dangerous poison) applies. All nicotine preparations that are claimed to have a therapeutic application (e.g. smoking cessation aid), must gain approval from the Therapeutic Goods Administration (TGA) and be listed on the *Australian Register of Therapeutic Goods* (ARTG) before being supplied within Australia.

In June 2008, The National Drugs and Poisons Scheduling Committee (NDPSC) considered the issue of e-cigarettes containing nicotine (National Drugs and Poisons Scheduling Committee [NDPSC], 2008). The Victorian jurisdictional member proposed that the Schedule 4 entry for nicotine be amended to cover internal human use (non tobacco), not solely for therapeutic use, to make electronic cigarettes available as 'Prescription Only' products. This option was rejected by the committee, which concluded "that the current scheduling of nicotine remained appropriate". At the time, Schedule 2 (over the counter Pharmacy sales) would apply to e-cigarettes that claimed to assist in smoking cessation. Schedule 7 (Dangerous Poison) would apply if this claim was not made.

In 2011, the NDPSC again considered e-cigarettes and the Nicorette inhaler/inhalator (NDPSC, 2011). The committee "noted that the current Schedule 2 entry for nicotine for inhalation was intended to capture oromucosal inhalators and not nicotine vaporiser products (e.g. e-cigarettes). Members clarified that e-cigarettes should be captured by Schedule 4 when for human therapeutic use or by Schedule 7 if for non-therapeutic use." The Schedule 2 entry for nicotine for inhalation was deleted and the Nicorette inhaler was renamed "inhalator" and included in the exemption from scheduling for smoking cessation aids containing nicotine "for oromucosal or transdermal use", thereby allowing them to be sold over the counter in

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general retail outlets. All other nicotine preparations for human therapeutic use, including e-cigarettes that gain TGA approval, would now be included under *Schedule 4* (Prescription only medicines). Nicotine for non-therapeutic use remains under *Schedule 7* (dangerous poisons). Since no e-cigarettes are currently listed on the *ARTG*, *schedule 7* applies to e-cigarettes and refill solutions if they contain nicotine, and if they do not make therapeutic claims.

In all Australian states it is an offence to manufacture, sell or supply nicotine as a schedule 7 poison, without a licence or specific authorisation. This means that e-cigarettes containing nicotine and nicotine refill solutions cannot be sold or supplied lawfully commercially in any Australian state for non-therapeutic purposes as no licences or authorities have been issued. There are several reported incidents where individuals have been charged with the illegal supply of liquid nicotine for use in e-cigarettes in Queensland (AAP, 2014; Cook, 2014). In all Australian states it is also either illegal to possess or illegal to use nicotine as a Schedule 7 poison (i.e. when not considered a therapeutic good) without an approval, permit or authority (Douglas et al., 2015). This presents a regulatory dilemma for state health departments. Prosecuting individual e-cigarette users who are using these products to remain abstinent from smoking is arguably not in the public interest. A good case can also be made for not expending scarce departmental resources on investigating and prosecuting individuals for possession or use, if there is no evidence of a serious threat to public health from this possession or use.

The current situation places e-cigarette users in the position of breaking the law for an activity that may be reducing their health risks. While some argue that access to unapproved e-cigarettes is unnecessary because approved nicotine products are available (Duff & Corderoy, 2014), it should be noted that none of these therapeutic products are approved for long-term substitution (which some e-cigarette users argue they need to maintain abstinence

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from smoking). Many e-cigarette users report that they have failed to quit smoking using these products and that they have only been able to become and remain abstinent by using e-cigarettes (Fraser, Weir, Keane, & Gartner, 2015). Smokers and e-cigarette users can reasonably question the rationality of regulations that make possession and use of e-cigarettes by adults illegal while allowing the retail sale of nicotine in the most harmful form (tobacco cigarettes) (Hall, Gartner, & Forlini, 2015).

