About from the fields Pharmaceutical https://ftfpharmaceutical.com/

from the fields Pharmaceutical Australia Pty Ltd (FTFP) is a leading, independent manufacturer and supplier of Australian standard therapeutic nicotine vaping products (NVPs) via the current TGO 110 regulatory framework. This includes their *Wild by Instinct* nicotine vaping brand since 1 October 2021.

As the lead manufacturer of Australian standard therapeutic NVPs, FTFP products are only sold with a prescription from an Authorised Prescriber (AP), dispensed via pharmacies.

Our vision is to support a pragmatic solution for Australian adult smoker cessation with NVPs under a therapeutic goods framework.

Our mission is to drive future adult smoking rates in Australia below 5% utilising pharmaceutical grade NVPs.

FTFP is headquartered in Adelaide. Its Founder and CEO is Mr. Wilhelm David.

from the fields Pharmaceutical - Range of therapeutic products

The range consists of a 50mg, 18mg, and 0mg in precise dose closed pods of 1ml, which is equivalent to a daily smoker's consumption, 4-day prefilled disposable for primarily elderly and non-technical patients and nicotine liquid in 30ml & 60ml bottles, for patients with their own vaping device.

Our liquids are primarily manufactured in the USA in very high-quality facilities that meet cGMP standards. Our closed pods and disposables are filled in ISO 13485 facilities and all products are independently laboratory tested in ISO 17025 facilities.

We have conducted internal emissions studies according to *Article 20 of Tobacco Product Directive (2014/40/EU)* where emissions were non detected on many carbonyls compounds or at a very low / significantly below the EU requirements. (Test results could be made available under confidentiality).

Our products are manufactured in facilities that hold ISO 13485, ISO 9001, ISO 14001, ISO 45001, SA 8000, HACCP and cGMP certification.

from the fields Pharmaceutical - Liquid standards positioning

Our flavours are defined at a molecular level effectively allowing us to design and formulate all ingredients to our specifications.

To eliminate impurities and inconsistencies, we only use US / EU Pharmacopoeia grade Propylene Glycol, Vegetable Glycerin and Nicotine. To reduce exposure to Carbonyl Compounds, Volatile Organic

Compounds (Toluene, Benzene, 1,3-Butadiene, Isoprene) and chemicals linked to cancer we ensure no HPHC's (Harmful & Potential Harmful Constituents), Prohibited Ingredients (Diacetyl, Pentane 2,3 dione, Acetoin, Vitamin E acetate, Benzaldehyde, Cinnamaldehyde, Ethylene Glycol, Diethylene Glycol) or Contaminant ingredients (Formaldehyde, Acetaldehyde, Acrolein) are used in our formulations.

To ensure compliance with our internal standards, we batch test our liquids for Prohibited & Contaminant ingredients, Nicotine concentration and Microbials.

Testing is also conducted at an Emissions (vapor) level for Carbonyl Compounds, Heavy Metals, Nicotine Consistency, Diacetyl & Pentane 2,3 dione, Ethylene Glycol and Diethylene Glycol, Specific Nitrosamines and VOC substances.

Ensuring that our e-liquids do not pose any risks, toxicology studies are conducted on chemical constituents. All testing is conducted by 3rd party, independent, ISO 17025 certified laboratories.

We achieve the lowest emissions via our proprietary firmware technology to control temperature with a larger medical grade stainless steel coil allowing us to heat the liquid at a lower temperature.

Liquids are manufactured in ISO 9001 and cGMP certified facilities and filled in cGMP, ISO 9001 & ISO 13485 certified facilities.

from the fields Pharmaceutical – Supporting pragmatic solutions to improve our national public health

As an independent, Australian company we remain at a major disadvantage in the current market due to the predominance and continued existence of a large local vaping black market.

As a legitimate enterprise, where principles matter, and following TGO 110 Australian standards by providing genuine products, FTFP is currently only able to reach <8% of the Australian adult vaping market who have a valid prescription.

In contrast, Australia's vaping black market, which has an estimated monthly average of over 1.7 million consumers, sells ~ 100 million units of illicit, unregulated vaping product per year in an AUD $1b retail value market.

We, however, acknowledge the current, significant efforts by the Australian, State and Territory Governments, through new stronger regulations and future legislation, to more effectively tackle a rampant black market of illicit, non-standard, non-approved product, sold through illegal sales channels.

