

ANALYSIS OF THE RESPONSE TO THE EUROPEAN COMMISSION'S 2023 PUBLIC CONSULTATION ON THE EVALUATION OF THE LEGISLATIVE FRAMEWORK FOR TOBACCO CONTROL

BY PIETER CLEPPE (LL.M), INTERNATIONAL RESEARCH FELLOW,
THOLOS FOUNDATION, AND EDITOR-IN-CHIEF, BRUSSELSREPORT.EU

CONTENTS

Executive Summary	3
Introduction.....	4
Responses to the Consultation	8
References.....	15

EXECUTIVE SUMMARY

The European Commission's 2023 Public Consultation on the Evaluation of the Legislative Framework for Tobacco Control was a significant public engagement initiative marked by record numbers of submissions, primarily from citizens. As policymakers deliberate on the most effective strategies to combat smoking, this presents a unique opportunity to analyse the perspectives of both citizens and academic & research institutions.

Despite robust evidence, both within the EU and internationally, indicating the effectiveness of alternative products in aiding smoking cessation, an increasing number of EU countries are contemplating restrictions on those alternatives. Notably, Sweden stands out as a success story within the EU, boasting a smoking rate of just 5.6% and nearing the "smoke-free" status.

Like many other EU member states, Sweden has implemented regulations and education programs focused on smoking cessation and prevention. However, Sweden also provides smokers with access to a diverse range of alternative products. Essential elements, such as flavours, make these products acceptable and realistic options for smokers to switch and stay away from cigarettes, and these products are also affordable. It's worth noting that Sweden has even negotiated a derogation from the EU's ban on products like snus when it joined the EU in the 1990s.

A sentiment in support of alternative products as a means to smoking cessation is echoed by many European citizens in their feedback to EU policymakers during the consultation, as well as by numerous academic & research institutions who advocate for similar measures.

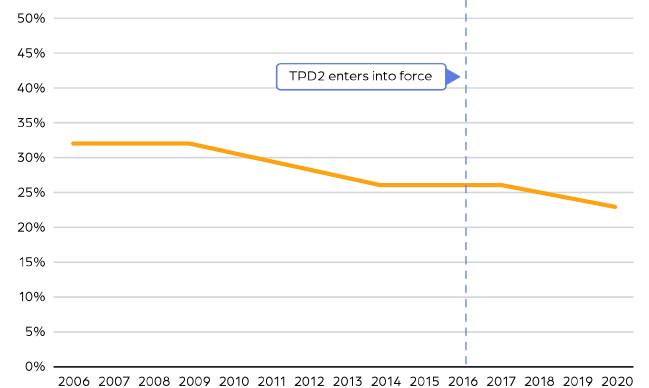
1. The vast majority of citizens and academic & research institutions are in agreement that alternative products can effectively assist in smoking cessation.
2. Flavors play a crucial role in alternative products for adult smokers, aiding in their decision to transition away from cigarettes and maintain abstinence.
3. Existing regulations on these emerging products are, in many instances, deemed to be more than adequate by various stakeholders.
4. Alternative products have not demonstrated to pose a significant public health risk. Instead, available evidence indicates they offer an opportunity to combat high smoking rates in the region.

As they look to legislate on the next iteration of the Tobacco Products Directive, EU policymakers must take note: for citizens and academic & research institutions, alternative products are essential to reduce the prevalence of cancer in Europe.

INTRODUCTION

The EU has introduced some of the strictest "tobacco control" measures globally, including a comprehensive ban on tobacco advertising,³ mandatory graphic health warnings on tobacco product packaging,⁴ and a prohibition of characterising flavours in tobacco products.⁵ The purpose of these EU policies is to engage in the global fight against cancer and non-communicable diseases. For this, it has rolled out its "Europe's Beating Cancer Plan". This policy sets a smoke-free ambition for 2040, with the objective of reducing smoking prevalence to below 5% across EU countries.

