

Why the Australian Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 is failing and will continue to fail.

The Australian Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 was implemented with the aim of controlling the vaping market, reducing youth access, and ensuring consumer safety. However, the bill has failed to achieve its objectives spectacularly due to several critical issues, including a thriving black market, inadequate enforcement, and unrealistic stock divestment options for lawful businesses. A major concern is the continued presence of Chinese manufacturers advertising illicit vaping products on social media, which has resulted in continued exponential growth of the black market. Here's why this issue, along with other factors, is leading to the resounding failure of the reforms.

1. Pharmacy Guild and Pharmacist Reluctance

The bill requires vapes to be sold through pharmacies, making pharmacists key gatekeepers in the controlled distribution of nicotine-containing vaping products once they become an S3 medicine in October. However, many pharmacists and the Pharmacy Guild of Australia are pushing back against this requirement. They cite concerns over the lack of clarity on the safety of vaping products and their potential long-term health effects – there are currently no vaping products on the ARTG. Pharmacists, who are trusted health professionals, feel uncomfortable being positioned as retailers for a product still surrounded by controversy – even being put at risk with dangerous syndicates that operating in this space. Moreover, the addition of vapes to pharmacies' inventory conflicts with their core mission of promoting health and wellness. Many pharmacists see selling vaping products as contradicting their public health responsibility, particularly when safer alternatives to smoking, such as nicotine replacement therapies (NRTs), whilst not as effective as vaping according to the latest Cochrane review, are already available.

The reluctance of pharmacists to sell vapes has also stifled efforts to promote vaping as a safer alternative for smokers looking to quit. Many former smokers who use vaping as a harm-reduction tool are now struggling to access regulated products, as pharmacies are not stocking them in sufficient quantities, in the correct nicotine strength, the required flavour for them, or at all. This situation has already pushed vapers back to cigarettes or onto high strength nicotine unregulated vapes - a far worse outcome for public health, and directly counteracts the harm-reduction goal that vaping is meant to support.

2. Violence Against Vape Stores and Tobacconists

A disturbing consequence of the regulatory environment is the rise in violent attacks on vape stores and tobacconists. In Victoria and Queensland alone, there have been over 100 fire bombings (Earn or Burn) and other forms of vandalism targeting these businesses. This violence is thought to be driven by conflicts over control of the lucrative illicit vape market, which has thrived under the current legislation.

The attacks not only endanger lives but also now deter Pharmacists from participating in the legal market for vaping products. Many tobacconists are fearfully forced into stocking illicit products by organized crime groups involved in the illegal sale of vapes.

3. Inadequate Enforcement of Black-Market Sales

Despite the bill's intent to regulate the vaping industry, black-market sales of illicit products have continued to grow. Enforcement has been considerably weak at federal and state level despite further funding to tackle illicit activity. The Australian Border Force (ABF)'s seizure of 4 million vapes since January 2024 is not even considered a drop in the ocean compared to the demand. With an estimated 1.7 million vapers in Australia, over 95% of them are using black-market, high-strength nicotine products. This highlights the inability of the current regulatory framework to control the supply of illegal vapes. They are entering Australia by the Tsunami load. To believe that the enforcement agencies can control this volume of illicit activity with the resource and investment that is currently in place is unrealistic, naïve and out of touch with the scale of the problem.

4. Chinese Manufacturers Exploiting Social Media

Compounding the problem is the aggressive marketing of black-market products by Chinese manufacturers on social media platforms. These manufacturers are advertising openly and widely, promoting illicit vaping products directly to Australian consumers and youth – including tactics such as the freight forwarding companies absorbing risk or seizure in their commercials. Despite the TGA's regulations, these manufacturers show no signs of stopping, as they face little risk and high profitability. Their constant presence on social media makes it easy for Australian consumers of all ages to access illegal products, further undermining the reforms. The black market has become even more profitable due to these dynamics. The limited legal options and high consumer demand have driven up prices for illicit products, increasing the profitability of illegal trade. The only tangible change since the reforms is that the price of black-market vapes has increased, allowing illegal sellers to make even more money. This has created an even stronger incentive for criminal organizations and foreign manufacturers to continue flooding the market with illicit products.

