

NO FIRE, NO SMOKE
GLOBAL STATE OF TOBACCO
HARM REDUCTION

2018

No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018

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Executive Summary

No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018

The GSTHR report maps for the first time the global, regional and national availability and use of safer nicotine products, the regulatory responses to these products, and the public health potential of tobacco harm reduction.

Every six seconds someone dies from a smoking-related disease and the problem is likely to worsen; the steep smoking declines in richer countries are slowing while in poorer countries smoking is set to rise. Existing forms of tobacco control are proving insufficient. While many people give up smoking, on their own or with medicinal products, many fail. 'Quit or die' is no longer the only option for those who cannot give up. Safer nicotine products offer another way. There is substantial international, independent evidence that these products are demonstrably safer than cigarettes. These potential lifesaving products could lead to a global revolution in public health.

The global smoking epidemic

- » More people smoke cigarettes than use any other form of combustible tobacco products
- » The tobacco cigarette is the most dangerous way of consuming nicotine
- » The combustion of tobacco is the problem – combustion releases highly dangerous toxins
- » People smoke for the nicotine but die from the tar and gases

- » Smoking is a major contributor to deaths from non-communicable diseases
- » It is the poor who suffer most from smoking and the poorest countries are least able to enforce effective tobacco controls
- » Many people give up smoking on their own and some with the help of medicinal products, but many fail
- » The steep declines in smoking prevalence in higher income countries are beginning to slow while in many poorer countries smoking is set to rise
- » Existing forms of tobacco control are not enough to help people shift away from smoking tobacco

Safer nicotine products and tobacco harm reduction

- » Safer Nicotine Products (SNP) deliver nicotine with a significant reduction in risk as compared to combusted tobacco products – there is 'No Fire, No Smoke'
- » International evidence shows that these products are safer for the individual smoker, immediate family and bystanders than smoking cigarettes
- » The provision of safer ways of delivering nicotine enables people to continue using nicotine but to avoid the health risks of smoking
- » 'Quit or Die' is no longer the only option for those who cannot give up nicotine. SNP – including e-cigarettes, heat-not-burn products and Swedish snus offer another way – 'Quit or Try'
- » The rapid rise in the use of SNP has been driven by consumer demand often in the face of public health or government opposition
- » Flawed science, misleading public information and sensational media reporting are all sowing seeds of doubt about SNP among consumers, politicians and the general public
- » Banning these products, or subjecting them to onerous regulation or high taxation effectively deny access to potentially lifesaving products
- » SNP could not only effect a global revolution in public health but also at no cost to governments

Key figures

Smoking

- » Every six seconds a person dies from a smoking-related disease
- » Half of all those who smoke will die prematurely from a smoking-related disease

- » Over six million people die from a smoking-related disease every year
- » More people die from smoking cigarettes than from malaria, HIV and tuberculosis combined
- » The WHO estimates that by the end of the century one billion people will have died from a smoking-related disease
- » The global cost of smoking-related diseases in terms of health care and lost productivity is estimated by the WHO at USD \$1 trillion annually

Safer nicotine products

- » E-cigarettes are estimated to be 95% safer than smoking cigarettes
- » Snus is not inhaled, so there is no risk of respiratory disease which accounts for nearly half of all smoking-related deaths; and no risk to bystanders. There is no significant association with premature deaths, diabetes, pancreatic and oral cancers, heart disease or strokes
- » It is estimated that by 2021, over 55 million people will be using e-cigarettes or heat-not-burn tobacco products and that the global market will be worth USD \$35 billion
- » Use of heat-not-burn products in Japan has seen cigarette sales fall by 27% in two years, an unprecedented national decrease in smoking
- » In Sweden snus has been instrumental in reducing smoking related mortality to the lowest in the EU
- » If the EU ban on snus is lifted, then around 320,000 premature deaths a year could be prevented in the EU
- » As Norwegian smokers switch to snus, the smoking rate among young Norwegian women has dropped to a world record of 1%
- » Over 50% of the UK's 3 million e-cigarette users are ex-smokers
- » 39 countries have inappropriately banned SNP including countries whose smoking prevalence is predicted to rise
- » 62 countries regulate e-cigarettes under tobacco legislation.

The report - key themes

The GSTHR report is founded on the principle of harm reduction. Harm reduction refers to policies, regulations and actions focussed on reducing health risks, usually by providing safer forms of hazardous products or encouraging less risky behaviours, rather than simply banning products or behaviours. Harm reduction is a proven public health strategy.

How does tobacco harm reduction work in practice? It works through the provision of SNP allowing people to be able to consume nicotine without also inhaling the cancer-producing chemicals found in cigarette smoke. New products include e-cigarettes which first appeared in the mid-2000s. More recently, heat-not-burn devices have been developed that work by heating tobacco below the level of combustion sufficient to release the nicotine but with significantly reduced levels of toxins. Smokeless Swedish snus has been around for about 200 years but has enjoyed a renaissance in the light of the evidence that it makes a significant contribution to tobacco harm reduction.

SNP and health. Independent national scientific, clinical and parliamentary reviews have concluded that:

- » There are no circumstances in which it is safer to smoke than to use SNP
- » There is a continuum of risk, with cigarettes the highest and non-combustible products the lowest risk
- » People who switch from smoking to vaping can experience an improvement in health
- » Switching to vaping can help people quit smoking
- » There are currently no known long-term adverse health effects of vaping or snus
- » While young people will experiment with e-cigarettes, there is no evidence that this leads to regular cigarette smoking. Smoking rates among young people are falling.
- » There is no evidence for adverse effects from passive vaping – hence no risk to bystanders
- » There are no known short or long term adverse effects from using nicotine meaning that being 'dependent' on nicotine of itself is not a health risk

Harm reduction is more than just health and safety - there is an important

human rights aspect. The preamble to the World Health Organization Constitution 1946 states that *"The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition"*. This includes smokers and their right to information, services and products that may assist them to achieve that objective.

Smokers should not be denied access to harm reduction products that will help them avoid disease and early death from smoking. This is recognised in

the Framework Convention on Tobacco Control 2005 which states that harm reduction is one of the defining strategies of tobacco control: *“A range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke”*.

Consumers of SNP. In only a few years there has been rapid uptake in the use of the newer SNP in many countries while in both Sweden and Norway snus has replaced smoking over a relatively short space of time. In Japan the uptake of heat-not-burn products has seen the biggest ever drop in cigarette sales. This indicates an appetite for SNP such that where they are available – and if they are attractive and suitable alternatives to smoking – many smokers will choose them over smoking.

A key question is whether use of SNP drives down smoking and improves public health. The strongest evidence so far comes from Sweden where the uptake of snus and the decline in smoking has given this country the lowest smoking related mortality in Europe.

The uptake of SNP has mostly occurred in the absence of government, tobacco control and public health endorsement. It has been the ordinary consumers whose interest in SNP has driven this and who have been active in offering help and advice to those who wish to switch from smoking.

Regulation and control. The advent of new SNP presents challenges to tobacco control regimes at both a national and international level. A consumer can vape nicotine reasonably freely in the USA, UK and New Zealand, but faces fines or imprisonment in Thailand and Australia.

Legislators and politicians are no less immune than health professionals or ordinary consumers to being confused by contradictory research findings or influenced by the work of anti-harm reduction organisations and sensationalised media reporting.

To use the law to deny or inhibit access to SNP denies the robust and independent evidence base, and paradoxically perpetuates use of cigarettes (which are freely available the world over) and ensures continuing profits for tobacco companies.

Appropriate regulation should ensure consumer safety and confidence, encourage product innovation, and favour use of SNP over cigarettes.

The harm reduction vision. It is imperative to keep eyes on the prize – an end to smoking – and not allow over-proscriptive regulation and control to deny access to safer products. SNP have the potential to be one of the most dramatic public health coups of modern times. While most global public health interventions come at great financial cost, this strategy costs governments, international agencies and NGOs nothing.

Scope and terminology

This Global State of Tobacco Harm Reduction (GSTHR) report was conceived against the backdrop of the major changes in tobacco harm reduction of the last decade. It takes its inspiration from the Global State of Harm Reduction report, which was first published by the International Harm Reduction Association (now called Harm Reduction International) back in 2006 and which is about to go into its sixth iteration.

It tracks the progress or otherwise of drug harm reduction throughout the world.

In the same vein, the GSTHR report is the first attempt to map global, regional and national changes in the availability and use of safer nicotine products and the regulatory response, with the aim of updating this information on a biennial basis.

The information in the GSTHR will be useful for policy-makers, policy analysts, consumers, legislators, regulators, civil society organisations, media, public health workers, academics and researchers, as well as manufacturers and distributors.

The report focuses on those products that are considered to be safer alternatives to combustible tobacco products such as cigarettes, cigars, and pipes. In policy terms, these safer products are generally considered to be tobacco harm reduction products, because they deliver nicotine with a significant reduction in risk as compared to combusted tobacco products.

There are many different terms for tobacco harm reduction products, including alternative nicotine products, new or novel nicotine products, next generation products, modified risk products, reduced risk products, and electronic nicotine delivery systems (ENDS). For the purpose of consistency, this report **refers to safer nicotine products (SNP)** when referring to all the tobacco harm reduction products: electronic-cigarettes (e-cigarettes), heat-not-burn (HNB) products and Western-style smokeless tobacco, particularly Swedish pasteurised snus. Forms of smokeless tobacco, such as betel quid, paan and gutkha, are not covered in this report. However, the products that currently have the most global reach are e-cigarettes. It is the current state of these products in terms of epidemiology, health research, use and control that is most reflected in this report.

Website

An interactive GSTHR website is available at www.gsthr.org, where you will find a downloadable PDF version of the report, country-by-country profiles, and slide versions of some of the infographics and tables. There is also a short summary of the report available with translations in various languages.

Updating

It is expected that this report will be updated every two years. However, the website will be updated regularly and therefore it would be very helpful if you could notify us of any new information, or information that may need to be corrected. Please contact us at www.gsthr.org/update and complete the online web form.

Data sources and report limitations

A wide range of data sources have been used to gather evidence on the prevalence of smoking, regulations and on the availability and use of SNP and legal and regulatory provisions.

The most recent World Health Organization (WHO) statistics have been used to outline smoking prevalence and related mortality globally and on a country-by-country basis. These data are readily available online.

Websites that interpret data have also been used as reference data in this report, including: *Our World in Data*,¹ an online data resource produced by the Oxford Martin Programme on Global Development at the University of Oxford; and *The Tobacco Atlas*,² an online resource that maps the nature and magnitude of tobacco use and is produced in partnership with the American Cancer Society and Vital Strategies. Information on the regulation of e-cigarettes has largely been gathered via *Vapetrotter*,³ a commercial website with a store directory and a database of vaping laws in each country, which is regularly updated.

¹ Oxford Martin Programme on Global Development, University of Oxford, *Our World in Data* <https://ourworldindata.org/smoking>

² American Cancer Society, *Tobacco Atlas* <https://tobaccoatlas.org>

³ *Vapetrotter* <https://www.vapetrotter.com/laws/>

Key contacts from academia, public health, policy institutes, industry and advocacy organisations in various countries have kindly provided information on e-cigarettes, snus and the availability of heat-not-burn products, where this has not been openly available from published sources.

Methodologies of estimates, survey dates, sample sizes, representativeness and categorisations of types of smoker or SNP users vary between studies, and this makes it very difficult to compare like with like in many cases. There is no standard approach to gathering data on SNP. Therefore, while the data displayed are accurate for each country, it may well have been gathered differently, or analysed differently across countries. Where we know this is the case, it is noted in the text. Readers are therefore advised to use caution if comparing one country's profile with another.

There are large gaps in the data on SNP, and the situation in terms of regulation and estimates of the prevalence of their use is changing all the time. The rapid growth and continuing development of SNP means that the whole landscape, from market analysis to control regimes, is very fluid and dynamic.

While every effort has been made to provide accurate information including on the legal status of SNP, Knowledge-Action-Change cannot be held responsible for any action taken on the basis of information contained in the report. The purpose of the report is to convey information in a consolidated format that may be relevant to interested parties, but no commercial or other decisions should be made on the basis of the compendium due to the limitations advised above.

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Forewords

Nancy Sutthoff

For all the political, public health, scientific, clinical and media discussions about safer nicotine products, there is little thought given to the consumers of these products, their reasons for utilising them, why they have found them to be effective and why they fight for the right to continue to use them. Which is interesting, because the genesis of tobacco harm reduction was entirely consumer driven. Those that would tell you that vaping is a “big tobacco construct” cannot believe that something so disruptive, so widespread and so popular could possibly be anything other than a revenue-raising campaign from the marketing department of a major corporation. Frankly, this is insulting to the thousands of us who have found the technology – on our own, through our own research – as a means of self-determination of our own health and wellbeing.

For some it was about the negative health effects of smoking, for others it was about the financial impact of increased taxes on tobacco that were negatively impacting the family budget. But for ALL of us, it was about making an individual, informed choice about our wellbeing. Most of us had tried “medically approved” nicotine replacement therapy for smoking cessation offered by the health system and had failed. Yet we persisted and found both vaping and the solution we needed.

But the switch is not just about health. While many may have begun to vape to switch from combustible tobacco, many now continue to vape as a lifestyle choice using a consumer product rather than a smoking cessation aid or a medicine. There have been entire communities built upon the shared journey of vape from a diverse cross-section of society. I have been at vape meets where government ministers, teachers, ex-gang members and housewives have sat together and had discussions that range from the weather to the latest sport scores, over a pint or glass of wine. As a social construct, vaping has created a support system and community that is egalitarian and tolerant.

Perhaps those opposed to tobacco harm reduction should think hard about how condoms prevent the spread of sexually transmitted infections and unwanted pregnancies, about how vaccinations have wiped polio off the face of the planet, or even all the different ways that their road travel is now far safer from seat belts

to crash helmets and then get back to us about what harm reduction and self-determination of wellbeing really means. The door is open, and we are waiting to have that conversation on equal, neutral territory.

Nancy Sutthoff is Co-founder and Co-Director of Aotearoa Vapers Community Advocacy (AVCA) in New Zealand (www.avca.org). She is also the President of the governing board of INNCO (the International Network of Nicotine Consumer Organisations (www.innco.org)): an international group of over 30 consumer organisations that work towards advocating for the rights of users of alternative nicotine consumption technologies.

David Sweanor

Our world has over a billion people smoking cigarettes, spending roughly US\$800 billion annually. Add in all those smoking other tobacco products (bidis, kreteks, etc.) and we face a seemingly unbeatable adversary as we seek to tackle the myriad diseases caused from the inhalation of smoke. But look more creatively, and we are facing not an insurmountable challenge so much as a tremendous opportunity.

At a time when new disruptive technology is upending so many markets, the technology of the cigarette (setting fire to dried leaves) is from the Stone Age. And unlike many other areas, where new products meet needs many of us did not know we had (who really had a pressing need to check what friends in another country were doing while out walking the dog?), the consumers of cigarettes are already highly dissatisfied with the status quo. Many want to stop smoking because they know the product is killing them.

Fortunately, we now have rapidly accumulating evidence that a range of non-combustion products can replace cigarettes. Together smokeless Swedish snus (which has actually been around for over 200 years), e-cigarettes and heated tobacco devices have led to massive declines in smoking in countries such as Japan, Norway, South Korea, the UK, France and Iceland.

These breakthroughs have largely occurred despite opposition from regulators, major health bodies and anti-smoking groups. Which raises the question of just how rapidly we could consign cigarettes to the ashtray of history by facilitating better options, better consumer information and the use of risk-proportionate regulation?

We have the ability right now to redirect market forces to solving the cigarette pandemic. As with past transformations, the problem is actually a solution awaiting those with the vision to see it and the willingness to seize the opportunity.

David Sweanor is Chair of the Centre for Health Law, Policy and Ethics and an Adjunct Professor of Law at the University of Ottawa. He has worked on tobacco and health issues since the early 1980s and played a key role in a wide range of Canadian and global tobacco control precedents. Recently, he has spent much of his time focused on appropriate policies for reduced risk products.

Martin Jarvis

More than 40 years have passed since Michael Russell's key insight: that cigarette smoking is fundamentally a form of nicotine-seeking behaviour. This led to his celebrated dictum that "people smoke for nicotine, but they die from the tar". That should have made tobacco use the poster boy for harm reduction approaches: nicotine, while not harmless, does not contribute much to smoking's effects on health. Cleaning up its contaminated delivery system, the cigarette, should radically mitigate the resulting burden of morbidity and mortality.

Unfortunately, there were numerous missteps and own-goals before tobacco harm reduction could begin to take on a semblance of plausible reality. Low-tar cigarettes offered the promise but not the reality of reduced exposure; nicotine replacement products, at least as formulated and marketed by pharmaceutical companies, reduced withdrawal and modestly assisted cigarette cessation, but did not offer consumers a satisfying way of using nicotine; in 1992, the European Union, aided and abetted by tobacco control activists, implemented an EU-wide ban on Swedish-type snus (the only real-world example of tobacco harm reduction in action); a ban that still stands some 25 years later. Most importantly, researchers had no success in developing alternative, non-combustible, forms of nicotine delivery that could compete with cigarettes.

Everything began to change in the early 2000s with the launch of the first electronic cigarettes. Developments in battery technology (driven by the needs of the mobile phone industry) and sophisticated electronic controls initiated a technological revolution which is still gathering pace, and began a process of

market disruption in the way consumers ingest nicotine. Increasingly effective vaping devices which permit consumers to titrate their nicotine intake have gained market share and have now been joined by heat-not-burn products which mimic cigarette pharmacokinetics but with much reduced toxicant yields.

The challenge now does not come so much from achieving viable non-combustible alternatives to the cigarette, although a process of continued evolution towards better products seems inevitable. The more intractable questions, about a transition away from cigarettes to non-combustibles, concern governments and regulatory authorities. Does the new generation of nicotine devices represent just the same old evil tobacco industry in a new disguise? Should vaping be encouraged or banned? How should it be taxed, how promoted, and what form should product regulation take? Is vaping among young people a major concern, and if so, how can they be protected? These issues have provoked bitter debate and schism and no consensus is yet in view. There is an urgent need for evidence and for informed discussion. This report forms a valuable contribution to that process.

Martin Jarvis is Emeritus Professor of Health Psychology at the Department of Behavioural Science and Health, University of London. He was for many years a close colleague of Michael Russell in his smoking research group. Over the past 40 years, he has researched and published widely on nicotine and tobacco. He was Specialist Adviser to the UK House of Commons Health Committee's inquiries into tobacco and health and into smoking in public places. He is a trustee of UK Action on Smoking and Health (ASH). He was for some years a member of the WHO's study group on Tobacco Product Regulation. He received the John Slade award of the Society for Research on Nicotine and Tobacco.

Key acronyms and abbreviations

ASH - Action on Smoking and Health (UK)

AFNOR - Association Française de Normalisation

BAT - British American Tobacco

BSI - British Standards Institute

CDC - Center for Disease Control and Prevention (USA)

CDER - Center for Drug Evaluation and Research (USA)

CEN - European Committee for Standardisation

COP - WHO Framework Convention on Tobacco Control, Conference of the Parties

COT - Committee on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment (UK)

CTP - Center for Tobacco Products (USA)

ENDS - Electronic Nicotine Delivery Systems

ESTOC - European Smokeless Tobacco Council

FCTC - WHO Framework Convention on Tobacco Control

FDA - US Food and Drug Administration

GSTHR - The Global State of Tobacco Harm Reduction

HNB - Heat-not-burn

HPHCs - Harmful and potentially harmful constituents

IARC - International Agency for Research on Cancer

ISO - International Organisation for Standardisation

JTI - Japan Tobacco International

LMIC - Low and middle-income countries

MHRA - Medicines and Healthcare products Regulatory Agency (UK)

MRTPA - Modified Risk Tobacco Product Application

NCD - Non-communicable diseases

NGO - Non-governmental organisation

NRT - Nicotine Replacement Therapy

ONS - Office for National Statistics (Great Britain)

PAHs - Polycyclic aromatic hydrocarbons

PMI - Philip Morris International

PMTA - Pre-Market Tobacco Application (USA)

RCP - Royal College of Physicians (UK)

SDA - UN 2030 Sustainable Development Agenda

SNP - Safer nicotine products

TPD - Tobacco Products Directive (EU)

TPSAC - Tobacco Products Scientific Advisory Committee (USA)

TSNAs - Tobacco-specific nitrosamines

WCO - World Customs Organization

WHO - World Health Organization

Chapter 1

Introduction: tobacco harm reduction

'Harm reduction' refers to policies, regulations and actions that are focused on reducing health risks, usually by providing safer forms of hazardous products, or encouraging less risky behaviours, rather than simply focusing on eradication of products or behaviours.

Arguably, harm reduction as a purely medical intervention (and not at the time called harm reduction) can be traced as far back as the 1920s. Following the first legal bans on the unauthorised possession of opiates, some doctors in both the USA and the UK prescribed morphine or heroin to dependent patients to help them manage their condition. In 1926, a committee of UK doctors agreed that as a treatment of last resort, it was legitimate medical practice to prescribe morphine, heroin or cocaine to a drug-dependent patient.¹

Consumer-led drugs harm reduction emerged in the 1960s, with the rise of recreational drug use across North America and Europe, and the development of lay advice about how to use drugs in a safer way.² Alcohol harm reduction goes back to early provisions to regulate the content of alcoholic drinks, in order to reduce contamination and risk of poisoning. Later, there were attempts to modify drinking practices in drinking venues (for example during the First World War), and by the 1970s, there was interest in making drinking safer for drinkers and those affected by drinking.

Our everyday lives are replete with examples of potentially dangerous products or behaviours being modified – often by manufacturers, regulators or consumers – to enable use of the product while reducing risk of harm. Consider, for example, the design of motor vehicles and roads to make travel safer, laws that separate drinking and driving, and driver licensing and education. Or the introduction of products offering safer options, such as refrigerators and improved food storage, leading to a reduction in disease due to food

contamination. This is harm reduction in practice, though rarely in name. It is notable too that many interventions to reduce risk emanate from manufacturers and consumer demand, or from regulators, but not necessarily from public health practitioners.

But, harm reduction as a health strategy came to prominence during the HIV/AIDS epidemic of the 1980s. The phrase came to be associated with those in gay communities on the American west coast and in New York, who banded together in grassroots action groups to help protect their health in the face of fear and vilification from society at large. This was encapsulated in the slogan 'safer sex' which acknowledged that sexual abstinence was not a moral or feasible method for preventing HIV transmission, and that condoms and safer sexual behaviour were key.

Once it became clear that those people who injected drugs were similarly at risk, new movements arose around the world to campaign for health interventions such as needle and syringe exchanges, opiate substitute therapy, overdose prevention and drug consumption rooms, that would help preserve the lives of those who, for whatever reason, continued to inject drugs.

Drug harm reduction is defined by Harm Reduction International as "Policies, programmes and practices that aim to reduce the harms associated with the use of psychoactive drugs in people unable or unwilling to stop. The defining features are the focus on the prevention of harm, rather than on the prevention of drug use itself, and the focus on people who continue to use drugs".³

This means that harm reduction is more than just health and safety, more than just the equivalent of wearing seats belts or crash helmets. It sits at the intersection of public health and human rights as expressed in the WHO Ottawa Charter on Health Promotion, which states that "People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health".⁴ In the 'carrot and stick' approaches to encouraging

¹ Departmental committee on morphine and heroin addiction, Ministry of Health. *Rolleston report*. Ministry of Health, UK, 1926

² Stimson, G.V., Minimising harm from drug use. In Strang, J. and Gossop, M. (eds) *Heroin Addiction and Drug Policy: The British System*. Oxford University Press, 1994

³ Harm Reduction International, *What is harm reduction? A position statement* <https://www.hri.global/what-is-harm-reduction>

⁴ World Health Organization. *Ottawa Charter for Health Promotion*. WHO, 1986. Available at <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>

changes in human behaviour, harm reduction is firmly at the carrot end of the strategy, with an ethos that sustainable changes in behaviour originate in, and are continued, only if they fit with what people both want and are able to do.

“Harm reduction is actually more than just health and safety... It sits at the intersection of public health and human rights”.

Smoking lagged behind other areas regarding harm reduction because there were few reduced risk options for smokers, with the exception of snus in Scandinavia and US smokeless tobaccos. From the 1980s onwards, the main tobacco harm reduction product was nicotine replacement therapy (NRT): the provision of controlled doses of pure nicotine via gums, patches, lozenges, inhalers and sprays. NRT was first used in the USA in 1984. It is now the medically approved way to consume nicotine without tobacco and is on the WHO’s List of Essential Medicines. Though still banned or tightly regulated in some countries, in others NRT is widely available, and in many places, it can be obtained without prescription.

Since the mid-2000s, however, a new harm reduction front has opened. We have seen the dramatic rise of electronic cigarettes (e-cigarettes), together with the realisation of significant public health gains from the switch from combustible tobacco to smokeless tobacco (snus) in Sweden,⁵ and a proliferation in the range of newer products, such as heat-not-burn (HNB) devices.

*“The tobacco harm reduction proposition is straightforward: smokers risk disease and premature death; most smokers say they want to stop smoking and many have tried; many find it hard to stop and many are unable or unwilling to give up nicotine. The provision of safer ways of delivering nicotine enables people to continue using nicotine but to avoid the health risks of smoking”.*⁶

The tobacco cigarette remains the most dangerous of all nicotine delivery systems. Harm reduction products have greatly expanded the choice for consumers who wish to continue to enjoy nicotine without the risks inherent in cigarettes, or who are looking for a more acceptable way to quit smoking than that provided by cold turkey, counselling, medicinal products, or NRT. With these products, quitting smoking can be pleasurable, rather than burdensome. It also

provides governments with an additional tool to reduce harms from smoking, alongside measures to reduce supply and demand, such as tobacco taxes, age restrictions, advertising restrictions and bans on smoking in public places.

“The tobacco cigarette remains the most dangerous of all nicotine delivery systems”.

These technological advances in nicotine delivery have been accompanied in some countries by developments and changes in the profile of manufacturers and distributors, product innovation, investment in research and development, and a market driven by product availability and consumer choice. In turn, this has raised challenges for governments in terms of appropriate regulatory models, resulting in conflicts between the aims of international tobacco control and the individual right to health.

The idea of tobacco harm reduction can be traced to Professor Michael Russell, a UK psychiatrist. He observed that people smoke for the effects of nicotine, but that illness and premature mortality result from the tar that they inhale. Russell pointed to the health gains that might be achieved if the tar in cigarettes could be reduced, while maintaining nicotine levels.⁷

“A case is advanced for selected nicotine replacement products to be made as palatable and acceptable as possible and actively promoted on the open market to enable them to compete with tobacco products. They will also need health authority endorsement, tax advantages and support from the anti-smoking movement if tobacco use is to be gradually phased out altogether.

“It is essential for policy makers to understand and accept that people would not use tobacco unless it contained nicotine, and that they are more likely to give it up if a reasonably pleasant and less harmful alternative source of nicotine is available. It is nicotine that people cannot easily do without, not tobacco.

⁵ Foulds J. et al. (2003). Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control*, 12:349-359

⁶ Stimson, G.V. (2016) A tale of two epidemics: drugs harm reduction and tobacco harm reduction in the United Kingdom. *Drugs and Alcohol Today*, 16 (3), p. 203-11

⁷ Russell, M.J. (1976) Low-tar medium nicotine cigarettes: a new approach to safer smoking. *British Medical Journal*. 1, p. 1430-3

"It will be assumed throughout that our main concern is to reduce tobacco-related diseases and that moral objections to the recreational and even addictive use of a drug can be discounted provided it is not physically, psychologically or socially harmful to the user or to others".

Michael Russell, *British Journal of Addiction*, 1991.⁸

Tobacco harm reduction has travelled a separate but parallel road to drugs, sex and alcohol harm reduction. There might be some as yet unexplored synergies: Michael Russell, for example, started his work at the Addiction Research Unit at the Institute of Psychiatry in London at the same time that the unit was researching heroin prescribing as a way of reducing risks for heroin users.

Tobacco harm reduction was advocated by the UK Royal College of Physicians (RCP) in the 2007 report *Harm reduction in nicotine addiction*. The report argued that "Harm reduction in smoking can be achieved by providing smokers with safer sources of nicotine that are acceptable and effective cigarette substitutes" and suggested the potential for rebalancing the market in favour of the safest nicotine products.⁹ At the time the report was written, the only safer nicotine option for most smokers was NRT. The exception was in Sweden, where snus – a moist, pasteurised low-risk oral tobacco – is popular amongst men and accounts for Sweden's low prevalence of lung cancer. The RCP put snus forward as proof of concept for tobacco harm reduction.

The following quotes demonstrate an increasing global recognition for tobacco harm reduction.

"We suggested [in 2007] that making effective, affordable, socially acceptable, low-hazard nicotine products available to smokers as a market alternative to cigarettes could generate significant health gains by allowing smokers to stop smoking tobacco without having to stop using nicotine to which they are addicted. As most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke, the health and life expectancy of today's smokers could radically be improved by encouraging as many as possible to switch to a smoke-free source of nicotine".

Royal College of Physicians, *Nicotine without smoke*, 2016.¹⁰

"We will help people quit smoking by permitting innovative technologies that minimise the risk of harm. We will maximise the availability of safer alternatives to smoking".

UK Department of Health, *Towards a smoke-free generation*, 2017.¹¹

"The BMA's ambition is to achieve a tobacco-free society, where there is significantly reduced mortality from tobacco-related diseases. Given that e-cigarettes are now the most popular device used in attempts to quit smoking, and that many people have used them to successfully quit tobacco use, they have significant potential to support this ambition, and help reduce tobacco-related harm".

British Medical Association, *E-cigarettes: balancing risks and opportunities*, 2017.¹²

"These individuals [who cannot quit smoking] should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products".

American Cancer Institute, *Position statement on e-cigarettes*, 2018.¹³

⁸ Russell, M. J. (1991) The future of nicotine replacement. *British Journal of Addiction*. 86(5), p. 653-8. Available at <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1360-0443.1991.tb01825.x>

⁹ Tobacco Advisory Group, Royal College of Physicians. *Harm reduction in nicotine addiction: helping people who can't quit*. London, RCP, 2007. p. 241

¹⁰ Tobacco Advisory Group, Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London, RCP, 2016. p.11. Available at https://www.rcplondon.ac.uk/file/3563/download?token=MuoK_ZR0

¹¹ UK Department of Health. *Towards a smoke-free generation: a tobacco control plan for England*. DH, 2017. p.5. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-_A_Tobacco_Control_Plan_for_England_2017-2022__2_.pdf

¹² British Medical Association. *E-cigarettes: balancing risks and opportunities*. BMA, 2017. p. 11. Available at <https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes>

¹³ American Cancer Institute, *Position statement on e-cigarettes* (2018)

<https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html>

“If long term smokers who have been unable to quit smoking tobacco cigarettes switch to e-cigarettes, thousands of lives could be saved”.

Trent Zimmerman MP, Chair of the Australian parliamentary committee report into the use and marketing of electronic cigarettes and personal vaporisers in Australia, 2018.¹⁴

“If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement”.

WHO, Electronic nicotine delivery systems and electronic non-nicotine delivery systems, 2016.¹⁵

“Tobacco control” means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke”.

WHO, Framework Convention on Tobacco Control, 2003.¹⁶

Conclusion

We end this chapter by putting forward what might be called the tobacco harm reduction proposition, which states that:

- » Harm reduction is based on the principle of trying to reduce the risk of using certain products or engaging in certain behaviours or activities;
- » It recognises the reality of aiming to reduce risk rather than believing that risk can be eliminated;
- » There are examples of harm reduction in many areas of daily life, such as road safety;
- » But in the context of public health it has particular resonance, existing as it does at the crossroads between public health and human rights;
- » The pioneering examples operating at this intersection were the grassroots activity among the gay and drug-using communities, looking to protect their health through safer sex and drug-using strategies in the face of official marginalisation and discrimination;

- » In the same way that unsafe sex and drug injecting leaves the individual at risk of life-threatening disease, the cigarette, as the most dangerous nicotine delivery system, similarly puts the smoker at risk of disease and death;
- » However, there is increasing international recognition that new options now exist for the smoker who cannot or does not want to stop consuming nicotine, but wants to switch away from smoking.

But, before we examine those new and safer options in detail, we look at the key driver for the report, the imperative behind all forms of tobacco control and the issue on which all those involved in public health can agree: the need to counteract the devastating impact of the global smoking epidemic.

¹⁴Trent Zimmerman MP. Foreword to the Australian parliamentary committee report into the use and marketing of electronic cigarettes and personal vaporisers in Australia. March 2018, p.5. Available at https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Report

¹⁵World Health Organization. Framework Convention on Tobacco Control: *Electronic nicotine delivery systems and electronic non-nicotine delivery systems (ENDS/ENND)*; a report by WHO. WHO, 2016. p.2. Available at www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf

¹⁶World Health Organization. Framework Convention on Tobacco Control. WHO, 2003. Article 1, para (d) p.4. Available at whqlibdoc.who.int/publications/2003/9241591013.pdf



The need for tobacco harm reduction is apparent from global data on smoking. The statistics relating to smoking-related mortality and morbidity across the world are grim:

Smoking tobacco results in the world's deadliest preventable diseases, prematurely ending the lives of half of all smokers.

Smoking cigarettes is a major cause of lung and oral cancer, progressive respiratory diseases such as emphysema, and heart disease.

One person dies from a smoking-related disease every six seconds.

Over six million people die from a smoking-related diseases every year.

More people die from smoking cigarettes than from malaria, HIV and tuberculosis combined.

The WHO estimates that by the end of the century one billion people will have succumbed to a smoking-related disease.¹

The US Surgeon General's report on tobacco published in 2014 estimated that in the 50 years since 1964, 20 million American citizens had died from a smoking-related disease.

The global cost of treating smoking-related diseases in terms of healthcare and lost productivity is estimated by the WHO at US\$1 trillion annually.²

Smoking-related death and disease disproportionately affects those living in poverty and deprivation in richer countries, and those with mental health and other substance use problems.

¹ World Health Organisation. WHO report on the global tobacco epidemic. WHO, 2008. Available at www.who.int/tobacco/mpower/mpower_report_tobacco_crisis_2008.pdf

² US National Cancer Institute and World Health Organisation. The Economics of Tobacco and Tobacco Control. National Cancer Institute Tobacco Control Monograph 21. NIH Publication No. 16-CA-8029A. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organisation; 2016

Chapter 2: The continuing global epidemic of cigarette smoking

"The WHO estimates that by the end of the century one billion people will have succumbed to a smoking-related disease".

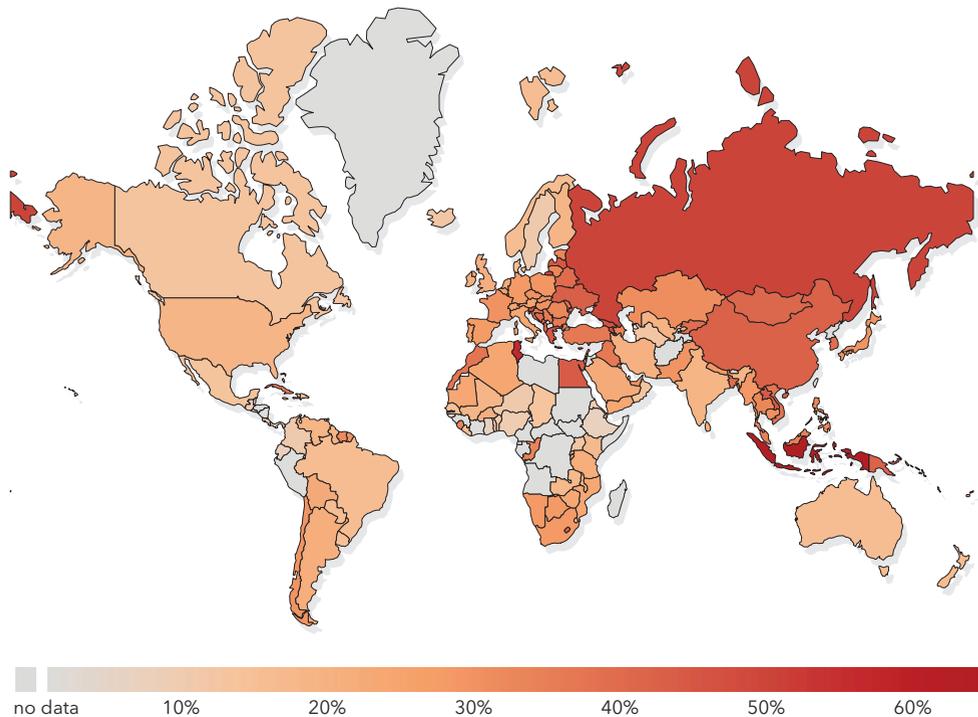
There are large differences between countries in the overall levels of smoking, and in the levels of smoking between men and women. According to WHO data for 2015, in 26 countries the prevalence of daily smoking amongst men is above 40 percent: in Indonesia, a staggering 65 percent of adult males smoke; 61 percent in East Timor; 57 percent in Tunisia; 51 percent in the Russian Federation and in Kiribati; 48 percent in Syria; 46 percent in Georgia and Armenia, 45 percent in Laos, Greece and Latvia; 44 percent in the Maldives and Egypt; 43 percent in the Solomon Islands and Ukraine; 42 percent in China, Papua New Guinea and Cyprus; 42 percent in Lesotho; 41 percent in Albania and Mongolia; and 40 percent in Bosnia and Herzegovina, Montenegro, Bangladesh, Belarus and Micronesia.³

These high levels persist despite major global initiatives led by the WHO to reduce smoking, and despite the investment of billions of dollars in tobacco control to reduce demand and supply.

The prevalence of smoking is lower globally among women than amongst men. This global picture of the differences in daily smoking prevalence between men and women is shown in Figs 2.1 and 2.2.

³ These data indicate of the national challenge to reduce smoking-related harms. Country profiles can be seen at www.gsthr.org

Figure 2.1
WHO estimate of daily (tobacco) smoking prevalence age 15+ male

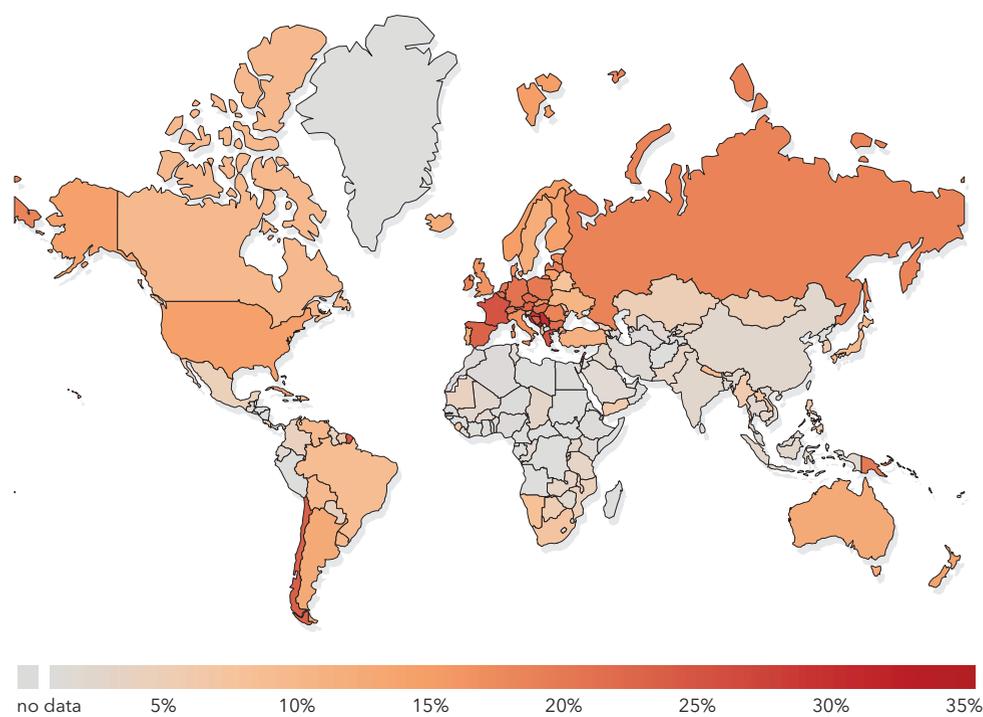


Source: WHO report on the global tobacco epidemic, 2017, Country profiles http://www.who.int/tobacco/surveillance/policy/country_profile/en/

In many higher income countries, levels of smoking have fallen since the early 1970s, and are now low by international standards as shown by Figure 2.3 (and defined as under 20 percent of adults smoking). This is largely due to greater public awareness of the importance of a healthier lifestyle including exercise, nutrition, diet, lower alcohol consumption, as well as the introduction of various tobacco control measures including advertising bans, smoke-free environments and higher taxation.

The WHO statistics in figures 2.1-2.3 demonstrate the comparison between countries based on 2015 data. Prevalence data changes over time - for example the latest UK Office for National Statistics report says 15.1% of people aged 18 years and above smoked cigarettes, considerably lower than the WHO adult smoking estimate.

Figure 2.2
WHO estimate of daily (tobacco) smoking prevalence age 15+ female



Source: WHO report on the global tobacco epidemic, 2017, Country profiles http://www.who.int/tobacco/surveillance/policy/country_profile/en/

However, despite reduced and lower levels of smoking in many countries, population growth adds to the increase in the total global number of smokers.⁴ This increase in the overall smoker numbers can be seen in Fig 2.4 which also forecasts further increases up until 2025.

In countries that have experienced steep falls in smoking prevalence over the years, the graphs have begun to level off, for example in Australia,⁵ suggesting there remains a substantial number of people who, for whatever reason, are determined to carry on smoking. The WHO trend data to 2025 predicts only very modest falls in smoking levels in several countries and predicts some rapid increases, mainly in Africa, the Middle East, some parts of Eastern Europe and republics of the former Soviet Union. Some of the more extreme examples

include Cameroon (from 14 percent to 43 percent); Republic of Congo (from 14 percent to 48 percent) and Bahrain (from 25 percent to 60 percent).⁶

Figure 2.5, from WHO data, shows the steep gradient of increases in smoking prevalence estimates in specific African countries, where the projected increases (both sexes) in daily smoking are 5 percent and higher.

Figure 2.3

Lowest prevalence of smoking in high income countries (2015)

Barbados	5.40%	Denmark	15.70%
Saint Kitts and Nevis	6.10%	United States	15.90%
Bahamas	8.10%	Finland	16.00%
Oman	9.10%	Qatar	16.40%
Canada	10.70%	Trinidad and Tobago	18.00%
Sweden	11.10%	United Kingdom	18.00%
Iceland	11.80%	Portugal	18.20%
Uruguay	11.80%	Luxembourg	18.40%
Saudi Arabia	13.00%	Kuwait	18.50%
Brunei	13.20%	Japan	19.10%
Singapore	13.30%	Ireland	19.30%
Australia	13.40%	Slovenia	19.30%
New Zealand	14.60%	Italy	19.80%
Norway	14.80%		

Source: WHO report on the global tobacco epidemic, 2017, Country profiles http://www.who.int/tobacco/surveillance/policy/country_profile/en/. Note: more recent national surveys may show different figures. Country data available at www.gsthr.org.

⁴ Institute for Health Metrics and Evaluation. Global Smoking Prevalence and Cigarette Consumption 1980-2012. IHME, 2014

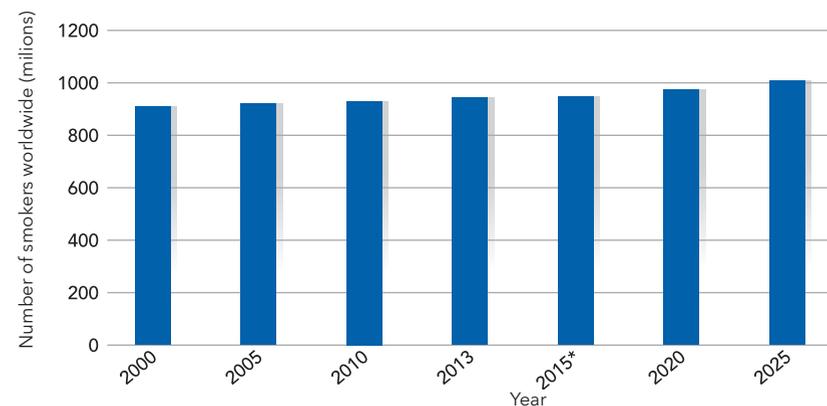
⁵ Data from Australian Institute of Health and Welfare household surveys from 1985 onwards presented by Professor Wayne Hall. E Cig Summit, London 2017

Available at <http://www.e-cigarette-summit.com/files/2014/07/16.25-Wayne-Hall.pdf>

⁶ World Health Organization. WHO global report on trends in prevalence of tobacco smoking 2015. WHO, 2015

Figure 2.4

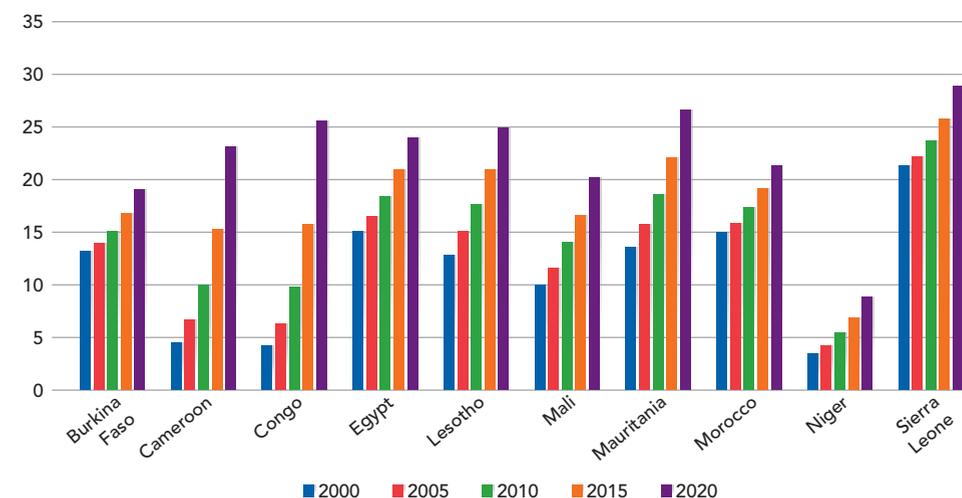
Increasing number of smokers worldwide



Sources: The Economist. 2017. Where is smoking on the rise? Available at: <https://www.economist.com/graphic-detail/2017/01/23/where-smoking-is-on-the-rise>

Figure 2.5

African region - increasing daily tobacco prevalence trends (male and female)



Note: These charts are projection estimates. The projection indicates a likely endpoint if the country maintains its tobacco control efforts at the same level that it has implemented to date.

Source: WHO global report on trends in prevalence of tobacco smoking 2015. Fitted daily smoking rates aged 15 & over. Point estimate (2015).

How well equipped is any low or middle-income country (LMIC) to deal with the smoking epidemic? No government is likely to reject, in principle, measures to reduce deaths and disease caused by smoking. But the degree to which countries can implement and enforce policies rather than simply signing up to good intentions is notably split between the 'developed' and the 'developing' world. As the authors of *Global Tobacco Control*,⁷ Cairney and Mamudu, point out, effective national implementation of the provisions of the 2005 WHO Framework Convention on Tobacco Control (FCTC) to which most countries signed up (see chapter six) is very much dependent on the overall public health climate.

"We identify the most relevant characteristics of the policy processes within 'leading' countries with the most comprehensive tobacco control: their department of health has taken the policy lead (replacing trade and treasury departments); tobacco is 'framed' as a pressing public health problem (not an economic good); public health groups are more consulted (often at the expense of tobacco companies); socioeconomic conditions (including the value of tobacco taxation, and public attitudes to tobacco control) are conducive to policy change; and, the scientific evidence on the harmful effects of smoking and second hand smoking are 'set in stone' within governments. These factors tend to be absent in the countries with limited controls. We argue that, in the absence of these wider changes in their policy environments, the countries most reliant on the FCTC are currently the least able to implement it".⁸

The numbers who die from smoking-related diseases are represented on the global map in Fig 2.6 and it is important to be clear that it is the smoking of tobacco that is the problem. *The Global Burden of Disease Study*⁹ calculates that in 2016 there were an estimated 6.3 million smoking-related deaths annually: 884,000 from second-hand smoke, and 48,000 from oral tobacco (none of which were related to snus).

There is a wider global concern here which relates to the UN 2030 Sustainable Development Agenda (SDA). The preamble states that, "This Agenda is a plan of action for people, planet and prosperity. It also seeks to strengthen universal peace in larger freedom. We recognize that eradicating poverty in all its forms and dimensions, including extreme poverty, is the greatest global challenge and an indispensable requirement for sustainable development", and that "nobody will be left behind".¹⁰

Goal 3 of the agenda is to "ensure healthy lives and promote well-being for all at all ages" with a sub-goal (3.4) of reducing premature deaths from non-communicable diseases (NCD) by one third by 2030. But as the recent WHO NCD report notes, "Country actions against NCDs are uneven at best. National investments remain woefully small and not enough funds are being mobilized internationally... There is no excuse for inaction, as we have evidence-based solutions".¹¹ The top three causes of NCD mortality are cardiovascular disease, cancer and respiratory disease; all closely associated with cigarette smoking.

When the American Cancer Society published the first edition of the Tobacco Atlas in 2002, the authors wrote, "The publication of this Atlas marks a critical time in the epidemic. We stand at the crossroads with the future in our hands". In the fifth edition (2015), they added "These words are as true today as they were then".

Given the devastating global public health impact of smoking, and concerns over a potential increase in the number of smokers in many parts of the world, it is undoubtedly logical for governments to embrace measures to enable the marketing of products which have the potential to switch smokers to less harmful alternatives. Regrettably, governments have been slow to follow this path, despite calls by many scientific, medical and policy commentators.

"Consumers have shown us that it is possible for the world to move away from smoking for ever".

The Atlas authors wrote about standing at the crossroads and now the promise of tobacco harm reduction has carved out a new path to take. Back in 2002, smokers had just two roads to choose from: one called 'Quit' and the other

⁷ Cairney, P. et al. *Global Tobacco Control - Power, Policy, Governance and Transfer*. Palgrave Macmillan UK, 2012

⁸ Cairney, P. and Mamudu M.H. (ND) *The WHO Framework Convention for Tobacco Control: What would have to change to ensure effective policy implementation?*

⁹ Gakidou E. et al (2017). Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet*. 390, p.1345-1422

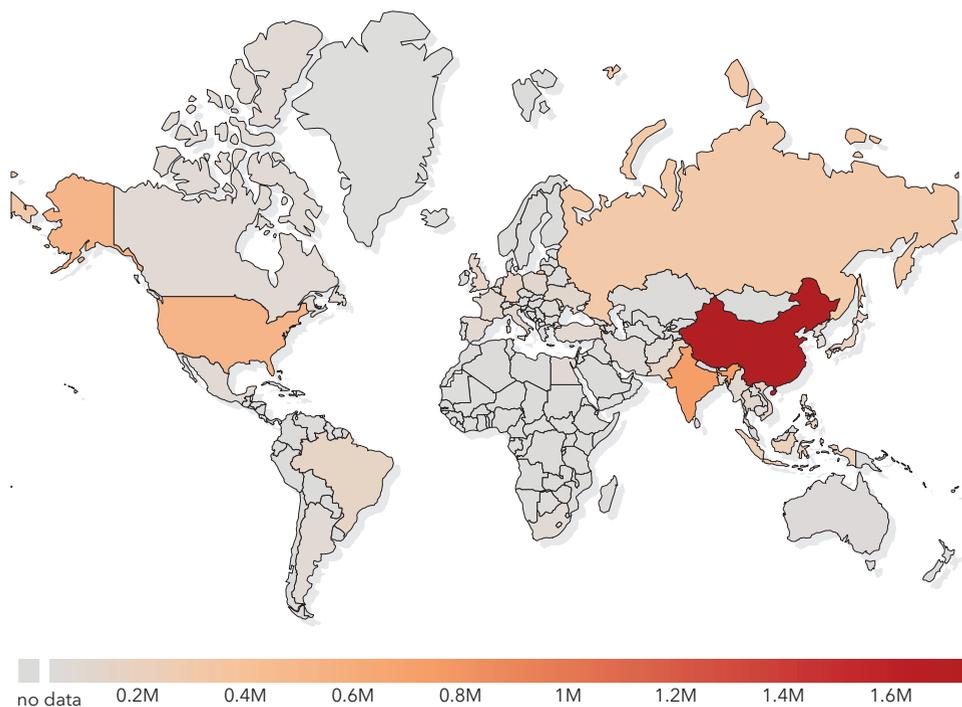
¹⁰ United Nations. *Transforming our World: The 2030 Agenda for Sustainable Development*. UN, 2015. Available at <https://sustainabledevelopment.un.org/post2015/transformingourworld/publication>

¹¹ World Health Organization. *Time to deliver: report of the WHO independent high-level commission on non-communicable diseases*. WHO, 2018. p.4

called 'Die'. Now, smokers who cannot, or do not wish to either quit or die have a third route to a smoke-free lifestyle. It has the potential to substantially reduce the global toll of death and disease from smoking, and to affect a global public health revolution - and all at no cost to governments. This route could be described as 'Quit or Try'.

