Legal status of electronic cigarettes in Australia

Updated October 2016

The regulation of electronic cigarettes in Australia is complex. While some states and territories have introduced laws specifically addressing electronic cigarettes, in other jurisdictions electronic cigarettes are regulated by a number of more general laws relating to poisons, therapeutic goods and tobacco control.

Below is a summary of key laws and regulations that impact electronic cigarettes in Australia.

ELECTRONIC CIGARETTES CONTAINING NICOTINE

Commercial retail sale and personal possession/use of nicotine electronic cigarettes

- The sale and personal possession or use (among other things) of nicotine electronic cigarettes is currently unlawful in every jurisdiction in Australia (unless specifically approved/authorised/licenced/etc)(1-9). This is due to controls on nicotine that apply in each state and territory by reason of it being classified as a 'Schedule 7- Dangerous Poison' under the Commonwealth Poisons Standard(10). This position could change in the future should an electronic cigarette product be registered by the Therapeutic Goods Administration ('TGA') (discussed below).

- Where a nicotine electronic cigarette is for therapeutic uses, such as smoking cessation or alleviation of nicotine withdrawal, the electronic cigarette must be registered by the TGA in order to be sold lawfully(9). This involves an assessment of elements including the safety, quality and efficacy of the liquid nicotine and an assessment of the design of the electronic cigarette to ensure it is safe to use(11, 12). Liquid nicotine for inhalation for therapeutic uses is a 'Schedule 4 – Prescription only' medicine under the national Poisons Standard(13), which means that any TGA registered nicotine electronic cigarette products would be available by prescription only. There are currently no TGA registered electronic cigarettes (11) and importation, exportation, manufacture and supply of unregistered therapeutic goods is a criminal offence under the *Therapeutic Goods Act 1989* (Cth)(9).

- Where the nicotine electronic cigarette is represented as being for recreational purposes only (that is, not for therapeutic use), the nicotine is classified as a 'Schedule 7 - Dangerous Poison' under the national Poisons Standard(13). This means that the manufacture, sale and possession of this kind of recreational product is currently unlawful in all states and territories (unless an approval, authority/ licence/ permit (as the case may be) can be sought and is granted by the relevant state or territory authority)(1-9, 14).

- Even if a specific electronic cigarette product were to receive TGA registration in the future, it is possible that its sale would still be banned in states and territories that specifically prohibit the retail sale of products that are designed to resemble tobacco products (i.e, South Australia ('SA') (15)and Western Australia ('WA')(16)).

Importation of nicotine electronic cigarettes for personal use

- Importation of nicotine electronic cigarettes for personal therapeutic use (e.g. use as a quitting aid) is exempt from TGA registration requirements where certain conditions are satisfied (see below). This exemption arises under the personal importation scheme provided for under the *Therapeutic Goods Regulations 1990* (Cth) (Schedule 5). It is therefore possible to lawfully import nicotine electronic cigarettes for personal use if the importer is able to comply with the requirements of the TGA's personal importation scheme. Under this scheme (among other requirements):

    - As the goods are listed in Schedule 4 of the Poisons Standard (Prescription only), the importer must have a prescription from a medical practitioner registered in the relevant state or territory (unless the importer carries the goods as a passenger on a ship or plane)(17).

    - The goods must be imported for use in the treatment of the importer or the importer's immediate family.

    - The quantity imported in one importation must not be more than three months' supply at the maximum dose recommended by the manufacturer.

    - The goods must not contain a substance the importation of which is prohibited under the *Customs Act 1901* (Cth) (while nicotine is not a prohibited import, other constituents of electronic cigarettes might be. Often constituents are not fully disclosed).

- The total quantity of the goods imported in a 12 month period must not exceed 15 months' supply (18, 19).

The requirement for a medical prescription may pose practical barriers for people in Australia wishing to order nicotine electronic cigarettes online, in the event that medical practitioners are unwilling or unable (for legal reasons) to provide a prescription for a product that has not been approved by the TGA.

- Even if TGA laws and regulations permit nicotine to be imported for personal use with a medical prescription, state and territory drugs and poisons laws may or may not permit possession of that product as different restrictions apply to "prescription" medicines. It would be prudent for consumers to check restrictions under their applicable state and territory poisons laws to see if there are any other restrictions on the possession and use of electronic cigarettes obtained with a medical prescription from overseas.

- Importation and/or possession of nicotine electronic cigarettes for recreational use is not covered by the TGA personal importation scheme and will be in breach of state and territory drugs and poisons laws (as such a product would be considered a Schedule 7 - Dangerous Poison) (1-9, 14).