Figure 1: EU prevalence in Europe remaining stubbornly high



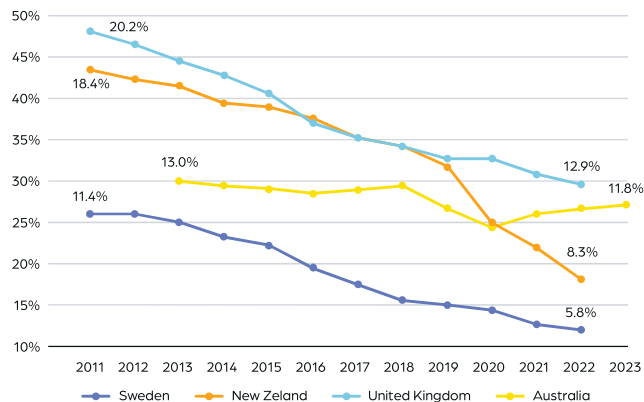
No great successes have been booked. Despite these initiatives, the reduction in smoking rates in the EU has been relatively modest, with a decrease of only two percentage points, from 25% to 23%, between 2016 and 2020.

Reflecting this, the WHO observed in its [Global Report on Trends in Prevalence of Tobacco Use 2000–2030](#) that its European region⁸ had the second-highest smoking rate of all WHO regions at 26.5% in 2022. Furthermore, it noted that “by 2030 the WHO European Region is projected to have the highest rates globally with a prevalence of just over 23%.”⁷ The WHO also found that only 11 countries in the region were expected to meet a target of at least a 30% relative reduction in smoking by 2025, compared to baseline figures from 2013.⁸

A significant development is, in any case, the broad consumer acceptance of alternative products such as vaping, nicotine pouches, and tobacco heating products. This is an effective contribution to public health, as it offers smokers safer means of consuming nicotine:

- Various literature reviews, including a comprehensive series commissioned by UK public health authorities, have consistently demonstrated that **vaping** is significantly safer than smoking cigarettes and has proven effectiveness in reducing smoking rates. These reviews repeatedly affirm that vaping carries only a fraction of the risks associated with smoking and is a viable tool for smoking cessation at a population level. The Cochrane International Research Network, among others, has also corroborated these findings. Since 2016, their series of literature reviews have consistently shown that vaping surpasses traditional nicotine replacement therapies like gum or patches in aiding smoking cessation.^{9,10,11,12,13}
- Public health advisory institutions like the UK’s Committee on Toxicity and the German Federal Institute for Risk Assessment have likewise concluded that **nicotine pouches** offer a safer alternative to cigarettes. Organizations such as the University of Medicine and Dentistry of New Jersey and the Swedish Institute for Tobacco Studies have published evidence demonstrating their effectiveness in reducing smoking-related harm by facilitating cessation.^{14,15,16,17,18,19}
- **Tobacco heating products (THP)** possess a smaller body of evidence compared to vaping, yet their relative safety in contrast to cigarettes has received validation from official entities such as the UK’s Office for Health Improvement and Disparities and the American Food and Drug Administration (FDA). The FDA, in particular, authorized the sale of the first THP in the United States in 2020, noting that “because [THP] heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke.”²⁰ Furthermore, studies from institutions like the Medical University of South Carolina and the American Cancer Society have affirmed the effectiveness of these products for smoking cessation, among others.^{21,22,23}

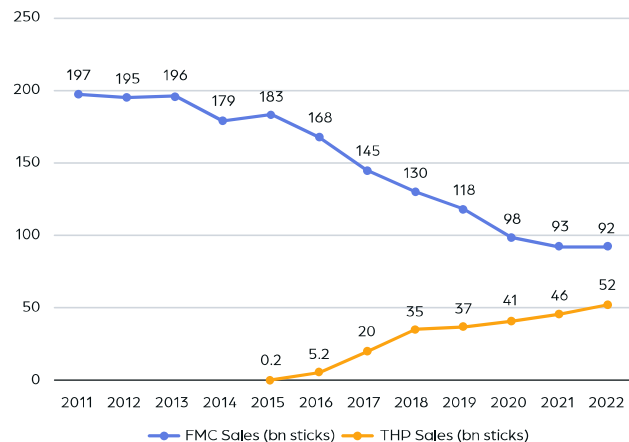
Figure 2: Australia lagging behind its peers



Academic findings on the products’ effectiveness in reducing smoking rates are also backed by evidence from a number of countries:

