



Changes to the Vape Legislation & how best to Navigate

Information for Pharmacies

We are from fields Pharmaceuticals, an innovative Australian owned wellness company. We are proudly independent and have no affiliations with any tobacco companies.

e-Book Disclaimer

****Disclaimer:****

This e-book is intended to provide an updated and structured overview of the critical information pharmacists need to understand and comply with vape regulations. While every effort has been made to ensure the accuracy and completeness of the information provided, it is not a substitute for professional advice, or the specific guidelines issued by regulatory authorities. Pharmacists are encouraged to consult the relevant regulatory bodies and professional guidelines to verify the information and ensure compliance with all current regulations. The authors and publishers of this e-book disclaim any liability for any loss or damage arising from reliance on the information contained herein.

Changes to the Vape Legislation & how best to Navigate

Key benefits: Unlock the Potential of a \$1.2bn Market!

Imagine helping just 30 vapers or smokers and generating \$4500 in revenue every month. With a staggering 1.7 million adult vapers and 2.3 adult million smokers, the opportunity is immense. On average, your store could attract a foot traffic of 100+ adults, driving significant growth, increasing basket size and profitability.

Don't miss out—tap into this new market today and help make Australia smoke free!

Here is a Simple 4 Step Guide to Help you:



1. Legislation and Standards

Overview of Vape Regulation Dates

- 1 July 2024: Comprehensive regulations for all vapes. Sales only in Pharmacy via prescriptions
- 1 October 2024: Introduction of S3 non-prescription therapeutic vapes with $\leq 20\text{mg/mL}$ nicotine for patients 18+.
 - Types of Vapes: Includes vaping substances, accessories, and devices.
 - Cannabis Vapes: Subject to separate regulations (see TGA Hub).

Vaping Laws & Restrictions

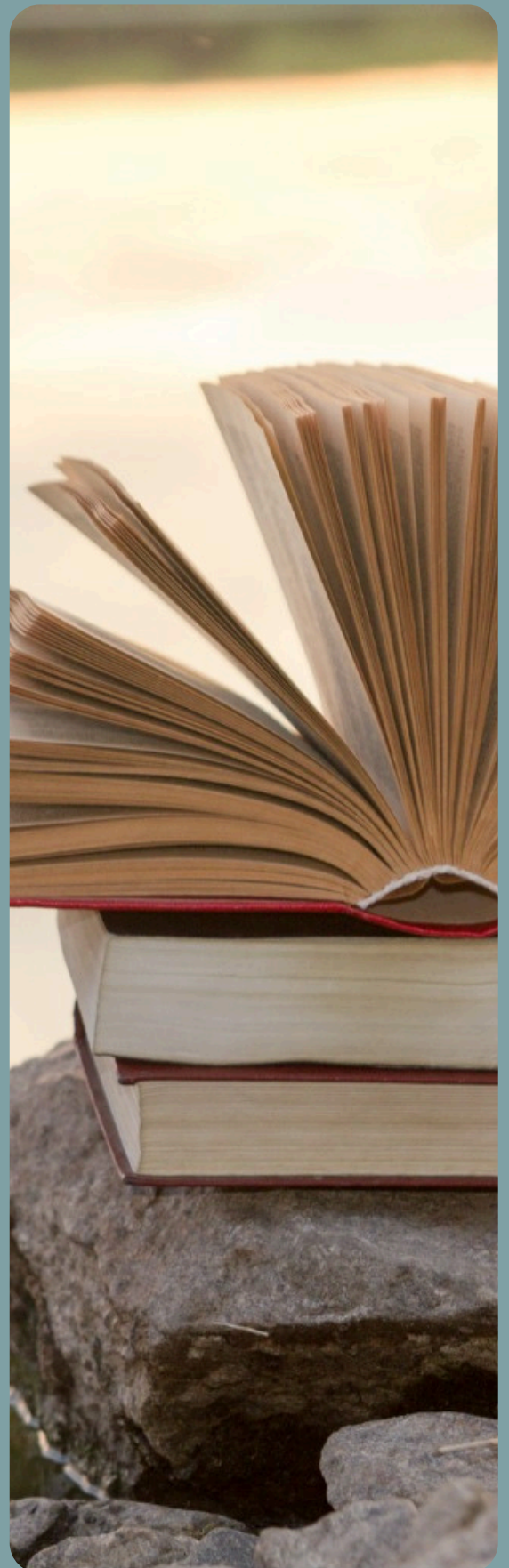
- Prohibits sale of vapes by non-pharmacy retailers.
- Until 30 September 2024: Prescription required for all vapes.
- From 1 October 2024: Therapeutic vapes with $\leq 20\text{mg/mL}$ nicotine available without prescription, under specific conditions.