Figure 2.6

Mortality - number of deaths attributable to tobacco smoking (2016)



Source: WHO report on the global tobacco epidemic, 2017, Country profiles http://www.who.int/tobacco/surveillance/policy/country_profile/en/

In fact, it is consumers themselves who have led the charge to develop and embrace alternative forms of nicotine, in products that both work and are desirable, mostly in the form of e-cigarettes. Consumers have shown us that it is possible for the world to move away from smoking forever.

Conclusion

That smoking has been in decline in much of the developed world is to be welcomed. But the fact that the steep drops since the 1970s have begun to level out in some countries demonstrates that despite all the efforts of tobacco control, even in the West, there are still millions of people who continue to smoke, most notably among the poorest and most vulnerable.

The situation is even more serious in LMIC, where most smoking deaths occur and where population growth is set to increase rather than decrease the smoking population. And it is precisely these poorer countries that simply do not have the resources to make serious inroads into their smoking problem. Overall, at the current levels, the WHO estimated in 2008 that by the end of the century, a billion people would have died from smoking at an annual cost to the global economy of US\$1 trillion amounting to a projected total of US\$92 trillion by 2100.

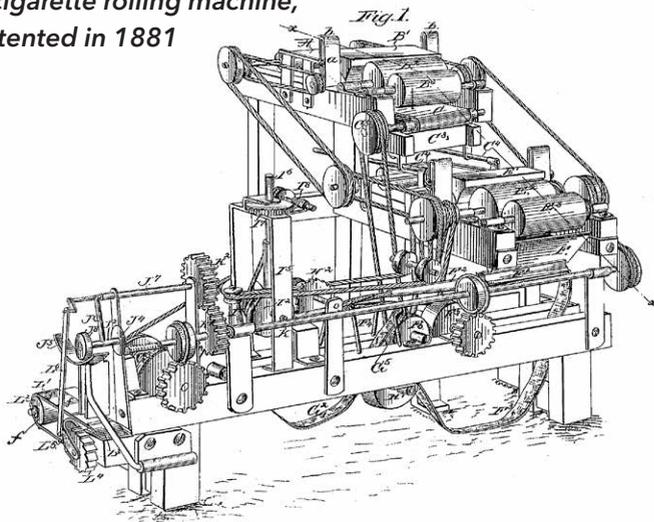
Yet there is now a proof of concept which offers a way for governments to tackle smoking-related deaths and disease and move towards the aspirations of the Sustainable Development Agenda, with no drain on national finances. Current SNP have the potential to replace and eradicate smoking. The history, development and growth in use of these products is the subject of the next chapter.

Chapter 3: Safer nicotine products – a global picture

From the mid-16th century, when it first reached the courts of Europe, to the mid-19th century, tobacco was primarily smoked in pipes or chewed. The cigarette first appeared in France around 1850. For the next forty years, cigarettes were hand rolled, but demand grew to the point where mechanisation was required. In 1881, an American inventor, James Bonsack, was granted a patent in the USA for a revolutionary machine. It chopped the tobacco and dropped a certain amount into a long tube of paper, which would then be rolled, pushed out and then sliced into individual cigarettes. The machine operated at thirteen times the speed of a human cigarette roller, transforming cigarette production and giving birth to the modern tobacco industry.

Figure 3.1

James Albert Bonsack's cigarette rolling machine, invented in 1880 and patented in 1881



In America, prior to 1900, cigarette smoking came behind chewing tobacco, pipes, roll-your-own tobacco and cigars as a way of consuming tobacco. The development of the safety match in 1899 allowed for a convenient and portable way of lighting cigarettes, while the power of advertising was first demonstrated in 1913 by Reynolds' national campaign promoting Camel cigarettes. Camel became the first national cigarette brand and the first cigarette to be pre-packaged. By 1916, Reynolds' share of the cigarette market surpassed those of the Liggett and Lorillard companies. By 1920, Reynolds were number one in the cigarette category, having also eclipsed American Tobacco.¹

During this period, the most dramatic rise in cigarette consumption came in the two World Wars, when cigarettes became part of military rations. Cigarettes now outstripped all other forms of tobacco consumption.²

Today, there are around one billion smokers in the world, consuming an estimated 5.8 trillion cigarettes a year.³ A lit cigarette burns at 600°-800°C. At those temperatures, you can melt zinc, aluminium, tin and lead. The temperature can rise to around 900°C when puffing, nearly the melting point of silver. A cigarette contains around 600 ingredients and when it is burned, it releases some 7,000 chemical substances, about 70 of which are known carcinogens.⁴

Most smokers interviewed by researchers, or who complete self-report surveys, say they want to quit, although Phillips and colleagues suggest this can be a "second order preference": what many smokers mean is that they wish they wanted to quit.⁵ There may also be a powerful response set, in that given the social pressure to quit, many feel obliged to affirm this. But many people do quit smoking, with or without any interventions, or try and fail. There can be many reasons why people fail to quit when they want to, but purely from a neuro-biological point of view, one key reason is that nicotine as delivered in cigarettes has powerful reinforcing properties.

¹ AdAge. R.J. Reynolds Tobacco Co. (Reynolds American).

<http://adage.com/article/adage-encyclopedia/r-j-reynolds-tobacco-reynolds-american/98855/>

² Burns, D.M. et al. Cigarette smoking behaviour in the United States.

³ American Cancer Society, Tobacco Atlas <https://tobaccoatlas.org/>

⁴ American Lung Association, Smoking Facts. Available at <http://www.lung.org/stop-smoking/smoking-facts/whats-in-a-cigarette.html>

⁵ Phillips, C. V. et al. (2015) Smoking or quitting; choice, true preferences, tobacco harm reduction, and other neglected considerations. Available at <https://epology.files.wordpress.com/2014/11/phillips-nissen-rodu-smoking-or-quitting-neglected-considerations.pdf>

According to the US National Institute on Drug Abuse:

*“A transient surge of endorphins in the reward circuits of the brain causes a slight, brief euphoria when nicotine is administered. Nicotine increases levels of the neurotransmitter dopamine in these reward circuits which reinforces the behaviour of taking the drug”. When cigarette smoke enters the lungs, nicotine is absorbed rapidly in the blood and delivered quickly to the brain, so that nicotine levels peak within 10 seconds of inhalation. But the acute effects of nicotine also dissipate quickly, along with the associated feelings of reward; this rapid cycle causes the smoker to continue dosing to maintain the drug’s pleasurable effects and prevent withdrawal symptoms”.*⁶

However, over the last decade, there are other options for ingesting nicotine which are not only less reinforcing than nicotine delivered in a combustible cigarette,⁷ but do not involve the high-level release of toxic chemicals. Just to repeat, this report calls them safer nicotine products (SNP) and they break down into three main types: e-cigarettes, heat-not-burn (HNB) devices and an option that is very far from new but enjoying a renaissance: smokeless tobacco, in the form of snus from Sweden.

To encourage people away from smoking, the new devices need to be easy to use and cost effective, but must also offer choice. These days, choice is what people expect - of beer in a pub, coffee in cafes, or butter in the supermarket. And just as design is critical to the marketing of smart phones, wearables and similar technology, the design of new nicotine devices is important. SNP design needs to fit into the modern technological zeitgeist; indeed, the look and feel of many SNP is light years from dried leaves wrapped in bits of paper.

E-cigarettes

A brief history

On 25th May 1927, one Joseph Robinson filed a patent in New York, which was granted in May 1931. It was for an ‘Electrical Vaporizer’, whereby an electrical element contained in a cylinder would be heated to vaporise a compound through a mouthpiece. In his patent application, Robinson did not make clear the practical application of his invention. The likely purpose was for inhaling medicinal products but in any event, it does not appear to have gone into production.⁸

If there was a godfather of e-cigarettes, it was probably Herbert Gilbert, a business studies graduate and 40-a-day smoker. In 1963, he filed a patent application for a ‘Smokeless Non-Tobacco Cigarette’. Interviewed by James Dunworth in 2016, Gilbert said he had a eureka moment. “The problem, as I concluded, was that when you burned leaves and wood, even if you did it in your back yard, it yielded a result that no one wanted to take into their lungs”.⁹ This led him to construct a device which was very similar to the basic modern-day e-cigarette; a long, cylindrical body, a battery, a heat source and a flavour cartridge. The most crucial difference, however, was that Gilbert’s device was nicotine-free. The device never made it to market and existing prototypes perished in a warehouse fire.

If Gilbert’s invention had gone into production, the fact that it did not deliver nicotine would probably have caused it to fail anyway. Yet Gilbert believed other forces were at work. As he explained to Dunworth, those he showed it to could have put it into production, “but they chose to wait for the patent to expire and then file their own versions”. Moreover, timing is everything and in the 1960s, with tobacco promotion at its height and cancer denial in full swing, it was not in the interests of the tobacco industry to be promoting a ‘safer cigarette’; the lawyers would not allow the fruits of the industry’s own damning research to see the light of day for fear of the consequences.

A significant next step came from outside the industry. Phil Ray, a space engineer at NASA, was best known for pioneering the microprocessor. In 2016, the vaping site Ashtray Blog interviewed Dr Norman Jacobson, who worked with Ray on a project to develop a new nicotine delivery system.¹⁰

Ray was a smoker and did not want to give up nicotine, but wondered if the harm could be reduced by simply inhaling nicotine without the smoke. Jacobson

⁶ National Institute on Drug Abuse. *Tobacco, Nicotine, and E-Cigarettes*. NIDA, 2018

⁷ Foulds, J. et al (2015) Development of a questionnaire for assessing dependence on electronic cigarettes among a large sample of ex-smoking e-cigarette users. *Nicotine and Tobacco Research*. Feb;17(2), p186-92. See also https://ec.europa.eu/health/scientific_committees/opinions_layman/tobacco/en/about.htm#7

⁸ Google Patents. US 1806646 <https://www.google.com/patents/US1806646>

⁹ Dufton, E. (2016) James Dunworth’s Interview with Herbert A. Gilbert, Inventor of the E-Cigarette. *Points: The Blog of the Alcohol & Drugs History Society*. Available at <https://pointsadhsblog.wordpress.com/2016/02/11/an-interview-with-herbert-a-gilbert-inventor-of-the-e-cigarette/>

¹⁰ Dunworth, J (2013) Vaping 1970’s Style: An Interview with One of the Pioneers. *Ashtray Blog*. Available at <https://www.ecigarettedirect.co.uk/ashtray-blog/2014/06/favor-cigarette-interview-dr-norman-jacobson.html>

was Ray's doctor. He conducted a small clinical trial, with eight smokers, to see what would happen. The trial used a plastic device, shaped like a cigarette, which contained paper soaked in nicotine. Nicotine's low volatility meant that all the user had to do was inhale from one end to draw out the nicotine, without any combustion or heating at all. In that sense, it was more like a Nicorette inhaler than a modern-day e-cigarette.

But the trial proved that the idea offered benefits: the levels of carbon monoxide in the subjects' blood were dramatically reduced to levels seen in non-smokers; they inhaled about half the nicotine from the average pull, and the subjects either smoked less or quit for up to two years after the trial.

In 1979, Dr Jacobson delivered these preliminary results to a meeting of the American College of Chest Physicians in Houston under the title, 'Nicotine inhalation or vaping', the first time the word 'vaping' had seen the light of day.

As part of their research, Jacobson and a colleague came to England in the early 1980s to meet with Michael Russell, one of the world's foremost tobacco researchers who, as we have seen, became convinced of the benefit of tobacco harm reduction measures. A company, Advance Tobacco Products Inc, with Jacobson as CEO, was also established in the early 1980s to commercialise the product. It appeared in 1985 under the trade name Favor (as in 'do yourself a favour').

Unfortunately, Favor failed on three counts. Firstly, nicotine evaporates very quickly, so the shelf-life of the cartridges was too short to be a practical alternative to smoking. Secondly, nicotine degrades to cotinine, which leaves a bitter taste unless refrigerated, which again makes it difficult to market. And finally, in February 1987, the US Food and Drug Administration (FDA) banned it outright, deeming it to be a new drug (nicotine removed from tobacco) delivered by an unproven drug delivery system.¹¹ This was just the beginning of a battle between the FDA and purveyors of SNP, which shows little sign of abating. Eventually, the patent for Favor was sold to a Swedish company, which converted the device to a nasal spray.

Through the 1980s and 1990s, several patents for similar devices, often citing Herbert Gilbert's original invention, were lodged in the USA, mainly by existing tobacco companies.¹² But the real tipping point for the e-cigarette revolution did not emerge from the secret vaults of Big Tobacco or Silicon Valley, but around 10,000 miles away across the Pacific in China.

The story of Hon Lik



Hon Lik was born in northern China in 1951. He graduated from the Liaoning College of Traditional Chinese Medicine and began his career working in plant agriculture, trying to devise easier ways for people to ingest traditional Chinese herbal remedies like ginseng. And like millions of Chinese men, he was a heavy smoker - two or three packs a day - and had been trying to quit using nicotine patches, to little effect. His father was a heavy smoker too, and would die from lung cancer.



¹¹ Center for Drugs and Biologics, Dept. of Health and Human Services, Office of Compliance. Michels, D.L. (1987). Regulatory Letter: Favor Smokeless Cigarettes, Regular Favor Smokeless Cigarettes, Menthol Favor Smokeless Cigarettes, Lights Favor Smoke-free Cigarettes, Regular Favor Smoke-free Cigarettes, Menthol Favor Smoke-free Cigarettes Lights. Philip Morris Records. Available at <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=xggy0038>

¹² Dufton, E. (2015) The Strange and Complicated History of Patenting the E-Cigarette. Points: The Blog of the Alcohol & Drugs History Society. Available at <https://pointsadhsblog.wordpress.com/2015/01/22/the-strange-and-complicated-history-of-patenting-the-e-cigarette/>
The article points out that pharmaceutical companies have also lodged patents based on the same technology as e-cigarettes in order to deliver medicines

Hon Lik recounts that the idea of delivering nicotine in a vapour came to him in a dream. One night he went to bed forgetting to remove his patch. Nicotine can generate vivid dreams¹³ and he dreamt he was drowning in a deep sea, when suddenly the sea vaporised and he found himself floating in a brightly coloured fog. From that, he says he reasoned that the steady delivery of nicotine through a patch was not satisfying enough. He reckoned that vaporising the nicotine would simulate more of the cigarette experience. He was right.

"In 2001, I devised a system on a large console, using food additives as solvents. At the time I was working on vaporisation by ultrasound, but the droplets formed were too big to resemble tobacco smoke. This technology is used for example in some household humidifiers; it consists of making a metallic diaphragm vibrate at an ultrasonic frequency in a liquid to create micro-droplets which then, upon contact with room-temperature air, form a sort of cold vapour".¹⁴

The challenge was to scale the mechanism down to a miniature size, suitable for a hand-held cigarette-sized device, and achieving the right dose of nicotine, while also getting the right odours from harmless additives.

In 2003, he came up with the idea of using a high frequency, piezoelectric, ultrasound-emitting element to vaporise a pressurized jet of liquid containing nicotine. Piezoelectricity is the electric charge that accumulates in certain solid materials (such as crystals, certain ceramics, and biological matter such as bone, DNA and various proteins) in response to applied mechanical stress. The principle has many practical applications, from sonar to ceramic cartridges on vinyl record decks, igniting cigarette lighters and push-start propane barbecues. Hon Lik's design created a smoke-like vapor that delivered nicotine. Arguably the crucial step forward from previous efforts was that the nicotine was protected from vaporisation until it was heated. Here was a stable nicotine delivery system and a smoke-like vapour wrapped in a device that looked like a cigarette.

Hon Lik filed the first patent in 2003. The company Hon worked for, Golden Dragon Holdings, changed its name to Ruyan, meaning 'like smoke', and the first e-cigarette went on sale in China in 2004. Ruyan now markets e-cigarettes, e-pipes and e-cigars globally. And unlike many inventors, Hon Lik profited from the fruits of his dream, selling his intellectual property rights to Imperial Tobacco for a reported \$7.5m in 2013.¹⁵

Types of e-cigarettes

There are now many types of e-cigarette. They range from entry level disposable types, which cannot be customised and are known as 'closed systems', through to mechanical modified types, or 'mods', which the vaper is able to fully customise and are at the top end of what are known as 'open systems'. The higher up the device scale you go, the more control the vaper has over the whole vaping experience. The product scene is extremely varied and complex, with many different devices, device components and flavours, and a bewildering lexicon of jargon and terminology, which, like everything else in this industry, is changing and evolving. What follows is therefore a snapshot of where we are in 2018.

All e-cigarettes have three basic elements; a battery, which heats up a coil or atomiser, turning the flavoured e-liquid or juice into a vapour, which is then inhaled.

E-liquid comprises four ingredients: vegetable glycerine, propylene glycol, nicotine, and flavouring. Some liquids can contain no nicotine. Vegetable glycerine (VG) is a thick, naturally sweet liquid that provides the vapour from the liquid. Propylene glycol (PG) is a thin liquid, which acts as the flavour carrier. Some people are allergic to PG and e-liquid without that ingredient is available. The VG/PG ratio is the ratio of VG and PG in a liquid. The higher the VG percentage, the more cloud and the smoother the vape, but there is less flavour. Higher PG gives less cloud, more 'throat hit' and possibly more flavour. Throat hit refers to the feeling a smoker gets when inhaling nicotine. The problem that most smokers switching to vaping report is the fact that they do not feel the same kind of throat hit that they would with a regular cigarette. The flavourings are the same as used in food and confectionery production and the range of flavours available for vaping runs into the thousands.^{16 17}

¹³ Page, F. et al (2006). The effect of transdermal nicotine patches on sleep and dreams. *Physiology and Behaviour*. 30;88(4-5), p. 425-32

¹⁴ Mawsley (2017). Hon Lik speech at ISOntech. Planet of the Vapes. Available at https://www.planetofthevapes.co.uk/news/vaping-news/2017-08-03_hon-lik-speak-at-isontech.html

¹⁵ Gustafsson, K. (2013) Imperial Tobacco Agrees to Acquire Dragonite's E-cigarette Unit. Bloomberg. Available at <https://www.bloomberg.com/news/articles/2013-09-02/imperial-tobacco-agrees-to-acquire-dragonite-s-e-cigarette-unit>

^{16, 17} →

There are three main types of device:

Figure 3.3

First generation e-cigarette



Figure 3.4

Second generation e-cigarette



Figure 3.5

Third generation e-cigarette



First generation e-cigarettes

First-generation e-cigarettes, called 'cigalikes', were designed to closely resemble an ordinary cigarette and are comprised of a battery, a combination disposable cartridge of e-liquid, and the heating element or atomiser, called a cartomiser. Most users at this level want the convenience of just using the device and disposing of the cartridge, but some brands are refillable. Some cigalike manufacturers have started to sell mini refillable tanks, or clearomisers (so named because you can see how much liquid is left). In general terms, each cartridge is roughly equivalent to a pack of cigarettes and last around 200 puffs. This type of e-cigarette is the most popular for many of those starting to vape, because it looks and feels like smoking a cigarette and is convenient to use.

Second generation e-cigarettes - 'Tank system' e-cigarettes

Second-generation e-cigarettes are the next level up for those looking for larger tanks. Some offer adjustable airflow for more and different flavours, some hold more liquid and have larger battery capacity for a longer charge, and some have adjustable power features. This type of device has been dubbed an eGo style, after the eGo battery developed by the Joytech company in China, now the world's leading brand in this type of battery.

Depending on the system itself, the larger battery gives more power, generating more vapour production, more flavour and a stronger throat hit. In this type of device, the tank and the atomiser are separate items.

¹⁶ Zhu, S. et al (2014) Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control* 2014; 23:iii3-iii9

In January 2014, the researcher identified 466 brands and 7764 unique flavours. From a previous search conducted in 2013, they calculated that around 10 new brands and 240 new flavours were appearing each month. If product development has continued at that rate, in 2018 there could now be over 700 brands and 15,000 flavours.¹⁷ Page, F. et al (2006). The effect of transdermal nicotine patches on sleep and dreams. *Physiology and Behaviour*. 30;88(4-5), p. 425-32

¹⁷ Any company wanting to make their SNP (such as e-liquid or device) available on the UK market is obliged to notify the Medicines Healthcare products Regulatory Agency (MHRA). In 2017, 32,000 products were notified to the MHRA; 90% were e-liquids and 10% devices

Figure 3.6
IQOS (PMI)



Figure 3.7
glo (BAT)



Figure 3.8
Ploom (JTI)



Third generation e-cigarettes ('mods') - Mechanical mod-style e-cigarettes

While many e-cigarette users probably do not label themselves as 'vapers' and are content just to walk into their local store, supermarket, gas station or vape shop to buy a basic device, there is a strong 'hobbyist' element among vapers. People in this group want maximum control over their devices, maybe mixing their own liquids, building coils, experimenting with battery wattage and voltage and tank sizes to fine-tune their vaping experience. This would be akin to building your own computer from component parts.

E-cigarettes have developed along two lines. Closed systems have disposable cartridges, rather like a fountain pen with cartridges and are simple to use. Open systems allow the user to customise their use with different parts, including mouthpieces, atomisers and batteries, refillable tank and a choice of liquids.

Tobacco heating systems or HNB products

Tobacco heating systems, also known as heated tobacco products, tobacco heating products - and more generally (and hereafter in this report) as HNB products - work on the principle of heating tobacco below the level of combustion.

A HNB device heats tobacco to a temperature of no more than 350°C, which is sufficient to release the nicotine but with significantly reduced levels of toxins.¹⁸

Tobacco for use in a HNB device is prepared differently than in a cigarette: the tobacco is powdered and mixed with glycerine, guar gum, and other ingredients. There are three methods in which tobacco is heated in these products. In the first method, tobacco is directly heated by a blade inserted into a small tobacco stick, which then heats the tobacco and releases the vapour. The second method is to indirectly heat the air, which in turn heats the tobacco, similar to the way a fan oven works. In the third, a liquid is heated to generate a vapour, which then passes through tobacco before being inhaled, picking up nicotine and flavours. This method is a similar process to placing food in a steamer.

Unlike the e-cigarette market, the major tobacco companies like Philip Morris International (PMI), British American Tobacco (BAT) and Japan Tobacco International (JTI) currently dominate the global market in these new products because the process of developing HNB alternatives to cigarettes is extremely expensive. For decades now, the industry has been trying to develop a product that is demonstrably safer than smoking, but still ticks the boxes of consumer satisfaction

¹⁸ Committee on Toxicity. *COT Meeting: 4 July 2017* (2017). Available at <https://cot.food.gov.uk/cot-meetings/cotmeets/cot-meeting-4-july-2017>

(nicotine hit and flavour) and can credibly defend itself against inevitable political and public health opposition. As far back as 1958, a tobacco executive wrote that whoever came up with such a product could dominate the whole market.¹⁹

In 1988, Reynolds launched an early version of a HNB product: the Premier cigarette. It worked by heating and aerosolising tobacco flavour and was intended to reduce or eliminate the health risks associated with smoking. But despite an estimated investment of up to US\$1 billion, the product failed. Smokers complained about a charcoal-like aftertaste, and although it looked like a conventional cigarette, special instructions were required to teach smokers how to light it. Reynolds estimated it would take two or three packs for a smoker to acquire a taste for Premier, but in practice, many smokers only smoked one cigarette and then shared the rest of the pack. It was withdrawn from the market in 1989, less than a year after its introduction. Reynolds tried a further launch in 2002, this time in India, one of the world's largest smoking markets. But it failed within 12 months.²⁰

Reynolds tried again in 1994 with another HNB product called Eclipse, which heated the tobacco instead of burning it by using a carbon tip wrapped in glass fibres. It was only available nationally in the USA from 2003-07, but remains available in some local US markets. It did seem to tick all the boxes, but in terms of general acceptance, may have been a product ahead of the time. It was rebranded as Revo in 2015, but has since been shelved.²¹ PMI also made initial attempts to develop and commercialise heated tobacco products in the late 90s and early 2000s, but these products were unsuccessful due to drawbacks in technological capability and low consumer satisfaction.²² The technical challenge has been considerable, involving how to remove or significantly lower five types of carcinogenic compounds: nitrosamines, the significant cancer-causing agents in tobacco smoke; aldehydes, formed by the burning of sugars and cellulose in tobacco; polycyclic aromatic hydrocarbons (PAHs), which form in the cigarette behind the burning tip; carbon monoxide, which binds with red blood cells and strongly affects cell respiration; and traces of heavy metals present in tobacco as a result of fertilisers used on the plant.

Smokeless tobacco

Many parts of the world have versions of smokeless tobacco, which can be chewed, inhaled as snuff, or placed under the lip. However, some varieties contain substances other than tobacco, which have been associated with oral cancers.

Chewing tobacco is one of the oldest methods of consuming tobacco. Indigenous peoples of the Americas, in both North and South, chewed the leaves of the plant long before the arrival of Europeans, frequently mixing them with the mineral lime, similar to the way coca leaves are chewed.

Tobacco chewing became widespread in the main tobacco growing areas of the American south and is still in vogue among some young males in the southern states, although its popularity was already on the wane before the Second World War.

Dipping tobacco is a type of finely ground or shredded, moistened smokeless tobacco product. It is used by placing a lump, pinch, or "dip" of tobacco between the lip and the gum.

Dipping tobacco evolved from the use of dry snuff in early American history. Up until the late 1700s, dry snuff was taken nasally. Then early Americans began to take snuff orally by chewing the end of a twig until it resembled a brush, and then "dipping" the twig in the snuff and placing it in their mouths until the snuff dissolved. This evolved into modern day moist snuff, with Copenhagen introduced in 1822, and Skoal introduced in the USA in 1934, betraying the Scandinavian roots of this type of smokeless, oral tobacco product. Dipping tobacco is typically flavoured, most commonly with mint and wintergreen, but also grape, cherry, apple, orange, lemon/citrus, peach and watermelon.

Snus

Of all the smokeless tobacco products, it is snus which has captured most attention, because of its success in reducing the prevalence of lung cancer and other tobacco-related diseases in Sweden.²³ Swedish snus dates back to the 18th century and is distinct from other types of smokeless tobacco products

¹⁹ Parker-Pope, T. (2001) 'Safer' Cigarettes: A History. *NOVA*

Available at <http://www.pbs.org/wgbh/nova/body/safer-cigarettes-history.html>

²⁰ Wikipedia. Premier (cigarette) [https://en.wikipedia.org/wiki/Premier_\(cigarette\)](https://en.wikipedia.org/wiki/Premier_(cigarette))

²¹ TVECA, Reynolds pursues another restart with revamped heat-not-burn cigarette Eclipse (2017)

<https://www.tveca.com/content/reynolds-pursues-another-restart-revamped-heat-not-burn-cigarette-eclipse>

²² Philip Morris International, Sustainability Report 2017 (2017). Available at

<https://www.pmi.com/docs/default-source/pmi-sustainability/pmi-sustainability-report-2017.pdf>

²³ Foulds, J. et al (2003). Effect of smokeless tobacco (snus) on smoking and public health in Sweden.

Tobacco Control 12; 4, p. 349-59

because of its composition, the manufacturing methods, and the specific standards for reducing several unwanted substances implemented by all major manufacturers.²⁴ Swedish snus is the dominant form of smokeless tobacco in the Nordic countries, although all major manufacturers are based in Sweden. In recent years, some smokeless products have been launched in North America marketed as “snus”, in addition to Swedish snus. However, the chemical properties of some of these products are distinct from traditional Swedish snus, and they are not manufactured according to the same quality standards as those produced by the major Swedish manufacturers.

Swedish snus

Figure 3.9

Snus



Swedish snus is a moist to semi-moist smokeless tobacco product, made from ground tobacco leaves and food-approved additives. Because the tobacco is ground into a powder instead of being cut, the final product is intended to be placed in the mouth, rather than chewed.

“Of all the smokeless tobacco products, it is snus which has captured most attention, because of its success in reducing the prevalence of lung cancer and other tobacco-related diseases in Sweden”.

Snus production involves a heat-treatment process, which substantially decreases the microbial activity in the final product. This contributes to its chemical stability and shelf-life. The manufacturing methods and ingredients have essentially remained the same over the past 200 years. However,

production changes introduced over the past few decades by the major manufacturers have resulted in substantial decreases in the levels of unwanted substances in Swedish snus including potentially carcinogenic tobacco-specific nitrosamines (TSNAs) and PAHs.

Loose snus is a moist powder, which can be portioned and packed into a cylindrical or spherical shape with the fingertips or a purpose-made cylindrical device. The result is often referred to as a pris (pinch), buga, prilla, or prell (slang). Some users (usually long-time users) simply pinch the tobacco and place it under their upper lip (‘farmer’s pinch’ or ‘living snus’). Over time, the demand for loose snus has been replaced by portioned varieties. The discrete nature of this more recent formulation has helped increase demand for snus.

Today, the dominant snus brands come in small teabag-like sachets. There are two varieties of portion snus. ‘Original portion’, introduced in 1973, is the traditional form. The sachet material is moisturised during the manufacturing process, resulting in a brown, moist pouch. ‘White portion’ is a milder-tasting and slightly slower-release form. The sachet material is not moisturised during the manufacturing process, resulting in a white, dry pouch. The tobacco within the portion material has nearly the same moisture content as original portion snus, but the nicotine and flavour are somewhat slower in delivery due to the drier sachet. ‘White portion’ refers to the style, not the colour, as many white portion snus manufacturers use a black material instead of white. Examples have included General Onyx and Grovsnus Svart (Black) and Blue Ocean (Blue).

The nicotine content of snus varies between brands, with the most common strength being 8 mg of nicotine per gram of tobacco. In recent years, snus manufacturers have released stark (strong or sterk) and extra stark (extra strong or extra sterk) varieties with greater nicotine content. Stark varieties contain, on average, 11 mg of nicotine per gram of tobacco, while extra stark varieties may contain up to 22 mg of nicotine per gram of tobacco.

Unlike in the European Union, snus has never been banned in the USA. Although Swedish snus was previously only available by mail order in the USA, an increasing number of tobacco retailers have now begun to stock it. R J Reynolds and Philip Morris USA, and the US Smokeless Tobacco Company now produce similar products called Camel snus, Marlboro snus, and Skoal snus, respectively.

²⁴Moist snuff is fire-cured as opposed to snus which is pasteurised

Swedish Match, the leading manufacturer of Swedish snus, is currently selling it in Canada, and several regions throughout the USA.

'Safer' cigarettes

Over the years, tobacco companies have sought to introduce a 'safer' cigarette, for example ones that produced less tar. Such efforts failed. In 2017, the US FDA announced the launch of a public conversation on the idea of forcing the tobacco companies to reduce the nicotine content of combustible cigarettes to 'non-addictive' levels. The FDA based its view on simulation modelling research, published in the *New England Journal of Medicine*, where the authors estimated that "approximately 5 million additional smokers [...] would quit smoking within a year after implementation of the hypothetical policy, a number that would increase to a total of 13 million additional former smokers [...] within 5 years[...]. By 2060, smoking prevalence drops from 7.9 percent in the baseline scenario to 1.4 percent".²⁵

The former director of UK Action on Smoking and Health (ASH), Clive Bates, has detailed the many reasons why this is unlikely to work. He considers that smokers would not buy the new product in sufficient numbers to make a positive population level health impact, but does concede that it could be "an important signal of a direction of travel - the end of combustible tobacco products as nicotine delivery products. This could make it an 'agency threat' - a big stick that has influence in setting direction and pressing companies and their investors to respond".²⁶

However, to dramatically reduce the nicotine content of a cigarette could equally result in the accelerated growth of an illicit market, an unintended consequence noted by the FDA in its press release announcing the consultation process.²⁷

The global e-cigarette market

On 20th July 2006, US Customs received a tariff enquiry asking about the import duty on a device described as "a spherical, metal tube with a plastic mouthpiece tip on the end which measures approximately 5 ½" in length. Inside the tube are a sensor, electronic atomizer, integrated circuits and a lithium ion battery. The spherical cartridge is attached to a plastic mouthpiece tip and contains nicotine and propylene glycol". The device was a Ruyan Electronic Cigarette, and the

letter came from Mark Weiss, a patent attorney from Scottsdale, Arizona who initially considered importing the Ruyan into the USA. Instead, in that same year, he founded NJOY, one of the first companies to manufacture and sell e-cigarettes in the USA. By the time NJOY was founded, British businessman Greg Carson had already introduced the 'Electro-Fag' into Europe in 2005 - and the rest is history. In 2012, Phil Hodson, founder of E Lounge Vaping, the UK's first dedicated e-cigarette retailer, told online magazine *Raconteur* "It's going to be huge".²⁸ And he was right. But how huge?

The growth of safer nicotine products

In 2013, the investment bank Goldman Sachs identified e-cigarettes as one of the eight emergent themes in the global economy capable of what it termed 'creative destruction', representing a whole new and totally disruptive technology, offering consumers a far safer product and forcing companies to either adapt or die.²⁹ The market research company Nielsen identified e-cigarettes as the fastest-growing product in British supermarkets in 2014, with sales up by almost 50 percent.³⁰

Increasing interest in SNP is encouraging many tobacco companies to shift the nature of their operations. Once, companies were engaged in manufacturing a single agricultural product - the tobacco cigarette - with little need for significant product innovation. In the last decade, however, many of the major tobacco companies have invested substantial sums in research and development of SNP. The science and technology of these new products involves, amongst other things: heating technology; battery design; consumer electronics; materials science; biotechnology; inhalation science; and flavour chemistry.

²⁵ Apelberg B.J. et al (2018). Potential public health effects of reducing nicotine levels in cigarettes in the United States. *The New England Journal of Medicine*. 378 p.1725-1733

²⁶ Bates, C. and Wade, C. (2017) *Reducing nicotine in cigarettes*. Available at <https://clivebates.com/documents/ReducedNicotineOct2017.pdf>

²⁷ Gottlieb, S. (2018) *Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health steps to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels*. FDA, 2018. Available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601039.htm>

²⁸ Sims, J. (2012) From 'electro fag' to e-cigarette. *Raconteur* <https://www.raconteur.net/lifestyle/from-electro-fag-to-e-cigarette>

²⁹ Boroujerdi, R.D. *The Search for Creative Destruction*. Goldman Sachs, 2013. Available at <http://www.goldman-sachs.com/investor-relations/financials/archived/annual-reports/2013-annual-report-files/search.pdf>

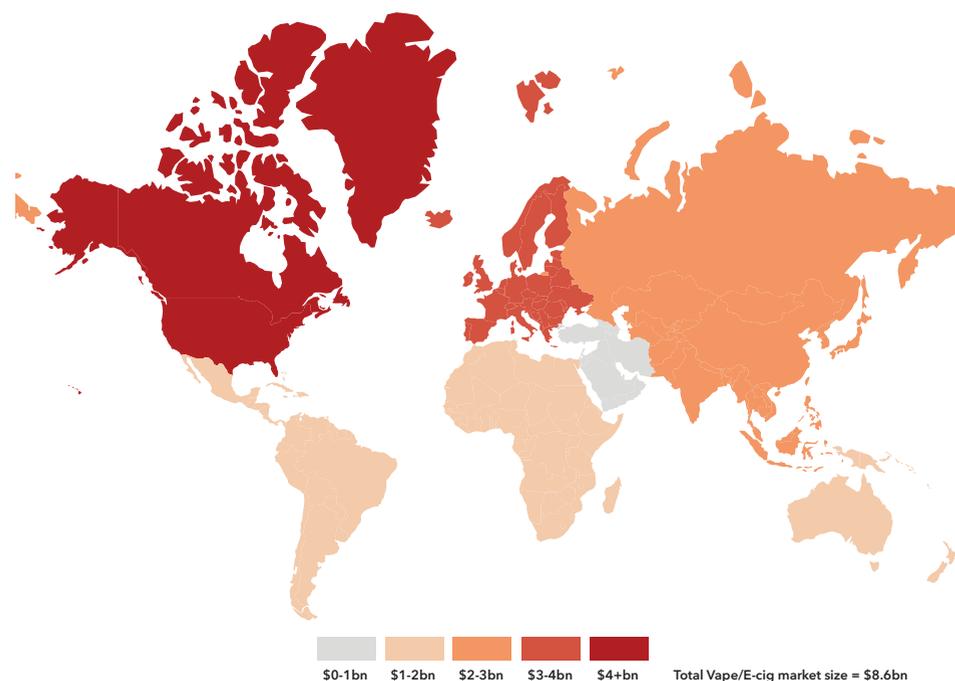
³⁰ Smithers, R. (2014) E-cigarettes and sports nutrition products lead grocery sales boost. *The Guardian*. Available at <https://www.theguardian.com/business/2014/dec/30/e-cigarettes-sports-nutrition-supermarkets-sales-rise-uk>

It is not only the tobacco industry feeling the heat as the e-cigarette market grows. Sales of NRT have fallen in some markets where e-cigarettes have a strong showing, to the extent that pharma giant GlaxoSmithKline considered getting into this rival market, but quailed in the face of potential controversy.^{31 32 33}

The consensus of analysts suggests that most of the metrics of the market in SNP will continue to grow. However, there are some signs that the initial surge of smokers switching away from cigarettes, at least in Great Britain, has begun to level off. Growth could be further slowed if product development is hindered by legislation and regulation (e.g. banning online sales) and taxation.

Figure 3.10

Regional e-cigarette market size estimates 2018



Source: ECigIntelligence, 2018

Trying to accurately represent market analysis in such a fast-moving and dynamic environment is challenging, even more so when attempting growth forecasts -

whether in terms of financial value, units sold, market share, or numbers of consumers. Some measures such as units sold might at first seem easy to acquire, but many market measures depend on sales till data, which do not necessarily include small independent shops and online sales.

Largest markets for e-cigarette products

North America is by far the largest e-cigarette market, followed by Western Europe, Eastern Europe, Asia Pacific, and then the rest of the world.³⁴

The market share for different products varies in different countries. For example, possibly due to their relatively low cost, cigalikes enjoy a 50 percent share in a very small market like Azerbaijan, followed by 43 percent in Austria, 42 percent in the USA, 39 percent in China, and 38 percent in Ecuador. The USA accounts for 70 percent of the US\$500m global market for the relatively new pod mod systems (a system similar to using coffee pods like Nespresso), with only UK, Italy, Poland, and France having a market share greater than 9 percent.

"In 2012, Phil Hodson, founder of E Lounge Vaping, the UK's first dedicated e-cigarette retailer, told online magazine Raconteur, 'It's going to be huge'. And he was right".

In the more mature e-cigarette markets, open systems are still dominant, the top five markets being USA, UK, Italy, Germany and France, followed by China, Russia, Poland, Canada and Malaysia. But, according to Euromonitor analysis, open systems do face future challenges. The analysis speculates that the ability to customise devices is likely to appeal to early adopters, who are frustrated by the inflexibility of cigalikes, which once offered the only safer option. Those early adopters are likely to continue populating the niche market in ultra-flexible devices. However, new products might appeal more to

³¹ Kelland, K. (2015) GSK's nicotine patches and gum feel the heat from e-cigarettes. *Reuters*. Available at <https://www.reuters.com/article/gsk-ceo-ecigarettes-idUSL6N0UU3TU20150116>

³² Weinbren, E. (2015) Smoking cessation: NRT v e-cigarettes. *Chemist and Druggist*. Available at <https://www.chemistanddruggist.co.uk/feature/nrt-v-e-cigarettes>

³³ Fox, L. (2015) GlaxoSmithKline's Patch and Gum Sales are Suffering Due to E-Cigs. *Ecigarette Reviewed*. Available at <https://ecigaretterevuewed.com/GSK-nrt-losing-sales-e-cigs>

³⁴ Data in this section sourced from *Global tobacco; key findings. Part II; vapour products*. Euromonitor International, October 2017

newer consumers who do not want basic cigalikes, but are not interested in customising devices. For those consumers, closed system products are likely to be more attractive, offering both convenience and choice. But it would be wrong to assume that those using SNP stick to one type of product. Some consumers will use a range of different e-cigarettes, HNB products and snus to suit both their mood and the environment they find themselves in.

Overview of e-cigarette industry structure

The e-cigarette industry has grown at an astonishing rate in the past five to ten years, from its earliest days as almost a cottage/craft business to a multi-billion dollar global enterprise. It is still a rapidly evolving industry, with a complex ecology of layered acquisitions. These involve parent and subsidiary companies, some of which are owned by the traditional tobacco companies, but are mostly independently run, with multiple brands and sub-brands. Currently, the pharmaceutical industry is hardly represented in the sector, but there are some exceptions. One of the leading e-liquid companies in the UK, Blend & Bottle, is owned by BSMW, itself a subsidiary of the pharmaceutical company Thornton and Ross. The US market is by far the most mature, followed by the UK, but a similar business landscape can be mapped across other markets.

There are companies that manufacture their own devices, device components and liquids, while others just produce liquids. Some manufacture their own devices and liquids, but also 'white label', rebadging devices and liquids from other companies and/or selling white label products to others. Some companies use the company name as a brand for devices, for instance, but have other brands for other elements of the business. Some companies have established niches in the market. In the UK, for example, MultiCig dominate the service/gas station market. There are also subsidiary services. For example, Vapourized also have a consultancy service, which advises other companies on liquid compliance. There are also scientific companies which specialise in testing products for safety and compliance.

Some manufacturing companies also have their own wholesale and distribution networks, either devoted exclusively to their own products or wholesaling products across the board. Others focus solely on distribution. At the consumer retail level, there are companies that are not only manufacturing and distributing products, but also running a vape shop franchise business. Finally, there are

stand-alone shops. As you would expect these days, at all levels of the business, from manufacturer to high street vape shops, most offer online purchasing options.

Retail

At the retail level, the primary high street sites are supermarkets, convenience stores and service stations. These sites are where potential consumers are most likely to first encounter e-cigarettes, as these outlets are where they are used to buying their cigarettes. As new consumers, they may want an experience close to cigarettes, and could therefore be attracted to the basic cig-a-like disposable device. Due to lack of space and lack of product knowledge on the part of the staff, this type of outlet (together with pharmacies) tend to stock basic products and are unable to give much, if any, advice to consumers.

In the UK, there are around 50,000 convenience stores, as opposed to around 2,000 vape shops, so the business potential of serving around three million UK vapers is significant. Because UK retailers must display cigarettes behind closed cabinets, some owners are now moving the cabinets out of sight and replacing them with vaping stands, displaying a much wider range of products. Pharmacies are also beginning to offer more choice. This is important for these stores. Once, consumers may have moved to purchase from a vape shop, as it offered them more options. Instead, they may now return to the convenience store, as it offers more choice, the opportunity to buy other products (such as groceries), and is open for longer hours than a vape shop.

Vape shops offer a different experience. The staff are likely to be more informed about vaping and the range of devices. The shop itself is often a social space for vapers to meet and exchange information. Shops cater for all levels of vaping knowledge and experience and this extends into the many online chat forums, festivals, exhibitions and publications that cater for the more advanced and technical end of the consumer market.³⁵

In France, the main retail channel is the vape shops (around 2,600, 60 percent of market share), and then tobacconists (about 25,000, 20 percent market share) which is also the only outlet for cigarettes in France. French supermarkets

³⁵Retail information drawn from panel discussion on UK retail market at UKVIA Vaping Industry Forum, 2018.

and convenience stores generally do not sell vaping products. Belgium and Switzerland have similar distribution channels.³⁶

Component production

Whether companies are manufacturing their own products or sourcing from elsewhere, many of the key components originate from the centre of global e-cigarette production located in Shenzhen, in south-east China, which links the mainland with Hong Kong. Shenzhen is the e-cigarette industry's Silicon Valley. It is listed in the top thirty global financial centres and, because of its status as China's first Special Economic Zone, has become a magnet for high tech start-up companies in many fields, including e-cigarettes. Chinese companies who have enjoyed global success include Joyetech, which developed the eGo battery, Kangertech, Innokin and ISmoka. The Chinese also boast major e-liquid manufacturers, Hangsen and Dekang.

E-cigarette product development and innovation

Apart from a few relatively minor modifications, the combustible cigarette has hardly changed in the last hundred years. But the advent of SNP (except for smokeless snus-style products) has brought with it a burgeoning technological revolution in nicotine delivery. It is commonplace now for innovations in mobile technology to lead to the development of multi-function devices, such as smart phones and watches. In 2015, the US company Vaporcade launched Jupiter, a combined phone/vaping device,³⁷ and other similar innovations are probably in the pipeline. But looking at more conventional developments, aimed at finessing or tweaking some of the existing problems with devices from a consumer satisfaction perspective, examples would include:

- » Products to improve the basic cigalike, by ensuring the stick remains charged, is always full of liquid, with lights telling the user when they have completed a vape session - and to more closely mimic the tank experience enjoyed by users of open systems;
- » Products with extended battery life and on-the-go charging;
- » Products which pay more attention to the look and feel of the device, in much the same way as mobile phone companies focus on design aesthetics;
- » E-liquids designed to work with newer closed system devices;
- » Localised and craft liquids mimicking the appeal of locally-sourced foods and the craft beer industry;
- » Products from closed system manufacturers offering personalisation elements (like device colour ranges) to offset the lack of customisation afforded by open systems.

Avoiding a Kodak moment: global tobacco companies take up the challenge

As with most modern disruptive technologies, it was the new start-up companies that took the lead in commercialising e-cigarettes, leaving the tobacco industry playing catch-up. It was not until six years after the launch of e-cigarettes in the USA that Lorillard became the first tobacco company to launch an e-cigarette in 2012. This was through its acquisition of the Blu brand from Jason Healy, the Australian entrepreneur who founded the company in 2009. Subsequently, Lorillard was taken over by Reynolds, which was then taken over by BAT. The Blu brand was sold to Imperial Brands. It is not uncommon for tobacco companies to take a stake in the new SNP market by acquiring pioneering companies. In the UK, some of the top brands such as 10 Motives, Logic and Vype, as well as Blu, are subsidiaries of major tobacco companies.³⁸

In the USA, the world's most mature and valuable market for e-cigarettes, it is estimated that the value of the e-cigarette business in 2018 will be US\$5.1bn. US\$3.5bn of this would be the value of the market still dominated by the independent sector. US\$1.5bn would be held by the tobacco industry, which largely controls the cigalike end of the market. In mid 2018, the independent company JUUL has over 70 per cent share e-cigarette market.³⁹ One analyst company calculated a 97 percent growth in the e-cigarette market in the USA during the last quarter through to the end of January 2018, with 88 percent

³⁶ Ouest France, *Les ventes de cigarettes électroniques repartent à la hausse* (2018) <https://www.ouest-france.fr/economie/les-ventes-de-cigarettes-electroniques-repartent-la-hausse-5794660>

³⁷ Cigbuyer.com, *Vaporcade Jupiter - A Smartphone You Can Vape* (2015) <https://www.cigbuyer.com/vaporcade-jupiter-smartphone-you-can-vape/>

³⁸ *The Grocer*, 10th February 2018, p.46

³⁹ Bloomberg, *E-cigarette maker JUUL is raising \$1.2 billion* (2018) <https://www.bloomberg.com/news/articles/2018-06-29/e-cigarette-maker-juul-labs-is-raising-1-2-billion>

Figure 3.11

US market consumer channels and industry shares⁴²

	2014	2015	2016	2017	Market Shares
E-cigarettes (Disposables and Closed system)	1000	1400	1600	1400	31.8%
Mass Market (Retail convenience store, Food, Drug stores)	600	600	700	700	15.9%
Online	200	400	500	400	9.1%
Other Retail (including kiosks)	200	400	400	300	6.8%
Vapors/Tanks/Mods & Personal Vaporizers (Open System)	1500	1900	2500	3000	68.2%
Convenience Store, Food, Drug and Mass Retail)	300	300	500	500	11.4%
Online and other retail outlets	300	400	600	700	15.9%
Vepe Shops	900	1200	1400	1800	40.9%
Total	2500	3300	4100	4000	100%

Market shares:

Type: Open Systems 68%, Closed Systems and Disposables 32%

Consumer sectors: Mass market retail 27%, Other retail 7%–20%, Online 15%–20%, Vape Shops 41%

Cigarette Manufacturers have a total market share of approximately 18%–25%

Source: Data presented by David Levy at Global Forum on Nicotine conference 2018

of that growth attributable to JUUL. Overall, it is likely that in the US tobacco companies have no more than an 18–25 percent share of the SNP market.⁴⁰

Currently, the major companies have taken differing views on where they invest most heavily in SNP. Imperial Brands appear to be focussing their effort in the e-cigarette market; JTI and BAT seem equally committed to both e-cigarettes and HNB products, while PMI are moving ahead in the HNB field. But while market analysts are often prepared to predict market trends five to ten years ahead, in this ever-changing environment the companies are much more cautious in their strategic planning. One guesstimate puts the investment to date at around US\$10bn.⁴¹

Of the major companies PMI have invested most heavily, some US\$3bn since 2008 with a further US\$1.7bn of additional spend planned. In 2009

the company opened a new R&D facility in Switzerland dedicated to smoke-free products, followed in 2010 by a new R&D and manufacturing facility in Singapore. New factories have also opened in Germany and Italy, while existing cigarette factories in Greece and Romania have been re-tooled to produce new smoke-free products. BAT has invested US\$2.5bn since 2012 in developing new products and JTI announced a three-year projected spend of US\$1bn to 2021.

⁴⁰Wells Fargo. *Nielsen; tobacco 'all channel' data thru [to] 5/19*. 29th May 2018

⁴¹Various contributors. *Panel on 'Rethinking Nicotine'*. Global Forum on Nicotine, 2018

⁴²Used with permission of Professor David Levy and taken from his presentation at Global Forum on Nicotine 2018 entitled *Modelling future impact of the uptake of e-cigarettes and other safer nicotine products*.

HNB products

HNB products are available in 36 countries⁴³. The HNB market is different to the e-cigarette market, it is currently dominated by Japan and its uptake of the Philip Morris product IQOS. JTI are planning to go nationwide in Japan in 2018 with their HNB product Ploom TECH, to compete with IQOS and BAT's product Glo. Other markets like Romania, Switzerland and Portugal currently lag behind. It is estimated that Japan will continue to dominate the HNB market over the next few years, both in terms of absolute value of the market and total market share in relation to cigarettes.