- In **Sweden**, where alternative products are integrated into a comprehensive strategy to combat smoking, the prevalence of daily smoking among individuals over the age of 16 decreased significantly from 11.4% in 2011 to just 5.6% in 2022. This remarkable decline brought the country closer to achieving smoke-free status, surpassing the EU’s target by nearly two decades.^{24,25}
- In **New Zealand**, the Ministry of Health’s [smoke-free plan](#) explicitly encourages smokers to transition to less harmful alternatives. Consequently, the current smoking rates among individuals aged 15 and over decreased from 18.4% in 2011 to 8.3% in 2022. The Ministry has also developed resources, such as the “Quit Strong” [website](#), aimed at supporting smokers in switching to vaping, with a particular emphasis on assisting ethnic minorities, who historically have higher smoking rates.²⁶
- In the **United Kingdom**, where government policy aims to maximize the public health benefits of vaping in reducing smoking, initiatives like the [Swap to Stop](#) program have contributed to a notable decrease in current adult smoking rates. These rates declined from 20.2% in 2011 (when comparable records began) to 12.9% in 2022.^{27,28}

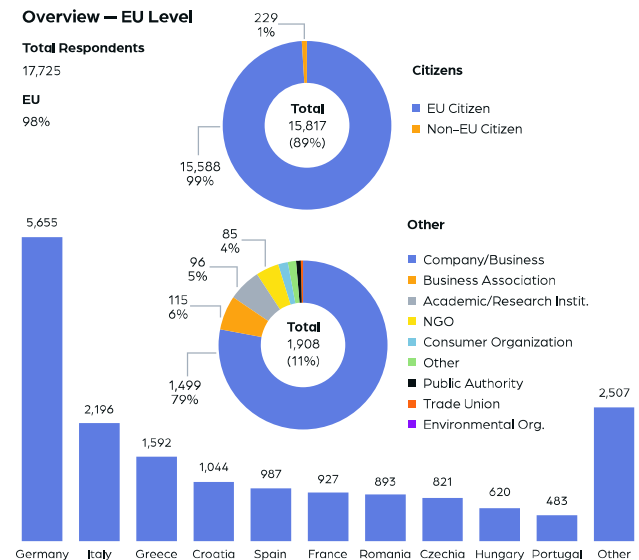
Figure 3: Japan’s sales show that THPs penetration is displacing smoking.



- In **Japan**, health authorities have not actively promoted alternative products to displace smoking, and nicotine-containing vaping has been effectively prohibited since 2010. However, the introduction of THP in 2016 has led to a significant reduction in cigarette sales. In 2016, 168 billion cigarettes were sold compared to only 5.2 billion THP consumables. By 2022, cigarette sales had decreased to 92 billion, while THP sales increased to 52 billion consumables.²⁹
- On the contrary, **Australia’s** restrictive approach to alternative products has impeded progress in reducing smoking rates. Australia is the only country mandating prescription-only access to vaping, de facto prohibiting their use. Similar restrictions apply to nicotine pouches, while tobacco heating products are outright banned. Coupled with ongoing negative messaging about alternative products, this has resulted in a stagnation in the decline of smoking rates, with only a marginal decrease from 2011 to 11.8% in 2023.³⁰

As the EU pursues its ambitious health goals and in anticipation of the forthcoming review of the Tobacco Products Directive, the European Commission is actively [assessing](#) the legislative framework for tobacco control, particularly focusing on further regulation of alternative products. A public [consultation](#) on the EU’s tobacco control legislative framework was conducted between February and May 2023, attracting over 17,000 responses from various stakeholders, including EU citizens, academic & research institutions, NGOs, consumer groups, and environmental organizations. An [analysis](#) of the submissions by Snusforumet revealed that an overwhelming majority of responses across all categories supported the notion that alternative products are pivotal in combating smoking.

RESPONSES TO THE CONSULTATION



Between February and May 2023, the European Commission's consultation garnered over 17,000 responses aimed at identifying knowledge gaps in measures to reduce smoking prevalence. The consultation sought to comprehend the diverse perspectives, problem perceptions, and arguments of various stakeholder groups. In addition, it gathered evidence-based practices and addressed emerging challenges related to tobacco and nicotine products. Questions covered key features of these products, including aspects of alternative products, such as flavours, which have been banned or restricted in some EU countries.

