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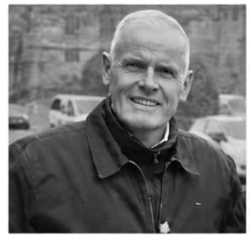
info@prohibitiondoesnotwork.com
www.prohibitiondoesnotwork.com

Tim Andrews
Director of Consumer Issues
Tholos Foundation
(United States)



Michael Ellis
Principal Global Advisor on Illicit Trade and Organised Crime
Prohibition Does Not Work
(The United Kingdom)

PDNW is an international network of think tanks, policy institutes, and experts dedicated to advancing evidence-based tobacco harm reduction policies grounded in science and international best practices. Our research has examined nicotine regulation across European Union, Australia, Brazil, and many other countries, with particular attention to public health, consumer behaviour, youth access, illicit markets and the unintended consequences of restricting safer alternatives to combustible cigarettes.

We respectfully submit that significant elements of the draft plan would undermine, rather than advance, its stated public-health objective. Specifically, a strategy designed to reduce tobacco-related disease should make it easier for adult smokers to move away from combustible cigarettes. Instead, the draft encourages Member States to ban, severely restrict, and tax products proven to help people quit smoking. These recommendations do not reflect the scientific evidence on harm reduction: nicotine is addictive, but it is not the primary cause of the cancers, chronic respiratory disease and other conditions caused by smoking. Products that remove combustion therefore occupy dramatically different positions on the continuum of risk.

The UK Government's comprehensive evidence review's have consistently concluded that vaping poses only a small fraction of the risks of smoking and reaffirmed that the longstanding estimate of at least 95 percent lower harm remains broadly accurate over the short and medium term. The independent Cochrane Collaboration[1], considered the gold standard of medical meta-analyses, has found high-certainty evidence that nicotine e-cigarettes produce higher smoking-cessation rates than conventional nicotine replacement therapies. Heated tobacco products likewise avoid tobacco combustion and substantially reduce exposure to many harmful constituents compared with cigarettes. Tobacco-free nicotine pouches involve no combustion, no inhalation and no tobacco leaf. The German Federal Institute for Risk Assessment has concluded[2] that switching completely from cigarettes to nicotine pouches can reduce health risks, while the UK Committee on Toxicity has reached a similar conclusion. We respectfully submit that a regulatory framework which treats these products as though they are interchangeable with combustible cigarettes is not following the science: It is in completely opposition to it.

We respectfully further note that consumer behaviour matters just as much as toxicology. There is no single alternative that works for every smoker. Some smokers switch through vaping, others through heated tobacco products, others through nicotine pouches or traditional oral nicotine products. Product design, flavour, nicotine delivery, price and accessibility all affect whether an alternative is acceptable enough to displace cigarettes.

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[1] **Electronic cigarettes for smoking cessation**
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub11/full#0
[2] Health risk assessment of nicotine pouches https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf

Japan should be of particular interest to WPRO because it is a Western Pacific success story. For fourteen years, between 2003 and 2017, Japan's smoking prevalence declined by less than two percentage points. Following widespread adoption of heated tobacco products, that decline accelerated dramatically. Cigarette sales fell by 32 percent in five years, and Japan achieved a greater reduction in smoking prevalence in only two years than it had during the previous fourteen.

New Zealand provides another example of a government allowing regulated safer alternatives to compete with cigarettes. Rather than forcing vaping entirely into a pharmaceutical model, New Zealand incorporated it into its broader smoking-cessation strategy, maintained legal consumer access, provided smokers with information on relative risk and established a national "Vaping to Quit Smoking" programme[3]. Smoking prevalence subsequently plummeted from 16.4 percent in 2011/12 to 6.8 percent in 2024/25, approaching the country's defined 'smokefree' threshold of below 5 percent.

Australia, also a Western Pacific country, provides the opposite lesson. PDNW's *Vapour Product Regulation in Australia: A Case Study in Failure* examined the consequences of attempting to suppress ordinary consumer access and channel vaping through a heavily medicalized system. By 2022–23, 93.2 percent of Australian vapers were already obtaining their products illegally. Following further restrictions, legal transactions have reportedly fallen to approximately one for every 1,700 illegal transactions. The illicit vapour market is now estimated at AUD $1–2 billion annually. The consequences extend well beyond lost revenue. Illegal sellers do not verify age, comply with ingredient standards or submit products for testing. Australia recorded a 14.5 percent current vaping rate among 14-to-17-year-olds in 2023 despite having one of the developed world's most restrictive regulatory systems. Criminal groups have meanwhile entered distribution, with more than 200 arson attacks, firebombings and violent incidents linked to competition over illicit tobacco and vaping markets.

This contrast based on real world data demonstrates quite conclusively the fundanemal flaws with the current plan: Japan and New Zealand allowed safer alternatives to displace cigarettes and saw smoking collapse. Australia suppressed the legal consumer market and produced a vast illicit market without preventing youth access, while seeing the fall in cigarette consumption stagnate. Yet almost all the recommendations in the draft plan would move Member States closer to the Australian model (which a report by the Coalition Taskforce into the illicit tobacco crisis in Australia released just today demonstrated comprehensively has completely failed.)