The sale of nicotine-free e-cigarettes and ‘juice’ are not specifically banned under legislation. In all states it is not illegal to possess a e-cigarette without nicotine. However, tobacco control legislation in some states bans the sale of any non-tobacco products that “are designed to resemble” a tobacco product (Douglas et al., 2015). The first prosecution of a e-cigarette vendor in Western Australia was initially unsuccessful, but on appeal a conviction was recorded. The vendor has since appealed this conviction. From the beginning of 2015, Queensland tobacco control legislation now applies the same restrictions to sale and use of e-cigarettes and refill solutions as apply to tobacco cigarettes. e-cigarettes and refill solutions containing nicotine are still banned in Queensland under drugs and poisons legislation. While this new legislation imposes substantial restrictions on the sale and use of e-cigarettes, it does explicitly make it legal to sell and use e-cigarettes in Queensland. Similar controls are also being considered in other states and territories.

Despite the current legal barriers, e-cigarettes and nicotine juice are widely available over the internet or ‘under the counter’ (Duff, 2013). The use of e-cigarettes has increased rapidly in recent years in Australia, from 2% of smokers and recent quitters reporting having ever used a vaporiser in 2010 to nearly 20% in 2013 (Yong et al., 2014). Of the 8.9% of Australian smokers who reported *current* use of a e-cigarette in 2013, 43% reported using nicotine in their e-cigarette and a further 21% did not know if their vaporiser contained nicotine or not. Levels of use are much higher in countries which regulate e-cigarettes as

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general consumer products rather than as medicines (e.g. USA and UK). Current e-cigarette use among smokers and recent quitters (<1 year) was 18% in USA and 19% in UK in 2013. If the overseas e-cigarette market continues to grow, these products could become even more widespread within Australia via international travel and internet purchases.

**Current legal options for accessing nicotine solutions for vaping in Australia****As a therapeutic good for smoking cessation**

One legal way for Australians to access nicotine solutions for e-cigarettes is via the TGA personal importation scheme for unapproved medicines. This is only available if the person uses the nicotine for therapeutic use (e.g. as a smoking cessation aid or to manage the symptoms of withdrawal of tobacco) (Therapeutic Goods Administration [TGA], 2013a). This scheme allows Australians to import up to a 3 month supply at a time of nicotine as an unapproved medicine without any approval required by the TGA, if the person holds a prescription from an Australian-registered medical practitioner for it. Compounding pharmacists can also legally compound a nicotine solution for supply to an individual patient on medical prescription. However, both of these options are probably too onerous and unattractive for most smokers unacquainted with vaping, especially socioeconomically disadvantaged smokers among whom ‘hardcore’ smokers are now concentrated in Australia (Clare, Bradford, Courtney, Martire, & Mattick, 2014). These are the smokers who are most likely to substantially benefit from using long term nicotine substitution so it is important to find another way to enable heavily addicted smokers or smokers unmotivated to quit to be able to access e-cigarettes for harm reduction purposes.

In principle, medical practitioners could prescribe an e-cigarette for therapeutic purposes, but there are no e-cigarettes listed for medical use on the ARTG. The main barrier to e-cigarettes gaining TGA registration for smoking cessation is that obtaining registration is an expensive and lengthy process. Furthermore, while ARTG listing would ensure e-

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cigarettes were of a consistent high quality, any substantive changes to e-cigarette devices would require new applications to the TGA to deal with changes in a rapidly evolving technology. This could deter further innovation and improvements in the product design (Bates & Stimson, 2013). Some commentators have also argued that regulating e-cigarettes as medicines works in favour of the tobacco industry, which now sells e-cigarettes. The tobacco industry have the financial resources to obtain medicines approval for their products while smaller independent e-cigarette manufacturers may not.

An optimistic view of the entry of tobacco companies into the e-cigarette market is that these products provide the tobacco industry with an 'exit strategy'. However, many public health professionals are suspicious of their motives and intentions because e-cigarette companies owned by tobacco companies may have less incentive to promote their products as complete replacements for cigarettes than companies that only manufacture e-cigarettes (Freeman 2014). Many of the Australian public health professionals who are concerned about tobacco industry involvement in the e-cigarette industry support regulation of e-cigarettes as medicines<sup>1</sup> (Carrick, 2014; Cancer Council Australia & National Heart Foundation of Australia, 2014). Paradoxically, restricting regulation of e-cigarettes to a medicines framework may work to the advantage of the tobacco industry by reducing the diversity of e-cigarette products on the market and also competition from e-cigarettes not owned by tobacco companies.