Analysis conducted by Snusforumet indicates that of the over 17,000 submissions, 89% were from both EU and non-EU citizens, while 11% were from organizations. Within this 11%, 79% of submissions came from companies and businesses, 6% from trade associations, 5% from academic & research institutions, 4% from NGOs, and 6% from other types of organizations. Notably, a vast majority of responses across all categories concurred that alternative products can aid in smoking cessation efforts.

THE VIEWS OF CITIZENS

European citizens overwhelmingly dominated the submissions, which is understandable considering that the majority of consumers of alternative products in the EU are former smokers. These individuals are directly impacted by regulations that can affect the accessibility and effectiveness of the products they rely on daily.

There was evident optimism among European citizens regarding the role of alternative products in smoking cessation. When asked about the potential of these products to help smokers quit, a significant majority of respondents agreed, with 62% strongly agreeing and 15% agreeing. Conversely, only a small minority of 9% disagreed or strongly disagreed with this statement.

Concerns regarding the addictive nature or public health impacts of the emerging products were largely met with scepticism by respondents. Notably, 57% strongly disagreed that these products pose a major health risk, while only 6% agreed or strongly agreed with this notion.

Regarding specific regulatory measures, a mere 5% believed that banning flavours in tobacco and related products significantly reduces health risks. A significant portion, 85%, opposed restrictions on the visibility of vaping in shops, while 74% were against similar measures for nicotine pouches.

9

while in **Spain** and **France**, two-thirds and 90% respectively held the same belief. Although slightly lower, **Italy** also showed significant agreement, with 70% supporting the efficacy of alternative products.

When it came to perceptions of the emerging products' public health risks at the country level, responses remained consistent. For instance, in **Germany** and **Italy**, only three and two percent respectively believed that the emerging products pose a major public health risk, while in **Greece**, fewer than one in six citizens shared this belief. In **France** and **Spain**, three-quarters disagreed that the emerging products represent a major public health risk, as did almost 85% of respondents from **Croatia**.

Regarding specific regulatory measures, views were also aligned across EU countries. For example, only a small percentage of citizens in **Germany**, **Italy**, **Czechia**, and **Croatia** believed that banning flavours would reduce health risks. Similarly, the majority of citizens in these countries found current restrictions on the visibility of vaping at the point of sale to be sufficient, along with restrictions on tobacco heating products and nicotine pouches.

It's important to note that restrictions may vary from country to country, and many EU countries are contemplating additional ones.

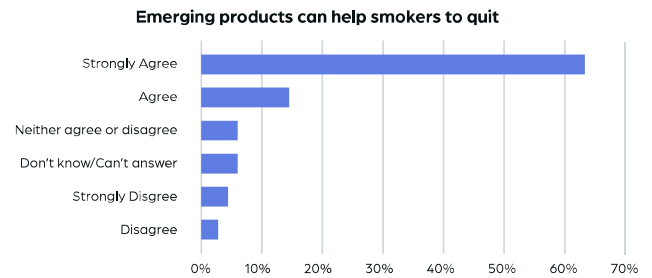
THE VIEWS OF ACADEMIC & RESEARCH INSTITUTIONS

96 responses were collected from academic & research institutions during the consultation. The responses indicate the following:

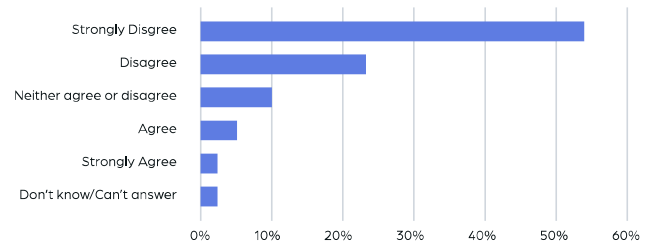
- Approximately 90% of academic & research institutions agreed that alternative products can aid smoking cessation.
- More than 80% disagreed with the notion that "emerging products represent a major risk" for public health due to their "addictive nature and their impact on human health."
- Only a small percentage of academic & research institutions considered the emerging products to be a threat to public health, with 7% of responding institutions believing THP to be a danger, and 13% viewing vaping as potentially harmful to public health.
- 68% of institutions did not believe that allowing the sale of flavoured alternative products increased their appeal towards the underaged.