Vaping Laws & Restrictions

- General Requirements include compliance with State tobacco/smoking product or e-cigarette control legislation.
- Retail license or notification may be needed.
- Restrictions on advertising, points of sale, and supply to persons under 18.

State Health Departments

- Please contact your local State Health Department for local requirements.



1. Legislation and Standards



Dispensing Vapes

- Prescription Vapes pathways for Unapproved Goods Prescribed by a Authorised Prescriber (AP) Scheme or Special Access Scheme B (SAS B) or Special Access Scheme C (SAS C). AP/SAS submission generates a reference number for validation.
- Only vapes listed by the TGA, on the TGA Hub, can be dispensed.

Non Prescription Vapes (from 1 October 2024)- Dispensing Conditions

- Patient must be 18+.
- Nicotine concentration $\leq 20\text{mg/mL}$.
- Limit supply to one month.
- Provide informed consent and professional advice on smoking cessation.
- Refer to SAS-C Guidelines for reporting requirements

Sourcing Vapes from Approved Sources

- Australian sponsors/wholesalers.
- Compliance Requirements, conformance to TGO 110 and device requirements.
- Importers must provide pre-market notifications and hold appropriate TGA & ODC licenses/permits.

Advertising & Promotion

- Prohibited Except in Specific Circumstances
- Labels and packaging standards.
- Directed exclusively to healthcare professionals and wholesalers.
- Direct advice by healthcare professionals.
- Please refer to State & Federal advertising regulations.

1. Legislation and Standards – cont.

Professional Guidelines & Resources

- PSA's Guidelines for pharmacists providing smoking cessation support.
- RACGP's guidelines for smoking cessation.
- TGA's Guidance on TGO 110
- Support Services
 - Quit Centre, Quitline (13 7848), quit.org.au.

Report Adverse Events & Safety

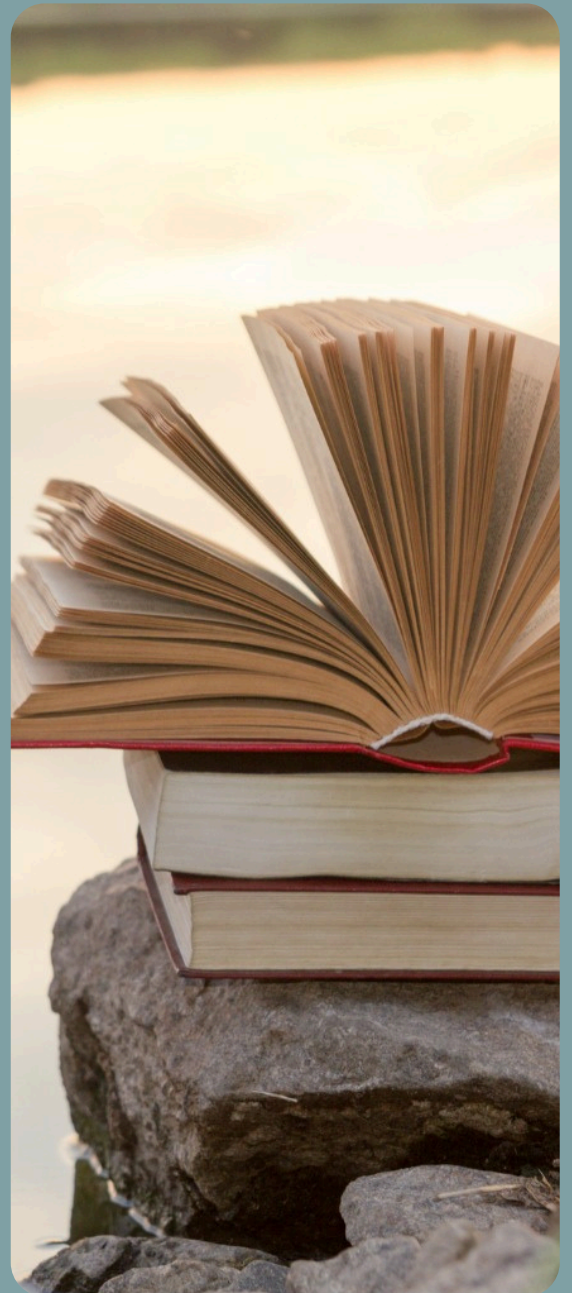
- Please follow current dispensing guidelines for reporting adverse events, as per State Health Department and TGA Guidelines.



