

PLAYING WITH FIRE: WHY AUSTRALIAN LEGISLATORS MUST LEGALISE E-CIGARETTES

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I. Introduction

E-cigarettes, also known as e-cigs, personal vaporizers, and Electronic Nicotine Delivery Systems (**ENDS**) are both increasingly popular and growingly scrutinized.¹ E-cigarettes were developed in China in 2003 and then released commercially to the Chinese market in 2004.² They have been marketed as a low-risk alternative to standard tobacco cigarettes.³

E-cigarettes operate differently compared to a traditional cigarette because they use vapor instead of smoke. More specifically, they are battery-operated devices that heat a cartridge filled with liquid to create vapor that users inhale.⁴ The liquid cartridge is inserted by the user and comes in a variety of flavors and/or liquid nicotine.⁵ Unsurprisingly, e-cigarettes are designed to mimic traditional cigarettes but have increasingly come in many designs, shapes, and sizes.⁶

¹ See H.R. STANDING COMM. ON HEALTH, AGED CARE & SPORT, PARLIAMENT OF THE COMMONWEALTH OF AUSTL., REPORT ON THE INQUIRY INTO THE USE AND MARKETING OF ELECTRONIC CIGARETTES AND PERSONAL VAPORISERS IN AUSTRALIA 46-50 (2018).

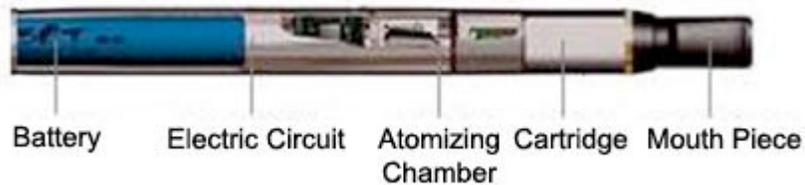
² *Id.* at 15 para. 2.1.

³ LEGIS. ASSEMBLY EDUCATION & HEALTH STANDING COMMITTEE, PARLIAMENT OF W. AUSTL., CLEARING THE AIR ON E-CIGARETTES: FACTORS REGARDING REGULATION THAT REQUIRE CONSIDERATION 12 (2017) [hereinafter CLEARING THE AIR ON E-CIGARETTES]; see also SELECT COMMITTEE ON E-CIGARETTES, 53RD PARLIAMENT OF S. AUSTL., FINAL REPORT OF THE SELECT COMMITTEE ON E-CIGARETTES 7 (2016).

⁴ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 1.

⁵ *Id.* at 1–2.

⁶ *Id.*

Figure 1 – Diagram of an E-cigarette⁷

The differing appearances coincide with the varying names or monikers given to these products. The Food & Drug Administration (FDA) noted that these products have been sold under several different trade names, including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes.⁸ Limited data is available on the uptake of e-cigarettes, but some international survey data suggests that e-cigarette use is increasing rapidly amongst adolescents, though most of these adolescents were already smokers.⁹ Vaping has increased substantially on a global level, mainly among smokers who use the products as a partial or complete replacement for cigarettes or as a short-term smoking cessation aid, similar to nicotine products that are approved as medicines.¹⁰ In the United Kingdom (“UK”), a 2018 survey found that about 3.2 million adults vaped, and of that population, 1.7 million used to smoke but no longer do.¹¹ There is limited but growing evidence that e-cigarette vape liquids are less harmful to users and bystanders, but they are nonetheless still *harmful*.¹²

This article will consider the legislation concerning e-cigarettes in New Zealand and the United States. Then, it will explain the Australian legislation in this area in depth, including legislation

⁷ SELECT COMMITTEE ON E-CIGARETTES, *supra* note 3 at 38.

⁸ Final Rule Subjecting Tobacco Products to FD&C Act, Restricting Sale & Distribution, & Requiring Warning Statements, 81 Fed. Reg. 28973, 28982 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143).

⁹ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3 at 11.

¹⁰ *See id.* at 1, 4.

¹¹ ACTION ON SMOKING AND HEALTH, Use of E-CIGARETTES (VAPOURISERS) AMONG ADULTS IN GREAT BRITAIN 1-2 (2018).

¹² *Personal Choice and Community Safety: Inquiry before the Legis. Council Select Comm. on Personal Choice and Cmty. Safety*, 40th Parliament of W. Austl. (2018) (statement on e-cigarettes, Cancer Council W. Austl.) (hereinafter Statement on E-Cigarettes).

concerning advertising, occupational health and safety, industrial relations and consumer law. Additionally, the article will consider federal and State/Territory jurisdictions. Ultimately, this article argues that major changes are needed to Australian legislation concerning e-cigarettes. Currently, the legislation is too restrictive because it does not give Australians sufficient easy access to e-cigarettes, given the product's ability to wean people off using traditional cigarettes.

II. Overseas Regulation of E-Cigarettes

Government regulation of e-cigarettes varies by country. The approaches taken internationally are, for this article's purposes, lumped into two rough categories: permissive and restrictive.

A. Permissive and Restrictive Approaches

Most of the Western world (UK, EU, USA, New Zealand, Canada) takes a permissive approach by allowing nicotine-containing e-cigarettes to be marketed either as consumer products or as medicines, if approved as a therapeutic good.¹³ For example, the United Kingdom Department of Health and Public Health England currently supports e-cigarettes as cessation aids.¹⁴ Separately, a few courts internationally have handed down decisions legalizing the sale of e-cigarettes, instead of the parliament in the relevant country passing legislation to that effect.¹⁵ For instance, Switzerland's Federal Administrative Court legalized the import and sale of

¹³ Daniel A. Erku et al., *Policy Debates Regarding Nicotine Vaping Products in Australia: A Qualitative Analysis of Submissions to a Government Inquiry from Health and Medical Organisations*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Nov. 18, 2019, at 2.

¹⁴ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3 at 12 (citing A. MCNEILL ET AL., PUB. HEALTH ENG., E-CIGARETTES: AN EVIDENCE UPDATE 7 (2015)) (Explaining two vaporised nicotine products were approved by the UK's MHRA (Medicines and Healthcare Products Regulatory Agency) as over the counter medicines. These products are (1) E-Voke, which is a battery-powered device, and (2) Voke, which uses a pressurised aerosol system. Neither product was commercialised. Finally, the company that developed both of these products, Nicoventures/Nicovations, is a wholly owned subsidiary of British American Tobacco.); see H.R. STANDING COMM. ON HEALTH, AGED CARE & SPORT., *supra* note 1, para. 5.18-5.19; see also Stanton A. Glantz & David W. Bareham, *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, 39 ANN. REV. PUBLIC HEALTH 215, 223 (2018) (discussing the lack of convincing evidence, and financial conflicts of interest).

¹⁵ See Erku, et al., *supra* note 13 at 2, 15.

nicotine liquid for e-cigarettes, effectively eliminating the ban previously implemented by the country's Federal Food Safety and Veterinary Office.¹⁶ At the same time, the Swiss Government already had a bill in Parliament under consideration for legalizing the importation and sale of nicotine liquid.¹⁷

B. Case Study: New Zealand

In New Zealand, the *Medicines Act 1981* (NZ)¹⁸ and the *Smoke-free Environments Act 1990* (NZ)¹⁹ (SFEA) collectively:

- a) regulate the sale, advertising and use of vaping products and nicotine liquids;
- b) schedule nicotine as a scheduled substance;
- c) prohibit the sale of a vaping product (with or without nicotine) while making a therapeutic claim (e.g. e-cigarettes help smokers quit), unless the product has been approved for that purpose by Medsafe; and
- d) provide that vaping product which are manufactured from tobacco are 'tobacco products' for the purposes of the SFEA.²⁰

The SFEA provides that no person shall "import for sale, sell, pack, or distribute any tobacco product labelled or otherwise described as suitable for chewing, or for any other oral use (other than smoking)." ²¹ For the Act, "tobacco product" includes e-cigarettes with nicotine.²² The scope of the definition set forth in the SFEA was at issue in 2018 in *Ministry of Health v Phillip Morris (New Zealand)*

¹⁶*Court Overturns Swiss Ban on E-Cigarettes*, SWISSINFO.CH (Apr. 28, 2018), https://www.swissinfo.ch/eng/business/immediate-effect_court-overturns-swiss-ban-on-e-cigarettes/44082174#.Wx6mIFfUous.facebook.

¹⁷*Id.*

¹⁸ Medicines Act 1981 (N.Z.).

¹⁹ Smoke-free Environments Act 1990 (N.Z.).

²⁰ See EM Greenhalgh, C Grace & MM Scollo, *18B.9 International Regulatory Overview*, in TOBACCO IN AUSTRALIA: FACTS AND ISSUES, <https://www.tobaccoinustralia.org.au/chapter-18-harm-reduction/indepth-18b-e-cigarettes/18b-9-regulatory-overview> (last updated Jan. 2019).

²¹ Smoke-Free Environments Act 1990, s 29(2) (N.Z.).

²² See *id.* at s 2; *Ministry of Health v Phillip Morris (New Zealand) Limited* [2018] NZDC 4478 at [4].

Limited.²³ In this case, Phillip Morris (New Zealand) was prosecuted for selling the HEET-using IQOS – an e-cigarette with nicotine.²⁴ The New Zealand Ministry of Health notified Philip Morris that “heated not burned” products were banned under section 29(2) of the SFEA because they contained tobacco for oral use.²⁵ As such, importing IQOS breached section 29(2) of the SFEA.²⁶

In his judgment, Judge Butler determined that HEETs did not fall under SFEA section 29(2) and therefore dismissed the charge.²⁷ Judge Butler reasoned that proper statutory interpretation revealed that the SFEA’s scope did not encompass e-cigarettes.²⁸ Additionally, Judge Butler considered the purposes of the Act and, in particular, the Act’s explicit purpose to reduce tobacco’s negative impact on the public’s health.²⁹ Judge Butler opined that HEETs may have associated risks, but they are less “harmful or potentially harmful” than ordinary cigarettes.³⁰ The implication of his judgment is that regulating HEETs falls beyond the scope of the SFEA’s legislative purpose.³¹

The broader implication of Judge Butler’s interpretation of the SFEA is this:

[A]ll tobacco products (except types that are chewed or otherwise absorbed through the oral mucosa e.g. snus) may be lawfully imported, sold and distributed under the SFEA. Therefore, the same SFEA regulatory controls, including the ban on sales to minors and restrictions on advertising, apply to smoked tobacco, heated tobacco and vaping products that are manufactured from tobacco.³²

²³ See generally [2018] NZDC 4478.

²⁴ *Id.* at [1], [4].

²⁵ *Id.* at [8].

²⁶ *Id.* at [31].

²⁷ *Id.* at [35].

²⁸ *Id.* at [34].

²⁹ *Id.* at [21]; see also Smoke-Free Environment Act 1990, s 21 (N.Z.).

³⁰ [2018] NZDC 4478 at [34].

³¹ *Id.* at [35].

³² Greenhalgh, Grace & Scollo, *supra* note 20.

The New Zealand Government interpreted this decision as legalizing both the sale of heated tobacco products and e-cigarettes, including other vaping products containing nicotine extracted from tobacco, but not as legalizing chewing tobacco and snuff.³³ The Court's decision was not appealed.³⁴ Moreover, the time permitted to appeal the judgment lapsed, though exceptions can be made under New Zealand's Appellate Procedure Rules.³⁵ Rather than appeal the judgment, the New Zealand government instead opted in 2018 to amend legislation in order to ban vaping in all smoke-free areas.³⁶

The New Zealand Advertising Standards Authority (NZASA) is a self-regulatory body established by industry, which adjudicates disputes arising under the *Advertising Standards Code* (NZ).³⁷ This Code's second principle prohibits misleading or deceptive advertising, which includes falsely (or without basis) advertising a good such as an e-cigarette as therapeutic.³⁸ Prior decisions of the Authority have held that advertisers are held to a high standard of social responsibility when making therapeutic claims, and must robustly substantiate any therapeutic claims.³⁹ For instance, in 2000, therapeutic-claim advertising for a weight-loss product was held to have breached the Code for Therapeutic Advertising 1996⁴⁰ due to a

³³ Sian Powell, *New Zealand E-Cigarette Decision Gives Hope to Australian Vapers*, THE AUSTRALIAN (May 11, 2018), <http://www.theaustralian.com.au/national-affairs/health/nz-ecigarette-decision-gives-hope-to-australian-vapers/news-story/34c2c9bfeddd39d39645f1c589494df7>.

³⁴ *Id.*

³⁵ Court of Appeal (Civil) Rules 2005, rr 29, 29A (N.Z.).

³⁶ Greenhalgh, Grace & Scollo, *supra* note 20.

³⁷ *Id.*; see also *Complaints Board (ASCB) Members*, ADVERTISING STANDARDS AUTHORITY, <https://web.archive.org/web/20190609233539/https://www.asa.co.nz/about-us/complaints-board-ascb-members/> (last visited Jun 28, 2019).

³⁸ See *Advertising Code of Ethics*, ADVERTISING STANDARDS AUTHORITY (2019), <https://web.archive.org/web/20190120013720/https://www.asa.co.nz/codes/codes/advertising-code-of-ethics/>; see also *In re Therapeutic Research Centre Sandra Foley CNP Advertisement* [2000] NZASA 142 (N.Z.) (discussing the principle that "Advertisements should not by implication, omission, ambiguity or exaggerated claim mislead or deceive or be likely to mislead or deceive consumers, abuse the trust of or exploit the lack of knowledge of consumers, exploit the superstitious or without justifiable reason play on fear"); Therapeutic and Health Advertising Code, r 2(a) (N.Z.) (mandating truthful representation in advertising of medicines, including goods claiming to be therapeutic).

³⁹ See *In re Therapeutic Centre Website Advertisement* [2014] NZASA 297 (N.Z.); *In re Therapeutic Research Centre Sandra Foley CNP Advertisement* [2000] NZASA 142 (N.Z.).

⁴⁰ *Advertising Code of Ethics*, *supra* note 38.

lack of substantiation for the claims, which provided no support other than a customer testimonial.⁴¹

C. Case Study: The United States

In 2016, the FDA finalized an executive rule (effective as of August 8, 2016) deeming tobacco products subject to regulation under the Food Drug and Cosmetic Act (FDCA).⁴² This rule deems *any* product within the statute's definition of "tobacco product" (barring exceptions) subject to the Act's restrictions and the FDA's jurisdiction. Consequently, the FDA can regulate "the manufacture, import, packaging, labelling, advertising, promotion, sale and distribution" of e-cigarettes in the United States.⁴³ Part 8 of this rule, titled "Regulation of Electronic Nicotine Delivery Systems," provides clarification "that although there are many types of ENDS (including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), all are subject to FDA's chapter IX authorities with this final deeming rule."⁴⁴ The FDA clearly defined the affected products, further stating:

FDA agrees that electronic nicotine delivery systems or ENDS are sold under several different names including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. These products all meet the definition of "tobacco product" and, therefore, under this rule, all are subject to FDA's tobacco control authorities, regardless of a novel name or heating source. In addition, the definition of tobacco product includes components and parts (the

⁴¹ *In re Therapeutic Research Centre Sandra Foley CNP Advertisement* [2000] NZASA 142 (N.Z.); see also *In re SleepDrops, Digital Marketing* [2018] NZASA 396 (N.Z.) (where the dispute was settled but the importance of substantiation was highlighted after considering medical literature: "*The Chair* noted the Complainant's concern there is little or no evidence for the effectiveness of the SleepDrops ingredients") (emphasis in original).