Already in 2018, HNB products have 14 percent of the total Japanese cigarette market (forecast to rise anything from 20-40 percent by 2021 depending on the analyst). This growth has seen a consequential and dramatic dip in cigarette sales recorded by the main company JTI. Overall, HNB products are forecast by Euromonitor to constitute 45 percent of the global SNP sales market in value over the next few years. More information on Japan will be found in Chapter 4.

Is the market in SNP on a continuous upward growth curve?

As with any economic forecasting, market analysts will have differing views as to the future state of commodity markets. This is particularly evident when making predictions about SNP, especially with uncertainties about global regulations.

In 2012, the global market value for e-cigarettes was estimated by Euromonitor at US\$2bn.⁴⁴ In 2018, their estimate for the global market was around US\$14bn (higher than the E Cig Intelligence estimate of US\$8.6bn).

Euromonitor now combines estimates for e-cigarettes and HNB into a single 'vapour product category'. In 2016, the figure for all vapour products had jumped to around US\$12.3bn.

At the moment, this puts vapour products behind all forms of tobacco products - not just cigarettes at US\$683.4bn, but also smoking tobacco (US\$26.8bn), cigars (US\$25.8bn) and smokeless tobacco (US\$12.5bn). Though still small in comparison with the cigarette market, the growth rates are significant:

Euromonitor reports growth in vapour products sales value of 818 percent over the period 2011 to 2016.

But by 2021 Euromonitor estimates, the all-product vapour market will be more valuable than the market for all tobacco products except cigarettes, with a global value of around US\$34bn.

There was a 43 percent growth in the value of the global market in 2015, but this had slowed to 34 percent in 2016. Analysts attribute this slowdown to the fact that in the strongest markets, like the USA, consumers were moving away from market leader cigalikes (as found in many service stations and convenience stores) towards more closed system products or pod mods, which combine the convenience of cigalikes with the greater flavour ranges and nicotine strengths offered by self-fill systems.

The chart below shows estimates from Euromonitor showing the continuing growth of the combined e-cigarette and HNB markets.

Snus

The Scandinavian snus market is estimated to have amounted to slightly more than 375 million cans in 2016, up by approximately four percent from the previous year. Over the past several years, consumption has been moving from traditional loose products to pouch products, which at the end of 2016 accounted for approximately 80 percent of volumes in Scandinavia.

Sweden is the largest snus market in Scandinavia, with approximately one million consumers. It is estimated that some 20 percent of Swedish men use snus on a regular basis. The overall percentage of women using snus is lower but growing.

In Norway, the snus market volume has grown by more than 20 percent over the past three years to the point where there are now more daily users of snus

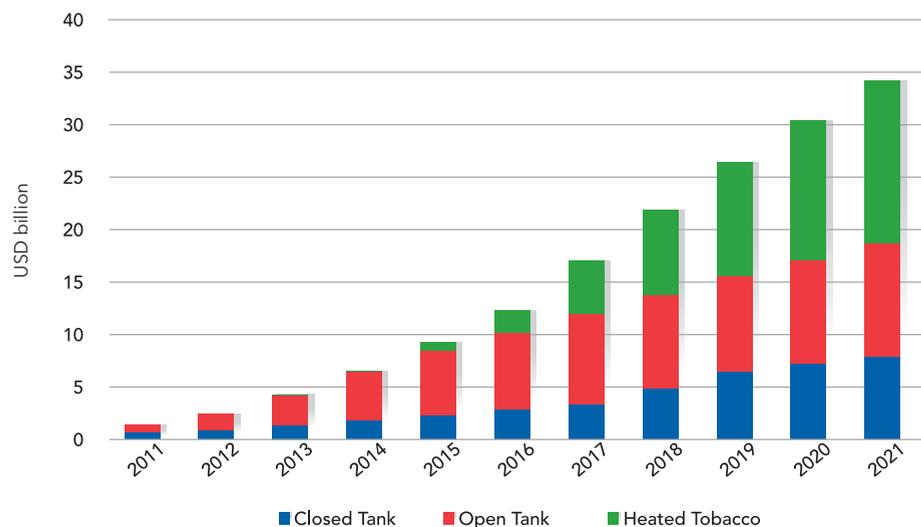
⁴³ Andorra, Greece, Poland, Bulgaria, Guatemala, Portugal, Canada, Israel, Romania, Canary Islands, Italy, Russian Federation, Colombia, Japan, Serbia, Croatia, Kazakhstan, Slovakia, Curacao, South Korea, Slovenia, Cyprus, Lithuania, South Africa, Czech Republic, Monaco, Spain, Denmark, Netherlands, Switzerland, France, New Zealand, Ukraine, Germany, Palestine, United Kingdom

⁴⁴ Data in this section sourced from *Global tobacco; key findings. Part II; vapour products*. Euromonitor International, October 2017

(12 percent) than cigarette smokers (11 percent).⁴⁵ Most snus use is among males in the 16–34 age groups, contrasting with very low levels of smoking in 16–24 age group. Fewer people smoke in the youngest age group than any other, with smoking prevalence among women aged 16–24 down to one percent.

Figure 3.12

Global market size for vapour (e-cigarette and HNB) products 2011–2021



Source: Euromonitor International. Passport tobacco 2017: new insights and system refresher. January 2018

It is clear that a mixed economy of vapour products is emerging.

Swedish Match sells Swedish snus in the US under the General brand, priced in line with premium priced moist snuff products. ZYN is the company's brand for its nicotine pouches without tobacco and was launched for sale in a selection of shops from December 2016.

An almost identical product to Zyn is Zonnica, from the pharmaceutical company Nicovum. It was launched in 2008 and released onto the Norwegian market a few years later. Zonnica is sold as a non-prescription product and can be bought at pharmacies and in kiosks and grocery stores. As it is regulated as a medicine, the producer can advertise it.⁴⁶ Nicovum also manufacture Nicopads (mouth powder containing nicotine) which consist of a white, dry powder packed into

small pads. The powder contains nicotine salts leached from tobacco leaves, to which aroma (lemon/mint), acid regulators, sweeteners, stabilisers and fillers are added.

In 2016, the US moist snuff market is estimated to have grown by approximately three percent, and amounted to approximately 1.5 billion cans, with the pouch segment accounting for approximately 15 percent of this market. The US snus market is growing but is still quite small and amounted to approximately 55 million cans in 2016.

Conclusion

The cigarette has been the dominant nicotine delivery system for the past hundred years and remains so today. However, the arrival of global e-cigarettes and HNB devices onto the market, and renewed interest in Swedish snus, have created a hugely disruptive landscape for the tobacco industry, allowing many new independent players into the business such as NJOY, JUUL, Kangatech and Hangsen to name but a few.

The new and safer options these companies provide very much fit into the zeitgeist of new technology. They offer consumers who want to continue using nicotine unprecedented choice. Consumers can choose whether they want simple and convenient devices or wish to create their own user experience. They have a choice of nicotine strengths and a bewildering array of flavours. None of these options are possible simply by burning some dried leaves wrapped in paper.

Everything about the new industry is dynamic and very fluid, making current estimates of market size, value and other metrics and forecasts of future growth hardly an exact science. It is clear, however, that these new technologies are here to stay. Over-zealous and disproportionate regulation could impede their growth. The only reasonable prediction at this stage is that the global industry is still on a learning curve. The industry will continue creating products that consumers want in the hope and expectation of encouraging more take-up of the widest range of options, and drawing more people away from smoking cigarettes.

⁴⁵ Statistics Norway, Snus more used than cigarettes. Statistics Norway, 2018. Available at <https://www.ssb.no/en/helse/artikler-og-publikasjoner/snus-more-used-than-cigarettes>

⁴⁶ Norwegian Institute of Public Health. Evaluation of harm reduction as a strategic element in tobacco work. NIPH, 2017

Despite all the caveats, the data does tell the story of how these new products have gained a foothold in many global markets in a remarkably short space of time. It is also important to examine this phenomenon in relation to changes in consumer awareness and knowledge of the products, and how this is shaping the market. The next chapter examines these factors in some detail.

Chapter 4: Consumers of safer nicotine products

The uptake of SNP has been driven by a combination of products, manufacturers and consumers: the availability of older (snus) and the development of newer (e-cigarettes and HNB) products, coupled with smokers' interest in alternatives to smoking.

In comparison to conventional tobacco control initiatives, this has occurred without any overall public health plan - without encouragement from governments, tobacco control experts or tobacco control NGOs. Only one country to date - the UK - has given strong policy support to this development, but this came after the initial spread of electronic cigarette use. Other governments are beginning to be supportive, but again after initial consumer interest. Until recently, no government had run a health promotion anti-smoking campaign that supported the use of e-cigarettes. In its 2017 'Stoptober' campaign, Public Health England (PHE) did endorse the use of e-cigarettes as a legitimate route to quitting.¹

Indeed, in many countries tobacco control leaders have been caught by surprise by the rapid uptake of SNP, have been antipathetic to these products and have tried to block their availability or discourage their use.

As we will argue in Chapter 7, this consumer interest is entirely consistent with a public health philosophy of enabling people to take control of their health, yet has been led by people themselves, not by public health experts. As one commentator put it, "E-cigarette makers, vaping stores, vaping forums and vapers are the new frontline in helping people switch from smoking. It is an example of public health objectives being delivered without the involvement of public health professionals".²

"E-cigarette makers, vaping stores, vaping forums and vapers are the new frontline in helping people switch from smoking. It is an example of public health objectives being delivered without the involvement of public health professionals".³

The story of SNP has yet to be fully told. Market data (as shown in Chapter 3) provide one measure of the uptake of products, but public health analysts are usually more interested in epidemiological data showing the numbers of people who use SNP, or the percentage of the population using them. Such data are still thin on the ground and they only give a snapshot at a point in time. Even rarer is information about trends in use over time and how this relates to changes in levels of smoking and longer-term health outcomes.

Starting to use e-cigarettes⁴

"About ten years ago my bad habit of smoking was beginning to annoy me, coughing in the morning and problems with breathing when I was active, so I decided to see if I could get rid of the cigarettes. First, I tried to just quit, I just put them away and said that's it, lasted for about two to three weeks then I was back to the cigs. I should mention that I managed to cut down on my use, but it didn't do anything for my health, so I tried to use some nicotine gum and patches, but it was like they gave me an urge to smoke more.

"After trying to stop for about two years a workmate introduced me to a strange looking pen with some liquid in and he told me I should try this. I tried a few puffs and was at first: 'I'm never gonna get used to this' - but he told me I could keep it (it was an eGo styled pen with a CE4 style tank) and he gave some apple flavoured E-juice also. After looking at it for a few days I thought what the heck, let's see if I can't get used to it. After a couple of days, I started

¹ Public Health England, Stoptober campaign website
https://www.nhs.uk/oneyou/stoptober/home?gclid=CjwKCAjwXo3OBRBpEiwAS7X62TMrdcX8YnoOh3G-4NQW_YzpdvFHulaxADGfGEqBQvwPtuZIH15nxoC4kAQAvD_BwE#GVG3ULMld2Jj9uOr.97

² Stimson, G. (2016) Public health should step aside. Vapers are now leading the fight against smoking. *Spectator (Health)*. Available at

<https://health.spectator.co.uk/public-health-should-step-aside-vapers-are-now-leading-the-way-against-smoking/>

³ Stimson, G. (2016) Public health should step aside. Vapers are now leading the fight against smoking. *Spectator (Health)*. Available at

<https://health.spectator.co.uk/public-health-should-step-aside-vapers-are-now-leading-the-way-against-smoking/>

⁴ Testimony of a Danish vaper provided by DADAFO, the Danish vapers association

to like the feel and taste of the e-cig and I managed to use it sometimes when I had the need for a smoke. It was around January 2010.

"I gradually used the e-cig more and more instead of cigs but it took me about two months to totally quit the cigs - so 13th April 2010 I smoked my last cigarette. And wow, only after a couple of weeks I started to smell way better and shortly after my taste got better, but most importantly I stopped coughing in the morning and my breathing got way better. The switch to vaping has been a life changer for me and I can't thank my work mate enough for the introduction to vaping!"

Danish vaper

But these bare facts will tell only part of the story. Description of how the changes in the use of tobacco and nicotine occur requires other kinds of information, using the tools of anthropology, history, and cultural studies, in addition to social and behavioural studies. It requires in-depth studies of how changes in tobacco users have occurred in different places over time. In the case of the cigarette, itself a disruptive innovation, we know that it took several decades for it to displace other ways of using tobacco. And indeed, in many countries, as is the case in India (Chapter 6), smoking cigarettes has not displaced the use of other types of tobacco. Few smoking researchers have turned their attention to how changes in the route of administration of nicotine have occurred in the past and are occurring now.

These changes are important to understand at a personal level, including, as in the example of the Danish vaper, the significance of advice and help from friends. A huge amount of information about e-cigarettes is also available on social media. For example, one e-cigarette forum in the UK gets 10,000 visits a day,⁵ a French site attracts 30,000 visits a day⁶ while an Australian site gets 75,000 visits a day from people across the globe.⁷ Smokers are turning to vapers for advice on switching from smoking, and vapers have access to massive sources of information and support from other vapers - a genuine example of community public health in action.

There is a serious lack of curiosity among tobacco control researchers concerning the processes by which changes in the prevalence of smoking occur. At the end of this chapter, we give some mini-case studies to show how smoking is

rapidly disappearing in Norway, how the decline in smoking in Sweden has been accompanied by dramatically low levels of smoking-related diseases, how Japanese smokers rapidly switched to HNB and how the tobacco market is collapsing, and how many UK smokers rapidly embraced e-cigarettes. These case studies merely scratch the surface of the complexity of changes in smoking and nicotine use.

"Smokers are turning to vapers for advice on switching from smoking, and vapers have access to massive sources of information and support from other vapers - a genuine example of community public health in action"

Global estimates of e-cigarettes and HNB use

According to the market analyst company Euromonitor, in 2011 there were an estimated seven million people who "were regular dual or sole users of e-cigarettes and vapour products" around the world - for this estimate Euromonitor combines data on e-cigarettes and HNB. That figure rose to around 35 million in 2016 and is estimated to rise to around 55 million by 2021.⁸ Euromonitor base their growth estimate of 55 million partly on the assumption that the market in HNB products will continue at the current rate, although there are signs that the rapid growth in the Japanese market is beginning to slow. Much caution is required in forecasting what will happen in the SNP market because of the uncertainties over both regulation and consumer uptake.

While the current figure of around 35 million is a fraction of the world smoking population, when matched against the smoking population in the 61 markets where Euromonitor International collect data, those using mainly e-cigarettes or HNB are equivalent to about seven percent of that smoking population. Euromonitor estimates that the total vaping population will grow to around ten per cent of the smoking population by 2021. This is a remarkable growth in the short period since these products have been available: even more so that this has been driven by consumer interests and not by public policy.

⁵ Personal communication, Oliver Kershaw

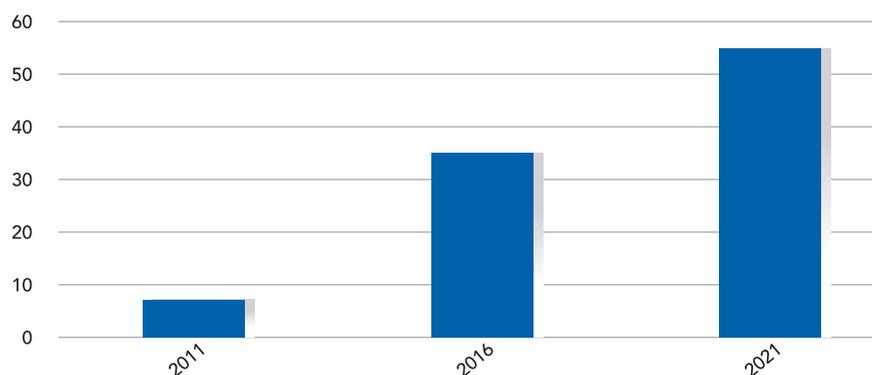
⁶ Personal communication, Jacques le Houezec

⁷ Data from Vapetrotter <https://www.vapetrotter.com>

⁸ Euromonitor. Global tobacco: key findings part II; vapour products. Euromonitor, 2017, p.11

Figure 4.1

Estimated numbers of people using vapour products (e-cigarettes and heat-not-burn) globally (millions)



Source: Euromonitor International, Passport Tobacco 2017: New Insights and System Refresher January 2018

There are no global estimates on the use of US style smokeless tobacco, though the US National Survey on Drug Use and Health estimates that there are around eight million consumers of smokeless tobacco in the USA.⁹ There are an estimated one million adult male and 200,000 adult female snus users in Sweden.

Country level data on e-cigarette users

For the first time we have tried to bring together the extant information on the prevalence of use of e-cigarettes, and this is summarised in Figure 4.22 at the end of the chapter. This information is also available online, on a country-by-country basis where it exists, at www.gsthr.org.

We have tried to gather information on current or daily use, as well as on the numbers who have ever used e-cigarettes. However, there are large gaps - we have only been able to obtain recent, reliable data from 36 countries, and much of the information comes from one major EU survey. Clearly global interest in e-cigarettes by consumers and some policy makers has not been matched by government or academic surveys to explore even the extent of use. Readers must be aware of limits to the comparability of the sources. Surveys can suffer from numerous differences, due to variations in sampling methods and questions asked. We therefore suggest caution in making country comparisons.¹⁰

Overall, as a percentage of the total adult population, levels of current use of e-cigarettes in different countries range between one percent and 6 percent. Levels of sometime experience with e-cigarettes range up to 27 percent of the adult population in Greece, and 20 percent or above in Estonia, Czech Republic, France, Cyprus, Latvia, and Austria.

Clearly there are many smokers who are interested in these products. But there is also a large gap between those who have shown enough interest to have tried an e-cigarette at some time, and those who have gone on to currently use them. The highest prevalence of vaping is found in Great Britain¹¹ where approximately six percent of the adult population currently vapes.

There are limitations with all surveys on vaping, but one of the most extensive datasets is from Eurobarometer 458. The European Commission used this public opinion gathering resource to conduct an extensive survey of e-cigarette use across the EU as part of a wider review of smoking habits.¹² The key findings were that across the 28 countries of the EU in 2017:

- » Around 15 percent of those aged 15 or over had tried an e-cigarette at least once - compared to 12 percent in 2014;
- » Two percent of the population are current users and this has remained stable since 2014;
- » Almost one in twenty current smokers now currently use e-cigarettes or similar devices (four percent), and four percent of ex-smokers;
- » Current use of e-cigarettes among people who have never smoked is rare. At most, one percent of e-cigarette users in any EU country are people who have never smoked.

Figure 4.2, generated from Eurobarometer data shows the prevalence of smoking cigarettes compared with the prevalence of e-cigarette use across the EU.

⁹ Rodu, B. (2014) How many Americans use smokeless tobacco? *Rstreet*. Available at <https://www.rstreet.org/2014/08/08/how-many-americans-use-smokeless-tobacco/>

¹⁰ Farsalinos, KE. et al (2016). Electronic cigarette use in the European Union; analysis of a representative sample of 27,460 Europeans from 28 countries. *Addiction*. Nov;111(11) p. 2032-2040. Available at <https://www.ncbi.nlm.nih.gov/pubmed/27338716>

¹¹ Great Britain is England, Scotland and Wales. The United Kingdom (UK) is England, Scotland, Wales and Northern Ireland - vaping prevalence in the UK is approximately five percent.

¹² European Commission. *Attitudes of Europeans towards tobacco and electronic cigarettes*. Special Eurobarometer 458. EC, 2017. Available at: <http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146>



Looking at the Eurobarometer 2017 findings by country in more detail:

The **UK** (5 percent), then **France** and **Belgium** (both 4 percent), have the highest levels of current e-cigarette use.

France (9 percent) and **Austria** (6 percent) have the largest proportion of respondents who have previously used e-cigarettes but no longer do so.

Latvia (20 percent) has the highest proportion of respondents who have tried e-cigarettes at least once or twice, followed by the **Czech Republic** (16 percent) and **Estonia** (15 percent).

France and **Belgium** have the highest proportion of current smokers who also currently use e-cigarettes (8 percent), followed by **Austria**, **Denmark** and **Lithuania** (7 percent).

The **UK** has by far the highest proportions of ex-smokers who say they are current users of e-cigarettes (14 percent) followed by **Ireland** (7 percent), then **Belgium** and **France** (6 percent).

Younger people are more likely to have tried e-cigarettes: 25 percent of 15–24 year olds have tried e-cigarettes, compared with 6 percent of those aged 55 plus.*

Those who have tried to quit smoking are more likely to say they are current or past users of e-cigarettes (47 percent) than those who have not (27 percent).*

The majority of e-cigarette users use them daily (67 percent). Older users and men are more likely to be daily users.*

55 percent of EU respondents think e-cigarettes are harmful. This proportion is 80% or above in **Netherlands**, **Finland**, **Latvia** and **Lithuania**.

*This statistic is relevant to the whole EU 28

E-cigarette use in the USA

Collating data from various national representative sources, the National Academy of Science report¹³ indicates that:

- » Between 8.5 and 12.6 percent of the adult population has tried e-cigarettes;
- » Current use (in the past 30 days) is estimated very widely at between 2.4 and 5.5 percent;
- » Although the data are hard to interpret, e-cigarette use in the USA has begun to level out;
- » About 20 percent of current users reported using e-cigarettes daily and nearly 70 percent were dual users, not just of combustible tobacco products but also smokeless products like snus;
- » E-cigarette use is mainly found in younger age groups and decreases with age - and more men use e-cigarettes than women;
- » US data reveals significant racial and ethnic differences with majority use among (non-Hispanic) whites, followed by Hispanic, Black, Asian and Native Indian;
- » In general, as frequency of use increased, so the consumer was more likely to use the more flexible devices with refillable tanks and more likely to use e-liquid containing nicotine;
- » About two-thirds of current users were using flavoured liquids.

An earlier analysis considered e-cigarette use among US adults based on the Population Assessment of Tobacco and Health (PATH) study,¹⁴ while another looked at reasons for use among a national representative sample.¹⁵ Taken together, and adding to the National Academy of Sciences review, the studies concluded:

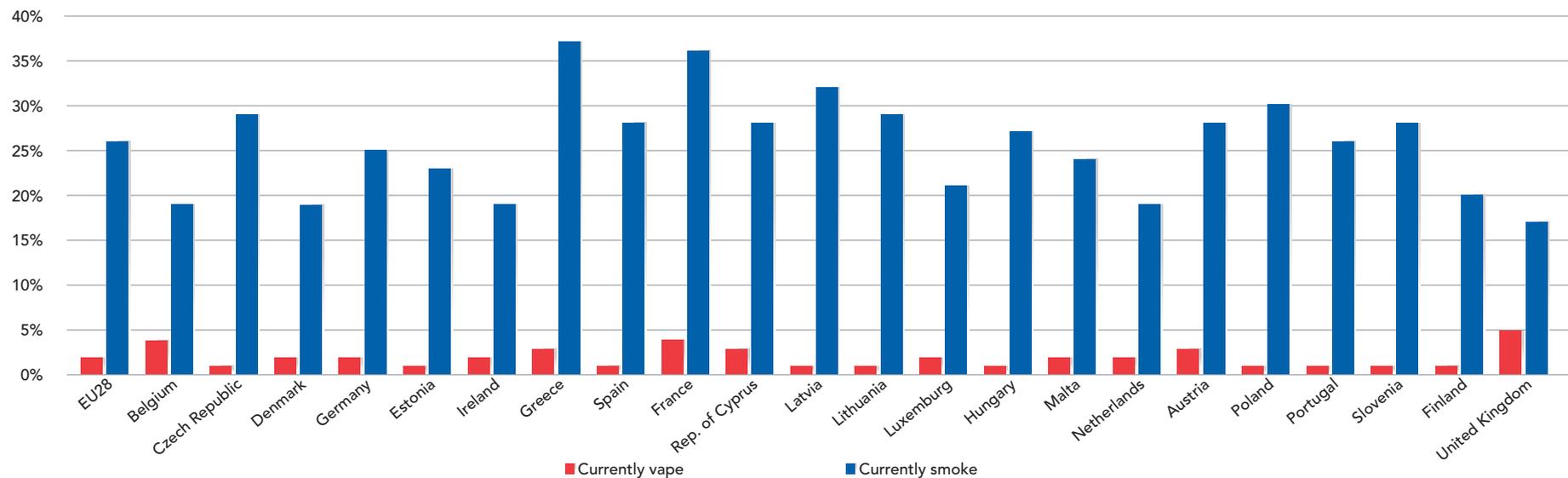
- » Most e-cigarette consumers were either current, or recent former, smokers;
- » The main reason for dual use or switching was concerned with personal health considerations and the health impact on others, followed by convenience, curiosity, flavour and cost;

¹³ National Academy of Sciences. *Public health consequences of e-cigarettes*. National Academies Press, 2018

¹⁴ Rodhu, B. and Plurphanswat, N. (2017). E-cigarette use among US adults: Population Assessment of Tobacco and Health (PATH) Study. *Nicotine and Tobacco Research*, p. 1-9

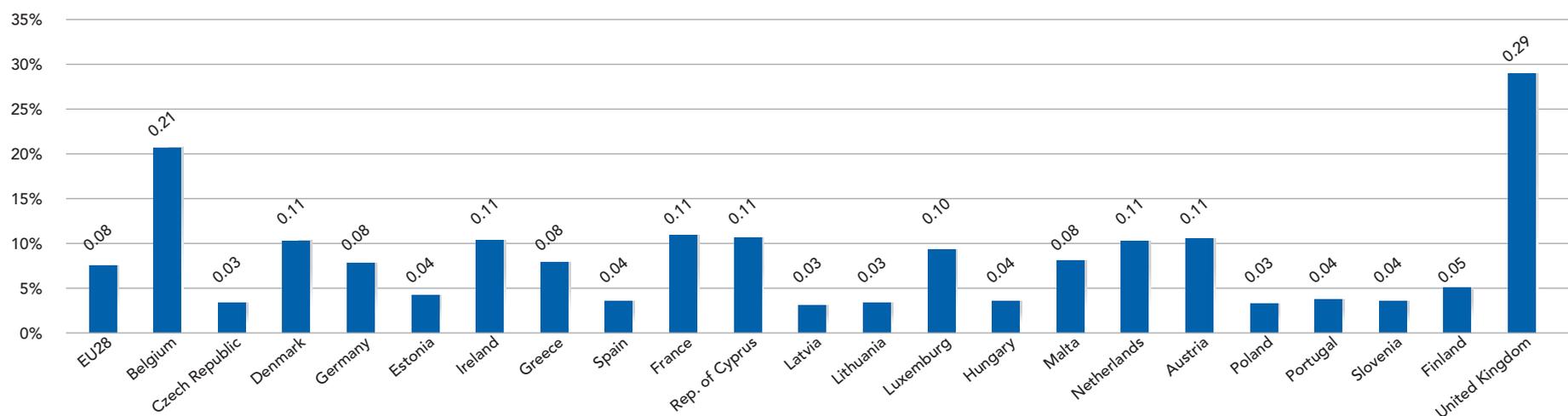
¹⁵ Patel, D. et al. (2016) Reasons for current e-cigarette use among US adults. *Preventative Medicine*. 93, p. 14-20. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5316292/>

Figure 4.2

Comparison of current smoking and vaping levels

The second chart develops a simple metric giving the ratio of current e-cigarette users to current smokers. This shows that the highest is the UK at 0.29. In other words, there are 29 e-cigarette users for every hundred smokers in the UK. In many other EU countries, the ratio is above 0.10.

Figure 4.3

Ratio of current vapers to current smokers

» The study by Patel¹⁶ also revealed variations in reasons for use by product type, including greater likelihood of citing cessation/health among tank users compared with disposable users. Research suggests that tank systems may deliver more nicotine than disposable e-cigarettes and that some e-cigarette users find disposable varieties less satisfying than tank systems.¹⁷ This aligns with research showing that e-cigarette users who use tanks are more likely to be former smokers than those who use disposable or cartridge style e-cigarettes.¹⁸

Australia - e-cigarettes are used despite nicotine being illegal

As we discuss in Chapter 6, in Australia a legacy ban means that nicotine for use in e-cigarettes is illegal unless obtained on a prescription. Nevertheless, despite prohibition, there is substantial use of e-cigarettes. The 2016 National Drug Strategy Report¹⁹ found that:

- » Almost one-third of smokers had tried e-cigarettes at some time;
- » Current use of e-cigarettes was 1.2 percent of people aged 14 or older reporting that they currently use e-cigarettes (this compares for example with 5 percent in the UK);
- » Current e-cigarette use was most common among smokers aged 18-24;
- » One in 20 smokers currently use e-cigarettes and only 1.5 percent use them daily;
- » Those aged 50 or older were more likely to use e-cigarettes as a cessation device, with more than half specifying that they used them to help them quit smoking;
- » About one in five used e-cigarettes because they thought they were less harmful than regular cigarettes.

The lesson from Australia is that while bans might make access difficult and result in fewer people using e-cigarettes than in countries with more liberal laws, bans do not deter interest in e-cigarettes.

The numbers using e-cigarettes are still small in many countries, but are still substantial given the limited time in which these products have been available, the lack of endorsement by most governments and discouragement from public health leaders, often seized upon by media in search of a story.

Why do people use e-cigarettes?

First experiences with e-cigarettes²⁰

"I bought my first e-cigarette, a cigalike, in a marketplace in July 2012. Until that day, I was convinced, that I would be the last smoker on earth, since I had already tried all the different quitting methods, all without success. I even tried Zyban, in the hope for a 'quick fix' - and that almost led me to commit suicide. If I hadn't stopped taking the pills, I wouldn't be here today... This new 'gadget' I bought in 2012 - 'the electronic cigarette' as it was called - was the first step on the road to a 'smoke-free living', but it wasn't until February 2013 [that] I could finally break my smoking habit, thanks to an eGo-battery and the CE4 atomizer. I started out with 36 mg/ml nicotine, and I felt no need to smoke. After three smoke-free days, everything around me started to smell of smoke - and I had to wash down all the walls in the house, the curtains, the blankets, all my clothes - because of the pungent smell of tobacco smoke.

"I'm down to 3-6 mg/ml nicotine - and I enjoy vaping. I can easily go for days without vaping, and for me it hasn't been the craving for nicotine that keeps me vaping - it's the sensation and the pleasure that comes from vaping - like a really good cup of coffee or a nice glass of red wine.

"I started smoking when I was 16, and kept on smoking a pack-a-day for the next 16 years and I've been 100 percent smoke-free for almost six years now, thanks to vaping. I still find pleasure in vaping, as I did with smoking - but I feel so much better - both physically and mentally. And I've found reassurance in vaping, found so many new friends, who also saw the potential in vaping.

¹⁶ Patel, D et al. (2016) Reasons for current e-cigarette use among US adults. *Preventative Medicine*. 93, p. 14-20. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5316292/>

¹⁷ Farsalinos, K. et al. (2014). Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices. *Scientific Reports*. 4:4133

¹⁸ Dawkins, L. et al (2015). First- versus second-generation electronic cigarettes: predictors of choice and effects on urge to smoke and withdrawal symptoms. *Addiction*. 110(4) p. 669-677

¹⁹ Australian Government. *National Drug Strategy Household Survey*. Australian Institute of Health and Welfare, 2017

²⁰ Testimony provided by DADAFO, the Danish vapers association

"Today, I'm fighting for smokers and vapers rights - every day - trying to slay misinformation, and educate people about 'the truth about vaping'".

Danish vaper

New Zealand

Penelope Truman from Massey University and colleagues conducted the first survey of New Zealand vapers, sampling a broad range of regular vapers who had completely switched from smoking, reflecting the estimated 63,000 daily vapers in New Zealand. In line with most consumer surveys, most vapers were white males aged 20–50. Vaping was a means of smoking cessation, smoking reduction, or avoidance of or mitigation of relapse to smoking, while cost was also a factor. First time vapers tended to start with devices that looked like a cigarette then moved on to explore more powerful devices. They also moved away from tobacco and menthol flavoured e-liquid over time.

The majority of those who still smoked only did so occasionally, and those who still smoked regularly had reduced their tobacco consumption by around 50 percent on a conservative estimate. Unlike nicotine patches and other smoking cessation methods, vaping appears to be pleasurable for many. Finding a pleasurable form of vaping may prove important for complete smoking cessation, since those who were smoking as well as vaping seemed less likely to report that they liked vaping. Exploration of different types of e-cigarette, different nicotine strengths, and different flavours of e-liquid was common and may be an important aspect of a successful vaping experience.²¹

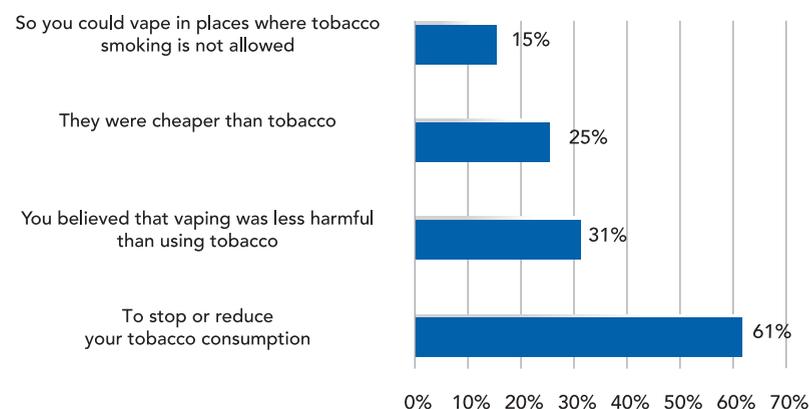
Eurobarometer also gives insights into why people use e-cigarettes. It might seem obvious but the top reason across the EU for using e-cigarettes is to stop using tobacco. The clear majority of people using e-cigarettes did so to stop, or to reduce tobacco use (61 percent). Following this the next reason was because they thought e-cigarettes were less harmful than cigarettes (31 percent), or less expensive (25 percent). Only six percent said they started because they felt using e-cigarettes was cool or attractive.

The flavour was relatively unimportant as a reason to start using e-cigarettes – only 12 percent mentioned this as a factor. However flavour is an important

factor in continued use, and in the previous Eurobarometer survey (2014) flavour was an important factor in choice of e-cigarette. Flavours preferred by current e-cigarette users in the 2016 survey were fruit (47 percent), tobacco (36 percent), then menthol/mint (22 percent). Women preferred tobacco flavour more, and men preferred fruit. Older respondents preferred tobacco flavour compared with the younger respondents who preferred fruit (72 percent) and candy flavours (11 percent).

Figure 4.4

Top four reasons for starting to use e-cigarettes



Source: European Commission (2017). Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes Available at: http://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG

However, a recent study of 15,000 US vapers indicated the importance of flavour in encouraging smokers to switch. The proportion of first e-cigarette purchases that were fruit-flavoured increased from 17.8 percent of first purchases made before 2011 to 33.5 percent of first purchases made between June 2015 and June 2016. Tobacco-flavoured first purchases almost halved during this time (46.0 percent pre-2011 to 24.0 percent between 2015 and 2016). Fruit/fruit beverage, dessert/pastry and candy, chocolate, or sweets all showed percentage increases over time and were the most popular currently used e-cigarette flavours. Tobacco and menthol flavours, the two most popular flavours for

²¹Truman, P. et al. (2018) An online survey of New Zealand vapers. *International Journal of Environmental Research and Public Health*; 15 (2) p. 222

initiating e-cigarette use prior to 2013, now rank as the fifth and sixth most popular currently used e-cigarette flavours, respectively. The authors conclude that current moves in the US to ban e-liquid flavours in the mistaken belief they have a special appeal for young people could in fact dissuade smokers from switching.²²

Safer nicotine products and changes in the prevalence of smoking

The key questions for tobacco harm reduction are whether SNP can replace and displace cigarette smoking, the way this occurs, and whether there are long-term health gains from this. In other words, do SNP help drive down smoking and smoking-related disease and premature death? If the ethos of tobacco control can be characterised (and possibly caricatured) as 'Quit or Die', does the harm reduction message of 'Quit or Try' really make a difference to individual and public health? Does smoking decline lead to less illness and less premature death? What is the weight of evidence for safer nicotine products and individual and population health?

“Does the use of SNP drive down smoking and improve public health?”

These questions cannot be answered through single epidemiological studies, market data, or policy studies. It requires bringing together a historical and cultural picture of tobacco use in particular countries, changes in the types of tobacco and nicotine used over time, epidemiological studies of tobacco users, scenario modelling, and measures on long-term changes in health. This work has barely begun. Few smoking researchers have synthesised the complex array of national information.

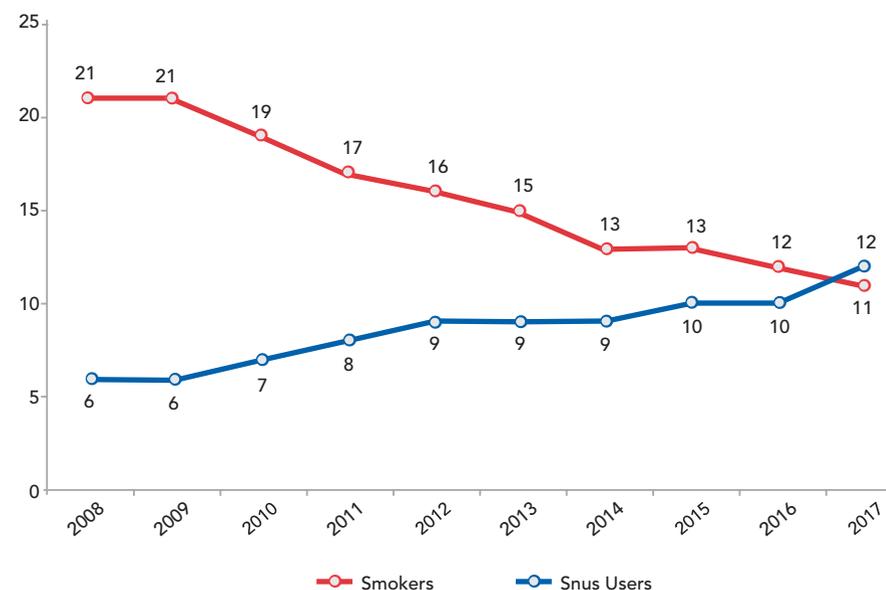
In this final section of the chapter, we give a brief overview of changes in tobacco and nicotine use, by way of national case studies: in Norway, where the evidence is that snus has rapidly displaced cigarettes and that smoking is fast disappearing; in Sweden, which has undergone a similar process and where there are epidemiological data on the low rates of tobacco related disease; in the UK, which has the highest uptake of e-cigarettes globally; and finally in Japan, which is the most important global example of how HNB products are displacing cigarette sales at a hitherto unseen rate.

Case study 1: Norway - smoking is fast disappearing and only one percent of young Norwegian women smoke

Snus is fast replacing cigarettes as the way that Norwegians consume nicotine.²³ As shown in Figure 4.5 there has been a long-term decline in daily smoking from 21 percent in 2008. In 2017, for the first time, the proportion of the population using snus - 12 percent - exceeded that of those smoking cigarettes. At 11 percent, Norway now has one of the lowest levels of daily smoking in developed countries. The fall in smoking is even more dramatic amongst younger people. Among young people snus became more popular than smoking around 2009-10, with a decline in smoking to three percent.

Figure 4.5

Prevalence (%) of daily smoking and snus use in the Norwegian population



²²Russell, C et al. (2018). Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduction Journal*; 15 p. 33. Available at <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6>

²³We are grateful to Karl Lund for contributions to this section

Figure 4.6

Daily usage as a percent of population (for those under the age of 25)

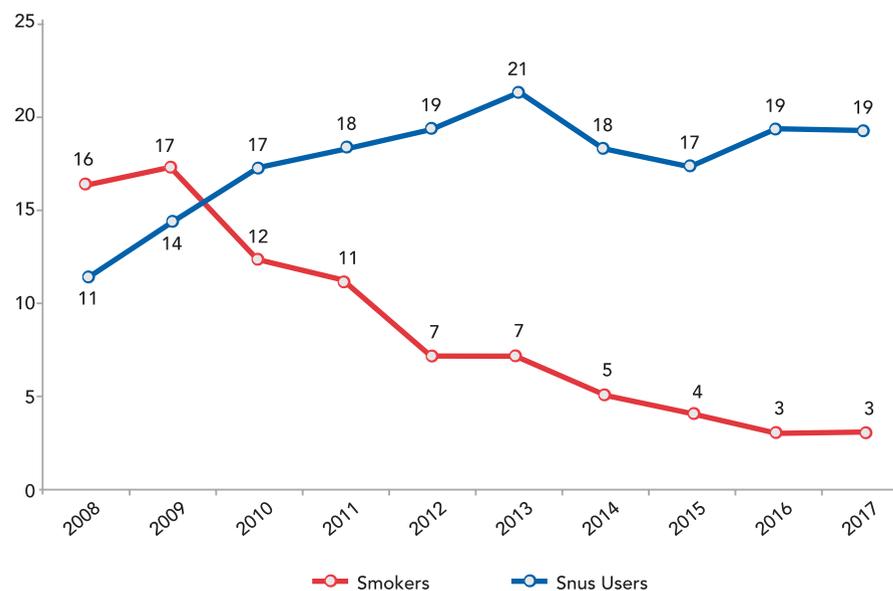
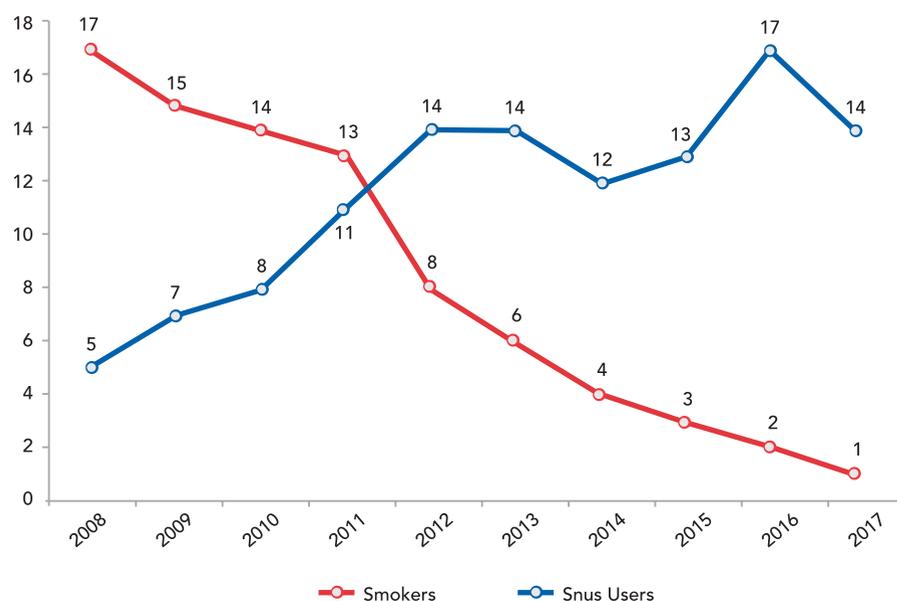


Figure 4.7

Daily usage as a percent of population (women under the age of 25)



Source: Statistics Norway/The Norwegian Directorate of Health

Even more dramatic is the changing tobacco habits of young women in Norway under the age of 25, with a precipitous fall in smoking among this group since 2008, from 17 percent to one percent.

It is likely that such a fall has not been witnessed anywhere else in countries where smoking has been common among women.

But women have not given up using tobacco – snus use hovers from around 14 percent to 17 percent. The overall percentage of people using nicotine via either snus or smoking has remained about the same over time – it is the choice of products that has changed over the last ten years.

How has this come about? The Government of Norway has taken a negative view on snus: at a recent European Court of Justice hearing (see Chapter 6) it referred to its use as an “epidemic” among young people. In Norway, all tobacco advertising has been banned since the middle of the 1970s. The uptake of snus has been within a public climate where messages from government, medical and tobacco control organisations have asserted that snus is not a safe alternative to smoking cigarettes, where there have been warnings against snus use including for smoking cessation, and both smokers and non-smokers over-estimate the health risks of snus.^{24 25}

The change in nicotine consumption began at the end of the 20th century. In 1997–99, about five percent of tobacco consumption was snus, and 95 percent was cigarettes. The use of snus accelerated from the turn of the century, linked with the availability of pasteurised snus and the new products that came onto the market in both Norway and Sweden in the late 1980s. Cleaner to use products in small pouches, a range of flavours and strengths, and smart packaging would seem to have been part of the appeal, in a context where people were being encouraged to avoid smoking. Overall tobacco consumption – by weight – declined by 40 percent between 1997 and 2017.

There appear to be three mechanisms behind the fall in smoking and the rise in the use of snus. First, snus is an exit from smoking for established smokers. Over

²⁴ Øverland, S., et al (2008). Relative harm of snus and cigarettes: What do Norwegian adolescents say? *Tobacco Control: An International Journal*, 17(6), p. 422–425

²⁵ Wikmans, T. and Ramström, L. (2010). Harm perception among Swedish daily smokers regarding nicotine, NRT-products and Swedish snus. *Tobacco Induced Diseases*, 13 p. 8–9

time, the use of snus at the last quit attempt has risen from ten percent in 2003 to around 23 percent, overtaking NRT by 2011.^{26,27} It is the most common way to quit smoking in Norway, after unassisted (cold turkey) quits. As with e-cigarettes, the preference of snus over NRT might be because snus is non-medical – a switch in route rather than a medication.

Former smokers make up the largest proportion of snus users,^{28,29} and there is evidence that using snus is associated with higher quit rates for smoking compared to not using snus³⁰ or using NRT.³¹ NRT is in fact widely available. It is plausible that there is a higher population impact of snus on exits from smoking than for other ways of quitting smoking.

Secondly, snus use helps smokers to reduce smoking. Many smokers in Norway appear to use snus to reduce the level of smoking, or use it where smoking is banned. Those who both smoke and use snus have a weekly cigarette consumption 37 percent below that of exclusive smokers.³² The proportion of dual users is small.³³

Thirdly, snus use has become an alternative way of using nicotine for those who might otherwise have started smoking. Norway provides suggestive evidence that snus is protective against smoking – in other words, people who want to use nicotine and who chose snus are unlikely to progress to smoking. Many young snus users have characteristics that usually predict uptake of cigarette smoking.³⁴ If, as seems possible, they are choosing snus instead, this is an important proposition given concerns about snus as a possible gateway to smoking.

Karl Lund, a Norwegian smoking and snus researcher, summarises the situation:

“In Norway and Sweden, the availability of snus has clearly influenced total tobacco consumption through its role in smoking initiation and smoking cessation. The combined numbers who have i) quit smoking for snus, ii) reduced smoking intensity by snus, iii) picked up snus instead of cigarettes, have outnumbered iv) snus users who otherwise would have been tobacco-free. Health gains from smoking cessation, smoking reduction and smoking substitution produced by snus, have more than out-weighed the (marginal) health loss in the small fraction of never-smokers taking up snus.”

Norway provides evidence that the availability of snus and consumer choices have driven these changes. It is interesting to speculate whether the reductions

in smoking might have been quicker had there been supportive messages from government and health experts.

Case study 2: Sweden and snus – low rates of smoking and the lowest level of tobacco-related mortality in Europe

It has often been remarked that Sweden provides a unique case study of the impact of snus on smoking. Sweden stands out in the EU as the only country where snus may be sold legally. This natural experiment, and the large amount of long-term epidemiological evidence, provides substantial information on the uptake and plausible impact of snus on smoking and tobacco related disease. The UK Royal College of Physicians argued in its 2016 report that the use of snus in Sweden is proof of concept for the efficacy and effectiveness of tobacco harm reduction:

“The availability and use of an oral tobacco product known as snus in Sweden, documented in more detail in our 2007 report (and revisited in Chapter 7),

²⁶ Lund K. E. (2012). Association between willingness to use snus to quit smoking and perception of relative risk between snus and cigarettes. *Nicotine and Tobacco Research*. 14 p. 1221-8

²⁷ Rutqvist L. E. (2012). Population-based survey of cessation aids used by Swedish smokers. *Harm Reduction Journal* 2012; 9 p. 38

²⁸ Lund K. E. et al (2011) The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies. *Addiction* 2011; 106 p. 162-7

²⁹ Wiium N. et al (2011). Smoking cessation among Norwegian adolescents and young adults: preferred cessation methods. *Scandinavian Journal of Psychology* 52 p. 154-60

³⁰ Lund I. and Lund K. E. (2014) How has the availability of snus influenced cigarette smoking in Norway? *International Journal of Environmental Research and Public Health* 11 p. 11705-17

³¹ Scheffels J. et al (2012) Contrasting snus and NRT as smoking cessation methods. An observational study. *Harm Reduction Journal*. 9 p.10

Lund K. E., et al (2010). The use of snus for quitting smoking compared with medicinal products. *Nicotine and Tobacco Research* 12 p. 817-22

³² Lund K.E. et al (2016). Do never smokers make up an increasing share of snus users as cigarette smoking declines? Changes in smoking status among male snus users in Norway 2003-15. *Addiction* 2016 Oct 14. Epub ahead of print.

³³ Lund K. E. and McNeill A. (2013) Patterns of dual use of snus and cigarettes in a mature snus market. *Nicotine and Tobacco Research* 15 p. 678-84

³⁴ Grøtvedt L. et al. (2008) Social differences in smoking and snuff use among Norwegian adolescents: a population based survey. *BMC Public Health* 8:12.

demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product. Particularly among men, the availability of snus as a substitute for smoking has helped to reduce the prevalence of smoking in Sweden, which is now by far the lowest in Europe. The magnitude of the contribution made by the availability of snus over and above conventional tobacco control measures is difficult to quantify, but a recent study of the effect of withdrawal of snus from the market in Finland in 1995, when both Finland and Sweden joined the EU, but only Sweden was allowed to continue its use, estimates that over the following ten years the availability of snus reduced smoking prevalence in Sweden by an additional 3.7 percentage points. Trends in snus use in Norway are similar to, and perhaps stronger than, those in Sweden, and there the use of snus is strongly associated with quitting smoking”.³⁵

Snus has been used in Sweden for over 200 years and, historically, tobacco use in Sweden was dominated by snus. From the early 1900s (a couple of decades after the invention of the cigarette rolling machine) cigarettes started to become more popular and the consumption of snus began to decline. From the late 1960s the trends were reversed and the use of snus increased. According to Swedish tobacco expert Lars Ramström:

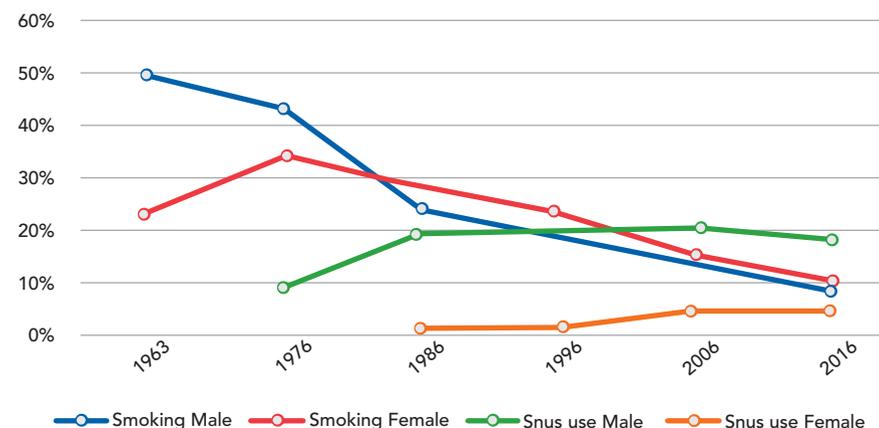
*“An important influence behind this change was the emerging scientific evidence of the health risks of smoking which were disclosed in the 1962 report of The Royal College of Physicians in London and the 1964 report of the US Surgeon General. These new pieces of evidence received a lot of attention in Sweden, both in news media and in professional circles. Many smokers who were encouraged to escape the health risks of smoking switched to snus”.*³⁶

The change was accelerated by the availability of newer types of the Swedish pasteurised snus. In 1981, Swedish Match (at that time called Swedish Tobacco Ltd) opened a newly built factory where the traditional pasteurisation process was made completely closed to avoid contamination.

