International regulations

Policies marked <u>yellow</u> are preferred options

	New Zealand	United Kingdom	USA	Australia
Classification	 Dual pathway Consumer product, or Medical product if making claims about safety or efficacy (currently none) 	 Dual pathway Consumer product, or Medical (therapeutic) product if higher nicotine concentration, or making claims of safety or efficacy. Submitted to MHRA for approval (currently none) 	Dual pathway Tobacco product Medicine. Submit to Centre for Drug Evaluation and Research (currently none)	 Prescription medicine Unapproved therapeutic products. Available to adult smokers with a prescription from a medical practitioner to purchase from a pharmacy or import from overseas Approved therapeutic products (by the TGA) if making claims about safety or efficacy. Registered on the Australian Register of Therapeutic Goods (currently none)
Nicotine concentration	 Freebase nicotine max 20mg/mL Nicotine salt max 50mg/mL Maximum 1,800mg nicotine per container 	 Max 20mg/mL for consumer products >20mg/mL for therapeutic products 	■ Uncapped	■ 100 mg/mL
Minimum age	■ 18 years (smoking 18) [link]	■ 18 years (smoking 18)	■ 21 years (smoking 21)	■ 18 years (smoking 18)

	New Zealand	United Kingdom	USA	Australia
	 Individuals under 18 years not permitted entry to specialist vape shops 			 Individuals under 18 years not permitted entry to specialist vape shops
Advertising	 It is prohibited to encourage the use, promote the sale, or notify the availability of vaping products [link] Sponsorship of activities, events etc is prohibited [link] However a specialist vape retailer may: Display it's trade name outside it's premises even if it is derived from 'vape' Talk to customers about using vape products Distribute vaping products for free or reduced charge from their premises May communicate health information or warnings 	 Prohibited except for outdoor, posters, cinema, side of bus, leaflets, direct hard copy mail, in trade press, blogs, tweets independently compiled [ASA] [TPD] 	 Unregulated, except must include a warning that nicotine is addictive Advertising on internet, print media, TV, retail stores, social media etc FDA has the authority to restrict some marketing, but this is rarely used 	 Prohibited Limited advertising by pharmacies re availability of vaping products, type of product, nicotine concentrations, no brands
Point of sale display	 Allowed 	Allowed	Permitted	 Pharmacies only. In-store advice that products are available
Retail and online sale	 A two tier retail system. Specialist vape shops and general retailers Specialist vape retailers 	 Retail stores including specialist vape shops and 'general retail' Online sales permitted 	 Retail stores 28 states currently require a retail licence to sell nicotine [link] 	 Only pharmacies can sell nicotine products

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	 are licensed, pay an annual fee [link] and are listed online. [link] may sell all legal vape products, including tank systems and liquid refills in a variety of flavours online sales permitted General retailers can only sell vaping products in tobacco, mint of menthol flavours. Are prohibited from discussions with customers that encourage, promote or notify the availability of vaping products. No online sales No vending machines in public areas [link] 		 Mandatory age verification No sale from vending machines Online sales permitted 	 Non-nicotine e-liquids, devices and accessories available from any retail store Online sales from Australian websites banned Importation from international websites allowed with a doctor's prescription under the TGA Personal Importation Scheme [link]
Bans	n/aDisposables available	n/aDisposables available	 Some states and cities have introduced bans on flavours, online sales and even vaping products [link] Disposables available 	n/aPrescription disposables available
Public vaping	Prohibited in smoke-free areas	 Vaping permitted outdoors including smoke-free areas 	 Varies by state from unrestricted to bans in smoke-free areas 	■ Prohibited in smoke-free areas

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	 Prohibited in workplaces, aircraft, public transport, restaurants, schools etc [link] Local authorities can make decisions on vaping in outdoor smoke-free areas Specialist vape retailers are exempt from the indoor workplace vaping ban 	 Local proprietors or organisations can decide policy on use in their premises [PHE] [ASH] 		 Specialist vape retailers have exemptions for vaping indoors in some jurisdictions
Labelling	 Names and quantities of ingredients, including nicotine concentration in mg/mL Safety of use instructions Volume or weight of substances Expiry date Batch number Manufacturer name and contact details PG:VG ratio [link] Safety warnings on package: "This product contains nicotine, which is a highly addictive substance" 	 Bottle or leaflet to display List of ingredients, including nicotine content use and storage contraindications possible adverse effects addictiveness and toxicity advice to keep out of reach of children warnings for at-risk groups batch number contact details of manufacturer no health claims Health warnings must cover 30% of label's surface area and must be placed on front and back Health warning: "This product contains 	 Label must say it contain nicotine Ingredient list mandatory Health warning: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 	■ TGO 110 standards - Ingredient list - Nicotine concentration ■ Safety Warnings - 'KEEP OUT OF REACH OF CHILDREN' - 'Avoid contact with eyes' and - 'Avoid contact with skin'.