⁴² See generally Final Rule Subjecting Tobacco Products to FD&C Act, Restricting Sale & Distribution, & Requiring Warning Statements, 81 Fed. Reg. 28973 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143).

⁴³ Greenhalgh, Grace & Scollo, *supra* note 20.

⁴⁴ Final Rule Subjecting Tobacco Products to FD&C Act, Restricting Sale & Distribution, & Requiring Warning Statements, 81 Fed. Reg. 28973, 29028 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143).

objects intended or reasonably expected to be used with or for the human consumption of a tobacco product that are not accessories) (e.g., e-liquids, tanks, cartridges, pods, wicks, atomizers), which, under this rule, have also been deemed to be subject to FDA's authority under chapter IX of the FD&C Act.⁴⁵

Given this new rule, FDA restrictions that apply to other tobacco products (e.g., prohibiting sales in vending machines and to minors) now apply to e-cigarettes in the United States.⁴⁶

As of September 2019, Michigan prohibited the sale of flavored e-cigarettes, with other States considering similar action.⁴⁷ Shortly thereafter, in the same month, the White House and FDA announced a coming ban on flavored e-cigarettes.⁴⁸ However, tobacco-flavored e-cigarettes will be excluded.⁴⁹ The United States Health and Human Services Secretary announced that the ban will be implemented and administered by the FDA.⁵⁰

D. How does Australia Compare?

Unsurprisingly, the United States and New Zealand are less restrictive in terms of tobacco products compared with Australia; Australia is the global standard in combatting smoking, as recognized by the World Health Organization in July of 2019.⁵¹

A major and important component of this lead is Australia's States and Territories' tobacco restriction legislation.⁵² The

⁴⁵ *Id.*

⁴⁶ *The Facts on the FDA's New Tobacco Rule*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm> (last updated June 16, 2016).

⁴⁷ Shiela Kaplan, *Trump Administration Plans to Ban Flavored E-Cigarettes*, THE NEW YORK TIMES (September 11, 2019) <https://www.nytimes.com/2019/09/11/health/trump-vaping.html>.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ See WORLD HEALTH ORG., WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2019 (2019). The WHO labelled Australia as a "best practice country" in six of seven tobacco regulation types: monitoring tobacco use, smoke-free environments, treating tobacco dependence, health warning labels, anti-tobacco media campaigns and tobacco taxation. However, Australia was not ranked as a best practice country for restricting advertising and promotion relating to tobacco. *Id.* at 70, 76, 82, 91, 96, 101, 106.

⁵² See generally Panel Reports, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, § 2.2, WTO Docs. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (adopted June 28, 2018) [hereinafter WTO Panel Report, *Certain Measures*].

involvement of the States is a necessary implication of three legal considerations:

1. Australia's Constitution, which
 - a. authorizes the States to legislate concurrently with and independent of the Commonwealth (including, in this area of law);⁵³
 - b. grants broad (including exclusive) legislative power to the Commonwealth;⁵⁴
 - c. mandates federal legislation prevails over state legislation only to the extent that they are inconsistent;⁵⁵ and
 - d. grants territories legislative independence from and by the Commonwealth.⁵⁶

⁵³ *Australian Constitution* ss 51, 106, 107, 108. For a recent example of both State and Commonwealth governments legislating to regulate a substance, see the legalisation of medicinal cannabis in Queensland, which requires both the Commonwealth and Queensland governments to exercise their power. Robyn Wuth, *Qld Cuts Hurdle for Medicinal Cannabis*, THE COURIER (April 4, 2019, 1:27 PM), <https://www.thecourier.com.au/story/5998985/qld-cuts-hurdle-for-medicinal-cannabis/?cs=10229>; see also H.R. STANDING COMM. ON HEALTH, AGED CARE & SPORT, *supra* note 1, para. 2.40.

⁵⁴ *Australian Constitution* ss 51 (i), (ii), (xx), (xxix) (addressing, respectively, interstate and international trade, taxation, corporations, external affairs); s 86 (addressing customs and excise).

⁵⁵ *Id.* at s 109. A law is consistent if it would alter, impair or detract from the operation of a Commonwealth law. See *Work Health Auth v Outback Ballooning Pty Ltd* [2019] HCA 2, [72] (Gageler J), [107] (Edelman J) (Austl.).

⁵⁶ *Northern Territory (Self-Government) Act 1978* (Cth) (Austl.); see also *Australian Capital Territory (Self-Government) Act 1988* (Cth) s 28 (Austl.); *Work Health Auth v Outback Ballooning Pty Ltd* [2019] HCA 2, [30] (Kiefel CJ, Bell, Keane, Nettle and Gordon JJ), [58] (Gageler J), [133] (Edelman J) (Austl.).

2. Commonwealth legislation,⁵⁷ including the immediately relevant legislation, often explicitly preserves State and Territory sovereignty to legislate concurrently.⁵⁸
3. Kiefel CJ's High Court has dispelled doubt that State laws can modify the practical operation of Commonwealth laws, notwithstanding that a law may be applied significantly differently between States and Territories.⁵⁹

As for current developments on general tobacco regulation, the current trend is that Australia is becoming more restrictive as opposed to other countries' increasing permissiveness. Indeed, Australia's regulations stack higher and higher each year, and have increased rapidly in the recent past. Concerningly, there have been factions within the federal Parliament that would seek to pull down tobacco regulations. In 2017, a federal parliamentary committee on tobacco retailing regulations issued a report recommending that all Australian jurisdictions loosen their tobacco product retailing restrictions and deregulate e-cigarettes.⁶⁰ In arguing for this recommendation, the committee relied heavily on the submissions of Philip Morris and the tobacco retail industry, to the almost total exclusion of submissions

⁵⁷ See *Work Health Auth v Outback Ballooning Pty Ltd* [2019] HCA 2, [68] (Gageler J) (Austl.) ("Most Commonwealth laws will have a definite area of affirmative operation which will admit of the concurrent operation of some, but not all, State and Territory laws."); see also *id.* at [78] ("the Commonwealth Parliament can, and not infrequently does, make the intended operation of the law express, either by stating that the law is to operate on a subject-matter to the exclusion of State or Territory laws or a category of State or Territory laws, or by stating that the law is to operate on a subject-matter concurrently with State or Territory laws or a category of State or Territory laws."); *id.* at [130] (Edelman J) ("Some Commonwealth laws and regulations contain a provision which evinces 'an intention that the statute is not intended to cover the field,' for example by providing that the law is 'not intended to exclude or limit' the concurrent operation of any State and Territory laws, or by referring to the 'concurrent operation' of laws of both States and Territories in the absence of 'direct inconsistency'" (citing *Corporations Act 2001* (Cth) s 5E(1), (4) (Austl.); *Personal Property Securities Act 2009* (Cth) s 254 (Austl.); *Competition and Consumer Act 2010* (Cth) s 51AAA (Austl.)).

⁵⁸ *Therapeutic Goods Act 1989* (Cth) s 4(2) (Austl.); see also *id.* at ss 6AAA – 6AAE, 9 (further recognising State and Territory sovereignty in regulating therapeutic goods); *Medicines, Poisons and Therapeutic Goods Act 2012* (NT) s 30 (Austl.) (listing State and Territory poisons legislation provisions); *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT) s 10 (Austl.); *Work Health and Safety Act 2011* (Cth) s 12(9) (Austl.); *Fair Work Act 2009* (Cth) ss 26, 27(1A) (Austl.).

⁵⁹ See e.g. *Rizeq v Western Australia* [2017] HCA 23 (Austl.) (holding that in the prosecution of a New South Wales resident in Western Australia, a State court exercising federal jurisdiction is nonetheless subject to the laws of evidence, juries and criminal procedure of that particular State).

⁶⁰ S. SELECT COMM. ON RED TAPE, COMMONWEALTH OF AUSTRALIA, EFFECT OF RED TAPE ON TOBACCO RETAIL: INTERIM REPORT 1 (2017).

by healthcare experts.⁶¹ Fortunately, no Australian jurisdiction's Parliament took action on these recommendations.⁶²

In 2011, Australia's Commonwealth government was the first worldwide to legislate plain packaging for cigarettes.⁶³ In 2012, the legislation survived two related constitutional challenges from British American Tobacco and JT International SA.⁶⁴ More recently, the legislation survived international trade law challenges in the Permanent Court of Arbitration,⁶⁵ and the World Trade Organization.⁶⁶ These successes have partially caused plain packaging laws to be increasingly adopted and considered overseas, but Australia is still relatively unique in having such a law, as depicted in the following table.

⁶¹ See *id.* at 7-24.

⁶² See e.g. S. SELECT COMM. ON RED TAPE, COMMONWEALTH OF AUSTR., POLICY AND PROCESS TO LIMIT AND REDUCE RED TAPE: FINAL REPORT 23 para. 2.76 (2017) (“[T]he [effect of red tape on tobacco retail] committee received substantial evidence of high levels of regulation adversely affecting businesses that legally retail tobacco products. The committee was concerned to ensure that regulation is evidence-based, including in relation to alternative nicotine delivery systems. The committee made three recommendations to which the Australian Government has not responded.”).

⁶³ *Tobacco Plain Packaging Act 2011* (Cth) s 3 (Austl.).

⁶⁴ High Court cases S389/2011 and S409/2011 respectively. See *JT Int'l SA v Commonwealth* (2012) 250 CLR 1 (Austl.); see also Nicola Berkovic, *High Court Clears Way for Plain Packaged Cigarettes to be Sold in Australia*, THE AUSTRALIAN (Aug. 15, 2012); Australian Broadcasting Corporation, *High Court Rejects Plain Packaging Challenge*, ABC NEWS (Aug. 15, 2012), <https://www.abc.net.au/news/2012-08-15/high-court-rules-in-favour-of-plain-packaging-laws/4199768>.

⁶⁵ See *Philip Morris Asia Ltd. v. Commonwealth* (H.K. v. Austl.), PCA Case No. 2012-12 (Perm. Ct. Arb. 2015).

⁶⁶ World Trade Org., *WTO Issues Panel Report on Tobacco Plain Packaging Requirements*, WTO NEWS & EVENTS (June 28, 2018), https://www.wto.org/english/news_e/news18_e/435_441_458_467r_e.htm; see also Reuters, “*Resounding Victory*”: *Australia Wins Tobacco Plain Packaging Dispute*, THE GUARDIAN, (June 29, 2018), <https://www.theguardian.com/business/2018/jun/29/resounding-victory-australia-wins-tobacco-plain-packaging-dispute>; WTO Panel Report, *Certain Measures*, *supra* note 55.

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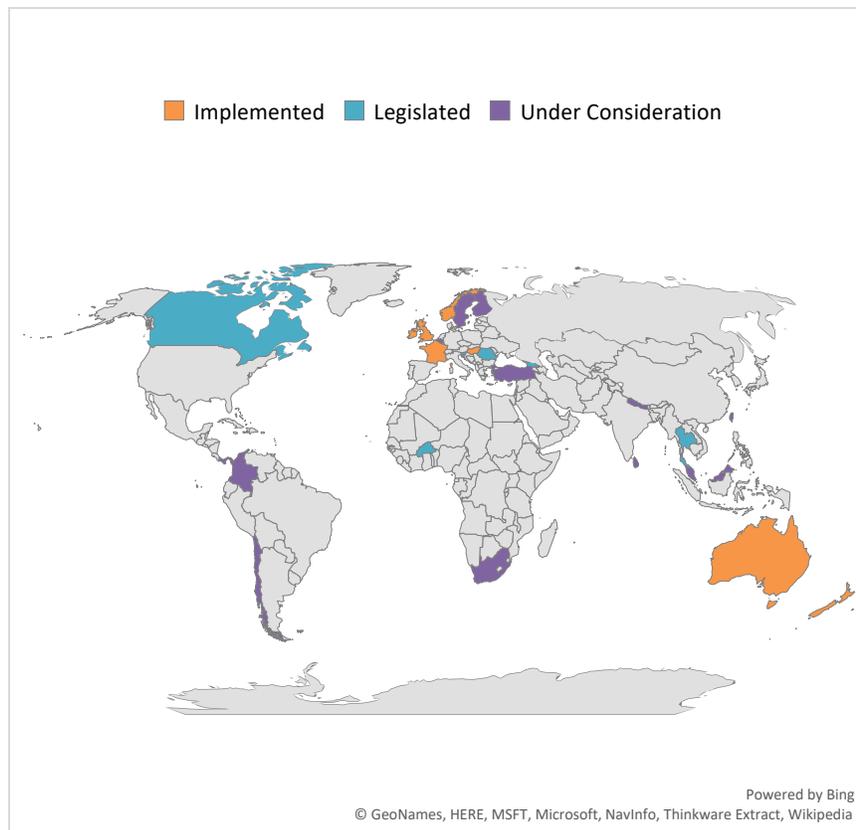
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Figure 2 – Plain Packaging Internationally⁶⁷

Legislated & Implemented	Legislated Only	Under Legislative Consideration
Australia	Burkina Faso	Belgium
France	Canada	Chile
Hungary	Georgia	Columbia
Ireland	Romania	Finland
New Zealand	Slovenia	Malaysia
Norway	Thailand	Mauritius
		Nepal
		Panama
		Singapore
		South Africa
		Sri Lanka
		Sweden
		Taiwan
		Turkey
		Uruguay

⁶⁷ PLAIN PACKAGING—INTERNATIONAL OVERVIEW, CANADIAN CANCER SOCIETY 1-5 (2019).

Figure 3 – Plain Packaging Map

As of writing, Australia's plain packaging legislation has not been extended to apply to e-cigarette packaging. Separately, through several judgments from the Supreme Court of Victoria, it became settled law that there is no constitutional right to smoke in Australia,⁶⁸ nor is smoking a recognized human right.⁶⁹

Although Australian judgments govern the right to smoke, Australian legislation deals with the regulation of substances related to smoking, which this article will now address in detail. To explain the approach of this article, we emphasize that the Therapeutic Goods

⁶⁸ *Knight v Minister for Corr [No. 2]* [2015] VSC 213 (20 May 2015) [40] (Austl.) (citing *Knight v Minister for Corr* [2015] VSC 56 (5 March 2015), [35] (Austl.)).