Snus overtook cigarettes among men in 1996. The change would seem to have been due to consumer interest in the face of opposition from the Swedish government and health bodies. It occurred primarily among Swedish men, and the reduction in smoking was faster for men than for women. Among men, the prevalence of smoking is now a sixth of what it was in 1963, and there has been

a sharp increase in the use of snus to around 18 percent. Female smoking levels continued to increase until 1976, but have since declined, at a slower rate than for men however. Unusually for many countries, more women now smoke than men. Nevertheless, the use of snus is increasing among women but is still below that for men (note that the official statistics for Sweden give somewhat higher levels of smoking than the Eurobarometer studies).

Figure 4.8
Prevalence of daily smoking and snus use in Sweden 1963-2016



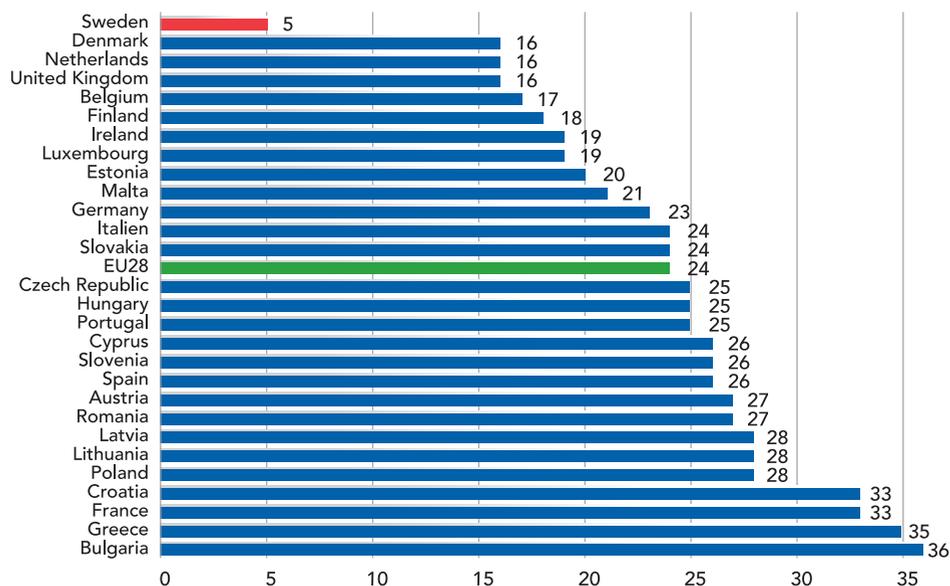
Data source: Lars Ramström, Institute for Tobacco Studies, Sweden. Sweden's pathway to Europe's lowest level of tobacco-related mortality. Poster. World Conference on Tobacco or Health, South Africa, 2018

Sweden now has the lowest level of smoking among men than for any other country in Europe. According to the European Commission's Eurobarometer 2017 report, only five percent of Swedish men now smoke. This is only one fifth of the EU average of 24 percent. The Eurobarometer report indicates that all other EU countries have a smoking prevalence three to seven times greater than Sweden. So, something is clearly different about Sweden - and the clear difference is that snus is allowed in Sweden yet banned in the other 27 EU countries.

³⁵ Royal College of Physicians, Tobacco Advisory Group. *Nicotine without smoke: Tobacco harm reduction*. RCP, 2016, p.6

³⁶ Lars Ramström, Institute for Tobacco Studies, Sweden. *Sweden's pathway to Europe's lowest level of tobacco-related mortality*. Poster. World Conference on Tobacco or Health, South Africa, 2018

Figure 4.9
Prevalence of daily smoking in the EU



Data source: Eurobarometer 458, May 2017 (TableQB4aT2)
Chart reproduced from: Lars Ramström, poster, Global Forum on Nicotine 2017

The changes in the way that tobacco is consumed has, in Sweden as in Norway, come about through two mechanisms. The first is the increasing preference of snus over cigarettes among those starting to use tobacco. Birth cohort data over four decades show that the proportion of men starting to initiate tobacco use from smoking dropped, whilst those initiating tobacco through snus increased. What is also striking is that during these periods the proportion of the population initiating any tobacco use dropped.

It is sometimes asserted that the use of snus could be a stepping stone to the smoking of tobacco. This is not supported by the population level smoking and snus data. Neither is it supported by research evidence. The largest study is an analysis of a nationally representative sample of the Swedish population recruited between 2003 and 2011, covering 60,675 individuals. Those who began daily tobacco use using snus were much less likely to subsequently take up smoking than those who had not.³⁷

The second mechanism leading to fewer smokers is the use of snus to quit or reduce smoking. Among men, snus is the most commonly used cessation product, while among women, nicotine gum or patches are more common. Success rates using snus are higher than for those using other means. A very high proportion of male (87 percent) and female (86 percent) smokers who take up snus use quit daily smoking.³⁸

“When the tobacco control score is plotted against smoking prevalence in different countries, Sweden is an outlier whose record low smoking prevalence is not explained by tobacco control activities alone”.

It has been suggested that the fall in smoking in Sweden might not be due to the availability of snus but rather to the imposition of tough tobacco control measures. However, on key indicators of tobacco control (price, smoking bans, treatment availability, health promotion spending, health warnings, advertising bans) Sweden is in the middle ranking among European countries and well below the UK, Ireland and Iceland.³⁹ When the tobacco control score is plotted against smoking prevalence in different countries, Sweden is an outlier whose record low smoking prevalence is not explained by tobacco control activities alone.

Sweden and tobacco-related mortality

In theory, the reduction in the number of smokers, and the use of lower-risk snus, should have an impact on morbidity and mortality in Sweden. Snus does not pose a respiratory risk, and across many studies snus is not associated with diabetes, pancreatic and oral cancers, heart disease or stroke (see Chapter 5). A limitation with the evidence on newer SNP such as e-cigarettes and HNB is the absence of long-term data on health outcomes. And it is in this respect that the Swedish experience adds considerably to our understanding of the impact of tobacco harm reduction on population level health measures.

³⁷ Ramström L. et al (2016). Patterns of smoking and snus use in Sweden: implications for public health. *International Journal of Environmental Research and Public Health*, 2016 Nov 9;13(11), pii: E1110

³⁸ Ramström L. et al (2016). Patterns of smoking and snus use in Sweden: implications for public health, *International Journal of Environmental Research and Public Health*, 2016 Nov 9;13(11), pii: E1110

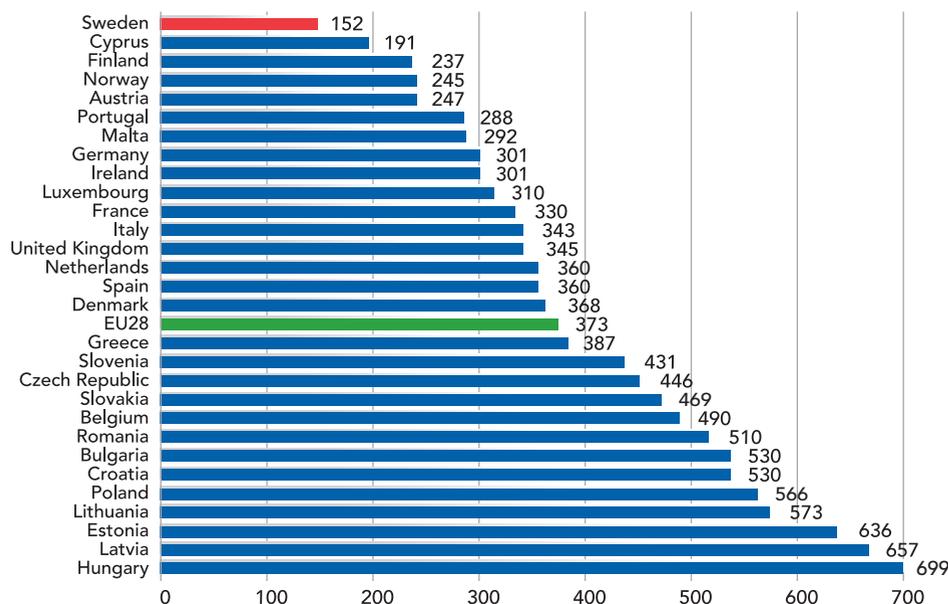
³⁹ Tobacco Control Scale <http://www.tobaccocontrolscale.org/results-last-edition/>

“Sweden has, for men, the lowest tobacco-related mortality in Europe at 152 per 100,000. The rate is less than half the EU28 average.”

Nineteen European countries have tobacco-related death rates that are twice that of Sweden.

Figure 4.10

Death rate per 100,000 attributable to tobacco, all causes of death, men 30 years and older



Data source: Lars Ramström, poster, Global Forum on Nicotine 2017. Data source World Health Organization. WHO Global Report: Mortality Attributable to Tobacco; WHO: Geneva, Switzerland, 2012; ISBN 978-92-4156443-4

Looking at it another way, we can assess what percentage of all deaths are tobacco-related - which gives an indication of the chances of dying of a tobacco-related disease. Using more recent data from the Global Burden of Disease study, it is calculated that in Sweden 11 percent of male and 12 percent of female deaths are tobacco-related. In all EU countries the percentage is higher: for example, in Greece 26 percent of male deaths are tobacco related; 23 percent in Spain, Belgium and the Netherlands; 21 percent in Italy and Denmark; and 20 percent in the UK and Luxembourg.⁴⁰

The Swedish experience indicates the human cost of the ban on snus. Dr Ramström calculated the potential future premature deaths that could be avoided in the EU if the ban on the marketing of snus is revoked:

“If snus is made available by lifting of the current ban in the EU, and truthful public education encourages substitution of snus for cigarettes as in Sweden, then around 320,000 premature deaths per year can conceivably be prevented among men 30 years and older in the current EU countries”.⁴¹

Case study 3:

E-cigarettes in the United Kingdom - rapid consumer uptake and official endorsement

The UK has taken many steps to embrace harm reduction. The use of safer forms of nicotine as alternatives to smoking was endorsed by the Royal College of Physicians back in 2007⁴² before e-cigarettes were in the public mind, and again in 2016.⁴³ The evidence reviews by PHE^{44 45} that conclude that ‘e-cigarettes are at least 95% less harmful than smoking’ have been very influential. Most of the anti-smoking and health NGOs, and medical bodies endorse the use of e-cigarettes. More recently the importance of innovation and less harmful alternatives is included in the latest tobacco control plan published by the Department of Health.⁴⁶ This was not the case from the beginning. A handful of vociferous

⁴⁰ Lars Ramström, Institute for Tobacco Studies, Sweden. *Sweden’s pathway to Europe’s lowest level of tobacco-related mortality*. Poster. World Conference on Tobacco or Health, South Africa, 2018. Data from database of *The Global Burden of Diseases, Injuries, and Risk Factors Study 2016*, *Lancet* 2017; 390: 1345-422 available on the website of The Institute for Health Metrics and Evaluation

⁴¹ Lars Ramström (2017). Poster, Global Forum on Nicotine 2017

⁴² Royal College of Physicians, Tobacco Advisory Group. *Harm reduction in nicotine addiction: helping people who can’t quit*. RCP, 2007

⁴³ Royal College of Physicians, Tobacco Advisory Group. *Nicotine without smoke; tobacco harm reduction*. RCP, 2016

⁴⁴ McNeill, A. et al (2015) *E-cigarettes: an evidence update: a report commissioned by Public Health England*. PHE publications gateway number: 2015260 2015. PHE, 2015. Available at <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

⁴⁵ McNeill A. et al (2018). *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. PHE, 2018

⁴⁶ UK Department of Health, *Towards a smoke-free generation: tobacco control plan for England*. DH, 2017. Available at <https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england>

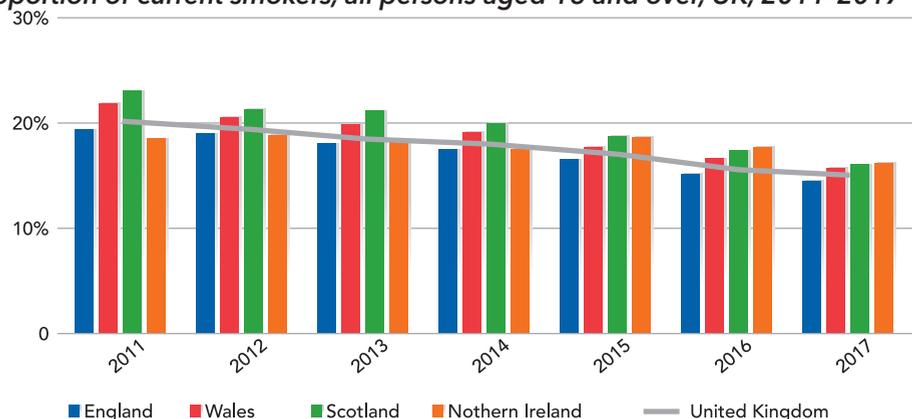
public health leaders opposed e-cigarettes. Early regulatory discussions by smoking research academics and leading tobacco control NGOs favoured regulating e-cigarettes as medical products; this influenced legislators in designing the updated EU Tobacco Products Directive. The legal and regulatory policy drive was thrown out by the European Parliament under pressure from vaper advocates (See Chapter 7).

Prevalence of smoking in the United Kingdom

Adult smoking prevalence has been in decline since the 1974 with the most rapid decline in the 70s and 80s. Since then the gradient of decline has been less steep. The decrease in smoking has come about due to a combination of smokers quitting and an increase in the proportion of people who have never taken up smoking.⁴⁷

Figure 4.11

Proportion of current smokers, all persons aged 18 and over, UK, 2011-2017



Source: Annual Population Survey – Office for National Statistics

Annual Population Survey (APS) data provided by the Office for National Statistics (ONS) shows the continued declining trend between 2010 and 2017 in each of the four UK countries (England, Wales, Scotland and Northern Ireland). Overall smoking prevalence in the UK in 2017 was 15.1 percent, which equates to around 7.4 million people in the population, a statistically significant decline of more than five percentage points since 2011. England

had the lowest level of smoking at 14.9 percent (approximately 6.1 million people), Wales at 16.1 percent (approximately 386,000 people), Scotland 16.3 percent (approximately 677,000 people) and Northern Ireland the highest at 16.5 percent (approximately 226,000 people).⁴⁸ Figure 4.11 shows the year on year decline for England, Wales and Scotland. Northern Ireland’s overall trend is down, but not as consistently as the other three countries.

Prevalence of e-cigarette use in the Great Britain

The anti-smoking charity ASH has conducted repeat surveys on the use of e-cigarettes in the adult population in Great Britain (England, Wales, and Scotland) since 2012. Sample sizes are substantial at around 12,000 adults (18 and over) each year.

These surveys show a steady increase in the proportion of the adult population who use e-cigarettes, up from just under two percent in 2012 to nearly six percent in 2017.⁴⁹ There appears to be some slowing of the increase in 2016 and 2017.

ASH, working with King’s College London, has estimated the prevalence of e-cigarette usage in Great Britain by using the findings of the surveys and applying these to the most recent population data available in each year.⁵⁰ This shows that in 2017:

- » An estimated 2.9 million adults in Great Britain were currently using e-cigarettes;
- » Of the 2.9 million current e-cigarette users, approximately 1.5 million (52%) were ex-smokers.

Figure 4.14 plots the data from Figure 4.11 and Figure 4.12 to show the trend in e-cigarette use in GB against the trend in smoking in the UK. The trends are rather similar to those seen in Norway and Sweden where snus gradually replaced smoking – bearing in mind that the process in both countries was over a longer period of time.

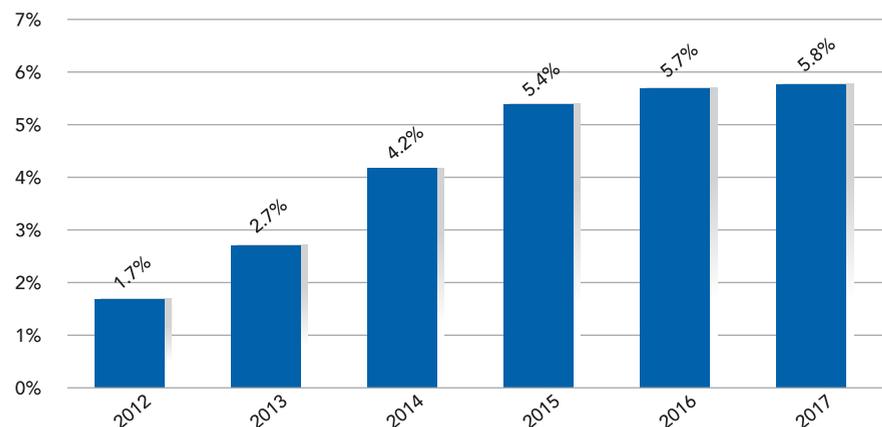
⁴⁷ ASH, *Factsheet no. 1 Smoking statistics*. ASH, 2017. Available at <http://ash.org.uk/category/information-and-resources/fact-sheets/>

⁴⁸ Office for National Statistics. *Statistical bulletin: Adult smoking habits in the UK: 2017* ONS, 2018. Available at <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2017>

⁴⁹ At the time of writing, new survey data from the ONS *Great Britain – Opinions and Lifestyle Survey (2017)* showed a slightly lower e-cigarette use prevalence (5.5 percent) for 2017 (2.8 million vapers)

⁵⁰ ASH. *Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain*. ASH, 2017. Available at <http://ash.org.uk/category/information-and-resources/fact-sheets/>

Figure 4.12

Proportion of e-cigarette users in Great Britain, 2012-2017

Data source: ASH (2017). Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain

Figure 4.13

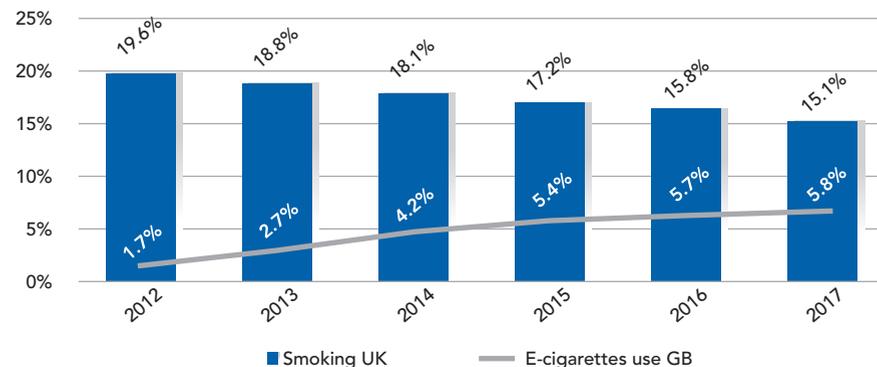
E-cigarette use in Great Britain

	% e-cigarette users in GB	no. of e-cigarette users in GB	rate of change
2012	1.70%	700,000	
2013	2.70%	1,300,000	+86%
2014	4.20%	2,100,000	+62%
2015	5.40%	2,600,000	+24%
2016	5.70%	2,800,000	+8%
2017	5.80%	2,900,000	+4%

Data source: ASH (2017). Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain⁵¹

Use of e-cigarettes is confined largely to current and ex-smokers and use amongst never smokers remains very low (at around two to three percent). Over time the proportion of current e-cigarette users who smoke tobacco has decreased and the proportion of ex-smokers has increased (and overtaken smokers). See figure 4.15.

Figure 4.14

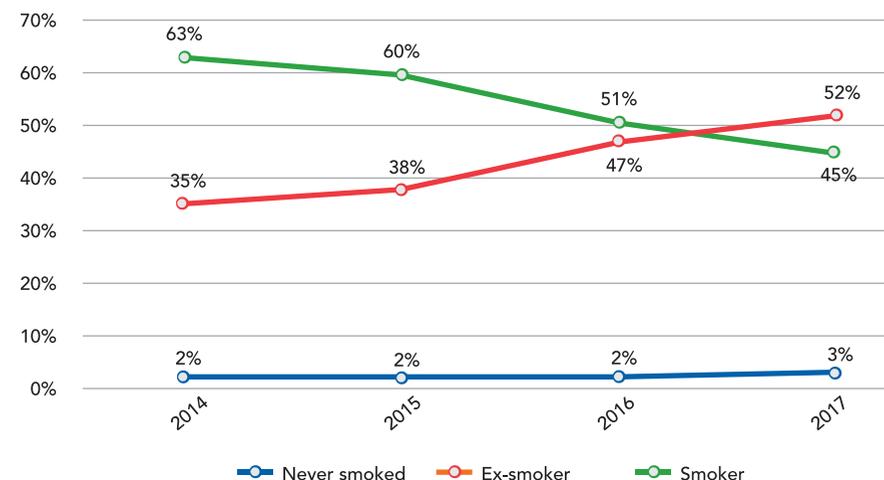
Trends in smoking (UK) and e-cigarette use (Great Britain) 2012-2017

Data sources:

Smoking statistics: Office for National Statistics Statistical bulletin: Adult smoking habits in the UK: 2017. (ONS, 2018)⁵²

E-cigarette use statistics: ASH Use of e-cigarettes (vapourisers) among adults in Great Britain. (ASH, 2017)⁵³

Figure 4.15

Current e-cigarette use by smoking status. Great Britain. 2014-2017

Data sources: ASH (2017). Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain

⁵¹ ASH. Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain. ASH, 2017. Available at <http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/>

⁵² Office for National Statistics. Statistical bulletin: Adult smoking habits in the UK: 2017 ONS, 2018. Available at <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2017>

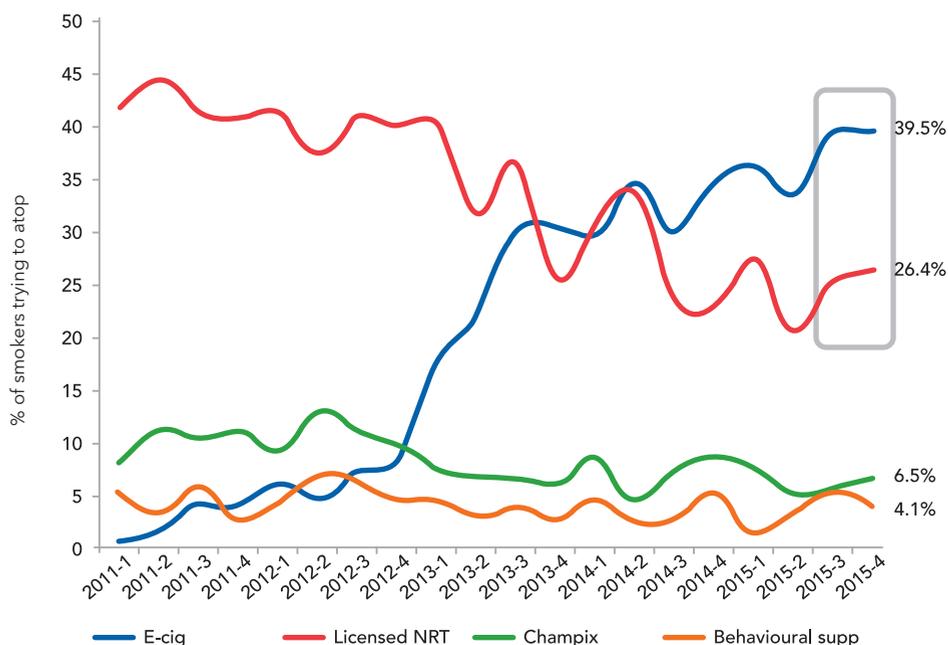
⁵³ ASH. Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain. ASH, 2017. Available at <http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/>

Changes in smoking cessation

The data suggest there are large numbers of smokers both trying e-cigarettes and using them, and who have quit smoking altogether. Coupled with the rapid decline in smoking, to 15.1 percent, this indicates a strong association between the rise of e-cigarettes and the ongoing decline in smoking.

There appears to be a new landscape of smoking cessation. E-cigarettes are now the most common method used to quit smoking, having overtaken NRT, medication and behavioural support by 2013 in England.

Figure 4.16
Aids used in quit attempt in past 12 months, England, Smoking Toolkit Study 2011-2015

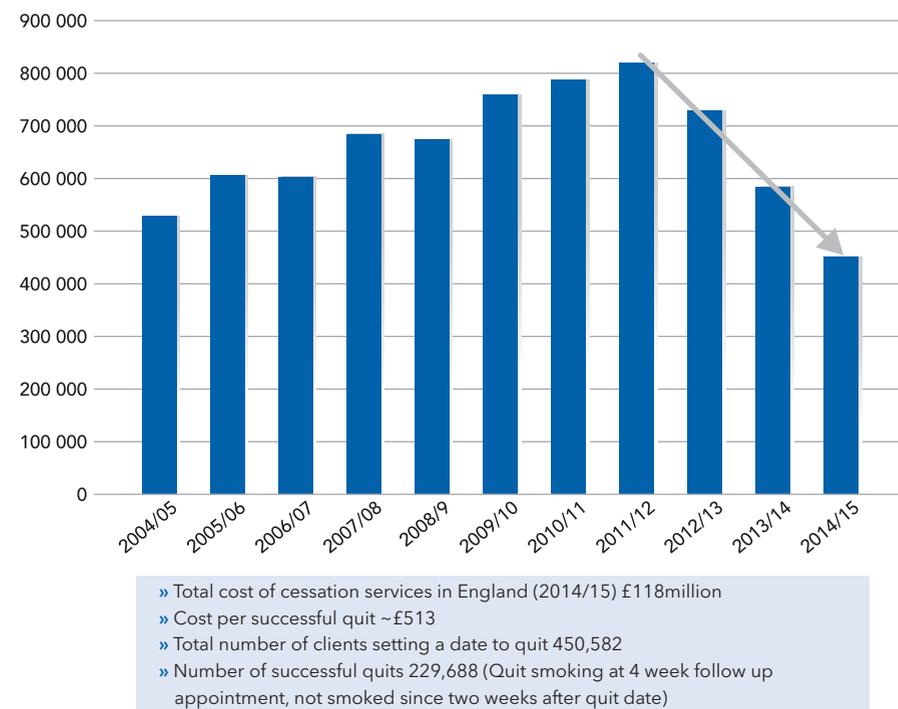


Source: Smoking Toolkit Study. <http://www.smokinginengland.info/latest-statistics/>

These changes are also reflected in the use of stop smoking services. The UK has a network of specialist stop smoking services and help with quitting is also provided through a wide range of NHS services. They have seen a rapid drop in

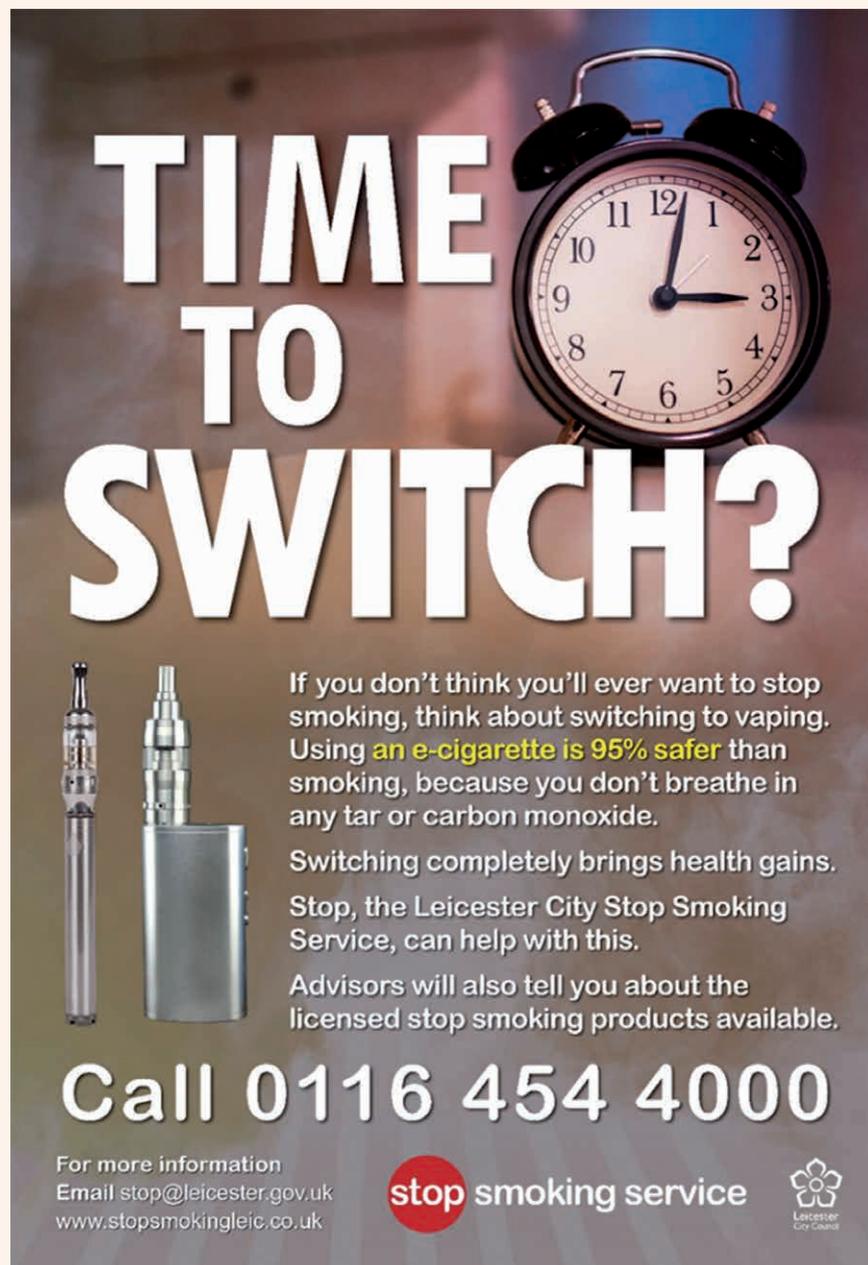
customers since 2011-12. In part this might be due to reduced resources, but is also likely to be linked to the fact that people now have additional ways to quit.

Figure 4.17
Smoking cessation services in England lose business - customers declined by 45% since 2011-2012



Source: Health and Social Care Information Centre. Statistics on NHS Stop Smoking Services in England, April 2014 to March 2015, April 2013 to 31 March 2014.

Given the interest in e-cigarettes, staff in stop smoking services have had to respond to patient requests as to whether using e-cigarettes is a good way to quit smoking. After some reluctance to embrace e-cigarettes, some stop smoking services now incorporate them into what they offer clients. The first to do this was the smoking cessation programme run by Louise Ross, then service manager for Leicester City (UK) stop smoking service, which started using e-cigarettes in their programme from 2014. The service achieved success with other health professionals, including persuading midwives to convince pregnant

Time to Switch poster


TIME TO SWITCH?

If you don't think you'll ever want to stop smoking, think about switching to vaping. Using an e-cigarette is 95% safer than smoking, because you don't breathe in any tar or carbon monoxide.

Switching completely brings health gains.

Stop, the Leicester City Stop Smoking Service, can help with this.

Advisors will also tell you about the licensed stop smoking products available.

Call 0116 454 4000

For more information
Email stop@leicester.gov.uk
www.stopsmokingleic.co.uk

stop smoking service

Leicester City Council

Source: <http://www.stopsmokingleic.co.uk/resources/>

women that vaping is safer than smoking, and convincing GPs to record vapers as ex-smokers. The Time to Switch poster went viral round the world within a couple of hours of appearing on billboards in Leicester. The call to action on the poster was that all smokers should consider switching to vaping, and that vapers should consider quitting smoking altogether.

What is remarkable is that in a few years, large numbers of smokers have started to use e-cigarettes, and many of them no longer smoke. There are 2.9 million current e-cigarette users, of whom 1.5 million are ex-smokers. Many more have tried e-cigarettes but did not continue. This is even more remarkable in that it was not a result of any planned public health campaign. Most public health campaigns are top down – governments and health agencies invest money in trying to persuade the population to adopt healthier behaviours (e.g. to have lower calorie intake and exercise more). No public health campaign could have achieved such a rapid success as the adoption of e-cigarettes in terms of people reached (numbers knowing about the issue), numbers attempting to change their behaviour (trying the product), the numbers actively using the product (continuing to use the product), and the numbers who successfully use the product to change their behaviour. This has the making of consumer-led public health success.

Although this achievement was not policy directed, it occurred in a policy environment that became more positive over time, so that now the UK has the most e-cigarette friendly environment in the world.

What explains the policy acceptance of e-cigarettes in the UK? The reasons are under-explored, and again highlight the need for in-depth analysis on a country level. Contributory factors would seem to be:

- » Historically, a pragmatic approach to public health issues including harm reduction for drugs and sex, and the historical playbook for tobacco harm reduction set out by the UK psychiatrist Michael Russell;
- » Support for tobacco harm reduction in medical political circles, as in the 2007 RCP report;
- » An academic evidence base tracking changes, and academics driven by evidence not rhetoric;
- » Support within PHE especially by those who understood the public health potential of e-cigarettes;
- » Supportive academics in key influential positions within anti-smoking and health organisations;

- » Support at high levels within government, especially among advisors to the then Prime Minister David Cameron in the 'Nudge Unit' (the Behavioural Insights Team);
- » A handful of key advocates and a larger linked network who campaigned for e-cigarettes;
- » Vociferous vaper advocates whose energy shifted the EU Tobacco Products Directive (TPD) legislation.

"No public health campaign could have achieved such a rapid success as the adoption of e-cigarettes in terms of people reached [...], numbers attempting to change their behaviour [...], the numbers actively using the product [...], and the numbers who successfully use the product to change their behaviour".

Case study 4:

Japan - rapid rise in sales of HNB products, rapid fall in cigarette sales

Japan provides an exceptional insight into rapid changes in smokers' preferences for using tobacco. According to the WHO, 19 percent of Japan's adult population were daily smokers in 2015, with smoking higher among men (at 30 percent) than women (at nine percent). These levels are much lower than the extraordinarily high percentage of male smokers back in 1968, at 78 percent. But the decline had, until recently, abated. Although we do not have current prevalence data, we know that something dramatic has changed in tobacco markets. There has been a rapid rise of HNB products to take 14 percent of the tobacco market by 2018, and a rapid fall in cigarette sales, by about 13 percent a year. E-cigarettes are allowed but only as medical products and none have been approved.

In comparison with many other countries, Japan does not have a distinctly hostile approach to tobacco. Until 1985, the tobacco industry was a state monopoly. The state still owns one-third of Japan Tobacco International (JTI) and is the largest shareholder. Unlike Australia, Europe and North America, there are no mandatory smoking bans in public places, though recently voluntary bans have been introduced by some companies and a street smoking ban introduced by some cities.⁵⁴

"Japan provides an exceptional insight into rapid changes in smokers' preferences for using tobacco".

HNB in Japan

In 2014, Phillip Morris International (PMI) introduced IQOS to the Japanese market, initially as a test in the city of Nagoya. It was then rolled out across Japan in 2016. JTI had started Ploom sales online in December 2013 and launched Ploom TECH in March 2016. British American Tobacco (BAT) started selling its HNB glo device in December 2016. There was extraordinary interest in IQOS, as reflected in internet searches in 2016.⁵⁵ The Figure 4.18 shows weekly Google searches from 2013 to 2017, normalised to 100 to show relative search volume.

Surveys of the adult population show the initial uptake of HNB. In 2015, 1.3 percent of adults were using e-cigarettes (despite their illegality) but only 0.3 percent were currently using IQOS and 0.3 percent Ploom TECH. One year later, in 2016, these levels had not changed greatly. By 2017, e-cigarette use had increased to 1.9 percent, while use of IQOS had increased to 3.6 percent, use of Ploom TECH increased to 1.2 percent, and use of the glo was 0.8 percent.

The other sources of information about HNB come from market data. PMI's IQOS uses 'HeatSticks' which accounted for 0.4 percent of the tobacco product market in December 2015, rising to a 14.1 percent share of the tobacco market by December 2017.⁵⁶ In two years, IQOS has overtaken specific cigarette brands - for example PMI's own Marlboro which has about eight percent of the tobacco market.

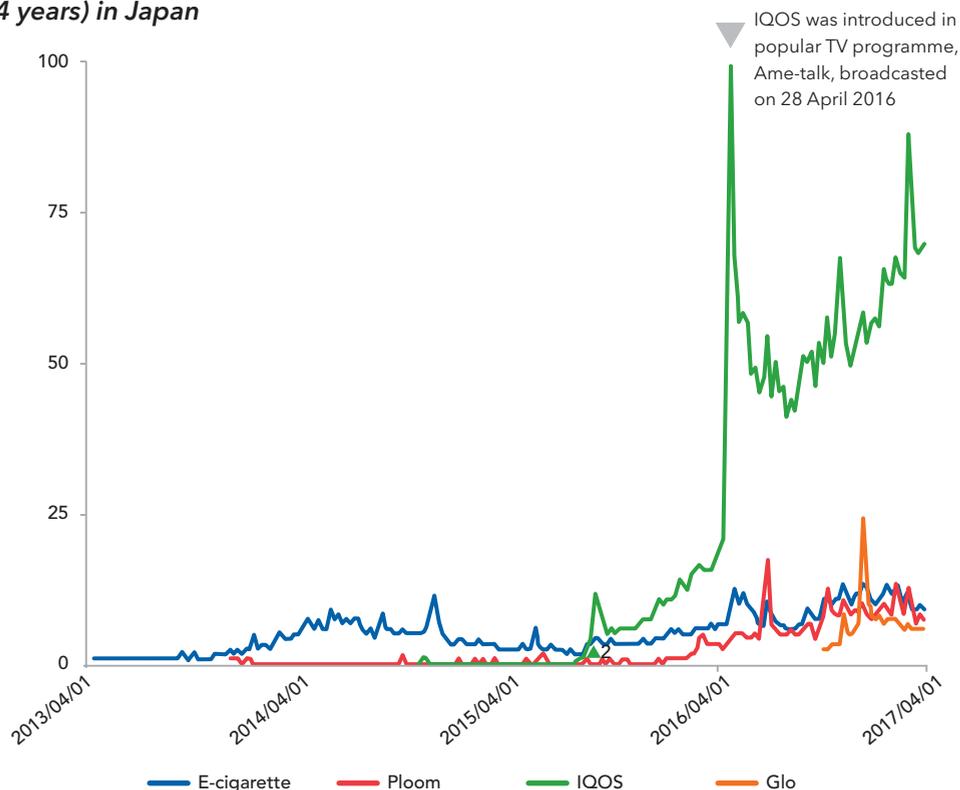
"A 27 percent drop in cigarette sales in two years is unprecedented in Japan... [and] likely the highest drop in cigarette consumption over that period of time seen in any country".

⁵⁴ Mark A Levin (2013) Tobacco control lessons from the Higgs Boson: Observing a hidden field behind changing tobacco control norms in Japan. *American Journal of Law Medicine*. 39 p.471-489

⁵⁵ Tabuchi, T. et al (2017) Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol. *Tobacco Control*. 16 doi:10.1136/Tabaccocontrol-2017-053947. Available at <http://tobaccocontrol.bmj.com/content/early/2017/12/15/tobaccocontrol-2017-053947.abstract?paperoc>

⁵⁶ PMI, Philip Morris International Inc. Presents at the Consumer Analyst Group of New York (CAGNY) Conference (2018) <https://www.pmi.com/investor-relations/overview/event-details/?eventId=5267394>

Figure 4.18
Weekly Google search volume for HNB tobacco/e-cigarette 2013-2017 (past 4 years) in Japan

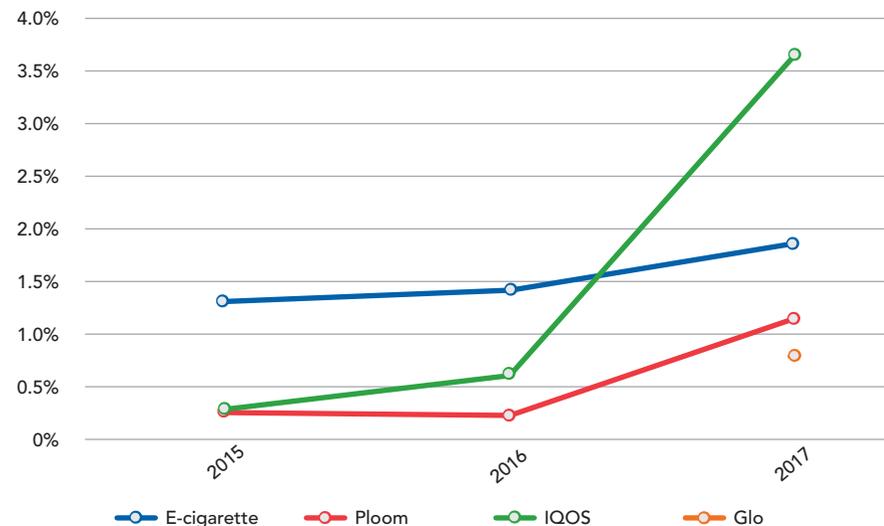


Graph source: Adapted from Takahiro Tabuchi et al (2017) Heat-not-burn tobacco product use in Japan. *Tobacco Control*.⁵⁷

The uptake of HNB products is disrupting the traditional Japanese cigarette market. JTI is the major tobacco company with around 60 percent of the Japanese cigarette market, and unlike some tobacco companies, releases monthly information on sales. From 2016 to 2017 its volume of cigarettes sales fell 14 percent, with a further fall of 13 percent in 2018 (based on 2016 levels). This is an extraordinary collapse in cigarette sales, of 27 percent over two years.

A 27 percent drop in cigarette sales in two years is unprecedented in Japan: over the 16 years from 1996 to 2012 domestic cigarette consumption fell by 46 percent – or just over 2.9 percent a year on average.⁵⁸ It is likely the highest drop in cigarette consumption over that time seen in any country.

Figure 4.19
Trends in current use of HNB tobacco/e-cigarette, both sexes, in Japan



Graph source: Takahiro Tabuchi, Silvano Gallus, Tomohiro Shinozaki, Tomoki Nakaya, Naoki Kunugita, Brian Colwell. *Tob Control* 16 December 2017, doi:10.1136/tobaccocontrol-2017-053947

Figure 4.20
Cigarette volume decline in Japan 2016-2018

Billion sticks	JT volume	JT share of market	Market vol	Market vol
Jan - March			(implied)	2016 = 100
2016	27.2	62.4%	43.6	100
2017	23.0	61.0%	37.7	86
2018	19.5	61.4%	31.8	73

Table source, Clive Bates. Data source: Japan Tobacco, Japanese Domestic Cigarette Sales Results

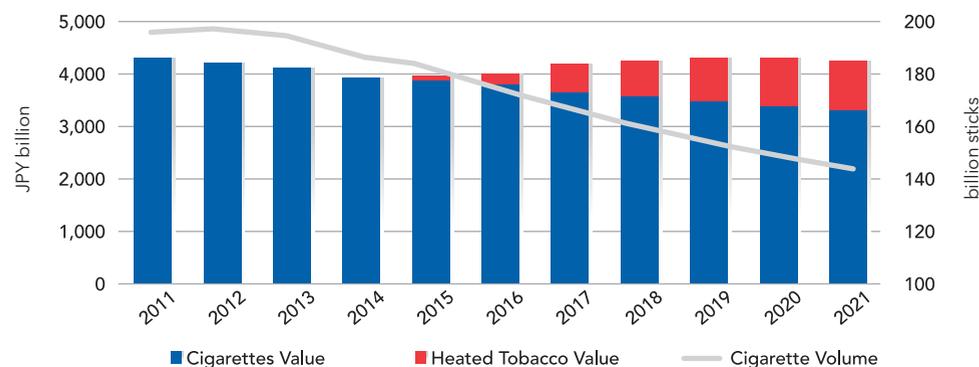
⁵⁷ Tabuchi, T. et al (2017) Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol. *Tobacco Control*. 16 doi:10.1136/abstract?paperoc

⁵⁸ Mark A Levin (2013) Tobacco control lessons from the Higgs Boson: Observing a hidden field behind changing tobacco control norms in Japan. *American Journal of Law Medicine*. 39 p. 471-489, p483

Euromonitor International expects that HNB will be at least 22 percent of the Japanese market for tobacco by 2021 if it continues to drive out cigarettes. What is interesting about the Euromonitor tracking is that the total volume of tobacco purchased is not expected to change, but the type of tobacco purchased is. This is somewhat different to the experience in Sweden and Norway where the switch to SNP has been accompanied by longer term declines in tobacco consumption – the difference, of course, being that tobacco users in Sweden and Norway have a much longer experience with SNP.

Figure 4.21

Japan: cigarettes and heated tobacco value and cigarettes volume 2011–2021



Source: Euromonitor International: Passport – Global Tobacco: Key Findings Part 2: vapour products. October 2017.

What is remarkable about this change in behaviour among tobacco users in Japan is that it came about not through the planned actions of tobacco control – indeed as has been observed, tobacco control measures are weaker than in many other countries, and Japanese law favours the tobacco industry.⁵⁹ The change has occurred by selling a safer alternative to smoking, smart marketing, and consumers switch from smoking to HNB. This ‘intervention’ has not required action on the part of public health and tobacco control (except perhaps to help create a climate where smokers wish to quit) and it has been at no direct cost to the Japanese taxpayer.

Conclusion

This chapter presents what is possibly the first deep dive into the disparate data on global consumer uptake of SNP as far as the data allows, but points to a need for much more research in this area.

The cross-sectional data show that in the space of a few years, there has been rapid uptake in the use of the newer SNP in many countries. The data from both Sweden and Norway shows how over a relatively short space of time, snus has replaced smoking. We take this as evidence for an appetite for SNP such that where they are available – and if they are attractive and suitable alternatives to smoking – smokers will tend to choose them rather than to smoke. Evidence from Norway and Sweden also suggest that snus may be protective against smoking. Given these significant trends, there are important implications for public policy: an end to smoking may be achievable, but not an end to nicotine use. The best example is that smoking prevalence among Norwegian women is down to one percent, yet still around 15 percent are using snus.

The survey data are a limited measure of what is happening in each country. Some datasets report on the prevalence of e-cigarette use among smokers. By itself this can be misleading, because such a measure excludes those people who use SNP and who have stopped smoking. More information is needed on the changes in the use of e-cigarettes or other SNP over time, and how this is linked to changes in the prevalence of smoking, and ultimately changes in smoking-related disease. This can be done for some countries for e-cigarettes and snus, where for example there are time trend data on the decline in smoking and the uptake of SNP (as shown in the Norway and Sweden case studies). More work needs to be done on selecting appropriate measures to describe the uptake of e-cigarettes and other SNP. Unfortunately, research in this field is mainly dominated by individual studies to answer small and specific questions.

There seems to be a marked lack of appetite or research capacity and ambition to undertake overviews which synthesise evidence on a national level to answer a key question: does the use of SNP drive down smoking and improve public health?

There – there is now good evidence that the uptake of SNP is associated with a decline in smoking. The evidence is stronger still for snus, which has been around for longer than e-cigarettes and HNB.

⁵⁹ Mark A Levin (2013) Tobacco control lessons from the Higgs Boson: Observing a hidden field behind changing tobacco control norms in Japan. *American Journal of Law Medicine*. 39 p. 471-489, p483

For the newer SNP, it is still too soon to determine whether these changes are followed by improvements in public health. The laboratory evidence that SNP are much safer than smoking (which we discuss in Chapter 5) suggests that this will be the case. Longer term studies are needed - and the strongest evidence yet again comes from Sweden, where the uptake of snus and the decline in smoking has given this country the lowest smoking related mortality in Europe.

What is also remarkable is that the uptake of SNP has occurred in the absence of government, tobacco control and public health endorsement. It has been the ordinary consumers whose interest in SNP has driven the product development process and who have been proactive in offering help and advice to an ever-widening global community.

Figure 4.22

Global vaping prevalence (%) - various surveys (see notes below)

	Year of survey	Currently vape - total adult population	Ever tried/ever vaped - total adult population
Australia ##	2016	1%	8%
Austria*	2017	3%	21%
Belgium*	2017	4%	16%
Bulgaria*	2017	NA	NA
Canada***	2013	2%	9%
Croatia*	2017	NA	NA
Czech Republic*	2017	1%	20%
Denmark*	2017	2%	16%
Estonia*	2017	1%	21%
EU 28*	2017	2%	15%
Finland*	2017	1%	17%
France*	2017	4%	24%
Germany*	2017	2%	12%

	Year of survey	Currently vape - total adult population	Ever tried/ever vaped - total adult population
Great Britain###	2015-16	6%	19%
Greece**	2017	5%	27%
Hungary*	2017	1%	9%
Ireland*	2017	2%	13%
Italy*	2017	NA	NA
Japan^	2017	1.90%	11.40%
Kazakhstan####	2014	1.70%	7.20%
Latvia*	2017	1%	24%
Lithuania*	2017	1%	15%
Luxembourg*	2017	2%	12%
Malta*	2017	2%	12%
Mexico#	2016-17	1%	6%
Netherlands*	2017	2%	15%
Northern Ireland^^	2016-17	6%	12%
Poland*	2017	1%	13%
Portugal*	2017	1%	8%
Rep. of Cyprus*	2017	3%	21%
Romania*	2017	NA	NA
Slovakia*	2017	NA	NA
Slovenia*	2017	1%	11%
Spain*	2017	1%	12%
Sweden*	2017	NA	NA
United Kingdom*	2017	5%	18%
United States****	2014-15	2%	9%

Notes:

The data in this table should be viewed as a snapshot for each country at the time that surveys were undertaken.

Estimates of prevalence cannot necessarily be compared between countries due to the reasons below:

1. There are significant disparities between survey estimates carried out in the same country.
2. Surveys have been conducted in different years and there is a rapidly changing picture and prevalence of vaping in many countries.
3. These data are for 'adults', however this is defined differently in different surveys (e.g. Eurobarometer 15+; Farsalinos 18+).
4. Sample sizes vary from quite small in certain countries (e.g. Eurobarometer survey) to large (e.g. Mexico) (ENCODAT 2016-17).
5. There are differences in the way e-cigarette users are categorised e.g. 'Current use' can be 'used in last 30 days' (e.g. Reid et al. 2015 [Canada]) or 'every day or some days' (Zhu et al. 2017 [USA]) OR 'daily or less than daily' (WHO. 2014 [Kazakhstan]) in some cases, with no specific timeframe.
6. In some instances, data have been not available (NA).

Data for this table have been gathered from freely available online sources. There are gaps in the data available - readers are invited to send in updated information to the GSTHR team.

Data sources:

*Reference: European Commission. *Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes*. EC, 2015. Available at http://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG

Note: EU 28 - European Union - weighted average for the 28 member states.

Note: Total sample N = 27901, aged 15 and over. Includes an estimate for United Kingdom which is England, Scotland, Wales and Northern Ireland.

Description: Eurobarometer data provide a representative sample of approximately 28,000 respondents and estimates the prevalence of vaping for the EU overall, as well as per country. Survey dated March 2017.

**Reference: Farsalinos K. et al (2018). Electronic cigarette use in Greece: an analysis of a representative population sample in Attica prefecture. *Harm Reduction Journal*. 15:20 Available at <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0229-7>

Note: This is a regional prevalence, and does not refer to the whole country. However 35 percent of the adult Greek population live in Attica.

Note from author: The data on number of vapers are extrapolated to the Attica population (one third of the Greek population). But the prevalence (five percent of the population) could be reasonably applicable to the whole population of Greece. That would mean there are about 450,000 vapers in Greece (in an adult population of about nine million).

Description: A cross-sectional survey of a representative sample of 4058 adults (aged 18 and over) living in Attica prefecture (35 percent of the Greek adult population) was performed in May 2017 through telephone interviews. Prevalence and frequency of e-cigarette use were assessed according to the smoking status, and logistic regression analysis was performed to identify correlates of use.