Promoting e-cigarettes as medicines is also likely to reduce their attractiveness to smokers. A survey of Australian e-cigarette users found that: 93% opposed access only via doctor's prescription (Schedule 4); 85% opposed access as a pharmacist only medicine

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<sup>1</sup> "If any manufacturer producer wants to sell e-cigarettes as a cessation aid, all they need to do is take the product to the Therapeutic Goods Administration with good evidence, and then see if they can get it approved. Whether it's a small businessman, this fellow Van Heerden in Perth, or whether it's the big tobacco companies that are buying into e-cigarettes big time.... That's the way to go." (Mike Daube, "E-Cigarettes: Should We Inhale". The Law Report, ABC Radio National. 10 June 2014)

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(Schedule 3); and 81% opposed access as a pharmacy only medicine (Schedule 2) (Fraser et al., 2014). The time and financial cost of obtaining a medical prescription for purchasing PVs is a further disincentive to use, especially in light of recent proposals from the Commonwealth government to force GPs to charge patients a co-payment for bulk-billed visits (Duckett, 2014).

**Policy options for regulating e-cigarettes and nicotine**

There are a number of policy options for regulating e-cigarettes and non-therapeutic nicotine available to the Australian government. The first option is to maintain the *status quo*, as described above. This current policy can be criticised on ethical grounds because it effectively denies access to a less harmful alternative to smoking while allowing widespread sale of a more harmful product (cigarettes) (Hall, Gartner & Forlini, 2015). It also does not address the growing illicit market in nicotine in Australia and the risk of childhood poisonings, which could be reduced through appropriate labelling and child-resistant packaging.

**Amend therapeutic goods regulation**

Australia's therapeutic goods regulations are not well suited for regulating products that are arguably non-therapeutic. An example of an approach to regulate recreational psychoactive substances to minimise harm and improve their safety and quality is New Zealand's *Psychoactive Substances Act 2013*, which requires all products to be approved by the Psychoactive Substances Regulatory Authority (Newberry, Wodak, Sellman & Robinson, 2014). The *Act* also requires all importers, researchers, manufacturers, wholesalers, and retailers to be licenced. The regulations that provide for product approval applications and licensing applications for importing, research and manufacturing to be processed, came into

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force in November 2014. Hence, there has been insufficient time to judge the success of this approach.

**Consumer protection legislation**

Existing consumer protection laws cover general aspects of product safety, including electrical safety. Specific standards for e-cigarettes and vaping solutions could be developed and adopted as an Australian Standard, similar to the proposed British Standards Institute standard (BSI, 2014). This could address many concerns related to the safety of PVs and liquids, including specifying which additives (e.g. diacetyl) should not be used in vaping solutions and setting performance standards for maximum emissions limits. However, development of an Australian Standard would not address the current legal barriers to sale, possession and use of nicotine-containing e-cigarettes in Australia.

**Amend or reinterpret poisons regulations**

One option to widen public access to nicotine for vaping would be to reschedule nicotine from Schedule 7 to Schedule 5. This would address packaging and labelling concerns, but would not place any restrictions on where or to whom nicotine could be sold without additional legislation. Rescheduling nicotine would require all Australian states and territories to agree to this change, which could present a substantial challenge. Alternatively, state health departments could consider allowing adults to access nicotine for vaping under the existing licensing/approval arrangements for schedule 7 poisons, a framework that has some resemblance to a licensing scheme proposed by Chapman and Liberman (2005). This is the option that we discuss in more detail because it is feasible to trial under current legislation in most Australian states and may be more likely to be supported by the Australian tobacco control and public health community than less restrictive options, given the conservative approach favoured by many leading Australian public health advocacy groups (Cancer Council Australia & National Heart Foundation of Australia, 2014). We do not propose this

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as the optimal regulatory approach, but rather a pragmatic option available under current regulations that deserves discussion and consideration.