⁶⁹ See *De Bruyn v Victorian Inst of Forensic Mental Health* [2016] VSC 111 (22 March 2016), [6] (Austl.).

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Administration and the NSW Department of Health have both noted that there is a wide range of state and commonwealth legislation relevant to regulating substances and therapeutic goods in Australia.⁷⁰ Consistent with this, the authors' approach considers a broad (but not exhaustive) range of relevant law.

III. Australian Regulation: As a Therapeutic Good

A. The Legislative Scheme

In Australia, the *Therapeutic Goods Act* (TGA) is the leading statute that regulates e-cigarettes as a therapeutic or medicinal product. This Act provides the general definition of therapeutic goods:

'therapeutic goods' means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7. . .⁷¹

⁷⁰ See *Legislation*, NSW Gov., <https://www.health.nsw.gov.au/pharmaceutical/pages/legislation.aspx> (last visited Mar. 2, 2019); *Electronic Cigarettes*, THERAPEUTIC GOODS ADMINISTRATION (Oct. 25, 2019), <https://www.tga.gov.au/community-qa/electronic-cigarettes>.

⁷¹ *Therapeutic Goods Act 1989* (Cth) s 3 (Austl.) (note that there are a series of exceptions that are omitted for their lack of relevance to the article).

Importantly, according to this definition, it is not necessary that therapeutic goods be *actually/literally* therapeutic. Rather, the definition emphasizes how certain goods are represented and how that representation is likely to be taken or understood by their ordinary and reasonable consumer.⁷²

The TGA establishes a scheme for the regulation of therapeutic goods in Australia.⁷³ In particular, therapeutic goods must be approved by the Therapeutic Goods Administration (TGA) and be listed on the Australian Register of Therapeutic Goods (ARTG) if they are to be supplied in Australia.⁷⁴

B. Application to Vaping Products and E-Cigarettes

As early as March 30, 2015, the TGA has taken an ostensibly concerned stance on e-cigarettes.⁷⁵ The TGA's position has been that there is insufficient evidence on the safety, efficacy and quality of e-cigarettes, unlike nicotine replacement therapy products.⁷⁶ Furthermore, the TGA is concerned about the potential for these products to harm Australians.⁷⁷ In sum, it appears the TGA has adopted a precautionary principle: being conservative and restrictive of e-cigarettes in the absence of clear scientific consensus about the safety of e-cigarettes. According to the Department of Health:

The precautionary approach encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive

⁷² See, e.g., *Sec'y, Dep't of Health & Ageing v Expt Corp (Austl) Pty Ltd* [2010] FCA 249 (15 March 2010), [5] (Austl.).

⁷³ See generally *Therapeutic Goods Act 1989* (Cth) s 3 (Austl.).

⁷⁴ See *id.* at s 1(6).

⁷⁵ See generally *id.*

⁷⁶ See *id.*

⁷⁷ See *id.*; see also EM Greenhalgh & MM Scollo, *18B Electronic Cigarettes (E-Cigarettes)*, in *TOBACCO IN AUSTRALIA: FACTS AND ISSUES* (2018), <http://www.tobaccoinaustralia.org.au/chapter-18-harm-reduction/indepth-18b-e-cigarettes>.

exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy.⁷⁸

1. ARTG Listing

As of writing, there are no e-cigarette products listed on the ARTG, let alone any listed as cessation aids.⁷⁹ However it is not legally impossible that this could change. The definitions of “tobacco product” in the *Tobacco Plain Packaging Act 2011* and *Tobacco Advertising Prohibition Act 1992* do not apply their prohibitions to tobacco products on the ARTG.⁸⁰ This implies that it is possible per current law for tobacco products to appear in the ARTG.

2. Importation and Medical Access

The TGA took the position that legal access to e-cigarettes was possible via the TGA Personal Importation Scheme which provides access to unapproved therapeutic goods from outside Australia.⁸¹ In addition, Parliament has not legislated a ban on importing e-cigarettes, despite opportunity to do so in recent reforms to tobacco importation laws that expanded upon prior regulations. For example, the recent *Customs (Prohibited Imports) Amendment (Collecting Tobacco Duties) Regulations 2019* prohibits the importation of “tobacco products” without government authorization or an applicable exemption.⁸²

⁷⁸ AUSTRALIAN GOV. DEP’T OF HEALTH, POLICY AND REGULATORY APPROACH TO ELECTRONIC CIGARETTES (E-CIGARETTES) IN AUSTRALIA (2019).

⁷⁹ See EM Greenhalgh, C Grace & MM Scollo, *18B.8 Legal Status in Australia*, in TOBACCO IN AUSTRALIA: FACTS AND ISSUES, <https://www.tobaccoinaustralia.org.au/chapter-18-harm-reduction/indepth-18b-e-cigarettes/18b-9-legal-status> (last updated Mar. 2019).

⁸⁰ *Tobacco Plain Packaging Act 2011* (Cth) sch 1 (Austl.); *Tobacco Advertising Prohibition Act 1992* (Cth) sch 2 (Austl).

⁸¹ See *Electronic Cigarettes*, *supra* note 73; *Importation of E-Cigarettes Containing Nicotine (and Nicotine-Containing Liquids for Use in E-Cigarettes)* AUSTRALIAN GOV. DEP’T OF HEALTH (Oct. 25, 2019), <https://www.tga.gov.au/behind-news/importation-e-cigarettes-containing-nicotine-and-nicotine-containing-liquids-use-e-cigarettes>.

⁸² See Explanatory Memorandum, *Customs (Prohibited Imports) Amendment (Collecting Tobacco Duties) Regulations 2019* (Cth) 2-3 (Austl.) (relevant exemptions apply to aircraft passengers bringing in duty-free tobacco, specific smokeless tobacco, cigars and specific unmanufactured tobacco); see generally Explanatory Memorandum, *Customs (Prohibited Imports) (Importation of Tobacco*

Notably, the definition of “tobacco product” for the *Customs Act 1901* is the same as goods classified under Headings 2401-2403 of the *Customs Tariff Act 1995*.⁸³ These definitions do not include e-cigarettes or vaporizers.⁸⁴

C. Interaction Between State and Commonwealth Laws

In addition to these customs restrictions, consumers must also comply with State and Territory drugs and poisons legislation once the imported liquid nicotine arrives.

3. Current Medical Practice

In terms of Australian medical practice, according to a Cancer Council publication, it is unlikely that Australian doctors would prescribe e-cigarettes as a cessation aid because they are untested and unapproved in a context where there are already TGA-approved and well-tested aids available.⁸⁵ Indeed, in a World Trade Organization dispute over Australia’s plain packaging legislation, Australia pointed to the fact that it provides access to “nicotine replacement therapies and other smoking cessation medicines (such as nicotine patches and gums).”⁸⁶

Other experts take a cautious approach similar to the Cancer Council’s. Authors of an article on the legal status of e-cigarettes in Australia advised doctors to adopt a cautious approach to prescribing e-cigarettes, writing “[m]edical 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.”⁸⁷ Such concerns

Products) Approval 2019 (Cth) cl 5; DEP’T OF HOME AFFAIRS, AUSTR. GOV., NOTICE NO. 2019/13, TOBACCO PROHIBITED IMPORT AND PERMIT ARRANGEMENT (2019).

⁸³ Compare *Customs Act 1901* (Cth) (Austl.), with *Customs Tariff Act 1995* (Cth) sch 3 (Austl).

⁸⁴ See generally *Customs Act 1901* (Cth) (Austl.); *Customs Tariff Act 1995* (Cth) sch 3 (Austl).

⁸⁵ See Greenhalgh, Grace & Scollo, *supra* note 82 (“Given that there are already a number of TGA-approved nicotine-containing therapeutic products available without restriction for smoking cessation, it may well be that in practice, Australian doctors would not choose to prescribe an unapproved and untested product for this purpose.”).

⁸⁶ See WTO Panel Report, *Certain Measures*, *supra* note 55, 110 para. 2.72.

⁸⁷ Heather Douglas, Wayne Hall & Coral Gartner, *E-cigarettes and the Law in Australia*, 44 AUST. FAM. PHYSICIAN 415, 417 (2015).

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are consistent with the positions of Australia's major public health organizations.⁸⁸ Likewise, in 2018, the chief executives of several of these organizations signed and submitted a position statement to the Parliament of Western Australia.⁸⁹ This statement proposed that e-cigarettes' harm to society (via direct health harms and precipitating smoking) outweighed any potential benefits, which were not sufficiently evidenced.⁹⁰

IV. Australian Regulation: "Therapeutic Use"

A. Introducing "Therapeutic Use"

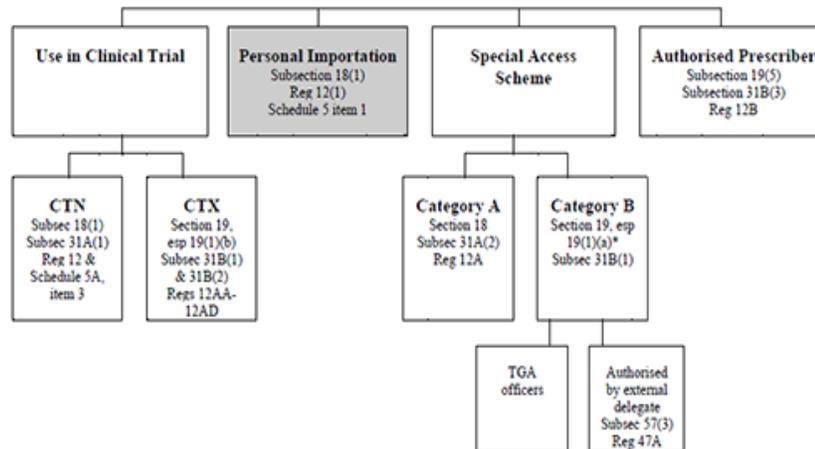
The term and embodied concept of therapeutic use (and analogous terms) appears in a series of Australian statutes with very different purposes. This concept is central to a variety of legislation because if the products are marketed as a cessation aid (and are therefore classed as a therapeutic good), their importation is subject to federal restrictions established for accessing unapproved therapeutic goods.

⁸⁸ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 11.

⁸⁹ See Statement on E-Cigarettes, *supra* note 12 (signatories include the Australian Medical Association, Cancer Australia, Cancer Council Australia, National Heart Foundation of Australia, Thoracic Society of Australia and New Zealand).

⁹⁰ See Statement on E-Cigarettes, *supra* note 12.

Figure 4 – Access to unapproved medicines and other therapeutic goods⁹¹



For consumers seeking to use e-cigarettes as a cessation aid, the governing access scheme is the TGA Personal Importation Scheme.⁹² This scheme's restrictions mean:

- a) the good must be personal treatment or an immediate family member's treatment; and
- b) the importer must hold a prescription from an Australian medical practitioner; and
- c) only import 3 months' supply at any one time; and
- d) the total quantity imported in 12 months cannot exceed 15 months' supply of the product at the manufacturer's maximum recommended.⁹³

1. Therapeutic Goods Act

The TGA defines "therapeutic use" of a good as use in or in connection with:

⁹¹ THERAPEUTIC GOODS ADMIN., AUSTRAL. GOV. DEP'T OF HEALTH, ACCESS TO UNAPPROVED THERAPEUTIC GOODS: PERSONAL IMPORTATION 7 (2004).

⁹² *Id.*

⁹³ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 4; *Personal Importation Scheme*, THERAPEUTIC GOODS ADMINISTRATION (Mar. 18, 2015), <https://www.tga.gov.au/personal-importation-scheme>.

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- a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- b) influencing, inhibiting or modifying a physiological process in persons; or
- c) testing the susceptibility of persons to a disease or ailment; or
- d) influencing, controlling or preventing conception in persons; or
- e) testing for pregnancy in persons; or
- f) the replacement or modification of parts of the anatomy in persons.⁹⁴

This concept of therapeutic use is applicable to the use of goods beyond those classified as “therapeutic goods” per the Act.

There are several judgments in determining whether an item is a therapeutic good pursuant to the TGA. For example, in *Re Johnson & Johnson Australia Pty Ltd and Minister for Aged, Family and Health Services*,⁹⁵ the Court held that a tampon falls within the definition of the term “therapeutic use” in the TGA⁹⁶ because tampons “inhibit or modify physiological process in persons” by keeping menstrual fluid in the vagina longer than it would otherwise remain.⁹⁷ The Court also explained that the word “class” in paragraph (b) of the therapeutic goods definition refers to a class of goods that has therapeutic use as its “sole or principle” use.⁹⁸

⁹⁴ Compare *Therapeutic Goods Act 1989* (Cth) s 3 (Austl.), with *Patent Act 1990* (Cth) sch 1 (Austl.). The definition of therapeutic use in the Patent Act is nearly identical to the Therapeutic Goods Act definition, except that it omits subheadings (d)-(f). See also *Alphapharm Pty Ltd v Smithkline Beecham (Australia) Pty Ltd* (1994) 121 ALR 373, 390 (Gummow J) (Austl.) (noting that Cimetidine’s blocking of histamine receptors prevents acid from entering the stomach gives it a “valuable therapeutic use,” hence why it was granted a patent).

⁹⁵ *Re Johnson & Johnson Austl Pty Ltd & Minister of Aged, Fam & Health Servs* (1992) 28 ALD 699 (Austl.).

⁹⁶ *Id.* at [26].

⁹⁷ *Id.* at [25].

⁹⁸ *Id.* at [26].

2. The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

Schedule 1 of the SUSMP also defines the term “therapeutic use.”⁹⁹ This definition is nearly identical to the one in TGA section 3 but is broader in that it extends to animals’ therapeutic use.¹⁰⁰

3. Customs Legislation

In addition, relevant customs legislation in Australia has dealt with “medicaments,” meaning goods intended for therapeutic use or purposes and goods with therapeutic properties.¹⁰¹ As expected, the arising case law necessarily interprets what these terms mean. Currently, under the *Customs Tariff Act 1995*, which contains several provisions assigning lower rates of import duties and tariffs to goods that have therapeutic or prophylactic properties or uses.¹⁰² Australian courts interpreted what these terms mean in several cases.

First, in *Re Pharm-A-Care Laboratories Pty Limited and Comptroller-General of Customs (Re Pharm-A-Care)*, the Administrative Appeals Tribunal (AAT) held that a weight-loss vitamin-containing product lacked therapeutic or prophylactic properties.¹⁰³ To explain, what follows is a high-level sketch of the AAT’s reasoning followed by a key quote from the judgment:

⁹⁹ See *Poisons Standard February 2019* (Cth) pt 1, pt 4 sch 1, 7-8 (Austl.).

¹⁰⁰ See *id.* at pt 1.

¹⁰¹ See *Customs Tariff Act 1995* (Cth) sch 3 ch 30 (Austl.).