5. Restrictive Flavour Ban Hurts Consumer Choice

One of the most restrictive aspects of the bill is its limitation on vaping flavours that can be sold through Pharmacies, allowing only tobacco, mint, and menthol varieties to be legally sold. These flavours account for only a fraction (~7%) of consumer preference in the vaping market. The vast majority of adult vapers prefer fruit, fruit-ice, dessert, and other non-tobacco flavours, which unequivocally from our near decade of experience, help smokers transition away from cigarettes.

By limiting the legal flavour options, the bill alienates a large portion of the vaping consumer base (93%). Many consumers, faced with only tobacco, mint, or menthol options from a Pharmacy are turning to black-market sources to obtain their preferred flavours. This further undermines the reform and both the public health goals of reducing smoking and the efforts to bring vapers into the legal, regulated market.

6. Collapse of Lawful Vape Stores with No Government Assistance

One of the most devastating consequences of the bill has been the collapse of lawful vape stores across Australia. These lawful vape stores have been forced to close their doors due to the rise of the black market followed by a retail ban on sales of all vaping products unless sold through a pharmacy. The government has provided no compensation or assistance to industry businesses, many of which have invested heavily in their business infrastructure, compliance and employed thousands of local Australians nationwide. Their closure has left the legal market in disarray, allowing the black market to dominate and put many Australians on the breadline amidst a cost of living crisis.

The entire industry was forced to shut down en masse as a result of the restrictive reform passing through the Senate via a last-minute deal between Mark Butler and the Greens. Without this deal being cut with The Greens, the bill would not have passed through parliament. The bill received royal assent on Friday 28 June 2024 with direction for industry to cease trading on Monday July 1 2024 – not even a single business days' notice. Many businesses such as ours have significant financial commitments such as large leases, full time staff, ongoing operational expenses, Plant and Equipment leases, staff members with families who rely on their employers to pay their rents and mortgages, trade accounts, the list of exposures for businesses is endless.

But Zero cares were afforded to the industry situation and businesses were forced to wind up or become insolvent, overnight. We have first-hand evidence of multiple business owners being admitted to hospital for a variety of stress, anxiety and depression related issues as theirs and thousands of other Australians have had their livelihoods stripped away with the stroke of a pen.

Despite the government's role in creating the regulatory environment that has driven these closures, there has been no compensation or assistance offered to affected businesses. Many have invested heavily in their businesses, only to see their livelihoods and a decade's worth of sweat equity destroyed by the bill. The lack of government support or financial assistance has left lawful operators out in the cold, unable to find a way forward in a market that has been all but erased and struggling to make ends meet. It is a disgrace. And yet – Ironically, Mark Butler has been posting on his social media platforms about R U OK day last week. Not once has he reached out to any of the industry operators and business owners to ask if they are ok after he robbed them of their livelihood during a cost-of-living crisis. It's a disgrace.

7. Transition to Pharmacy Supply Model is Commercially Unfeasible

A key flaw in the bill is the unrealistic expectation that pharmacies can replace dedicated vape stores as the primary distribution point for legal vaping products. Not only have the Pharmacy Guild said they don't want a part of it as they are not tobacconists. Commercially, this transition is not feasible. The continued strength of the black market and variety of consumer choice in flavours means that the legal throughput of vape products sold through pharmacies is too low to sustain the infrastructure and business operations needed for a successful supply chain. This is especially true when the businesses such as ours that are expected to transition are being forced to destroy their stock with no financial assistance due to it being non-compliant for sale into Pharmacy channel.