The previous lack of effective enforcement and regulation, particularly in regard to non-NVPs, has led to a public health crisis and threatens the sustainability of patient treatment with legitimate adult therapeutic smoking cessation products. The ambiguity of recreational vapes versus therapeutic vapes and the nicotine and non-nicotine status adds to this problem.

FTFP welcomes the overall policy direction and supports our national public health policy where therapeutic vaping has a genuine and growing role in driving adult smoking rates down to 5% by 2030.

We support a pragmatic solution for adult smoker cessation with NVPs under a therapeutics goods framework.

We want all Australian Governments to make the sale of NVPs illegal unless medically prescribed and sold by a pharmacist to adults wanting to break their cigarette addiction.

The key to a workable solution is preventing the black market, which in turn curtails youth access, while advocating regulation that considers the potential benefits of approved NVPs for adult smokers, which can be substantial, immediate, and potentially lifesaving.

from the fields Pharmaceutical – Supporting the right, future balance for NVPs in Australia

It is important for Australian Governments and regulators to strike the right balance to these concerns whilst advancing our globally recognised and innovative approach to addressing smoking cessation.

FTFP continues to provide insight into **five** important areas around future reform of vaping in Australia:

1. **Nicotine Vaping Products - NVPs - can be an effective tool for quitting smoking**
2. **Within a medical model, Flavours, Menthol, disposables and adequate nicotine strength play a key role in successful smoking cessation among adults**
3. **FTF Pharmaceutical can address the supply side constraints in the Australian market if proper enforcement (around the black market) comes into place**
4. **There is a serious, rampant black market for vaping across Australia and this must be addressed**
5. **Moving Australian adult smoking rates towards and below 5% by year 2030.**

Area 1: NVPs can be an effective tool for quitting smoking

There is a strong body of evidence suggesting that e-cigarettes or NVPs can be an effective tool for quitting smoking and can serve as a substitute for traditional cigarettes. By correctly regulating and prescribing e-cigarettes through a healthcare professional, we can achieve better, faster, and more clearly demonstrated public health outcomes.

There have been several types of studies, including randomized controlled trials, observational studies, and population data, that have found that e-cigarette use is associated with a reduction in smoking and a corresponding positive impact on public health.

The latest Cochrane Review of vaping found "high certainty" evidence that vaping is significantly more effective than nicotine replacement therapy. The Cochrane studies are the gold standard for testing if a treatment worked. It found that "For every 100 people using nicotine e-cigarettes to stop smoking, 9 to 14 might successfully stop, compared with only 6 of 100 people using nicotine-replacement therapy."

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub8/epdf/full

The Royal College of Physicians (London) in its 2016 report, highlighted E-cigarettes appear to be effective when used by smokers as an aid to quit smoking. A systematic review and meta-analysis published in the journal *Addiction* in 2020 found that e-cigarette use was associated with a significantly higher likelihood of smoking cessation compared to no aid or other quitting methods.

An observational study published in the journal *PLOS ONE* in 2018 found that e-cigarette use was associated with a higher likelihood of smoking cessation and a reduction in cigarette consumption among smokers who were not planning to quit.

A population study published in the journal *Tobacco Control* in 2017 found that e-cigarette use was associated with a reduction in smoking prevalence among adults in the United Kingdom.

Here in Australia, there is significant research for the RACGP and the Pharmacy Guild of Australia to have confidence in supporting NVP's as a smoking cessation tool. We continue our endeavour to get the medical fraternity across Australia on board.

Refer – RACGP draft guidelines : Draft Guidelines Link

'The RACGP commissioned Health Research Consulting (HERECO) to review the certainty ratings of the GRADE evidence ratings, based on the new studies in the Cochrane 2022 review. HERECO facilitated a workshop with the RACGP EAG to discuss the evidence to decision process, and in particular, study biases that may be relevant to consider in a clinical context. Following this workshop, all EAG members cast a vote (anonymously) on the certainty of evidence rating. The consensus was to change the certainty of the evidence of the RACGP e-cigarette GRADE evidence rating in recommendation 15 from 'low' to 'moderate'. The key reason for the difference from the Cochrane review was a different assessment of the risk of bias.'

Area 2: Flavours, Menthol, disposables and adequate nicotine strength all play a key role in successful smoking cessation among adults – four areas to constructively review the Government's NVP reforms.