¹⁰² See, e.g., *id.* (heading 3004 governs “MEDICAMENTS (EXCLUDING GOODS OF 3002, 3005 OR 3006) CONSISTING OF MIXED OR UNMIXED PRODUCTS FOR THERAPEUTIC OR PROPHYLACTIC USES, PUT UP IN MEASURED DOSES (INCLUDING THOSE IN THE FORM OF TRANSDERMAL ADMINISTRATION SYSTEMS) OR IN FORMS OR PACKINGS FOR RETAIL SALE”); see also *Customs Tariff Act 1982* (Cth) sch 3 ch 30 note 1(1) (Austl.) (repealed 1988) (“In 30.03, ‘medicaments’ means goods (other than dietetic, diabetic or fortified foods, tonic beverages, spa water or similar foods or beverages) that are - (a) goods comprising 2 or more constituents that have been mixed or compounded together for a therapeutic or prophylactic use; or (b) unmixed goods suitable for such a use that have been put up in measured doses or in forms or in packs of a kind sold by retail for *therapeutic or prophylactic purposes*, but does not include goods falling within 30.02 or 30.04.”) (emphasis added).

¹⁰³ *Pharm-A-Care Lab’ys Pty Ltd & Comptroller-General of Customs* [2017] AATA 1816 (19 October 2017) (Austl.).

- a) the product's intended function was to
 - a. fight disease and
 - b. improve physical appearance; and
- b) the intended functions of the product's vitamins provided the product's essential character; and
- c) the intended functions are not therapeutic or prophylactic because it treats no disease or ailment; therefore
- d) The essential character of the product was therapeutic or prophylactic.

We doubt that a weight-loss product, as such, is for a therapeutic or prophylactic purpose, and we doubt that the product is properly described as a medicament. It would be different if it treated or prevented obesity or some related disease or ailment. The main purpose of the garcinia preparations appear to us to be cosmetic.¹⁰⁴

It is also worth noting that the Tribunal rejected the Queens Bench's reasoning in *Unigreg*.¹⁰⁵ In that case, a vitamins and minerals capsule (named "Forceval capsules") held that a product can be classified as a medicament notwithstanding it only has a "a broad spectrum of prophylactic or preventative functions" which improve health in a very general sense, rather than specific targeted functions.¹⁰⁶ Finally, it is again worth noting that the Tribunal made its finding without relying on the product label's references to the product's intended use, and further stated that labels alone cannot alter whether a product has prophylactic and therapeutic properties.¹⁰⁷ On appeal to both the Full Federal Court and the High Court, the

¹⁰⁴ *Id.* at [85].

¹⁰⁵ *Unigreg Ltd. v. Her Majesty's Customs & Excise* (1999) 45 BMLR 179 (Eng.); *see also Comptroller-General of Customs v Pharm-A-Care Lab 'ys Pty Ltd* [2018] FCAFC 237 (21 December 2018), [59] (Austl.); *Pharm-A-Care Lab 'ys Pty Limited v Comptroller-General of Customs* [2017] AATA 1816, [33]-[41].

¹⁰⁶ *Unigreg Ltd.*, 45 BMLR at 187.

¹⁰⁷ *Pharm-A-Care Lab 'ys Pty Limited v Comptroller-General of Customs* [2017] AATA 1816, [66]; *Comptroller-General of Customs v Pharm-A-Care Lab 'ys Pty Ltd* [2018] FCAFC 237, [66].

Tribunal's aforementioned reasoning and findings were not challenged.¹⁰⁸

The second relevant case is *Chinese Food and Wine Supplies Pty Ltd v Collector of Customs (Victoria)*.¹⁰⁹ In this case, the applicant imported into Australia, from The Peoples' Republic of China, a quantity of highly-alcoholic liquids in 500ml bottles of:

- a) Wu Chia Pi Chiew (53% alcohol)
- b) Chu Yeh Ching Chiew, (44% alcohol)¹¹⁰

These liquids were prepared in China in accordance with traditional Chinese recipes and techniques.¹¹¹ The applicant submitted that the liquids are medicaments¹¹² and as such could properly be classified under Item 30.03 of Schedule 3 to the CTA 1982.¹¹³ The Collector maintained that the goods are properly classified under paragraph 22.09.91, relating to certain spirits, liqueurs and other spirituous beverages and to compound alcoholic preparations for the manufacture of beverages containing not more than 57% by volume of alcohol.¹¹⁴ The sole question argued on this appeal was whether the goods, which admittedly comprise two or

¹⁰⁸ For a crucial passage in the Full Federal Court judgment, see *Comptroller-General of Customs v Pharm-A-Care Lab 'ys Pty Ltd* [2018] FCAFC 237, [58] ("the finding of fact below was that the essential character of the vitamin preparations were the vitamins they contained, and that they have prophylactic and therapeutic properties. As noted, those findings were not challenged before us. No finding was made below that the prophylactic or therapeutic effects of the preparations were only incidental or subordinate to the quality of the preparations as something to be eaten."). For the High Court judgment, see *Comptroller-General of Customs v Pharm-A-Care Lab 'ys Pty Ltd* [2020] HCA 2, [45]-[48], [68]-[70] (Austl.).

¹⁰⁹ *Chinese Food & Wine Supplies Pty Ltd v Collector of Customs (Vic)* (1987) 72 ALR 591 (Austl.).

¹¹⁰ *Id.* at 592.

¹¹¹ *Id.* at 594 ("It is common ground that both products were manufactured in China in accordance with the requirements of two books in Chinese script, *the China Pharmacopoeia* and *Chinese Tinctures*. The latter is referred to in the evidence also as *Chinese Elixirs* or *Chinese Elixirs (Tonics)*. The precise standing or authority of these two books is not clear from the evidence, although it appears that the *China Pharmacopoeia* provides methods for the preparation of medicinal products for use in Chinese traditional medicine.").

¹¹² *Customs Tariff Act 1982* (Cth) ch 30 s 1 (Austl.) (medicaments meaning goods for therapeutic or prophylactic purposes).

¹¹³ *Chinese Food & Wine Supplies Pty Ltd*, 72 ALR 591 at 591-2

¹¹⁴ *Chinese Food & Wine Supplies Pty Ltd*, 72 ALR 591 at 592. This is important for an importer because if the goods fell within Item 30.03 as medicaments a far lower rate of duty was attracted than if they fell under paragraph 22.09.91. See *Customs Tariff Act 1982* (Cth) ch 22 item 22.09.91 (Austl.).

more constituents that have been mixed or compounded together, attract the description "for a therapeutic use."¹¹⁵

On appeal, the court refused to overturn the AAT's decision to classify the liquids as alcoholic beverages instead of classifying them as medicaments. In upholding the lower court's decision, the court rejected an argument that the liquids should be classified as such merely because the constituent ingredients were used therapeutically in China.¹¹⁶ Rather, proper identification of the goods as prophylactics or therapeutic requires an objective assessment of goods, independent of the manufacturer, importer, or exporter's professed intention.¹¹⁷ Further, while inspection of labelling and packaging are relevant and sometimes helpful, it is not necessarily determinative.¹¹⁸ In this instance, the fact that these liquids were sold as wine in Chinese liquor stores suggested to the Tribunal below that these liquids were alcoholic beverages.¹¹⁹

B. Recommendations

These judgments *inter alia* distill several broad principles as to what the terms "therapeutic" or "therapeutic use" (and analogous terms) mean in the table below. The authors propose that the case law interpreting "therapeutic"/ "therapeutic use" and analogues apply to the definitions across the various statutes.¹²⁰ This recommendation

¹¹⁵ *Chinese Food & Wine Supplies Pty Ltd*, 72 ALR 591 at 594.

¹¹⁶ *Id.* at 598 ("I cannot discern any convincing reason why the Tariff Act would fasten on the therapeutic or prophylactic use of constituents that have been mixed or compounded together to produce goods as determinative of the character of the goods as medicaments and therefore afford a far more favourable rate of customs duty. There is no sound reason why Item 30.03 in Schedule 3 of the Tariff Act would be concerned with therapeutic or prophylactic use of the constituents of goods as distinct from the goods themselves. . . . It is the goods to which Item 30.03 is directed.").

¹¹⁷ See *Chinese Food & Wine Supplies Pty Ltd v Collector of Customs* [1986] AATA 286 (2 October 1986), [26] (Austl.) (discussing other factors, such as dosage and directions, which might move a spirit from a tonic to a depressant); *id.* at [42] (considering evidence that goods were professed to be prepared as a therapeutic good, as well as other evidence that goods were prepared to be exported as a beverage).

¹¹⁸ *Id.*

¹¹⁹ *Id.* at [43] ("evidence of that is, first, the sales catalogue issued by the manufacturer with the title "Wines" on its cover and with both types of goods included in it. The display of goods of those types in the liquor department of the supermarket in Hong Kong is not of itself alone evidence of the manufacturer's purpose in preparing them; but, when viewed in combination with the sales catalogue, it has significance.").

¹²⁰ For support of the authors' position, see *Hargreaves v Univ. of New England* [2013] NSWADT 233, [12], [15], [16], [18], [19] (Austl.). In *Hargreaves*, the term "client legal privilege" as

finds support in *Hargreaves v University of New England*, in which the New South Wales Administrative Decisions Tribunal adopted a harmonious interpretation of a term used in two different statutes.¹²¹

Figure 5 – Principles of Therapeutic use and Analogous Terms

Principle #	Principle	Statute in Question	Cases
1	Reference to an ordinary dictionary can assist in conceptualizing what “therapeutic” or “prophylactic” means.	CTA 1982, CTA 1995	<i>Re Chinese Food and Wine</i> . ¹²² <i>Re Pharm-A-Care</i> . ¹²³
2	Use for improving cosmetic appearance is insufficient to qualify as therapeutic use.	CTA 1995	<i>Re Pharm-A-Care</i> . ¹²⁴

found in the *Government Information (Public Access) Act 2009* (NSW) was given a harmonious interpretation (in this instance, by applying the law of that term found in the relevant evidence statute). This decision was made on the basis that if two statutes make use of the same term, and there’s no legislative intention for different interpretations, the terms should be interpreted the same way.

¹²¹ See *id.* at [12], [15], [16], [18], [19] (the case law interpreting these terms in the context of the CTA 1995 is generally applicable to interpreting the terms in the context of the TG Act or Patents Act etc., and vice versa).

¹²² *Chinese Food & Wine Supplies Pty Ltd v Collector of Customs* [1986] AATA 286 (2 October 1986), [39] (Austl.). (“We are satisfied goods of that type have a therapeutic use, within the meaning of that phrase in the Therapeutic Goods Act 1966. It is also a therapeutic use within the meaning ascribed to ‘therapeutic’ in the Shorter Oxford English Dictionary, namely ‘of or pertaining to the healing of disease.’”).

¹²³ *Pharm-A-Care Lab ’ys Pty Ltd v Comptroller-General of Customs* [2017] AATA 1816 (19 October 2017), [67], [72] (Austl.).

¹²⁴ *Id.* at [85].

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3	Use the “Wharfside” test. ¹²⁵	CTA 1995	<i>Re Chinese Food and Wine</i> , ¹²⁶ <i>Re Pharm-A-Care</i> . ¹²⁷
4	The manufacturer’s intended use is not relevant.	CTA 1982, CTA 1995	<i>Re Chinese Food and Wine</i> , ¹²⁸ <i>Re Pharm-A-Care</i> . ¹²⁹
5	Reference can be made to uses indicated on the good’s ARTG listing	CTA 1995, <i>GST-free Supply (Health Goods) Determination 2011 (Cth)</i> ¹³⁰	<i>Re Pharm-A-Care</i> , ¹³¹ <i>ATO Ruling 1051374938930 (22 May 2018)</i> . ¹³²
6	The essential purpose of the entire good, rather than its individual components, determines whether the good is for a therapeutic or	CTA 1995	<i>Re Pharm-A-Care</i> . ¹³³

¹²⁵ See *Cameron Austl Pty Ltd v Chief Exec Officer of Customs* [2012] AATA 865 (10 December 2012), [33] (Austl.) (“The wharfside test as discussed in *Chinese Food and Wine Supplies Pty Ltd v Collector of Customs (Vic)* (1987) 72 ALR 591 involves an inspection of the goods, and the condition in which they are imported.”). See also *id.* at [34] (citing *Voxson Sales Pty Ltd v Collector of Customs* (1993) 19 AAR 129, where the court in applying the wharfside test held that “in identifying goods for customs purposes one looks at the goods themselves and the condition in which they are imported”).

¹²⁶ *Chinese Food & Wine Supplies Pty Ltd*. [1986] AATA 286, [26].

¹²⁷ *Pharm-A-Care Lab’ys Pty Ltd* [2017] AATA 1816, [37], [83].

¹²⁸ *Chinese Food & Wine Supplies Pty Ltd*. [1986] AATA 286, [25]-[26], [40]-[42].

¹²⁹ *Pharm-A-Care Lab’ys Pty Ltd* [2017] AATA 1816, [83]-[88].

¹³⁰ *GST-free Supply (Health Goods) Determination 2011 (Cth)* (Austl.)

¹³¹ *Pharm-A-Care Lab’ys Pty Ltd* [2017] AATA 1816, [6], [74]-[76].

¹³² Australian Tax Office, *GST and Supply of X as GST-Free Supply*, No. 1051374938930, 22 May 2018, 2-3.

¹³³ *Pharm-A-Care Lab’ys Pty Ltd* [2017] AATA 1816, [60].

	prophylactic purpose.		
7	Reference to extrinsic labelling can be considered but is not determinative.	CTA 1982, CTA 1995	<i>Re Pharm-A-Care</i> ¹³⁴
8	Ordinary language of the statute should be applied, but where a term has specific or technical meaning that meaning should be applied.	TG Act, <i>A New Tax System (Goods and Services Tax) Regulations</i> , CTA 1995	<i>Re Pharm-A-Care</i> , ¹³⁵ <i>Re Johnson & Johnson</i> , ¹³⁶ <i>ATO Ruling 1051407996497</i> (31 July 2018),
9	In the context of the TG Act, the sole or principal use (of the good) test should be used to determine whether it is for a therapeutic use	TG Act	<i>Re Johnson & Johnson</i> . ¹³⁷
10	Reference to typical marketing of the product is instructive.	<i>GST-free Supply (Health Goods) Determination</i>	<i>Re Chinese Food and Wine</i> ¹³⁹ <i>ATO Ruling 1051374938930</i>

¹³⁴ *Id.* at [75]-[76].¹³⁵ *Id.* at [25], [56]-[57], [61]-[62].¹³⁶ *Id.* at [2], [10]-[12].¹³⁷ *Id.* at [10], [26].¹³⁹ *Pharm-A-Care Lab'ys Pty Ltd* [2017] AATA 1816, [7], [27], [43].