**A nicotine licensing scheme for non-therapeutic nicotine use**

In 2005, Chapman and Liberman proposed a ‘smoker licensing scheme’ that would restrict sales of tobacco to licensed smokers (Chapman & Liberman, 2005). In 2012, Chapman elaborated on the merits of this scheme and argued that a smoker’s licence would be similar to how a doctor’s prescription provides a temporary licence to purchase and use Schedule 4 medicines (Chapman, 2012). In a published debate on how e-cigarettes should be regulated, Chapman proposed the application of a user licence to these nicotine products, arguing that this “would balance the right to use e-cigarettes with all the constraints and disincentives that are now, and should be further, applied to cigarettes” (Chapman, 2013). Using the analogy of a medical prescription as a temporary licence, a nicotine licence for buying and selling non-TGA approved e-cigarettes would restrict access to e-cigarettes in much the same way as access to prescription-only medicines is restricted. The critical difference would be that the government would not provide “some tacit support for (medically supervised) use of an untested and unproven product” (National Drugs and Poisons Scheduling Committee, 2008).

The main elements of a smoker licensing scheme outlined by Chapman and Liberman (2005) include:

- Requirement of a knowledge test of the risks of smoking
- Presentation of a photo ID smart card on each occasion of purchase
- Recording all purchases were recorded against a licence
- Purchasing limits in the smart card to prevent large scale purchasing for on-selling to unlicensed smokers

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- Provision of financial incentives to encourage licensed smokers who quit to surrender their cards to reduce the chance of relapsing (because they would need to apply for a new licence to purchase cigarettes if they did so)

Implementing a smoker's licensing scheme would be a major undertaking and would radically change the way that tobacco is currently sold in Australia. However, applying a similar scheme to nicotine-containing e-cigarettes would be more straightforward since there is no current legal market for these products for non-therapeutic use and there are many fewer users of e-cigarettes than cigarette smokers. While a survey of Australian vapers found that a majority opposed a licensing scheme (60%), there were twice as many participants 'open' to the idea than was the case for over the counter pharmacy only sales (Fraser et al., 2015). This suggests a licensing option may potentially be more acceptable to current e-cigarette users than other options that use a medical framework (Schedules 2-4), as long as the regulations were not too burdensome.

The potential benefits of trialling a nicotine licensing scheme are that it provides regulated access to adults who want to use these products in a way that: targets adult smokers and deters young non-smokers; provides an alternative to the black market of inappropriately labelled and packed nicotine products; and provides critical data to assess uptake of nicotine-containing e-cigarettes by smokers and non-smokers, their impact on smoking and the extent to which users engage in dual use (i.e. continue to smoke cigarettes when able to do so).

**A License under the Schedule 7 poison regulations**

The Australian regulations for Schedule 7 'dangerous poisons' provide an existing framework for a 'nicotine licence' for sellers and buyers of nicotine-containing e-cigarettes for non-therapeutic human use. The Schedule 7 listing of nicotine has been justified by the NDPSC because it prohibits the use of nicotine intended for non-therapeutic use in order to protect public health and ensures that "individuals cannot gain access" (NDPSC, 2008).

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However, state drugs and poisons legislation also allow persons to have controlled access to Schedule 7 poisons via a 'licence' and/or 'approval' process in certain circumstances. These provisions could, in principle, be adapted to 'license' or 'approve' nicotine sellers and users for the purposes of a trialling sales of non-therapeutic nicotine for vaping in Australia.

**Proposed Nicotine Licensing/approval scheme**

Wholesalers and retailers could apply for a poison seller's licence/approval that was restricted to the sale of nicotine products up to a maximum strength concentration. Users could apply for an approval for the purchase, possession and use of nicotine products. If desirable, or necessary under current legislation, 'fit and proper' or 'suitable' person requirements for retailer licence and/or user approvals *could* include:

- No history of previous conviction for selling tobacco or alcohol to underage persons
- No history of previous conviction for selling illicit drugs
- Demonstration of adequate knowledge of safe storage and handling practices for nicotine
- Demonstration of adequate knowledge of their legal requirements as a licensed nicotine retailer/approved nicotine user

**Other *possible* inclusions not currently required under current legislation:**

- Users could be required to acknowledge that they understand that the products purchased under the approval may not meet the standards of therapeutic goods
- Limits could be set on the amount of nicotine and maximum % concentration approved users are allowed to possess at any time to avoid commercial quantities being purchased and sold on black market
- If an application fee for user approvals is charged, this could be fully refunded if surrendered within 3 months (or at any longer time) to reduce barriers for

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smokers wanting to try the products without committing to long-term use or using them to quit.

