

# E-cigarettes and the law in Australia

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## Background

Australian laws covering electronic cigarettes (e-cigarettes) are complex and vary between jurisdictions. The supply of nicotine-containing e-cigarettes in Australia is illegal. Possession or use of nicotine in e-cigarettes without approval is also illegal and the sale of non-nicotine e-cigarettes is illegal in some states. Despite the current legal barriers, the use of e-cigarettes by Australian smokers has increased over recent years.

## Objective

This article summarises these laws, recent cases involving e-cigarettes and what is known about their safety and efficacy as cessation aids.

## Discussion

Australian medical practitioners are likely to be asked about e-cigarettes by patients who smoke and may be interested in using them to quit smoking. The efficacy of e-cigarettes as a cessation aid has not been fully established. The health risk of long-term use is also unknown, although it is probably less than that of smoking cigarettes. There is an urgent need for research on the health effects of e-cigarettes and their use in quitting smoking.

**E**lectronic cigarettes, or e-cigarettes, have gained popularity in Australia and overseas, particularly among smokers. In the US, around 3.5 million people have reportedly used e-cigarettes<sup>1</sup> and around 2.1 million adults in the UK.<sup>2,3</sup> Data from the *International tobacco control four country study* found the proportion of Australian smokers who have tried e-cigarettes has increased in recent years.<sup>4</sup>

A survey of medical practitioners in the US recently reported around half had received patient inquiries about e-cigarettes 'frequently' or 'sometimes'.<sup>5</sup> It also found around one-third of practitioners had recommended patients use e-cigarettes as a cessation aid.<sup>5</sup> One may reasonably expect that some Australian smokers will also ask their doctors for advice about e-cigarettes.

## What are e-cigarettes?

E-cigarettes are battery-powered devices designed to deliver nicotine and/or other substances as an aerosol that is then inhaled. They often resemble cigarettes but can also look like pens. E-cigarettes have a heating element, a disposable or refillable cartridge and an atomiser. Heating the atomiser aerosolises the liquid stored in the cartridge (usually referred to as e-juice or e-liquid), which usually contains nicotine and humectants (such as propylene glycol and/or vegetable glycerol) mixed with flavours.

An e-cigarette cartridge may last several hours, or up to several days, depending on factors such as nicotine content and cartridge volume, and the way it is used. Studies of inexperienced users show low-nicotine uptake but experienced users (who are usually former smokers) can achieve similar blood nicotine levels to smoking cigarettes.<sup>6</sup> This suggests users learn to regulate their nicotine intake from e-cigarettes in much the same way as smokers regulate their nicotine intake from combustible cigarettes.<sup>6</sup> Not all e-cigarettes contain nicotine, as some contain tobacco flavoured liquid, while others contain mint, fruit or other flavours.

## Health impacts

Two major claims are made for e-cigarettes: they increase quitting and are safer to use in the long term than smoking cigarettes. There is limited research on whether e-cigarettes assist quitting.<sup>4,7-10</sup> The health effects of long-term use are also unknown, although probably lower than those of smoking cigarettes because e-cigarette users do not inhale the carcinogens contained in tars. Analyses of e-cigarette aerosols have found toxic compounds are present at much lower levels than in cigarette smoke and sometimes similar to those in medicinal nicotine products.<sup>11</sup>

Some critics argue e-cigarettes deliver nicotine, and therefore, can maintain addiction.<sup>1</sup> Others have expressed

apprehension about the dual use of e-cigarettes with conventional cigarettes, which may result in smokers continuing to smoke rather than quit.<sup>12</sup> There are also reports of tobacco companies purchasing e-cigarette companies, which raises concern about a marketing push for the uptake of e-cigarettes or dual use, and promoting the normalisation of cigarette smoking.<sup>13</sup> Concerns have also been raised about accidental nicotine poisoning of children.<sup>14</sup> Bottles of e-liquid are reportedly being sold without proper warnings and advice, or in child-resistant packaging.

### Australian law

Australian laws about e-cigarettes are complex and vary between different jurisdictions (refer to *Appendix 1*, available online only). In Australia, Commonwealth law overrides state and territory law when there is any inconsistency. Most Australian states and territories (with the exception of New South Wales) follow the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).<sup>15</sup> New South Wales has established its own NSW Poisons List which reflects the SUSMP with respect to nicotine.