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		2011 (Cth), ¹³⁸ CTA 1982	(22 May 2018). ¹⁴⁰
11	Determining whether a good is for a therapeutic use or purpose doesn't involve a comprehensive scientific examination of the properties of a substance; rather it involves considering the bona fide claims made for the goods by the seller and the purposes for which consumers purchase the product.	CTA 1995	<i>Re Pharm-A-Care</i> . ¹⁴¹

¹³⁸ *GST-free Supply (Health Goods) Determination 2011 (Cth)* (Austl.)

¹⁴⁰ Australian Tax Office, *GST and Supply of X as GST-Free Supply*, No. 1051374938930, 22 May 2018, 2-3.

¹⁴¹ *Pharm-A-Care Lab'ys Pty Ltd* [2017] AATA 1816, [68] (citing *Trustee for the Kurowski Family Trust, Re & Chief Exec Officer of Customs*; 118 ALD 688, [22]-[25]).

V. Australian Regulation: Nicotine as a Dangerous Poison

A. Introducing Australian Poisons Law

The Commonwealth's Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) compiles decisions by the Secretary of the Department of Health (or their delegate).¹⁴² The Secretary is formally advised of these decisions, by two expert advisory committees, the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS).¹⁴³

There are ten schedules (nine in use) which classify medicines and poisons according to the level of access deemed appropriate for consumers based on the substances contained within them.¹⁴⁴ The SUSMP includes various requirements related to scheduled substances including packaging and labelling, restrictions on sale, possession and use.¹⁴⁵ Scheduling of substances occurs at the federal level, however the provisions of the SUSMP are implemented through State and Territory legislation.¹⁴⁶

In practice, today, all the States and Territories adopt and legislate the SUSMP by reference. However, the restrictions about handling, storing, labelling, and prescribing these substances are often meaningfully different between jurisdictions.

The potential for discrepancies between jurisdictions is demonstrated with Schedule 8 Poisons. For instance, the rules of prescribing Schedule 8 ("Controlled Drugs," e.g., dexamphetamine), are significantly different across jurisdictions.¹⁴⁷

¹⁴² AVI REBERA, AUSTL. DEP'T OF HEALTH, POISONS STANDARD FEBRUARY 2019, iii (2018).

¹⁴³ Explanatory Statement, *Poisons Standard February 2019* (Cth) 1 (Austl.) (these committees are created by the TG Act ss 52B and 52C).

¹⁴⁴ REBERA, *supra* note 142, at iv-v.

¹⁴⁵ THERAPEUTIC GOODS ADMIN., AUSTL. DEP'T OF HEALTH, SCHEDULING HANDBOOK: GUIDANCE FOR AMENDING THE POISONS STANDARD 6 (2019).

¹⁴⁶ *Id.* at 8.

¹⁴⁷ Andrew Tooms, *Opinion: Why We Need a National Poisons Law*, AUSTL. J. PHARM. (Oct. 31, 2017), <https://ajp.com.au/columns/opinion/opinion-need-national-poisons-law/>. For instance, in some jurisdictions repeat prescriptions for Schedule 8 poisons must be collected from the same pharmacy unless government approval to change pharmacies is obtained. This is the case in Western Australia, Tasmania, and New South Wales. To add further complexity, each of these States has their own procedure and prerequisites for obtaining approval. Separately, in all jurisdictions *except*

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The following table exhibits the ten SUSMP schedules and the relative seriousness of each schedule:

Figure 6 – The SUSMP No 23. February 2019¹⁴⁸

SUSMP Schedule	Definition¹⁴⁹	Examples¹⁵⁰
1 N/A	“This Schedule is intentionally blank.”	
2 Pharmacy Medicine	“Substances, the safe use of which may require advice from a pharmacist, and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.”	ASPIRIN, DICLOFENAC, IBUPROFEN, LIDOCAINE, NAPROXEN, TETRYZOLINE.

Queensland, health professionals may destroy Schedule 8 controlled drugs when allowed by law, with a health professional as a witness. In Queensland, a government facility must destroy the drugs. Finally, out-of-jurisdiction prescriptions for Schedule 8 stimulants can be dispensed in the Australian Capital Territory, South Australia, and Victoria. In contrast, other jurisdictions prohibit such dispensing for some (or all) Schedule 8 poisons. *The Northern Territory alone* prohibits dispensing more than one month’s supply of methylphenidate, whereas all other jurisdictions allow the PBS standard quantity of 100 10mg tablets to be dispensed. *Id.*

¹⁴⁸ Poisons Standard February 2019 (Cth) pts 2, 4 (Austl.)

¹⁴⁹ For reference to these definitions, see *id.* at Introduction.

¹⁵⁰ See generally *id.* at pt 4 schs 1-10. Note, some substances appear on multiple Schedules; some substances ascend and descend the Schedules depending on their use and/or quantity. This detail is omitted.

<p>3 Pharmacist Only Medicine</p>	<p>“Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.”</p>	<p>KETOPROFEN, PSEUDOEPHEDRINE, ULIPRISTAL</p>
<p>4 Prescription Only Medicine or Prescription Animal Remedy</p>	<p>“Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.”</p>	<p>ALCLOFENAC, ALLERGENS, AMOXICILLIN, ANABOLIC STEROIDAL AGENTS, BORAX PNEUMOCOCCAL VACCINE, PREGABALIN, TENOFOVIR</p>
<p>5 Caution</p>	<p>“Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with</p>	<p>AKLOMIDE, BENTAZONE, CHLORFENAC, DINICONAZOLE, PYRIFENOX.</p>

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	simple warnings and safety directions on the label.”	
6 Poison	“Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.”	ALKALINE SALTS, CASTOR OIL, CHLORINATING COMPOUNDS, CHLOROFORM, METHANOL
7 Dangerous Poison	“Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling, or use. These poisons should	ARSENIC, BORON TRIFLUORIDE, BROMINE, CYANIDES, 4-DIMETHYLAMINOAZOBENZENE, NICOTINE, ¹⁵¹ THALLIUM.

¹⁵¹ “NICOTINE **except:** a) when included in Schedule 6; b) in preparations for human therapeutic use; or c) in tobacco prepared and packed for smoking.” *Id.* at pt 4 sch 7 (emphasis in original).

	be available only to specialized or authorized users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage, or use may apply.”	
8 Controlled Drug	“Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.”	AMFETAMINE, BUTORPHANOL, CANNABIS, COCAINE, CODEINE, DEXAMFETAMINE, FENTANYL, HYDROCODONE, KETAMINE, METAMFETAMINE, MORPHINE,
9 Prohibited Substance	“Substances which may be abused or misused, the manufacture, possession, sale or use of which should be	ACETORPHINE, CLONAZOLAM, HEROIN, LYSERGIC ACID, PROPERIDINE

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	prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”	
10 Substances of such danger to health as to warrant prohibition of sale, supply and use	“Substances which are prohibited for the purpose or purposes listed for each poison.”	COAL TAR, 1,3-DIMETHYLAMYLAMINE (DMAA), LEAD COMPOUNDS, TRIPARANOL

B. Liquid Nicotine and the SUSMP

Nicotine is classified as a Schedule 7 (“dangerous poison”) under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).¹⁵² Nicotine is listed in Schedule 7 of the Poisons Standard as follows:

“NICOTINE except:

¹⁵² CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 3.

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- a) when included in Schedule 6;¹⁵³
- b) in preparations for human therapeutic use; or
- c) in tobacco prepared and packed for smoking.”¹⁵⁴

This definition implies that liquid nicotine for e-cigarette use is a Schedule 7 nicotine. This is because such a liquid does not fall into any of the three exceptions listed in the above definition.

C. Implications

The legal consequences for liquid nicotine being a Schedule 7 position are significant. All Australian States and Territories adopt the SUSMP’s recommended offenses.¹⁵⁵ This means that it is an offense to manufacture, sell, or supply nicotine as a Schedule 7 substance without a license or specific authorization. In addition, pursuant to the SUSMP, it is an offense to use a Schedule 7 substance.¹⁵⁶

In 2018, the Northern Territory (NT) Minister for Health, the Honorable Natasha Fyles, stated that nicotine juice is restricted in the NT under the *Medicines, Poisons and Therapeutic Goods Act 2014* (NT) as a Schedule 7 poison, and e-cigarettes for sale are not permitted to contain nicotine.¹⁵⁷

Despite there being meaningful differences between the restrictions and regulations on Poisons between the States and

¹⁵³ Nicotine is a Schedule 6 poison where it is in a preparation which is labelled and packed for the treatment of animals. Such a preparation must have a nicotine content of 3% or less. See *Poisons Standard February 2019* (Cth) pt 4 sch 6 (Austl.).

¹⁵⁴ PARLIAMENT OF W. AUSTRAL., *supra* note 1, at 3.

¹⁵⁵ See *Poisons Standard February 2019* (Cth) pt 2 (Austl.).

¹⁵⁶ See *id.* at pt 2 s 6.2.

¹⁵⁷ See ECON. POL’Y SCRUTINY COMM., LEGIS. ASSEMB. N. TERR., *Inquiry into the Tobacco Control Legislation Amendment Bill 2018* 14 (2018).

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Territories, with definitions¹⁵⁸ and strictness¹⁵⁹ varying between jurisdictions, there is a strong consistency in important restrictions on Schedule 7 dangerous poisons, as exemplified in Figure 7.

Figure 7 – Key Legislative Provisions for Schedule 7 Dangerous Poisons (Selected Jurisdictions)

Jurisdiction	Legislation and Regulations	Sch 7 Use Ban	Sch 7 Sale/Supply Ban	Sch 7 Possession Ban	Incorporating SUSMP
ACT	<i>Medicines, Poisons and Therapeutic Goods Act 2008</i> (ACT) ¹⁶⁰	s 37	s 26	ss 35, 36	Ch 3
NSW	<i>Poisons and Therapeutic Goods Act 1966</i> N.S.W. Stat. ¹⁶¹				Pt 4A Div 1

¹⁵⁸ ECON. POL'Y SCRUTINY COMM., *supra* note 157 at 14. For instance, a Northern Territory Parliamentary Committee noted that the definition of e-cigarette in the NT e-cigarette restriction Bill of 2018 (now Act) differed from the definition implemented in NSW legislation. Specifically, the Committee was concerned that the NT Bill (as it then was) was ambiguous in whether it applied to non-nicotine e-cigarettes. This is because the definition of e-cigarette was limited to products that replicate or produce a similar experience to smoking tobacco.) This definition was not amended before being passed into legislation. See Tobacco Control Legislation Amendment Bill 2018 (NT) s 2.5 (Austl.); *Tobacco Control Act 2002* (NT) pt 1 s 5 (Austl.). This is in contrast to the NSW legislation which explicates that e-cigarettes/vaporiser as meaning both non-tobacco and tobacco products. See *Public Health (Tobacco) Act 2008* (NSW) pt 1 s 4(a) (Austl.). The Committee's report records that the Minister gave a statement to the Committee that the legislation's purpose is to include e-cigarettes as "conventional tobacco products" ECON. POL'Y SCRUTINY COMM., *supra* note 162, at 11.

¹⁵⁹ Tooms, *supra* note 147. See also ECON. POL'Y SCRUTINY COMM., *supra* note 157, at 11.(noting that the Northern Territory had the weakest tobacco control laws of all Australian States and Territories (as of late 2018)).

¹⁶⁰ This act covers bans on declared substances, which is defined for purposes of sections 26-45 as a medicine, dangerous poison, prohibited substance, schedule 10 substance or low harm/moderate harm poison as prescribed by regulation. *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT) s 25 (Austl.).

¹⁶¹ *Poisons and Therapeutic Goods Act 1966* (NSW) pt 4A s 1 (Austl.).

	<i>Poisons and Therapeutic Goods Regulation 2008</i> N.S.W. Stat. ¹⁶²	r 20(1)	r 20(2)	r 20(1)	
Qld	<i>Health (Drugs and Poisons) Regulation 1996</i> Queensl. Stat. ¹⁶³	Ch 4 Pt 4	Ch 4 Pt 4	Ch 4 Pt 4	Ch 1 Pt 2, Appendix 9 cl 3
WA	<i>Medicines and Poisons Act 2014</i> W. Austl. Stat. Pt 1 ss 3-11, Pts 2-11 ¹⁶⁴	s 16(2)	s 16(1)	s 16(2)	
	<i>Medicines and Poisons Regulations 2016</i> W. Austl. Stat. ¹⁶⁵		r 93		rr 6, 7

¹⁶² *Poisons and Therapeutic Goods Regulation 2008* (NSW) pt 4 s 20(1)-(2) (Austl.).

¹⁶³ *Health (Drugs and Poisons) Regulation 1996* (Qld) ch 4 pt 4, ch 1 pt 2 (Austl.).

¹⁶⁴ Schedule 7 bans are found in *Medicines and Poisons Act 2014* (WA) s 16(1)-(2) (Austl.).

¹⁶⁵ *Medicines and Poisons Regulations 2016* (WA) rr 93, 6, 7 (Austl.).

There is controversy about whether liquid nicotine may be imported lawfully for human therapeutic use, thus exempting it from a Schedule 7 classification.

In the context of e-cigarettes, the TGA has taken the position that liquid nicotine can be imported as prescription medicine under the Personal Importation Scheme.¹⁶⁶ Similarly, Tasmania's Department of Health has provided that it is legal to import nicotine for therapeutic use with a prescription personally.¹⁶⁷

However, a conflict of law and/or understanding seems to exist in Queensland. The State's health department has a contrary view that nicotine is unlawful to import under the personal importation scheme. In a submission to a Commonwealth Parliamentary inquiry, Queensland's Department of Health submitted that in Queensland:

[I]t is an offence for a person to manufacture, obtain, possess, prescribe, dispense, sell, advertise, use or destroy nicotine, unless the person is specifically authorized or holds an approval under the *Health (Drugs and Poisons) Regulation 1996*. This includes importing electronic cigarettes containing nicotine for personal or therapeutic use even with a prescription from a medical practitioner.¹⁶⁸

D. Developments

As of writing, there is little sign of nicotine or tobacco products being exempted or loosened from the Poisons legislation, or having this legislation otherwise loosened for tobacco.

¹⁶⁶ See *Liquid Nicotine and Personal Importation for Use in Electronic Cigarettes*, THERAPEUTIC GOODS ADMIN. (June 4, 2014), <https://www.tga.gov.au/behind-news/liquid-nicotine-and-personal-importation-use-electronic-cigarettes>.

¹⁶⁷ See *Electronic Cigarettes Fact Sheet*, DEP'T OF HEALTH AND HUM. SERVS. (TAS.), https://www.dhhs.tas.gov.au/publichealth/tobacco_control/electronic-cigarettes/fact_sheet_-_electronic_cigarettes2 (last visited Jun 23, 2019).