Use of nicotine electronic cigarettes in smokefree areas

- It is important to note that use of electronic cigarettes in smokefree areas is prohibited in some states/territories. These laws will apply to use of nicotine electronic cigarettes which have been imported under the personal importation scheme.

- In QLD, use of electronic cigarettes is prohibited in all legislated smokefree areas (20). Similar laws have been introduced in the ACT, and came into effect on 1 August 2016(21).
- From 1 August 2017, the use of electronic cigarettes in legislated smokefree areas will also be prohibited in Victoria(22).
- In NSW, use of electronic cigarettes is prohibited in motor vehicles where a child under the age of 16 is present (23).

NON-NICOTINE ELECTRONIC CIGARETTES

Retail sale of non-nicotine electronic cigarettes

- SA (15) and WA (16) laws prohibit retail sale of products that resemble tobacco products. Therefore, even if non-nicotine electronic cigarette products make no therapeutic claims, the retail sale of particular models in those jurisdictions may still be an offence.

- QLD (24), NSW (25) and the ACT (26) have introduced laws banning the sale of all electronic cigarettes to persons under the age of 18. From 1 August 2017, sale of electronic cigarettes to minors will also be prohibited in Victoria(22).

Advertising/promotion of non-nicotine electronic cigarettes

- QLD, NSW and the ACT have introduced laws restricting advertising, promotion and display of all electronic cigarettes at retail outlets (27) (28, 29). From 1 August 2017, laws restricting advertising, promotion and display of electronic cigarettes will also come into operation in Victoria.(22)

- At the moment, electronic cigarettes are not specifically referred to in the *Tobacco Advertising Prohibition Act 1992* (Cth) ('TAP Act') (which prohibits advertising of tobacco products via TV, radio, magazines, newspapers etc). However, in certain circumstances, advertisements for electronic cigarettes will breach the TAP Act (for example, where an electronic cigarette advertisement has the effect of promoting smoking).

Use of non-nicotine electronic cigarettes in smokefree areas

- In QLD, use of electronic cigarettes is prohibited in all legislated smokefree areas (20). Similar laws have been introduced in the ACT, and came into effect on 1 August 2016 (30).
- From 1 August 2017, use of electronic cigarettes in legislated smokefree areas will also be prohibited in Victoria.(22)
- In NSW, use of electronic cigarettes is prohibited in motor vehicles where a child under the age of 16 is present (23).

Commercial importation of non-nicotine electronic cigarettes

- Importation for commercial purposes and retail sale of non-nicotine electronic cigarettes that are marketed with therapeutic claims is unlawful across Australia

unless the product is registered by the TGA(9). There are currently no TGA registered electronic cigarettes(11).

- Commercial importation and retail sale of non-nicotine electronic cigarettes that do not make therapeutic claims is not covered by laws relevant to therapeutic goods, meaning that they can be imported and sold by retailers without needing to comply with laws relevant to therapeutic goods. Restrictions under customs and/or drugs and poisons laws may apply depending on the constituents of a particular product (and often constituents are not fully disclosed). Restrictions regarding retail sale may also apply in some states/territories (discussed further below).

Importation of non-nicotine electronic cigarettes for personal use

- Importation of non-nicotine electronic cigarettes that are marketed with therapeutic claims is covered by therapeutic goods laws and regulations and it is lawful to import these products for personal use or use by an immediate family member if the importer complies with the personal importation scheme (described above). Because the products do not contain a prescription only medicine (i.e. nicotine), no medical prescription is required, but the other conditions outlined further above (for example, regarding personal/family use, three months' supply and 15 months' supply within 12 months and restrictions on prohibited imports) all apply.

- Personal importation of non-nicotine electronic cigarettes that do not make therapeutic claims is not covered by laws relevant to therapeutic goods, meaning that they can be imported for personal use and commercial purposes without needing to comply with laws relevant to therapeutic goods. However, restrictions under customs and/or drugs and poisons laws may apply depending on the constituents of a particular product (and often constituents are not fully disclosed).

Please note: This information sheet does not constitute legal advice and should not be relied on as such. Consider whether you or your organisation should seek legal advice tailored to your specific circumstances.