11

Figure 4: A positive attitude among EU citizens towards alternative products



Emerging products represent a major risk due to their addictive nature and their impacts on public health



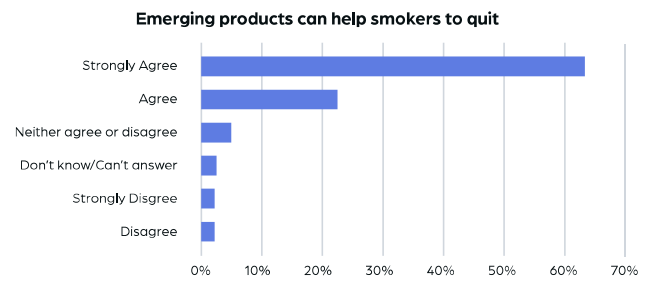
COUNTRY BY COUNTRY

Views were largely consistent across EU countries regarding the efficacy of alternative products and the perception of public health risks.

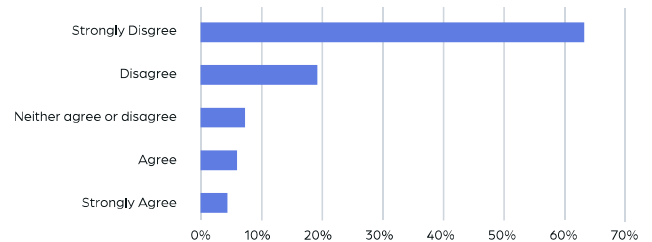
For instance, in countries like **Germany**, **Czechia**, and **Romania**, which were among the top contributors to the survey, four out of five citizens agreed that alternative products can aid smokers in quitting. Similarly, over 90% of respondents in **Croatia** shared this view,

10

Figure 5: Academic & research institutions endorsing alternative products



Emerging products represent a major risk due to their addictive nature and their impacts on public health



COUNTRY-BY-COUNTRY

Opinions from academic & research institutions across EU countries exhibited significant consistency in terms of the efficacy of alternative products:

- In countries like **Germany**, **Italy**, **Spain**, and **Poland**, over 80% of institutions concurred that the emerging products could aid smokers in quitting. This viewpoint was unanimously supported by all institutions in **Lithuania** (seven), **Romania** (five), and **Austria** (four).

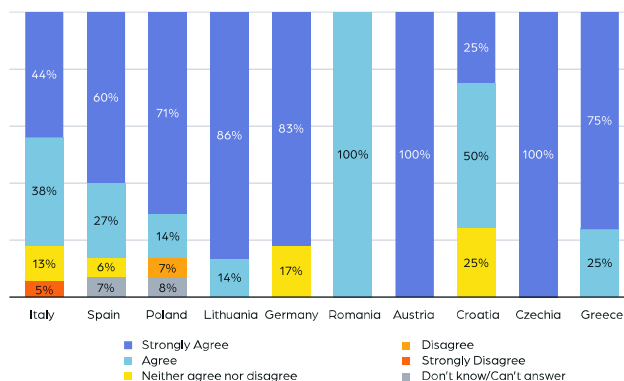
12

- Similarly, a substantial majority of institutions in **Italy** (87%), **Spain** (80%), **Poland** (86%), and four out of six in **Germany** disagreed or strongly disagreed with the notion that emerging products pose a major public health risk. This stance was also echoed unanimously by all seven responding institutions from **Lithuania** and all four from **Austria**.

And in terms of the need for additional regulatory measures:

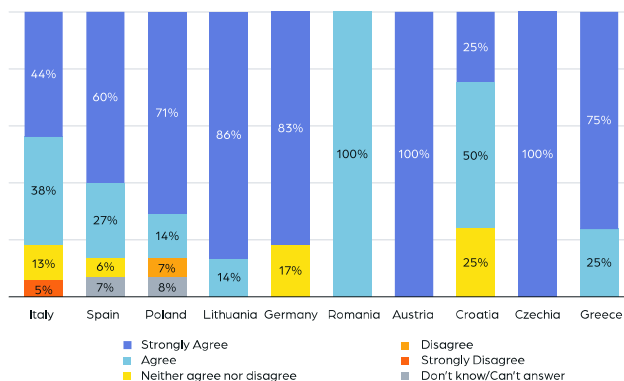
- In **Germany**, the majority of responding institutions (five out of six) deemed current restrictions on the visibility of vaping at points of sale sufficient. This sentiment was echoed by 13 out of 16 responding institutions in **Italy**, all four institutions from **Greece**, and three out of four from **Croatia**. Similarly, in **Czechia**, all four responding institutions stated that current visibility restrictions for vaping were adequate, with three out of four also agreeing regarding nicotine pouches. In **Spain**, only one in ten academic & research institutions believed there was a need for stricter restrictions on the visibility of vaping at points of sale.