¹⁶⁸ JEANNETTE YOUNG, DEP'T OF HEALTH (QLD), INQUIRY INTO THE USE AND MARKETING OF ELECTRONIC CIGARETTES AND PERSONAL VAPORISERS IN AUSTRALIA 6 (2017).

In May 2016, Australia's Senate Economic References Committee inquiry published an interim report just prior to Parliament's dissolution. In this report the committee urgently recommended that nicotine suitable for e-cigarettes be exempted from Schedule 7.¹⁶⁹

In 2017, the Assistant Health Minister, Dr. David Gillespie, was asked whether the exemption from Schedule 7 of the Poisons Standard would apply to Philip Morris' IQOS product, which is a heated tobacco product.¹⁷⁰ He stated, "The department is of the view that these exemptions would not likely apply to heat-not-burn products as the nicotine in them would not be in the form of tobacco prepared and packed for smoking."¹⁷¹ Dr Gillespie also stated that his Department believes Australia's comprehensive tobacco control measures, including the *Tobacco Plain Packaging Act 2011* (Cth) and the *Tobacco Advertising Prohibition Act 1992* (Cth), would likely apply to heat-not-burn products.¹⁷² This is one of the many examples demonstrating how the legal status of heated tobacco products in Australia is unclear.

In March 2017, the TGA rejected New Nicotine Alliance Australia's application to have "for use in e-cigarettes" exempted from Schedule 7.¹⁷³ The effect of this decision was "that the commercial supply of nicotine for use in e-cigarettes [remained illegal] . . ."¹⁷⁴ In making this decision the TGA cited, among other reasons, insufficient evidence of the long-term safety of nicotine exposure through e-cigarettes.¹⁷⁵ There was also a significant concern

¹⁶⁹ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 7–9.

¹⁷⁰ Tony Wright, *Philip Morris's "Smoke-Free" Cigarette Seems Unlikely to Ignite in Australia*, SYDNEY MORNING HERALD (Feb. 16, 2017, 12:01 PM), <https://www.smh.com.au/politics/federal/philip-morriss-smokefree-cigarette-seems-unlikely-to-ignite-in-australia-20170215-gudjx5.html>.

¹⁷¹ *Id.*

¹⁷² *Id.* ("Australia also has a comprehensive set of tobacco control measures, a number of which may apply to heat-not-burn products. For instance, the Tobacco Plain Packaging Act 2011 and the Tobacco Advertising Prohibition Act 1992 would likely apply to heat-not-burn products.")

¹⁷³ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 7.

¹⁷⁴ Joe Hildebrand, *Vaping Laws: Government Members Announce Opposite Responses in 60 Seconds*, NEWS LIMITED (May 30, 2017, 3:38 PM), <https://www.news.com.au/lifestyle/health/gone-in-60-seconds-govt-backs-vaping-law-then-announces-inquiry-one-minute-later/news-story/5bd2054762d722a2fbc12ec0d26bc75d>; CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 7–9.

¹⁷⁵ CLEARING THE AIR ON E-CIGARETTES, *supra* note 3, at 8.

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over the health risks posed by increased access to the liquid, particularly to children through unintentional ingestion.¹⁷⁶ Subsequently, the Australian Government stood by the TGA's decision in response to an objecting letter addressed to the Prime Minister, which was a letter signed by 140 doctors, scientists and experts from around the world.¹⁷⁷

VI. Australian Regulation: Nicotine As a Schedule 6 Product & E-Cigarette Devices

A. Introduction

Nicotine products covered by SUSMP Schedule 6 are regulated by a variety of different legislative schemes across Australia's jurisdictions. Notwithstanding any differences, "the commercial supply of nicotine for use in E-cigarettes is prohibited by legislation in all states and territories."¹⁷⁸ In addition, there has been a rapid increase in the legislation and case law that regulates e-cigarette devices themselves. The relevant regulations will now be examined in greater detail.

B. Advertising

The advertising of Schedule 6 nicotine is highly restricted in Australia.¹⁷⁹ Australian law specifically regulates the advertising of therapeutic goods, and there is case law suggesting that the general advertising restrictions found in contemporary consumer law are applicable to e-cigarette advertising.

1. Tobacco-Specific Laws

First, the *Tobacco Advertising Prohibition Act 1992* (Cth) and *Smoking and Tobacco Products Advertisements (Prohibition) Act 1989* (Cth) generally prohibit tobacco advertisements in/on print

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ H.R. STANDING COMM. ON HEALTH, AGED CARE & SPORT., *supra* note 1, para 2.42.

¹⁷⁹ While it will not be covered here, there are additional provisions of a variety of laws which regulate tobacco advertising at the state and federal level. For a relevant provision in a state law, see, e.g., *Tobacco and E-Cigarette Products Act 1997* (S. Austl.) pt III s 40; see also *Tobacco Products Control Act 2006* (W. Austl.) pt VII div 2 s 104.

media, films, videos, television, radio, the internet, a retailer, tickets, public displays or billboards, workplaces and public transport.¹⁸⁰ More recently, advertising “over the counter” and on the internet has been restricted, though the restrictions are subject to exceptions (most notably, accidental or incidental advertising).¹⁸¹ Further, concurrent State and Territory laws restrict print and other physical advertising.¹⁸²

Second, as mentioned earlier in Part 2 of this article, all jurisdictions in Australia require cigarettes to be sold in plain packaging.¹⁸³

2. Consumer Law

The *Australian Consumer Law* (ACL),¹⁸⁴ and the concurrent fair-trading laws of the States and Territories,¹⁸⁵ are relevant to e-cigarette marketing. These laws are administered by the Australian Competition & Consumer Commission (ACCC), as well as State and Territory agencies.¹⁸⁶

At the Commonwealth level, section 18 of the ACL broadly prohibits misleading and deceptive conduct. Conduct in this context includes advertising and promotion of a product.¹⁸⁷

¹⁸⁰ See WTO Panel Report, *Certain Measures*, *supra* note 55, at 105 para. 2.56 n.294, 106 paras. 2.57-2.60.

¹⁸¹ See *Tobacco Advertising Prohibition Act 1992* (Cth) ss 10, 13, 14, (Austl.). Such restrictions are enabled by the Commonwealth’s power to make laws “with respect to postal, telegraphic, telephonic, and other like services.” *Australian Constitution* s 51(v).

¹⁸² C. Grace, *11.4 State and Territory Legislation*, TOBACCO IN AUSTRALIA: FACTS AND ISSUES, <https://www.tobaccoinaustralia.org.au/chapter-11-advertising/11-4-state-and-territory-legislation> (last updated Sept. 2018).

¹⁸³ See *Tobacco Plain Packaging Act 2011* (Cth) pt II div 18 s 18 (Austl.).

¹⁸⁴ See *Competition and Consumer Act 2010* (Cth) pt XI div 2 (Austl.).

¹⁸⁵ See *Fair Trading Act 2010* (W. Austl.) pt III (operating concurrently with the ACL). See generally Letter from Hon. Michael Quigley, Att’y Gen., Minister for Commerce, to Hon. Aaron Stonehouse (Dec. 19, 2018) (on file at [http://parliament.wa.gov.au/Parliament/commit.nsf/\(Evidence+Lookup+by+Com+ID\)/2B69848E886DA0D3482583A50008B397?opendocument](http://parliament.wa.gov.au/Parliament/commit.nsf/(Evidence+Lookup+by+Com+ID)/2B69848E886DA0D3482583A50008B397?opendocument)).

¹⁸⁶ See *the Australian Consumer Law*, COMMONWEALTH OF AUSTR., <https://consumerlaw.gov.au/australian-consumer-law> (last visited Jan. 16, 2021); *Fair Trading Laws*, AUSTRAL. GOV., <https://www.business.gov.au/products-and-services/fair-trading/fair-trading-laws#> (last updated Jan. 16, 2021).

¹⁸⁷ *Tobacco Plain Packaging Act 2011* (Cth) pt II div 18 s 18 (Austl.).

Recent case law, such as *ACCC v Heinz*,¹⁸⁸ has helpfully confirmed that false claims that a product is healthy or beneficial to health is a violation of this section. In this case, claims about the healthfulness of sugary snacks (Heinz’s “Peach Product” and “Fruit and Chia Product”) were found to violate section 18.¹⁸⁹

Similarly, in *ACCC v Reckitt Benckiser*,¹⁹⁰ the Federal Court held that it was misleading and deceptive to advertise several different painkiller products (non-steroidal anti-inflammatory drugs) as targeting different areas of the body, despite the products all being identical with no such targeting effect. These cases confirm the ACCC’s jurisdiction and willingness to protect the public from dangerous products; particularly those that are deceptively marketed. In regard to e-cigarettes, the ACCC has taken a cautious position that the safety and quality of e-cigarettes is not known due to a lack of scientific assessment.¹⁹¹

Pursuant to this position, the ACCC has successfully prosecuted *Australian Competition and Consumer Commission v The Joystick Company Pty Ltd*.¹⁹² In this case, three online e-cigarette retailers engaged in misleading and deceptive conduct by falsely claiming that their products did not contain harmful carcinogens and toxins. The specific representations were that the products:

- (a) did not contain carcinogens and toxic substances;
- (b) did not contain any of the carcinogens and toxic substances found in traditional tobacco cigarettes;
- (c) did not contain Formaldehyde; and

¹⁸⁸ See *ACCC v H.J. Heinz Co.* [2018] FCA 360 (19 March 2018), [262], [270] (Austl.).

¹⁸⁹ *Id.* at [314]-[315].

¹⁹⁰ See *ACCC v Benckiser (Australia) Pty* [2015] FCA 1408 (11 December 2015), [13]-[15] (Austl.).

¹⁹¹ See *ACCC v Joystick Co.* [2017] FCA 397 (2 May 2017), [50]-[51] (Austl.).

¹⁹² See generally *id.*

(d) had flavors all of which had received "compliance" approval from the ACCC.¹⁹³

The Federal Court declared that the ACL had been breached and imposed pecuniary penalties (among other measures), per orders agreed upon by the ACCC and the defendants. In addition, the Court's reasoning provided insight into the seriousness of misleading consumers about the safety of e-cigarette products:

I find that the contraventions are serious. The conduct was in respect of serious matters concerning public health. The conduct was directed to the general public and the medium of communication was the internet, which is far-reaching. The Representations had the potential to mislead a wide range of consumers about the health effects of non-nicotine e-cigarettes. Consumers were not in a position to ascertain the falsity of the Representations. The misrepresentations deprived consumers of the opportunity to make properly informed decisions.

Consumers of Joystick's e-cigarette products were misled, or were likely to have been misled, into believing that the use of those products would not expose them to carcinogens or toxic substances, like those contained in conventional tobacco cigarette smoke. The exposure to those carcinogens or toxic chemicals may have caused harm to the health of those consumers who, if they had been informed of the presence of these chemicals in the e-cigarettes, may have chosen not to purchase and use them.¹⁹⁴

In addition, the separate obligation of the industry to be truthful in promoting e-cigarettes under *State* legislation was reiterated in 2018 by the Attorney-General and the Minister for Commerce of Western

¹⁹³ *Id.* See also Quigley, *supra* note 185; *E-Cigarette Companies to Pay Penalties*, ACCC (May 8, 2017), <https://www.accc.gov.au/media-release/e-cigarette-companies-to-pay-penalties>.

¹⁹⁴ *ACCC v Joystick Co.* [2017] FCA 397, [53]-[55].

Australia, in a letter to the Select Committee on Personal Choice and Community Safety.¹⁹⁵

From the foregoing case law and statements from officials, it is made plan that the general advertising restrictions, found in Australia's consumer law, are applicable to e-cigarette advertising.

3. Therapeutic Goods Advertising Code

Separately, the advertisement of therapeutic goods in Australia is governed by the *Therapeutic Goods Advertising Code (No 2) 2018* (Cth) (TGAC),¹⁹⁶ which is a legislative instrument made under the TG Act section 42BAA.¹⁹⁷ Unlike industry self-regulatory codes, the TGAC is enforceable by the TGA, with breaches of the TGAC constituting civil penalty offences.¹⁹⁸ The TGAC imposes particular restrictions on the advertising of therapeutic goods.¹⁹⁹ The rationale for this is (partially) that such advertising affects the populations' health, and, such advertising can influence people to make inappropriate or uninformed health decisions which carry private and public costs.²⁰⁰ Relevantly for e-cigarettes, if they are taken to be therapeutic goods for the sake of argument, the TGAC Pt

¹⁹⁵ Quigley, *supra* note 185.

¹⁹⁶ See generally *Arborvitae Arthritis Pain Relief and Health Supp.*, Complaint 2017-11-011 (Complaints Resolution Panel 18 Jan. 2018) (final determination) to illustrate the operation of the TGAC. This ruling is from the former Complaints Resolution Panel established under the now repealed r 42R of the *Therapeutic Goods Regulations 1990* (Cth).

¹⁹⁷ Explanatory Statement, *Therapeutic Goods Advertising Code (No. 2) 2018* (Cth) 1 (Austl.) (this replaced the *Therapeutic Goods Advertising Code 2015* (Cth)).

¹⁹⁸ *Id.* (referencing *Therapeutic Goods Act 1989* (Cth) ch 5 pt I div 3A ss 42DM, 42DMA (Austl.)).

¹⁹⁹ An advertisement for therapeutic goods is defined in the *Therapeutic Goods Act 1989* (Cth) ch 1 s 3(1) (Austl.) to include "any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods . . ." This definition is broad enough to include online advertising because it is "consistent with the ordinary principles of statutory interpretation to choose an interpretation that gives effect to the purpose of . . . the Code." See *id.* at 21. For an example where online advertising was found to be in breach of the repealed *Therapeutic Goods Advertising Code 2015* (Cth), see *Arborvitae Arthritis Pain Relief and Health Supp.*, Complaint 2017-11-011, 9-10 (Complaints Resolution Panel 18 Jan. 2018) (final determination).

²⁰⁰ See Explanatory Statement, *Therapeutic Goods Advertising Code (No. 2) 2018* (Cth) 8 (Austl.). The objectives of the TGAC are contained in section 5 of the act. These are (in summary): (a) promoting safe and proper use of therapeutic goods, (b) ensuring ethical advertising of therapeutic goods, (c) supporting informed healthcare choices, and (d) ensuring therapeutic goods advertising is consistent with public health campaigns. *Therapeutic Goods Advertising Code (No.2) 2018* (Cth) pt I s 5 (Austl.).

