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Sorting Out Australia's New E-cigarette Regulation Policies and Existing Research Gaps

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ABSTRACT

With the spread of electronic cigarettes around the world, many countries have implemented various regulations, and Australia has one of the stricter systems globally. Systematically review the new regulations on electronic cigarettes in Australia and focus on the transition to a strict prescription-only system and a wide-ranging ban on non-therapeutic and disposable vaping products. Based on the changes in legislation, the government aims to prevent new smokers among young people at the same time as enabling older smokers to use nicotine e-cigarettes for quitting. Notwithstanding the above measures, implementation problems have arisen, such as the spread of black markets, the unwillingness of general practitioners, and a low compliance rate. Therefore, this paper will outline the current research deficiencies in the above policies. The identified deficiencies are the absence of extended data on how the black market has responded to import bans, the duration over which the medicalised model has been ineffective compared with consumer-regulated models, and the sociocultural causes of illicit youth access. Based on the above analysis, in order to improve the public health situation and promote good policy construction in the future, these deficiencies need to be rectified.

KEYWORDS

Electronic Cigarettes; Tobacco Regulation; Prescription Model; Public Health; Research Gaps

1. INTRODUCTION

In the past ten years, the rapid spread of electronic cigarettes around the world has posed very serious health risks for the public. At first, these devices were promoted to help severely addicted adult smokers reduce harm by giving up smoking tobacco cigarettes; recently, they have also gained the attention of scientists and regulatory authorities for various reasons. While some foreign countries have incorporated electronic cigarettes into their national smoking cessation plans, others have taken a very cautious approach and raised concerns about the unknown long-term health effects of aerosolised chemicals and a steep increase in young people's use of vapes. Given the division of the world today, Australia has consistently chosen to maintain one of the stricter regulatory systems among developed countries and actively enforces them.

Australia's foundation is that liquid nicotine is a poisonous substance, so it has not been classified as a consumer product in places such as the UK, New Zealand and the United States. Recently, the Australian federal government has increased regulatory requirements to some extent. Strictly prescribe-only for all nicotine vaping products and impose comprehensive legislative bans on the import and sale of disposable, single-use electronic cigarettes are being implemented in tandem to create a strong ideological foundation for a strictly medicalised route. The purpose of the above policy system is to achieve a fine balance in public health: urgently prevent new cases of adolescent smoking and the possible re-emergence of smoking habits among older smokers, while also maintaining a legal,

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medically supervised route for adult smokers who have repeatedly failed to quit through traditional pharmacological treatments.

However, the application of the above regulatory ideas in actual work has not been smooth. Due to the quick introduction of the above-mentioned stringent policies, some serious unintended economic and social problems have emerged, such as a large-scale, organised illicit black market. Moreover, although the medical community has responded by reducing caution, logistical constraints have thus emerged that restrict access to cessation services for adult smokers who need them. As the world of public health watches Australia's regulatory experiment, we need to examine how good or bad these policies have been so far.

Systematically organise the present situation of new electronic cigarette regulation policies in Australia and rigorously identify the existing empirical research deficiencies. Thus, it aims to offer the subsequent direction for new research and exploration. Section 2 introduces the background and current form of the Australian regulatory system. Section 3 will examine the problems in the practical implementation and systemic friction of the prescription-only model. Section 4 will identify the specific shortcomings in the current research that prevent evidence-based policy evaluation. Finally, Section 5 will summarize the above contents and propose some ideas for the future development direction of tobacco control research and regulations.

2. EVOLUTION AND CURRENT STATUS OF AUSTRALIA'S E-CIGARETTE POLICIES

To know about the present situation of Australian electronic cigarette regulation, one should learn the history of tobacco control and harm reduction in Australia. The first scientific studies on electronic cigarettes were quite complex and inconsistent. The first all-encompassing evaluation indicated that although electronic cigarettes produced less harmful combustion products than traditional cigarettes, they were not without problems; thus, their long-term effects on the heart and blood vessels and lungs were still unknown [1]. At the same time, public health authorities in the UK have been very clear in stating that electronic cigarettes are considerably safer than smoking traditional tobacco, and they have been promoted by the government as an alternative for smoking cessation [2]. Given the different foreign assessments, the Australian regulatory authorities have chosen a very cautious approach and will continue to treat liquid nicotine as a schedule 7 dangerous poison under the standard for the uniform scheduling of medicines and poisons.