***Reference: Reid J. L. et al (2015). Who is using e-cigarettes in Canada? Nationally representative data on the prevalence of e-cigarette use among Canadians. *Preventive Medicine* 81 p. 180-183

Description: The study examined prevalence and correlates of e-cigarette use in the Canadian population, using data from the nationally representative 2013 Canadian Tobacco, Alcohol and Drugs Survey (n = 14,565). Sociodemographic correlates of e-cigarette use (ever, and in the past 30 days) were examined using logistic regression models. Data is from people aged 15 and over.

****Reference: Zhu, S. H. et al (2017). E-cigarette use and associated changes in population smoking cessation: Evidence from U.S. current population surveys. *The British Medical Journal* 358:j3262.

Description: Sample 161,054. Adults aged 18 and over; *US Current Population Survey-Tobacco Use Supplement (CPS-TUS)*. 2014-15. Ever users of e-cigarettes were those who 'ever used e-cigarettes, even one time'. Current users of e-cigarettes were ever users who answered 'every day' or 'some days'.

#Reference: *Encuesta Nacional de Consumo de Drogas, Alcohol y Tabaco*, ENCODAT 2016-2017. Available at <https://drive.google.com/file/d/11ktpvdu2nsrSpMBMT4FdqBlk8gikz7q/vie>

Description: Data on Mexico (in Spanish) can be found in the *National Poll on Consumption of Drugs Alcohol and Tobacco*. It is official government data and is publicly available. Data on e-cigarette usage is found in the tobacco section and a pdf version can be downloaded in this link. Around 59,000 people were polled in the survey.

##Reference: *National Drug Strategy Household Survey 2016*, tobacco chapter, supplementary data tables. The Australian Institute of Health and Welfare, September 2017

Description: Age from 14 and over. Current use of e-cigarettes was relatively low in the general population with only 1.2 percent of people aged 14 or older reporting that they currently use e-cigarettes. Warning provided about very wide sampling errors in the estimates.

###Reference: Office for National Statistics. *E-cigarette use in Great Britain*. Available at

<https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/drugusealcoholandsmoking/datasets/ecigaretteuseingreatbritain>

Note: Great Britain is England, Scotland and Wales. Survey covers adults aged 16 and over.

####Reference: World Health Organisation *Global Adult Tobacco Survey (GATS)*. WHO, 2014. The Republic of Kazakhstan, 2014, Country Report.

Note: Adults are those aged 15 and over.

^Reference: Tabuchi, T. et al (2017) Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol. *Tobacco Control* 16 doi:10.1136. Available at <https://tobaccocontrol.bmj.com/content/early/2017/12/15/tobaccocontrol-2017-053947?paperoc=#DC1>

^^Reference: Health Survey Northern Ireland, 2016 -17. Available at <https://www.gov.uk/government/statistics/health-survey-northern-ireland-first-results-201617>

Chapter 5: Safer nicotine products and consumer health

A chasm exists between those in the global public health community who work to reduce the death and disease toll from smoking, and the tobacco industry, which both produces the product causing all the damage and actively tries to undermine national and international tobacco control efforts. As the sale of cigarettes still reaps vast profits for the industry, that chasm remains as wide as ever. Does the arrival of e-cigarettes and HNB, and the involvement of some tobacco companies in producing SNP do anything to bridge the gap?

As it transpired, the advent of SNP left the global public health community itself divided. Many working in tobacco control regard SNP as a ruse by tobacco companies to renormalise smoking, especially in countries where adult smoking rates have been in decline for decades - and citing in particular a fear of young people being led through a 'gateway' to regular smoking.

Others - public health officials, academics, clinicians and consumer advocates among them - point to evidence that SNP are significantly less harmful than smoking cigarettes for those who cannot or do not want to give up nicotine, those who want to cut back on smoking, or quit altogether. From this follows the conclusion that a switch to SNP has the potential to save many lives and moreover, at no cost to governments or taxpayers.

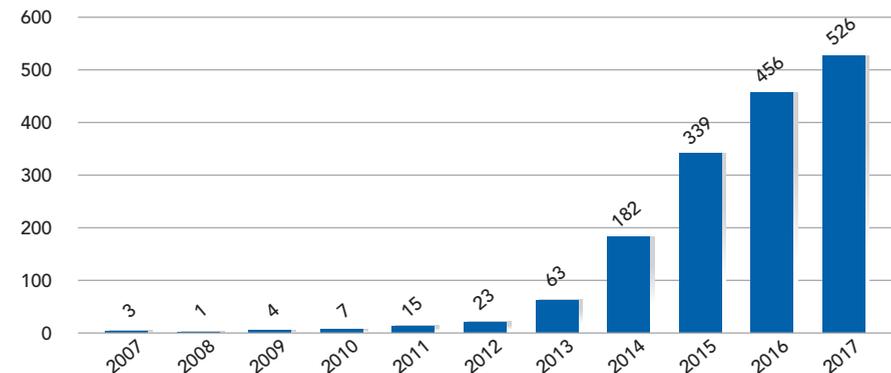
These debates continue against a backdrop of the emerging scientific understanding of much less harmful nicotine products. There has been a major increase in the number of publications on e-cigarettes. Our search for articles on them shows the increasing interest in the subject over the last ten years. From 2007-12, there were only 53 publications recorded. Between 2013 and 2017, the figure jumped to over 1500.

But more science does not always mean better science (as we will show below) or better science communication. Poorly formulated and designed research,

over-cooked announcements of research results, over-hyped university press releases and an uncritical media with an appetite for bad news stories all create a perfect storm of confusion among the general public, smokers and users of SNP as to the advisability of switching away from smoking to SNP.

Figure 5.1

Number of Pubmed search results for articles on e-cigarettes 2007-2017



PubMed searches databases of abstracts and publications in biomedicine and life sciences. Search terms were e-cigarette OR electronic cigarette OR e-cig in the abstract/title field.

Media-driven confusion

The confusion generated by popular media reporting is exemplified by this article from the UK Daily Mail published on 24th February 2017.¹ The headline and straps were:

Do you use e-cigarettes? You may be at greater risk of a STROKE: Exposure to vapours damages chemicals in the brain

- » *Researchers exposed mice to both e-cigarette vapour and smoke from tobacco*
- » *They found the animals were more likely to have a stroke from e-cigarette puffs*
- » *Experts now warn that the popular gadgets are not any safer than cigarettes*

¹ Mail Online (2017). *Do you use e-cigarettes? You may be at greater risk of a STROKE: Exposure to vapours damages chemicals in the brain*. Available at: <http://www.dailymail.co.uk/health/article-4255696/Do-use-e-cigarettes-risk-STROKE.html>

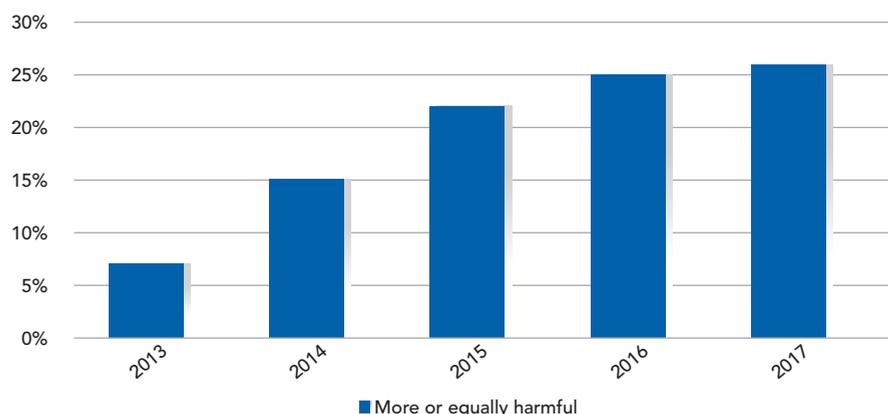
Most consumers get their information about SNP (and other health issues, climate change and so on) from the media and friends. Given the extent and focus of media reporting, it is perhaps unsurprising that many people are confused or concerned about SNP. The real concern for harm reduction is that perception of the risk of SNP is actually increasing; more people think (incorrectly) that SNP are as dangerous as cigarettes.

In a global survey conducted by the Foundation for a Smoke-Free World², a majority of those polled in 11 of the 13 countries surveyed thought nicotine more harmful to general health than alcohol, sugar, fat and salt while all those surveyed believed the nicotine in e-cigarettes presented a risk of heart disease and a range of cancers.

In Great Britain, despite the well-publicised findings (cited below) from PHE and the RCP about the relative safety of e-cigarettes, the stop smoking charity ASH found that perceptions of harm concerning e-cigarettes worsened between 2013 and 2017. Over time more people thought that e-cigarettes were more or equally as harmful as smoking, and fewer people thought that they were a lot less harmful.

Figure 5.2

Adult population perception of harm from e-cigarettes relative to smoking 2013–2017, Great Britain



Source: ASH fact sheet (May 2017) Use of e-cigarettes (vapourisers) among adults in Great Britain.

The chart refers to the population in general, but as ASH stated, more worrying is the worsening perception among smokers:

“The poor understanding among smokers in general about the relative harms of e-cigarettes compared to smoking is of concern [...]. The proportion of smokers who think e-cigarettes are just as, or more, harmful than smoking has increased significantly from 9 percent in 2013 to 22 percent in 2017. [...] Smokers who have never tried e-cigarettes are less likely to accurately believe they are a lot less harmful than tobacco smoking than smokers who are currently using e-cigarettes. Among smokers who have never tried an e-cigarette, one in three (30 percent) believe e-cigarettes are more or equally harmful as smoking. This is a view that has grown over time among smokers who have not tried an e-cigarette with 25 percent holding this opinion in 2016.”³

“The poor understanding among smokers in general about the relative harms of e-cigarettes compared to smoking is of concern”.

In the USA, the perception among smokers that e-cigarettes were as, or more harmful than, cigarettes jumped from 11.7 percent in 2012 to 35 percent in 2015 while a belief that e-cigarettes were addictive went from 25.3 percent to 56 percent.⁴

Tobacco products are not all the same: a continuum of risk

How can a smoker be sure that a safer nicotine product is safer than smoking a cigarette?

This chapter considers the main issues surrounding relative product safety, starting with e-cigarettes and then snus, for which there is now an extensive evidence base. It also covers the evidence regarding HNB products as tobacco harm reduction options.

The scientific understanding of SNP brings to attention the fact that not all nicotine containing products are equally risky. There is clearly a difference between cigarettes and therapeutic nicotine products. But there are also differences between different types of tobacco products. This fact is often

² Foundation for a Smoke Free World. Worldwide State of Smoking Survey 2018

³ ASH. Fact sheet. Use of e-cigarettes (vapourisers) among adults in Great Britain. ASH, 2017. Available at <http://ash.org.uk/category/information-and-resources/fact-sheets/>

⁴ Majeed, B.A. et al. (2017). Changing perceptions of harms of e-cigarettes among US adults 2012-2015. *American Journal of Preventative Medicine*: 52 (3), p.331-338

ignored or glossed over in campaigns that target tobacco consumption per se. The differential risk is reflected in mortality figures: globally an estimated six million deaths from smoking a year, and 48,000 deaths from oral tobaccos mainly in south Asia.⁵

The health outcomes from smoking tobacco are well known from the huge amount of clinical and epidemiological evidence on disease and premature death associated with smoking. The same type of epidemiological evidence shows that the health impact of Swedish snus is markedly dissimilar to that of smoking tobacco – there is a significant decrease in risk of tobacco-related disease.

The fact that there are differences in the harmfulness of different tobacco products is also apparent from an understanding of the constituents of different tobacco products – for example, the complex constituents of tobacco smoke compared with e-cigarette emissions.

The evidence shows that the key difference in health risks is associated with combustion. The tobacco cigarette turns out to be the dirtiest and most harmful nicotine delivery system.

Comparing different tobacco products on the basis of clinical, epidemiological, and laboratory studies puts cigarettes at the high-risk end, with HNB products, snus, e-cigarettes and medicinal nicotine products at the low risk end.

As Fig 5.3 shows, risk falls dramatically beyond combustible cigarettes, indicating that any form of nicotine delivery system that does not involve combustion is safer than smoking tobacco. There is a continuum of risk – or perhaps it is better described as a ‘cliff drop of risk’.

Estimating and communicating the risk of safer nicotine products

Just how much less harmful are SNP than cigarettes is a matter of scientific assessment and science communication. The risk continuum is one way of communicating the differences in risk when using different kinds of nicotine-containing products. The problem in trying to compute a risk continuum, and then communicating this, is that there are hundreds of different measures that could be considered, derived from laboratory studies, clinical studies of short-term health impacts, through to long-term epidemiological studies.

Two landmark reviews brought the evidence together on e-cigarettes and have been published in the UK, from Public Health England⁶ and the Royal College of Physicians.⁷ The first key point is that there are no circumstances in which it is safer to smoke than to use e-cigarettes. Their headline conclusions are:

- » Vaping is substantially safer than smoking;
- » People who switch from smoking to vaping can experience an improvement in respiratory health;
- » Switching to vaping can help people quit smoking;
- » There are currently no known long-term adverse health effects due to vaping;
- » There is no evidence that young people who experiment with e-cigarettes will become regular cigarette smokers.

The more cautious and conditional evidence review from the US National Academy of Sciences, *The Public Health Consequences of E Cigarettes* (2018), stated nonetheless: “There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes”.

And while opposed to SNP, the WHO briefing on e-cigarettes conceded that “it is very likely that average ENDS use produces lower exposures to toxicants than combustible products”.⁸

Public Health England has asserted that “based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously...”.⁹ This means that e-cigarettes are not totally harmless, but that the appropriate scientific approach is to compare their safety (and all SNP) relative to combustible cigarettes, rather than examine the absolute safety of the products in isolation. In other words, harm reduction, not harm eradication.

⁵ *The Lancet*. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet*, 2017. Available at [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(17\)32366-8.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(17)32366-8.pdf)

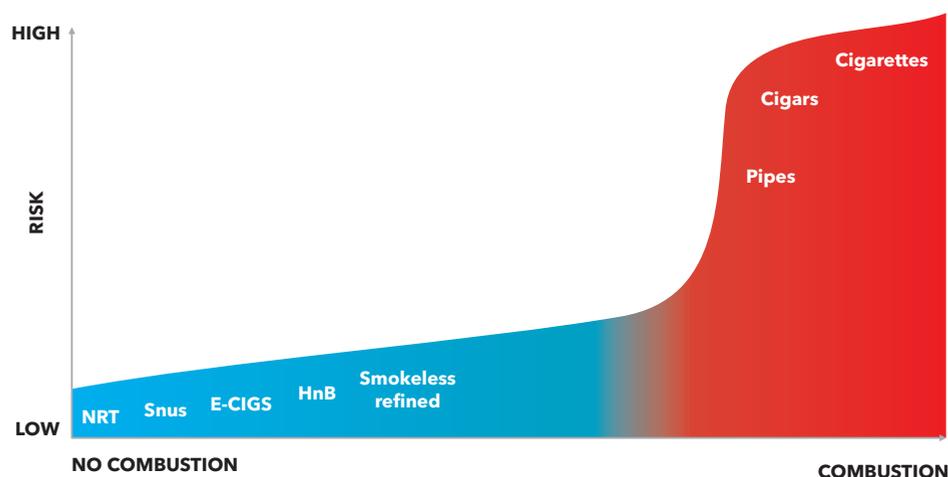
⁶ McNeill, A. et al. *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. PHE, 2018

⁷ Royal College of Physicians. *Nicotine without smoke; tobacco harm reduction. A report by the Tobacco Advisory Group of the Royal College of Physicians*. RCP, 2016

⁸ World Health Organisation. *Electronic nicotine delivery systems: a report by WHO*. 201, p.4

⁹ McNeill, A. et al. *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. PHE, 2018, p.20. Relative risk figure calculated on an estimate that cancer-related emissions from e-cigarettes are 0.5% that of combustible cigarettes.

Figure 5.3
Continuum of risk for nicotine containing products



“Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously”.

There needs to be a commonly accepted and credible assessment process for establishing this relative product safety. There are several key elements to the process of assessing risk of SNP:

1. Chemical and physical characterisation of emissions: what chemicals and toxins are released?
2. In vitro and animal toxicological studies: laboratory studies of potential effects of the chemicals and toxins from SNP.
3. Quantification of human exposure to chemicals and toxins: clinical studies of changes in biomarkers of exposure when switching from smoking to SNP.
4. Substantiation of reduced health risk: clinical studies evaluating short and long range impact on health effect indicators when switching from smoking to vaping.
5. Long-term epidemiological studies of the health of SNP users over time.

Additionally, there are shorter and longer-term impacts on the numbers in the population that are smoking – which includes both SNP as an exit route from smoking, but also the potential for new nicotine users to be recruited to regular smoking (so-called gateway effect).

E-cigarettes

The reason people die prematurely or develop life-threatening diseases from smoking cigarettes is due to the toxic chemicals released when a cigarette is lit and the fumes inhaled. The composition of cigarette smoke is complex, but the main toxins identified as potentially harmful include carbon monoxide (CO), volatile organic compounds, carbonyls, aldehydes, tobacco-specific nitrosamines (TSNAs) and metal particles. All these are present in e-cigarette and HNB vapour but at much lower levels than in cigarettes, often at exposure levels no greater than present in the general environment. The relative levels of toxins have been demonstrated by mechanically aided puff tests in the laboratory, measuring the toxin release when a cigarette, a HNB product or an e-cigarette are puffed.

A visual representation of the relative emissions for smoked cigarettes, e-cigarettes and HNB products can be seen Figures 5.4-6.

These are three dimensional chromatograms of emissions/aerosol generated from a single puff of a cigarette, a HNB device and an e-cigarette. The colours indicate quantity of chemicals and toxins in each puff; red indicating most compounds. The height of peaks illustrates chemical and toxins levels (note that the three pictures are not in the same scale). The fewer the peaks, the less complex and thus harmful the emissions. The complexity of HNB emissions lies between the cigarette smoke and the aerosol from an e-cigarette.¹⁰

There are various laboratory tests which can be carried out on cells to demonstrate the relative safety of e-cigarette vapour over cigarette smoke. One test involves deliberately ‘damaging’ cells to see how long they take to repair themselves, depending on whether they are exposed to cigarette smoke or e-cigarette vapour. What scientists find is that the cells exposed to e-cigarette vapour will repair themselves at nearly the same rate as they would naturally. However, when exposed to cigarette smoke, repair will take much longer.

¹⁰Photos used with the permission of BAT Science.

Another test involves exposing certain lung cells to vapour and smoke. The purpose of these cells is to clear mucus and debris from the lungs. They do it by a 'beating' action, which is not compromised by e-cigarette vapour but weakened when exposed to cigarette smoke.

A common test used to assess the safety of emissions is that of cytotoxicity, during which the percentage of dying cells (usually epithelial cells from human airways) is calculated when exposed to aerosols or smoke. Although some cell death can be shown with SNP emissions, these effects are much less than those observed with cigarette smoke.¹¹

A major criticism of much laboratory testing of e-cigarette toxicity is that the experiments do not match real world use and experience of the devices. A good example of this was the concern raised in one study about the levels of formaldehyde, acrolein and acetaldehyde released when the propylene glycol and glycerine in the e-liquid are heated. Yet the heating temperature in the study was much higher than any user would tolerate (so called bad tasting 'dry puff') and was akin to burning toast that nobody would eat and then claiming that toast causes cancer.¹²

As the Royal College of Physicians states, "In normal conditions of use, toxin levels in inhaled e-cigarette vapour are probably well below present threshold limit values for occupational exposure in which case significant long-term harm is unlikely. Some harm from sustained exposure to low levels of toxins over many years may yet emerge, but the magnitude of these risks relative to sustained tobacco smoking is likely to be small". The RCP goes on to observe that most reviews raising concerns about constituents, were related to their presence rather than absolute levels which are "generally the more important determinant of toxicity". They commented that all the constituents identified were at lower levels than in cigarette smoke, but that long-term use even at these low levels

could be problematic, although "the magnitude of these risks relative to those from sustained tobacco smoking is likely to be small".¹³

Figure 5.4
Cigarette emissions

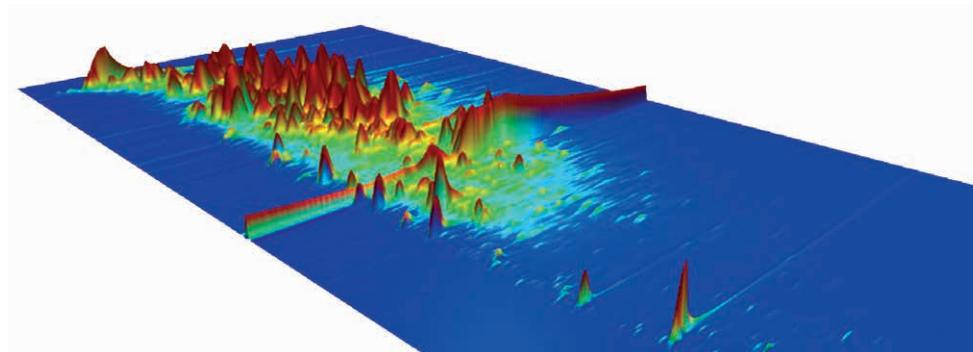


Figure 5.5
HNB emissions

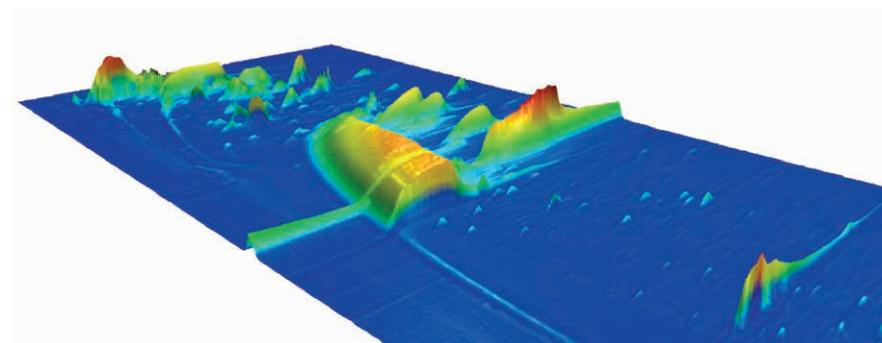
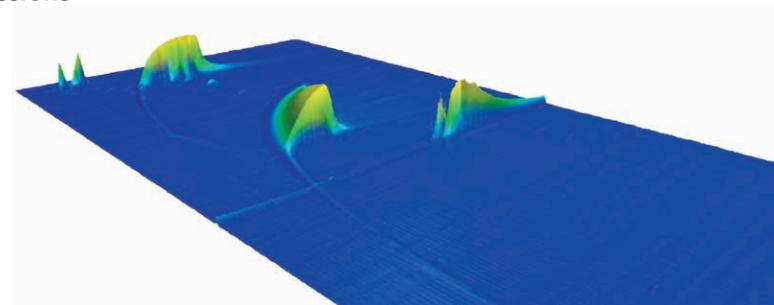


Figure 5.6
E-cigarette emissions



¹¹ For more explanation of relative emissions and impact on cells, go to BBC iPlayer and the Horizon programme broadcast in 2016. Available at <https://www.bbc.co.uk/programmes/b07c6ll4>

¹² The original study was Jensen, R.P et al (2015). Hidden formaldehyde in e-cigarette aerosols. *New England Journal of Medicine*, 372 (4), p. 392-4. This was then replicated at normal temperature by Farsalinos, K. et al (2017), E-cigarettes emit very high formaldehyde levels only in conditions that are aversive to users. *Food and Chemical Toxicology*, 109, p. 90-4. It is not just the temperature settings that are a factor. Researchers, not familiar with product range and development may be using old-style components in the laboratory that have been superseded in the real world.

¹³ Royal College of Physicians. *Nicotine without smoke; tobacco harm reduction. A report by the Tobacco Advisory Group of the Royal College of Physicians*. RCP, 2016, p.79

“A major criticism of much laboratory testing of e-cigarette toxicity is that the experiments do not match real world use and experience of the devices”.

The next level of assessment for establishing relative product safety concerns exposure. Studies of e-cigarettes,¹⁴ HNB¹⁵ and snus¹⁶ have shown substantial reductions in exposure to a wide range of chemicals and toxins relative to cigarette smoking.

Substantiation of reduced health risk by evaluating short and long-range impact of SNPs on biomarkers that might indicate a health concern is another key element for establishing relative product safety. However, given their relatively recent introduction, there are no studies of the long-term effects of e-cigarette or HNB use, so the areas of concern about long-term exposure remain largely hypothetical. The most obvious areas for consideration would be vapour constituent deposits in the mouth, upper airway and lungs and the overall effects on bodily functions of vapour inhalation. These constituents would include nicotine, propylene glycol, glycerine and flavours.

Nicotine is a psychoactive substance that in the extremely rare cases where ingestion of high doses happens, whether by accident or on purpose, can be fatal. But at commonly used dose levels, short-term nicotine use does not result in clinically significant harm¹⁷ while the long-term adverse effects are also likely to be minimal.¹⁸

According to the International Agency for Research on Cancer (IARC) nicotine is not a carcinogen¹⁹ and a recent US Surgeon General’s report concluded that it does not contribute to respiratory diseases.²⁰

Tobacco smoke and e-cigarette vapour follow the same pathway into the mouth and upper airway, through the gastrointestinal tract and are then excreted. The deposit and absorption of smoke-derived carcinogens increase the cancer risk impacting on various organs but, given the very low level of potential carcinogens in e-cigarette vapour, the risk either relative or absolute is low. In respect of the respiratory system, while the risk of vapour causing lung cancer is low, there is the possibility of vapour-induced lung irritation and the attendant increased risk of adverse respiratory impact in people with hypersensitivities to certain chemicals. That said, many smokers who switch report improvements in lung function.²¹

Regarding propylene glycol in e-cigarettes, this is also the primary ingredient generating synthetic “smoke” at rock concerts and other events and is considered to be safe. Apart from possible minor irritation causing a cough, there are no other known harmful effects, while animal studies have failed to demonstrate any harmful effects on the lungs of inhaling glycerine. By virtue of its bactericidal properties, propylene glycol in its aerosol form was used to sanitise hospitals and military barracks. Thus, regular vaping of pharma grade propylene glycol could have additional theoretical health benefits. Lower incidence of airway infections of smokers who had switched to e-cigarettes has been reported.^{22 23}

Turning to the flavours added to e-cigarette liquids, there has been much media coverage of a condition known as ‘popcorn lung’. This has emerged through concerns that some flavours contain diacetyl, an organic compound with an intense buttery taste used to flavour products, such as margarine, that might cause bronchiolitis obliterans, as suffered by employees working in popcorn factories who have been exposed to high levels of this compound.

¹⁴Shahab L. et al. (2017) Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. *Annals of Internal Medicine*. 2017 Mar 21;166(6):390-400. doi: 10.7326/M16-1107

¹⁵Haziza C. et al. (2017) Assessment of the reduction in levels of exposure to harmful and potentially harmful constituents in Japanese subjects using a novel tobacco heating system compared with conventional cigarettes and smoking abstinence: a randomized controlled study in confinement. *Regulatory Toxicology and Pharmacology* 2017; 81: 489-499

¹⁶Sarkar M. et al. (2010) Evaluation of biomarkers of exposure in adult cigarette smokers using Marlboro snus. *Nicotine and Tobacco Research* 2010; 12(2): 105-116

¹⁷Royal College of Physicians. *Nicotine without smoke; tobacco harm reduction. A report by the Tobacco Advisory Group of the Royal College of Physicians*. RCP, 2016, p.58

¹⁸National Institute for Health and Care Excellence. *Tobacco harm reduction (PH45)*. NICE 2013

¹⁹World Health Organisation International Agency for Research on Cancer. IARC monographs on the evaluation of carcinogenic risks to humans. In: Cancer IAFRo, editor. *Tobacco Smoke and Involuntary Smoking 2004*. Geneva: World Health Organisation International Agency for Research on Cancer; 2004

²⁰US Department of Health and Human Services CfDCaP, editor. *The health consequences of smoking: 50 years of progress: a report of the surgeon general*. National Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta: US Department of Health and Human Services CfDCaP; 2014

²¹Polosa, R. et al (2014). Effect of smoking abstinence and reduction in asthmatic smokers switching to electronic cigarettes; evidence for harm reversal. *International Journal of Environmental Research and Public Health* 11: 4965-77

²²Polosa, R. et al (2016). Evidence for harm reduction in COPD smokers who switch to electronic cigarettes. *Respiratory Research* 17, 166

²³Miler J.A. et al (2016). Changes in the Frequency of Airway Infections in Smokers Who Switched To Vaping: Results of an Online Survey. *Journal of Addiction Research* 2016, 7:4

The symptoms such as coughing, shortness of breath and wheezing might be indistinguishable from the effects of long-term smoking in an e-cigarette user who had switched, while in any event exposure levels would be several orders of magnitude lower than a factory environment. This respiratory condition has never been reported in vapers, despite widespread e-cigarette use. Even so, manufacturers are now avoiding flavours that contain diacetyl. Some flavours like cinnamon may be more cytotoxic than other flavours, if there is direct contact with the e-liquid, but no studies have demonstrated harmful effects in real world vapour situations.

There are other components in e-cigarette liquids that are generated when the liquid is heated, including formaldehyde (see above) and acrolein, while the device and the device elements can also release aerosolised particles of metal, ceramic and rubber when heated. Again, exposure will be well below recognised safety thresholds, but could be reduced still further by improved manufacturing standards.

HNB products

HNB products are more recent than e-cigarettes and, so far, most of the evidence has come from the manufacturers, which is to be expected with any new product. However, the body of independent research on these products is growing. To date, independent research on heated tobacco products has focused on a number of areas including aerosol chemistry, indoor air quality, toxicity, exposure to toxicants, and risk.

Unlike e-cigarettes, these products contain tobacco which is heated at different temperatures depending on the device, although never above 350°C, and so well below the combustion temperature of cigarettes and below the typical combustion temperature of 600 to 900°C. It is crucial to demonstrate that no combustion occurs when heated tobacco products are used as intended because most of the harm from tobacco is produced under combustion. One manufacturer has indicated that while the temperature of the blade that heats the tobacco can reach up to 350°C, the tobacco itself never reaches this temperature and the temperature of the majority of the tobacco does not exceed 250°C.²⁴ Recently, an independent assessment, conducted for New Zealand's Ministry of Health, confirmed that no combustion occurs in the heated tobacco product IQOS, when used as intended.²⁵



The scientific assessment process is very similar to that for e-cigarettes i.e. it focuses on chemical and physical characterisation of emissions; laboratory studies of potential effects of the chemicals and toxins; quantification of human exposure to chemicals and toxins; clinical studies of changes in biomarkers of exposure; clinical studies evaluating short and long range impact on health effect indicators when switching from smoking to using heated tobacco products, and long-term epidemiological studies of the health of users. Another important aspect of such assessment has to include consumer behaviour at the population level, e.g. whether these products create a new generation of tobacco users who may or may not eventually move on to smoking cigarettes (the purported 'gateway' effect), and whether at the population level there is long term dual use of these products, along with cigarettes among smokers who switch.

PHE and the UK Committee on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment considered the available evidence in 2017.²⁶ The UK Committee on Toxicity (COT) highlighted

²⁴ Script of Philip Morris International's Presentation before the Tobacco Products Scientific Advisory Committee (TPSAC), 24 January 2018. Available at https://pmiscienceprd.s3.amazonaws.com/docs/default-source/news-documents/pmi-tpsac_final-script.pdf?sfvrsn=10dcce06_2

²⁵ Ministry of Health v Philip Morris (New Zealand) Limited [2018] NZDC 4478. Available at <http://www.districtcourts.govt.nz/assets/unsecure/2018-03-27/2018-NZDC-4478-MOH-v-Morris.pdf>

²⁶ UK Committee on Toxicity. *Statement on the toxicological evaluation of novel heat-not-burn tobacco products*. 2017. Available at https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

significant reductions in levels of harmful and potentially harmful constituents (HPHCs) in the aerosol of heated tobacco products compared to cigarette smoke and stated that “[t]here would likely be a reduction in risk for conventional smokers deciding to use heat-not-burn tobacco products instead of smoking cigarettes”.²⁷ COT added that “[a] reduction in risk would also be experienced by bystanders where smokers switch to heat-not-burn tobacco products”.²⁸

In 2018, PHE reviewed 20 extant studies (12 of which were tobacco company research) and reiterated these points based on the available evidence and noted the potential of HNB tobacco: “Compared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds. The extent of the reduction found varies between studies. [...] The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes.”²⁹

The conclusions from both reports were necessarily cautious because of limited independent evidence at the time of publication and also because the products are new to the global market. But the headline data show that because the tobacco is not burnt at the same high temperatures as cigarettes, and like e-cigarettes, the level of ‘chemicals’ and ‘toxins’ emission is greatly reduced. A number of independent analytical chemistry studies on HNB products have recently been published. These have mostly confirmed manufacturers’ findings by showing that HNB products generate much lower levels of harmful constituents compared to tobacco cigarettes.^{30 31 32} In terms of cancer potency a review of extant studies of toxicological of risk and likely daily exposure indicated that cancer risk from heat-not-burn products is between one and 10 percent that of cigarettes.³³

To date PMI’s IQOS is the most widely available HNB product on the market, followed by BAT with their glo brand and JTI with their Ploom TECH brand. National companies such as KTNG from South Korea have launched their own HNB products under the Lil brand.

PMI and BAT have a product development and assessment programme, which includes aerosol chemistry, indoor air quality, toxicology, clinical studies, and population studies.

Both BAT and PMI have published scientific papers that describe the operation of these products and their assessment in a series of preclinical, clinical and

population-based studies (for an example refer to reference³⁴). The key findings of these studies are that emissions on use correspondingly showed around 90–95 percent fewer tested toxicants than those measured in cigarette smoke. The environmental emissions were substantially reduced when consumers used these heated tobacco products compared with when they smoked cigarettes, to the extent that for the majority of measured constituents, the environmental emissions were at similar levels as those from the baseline measurements, when the consumers were not using any products.

The latest independent study on HNB products was published in June 2018.³⁵ It compared the levels of carbonyl emissions from IQOS, an E-cigarette, and Marlboro Red cigarettes using three puffing regimes. The authors conclude that “[t]he IQOS heated tobacco product emits substantially lower levels of carbonyls than a commercial tobacco cigarette (Marlboro Red) but higher levels than a Nautilus Mini e-cigarette.” However, the authors highlight “that the absolute difference in carbonyl emissions between the heated tobacco products and the e-cigarette is low when compared to the difference between these products and tobacco cigarette smoke.”

²⁷ UK Committee on Toxicity. *Statement on heat not burn tobacco products*, 12 December 2017. Available at <https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products>

²⁸ UK Committee on Toxicity. *Statement on heat not burn tobacco products*, 12 December 2017. Available at <https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products>

²⁹ McNeill A. et al *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. Public Health England, 2018. Available at <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review>

³⁰ Bekki K. et al (2017) Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes. *Journal of OEH*. 2017;39(3):201-207. doi: 10.7888/juoeh.39.201

³¹ Li X. et al (2018). Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes. *Nicotine and Tobacco Research*. 2018 Jan 8. doi: 10.1093/ntr/nty005. [Epub ahead of print] PubMed PMID: 29319815

³² Mallock N. et al (2018) Levels of selected analytes in the emissions of “heat not burn” tobacco products that are relevant to assess human health risks. *Archives of Toxicology*. 2018 May 5. doi: 10.1007/s00204-018-2215-y.[Epub ahead of print] PubMed PMID: 29730817

³³ Stephens E (2018) *The role of emissions in the debate on health effects across the spectrum of nicotine delivery*. Global Forum on Nicotine. Available at <https://gfn.net.co/downloads/2018/PRESENTATIONS/SATURDAY/Plenary%202/EdStephens.pdf>

³⁴ Proctor C (2018) Assessment of tobacco heating product THP1.0. Part 1: Series introduction. *Regulatory Toxicology and Pharmacology* 93, 1-3

³⁵ Farsalinos et al. (2018), Carbonyl emissions from a novel heated tobacco product (IQOS): comparison with an e-cigarette and a tobacco cigarette, *Addiction*. Available at <https://doi.org/10.1111/add.14365>

The toxicological and clinical biomarker studies offer an insight into potential reduction to harmful exposures but need to be followed through to examination of whether reductions in toxicant exposure occur in real world settings.

Snus

The relatively lower risks from smokeless tobacco products in general and Swedish-style snus in particular are well evidenced in the literature backed by decades of research. In summary, snus is a safer nicotine delivery product because:

- » It is pasteurised to remove toxins;
- » There is no inhalation, so no risk of respiratory disease which accounts for nearly half of all smoking-related deaths;
- » There is no significant association with premature deaths, diabetes, pancreatic and oral cancers, heart disease or strokes.

In the case of snus - in contrast to e-cigarettes and HNB - there is a large amount of long-term epidemiological data. The first indication that there is something different about Sweden compared with the rest of Europe is the high level of snus use compared with smoking (see also Chapter 3). Sweden has - using WHO data - the lowest rate of tobacco-related mortality in Europe - and its rate of tobacco-related disease is half that of the EU average. The low levels of smoking mean that there will be low levels of respiratory disease linked with inhalation. But there remains the possibility that snus has other non-respiratory health effects such as on cancers of the mouth and digestive tract, diabetes, and cancer of the pancreas. However, the epidemiological evidence is that snus is not associated with premature mortality, nor in Sweden with diabetes, oral and pancreatic cancers, or cardiovascular disease.

In its 2008 investigation, the EU Scientific Committee on Emerging and Newly Identified Health Risks reported several conclusions about the health effects of smokeless tobacco products (STP) and snus. Primarily, it found that there is consistent evidence that use of STP does not cause any major respiratory disease and that complete substitution of STP for tobacco smoking would ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, and reduce the cardiovascular mortality that currently arises from smoking by at least 50 percent. They also concluded that there was no obvious gateway effect from snus to cigarettes among young Swedish people.³⁶



Health risks of snus

Premature mortality

The Global Burden of Diseases, Injuries and Risk Factor Study provides a comprehensive assessment of risk factor exposure and attributable burden of disease. For example, the 2016 study states, "for the first time in the GBD study, we estimated exposure to and burden attributable to smokeless tobacco...RR [Reduced Risk] estimates were derived from prospective cohort studies and case-control studies...Based on available evidence, for chewing tobacco RRs were significantly higher than one for oral cancer and oesophageal cancer, while for snus or snuff we did not find sufficient evidence of a RR greater than one for any health outcome".³⁷

Diabetes

A combined analysis of five large Swedish studies compared men who had never smoked with men who used snus, and found that the use of snus was

³⁶ Scientific Committee on Emerging and Newly Identified Health Risks. *Health effects of smokeless tobacco products*. Health and Consumer Protection Directorate, European Commission, 2008. Available at ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

³⁷ Global, regional and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet*; 2017, 390, 1345-1422

associated with a small (15%) increased risk of type 2 diabetes.³⁸ In four of the studies the risk of diabetes was actually lower for snus users than for non-smokers or close to no difference between the two groups. The overall results of the combined analysis are markedly affected by the largest study, conducted in northern Sweden region with elevated risks of many health problems. In a separate case control study of people with type 2 diabetes, the risk was unrelated to snus use.³⁹ Differences in consumption level, with significant associations only reported for heavy users but not for light users, can explain some of the disagreement among studies.

Oral and pancreatic cancers

The conclusion of a meta-analysis of major Scandinavian studies was that there was “no overall association [with snus] seen for oropharyngeal cancer”,⁴⁰ while a study into pancreatic cancer conducted by the Karolinska Institute concluded that, “compared to never snus use, current snus use was not associated with risk of pancreatic cancer after adjustment for smoking”.⁴¹

Cardiovascular disease

In one longitudinal study, nearly 17,000 Swedish male twins participating in the Screening Across the Lifespan Twin Study, conducted in 1998–2002, were followed up for incidence of cardiovascular disease. The researcher concluded, “Overall, there was no association between use of snus and risk for cardiovascular disease. Current snus users, without a smoking history, had a relative risk of 1.00 for cardiovascular disease as compared to non-users. Corresponding relative risks for ischemic heart disease and stroke were 0.85 and 1.18 respectively. In smoking adjusted models, risk estimates for ischemic heart disease in relation to snus use were all close to unity regardless of timing or intensity of snus use”.⁴²

Adding to these studies, the WHO Scientific Advisory Committee on Tobacco Product Regulation reported in 2010 that, “Among the smokeless tobacco products on the market, products with low levels of nitrosamines such as Swedish snus, are considerably less hazardous than cigarettes”.⁴³

Passive exposure to SNP

When somebody is seen blowing out clouds of vapour from a device, it is understandable that passers-by might equate this with cigarette smoke and

be concerned about the possible effects of their own inhalation. Clouds of vapour can irritate the throat in enclosed spaces, however, most people who vape are reasonably discrete about their use, adopting ‘stealth vaping’, more like sucking on a pen than smoking a cigarette, and so never produce clouds of vapour anyway. Although some annoyance might be caused by vaping, as we have established above, vapour is not smoke. To quote PHE, “there is no side-stream vapour emitted from the end of an e-cigarette, just the exhaled vapour entering the atmosphere”.⁴⁴ In their 2015 review, “we concluded that there was no identified health risk to bystanders”. More recent studies leave the PHE conclusion from 2015 unchanged.^{45 46} And obviously since snus is an oral product, there is no passive exposure.

Is nicotine addiction a problem?

It is important to consider the issue of nicotine ‘addiction’ because in absence of any evidence that SNP carries substantial health risks when compared with smoking to either those who use them or to bystanders, warnings on SNP packaging generally fall back on the issue of addiction.

Addiction is an ill-defined concept which can be applied to many substances and activities; the whole range of psychoactive drugs – both legal and illegal – gambling, shopping, sex, eating, or playing video games. When deemed to be

³⁸ Carlsson, S et al. (2017) Smokeless tobacco (snus) is associated with an increased risk of type 2 diabetes: results from five pooled cohorts. *Journal of Internal Medicine*. 281, 398–406

³⁹ Rasouli, B. et al. (2017) Use of Swedish smokeless tobacco (snus) and the risk of Type 2 diabetes and latent autoimmune diabetes of adulthood. *Diabetic Medicine*; 34, 514–521

⁴⁰ Lee, P. (2011). Summary of the epidemiological evidence relating snus to health. *Regulatory Toxicology and Pharmacology*, 59 (2), 197–214

⁴¹ Araghi, M. et al (2017). Use of moist oral snuff (snus) and pancreatic cancer: pooled analysis of nine prospective observational studies. *International Journal of Cancer*. 141(4):687–693

⁴² Hansson, J et al (2009). Use of snus and risk of cardiovascular disease; results from the Swedish Twin Registry. *Journal of Internal Medicine* 265(6):717–24

⁴³ World Health Organisation. *Scientific Basis of Tobacco Product Regulation*. Tobacco Regulation Report 955. 2010

⁴⁴ McNeill, A. et al. *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. PHE, 2018, p.162

⁴⁵ Glasser, A. M. et al. (2017). Overview of electronic delivery systems: a systematic review. *American Journal of Preventative Medicine*. 52 (2), e33–e66

⁴⁶ Zwack, et al (2017). *Evaluation of chemical exposures at a vape shop*. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. Available at www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279pdf

out of control and adversely affecting other areas of life, all these are classified by the medical profession as psychiatric conditions, but from a common sense real-world point of view, there is a clear difference between injecting heroin and gambling on horses. The question remains: what is 'addiction'?

From a neuro-biological standpoint, nicotine is a mild stimulant drug which binds to the equivalent receptors in the brain like a key fitting into a lock. Once locked in, nicotine stimulates the release of the chemical dopamine which is crucial to reward and reinforcement effects that users of many different drugs experience. Simply put, it could be called 'the good time chemical' in that it is responsible not just for the pleasure people derive from intoxication,⁴⁷ but also for sexual gratification and the satisfaction of eating, without which humans as a species would die out. So there has to be drug/brain interaction to start the process - and the quicker the drug gets to the brain through the blood-brain barrier, the stronger the sensations; so injecting would be the quickest route, followed very closely by smoking, then snorting, and the slowest route would be oral or transdermal use. This explains why many users of NRT find the experience unsatisfying because nicotine ingested in this way takes longer to hit the brain than smoking.

But as the recent RCP report points out, the rewards and reinforcement of smoking are not just about the specific drug/brain interaction, although of course, the brain has a role to play in all our sensory experiences: "Continued pairing of the rewarding/reinforcement pairing with specific and sensory and environmental stimuli (which for example, could include the smell of tobacco or the sight of a packet of cigarettes...) results in these stimuli also acquiring reinforcing properties."⁴⁸ This would also involve certain rituals like first cigarette in the morning, or always having a smoke with a drink or a meal, even the post-coital cigarette, which has been used as a coy symbol in film and TV to indicate that sex had taken place even if not shown.

Hence from that point of view, nicotine is 'addictive'; people say they crave cigarettes, get 'withdrawal symptoms', feel agitated and irritable and find it hard to concentrate if they run out. Influenced strongly by the psychiatric and rehabilitation industries, addiction is viewed in society as an irreducible scientific and biological syndrome, a disease caused by the brain being hijacked.

Yet if you match up the criteria for a 'substance use disorder' as set out in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (2013), the

American Psychiatric Association's gold-standard text on the names, symptoms, and diagnostic features of every recognised mental illness including addiction, you find that nicotine falls short on several counts. For example; taking the substance in larger amounts or for longer than you're meant to; spending a lot of time getting, using, or recovering from use of the substance; not managing to do what you should at work, home, or school because of substance use; continuing to use, even when it causes problems in relationships; giving up important social, occupational, or recreational activities because of substance use; needing more of the substance to get the effect you want. None of these apply to the use of nicotine on a regular, long-term basis.

And more generally, there is a counter-view on the whole notion of addiction as a disease. The psychologist Stanton Peele has written at length as to why he regards 'addiction' as more of a modern day cultural concept than a medical given.⁴⁹ And he along with others, convincingly challenges the seemingly universal assumption that addiction is a disease comparable to cancer or diabetes.⁵⁰

In US medical circles, the word was originally associated simply with the consequences of heroin use and as such became freighted with all kinds of visceral imagery depicting the worst outcomes of chronic injecting drug use. Prompted by films and television, in the public mind, the word conjures up a life in chaos and ruin, where the drug becomes all-consuming, where family and friends, school, college or job, everything in the person's life, takes second place behind securing the next dose which (in the case of illegal drugs) may also involve criminal activity.

All this produces a welter of discrimination and prejudice against drug users, discussion of which is beyond the scope of this report. But looking at what happens in the real world, does this picture of misery and despair map across

⁴⁷ See Siegal R., *Intoxication: the universal drive for mind-altering substances* (reissue) Park Street Press, 2005. The author details how not only humans throughout history, but also animals seek to alter their state of consciousness.

⁴⁸ Royal College of Physicians. *Nicotine without smoke; tobacco harm reduction. A report by the Tobacco Advisory Group of the Royal College of Physicians*. RCP, 2016, p.57

⁴⁹ Even with heroin, the idea that addiction is inevitable and permanent was challenged in the classic study by Lee Robins published in the *American Journal of Public Health* in 1974 following soldiers returning from Vietnam. Many became dependent on heroin while in the midst of war, but gave it up on return, thus confounding fears that thousands of new heroin users would be coming back to the USA.

⁵⁰ For example, Peele, S, *The meaning of addiction*. Jossey-Bass, 1985; Lewis, M. *The biology of desire; why addiction is not a disease*. Scribe 2015. Szalavitz, M. *The unbroken brain: a revolutionary new way of understanding addiction*. St Martin's Press, 2016.

to the person who is 'addicted' to nicotine? Because as the clinical literature confirms, if there are no significant short or long-term effects from using nicotine, and if you take the cigarettes out of the equation by changing the nicotine delivery system, the somewhat heretical question becomes - what's the problem with being 'addicted' to nicotine? In this specific context, should we even talk about 'addiction' at all? In the absence of serious clinical or societal harm, isn't this just a pleasurable habit? In which case, does the concept of 'addiction' become more of a moral or ideological construct than a clinically-based public health concern?^{51 52}

"As the clinical literature confirms, if there are no significant short or long-term effects from using nicotine, and if you take the cigarettes out of the equation by changing the nicotine delivery system, the somewhat heretical question becomes - what's the problem with being 'addicted' to nicotine?"

This is an important point because as the evidence accumulates that, in all respects, using SNP is far safer than smoking cigarettes, there is still the question of 'addiction', warnings about which as we say appear on much SNP packaging. The risk perception of SNP has actually increased, while smokers often cite the guilt and shame of being 'addicted' to nicotine as a reason for trying to quit. For the many unable to do so, it would be invidious to allow guilt and shame about nicotine 'addiction' to inhibit quit or switch attempts using SNP, if nicotine 'addiction' is being heralded as the worst outcome of using SNP.⁵³

Renormalisation of smoking

Some public health leaders have asserted that SNP will undermine efforts to 'denormalise' smoking by for example, encouraging those who have never smoked cigarettes to take up vaping and from there move onto smoking. This kind of thinking is grounded in the misconception that there is no difference between the two delivery systems, making that transition a real risk.⁵⁴

Most tobacco control strategies are aimed at engineering a change in social norms away from smoking, so ensuring maximum barriers to smoking in public, to affording cigarettes, or to be subjected to any form of advertising or promotion which encourages smoking, while making every effort to warn of the dangers of smoking. And while not the whole story, these strategies have

contributed to reducing smoking at a population level. But firstly, there is no evidence from mature e-cigarette markets around the world that non-smokers are taking up vaping in anything other than barely significant numbers.⁵⁵ Secondly, the idea of 'renormalising' smoking is a very 'western-centric' approach. Levels of smoking in some low-middle income countries are far higher than in the West and the number of smokers is rising in some countries due to population growth. Unlike in the West, where the tobacco control policy success has also been significantly helped by a general move towards healthier lifestyles among large sections of the more well-off population, smoking in low-middle income countries is far more 'normal'. These regions of the world would clearly benefit from more ready access to SNP.

Gateway effect

The idea that one drug leads to another - classically the supposed transition from a 'soft' drug (e.g. marijuana) to a 'hard' drug (e.g. heroin) - was first mooted by the head of the Federal Bureau of Narcotics back in the 1950s, as he sought to extract more funding from US Congress when earlier claims of 'reefer madness' were looking highly suspect.⁵⁶ The idea gained more sustained traction in the mid-1980s through Dr Robert DuPont, a psychiatrist and vehement anti-marijuana campaigner, who was the White House drugs advisor under Presidents Richard Nixon and Gerald Ford. The main problem with the thesis is that it grossly over-simplifies the dynamics of drug use and completely ignores

⁵¹ As an interesting aside, there is evidence that nicotine might be more 'addictive' when smoked in cigarettes because of other additives in the smoke that aid nicotine delivery and absorption including MAO inhibitors, sugars and polysaccharides. Royal College of Physicians. *Nicotine without smoke; tobacco harm reduction. A report by the Tobacco Advisory Group of the Royal College of Physicians*. RCP, 2016, p.61

⁵² Some clinicians prefer 'dependence' to 'addiction' and would argue that nicotine 'enjoyment' is simply a manifestation of dependence keeping the regular use of nicotine within a medical context.