2 would impose especially relevant “*general requirements for the advertising of therapeutic goods*” including:

- a) All claims made in therapeutic goods advertising must be valid and accurate, and any contained information must be substantiated prior to advertising;²⁰¹
- b) Therapeutic goods advertisements must be truthful, balanced, and not misleading or likely to mislead;²⁰²
- c) Comparisons (to other goods) in therapeutics goods advertising must not directly or indirectly claim the other goods are harmful or ineffectual;²⁰³
- d) Therapeutic goods advertising must not claim, represent, state or imply that;
 - i. Therapeutic goods are safe or cannot cause harm, or have no side effects;²⁰⁴ or
 - ii. Therapeutic goods are effective in all cases of a condition, or that the desired outcome from the goods’ use is a “guaranteed sure cure”;²⁰⁵ or
 - iii. Therapeutic goods are infallible, unfailing, magical or miraculous;²⁰⁶
- e) Therapeutic goods advertising must not contain or imply an endorsement from a government authority,²⁰⁷ and;
- f) Therapeutic goods advertising must not be inconsistent with Commonwealth, State or Territory public health campaigns.²⁰⁸

C. Industrial Relations Law

There are several important industrial relations laws across Australia’s jurisdictions which provide relevant restrictions on

²⁰¹ *Therapeutic Goods Advertising Code (No. 2) 2018* (Cth) pt II s 9(a) (Austl.).

²⁰² *Id.* at pt II s 9(b).

²⁰³ *Id.* at pt II s 9(c).

²⁰⁴ *Id.* at s 10(d)(i).

²⁰⁵ *Id.* at s 10(d)(ii).

²⁰⁶ *Id.* at s 10(d)(iii).

²⁰⁷ *Id.* at s 16(2)(a).

²⁰⁸ *Id.* at ss 4, 21.

smoking in the workplace.²⁰⁹ These industrial relations laws are important because they impose umbrella obligations on employers and employees to create safe and healthy workplaces, which in turn requires workplaces to be free from unnecessary aerosol pollutants.

All Australian States and Territories have relevant Occupational Health and Safety (OH&S) legislation alongside the complementary common law and civil liability legislation.²¹⁰ In terms of specific OH&S statutes, as of writing, all Australian jurisdictions (except Victoria and Western Australia) have joined the ‘national system’ of employment law. Specifically, the Commonwealth and all States and Territories (excluding Victoria and Western Australia)²¹¹ have adopted the model *Work Health and Safety Act 2011* (Cth). The participating States and territories adopted it by passing their own mirror Acts (WHS Acts).²¹² Though note that the WHS Acts apply concurrently with other State and Territory OH&S legislation that has been retained.²¹³ In terms of relevant provisions, the WHS Acts oblige the subject employers and employees²¹⁴ to provide and maintain a safe system of work.²¹⁵ This workplace obligation is relevant because airborne poisons, including tobacco smoke, have been recognized in case law and government guidance to be a major health hazard.²¹⁶ According to Comcare, such obligations may be

²⁰⁹ See generally EM Greenhalgh, MM Scollo & MH Winstanley, *16.3 Litigation Relating to Injury from Exposure to Second-Hand Smoke*, in TOBACCO IN AUSTRALIA: FACTS AND ISSUES (2018), <https://www.tobaccoin australia.org.au/chapter-16-litigation/16-3-litigation-relating-to-injury-from-exposure-t>.

²¹⁰ All Australian jurisdictions retain the common law and civil liability legislation, which obliges employers to avoid being negligent towards the safety of employees and visitors (e.g. customers, contractors). See *Ellis, v South Australia* [2006] WASC 270 (8 December 2006), [17], [534], [554]-[571] (Austl.). The relevant legislation is the various civil and occupiers’ liability Acts. See e.g. *Civil Liability Act 2002* (WA); *Occupiers’ Liability Act 1985* (WA).

²¹¹ See *Occupational Health and Safety Act 2004* (Vic) (Austl.); *Occupational Safety and Health Act 1984* (WA).

²¹² Henceforth all are collectively referred to as the WHS Acts.

²¹³ *Work Health and Safety Act 2011* (Cth) s 12(9)-(13) (Austl.).

²¹⁴ *Id* at s 12(1).

²¹⁵ There are also converse obligations on employees to ensure (and avoid endangering) workplace safety. See, e.g., *Occupational Safety and Health Act 1984* (WA) s 20.

²¹⁶ See COMCARE, AUSTL. GOV., SMOKING IN OR NEAR COMMONWEALTH WORKPLACES (2012); NATIONAL OCCUPATIONAL HEALTH & SAFETY COMMISSION, GUIDANCE NOTE ON THE ELIMINATION OF ENVIRONMENTAL TOBACCO SMOKE IN THE WORKPLACE [NOHSC:3019(2003)] Part 1 (2003), https://www.safeworkaustralia.gov.au/system/files/documents/1702/guidancenote_eliminationofenvironmentaltobaccosmoke_workplace_nohsc3019-2003_pdf.pdf; DEPARTMENT OF HEALTH (WA), *Supporting smoke-free workplaces: a policy implementation guide* (2014),

breached if a worker or other person is exposed to “Environmental Tobacco Smoke” (ETS).²¹⁷ Exposure to ETS can occur when workers are entering and exiting the building when smokers are nearby, or can occur inside buildings if ETS enters through doors, air conditioning or air intakes.²¹⁸ Further, Comcare recommends that employers “ensure workers do not smoke in places where their smoke could enter a building, where other workers and third parties enter or exit the building, and in frequently used transit areas.”²¹⁹ This obligation is also found in Western Australia and Victoria’s local legislation, meaning the obligation is Australia-wide.²²⁰ Further, the obligation on the employer includes reasonably disciplining or dismissing employees who illicitly smoke within a workplace in violation of the law.²²¹

1. No-Smoking Policies

Separate to statutory obligations, employers may impose their own specific no-smoking policies and reasonably dismiss or

<https://www.commerce.wa.gov.au/publications/supporting-smoke-free-workplaces-policy-implementation-guide>.

²¹⁷ COMCARE, *supra* note 216.

²¹⁸ *Id.* (“Under Section 19 of the [*Work Health and Safety Act 2011* (Cth)], a [Person Carrying on a Business or Undertaking (PCBU)] must ensure—so far as is reasonably practicable—the health and safety at work of their workers, and that the health and safety of other persons at the workplace is not put at risk from the work carried out as part of the conduct of the business or undertaking. The health and safety of workers and other persons may be adversely affected by the inhalation of [Environmental Tobacco Smoke (ETS)], meaning that a PCBU may be in breach of their obligations if a worker or other person is exposed to ETS. Exposure to ETS can occur when workers are entering and exiting the building when smokers are nearby or can occur inside buildings if ETS enters through doors, air conditioning or air intakes. Section 20(2) also requires a person with management or control of a workplace (PMCW) to ensure—so far as is reasonably practicable—that the workplace, the means of entering and exiting the workplace and anything arising from the workplace are without risks to the health and safety of any person. This means that the PMCW must ensure that workers and others are able to enter and exit a workplace without exposure to ETS.”).

²¹⁹ *Id.*

²²⁰ *Occupational Health and Safety Act 2004* (Vic) pt 3 (Austl.); *Occupational Safety and Health Act 1984* (WA) pt 3 iv 2; NATIONAL OCCUPATIONAL HEALTH & SAFETY COMMISSION, GUIDANCE NOTE ON THE ELIMINATION OF ENVIRONMENTAL TOBACCO SMOKE IN THE WORKPLACE (2003); *Smoking, the Law and OH&S Obligations*, QUIT VICTORIA (2019), <https://www.quit.org.au/resources/workplaces/smoking-law-and-ohs-obligations/>; Patrick Williams, *Job’s Yours, as Long as You Butt Out. Why Employers Are Allowed to Only Hire Non-Smokers*, ABC NEWS (Austl.) (Mar. 15, 2018), <https://www.abc.net.au/news/2018-03-15/why-employers-allowed-hire-non-smokers-only/9546204>.

²²¹ NATIONAL OCCUPATIONAL HEALTH & SAFETY COMMISSION, *supra* note 220, pt 2.

discipline breaching employees accordingly.²²² A nationally relevant example is the Australian Public Service's no-smoking policy (since 1988).²²³ As for the seriousness of violating such policies, a single incident of smoking contrary to policy may not be sufficient to warrant dismissal unless there are aggravating factors (e.g. smoking near customers' food). However, continued smoking is uncontroversial grounds for dismissal.²²⁴

A crucial implication from the foregoing is that if e-cigarettes are a health hazard to bystanders (who would be passive vaping), then OH&S legislation would automatically and indeed *already* oblige employers to restrict e-cigarette use at their workplaces. Notwithstanding this, employers could make them part of their extant no-smoking policies today if they wanted.

D. Discrimination Law

Discrimination law, which is embodied in several statutes across Australia's jurisdictions, also provides important legal rules for the regulation of smoking.²²⁵ At the federal level, the *Disability Discrimination Act 1992* (Cth) protects the rights of people with disabilities, such as the right to access and use public places.²²⁶ For the purposes of this Act, asthma and cystic fibrosis are considered disabilities.²²⁷ For an employer or occupier to allow smoking at their workplace or establishment could constitute illegal discrimination against people affected by such disabilities.²²⁸ Indeed, prior case law supports this. In *Francey v Hilton Hotels of Australia*,²²⁹ HREOC Commissioner Innes considered a complaint brought by a person with

²²² KERRY RISELEY, WHO, REPORT ON SMOKE-FREE POLICIES IN AUSTRALIA 3 (2003).

²²³ *Id.*

²²⁴ See, e.g., *Tisdell v Woolworths Pty Ltd* [1997] IRCA 255 (Austl.); *Tisdell v Woolworths Ltd* [1997] FCA 949 (3 September 1997) (Austl.); *Bajada v Trend Windows and Doors Pty Ltd* [2018] FWC 5397 (Austl.); *Anti-Discrimination Act 1977* (NSW) (Austl.); *Equal Opportunity Act 2010* (Vic) (Austl.); *Anti-Discrimination Act 1991* (Qld) (Austl.); *Equal Opportunity Act 1984* (WA) (Austl.); *Equal Opportunity Act 1984* (SA) (Austl.); *Anti-Discrimination Act 1998* (Tas) (Austl.); *Discrimination Act 1991* (ACT) (Austl.); *Anti-Discrimination Act 1996* (NT) (Austl.).

²²⁵ See generally Greenhalgh, Scollo & Winstanley, *supra* note 209, at.16.3.5.

²²⁶ *Disability Discrimination Act 1992* (Cth) pt 2 div 2 (Austl.).

²²⁷ *Francey v. Hilton Hotels of Austl. Pty Ltd* [1997] EOC ¶92-903, s 4.1 (Austl.).

²²⁸ *Id.*

²²⁹ *Id.*

asthma (and her associate) that the respondent's policy of allowing people to smoke in their nightclub made it a condition of access to those premises that patrons be able to tolerate environmental tobacco smoke.²³⁰ This was a condition with which the complainant could not comply.²³¹ In finding that the defense of unjustifiable hardship was not made out, Commissioner Innes considered the benefits and detriments to the complainants, the respondent, staff and potential staff, patrons and potential patrons of the nightclub.²³²

This Commonwealth discrimination legislation is supplemented by concurrent State and Territory legislation, which also serves to restrict discrimination in employment.²³³

Interestingly, smoking is not protected under Commonwealth or State and Territory discrimination legislation. According to the Anti-Discrimination Commission Queensland, smoking is not a protected attribute under Queensland's *Anti-Discrimination Act 1991* (Qld). Further, the fact that smokers may be addicted to nicotine is not sufficient to be protected by the legislation, because they have alternatives to smoking such as nicotine patches. Separately, the Commission confirmed that employers and occupiers (including landlords) can impose reasonable restrictions on smoking under this legislation.²³⁴

The position in broader Australia is the same as in Queensland. The absence of protection for smoking is why employers frequently advertise jobs requiring applicants to be non-smokers.²³⁵ Indeed, an argument can be made that even if discrimination against smokers was generally unlawful, selective hiring disfavoring smokers would be lawful under exemptions which allow discrimination that

²³⁰ *Id.* at ss 3, 3.2, 3.3.

²³¹ *Id.* at s 4.1.

²³² AUSTRALIAN HUM. RTS. COMM'N, *Federal Discrimination Law: Chapter 5 The Disability Discrimination Act* 5.5.1 (2009), <https://www.humanrights.gov.au/federal-discrimination-law-chapter-5-disability-discrimination-act> (citing *Francey v Hilton Hotels of Austl. Pty Ltd* [1997] EOC ¶92-903).

²³³ See generally *State Legislation*, AUSTRALIAN DISABILITY CLEARINGHOUSE ON EDUC. & TRAINING, <https://www.adcet.edu.au/students-with-disability/disability-and-discrimination/state-legislation#content> (last visited Jan. 16, 2021). See e.g. *Equal Opportunity Act 1984* (WA) pt 4A div 2, pt 4A div 3 which protects people against such discrimination in employment and access to public facilities.

²³⁴ Greenhalgh, Scollo & Winstanley, *supra* note 209.

²³⁵ Williams, *supra* note 220.

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enhances occupational health and safety or merely imposes genuine occupational standards.²³⁶

These exemptions are interpreted broadly and are especially applicable where an impairment would exacerbate a foreseeable emergency that can arise at work; the exemptions can be relied on where the impairment interferes with the impaired person's interaction with others. This was the opinion of Justice James Burchett in *Commonwealth v Human Rights & Equal Opportunity Commission*. The Justice wrote:

In my opinion, the Commissioner's admittedly "narrow and restrictive" view of s 15(4) is too narrow, and therefore wrong. The inherent requirements of a particular employment are not to be limited to a mechanical performance of its tasks or skills. They will frequently involve an interaction with other employees, or with outsiders. . . .

Where work involves interaction or contact with others, this will generally be a relevant factor that it is reasonable to take into account. Another such factor may be the existence of a liability in a particular employment to the arising of a known type of emergency. Inherent requirements are not confined to what normally has to be done; they may include what will have to be done in foreseeable circumstances. A fisherman disabled from coping with a tangled trawling net may argue the net should not normally get tangled, but may be unable to carry out an inherent

²³⁶ See *Fair Work Act 2009* (Cth) s 351(2)(b) (Austl.); *Equal Opportunity Act 1984* (WA) ss 50, ss 60; *Disability Discrimination Act 1992* (Cth) s 21A(1) (Austl.). Note that s 21A(1) of the *Disability Discrimination Act 1992* replaces the repealed equivalent section 15(4) referred to in AUSTRALIAN HUM. RTS. COMM'N, *supra* note 237, at 5.3.1(d). For example, it's arguable that workers involved with preparing food would reasonably be prohibited from using tobacco or vapes during breaks, as it could result in offensive smells to be transferred to the food they prepare. See *Tisdell v Woolworths Pty Limited* [1997] IRCA 255 (Austl.); *Tisdell v Woolworths Limited* [1997] FCA 949 (3 September 1997) (Austl.); See also Williams, *supra* note 220; See also *Discrimination in Employment*, QUEENSLAND HUMAN RIGHTS COMMISSION, <https://www.qhrc.qld.gov.au/your-rights/discrimination-law/discrimination-in-employment> (last visited Jan. 16 2021).

requirement of employment on a trawler nevertheless. To rule otherwise might be to put lives and valuable equipment at risk.²³⁷

Finally, as mentioned earlier, all States and Territories (except Victoria and Western Australia) are governed by the *Fair Work Act 2009* (Cth), which includes another prohibition on discrimination on the basis of disabilities in employment.²³⁸

The use of e-cigarettes is not protected under anti-discrimination legislation for the same reason that smoking tobacco is not. Like cigarettes, alternatives to cigarettes for smoking cessation exist (and indeed are on the ARTG).²³⁹ However, if the ARTG were to include e-cigarettes as a smoking cessation tool, to then discriminate against people for using ARTG-listed therapeutic goods could plausibly be unlawful or require more justification. Such discrimination could be unlawful in the same way that it would be illegal to discriminate against people using other therapeutic goods (such as nicotine patches).