1. Legislation and Standards

Regulatory Standards for Nicotine Vaping Products & Devices

- Labelling Requirements
 - Ingredient List: Must include the name of the active ingredient (nicotine), all excipient ingredients, and any flavours.
 - Nicotine Concentration: Must specify the nicotine base form concentration in mg/ml.
 - Warning Statements: Must include the following warnings:
 - KEEP OUT OF REACH OF CHILDREN
 - Avoid contact with eyes
 - Avoid contact with skin
- Packaging Requirements
 - Child-Resistant Packaging: All products must have child-resistant packaging to minimise the risk of accidental exposure.
 - Tamper-Evident Packaging: While not mandatory, it is recommended that products comply with the non-mandatory code for tamper-evident packaging to ensure product security.



1.1 Product Standards

Regulatory Standards for Nicotine Vaping Products & Devices

- Ingredient Requirements
 - Active Ingredients: Only nicotine (in base or salt form) is permitted as the active ingredient.
 - Nicotine Concentration: The nicotine concentration must be within 90-110% of the stated amount, with a maximum allowable concentration of 100 mg/mL.
 - Prohibited Ingredients: The following ingredients are prohibited due to their known health risks:
 - Acetoin
 - Benzaldehyde
 - Cinnamaldehyde
 - Diacetyl
 - Diethylene glycol
 - Ethylene glycol
 - Pentane-2,3-dione (2,3-pentanedione)
 - Vitamin E acetate



1.1 Product Standards – cont.

- Flavours: Only Mint, Menthol & Tobacco flavours are allowed.

	Test items conducted	Test results
Required under TGO 110	ACTIVE INGREDIENTS: Nicotine content, Taurine, Caffeine, THC, CBD	Not detected
	PROHIBITED INGREDIENTS: Formaldehyde, Acetaldehyde, Acrolein, Diacetyl, Pentane 2,3 dione, Acetoin, Vitamin E Acetate	Not detected
	CONTAMINANTS: Ethylene Glycol, Diethylene Glycol, Benzaldehyde, Cinnamaldehyde	Not detected
	MICROBIALS: Total Aerobic microbial Unit, Total combined Yeast/Mold count, Bile-tolerant gram-negative bacteria, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia Coli, Salmonella, Aspergillus Flavus, Aspergillus Fumigatus, Aspergillus Niger, Aspergillus Terreus, E. Coli	Not detected
	Test items conducted	Test results
Additional to TGO 110	PESTICIDES: 57 pesticides analyzed	Not detected
	RESIDUAL SOLVENTS: 2-Propanol, Acetone, Acetonitrile, Butane, Ethyl Ether, Heptane, Hexane, Isobutane, M/P-Xylene, Methanol, O-Xylene, Pentane, propane, Toluene, Total Xylenes	Not detected
	HEAVY METALS: Arsenic, Cadmium, Lead, Mercury	Not detected
	MYCOTOXINS: Aflatoxin B1 & B2, Aflatoxin G1 & G2, Ochratoxin A+	Not detected
	TOXICOLOGY STUDIES: Toxicity, carcinogenicity, and mutagenicity studies conducted on ingredients	Compliant
	EMISSIONS: Carbonyl Compounds, Metals, Diacetyl and Pentane 2,3 dione, Nitrosamines, VOC substances	Not detected
	NICOTINE DOSE CONSISTENCY: to CORESTA RECOMMENDATION METHOD n 81 method parameter and AFNOR standardization XP D90-300-3	Within standards

Testing to confirm compliance to TGO 110 and internal standards conducted at independent ISO17025 certified labs
 Source: Test report 072121UD0002, TCT210830C050-1, TCT210119C060

1.1 Product Standards – cont.

Record Keeping Obligations

- Sponsor Records: Sponsors must maintain records to demonstrate compliance with TGO 110. These records should include labels, packaging design, and evidence of ingredient conformity.
- Record Retention: Records must be retained for at least 12 months after the product's expiry date or 5 years after the last import or manufacture, whichever is later.