Nicotine for human consumption is listed in the SUSMP as a prescription-only medicine in the schedule 4 (S4) classification, except when used as an aid in the withdrawal from tobacco smoking in preparations intended for oromucosal or transdermal use (eg nicotine patches, gum or mouthsprays). In the schedule 7 (S7) classification, nicotine is listed as a poison, except in preparations for human therapeutic use or in tobacco prepared and packed for smoking. Nicotine used for e-cigarettes will fall within S7 classification if it is not treated as a therapeutic good. There are no restrictions on importation but individuals may commit an offence under state and territory laws when they take possession of, or use, imported nicotine.

In all Australian states and territories, it is an offence to manufacture, sell or supply nicotine as an S7 poison without a licence or specific authorisation. This means

e-cigarettes containing nicotine cannot be sold in any Australian state or territory. There are several reported instances where individuals have been charged with the illegal supply of liquid nicotine for use in e-cigarettes in Queensland.<sup>16,17</sup>

A recent clarification from the Federal Department of Health has advised that nicotine can be imported by an individual for use as an unapproved therapeutic good (eg a smoking cessation aid), but the importer must hold a prescription from an Australian registered medical practitioner and only import 3 months' supply at any one time. The total quantity imported in 12 months cannot exceed 15 months' supply of the product at the maximum dose recommended by the manufacturer.<sup>18</sup> Most current consumers are unlikely to visit medical practitioners for a prescription of products that are readily available over the internet. The purchase and possession of nicotine by individuals are not regulated by Commonwealth legislation except for importation as allowed under Commonwealth law.

Non-nicotine e-cigarettes are currently not regulated as a therapeutic good under the Commonwealth *Therapeutic Goods Act*. To date, none have been approved by the Therapeutic Goods Administration (TGA) for registration as a medical device.<sup>18</sup> If the packaging of e-cigarettes includes a claim about therapeutic benefit, it would be referred to the TGA.<sup>19</sup>

In South Australia, Western Australia, and New South Wales, the law prevents the sale of products that resemble a tobacco product. The issue recently came to prominence in Western Australia in the case of *Hawkins v Van Heerden*.<sup>20</sup> Van Heerden was charged with offences against section 106(a) of the *Tobacco Products Control Act 2006* (WA), which states 'a person must not sell any food, toy or other product that is not a tobacco product but is designed to resemble a tobacco product or a package; or in packaging that is designed to resemble a tobacco product or a package'. He was found to be in possession of 60 e-cigarettes. He pleaded not guilty, arguing

the e-cigarettes were not 'designed to resemble a tobacco product' as the offence required. He sold e-cigarettes and nicotine-free e-juice via a website.

The initial magistrate found Van Heerden not guilty. Hawkins (a compliance officer with the Department of Health) appealed the decision to the Supreme Court and the judge reversed the magistrate's decision. The judge, on appeal, differed from the magistrate in defining the word 'resemble' in the relevant provision. He found the word had a broad definition that only required the product had a 'likeness or similarity to, or some feature in common with' a tobacco product. He found e-cigarettes did resemble cigarettes, noting that 'evidence supported the conclusion that the items were used for inhaling vapour (whether or not containing nicotine), which was exhaled in a manner reminiscent of the smoke from a cigarette'.<sup>20</sup>

Queensland state law also prohibits the sale of products that resemble a tobacco product. In 2014 Queensland amended its law to include 'personal vaporisers' in the definition of 'smoking product'. This legislation applies the same restrictions on the sale and use of non-nicotine-containing e-cigarettes (or personal vaporisers) as those applicable to combustible tobacco cigarettes.

In the Australian Capital Territory and Tasmania, state law prevents the sale of a 'toy or food' that resembles, or is intended to represent, a tobacco product. In the Australian Capital Territory and Tasmania, if it could be proven that e-cigarettes were intentionally marketed to children, it might be possible to argue they were being marketed as a toy and therefore breach the law. In these two jurisdictions, the sale of e-cigarettes is unregulated when no therapeutic claim is made and not targeted to children as 'toy or food'.

In the Northern Territory, the law prevents the sale of a product designed for consumption by children if it resembles, or is packaged to resemble, a tobacco product; or it has, or is likely to have, the effect of encouraging children to smoke.

The sale of e-cigarettes is unregulated if no therapeutic claim is made and if they are not targeted to children or likely to encourage children to smoke.

In all states, it is not illegal to possess an e-cigarette without nicotine. However, inhaling from an e-cigarette is included in smoking bans in Queensland. There is at least one example in New South Wales of a man being fined for 'smoking' an e-cigarette on a train station platform.<sup>21</sup> This incident underlines the uncertainty around how current laws may be applied when there is no e-cigarette-specific provision in the law. Whether public smoking bans apply to e-cigarette use in states without specific e-cigarette laws has not been tested in the higher courts, or in other jurisdictions. In all Australian states and territories, it is either illegal to possess or use nicotine as an S7 poison (ie when not considered to be a therapeutic good) without an approval, permit or authority.