The pharmacy distribution model relies on a high volume of sales to justify the costs of stocking, handling, and regulatory compliance for vaping products. However, as long as the black market continues to dominate due to widespread availability and vast array of flavours for consumer choice, pharmacies will see only limited demand for their restricted, legal products. This low volume of sales is insufficient to cover operational costs for an organisation that is the size of ours, but also renders it unprofitable for pharmacies to fully commit to selling vaping products. Without significant government intervention or a serious crackdown on the black market, pharmacies cannot generate the level of sales needed to sustain the infrastructure required for a regulated supply chain to 1.7 million vapers. With such a bleak outlook on the success of the transition of Vape sales of significant volume into the Pharmacy channel – how can the TGA expect a business such as ours to invest any further capital into at what is at this point, are unrealistic hopes and dreams! It is hardly a sound business transition proposal from the TGA. Although it has become increasingly obvious that throughout the consultation process – vape industry business leaders, stakeholders and their expertise in the category have been largely ignored with their recommendations for the framework. Furthermore, when asked for meetings with vape industry professionals – State Health Departments and Labor Politicians have consistently hid behind the WHO FCTC article 5.3 to avoid dialogue with industry and pushed on with an ideological, top-down approach to the reform which will ultimately contribute further to the catastrophic failure of the legislation. Businesses would simply receive an internally circulated regurgitated Labor Party policy response email to palm off all enquiries or requests for meetings. Democracy at work!

8. Unfeasible Options for Lawful Vape Businesses to Divest Stock

The TGA has presented lawful vape businesses who hold a commercial quantity with three options for “divesting” their stock, but all of these options are commercially unviable and unrealistic, resulting in significant financial loss for operators. Here’s why these options are a slap in the face to legitimate businesses:

- **Exporting Stock: Impossible for Australian standard Zero-Nicotine Products**
The TGA suggests exporting vape products as one option, but this is not feasible for most businesses. The stock held by these businesses is zero-nicotine, which is not in demand in overseas markets. International markets require vaping products to either contain nicotine or be short-filled for nicotine to be added. Additionally, exported products must comply be registered & approved for sale, with strict territorial regulations like the Tobacco Products Directive (TPD) in Europe, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, or the Premarket Tobacco Application (PMTA) in the U.S. Most Australian products do not meet these stringent labelling, chemical, and ingredient requirements. Even if businesses found buyers overseas, the commercial viability of exporting would result in huge financial losses. The costs associated with shipping and compliance would wipe out any margins, making this option impractical.
- **Notify and Sell to Pharmacies: This is not possible for 95% of stock**
Another option presented is selling stock to pharmacies. However, this is impossible for most vape businesses because their products are predominantly

flavoured, and pharmacies are not allowed to sell flavoured liquids. Additionally, the products are zero-nicotine, meaning they would have to be sold with base nicotine shots or 100mg nicotine, creating further complications. Pharmacies would be required to stock two products—e-liquids and nicotine base—while consumers would have to mix them at home, adding extra risk for dispensing Pharmacists. Pharmacies are unlikely to take on this liability, especially given the complexity of titrating nicotine without supervision. The model would only work through a compound pharmacy, but this adds layers of complexity and additional costs, making it commercially unattractive and logistically unfeasible.

- **Business Surrender Scheme: No Compensation for Millions in Stock**

The most outrageous option is the “business surrender scheme,” in which businesses are expected to hand over their entire stock to the TGA for destruction. This includes stock holdings worth millions of dollars, and operators are expected to do so without receiving any compensation. This is unprecedented, as previous government buyback schemes—such as the buyback of guns or sunbeds—provided compensation to business owners. Even in historical contexts like the UK’s abolition of slavery, owners were paid “Just Terms” compensation. The live export ban is due to commence in 2028 giving farmers and businesses 4 years to work towards compliance. They have also been given multiple industry compensation packages in the hundreds of millions to assist in transition and extensive social support and wellbeing for losing their livelihoods – no such thing has been afforded to the vape industry.

<https://www.agriculture.gov.au/biosecurity-trade/export/controlled-goods/live-animals/livestock/live-sheep-exports-phase-out>

Forcing vape businesses to destroy their stock with no compensation adds insult to injury, especially when they have invested heavily in stocking previously compliant products.

