Potential reforms to the regulation of nicotine vaping products Submission by from the fields pharmaceuticals Australia Pty Ltd (ACN 662 953 826)

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Introductory statement

From the fields pharmaceuticals Australia Pty Ltd (FTF) is an independent company manufacturing and supplying Australian standards nicotine vaping products via the current TGO 110 regulatory framework in Australia with its Wild By Instinct Nicotine vaping brand.

As an independent company, our products are only sold with a prescription from an authorised prescriber (AP), dispensed via Pharmacies. Our 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 & 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.

Our business has been at a disadvantage due to the growth of the black market. As a legitimate business, that follows Australian standards that provides genuine products, FTF Pharmaceuticals is currently only able to reach 2% of the adult vaping population who have a valid prescription. In contrast, the black market, which has an estimated monthly average of over 1 million consumers, is able to sell 30 million units (equivalent of 1ml PODs) per month.

The lack of effective enforcement and regulation, particularly in regard to non-nicotine products, has led to a public health crisis and threatens the sustainability of patient treatment with legitimate adult smoking cessation products. The ambiguity of TGO 110 regulations only adds to this problem.

We support a pragmatic solution for adult smoker cessation with NVPs under therapeutics goods framework. We want the Government to make the sale of NVPs illegal unless sold by a pharmacist to adults wanting to break their cigarette addiction. We believe we are part of the solution, not the problem. 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.

It is important for regulators to find the right balance between these concerns. We have based our submission on 5 key overarching points;

1. **There is a strong body of evidence suggesting that e-cigarettes (NVP) can be a 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 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. (Nicotine without Smoke: tobacco harm reduction, link) 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.

2. **Key Issue – It is still early days in Australia for the prescription model. However, it can properly work for better health outcomes for Australians who smoke. The model is presently severely hamstrung by the failure of medical authorities and organisations (such as RCAGP, Pharmacy Guild) to not agreeing to adopt NVPs nor communicating to their members, that NVPs are a smoking cessation 'tool'.**

The awareness and process of doctors becoming authorised prescribers have been poorly understood and no clear communication provided by the above-mentioned professional associations.

There seems to be a reluctance politically to support NVP's as a harm reduction pathway for addicted smokers. Formal and informal Communication restrictions placed on professional media (B2B) by professional bodies such as the Pharmacy Guild of Australia has meant effective communication reaching both doctors and pharmacies has been problematic.

There is significant amounts of research for the RACGP and the Pharmacy Guild to have confidence in supporting NVP's as a smoking cessation tool instead of forming bias views based around general media publications. We continue to seek to get more of the medical fraternity across Australia to get on board.

3. **Key Issue – There is a serious, rampant black market for vaping (an estimated market ~1.5m Australians) and it is particularly impacting on Australian youth.**

With no 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 product. The illegal, unregulated trade has rapidly created a major public health issue in Australia. This now needs to be immediately addressed.

The prevalence of youth vaping is a legitimate concern. Young people should not vape or smoke. Currently the black market and illicit products sold in general trade are responsible in providing access to products to young Australians including minors.

If there were a complete ban on importing nicotine and non-nicotine vaping products, with

the exception of the S4 importation model, the access of this product to Australian youth will be significantly reduced.

Multiple sources identified there are estimated to be 1.1m to 1.5m adults vaping. Further to this, from a youth perspective, the Australian Alcohol and Drug Foundation (ADF) latest published research has shown around 14% of 12 to 17-year-olds have tried an e-cigarette, with around 32% of these students having used one in the past month.[8] According to a study conducted by the Queensland University of Technology (QUT), the prevalence of e-cigarette use among Australian youth has increased from 1.3% in 2013 to 8.8% in 2018.

Further, the vast majority of Australians are accessing vape product via illegal trade channels. The ability for an adult vaper to simply walk into a general trade store and unknowingly purchase an illicit vape means there is no real motivation for consumers to gain a prescription and purchase Australian standard products from pharmacies.

4. **Key Issue – Firms like FTF Pharmaceuticals Australia 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 withing 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.