- **Review of Flavours ban**
- **Menthol Ceiling at between 5%-10%**
- **Review disposable NVP ban**
- **50mg closed pod nicotine ceiling.**

Multiple sources have identified up to 1.7 million Australian adults vaping.

Within a controlled medical prescription and pharmacy distribution model, flavour variety, Menthol concentration, use of disposable NVPs and adequate nicotine strength play a key role in successful smoking cessation among adults.

Over restriction of these will seriously impact levels of adults seeking to quit smoking. We propose the following amendments to the current proposal by TGA.

ITEM A: Review of Flavours ban

Our FTF Pharmaceutical portfolio has been specifically designed against two clear therapeutic cessation objectives:

I. to transition adult smokers off cigarettes and keep these patients from relapsing to smoking
II. to provide the highest possible standard products.

The restrictions on flavours imposed by the TGA and adopted by the Government negatively impact both of the above objectives.

Currently over 80% of NVP products sold to adults in the Australian market are of a non-tobacco flavour.

For the Australian Government's and TGA's background, currently 43% of our FTF Pharmaceutical products prescribed by doctors are simple flavours.

Flavours continue to play a critical role in both transitioning adult smokers off cigarettes and preventing these patients from relapsing.

This is evidenced in many studies available. Includes example:

(*How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys - PMC (nih.gov))*

We also acknowledge, outside of the existing prescription model, but within the black market, that a range of flavours can be attractive to a younger cohort.

However, we question the relevance of this under the Prescription model for NVPs.

For patients fighting a smoking addiction, like any other addiction, a cessation tool that reminds a patient of the flavour of the product they are trying to escape, seems counterintuitive.

Flavours, outside of tobacco, play a role in aiding the cessation journey, while the physiological and behavioral benefits of the product help support the patient away from cigarettes.

With that said, we do support the banning of flavours that potentially could be attractive to youth such as sweet, overly confectionary and unusual descriptors.

We continue to recommend Australian regulations to be amended to include simple fruit flavours such as Mango, Blueberry, Apple in addition to Mint and Tobacco.

Our FTF Pharmaceutical liquids have been formulated for the adult palette with subtle flavours, not overly sweet, fruity, or attractive to the younger cohort. We believe that this balanced approach is best.

Our FTF Pharmaceutical portfolio has been designed and flavours formulated for the adult palette to facilitate smoking cessation. Simple fruit (not fruity or candy) flavours are critical for transitioning patients off cigarettes.

Patients also want to distance themselves from tobacco and do not want to be reminded of tobacco flavour for fear of relapse. Limiting flavours essentially limits the ability and success of transitioning smokers off cigarettes.

Under the smoking cessation prescription model, where products are restricted to smokers for cessation purposes only, the attractiveness to flavours to non-smokers and youth effectively becomes a redundant topic, as these cohorts would not have access to vapes.

Restriction on flavours also has the unintended result of restricting safer products. All flavours, including Tobacco flavour, are formulated with multiple individual ingredients and therefore not necessarily as safe as other flavours.

This is evidenced in internal emissions testing conducted according to Article 20 of Tobacco Product Directive (2014/40/EU) where emissions on Mango flavour are below those of Tobacco flavour.

We propose limiting to simple flavours, adopting a list of banned ingredients *(New Zealand's Smokefree Environment and Related Products Regulation 2021)*, quality standards for ingredients (pharmacopoeia grade), prohibiting various additives such as colouring agents, cooling agents, sweeteners, vitamins, minerals, and stimulants, and minimum emissions standards such as stated within the EU TPD.

ITEM B: Menthol ceiling at between 5%-10%

Currently the TGA proposal for menthol at 0.1% is extremely low, especially for a current menthol smoker to transition to a vape.

It remains our recommendation to increase the 'Menthol products' ceiling to between 5% - 10%.

We note the TGA's intent to deter menthol of the cooling / masking effect. However, in some instances, the black-market products have greater than 10% flavouring, which is currently being consumed by a significantly large cohort of adult vapers. This should be a reference point for effective adult smoker cessation.

Furthermore, higher levels of menthol have been included in cigarettes by major tobacco companies.

Available public data indicates Menthol was included at a rate of 18,000 ppm in a study and no adverse effects were noted. *(Carmines, 2002; Roemer et al., 2002; Rustemeier et al., 2002; Vanscheeuwijck et al 2002)*

The proposed ceiling is significantly lower than what's currently in combustible cigarettes.