- Approval and photo id could be presented to licensed retailers when making purchases.

Current legislative requirements include maintaining records of all Schedule 7 poisons sales for a minimum period of time (e.g. 2 years in Queensland). Retailers could also be required to periodically provide aggregated data on sales to facilitate public health research on the nicotine market. Approved purchasers could also be periodically surveyed about their nicotine use, cigarette consumption and any adverse effects to monitor impact of nicotine use on smoking and health.

**Advantages and disadvantages**

A major advantage of the licensing approach to nicotine for use in e-cigarettes is that it could be implemented immediately under current legislation covering Schedule 7 chemicals in some states. This would provide a legal way for smokers to access these products until TGA approved products become available or other regulatory options requiring a change of laws are approved. The scheme could be easily wound up if it was no longer necessary. Schedule 7 regulations would require these products to be sold in child-resistant packaging and to be accurately labelled in terms of nicotine content and labelled with safe storage and handling instructions (e.g. 'keep out of the reach of children'). If the scheme is successful (i.e. most Australian vapers switch to purchasing their nicotine products via the scheme), this could reduce some of the potential hazards of the proliferation of black-market products that are packaged in non-child resistant packages and are inappropriately labelled (no ingredients list, inaccurate nicotine content, no safe handling advice). This approach

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could address the reported increase in child poisonings related to nicotine products that have been inappropriately packed and labelled (Hagan, 2014).

The current legislative requirements for recording and retention of Schedule 7 poison sales data would allow diversion of legally purchased nicotine products to the illicit market by approved purchasers and licensed retailers to be investigated (most likely on a complaints-driven basis). Measures to proactively reduce diversion by enforcing limits on total quantities that could be sold and monitoring transactions along the supply chain (from manufacturer/wholesaler to retailer to consumer) would require a more sophisticated system, such as is mandated for pseudoephedrine sales in Queensland (Bebatis, Sunderland, & Dhaliwal, 2009). This involves a secure website which records in real-time pseudoephedrine sales against purchasers' details. Individuals wishing to purchase preparations containing pseudoephedrine present their photo id to the pharmacist who then enters the purchaser into the database (Devaney, Ferris & Mazerolle, 2014). Such a monitoring system would involve a significant cost burden. Project STOP (pseudoephedrine real-time monitoring system) is funded by the Pharmacy Guild and cost \$500,000 to setup and \$650,000 per year to maintain (The Pharmacy Guild of Australia, 2013). Another example of a seller/purchaser licensing model is Uruguay's proposed cannabis licensing scheme, which will allow licenced growers and sellers to produce and sell cannabis within specified limits (quantity and THC content). Purchasers will be required to register with a database run by the Ministry of Health and will be limited to purchasing 40 grams/month through pharmacies and the user registry aims to prevent the bundling of repeat purchase of small amounts to avoid detection (Pardo, 2014). The government will need to determine if the risk of diversion of nicotine for vaping to the black market warrants this level of monitoring.

The major advantage of utilising existing legislation is that it is not clear what level of regulation of these products is most likely to benefit public health. A trial of a nicotine

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licensing scheme would allow valuable data to be collected that would assist in determining what form of regulation is appropriate for nicotine-containing e-cigarettes. If there was a need for a longer term scheme, then legislative changes could make it more appropriate for e-cigarettes. For example, labelling requirements could be amended to provide specific advice for use of e-cigarettes, or if monitoring sales of nicotine at the user end was found to be unnecessary, recording of sales against approval numbers could be removed. There is also considerable scope within this option to implement a range of approaches from a relatively 'light touch' basic version (e.g. just licensing retailers) up to a more tightly controlled version closer to Chapman's proposed "smoker's licence".