⁵³ The term 'hardcore' in relation to smokers is equally meaningless in research terms as addiction and similarly pejorative. See West, R and Jarvis, M. (2017). Is 'hardcore smoker' a useful term in tobacco control? *Addiction*: 113, p.3-4

⁵⁴ Voigt, K. (2015). Smoking norms and the regulation of e-cigarettes. *American Journal of Public Health*. 105 (10), 1967-1972

⁵⁵ Farsalinos, K.E. et al (2016). Electronic cigarette use in the European Union; analysis of a representative sample of 27,460 Europeans from 28 countries. *Addiction*. Nov;111(11) p. 2032-2040. Available at <https://www.ncbi.nlm.nih.gov/pubmed/27338716>, and McNeill A. et al (2018). *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. PHE, 2018

⁵⁶ McWilliams, J.C. *The protectors: Harry J Anslinger and the Federal Bureau of Narcotics 1930-1962*. Associated University Presses, 1990

all the co-founding factors that might lead young people to experiment with one drug and then another. As one academic has suggested, once the hypothesis had been popularised, “it suffered the death of a thousand qualifications – it becomes an empty peg whose removal is long overdue...reflecting the interests of certain stakeholders rather than wise social policy”.⁵⁷

From this it follows that the hypothesis of a gateway from vaping to smoking is just as flawed and has just as many caveats as for any other drug, but nevertheless does feature heavily in debates about young people and the new products. Therefore an important aim of tobacco harm reduction is to ensure that while current smokers benefit from a switch to SNP, there are no unintended consequences which lead young people who might experiment with SNP to go on to become regular smokers.

“[The gateway effect theory] suffered the death of a thousand qualifications – it becomes an empty peg whose removal is long overdue...reflecting the interests of certain stakeholders rather than wise social policy”.

To date, there is no evidence of a gateway effect to regular smoking, although some young people will experiment with e-cigarettes because of the novelty factor and may also try cigarettes too. Specific studies show that use of e-cigarettes among young people is largely experimental⁵⁸ with the majority using flavours that do not even contain nicotine.^{59 60}

But the chances are that they would have tried cigarettes anyway, they will drink alcohol and probably smoke a cannabis joint too, go to loud rock concerts, have unprotected sex and ride motorbikes. There will be teenagers who do all, some or none of these things, but it is a given that this is the age of experimentation, of pushing boundaries and indulging in behaviour designed to provoke disapproval. Given that e-cigarettes have been on the market for more than a decade, if there was going to be a gateway effect, demonstrated by rising prevalence of smoking among those young people who had started vaping, it would show up in official data – but it doesn't. Levels of past 30-day smoking prevalence among young people in the USA and UK are among the lowest ever recorded.⁶¹

From a public health perspective, it is more important to measure prevalence of frequent e-cigarette use and to establish whether use occurs in non-smoking youth. Data from the US National Youth Tobacco Survey 2015 show that the vast

majority of e-cigarette use is experimental or infrequent, while regular use is rare among never smoking adolescents.⁶²

The National Academy of Sciences report concluded that there was ‘substantial’ evidence of a gateway effect, but this was based on mainly US evidence from studies with a different methodological approach from other studies. Quite simply, studies which conflate ‘ever use’ (which might only mean once) with ‘use’ are bound to show quite high levels of ‘use’ by young people.

One recent phenomenon, which has captured media attention in the USA to the extent of a ‘moral panic’, is the use of JUUL e-cigarette devices. These devices have been extremely successful in the market place and may well feature in youthful experimentation, although currently no studies have been published and media coverage has been anecdotal.

The place of SNP in smoking cessation

When surveyed, most smokers say they want to give up or are planning to quit and most have tried to quit completely or cut down many times, either going ‘cold turkey’ or in conjunction with various nicotine replacement therapies utilising gum, patches or inhalers. Pharmacotherapy does not work well for many people, whereas SNP are much more promising. The smoker trying to quit smoking is still getting the nicotine hit. When surveyed, smokers who have switched to vaping cite health concerns as the main reason for a move to vaping. Smokers who switch often start with high nicotine content liquid and then reduce

⁵⁷ Kleinig, J. (2015) Ready for retirement: the gateway drug hypothesis. *Substance use and misuse*; online 1-5

⁵⁸ Bauld, L. et al. (2017). Young people's use of e-cigarettes across the United Kingdom; findings from five surveys 2015-2017. *Int J Environ Res and Public Health*; 14, 973

⁵⁹ Miech, R. et al. (2017). What are kids vaping? Results from a nationwide survey of US adolescents. *Tobacco Control*. 26: 386-391

⁶⁰ A very small qualitative study was conducted with existing young Scottish smokers and their experience with vaping. While limited in scope, it did suggest that some young people might start vaping as a trial but return to cigarettes for a raft of reasons including peer group smoking culture, satisfaction and ease of use. McKeganey, N. et al. (2018). Vapers and vaping: e cigarettes users and views of vaping and smoking. *Drugs: education, prevention and policy*. 25 (1), p.13-20

⁶¹ Harrell, P.T et al (2016). Patterns of youth tobacco and poly-tobacco usage. The shift to alternative products. *American Journal of Drug Alcohol Abuse*. 1-9

⁶² Farsalinos K. et al (2018). Frequency of Use and Smoking Status of U.S. Adolescent E-Cigarette Users in 2015. *American Journal of Preventative Medicine*. 2018 Jun;54(6):814-820.doi: 10.1016/j.amepre.2018.03.003. Epub 2018 Apr 7. PubMed PMID: 29631871

to very low levels, or no nicotine content at all, while still wanting to replicate the cigarette 'experience'.⁶³

There are divided opinions about the effectiveness of e-cigarettes as smoking cessation tools, with evidence pooled from observational studies and randomised control studies reaching conflicting conclusions; some showing improved success⁶⁴ and others demonstrating either no efficacy,⁶⁵ or even suggesting that e-cigarettes suppress the chances of successful smoking cessation.⁶⁶

Even though there will be those vapers who have switched with no intention of totally quitting, there is no evidence that overall the advent of e-cigarettes has slowed quitting rates or caused relapse in long-term quitters. On the contrary, studies show a switch to e-cigarettes increases the chance of quitting altogether.⁶⁷ In Europe as a whole, it has been estimated in 2014 that six million people have quit smoking using e-cigarettes.⁶⁸

Beyond cessation and the 'pleasure principle'

The medicalisation of any illegal drug use has meant notions of pleasure derived from use have been completely written out of the script of public policy, leaving a 'pathology paradigm' as the dominant discourse.^{69 70} The denormalisation of smoking has created a similar paradigm, where smoking is more regarded as an illness that needs to be treated. Not surprising then that the use of SNP is only viewed as legitimate by some of the public health community, so long as SNP are part of a smoking cessation strategy. But some studies have looked into the issue of 'loss of identity' when embarking on smoking cessation,⁷¹ which can arguably be recaptured by a change of identity to vaper, rather than smoker, and engaging with a new social grouping. This is underlined by recent research revealing that many ex-smokers embrace the new social context of vaping.^{72 73 74}

One UK study⁷⁵ asked vapers to rank statements about e-cigarettes along a continuum of agree/disagree, and to sort these into groups. The three groupings that emerged were:

1. Vaping as pleasure or 'having your cake and eating it';
2. Vaping as medical treatment;
3. Ambivalent about using e-cigarettes.

The majority of participants signed up to the first group and stated the many positives about using e-cigarettes while rejecting the notion of smoking as an illness including the following statements:

"I smoked for 53 years and gave up almost immediately after trying an e-cigarette". (Female aged 69)

"I loved the smoking experience, now the vaping experience". (Male aged 37)

"Vaping is a hobby now. Rebuilding mods, coils, drip tip carving and mixing your own juices, there are no 'NRT' forums and only a few smokers forums". (Male aged 41)

"Flavours are a big part of the e-cig experience. I vape sweet flavours. Once your taste buds come back, tobacco flavours are not nice". (Male aged 41)

"Flavours are essential for disassociation from smoking". (Male aged 37)

⁶³ Personal communication with ex-smokers who have switched.

⁶⁴ Hartmann-Boyce J. et al (2016). Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews* 2016: 9: CD010216

⁶⁵ Khoudigian S. et al (2016). The efficacy and short-term effects of electronic cigarettes as a method for smoking cessation: a systematic review and a meta-analysis. *International Journal of Public Health* 2016: 61(2): 257-267

⁶⁶ Kalkhoran S. and Glantz S.A. (2016). E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis. *The Lancet Respiratory Medicine* 2016: 4(2): p.116-128

⁶⁷ Shu-Hong, Z. et al. (2017) E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *British Medical Journal* 2017;358:j3262

⁶⁸ Farsalinos, K.E. et al (2016). Electronic cigarette use in the European Union; analysis of a representative sample of 27,460 Europeans from 28 countries. *Addiction*. Nov;111(11) p. 2032-2040. Available at <https://www.ncbi.nlm.nih.gov/pubmed/27338716>

⁶⁹ Moore, D (2007). Erasing pleasure from public discourse on illicit drugs: on the creation and reproduction of an absence. *International Journal of Drug Policy*; 19, p.353-358

⁷⁰ Duff, C (2007). The pleasure in context. *International Journal of Drug Policy*; 19, p.384-392

⁷¹ Pechacek, T.F et al (2017) Reassessing the importance of 'lost pleasure' associated with smoking cessation: implications for social welfare and policy. *Tobacco Control*. Available at: <https://tobaccocontrol.bmj.com/content/early/2017/11/24/tobaccocontrol-2017-053734>

⁷² Keane, H et al (2017) 'Anytime, anywhere: vaping as social practice. *Critical Public Health*. 27 (4), p. 465-476.

⁷³ Bevan, I. (2016). E-cigarettes: smoking pleasure reinvented? The many faces of harm reduction in France. *Contemporary Drug Problems*. 43(3), p.228-241

⁷⁴ Saddleson, M.L et al. (2016). Enjoyment and other reasons for electronic cigarette use: results from college students in New York. *Addictive Behaviour*; 54, p.33-39

⁷⁵ Farrimond, H. (2017) A typology of vaping: identifying different beliefs, motivations for use, identity and political interest among e-cigarette users. *International Journal of Drug Policy*; 48, p.81-90

"I absolutely love vaping. My health has improved. No more coughing!"

(Female aged 62)

"Medicine? I assume medicine is to treat an illness. I am not ill!!!" (Female

aged 62)

"I do not smoke anymore. I am not taking medicine. There is no doubt e-cigs offered a viable alternative to smoking but in themselves they are not a medicine". (Male aged 60).

"Part of why vaping works is that it doesn't medicalise smokers or frame nicotine consumption as a problem. I think it's more like caffeine". (Female aged 45)

General product safety

Given the controversial and innovative nature of the new technologies associated with e-cigarettes and HNB products, it is in the interests of manufacturers to be at the forefront of establishing product safety, through development and implementation of product standards.

The importance of standards was underlined at the WHO Framework Convention on Tobacco Control Conference of the Parties (COP) in 2016, in India, when its Secretariat was tasked with reporting back to the next COP on the development of methods used by regional and international standards bodies for the testing and measuring of contents and emissions of the new products.

A number of international, regional and national bodies are charged with the development of standards and many of these are now working on standards specific to vaping liquids and devices. Those safety standards cover three key areas: the composition of e-liquids and other consumables, the safety of the devices and emissions from those devices.

The International Organisation for Standardisation (ISO) is an independent, non-governmental organisation, with a membership comprising standards organisations of the 162 member countries. It is the world's largest developer of voluntary international standards and facilitates world trade by providing common standards between nations. Over 20,000 standards have been set, covering everything from manufactured products and technology, to food

safety, agriculture and healthcare. The ISO tobacco committee has established an e-cigarette sub-committee with two working groups, looking at safety and quality requirements for electronic cigarette devices and e-liquids; test methods for devices and e-liquids; determination of substances in e-liquids; testing conditions, equipment, reference products, emissions, vaping machines and user information and services provided by retailing.⁷⁶

At the regional level there is the European Committee for Standardisation or CEN, which has four working groups covering devices, e-liquids and emissions.

In Great Britain, there is the British Standards Institute (BSI) which has produced PAS 54115 in 2015, a manufacture, importation, testing and labelling guide covering vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products. Subjects covered include: the purity of e-liquid ingredients; potential contaminants from device materials and potential emissions from devices; an outline for the toxicological and chemical analysis of emissions and the safety of batteries and chargers. The French have a similar organisation, the Association Française de Normalisation (AFNOR) which has published similar guidance standards.

There is a voluntary product standard for Swedish snus called the Gothiatek standard introduced by the snus industry in 2001.⁷⁷ In 2007, the Gothiatek standard was accepted as a standard for all STPs by the European Smokeless Tobacco Council (ESTOC), an organisation representing all the major manufacturers of snus.

The Gothiatek standard sets maximum permissible levels for several unwanted substances. The mandated maximum levels have been lowered on several occasions since the introduction of the standard. In 2010 the WHO Study Group on Tobacco Product Regulation proposed maximum levels for some nitrosamines (NNN, NNK) and one PAH (BaP, benzo(a)pyrene) in STPs. These levels are, however, higher than the maximum levels currently mandated by Gothiatek.

⁷⁶Tranchard, S. (2016) Vaper and vapour products make their debut in international standardization. *International Organization for Standardization*. <https://www.iso.org/news/2016/04/Ref2074.html>

⁷⁷Rutqvist, L.E. et al (2011). Swedish snus and the Gothiatek standard. *Harm Reduction Journal*. 8:11 Available at <https://www.ncbi.nlm.nih.gov/pubmed/21575206>

The levels of such substances in Swedish snus are well below the levels for STPs proposed by the WHO Scientific Advisory Committee on Tobacco Product Regulation⁷⁸ as well as below the maximum levels for snus recently set by the Swedish Food Authority in its recent regulation which came into force on 11 April 2016.⁷⁹

How to improve the science of SNP

We started this chapter by highlighting the quality of science and of science reporting. There are many areas of public life and health where there are scientific disputes and questionable media reporting with consequent myths and misconceptions.

The problem with research into SNP

It might seem strange to end with a quote from a philosopher who lived 400 years ago, but what Francis Bacon had to say in 1620 in his *New Organon or True Directions* concerning the interpretation of nature about approaches to new science is still relevant today:

“The human understanding when it has once adopted an opinion draws all things else to support and agree with it. And though there be a greater number and weight of instances to be found on the other side, yet these it either neglects and despises, or else by some distinction sets aside and rejects, in order that by this great and pernicious predetermination the authority of its former conclusion may remain inviolate.”

This resistance to the paradigm shift in nicotine delivery will most likely be manifest in those researchers who have been involved in tobacco research for a long time. They would have seen the damage caused by cigarettes, the smoke and mirror activities of the big tobacco companies, and so may well come at research into new and very different, disruptive products manufactured by so-called ‘Big Tobacco’ and the much wider independent sector, through the same prism of antipathy and suspicion. This in turn can consciously or sub-consciously result in ‘confirmation’ bias in research. As policy makers and legislators involved in tobacco control will often harbour the same antipathies and suspicions, negative research has the potential to exert the most influence in inhibiting the progress of tobacco harm reduction.

The same kind of problem attaches itself to research funding bodies, both public and private, who are ill-disposed towards the tobacco industry and would likely only be interested in funding research that calls into question SNP as a new harm reduction pathway, without fully realising or choosing to ignore the fact that the tobacco companies do not have a monopoly on the e-cigarette business.

Then there are the faulty mechanisms of academic publishing. There are concerns about the peer review process itself,⁸⁰ journal editors and editorial boards may demonstrate the same biases as the authors of the papers under review – and academic careers stand or fall on publishing. Therefore, it is hardly surprising that researchers will headline their findings in the most dramatic way, in order to increase the chances of publication in the first place (especially in high impact journals) and then to capture the media’s attention. A study in *The Lancet* revealed that those papers demonstrating a null effect for those infants whose mothers used crack cocaine during pregnancy were less likely to be published than those that showed negative outcomes, even if the methodology of the latter was less robust.⁸¹

There is a well-worn cliché about the devil being in the detail and this applies acutely in the whole new research arena around SNP and tobacco harm reduction. With a 24/7 news cycle and new and often conflicting research appearing on an almost daily basis, it is impossible for most people to discern what research really stands up to scrutiny.

Professor David Abrams from the College of Global Public Health at New York University summarised the issue of bad science and SNP as follows:

“We suggest that current divisiveness that paralyzes policy-making can be mitigated by paying close attention to the strongest evolving scientific syntheses and not relying on select, isolated studies that exaggerate claims of harms and/or omit direct comparisons of harms relative to smoking.”

⁷⁸ World Health Organisation. WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation (2010). Available at www.who.int/tobacco/global_interaction/tobreg/publications/tsr_955/en/

⁷⁹ Swedish Match, *Snus and the Swedish Food Act*. Available at: <https://www.swedishmatch.com/Snus-and-health/snus-and-the-swedish-food-act/>

⁸⁰ Mccook, A (2006) Is Peer Review Broken? *The Scientist*. Available at <https://www.the-scientist.com/?articles.view/articleNo/23672/title/Is-Peer-Review-Broken-/>

⁸¹ Koren G. et al (1989). Bias against the null hypothesis: The reproductive hazards of cocaine. *Lancet*; 2:1440-1442

Strong assertions that go beyond the science (e.g., conflating correlation with causation, cherry picking results to highlight a particular viewpoint) are troubling trends that feed divisiveness rather than provide a basis for rational recommendations. Adhering to good research practices (e.g., research integrity; respect, ethics and professional standards; honesty and transparency; openness and accountability) is also necessary to reduce these apparent conflicts.”⁸²

A research evaluation check-list for SNP⁸³

1 Toxic chemicals have been identified in e-cigarette vapor or e-liquids

- 1.1 Did they show potentially harmful *exposure* not just the presence of a chemical? “The dose makes the poison”.
- 1.2 How risky is the exposure compared to smoking?
- 1.3 How risky is the exposure compared to other risks such as those accepted under occupational health limits?
- 1.4 Were measurements made in realistic human operating conditions or in extreme or unrealistic conditions?
- 1.5 Are inappropriate proxies being used for risk - for example effects that are also seen with coffee or exercise?
- 1.6 Are flawed analogies being used - for example assuming all ultrafine particles are equally toxic?

2 Adverse health effects from e-cigarettes are reported

- 2.1 Was vaping the real cause?
- 2.2 Was the person suffering from adverse impacts of being a smoker before using e-cigarettes?
- 2.3 Is the study just observing the effect of nicotine on the body (though no serious disease is caused by nicotine)?
- 2.4 Is there evidence of actual harm or is it just a change in the body or brain?
- 2.5 Is it based on a cell culture study, are the limitations recognized and was exposure realistic proxy for human use?
- 2.6 Is it based on an animal study and are the limitations recognized?

3 Claims second-hand vapor is toxic and indoor vaping should be banned

- 3.1 Are vapor exposures to bystanders potentially harmful given they pose little risk to direct users?

3.2 Is the difference between risk or harm and nuisance or personal preference recognized?

3.3 Have false choices been proposed? e.g. between a ban and *laissez faire*.

4 Nicotine damages the adolescent brain

4.1 What is the specific nature of the detriment to human health?

4.2 Where is the evidence for the brain damage from nicotine in the longstanding human population of smokers?

4.3 How does this compare to damage from alcohol, cannabis or caffeine?

5 More children using e-cigarettes and gateway effects

5.1 Did they characterize use properly? For example, ‘ever use’ of an e-cigarette is a marker of experimentation.

5.2 Could the rising use of e-cigarettes be a good thing if it is displacing smoking?

5.3 High level of smoking associated with vaping - but is this due to independent common factors (confounding)?

5.4 Have they defined a gateway effect?

5.5 Are they assuming prior behaviour caused the later behaviour?

6 E-cigarettes keep people smoking and reduce quit rates

6.1 Has vaping been wrongly conceptualized as though it is a medical intervention?

6.2 Has the importance of product’s consumer appeal been recognized?

6.3 Was “dual use” described as problematic - any cutting down is beneficial and may be part of a longer transition?

6.4 Did they claim there are no benefits to cutting down?

6.5 Have the limitations of randomized controlled trials been acknowledged?

7 Flavours and e-cigarette marketing aimed at children

7.1 Do they assume it is just obvious that childish names appeal to kids?

7.2 Why would adolescents try to emphasize their childishness?

7.3 Have preferences for particular flavours been misrepresented as a cause of vaping?

7.4 Could it be a benefit that some flavours are attractive to adolescents if it means they don’t smoke?

7.5 Is an e-cig advertising in effect an anti-smoking ad?

8 Citing uncertainty and appeal to the 'precautionary approach'

- 8.1 Have they understood what is known and recognized that the physical processes in vaping are different to smoking?
- 8.2 Are they asking the impossible? E.g., by saying we will only know the risks when we have 40 years of data?
- 8.3 Do they realize that 'precautionary approach' can be harmful if it blocks access to beneficial technology?

9 Tobacco industry involvement implies inevitable harm

- 9.1 Is the malign influence of tobacco companies assumed or demonstrated?
- 9.2 Is there over-reliance on decades old industry statements, documents or behaviours?
- 9.3 Is there a proper understanding of how the nicotine and tobacco market works?
- 9.4 Are the authors concerned about the right things? For example, are they fighting ill-health or capitalism?

10 Policy recommendations in a scientific paper

- 10.1 Do policy recommendations go beyond what their research justifies?
- 10.2 Have policy-making disciplines been followed - options generation, impact assessment, consultation etc.?
- 10.3 Are the authors' policy positions revealing their biases and priors?
- 10.4 Have unintended consequences been ignored? Many e-cigarette policy proposals could lead to more smoking.

Conclusion

All those working in public health acknowledge the gravity of the global smoking epidemic and seek ways to reduce cigarette consumption. Many people quit smoking without any intervention and are aided in this by measures such as smoking bans and high prices. But this leaves many millions of people around the world who for whatever reason, cannot or do not want to stop using nicotine. The question then becomes, what more can be done to smooth a transition away from deadly cigarettes? New technologies have brought e-cigarettes and heated tobacco products to market and refocused attention on smokeless tobacco products like snus, all of which present a new pathway to a less risky use of nicotine and, for some, complete cessation. The assertions that by any measure SNP are less harmful than cigarettes are based on a growing

body of independent scientific evidence from around the world which we have brought together in this chapter. But the watchword here is harm reduction, not harm elimination; SNP are not magic bullets, but a valid and potentially lifesaving public health option.

Nonetheless, there is an over-cautious approach among many public health and medical professionals who warn against SNP because there is not enough evidence about the long-term individual and population level effects. At times this is used to justify misleading public information on the premise that 'because we don't know everything, we don't know anything', so the only reasonable course of action is to guard against some unknown catastrophic future. This is known as the precautionary principle, which might be justified, if, as we say, it was not already demonstrably clear that there is a potentially huge saving in mortality and morbidity to be made by actively encouraging persistent smokers to switch to SNP. This holds true even if it turned out 20 years down the line that across the board SNP turned out to be just 50 percent safer than smoking cigarettes.

"[The precautionary principle] is used to justify misleading public information on the premise that 'because we don't know everything, we don't know anything'".

Of more immediate danger to the acceptance of tobacco harm reduction, however, is the global drive to over-regulation and control, where those charged with the responsibility for tobacco control are similarly influenced by the same misunderstandings of the science and the epidemiology, a misreading of industry involvement, but also a suspicion of a potentially highly significant public health benefit not initiated, funded or controlled by national or international public health bodies.

⁸² Abrams, D. From a talk entitled, *Harm minimisation: reframing societal nicotine to save more lives NOW* given at Vermont Center on Behavior and Health conference 2017.

⁸³ Check list adapted from submission by Clive Bates for the UK House of Commons Science and Technology Committee Enquiry into e-cigarettes 2017

Chapter 6:

Regulation and control

The advent of new SNP products presents a serious challenge to established tobacco regulatory control regimes at both a national and international level. As a consequence, the global legislative landscape is highly varied, with many countries having no specific controls on different SNP, while others ban some of these products. There are also wide differences in the control of older SNP such as snus – which is allowed in much of the world but is banned throughout the EU, with the exception of Sweden.

National tobacco control measures are well-documented (see for example, the WHO Report on the Global Tobacco Epidemic, 2017).¹ However, the global legal and regulatory profile for SNP is less enumerated. At the end of this chapter we summarise the legal situation regarding e-cigarettes, including how they are regulated (whether they are banned regulated or if there is simply no specific law or regulation). In addition, we cover whether it is legal to sell the devices or nicotine, and whether there are restrictions on their use in public places. Further information is available in the country profiles at www.gsthr.org.

Broadly speaking, the global regulatory picture is comprised of a majority of countries who have no specific legal or regulatory provision for e-cigarettes, and a smaller group that have introduced or are in the process of introducing specific legal and regulatory provision (as for example in the EU), as well as those which have outright bans. In some countries, such bans are legacies of legislation that predate e-cigarettes. For example, in Australia the ban on the unauthorised sale, possession or use of nicotine preceded the arrival of e-cigarettes. In some cases, countries have introduced bans on e-cigarettes and/or nicotine in response to the arrival of these products on the market.

“In Australia the ban on the unauthorised sale, possession or use of nicotine preceded the arrival of e-cigarettes”.

The three main approaches to regulation are to control SNPs as tobacco products, as consumer products, and/or as medicinal products. However, these broad categories hide wide nuances in regulatory provision, and have become the focus of legal argument and in some cases legal challenge. The quandary for governments is how to categorise these new products, and how to determine where they fit in terms of potential risks (and sometimes but more rarely in terms of potential benefits) within the dominant tobacco control model that has been developed over the last two decades.

There seems little doubt that contradictory research findings, together with the work of individual influential activists and sensationalised media reporting, have all served to influence the legal framework within which SNP are supposed to fit. However, laws aimed at inhibiting the manufacture, sale and use of SNP should also be seen through the prism of the long and complex past of tobacco control. Therefore, our discussion needs first to look at the history of tobacco control.

A brief history of tobacco control

Since the French diplomat Jean Nicot and British explorer Sir Walter Raleigh first brought tobacco from the Caribbean to the courts of France and England respectively in the late 16th century, tobacco has been a controversial drug. Initially hailed as a universal panacea for a whole range of ailments, as early as 1604 James 1st of England published his famous *Counterblaste to tobacco* in which he not only railed against tobacco itself, but also attacked the morality of smokers in ways which resonate today among anti-tobacco activists:

“Have you not reason then to bee ashamed, and to forbear this filthie noveltie, so basely grounded, so foolishly received and so grossely mistaken in the right use thereof? In your abuse thereof sinning against God, harming your selves both in persons and goods, and raking also thereby the markes and notes of vanitie upon you: by the custome thereof making your selves to be wondered at by all forraine civil Nations, and by all strangers that come among you, to be scorned and contemned. A custome lothsome to the eye, hatefull to the Nose, harmefull to the braine, dangerous to the Lungs, and in the blacke stinking

¹ World Health Organisation, *WHO report on the global tobacco epidemic 2017*. WHO, 2017. Available at www.who.int/tobacco/global_report/en/

fume thereof, nearest resembling the horrible Stigian smoke of the pit that is bottomelesse".²

A very early anti-tobacco law was enacted by Pope Urban VII, who in 1590 threatened to excommunicate anybody who "Took tobacco in the porchway of or inside a church, whether it be by chewing it, smoking it with a pipe, or sniffing it in powdered form through the nose".³

Ottoman ruler Sultan Murad IV (1623-1640) went further than any other potentate to stamp out tobacco. He banned alcohol, coffee and tobacco in Istanbul and reportedly toured the less salubrious districts of the city in disguise, personally beheading on the spot anybody he caught smoking.⁴ Serious physical punishments could also befall smoking Muscovites.⁵ Most authorities, however, restricted controls on smoking (for example in some German cities) to personal civil penalties for breaking local ordinances, up until the turn of the 20th century.

The first coordinated non-governmental action against tobacco was probably the creation of the Anti-Cigarette League in America, founded in 1899. The drive behind the League was very closely linked to temperance and anti-drug groups spearheaded by coalitions of faith groups and moral and social reformers. The Anti-Cigarette League was influential in states-wide tobacco controls. Fifteen states enacted laws banning the sale, manufacture, possession, or use of cigarettes, and 22 other states considered such legislation, although by 1930 all states had repealed these various laws.⁶

Most US laws focused on minimum legal age for purchase and similar legislation was enacted in the UK, under the Children's Act 1908. Nazi Germany provided an early example of a nationwide anti-tobacco campaign: bans on smoking on public transport; limiting cigarette rations for soldiers; and raising tobacco tax, as part of the ethos of racial purity and which was no doubt inspired by Hitler's personal disgust of smoking, and nascent research on the effects of tobacco.

Although German scientists and an Argentinian Angel Roffo between them first made the link between smoking and cancer, it was the work of British professors Sir Richard Doll and Sir Austin Bradford Hill, published in 1954,⁷ which set in motion subsequent research leading to two landmark health reports from the UK's Royal College of Physicians (1962) and the US Surgeon-General (1964), heralding the first concerted attempts at national tobacco controls.

But as King James 1st quickly realised, whatever the adverse effects of smoking, the drug was a source of vital tax revenues and it was imperative for the generation of income. More recently this, coupled with an industry determined to maintain profits, politicians fearful of losing votes especially among working people, and the general ethos of personal freedom in western liberal democracies, meant that progress to enact comprehensive national tobacco controls was slow.

The legal tipping point came in 1980-81 with the publication of evidence concerning passive smoking.⁸ This enabled activists and legislators to frame the tobacco control issue as one of environmental health, potentially affecting the whole community, especially family members and co-workers – not just individual smoker themselves. Partial or full public smoking bans, alongside taxation probably now account for the most common form of tobacco control across the world.

By the 1990s and subsequently, most countries in the developed world have in place a raft of measures which variously include: health warnings on packets; bans on media advertising and sports' sponsorship; bans on sales to minors and sales of single cigarettes, or smaller packet cigarettes mainly sold to poorer people; and rapidly rising rates of taxation. Significant and effective controls have also been enacted against smoking in public places.

Aside from illegal smuggling and cross-border advertising, smoking was and remains largely a matter for domestic laws rather than a transnational issue – one nation's tobacco consumption does not have cross-border health impacts. But starting in the late 1960s, the scientists, clinicians, public health officials, and especially NGO activist delegates attending world conferences on tobacco,

² Texas Liberal Arts, *A Counterblaste to Tobacco* (2002) <http://www.laits.utexas.edu/poltheory/james/blaste/>

³ Henningfield, J. *Nicotine: an old-fashioned addiction*. Chambers, 1985

⁴ Davis, W. *A short history of the Far East*. MacMillan, 1922

⁵ Dr Murray. *A general history of the tobacco plant*. Parsons, 1836

⁶ Wikipedia, *Anti-Cigarette League of America* https://en.wikipedia.org/wiki/Anti-Cigarette_League_of_America

⁷ Proctor R.N. (2012) The history of the discovery of the cigarette-lung cancer link: evidentiary traditions, corporate denial, global toll. *Tobacco Control* 2012;21:87-91. Available at http://tobaccocontrol.bmj.com/content/21/2/87?utm_source=njam&utm_campaign=sponsorcontent&utm_medium=display

⁸ Bayer, R and Colgrove, J. Children and bystanders first; the ethics and politics of tobacco control in the United States. In: Feldman, E and Bayer, R eds. *Unfiltered: conflicts over tobacco policy and public health*. Cambridge, Harvard University Press, 2004, p.21

wanted to move beyond simple information exchange towards an action agenda which would demand the legislative glue to help such action hang together across countries.⁹

Increasing evidence of wider health harms was not the only driving force towards international action. At one time, some activists thought they could work with the industry. That all changed in 1998.

In the face of a growing number of multiple lawsuits across several US states, the four largest US tobacco companies: Phillip Morris; R.J Reynolds; Brown & Williamson; and Lorillard entered into an agreement in November 1998 with the Attorney's General of 46 states called the Tobacco Master Settlement Agreement. The states settled their Medicaid lawsuits against the tobacco industry for recovery of their tobacco-related health-care costs. In exchange, the tobacco companies agreed to curtail or cease certain advertising practices as well as to pay, in perpetuity, various annual payments to the states to compensate them for some of the medical costs of caring for those with smoking-related illnesses.

In the course of concluding this agreement, disclosures from within the industry revealed misleading industry publicity over low-tar and 'light' cigarettes, the suppression of evidence of passive smoking and generally exposed the depth of industry deception in all areas of tobacco health risks. As a result, a trust deficit opened up between anti-tobacco activists and the industry, which remains to this day.¹⁰ More broadly, the general spread of smoking came to be seen as, "A series of complex developments including trade liberalization, direct foreign investment in companies, global marketing, transnational advertising and sponsorship and the international movement of contraband or counterfeit tobacco",¹¹ which all played to a view that a global public health response was required.

The Framework Convention on Tobacco Control (FCTC)

In fact, 'global' became the new watchword; 'international' could just mean bi-lateral agreements between countries, whereas 'global' signified a more universally inclusive approach.¹² Until the mid-1990s, tobacco control was not a priority issue for the WHO, more concerned as it was to tackle infectious

diseases. But in 1994, at the Ninth World Conference on Tobacco and Health in Paris, a resolution was passed on the need to take international legal action to combat the global smoking epidemic. The following year, the World Health Assembly instructed the Director-General of the WHO, Gro Harlem Brundtland, former Prime Minister of Norway, to investigate the feasibility of "Developing an international convention on tobacco control to be adopted by the United Nations".¹³ It took several years of arduous negotiations in six Intergovernmental Negotiating Body (INB) meetings, between the 193 WHO member governments in Geneva, followed by unanimous adoption at the 56th World Health Assembly in May 2003. In February 2005 the FCTC entered into force in international law as the world's first multi-lateral health treaty.

It was a singular event in UN history; the world's first public health treaty and the first example of the WHO using its constitutional authority in global public health to develop a legal instrument aimed at improving population health. The FCTC became the most accepted and ratified treaty since the formation of the UN: it was signed by 168 countries during its year-long initial open period and has been ratified or acceded to by 181 countries, known as Parties to the FCTC. Parties to the FCTC have legal obligations to implement its provisions and to participate in meetings of the Parties, known as the FCTC Conference of the Parties (COP). As of July 2017, there were nine UN member states who have neither signed nor ratified the Convention: Andorra; Dominican Republic; Eritrea; Indonesia; Liechtenstein; Malawi; Monaco; Somalia and South Sudan. A further seven Member States have signed but not ratified the Convention: Argentina; Cuba; Haiti; Morocco; Mozambique; Switzerland and the USA.¹⁴

⁹ Reubi, D and Berridge, V. (2016) The internationalisation of tobacco control 1950-2010. *Medical History*. 60 (4), 2016, p.453-472

¹⁰ Reubi, D and Berridge, V. (2016). The internationalisation of tobacco control 1950-2010. *Medical History* 60 (4), 2016, p.453-472

¹¹ Sparks, M. (2010). Governance beyond governments: the role of NGOs in the implementation of the FCTC. *Global Health Promotion*; Supp (1), 2010, p. 67-72

¹² Reubi, D and Berridge, V. (2016). The internationalisation of tobacco control 1950-2010. *Medical History* 60 (4), 2016, p.453-472

¹³ Wikipedia, *WHO Framework Convention on Tobacco Control*. https://en.wikipedia.org/wiki/WHO_Framework_Convention_on_Tobacco_Control

¹⁴ The USA has a long history of not ratifying international treaties. This is partly to do with the definition of the word 'treaty' in US law and it seems also that any treaty which conflicted with the US Constitution would not be ratified. For more explanation see: <https://www.asil.org/insights/volume/2/issue/5/international-agreements-and-us-law>

FCTC structure

During the establishment and negotiation of the FCTC, the WHO's Tobacco Free Initiative (TFI) was the treaty secretariat and it remains within the WHO to administer tobacco-related issues. In addition, the FCTC provided in Article 24 for a specialist secretariat to be established by the COP, and this body, known as the FCTC COP Secretariat, administers the reporting and coordination of all FCTC related matters, provides support to developing country Parties, including organising knowledge hubs and regional workshops, as well as facilitating the financial resources of the implementation of the FCTC.

The first COP meeting (COP1) was held in 2006 in Geneva. It met again in 2007 and 2008, and since then it has met every two years. The meeting is open to all 193 WHO members; however, different status categories exist. The FCTC Parties, those who have formally ratified or acceded to the Convention, have full participation and voting rights. Those WHO members who are not Parties, such as the USA and Indonesia, are known as Observers and they can participate in the COPs, but sit separately and do not take part in informal government working groups, unless special permission is granted, which did happen during negotiation of the FCTC guidelines. International organisations such as the World Customs Organization or the World Trade Organization, also have the status of Observers.

Although the COP is an intergovernmental meeting of WHO member Parties, access is also given to non-governmental organisations (NGOs). NGOs with official accreditation to the WHO, as well as NGOs with official accreditation to the COP, are also permitted NGO Observer status, such as the Framework Convention Alliance (FCA).

The FCA was formed in 1999 at the start of the FCTC negotiations. It is a confederation of nearly 500 organisations from more than 100 countries which banded together to support the negotiation, ratification and implementation of the FCTC. Compared with some other UN bodies, access to COP meetings is difficult for most NGOs, unless they join the FCA and agree with its aims and positions.

Members of the public, including industry, students, or NGOs not accredited to the WHO are required to apply for access to observe proceedings from

the public gallery. However, since 2009, the COP has undemocratically made provision to close the public gallery, denying the public access, which sets the WHO practice apart from most other UN bodies.

The FCTC is a comprehensive instrument, obliging Parties to implement a wide range of tobacco control provisions contained in its 38 articles. The whole process, from the earliest days of negotiation to the final agreements on the Convention text, were seen through a prism of anti-tobacco sentiment, and any considerations that might be deemed to dilute this discourse, such as the idea of *relative* tobacco harm, were brushed aside. At that time (1999-2003) e-cigarettes and vaping were unheard of and the only reduced harm product known was Swedish snus. The only alternatives to smoking spoken about were pharmaceutical nicotine replacement products, as referenced in the cessation section of the FCTC contained in Article 14, and this was largely due to the significant funding that was provided to tobacco control from the pharmaceutical industry at that time. So, the thrust of the FCTC is to reduce all tobacco use, rather than to focus in a proportionate way according to the risk of different tobacco products. Hence, FCTC is a treaty against tobacco rather than a treaty against smoking.

■ *"The FCTC is a treaty against tobacco rather than a treaty against smoking".*

The opening Convention statements, known as the treaty Preamble, make specific reference to the right to health, a matter to which we return in Chapter 7:

"Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

Although most tobacco control measures promoted under the FCTC have focused on reducing the supply of and demand for tobacco, the Convention does in fact specifically refer to harm reduction. This would be viewed as a surprising and positive outcome by many drug policy and public health reformers who have argued (for a long time unsuccessfully) to have harm reduction language in the positions of the United Nations Office on Drugs and Crime and the Commission on Narcotic Drugs (the equivalent of the COP).

In the very first article of the FCTC (Article 1d) it defines tobacco control as: “A range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke”.

However, harm reduction *per se* is not defined and in its widest sense, could be interpreted as applying to any control intervention. Harm reduction has been neglected in subsequent position papers from the FCTC and in discussions at COP meetings. It is only recently, since the advent of smoking alternatives, that the WHO and the FCTC COP Secretariat has had to begin to consider safer nicotine products and initial discussion papers have been put onto the agenda at recent COPs.

The arrival of e-cigarettes and later HNB devices comes after a global tobacco control ethos which sees an end to the use of all tobacco products and an end to the tobacco industry. It is not surprising then that WHO advisers have tried to fit SNP into this existing framework with the inclination to see all SNP as potentially problematic both for individual health, and also for the ambitions of tobacco control. The WHO has shown little inclination to acknowledge the role of SNP in trying to reduce the harm from smoking from a consumers’ point of view, using instead the precautionary principle to advise action regarding these products. The WHO suggests a range of regulatory actions that states might take, including bans.

“The WHO has shown little inclination to acknowledge the role of SNP in trying to reduce the harm from smoking from a consumers’ point of view”.

It would appear that the anti-tobacco sentiment was consequent to the involvement of major anti-tobacco NGOs. Gregory Jacob is a lawyer who was a member of the US delegation involved in negotiating the FCTC. He wrote a paper generally criticising the process, but noted especially the very influential role of (mainly US) NGOs in assisting government delegates, many of whom were inexperienced in international treaty law, coming as they did from health ministries. The WHO itself was not well versed in the standard procedures either, as this was a first for them too.¹⁵ The most active NGOs formed themselves into the FCA and since its formation, backed by US philanthropic funding, has helped the WHO implement the FCTC around the world, especially in LMIC where

tobacco control has varied from being very weak to non-existent.¹⁶ This was a great coup for civil society, as NGOs are usually sidelined in international treaty meetings like the Commission on Narcotic Drugs, reduced mainly to providing information, giving short speeches at the discretion of the chair or holding fringe events of their own.

But perversely the effect of NGO involvement in international tobacco control has been counter-productive in terms of benefits to public health. It is these influential American NGOs who have been leading the fight the longest against the tobacco industry, and who see the advent of SNP as just another ploy to boost industry profits in the face of declining prevalence of smoking in the developed world.

“Perversely the effect of NGO involvement in international tobacco control has been counter-productive in terms of benefits to public health”.

The WHO, the FCTC and the tobacco industry

Wariness of the industry and its intentions is expressed formally, but in quite measured terms, in Article 5.3 of the Convention which states that “In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law”. These were the words that were agreed to by a consensus of the 193 governments drafting the treaty. Subsequently, however, during the less formal and legal negotiation of the FCTC Guidelines (in COP working groups of only a small number of governments together with NGOs), Article 5.3 was extrapolated to a set of Principles. While the FCTC text for 5.3 is legally binding and the FCTC Guidelines for 5.3 are not binding, NGOs and the WHO itself have pushed the 5.3 principles for interpretation to be the norm and they have become almost customary in terms of national interpretation and subsequent implementation.

¹⁵ Jacob, G. (2004) Without reservation. *Chicago Journal of International Law*; 5 (1), Article 19

¹⁶ Sparks, M. (2010). Governance beyond governments: the role of NGOs in the implementation of the FCTC. *Global Health Promotion*. Supp (1), 2010, p. 67-72

The Guidelines applicable to Article 5.3 state these Principles:

“Principle 1: *There is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests. The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible”.*

“Principle 2: *Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent. Parties should ensure that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent”.*

“Principle 3: *Parties should require the tobacco industry and those working to further its interests to operate and act in a manner that is accountable and transparent. The tobacco industry should be required to provide Parties with information for effective implementation of these guidelines”.*

“Principle 4: *Because their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses. Any preferential treatment of the tobacco industry would be in conflict with tobacco control policy”.*

Two important points emerge from these principles and the eight recommendations that follow. The first is that these Guidelines are in urgent need of revising, as it is now clear that SNP are very far from ‘lethal’ or give rise to ‘a variety of social ills’. Second, all it requires of Member States is that their dealings with the industry are open, accountable and transparent. But this has been over-interpreted to mean that any and all kinds of interaction with industry personnel – simply holding meetings or being present at events where tobacco industry staff are present – is deemed to be in contravention of the FCTC. This extends to anybody – and not just Member State officials – with any connection to the industry; they can be banned from attending the COP or international tobacco control meetings¹⁷ while complaints are lodged by NGOs and medical organisations if industry representatives are invited to speak to parliamentarians and other public bodies investigating the new products.¹⁸

FCTC Article 5.3 seems increasingly problematic when tobacco companies manufacture SNP and spotlights the difficult relationship between UN bodies such as the WHO and manufacturers of products that contribute positively or negatively to individual and population health.

There is a paradox here: in 2014, the WHO published a report, *Electronic nicotine delivery systems*, which states that public health authorities should prioritise research into ENDS, and to invest adequately to develop the evidence as soon as possible: “However, the greater responsibility to prove claims about ENDS scientifically should remain with the industry”.¹⁹ Yet this is problematic when industry scientists are denied conference platforms, when leading peer-reviewed journals will not accept their papers and where anybody who undertakes industry-funded research is discredited.²⁰

This is reiterated in the WHO’s *Time to Deliver* report on tackling non-communicable diseases. In the section dealing with private sector relationships, the WHO encourages Member States to engage “constructively” with the private sector but specifically excludes the tobacco industry citing Article 5.3. Yet regarding alcohol, a major cause of global death and disease and the source of much domestic and community violence, governments are encouraged to work with the industry by encouraging “economic operators in the area of alcohol production and trade to consider ways in which they could contribute to reducing the harmful use of alcohol in their core areas”.²¹

However, there is evidence that antipathy towards tobacco harm reduction goes beyond even distrust of the industry. The direction of travel of international tobacco control, as expressed in the FCTC, is not just about controlling smoking,

¹⁷ Health 24. *Ex-WHO expert banned from tobacco conference after links to Marlboro* (2018).

<https://m.health24.com/News/Public-Health/ex-who-expert-banned-from-tobacco-conference-after-links-to-marlboro-maker-20180307>

¹⁸ For example, *The Australian Parliament Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia* (2018)

¹⁹ World Health Organisation. *Electronic nicotine delivery systems; report by WHO*. WHO, 2014. FCTC/COP/6/10 – 21 July 2014 Paragraph 35 p.10

²⁰ Godlee, F. et al (2013). *Journal policy on research funded by the tobacco industry. Thorax, British Medical Journal*. Available at <http://thorax.bmj.com/content/68/12/1090>; and *The Australian Parliament Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia* (2018)

²¹ World Health Organisation. *Time to Deliver*. WHO, 2018. p.23. Available at <http://www.who.int/ncds/management/time-to-deliver/en/>

or even just controlling tobacco, but a vision to eliminate non-medical nicotine use entirely.²²

As far back as 1987, influential US tobacco control activist Stanton Glantz stated that the evidence for passive smoking meant reframing activism in terms of protecting others, “Rather than the rhetoric of protecting smokers from themselves or the cigarette companies”.²³ In a paper published in *Addiction*, Hall and Kozlowski asserted that, “The policy goal of some US tobacco control advocates is the elimination of the recreational use of nicotine”.²⁴ This was underscored by the 2014 WHO ENDS report which declared that “While medicinal use of nicotine is a public health option under the treaty, recreational use is not”,²⁵ denying the possibility of a public health response to smoking that was not medicalised. Moreover, there is a definite sense that part of the antipathy towards tobacco harm reduction is that from the start it was a consumer-led grass roots public health intervention that circumvented the need for any involvement in the formal structures of public health itself.

“The direction of travel of international tobacco control...is a vision to eliminate non-medical nicotine use entirely”.

The lack of leadership demonstrated by the WHO in refusing to acknowledge the role of tobacco harm reduction in helping to deliver FCTC objectives to reduce smoking-related death and disease is likely to impact most on those countries least able to tackle rampant and growing cigarette consumption. But while the WHO does not support tobacco harm reduction, nor does it compel member states to regulate SNP, its stated opposition provides an easy ‘get out of jail free’ card for health ministries across the world to avoid devising the most appropriate national SNP policy.

The current global control landscape for e-cigarettes

Moving on from the FCTC as the most universal tobacco control measure, it may come as a surprise to both those in tobacco control and those advocating for tobacco harm reduction that at present most countries do not have any specific law regulation regarding e-cigarettes: 101 countries have no specific law on e-cigarettes. It is possible that if it came to a government or court decision, it might be that in some of these countries e-cigarettes would be found to be

covered by tobacco control legislation. However, this has yet to be determined in many countries. This includes many LMIC, where it is likely that e-cigarettes are not yet available or are only used by a minority.

At the other end of the spectrum there are 39 countries where the sale of e-cigarettes or nicotine liquids is banned. It is worth noting that rather like the failure of bans on recreational drugs to be effective, e-cigarettes are known to be available in at least 14 of these 39 countries. For example, e-cigarettes and nicotine are widely available and used in Australia. Some of the banning countries had pre-existing laws in which e-cigarettes and nicotine liquids were caught up – as again for example in Australia where the poisons regulations under the jurisdiction of the Therapeutic Goods Administration (TGA) prohibit the unauthorised sale, possession and use of nicotine (see box).

Several countries have a legal and regulatory framework for e-cigarettes, and this is generally a mix of a legal framework – often within the context of tobacco control legislation (as in the USA and Europe), plus product standards and legal or voluntary control over access to the products by young people. The most usual legislative route is to regard them as tobacco products, and/or as consumer products.

In most jurisdictions manufacturers are only allowed to promote e-cigarettes as safer than cigarettes and as aids to quitting if they are registered as medicinal products, similar to the regulations governing nicotine replacement therapies. In ten countries there is provision for medically regulated products.

Figure 6.1
Global e-cigarette regulation as of July 2018 →

²²Kozlowski, L and Abrams, D. (2016) Obsolete tobacco control themes can be hazardous to public health: the need for updating views on absolute product risks and harm reduction. *Public Health*, 16: 432

²³Glantz, S. (1984) ‘Achieving a smoke-free society’ *Circulation*; 76, 750 1984, and Bayer, R and Colgrove, J. Children and bystanders first; the ethics and politics of tobacco control in the United States. In: Feldman, E and Bayer, R eds. *Unfiltered: conflicts over tobacco policy and public health*. Cambridge, Harvard University Press, 2004, p.23

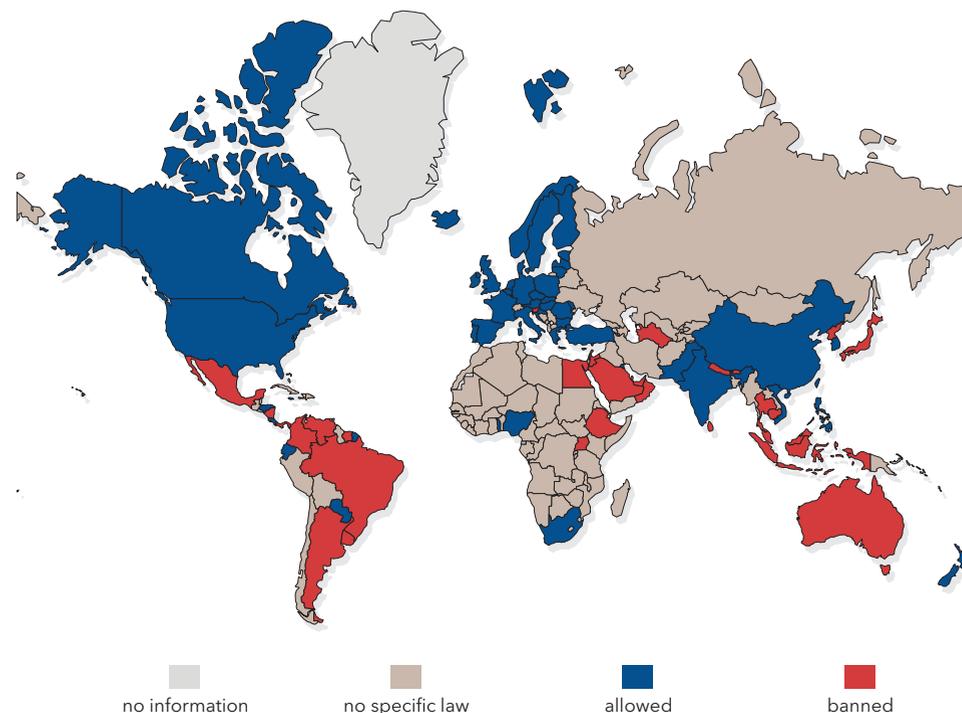
²⁴Hall, W and Kozlowski, L (2017). The diverging trajectories of cannabis and tobacco policies in the United States: reasons and possible implications. *Addiction* 113, p.595-601

²⁵World Health Organisation. *Electronic delivery systems; report by WHO*. WHO, 2014. FCTC/COP/6/10-21 July 2014 Paragraph 35 p.14



But the pharmaco-diligence bar for bringing a medicinal product to market is set far higher and is significantly more expensive than for tobacco products. With the possible exception of BAT's VOKE inhaler (since discontinued),²⁶ and the E-Voke inhaler²⁷, no SNP devices have been granted a medical licence.