Contaminants & Product Quality

- Contaminants: Sponsors should take all reasonable steps to minimise levels of contaminants such as acetaldehyde, acrolein, and formaldehyde in their products. These contaminants should be present at levels less than 10 parts per million (ppm).

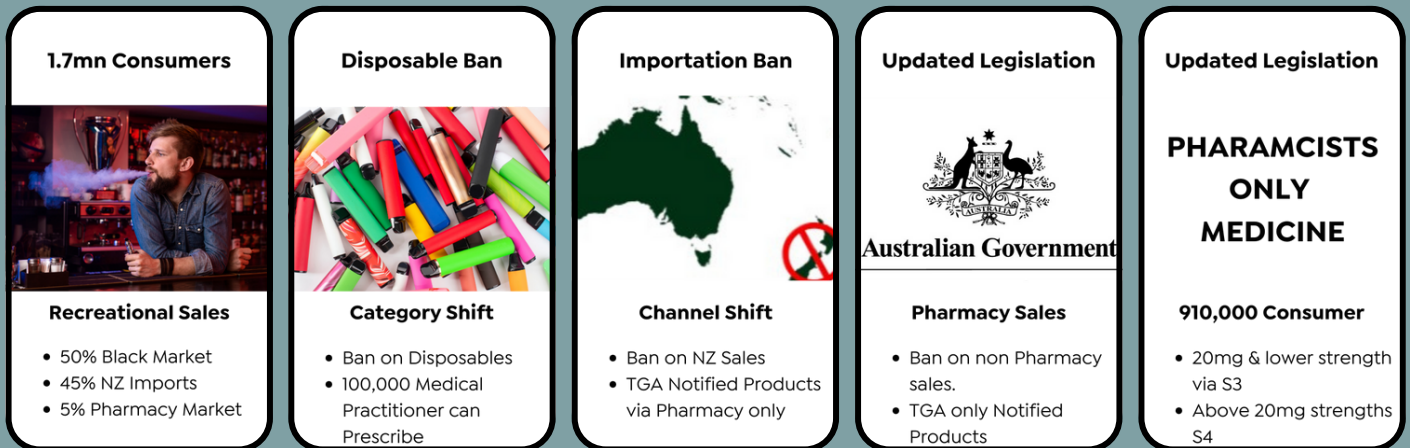
Vaping Devices & Accessories

- Compliance: All vaping devices and accessories must comply with the Essential Principles or the Therapeutic Goods (Medical Device Standard–Therapeutic Vaping Devices) Order 2023 (MDSO).

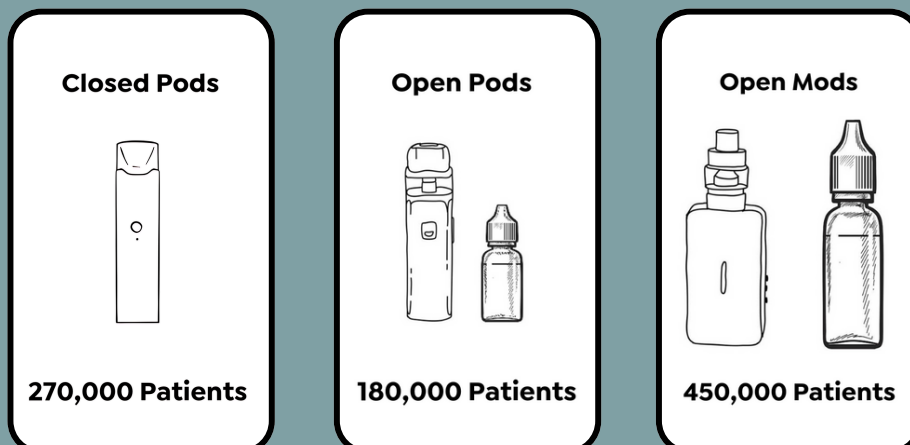


2. Market Size & Opportunity

Vaping Reforms in 2024 Stages



An Estimated 900,000 adult vapers expected to transition to Pharmacies.