2. State and Territories' Tobacco/Smoking Product Restrictions

a. Established Restrictions

Every state and territory have legislation that restricts the use, sale and supply of “tobacco products” or “smoking products.”²⁴⁰ This legislation targets traditional tobacco products (i.e. SUSMP Schedule 6 tobacco). An exhaustive review of this legislation is beyond the scope of this article. It suffices to say that Australia’s states and territories have similarly comprehensive restrictions on the use, sale, and supply of tobacco/smoking products. The common restrictions and mandates include:

²³⁷ *Commonwealth v Human Rights & Equal Opportunity Comm'n* (1998); 76 FCR 513 (Burchett J) (Austl.).

²³⁸ *Fair Work Act 2009* (Cth) s 351 (Austl.).

²³⁹ See Greenhalgh, Grace & Scollo, *supra* note 82.

²⁴⁰ See Douglas, Hall, & Gartner, *supra* note 87, app. at 1 (outlining Australian laws governing nicotine use and e-cigarettes); see also Figure 8.

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- (a) requiring vendors of tobacco/smoking products to be licensed;²⁴¹
- (b) prohibiting the sale and supply of tobacco/smoking products to minors;²⁴²
- (c) prohibiting the sale tobacco/smoking products in vending machines;²⁴³
- (d) prohibiting smoking in particular public places (e.g. restaurants);²⁴⁴
- (e) mandating anti-smoking signage at tobacco retail outlets and vending machines;²⁴⁵ and
- (f) regulating the advertisement or promotion of tobacco/smoking products in retail stores.²⁴⁶

Notwithstanding the significant commonality between different jurisdictions' tobacco/smoking product restrictions, some jurisdictions do have additional restrictions. Some selected common restrictions are:

- (a) bans on child possession of Schedule 6 nicotine;²⁴⁷
- (b) occupational health and safety laws prohibiting workplace smoking explicitly;²⁴⁸ and

²⁴¹ Greenhalgh, Grace & Scollo, *supra* note 20.

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ See e.g., *Tobacco and E-Cigarette Products Act 1997* (SA) pt IV s 46. The *Tobacco and E-Cigarette Products Regulations 2019* designates particular public areas and events in South Australia as being subject to a smoking ban (e.g. Henley Square and the Royal Adelaide Show). *Tobacco and E-Cigarette Products Regulations 2019* (SA) pts XI, XIII, sch 2. See also *Tobacco Products Control Amendment Regulations 2019* (WA) pt V.

²⁴⁵ See e.g., *Tobacco Products Control Amendment Regulations 2019* (WA) pts XII, XIII, schs 2, 3.

²⁴⁶ Greenhalgh, Grace & Scollo, *supra* note 20.

²⁴⁷ See e.g., Greenhalgh & Scollo, *supra* note 82 (citing *Public Health (Tobacco) Act 2008* (NSW)). In South Australia, a prescribed person (e.g. a police officer or a teacher) may confiscate tobacco products from a child. *Tobacco Products Regulation Act 1997* (SA) pt VII s 70A (Austl.). See also *Public Health Act 1997* (Tas) pt IV div 1 ss 63, 66 (Austl.); *Tobacco Products Control Act 2006* (WA.) pt VII s 99 (Austl.).

²⁴⁸ See e.g., *Tobacco and E-Cigarette Products Act 1997* (SA) pt IV s 46 (Austl.) (formerly the *Tobacco Products Regulation Act 1997*). Smoking tobacco products is prohibited by law in all enclosed workplaces and shared work areas such as offices, shops, factories, and work vehicles. *Smoking*, SAFEWORK S. AUSTL., <https://www.safework.sa.gov.au/workers/health-and-wellbeing/smoking> (last visited Oct. 16, 2020). *Accord Tobacco Act 1987* (Vic) pt II div 1 ss 5A, 5B (Austl.). See also *Smoking, the Law and OH&S Obligation*, *supra* note 225 ("The *Tobacco Act 1987* (Vic) prohibits smoking in all enclosed workplaces. 'Workplace' means any premises or area where one or more employees or self-

- (c) bans on selling products resembling tobacco or smoking products.²⁴⁹

b. Applicability to E-Cigarettes

A recent development in Australia is that all States and Territories now address e-cigarettes in their legislation for tobacco/smoking product regulation. Much like the TGA, State Parliaments have adopted the precautionary principle in the approach to regulating e-cigarettes.²⁵⁰ The table below summarizes the authors' survey of these regulations.

Figure 8 – Applicability of Tobacco Restriction Legislation to E-Cigarettes

Jurisdiction	Term for Restricted Products	Addresses E-cigarettes
ACT	Smoking Products ²⁵¹	Yes ²⁵²
NSW	Tobacco Products	Yes ²⁵³
NT	Tobacco Products	Yes ²⁵⁴

employed persons (or both) work, whether or not they receive payment for that work.”) See also *Occupational Safety and Health Regulations 1996* (WA) pt III div 3 sub-div 1 s 3.44B (Austl.).

²⁴⁹ *Tobacco and Other Smoking Products Act 1998* (Qld) pt IID s 26ZS (Austl.). Accord Douglas, Hall, & Gartner, *supra* note 87, app. at 1. For Western Australia’s leading case on this prohibition, see *Van Heerden v Hawkins* [2016] WASCA 42 (Austl.). See also *Tobacco Control Legislation Amendment Act 2019* (NT) (Austl.) (placing restrictions upon e-cigarettes which are defined, in effect, as products which replicate smoking). Accord ECON. POL’Y SCRUTINY COMM., *supra* note 157, at 14.

²⁵⁰ ECON. POL’Y SCRUTINY COMM., *supra* note 157, at 4, 13, 17.

²⁵¹ *Tobacco and Other Smoking Products Act 1927* (ACT) pt I s 3A (Austl.).

²⁵² *Id.*

²⁵³ *Electronic Cigarettes*, NSW HEALTH (July 12, 2019), <https://www.health.nsw.gov.au/tobacco/Pages/e-cigarettes.aspx> (citing *Smoke-free Environment Act 2000* (NSW) (Austl.)). See also *Passenger Transport (General) Regulation 2017* (NSW) pt II div 5 s 51 (Austl.).

²⁵⁴ *Tobacco Control Act 2002* (NT) pt I ss 4A, 6 (Austl.) (as amended by *Tobacco Control Legislation Amendment Act 2019* (NT) (Austl.)). See also ECON. POL’Y SCRUTINY COMM., *supra* note 157, at 11-14.

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Qld	Tobacco Products	Yes ²⁵⁵
SA	Tobacco Products	Yes ²⁵⁶
Tas	Smoking Products	Yes ²⁵⁷
Vic	Tobacco Products	Yes ²⁵⁸
WA	Tobacco Products	Yes ²⁵⁹

E. Case Study: Western Australia**1. Tobacco Products Control Act**

In Western Australia, the *Tobacco Products Control Act 2006* and its regulations restricts smoking.²⁶⁰ Specifically, this legislation restricts “tobacco products,” which are:

- a) tobacco designed for human consumption,
- b) any product the main ingredient of which is tobacco and that is designed for human consumption, or
- c) a tobacco or non-tobacco product which is
 - a. prepared for smoking, and
 - b. contains a herb, or
 - c. contains other plant matter.²⁶¹

The legislation excludes nicotine or any product containing nicotine to the extent that it is in the form of a poison as defined by the *Medicines and Poisons Act 2014*.²⁶²

²⁵⁵ *Tobacco and Other Smoking Products Act 1998* (Qld) pt I s 5A (Austl.) (amending Queensland law to include “personal vaporisers” in the definition of “smoking product”). See also Douglas, Hall, & Gartner, *supra* note 87, at 416 (“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.”).

²⁵⁶ *Tobacco Products Regulation (E-Cigarettes and Review) Amendment Act 2018* (SA) pt II ss 15, 17, 18 (Austl.).

²⁵⁷ *Public Health Act 1997* (Tas) pt IV (Austl.).

²⁵⁸ *Tobacco Amendment Act 2016* (Vic) pt I s 1 (Austl.) (“The main purpose of this Act is to amend the *Tobacco Act of 1987* . . . to regulate the same, promotion and use of e-cigarette products.”).

²⁵⁹ See generally *Van Heerden v Hawkins* [2016] WASCA 42 (Austl.).

²⁶⁰ See generally *Tobacco Products Control Regulations 2006* (WA) (Austl.).

²⁶¹ *Tobacco Products Control Act 2006* (WA) cl 1 (glossary) (Austl.).

²⁶² *Tobacco Products Control Act 2006* (WA) cl 1 (glossary) (Austl.).

2. Van Heerden Case

In Western Australia, the landmark *Van Heerden* decision in Western Australia's Court of Appeal held that it is illegal to sell an e-cigarette, even one that does not contain nicotine; this rule applies even where the e-cigarette does not physically resemble a cigarette.²⁶³ In *Van Heerden v. Hawkins* [2016] WASCA 42, the Court of Appeal held that the "subjective intention of the designer" of an e-cigarette can be taken into account when deciding whether the *Tobacco Products Control Act 2006* section 106 was breached.²⁶⁴ The Court of Appeal held that a breach occurred on the facts of this case, and that Mr. Van Heerden could not sell e-cigarettes notwithstanding they did not contain nicotine.²⁶⁵

Consequently, the effect of this decision is that e-cigarettes containing nicotine that the TGA approves as a therapeutic good nevertheless are illegal to sell in Western Australia.²⁶⁶ This difference could be problematic. If the TGA approves an e-cigarette for therapeutic use, Western Australians may wrongly assume that they could sell e-cigarettes in the State.

3. OH&S Legislation (WA)

Western Australia has retained its own occupational health and safety legislation, rather than signing on to the national system. This means that the law in this regard is distinct but nonetheless similar. Western Australia's relevant occupational health and safety legislation is as follows, noting the definitions of smoke and tobacco product are the same as under the *Tobacco Products Control Act 2006*:²⁶⁷

²⁶³ See generally *Van Heerden v Hawkins* [2016] WASCA 42, 56 (Austl.).

²⁶⁴ *Tobacco Products Control Act 2006* (WA) s 106 (Austl.) (provides that a person must not sell any food, toy or other non-tobacco product that is designed to resemble a tobacco product or a package; or in packaging that is designed to resemble a tobacco product or a package).

²⁶⁵ *Van Heerden v Hawkins* [2016] WASCA 42, 51 (Austl.).

²⁶⁶ See *Vaping Devices*, AUSTRALIAN TOBACCO HARM REDUCTION ASSN., <https://www.athra.org.au/vaping/the-law/> (last visited Jan. 16, 2021).

²⁶⁷ The definition of smoking in the TPCA is "smoke, hold or otherwise have control over an ignited tobacco product[.]" *Tobacco Products Control Act 2006* (W. Austl.) cl 1 (glossary). See also PARLIAMENT OF W. AUSTRALIA, *supra* note 1, at 8.

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- a) The State's *Occupational Safety and Health Act 1984* requires an employer to provide and maintain a working environment in which the employees are not exposed to hazards.²⁶⁸
- b) The State's *Occupational Safety and Health Regulations 1996*:
 1. creates an offence for smoking a tobacco product in enclosed workplaces by
 - i. employers;
 - ii. employees; and
 - iii. self-employed persons.²⁶⁹
 2. authorizes OSH inspectors to order smokers to extinguish tobacco products where they are being used in the commission of the immediately aforementioned offence.²⁷⁰

F. Comments on Constitutionality

As can be seen, the states and territories are applying tighter restrictions to e-cigarettes. These restrictions are seemingly subject to the TGA's decision-making on whether to include e-cigarettes in the ARTG. If they were included, it is plausible that some or all of the restrictions could become unlawful if they were sufficiently burdensome or restrictive. This is because by preventing citizens

²⁶⁸ *Occupational Safety and Health Regulations 1996* (WA) pt III div 3 sub-div 1 s 3.44B (Austl.).

²⁶⁹ *Id.* Though it is not an offence where the enclosed workplace is a vehicle or residence owned by the smoker; and no employee (or other employee) is present. *Occupational Safety and Health Regulations 1996* (WA) pt III div 3 sub-div 1 s 3.44D; see also *Occupational Safety and Health Regulations 1996* (WA) pt III div 3 sub-div 1 s 3.44E (permitting performative/artistic smoking). See generally GOV'T OF W. AUSTR., Supporting Smoke-Free Workplaces: A Policy Implementation Guide (May 21, 2014), at 5-9, <https://www.commerce.wa.gov.au/publications/supporting-smoke-free-workplaces-policy-implementation-guide>.

²⁷⁰ *Occupational Safety and Health Regulations 1996* (WA) pt III div 3 sub-div 1 s 3.44I (Austl.).

from accessing an ARTG-listed therapeutic good (e-cigarettes, in this case), such restrictions would interfere with the operation of the TGA's decision, which is a Commonwealth law for the purposes of section 109.²⁷¹

VII. Final Thoughts

The landscape regarding e-cigarettes in Australia is confusing to many and unfair to those people who want to use e-cigarettes as an alternative to cigarettes. There are many ways to improve this situation. Firstly, the government should harmonize the definitions of vaporizer and update the *Customs Act 1901* and *Excise Tariff Act 1921* definitions of a tobacco product so that they include vaporizers that are consistent with state and territory legislation. Customs legislation should: (1) treat the importation of e-cigarettes the same way that it treats tobacco products; (2) give more clarity on employment discrimination on the basis of the use of vaporizers; (3) give an explicit prohibition on enclosed workplace smoking laws; (4) extend the plain packaging of traditional cigarettes to e-cigarettes; and (5) better enforce existing laws. For the foregoing reasons, the state statutes and regulation definitions and standards should be standardized.

²⁷¹ *Work Health Auth v Outback Ballooning Pty Ltd* [2019] HCA 2, [83] (Austl.) (noting that statutory rules are considered laws for the purposes of the Australian Constitution).