Figure 6.2

Global status of e-cigarettes

Source: see Figure 6.7

Because of the rapid development of e-cigarettes globally, the legal landscape is complex, as Ryan Kennedy and colleagues of the John Hopkins School of Public Health discovered when they conducted a review of global approaches to e-cigarette control. In 2017, they identified 68 countries that regulate

²⁶ Vaped, *The only medically licensed e-cig axed by BAT* (2018) <https://www.totallywicked-liquid.co.uk/vaped/the-only-medically-licensed-e-cig-is-axed/>

²⁷ Vape Ranks, *E-Voke Becomes First E-Cigarette to Be Awarded Medicine License in the UK* (2016) <http://vaperanks.com/first-e-cigarette-to-be-awarded-medicine-license-in-the-uk-is-not-really-an-e-cigarette/>

e-cigarettes, of which “22 countries regulate e-cigarettes using existing regulations, 25 countries enacted new policies to include e-cigarettes; seven countries made amendments to existing regulations, 14 countries use a combination of new/amended and existing regulations [and] many countries regulate e-cigarettes using legislation not written for e-cigarettes”.²⁸

Australia and the ban on nicotine²⁹

Australia has a strict regulatory environment for vaping with a complex mix of federal and state laws. The possession and use of nicotine for vaping is effectively banned under federal poisons regulation. The laws governing the sale, use in public places, age limits on sale, display and promotion of vaping products are managed by the states and territories and are generally covered under each state and territories’ tobacco control legislation.

Australia Commonwealth regulation of nicotine

Medicines and poisons are listed in the Poisons Standard and are classified into Schedules which determine how they are regulated. Nicotine is a Schedule 7 ‘dangerous poison’ (S7) which also includes arsenic, cyanide and strychnine, and it is therefore illegal to buy, possess or use nicotine for vaping without prescription from a registered Australian medical practitioner. Nicotine in tobacco for smoking and approved nicotine replacement products are specifically exempt and are freely available.

Australian states can make variations to the Poisons Standard and could legalise the sale and possession of nicotine e-liquid on an individual state basis. However, none have chosen to do so.

There are three main ways to legally access nicotine e-liquid, all requiring a prescription from a registered Australian medical practitioner:

1. Smokers can import nicotine from overseas under the Therapeutic Goods Administration (TGA) Personal Importation Scheme.³⁰ Users can import three months’ supply at a time for personal use, up to a total of 15 months’ supply per year.
2. An approved Australian compounding pharmacy can prepare nicotine liquid for individual patients, under the extemporaneous compounding exemption of the Therapeutic Goods Regulations 1990³¹ (Item 6 of

Schedule 5). This service is currently only available through Nicopharm, an e-cigarette company, which provides an online prescribing service which includes a nicotine prescription.

3. Use of a nicotine-containing product approved for therapeutic use by the medicines regulator, the TGA. There are currently no nicotine-containing e-cigarettes approved. The approval process is expensive, onerous and time-consuming and not feasible for most manufacturers.

In reality, few vapers use these methods. Although it is legal to do so, very few Australian doctors will write prescriptions for nicotine due to the lack of official endorsement and knowledge about vaping.

Most users import nicotine illegally without a prescription, or purchase it from the unregulated black market. There are harsh penalties for possessing or using nicotine e-liquid, which vary from state to state, including jail sentences of up to two years and fines of up to AU\$45,000. So far, no vapers have been convicted although the threat is clear and is advertised on some state government websites, for example, this notice appears on the Queensland state website:

“Under the Health (Drugs and Poisons) Regulation 1996 it is an offence for a person to manufacture, obtain, possess, prescribe, dispense, sell, advertise, use or destroy nicotine, unless the person is specifically authorised or holds an approval under the HDPR. This includes importing electronic cigarettes containing nicotine for personal or therapeutic use. The maximum penalty is \$9,108”.

It is not an offence to import nicotine e-liquid into Australia under the Customs (Prohibited Imports) Regulations 1956³² and an import permit

²⁸ Kennedy, R.D et al (2017). Global approaches to regulating electronic cigarettes. *Tobacco Control*; 26, p.440-445

²⁹ Text by Colin Mendelsohn, Associate Professor, School of Public Health and Community Medicine, University of New South Wales. Chairman, Australian Tobacco Harm Reduction Association. Available at www.athra.org.au

³⁰ Therapeutic Goods Administration Personal Importation Scheme, Department of Health, Australian Government. Available at <https://www.tga.gov.au/personal-importation-scheme>

³¹ Therapeutic Goods Regulations 1990. Federal Register of Legislation, Australian Government. Available at <https://www.legislation.gov.au/Details/F2017C00528>

³² Federal Register of Legislation, Australian Government. Customs (Prohibited Imports) Regulations. Available at <https://www.legislation.gov.au/Details/F2016C00795>

is not required. However, it is an offence to take possession of it, unless a prescription is held and the TGA Personal Importation Scheme criteria are met.

State and territory regulation

Legislation varies from state to state. Generally, vaping is managed under tobacco control laws rather than consumer legislation. There are currently no regulations for vaping in South Australia (although a Bill is before the Parliament) or the Northern Territory. As well as the state and territory governments, the Australian Competition and Consumer Commission (ACCC) has a role in regulating the marketing of vaping devices and product safety:

» Sale of vaporisers

Sale of vaping devices is legal in all states and territories except Western Australia where a retailer was prosecuted for selling nicotine-free vaping devices online in 2014 (upheld on appeal in 2016) on the basis that they resemble tobacco products. Sale to minors is an offence in most states. Products must not make a therapeutic claim, such as 'this product will help you quit or reduce smoking' unless approved by the TGA (see above).

» Vaping in smoke-free areas

Banned in Victoria, Queensland, Tasmania and the Australian Capital Territory (ACT) but allowed in New South Wales (NSW), South Australia, Western Australia and the Northern Territory. NSW currently has a Bill before the Parliament to ban vaping in smoke-free areas.

» Advertising of vaping products

Banned in Victoria, Queensland, Tasmania and the ACT.

» Retail display, free samples, sponsorship or shopper loyalty programmes

Banned in NSW, Victoria, Queensland, Tasmania and the ACT.

» Vaping in cars with minors present

Banned in NSW and Victoria (<18 years); Queensland and ACT (<16 years); Tasmania (any age).

» Sampling e-liquids in stores

Banned in Victoria.

This is just an idea of how mixed the picture is. Each state has its own particular regulations.³³

Country approaches to e-cigarette regulation - snapshots from around the world

Brazil: E-cigarettes cannot be sold in Brazil. According to Resolution 46 issued from the National Health Surveillance Agency, if they are presented as smoking cessation devices, toxicology reports and scientific proof of the health and environmental effects are required in order to obtain a licence. However, no detailed process is in place for obtaining a licence. Vapers buy online as they do in other countries where they are banned such as Argentina and Uruguay.

Chile: Nicotine-containing e-liquid cannot be sold without a pharmaceutical licence.

Canada: The Canadian federal government legalised vaping on May 23, 2018 with the introduction of the Tobacco and Vaping Products Act (TVPA). The law regulates tobacco products as well as now providing a legal framework for adults to legally obtain vaping products with nicotine as a less harmful option than smoking. There are four separate laws that govern vaping products.

The TVPA governs how vape products are to be sold, produced, labelled, and promoted. This new Act will continue to govern tobacco products but adds the new dimension to cover vaping products. Youth appeal and access restrictions form a significant part of the new law - sales are not to be permitted to under 18s and flavours that may appeal to youth are to be restricted.

E-cigarettes that make a health claim will need to be approved by Health Canada and will be regulated by the Food and Drugs Act (FDA), and this includes e-cigarettes imported into Canada. The Canada Consumer Product Safety Act (CCPSA) will govern all e-cigarettes that do not make a health claim classified as consumer products. The CCPSA regulates ingredients, health warning labels, packaging as well as all health and safety requirements. In addition, vaping liquids are to be subject to the existing Consumer Chemicals and Containers Regulations, 2001 (CCCR, 2001) which include provisions for labelling and child resistance.

³³Sydney Vape Co, *Australian Vaping Laws* <https://sydneyvapeco.com.au/blogs/news/australian-nicotine-laws>

The Non-smokers Health Act (NSHA) addresses second-hand smoke and vapor. This Act applies to federally regulated workplaces, including banks, ferries, aircraft and government offices. There are also new provincial, territorial, and municipal laws to regulate vaping products and their use.

The government has established a scientific advisory board to review science on vaping products and provide evidence on a regulatory basis to ensure legislations remain current and applicable.

Georgia: Adopted comprehensive restrictions and bans for the marketing, sale, labelling and public use of cigarettes, which also apply to vaping and heated tobacco products.

Hong Kong: Nicotine is classified as a 'poison' under the Pharmacy and Poisons Ordinance. E-cigarettes with nicotine are considered pharmaceutical products, which are required to be registered with the Department of Health.

Japan: E-cigarettes and e-liquids with nicotine cannot be sold in Japan without a pharmaceutical licence; however, limited imports for personal use are allowed. HNB products are available and not subject to advertising and marketing restrictions.

Malaysia: The manufacture, distribution or sale of nicotine-containing e-cigarettes and e-liquids requires a pharmaceutical or medical licence. Non-nicotine e-cigarettes and e-liquids are treated as consumer products. Products are widely available.

Mexico: The Federal Commission for the Protection Against Health Risks (COFEPRIS), part of the Health Ministry, has an obligation to seize e-cigarettes because they are considered to be under the scope of article 16 of the Mexican Tobacco Control Act which forbids the sale of any product that resembles tobacco, but is not tobacco. The Mexican Supreme Court declared Article 16 of the Tobacco Control Act unconstitutional for being disproportionate against e-cigarettes. But decisions only apply to this case, and only the e-cigarette retailer that appealed will benefit from this decision and is now authorised to sell e-cigarettes.

New Zealand: E-cigarette and HNB products can be legally imported and sold in New Zealand under the Smoke-free Environments Act 1990. All the

requirements of the Act also apply to vaping and heated tobacco products, including banning advertising these products and making it illegal to sell them to young people under the age of 18. The smoking ban in indoor workplaces only applies to smoked tobacco and does not apply to vaping or other products that are not smoked. Individual employers and business owners can decide whether they want to include vaping in their smoke-free policies.

Singapore: Banned all new tobacco and nicotine products in 2015 - this applies to e-cigarettes, HNB products, smokeless tobacco products and any other new alternatives to cigarettes.

Turkey: A licence is required to sell nicotine-containing e-cigarettes in Turkey. This measure, while not strictly outlawing retail sale of e-cigarettes, has made it virtually impossible to sell e-cigarettes legally. The government recently decided not to allow the importation of HNB products (and e-cigarettes).

Tobacco harm reduction and e-cigarettes in India³⁴

India is one of the fastest growing large economies of the world, is the second most populous country, and 65% of its over 1.34 billion strong population is under the age of 35 years. Two thirds of the population are rural, agrarian, economically marginalised and educationally weak. All this makes the Indian population highly vulnerable to tobacco use, not least because India is the second largest cultivator of tobacco in the world.

Besides having about 12 percent of the world's cigarette smokers, large sections of the Indian population smoke tobacco in its alternative or local forms (e.g., *bidis*, *hookah*, *chilam*, etc.) or chewing it in the form of smokeless tobacco such as *khaini*, *zarda*, *gutkha*, etc.

In addition, a large section of the population chew areca nut in various forms (e.g., *supari*, *kwai*, *tambul*, betel quid, *paan masala*, mouth-fresheners, etc.). The alkaloids, tannins, polyphenols of areca nuts, alone or in combination with other additives, potentially form ultimate carcinogens in the body and have been strongly associated with high incidence of oral and gastrointestinal cancers in India.

³⁴Text provided by Professor R Sharan, of the North-Eastern Hill University

These products are relatively inexpensive, minimally regulated, produced in home and small industrial set ups and are widely available in convenient, small, single-use packaging. Further complicating this situation is that there are 'mixed' users who chew areca nut products, chew or smoke other forms of tobacco and smoke cigarettes. India's complex usage pattern have roots in its prevailing cultural ethos and diversity, agrarian orientation, and socio-economic inequalities, as well as in its political prudence. Similar patterns of diverse tobacco usage prevail in other regional LMIC especially Indonesia, Thailand, Sri Lanka, Pakistan, Bangladesh and Afghanistan.

The idea of tobacco harm reduction is hardly developed at all in India, especially among the disadvantaged and most vulnerable sections of the population, who are at the same time the highest at-risk group for tobacco-related death and disease.

This is not helped by the legislative climate surrounding e-cigarettes. Currently, they are banned in six provinces of India. Punjab was the first to do so in 2015 followed by Karnataka (2016), Mizoram (2016), Kerala (2017), Jammu and Kashmir (2017) and Bihar (2018). Maharashtra and Delhi are also considering bans. In addition, the central government is considering a ban on e-cigarettes and has recently filed an affidavit in the Delhi High Court to this effect.³⁵

"The idea of tobacco harm reduction is hardly developed at all in India, especially among the disadvantaged and most vulnerable sections of the population, who are at the same time the highest at-risk group for tobacco-related death and disease".

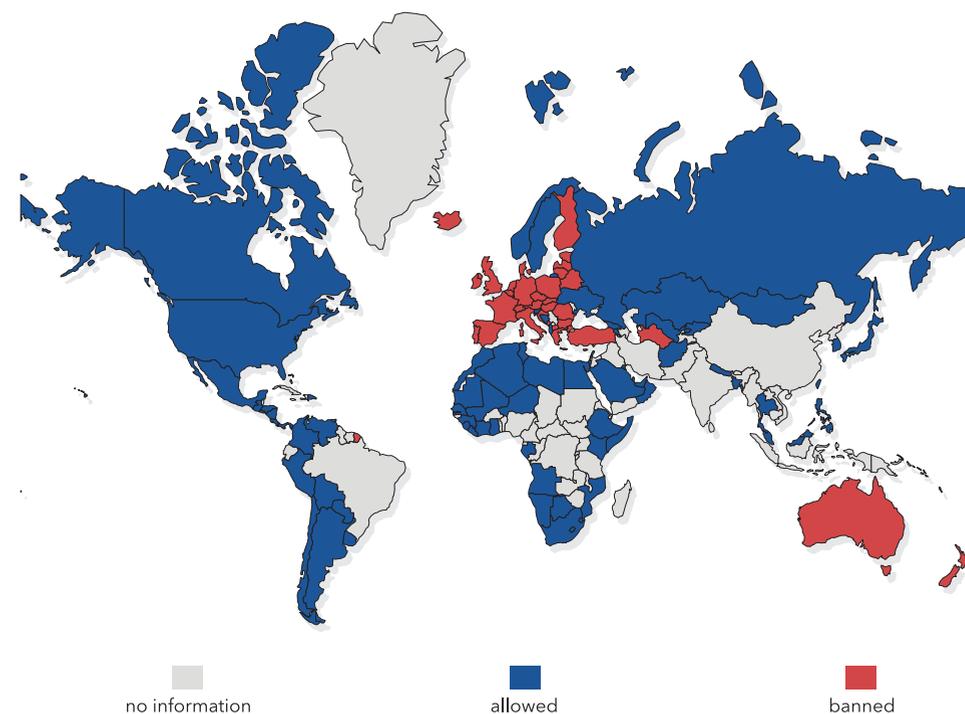
Professor Sharan, of the North-Eastern Hill University considers that different SNP should be made available to suit different economic, educational and cultural backgrounds. For example, while e-cigarettes or HNB products can help consumers using all forms of tobacco, a smokeless oral product such as Swedish snus might be more effective and appropriate for masticators and chewers of the more dangerous smokeless forms currently used. An appropriate regulatory framework for all such products, strict enforcement of quality standards, and affordability would be essential components to bring about a successful penetration of these alternatives into the tobacco using

population. Simultaneously, he says for this report, "we need to speedily initiate and strengthen scientific endeavours to develop new safer products that are relevant to the world's poorer populations in order to ensure that solutions to this problem are truly global".

Regulation of Swedish snus

The EU stands out prominently as the only region to have a comprehensive ban on the sale of snus, which was implemented in 1992 and then incorporated into subsequent Tobacco Products Directives (TPD).

Figure 6.3
Global status of snus



Source: see Figure 6.8

³⁵ Deccan Herald, Considering ban on e-cigarettes, Centre tells HC (2018) <https://www.deccanherald.com/national/considering-ban-e-cigarettes-centre-tells-hc-666088.html>

The UK started the ban when, in 1989, it outlawed oral snuff in response to the introduction of 'Skoal Bandits'. When the first TPD was drafted, the EU legislators included a ban on snus as part of market harmonisation, in that three EU countries had implemented a ban, and the 'market harmonisation' reasons were used to enforce this across all EU countries:

- » 1992, EU Directive 92/41 banned sales of snus;
- » 1995, on accession to the EU, Sweden obtained an exemption;
- » 2001, EU Tobacco Products Directive continued the ban;
- » 2014, EU Tobacco Products Directive continued the ban.

The wording in the TPD is carefully constructed so that it does not apply to snuff, or to chewing tobaccos such as South Asian tobaccos:

"No person may produce or supply tobacco for oral use.

Tobacco for oral use is:

A tobacco product which is -

- (a) intended for oral use, unless it is intended to be inhaled or chewed; and*
- (b) in powder or particulate form or any combination of these forms, whether presented in a sachet portion or a porous sachet, or in any other way".*

The sale of snus is allowed in 79 countries in total and banned in 39 countries including the EU 28. The sale of snus is allowed in the non-EU Norway and although officially banned in Iceland, Icelanders import a slightly different 'cut' of what is officially known as 'nasal tobacco'. This is used either in a small lump under the lip or made into a snus-like parcel using separate paper like the Swedish snus packaging. Despite being much less harmful than cigarettes this Icelandic 'snus' is taxed at the same level and the tax level has increased over the last eight years (over 140%). The same rules apply as for cigarettes - age restricted sales (18+), no advertising, health warnings on packets, and no claims of health benefits such as help quitting cigarettes. Notwithstanding the restrictions, snus sales have increased by 330% since 2001.³⁶

Figure 6.8 shows for each country whether snus is allowed, banned or whether there is no specific legislation. However, as will be seen even in countries where its sale is banned, importation for personal use is often not banned.

Figure 6.8 shows 31 countries where the use of snus is legal, even where its sale is banned. In most countries where import for commercial purposes is banned,

importation for personal use is allowed. Online forums also indicate that people often import snus for personal use, although in some cases incur tax or duty charges where these are intercepted at customs.

Information about the specific legal regulation of snus is sparse, however two countries where reasonably detailed information has been gathered are Israel and Norway. In Israel snus can be imported commercially and advertised fairly freely, however, health claims are not allowed and health warnings are required on the packaging. There is no restriction on nicotine content or the flavours available and snus is taxed at the general taxation rate.

In Norway importation and online sales are allowed, however, advertising is restricted. Health claims are not allowed and health warnings are required. Authorities have to be notified of new products on the market and tax rates are lower than other tobacco products.

On 31 May 2018, New Zealand permitted the online sale of snus and removed its earlier ban as part of its aims to be smoke-free by 2025,³⁷ although the exact details of the new legislation await clarification.

HNB regulation

HNB products are available in more than 37 countries, including Japan, Korea, New Zealand, Italy, Portugal, Switzerland, Spain, Ukraine, Russia, the United Kingdom, Guatemala, Colombia, and South Africa. Many of these countries, and others, regulate these products differently than cigarettes and other combustible tobacco products.

European Union

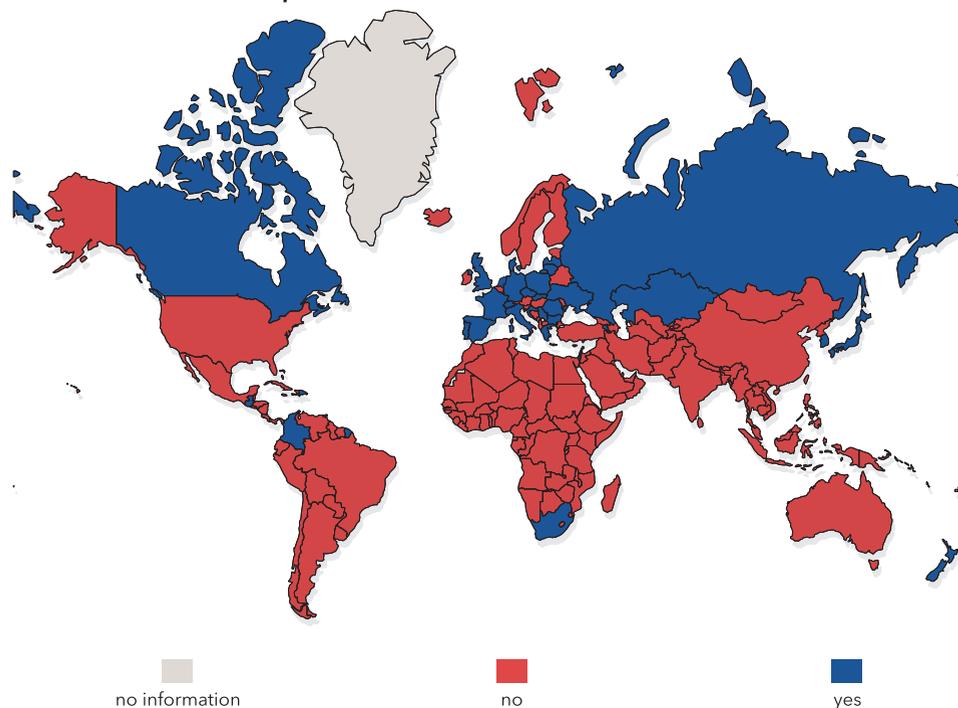
In the EU, these products are regulated as novel smokeless tobacco products under Article 19 of the European Union TPD.³⁸ Article 19 establishes a separate regulatory category for novel tobacco products that do not fall within the tobacco product categories as defined in Article 2. Novel tobacco products can

³⁶ Personal communication, Dr Karl Snaebjornsson.

³⁷ Ministry of Health. *Vaping, smokeless, including heated tobacco*. New Zealand Government, 2018. Available at <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco>

³⁸ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014. Available at https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf

Figure 6.4

Countries where HNB products are sold

Source: Philip Morris International website. Available at: <https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system>

either be products for smoking or smokeless; the key differentiator being the presence or absence of combustion. However, the electronic part of an HNB device is not subject to regulation under the TPD.

In addition to receiving a separate regulatory category under the TPD, HNB products are also regulated differently than combustible tobacco products. For example, health warnings for these products are different from those required for cigarettes, both in terms of size and content. Other elements in the TPD also treat these products differently, such as the use of additives and ingredients necessary to produce products that operate differently from combustible cigarettes.

Under the TPD, Member States must establish a system of notification or authorisation, with which manufacturers must comply before placing a product on the

market, consisting of available scientific studies on a number of topics and other available and relevant information, such as risk/benefit analysis of the product.

Italy

In Italy, regulators have developed a regulatory scheme³⁹ that authorises manufacturers to communicate information about product toxicity. The ministerial decree defines the rules and procedures whereby research is submitted by a manufacturer and is evaluated by government "In order to recognise the reduction of toxic components and the potential risk reduction of novel tobacco products, compared to combustible tobacco products".

Japan

In Japan, heated tobacco is regulated as pipe tobacco. Mandatory health warnings relate to addiction, smoking, smoking-related diseases, the risks of smoking during pregnancy, and the health effects of second-hand smoke. These warnings do not differentiate between combustible and non-combustible products. Point of sale advertising is allowed. Regarding indoor use, legislation states that managers of indoor spaces must try to prevent second-hand smoke but there are no penalties for non-compliance.⁴⁰ Amendments have been proposed to allow the use of heated tobacco in areas where smoking is prohibited.⁴¹

Switzerland

Switzerland follows an approach similar to the EU TPD with respect to health warnings. HNB products are sold with different and smaller health warnings than those required for cigarettes. Furthermore, cigarettes must bear graphic health warnings, whereas HNB products do not. Indoor public use of HNB products is not prohibited in the same way it is for cigarettes, but is left to the discretion of the owner or manager of the premises.

Russia

The Russian Tobacco Technical Regulation Law does not contain any specific provisions regulating HNB products and devices, only general consumer goods

³⁹ Gazzetta Ufficiale Della Repubblica Italiana, Ministero Della Salute (2017). Available at http://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?sessionId=kpWuzjXuemHEWj9LC7yjnA__ntc-as5-guri2a?atto.dataPubblicazioneGazzetta=2017-08-12&atto.codiceRedazionale=17A05676&elenco30giorni=true

⁴⁰ Feldman, E.A. (2018) IQOS, E-Cigarettes, and Tobacco Control, Harm Reduction the Japanese Way. Available at <https://www.e-cigarette-summit.us.com/files/2018/05/Eric-Feldman.pdf>

⁴¹ Feldman, E.A. (2018) IQOS, E-Cigarettes, and Tobacco Control, Harm Reduction the Japanese Way. Available at <https://www.e-cigarette-summit.us.com/files/2018/05/Eric-Feldman.pdf>

regulations are applied to them. A specific standard, known as the National Standard GOST R 57458-2017 Heated Tobacco Technical Specifications, has been established for HNB. Although voluntary, the standard establishes definitions for HNB products and sets basic design and performance requirements that differentiate the category from combustible tobacco products, including the maximum permissible CO yield (0.3 mg per 100 cm³ of aerosol) as the criteria to determine absence of combustion. The standard also introduces packaging and labelling requirements, including health warning requirements.

Ukraine

In Ukraine, HNB products are generally not subject to the same regulations as cigarettes. For example, there is no specific health warning for HNB products, and the only product on the market today voluntarily applies the EU TPD novel smokeless tobacco product health warning.

New Zealand

In December 2016, PMI started sales of IQOS in New Zealand and was taken to court by the New Zealand Ministry of Health in May 2017. The Ministry argued that the tobacco plug used with IQOS, known as HEETS, is a smokeless tobacco product and therefore, banned under the Smoke-free Environments Act 1990 (SFEA), which provides: "No person shall import for sale, sell, pack, or distribute any tobacco product labelled or otherwise described as suitable for chewing, or for any other oral use (other than smoking)". In March 2018, the District Court of Wellington dismissed the charge brought by the Ministry.

Among other things, the Court considered an independent assessment conducted at the request of the Ministry, aimed to determine whether combustion occurs when IQOS is operated. Ultimately, the report concluded: "Based on the literature surveyed and the analytical results of the investigation it is my opinion that no combustion is taking place during normal operation of the IQOS system".

The Ministry decided not to appeal the court decision and said that whilst HNB and other reduced-harm products are subject to the Act's controls on advertising, they are not subject to the ban on indoor use in workplaces and that this would be up to individual property owners to decide.

Following the case, the NZ Ministry clarified the legal position:⁴²

"Therefore, the same SFEA regulatory controls apply to smoked tobacco, heated tobacco and vaping products that are manufactured from tobacco. This includes the ban on sales to minors and restrictions on advertising.

The ban on smoking in indoor workplaces, early childhood centres and schools only applies to smoking. It does not apply to vaping or products that are not smoked, such as heated tobacco products. Individual employers and business owners decide whether or not to include vaping in their smoke-free policies.

The Ministry of Health is considering how best to apply risk-proportionate regulation across all tobacco products including smoked tobacco, smokeless tobacco and vaping products.

Until the SFEA is amended, retailers should continue to trade responsibly and, in particular, not to advertise or sell vaping products to children and young people under 18 years of age.

Consumers of vaping products should not notice any difference as nicotine vaping liquid has been available for purchase in retail shops for some time. Heated tobacco products might also become available for sale in New Zealand".

United Kingdom

Regulation of HNB products is covered by the EU TPD. For HNB products, UK law does not require the same plain packaging with graphic health warnings as it does for cigarettes. Regarding indoor use, e-cigarettes and HNB are considered smoke-free products. In practice this means that as elsewhere, allowing indoor use of HNB is at the discretion of premises owners.

United States

On 28th July, 2017, the US Food and Drug Administration (FDA) announced a comprehensive regulatory plan for tobacco and nicotine-containing products. The plan will apply risk-based product-specific regulation - increasing restrictions on the riskiest forms of nicotine delivery (cigarettes) and allowing "greater flexibility" for non-combustible products.

On January 24th-25th, 2018, the Tobacco Products Scientific Advisory Committee (TPSAC) discussed PMI's IQOS Modified Risk Tobacco Product

⁴² Ministry of Health. *Vaping, smokeless, including heated tobacco*. New Zealand Government, 2018. Available at <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco>

(MRTP) applications. The TPSAC is a body established by the US Tobacco Control Act (see below), comprised of nine public health experts and three non-voting tobacco industry representatives, appointed by the Commissioner of the FDA to provide nonbinding recommendations to FDA on tobacco matters from a public health perspective. TPSAC voted eight to one that IQOS “Significantly reduces a person’s exposure to harmful or potentially harmful chemicals”.

* * *

Having considered the FCTC to which most countries in the world are signatories, nevertheless as we have seen, every country handles the challenge of regulating SNP differently. By any metric, the two largest SNP markets in the world are the USA and the 28 countries that collectively make up the European Union. Both markets have their own comprehensive tobacco regimes. So for this final section we look at the history and development of the regulatory frameworks of these two jurisdictions. This is not to endorse the approach of either of these two regimes, but rather to highlight the complexities, and some of the consequences of these two very different regulatory models.

Overview of USA Federal and State law relating to SNP

Background

In 1938, Congress passed the Federal Food, Drug and Cosmetic Act (FDCA) under the jurisdiction of the FDA. The FDCA covered a range of provisions aimed at consumer safety including food colouring and additives, cosmetics and medical devices. There were no provisions in the FDCA for the FDA to have jurisdiction over tobacco products, save for issues around import and export. Traditionally the US Bureau of Alcohol, Tobacco, Firearms and Explosives was responsible for enforcing laws against any criminal activities involving tobacco, such as smuggling, while the Federal Communications Commission had jurisdiction over tobacco broadcast advertising. Federal tobacco control was housed at the Center for Disease Control and Prevention (CDC) Office on Smoking and Health (OSH) which is responsible for convening the Interagency Committee on Smoking where no less than eleven Federal agencies and institutions are involved, including the FDA.

In 1995 the FDA decided that it did have overall jurisdiction over tobacco products insofar as nicotine was a ‘drug’ and the cigarette was a ‘drug delivery

system’, and so fell under the provisions of the FDCA. The tobacco company Brown & Williamson challenged the FDA on this and won on the grounds that the FDA had never tried to claim jurisdiction before and that it was never the intention of Congress back in 1938 to grant it this power. The judgement was handed down in 2000, but it kick-started a process which led to the Family Smoking Prevention and Tobacco Control Act 2009, which finally gave the FDA the legislative power to regulate tobacco that it had been seeking.

Federal law⁴³

The FDA has long held the authority to regulate nicotine replacement therapies such as gum, patch, and lozenges through the Center for Drug Evaluation and Research (CDER). In 2009, with the passage of the Family Smoking Prevention and Tobacco Control Act,⁴⁴ the FDA gained the authority to regulate tobacco products and marketing for cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On May 10, 2016, the FDA published a final ‘deeming rule’ allowing the agency to begin regulating all tobacco products, including cigars, pipe tobacco, waterpipes (or hookahs), dissolvable products, e-cigarettes, and other electronic nicotine delivery systems.⁴⁵

The deeming rule requires that any new product (any tobacco product not commercially marketed in the US as of February 15, 2007) must go through a Pre-Market Tobacco Application (PMTA) process to stay on the market (the deadline to submit a PMTA is August 8, 2022 for non-combustible products and August 8, 2021 for combustible products), and a Modified Risk Tobacco Product Application (MRTPA) in order to make any health claims about relative risk compared to continuing to smoke cigarettes.⁴⁶

Products that have been subjected to small changes from the original “grandfathered product” (products on the market before February 15, 2007) must submit a Substantial Equivalence Report (SE) or an Abbreviated SE report

⁴³Text for the US section provided by Amy Arthur of Pinney Associates.

⁴⁴Govtrack, H.R. 1256 (111th): Family Smoking Prevention and Tobacco Control Act, 2009. Available at <https://www.govtrack.us/congress/bills/111/hr1256/summary#libraryofcongress>

⁴⁵Federal Register, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 2016. Available at <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>

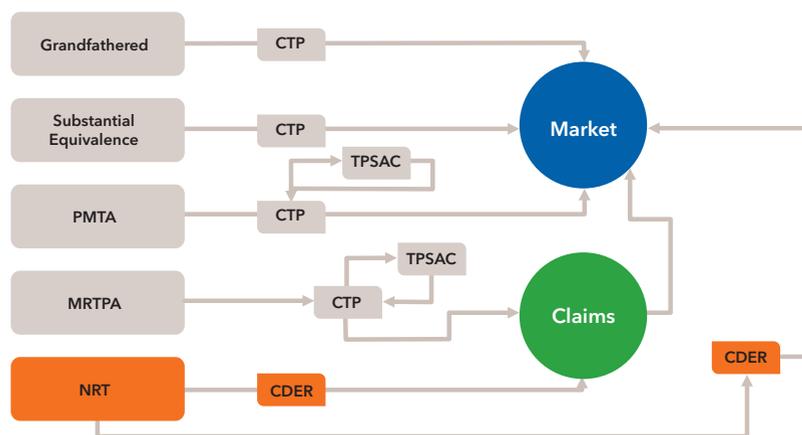
⁴⁶Food and Drug Administration, *Pipe, Cigar, and Vape Shops that Are Regulated as Both Retailers and Manufacturers*. Available at <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm514606.htm>

so the product can stay on the market without a PMTA. (See Figure 6.5⁴⁷ for all the pathways a nicotine containing product can take to get to market).

The PMTA pathway requires that the applicant proves that the product would be appropriate for the protection of the public health. The statute does not define that standard further. The FDA has released draft guidance documents, however, at the time of writing, none of them have been finalised meaning that they are not enforceable and the agency can change them at any time. To date, only eight PMTA orders have been granted for Swedish Match's General Snus products.⁴⁸

Figure 6.5

Center for Tobacco Products (CTP) map^{49 50}



There are two types of MRTPA orders. The Risk-Modification standard requires that the product significantly reduces the harm and risk of tobacco-related disease to individual tobacco users, and benefits the health of the population as a whole. The Exposure-Modification order asks applicants to prove that the "Reduction in exposure to substance is substantial, substance is harmful, and the product as actually used exposes consumers to a specified reduced level of the substance". As manufacturers seek to understand how to navigate proving this, an extensive and costly application is necessary. To date, no MRTPA order has been issued.⁵¹

The deeming rule extends several provisions of the federal Tobacco Control Act to these new tobacco products. For example, these products are now subject to the federal prohibition on sales to minors, the federal prohibition on free sampling,

federal warning label requirements, and the requirement that tobacco manufacturers register with the FDA and seek the agency's review of new tobacco products.

In July, 2017, the FDA announced a new, comprehensive regulatory framework aimed at further reducing tobacco-related disease and death in the US. The plan has two major objectives:

1. To reduce the nicotine levels in combustible cigarettes and other tobacco products to levels that minimise their addictiveness - known as Very Low Nicotine Cigarettes - or VLNC, and;
2. To encourage the development and broader use of innovative nicotine replacement products that can help more smokers quit.⁵²

The FDA's new tobacco strategy has two primary parts: reducing the addictiveness of combustible cigarettes while recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health.

*Scott Gottlieb and Mitch Zeller (2017)*⁵³

⁴⁷ Figure originally presented by Dr. Michael Hufford at FDLI's Introduction to US Tobacco Law and Regulation workshop in 2017. Available at <https://www.fdpi.org/2018/10/introduction-u-s-tobacco-law-regulation-2/>

⁴⁸ Food and Drug Administration, Tobacco Product Marketing Orders <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm#1>

⁴⁹ The CTP is the Center for Tobacco Products which oversees the implementation of the Family Smoking Prevention and Tobacco Control Act. Some of the Agency's responsibilities under the law include setting performance standards, reviewing premarket applications for new and modified risk tobacco products, requiring new warning labels, and establishing and enforcing advertising and promotion restrictions. The TPSAC is the Tobacco Products Scientific Advisory Committee who review and evaluate safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

⁵⁰ The Center for Drug Evaluation and Research is a division of the U.S. Food and Drug Administration (FDA) that monitors most drugs as defined in the Food, Drug, and Cosmetic Act. Some biological products are also legally considered drugs, but they are covered by the Center for Biologics Evaluation and Research. The Center reviews applications for brand name, generic, and over the counter pharmaceuticals, manages US current Good Manufacturing Practice (cGMP) regulations for pharmaceutical manufacturing, determines which medications require a medical prescription, monitors advertising of approved medications, and collects and analyses safety data about pharmaceuticals that are already on the market.

⁵¹ Food and Drug Administration, Modified Risk Tobacco Products <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304465.htm#4>

⁵² Food and Drug Administration. Protecting American Families: Comprehensive Approach to Nicotine and Tobacco. Speech by Scott Gottlieb, M.D., Commissioner of the FDA, July 28th 2017. Available at https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm?utm_source=CTPPartnerTwitter&utm_medium=social&utm_term=gov&utm_content=speech&utm_campaign=ctp-728regplan

⁵³ Gottlieb, S. and Zeller, M. (2017) A Nicotine-Focused Framework for Public Health. *New England Journal of Medicine* 2017; 377:1111-1114. Available at www.nejm.org/doi/full/10.1056/NEJMp1707409

The FDA approach to SNP created a raft of critical media comment and opinion which focused on the premise that to over-regulate SNP was not only counter-productive in health terms but would benefit the major tobacco companies, not only by protecting cigarette businesses but also through the onerous licensing and testing requirements, which would mean that compliance would only be possible for the major tobacco companies with large resources.⁵⁴

US state and local regulation

The deeming rule makes clear that state and local governments can continue to adopt and enforce laws relating to tobacco product sales, use, distribution, and advertising (within constitutional limitations). These state and local laws can be "In addition to, or more stringent, than, the requirements of the Tobacco Control Act and its implementing regulations". States and localities have taken many different approaches in terms of bans, taxation, restriction, purchase age, and other regulations, which all adds to the legislative confusion over SNP in the USA. Readers are referred to the Public Health Law Center overview of state and local regulations cited below with the obvious caveat that the laws are in a seemingly constant state of flux. For example, San Francisco recently voted for a ban on flavoured tobacco products including e-liquids.⁵⁵

European Union Tobacco Control Directive (TPD)

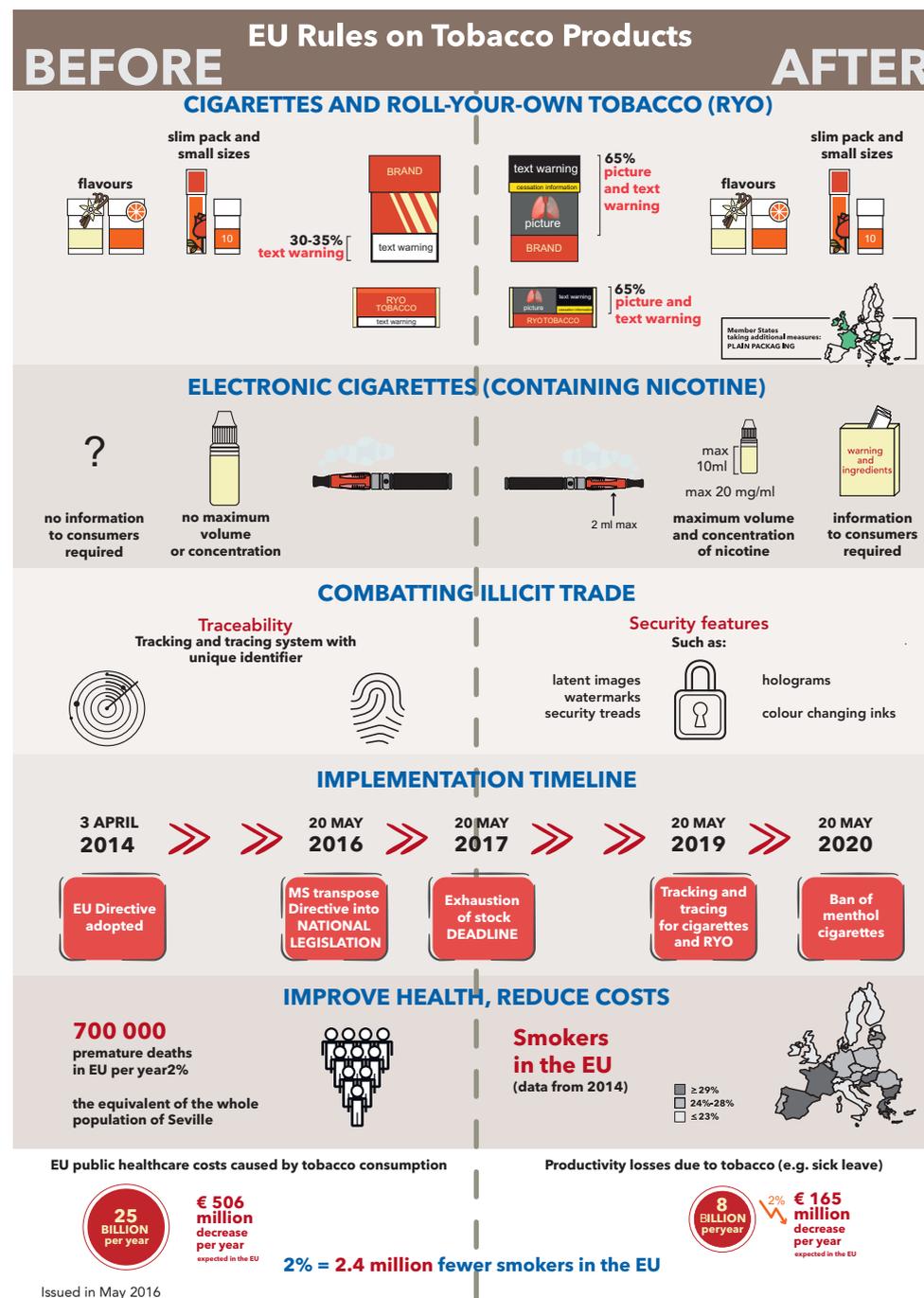
The TPD is a Directive of the EU which means that all EU countries must 'transpose' or incorporate the TPD requirements into their national laws. The only flexibility permitted is the ability to enact additional regulations. The current Directive entered into force on 19th May 2014 and became applicable in the EU Member States on 20th May 2016.

Figure 6.6
The European Union (EU) Tobacco Products Directive (TPD)
2016 changes to the EU TPD →

Figure adapted from https://ec.europa.eu/health/tobacco/products_en

⁵⁴ For example, Fortune, *Feds cracked down on e-cigarettes, vaping industry* (2016) <http://fortune.com/2016/05/05/fda-e-cigarettes-cigar-tobacco/>; and National Review, *Promote health by not defending the e-cigarette ban* (2017) <https://www.nationalreview.com/2017/05/cigarette-smoking-vaping-ban-bad/>

⁵⁵ Park, M. and Selig, R. (2018) *San Francisco bans sales of flavoured tobacco products*, CNN. Available at <https://edition.cnn.com/2018/06/06/health/san-francisco-flavored-cigarettes-proposition-e/index.html>



Background

The EU has been active in tobacco control policy since 1985 when the Milan Council announced its intention to establish a Europe Against Cancer (EAC) Programme, although the EU had previously adopted several Directives on aspects of tobacco taxation. Shortly after the adoption of the EAC's first action plan, the European Commission presented its first legislative proposals on tobacco control. The proposals on labelling became Directives by 1992, and the proposal on tobacco advertising became law in 1998.

In 1996 the Commission published a Communication on the future of EU tobacco control and in 1999 at the second European Conference on Tobacco and Health, the Social Affairs Commissioner announced his intention to bring forward further legislative proposals to amend and consolidate existing EU legislation in this sector.⁵⁶ This led eventually to the Directive on Tobacco Products (2001), the first major European legislation specifically related to tobacco products. The Directive required manufacturers to put health warnings on tobacco products; banned the use of descriptive terms such as 'light', 'mild' or 'low tar'; forced producers to provide full information on all ingredients utilised in their products, and set maximum limits for nicotine and carbon monoxide in cigarettes.

The Directive on Tobacco Advertising (2003) banned cross-border advertising of tobacco products in printed media, radio and on-line services and banned sponsorship of cross border events if it had the effect of promoting tobacco products. Tobacco advertising and sponsorship on television was already prohibited since 1989.

The first attack on what turned out to be a significant tobacco harm reduction product was the EU wide ban on the sale of snus in 1992 as a response to the attempt in the UK to introduce Skoal Bandits oral tobacco from the USA.⁵⁷ Directive 2001/37/EC reaffirmed that prohibition, but Sweden was exempted by Article 51 of the European Act of Accession because snus was in widespread use in Sweden and the ban was introduced before Sweden joined the EU. Only a narrow majority of Swedes supported their country's accession to the EU and there was a strong request to be excluded from the snus ban.

However, in Commission reports from 2005 and 2007, new areas were identified "In which further action was considered useful for the 'smooth functioning of the internal market'".⁵⁸ The preamble to the 2014 TPD noted "Substantial

differences" in the way member states dealt with "Tobacco and related products" and "In the light of scientific, market and international developments, these discrepancies are expected to increase". These 'discrepancies' also extended in the Commissions' remit to include e-cigarettes.

As the sale of e-cigarettes was growing throughout the EU, member states were seeking advice and clarification from the Commission. In May 2008 an Orientation Note from the Commission Directorate in charge of Health and Consumer Protection suggested that an e-cigarette which did not contain nicotine was not a tobacco product but could be regarded as a medicinal product.

In 2010, the consultants Rand Europe produced a massive 345-page report on the impact of revising the 2001 Directive. The report made few references to e-cigarettes other than to point out that very little was known about any aspect of their use, manufacture or health effects and outlined regulatory options of harmonising regulation as tobacco products, pharmaceutical products or simply banning them altogether.⁵⁹

In 2012, the Health and Consumer Directorate produced a proposal for the revision of the TPD in which, under Article 18, products with a nicotine content over a certain level - including most e-cigarettes currently on the market - would have to be authorised as medicines.⁶⁰ When the proposal came before the EU Parliament in 2013, numerous amendments to the Article were proposed including deleting Article 18 altogether so that all e-cigarettes could only be sold as medicines under pharmaceutical regulations. Significant to these deliberations were major objections from e-cigarette consumers. Eventually in December 2013, a compromise text was agreed between the European Parliament and the Council of Ministers.⁶¹

⁵⁶ Godfrey, F (2000). An overview of European tobacco control legislation. *Central European Journal of Public Health*; 8(2), p.128-31

⁵⁷ Skoal Bandits were banned in the UK in 1989. The Herald, *Safety ban on Skoal Bandits* (1989) http://www.heraldscotland.com/news/11972277.Safety_ban_on_Skoal_Bandits/

⁵⁸ European Union, *Directive 2014/40/EU of The European Parliament and of The Council* (2014) <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014L0040&from=EN>

⁵⁹ Tiessen, J. et al (2010) *Assessing the Impacts of Revising the Tobacco Products Directive*. Rand Europe. Available at https://ec.europa.eu/health/sites/health/files/tobacco/docs/tobacco_ia_rand_en.pdf

⁶⁰ European Commission, *Directive of the European Parliament and of the Council*. EC, 2012. Available at https://ec.europa.eu/health/sites/health/files/tobacco/docs/com_2012_788_en.pdf

⁶¹ European Parliament, *Tobacco directive: MEPs reach agreement with Council Ministers*. European Parliament, 2013. Available at <http://www.europarl.europa.eu/news/en/press-room/20131216IPR31001/tobacco-directive-meps-reach-agreement-with-council-of-ministers>

Key provisions of TPD2 2014

In 2014 a revised Tobacco Products Directive known as TPD 2 was issued by the EU to update the 2001 Tobacco Products Directive.

TPD2 regulates all tobacco products in the European Union and its scope is wide. It covers product regulation in terms of reporting obligations of ingredients and emissions for all tobacco products. It includes product packaging and labelling including the size and appearance of products, traceability features to be fixed onto packaging as well as health warnings. It covers cross-border advertising of tobacco products; it reinforces the ban on oral tobacco products (snus), but importantly it provides for the placing on the market of e-cigarettes and refill containers, as well as making provision for notification of novel tobacco products. It also provides for herbal cigarettes.

Smokeless Tobacco Products

TPD2 regulates smokeless tobacco products and contains a specific requirement for the labelling of smokeless tobacco products including a specific health warning text in Article 12: "This tobacco product damages your health and is addictive". The provisions on Traceability and Security features also apply to "Tobacco products other than cigarettes and RYO" - only at a later date for implementation.

TPD2 defines a 'Smokeless tobacco product' as "A tobacco product not involving a combustion process, including chewing, tobacco, nasal tobacco and tobacco for oral use". 'Tobacco for oral use' is defined as "Tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets" - it is clear they are referring to snus. So, while smokeless tobacco products are permitted and regulated in TPD 2, snus remains banned except in Sweden. This is made clear in the very short Article 17: "Members States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden". The outcome is a questionable one on reduced harm grounds, as Swedish snus is known worldwide as the least harmful tobacco product backed up by more than 50 years of scientific and epidemiological research, and Sweden has the lowest number of tobacco related deaths in Europe.

Novel tobacco products

TPD 2 provides for new and modified products in Article 19 through a notification system. Manufacturers of novel tobacco products, defined as products that do not fall into the categories of: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco, or tobacco for oral use, are required to give six months' notice before putting a product on the market.

What is required is a detailed description of the novel product, instructions for its use, information about ingredients and any emissions it may have. In addition, other information that can be provided should be provided, including: any available scientific studies on toxicity, addictiveness and attractiveness of the novel product; any available studies or market research, including any information known about preferences of consumer groups, including from young people and current smokers; any available risk/benefit analysis of the product; its expected effects on cessation; its expected effects on initiation of tobacco consumption; and any predicted consumer perceptions. Member States may require manufactures to carry out additional tests if they believe there is a need for more information.

Any novel products placed on the market must respect the TPD2 in terms of its other provisions where applicable, and depend on whether the novel product is defined as a smokeless product or a tobacco product for smoking.

In addition to the notification system for novel products, TPD2 allows Member States to introduce an authorisation system and charge fees for that authorisation. In the UK, this option is available via the MHRA.

E-cigarettes

There were high expectations placed on the outcome of the TPD regarding e-cigarette regulation. Although some would argue that the regulations are not optimal in terms of nicotine levels, or with the requirements of the refill containers, most would agree that the ultimate regulation of e-cigarettes in Europe as consumer products far outweighs the pharmaceutical medicinal outcome or a complete ban, which were both possible options. The driving force behind the TPD seemed less to do with public health and is more concerned with legislative harmonisation and "The smooth running of the internal market".

E-cigarettes, and refill containers, can only be placed on the market as consumer products in the EU if they comply with the TPD2, although e-cigarettes that take the medicinal authorisation route do not have to comply. Just like novel products, a manufacturer of e-cigarettes must notify the authorities of the intention to put a product on the market six months prior and provide a further new notification for any modifications. Notification needs only to include the name of manufacturer, a list of ingredients and emissions, by name, brand, and type. The notification must also include the nicotine dose and uptake information. There must be a description of the components of the product, such as how the refill container opens and how the mechanisms work. A description of the production process and its conformity with the TPD is also required, as well as a declaration taking full responsibility for the product's safety and quality is needed.

Other requirements of the e-cigarette provisions of the Directive:

- » The capacity of e-cigarette refill tanks is restricted to no more than 2ml and a maximum volume of e-liquids containing nicotine for sale for one refill container to 10 ml;
- » The nicotine strength of e-liquids is restricted to no more than 20mg/ml;
- » Products containing nicotine and their packaging must be tamper proof and resistant to child tampering;
- » The use of certain ingredients including taurine, colourings, and caffeine, are prohibited;
- » The mandatory use of new labelling and health warning signs on the packaging;
- » Packages include a leaflet with information on instructions for use and storage; warnings for young people and non-smokers; possible side effects; addictiveness and toxicity; and contact details for the manufacturer or importer within the EU;
- » Labelling for both e-cigarettes and refill containers must include a list of ingredients in descending order of weight;
- » Products must carry a health warning that says either: "This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers" or "This product contains nicotine which is a highly addictive substance";
- » Commercial communications are prohibited except in trade publications and in specialist tobacco outlets.