### How should medical practitioners respond to patient inquiries about e-cigarettes?

A patient inquiry about e-cigarettes is a good opportunity to discuss smoking

cessation and provide advice on what cessation support is available, including approved cessation aids (eg nicotine replacement therapy, Varenicline, Bupropion) and other support (eg Quitline counselling, self-help materials, etc). There is one clinical trial that suggests e-cigarettes are at least as effective as a cessation aid as nicotine patches.<sup>7</sup> Specific information medical practitioners can provide to their patients about e-cigarettes is shown in *Table 1*.

Some patients may request a prescription for nicotine to allow them to legally import an S4 medicine under the TGA Personal Importation Scheme.<sup>18</sup> Medical practitioners should exercise caution in deciding whether it is in the patient's best interest to prescribe nicotine for inhalation as a smoking cessation aid.

### Conclusion

There are a range of ways to quit smoking, including abrupt cessation or using one of the many cessation aids currently on the market (eg nicotine patches, gum and mouth sprays). These are usually available in supermarkets. The laws around e-cigarettes in Australia

are confusing and complex and vary between different jurisdictions. Currently, the sale or supply of nicotine e-cigarettes in Australia is illegal. Despite this, some Australian smokers are using e-cigarettes as a cessation aid or long-term substitute for cigarettes. There is an urgent need for research on the health effects of e-cigarettes and their contribution to quitting smoking. The legislation governing their sale and use should be clarified one way or another as has occurred Queensland.

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**Table 1. Advice medical practitioners can give to patients about e-cigarettes**

- There are many options in the effort to quit smoking. These include abrupt cessation and a range of approved cessation aids such as nicotine patches, gum and mouth sprays.
- It is illegal to sell e-cigarettes that contain nicotine.
- It is illegal to use nicotine in e-cigarettes without a prescription or other authority.
- In Queensland it is legal to sell e-cigarettes that do not contain nicotine under the same conditions as for tobacco products. In some other states, it may be illegal to sell e-cigarettes even if it does not contain nicotine.
- The efficacy of e-cigarettes as a cessation aid has not been established and the quality may be variable.
- More research is needed on the health risks of using e-cigarettes to quit smoking, but these are probably similar to using medicinal nicotine products.
- The health risks of long-term e-cigarette use are unknown, although probably less than those of cigarette smoking.
- To receive health benefits, patients should aim to stop all smoking rather than just replacing some cigarettes with e-cigarettes. Dual use of e-cigarettes and conventional cigarettes should be strongly discouraged.
- Nicotine liquids should be handled with care (immediately wash any spills off skin with soapy water).
- Nicotine liquids are potentially harmful to children and should be kept out of reach, preferably in child-proof containers.

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**Appendix 1. Australian laws relevant to electronic cigarettes and nicotine solutions**