As an independent company we have invested in assessing the potential demand based on the current (TGO 110) model. We have conducted an 8- week trial, which commenced in November 2022 in two LGA's in Sydney. We have approached 150 doctors and informed the process of becoming an authorised prescriber (AP). Currently 75 have successfully been approved to be AP's. Furthermore nearly 500 pharmacies in the surrounding areas have shown interest to dispense prescriptions.

5. **Towards and Below 5% - Australia could achieve less than 5% adult smokers by 2030 if nicotine vaping is used actively as a smoker cessation tool.**

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 the public health benefit could be realised, this will add back 12-13 years for a smoker's life.

(The 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 a 65% or 8 years lift by individual productivity.

Options for border control

12. Which border control option for regulating NVPs is preferred by you? Why?

FTF Pharmaceutical would support options 2 & 3 with some modification included from option 4.

- Support the Remove Personal Importation Scheme exemption for NVPs. Australian physical pharmacy or Australian online pharmacy are fully capable of transitioning quickly to ensure continuity of supply with current legal TGO 110 Australian standard products. Currently there are 5500 physical pharmacies and many online pharmacies to provide adult access to support our local market. If no significant changes to the current TGO 110 Australian standards on product ingredients and labeling supply chain could meet the immediate requirements to replace current illicit products in market.
- We support tighter controls on the importation of NVP's. However, we would also propose to extend the same requirements to non-nicotine products as well. Permit the importation to only a licensed S4 warehouse and permit the wholesale distribution only by S4 dealer licensed wholesalers. This would be a simpler approach and enable for a less complex enforcement at the border. Today's black market is fueled by mislabeled products entering Australia.
- Treat Nicotine and Non-Nicotine NVP's as same category for importation and border control purpose. The role of non-nicotine is to generally address behavior requirements under a smoking cessation and nicotine cessation program. Generally, this is a final stage of treatment. The size of market for non-nicotine is relatively small (estimated <2%) in countries such as UK. Not regulating non nicotine will still allow the black market to thrive and make it very hard for border force to enforce.

2. Would any of these options have an impact on you? How?

- Options 2,3,4 with modifications would support our goal of providing adult smokers with an Australian standard nicotine vaping products via a prescription model. By eliminating the illicit importation our Australian independent company would become sustainable.

3. In relation to options 2, 3 and 4, how much time would you require, if any, to become familiar with the reforms, and to organize procurement of compliant products as necessary, before the reforms come into effect

- Currently our product range is compliant to TGO 110 standards. If no change is required to labeling, packaging and ingredients normal supply chain timing would apply. Any increase in demand could be met within a 8-12 weeks supply. Our range at FTF Pharmaceutical will meet all vapers needs of disposable, prefilled pods or liquids. Furthermore, our products are only imported in to a S4 licensed warehouse.

Options for pre-market assessment of NVPs by TGA

13. Which option (for pre-market assessment of NVPs) do you prefer? Why?

A pre-market notification option is preferred rather than a pre-market approval.

- A pre-market notification system for nicotine liquids could be established in Australia, which requires manufacturers to notify the regulatory body that their products meet Australian standards and provide supporting data before being allowed to be marketed. This system could streamline the process for manufacturers and ensure that only compliant products are introduced to the market. This would also provide vital clarity to authorised prescribers and dispensing pharmacies, of what products to prescribe or dispense. A similar model is used in the following countries:
  - New Zealand. All products are registered with the Ministry of Health's Vaping Regulatory Authority's Health Advisory and Regulatory Platform (HARP). All notified products are recorded in a publicly available searchable database eg the HARP database in New Zealand [link]
  - United Kingdom. Under the TPD, 6 months prior to marketing, producers must supply a list of all ingredients in the product (liquid); Emissions from the product and Toxicological data and Components of the product.

It is not advisable for the Therapeutic Goods Administration (TGA) to require pre-market authorisation for every product, as this process can be costly, time-consuming, and burdensome. The U.S. Food and Drug Administration's use of pre-market authorisation has faced difficulties and lawsuits, with over 4 years of delays in decisions. Pre-market approval process in the US in now more than 4 years post announcement with very little progress.