The main disadvantage of this approach is the substantial administrative burden it imposes on government, retailers and users. Some e-cigarette users may be opposed to records being kept of their nicotine purchases or being required to apply for an approval to possess and use nicotine when no such requirement is placed on tobacco. Some labelling requirements for Schedule 7 poisons (e.g. the warning "Dangerous Poison")(TGA, 2013b) may be inappropriate for e-cigarettes given that similar levels of nicotine can be found in currently unscheduled nicotine products (e.g. Nicorette inhalator, Nicorette Quickmist Mouthspray). Some states place restrictions on the purposes for which Schedule 7 user permits/approvals can be issued. One of the allowed purposes is 'research', hence it is possible that issuing approvals as part of a research trial could be facilitated. Only one state (Victoria) explicitly prohibits Schedule 7 poison sellers licences to be issued for retailing nicotine for non-therapeutic human use.

Current tobacco control legislation in Western Australia, New South Wales, and South Australia could present a barrier to sale of the e-cigarette devices (Douglas et al., 2015). The final outcome of the Van Heerden case will be critical in determining whether the sale of *all* e-cigarette devices is prohibited by this legislation in Western Australia, or only

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those that physically resemble cigarettes. If necessary, this legislation could be amended to permit sale by licensed sellers to approved adult purchasers. Otherwise, the licensing scheme may be limited to refill solutions only. Users in these states would need to source the devices from other states or from overseas (e.g. via the internet). This restriction would probably reduce the number of smokers who would switch to e-cigarettes. The proposed licensing scheme is more paternalistic and restrictive than current controls on smoked tobacco but much less so than the current *de facto* ban on the sale and use of nicotine in e-cigarettes (Hall et al., 2015). Current users may (justifiably) feel that the extra controls on sale and purchase are an unfair imposition when such controls are not placed on tobacco purchases. However, there is an even larger regulatory gap between the current approach to non-therapeutic nicotine use (prohibition) and what current users may see as an acceptable level of regulation (e.g. only an 18+ age restriction on sales). Where current laws allow for approvals to be issued to obtain, possess and use Schedule 7 poisons, it is arguably more ethical to allow adults who can demonstrate they are able to store and use nicotine safely to obtain an approval under these conditions than to deny them the option of applying for and obtaining an approval.

Some may raise objections that introducing licensing for nicotine could be a potential ‘Trojan horse’ for licensing smokers (Chapman, 2013). Regardless of whether a licensing scheme for smokers is desirable or not, we don’t believe this is a sufficient reason not to discuss this option as a viable one for nicotine-containing e-cigarettes, given the limited options that are available under current Australian laws. This option is a compromise that may facilitate legal access to nicotine for vaping in a way that allows the collection of valuable data that can help to decide what sort of regulatory scheme Australia should ultimately adopt toward these products. Running a research trial of such a scheme for a limited time period (e.g. 2 years) would allow these data to be collected and set a date for

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review and evaluation of how useful and appropriate this regulatory option was compared to the other current alternatives such as medicines approval or a *de facto* ban.

### Conclusion

Current Australian regulations prohibit the possession and use of nicotine for non-therapeutic purposes without an approval or other authority. The proposed nicotine licensing scheme could potentially provide Australian adult smokers with a way to legally access nicotine for use in e-cigarettes to reduce their health risk under current poisons regulations without the barriers of medicines regulation. It could also address the risk of child poisonings from inappropriately packed and labelled nicotine solutions. This scheme may serve as an interim measure until TGA approved e-cigarettes are available or other regulatory options are adopted. Alternatively, if there are benefits in maintaining the licensing scheme, it would be possible to make legislative amendments to make it more appropriate for e-cigarette products.

### Acknowledgements

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### References

- AAP. (2014, July 10). Old man fined for selling e-cigarettes. The Australian. Retrieved 30<sup>th</sup> September from <http://www.theaustralian.com.au/news/latest-news/qld-man-fined-for-selling-e-cigarettes/story-fn3dxiwe-1226984769775>
- Abrams, D. B. (2014). Promise and peril of e-cigarettes: can disruptive technology make cigarettes obsolete? The Journal of the American Medical Association, 311(2), 135-136. doi: 10.1001/jama.2013.285347