Reference to use and the safety profile of Menthol, we reference the following:

- Menthol is on the FDA *'Everything added to food in the US' (EAFUS) list, and the FDA list of 'Synthetic flavouring substance and adjuvants' (21 CFR 172.515)* It is also on the FDA list of *'Essential oils, oleoresins (solvent free), natural extractives (including distillates) (21 CFR 182.20)*
- Menthol has been listed since 1965 as generally recognized as safe (GRAS) as a food ingredient by the flavour and extract manufacturers association (FEMA), (hall and Oser 1965)
- In 1994, the FEMA found menthol concentrations of up to 2274ppm in 'chewing gum'. The FEMA also considered that the possible average daily intake was 13.4mg

ITEM C: Review Disposable NVP ban

We believe there is an ongoing need within the community for simple, easy-to-use disposable therapeutic vape devices that don't involve complicated instructions, recharging or refilling of liquids.

Australia should retain disposable NVPs.

Our position with respect to single-use disposable vaping products comes from our determination to protect some of Australia's most at-risk people. These include older people and those with physical and intellectual disabilities who may otherwise struggle with a more complex vaping device that requires recharging.

Further, populations such as prisoners and the homeless require disposable vapes without the barrier of recharging.

Many of these people are also located in remote or rural communities and peri-urban centres, making access an even greater issue.

We know that disposable vapes are often associated with low-quality, black-market products.

But in reality, our FTFP *Wild by Instinct* single-use therapeutic vape products meet Australian Standards, contain quality ingredients, are recyclable and designed to assist smokers who may for a variety of health and social reasons find these products easier to use.

Within the *Wild by Instinct* portfolio, prior to December 31st 2023, 19% of prescriptions written by doctors where for disposable products.

We fully understand the Government and TGA's position in an open market environment, where youth are at risk with these products.

But to have assumed that medical practitioners and pharmacists, in a prescription and pharmacy only model, will exploit Australia's youth with this range, remains questionable, if in pursuit of improved public health policy outcomes around smoking cessation.

Product track and trace is clear, through the notification and Office of Drug Control license and permit process, helping Australian Border Force identify legal from illegal disposable products.

We urge the TGA and Federal Government to take this into account with their reforms and re-consider disposables. Some disposable users will relapse back to smoking if their preferred product is not available. This is counter to the public health policy outcome being pursued.

The FTF Pharmaceutical product suite of disposable vapes are designed for smokers including those with severe mental illness, learning disabilities, hospital inpatients and older smokers who would struggle with more complex devices.

The device design is similar if not larger than POD devices to enable better grip. The device is significantly different to the black-market products and cannot be concealed and is plain white in design.

Our FTFP disposable design has taken into consideration the requirements of the elderly and disabled and is significantly larger for grip and a similar size to our POD system.

Over 90% of vape litter is from black-market disposable products over which there is currently no control.

FTFP devices meet EU guidelines for recyclability. Our products have also been tested at a reuse rate of 98.64% vs the EU requirement of 75% under European Union's Waste Electrical and Electronic Equipment (WEEE) Directive.

At minimum, we would request and argue a pathway for approval on a case-by-case basis via the product registration mechanic that has been proposed by the TGA.

FTFP currently sells disposable products only via pharmacies and this will cease post the stock running out due to the blanket ban. Our experience shows our consumers, many of whom are over 45 years, have been prescribed disposable vape products by doctors.

Currently we have 15% of consumers who are aged over 45 who have been prescribed disposables by doctors. They will struggle with alternative smoking cessation formats.

ITEM D: 50mg closed pod nicotine ceiling

As stated in the National Institute on Drug Abuse Report, published in the US in May 2022, a cigarette smoker ingests between 1 and 2 milligrams of nicotine per cigarette smoked.

With a smoker smoking between 12 and 25 cigarettes a day, the assumed nicotine daily absorption is between 12 & 50 milligrams a day.

This is important to note, as to replace the cause of the addiction, nicotine, and aid in cessation, the tool needs to match the product it is replacing.

Cigarettes have the fastest absorption rate of nicotine delivery. Due to the small molecule size of combustible form of delivery of nicotine, there is no vape that is able to replicate this size.