	New Zealand	United Kingdom	USA	Australia
	 Safety warnings on containers "CAUTION: Keep this substance out of reach of children or pets.": "Do not swallow this substance is taken into the mouth, rinse mouth thoroughly.": "Contact 0800 POISON (0800 764 766) for advice if this substance is swallowed.": "Seek medical advice if you feel unwell after contact with this substance or use of this product." [link] 	nicotine which is a highly addictive substance"		
Containers	 Child-resistant closures and tamper-evident measures Breakage, leakage and antispill protection Maximum bottle size 120mL unless containing zero nicotine 	 Nicotine-containing products or their packaging to be child-resistant, tamper evident, breakage and leak proof Refillable without leakage Limit of 2ml for tanks or pods Limit of 10ml for nicotine e-liquids 	 Mandatory child-resistant closures 	■ Child resistant container
Product safety	 Must not contain restricted substances [link] 	 Emissions testing No vitamins, colourings or prohibited additives (including caffeine and taurine) 	For existing products, safety is assessed as part of the PMTA process to determine whether the product can continue to be marketed	 Must not contain other 'active' ingredients other than nicotine eg caffeine, THC, stimulants or vitamins

	New Zealand	United Kingdom	USA	Australia
	 Testing of liquid by an accredited laboratory (no mandatory emission testing) USP quality for nicotine, PG, VG, alcohol, water Flavours must be watersoluble. Flavours other than tobacco extracts to meet food standards Electrical safety compliance for devices Consistent nicotine delivery No food colourings allowed 	 Using only ingredients of high purity Must not include ingredients (except for nicotine) which pose a risk to human health Deliver a dose of nicotine at consistent levels Mechanism for ensuring refilling without leakage 	Future products assessed by FDA prior to marketing	 Must not contain acetoin, benzaldeyde, cinnamaldehyde, diacetyl, diethylene glycol, ethylene glycol, pentane-2,3-dione, vitamin E acetate Maximum concentration of 100mg/mL Nicotine to be within 10% of concentration stated on label [TGO 110 standards]
Reporting	 Manufacturers and importers must advise the Vaping Regulatory Authority of any adverse reaction [link] 	 Side effects and safety concerns can be reported to MHRA through the <u>Yellow</u> <u>Card</u> reporting system 	 Reporting of safety issues, faulty products, side effects to FDA Safety Reporting Portal [link] 	 Importers, exporters or manufacturers to maintain records demonstrating compliance Reporting of adverse effects or faulty products to TGA
Pre-market Notification or Authorisation	 Manufacturers and importers must notify products through the Ministry of Health's Vaping Regulatory Authority's Health Advisory and Regulatory Platform (HARP) 	 6 months prior to marketing, producers must supply: A list of all ingredients in the product (liquid) Emissions from the product Toxicological data, including health and addictive effects 	 Manufacturers apply to FDA for pre-market authorisation, PMTA (Premarket Tobacco Product Application) [link] Only 3 manufacturers have authorised products so far (as of September 2022) [link] Vuse Logic 	■ Not applicable

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	 All notified products are available on the HARP searchable database [link] 	 Nicotine dose and uptake when consumed Components of the product Production process details 	 NJoy Only tobacco flavoured products have been approved so far 	
Flavours	 Specialist vape shops: No flavours prohibited General retailers: Tobacco, mint and menthol only 	■ No flavours prohibited	 Restricted in some cities and states 	 No flavours prohibited Certain flavouring chemicals banned for health reasons: benzaldeyde, cinnamaldehyde, diacetyl
Vaping in retail stores	Specialist vape shops: permittedGeneral retailers: Prohibited	Not restricted	 Not restricted 	 Permitted in vape shops in most states
Taxation	■ 15% GST. No excise tax	 20% VAT, no excise tax [link] Current proposal to reduce this to 5% [link] 	■ Varies by state [link]	 Nicotine e-liquids not taxed
Federal regulator	 Ministry of Health's Vaping Regulatory Authority [link] 	 Medicines and Healthcare Products Regulatory Agency (MHRA) 	Food and Drug Administration (FDA)	 Therapeutic Goods Administration (TGA)
Legislation	Smokefree Environments and Regulated Products Regulations Act 2021 [link]	The Tobacco and Related Products Regulations 2016 (Parts 6, 7 and 8) [link]		Therapeutic Goods Regulations 1990 [link]

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	E-cigarettes: regulations for consumer products 2019 [link] Advice for retailers (MHRA) [link] E-cigarettes and vaping: policy, regulation and guidance 2020 [link] TPD restrictions on the advertising of e-cigarettes 2016 [link] Advertising Standards Authority. Guidance on electronic cigarette advertising prohibition 2017 [link] Licensing procedure for electronic cigarettes as medicines [link] Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 [link] Use of e-cigarettes in public places and workplaces. Public Health England [link]		Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 [link] Pharmacy advertising Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 2021 Customs Customs Tariff Act 1995 [link]