PDNW's broader international research reaches the same conclusion. *Nicotine Pouches in Germany* found that Germany's de facto prohibition did not eliminate demand. Instead, as many as 1.4 million consumers continued using products supplied through an unregulated market, with an estimated 444 million illegal pouches sold in 2024 and products containing nicotine levels far beyond those normally available in regulated markets. PDNW's research on Brazil and Mexico demonstrates that similar points. Brazil's outright prohibition has not eliminated demand: millions of consumers continue to use vapour products supplied through an unregulated market, with some estimates placing the number of users as high as 2.9 million. In Mexico, more than a decade of prohibition has produced an illicit vapour market estimated at between US$658 million and US$1.39 billion, while adult use has continued to increase and organized

[3] https://www.healthnz.govt.nz/about-us/what-we-do/programmes-and-initiatives/vaping

criminal groups have moved into distribution. The lesson is consistent across jurisdictions: prohibition does not eliminate consumer demand; it simply determines whether that demand is met by a regulated market or an illicit one.

Furthermore we draw your attention to a report by Professor Sinclair Davidson's from RMIT University in Australia for PDNW entitled *When Regulation Becomes Prohibition* which documents the same mechanism across Australia, Brazil, Belgium, the Netherlands and Denmark: when governments suppress lawful supply without eliminating demand, activity moves into informal and illicit channels while the state loses the very regulatory tools it needs to protect consumers, and come at great taxpayer costs. A legal market allows products to be tested, batches recalled, retailers inspected, ingredients disclosed and age-verification rules enforced. An illicit seller can do none of these things reliably and has little incentive to try.

Michael Ellis, the former Head of Interpol's Anti Illicit Trade Unit, PDNW Principal Global Advisor on Illicit Trade and Organised Crime:

'I was responsible for coordinating Interpol's response to this crime type across 192 member countries, investigating international illicit trade and IP crime for over 25 years and been involved in investigations, training and capacity building in all regions of the globe including Asia Pacific countries. I have repeatedly seen how introducing a blanket ban or access to a legitimate and legal product, especially those which have a high consumer demand, the end user will be driven towards illicit suppliers'.

The supply of illegal vapes is not a petty crime, nor it is a victimless crime.

It is a highly organized cross border enterprise, conducted by international crime gangs that ultimately gain huge profits. These gangs will source raw materials, arrange manufacture, organize smuggling routes and hidden techniques, to meet the consumers demand for the banned vapes.

These criminal networks are highly structured and have no hesitation turning to violence or corruption of customs and political officials to meet their illegal targets.

One of the most serious consequences therefore is the increased health risk to users, as illicit non-original vape products may contain unsafe levels of nicotine, harmful chemicals, unapproved ingredients, even controlled drugs, including heroin or fentanyl.

Due to the lack of regulation of illegal vapes there are of course no manufacturing standards or quality control. This can lead to a broader addiction to illicit substances, and long-term health issues, especially among teenagers and young adults who are attracted by the low price of illicit goods.

If the measures proposed the WHO Regional Office for the Western Pacific are implemented transnational crime groups will exploit the subsequent gaps in national policing and border control bringing increased health and enforcement challenges to in a region where resources, technical capacity and cooperation are already limited.

A weakness in legislation in one geographical location will undermine regional security, enabling criminal networks to operate across borders with reduced resistance from law enforcement.

No one can know exactly how large the illicit market in tobacco products, such as vapes has become as black markets are, by their nature hidden. However, from the data collected in other regions of the world focused on illicit consumption and excise revenues show that the problem is massive bringing a dramatic collapse in lawful consumption and legitimate tax revenue.

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Simply banning access to a legitimate product will be counter-productive to ensuring regional safety and security. It places pressure on law enforcement and public health systems, which must spend more resources controlling illegal sales and treating related health problems.

From an economic perspective, illicit vape trade will reduce government tax revenue, it will bring harm to consumers, and it will destroy the legitimate businesses that follow legal standards and pay taxes.

In closing illicit vapes create serious social, economic, and health challenges that require stronger regulation and public awareness, and a more balanced approach rather than an outright ban.

This is why the draft's recommendations on flavour restrictions and nicotine limits also require reconsideration.

If WPRO genuinely wishes to accelerate progress towards 2030, it should encourage Member States to regulate nicotine products according to their relative risk, maintain legal access to effective alternatives for adult smokers, protect young people through enforceable age restrictions and product standards, provide accurate information about relative harm, and preserve legal markets that governments can actually supervise.

An **international cooperation, stronger policing capabilities, improved technology and collective action are essential to prevent harm, protect victims and disrupt increasingly interconnected criminal networks.**

As such, we respectfully urge WPRO and Member States to substantially revise it.

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