## A LICENCE TO VAPE

- Bates, C., & Stimson, G. (2013). Costs and burdens of medicines regulation for e-cigarettes. London: Nicotine Science and Policy.
- Berbatis, C. G., Sunderland, V. B., & Dhaliwal, S. S. (2009). Linked electronic medication systems in community pharmacies for preventing pseudoephedrine diversion: a review of international practice and analysis of results in Australia. *Drug and Alcohol Review*, 28(6), 586-591. doi: 10.1111/j.1465-3362.2009.00051.x
- Brown, G. (2014, February 8). Birmingham firm Nicolites in talks to have e-cigarettes classed as medicine. *Birmingham Post*. Retrieved on 30<sup>th</sup> 2014 September from <http://www.birminghampost.co.uk/business/manufacturing/birmingham-firm-nicolites-talks-e-cigarettes-6683552>
- Brown, J., West, R., Beard, E., Michie, S., Shahab, L., & McNeill, A. (2014). Prevalence and characteristics of e-cigarette users in Great Britain: Findings from a general population survey of smokers. *Addictive Behaviors*, 39(6), 1120-1125. doi: 10.1016/j.addbeh.2014.03.009
- Bullen, C., Howe, C., Laugesen, M., McRobbie, H., Parag, V., Williman, J., & Walker, N. (2013). Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*, 382(9905), 1629-1637. doi: 10.1016/S0140-6736(13)61842-5
- BSI. (2014). PAS 54115 PUBLICLY AVAILABLE SPECIFICATION Manufacture, importation, testing, and labelling of vaping products, including electronic cigarettes, e-shisha and directly-related products – Code of practice. The British Standards Institution. Available at <http://www.pdf-archive.com/2014/11/07/pas-54115-draft-2-3-for-pr/>
- Cancer Council Australia, & National Heart Foundation of Australia. (2014). Position Statement: Electronic Cigarettes. Available from: [http://wiki.cancer.org.au/policy/Position\\_statement\\_-\\_Electronic\\_cigarettes](http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes)

## A LICENCE TO VAPE

Carrick, D. (2014). E-Cigarettes: Should we inhale? The Law Report. ABC Radio National Broadcast 10

June 2014 5:30PM. Available from:

<http://www.abc.net.au/radionational/programs/lawreport/e-cigarettes/5505756#transcript>

Caponnetto, P., Campagna, D., Cibella, F., Morjaria, J. B., Caruso, M., Russo, C., & Polosa, R. (2013).

Efficiency and Safety of an eElectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. PLoS One, 8(6), e66317. doi:

10.1371/journal.pone.0066317

Chapman, S. (2012). The case for a smoker's license. PLoS Medicine, 9(11), e1001342. doi:

10.1371/journal.pmed.1001342

Chapman, S. (2013). Should electronic cigarettes be as freely available as tobacco cigarettes? No.

BMJ, 346, f3840. doi: 10.1136/bmj.f3840

Chapman, S. (2014). Simon Chapman on e-cigarettes: the best and the worst case scenarios for

public health. BMJ Blogs. <http://blogs.bmj.com/bmj/2014/03/14/simon-chapman-on-e-cigarettes-the-best-and-the-worst-case-scenarios-for-public-health/>

Chapman, S., & Liberman, J. (2005). Ensuring smokers are adequately informed: reflections on

consumer rights, manufacturer responsibilities, and policy implications. Tobacco Control, 14 (Suppl II), ii8-13. doi: 10.1136/tc.2005.012591

Clare, P., Bradford, D., Courtney, R. J., Martire, K., & Mattick, R. P. (2014). The relationship between

socioeconomic status and 'hardcore' smoking over time - greater accumulation of hardened smokers in low-SES than high-SES smokers. Tobacco Control. doi: 10.1136/tobaccocontrol-2013-051436

Cook, B. (2014, February 25). Hervey Bay Authorities cracking down on illegal e-cigarettes. Fraser

Coast Chronicle. Retrieved on 30<sup>th</sup> September 2014 from

<http://www.frasercoastchronicle.com.au/news/hervey-bay-authorities-cracking-down-illegal-e-cig/2180697/>