Pre-market authorisation may unfairly disadvantage reduced-risk products in comparison to cigarettes, which do not need to undergo such assessment. It may also serve as a barrier to entry and innovation for manufacturers of nicotine vapor products (NVPs), potentially giving an advantage to big tobacco companies that have the resources to make such submissions.
Any complicated premarket authorisation such as the US PMTA would also only allow the black market to further thrive.

14. Would any of these options have an impact on you? How?

Yes, currently our products are developed based on the TGO 110 standards. Any unnecessary and significant change would place a significant financial burden on an independent company such as ours. Our products could meet EUTPD, UK and NZ regulatory requirements. As these markets are advanced in the NVP space we feel that standards are adequate. We support a pre-market notification system.

15. If changes are made to pre-market assessment of NVPs by the TGA, how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary before the reforms come into effect? What impact would any requirement to pay a fee have on you?

If similar to the NZ product standards – Quality of vaping substance ingredients or the UK's

Tobacco & related products regulation we may require 3-6 months to prepare documentation and upload product details. In the interim reporting of Australian standards certificate of analysis could be provided and uploaded immediately.
Fees for this process should be minimal. Any fees will also financially impact independent companies like ours in an effective start-up market.

Minimum quality and safety standards for NVPs

18. Which option to restrict flavours in NVPs do you prefer? Why?

We say make no change to the list of currently restricted flavoring agents in NVPs.

Recommendation for flavours could include

a. Simple adult pallet-based flavours with simple descriptions of flavour profiles only eg 'mint', 'blueberry', 'tobacco', 'mango'. Flavours to be found to have a material risk to health should be banned as in the prohibited ingredient list. The EUTPD & FDA have lists that can be referenced.
b. Prohibit however descriptive flavour names that specifically appeal to youth eg 'dragon vomit' ' candy Floss'

Flavored e-cigarettes have been a controversial topic in recent years, with some arguing that they are primarily marketed towards youth and contribute to the youth vaping epidemic. However, it is important to recognize that flavored e-cigarettes can also be a useful tool for adult smokers looking to switch to a potentially less harmful alternative. Flavours are an integral part of transitioning an adult smoker to vaping as part of smoking cessation journey. Restricting non tobacco flavours would reduce the transition of smokers to vaping and lead to more smoking and smoking-related death and disease. Non tobacco flavoured e-liquids also increase quit rates compared to tobacco flavours and reduce the rate of relapse. [3,4] Those who vape with non tobacco flavours also have higher odds of making a quit attempt. [4]
One study published in the New England Journal of Medicine found that adults who used e-cigarettes containing flavors other than tobacco or menthol were more likely to successfully quit smoking compared to those who used non-flavored or menthol-flavored e-cigarettes. This suggests that flavors may be an important factor in helping adults switch to e-cigarettes.[6]
Another study published in the journal Tobacco Control also found that flavors can play a role in reducing cigarette consumption among adult smokers. The study surveyed over 6,000 adult smokers and found that those who used flavored e-cigarettes were more likely to report decreased cigarette consumption and an increased likelihood of trying to quit smoking.[7]
Overall, the evidence suggests that flavors can be an important factor in helping adult smokers switch to e-cigarettes and potentially reduce their cigarette consumption. However, it is also important to ensure that e-cigarettes are regulated in a way that prevents youth access and use. Non tobacco flavour bans would also lead to increased black-market supplies.

19. Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients?

Yes

similar to the NZ product standards – Quality of vaping substance ingredients or UK's Tobacco & related products regulation, we believe restriction should focus on hazardous agents in quantities that pose a material risk to users

20. Do you support introducing plain packaging requirements for NVPs? If so, should this entail packaging similar to other prescription-only medicines, or should additional measures be considered?

No

As prescribed products are sold via pharmacies as a S4 medicine there is no need of plain packaging. Furthermore, there are adequate advertising and marketing restrictions relevant to S4 medicine, therefore plain packaging is a unnecessary requirements.

21. Do you support introducing additional warning statements for NVPs? If so, which warning statements should be included? How would this align with the treatment of NVPs as a prescription-only medicine?

No

Currently the consumer medicine information (CMI) and relevant information by the medical practitioner should be sufficient for patients to be adequately informed of the dangers. Furthermore, child restrictive packaging and other safety mechanics are sufficient. The product is dispensed via AP's and Pharmacists who are responsible in communicating warnings.