<b>Jurisdiction</b>	<b>Legislation</b>	<b>Summary</b>
<b>Cmth</b>	<i>Commonwealth Poisons Standard</i>	<ul style="list-style-type: none"> <li>Nicotine in preparation for human therapeutic use except for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use (schedule 4 [S4]).</li> <li>Nicotine except in preparations not for human therapeutic use or in tobacco prepared and packed for smoking (Schedule 7 [S7]).</li> <li>Nicotine in preparations for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use or in tobacco intended for smoking (unscheduled).</li> </ul>
	<i>Therapeutic Goods Act 1989</i> esp: ss1; 3, 20A; 41BD.  Note: Currently no e-cigarette has been registered as a therapeutic good in Australia.	<ul style="list-style-type: none"> <li>Regulates and defines therapeutic goods: Goods that have or are likely to have a 'therapeutic use'.</li> <li>Therapeutic use includes use in connection with 'preventing a disease'.</li> <li>A therapeutic device includes an instrument or appliance which does not achieve its principal intended action by pharmacological or chemical means 'though it may be assisted in its function by such means'.</li> <li>A medical device is an instrument, apparatus or an appliance intended to be used for ... prevention of disease.</li> <li>The Act establishes a system of registration and the Australian Register of Therapeutic Goods.</li> <li>Criminal offences and civil penalties apply for importing, exporting, supplying and manufacturing therapeutic goods and medical devices not included in the Register.</li> <li>Individuals are permitted to import up to 3 months' supply of unapproved therapeutic goods for personal use via the TGA's personal importation scheme. For S4 preparations, the importer must hold a prescription from an Australian registered medical practitioner.</li> </ul>
	<i>Tobacco Act 1927</i> , ss3, 18	<ul style="list-style-type: none"> <li>It is an offence to sell or import a food or toy that resembles a smoking product.</li> <li>A food or toy resembles a smoking product if a reasonable person would believe a resemblance exists or is likely to exist.</li> </ul>
<b>ACT</b>	<i>Medicines, Poisons and Therapeutic Goods Act 2008</i> , ss14, 20, 22,23, 26, 36, 74	<ul style="list-style-type: none"> <li>Adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>It is an offence to manufacture, supply, sell, dispense, possess or deal with nicotine in S7 preparations unless authorised.</li> <li>A regulated therapeutic good is any of the following within the meaning of the <i>Therapeutic Goods Act 1989</i> (Cmth) (see above): A therapeutic good (other than a regulated substance); a medical device or a therapeutic device.</li> <li>It is an offence to deal with a regulated therapeutic good without a licence.</li> </ul>
<b>NSW</b>	<i>Public Health (Tobacco) Act 2008</i> s21	<ul style="list-style-type: none"> <li>It is an offence to sell a product that resembles a tobacco product or is packaged to resemble a tobacco product.</li> </ul>
	<i>Poisons List NSW</i> (Ministry of Health NSW)	<ul style="list-style-type: none"> <li>Reflects <i>Commonwealth Poisons Standard</i> for nicotine (above).</li> </ul>
	<i>Poisons and Therapeutic Goods Act 1966</i> s9, 11, 16, 17A, 31, 36A	<ul style="list-style-type: none"> <li>It is an offence to possess nicotine in S4 preparations unless a licensed health practitioner or certain other persons, or authorised (with a medical prescription).</li> <li>Offences apply to those who supply or sell wholesale therapeutic goods without a licence.</li> </ul>
	<i>Poisons and Therapeutic Goods Regulation 2008</i> , reg 20; part 8.	<ul style="list-style-type: none"> <li>Offences apply to obtaining or using a S7 substance without authority (eg under part 8 – Must be deemed a 'fit and proper person')</li> <li>Supply of S7 substances only permitted by authorised persons to an authorised person.</li> </ul>

Appendix 1. Australian laws relevant to electronic cigarettes and nicotine solutions

Jurisdiction	Legislation	Summary
NT	<i>Tobacco Control Act 2002</i> sections 6, 46	<ul style="list-style-type: none"> <li>It is an offence to sell a product designed or marketed for consumption or use by children if it resembles, or is packaged to resemble, a tobacco product; or has or is likely to have the effect of encouraging children to smoke (whether it is intended to have that effect or not).</li> </ul>
	<i>Medicines Poisons and Therapeutics Goods Act 2012</i> sections 7, 19	<ul style="list-style-type: none"> <li>Adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>Offences apply to those who sell or supply nicotine in S4 and S7 preparations unless they are a pharmacist or medical practitioner or otherwise licensed to sell or supply.</li> <li>Some exemptions apply (eg when supplied on a prescription or administered by a medical practitioner).</li> <li>It is an offence to possess, use, produce or manufacture nicotine in S7 preparations (unless the person has a permit).</li> </ul>
Qld	<i>Tobacco and Other Smoking Products Act 1998</i> , s5A, s26ZS	<ul style="list-style-type: none"> <li>It is an offence to supply, as part of a business activity an object that resembles a smoking product.</li> <li>A personal vaporiser is defined as a smoking product.</li> <li>'Resembles' is broadly defined to include an object that has an appearance that is likely to cause a reasonable person to consider the object resembles a tobacco product or tobacco product package.</li> </ul>
	<i>Health Legislation Amendment Bill 2014 Part 8 Amendment of Tobacco and Other Smoking Products Act 1998</i>	<ul style="list-style-type: none"> <li>Exempts 'personal vaporisers' (e-cigarettes) from the ban on sale of products that resemble tobacco products (see above).</li> <li>Personal vaporisers included in the definition of a 'smoking product'.</li> <li>Restrictions apply on the sale and use of e-cigarettes as a smoking product, including prohibiting use wherever smoking is prohibited and age restriction on sales to 18+ years.</li> </ul>
	<i>Health Act 1937</i> s132	<ul style="list-style-type: none"> <li>Regulations may be made about manufacture, supply, possession, use of poisons and restricted drugs.</li> </ul>
	<i>Health (Drugs and Poisons) Regulation 1996</i> (Qld) chapter 4 esp. r271, Appendix 7, r3 .	<ul style="list-style-type: none"> <li>Adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>Nicotine in S7 preparations can only be manufactured and sold under licence, offences apply.</li> <li>A person must not manufacture, sell, prescribe, administer, dispense, possess or use nicotine in S7 preparations, without an approval.</li> <li>It is an offence for a person to sell or use an electric vaporising device or other heating device for vaporising a poison unless it has a vaporisation rate of more than one gram per day when fully charged with poison and it is certified for the purpose.</li> </ul>
SA	<i>Tobacco Products Regulation Act 1997</i> s36	<ul style="list-style-type: none"> <li>It is an offence to sell a product that is designed to resemble a tobacco product.</li> </ul>
	<i>Controlled Substances Act 1984</i> s13, 15, 23, 27;	<ul style="list-style-type: none"> <li>Adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>A person must not manufacture or pack a poison (eg nicotine, or medical device as defined by Therapeutic Goods Administration Act Cth above) or sell or supply a poison (eg nicotine in S7 preparations) unless they are a registered health practitioner or licenced to do so.</li> </ul>
	<i>Controlled Substances (Poisons) Regulations 2011</i> reg 9–15, 30.	<ul style="list-style-type: none"> <li>A person must not sell, supply, purchase or use a S7 poison for a domestic purpose or domestic gardening purpose. Domestic purpose is not defined.</li> </ul>