3. Guidelines & Training



Introduction

- Purpose: To provide essential information and guidelines for pharmacists on supporting smoking cessation and handling nicotine vaping products.
- Scope: Covers the roles, responsibilities, and best practices for pharmacists in all practice settings.

Smoking Cessation Australia

- Health Impact: Smoking is a leading cause of preventable death and disability. Health benefits of cessation include improved lung function, reduced risk of cardiovascular diseases, and improved fertility.
- 2.7 million Australians smoke and 1.7 million adults vape.

Pharmacists Role in Smoking Cessation

- Behavioural Support: Provide brief advice and ongoing support. Use the Ask, Advise, Help approach.
- Pharmacotherapy: First-line options include Nicotine Replacement Therapy (NRT), bupropion, and varenicline. Combining pharmacotherapy with behavioural support increases success rates.
- Special Populations: Tailor support for Aboriginal and Torres Strait Islander people, those with mental illness, disabilities, and from culturally diverse backgrounds.

3. Guidelines & Training - cont

Pharmacotherapy Options

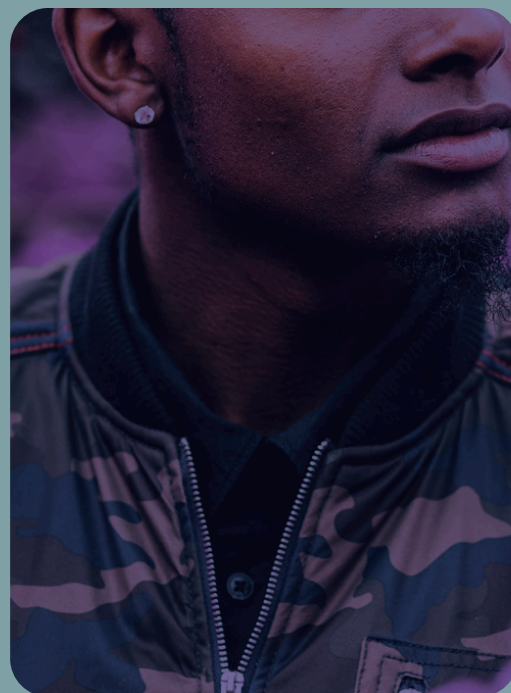
- NRT: Includes gum, patches, lozenges, and sprays.
- Bupropion and Varenicline: Effective for long-term cessation but have specific usage guidelines and potential side effects.
- Other Options: Nortriptyline, clonidine, and cytisine as second-line treatments.

Nicotine Vape Products

- More effective than NRT based on Cochrane review.
- Must comply with Therapeutic Goods Order (TGO) 110.
- Safety Considerations: Long-term health effects are unknown. Risks include poisoning, acute nicotine toxicity, and dual use with smoking.
- Counseling: Provide tailored information on safe use, potential side effects, and storage. Emphasise the importance of behavioural support.

Dispensing

- Compliance: Adhere to professional standards and guidelines when dispensing nicotine vaping products.
- Accessing Unapproved Products: Pharmacies can hold stock of unapproved products in anticipation of prescriptions.
- Labelling and Documentation: Ensure products meet labelling requirements and document all relevant information.



3. Guidelines & Training - cont

Special Considerations for Nicotine Vaping Products

- Flavourings and Contaminants: Avoid flavours appealing to adolescents. Confirm products are free from harmful contaminants.
- Device Recommendations: Closed systems with non-refillable pods are preferred to minimise risks. Use only specified devices with open tank liquids.
- For Liquid Bottles used in Open Devices, the preference is to match the pre-calibrated manufactures Device.
- Dilution and Use: At-home dilution is discouraged due to safety risks.

Additional Resource & Support

- Follow-Up: Regular follow-up with patients to provide support and address any issues.
- Reporting Adverse Events: Report any adverse events or product deficiencies, as per normal State & Federal regulations.



3. Guidelines & Training - cont

Criteria for Doctors to Prescribe Schedule 4 Range

- Evidence-based Practice:
 - Prescriptions should be based on evidence supporting the use of vaping products for smoking cessation or nicotine dependence.
- Patient Assessment:
 - Comprehensive assessment of the patient's health status and history of nicotine use.
- Informed Consent:
 - Ensure patients are informed about the benefits, risks, and alternative cessation therapies.
- Documentation:
 - Maintain accurate records of prescriptions and patient interactions.