The Business Surrender Scheme is also not ready! Businesses are expected to hold the stock at their premises at their cost from July 1 – November 30 2024 until such time as the TGA can work out what to do with the stock! The lack of organisation and planning for this debacle is scandalous. And again, little to no consideration has been given to businesses. Especially those that are now insolvent - how are they are supposed to hold the stock when they are winding up a business? The lack of commercial aptitude in this scheme is astounding.

9. No Benchmark for Success

One of the most fundamental flaws of the bill is the complete absence of clear Key Performance Indicators (KPIs) or benchmarks for success. During the latest Senate Vaping inquiry, Senator Ross Cadell questioned the TGA about how they would measure the success of the reforms, and they had no answers. The TGA admitted they had no specific benchmarks or measurable goals for assessing whether the legislation was achieving its intended outcomes. Unbelievable.

Without any clear KPIs, it’s impossible to determine whether the bill is reducing youth vaping, cutting down black-market sales, or improving public health. The lack of a success framework highlights the government’s short-sightedness in implementing

such sweeping reforms. By failing to define what success looks like, the TGA and the government are essentially operating in the dark, with no way to assess whether the changes are working or making the situation worse.

This lack of accountability also raises concerns about the long-term impact of the reforms. Without measurable goals, there's no way to course-correct or make adjustments if the bill is not meeting its objectives. This makes the legislation not only flawed but also unsustainable in the long run.

10. Youth Vaping Still Prevalent

Despite the bill's focus on limiting youth access to vapes, young people are still easily able to obtain vaping products from illegal sources whether that be in unruly tobacconists on every street corner nationwide, social media, from their peers or directly from overseas suppliers. While the legal framework aims to protect younger Australians, the lack of robust enforcement coupled with pharmacies essentially opting out of the supply chain has driven the market to extraordinary levels. Consequently, the widespread availability and lack of serious enforcement is continuing to fuel youth vaping, an issue the legislation was specifically designed to tackle. It is worth noting, the black market has no problem in selling to the youth.

The consequences are profound as we are essentially exposing the youth to using unregulated products. Which contain obscene amounts of nicotine - up to 60mg has been reported. Unregulated ingredients with no batch traceability – often with toxic chemicals. No quality control or manufacturing standards – exposing consumers to poor practices through contamination. No battery safety standards – exposing consumers to potential explosion from devices or leaking of battery acid into the cotton. Consequently, the youth and all black market consumers are being put at huge risk through a lack of enforcement and removing these products from our streets.

11. Public Health Messaging Confusion (Deliberate Misinformation?)

The vaping reforms have caused significant confusion around public health messaging. By cracking down indiscriminately on all vaping products, the crucial distinction between safer, regulated products and harmful, illegal ones has been blurred, leading to the misguided perception that all vaping is equally dangerous—an overwhelmingly incorrect view. This confusion will undoubtedly discourage smokers from switching to less harmful alternatives like vaping. Government-funded public health campaigns, national health bodies, and certain anti-vaping advocates, including those associated with the World Health Organization, bear responsibility for this outcome and should be held accountable for their dissemination of misinformation. Throughout the legislative reform process, their inaccurate, anti-vaping messaging—spread through both media and their own platforms—has been nothing short of shocking, especially given the responsibility these professionals have to public health as tobacco smoking kills 22,000 Australians every year. Yet, despite lacking expertise in the vaping industry, black-market dynamics, vaping product standards, consumer behaviour, organised crime, chemical and ingredient analytics, or the economic implications of the reform, they campaigned tirelessly to shut down the lawful industry.

What are we left with? The closure of the dedicated vape industry which was the only market competitor to the black market, in doing so – they have funnelled more customers to organised crime.