Put simply, there are two forms of nicotine used in nicotine vaping products, a free base nicotine and nicotine salts. As researchers suggest, as shown in the paper published by the Department of Pharmaceutics, School of Pharmacy in Virginia Commonwealth University, (USA) in December 2020, ‘nicotine salt products, based on the deposition theory, is the higher and faster absorption of nicotine from its salt form (protonated) could be that protonated nicotine in aerosol has a higher chance of reaching the lungs since protonated nicotine is less volatile as compared to free base nicotine’.

Due to the nicotine salts performance of replicating the speed of absorption of a cigarette, Authorised Prescribing doctors today in Australia are prescribing this nicotine form for smokers, first looking to quit. Australian doctors are prescribing 50mg precise dose 1ml products, to replace the daily nicotine intake of a smoker.

Area 3: FTF Pharmaceutical can address the supply side constraints in the Australian market if proper enforcement (around the black market) comes into place

Supply Chain

FTF Pharmaceutical can address the supply side constraints should there be a major contraction or immediate regulatory change to product availability and can effectively implement the TGO110 standards if proper enforcement and support is in place.

From a supply chain point of view, the Australian market requirements could be met within 12 weeks at earliest post reforms under enforced, major regulatory change to product accessibility.

Legitimate products manufactured in cGMP, ISO 13485 and fully compliant to TGO 110 could be procured. This includes a 4-week shipping lead time from a supply chain point. To facilitate simpler and cost-effective supply chain transition we would recommend the following:

a. Packaging to be in line with S4 – prescription medicine. Additional requirements from tobacco centric policy are unnecessary for therapeutic products and would complicate. A simplified and streamlined process with clear guidance is required.

b. Currently we are 100% complaint to the current TGO110 standards and only supply to pharmacies.

c. With the exception of some simple flavours, there is sufficient product and range within the Australian market for a successful transition to the prescription model. This is an important point in support of the Federal Government and TGA's approach towards successful transition and addressing the large black market. The ability for the market to respond should be confidently outlined by the regulator.

d. However, if the current adult vapers are not able to understand the process of securing legitimate therapeutic vapes and are unable to access a reasonable range of vapes in flavours and formats, the risk of the black-market continuing is significantly high. There needs to be an approach to advertisement of how adults can access medical nicotine vapes.

Area 4: There is a serious, rampant black market for vaping across Australia and this must be addressed

There is a serious, rampant black market for vaping (an estimated market ~1.7m Australians) and it is particularly impacting on the health of Australia's youth. The key driver of the black market has been the legislative ambiguity of Non Nicotine vape and nicotine vape definition and legal enforcement.

With no previous enforcement of legislation on the importation of NVP's by general trade, there has been the creation of a thriving black market with easy access for youth to vaping products.

The illegal, unregulated trade has rapidly created a major public health issue in Australia. This now needs to be effectively addressed.

We support the complete ban on the manufacturing or importation of recreational nicotine and non-nicotine vaping products, with only TGA notified and ODC licensed and permitted products being allowed to be manufactured or imported, for access to prescription only adults, via a pharmacy. This will ensure that access to this product by Australian youths will be significantly reduced.

With over 5500 pharmacies across Australia, access to adult smokers and vapers should not be an issue.

The end goal should be moving the product from a S4 classification to Schedule 2 Pharmacy Medicine, allowing easier access to adult smokers, while maintaining restrictions on youth and non-smoker access.

Area 5: Moving Australian adult smoking rates towards and below 5% by year 2030

Australia could achieve less than 5% adult smokers by year 2030 if nicotine vaping is used actively as a smoker cessation tool.

If our nation wants this future 5% goal, the biggest risk to this may come from consumer focused, recreational brands entering the therapeutic space seeking an alternative nicotine industry.

Therapeutic vaping products are focused solely on smoking cessation and nicotine consumption reduction. There is a big difference to the approach.

Public health benefit of use of prescribed NVPs to smokers estimates improvement of a smoker age after 35 years as 3 months per year. If such a public health benefit could be realised, this will add back 12-13 years to a smoker's life.

(Example). By vaping we assume the health improvement of a smoker age after 35 years is 3 months per year and based on the average life expectancy in Australia of 84 years. This gives back 12-13 years of life.

As another measure, if we assume this includes 32 years of working life and 17 years of retirement that is 65% or 8 years lift by individual productivity.

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Published at April 2024