3. Guidelines & Training - cont

Criteria for Pharmacies to Dispense the Schedule 3 Range

- Age Verification:
 - Confirm patient is 18 years or older and verify identity.
- Supply Limitations:
 - Supply no more than a one-month quantity per patient, with a maximum nicotine concentration of 20 mg/ml.
- Professional Advice:
 - Provide advice on alternative cessation supports, dosage, and potential interactions with other medications.
- Adverse Event Reporting:
 - Report any adverse events or product defects to the Therapeutic Goods Administration (TGA) and the product sponsor.
- Storage and Handling:
 - Store therapeutic vaping products in areas not accessible to the public.

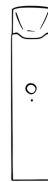


4. Category and Ranging

OUR POD RANGE

Precise dose 1ml closed pods

Closed Pods



270,000 Patients



Our Closed Pod Range

Australian standard, precise dose, 1ml closed pods, have their liquids manufactured in ISO 9001 facilities, that meet cGMP standards & filled in ISO 13485 facilities.

All liquids contain pharmacopeia grade PG, VG & Nicotine.

They are purposefully designed to manage smoking cessation from first quitting, to exiting the category entirely.

All products are independently 3rd party tested in ISO 17025 laboratories, to ensure they meet Australian standards.



4. Category and Ranging

OUR LIQUID RANGE

30ml Nicotine Salt Liquids

Open Pods



180,000 Patients



Our 30ml Liquid Range



Australian standard, therapeutic open pod liquids are manufactured under cGMP conditions.

All liquids contain pharmacopeia grade PG, VG & Nicotine.

They are purposefully designed for the use of experienced adult vapers, who are using their own purchased hardware to manage their cessation journey.

All products are independently 3rd party tested in ISO 17025 laboratories, to ensure they meet Australian standards.

These Open Pod liquids are calibrated to be used with the Wild by Instinct Pro Pod.

4. Category and Ranging

OUR LIQUID RANGE

60ml Freebase Liquids

Open Mods



450,000 Patients



Our 60ml Liquid Range

Australian standard, therapeutic open mod liquids are manufactured under cGMP conditions.

All liquids contain pharmacopeia grade PG, VG & Nicotine.

They are purposefully designed for the use of experienced adult vapers, to manage their cessation journey.

All products are independently 3rd party tested in ISO 17025 laboratories, to ensure they meet Australian standards.

These Open Tank liquids are calibrated to be used with the Wild by Instinct W75 Tank Device.

4. Category and Ranging

OUR TANK RANGE

3,000mAh, 5ml Open Tank

Open Pods



180,000 Patients



Our Open Pod Device

Australian standard, Pro Pod device, is designed to go with the Wild by Instinct 30ml range.

This 2ml Open Tank, with a 0.8 Ω Mesh Coil, is designed for experienced vapers, who want to use a nicotine salt liquid, but fill their own pod.

The Pod is a button or draw activated platform, with built in display, showing a count of puffs taken, battery status & the wattage setting.

Replacement Pods are available, as they will last inside the device for approximately 5 days.

4. Category and Ranging

OUR TANK RANGE

3,000mAh, 5ml Open Tank

Open Mods



450,000 Patients



Our Open Tank Device

Australian standard, W75 Open Tank device, is designed to go with the Wild by Instinct 60ml range.

This 5ml Open Tank, with a 0.6 Ω Mesh Coil, is designed for experienced vapers, who have move to a slow release freebase nicotine range.

It's simplicity is focused on auto setting the device once the coil is installed, for ease of use.

Replacement coils are available, as they will last inside the tank for approximately 5 days. Replacement tanks are also available, if required.

A PERSONAL NOTE



Wayne Jones

Chief Operations Officer

Our range of Australian designed, therapeutic nicotine cessation products, have been created to support a smokers pathway to smoking & nicotine freedom.

Our products are designed for adult smokers seeking to quit smoking, as well as reduce or exit the usage of nicotine

Our focus is to help drive adult smoking rates below 5% in Australia by 2030.

We understand the vital role Pharmacists and Medical Practitioners play in supporting smoking cessation, to ensure therapeutic nicotine vaping products, are available to meet adult patient demand.

We to will ensure our Wild by Instinct range is manufactured to the highest quality and compliance, to support your patients needs.

Please feel free to contact me at wayne.jones@teamftf.com, or via 1300 926 540.

Thank you

Wayne