Vaping has been the most significant displacer of tobacco use in the past century, yet the anti-vaping ‘tobacco control’ campaigners sought to ban vaping citing that Big Tobacco was behind the category. Which is categorically false. In Australia there wasn’t a single Big Tobacco brand of note in the dedicated vape industry. This is one of many misinformation pieces that have been peddled in the media by Mark Butler, health bodies and Public Health advocates. The only place you could find a Big Tobacco vape product, is in the Pharmacy channel. Go Figure.

Given Vaping’s undeniable global success in reducing smoking rates in all countries where they have adopted a consumer model, it is perplexing that Tobacco Control campaigners would rather effectively ban vaping removing nearly all consumer options than advocate for its tight regulation as a smoking cessation tool that is widely available at every place you can buy a cigarette. It is counterproductive to tobacco harm reduction efforts in Australia.

12. Mind-Blowing Contradiction: Cigarettes Still Widely Available and Illicit Cigarette Trade Rife

One of the most striking contradictions in the Australian Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 is that while vaping—widely recognised as between 70-95% less harmful than smoking—is being heavily regulated, cigarettes remain freely and widely available at almost every convenience store and tobacconist across the country. Despite vaping’s proven potential as a harm-reduction tool, cigarettes, which are far more damaging to public health, continue to be sold far and wide with huge taxation to boot. This accessibility of traditional tobacco products makes a mockery of the legislative intent to improve public health, as smokers are presented with far easier access to harmful cigarettes than to safer vaping alternatives. Adding to this contradiction is the rampant illicit cigarette trade in Australia. Despite the strict regulation of legal tobacco sales, illegal tobacco is thriving across the country, with black-market operators smuggling untaxed, unregulated cigarettes into Australia. This illicit cigarette trade, known as "chop-chop," is estimated to make up a significant portion of the overall tobacco market, circumventing government controls and tax revenue. The irony is stark—while the government is aggressively targeting vaping through prohibitive regulations, the illicit cigarette trade continues to flourish. The availability of illegal cigarettes, combined with the legal sale of traditional tobacco, offers smokers easy access to harmful products, which completely undermines the government’s health-focused rationale for regulating vaping in the Pharmacy channel. This double standard not only highlights the flawed nature of the vaping reforms but also perpetuates the very smoking epidemic the legislation is supposed to combat. Instead of promoting safer alternatives, the current regulatory framework makes it easier for people to continue smoking either through legal or illicit means, while vapers are left with limited, more expensive, and harder-to-access options. This contradiction calls into question the overall strategy of the vaping reforms, where the far more dangerous option remains both legal and illicitly available, while the less harmful solution is being aggressively suppressed.

Conclusion

The Australian Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 is failing for a multitude of reasons. The aggressive advertising by Chinese manufacturers on social media, the ineffective enforcement of black-market sales, and the lack of clear benchmarks for success have all contributed to the bill's shortcomings. The seizure of 4 million vapes by the ABF is insignificant compared to the vast number of illegal products flooding the market, and the black market has only become more profitable as prices have increased. Without addressing these critical issues—particularly the ongoing influence of Chinese manufacturers and the dominance of the black market—the legislation will continue to fail, hurting lawful businesses and undermining public health.

Despite support from the Coalition for a tightly regulated consumer model should they be re-elected, the damage has been done. Any attempt to backflip from this point is going to be a long road back and the landscape for a regulated market will look markedly different. For these reasons and the details outlined – we have subsequently chosen to close all business operations and will no longer be a stakeholder in the Australian Vape Industry. I am looking forward to seeing how the government tackle the issue of the illicit market from afar. However, unless there are substantial changes I won't hold my breath!

Personally, I am delighted to have played an integral role in the development of the Australian Vape Industry as a manufacturer and distributor that brought a level of production and operational excellence with ISO QMS certifications that the country had otherwise not seen before. With production volume of tens of thousands of bottles per week, quality control over the entire process, full supply chain batch traceability and innovative products manufactured in a purpose-built ISO facility - we have certainly played a significant part in assisting hundreds of thousands of people quit cigarettes in Australia over the course of our business lifetime and for that I am extremely proud.

It's been a ride!

Liam Croasdale