22. Do you support restricting nicotine concentrations in NVPs to 20mg/mL (or base form equivalent concentration for nicotine salt products)? If not, what alternative do you support?

No

We support similar to the NZ product standards – Quality of vaping substance ingredients products regulation.

The strength of free-base nicotine in a vaping substance must not exceed 20 mg/mL.

The strength of nicotine salt in a vaping substance must not exceed 50 mg/mL.

A 10 stick daily cigarette smoker (8mg) will consumer 80mg nicotine per day. A 1ml / 50mg closed pod user will still consumer less than a cigarette smoker. A 1ml / 50mg closed pod user will still consumer less than a cigarette smoker.

A freebase adult consumer uses between 3 to 12mg per 1 ml and vapes on average 5mls a day. That means they ingest between 15mg and 60mg of nicotine a day.

A nicotine salt consumer vapes between 18mg to 50mg per 1ml and vapes between 1 and 1.5mls a day. That means they ingest between 18mg and 75mg of nicotine a day.

This is why the NZ legislation is written the way it is, to cap ingestion at below 100mg per day.

Nicotine salt is mostly used in disposable and precise dose closed pod devices. These devices require a lower heat to vaporize and consequently have lower emissions. Freebase nicotine used mainly by open tank users.

23. Do you support limiting the maximum volume of liquid NVPs? If so, what maximum

volume should be specified?

Yes
We support no more than 800 puff equivalent in disposable vaping units which is sufficient for 4-5 days of dosage. A 1ml / 50mg closed pod system as its similar to current daily nicotine intake of an average smoker.
We support a maximum amount of nicotine per container similar to the New Zealand limit of 1800mg nicotine per container is a sensible compromise. [link] This would be 100mL of 18mg/mL or 36mL of 50mg/mL.
All bottles should have child-proof caps, and be leak proof, unbreakable (PET plastics) and have anti-spill protection making accidental poisoning very unlikely.

24. Do you support preventing access to disposable NVPs?

No
Disposable vape devices are a popular aid for adults transitioning from smoking as they are convenient, easy-to-use, require no maintenance or charging and provide good nicotine delivery. They are especially useful for elderly, disabled and non-technical users. Disposable devices are also most appropriate device for a hospital inpatient as they require no refilling or recharging and are tamper proof.

25. Would any of the options set out in questions 18 to 24 have an impact on you? How?

Yes
Excessive regulation can have negative effects such as limiting patient choice, impeding innovation, and potentially endangering adult smoker lives by delaying access to necessary products to support smoking cessation such as NVPs.
It can also create barriers to entry that make it difficult for independent companies to enter the market, while giving an advantage to established, large tobacco companies already here in Australia with significant budgets and control the rate of smoker cessation.

26. If changes to product quality and safety standards are made, how much time would you require, if any, to become familiar with the reforms, and to organise the procurement of compliant products as necessary, before the reforms come into effect?

3 months
If similar to the NZ product standards – Quality of vaping substance ingredients or the UK's Tobacco & related products regulation we may require 3 months to procure compliant products. Provision to run out current TGO 110 compliant stock would be required.

27. Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?

Yes
- Standards for the manufacture of vaping liquids
- Standardised testing regimes
- Emission testing

Clarifying the status of NVPs as 'therapeutic goods'

28. Do you support regulating NVPs that contain nicotine, but are not labelled as containing nicotine, under the therapeutic goods framework?

No
All products with nicotine should be labelled correctly. Many illegally imported products currently in the Australian market do not list nicotine to avoid detection by the Border Force. This is the single biggest driver of black market, greater youth access and underpinning this emergent public health crisis.

Non nicotine vaping products are only designed for smokers to address a behavioral purpose. In a nicotine reduction and smoking cessation strategy having a gradual reduction in nicotine strengths and ultimately a non-nicotine product may assist in the behavioral aspects. The importation of non-nicotine should be under the same pathway of S4 nicotine products to avoid general trade importing under false labeling and fueling a black market, which is now already well-established with the commensurate poor public health and societal outcomes.

References

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