Therefore, this basic scheduling decision has effectively criminalised the domestic commercial sale, possession and use of nicotine-containing vaping liquids without medical approval. Therefore, the first comparison study of electronic cigarette awareness and trial rates found that the strict Australian regulatory environment reduced overall use compared with the relatively free-market consumer areas in the United Kingdom [3]. However, at the same time, it was also known that in a highly globalised and digitally connected market, an all-encompassing ban was out of the question. By the late 2010s, authoritative scientific consensus had gradually developed that although youth consumption represented a serious public health issue, fully replacing combustible cigarettes with electronic cigarettes would not cause significant short-term harm reduction for difficult-to-treat adult smokers [4].

Given the increased pressure and the fact that regulatory uncertainty is also rising, the Australian government has implemented a broad-ranging policy adjustment in October 2021. The therapeutic goods administration has legally established a prescription-only system and reclassified nicotine for human consumption in electronic cigarettes as a Schedule 4 prescription-only drug. Theoretically, the above model can enable adult smokers to legally import or purchase nicotine vape products from registered pharmacies after receiving a doctor's prescription. A government investigation into the medicalisation of smoking has pointed out reasons for this measure; proponents believe it is necessary

to restrict young people's access to smoking, while others argue that this will create an insurmountable barrier for disadvantaged smokers [7].

Despite the 2021 regulations, compliance was still at a very low level, and illicitly produced, highly palatable and strongly flavoured disposable devices specifically for teenagers had spread widely in the domestic market. Given the failure of the border control system built in 2021, a large-scale reform package was released by the government in late 2023 and 2024. Under the new policy, all single-use electronic cigarettes that contain nicotine are no longer allowed in Japan. In addition, the reform set a strict limit on product flavours, established demanding pharmaceutical packaging standards, and reduced nicotine content to the minimum extent possible. This proactive legislative action aimed to eliminate the recreational vaping market and regulate electronic cigarettes as strictly controlled, less appealing therapeutic smoking-cessation devices.

3. THE PRESCRIPTION-ONLY MODEL: IMPLEMENTATION AND SYSTEMIC CHALLENGES

Although the theoretical structure of the prescription-only model is reasonable in terms of addressing the cessation needs of adults and the prevention of youth suicide, many serious problems have arisen in its application. The construction of the medicalised system will not be effective unless the front-line medical staff actively participate in it. General practitioners in Australia have shown a general reluctance to prescribe nicotine vaping products. Healthcare professionals have pointed out a serious lack of standardised, authorised clinical guidelines; no products have been formally listed on the Australian Register of Therapeutic Goods (ARTG), and serious problems have arisen over potential long-term legal liability. Therefore, accessing a willing prescriber has become a significant logistical problem for adult smokers and is thus unlikely to be feasible [5].

The general reluctance to seek medical help has thus weakened the support for the prescription model in reducing the national smoking rate. Prominent harm reduction advocates have repeatedly pointed out that for vaping to reduce smoking rates effectively, the alternative nicotine delivery system must be as easy to obtain as combustible tobacco products [6]. Many administrative barriers have been created; for example, one must book a doctor's appointment for smoking cessation, pay consultation fees, choose from a small number of pharmacies, and may be ostracised by unsupportive doctors; thus, the policy has reduced the motivation for smokers to quit.

In addition, all-encompassing national reviews have formally endorsed the prescription model based on serious toxicological risks and a relatively high potential for nicotine addiction among vulnerable adolescents [8]. The Government's first goal was full-scale market planning. However, it was not the case. Due to the serious friction in the legal supply chain, a relatively large, high-profit vacuum quickly appeared, which was then taken advantage of by organised crime groups. The black market for electronic cigarettes in Australia has grown rapidly and entirely avoided all regulatory quality controls, age verification systems and tax collection. Illicit vendors are directly targeting the younger generation on social media and have constructed an organised, distributed delivery network that is very difficult for law enforcement and border security authorities to break down.