In relation to the best interests of tobacco harm reduction, treating e-cigarettes as if they were tobacco products is problematic, and, in effect, TPD2 dealt with

a public health problem the EU did not have. Some of the most significant issues highlighted by former UK ASH Director Clive Bates are:

- » Banning advertising hampers the development of trusted brands, communication of innovation and the aspirational messages that help new products succeed in encouraging a switch away from cigarettes. It means, for example, that a tobacco company cannot put a leaflet in a cigarette packet suggesting a smoker switch to an e-cigarette;
- » Limiting the strength of nicotine liquid to 20mg/ml (two percent) is a potential problem because:
 - ‡ Stronger liquids may be more important for more heavily dependent smokers to switch;
 - ‡ They are important for smokers in the process of switching - new users may not have acquired the skill or familiarity to find vaping a satisfactory alternative to smoking in the early days - the strength limit is likely to cause more to relapse;
 - ‡ In a market that values miniaturisation it may be a barrier to innovation - allowing more nicotine to be kept in a smaller volume may be important in future product design;
 - ‡ For those users who would prefer stronger e-liquids, it will mean they will need to inhale more vapour to get the nicotine they want - if there are any hazardous substances in vapour, this policy will increase exposure. If the concern is poisoning, then child-resistant containers are the answer;
- » Limiting the size of nicotine liquid containers to 10ml and tanks or cartridges to 2ml is probably based on a misunderstandings of nicotine toxicity and overstated LD50 (lethal dose). What it means for consumers is more frequent refilling, more spillage possibilities, more chance of running out, and high costs for users etc.;
- » The need for warnings is debatable as there is nothing like the risk inherent in cigarettes. In addition, each pack is required to contain a leaflet - even though nothing similar is required for cigarettes.
- » The procedure for bringing a product to market is far more onerous than for a new cigarette brand which requires minimal testing of crude metrics (TAR, nicotine and carbon monoxide) with long established protocol".⁶²

⁶²The counterfactual, *What is wrong with the Tobacco Products Directive for vapour products?* (2015) <https://www.clivebates.com/what-is-wrong-with-the-tobacco-products-directive-for-vapour-products/>

“In relation to the best interests of tobacco harm reduction, treating e-cigarettes as if they were tobacco products is problematic and in effect dealt with a public health problem the EU did not have.”

A brief note on taxation

A central tenet of tobacco harm reduction is to make those products which are demonstrably safer than cigarettes as easy as possible for existing smokers to access, in order to encourage them to switch away from cigarettes. An important factor in promoting that switch is the price of products compared to cigarettes including tax levied by local and national governments.⁶³

As a commodity, tobacco along with alcohol and gambling are subject to what is often called a ‘sin tax’, an extra levy which represents society’s disapproval of a commodity or activity or at least a behaviour or activity which is not necessarily ‘disapproved’ of, but where the state wants to ‘nudge’ people in a different direction. Recently the UK introduced a ‘sugar tax’ on soft drinks and there is a US proposal that would block pornography on devices unless consumers paid a tax,⁶⁴ while those states which have legalised or are planning to legalise marijuana expect to raise significant ‘sin’ tax revenues.⁶⁵ Regulators like sin taxes as they aim to discourage unhealthy behaviours like smoking and excessive drinking, they help pay for the health costs of those behaviours, and they are popular with voters because only those who indulge have to pay. Regulators also like this type of tax because, so long as the tax is not unduly onerous, people will continue to buy the commodity despite tax increases thus securing a tax revenue stream.

However, in their article published in the *New England Journal of Medicine*, Frank Chaloupka and colleagues argued there should be differential tax levies to signal differential risk in nicotine products.⁶⁶ But the authors acknowledged that a balancing act needs to be achieved, *“To alleviate concerns that low prices on [SNP] might encourage uptake among young people, taxes on such products could be set high enough to discourage initiation. At the same time, taxes on combustible products could be further increased in order to raise their prices relative to less harmful non-combustible products. Such a strategy would maximize the likelihood of current smokers switching to lower-risk products while deterring users of lower-risk products from switching to more harmful ones. Higher prices for combustible products would have the added benefit of further reducing the likelihood that young people would take up smoking.”*⁶⁷

The current state of play regarding SNP taxation is very fragmented. At the global level, the FCTC has little to say about tax excepting a WHO report on SNP that suggested Member States should tax SNP “At a level that makes the devices and e-liquids unaffordable to minors in order to deter its use in this age group”.

However, the WHO has commended the World Customs Organization (WCO) to confirm a proposal to move e-liquids from their current categorisation under Chemicals to a new sub-section under Tobacco to be designated as non-tobacco products containing nicotine.

The WCO, established in 1952, is an independent intergovernmental body representing around 200 Member State customs administrations across the globe that collectively process approximately 98 percent of world trade. Among many functions, the Brussels-based organisation maintains the international Harmonised System (HS) of naming goods. HS codes are used by customs authorities, statistical agencies, and other government regulatory bodies, to monitor and control the import and export of commodities. And the penalties for mis-classifying a product can be punitive, including import bans and seizures.

In November 2016 the WCO Member States unanimously decided to classify e-liquids as Chemical Products in the HS. Now they are looking at reclassifying e-liquids under ‘Tobacco and manufactured tobacco substitutes’.

The WCO published a document in which it discussed shifting e-cigarettes and e-liquids out of the chemicals category and into the tobacco category. Despite the actions of many Member States, for the purposes of international trade, e-cigarettes are not classified as tobacco products. But there are some potentially serious consequences for tobacco harm reduction and affordability of products:

⁶³ There is also the issue of the cost of the devices, so that cigarettes need to be taxed at a level which still encourages switching, even taking into account the costs of purchasing the device. Liber, A.C et al (2017). Combustible cigarettes cost less to use than e-cigarettes: global evidence and tax policy implications. *Tobacco Control*; 26 (2), 158-163

⁶⁴ AZFamily.com, *Bill would block porn on new phones, computers unless consumers pay a tax* (2017) <http://www.azfamily.com/story/35195078/bill-would-block-porn-on-new-phones-computers-unless-consumers-pay-a-tax>

⁶⁵ ZeroHedge, *Marijuana Expected To Be California’s Largest ‘Sin Tax’ As Jerry Brown Set To Release Surplus Budget* (2018) <https://www.zerohedge.com/news/2018-01-10/marijuana-expected-be-californias-largest-sin-tax-jerry-brown-set-release-surplus>

⁶⁶ Chaloupka, F. et al. (2015). Differential taxes for differential risks – toward reduced harm from nicotine-yielding products. *New England Journal of Medicine*; 373:594-597

⁶⁷ WHO (2016). *Electronic delivery systems and electronic non-nicotine delivery systems: report for the COP meeting 2016*, p.6

- » Some regions apply a 100 percent additional tax on tobacco products in addition to import tariffs;
- » Tobacco products are left out of trade deals, so if classified as tobacco products, there could be no tariff discount deals struck on behalf of safer nicotine products;
- » Tobacco products are excluded from foreign investor protection under most new trade deals. So if somebody started an e-cigarette business in one country and found that the government in that country changed all its policies to become highly anti-vaping, the owners would not be protected by foreign investor protection treaties.⁶⁸

Outside of the EU and some US states, only Bangladesh, Indonesia, Kenya, Russia, Serbia and South Korea levy tax on e-cigarettes with Kazakhstan set to levy a tax.⁶⁹ Within the EU, the TPD, like the FCTC, does not instruct on domestic tax matters leaving it to Member States to decide on whether or not to tax SNP. Currently 13 EU countries have opted to tax. However, the EU's Directorate-General for Taxation and Customs Union has been considering proposals for a harmonising Europe-wide tax on e-cigarettes and HNB products recently launching the second of two consultations.

In the US, while there is a Federal tax on snus-type products, there is no tax on e-cigarettes again leaving individual states to decide on whether or not to impose a tax. Most states have chosen not to impose a tax, but around ten states have a tax regime in place. Minnesota was the first state to impose a volume tax in 2010 on 'other tobacco products' at 70 percent of the wholesale price which leapt to 95% in 2013. Other state wholesale taxation levels include the District of Columbia (70 percent), California (65 percent) and Pennsylvania (40 percent). However, some states like North Carolina and Kansas have adopted taxation by volume per ml of liquid which is to the advantage of closed cig-a-like systems whose liquid level is 1-2ml and to the disadvantage of open systems which have much higher liquid levels in turn favouring some larger manufacturers over smaller, independent companies.⁷⁰

On the other hand, Kentucky has taken a ground-breaking tobacco harm reduction approach. In May, the Kentucky legislature passed a tax reform bill that increased cigarette excise taxes from \$0.60 to \$1.10, while leaving taxes on smokeless products unchanged with no excise tax at all on e-cigarettes. This was in line with the tax regime proposed by Kentucky University's Brad Rodhu and his colleague Nantaporn Plurphanswat⁷¹.

Kentucky's General Assembly recognised that "Increasing taxes on tobacco products should reduce consumption, and therefore result in healthier lifestyles for Kentuckians. The relative taxes on tobacco products [...] reflect the growing data from scientific studies suggesting that although smokeless tobacco poses some risks, those health risks are significantly less than the risks posed by other forms of tobacco products. Moreover, the General Assembly acknowledges that some in the public health community recognize that tobacco harm reduction should be a complementary public health strategy regarding tobacco products. Taxing tobacco products according to relative risk is a rational tax policy and may well serve the public health goal of reducing smoking-related mortality and morbidity and lowering health care costs associated with tobacco-related disease".

■ ***"Taxing tobacco products according to relative risk is a rational tax policy".***

Conclusion

The advent of new SNP products presents a serious challenge to established tobacco regulatory control regimes at both a national and international level. As a result, far too many regulatory anomalies exist in the global SNP space. It is an odd regulatory world where the safest tobacco product is banned, as snus is in the EU, and yet the most lethal (cigarettes) can be bought freely almost anywhere. E-cigarettes and HNB - are they different categories? Or are they both e-cigarettes producing vapor where in one the nicotine is derived from liquid, while in the in the other the nicotine is derived from tobacco? Should they be regulated equally or differently? Should all non-combustible SNPs be allowed, and consumers be the ones that choose what works? If all are deemed safer compared to cigarettes, should the regulator decide what a consumer should have access to, or should the consumer be permitted to decide what he/she prefers? These are the regulatory questions that must be addressed as a matter of urgency for the sake of global public health.

⁶⁸ Velvet Glove, Iron Fist, *E-cigarettes to be re-classified as tobacco?* (2018) <https://velvetgloveironfist.blogspot.com/2018/05/e-cigarettes-to-be-re-classified-as.html>

⁶⁹ Personal communication, E Cig Intelligence

⁷⁰ Public Health Law Center. *US e-cigarette regulation: a 50-state review*. Mitchell Hamline School of Law, 2017

⁷¹ Tobacco Truth, *Kentucky Adopts a Rational Tobacco Tax Plan* (2018) <https://rodutobaccotruth.blogspot.com/2018/05/kentucky-adopts-rational-tobacco-tax.html>

But significant barriers exist to evidence-based proportionate regulation. In their deliberations over legal controls on SNP, legislators and politicians are no less immune than health professionals or ordinary consumers from being confused by contradictory research findings, or influenced by the work of individual influential activists and sensationalised media reporting. Regulatory outcomes also need to be viewed from the prism of the complex story of tobacco control and the infamous and well documented history of the tobacco industry attempts to undermine those control efforts.

However, this understandable antipathy toward the industry has been wildly over-interpreted by the WHO to make it impossible for there to be any meaningful dialogue about SNP and tobacco harm reduction between an industry, by no means dominated by the major tobacco companies, and those charged with determining international global tobacco policy. Exclusion from the debate also extends to a wide range of academics, clinicians, public health analysts and consumer groups. This particularly impacts on LMIC, which both suffer from the highest levels of death and disease from smoking and are at the same time least able to implement FCTC provisions through lack of resources and other political and bureaucratic obstacles.

It is perfectly valid for there to be laws and regulations to protect consumers through the raft of general product safety standards and regulations that exist in many countries. However, to use the law to deny or inhibit access to SNP, through outright bans to cumbersome, bureaucratic and crippling expensive processes for bringing products to market, is not only to deny the current robust and independent evidence base. It also squanders the opportunities for major public health benefit. To repeat, paradoxically, it simply perpetuates use of the cigarettes (which are freely available the world over) and ensures continuing profits for major international corporations.

To act in this way against SNP also puts global tobacco control at odds with many internationally agreed treaties focusing on the fundamental right to the best possible health for all citizens. This takes us to the last chapter of this report.

Figure 6.7

E-cigarette legal/regulatory status

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertising allowed in Media (Press, TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Afghanistan	no specific law						
Albania	no specific law						
Algeria	no specific law						yes
Andorra	no specific law						
Angola	no specific law						no
Antigua and Barbuda	banned	yes	no	no	no		yes
Argentina	banned	yes	no	no	no		yes
Armenia	no specific law						yes
Australia	banned	no	yes	no	no		yes
Austria	allowed	yes	yes	yes	no	Yes 16+	yes
Azerbaijan	no specific law						no
Bahamas	no specific law						
Bahrain	banned	yes	no	no	no		yes
Bangladesh	no specific law						no
Barbados	allowed	yes	yes	yes		yes 18+	yes
Belarus	no specific law						yes
Belgium	allowed	yes	yes	yes	no	Yes 16+	yes
Belize	no specific law						
Benin	no specific law						yes
Bhutan	banned	yes	no	no		yes 18+	yes
Bolivia	no specific law	yes	yes	yes			no

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertisiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Bosnia and Herzegovina	no specific law						
Botswana	no specific law						yes
Brazil	banned	yes	no	no	no		yes
Brunei	banned	yes	no	yes			yes
Bulgaria	allowed	yes	yes	yes	no	yes 18+	yes
Burkina Faso	no specific law						yes
Burma (Myanmar)	no specific law						
Burundi	no specific law						
Cambodia	banned	no					
Cameroon	no specific law						
Canada	allowed	yes	yes	yes			
Cape Verde	no specific law						
Central African Republic	no specific law						
Chad	no specific law						
Chile	no specific law	yes	yes	yes			no
China	allowed	yes	yes	yes		yes 18+	yes
Colombia	banned	yes	no	no	no		yes
Comoros	no specific law						
Congo	no specific law						
Congo, Democratic Republic of	no specific law						
Cook Islands	no information						
Costa Rica	allowed	yes	yes	yes	no	yes 18+	yes

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targetted) Advertisiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Croatia	allowed	yes	yes	yes		yes 18+	yes
Cuba	no specific law						
Cyprus	allowed	yes	yes			yes 18+	yes
Czech Republic	allowed	yes	yes	yes	no	yes 18+	yes
Denmark	allowed	yes	yes	yes	no	yes 18+	yes
Djibouti	no specific law						
Dominica	no specific law						
Dominican Republic	no specific law						
East Timor	banned						
Ecuador	allowed	yes	yes	yes	no	yes 18+	yes
Egypt	banned	yes	no	no			no
El Salvador	no specific law						
Equatorial Guinea	no specific law						
Eritrea	no specific law						
Estonia	allowed	yes	yes	yes	no	yes 18+	yes
Ethiopia	banned	yes	no	no	no		yes
Fiji	allowed	yes	yes	yes	no	yes 18+	yes
Finland	allowed	yes	yes	yes	no	yes 18+	yes
France	allowed	yes	yes	yes	no	yes 18+	yes
French Guiana	no specific law	yes	yes	yes			
Gabon	no specific law						
Gambia	banned	no	no	no	no		

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertsiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Georgia	no specific law	yes	yes	yes	no	yes 18+	
Germany	allowed	yes	yes	yes	no	yes 18+	
Ghana	no specific law						
Greece	allowed	yes	yes	yes	no	yes 18+	
Grenada	no specific law						
Guatemala	no specific law						
Guinea	no specific law						
Guinea-Bissau	no specific law						
Guyana	no specific law	yes					
Haiti	no specific law						
Honduras	allowed	yes	yes	yes	no	yes 21+	
Hungary	allowed	yes	yes	yes	no	yes 18+	
Iceland	allowed	yes	yes	yes			
India	allowed	yes	yes	yes		yes 18+	
Indonesia	banned	no	no	no			
Iran	no specific law						
Iraq	no specific law						
Ireland	allowed	yes	yes	yes	no	yes 18+	
Israel	no specific law						
Italy	allowed	yes	yes	yes	no	yes 18+	
Ivory Coast	no specific law					yes 15+	
Jamaica	allowed	yes	yes	yes			

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertisiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Japan	banned	yes	yes	no		yes 20+	yes
Jordan	banned	no					
Kazakhstan	no specific law						
Kenya	no specific law						
Kiribati	no specific law						
Korea, North	banned						
Korea, South	allowed	yes	yes	yes	yes	yes 19+	yes
Kosovo	no specific law	yes	yes	yes			
Kuwait	allowed	yes	yes	yes			
Kyrgyzstan	no specific law						
Laos	no specific law						
Latvia	allowed	yes	yes	yes	no	yes 18+	yes
Lebanon	banned	yes					
Lesotho	no specific law						
Liberia	no specific law						
Libya	no specific law						
Liechtenstein	allowed	yes	yes	yes		Yes 16+	no
Lithuania	allowed	yes	yes	yes	no	yes 18+	yes
Luxembourg	allowed	yes	yes	yes	no	yes 18+	yes
Macedonia	no specific law						
Madagascar	no specific law						
Malawi	no specific law						

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertsiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Malaysia	banned	yes	yes	yes		yes 18+	yes
Maldives	no specific law						
Mali	no specific law						
Malta	allowed	yes	yes	yes	no	yes 18+	no
Marshall Islands	no information						
Mauritania	no specific law						
Mauritius	banned	yes					
Mexico	banned	yes	no	no	no	yes 18+	no
Micronesia	no information						
Moldova	allowed	yes	yes	yes		yes 18+	
Monaco	no specific law						
Mongolia	no specific law						
Montenegro	no specific law						
Morocco	no specific law	yes	yes	yes			no
Mozambique	no specific law						
Namibia	no specific law	yes	yes	yes			yes
Nauru	no specific law						
Nepal	banned	yes	no	no	no		yes
Netherlands	allowed	yes	yes	yes	no	yes 18+	
New Zealand	allowed	yes	yes	yes		yes 18+	no
Nicaragua	banned	no		no			
Niue	no information						

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertisiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Niger	no specific law						
Nigeria	allowed	yes	yes	yes			no
Norway	allowed	yes		no	no	yes 18+	yes
Oman	banned	yes					
Pakistan	allowed	yes	yes	yes			
Palau	allowed		yes	yes	no	yes 18+	yes
Palestine	no specific law						
Panama	banned	yes		no	no		
Papua New Guinea	no specific law						
Paraguay	allowed	yes	yes	yes			no
Peru	no specific law						
Philippines	allowed	yes	yes	yes			yes
Poland	allowed	yes	yes	yes	no		yes
Portugal	allowed	yes	yes	yes	no	yes 18+	yes
Qatar	banned	no	no	no			
Romania	allowed	yes	yes	yes	no		yes
Russian Federation	no specific law	yes					no
Rwanda	no specific law						
Saint Kitts and Nevis	no specific law						
Saint Lucia	no specific law						
Saint Vincent and the Grenadines	no specific law						

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertsiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Samoa	no specific law						
San Marino	allowed	yes	yes	yes	no	yes 18+	yes
Sao Tome and Principe	no specific law						
Saudi Arabia	banned	yes	no	no			
Senegal	no specific law						
Serbia	no specific law						
Seychelles	banned	yes	no	no			
Sierra Leone	no specific law						
Singapore	banned	no	no	no			
Slovakia	allowed	yes	yes	yes	no	yes 18+	yes
Slovenia	allowed	yes	yes	yes	no	yes 18+	yes
Solomon Islands	no specific law						
Somalia	no specific law						
South Africa	allowed	yes	yes	yes			no
South Sudan	no specific law						
Spain	allowed	yes	yes	yes	no	yes 18+	yes
Sri Lanka	banned	yes	no	no			
Sudan	no specific law						
Suriname	banned	yes	no	no			
Swaziland	no specific law						
Sweden	allowed	yes	yes	yes	no		yes
Switzerland	no specific law	yes	yes	no			

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertisiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Syria	no specific law						
Taiwan	allowed						
Tajikistan	no specific law						
Tanzania	no specific law						
Thailand	banned	yes	no	no			
Togo	allowed	yes	yes	yes	no	yes 18+	yes
Tonga	no specific law						
Trinidad and Tobago	no specific law						
Tunisia	no specific law						
Turkey	allowed	yes	yes	yes	no	yes 19+	yes
Turkmenistan	banned	no	no	no			
Tuvalu	no specific law						
Uganda	banned	yes	no	no			
Ukraine	no specific law					yes 18+	no
United Arab Emirates	banned	no	no	no			
United Kingdom	allowed	yes	yes	yes	no	yes 18+	no
United States	allowed	yes	yes	yes			yes
Uruguay	banned	yes		no			
Uzbekistan	no specific law						
Vanuatu	no specific law						
Vatican City	banned						
Venezuela	banned	yes					yes

Country	Selling e-cigarettes (containing nicotine) Sale of e-cigarettes – allowed/banned/no specific laws/no information	General use and availability			Advertising & promotion Public (non targeted) Advertisiing allowed in Media (Press,TV, billboards)	Health	
		Legal to use	Legal to sell device	Legal to sell nicotine		Minimum age restrictions – sales	Restrictions on vaping in public places
Vietnam	allowed	yes	yes	yes	no	yes 18+	
Yemen	no specific law						
Zambia	no specific law						
Zimbabwe	no specific law						

Sources: see also www.gsthr.org for more details on sources and methods.

1 Vapetrotter. Available at: <https://www.vapetrotter.com/laws/>

2 Tobacco Control Laws website. Available at: <https://www.tobaccocontrolaws.org/legislation/>

3 E-cigarette Politics website. Available at: <http://www.ecigarette-politics.com/why-snus-is-important.html>

4 Global tobacco control website. Available at: <http://globaltobaccocontrol.org/e-cigarette/>

5 Appiah P. (2018). Ghana to ban Shisha, electronic cigarette by June . Joy Online. Available at: <https://www.myjoy-online.com/lifestyle/2018/march-12th/ghana-to-ban-shisha-electronic-cigarette-by-june.php>

6 Information also provided by in-country experts

Figure 6.8

Snus legal/regulatory status

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Afghanistan	allowed	yes			
Albania	allowed	yes			
Algeria	allowed	yes			
Andorra	no information				
Angola	allowed	yes			
Antigua and Barbuda	no information				
Argentina	allowed	yes			
Armenia	allowed	yes			
Australia	banned	yes		yes	
Austria	banned	yes	no	yes	no
Azerbaijan	no information				
Bahamas	allowed	yes			
Bahrain	banned				
Bangladesh	allowed	yes			
Barbados	allowed	yes			
Belarus	banned				
Belgium	banned	yes	no	yes	no
Belize	no information				
Benin	no information				
Bhutan	no information				
Bolivia	allowed	yes			

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Bosnia and Herzegovina	allowed	yes			
Botswana	allowed	yes			
Brazil	no information				
Brunei	no information				
Bulgaria	banned	yes	no	yes	no
Burkina Faso	no information				
Burma (Myanmar)	no information				
Burundi	no information				
Cambodia	no information				
Cameroon	no information				
Canada	allowed	yes			
Cape Verde	no information				
Central African Republic	no information				
Chad	no information				
Chile	allowed	yes			
China	no information				
Colombia	allowed	yes			
Comoros	no information				
Congo	no information				
Congo, Democratic Republic of	no information				
Cook Islands	no information				
Costa Rica	allowed	yes			

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Croatia	banned	yes	no	yes	no
Cuba	no information				
Cyprus	banned	yes	no	yes	no
Czech Republic	banned	yes	no	yes	no
Denmark	banned	yes	no	yes	no
Djibouti	no information				
Dominica	no information				
Dominican Republic	allowed	yes			
East Timor	no information				
Ecuador	no information				
Egypt	allowed	yes			
El Salvador	allowed	yes			
Equatorial Guinea	no information				
Eritrea	no information				
Estonia	banned	yes			
Ethiopia	allowed	yes			
Fiji	no information				
Finland	banned	yes	no	yes	no
France	banned	yes	no	yes	no
French Guiana	no information				
Gabon	allowed	yes			
Gambia	allowed	yes			

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Georgia	allowed	yes			
Germany	banned	yes	no	yes	no
Ghana	allowed				
Greece	banned	yes	no	yes	no
Grenada	no information				
Guatemala	allowed	yes			
Guinea	allowed	yes			
Guinea-Bissau	no information				
Guyana	no information				
Haiti	no information				
Honduras	allowed	yes			
Hungary	banned	yes	no	yes	no
Iceland	banned				
India	no information				
Indonesia	no information				
Iran	no information				
Iraq	no information				
Ireland	banned	yes	no	yes	no
Israel	allowed	yes	yes	no	yes
Italy	banned	yes	no	yes	no
Ivory Coast	allowed	yes			
Jamaica	no information				

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Japan	allowed	yes			
Jordan	no information				
Kazakhstan	allowed	yes			
Kenya	allowed	yes			
Kiribati	no information				
Korea, North	no information				
Korea, South	allowed	yes			
Kosovo	allowed	yes			
Kuwait	allowed	yes			
Kyrgyzstan	allowed	yes			
Laos	no information				
Latvia	banned	yes	no	yes	no
Lebanon	allowed	yes			
Lesotho	allowed	yes			
Liberia	allowed	yes			
Libya	allowed	yes			
Liechtenstein	banned				
Lithuania	banned	yes	no	yes	no
Luxembourg	banned	yes	no	yes	no
Macedonia	banned				
Madagascar	no information				
Malawi	no information				

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Malaysia	allowed	yes			
Maldives	no information				
Mali	allowed	yes			
Malta	banned	yes	no	yes	no
Marshall Islands	no information				
Mauritania	allowed	yes			
Mauritius	allowed	yes			
Mexico	allowed	yes			
Micronesia	no information				
Moldova	no information				
Monaco	no information				
Mongolia	allowed	yes			
Montenegro	banned				
Morocco	allowed	yes			
Mozambique	allowed	yes			
Namibia	allowed	yes			
Nauru	no information				
Nepal	allowed	yes			
Netherlands	banned	yes	no	yes	no
New Zealand	banned	yes		yes	yes
Nicaragua	allowed	yes			
Niue	no information				

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Niger	allowed	yes			
Nigeria	no information				
Norway	allowed	yes	yes	yes	yes
Oman	allowed	yes			
Pakistan	no information				
Palau	no information				
Palestine	allowed	yes			
Panama	allowed	yes			
Papua New Guinea	no information				
Paraguay	allowed	yes			
Peru	allowed	yes			
Philippines	allowed	yes			
Poland	banned	yes		yes	no
Portugal	banned	yes		yes	no
Qatar	allowed	yes			
Romania	banned	yes			
Russian Federation	allowed	yes			
Rwanda	no information				
Saint Kitts and Nevis	no information				
Saint Lucia	no information				
Saint Vincent and the Grenadines	no information				

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Samoa	no information				
San Marino	no information				
Sao Tome and Principe	no information				
Saudi Arabia	allowed	yes			
Senegal	allowed	yes			
Serbia	no information				
Seychelles	no information				
Sierra Leone	allowed	yes			
Singapore	no information				
Slovakia	banned	yes		yes	no
Slovenia	banned	yes		yes	no
Solomon Islands	no information				
Somalia	allowed	yes			
South Africa	allowed	yes			
South Sudan	no information				
Spain	banned	yes		yes	no
Sri Lanka	no information				
Sudan	no information				
Suriname	no information				
Swaziland	allowed	yes			
Sweden	allowed	yes	yes	yes	
Switzerland	banned	yes		yes	no

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Syria	allowed	yes			
Taiwan	allowed	yes			
Tajikistan	no information				
Tanzania	no information				
Thailand	allowed	yes			
Togo	no information				
Tonga	no information				
Trinidad and Tobago	allowed	yes			
Tunisia	allowed	yes			
Turkey	banned				
Turkmenistan	banned				
Tuvalu	no information				
Uganda	no information				
Ukraine	allowed	yes			
United Arab Emirates	allowed	yes			
United Kingdom	banned	yes			
United States	allowed	yes	yes	yes	yes
Uruguay	allowed	yes			
Uzbekistan	allowed	yes			
Vanuatu	banned				
Vatican City	no information				
Venezuela	allowed	yes			

Country	Selling Swedish Snus Allowed/banned/no specific law/no information	General use and availability			
		Legal to use	Legal to sell online – personal use	Legal to import – personal use	Legal to import – commercial
Vietnam	no information				
Yemen	no information				
Zambia	no information				
Zimbabwe	no information				

Sources: see also www.gsthr.org for more details on sources and methods.

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5. Snuscentral website available at: <https://www.snuscentral.com/blog/snus-users-in-switzerland-can-legally-buy-snus-from-snuscentralcom-n44>

Chapter 7: Human rights, public health and tobacco harm reduction

This section brings us back to the heart of the matter - the right to health for all, as enshrined in international conventions and in public health policies. Linked to that are issues of personal autonomy, the obligations of the state to give people the information they need to make informed choices about personal health, and how advocacy groups have taken matters into their own hands when the state is seen not to be acting in their best interests.

The notion of public health was born during the 19th century in newly industrialised cities across Europe and North America, to combat the appalling toll of death and disease suffered by those living in dire poverty. This moved into more individualised areas of public health, with the discovery of germ theory and the benefits of immunisation, vaccination and family planning. But as poor sanitation, which caused diseases like cholera to ravage cities, was improved, the drive towards public health gave way to a greater emphasis on medical intervention. The medical profession enjoyed increasing power, underpinned by the discovery of drugs such as insulin and antibiotics. John Ashton and Howard Seymour argue in their book *The New Public Health*¹ that public health rose even higher up the health policy agenda following the publication of a Canadian report in 1974, which demonstrated that much of the premature death and disability in Canada was preventable. This created an environment which acknowledged that there were many factors associated with ill-health, not just individual pathology. This in turn opened the door to a new era of public health, centred on proactive health promotion. The process whereby mortality in higher-income countries has ceased to be linked primarily to infectious disease and has instead been linked to degenerative disease has been described as the 'epidemiological transition'.²

"There is a fundamental right for all people - including smokers - to the enjoyment of the highest attainable standard of health, and to have the right to information, services and products that may assist them to achieve that objective".

Jeannie Cameron - international consultant in advocacy and public affairs

Many of these health-related rights are enshrined in international agreements, some of which are outlined below. There are many factors globally that may prevent the desired level of health being achieved due to differing levels of prosperity and stability in the countries of the world, which leads therefore to inequality. However, where information, services and products do exist, then there is a corresponding obligation for the providers of that information, service and product to make it available to those that want it.

In the context of smoking, it should be the right of smokers to gain access to information, services and products that can reduce the harm from smoking to enable them to achieve a higher quality of health and life should they wish to do so. Governments should perform their obligations in this regard by creating policy, regulation and legislation that enables smokers to have information about and access to services and products that can reduce the harm from smoking. At present, only a few governments are allowing and facilitating these rights. Equally, it is important that companies, including tobacco companies, which can provide products that are less harmful than smoking, are permitted, indeed encouraged, to produce them for consumers and put them on the market. At this point in the global debate on SNP, these two elements are not aligned. Products are available, but governments are not providing access to them or information about them. Scientific evidence is available, from some of the world's leading scientific and medical institutions such as the UK Royal College of Physicians, and yet there is a resistance to accept it from some of the world's most significant tobacco control activists. This is especially the case for Swedish snus, where there is approximately 50 years of epidemiological evidence to prove the issue. From a human rights perspective, smokers should be allowed to have information about and access to snus, and yet it is banned in many

¹ Ashton J.R. and Seymour H. *The New Public Health*. Open University Press, 1988

² Omran, A.R. (1971). The epidemiologic transition: a theory of the epidemiology of population change. *Milbank Q.* 49 (4) p. 509-538

countries in the world. This makes no sense when the most harmful of nicotine delivery devices, a cigarette, is freely available almost everywhere in the world.

The FCTC itself is very clear about health rights and its text reminds and recalls the world's most significant human rights agreements. "The FCTC makes clear that harm reduction strategies are part of tobacco control. It provides an obligation on FCTC parties to not only allow reduced-risk products but actively promote them as part of implementing their tobacco control policies based on the most current and relevant scientific, technical and economic considerations – so as to provide for the universal right to the highest attainable standards of health, politically, practically or otherwise."³

Human rights, the right to health, smoking and SNP

Framework Convention on Tobacco Control 2005: Article 1d refers to harm reduction as one of the defining strategies of tobacco control: "A range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke".

The International Covenant on Economic, Social and Cultural Rights 1966: Article 12 recognises: "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and that States Parties must take steps regarding "The prevention, treatment and control of epidemic, endemic, occupational and other diseases".

World Health Organization Constitution 1946: The preamble states that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."

European Social Charter 1965: "Everyone has the right to benefit from any measures enabling them to enjoy the highest possible standard of health attainable". Article 11 requires states to take measures to prevent disease and to encourage individual responsibility in matters of health.

The EU Charter on Fundamental Rights 2000. Article 35 stipulates that a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

The momentum for a new approach to public health found its expression in the WHO Global Strategy of Health for All by the Year 2000 published in 1981.⁴ Its guiding principle was that "All people in all countries should have at least such a level of health that they are capable of working productively and of participating actively in the social life of the community in which they live".

The key question was, how do states deliver on this? And the answer was a commitment to health promotion enshrined in the 1986 Ottawa Charter for Health Promotion.⁵ The Charter stressed, at the top of the list, the imperative to build public policies which support health, such that health promotion is an agenda item in all areas of government and organisational policy-making: "Any obstacles to health promotion should be removed with the aim of making healthy choices the easiest choices". The Charter makes clear that: "Health promotion policy requires the identification of obstacles to the adoption of healthy public policies in non-health sectors, and ways of removing them. The aim must be to make the healthier choice the easier choice for policy-makers as well". Furthermore, it puts people at the centre of this: "People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health".

Harm reduction, drugs and HIV

At the time the Ottawa Charter was published, the USA was in the grip of an HIV/AIDS epidemic. There were all kinds of myths and misinformation about AIDS, ranging from a public perception that you can 'catch' AIDS from toilet seats, or touching sufferers, through to pulpit rantings about God's revenge on homosexuals. But once it was established that the AIDS virus was transmitted through bodily fluids, gay activists in the most affected cities of San Francisco and New York began a grass roots, community-based, self-help initiative to educate and support their peers about safer sexual practices.

³ Tobacco Reporter, *By the Book* (2015) <https://www.tobaccoreporter.com/digital/december2015/html5/index.html#>

⁴ World Health Organisation, *Global Strategy of Health for All by the Year 2000*. WHO, 1981. Available at <http://apps.who.int/iris/handle/10665/38893>

⁵ World Health Organisation, *Ottawa Charter for Health Promotion*. WHO, 1986. Available at <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>

It soon became apparent that those who were injecting drugs were similarly at risk and this created a new arena for community-based self-help. It is hard to imagine a more marginalised and despised group in society than injecting drug users. They were on nobody's public health or even primary care agenda, while drug treatment services were patchy and poorly funded in all western countries. By the mid-1980s, there was already a Dutch drug-using group who were offering help and peer support to users in the Netherlands. It was there, in the wake of the AIDS crisis, that the idea of encouraging people not to share needles and syringes by giving out clean equipment first took root. This was very much in the context of what might be termed 'guerrilla public health', initially undertaken with no support from health professionals.

The UK took this further: a partnership of user activists and enlightened public health officials and clinicians offered both practical support and secured critical political backing. This created a safe environment for injecting drug users, who had access to opiate substitute prescribing and needle exchange facilities. This led to the UK registering the lowest prevalence of drug-related HIV in Europe.⁶

And it was in the UK that the term 'harm reduction' was first coined, becoming not only a health intervention but taking on the colour of a social movement.⁸

Notwithstanding the WHO commitment to 'health for all', this did not initially extend to accepting health interventions for drug users that would help keep them alive. There was no attempt to encourage Member States to empower and strengthen these individuals and their communities to make healthier choices. Instead, the WHO and the UN Office of Drugs and Crime (UNODC) were staunchly opposed to the whole concept of harm reduction. Public health was viewed through a prism of abstinence, prevention, treatment and regulation.⁹ As far as the WHO, UNODC (and their primary funder, the US Government) were concerned, harm reduction was simply a mechanism for condoning drug use and a stalking horse for those who were campaigning for drug law reform. Fortunately, these international bodies came to endorse drug harm reduction interventions such as needle exchange.

While drug harm reduction has gained some acceptance at an international level, unfortunately, at a global level, tobacco harm reduction has not done well.

In 1998, the UN declared "A drug-free world. We can do it", the idea being that as the drugs being referenced were illegal, drug enforcement policies would deliver on this political ambition. With the entry into force of the FCTC in 2005, we now have the political ambition of a tobacco-free world, built on a similar premise of enforcement and control.

However, given the evidence of the relative safety of non-combustible nicotine products, opposition to tobacco harm reduction directly contravenes all of the international human rights agreements and basic principles of the Ottawa Charter of making the healthier choice the easiest choice. It does this not only by using stigma as health policy, and/or by restricting access to the healthier choice, but (as outlined in Chapter 5) to the extent of deliberately circulating misinformation and sowing public confusion about the potential health benefits of switching to SNP.

"Opposition to tobacco harm reduction directly contravenes all of the international human rights agreements and basic principles of the Ottawa Charter".

For nearly 20 years now, US Professor Lynn Kozlowski has been writing about the rights of smokers to be properly informed about harm reduction options. One of his earliest papers framed this premise as follows:

"The right to information derives from the principle of respect for autonomy [...]. If people are deprived of information relevant to their health, they will necessarily be deprived of choices that might protect their health. In a tradition deriving from the Nuremberg Code (1949)¹⁰ and the United Nations Declaration of Human Rights (1948), the American Public Health Association concluded, 'Human rights must not be sacrificed to achieve public health

⁶ Stimson, G.V. (1995). AIDS and injecting drug use in the United Kingdom 1988-93: the policy response and the prevention of the epidemic. *Social Science and Medicine*; 41 (5) p.699-716

⁷ Newcombe, R. (1987) High time for harm reduction. *Druglink Jan/Feb*

⁸ Stimson, GV (2016). A tale of two epidemics: drugs harm reduction and tobacco harm reduction in the United Kingdom. *Drugs and Alcohol Today*; (16) 3, p.203-211

⁹ MacCoun, R.J. (2012). Moral outrage and opposition to harm reduction. *Goldman School of Public Policy*. Available at <https://gspp.berkeley.edu/research/selected-publications/moral-outrage-and-opposition-to-harm-reduction>

¹⁰ A ten-point code concerned with the rights and safety of those volunteering to take part in medical research.

goals, except in extraordinary circumstances in accordance with internationally recognised standards".¹¹

Figure 7.1

Right to use safer nicotine products = Individual and public health benefit



Kozlowski's paper, published in 2002 before the first e-cigarette was available anywhere, focused on the harm reduction potential offered by snus and medicinal nicotine. He concluded that there was no evidence that these products presented a risk sufficient to negate the rights of smokers to access relevant public health information.

More recent papers published by Professor Kozlowski and colleagues suggest that little has changed in terms of the withholding of truthful information and communication of misinformation to the public about tobacco harm reduction options:^{12 13} "Ethical and effective public health campaigns need to respect and work with consumers to facilitate better informed choices. Campaigns that fail to address existing misinformation that may be leading to much more hazardous behaviours, and worse, campaigns that continue deceptions, can be expected to impose a real cost."¹⁴

He goes on to assert that, as the tobacco companies have been ordered to come clean about past lies and deceptions, the same obligations of openness and transparency should apply to government agencies and health campaigning groups.

Ironically, while the US Government has failed to make it clear that smokeless tobacco is much safer than combustible tobacco, as Kozlowski and colleagues have also highlighted, the opioid crisis which has hit the USA in the past 10-15 years has changed official thinking on drug harm reduction.

Funding is now available for opiate substitute treatment and the provision of the drug naloxone which immediately reverses the effect of opioid overdose, while the Surgeon General has publicly supported the provision of needle exchange.¹⁵ Over the same period (2000-16), around 7.5 million Americans have died from a smoking-related disease. From a health perspective, the same US government agencies are responsible for both drugs and tobacco, and it would be a very significant step forward if they were now to apply the principles of harm reduction across the board.

Figure 7.2

HARM REDUCTION + HUMAN RIGHTS = HR²



¹¹ Kozlowski, L.T. (2002). Harm reduction, public health, and human rights: smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Research* s.67-72

¹² Kozlowski, L. T and Edwards, B.Q. (2005) 'Not safe' is not enough; smokers have a right to know more than there is no safe tobacco product. *Tobacco Control*; 14, 3-7

¹³ Kozlowski, L.T. and Sweanor, D. (2016). Withholding differential risk information on legal consumer nicotine/ tobacco products; the public health ethics of health information quarantines. *International Journal of Drug Policy*; 32, p.17-23

¹⁴ Kozlowski, L. T. and Sweanor, D. (2017) Young or adult users of multiple tobacco/nicotine products urgently need to be informed of meaningful differences in product risk. *Addictive Behaviour*: 76, p. 376-381. Follow up commentary (2018). 'Not harmless' messages without comparisons disserve consumers, potential consumers and public health approaches to tobacco/nicotine products. *Addictive Behaviour*, 76, p.390-391

¹⁵ Meehan, M. (2018) Surgeon General Supports Needle Exchanges To Limit Disease From Opioid Crisis. 89.3 WFPL. Available at: <http://wfpl.org/surgeon-general-supports-needle-exchanges-to-limit-disease-from-opioid-crisis/>

Special populations

Smokers who are thinking of quitting or want information on a healthier option for consuming nicotine are often poorly served by public health authorities. But, some groups of smokers are in the greatest need of easy access to SNP. These are: smokers who belong to those mainly lower-income groups with a higher smoking prevalence than the general population; who have disproportionate tobacco-related health disparities; who are more likely to have enduring drug, alcohol or mental health problems; and have less access to smoking cessation services.

Special populations of smokers, especially those living in the poorer countries, potentially face several disadvantages in trying to access SNPs. These include: outright domestic bans (which further impact on those living in public housing or institutions such as prisons and mental health hospitals); internet only access where a credit card or address is needed for purchase and delivery; the initial cost of the products themselves compounded by onerous taxation; and the simple inability to charge a device due to lack of ready access to electricity.

Figure 7.3

Smoking prevalence among US special population groups¹⁶

Schizophrenia	64–74%
Depression	34–60%
Alcohol dependence	67.9%
Bipolar disorder	69%
Generalised anxiety	54%
Drug use	74–88%
Native American	32.4%
Mobility impaired	32.5%
HIV/AIDS	40–65%
Homeless	70–78%
Below poverty level	30%
Men who have sex with men	33%
Military	33%

Average prevalence of those with serious heart and respiratory conditions 37%

Source: Borelli, B. (2010). Smoking cessation; next steps for special populations research and innovative treatments. *J Consulting and Clinical Psychology*. 78 (1), p.1–12

Although Figure 7.3 focuses on US data, the list of those groups containing smokers in special need of other routes out of smoking is reasonably similar to other countries. For example, a WHO report on tobacco and inequities observed “In general terms, lower socioeconomic groups in Europe have higher rates of smoking than higher socioeconomic groups. Lower socioeconomic groups also commonly start smoking at a younger age, smoke more cigarettes per day and stop smoking less often than people in higher socioeconomic groups. Low-income smokers are more intensely addicted to nicotine and are likely to require more support to stop smoking”.¹⁷ Smoking prevalence among these vulnerable groups in the UK is considerably higher than in the general population.¹⁸ In New Zealand, 38 percent of Maori women smoke. This is at an even higher level than Maori men (32 percent), which itself is double that of New Zealand men in the general population.¹⁹ In 2018, the Australian Parliament conducted a review of e-cigarettes and heard evidence from academics and clinicians about the smoking toll among vulnerable groups. One witness focused on the risks of smoking posed to Aboriginal and Torres Straits islanders, while another stated that 70 percent of those with a diagnosis of schizophrenia and 61 percent of bipolar patients smoked.²⁰ In Bangladesh, tobacco use is higher in the most vulnerable groups. Greater percentages of slum and illiterate Bangladeshis use smokeless tobacco (26 percent and 24 percent, respectively) compared to urban and highly-educated Bangladeshis (eight percent and six percent, respectively). A greater percentage of urban (46 percent) and highly-educated (52 percent) Bangladeshis did not use any tobacco at all compared to slum residents (36 percent) and illiterate Bangladeshis (32 percent). Moreover, the study concluded that the poorest people had the least awareness of the risks of tobacco.²¹

Why is smoking prevalence so high among these various groups? At one level, people in these groups simply enjoy nicotine the same as anybody else. But

¹⁶ Borelli, B. (2010). Smoking cessation; next steps for special populations research and innovative treatments. *Journal of Consulting and Clinical Psychology*. 78 (1), p.1–12

¹⁷ World Health Organisation. *Tobacco and inequities; guidance for inequities in tobacco-related harm*. WHO, 2014

¹⁸ Szatkowski, L and McNeill, A (2015). Diverging trends in smoking behaviours according to mental health status. *Nicotine and tobacco research*. 17; 356–60

¹⁹ Personal communication, Professor Marewa Glover, Massey University, New Zealand.

²⁰ Parliament of the Commonwealth of Australia. *Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia*.

²¹ Driezen, P. et al (2016). Awareness of tobacco-related health harms among vulnerable populations in Bangladesh: findings from the international tobacco control (itc) Bangladesh survey. *International Journal of Environmental Research and Public Health*. 13 (9), 848.

there is some evidence that, for example, nicotine can help those suffering from schizophrenia by enabling them to be more focused.²² For other groups, such as homeless people on the streets, smoking and sharing cigarettes can be an aspect of social glue or a way of coping with both stress and boredom for a group of otherwise isolated and marginalised people. This is also the case for those inside prison, another venue for very high smoking prevalence, or those generally living a poor and disadvantaged life and living alongside generations of smokers.

But why people in special or vulnerable groups smoke more than the general population, while not exactly irrelevant, is nevertheless simply a fact. All the incumbent ill-health which follows should be a driver to open all the available pathways for people to switch away from smoking.

Tobacco harm reduction advocacy

Just like the gay and drug user activist groups, SNP consumers have not sat on the sidelines waiting for governments to act reasonably over consumer health protection. Consumers have also banded together to offer help and peer support, to provide accurate information about SNP, campaign against restrictions on access to the widest range of SNP choices, write opinion pieces and run blog sites, supply written and oral evidence to government enquiries into SNP, track legislative developments and embark on legal challenges.

One of the earliest groups formed was the American Consumer Advocates for Smoke-Free Alternatives Association (CASAA) founded in 2009.²³ Since then, similar groups have sprung up all over the world and now many such organisations form the membership of the International Network of Nicotine Consumer Organisations (INNCO).²⁴ Activists in Europe bombarded their Members of the European Parliament with communications expressing concerns over the Tobacco Products Directive, while those in Australia have been campaigning hard to challenge the intransigence of the government over the SNP ban. And gradually, the consumer advocacy groups are being consulted by policy makers and invited to high level meetings, as well as banding together with independent industry companies and associations to fight against anti-tobacco harm reduction legislative proposals especially in the USA. One high-profile activity was undertaken by the UK National Nicotine Alliance (NNA).²⁵ They joined the challenge to the EU ban on snus.

UK - a challenge to the EU ban on snus - a right to health argument

In 2016, Swedish Match, the main European manufacturer of snus, started a legal action in the UK High Court against the ban on snus. The New Nicotine Alliance (NNA), a consumer advocacy charity, was given leave by the UK High Court to join the challenge as a third-party intervenor acting in the public interest. Because UK tobacco law is based on the European TPD, the case was referred to the European Court of Justice (ECJ). The NNA made its case in January 2018. It was the first time that a 'right to health' argument has been used to challenge a bad tobacco control law and could prove a template for other similar actions around the world. The NNA argued comprehensively that the ban contravened all the EU and international health rights and so was disproportionate and inimical to the goals of public health.

The evidence was presented in the ECJ in January 2018. In April, the Advocate General Saugmandsgaard Øe issued his opinion upholding the ban. He agreed that the evidence showed snus is less hazardous than cigarettes but was of the opinion that it was not up to the ECJ to evaluate the evidence, simply to ascertain whether or not the ban was lawful.

At the E-Cigarette Summit held in London in November 2017, Sarah Jakes from the NNA made some key points that from a consumer point of view, smoking is not a disease, but a pleasurable activity that nonetheless presents serious health risks which smokers should be able to mitigate through personal choice access to SNP.

"The word 'pleasure' seems to be something of an anathema to some in public health. One of the biggest challenges for consumers is in getting regulators, and those who advise them, to understand that for a great many people vaping is not a medicine, or simply a smoking cessation intervention, it works precisely because it isn't those things. It works because they enjoy it. They love the

²² Schizophrenia.com, *Schizophrenia and Smoking, Cigarettes, and Nicotine* www.schizophrenia.com/smokereport.htm#pos

²³ Consumer Advocates for Smoke-Free Alternatives Association (CASAAA) www.csaaa.org

²⁴ International Network of Nicotine Consumer Organisations (INNCO) www.innco.org

²⁵ National Nicotine Alliance (NNA) www.nnalliance.org

personalisation that's made possible by the diversity of the market in devices, and the thousands of flavours available. They enjoy the identity of being a vaper and the sense of community that that entails. They love that vaping is similar to smoking, but at the same time a million miles away from it.

"But vaping is more than just a pro-choice campaign. Whilst many vapers do regard it simply as a more pleasurable alternative to smoking, many others place more importance on the reduction in harm to their health, or the ability to use e-cigarettes to stop smoking.

"We want to be able to make our own choices based on accurate information [but] we see the choices that are taken away from people by the arbitrary and counter-productive restrictions on reduced risk products in [for example] the TPD. We see our smoking friends being put off vaping by the appalling media coverage".

Conclusion

What this report has tried to do is enumerate and explain the advantages of embracing tobacco harm reduction as a legitimate approach to help tackle the global smoking epidemic. Apart from being founded on the well-established principles of the right to health for the world's citizens, as enshrined in many international documents, it is also grounded in evidence-based pragmatism. The tobacco cigarette is the most dangerous nicotine delivery device. Safer Nicotine Products deliver nicotine with a significant reduction in risk as compared to combusted tobacco products - there is 'No Fire, No Smoke' . All the independent science points to SNP being just that - not just safer, but much safer, than smoking cigarettes.

To reiterate: this is harm reduction, not harm elimination, although on current evidence, the reduction seems so significant that we should not be distracted by concerns about 'gateway' effects or 're-normalising' smoking. There is simply no robust evidence to support these concerns, despite e-cigarettes being on the market for more than a decade. Nor should we be overly swayed by talk of nicotine 'addiction', a word freighted with the worst images of serious and chaotic drug and alcohol use, but which simply does not apply to nicotine.

SNP have been disruptive commodities in all ways imaginable, but it is imperative to keep the eyes on the prize - an end to smoking. We must not allow

over-proscriptive regulation and control to deny access to products that have the potential to be one of the most dramatic public health coups of modern times. We make no apologies for repeating this point - whereas all other global public health interventions come at great financial cost, this one costs governments, international agencies and NGOs nothing.