Emerging products can help smokers quit



- Regarding the inclusion of flavours in alternative products, a significant portion of responding institutions in **Czechia** (three out of four) expressed the opinion that this did not increase their attractiveness to underage individuals. This viewpoint was also shared by three out of five responding institutions from **Romania**, three out of four from **Croatia**, and the vast majority (15 out of 16) from **Italy**.

Emerging products can help smokers quit



REFERENCES

- Snusforumet <https://snusforumet.se/en/eu/tbd-consultation-key-results/> and <https://snusforumet.se/en/record-public-response-ahead-of-eu-tobacco-law-revisions/>, 2023.
- "Beat smoking like the Swedes", https://tvr.com/peterchenze/status/166381715009648578_2023.
- EU, [Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products \(Text with EEA relevance\)](#), 2003.
- EU, [Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC \(Text with EEA relevance\)](#), 2014.
- Idem.
- The WHO European Region comprises the 27 EU countries as well as 26 other states including Russia, Turkey, the UK, and others.
- WHO, [Tobacco use declines despite tobacco industry efforts to jeopardize progress](#), 2024.
- WHO, [WHO global report on trends in prevalence of tobacco use 2000-2030](#), 2024.
- Cochrane Database of Systematic Reviews, [Electronic cigarettes for smoking cessation](#), 2024.
- Annals of Internal Medicine, [Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users](#), 2017.
- Addiction, [Biomarkers of potential harm in people switching from smoking tobacco to exclusive e-cigarette use: dual use or abstinence: secondary analysis of Cochrane systematic review of trials of e-cigarettes for smoking cessation](#), 2022.
- Health New Zealand, [Vaping Facts](#), 2022.
- The American Journal on Addictions, [Initial Information on a Novel Nicotine Product](#), 2020.
- International Journal of Environmental Research and Public Health, [Patterns of Smoking and Snus Use in Sweden: Implications for Public Health](#), 2016.
- Nicotine & Tobacco Research, [A single-blind, randomized, crossover trial of the effects of a nicotine pouch on the relief of tobacco withdrawal symptoms and user satisfaction](#), 2009.
- FDA, [FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information](#), 2020.
- The American Journal on Addictions, [Initial Information on a Novel Nicotine Product](#), 2020.
- Nicotine & Tobacco Research, [A single-blind, randomized, crossover trial of the effects of a nicotine pouch on the relief of tobacco withdrawal symptoms and user satisfaction](#), 2009.
- Health Canada, [Product Information](#), 2023.
- FDA, [FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information](#), 2020.
- Tobacco Control, [Effect of IQOS introduction on cigarette sales: evidence of decline and replacement](#), 2020.
- Cochrane Database of Systematic Reviews, [Heated tobacco products for smoking cessation and reducing smoking prevalence](#), 2022.

- JMIR Public Health Surveillance, [Comparing the Effectiveness, Tolerability, and Acceptability of Heated Tobacco Products and Refillable Electronic Cigarettes for Cigarette Substitution \(COPAS-ETRE\): Randomized Controlled Trial](#), 2023.
- The Public Health Agency of Sweden, [Use of tobacco and nicotine products \(self-reported\) by age, gender and year](#), 2022.
- The Public Health Agency of Sweden, [Tobacco smoking, daily by age, sex and year: Share \(percentage\)](#), 2022.
- Ministry of Health of New Zealand, [Annual Data Explorer 2022/23: New Zealand Health Survey](#), 2023.
- UK Parliament, [Smoke-free Society by 2030](#), 2021.
- Office for National Statistics (UK), [Adult smoking habits in the UK: 2022](#), 2023.
- Japan Tobacco Association, [Heat-not-burn tobacco sales results \(quantity/price\) list by year and list of sales results \(quantity/price\) trends by year](#), 2023.
- Cancer Council Victoria, [Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023](#), 2023.