According to the official policy summary of Australia's 2024 vaping reforms, import restrictions will be introduced in conjunction with domestic controls over manufacturing, supply, advertising, packaging and therapeutic access pathways [9]. In fact, the prescription-only policy has not achieved the goals of both sides at present. It has failed to help adults quit smoking by providing insufficient medical access, and it has not protected young people as a result of the thriving, unregulated underground market for their devices. The difference between what the legislature intended to achieve and the actual results needs to be addressed promptly by research.

4. IDENTIFICATION OF EXISTING RESEARCH GAPS

Australia's electronic cigarette regulatory environment has changed rapidly in recent years, and as a result, there is a lack of long-term, comprehensive data for research. As a result, many serious deficiencies in the current research environment have hindered public health authorities' ability to assess how effective the 2024 policy reforms have been objectively. The first and most obvious empirical deficiency is a lack of all-encompassing epidemiological monitoring for the black market. Although there are many stories and reports in the media of an extensive illegal supply chain, very little concrete, data-driven studies have been conducted on how it operates specifically, how changes in price affect consumption, or what chemical substances are in the products. Since there is no specific data showing how the illegal network has responded to the strengthened border checkpoints, adjustments to the enforcement strategy have not been made.

The second significant research deficiency is the comparison of the long-term cessation effects of the strict medicalised model and the liberalised consumer model used abroad. Based on the latest disease data, despite relatively strict restrictions, all age groups in Australia are still smoking e-cigarettes to some extent [10]. It has not been found from the current rise in cases whether there will be a corresponding significant drop in the rate of combustible tobacco use among the public. A longitudinal cohort study will be organised to follow up on adult smokers in the legal prescription group. Identify the specific attrition rate at each stage in the medical care process - from the first request for a prescription to its actual collection at a pharmacy - and determine the long-term relapse rate of people in the consumer-regulated market.

Conduct more in-depth qualitative research on the reasons for the prescribing behavior of general practitioners. A prominent problem in the critical review of the prescription-only policy is a general lack of willingness among doctors [11]. However, no particular educational interventions, legal protection measures or clinical practice guidelines have been developed to promote the healthy use of nicotine vaping products in primary care currently. Research needs to clarify what particular evidence standards Australian doctors believe are required before they feel professionally comfortable prescribing these unregistered therapeutic goods.

Lastly, there are still many research deficiencies in the sociocultural mechanisms of youth learning. Although the 2024 ban on disposable devices aims to reduce the main products used by young people, research has not comprehensively investigated peer-to-peer distribution networks or the role of encrypted digital platforms in facilitating access for youth. Understand the psychosocial appeal of vaping for Australian adolescents in a highly prohibitive environment. Research will be conducted to determine whether the illicit character of the product is, in fact, more rebellious. To close these multiple empirical gaps, we need to ensure that the special-case regulatory experiment in Australia results in positive and long-lasting public health benefits rather than fostering hidden system failures.

5. CONCLUSION

The problem of regulating electronic cigarettes is serious and highly contentious in public health policy at present. Australia has taken an exceptionally restrictive path and, in line with this, actively rejected the consumer product model in favour of a strictly medicalised, prescription-only system. Recently, in light of this development, a broad-ranging 2024 ban on the import and sale of all non-medical and single-use vaping products has been introduced by the government to curb the problem of youth vaping. Theoretically speaking, the system of regulations is sensible; it hopes to create a high barrier to entry for young people while maintaining an orderly clinical path for older smokers who wish to reduce harm.

However, the application of this theory in practice has shown some serious system-wide defects. Many bureaucratic and medical barriers have been established to reduce the number of adults who

smoke, and a lack of knowledge among primary healthcare workers has further reduced legal assistance. At the same time, the policy has unintentionally promoted the rapid development of a vigorous and highly adaptable black market that efficiently targets the very adolescent group the legislation aims to protect.

At this time, the identification and systematic resolution of existing research deficiencies need to be carried out. The public health community urgently needs high-quality, long-term data to determine how well the prescription model has actually reduced illicit supplies, understand the detailed working mechanism of the illicit supply chain, and uncover the psychosocial reasons for both doctors' reluctance and adolescents' use. These deficiencies in the empirical data must be corrected to promote the public health of all people. Only after a long period of serious scientific research has the government flexibly adjusted the implementation plan and strengthened clinical recommendations to help Australia reduce tobacco-related illnesses and deaths.

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