## A LICENCE TO VAPE

- Devaney, M., Ferris, J., & Mazerolle, L. (2014). Online reporting of pseudoephedrine pharmacy sales: does Australia require a mandatory system? *International Journal of Pharmacy Practice*. In press. doi: 10.1111/ijpp.12153
- Dockrell, M., Morrison, R., Bauld, L., & McNeill, A. (2013). E-cigarettes: prevalence and attitudes in Great Britain. *Nicotine and Tobacco Research*, 15(10), 1737-1744. doi: 10.1093/ntr/ntt057
- Douglas, H., Hall, W., & Gartner, C. (2015). E-cigarettes and the law in Australia. *Australian Family Physician*. In Press.
- Duckett, S. (2014, 29 July). Higher health co-payments will hit the most vulnerable. *The Conversation*. Retrieved on 30<sup>th</sup> September 2014 from <http://theconversation.com/higher-health-co-payments-will-hit-the-most-vulnerable-29590>
- Duff, E. (2013, September 22). Deadly nicotine blows its way into e-cigarettes. *The Sun Herald*, p. 8.
- Duff, E., & Corderoy, A. (2014, April 27). Electronic cigarettes: the truth behind smoke and mirrors. *The Sun-Herald*, p. 24.
- Fraser, D., Weir, M., Keane, H., & Gartner, C. (2015). Vapers' perspectives on electronic cigarette regulation in Australia. *International Journal of Drug Policy*. In press.
- Freeman, B. (2014). Is big tobacco abandoning smokes for e-cigarettes? *The Conversation*. 9/7/2014. Available at: <http://theconversation.com/is-big-tobacco-abandoning-smokes-for-e-cigarettes-28328>.
- Hagan, K. (2014, June 7). E-cigarettes poisoning Victorian toddlers. *The Age*. Retrieved on 30<sup>th</sup> September 2014 from <http://www.theage.com.au/national/ecigarettes-poisoning-victorian-toddlers-20140606-39ohu.html>
- Hajek, P., Etter, J. F., Benowitz, N., Eissenberg, T., & McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*, 109(11), 1801-1810. doi: 10.1111/add.12659
- Hall, W., Gartner, C., & Forlini, C. (2015). Ethical issues raised by a ban on on the sale of Electronic Nicotine Devices. *Addiction*, In press.

## A LICENCE TO VAPE

- McRobbie, H., Bullen, C., Hartmann-Boyce, J., & Hajek, P. (2014). Electronic cigarettes for smoking cessation and reduction. *Cochrane Database of Systematic Reviews*. Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub2
- National Drugs and Poisons Scheduling Committee. (2008). Record of reasons for decisions: June 2008. ACT: Therapeutic Goods Administration.
- National Drugs and Poisons Scheduling Committee. (2011). Record of reasons for decisions: September 2011. ACT: Therapeutic Goods Administration.
- Newberry, J., Wodak, A., Sellman, D., & Robinson, G. (2014). New Zealand's regulation of new psychoactive substances. *BMJ*, 348:g1534.
- Pardo, B. (2014). Cannabis policy reforms in the Americas: A comparative analysis of Colorado, Washington, and Uruguay. *International Journal of Drug Policy*, 25, 727-35.
- Royal College of Physicians. (2007). Harm reduction in nicotine addiction: Helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: Royal College of Physicians.
- Therapeutic Goods Administration. (2013a, 21 August 2013). Personal importation scheme. Retrieved on 30<sup>th</sup> September 2014 from <http://www.tga.gov.au/consumers/personal-importation-scheme.htm#.U2XQ6RCuDm4>
- Therapeutic Goods Administration. (2013b). Standard for the Uniform Scheduling of Medicines and Poisons No. 5. Department of Health and Ageing: Australian Government.
- The Pharmacy Guild of Australia. (2013). Media release: Access to Project STOP for non-Guild Members. 18 January 2013. [http://www.guild.org.au/docs/default-source/public-documents/news-and-events/media-releases/2013/mr\\_projectstop\\_18jan13.pdf?sfvrsn=](http://www.guild.org.au/docs/default-source/public-documents/news-and-events/media-releases/2013/mr_projectstop_18jan13.pdf?sfvrsn=)
- Yong, H. H., Borland, R., Balmford, J., McNeill, A., Hitchman, S., Driezen, P., . . . Cummings, M. (2014). Trends in e-cigarette awareness, trial, and use under the different regulatory environments of Australia and the UK. Manuscript submitted for publication.

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