**Appendix 1. Australian laws relevant to electronic cigarettes and nicotine solutions**

<b>Jurisdiction</b>	<b>Legislation</b>	<b>Summary</b>
<b>Tas</b>	<i>Public Health Act 1997</i> ss 68A.	<ul style="list-style-type: none"> <li>It is an offence to display, sell or supply a toy that resembles, or is intended to represent a tobacco product.</li> </ul>
	<i>Poisons Act 1971</i> ss3, 26, 27, 36, 37.	<ul style="list-style-type: none"> <li>Adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>It is an offence for a person to manufacture, sell, supply, obtain or possess a poison (eg nicotine in S7 preparations) unless licenced or authorised to do so. An authorised person includes a medical practitioner.</li> <li>It is an offence to obtain or possess nicotine in S4 preparations unless authorised or licenced to do so.</li> </ul>
	<i>Poisons Regulation 2008</i> reg 74	
<b>Vic</b>	<i>Tobacco Act 1987</i> s 15N, 15S, 15O	<ul style="list-style-type: none"> <li>Ban orders may be recommended where the product (or class of products) has been banned by the commonwealth or another state; where a product is not a tobacco product but resembles a tobacco product; and in cases where advertising of the product may encourage children or young people to smoke.</li> <li>Offences exist for selling a banned product. However, no ban order on e-cigarettes has been made.</li> </ul>
	<i>Drugs, Poisons and Controlled Substances Act 1981</i> s12D, 13, 20, 26, 36 B; 46.	<ul style="list-style-type: none"> <li>Adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>It is an offence for a person to manufacture, supply or sell nicotine in S7 preparations without a licence.</li> <li>Nicotine for human use when an S7 is listed in the Poisons Code as a substance not for general retail sale and licences to retail it cannot be issued.</li> <li>It is an offence to obtain or possess nicotine in S4 preparations unless authorised or licenced to do so.</li> </ul>
	<i>Drugs, Poisons and Controlled Substances Regulations 2006</i> , reg 6, 15A and 65.	<ul style="list-style-type: none"> <li>Nicotine in S4 preparations may be approved for possession and use by a person or class of persons.</li> <li>It is an offence to obtain or possess nicotine in S7 preparations unless authorised or licenced to do so.</li> </ul>
<b>WA</b>	<i>Tobacco Products Control Act 2006</i> , ss106, 115	<ul style="list-style-type: none"> <li>It is an offence to sell any food, toy or other product that is not a tobacco product but is designed to resemble a tobacco product or a package; or in packaging that is designed to resemble a tobacco product or a package.</li> </ul>
	<i>Poisons Act 1964</i> , S25(1) and 62	<ul style="list-style-type: none"> <li>Generally adopts <i>Commonwealth Poisons Standard</i> (above).</li> <li>It is an offence for a person to manufacture, distribute, supply or sell nicotine in S7 preparations without a licence.</li> <li>'Fit and proper' persons may be permitted to obtain poisons for use for industrial, educational or research purposes or for the purpose of providing health services, but not for re-sale. Other uses not expressly prohibited, but could be illegal as not listed as purposes that may be permitted.</li> </ul>