References

1. *Drugs, Poisons and Controlled Substances Regulations 2006* (Vic) r 65. See also Victorian Department of Health, Electronic cigarettes containing nicotine are prohibited in Victoria. Available from: http://docs.health.vic.gov.au/docs/doc/Electronic-cigarettes-containing-nicotine-are-prohibited-in-Victoria.
2. *Poisons and Therapeutic Goods Regulation 2008* (NSW) r 20. See also NSW Government, Are electronic cigarettes legal in NSW?'. Available from: http://www.health.nsw.gov.au/tobacco/Factsheets/e-cigs-are-they-legal.pdf.
3. *Health (Drugs and Poisons) Regulation 1996* (Qld) r 271. See also Queensland Health, Electronic cigarettes. Available from: https://www.health.qld.gov.au/public-health/topics/atod/tobacco-laws/electronic-cigarettes/default.asp.
4. *Controlled Substances (Poisons) Regulations 2011* (SA) regs 9, 11, 12, 15 and 30; *Controlled Substances Act 1984* (SA) sections 13, 15, 16 and 27.
5. *Poisons Act 1964* (WA) sections 23, 24(1)(d), 25(1) and 40. See also Government of Western Australia, Department of Health, Electronic cigarettes (e-cigarettes). Available from: http://www.healthywa.wa.gov.au/Healthy-WA/Articles/A_E/Electronic-cigarettes-e-cigarettes.
6. *Poisons Act 1971* (Tas) s 37(2); *Poisons Regulations 2008* (Tas) r 74(11). See also Tasmanian Government, Population Health Services, E-cigarette facts. Available from: http://www.dhhs.tas.gov.au/__data/assets/pdf_file/0018/151182/PHS_E-Cigarettes_Final.pdf.
7. *Medicines, Poisons and Therapeutic Goods Act 2012* (NT) ss 42-44.
8. *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT) sections 26(1), 33, 35(1), s 36
9. *Therapeutic Goods Act 1989* (Cth) s 19B.
10. *Standard for the Uniform Scheduling of Medicines and Poisons*, commonly referred to as the 'Poisons Standard'.
11. Therapeutic Goods Administration. Electronic cigarettes. Symonston, Australian Capital Territory: Australian Government Department of Health and Ageing; 2013 [15 October 2013]; Available from: http://www.tga.gov.au/consumers/ecigarettes.htm.
12. National Coordinating Committee on Therapeutic Goods. Scheduling Policy Framework for Medicines and Chemicals. Symonston, Australian Capital Territory: Department of Health; 2010.
13. *Standard for the Uniform Scheduling of Medicines and Poisons No 4* ('Poisons Standard 2013').
14. Each state and territory has its own scheme for approving/authorising/ licensing dealings with dangerous poisons. It is beyond the scope of this paper to address these schemes.
15. *Tobacco Products Regulation Act 1997* (SA) s 36.
16. *Tobacco Products Control Act 2006* (WA) s 106. See also *Hawkins v Van Heerden* [2014] WASC 127.
17. Item 1(d) of Schedule 5 of the *Therapeutic Goods Regulations 1990* (Cth) states that a person needs a 'written authority' issued by a registered medical practitioner for the purpose of the personal importation scheme. The TGA has made clear that it considers a valid prescription to be the 'written authority' required under the regulations. See: http://www.tga.gov.au/newsroom/btn-liquid-nicotine.htm#.U6EDx-RQG5I.

18. *Therapeutic Goods Act 1989* (Cth) s 18(1); *Therapeutic Goods Regulations 1990* r 12(1) and Schedule 5, item 1(d).
19. Therapeutic Goods Administration. Personal Importation Scheme. Australian Government Department of Health; 2013 [7 April 2014]; Available from: http://www.tga.gov.au/consumers/personal-importation-scheme.htm.
20. See Parts 2B, 2BA and 2C of the *Tobacco and Other Smoking Products Act 1998* (QLD), which came into effect on 1 January 2015. .
21. See the *Smoke-free Legislation Amendment Bill 2016* (ACT).
22. See Part 4 of the *Tobacco Amendment Act 2016* (Vic).
23. See s 30 of the *Public Health (Tobacco) Act 2008* (NSW).
24. *Tobacco and Other Smoking Products Act 1998* (QLD), s 10.
25. *Public Health (Tobacco) Act 2008* (NSW), s 22.
26. See *Tobacco and Other Smoking Products Act 1927* (ACT), sections 3A, 3B and 15.
27. See Part 2A of the *Tobacco and Other Smoking Products Act 1998* (QLD), which came into effect on 1 January 2015.
28. See Parts 2 and 3 of the *Public Health (Tobacco) Act 2008*. The NSW amendments regarding advertising, display and promotion came into effect on 1 December 2015.
29. See *Tobacco and Other Smoking Products Act 1927* (ACT), Part 4.
30. See *Smokefree Public Places Act 2003* (ACT), section 5B. .